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Paper 32
Date: July 14, 2023

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
Determining No Challenged Claims Unpatentable
35 U.S.C. § 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 '629 patent"), assigned to Patent Owner, Medtronic Ireland Manufacturing Unlimited Co. We have jurisdiction under 35 U.S.C. § 6, and we issue this Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons below, we conclude that Petitioner has not proven, by a preponderance of the evidence, the unpatentability of any of the challenged claims.

A. Procedural History

Petitioner filed a Petition to institute *inter partes* review of claims 1–4 and 8–12. Paper 1 ("Pet."). Patent Owner filed a Preliminary Response. Paper 10.[1] Upon review of the arguments and supporting evidence, we instituted *inter partes* review of all challenged claims and on all grounds asserted in the Petition. Paper 11 ("Dec. Inst."). After institution, 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 relies on the declaration testimony of Dr. Chris Daft (Ex. 1002 (the "Daft Petition Declaration" or "Daft Pet. Decl.")) and of Dr. Farrell Mendelsohn (Ex. 1056 ("Mendelsohn Decl.")), filed with the Petition, and also relies on the declaration testimony of Dr. Daft (Ex. 1071)

[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 in the '629 patent. *See* Paper 8; Paper 10 at 1.

and of Dr. John Moriarty (Ex. 1072), filed with the Reply. Patent Owner relies on the declaration testimony of Dr. Robert Tucker (Ex. 2031, "Tucker Decl.") and of Dr. Daniel van der Weide (Ex. 2032, "van der 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 ("Tr.").

B. Related Proceeding

The parties have identified a proceeding in the U.S. District Court for the Northern District of California involving the '629 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 8 (Patent Owner's Updated Mandatory Notices) at 3.

C. The '629 Patent

The '629 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 '629 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 '629 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:

