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Paper 50
Date: November 3, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RECOR MEDICAL, INC. and
OTSUKA MEDICAL DEVICES CO., LTD.,
Petitioner,

v.

MEDTRONIC IRELAND
MANUFACTURING UNLIMITED CO.,
Patent Owner.

IPR2022-00431
Patent 8,845,629 B2

Before WILLIAM V. SAINDON, ERIC C. JESCHKE, and ALYSSA A. FINAMORE, *Administrative Patent Judges*.

JESCHKE, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision on Remand
Determining Some Challenged Claims Unpatentable
35 U.S.C. §§ 144, 318(a)

I. BACKGROUND

ReCor Medical, Inc. and Otsuka Medical Devices Co., Ltd. (collectively, "Petitioner") challenge claims 1–4 and 8–12 of U.S. Patent No. 8,845,629 B2 (Ex. 1001, "the challenged patent"), assigned to Patent Owner, Medtronic Ireland Manufacturing Unlimited Co. In the original Final Written Decision in this proceeding, we determined that Petitioner had not proven by a preponderance of the evidence that any of claims 1–4 and 8–12 are unpatentable. *See* Paper 32 ("FWD").

Petitioner appealed to the United States Court of Appeals for the Federal Circuit (Paper 33), which vacated the original Final Written Decision and remanded the proceeding to the Board. *See ReCor Med., Inc. v. Medtronic Ir. Mfg. Unlimited Co.*, No. 2023-2251, 2025 WL 944511 (Fed. Cir. Mar. 27, 2025) ("the Appeal Decision" or "Appeal Dec."); *see also* Paper 41 (copy of the Appeal Decision). The Federal Circuit's mandate issued on May 5, 2025. *See* Paper 40.

We have jurisdiction under 35 U.S.C. § 6, and we issue this Final Written Decision on Remand under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons below, on the complete record, we conclude that Petitioner has proven, by a preponderance of the evidence, the unpatentability of claims 1–3 and 8–12 of the challenged patent, and we conclude that Petitioner has *not* proven, by a preponderance of the evidence, the unpatentability of claim 4.

A. Procedural History

1. Background of the Trial

Petitioner filed a Petition to institute *inter partes* review of claims 1–4 and 8–12. Paper 3 ("Pet."). Patent Owner filed a Preliminary Response.

Paper 10.[1] We instituted *inter partes* review as to all challenged claims and on all grounds asserted. Paper 11. During trial, Patent Owner filed a Response (Paper 16, "PO Resp."), Petitioner filed a Reply (Paper 20, "Pet. Reply"), and Patent Owner filed a Sur-reply (Paper 24, "PO Sur-reply").

Petitioner relied on the declaration testimony of Dr. Chris Daft (Ex. 1002, "Daft Pet. Decl.") and Dr. Farrell Mendelsohn (Ex. 1056, "Mendelsohn Pet. Decl.") filed with the Petition and relied on the declaration testimony of Dr. Daft (Ex. 1071, "Daft Reply Decl.") and Dr. John Moriarty (Ex. 1072, "Moriarty Reply Decl.") filed with the Reply. Patent Owner relied on the declaration testimony of Dr. Robert Tucker (Ex. 2031, "Tucker Decl.") and Dr. Daniel van der Weide (Ex. 2032, "Weide Decl.") filed with the Response. An oral hearing was held on May 4, 2023, and a copy of the transcript was entered into the record. Paper 31.

2. Related Proceeding

The parties previously identified a proceeding in the U.S. District Court for the Northern District of California involving the challenged patent: *ReCor Medical, Inc. v. Medtronic Ardian Luxembourg S.A.R.L.*, No. 4:22-cv-00236 (N.D. Cal., filed January 13, 2022). Paper 4 (Petitioner's Updated Mandatory Notices) at 2; Paper 6 (Patent Owner's Mandatory Notices) at 2; Paper 8 (Patent Owner's Updated Mandatory Notices) at 3. That proceeding has been dismissed without prejudice. *See* Notice of Voluntary Dismissal

[1] Petitioner named Medtronic Ardian Luxembourg S.A.R.L. as the patent owner of record. Pet. 1. With the filing of the Preliminary Response, Patent Owner identified itself as the proper corporate entity with ownership rights of the challenged patent. *See* Paper 8; Paper 10 at 1.

Without Prejudice, No. 4:22-cv-00236 (N.D. Cal. Sept. 16, 2024), ECF No. 22.

3. The Appeal to the Federal Circuit

After issuance of the original Final Written Decision, Petitioner filed a Notice of Appeal. Paper 33. Specifically, Petitioner appealed the determinations that it had *not* shown by a preponderance of the evidence (1) claims 1–4 and 8–11 as unpatentable based on Levin[2] and Acker[3], (2) claim 12 as unpatentable based on Levin, Acker, and Yock[4], (3) claims 1–4 and 8–11 as unpatentable based on Acker and the knowledge of a person of ordinary skill in the art, and (4) claim 12 as unpatentable based on Acker, the knowledge of a person of ordinary skill in the art, and Yock.[5] *Id.* at 1.

The Federal Circuit vacated and remanded. *See* Appeal Dec. Specifically, the Federal Circuit determined as unsupported by substantial evidence (1) the finding that one of ordinary skill in the art would not have been motivated to use Acker's ultrasound catheter in renal neuromodulation applications and (2) the determination as to Petitioner's obvious-to-try theory. *See id.*

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[2] US 2003/0216792 A1, published November 20, 2003 (Ex. 1004, "Levin").

[3] US 6,669,655 B1, issued December 30, 2003 (Ex. 1005, "Acker").

[4] US 5,000,185, issued March 19, 1991 (Ex. 1017, "Yock").

[5] The appeal did not address the third ground presented in the Petition, which alleged anticipation of claims 1–3, 8, and 9 by Acker. *See* Appeal Dec. *1–*2 (summarizing grounds at issue on appeal, but not discussing alleged anticipation by Acker).

4. After Remand from the Federal Circuit

Following an Order seeking input from the parties on the procedures for remand (Paper 42), the parties timely filed a Joint Submission of their positions (Paper 45). After considering the Joint Submission, we issued an Order aligning with the parties' proposal for no additional briefing and no supplementation of the evidentiary record. *See* Paper 46 at 2.

Having fully considered anew the evidence and arguments in this proceeding, in light of the Federal Circuit's Appeal Decision, we issue this Final Written Decision on Remand.

B. The Challenged Patent

The challenged patent "relates to methods and apparatus for achieving renal neuromodulation via thermal heating and/or cooling mechanisms" in order to alleviate certain medical issues. Ex. 1001, 1:42–44. According to the challenged patent, in addition to playing a role in the progression of Congestive Heart Failure ("CHF"), "the kidneys play a significant role in the progression of Chronic Renal Failure ('CRF'), End-Stage Renal Disease ('ESRD'), hypertension . . . and other cardio-renal diseases." *Id.* at 1:62–66. Specifically, the challenged patent discloses that "thermally-induced renal neuromodulation . . . may alleviate clinical symptoms of CHF, hypertension, renal disease . . . and/or other cardio-renal diseases." *Id.* at 15:49–54.

Figure 1 is reproduced below:

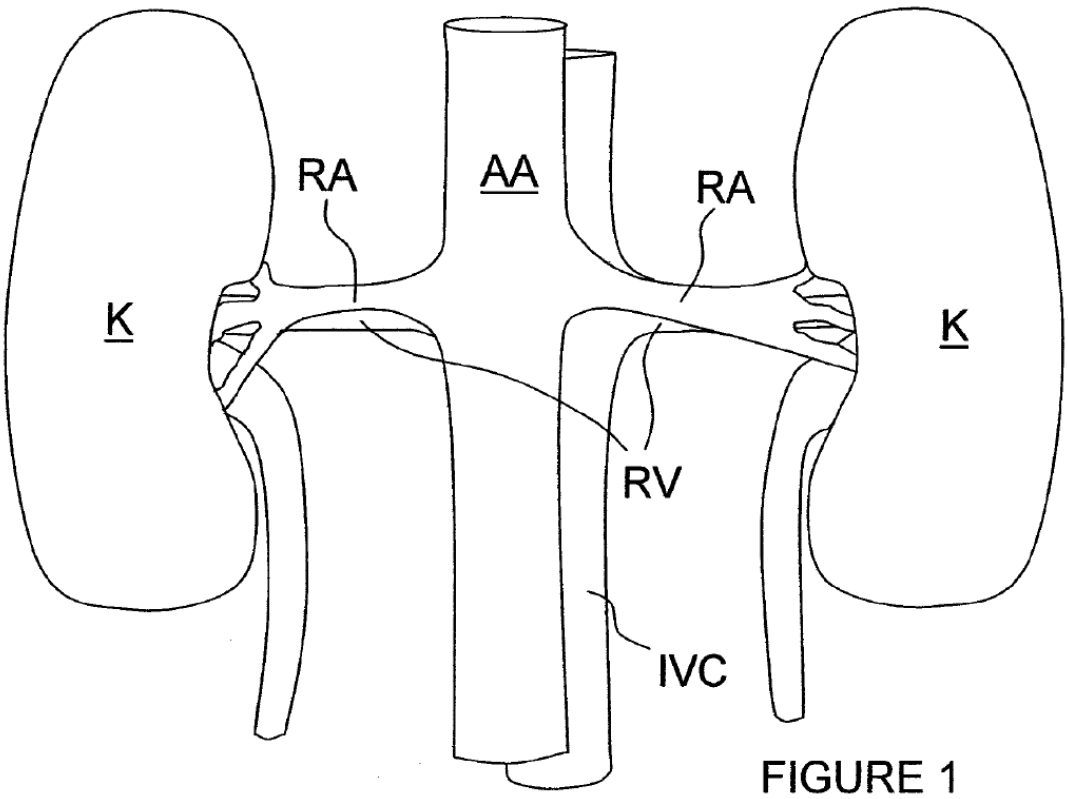

FIGURE 1

Figure 1 depicts the anatomy of the kidneys. Ex. 1001, 3:11–12. The renal arteries (RA) supply oxygenated blood to the kidneys (K), while renal veins (RV) carry deoxygenated blood from the kidneys to the heart. *Id.* at 5:44–49. Renal nerves extend longitudinally along the renal arteries. *See id.* at 5:51–53, Fig. 2. According to the challenged patent, neuromodulation of the renal nerves "may be achieved via [an] apparatus positioned proximate target neural fibers, for example, positioned within renal vasculature." *Id.* at 3:65–4:3. The challenged patent discloses that "non-target tissue additionally or alternatively may be protected by focusing the thermal heating or cooling energy on the target neural fibers such that an intensity of the thermal energy is insufficient to induce . . . thermal damage in the non-target tissue." *Id.* at 5:21–25.

Figures 12A and 12B are reproduced below:

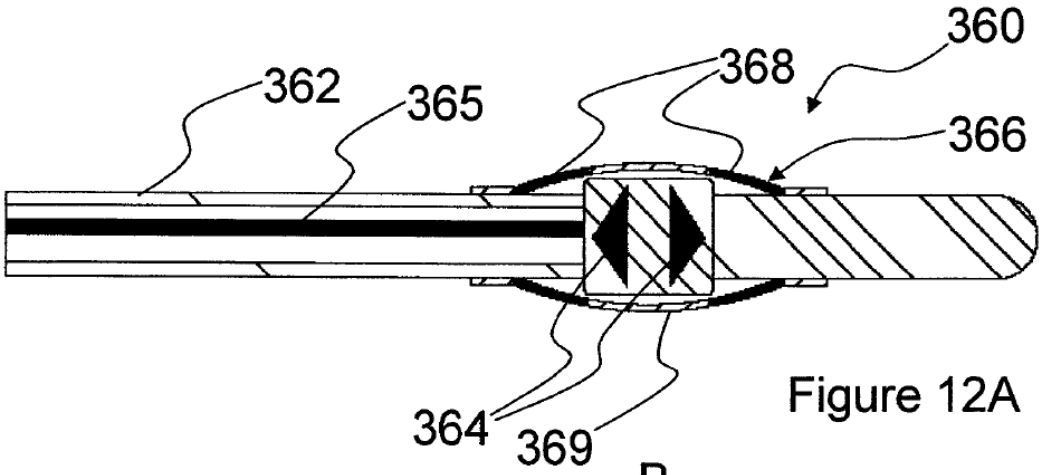

Figure 12A

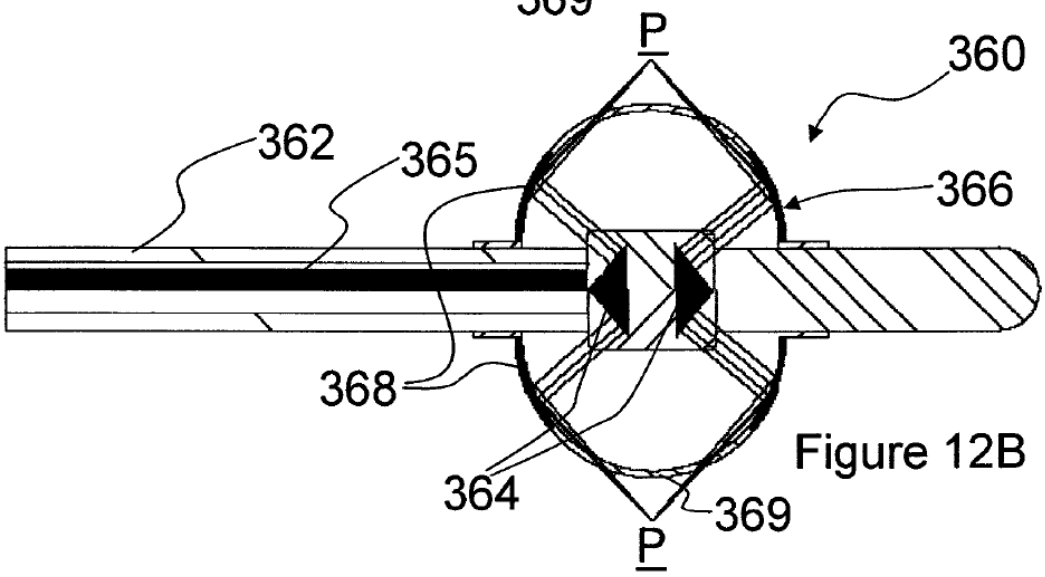

Figure 12B

Figures 12A and 12B depict an apparatus for delivering focused ultrasound to renal nerves to achieve thermal neuromodulation. Ex. 1001, 14:23–31. Apparatus 360 includes catheter 362, which has ultrasound transducers 364 located on the shaft of the catheter. *See id.* at 14:31–34. Apparatus 360 additionally has inflatable balloon 366 with acoustically reflective portion 368 and acoustically transmissive portion 369, which together focus an ultrasonic wave at focal point P. *See id.* at 14:35–41. Figure 12A shows inflatable balloon 366 in a *deflated* state for delivery and retrieval of apparatus 360. *See id.* at 14:57–58. In contrast, Figure 12B

shows inflatable balloon 366 in an *expanded* state during deployment of apparatus 360. *See id.* at 14:58–59. According to the challenged patent, "[t]he focal distance may be specified or dynamically variable such that, when positioned within a blood vessel, the ultrasonic wave is focused at a desired depth on target neural fibers outside of the vessel." *Id.* at 14:44–47. The challenged patent discloses that "[f]ocusing the ultrasound wave may produce a reverse thermal gradient that protects the non-target tissues and selectively affect the target neural fibers to achieve thermal renal neuromodulation via heating." *Id.* at 14:52–55.

Figure 13 is reproduced below:

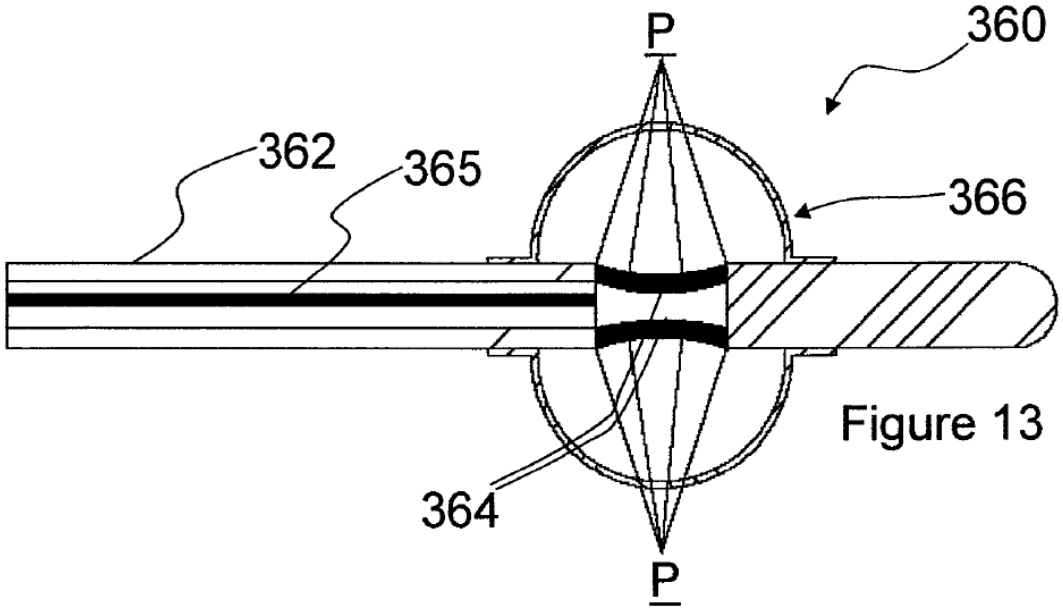

Figure 13

Figure 13 depicts an alternative embodiment of the apparatus in Figure 12. Ex. 1001, 14:59–64. In contrast to the apparatus in Figures 12A and 12B, here, "ultrasound transducers 364′ are concave, such that the

ultrasound signal is self-focusing without need of the reflective portion of the balloon 366."[6] *Id.* at 14:61–63.

C. Challenged Claims

Petitioner challenges claims 1–4 and 8–12, of which only claim 1 is independent. Independent claim 1 is reproduced below, with Petitioner's designations in brackets to identify certain language:

> 1. [**1a**] An ultrasound apparatus for thermally-induced renal neuromodulation, the apparatus comprising:
>
> [**1b**] a catheter sized and shaped for delivery within a blood vessel to a vicinity of neural fibers that contribute to renal function;
>
> [**1c**] an ultrasound transducer carried by the catheter, [**1d**] wherein the ultrasound transducer is configured to transmit ultrasound energy waves to target renal neural fibers outside of the blood vessel to thermally induce modulation of target neural fibers while protecting non-target tissue in the blood vessel wall from thermal injury; and
>
> [**1e**] an expandable member carried by a distal region of the catheter, wherein the expandable member is configured to vary between a reduced configuration for delivery and retrieval and an expanded deployed configuration, and
>
> [**1f**] wherein the ultrasound transducer is positioned on a shaft of the catheter and within the expandable member.

Ex. 1001, 16:5–20.[7]

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[6] In this Decision, we omit emphasis of reference numerals in quotations from the challenged patent and cited references.

[7] We adopt, and apply below, Petitioner's labels for the elements of the challenged claims. *See, e.g.*, Pet. 41–48 (showing labels).

D. Instituted Grounds of Unpatentability

We instituted *inter partes* review of the challenged claims based on all of the grounds asserted by Petitioner, which are listed below:

Claim(s) Challenged	35 U.S.C. §[8]	Reference(s)/Basis
1–4, 8–11	103(a)	Levin, Acker
12	103(a)	Levin, Acker, Yock
1–3, 8, 9	102(e)(2)	Acker
1–4, 8–11	103(a)	Acker, knowledge of a person of ordinary skill in the art
12	103(a)	Acker, knowledge of a person of ordinary skill in the art, Yock

II. DISCUSSION

A. The Level of Ordinary Skill in the Art

In the original Final Written Decision, we determined the applicable level of ordinary skill in the art. *See* FWD 8–10 (§ II.A). Under that definition,

> [t]he level of ordinary skill encompassed a team of people, having a person with a Ph.D. or M.D. and five years of clinical and/or research experience treating diseases of the kidneys and circulatory systems and a person with at least a Bachelor's degree

[8] The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. §§ 102, 103 that became effective on March 16, 2013. Pub. L. No. 112-29, §§ 3(b)–3(c), 3(n)(1), 125 Stat. 284, 285–87, 293 (2011). Because there is no dispute that the challenged claims of the challenged patent have an effective filing date before March 16, 2013, we apply the pre-AIA versions of these statutes.

> in biomedical engineering or a related field and at least five years of experience designing catheter-based ablation systems.

FWD 9 (quoting Pet. 40). Neither party addressed that issue on appeal. *See generally* Appeal Dec. We continue to apply the same level of ordinary skill in the art in this Final Written Decision on Remand.

B. Claim Construction

In *inter partes* reviews, the Board interprets claim language using the same claim construction standard that would be used in a civil action under 35 U.S.C. § 282(b), as described in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). *See* 37 C.F.R. § 42.100(b) (2021). 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.

1. "Configured to"

Both Petitioner and Patent Owner propose constructions for "configured to" as used in the phrases "configured to transmit ultrasound energy waves to target renal neural fibers" (claim 1, element 1d) and "configured to [perform certain functions] to the target neural fibers" (claims 3, 4, 8, and 9). *See* Pet. 23–25; PO Resp. 17–22; Pet. Reply 10; PO Sur-reply 1–2. Petitioner asserts that the phrase "configured to" should be construed as "able to." Pet. 23; *see* Pet. 23–24 n.5 (discussing how "able to" has the same meaning as "capable of"). Patent Owner responds that "[t]he Board need not reach the construction of this term as Petitioner['s]

arguments fail under either construction, but to the extent a construction is required, 'configured to' should be construed as 'designed to.'" PO Resp. 18. Based on the complete record, we do not discern a need to construe explicitly this phrase because doing so would not change the result of the analysis below. *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))).

2. The "Protecting" Limitation

Petitioner and Patent Owner both discuss the phrase "protecting non-target tissue in the blood vessel wall from thermal injury" as recited in element 1d ("the 'protecting' limitation"). *See* Pet. Reply 10–11; PO Sur-reply 2–3. Petitioner asserts that this phrase "means protecting some non-target tissue from some thermal injury." Pet. Reply 10. Patent Owner responds that Petitioner's proposed construction "rewrites" the claim language at issue and states that the "plain and ordinary meaning should instead apply." PO Sur-reply 2. For the reasons below, we construe the "protecting" limitation in line with Petitioner's proposed construction.

Although we start a claim construction analysis with the language of the claims (*TQ Delta, LLC v. DISH Network LLC*, 929 F.3d 1350, 1357 (Fed. Cir. 2019)), here, the claim language at issue, as well as the surrounding language, does not provide additional clarity.

Next, we turn to the Specification of the challenged patent. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[T]he specification is always highly relevant to the claim construction

analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term."), *quoted at Phillips*, 415 F.3d at 1315. The Specification here strongly supports Petitioner's construction of the "protecting" limitation as meaning protecting *some* non-target tissue in the blood vessel wall from *some* thermal injury. For example, after disclosing the use of cooling elements to protect non-target tissue, the Specification turns to an additional or alternative approach for protecting non-target tissue—the use of focused thermal energy on target tissue:

> As discussed previously, cooling elements, such as convective cooling elements, may be utilized to protect non-target tissues like smooth muscle cells from thermal damage during thermally-induced renal neuromodulation via heat generation. Non-target tissues additionally or alternatively may be protected by focusing the thermal energy on the target neural fibers such that an intensity of the thermal energy is insufficient to induce thermal damage in non-target tissues distant from the target neural fibers.

Ex. 1001, 12:35–43. The sentence describing the use of focused thermal energy explains the level of protection provided to non-target tissue, specifically disclosing that the "intensity of the thermal energy is insufficient to induce thermal damage in non-target tissues *distant from* the target neural fibers." *Id.* at 12:39–43 (emphasis added), *quoted at* Pet. Reply 25. Patent Owner cites this passage as showing that the challenged patent "describes protecting non-target tissue in the blood vessel wall from thermal injury using several distinct methods," but Patent Owner does not address the

phrase "distant from." *See* PO Sur-reply 2–3 (citing Ex. 1001, 5:6–25, 8:55–9:20, 12:35–43, 14:52–57).[9]

This description of the level of protection provided to non-target tissue supports Petitioner's construction, indicating that *some* non-target tissue—i.e., non-target tissue *not* "distant from" the "target tissue"—may receive *some* level of injury and still align with the protection disclosed in the challenged patent and recited in the "protecting" limitation. The passage from the challenged patent quoted above conflicts with Patent Owner's proposed construction, which would not allow *any* thermal injury, even to "non-target tissue" close to "target tissue." *Compare* PO Sur-reply 2–3, *with* Ex. 1001, 12:39–43.

Moving along in the claim construction analysis, the prosecution history does not provide additional clarity on the scope of the "protecting" limitation.

Although we do not view the meaning of the "protecting" limitation as unclear or ambiguous, we note that extrinsic evidence also supports Petitioner's construction. *See Seabed Geosolutions (US) Inc. v. Magseis FF LLC*, 8 F.4th 1285, 1287 (Fed. Cir. 2021) ("If the meaning of a claim term is clear from the intrinsic evidence, there is no reason to resort to extrinsic evidence."). Specifically, during the deposition of Patent Owner's declarant, Dr. Tucker, when directly asked whether the "protection" limitation requires

[9] Patent Owner also quotes a similar description of the use of focused thermal energy in its summary of the challenged patent. *See* PO Resp. 7 ("For example, '[t]he non-target tissue . . . may be protected by focusing the thermal heating . . . on the target neural fibers' such that the thermal energy is insufficient to damage 'non-target tissue distant from the target neural fibers.'" (alteration by Patent Owner) (quoting Ex. 1001, 5:20–25)).

"protect[ing] all nontarget tissue in the blood vessel wall from all thermal injury or just some nontarget tissue in the blood vessel wall from some thermal injury," Dr. Tucker explained that "you can destroy the nerves that are a few tenths of a millimeter away from the wall and yet *minimize the damage* to the wall" and Dr. Tucker also stated that, with this requirement, "[y]ou're protecting the wall against *unnecessary damage*." *See* Ex. 1069, 32:15–33:18 (emphasis added), *cited at* Pet. Reply 10. Even though this testimony was raised by Petitioner in the Reply, Patent Owner declines to address this testimony in its Sur-reply, instead erroneously concluding that "[n]one of Petitioner['s] cited evidence suggests this limitation is met if only some non-target tissue is protected from some amount of thermal injury." PO Sur-reply 2.

We turn now to Patent Owner's contention that Petitioner's proposed construction of the "protecting" limitation "makes little practical sense as it is satisfied even if all or nearly all of the blood vessel wall is ablated—killing the patient." PO Sur-reply 3. On the complete record, we are not persuaded that one of ordinary skill in the art would view Petitioner's proposed construction—protecting *some* non-target tissue in the blood vessel wall from *some* thermal injury—as including the total ablation or perforation of the blood vessel wall, leading to patient death. Indeed, the testimony cited by Patent Owner on this point addresses potential energy sources and their potential disadvantages, but does not address the scope of the "protecting" limitation at all. *See id.* (citing Tucker Decl. ¶ 115; Ex. 2033 (deposition of Dr. Daft), 57:16–60:11; Ex. 2034 (deposition of Dr. Mendelsohn), 21:19–22:5 (stating how "perforation of the renal artery . . . can ultimately lead to death"), 75:16–77:25).

For the reasons above, on the complete record, we construe the "protecting" limitation in element 1d as requiring protecting some non-target tissue in the blood vessel wall from some thermal injury.

C. Asserted Obviousness of Claims 1–4 and 8–11 Based on Levin and Acker

Petitioner asserts that claims 1–4 and 8–11 of the challenged patent would have been obvious based on Levin and Acker. Pet. 12, 25–57; Pet. Reply 12–34. Patent Owner provides arguments addressing this ground. PO Resp. 22–54; PO Sur-reply 3–24. We summarize aspects of Levin and Acker and then address the parties' arguments.

1. Levin

Levin "relates to methods and apparatus for treatment of congestive heart failure, chronic renal failure and hypertension by nerve stimulation" and to improving these conditions by "by blocking signals to the renal (kidney) nerve." Ex. 1004 ¶ 2. Specifically, Levin teaches treating "heart failure, renal failure and hypertension by electrically or chemically modulating the nerves of the kidney." *Id.* ¶ 48. Levin teaches electric stimulus and use of a chemical agent as methods of modulating renal nerves (*id.* ¶ 51), but Levin also teaches ablation (i.e., destruction) of renal nerves by surgical, electrical, or chemical means (*id.* ¶¶ 51, 64). *See also id.* ¶¶ 128–129 (discussing both modulation and denervation). In addition, Levin teaches the use of a catheter, positioned in a renal vein or renal artery, to perform the disclosed modulation of renal nerves. *See id.* ¶¶ 92–94.

Figure 3 of Levin is reproduced below:

Figure 3

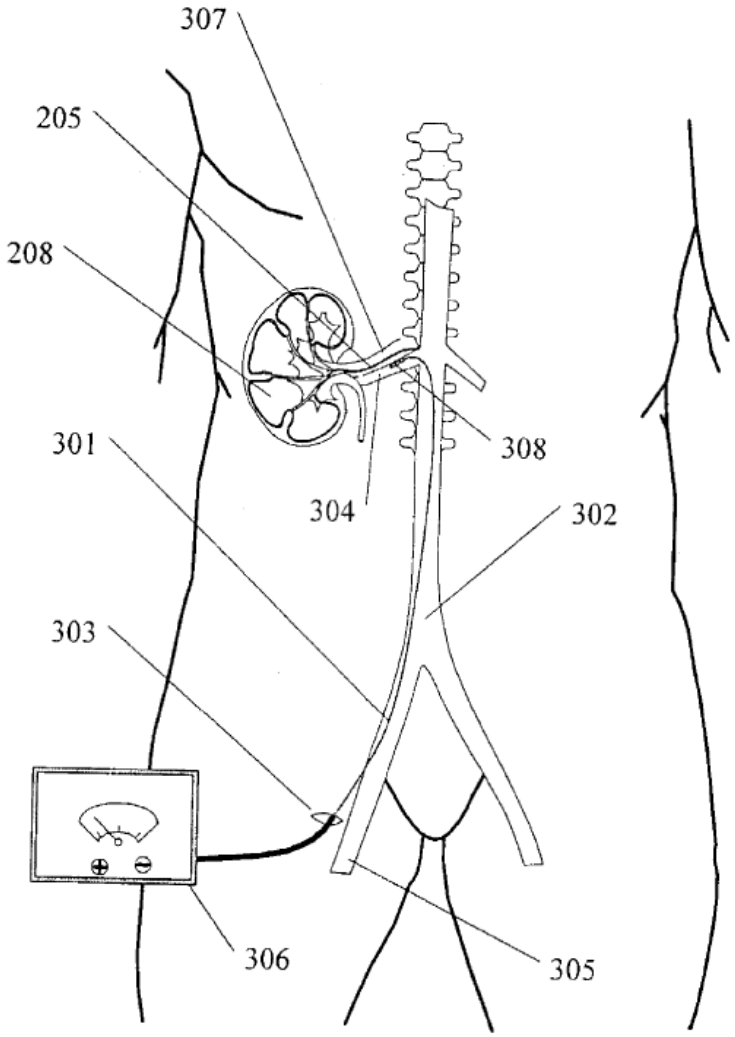

Figure 3 depicts "stimulation of renal nerves across the wall of the renal vein." Ex. 1004 ¶ 69. Specifically, Figure 3 shows external renal nerve stimulator apparatus 306 connected to electrode tip 308 by catheter 301, which is "inserted via an insertion site 303 into the femoral vein 305 into the vena cava 302 and further into the renal vein 304." *Id.* ¶ 92. Tip

308 is brought into electric contact with the wall of vein 304. *See id.* The electrodes then generate an electric field "sufficiently strong to influence traffic along the renal nerve 205 stimulating the kidney 208." *Id.* In the alternative, the catheter could be positioned in a renal artery. *See id.* ¶ 94.

Figure 9 of Levin is reproduced below:

Figure 9

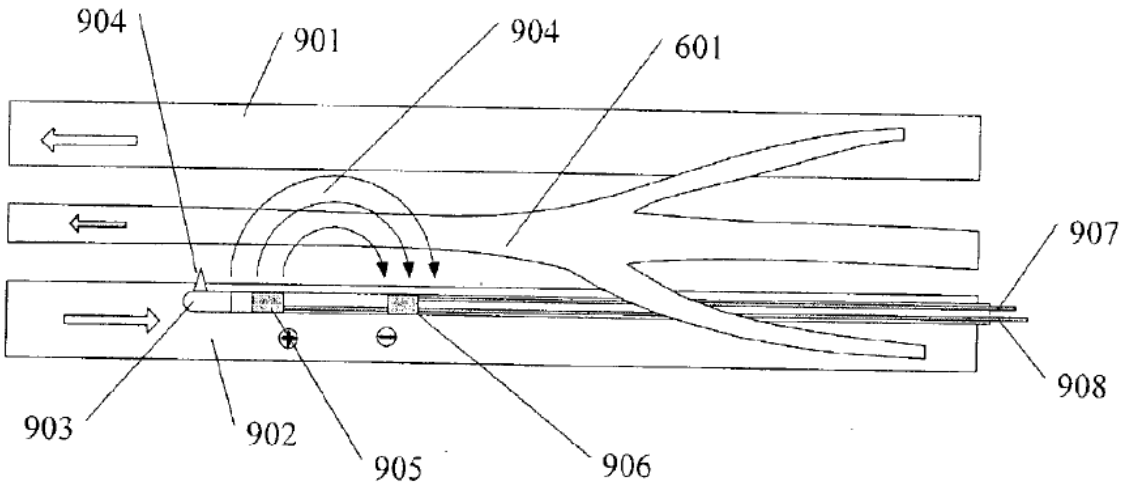

Figure 9 depicts "transvenous stimulation of the renal nerve with [an] electric field." Ex. 1004 ¶ 75. Specifically, Figure 9 shows stimulation catheter 903, which includes electrodes 905/906, within renal vein 902. *Id.* ¶ 111. Levin discloses that electrodes 905/906 induce electric field 904 to create a "local polarization of the segment of the renal nerve trunk 601." *Id.*

2. Acker

Acker discloses the use of a catheter with an ultrasonic transducer "to provide ultrasonic energy in a ring-like zone surrounding a blood vessel." Ex. 1005, code (57).