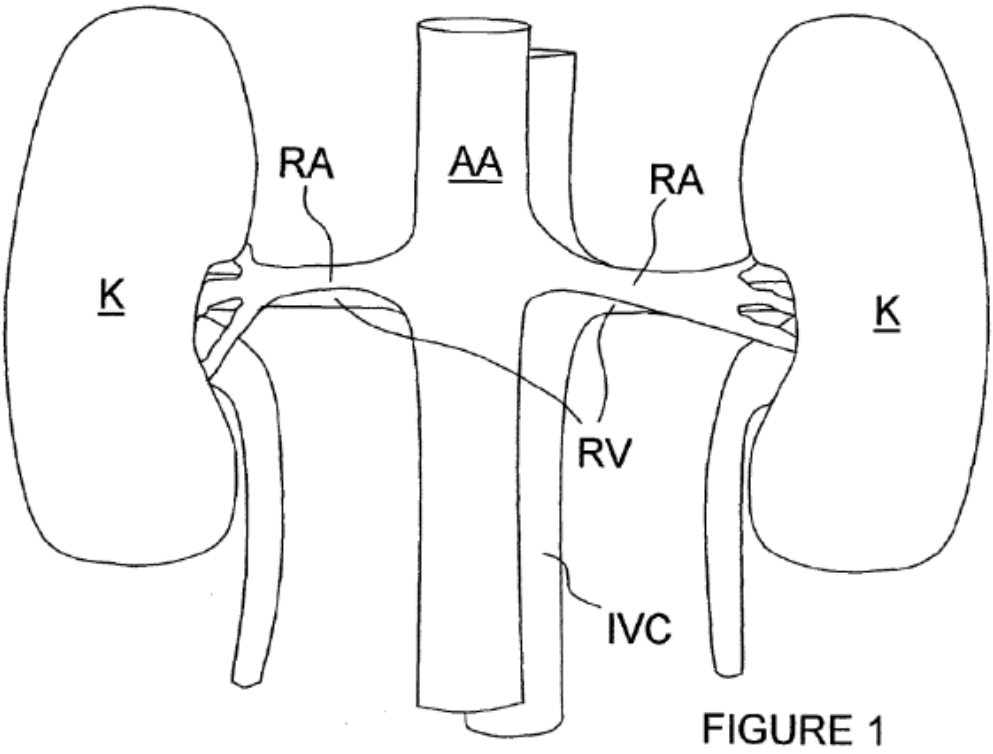
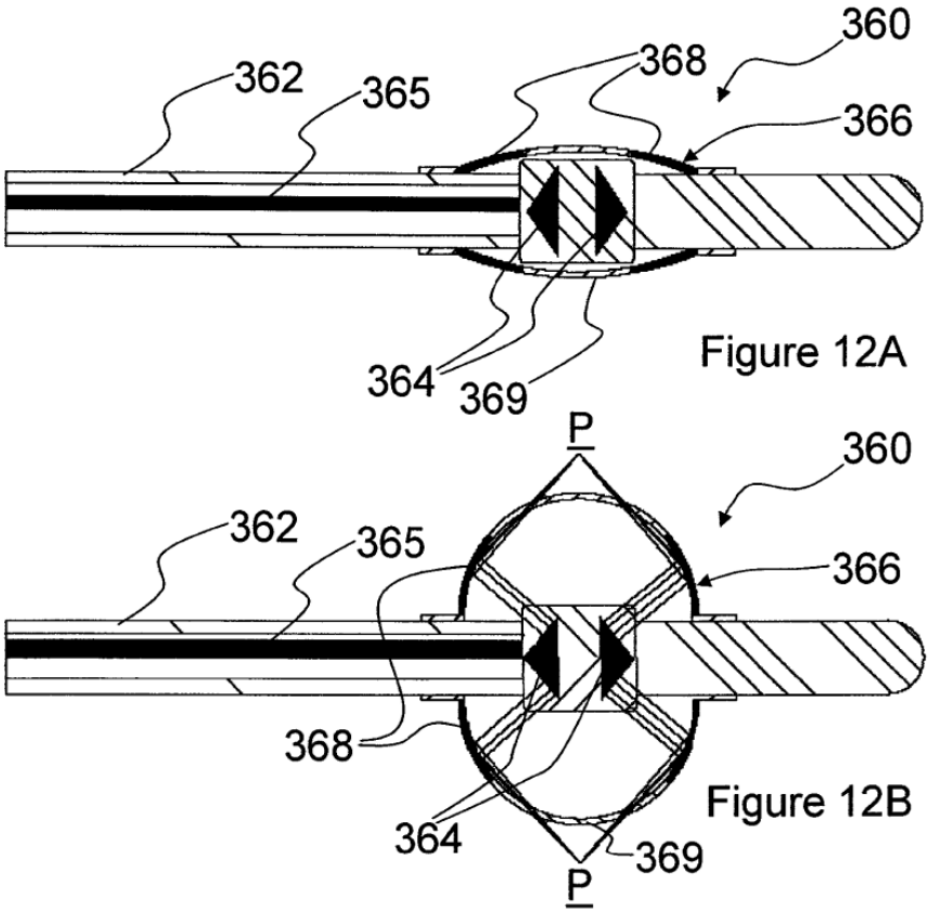


FIGURE 1

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 '629 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 '629 patent discloses that "non-target tissue 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:



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 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 '629 patent, "the focal distance may be specified or dynamically variable such that, when positioned in 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 '629 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:

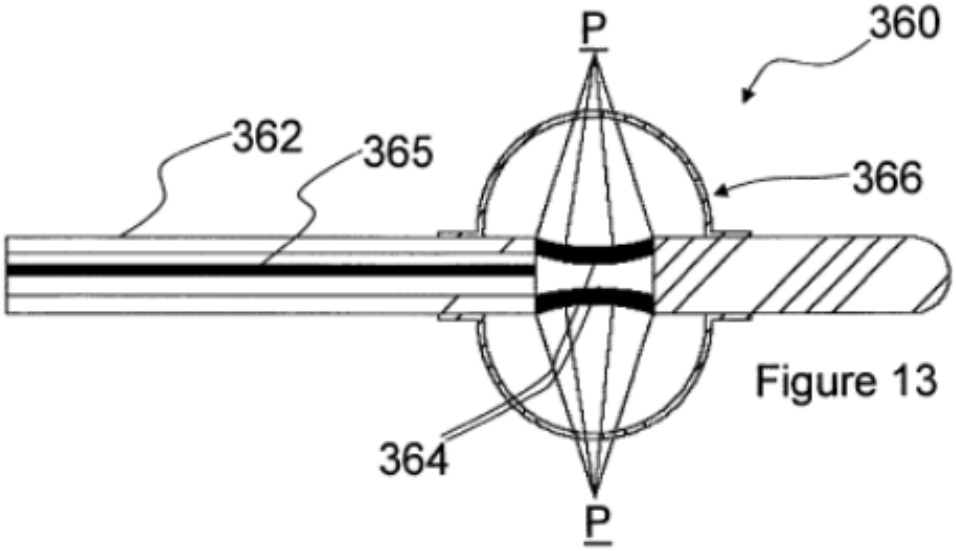


Figure 13

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."[2] *Id*. at 14:61–63.

[2] In this Decision, we omit emphasis of reference numerals in quotations from the '629 patent and cited references.

D. 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 alphanumeric 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.[3]

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

E. 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. §[4]	Reference(s)/Basis
1–4, 8–11	103(a)	Levin,[5] Acker[6]
12	103(a)	Levin, Acker, Yock[7]
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

The level of ordinary skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). The person of ordinary skill in the art

[4] 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 '629 patent have an effective filing date before March 16, 2013, we apply the pre-AIA versions of these statutes.

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

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

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

is a hypothetical person presumed to have known the relevant art at the time of the invention. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, we may consider certain factors, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *Id*.

Petitioner contends, with accompanying declaration testimony, that

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

Pet. 40 (emphasis omitted) (citing Daft Pet. Decl. ¶¶ 64–68).

Patent Owner responds that, "[f]or purposes of this proceeding, [Patent Owner] does not object to the definition of a person of ordinary skill in the art ('POSITA') proffered by Petitioner[] and adopted by the Board at institution as the result remains the same regardless of the definition—the Challenged Claims are valid." PO Resp. 16; *see also* Dec. Inst. 15–17 (adopting, for purposes of institution, Petitioner's proposed definition of the person of ordinary skill in the art). In addition, however, Patent Owner proposes a different level of ordinary skill in the art "should the Board believe that the difference in definition impacts the outcome" of this proceeding.[8] PO Resp. 16. Both Petitioner and Patent Owner discuss how

[8] Specifically, Patent Owner proposes that "the proper definition is a 'person [or combination of persons] having a medical degree or equivalent

the opposing declarants do not possess adequate experience to satisfy the level of skill in the art, but neither side moves to exclude any declarants' testimony. *See id.* at 16–17; Pet. Reply 11–12; PO Sur-reply 27–28.

We determine that the differences in the two proposed definitions do not impact the outcome here. Thus, we continue to apply Petitioner's proposed level of ordinary skill in the art in this proceeding.

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.

Petitioner and Patent Owner discuss two claim phrases. First, both propose constructions for "configured to" as used in the phrases "configured

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in a discipline relevant to the claimed invention, specific knowledge of the circulatory and nervous system in relation to the kidneys, and a bachelor's or master's degree in chemical, mechanical, electrical, or biomedical engineering with at least five years practical experience in designing and developing medical devices.'" PO Resp. 16 (quoting, with bracketed text added by Patent Owner, Ex. 1062 at 5) (citing Tucker Decl. ¶¶ 28–34; van der Weide Decl. ¶¶ 25–30; Ex. 2013 at 10 n.2).

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))).

Second, both Petitioner and Patent Owner discuss the phrase "protecting non-target tissue in the blood vessel wall from thermal injury" as recited in element 1d. *See* Pet. Reply 10–11; PO Sur-reply 2–3. Petitioner asserts that the 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. According to Patent Owner, "the claims are patentable under either parties' construction." *Id.* 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*, 868 F.3d at 1017.