Figure 1 of Acker is reproduced below:

FIG. 1

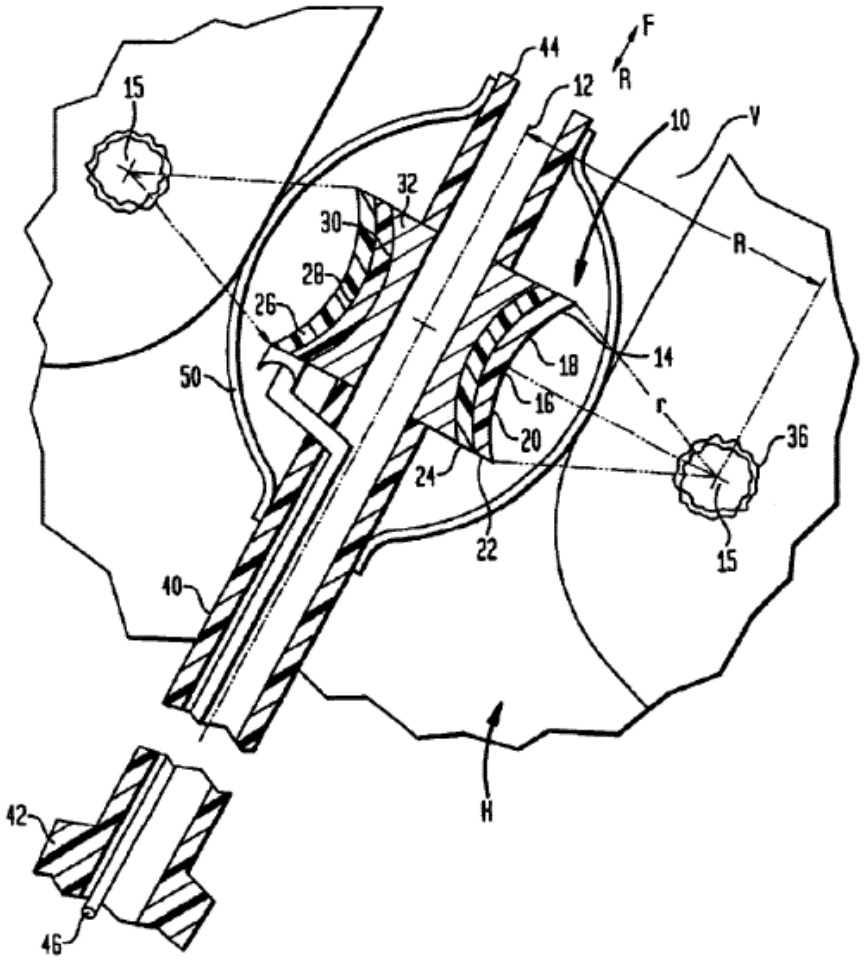

Figure 1 depicts a catheter treating tissue. *See* Ex. 1005, 2:64–67. Specifically, Figure 1 shows catheter 40 positioned in vein V. *See id.* at 4:12–16, Fig. 1. Piezoelectric element 10 emits sonic waves that "reinforce one another in a ring-like region 36 centered on a circle corresponding to the theoretical ring swept by the center 15 of the generatrix of surface 14" of element 10. *Id.* at 4:1–11.

3. Analysis

a. Independent Claim 1

Petitioner contends that the combination of Levin and Acker satisfies each limitation of claim 1. Pet. 31–48; Pet. Reply 12–33. In support, Petitioner identifies certain passages in the cited references and explains the significance of each passage with respect to the corresponding claim limitation. Pet. 31–48. Petitioner also articulates (1) reasons to combine the relied-upon aspects of Levin and Acker, (2) why there would have been a reasonable expectation of success in the combination, and (3) why Levin and Acker are analogous art to the claimed invention. Pet. 31–41.

Patent Owner (1) argues that the proposed combination does not disclose or render obvious "a catheter sized and shaped for delivery within a blood vessel to a vicinity of neural fibers that contribute to renal function" as recited in element 1b, (2) argues that the proposed combination does not disclose or render obvious "an ultrasound transducer . . . configured to transmit ultrasound energy waves to target renal neural fibers outside of the blood vessel to thermally induce modulation of target neural fibers while protecting non-target tissue in the blood vessel wall from thermal injury" as recited in element 1d, and (3) challenges the articulated reasons to combine Levin and Acker. *See* PO Resp. 24–52; PO Sur-reply 3–23. For the reasons below, we determine, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that claim 1 would have been obvious based on Levin and Acker.

(1) Element 1a

In element 1a, claim 1 recites "[a]n ultrasound apparatus for thermally-induced renal neuromodulation, the apparatus comprising."

Ex. 1001, 16:5–6. To address this recitation, Petitioner states that "Levin generally teaches an **apparatus for thermally-induced renal neuromodulation**" and adds it would have been obvious to use Acker's ultrasound catheter to perform neuromodulation within the renal artery. Pet. 41–42 (citing Ex. 1004, code (57), ¶ 64; Daft Pet. Decl. ¶¶ 115–119). According to Petitioner, "[w]hen used in the renal artery per the combination, it renders obvious an **ultrasound apparatus for thermally-induced renal neuromodulation**." Pet. 42 (citing Daft Pet. Decl. ¶ 119).

Patent Owner does not dispute that the combination of Levin and Acker discloses the subject matter of this recitation.[10] To the extent element 1a is limiting, we find, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that the combination of Levin and Acker discloses the subject matter of element 1a.

(2) Element 1b

In element 1b, claim 1 recites "a catheter sized and shaped for delivery within a blood vessel to a vicinity of neural fibers that contribute to renal function." Petitioner relies on the combination of Levin and Acker to address this element. *See* Pet. 42–44 (citing Daft Pet. Decl. ¶¶ 120–125). In support, Petitioner highlights Acker's teachings of catheters for use in vessel-like structures in the human body, and, specifically, Acker's teaching of a piezoelectric element (i.e., transducer) "readily formed into the shape desired," including one "desirably less than about 2 mm in diameter." Pet. 43 (quoting Ex. 1005, 4:42–52) (citing Ex. 1005, 2:18–2:38, 8:15–22; Daft Pet. Decl. ¶¶ 120–121). Because (1) the transducer forms the outer

[10] We address below Petitioner's position that one of ordinary skill in the art would have combined Levin and Acker. *See* § II.C.3.a(7).

diameter of the catheter (*see* Ex. 1005, Fig. 1) and (2) renal arteries in human adults range from 3.9 to 10 mm in diameter (*see* Mendelsohn Pet. Decl. ¶ 92), Petitioner asserts that one of ordinary skill in the art would have understood Acker to teach a catheter sized and shaped for delivery in "any particular blood vessel required for a treatment." *See* Pet. 43–44 (citing Daft Pet. Decl. ¶¶ 120, 122; Ex. 1005, 2:18–38, 8:15–22). Petitioner adds that, for reasons discussed below (*see* § II.C.3.a(7)), it would have been obvious to adapt Acker's catheter based on Levin to be sized and shaped for delivery within the renal artery, which is in the vicinity of neural fibers that contribute to renal function. *See* Pet. 44 (citing Daft Pet. Decl. ¶¶ 123, 124; Ex. 1004 ¶¶ 92, 94, 127).

Patent Owner presents two arguments challenging Petitioner's positions as to element 1b. *See* PO Resp. 24–34; PO Sur-reply 3–12. First, Patent Owner contends that Acker's catheter could not have been delivered to a renal blood vessel without "extensive modification." *See* PO Resp. 26–30. For the reasons below, this first argument does not identify a deficiency in Petitioner's position.

In support of this argument, Patent Owner first highlights disclosures in Acker relating to use of its catheter in *pulmonary* (rather than *renal*) arteries. *See* PO Resp. 26–27 (citing Ex. 1005, 1:23–27, 2:7–12, Fig. 1). Although certain passages in Acker focus on uses of its catheter in pulmonary vasculature, numerous other passages disclose use throughout the circulatory system. For example, as noted by Petitioner, Acker's Abstract summarizes its invention as "provid[ing] ultrasonic energy in a ring-like zone surrounding *a blood vessel*," and the Summary of the Invention discloses that "the catheter is positioned within *a circulatory vessel* with a

central axis of the emitting element substantially aligned with an axis of *the circulatory vessel*." Ex. 1005, code (57) (emphasis added), 2:23–25 (emphasis added), *cited at* Pet. Reply 12–13.

On appeal, the Federal Circuit expressly highlighted these two passages (among others) in holding that, in the original Final Written Decision, the Board improperly limited Acker to uses in pulmonary vasculature. *See* Appeal Dec. *2–*3. On this issue, the Federal Circuit stated that, although "Acker includes specific embodiments where the catheter is placed into a pulmonary vein, Acker clearly contemplates a wider use for its catheter to ablate other tissues with ultrasonic energy." *Id.* at *2 (citing Ex. 1005, 8:15–18); *see also id.* at *3 (stating that "the Board legally erred in dismissing Acker's broader teachings").

Patent Owner also contends, in support of this first argument, that Petitioner has not adequately explained "how Acker's catheter is ***shaped for delivery*** into the renal vasculature." PO Resp. 26. According to Patent Owner, Petitioner "ignore[s] the vast anatomical differences between the pulmonary vein (and other tubular structures) of Acker and the renal vasculature of Levin." *Id.* at 27. Patent Owner contends that Petitioner has not shown that Acker's catheter has the flexibility "to navigate the acute angle of branch from the abdominal aorta to the renal artery." *Id.* at 27–29.

This argument is based on a faulty premise—that Acker's catheter is limited to uses in pulmonary vasculature. That premise is clear from Patent Owner's argument and Dr. Tucker's supporting declaration testimony, both of which focus on the idea that Acker's alleged *pulmonary* catheter would not adequately operate as a *renal* catheter. *See* PO Resp. 26–30 (citing Tucker Decl. ¶¶ 74–83, 122). For example, in the cited testimony, Dr.

Tucker states that "Acker does not teach a catheter sized and shaped for delivery within a renal blood vessel" because "Acker teaches that its catheter is like the other prior art catheters in its field for *pulmonary vein isolation*." Tucker Decl. ¶ 74 (emphasis added). Dr. Tucker adds that "[a] catheter for delivery to the renal artery must be more flexible than a catheter for cardiac ablation; however, the distal end of the Acker's catheter is inflexible." *Id.* ¶ 78.

Patent Owner argues that Acker's catheter—having been allegedly designed solely for use in pulmonary vasculature—would not have been used for (and could not have been modified for use in) renal vasculature. *See, e.g.*, PO Resp. 27 (arguing that Petitioner "ignore[s] the vast anatomical differences between the pulmonary vein (and other tubular structures) of Acker and the renal vasculature of Levin"). For the same reasons discussed above, and as stated by the Federal Circuit, however, Acker is not properly limited to use in pulmonary vasculature.

We turn now to Patent Owner's assertion of error in Dr. Daft's statement that Acker "direct[s] use of its catheter in ***any blood vessel*** appropriate for a given therapeutic purpose" because the disclosed 2-mm-diameter of Acker's catheter may be slightly too large for use in *some* blood vessels. *See* PO Resp. 27 (quoting Daft Pet. Decl. ¶ 177) (citing Ex. 2034, 77:9–12, 54:7–25) (discussing how some blood vessels are less than 1 mm in diameter). Here, even if Dr. Daft's statement was slightly overbroad as to use in *all* human blood vessels, the record still supports that Acker's 2-mm-diameter catheter is sized and shaped for delivery in renal vasculature, the 3.9-mm to 10-mm size of which Patent Owner has not challenged. *See* Pet. 43 (citing Mendelsohn Pet. Decl. ¶ 92; Ex. 1047 at 436).

Continuing as to its first argument, Patent Owner presents file histories in which Petitioner and Petitioner's current Chief Scientific Officer (CSO), Dr. Neil Barman, allegedly sought to overcome rejections of claims to *renal* ultrasound catheters based on prior art disclosing *pulmonary* ultrasound catheters. *See* PO Resp. 27–29 (discussing Ex. 2008 (file history of EP 1802370 B1); Ex. 2017 (file history of US 9,981,108 B2)). Patent Owner first highlights a statement by Dr. Barman during prosecution before the European Patent Office as to how a renal denervation device must "adapt to diverse and tortuous vasculature profiles and to the large deflections the vasculature is subject to due to respiration" whereas a "cardiac ablation device needs to be stiff enough to bear against the heart tissue." PO Resp. 27–28 (quoting Ex. 2008 at 753). Next, Patent Owner raises Petitioner's prosecution statement that "[t]he Office action provides no additional disclosure supporting its conclusion that . . . Lesh's deflectable tip catheter for use in ablating the pulmonary vein ostium could be used within the renal artery in the manner described and claimed in the present application" because the "pulmonary vein ostium is anatomically distinct from a renal artery and would require a device of length, diameter and shape unique for use in that anatomy." Ex. 2017 at 865, *cited at* PO Resp. 28–29; *see also* Ex. 2006 (US 2022/0165535 A1 to Lesh).

As an initial matter, Patent Owner does not present persuasive case law support for limiting Petitioner's unpatentability arguments in this proceeding based on arguments made when prosecuting its own unrelated renal neuromodulation applications. In a footnote, Patent Owner offers *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 584 U.S. 325, 335 (2018) as support, highlighting the statement that "the grant of a patent

is a matter between 'the public, who are the grantors, and . . . the patentee.'" PO Resp. 25 n.5. But we do not view that general proposition as supporting the specific estoppel argument presented. *See also id* at n.5 (stating that Patent Owner "and the public at large are entitled to hold Petitioner[] to the statements [it] made"). In addition, as argued by Petitioner, Patent Owner failed to present in its Response any case law supporting the application of judicial estoppel to Petitioner's arguments in this proceeding based on statements by Dr. Barman made prior to his employment with Petitioner and while he was a paid consultant *for Patent Owner* in seeking a European patent. *See* Pet. Reply 16 (discussing Ex. 2008 at 751).

In the Sur-reply, for the first time, Patent Owner attempts to address the elements of judicial estoppel. *See* PO Sur-reply 12. As an initial matter, we view that argument as untimely. *See* Consolidated Trial Practice Guide 74 (Nov. 2019), https://www.uspto.gov/TrialPracticeGuideConsolidated ("TPG") ("Generally, a reply or sur-reply may only respond to arguments raised in the preceding brief. . . . While replies and sur-replies can help crystalize issues for decision, a reply or sur-reply that raises a new issue or belatedly presents evidence may not be considered."); *see also* Pet. Reply 23 n.2 (arguing that Patent Owner "has not even *attempted* to show that the four elements of judicial estoppel (PO[Resp.] 1) are met for any of its citations to [Petitioner's] patent prosecutions" (citing *Egenera, Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1378 (Fed. Cir. 2020))).

Moreover, on the complete record, we determine that *at least* the first element of judicial estoppel—that the party's earlier and later positions are "clearly inconsistent" (*see Egenera, Inc.*, 972 F.3d at 1378)—is not satisfied on the record here. Even assuming that estoppel *could* apply in this

proceeding based on a prosecution argument by a petitioner or prior statements by a petitioner's current employee prior to employment, the prosecution history statements at issue take a different position in that they seek to distinguish *pulmonary* catheters from *renal* catheters. *See, e.g.*, Ex. 2008 at 753 (contrasting a renal denervation intravascular device and a "cardiac ablation device"). In contrast, as discussed above, Acker is not properly limited to use in pulmonary vasculature. On the complete record here, Petitioner need not and does not make an inconsistent argument—that *pulmonary* catheters can be used as *renal* catheters. *See* Pet. Reply 24 (discussing how the statements distinguishing Lesh (Ex. 2017 at 865) are "not relevant with respect to the present combination, where Acker is clearly directed to 'blood vessels' beyond the pulmonary veins, and Levin *specifically* motivates renal denervation").

As the second of its two arguments addressing element 1b, Patent Owner contends that Petitioner has failed to adequately explain how Acker's catheter would have been modified for delivery to renal vasculature. *See* PO Resp. 30–34. According to Patent Owner, Petitioner "failed to show how the adaptations necessary for Acker's catheter to be shaped flexibly enough for delivery to a renal blood vessel would function with pre-existing catheter elements such as Acker's inflexible ultrasound transducer." *Id.* at 32 (citing Tucker Decl. ¶¶ 83–86; Weide Decl. ¶ 50). Patent Owner again relies on Petitioner's alleged "prior admissions" during prosecution of other patent applications. *Id.* Patent Owner also contends that one of ordinary skill in the art would not have been motivated "to position Acker's catheter in renal vasculature" because "Levin discloses positioning a catheter of a very different form than that of Acker." *Id.* Patent Owner asserts that Petitioner

has not shown that Acker's catheter "would make the 'right turn' from the abdominal aorta to the renal artery." *Id.* at 33.

Patent Owner's second argument is again based on the faulty premise that Acker's catheter is limited to use in pulmonary vasculature. As expressly stated by the Federal Circuit, "Acker clearly contemplates a wider use for its catheter to ablate other tissues with ultrasonic energy." Appeal Dec. *2. As argued by Petitioner, and as supported by the testimony of Dr. Daft and Dr. Moriarty, one of ordinary skill in the art implementing the teachings of Acker would have "had wide latitude to select an appropriately-sized transducer to navigate into renal arter[ies]"—i.e., one of the many "circulatory vessel[s]" within the scope of Acker's teachings. Pet. Reply 20 (citing Daft Reply Decl. ¶ 2; Moriarty Reply Decl. ¶ 28); *see* Ex. 1005, 2:23–25; Appeal Dec. *2–*3; *see also* Pet. Reply 21 (stating that one of ordinary skill in the art "would reasonably have expected to be able to select a sufficiently small transducer to ensure navigability" (citing Daft Reply Decl. ¶¶ 2–4; Moriarty Reply Decl. ¶¶ 26–30)). For example, Dr. Daft testifies that "[a] person having ordinary skill in early 2005 would have chosen transducer dimensions appropriate for the application, in this case renal denervation" and would have "appl[ied] ordinary engineering principles to select parameters like the focal length and numerical aperture to optimize renal denervation outcomes." Daft Reply Decl. ¶ 2. This testimony and the broad applicability of Acker's teachings throughout the circulatory system support Petitioner's position.

This understanding of the complete record is also supported by the lack of disclosure in the challenged patent on how its ultrasound transducer is sized and shaped for use in renal neuromodulation. *See In re Epstein*, 32

F.3d 1559, 1568 (Fed. Cir. 1994) (stating that "the Board's observation that appellant did not provide the type of detail in his specification that he now argues is necessary in prior art references supports the Board's finding that one skilled in the art would have known how to implement the features of the references"); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (stating, in a discussion of enablement, that "a patent need not teach, and preferably omits, what is well known in the art"). To the extent Patent Owner addressed these technical issues when developing the challenged patent technology, the disclosure does not appear to reflect such alleged advancements. *See Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1381–82 (Fed. Cir. 2013) (addressing a patent owner's argument as to an alleged technical issue in the proposed combination, stating that "[t]his naturally raises the question of how [patent owner] managed to make such a combination work"); *see also* PO Sur-reply 4–5 (detailing several alleged "factors [that] impact deliverability").

In the Reply, Petitioner discusses the lack of disclosure on these issues in the challenged patent (Pet. Reply 21–23), but Patent Owner only responds to allege certain differences between the Figure 13 embodiment in the challenged patent and the Figure 1 embodiment in Acker. *See* PO Sur-reply 9–10; *see also* Pet. Reply 23 (arguing that the Board "can and should infer from the [challenged] patent's silence on the issues [Patent Owner] now deems problematic that those issues were not significant, or were within ordinary skill to resolve"). Patent Owner does not, however, address Petitioner's *broader* argument and, moreover, seeks to limit Acker to solely its Figure 1 embodiment, which we do not. *See* Appeal Dec. *2–*3.

As to Patent Owner's continued reliance on Petitioner's (or Dr. Barman's) statements in the prosecution of unrelated applications, for the same reasons discussed above (in this section), we are not persuaded that judicial estoppel should apply to prevent Petitioner's allegedly contrary arguments in this proceeding.

For the reasons above, we find, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that the combination of Levin and Acker discloses the subject matter of element 1b.

(3) Element 1c

In element 1c, claim 1 recites "an ultrasound transducer carried by the catheter." Ex. 1001, 16:9. Petitioner states that Acker discloses this requirement. *See* Pet. 44 (citing Ex. 1005, code (57), 2:20–27, 3:44–47, 4:12–30; Daft Pet. Decl. ¶ 126). Patent Owner does not present arguments for this limitation. We find, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that Acker discloses this element.

(4) Element 1d

In element 1d, claim 1 recites "wherein the ultrasound transducer is configured to transmit ultrasound energy waves to target renal neural fibers outside of the blood vessel to thermally induce modulation of target neural fibers while protecting non-target tissue in the blood vessel wall from thermal injury." Ex. 1001, 16:9–14. Petitioner relies on the combination of Levin and Acker for this element. *See* Pet. 44–46; Daft Pet. Decl. ¶¶ 128–133. Specifically, Petitioner relies on Acker as disclosing that its "ultrasound transducer is configured to transmit ultrasound energy waves." *See* Pet. 44–45 (citing Ex. 1005, code (57), 2:18–38, 4:1–11, 4:35–41, 6:65–

7:14; Daft Pet. Decl. ¶ 128). Petitioner also relies on Acker as teaching the use of ultrasonic energy waves to target tissue outside of a blood vessel generally (although not "renal neural fibers" specifically) to thermally induce modulation of the target tissue. *See* Pet. 44–45 (citing Ex. 1005, 4:32–41; Daft Pet. Decl. ¶ 129; Ex. 1006, code (57), 13:3–6[11]). Referencing the discussion of the motivation to combine, Petitioner adds that "it would have been obvious to use Acker's catheter within the renal artery to target renal nerves." *See* Pet. 46 (citing Pet. 31–37; Daft Pet. Decl. ¶ 131).

As to the recitation "protecting non-target tissue in the blood vessel wall from thermal injury"—i.e., the "protecting" limitation—Petitioner relies on the combination of Levin and Acker. *See* Pet. 45–46 (citing Daft Pet. Decl. ¶¶ 129–131). Specifically, Petitioner states: "Acker teaches ablating tissue in a 'narrow, ring-like focal zone' that 'can be located at any distance from the central axis 12 of the emitting element" and 'may lie on the surface of the vein wall.'" Pet. 45 (quoting Ex. 1005, 4:34–41) (citing Daft Pet. Decl. ¶ 129). Then, Petitioner discusses a problem in prior art devices related to damage to "adjacent tissue," with Petitioner stating that Acker "teaches that in its own device, because the ultrasound energy is focused, there is a concentration of intensity within the focal region causing ablation, while ablation is not caused outside the focal region." Pet. 45–46 (citing Ex. 1005, 1:50–64, 2:13–18, 4:1–41, Fig. 1, claims 12 & 13; Daft Pet. Decl. ¶ 130). Referencing the discussion of the motivation to combine, Petitioner states, "it would have been obvious to use Acker's catheter within

[11] Like Petitioner and Patent Owner, we cite to the native pagination of Diedrich rather than the page numbering added by Petitioner.

the renal artery to target renal nerves." *See* Pet. 46 (citing Pet. 31–37; Daft Pet. Decl. ¶ 131).

Patent Owner presents two arguments challenging Petitioner's positions as to element 1d. *See* PO Resp. 34–38; PO Sur-reply 12–16. First, Patent Owner contends that "Acker's catheter, even if positioned within the renal artery, would not 'target renal neural fibers . . . ***while protecting non-target tissue in the blood vessel wall***." PO Resp. 34. According to Patent Owner, Petitioner has not explained "how Acker's catheter could be modified to do so given that the proposed fixed-focus ultrasound transducer ablates everything within its ring-like focal region—including the blood vessel wall on which the nerve plexus is located." *Id.* at 34–35 (citing Tucker Decl. ¶¶ 103–106). Patent Owner adds that, "while Acker discloses 'tissue disposed outside of said focal region is not ***ablated***,' Acker fails to meet the requirement that the tissue outside the focal region be protected from '***thermal injury***,' which is a more specific requirement than mere protection from ablation." *Id.* at 36 (citing Tucker Decl. ¶ 101).

As discussed above (*see* § II.B.2), we construe the "protecting" limitation as requiring protecting only *some* non-target tissue in the blood vessel wall from *some* thermal injury. Patent Owner, in contrast, takes the position that the "protecting" limitation precludes *any* "thermal injury," which (in Patent Owner's view) follows from any "non-target tissue" receiving *any* ultrasound energy. *See, e.g.*, PO Resp. 37 (arguing that "Acker's 'ring-like' ablation pattern, focused on nerves in or on the external surface of the renal artery, would at minimum cause thermal injury to the artery's wall where it is thickest"). By applying a construction not supported by the record, Patent Owner has not identified a deficiency in Petitioner's

showing as to the "protecting" limitation. *See* Pet. Reply 25 (arguing that this argument is "incorrect" because Patent Owner has "interpreted this limitation in an overly-narrow fashion").

Based on the compete record, we determine that Petitioner has shown that the combination of Levin and Acker satisfies the "protecting" limitation in the same way as the challenged patent—the use of "focused ultrasound" within renal vasculature. *See* Pet. Reply 25–26. For example, as noted by Petitioner, the challenged patent expressly discloses that "[f]ocusing the ultrasound wave may produce a reverse thermal gradient that protects the non-target tissues and selectively affect the target neural fibers to achieve thermal renal neuromodulation via heating." Ex. 1001, 14:52–55, *quoted at* Pet. Reply 25. And, as further noted by Petitioner, the use of "focused ultrasound energy waves" and a "reverse thermal gradient" are recited in claim 11, which depends from claim 1, showing they are within claim 1's scope. *See* Pet. Reply 25–26; *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003) ("If the dependent claims expressly recite 'up to about 10%' silicon, then the independent claims, which must be at least as broad as the claims that depend from them, must include aluminum coatings with 'up to about 10%' silicon."). Petitioner presents argument and evidence that Acker satisfies the added limitations in claim 11, including the use of "focused ultrasound energy waves" and a "reverse thermal gradient." *See* Pet. 54–57 (citing Daft Pet. Decl. ¶¶ 161, 162, 164).

Patent Owner presents its response to this line of argument in a footnote, pointing out that the passage at issue from the challenged patent (Ex. 1001, 14:52–55) says that focused ultrasound "may" produce a reverse thermal gradient that protects non-target tissue; it does not disclose that a

reverse thermal gradient "always" protects non-target tissues. PO Sur-reply 15 n.5. We do not agree with Patent Owner's understanding.

Other passages in the challenged patent make clear that the use of focused ultrasound *alone* is sufficient to "protect non-target tissue." For example, as highlighted by Petitioner, the challenged patent describes that "[n]on-target tissues additionally or alternatively may be protected by focusing the thermal energy on the target neural fibers such that an intensity of the thermal energy is insufficient to induce thermal damage in non-target tissues distant from the target neural fibers." Ex. 1001, 12:39–43, *cited at* Pet. Reply 25.

And the use of "may" in the passage at issue does not indicate that the "non-target tissue" *might not* be protected by focused ultrasound; instead, "may" indicates that the challenged patent describes numerous *other* ways to protect non-target tissue, such as the use of "cooling elements," described immediately prior. *See* Ex. 1001, 12:35–39. Supporting that understanding of "may," Patent Owner lists five alternative ways of protecting non-target tissue described in the challenged patent and argues that "[n]othing like these techniques is disclosed or rendered obvious by Acker alone or in combination with" Levin. PO Sur-reply 13–14. Petitioner, however, need not show that these *other* techniques—not required by claim 1—are disclosed or suggested by the relied-upon prior art.

For the reasons above, we determine that Petitioner has shown that Acker discloses the use of focused ultrasound (a point not disputed by Patent Owner) and Petitioner has adequately shown that the use of focused

ultrasound is *sufficient* (although not *necessary*) to satisfy the "protecting" limitation. *See, e.g.*, Ex. 1001, 12:39–43; Pet. Reply 25–26.[12]

As part of the argument above, Patent Owner also contends that Acker's "fixed-focus ultrasound transducer" *cannot* satisfy the "protecting" limitation because it "ablates everything within its ring-like focal region." PO Resp. 34–35; *see also id.* at 36 (arguing that Petitioner "fail[s] to explain how, despite ablating a 'ring-like . . . region' located at a ***fixed*** focal distance defined by the 'curvature and dimensions' of the transducer . . . , the combination can 'focus[] energy within [an ablation] ring' such that it both ablates the nerves 'on the external surface [of the] renal artery' and protects that external surface from thermal injury" (citations omitted)). We address three specific aspects of that assertion.

As to Acker's use of a "fixed focus" (PO Resp. 35), the challenged patent describes the use of "dynamically variable" focal distances for the ultrasound transducer (*see* Ex. 1001, 14:44–51), but claim 1 does not require that. *Cf. id.* at 16:42–44 (claim 7 reciting: "The apparatus of claim 5 wherein expansion of the balloon is calibrated to dynamically vary the focal distance point."). And the same passage of the challenged patent describing "dynamically variable" focal distances also discloses "specified focal distances" (*id.* at 14:48–49), like the fixed focal distance in Acker.

As to Acker's "ring-like focal region" (PO Resp. 35), the challenged patent discloses that the ultrasound energy may be delivered "over a radial

[12] Notably, Patent Owner's only argument as to claim 11 is a general argument (shared with all dependent claims in this ground except claim 4) that Petitioner failed to make a *prima facie* case of obviousness. *See* PO Resp. 52, *cited at* PO Sur-reply 15 n.5.

segment of less than 360º" (*see* Ex. 1001, 14:27–31), but claim 1 does not require that. And the same passage of the challenged patent describing a "radial segment of less than 360º" discloses that "the ultrasound may be delivered over a full 360º" (*id.* at 14:27–28), like the "ring-like focal region" in Acker.

We turn now to the assertion that *all* tissue in Acker's "ring-like focal region"—both target tissue and non-target tissue—is completely ablated, such that the proposed combination does not satisfy element 1d. *See* PO Resp. 35–38. According to Patent Owner, Dr. Mendelsohn "admitted that Acker does not disclose targeting renal nerves while protecting non-target tissue in the vessel wall from thermal injury." *Id.* at 36 (citing Mendelsohn Pet. Decl. ¶¶ 66, 73; Ex. 2034, 84:22–86:18). We disagree. As noted by Petitioner, Dr. Mendelsohn never took the position that Acker expressly taught targeting *renal* nerves at all; rather, his declaration testimony "supported *using* Acker's method *in order to* target renal nerves, *motivated by* teachings in Levin." Pet. Reply 26 (citing Mendelsohn Pet. Decl. ¶ 73).

Moreover, Patent Owner argues that neither Acker nor Levin expressly teaches how to locate and target *each* renal nerve fiber in a given renal vessel, which have irregular thicknesses. *See* PO Resp. 36–37; PO Sur-reply 14–16; *see also* PO Sur-reply 16 ("Petitioner[] fail[s] to explain how Acker's fixed focus can be used or modified to target these nerves at undetermined depths."). As noted by Petitioner, however, Patent Owner demands more of the prior art regarding "target[ing] renal neural fibers" than is provided in the challenged patent, which (as discussed above) also describes, in the context of the invention, the use of fixed-focus ultrasound

in a 360º ring. *See* Pet. Reply 27 (citing *In re Epstein*, 32 F.3d at 1568); *Smith & Nephew, Inc.*, 721 F.3d at 1381–82.

On this issue, Petitioner also highlights that one of ordinary skill in the art would have "understood that denervation occurred at lower temperatures than required to injure blood vessels" and that one of ordinary skill in the art would have "had the ability to model heating with focused ultrasound . . . , allowing [one of ordinary skill in the art] to both target the ring-like ablation zone outside of the renal artery and correctly project the temperature increase both therein and in surrounding tissues." Pet. Reply 26 (citing Pet. 40; Mendelsohn Pet. Decl. ¶¶ 74, 92–93; Daft Pet. Decl. ¶ 112; Moriarty Reply Decl. ¶¶ 29–33). Supporting this, Dr. Moriarty testifies that "the Acker device would have been effective at depositing sufficient energy in a ring-like ablation zone surrounding a blood vessel, and raising the temperature high enough to cause renal denervation, but still keeping the temperature low enough to prevent thermal injury in surrounding tissue" and that, "[e]ven if a portion of the target zone overlapped with the vessel wall, a person having ordinary skill in the art would have reasonably expected that the renal nerves could be targeted at a temperature low enough to not cause damage to the vessel wall." Moriarty Reply Decl. ¶ 30, *cited at* Pet. Reply 26. Patent Owner does not address these positions (which we find persuasive and supported by the record), instead relying on its narrower proposed construction of the "protecting" limitation, which precludes *any* thermal injury to non-target tissue. *See* PO Sur-reply 13–15.

As the second argument addressing element 1d, Patent Owner again argues that Petitioner has "contradict[ed] the position they took when

prosecuting their own patents before the USPTO." PO Resp. 38. Specifically, Patent Owner asserts that Petitioner

> successfully distinguished claims directed to [renal denervation] using an ultrasound catheter from prior art teaching [pulmonary vein isolation] using an ultrasound catheter by arguing that the "prior art of record," which included Levin, "provides no clue as to how the operating parameters required to ablate the pulmonary vein . . . could or should be adjusted to achieve renal denervation in a different portion of the vasculature ***while also avoiding unwanted tissue damage***."

PO Resp. 38 (quoting Ex. 2015 (file history of US 9,943,666 B2) at 478–479) (citing Ex. 2015 at 161; Tucker Decl. ¶ 108). For the same reasons discussed above (*see* § II.C.3.a(2)), we are not persuaded that judicial estoppel should apply to prevent Petitioner's allegedly contrary arguments in this proceeding.