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 '629 patent would have been obvious under 35 U.S.C. § 103(a) 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

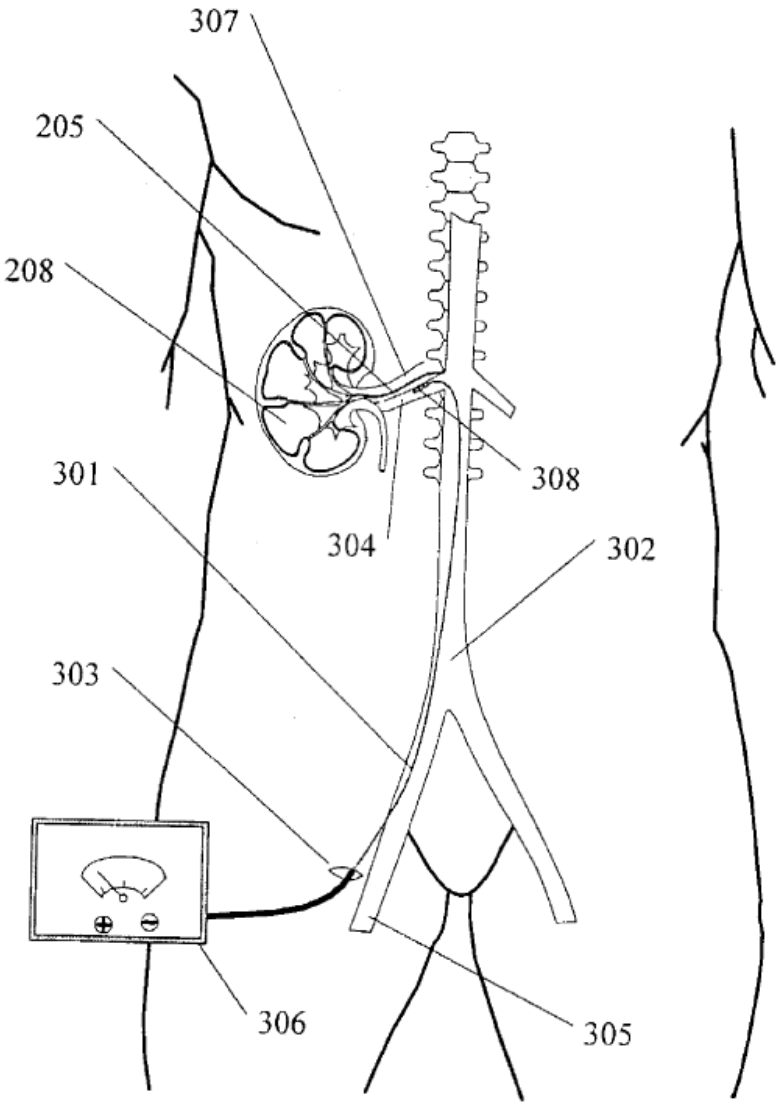

Figure 3 depicts "stimulation of renal nerves across the wall of the renal vein." Ex. 1004 ¶ 69. Specifically, Figure 3 shows external renal nerve stimulator apparatus 306 connected to electrode tip 308 by catheter 301, which is "inserted via an insertion site 303 into the femoral vein 305