Based on the complete record, we find that Petitioner has demonstrated by a preponderance of the evidence that the combination of Levin and Acker discloses the subject matter of element 1d.

(5) Element 1e

In element 1e, claim 1 recites "an expandable member carried by a distal region of the catheter, wherein the expandable member is configured to vary between a reduced configuration for delivery and retrieval and an expanded deployed configuration." Ex. 1001, 16:14–15. Petitioner identifies balloon 50 in Figure 1 of Acker as the "expandable member" and explains how balloon 50 varies between an uninflated configuration for delivery and an inflated configuration for deployment. *See* Pet. 46–47 (citing Ex. 1005, 4:12–32; Daft Pet. Decl. ¶¶ 134–138). Patent Owner does not present arguments for this limitation. We find, based on the complete

record, that Petitioner has demonstrated by a preponderance of the evidence that Acker discloses this element.

(6) Element 1f

In element 1f, claim 1 recites "wherein the ultrasound transducer is positioned on a shaft of the catheter and within the expandable member." Ex. 1001, 16:19–20. Petitioner states that "Acker's ultrasound transducer is **positioned on a shaft of the catheter**, because its 'emitting element' (*i.e.*, the ultrasound transducer) is 'mounted on an elongated catheter body 40 having a proximal end 42 and a distal end 44.'" Pet. 48 (citing Ex. 1005, 4:12–14, Fig. 1; Daft Pet. Decl. ¶ 139). In addition, Petitioner states that "Acker further discloses the ultrasound transducer is within an expandable 'outer balloon' (*i.e.*, **within the expandable member**)." Pet. 48 (citing Ex. 1005, 7:35–54; Daft Pet. Decl. ¶ 139).

Patent Owner does not present arguments for this limitation. We find, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that Acker discloses this element.

(7) The Reasons to Combine Levin and Acker

Petitioner provides the following summary of the proposed combination of Levin and Acker:

> In brief, Levin teaches using a catheter-based approach within a renal artery to modulate renal nerves lying on the external surface of the arterial wall. While Levin does not teach using ultrasound, Acker does. Specifically, Acker provides an ultrasound catheter for ablating tissue lying outside a blood vessel. A person of ordinary skill . . . would have found it obvious to use Acker's ultrasound-based catheter in one of the treatment methods suggested by Levin.

Pet. 31. In discussing this asserted ground, Petitioner addresses (1) reasons that one of ordinary skill in the art would have combined Levin and Acker in

the manner proposed (Pet. 31–37), (2) why one of ordinary skill in the art would have had a reasonable expectation of success in the proposed combination (Pet. 37–40), and (3) why Levin and Acker are analogous art to the invention in the challenged patent (Pet. 41).

As to the reasons to combine, Petitioner first states that "Levin itself" motivates the combination as it teaches that renal neuromodulation in general can alleviate congestive heart failure, chronic renal failure, and hypertension, and also teaches that ablation is a form of modulation. *See* Pet. 31–32 (citing Daft Pet. Decl. ¶¶ 78–90, 96–103; Ex. 1004 ¶¶ 2, 33, 28–60, 64, 128–129, claim 17; Mendelsohn Pet. Decl. ¶¶ 52, 53). Petitioner further states that Levin also teaches that modulation "can be performed using a catheter-based procedure from within the renal artery, by modulating nerves situated on the external surface of the renal artery" and that one of ordinary skill in the art would have understood that Acker's catheter with an ultrasound transducer "is designed for such purposes." *See* Pet. 32 (citing Daft Pet. Decl. ¶¶ 97–98; Ex. 1004 ¶¶ 64, 94, 111, 127, Figs. 3 & 9; Ex. 1005, 3:22–4:42; Mendelsohn Pet. Decl. ¶¶ 50, 63, 64). According to Petitioner, one of ordinary skill in the art "would have been motivated to adapt the Acker catheter (including specifically sizing and shaping) for the purpose disclosed in Levin." Pet. 32 (citing Ex. 1005, 2:18–38, 8:15–22; Daft Pet. Decl. ¶ 98).

Petitioner also asserts that one of ordinary skill in the art would have expected certain advantages from using Acker's catheter in Levin's renal neuromodulation method, including that Acker's ability to focus energy within a ring around the catheter would have avoided damage to the wall of the renal artery and reduced the risk of arterial stenosis or perforation.

Pet. 32–33 (citing Daft Pet. Decl. ¶¶ 93, 94, 99; Mendelsohn Pet. Decl. ¶ 73; Ex. 1005, 1:53–56, 4:1–11, 4:35–42, 7:5–13, 8:15–21, code (57), claims 12 & 13, Fig. 1; Ex. 1006, 49:5–14). According to Petitioner, one of ordinary skill in the art would have understood ultrasound as a "known and predictable alternative to using electrical current as suggested by Levin" in that both would cause the same result: "heating of the nerves to a temperature causing nerve ablation." Pet. 33–34 (citing Daft Pet. Decl. ¶¶ 94, 102, 105; Ex. 1006, 22:26–23:7; Mendelsohn Pet. Decl. ¶¶ 69, 75). Petitioner also discusses why Levin does not teach away from use of ablation. *See* Pet. 34–37.

As to reasonable expectation of success, Petitioner discusses why one of ordinary skill in the art would have expected success in achieving the claimed features with the proposed combination. Pet. 37–38 (citing Ex. 1004 ¶¶ 92, 94, 111, Figs. 3 & 9; Daft Pet. Decl. ¶¶ 104–111; Exs. 1035–1046); *see* Pet. 39 ("Based on Acker's flexibility and the prior use of catheter-based treatments within the renal artery, [one of ordinary skill in the art] would have reasonably expected success in adapting Acker's catheter (and in particular, to making Acker's catheter the proper size and shape) to use within the renal artery, to the extent any such adaptation were necessary." (citing Daft Pet. Decl. ¶ 112)).

Petitioner asserts that Acker's catheter is similar to catheters that have been successfully used for transvascular ablation procedures in the past. Pet. 38–39 (citing Daft Pet. Decl. ¶¶ 110, 111, 135–138; Ex. 1005, 1:19–22, 4:12–24; Ex. 1006, 11:14–19, 16:10–15, 31:3–11, 38:26–39:13; Exs. 1015 & 1016). Petitioner also discusses various teachings in Levin and Acker that allegedly support that one of ordinary skill in the art would have had a

reasonable expectation of success that the proposed combination would have provided element 1d. *See* Pet. 39–40 (citing Daft Pet. Decl. ¶¶ 109, 113; Mendelsohn Pet. Decl. ¶¶ 74, 82–83, 92–93; Ex. 1004 ¶ 127; Ex. 1005, 4:1–41, Fig. 1, claims 12 & 13; Ex. 1006, code (57), 13:3–6).

Patent Owner presents four arguments challenging the reasons to combine Levin and Acker and the reasonable expectation of success in the combination. *See* PO Resp. 38–52; PO Sur-reply 16–23. First, Patent Owner argues that Petitioner has not shown that one of ordinary skill in the art would have understood ultrasound as a known substitute for radio frequency (RF) for the renal neuromodulation application recited in claim 1 and that one of ordinary skill in the art "would not have been motivated to use or reasonably expected to succeed in using Acker's ultrasound catheter for Levin's RDN treatment."[13] PO Resp. 38 (citing Tucker Decl. ¶¶ 110–119; Weide Decl. ¶¶ 66–72); *see id.* at 38–41 (entire argument). With this argument, Patent Owner has not identified a deficiency in Petitioner's position.

The record supports Petitioner's argument that Levin teaches using a catheter-based apparatus to modulate nerves on a renal artery, including by ablation. Pet. 31–32 (citing, e.g., Daft Pet. Decl. ¶ 97; Ex. 1004 ¶¶ 51, 64, 94, 111, 127–129, claim 17, Figs. 3 & 9); *see* Appeal Dec. *4. And, as discussed above (*see* § II.C.3.a(2)), Acker broadly teaches the use of its catheter to ablate tissue—not just pulmonary vasculature tissue—using

[13] Like the parties, we use the terms "renal denervation," "RDN," and "renal neuromodulation" interchangeably. *See* PO Resp. xi (defining "RDN" as "renal denervation"), 2–4 (using RDN and "renal neuromodulation" to describe the invention of the challenged patent).

ultrasound energy. Pet. 32–33 (citing Daft Pet. Decl. ¶ 98; Mendelsohn Pet. Decl. ¶¶ 50, 63, 64; Ex. 1005, 3:22–4:42) (arguing that one of ordinary skill in the art "would have understood that Acker's catheter is designed for such purposes"—i.e., the renal neuromodulation procedures disclosed in Levin and performed by the apparatus of claim 1 of the challenged patent—in that "Acker teaches using an intravascular catheter with an ultrasound transducer within a blood vessel"); *see* Appeal Dec. *2–*4.

On the complete record, Petitioner has adequately explained why (contrary to Patent Owner's first argument), one of ordinary skill in the art would have understood ultrasound (like that disclosed in Acker) "to be a known and predictable alternative to using electrical current as suggested by Levin." Pet. 33 (citing Daft Pet. Decl. ¶ 102); *see* Appeal Dec. *3–*4 (framing this as an "obvious-to-try theory"). For example, Petitioner highlights how Diederich (incorporated by reference into Acker (*see* Ex. 1005, 1:19–22))[14] teaches ultrasound as a known alternative to electrical current (among other thermal energy sources) for ablation of tissue. Pet. 33–34 (citing Ex. 1006, 22:26–23:7; Daft Pet. Decl. ¶ 95; Mendelsohn Pet. Decl. ¶¶ 69, 75). In this same discussion, Petitioner cites to Dr. Daft's testimony discussing Huang.[15] *See* Pet. 33–34 (citing Daft Pet. Decl. ¶ 102). There,

[14] "Diederich" is World Intellectual Property Organization International Publication WO 99/02096 A1, published January 21, 1999. *See* Ex. 1006. Diedrich is incorporated by reference into Acker, effectively making the disclosures in Diedrich part of Acker. *See Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (discussing the effect of incorporation by reference in anticipation).

[15] Huang is an excerpt from a 2000 textbook titled "Radiofrequency Catheter Ablation of Cardiac Arrhythmias." *See* Ex. 1059.

Dr. Daft states that "[u]ltrasound ablation was a known substitute for RF ablation," relying for support on Table 1 of Huang, reproduced below:

Table 1
Methods and Energy Sources for Lesion Generation

- Radiofrequency heating
- Direct current heating
- Cryogenics
- Focused ultrasound
- Microwave heating
- Laser heating
- Chemical destruction
- Induction heating
- Radiation
- Mechanical methods

Ex. 1059 at 4 (Table 1). Table 1 lists "Methods and Energy Sources for Lesion Generation" including, among others, "Radiofrequency heating" and "Focused ultrasound." *Id.*

Patent Owner argues that neither Diederich nor Huang would have motivated the use of Acker's ultrasound apparatus in Levin's renal neuromodulation procedure because Diederich is directed to uses only in pulmonary contexts and Huang's highlighted teachings are focused on lesion generation. *See* PO Resp. 40–41 (citing Tucker Decl. ¶¶ 116–118). The record does not support this argument. In the passage at issue, Diederich generally discusses "[s]uitable 'energy emitting' ablation elements" that are exemplary "specific structures adapted to ablate a defined region of tissue." *See* Ex. 1006, 22:26–23:8. Dr. Daft's cited testimony supports this broader understanding of Diederich, indicating that one of ordinary skill in the art would have understood that reference as disclosing "that RF ablative

intravascular catheters are interchangeable with ultrasound ablative intravascular catheters for ablating around a blood vessel." Daft Pet. Decl. ¶ 95, *cited at* Pet. 34. Dr. Tucker focuses on Diederich's specific disclosures regarding use in pulmonary contexts, but does not address its broader teachings of suitable "ablation elements." *See* Tucker Decl. ¶ 118.

As to Huang, Table 1 above mentions an application for "[l]esion [g]eneration," but Dr. Daft testifies that one of ordinary skill in the art seeing Huang would have understood it to indicate that "[u]ltrasound ablation was a known substitute for RF ablation" in other applications. *See* Daft Pet. Decl. ¶ 102, *cited at* Pet. 34. Patent Owner counters that Huang "fails to suggest that focused ultrasound could be a substitute for RF energy in RDN" (PO Resp. 40 (citing Tucker Decl. ¶ 117 (same); Weide Decl. ¶ 68 (same)), but an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Patent Owner and its declarants point to a statement in Huang implying that some options in Table 1 "border on the diabolical" as evidence that one of ordinary skill in the art would not have viewed all listed options as "viable substitutes." PO Resp. 40; Tucker Decl. ¶ 117; Weide Decl. ¶ 68. On the complete record, we are persuaded by Dr. Daft's contrary testimony, and we view the "diabolical" comment as not sufficiently specific to undermine the use of focused ultrasound (used by Acker, which was filed near the time of Huang's publication) as a substitute for RF in tissue ablation. *See* Daft Pet. Decl. ¶ 102.

To support this argument, Patent Owner again relies on statements by Petitioner during prosecution of unrelated applications. *See* PO Resp. 41 (citing Ex. 2015 at 1, 523, 530). For the same reasons discussed above (*see* § II.C.3.a(2)), we are not persuaded that judicial estoppel should apply to prevent Petitioner's allegedly contrary arguments here. *See* Pet. Reply 29. On the complete record, we find that both Diederich and Huang teach a limited universe of thermal energy sources for ablation of tissues and as showing the presence of a sufficiently finite universe of options, both supporting Petitioner's obvious-to-try rationale. *See* Pet. 33–34; Appeal Dec. *3–*4.

As its second argument addressing the reasons to combine, Patent Owner contends that one of ordinary skill in the art would not have been motivated to use Acker's "fixed-focus ultrasound-based ablation ring" to target renal neural fibers and would not have had a reasonable expectation of success. *See* PO Resp. 41–46. This argument does not identify a deficiency in either aspect of this asserted ground.

Patent Owner argues that "[n]either Levin nor Acker teaches or renders obvious (individually or collectively) how to traverse the obstacles of targeting renal nerves with Acker's fixed-focus ultrasound-based ablation ring while protecting non-target tissue in the blood vessel wall from thermal injury." PO Resp. 42. As discussed above as to element 1d (*see* § II.C.3.a(4)), however, the challenged patent describes the use of a "specified focal distance[]" (Ex. 1001, 14:48–49) and of ultrasound "delivered over a full 360º" (*id.* at 14:27–28), like the aspects of Acker that Patent Owner now contends are problematic to the success of the combination.

Patent Owner also contends as part of this argument that Levin and Acker are different than each other and that neither reference teaches the entirety of claim 1. *See, e.g.*, PO Resp. 42–45 (asserting that "Levin's teachings are of an entirely different type and implementation of catheter than Acker's," that "[u]nlike Petitioner['s] proposed combination, Levin's intravenous catheter embodiments teach using RF," and that Acker does not form a ring-like ablation pattern "outside of the blood vessel wall"); *see also* PO Sur-reply 18 (arguing that "none of Petitioner['s] references suggests using ultrasound for RDN").

"A finding of obviousness, however, cannot be overcome 'by attacking references individually where the rejection is based upon the teachings of a combination of references.'" *Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1050 (Fed. Cir. 2019) (quoting *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986)). Moreover, much of this line of argumentation again relies on Petitioner's (or Dr. Barman's) statements in the prosecution of unrelated applications. *See* PO Resp. 44–45 (citing Ex. 2008 at 751–753). For the same reasons discussed above (*see* § II.C.3.a(2)), we are not persuaded that judicial estoppel should apply to prevent Petitioner's allegedly contrary arguments in this proceeding.

Patent Owner further argues that, "[r]egarding treatment efficacy, [one of ordinary skill in the art] would not have used Acker's fixed-focus ablation ring for RDN because there was no reasonable expectation that it would be efficacious." PO Resp. 45–46. For this argument, Patent Owner again relies on Petitioner's statements in the prosecution of unrelated applications. *See id.* (citing Ex. 2017 at 686; Ex. 2019 (file history of US 10,039,901 B2) at 567–568). For the reasons discussed above (*see* § II.C.3.a(2)), we are not

persuaded that judicial estoppel should apply to prevent Petitioner's allegedly contrary arguments in this proceeding.

As its third of four arguments addressing the reasons to combine, Patent Owner contends that targeting renal neural fibers outside of the blood vessel using a fixed-focus ablation ring would have risked injury and been unpredictable. *See* PO Resp. 46–50. This argument does not identify a deficiency in Petitioner's position.

As part of this argument, Patent Owner contends that one of ordinary skill in the art "would have understood that Acker's ablation ring, which extends 360° about the catheter's central axis, would be unsuitable for RDN because it would risk ablating any additional anatomical structures within the ring." PO Resp. 47 (citing Tucker Decl. ¶¶ 134–140); *see* PO Resp. 47–50 (discussing the alleged potential damage). Again, as discussed above as to element 1d (§ II.C.3.a(4)), the challenged patent describes the use of a "specified focal distance" (Ex. 1001, 14:48–49) and of ultrasound "delivered over a full 360º" (*id.* at 14:27–28), like the aspects of Acker that Patent Owner now contends are problematic to the success of the combination. Further, as also discussed above (§ II.C.3.a(4)), we are not persuaded that one of ordinary skill in the art would have used Acker's ultrasound catheter (or a modified version) to completely ablate all tissue within its focal region, especially given Petitioner's unrebutted discussion of how one of ordinary skill in the art would have known that denervation occurs at lower temperatures than required to injure blood vessels. *See, e.g.*, Daft Pet. Decl. ¶ 112 (discussing how any changes to Acker would have "been the sort of thing routinely done by biomedical engineers in the relevant timeframe, and would have been well within ordinary skill"), *cited at* Pet. 37; Pet. Reply 32.

Moreover, as argued in response by Petitioner, "Acker's catheter avoids unwanted tissue injury by *focusing* ultrasound energy to within a small treatment zone" (Pet. Reply 32) and, as discussed above, the challenged patent makes clear that the use of focused ultrasound alone is at least sufficient to "protect non-target tissue" (*see* § II.C.3.a(4)). *See* Pet. Reply 33 ("Though the [challenged] patent's ultrasound embodiments use focused ultrasound (like Acker), though they have 360-degree embodiments with the same depth of focus circumferentially (like Acker), and though they use a reverse thermal gradient (like Acker) to protect non-target tissue, the [challenged] patent provides no hint that there would be any enhanced risks to the patient, nor provide any way to overcome such risks."). In addition, much of the support for this argument is from Petitioner's statements in the prosecution of unrelated applications, and, as discussed above (*see* § II.C.3.a(2)) Patent Owner has not shown judicial estoppel should apply to these statements. *See* PO Resp. 49 (citing Ex. 2008 at 755; Ex. 2017 at 685–686, 861; Ex. 2019 at 545, 566–567); PO Sur-reply 22 (citing Ex. 2017 at 686; Ex. 2019 at 545, 567).

As its fourth argument addressing the reasons to combine, Patent Owner contends that "vast, anatomical differences" between pulmonary veins and renal vasculature would have discouraged using (or modifying) Acker's ultrasound catheter for use in Levin's renal neuromodulation method. *See* PO Resp. 50–52. In support, Patent Owner again relies on Petitioner's (or Dr. Barman's) statements in the prosecution of unrelated applications. *See id*. at 51–52 (citing Ex. 2008 at 752, 753; Ex. 2015 at 478).

This argument does not identify a deficiency in Petitioner's reasons to combine Levin and Acker. As an initial matter, we reject the premise of the

argument because, for the same reasons discussed above (*see* § II.C.3.a(2)), Acker is not properly limited to use in pulmonary vasculature. Moreover, for the same reasons also discussed above (*see id.*), we are not persuaded that judicial estoppel prevents Petitioner's allegedly contrary arguments here.

For the reasons above, we determine, based on the complete record, that Petitioner has shown by a preponderance of the evidence that one of ordinary skill in the art at the time of the invention would have had reason to use (or modify) the device of Acker for the renal neuromodulation method of Levin, as proposed, and would have had a reasonable expectation of success in the combination.

(8) Objective Indicia of Nonobviousness

We next turn to Patent Owner's objective evidence of nonobviousness and Petitioner's rebuttal evidence. Objective evidence of nonobviousness, when present, must be considered as part of an obviousness inquiry. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012). Notwithstanding what the teachings of the prior art would have suggested to one of ordinary skill in the art, the totality of the evidence submitted, including objective evidence of nonobviousness, may lead to a conclusion that one or more of the challenged claims would not have been obvious to one of ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984).

"In order to accord substantial weight to secondary considerations in an obviousness analysis, the evidence of secondary considerations must have a nexus to the claims, i.e., there must be a legally and factually sufficient connection between the evidence and the patented invention." *Fox Factory,*

Inc. v. SRAM, LLC, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (cleaned up). Applying *Fox Factory*, the Board uses a two-step analysis in evaluating nexus between the claimed invention and objective evidence of nonobviousness. *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 33 (PTAB Jan. 24, 2020) (precedential). We first consider whether the patent owner has demonstrated "that its products are coextensive (or nearly coextensive) with the challenged claims," resulting in a rebuttable presumption of nexus. *Id.* If not, that does not end the inquiry; "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.* (quoting *Fox Factory*, 944 F.3d at 1373–75).

Patent Owner argues several objective indicia: (1) unexpected results and skepticism, (2) copying, (3) industry praise, and (4) long-felt but unsolved need and failure of others. PO Resp. 60–68; PO Sur-reply 25–27. Petitioner responds. *See* Pet. Reply 36–37. We address each below.

(a) Unexpected Results & Skepticism

"[E]vidence of unexpected results may be strong support for a conclusion of nonobviousness." *Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1461 (Fed. Cir. 1984). In addition, "[i]f industry participants or skilled artisans are skeptical about whether or how a problem could be solved or the workability of the claimed solution, it favors non-obviousness." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1335 (Fed. Cir. 2016).

Patent Owner first argues that "Dr. Mendelsohn in fact admits, as late as 2014, there was skepticism in the field that RDN was effective." PO

Resp. 62 (citing Ex. 2034, 86:20–88:9). As an initial matter, much of Dr. Mendelsohn's cited testimony relates to skepticism about the efficacy of renal denervation *in general*, rather than catheter-based renal denervation *using ultrasound*. *See, e.g.*, Ex. 2034, 87:8–11, 87:20–88:9. We do not view that testimony as supporting industry skepticism sufficiently specific to help show nonobviousness of the claimed invention. *See Auris Health, Inc. v. Intuitive Surgical Operations, Inc.*, 32 F.4th 1154, 1159 (Fed. Cir. 2022) (citing *WBIP*, 829 F.3d at 1335–36 (stating that, in the context of objective indicia, "the evidence of skepticism must be specific to the invention, not generic to the field")).

That said, Dr. Mendelsohn also testifies that the industry was "generally" skeptical "about whether catheter-based ultrasound would work for renal denervation." Ex. 2034, 87:14–17; *see also id.* at 87:2–6. Although Dr. Mendelsohn did not identify who held these views or provide evidence of those views, we find at least some evidence of industry skepticism of the claimed invention.

Next, Patent Owner again relies on Petitioner's (or Dr. Barman's) statements in the prosecution of unrelated applications. PO Resp. 62–64 (citing Ex. 2015 at 523, 530; Ex. 2017 at 686, 861; Ex. 2019 at 545, 567; Ex. 2008 at 754–756, 768–779; Tucker Decl. ¶¶ 171–173). For the reasons discussed above (*see* § II.C.3.a(2)), we are not persuaded that judicial estoppel should apply to prevent Petitioner's allegedly contrary arguments here.

Patent Owner also argues that, although its "Symplicity™ RDN catheter used RF, not ultrasound, the scientific community's skepticism of the efficacy of RDN generally is objective evidence [one of ordinary skill in

the art] would not have found it obvious to use a catheter to 'thermally induce modulation of target neural fibers' as recited" in the challenged claims. PO Resp. 64 (citing Tucker Decl. ¶ 174).

For the reasons discussed above, and as argued by Petitioner, industry skepticism of renal denervation in general (e.g., using an RF-based system) is not sufficiently linked to the claimed invention to support nonobviousness. Pet. Reply 36 (stating that Patent Owner "alleges **unexpected results and skepticism**" but that "these relate to the catheter-based renal denervation process *using RF*" (citing PO Resp. 64)); Pet. 76 ("SYMPLICITY is an RF catheter. It does not use ultrasound and has no nexus with the claimed ultrasound catheter."), 77 (arguing no nexus for unexpected results because SYMPLICITY is an RF catheter); *Auris Health*, 32 F.4th at 1159.

For the reasons above, we determine that Patent Owner's evidence of industry skepticism and unexpected results are entitled to minimal weight supporting nonobviousness.

(b) Copying

Copying of a claimed invention may be a "'form of flattering praise for inventive features,' and thus evidence of copying tends to show nonobviousness." *WBIP*, 829 F.3d at 1336 (quoting *Crocs, Inc., v. Int'l Trade Comm'n*, 598 F.3d 1294, 1311 (Fed. Cir. 2010)). Although "copying is not alone dispositive of nonobviousness, we have usually considered a determination of copying to be 'strong evidence of nonobviousness.'" *Volvo Penta of the Ams., LLC v. Brunswick Corp.*, 81 F.4th 1202, 1213 (Fed. Cir. 2023) (quoting *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1099 (Fed. Cir. 1985)). "Evidence of copying may include internal documents,

direct evidence such as photos of patented features or disassembly of products, or access and similarity to a patented product." *Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1137 (Fed. Cir. 2019).

Patent Owner contends that the claimed invention "was extensively copied" by Petitioner, "who obtained claims similar to those of the [challenged patent] long after [it] issued." PO Resp. 64. In support, Patent Owner contends that Petitioner's U.S. Patent Nos. 9,943,666 B2 (Ex. 2014); 9,981,108 B2 (Ex. 2016); and 10,039,901 B2 (Ex. 2018) issued after the challenged patent but have "similar" claims. *See* PO Resp. 64 (citing Tucker Decl. ¶¶ 179–180 (comparing claim language)).

Petitioner responds that copying requires "copying of a *product*, not copying of *patent claims*" and that Dr. Tucker's claim chart "deceptively edits" the claims of Petitioner's patents, removing limitations not found in claim 1 of the challenged patent. *See* Pet. Reply 36–37 (citing *Fleming v. Cirrus Design Corp.*, 28 F.4th 1214, 1224 (Fed. Cir. 2022); Tucker Decl. ¶ 179). For the reasons below, we determine that Patent's evidence of copying is entitled to no weight.

As an initial matter, we do not agree with Petitioner that the decision in *Fleming* stands for the broad proposition that copying (as an objective indicia) *cannot* include copying of patent claims. Instead, we agree with Patent Owner's view that copying claims—if established—*can* support nonobviousness. *See* PO Sur-reply 26–27. In *Fleming*, when determining that the Board's finding of no copying was adequately supported by the record, the Federal Circuit highlighted that the allegedly copied claims had "limitations different from those in the" original patent's claims. *Fleming*, 28 F.4th at 1224. If copying of claims *could not* (as a matter of law) help

show nonobviousness, the Federal Circuit would not have addressed whether copying *of claims* had in fact occurred.

Regardless, on the complete record, Patent Owner has not provided direct, credible evidence that Petitioner copied the challenged patent's claims. *See Liqwd, Inc.*, 941 F.3d at 1137–38 (discussing prior Federal Circuit decisions addressing alleged copying, and stating that, "[i]n each case, the question of legal relevancy was determined by whether there was *actual evidence of copying efforts* as opposed to mere allegations regarding similarities between the accused product and a patent" (emphasis added)). As merely one example that might have shown copying here, Patent Owner has not provided evidence indicating that Petitioner was aware of the challenged patent and knowingly copied the challenged patent claims when drafting claims in *its own* patents. *Cf. Fleming*, 28 F.4th at 1224. Instead, Patent Owner relies solely on alleged similarity between claims in patents issued to two corporations in the renal neuromodulation catheter market. Numerous other factors, however, could account for those similarities, including the technical needs of *any* renal ultrasound catheter.

Moreover, as noted by Petitioner, Dr. Tucker's claim chart uses ellipses to remove the term "unfocused" as a descriptor for the type of "ultrasound energy" required by each of the inventions in Petitioner's three patents. *See* Pet. Reply 36–37; *compare* Tucker Decl. ¶ 179, *with* Ex. 2014, 11:49–50; Ex. 2016, 11:49–50; Ex. 2018, 11:58–59 (all reciting "unfocused" ultrasound). Patent Owner makes no effort to explain why Petitioner's three patents—which expressly claim "unfocused" ultrasound energy—are similar to, or could have been copied from, claim 1 of the challenged patent. Put simply, Patent Owner's position as to copying is little more than speculation

that Petitioner *may have* copied the challenged patent's claims; any inference that copying *did* occur is not supported by the complete record.

For the reasons above, we determine that Patent Owner's evidence of copying is entitled to no weight.

(c) Praise

Praise from industry participants, especially competitors, is probative as to nonobviousness because such participants "are not likely to praise an obvious advance over the known art. Thus, if there is evidence of industry praise of the claimed invention in the record, it weighs in favor of the non-obviousness of the claimed invention." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1053 (Fed. Cir. 2016) (en banc).

Patent Owner argues that the challenged claims "recite[] using an ultrasound-based catheter for RDN." PO Resp. 65. In support of alleged praise, Patent Owner asserts that (1) Dr. Mendelsohn "admitted [that] he is aware of multiple colleagues praising the use of ultrasound for RDN at public conferences" and (2) "ultrasound-based endovascular RDN has received praise from multiple sources." *Id.* (citing Ex. 2034, 89:4–90:3, 94:9–18; Exs. 2037–2040; Tucker Decl. ¶ 178). Petitioner responds that Patent Owner has not adequately established a nexus between the evidence of alleged praise and the challenged claims. *See* Pet. Reply 37 (citing *Fox Factory*, 944 F.3d at 1373). For the reasons below, we agree with Petitioner.

When arguing objective indicia of nonobviousness, "[t]he patentee bears the burden of showing that a nexus exists." *Fox Factory*, 944 F.3d at 1373. Given that Patent Owner has not provided *any* evidence that a product embodies the claimed features and is coextensive with the claims, Patent Owner is not entitled to presumption of nexus. *Lectrosonics*, Paper 33 at 33.

We thus turn to whether Patent Owner has shown that "the evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Id.* (quoting *Fox Factory*, 944 F.3d at 1373–75). Having considered Patent Owner's evidence concerning alleged industry praise, we determine that Patent Owner has not carried its burden to show that the evidence of praise is the direct result of any unique characteristic of the claimed invention. *See* PO Resp. 64–65; PO Sur-reply 26. For example, none of the evidence mentions the challenged patent or any specific products that Patent Owner discusses as to nexus. *Cf. Ancora Techs., Inc. v. Roku, Inc.*, 140 F.4th 1351, 1361 (Fed. Cir. 2025) (finding no error in the Board's determination of no nexus for praise evidence even when the evidence expressly identified the challenged patent by number). Patent Owner also does not mention any alleged unique characteristic of the claimed invention. *See* PO Resp. 64–65; PO Sur-reply 26.

Instead, the evidence shows (at best) praise for the use of catheter-based ultrasound for renal neuromodulation *generally*. *See* Ex. 2034, 89:4–90:3, 94:9–18; Ex. 2037 at 1; Ex. 2038 at 1; Ex. 2039 at 1; Ex. 2040 at 1; Tucker Decl. ¶ 178. Under Patent Owner's logic, because the general use of catheter-based ultrasound for renal neuromodulation at least overlaps with the scope of claim 1, any praise for such use supports nonobviousness. *See, e.g.*, PO Sur-reply 26 ("And evidence of industry praise was directed particularly toward an ultrasound-based catheter for RDN as set forth in the Challenged Claims, which are not limited to focused ultrasound."). The nexus requirement demands a closer linkage to the claims.

For these reasons, on the current record, Patent Owner has not demonstrated a legally and factually sufficient connection between the

evidence of praise and the claims. *See Fox Factory*, 944 F.3d at 1373. Thus, we determine that the evidence of praise is entitled to no weight.

(d) Long-Felt but Unsolved Need and Failure of Others

Evidence of a long-felt but unsolved need tends to show nonobviousness "because it is reasonable to infer the need would not have persisted had the solution been obvious." *Apple Inc.*, 839 F.3d at 1056. Establishing long-felt but unsolved need requires objective evidence that an art-recognized problem existed in the art for a long period of time without solution (*Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988)) and also requires that the claimed invention satisfies the long-felt need (*Sjolund v. Musland*, 847 F.2d 1573, 1582 (Fed. Cir. 1988)). Moreover, the alleged long-felt need must not have been satisfied by another before the claimed invention. *See Newell*, 864 F.2d at 768 ("[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved . . . .").

Consideration of objective indicia also includes "the failure of others to produce alternatives to the patented invention." *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). As with other objective indicia, this evidence must demonstrate that any "inability or unwillingness of competitors" to develop alternative products "is rooted in the subject matter" of the challenged claims. *See id.*

Patent Owner contends that, "[i]n 2005, there was a long-felt, but unmet need for other hypertension treatments beyond catheter-based RDN using RF, as even Dr. Mendelsohn admits." PO Resp. 65 (citing Ex. 2034, 90:6–94:8). According to Patent Owner, "when asked if he was aware of any teaching of an ultrasound catheter-based ablation system for RDN prior

to the [challenged patent], Dr. Mendelsohn only identified a provisional application, unpublished in 2005, to which the [challenged patent] claims priority." PO Resp. 65–66 (citing Ex. 2034, 96:7–98:15; Tucker Decl. ¶ 175).

We are not persuaded that the cited evidence shows a long-felt but unsolved need. As an initial matter, Dr. Mendelsohn's only statement regarding hypertension was responding affirmatively to the question of, "[u]p to May of 2005, was there a need for a more efficacious way to treat hypertension." Ex. 2034, 90:6–8. The record does not support that such need was long-felt. Moreover, Patent Owner has provided little to no evidence that the claimed invention treats hypertension whereas the prior art did not. Hypertension is mentioned only twice in the challenged patent: once in the background in a list of issues related to kidney function (*see* Ex. 1001, 1:62–66) and once in a list of symptoms that "thermally-induced renal neuromodulation" *in general* "may alleviate" (*see id.* at 15:49–54). Notably, the second statement is not limited to renal neuromodulation from ultrasound and is not presented as a result of the claimed invention.