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

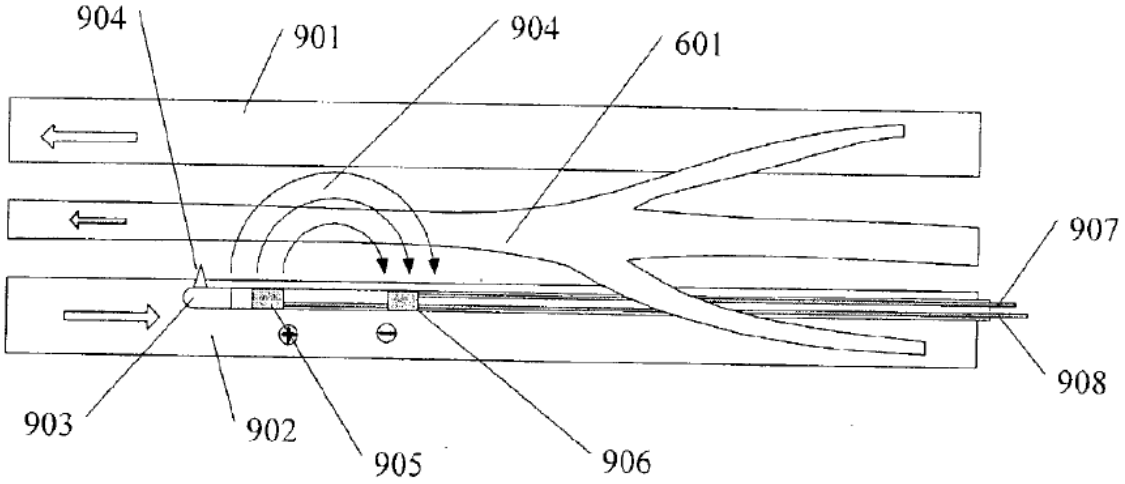

Figure 9 depicts "transvenous stimulation of the renal nerve with [an] electric field." Ex. 1004 ¶ 75. Specifically, Figure 9 shows stimulation catheter 903, which includes electrodes 905/906, within renal vein 902. *Id.* ¶ 111. Levin discloses that electrodes 905/906 induce electric field 904 to create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

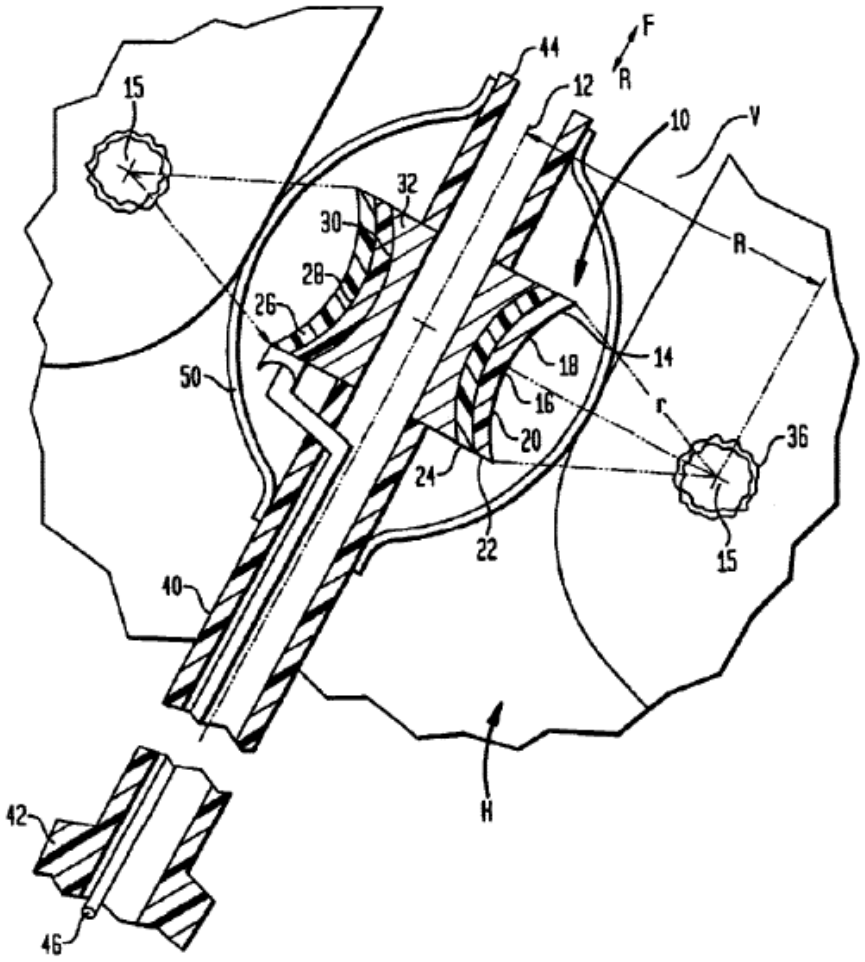

Figure 1 depicts a catheter treating tissue. *See* Ex. 1005, 2:64–67. Specifically, Figure 1 shows catheter 40 positioned in vein V. *See id.* at 4:12–16, Fig. 1. Piezoelectric element 10 emits sonic waves that "reinforce one another in a ring-like region 36 centered on a circle corresponding to the 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. Below, we discuss the parties' positions with respect to the proposed reasons to modify Levin based on Acker. 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 would have been obvious based on Levin and Acker.

(1) The Proposed Reasons to Modify Levin Based on 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. As part of the discussion of 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 '629 patent (Pet. 41).