The record does not support that the claimed invention satisfied a long-felt need to treat hypertension that was not already addressed by *prior* renal neuromodulation devices. Indeed, Levin (published in 2003), expressly discloses treating hypertension using renal denervation. *See, e.g.*, Ex. 1004 ¶ 2, ¶ 48 ("The treatment breaks with tradition and proposes a counterintuitive novel method and apparatus of treating heart failure, renal failure and hypertension by electrically or chemically modulating the nerves of the kidney."), claim 19); *see Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1304–05 (Fed. Cir. 2010) (holding that evidence

of long felt but unsolved need, and failure of others, was insufficient because "[t]he record shows . . . this 'need' had been met by prior art machines").

Dr. Mendelsohn's only statement as to an alleged "long-felt need" was answering affirmatively to whether, "up to May of 2005 . . . , was there a need for a *better way* to perform renal denervation." Ex. 2034, 91:15–24 (emphasis added). Such a vague statement does not adequately support Patent Owner's argument here. As to Patent Owner's comment regarding asking Dr. Mendelsohn "if he was aware of any teaching of an ultrasound catheter-based ablation system for RDN prior to the [challenged patent]" (PO Resp. 65–66), that merely shows that no anticipatory teaching exists; it does not establish a long-felt but unsolved need. *In re Kavanagh*, 851 F. App'x 1028, 1035 (Fed. Cir. 2021) (nonprecedential) (discerning no error in the Board's finding of no long-felt but unsolved need, stating that "[t]he Board merely explained that 'absence of the specific claimed process does not conclusively prove that there was a long felt need for that method of manufacturing food products'").

In support of this argument, Patent Owner again relies on Petitioner's statements in the prosecution of unrelated applications. PO Resp. 66–67 (citing Ex. 2015 at 242–243, 246–247, 482; Ex. 2019 at 317, 499, 554–554, 565–567, 570–571; Ex. 2017 at 681, 684–685, 689–690, 835, 868; Tucker Decl. ¶ 176). For the reasons discussed above (*see* § II.C.3.a(2)), we are not persuaded that judicial estoppel should apply to prevent Petitioner's allegedly contrary arguments in this proceeding.

On the complete record, Patent Owner has not presented sufficient objective evidence to show that a particular art-recognized problem existed

for a long period of time without solution and that the challenged patent satisfied that alleged long-felt need.

Turning to alleged failure of others, Patent Owner argues that others "had tried and failed to treat hypertension with RDN." PO Resp. 67. In support, Patent Owner cites three studies—from 1934, 1935, and 2001—allegedly showing no reduction in blood pressure using renal denervation. *See id.* at 67–68 (citing "Page 1934"; "Page 1935"; Ex. 1062 at 34; Tucker Decl. ¶ 177). As noted above, however, the record contains little to no evidence that the invention in the challenged patent *actually* treats hypertension. And Levin (for example), expressly discloses treating hypertension using renal denervation, undermining Patent Owner's argument of failure of others. *See, e.g.*, Ex. 1004 ¶¶ 2, 48.

For these reasons, we determine that the evidence of long-felt but unsolved need and failure of others are entitled to no weight.

(9) Conclusion

For the reasons discussed above (§§ II.C.3.a(1)–(7)), the evidence presented by Petitioner strongly indicates that claim 1 would have been obvious over the combination of Levin and Acker. For the reasons also discussed above (§ II.C.3.a(8)), Patent Owner's objective evidence weighs minimally in favor of nonobviousness. When considering the evidence of obviousness and nonobviousness together (*see In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1079 (Fed. Cir. 2012)), we find Petitioner's evidence of obviousness strongly outweighs Patent Owner's objective evidence of nonobviousness. Thus, we conclude Petitioner has demonstrated by a preponderance of the evidence that claim 1 would have been obvious over Levin and Acker.

b. Dependent Claims 2, 3, and 8–11

Claims 2, 3, and 8–11 all depend from claim 1. *See* Ex. 1001, 16:21–25, 16:45–60. To address these claims, Petitioner states that the combination of Levin and Acker satisfies the additional claim limitations. Pet. 48–57. The record evidence supports Petitioner's position as to the limitations in these claims. Patent Owner does not present arguments for these claims. *See* PO Resp. 52–54 (presenting argument for only claim 4).

When considering the evidence of obviousness and nonobviousness together (*see In re Cyclobenzaprine*, 676 F.3d at 1079), we find Petitioner's evidence of obviousness strongly outweighs the objective evidence of nonobviousness. Thus, we determine, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that claims 2, 3, and 8–11 would have been obvious based on Levin and Acker.

c. Dependent Claim 4

Claim 4 recites: "The apparatus of claim 3 wherein the balloon further comprises an acoustically reflective portion configured to reflect ultrasound energy waves via the acoustically transmissive portion to the target neural fibers." Ex. 1001, 16:26–29. Solely as background for the claimed subject matter, we again reproduce Figure 12B:

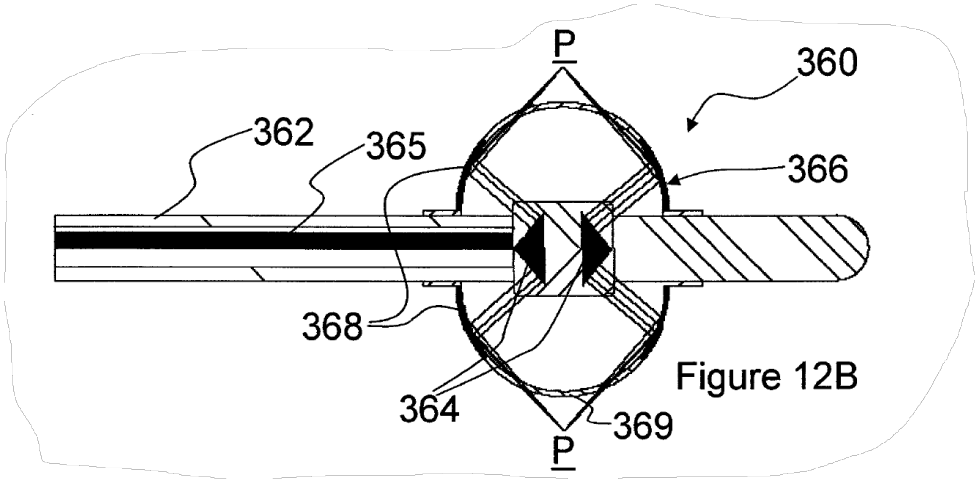

Figure 12B

Figure 12B depicts an apparatus for delivering focused ultrasound to renal nerves to achieve thermal neuromodulation. Ex. 1001, 14:23–31. As depicted, apparatus 360 includes inflatable balloon 366 with acoustically reflective portions 368 and acoustically transmissive portions 369, which together focus an ultrasonic wave at focal point P. *See id*. at 14:35–41.

Petitioner relies on Acker and Diederich (incorporated by reference into Acker) for claim 4. *See* Pet. 49–50 (citing Daft Pet. Decl. ¶¶ 146–147). Specifically, Petitioner highlights Acker's teaching that the catheter may include a "balloon similar to the balloon discussed in" Diederich (Ex. 1005, 4:20–22) and then highlights Diederich's teaching of a balloon with "a filter . . . adapted to shield tissue from the ultrasound signal, for example, by either absorbing or reflecting the ultrasound signal" (Ex. 1006, 63:13–16). *See* Pet. 49. Petitioner adds that Diederich discloses that "[t]he filter . . . can be constructed, for example, by coating the balloon . . . with an ultrasonically reflective material, such as with a metal, or with an ultrasonically absorbent material, such as with a polyurethane elastomer." Ex. 1006, 63:18–21, *cited at* Pet. 49 (citing Daft Pet. Decl. ¶ 146). Petitioner argues that one of ordinary skill in the art would have further modified Levin and Acker with the relied-upon aspects of Diederich (all of which is incorporated into Acker). *See* Pet. 49–50 (citing Daft Pet. Decl. ¶ 147).

Patent Owner counters that Petitioner has failed to make a *prima facie* case that Diederich discloses the limitations of claim 4 and that, instead, Diederich teaches "a partially ultrasonically-reflective balloon that blocks unfocused ultrasound emitted by its transducer." PO Resp. 53 (emphasis omitted); *see id.* at 52–54 (asserting that Petitioner failed to make a *prima*

facie case of obviousness); *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378–79 (Fed. Cir. 2015) ("In an *inter partes* review, the burden of persuasion is on the petitioner to prove 'unpatentability by a preponderance of the evidence,' 35 U.S.C. § 316(e), and that burden never shifts to the patentee."). For the reasons below, we agree that Petitioner has failed to show that Diederich discloses the additional limitations in claim 4.

In support of its argument as to claim 4, Patent Owner provides the following annotated version of Figure 18A of Diederich, which is the embodiment discussed in the passages relied upon by Petitioner:

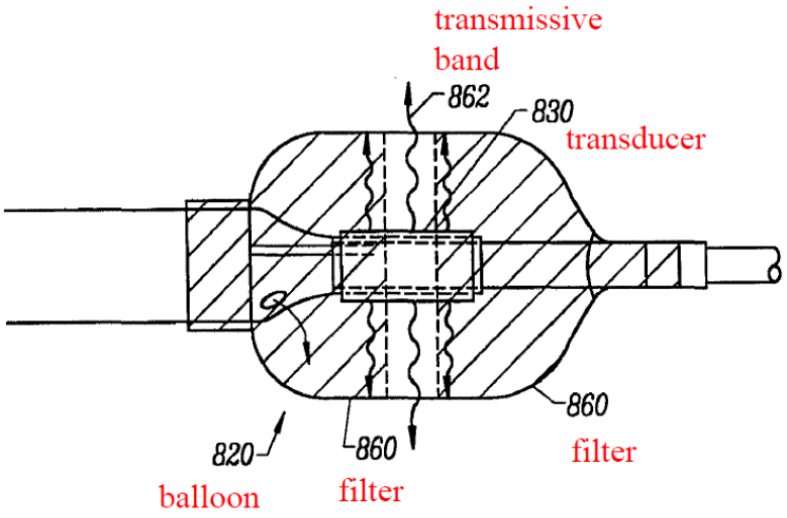

FIG. 18A

PO Resp. 53. Figure 18A of Diederich is a "cross-sectional view of the distal end portion of another circumferential ablation catheter." Ex. 1006, 20:10–14. In the annotated version of Figure 18A here, Patent Owner added (1) text identifying element 820 as a "balloon," (2) text identifying element 830 as a "transducer," (3) text identifying element 860 as a "filter," and (4) text identifying element 862 as a "transmissive band." PO Resp. 53.

As noted by Patent Owner (PO Resp. 53), filter 860 in Diederich "blocks" the ultrasound signal from emitting from balloon 820 by

"absorbing or reflecting the ultrasound signal" (Ex. 1006, 63:13–21). But even to the extent Diederich discloses "reflecting" the ultrasound signal, Petitioner has not adequately shown that filter 860 is "configured to reflect ultrasound energy waves via the acoustically transmissive portion *to the target neural fibers*," as recited in claim 4. Ex. 1001, 16:26–29 (emphasis added). Instead, any ultrasound energy reflected off filter 860 would stay within balloon 820; it would *not*—after reflection off filter 860—exit balloon 820 to the target neural fibers. *See* PO Sur-reply 23 (arguing that "'blocking [non-dissipated] energy' ([Pet.] Reply 33–34) does not meet claim 4's 'reflect[ing] ultrasound energy waves . . . to the target neural fibers'" (citing PO Resp. 53–54; Tucker Decl. ¶ 149; Weide Decl. ¶¶ 74–77)). This understanding of Diederich is supported by the cited declaration testimony of Dr. Tucker and Dr. van der Weide. *See* Tucker Decl. ¶ 149 ("Diederich teaches using a reflective portion of a balloon to 'shield[] tissue'—but not to 'reflect ultrasound energy waves via the acoustically transmissive portion' of the balloon, as . . . claim 4 requires."), *cited at* PO Resp. 54; *see also* Weide Decl. ¶ 74 (similar), *cited at* PO Resp. 54.

As argued by Patent Owner (PO Sur-reply 23), Petitioner does not substantively address how the relied-upon prior art satisfies the requirement that ultrasound energy waves are reflected "to the target neural fibers." Instead, Petitioner takes the position that, by merely blocking or filtering ultrasound energy, Diederich's filter satisfies the requirements of claim 4. *See, e.g.*, Pet. 49 (discussing how, in Diederich, "the reflective portions of the balloon serve as a filter to avoid the introduction of ultrasonic energy to portions of the tissue that are not intended to receive such energy"); Daft Pet. Decl. ¶ 147 (same). Petitioner has the burden of persuasion to show that

the relied-upon prior art, including Diederich, teaches or suggests the requirements of claim 4 by a preponderance of the evidence, but Petitioner failed to do so on the complete record.

D. Asserted Obviousness of Claim 12 Based on Levin, Acker, and Yock

Petitioner asserts that claim 12 would have been obvious based on Levin, Acker, and Yock. Pet. 12, 57–60; Pet. Reply 34–35. Patent Owner provides arguments addressing this asserted ground. PO Resp. 54–56; PO Sur-reply 24. We first summarize aspects of Yock.

1. Yock

In this ground, Petitioner relies on Yock, in addition to Levin (*see* § II.C.1) and Acker (*see* § II.C.2). Yock discloses an "[u]ltrasonic apparatus . . . for high resolution intravascular imaging" "[b]y receiving ultrasonic energy reflected from the interior surface [or wall] of [a blood] vessel." Ex. 1017, Abstract, 1:45–49. Figure 2 of Yock is reproduced below:

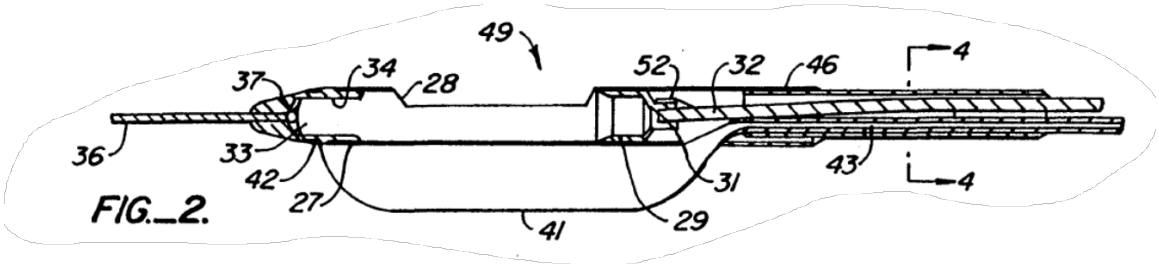

FIG._2.

Figure 2 "is an enlarged cross-sectional view of the distal extremity" of a catheter apparatus. Ex. 1017, 2:25–26. Depicted system 49, at the distal end of the catheter, includes expandable balloon 41 and ultrasonic imaging transducer assembly 52 (among other features). *See id.* at 4:41–48, 4:56–63.

Yock teaches that ultrasound imaging transducer 52 can produce a cross-sectional image of a blood vessel including the vessel walls, as shown in Figure 7, reproduced below:

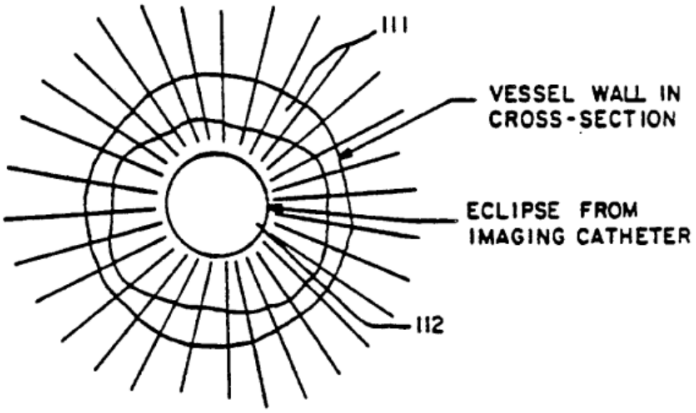

FIG.—7

Figure 7 is "two-dimensional display of an ultrasonogram which can be obtained with the apparatus and system" in Figure 2. *See* Ex. 1017, 2:42–44. According to Yock, its methods can be used in the context of therapeutic ultrasound, among other techniques. *See id.* at 3:34–44.

2. Analysis

Claim 12 recites: "The apparatus of claim 1, further comprising an imaging transducer." Ex. 1001, 16:61–62. Petitioner relies on Yock for its teachings of ultrasonic imaging transducer assembly 52 (shown in Figure 2 above) and states that it would have been obvious for one of ordinary skill in the art to have modified Acker's catheter based on Yock. *See* Pet. 57–58 (citing Daft Pet. Decl. ¶¶ 166, 168, 169). Petitioner highlights Yock's teachings of using the ultrasonic imaging transducer assembly to produce a cross-sectional image or profile of a blood vessel, such as that shown in Figure 7 above. *See* Pet. 58–59 (discussing Ex. 1017, 1:43–49, 6:45–52) (citing Daft Pet. Decl. ¶¶ 169–170). Petitioner notes that Yock discloses that

one suitable interventional technique for its ultrasonic imaging transducer assembly is "**therapeutic ultrasound**," which Petitioner argues refers to "ultrasound that is used to treat (like the ultrasound in Acker), as opposed to the ultrasound of Yock, which is merely used for imaging." Pet. 59 (citing Daft Pet. Decl. ¶ 171).

According to Petitioner, one of ordinary skill in the art "would have found it advantageous to be able to view the cross-section of the renal artery during the course of a treatment with Acker's catheter, particularly prior to placement of the catheter, for determining the size of the artery and possible occlusions." Pet. 59–60 (citing Daft Pet. Decl. ¶ 172). Petitioner also argues that one of ordinary skill in the art would have had a reasonable expectation of success in the proposed combination because Yock's catheter (which includes the ultrasonic imaging transducer assembly) is (1) properly sized and shaped for Levin's procedure, (2) appropriate for introduction through femoral arteries, and (3) can be included in catheters using inflatable balloons and for therapeutic ultrasound. Pet. 60 (citing Daft Pet. Decl. ¶ 173; Ex. 1004 ¶ 94; Ex. 1017, 3:37–44, 4:41–55, 6:52–7:1).

Patent Owner presents two arguments as to claim 12. *See* PO Resp. 54–56; PO Sur-reply 24. First, Patent Owner relies on the arguments presented as to claim 1, from which claim 12 depends. *See* PO Resp. 54. Because those arguments did not identify a deficiency as to claim 1, they do not do so as to claim 12.

Second, Patent Owner argues that Petitioner has not adequately explained how or why one of ordinary skill in the art would have combined the relied-upon teachings of Yock with Levin and Acker. *See* PO Resp. 55–56 (citing Tucker Decl. ¶¶ 151–155; Weide Decl. ¶¶ 78–81); PO Sur-

reply 24. Specifically, Patent Owner contends that "Yock's imaging transducer scans the vascular wall by being rotated 360° about the catheter axis by a motor," whereas "Acker's catheter uses an ultrasound transducer that emits in all directions simultaneously to avoid using 'an emitter [that] can be physically rotated.'" PO Resp. 55–56 (citing Ex. 1017, code (57), 1:42–46, 2:66–3:2, 5:58–6:28). According to Patent Owner, the use of an entire rotatable assembly "entails considerable practical difficulties" and "[t]hat is precisely why Acker uses a transducer that 'wrap[s] around' the catheter's axis and forms a 'ring-like ablated region.'" PO Resp. 55–56 (quoting Ex. 1005, 2:4–12) (citing Ex. 1005, 2:39–55, 4:35–40, 4:50–52, Fig. 1). For the reasons below, this argument does not identify a deficiency in Petitioner's position as to claim 12.

As background, we reproduce below the passage in Acker addressing rotation, highlighted by Patent Owner:

> As a further alternative, [Diederich] shows an ultrasonic emitter in the form of a hollow concave disk. [Diederich] suggests that such an emitter can be physically rotated around the axis of a catheter so as to ablate a ring-like zone. This approach entails considerable practical difficulties inasmuch as entire rotatable assembly must be made to fit into a catheter which can be threaded through the circulatory system of the patient and into the pulmonary veins, typically a catheter having a diameter no more than a few mm.

Ex. 1005, 2:3–12, *cited at* PO Resp. 55–56. We do not view this passage as supporting Dr. Tucker's and Dr. van der Weide's conclusions that "Acker's objective is to avoid using any rotatable elements." *See* Tucker Decl. ¶ 154; *see* Weide Decl. ¶ 80 ("Therefore, Acker's objective is to avoid using any rotatable elements altogether."). The passage at issue does not teach the preclusion of "rotatable elements altogether," but rather, it teaches that

rotatable elements *may* lead to impermissibly large-diameter catheters. *See* Ex. 1005, 2:7–12; Pet. Reply 34–35 (arguing that the relevant passage from Acker focuses on catheter *size*, not *rotatability*). Specifically, Acker discloses that "typically a catheter ha[s] a diameter no more than a few mm." Ex. 1005, 2:7–12. But, as noted by Petitioner, Yock expressly teaches that "[s]izes down to 3 French and below can be accomplished with the construction of the present invention." Ex. 1017, 6:55–57, *cited at* Pet. 60. Because it is undisputed that 3 French catheters have a diameter of 1mm (*see* Daft Pet. Decl. ¶ 173, *cited at* Pet. 60), the record does not support that the passage at issue in Acker would teach away from the combination or otherwise undermine the motivation to combine presented.

In the Sur-reply, the argument changes, with Patent Owner asserting that the proposed combination "violates Acker's principle of operation." PO Sur-reply 24 (citing *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F. App'x 755, 757–58 (Fed. Cir. 2015)). As an initial matter, we view this argument as untimely. *See* TPG 74. Moreover, Patent Owner has not adequately explained why the presence of a rotatable element—such as an imaging transducer like that included in Yock—would undermine the operation of Acker's non-rotating ultrasonic transducer. *See, e.g.*, Ex. 1005, 3:22–4:11 (discussing the operation of piezoelectric element 10); *cf. In re Ratti*, 270 F.2d 810, 813 (CCPA 1959) (stating that the proposed modification would "require a substantial reconstruction and redesign of the elements shown in [the prior art] as well as a change in the basic principles under which the [prior art] was designed to operate"). As to Patent Owner's argument that Yock's balloon is on only one side of the catheter (PO Sur-

reply 24), that argument is both untimely and does not address the proposed combination, which does not rely on Yock for its balloon. *See* Pet. 57–60.

Patent Owner also generally contends that Petitioner has not adequately explained the proposed combination. *See* PO Resp. 55. We disagree, and we find adequate the explanation summarized above. Patent Owner has not alleged any *specific* deficiency in Petitioner's reasoning aside from the alleged preclusion of rotatable elements (discussed above). As to the alleged combinability, we find particularly persuasive Yock's statement that the suitable interventional techniques for its imaging transducer include "therapeutic ultrasound," which Patent Owner does not dispute includes a system such as Acker's. *See* Pet. 59 (citing Ex. 1017, 3:34–44; Daft Pet. Decl. ¶ 171). As noted by Petitioner, neither Patent Owner nor its declarants dispute that an imaging transducer such as Yock's provides an advantage in intravascular renal denervation. *See* Pet. Reply 35.

For the reasons above, we determine, based on the complete record, that Petitioner has demonstrated by a preponderance of the evidence that claim 12 would have been obvious based on Levin, Acker, and Yock.

E. Asserted Anticipation of Claims 1–3, 8, and 9 by Acker

Petitioner asserts that claims 1–3, 8, and 9 are anticipated by Acker. Pet. 12, 60–65; Pet. Reply 35. Patent Owner provides arguments addressing this ground. *See* PO Resp. 56–57; PO Sur-reply 25. In this ground, Petitioner relies only on Acker (summarized above (*see* § II.C.2)).

1. Independent Claim 1

Petitioner contends that Acker discloses each limitation of claim 1. Pet. 61–63; Pet. Reply 35. In the "Overview of the Ground" section, Petitioner references its proposed construction of the phrase "configured to"

and states that "it is proper to consider whether the prior art is 'capable of' performing the recited functions, as opposed to requiring that a designer of a prior art device have actually conceived of the recited functional language." Pet. 61. Petitioner continues: "If the PTAB agrees that this is the proper approach to claim construction, then Acker also anticipates the claims challenged in this ground." *Id.* For the reasons below, we determine, based on the complete record, that Petitioner has not demonstrated by a preponderance of the evidence that claim 1 is anticipated by Acker.

As to element 1d, which includes the phrase "configured to,"[16] Petitioner states that Acker is

> capable of being used **to target renal neural fibers outside of the blood vessel to thermally induce modulation of target neural fibers while protecting non-target tissue in the blood vessel wall from thermal injury** for the reasons discussed under claim 1, limitation [1d] and in the section entitled "Reasonable Expectation of Success", beginning on page 37 [of the Petition].

Pet. 62–63 (citing Daft Pet. Decl. ¶ 179) (first bracketed text added by Petitioner).

Patent Owner argues that, in the context of this asserted ground based on anticipation, Petitioner improperly relies on modifications to Acker as to certain claim limitations, including element 1d. *See* PO Resp. 56. We agree with Patent Owner that, for this anticipation ground, Petitioner has "misplaced" reliance on the section of the Petition addressing "Reasonable

[16] Element 1d recites that "the ultrasound transducer is configured to transmit ultrasound energy waves to target renal neural fibers outside of the blood vessel to thermally induce modulation of target neural fibers while protecting non-target tissue in the blood vessel wall from thermal injury." Ex. 1001, 16:9–14.

Expectation of Success" as to the asserted ground of obviousness based on Levin and Acker, and, in particular, that section's discussion of modifying Acker (*see, e.g.*, Pet. 39). PO Resp. 56; *see* Pet. 62–63 (citing Pet. 44–46 (which in turn cites the reasons to combine at Pet. 31–37) & Pet. 37–40 (reasonable expectation of success)).

As noted by Patent Owner, both parts in the Petition cited by Petitioner as to this anticipation ground expressly discuss *modifying* Acker prior to use in renal neuromodulation applications. *See, e.g.*, Pet. 32 (stating that "Acker teaches that the catheter is useful for a wide variety of blood vessels or tubular structures in the body, and [one of ordinary skill in the art] *would have been motivated to adapt the Acker catheter (including specifically sizing and shaping) for the purpose disclosed in Levin*" (emphasis added) (citing Ex. 1005, 2:18–38, 8:15–22; Daft Pet. Decl. ¶ 98)); *see also* Pet. 39 ("Based on Acker's flexibility and the prior use of catheter-based treatments within the renal artery, [one of ordinary skill in the art] would have reasonably expected success in adapting Acker's catheter (and in particular, to making Acker's catheter the proper size and shape) to use within the renal artery, to the extent any such adaptation were necessary." (citing Daft Pet. Decl. ¶ 112)).

In the Reply, Petitioner states that "[t]he Petition's reference to the 'reasonable expectation of success' portion of [the obviousness ground based on Levin and Acker] was proper, because the evidence in that section shows that Acker is more likely than not 'able to' meet the functional requirements of the claims." Pet. Reply 35. On the complete record, we determine that Petitioner has not adequately shown how Acker *alone* satisfies element 1d without the modifications *expressly discussed* in the

portions of the Petition referenced when addressing element 1d for this asserted ground, especially given that (as discussed above) Acker does not expressly disclose use of its ultrasound catheter for renal neuromodulation. *See* PO Resp. 56–57 ("Even under Petitioner['s] construction, Acker simply does not provide the requisite teachings of an ultrasound catheter able to meet the limitations" of claim 1.); *Enplas Display Device Corp. v. Seoul Semiconductor Co., Ltd.*, 909 F.3d 398, 405 (Fed. Cir. 2018) ("Prior art that must be modified to meet the disputed claim limitation does not anticipate the claim."). In other words, if a device must be modified in order to perform a function, that device (prior to modification) is not capable of performing that function. Here, Petitioner's statement that a person of ordinary skill in the art would reasonably expect success in adapting (i.e., modifying) Acker's catheter means that Acker's catheter cannot perform the claimed function without such adaptation and, thus, cannot anticipate.

For this ground based on anticipation, the burden is on Petitioner to show Acker's device meets the requirements of claim 1 without modification; the burden is not on Patent Owner to show modifications are necessary to practice claim 1. *See Dynamic Drinkware*, 800 F.3d at 1378–79; *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1376 (Fed. Cir. 2016) (discussing how "it is inappropriate to shift the burden to the patentee after institution to prove that the patent is patentable"). Based on the complete record, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claim 1 is anticipated by Acker.[17]

[17] This analysis as to alleged anticipation of claim 1 based on Acker was in the Original Final Written Decision, and Petitioner did not challenge this

2. Dependent Claims 2, 3, 8, and 9

Petitioner asserts that claims 2, 3, 8, and 9 are anticipated by Acker. Pet. 63–65; Pet. Reply 35. As discussed in the prior section, Petitioner has not demonstrated by a preponderance of the evidence that independent claim 1, from which claims 2, 3, 8, and 9 depend, is anticipated by Acker. *See* § II.E.1. Thus, we determine, based on the complete record, that Petitioner has not demonstrated by a preponderance of the evidence that claims 2, 3, 8, and 9 are anticipated by Acker.

F. Asserted Obviousness of Claims 1–4 and 8–11 Based on Acker and the Knowledge of a Person of Ordinary Skill in the Art

Petitioner asserts that claims 1–4 and 8–11 of the challenged patent would have been obvious based on Acker and the knowledge of one of ordinary skill in the art. Pet. 12, 65–75; Pet. Reply 35–36. Patent Owner provides arguments specifically addressing this asserted ground. PO Resp. 57–60; PO Sur-reply 25. In this asserted ground, Petitioner relies on Acker (summarized above (*see* § II.C.2)) in combination with the knowledge of one of ordinary skill in the art.

1. Claims 1–3 and 8–11

Because the obviousness ground based on Levin and Acker is dispositive as to challenged claims 1–3 and 8–11, we need not reach this additional ground as to those claims. *See SAS Inst. Inc. v. Iancu*, 584 U.S. 357, 371 (2018) (holding that a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *Boston Sci. Scimed,*

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analysis in the appeal to the Federal Circuit. *See* Appeal Dec. *1–*2 (summarizing grounds at issue on appeal and not discussing anticipation based on Acker).

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"); *SK Hynix Inc. v. Netlist, Inc.*, IPR2017-00692, Paper 25 at 40 (PTAB July 5, 2018) (determining all challenged claims to be unpatentable and not addressing additional grounds).

2. Dependent Claim 4

As to dependent claim 4, in the context of this ground, Petitioner relies on Acker as to the additional limitations in claim 4 in the same manner as relied on in the context of the ground based on Levin and Acker. *See* Pet. 73 ("The combination teaches this element for the same reasons described in [the obviousness ground based on Levin and Acker], claim 4, with the exception that [one of ordinary skill in the art] would have been motivated based on his or her knowledge of prior renal denervation work, as noted above."). Thus, for the same reasons discussed above (*see* § II.C.3.c), we determine, based on the complete record, that Petitioner has not demonstrated by a preponderance of the evidence that claim 4 would have been obvious based on Acker and the knowledge of one of ordinary skill in the art.

G. Asserted Obviousness of Claim 12 Based on Acker, the Knowledge of a Person of Ordinary Skill in the Art, and Yock

Petitioner asserts that claim 12, which depends from independent claim 1, would have been obvious based on Acker, the knowledge of one of ordinary skill in the art, and Yock. Pet. 12, 75; Pet. Reply 35–36. Patent Owner provides arguments addressing this ground. PO Resp. 57–60; PO

Sur-reply 25. In this ground, Petitioner relies on Acker (*see* § II.C.2), the knowledge of one of ordinary skill in the art, and Yock (*see* § II.D.1).

Because the obviousness ground based on Levin and Acker is dispositive as to challenged claim 12, we need not reach this additional ground as to that claim. *See SAS*, 138 S. Ct. at 1359; *Boston Sci. Scimed, Inc.*, 809 F. App'x at 990; *SK Hynix Inc.*, IPR2017-00692, Paper 25 at 40.

III. CONCLUSION

Upon consideration of the briefing and the evidence of record, we determine that Petitioner has proven, by a preponderance of the evidence, the unpatentability of claims 1–4 and 8–12 of the challenged patent.[18]

[18] 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, 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).

In summary:

Outcome of the original Final Written Decision:

Claim(s)	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–4, 8–11	103(a)	Levin, Acker		1–4, 8–11
12	103(a)	Levin, Acker, Yock		12
1–3, 8, 9	102(e)(2)	Acker		1–3, 8, 9
1–4, 8–11	103(a)	Acker, knowledge of a person of ordinary skill in the art		1–4, 8–11
12	103(a)	Acker, knowledge of a person of ordinary skill in the art, Yock		12
Overall Outcome				1–4, 8–12

Outcome of this Final Written Decision on Remand:

Claim(s)	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–4, 8–11	103(a)	Levin, Acker	1–3, 8–11	4
12	103(a)	Levin, Acker, Yock	12	
1–3, 8, 9	102(e)(2)	Acker		1–3, 8, 9
1–4, 8–11	103(a)	Acker, knowledge of a person of ordinary skill in the art[19]		4
12	103(a)	Acker, knowledge of a person of ordinary skill in the art, Yock		
Overall Outcome			1–3, 8–12	4

[19] As explained above, because we have already explained how these claims are unpatentable over other grounds, we do not reach (1) the asserted ground of obviousness based on Acker and the knowledge of a person of ordinary skill in the art as to claims 1–3 and 8–11 or (2) the asserted ground of obviousness based on Acker, the knowledge of a person of ordinary skill in the art, and Yock as to claim 12.

IV. ORDER

Accordingly, it is hereby:

ORDERED that Petitioner has proven, by a preponderance of the evidence, that claims 1–3 and 8–12 are unpatentable;

FURTHER ORDERED that Petitioner has *not* proven, by a preponderance of the evidence, that claim 4 is 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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