As to the reasons to combine, Petitioner first states that "Levin itself" motivates the combination in that it teaches that renal neuromodulation can

treat 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; Mendelson Decl. ¶¶ 52, 53). Petitioner continues that Levin 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 intravascular 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; Mendelson 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." *Id*. (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 allegedly 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; Mendelson 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, 51:5–14[9]). According to Petitioner, one of ordinary skill in the art would have also understood ultrasound as a "known and predictable alternative to using electrical current as suggested by Levin"

[9] Petitioner cites to the native pagination of Exhibit 1006 (Diederich). We cite to the page numbers added by Petitioner.

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, 24:26–25:7; Mendelson Decl. ¶¶ 69, 75). Petitioner also discusses why Levin allegedly 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 by adapting Acker's catheter for use in a renal artery. Pet. 37–38 (citing Ex. 1004 ¶¶ 92, 94, 111, Figs. 3 & 9; Daft Pet. Decl. ¶¶ 104–111; Exs. 1035–1046); *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)).

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, 13:14–19, 18:10–15, 33:3–11, 40:26–41:13; 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 modified device would provide limitations recited in element 1d. *See* Pet. 39–40 (citing Daft Pet. Decl. ¶¶ 109, 113; Mendelson Decl. ¶¶ 74, 82–83, 92–93; Ex. 1004 ¶ 127; Ex. 1005, 4:1–41, Fig. 1, claims 12 & 13; Ex. 1006, code (57), 15:3–6).

In response, Patent Owner presents several arguments challenging Petitioner's stated reasons to modify Levin with Acker and whether there would have been a reasonable expectation of success in combining the references' teachings to achieve the claimed apparatus. *See* PO Resp. 38–52; PO Sur-reply 16–23. 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 applications recited in claim 1 of the '629 patent 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."[10] PO Resp. 38 (citing Tucker Decl. ¶¶ 110–119; van der Weide Decl. ¶¶ 66–72); *see id.* at 38–41 (entire argument). For the reasons below, we agree that the record does not support Petitioner's position as to the reasons to modify Levin based on Acker to arrive at the renal neuromodulation apparatus recited in claim 1. *See Axonics, Inc. v. Medtronic, Inc.*, No. 2022-1451, 2023 WL 4410686, at *5 (Fed. Cir. July 10, 2023) ("When an obviousness challenge asserts a combination of identified prior art, the motivation-to-combine portion of the inquiry is 'whether "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve *the claimed invention.*"'") (quoting *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016)).

[10] We use the terms "renal denervation," "RDN," and "renal neuromodulation" interchangeably in this Decision. *See* PO Resp. xi (defining "RDN" as "renal denervation"); PO Resp. 2–4 (using RDN and "renal neuromodulation" to describe the invention of the '629 patent).

We first address Petitioner's assertion that "Levin itself motivates the treatment method." Pet. 31 (citing Daft Pet. Decl. ¶¶ 78–90, 96–103). Although the record supports Petitioner's argument that Levin teaches ablation using a catheter-based apparatus to modulate nerves on a renal artery (Pet. 31–32 (citing, e.g., Daft Pet. Decl. ¶ 97; Ex. 1004 ¶¶ 51, 64, 94, 111, 127–129, claim 17, Figs. 3 & 9)), Petitioner has not adequately explained why one of ordinary skill in the art would have understood "Levin itself" as teaching or motivating the use of the particular catheter-based ultrasound device disclosed in Acker for renal neuromodulation applications, as recited in claim 1 and as proposed in the context of this asserted ground. *See, e.g.*, 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." (emphasis added) (citing Daft Pet. Decl. ¶ 112)).

As one potential reason for why one of ordinary skill in the art would have allegedly used Acker's device in the context of Levin's renal neuromodulation method, we first address U.S. Patent No. 6,292,695 B1 ("Webster"), which is referenced by its patent number in paragraph 64 of Levin. *See* Ex. 1004 ¶ 64 ("U.S. Pat. No. 6,292,695 describes in detail a method and apparatus for transvascular treatment of tachycardia and fibrillation with nerve stimulation and ablation. Similar catheter based apparatus can be used to ablate the renal nerve with an intent to treat [Chronic Renal Failure]."). Paragraph 64 of Levin is then cited in the Petition. *See* Pet. 32. Under this potential reason, one of ordinary skill in

the art would have seen the discussion of Webster in paragraph 64 of Levin, and then looked to the catheter-based ultrasound device in Acker for use in Levin's renal neuromodulation method.

Petitioner does not actually discuss Webster in the Petition; instead, Petitioner cites to Dr. Daft's declaration testimony regarding Webster to support the argument that "Levin itself motivates the treatment method." Pet. 31 (citing Daft Pet. Decl. ¶¶ 78–90, 96–103). For example, cited paragraph 97 of the Daft Petition Declaration provides: "Webster teaches transvascular nerve ablation using RF thermal ablation or 'any thermal means' and Levin teaches catheters similar to Webster's can be used for renal denervation. Ultrasound ablation disclosed in Acker is a 'thermal means' of ablation. Thus, I agree with Dr. Mendelsohn that Levin itself motivates the combination." Daft Pet. Decl. ¶ 97 (citing Mendelsohn Decl. ¶¶ 71–74); *see also* Ex. 1052 (Webster), 3:40–42 ("Alternatively, ablation may be achieved by any other suitable means, for example any thermal means or cryoablation means.").

We do not find persuasive Petitioner's reliance on Webster to support the alleged motivation to use the device of Acker in Levin's renal neuromodulation method. As noted by Patent Owner, after introducing Webster (by patent number), Levin states that "[*s*]*imilar catheter based apparatus* can be used to ablate the renal nerve with an intent to treat [Chronic Renal Failure]." Ex. 1004 ¶ 64 (emphasis added) (cited at PO Resp. 39 (discussing how "Levin explicitly qualif[ies] its statement by referring to 'similar' (not identical) catheters")). But neither Petitioner nor its declarants have established that Acker's ultrasound catheter is in fact "[s]imilar" to that in Webster in a manner that would support the view that

one of ordinary skill in the art would have understood that Acker's catheter could be used to "ablate the renal nerve with an intent to treat [Chronic Renal Failure]" as disclosed in paragraph 64 of Levin—i.e., to perform Levin's renal neuromodulation method. *See id.* Dr. Mendelsohn states that Acker's use of ultrasound-based ablation falls within the "any thermal means" disclosure in Webster (*see* Ex. 1052, 3:40–42), but Dr. Mendelsohn does not address why Acker's ultrasound catheter is "[s]imilar" to the catheter in Webster (even after expressly noting the presence of that statement in Levin). *See* Mendelsohn Decl. ¶ 71 ("Moreover, Webster teaches transvascular nerve ablation using RF thermal ablation or 'any thermal means' and Levin teaches catheters similar to Webster's can be used for renal denervation. Ultrasound ablation disclosed in Acker is a 'thermal means' of ablation.").

As another potential reason for why one of ordinary skill in the art would have used Acker's device in Levin's renal neuromodulation method, Petitioner states 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 '629 patent—in that "Acker teaches using an intravascular catheter with an ultrasound transducer within a blood vessel." Pet. 32–33 (citing Daft Pet. Decl. ¶ 98; Mendelsohn Decl. ¶¶ 50, 63, 64; Ex. 1005, 3:22–4:42). Although Acker does, in certain passages cited by Petitioner, use broader phrases such as "blood vessel" and "tubular anatomical structures" (*see, e.g.*, Ex. 1005, 8:15–18, *cited at* Pet. 32) as potential locations for the device's use, the record does not support that one of ordinary skill in the art would have understood from these broader

statements that Acker's ultrasound catheter could have been used effectively on *any* anatomical structures near *any* human blood vessel, including, more specifically, on renal nerves near renal arteries. Indeed, some of the relied-upon statements in Acker are conclusion statements at the end of lengthy passages disclosing *more specific uses* that do not support Petitioner's position. For example, Acker's Background of the Invention focuses *almost entirely* on the use of its ultrasound catheters in a "pulmonary vein" (rather than a renal vessel) before broadening, in a final conclusion sentence, to use "around a blood vessel." *See* Ex. 1005, 1:19–2:15; *see also* Pet. 32 (citing Ex. 1005, 2:14–15 (conclusion sentence only); Pet. Reply 12 (quoting Ex. 1005, 2:13–15 (conclusion sentence only)).

Similarly, in the discussion of Figure 1 relied upon by Petitioner, Acker discloses the use of piezoelectric element 10 inside "pulmonary vein V." Ex. 1005, 3:22–4:42, *cited at* Pet. 32. In the relied-upon declaration testimony, Dr. Daft cites this entire passage in Acker as support for the proposition that "Acker teaches using an intravascular catheter to position an ultrasound transducer *within a blood vessel*" (Daft Pet. Decl. ¶ 98 (emphasis added), *cited at* Pet. 32), but Dr. Daft does not adequately explain why a teaching specifically directed to use *in a pulmonary vein* supports the broader alleged teaching of use *in any blood vessel*, including renal vessels.

Like Dr. Daft, Dr. Mendelsohn highlights many of the same broader statements in Acker, but Dr. Mendelsohn does not adequately explain why those broader statements would have been understood as applying to the use of Acker's device *in renal vessels*. *See* Mendelsohn Decl. ¶¶ 50, 63, 64, 66, 67, *cited at* Pet. 32. For example, like Dr. Daft, Dr. Mendelsohn discusses the Background of the Invention and Figure 1 in Acker as supporting the

alleged disclosure of the use of Acker's device *in any blood vessel*, even though (as noted above) those disclosures focus on use *in a pulmonary vein*. *See* Mendelsohn Decl. ¶ 67 ("[One of ordinary skill in the art] understands from [column 1, lines 19–23 and column 2, lines 14–15] and Fig[ure] 1 of Acker (which shows a focal region well beyond the interior surface of the blood vessel) that Acker is suggesting ablation outside a vessel wall.").

Turning to Acker's disclosure regarding "ablat[ing] ring-like regions around other tubular anatomical structures" (Ex. 1005, 8:15–18), the record does not support that one of ordinary skill in the art would have viewed this generalized statement as teaching or suggesting the use of Acker's ultrasound catheter in applications around *any* "tubular anatomical structure[]," let alone supporting the use of Acker's ultrasound catheter for renal neuromodulation around a renal vessel. Supporting this, Patent Owner's declarant Dr. Tucker testifies that, as of the time of the invention in the '629 patent, "ultrasound was not a known substitute for RF, generally, and particularly not for renal neuromodulation procedures." Tucker Decl. ¶ 113, *cited at* PO Resp. 38. Petitioner does not contend otherwise in the Petition or Reply, only asserting that "there were numerous other examples of ultrasound *for ablation*." Pet. Reply 29 (emphasis added) (citing Ex. 2033, 23:12–24:11). But that assertion does not address use of an ultrasound catheter like Acker's in the renal neuromodulation applications relevant here.

More specifically, and as a separate basis undermining Petitioner's position on this issue, the record also supports Dr. Tucker's testimony questioning the applicability of the fixed ablation ring around Acker's device in the renal neuromodulation application context when the target

renal nerve fibers will often not be within the target region. *See* Tucker Decl. ¶ 123 ("[T]he renal nerves that form a plexus on the renal artery are definitely not tubular anatomical structures. Levin explains that the 'nerve fibers . . . that form the renal plexus . . . look like a spider web,' which is illustrated in Fig. 15 as having multiple branches, loosely spaced, and running at various angles along the renal blood vessel.' Levin ¶ 122, Fig. 3."), *cited at* PO Resp. 42, 43–44 & PO Sur-reply 18 ("That ultrasound was known for PVI (or other procedures in 'tubular' structures) would not have motivated using ultrasound in the entirely different non-homogenous context of RDN where the targeted nerve plexus (or trunk) is unlike the homogeneous tubular structures considered in Acker."). Even in Dr. Tucker's deposition testimony on this issue highlighted at pages 12–13 of the Petitioner's Reply, Dr. Tucker qualified his response by saying that Acker's device could have been used in "other veins and arteries, *if appropriate*" (Ex. 1069 (Tucker Deposition), 41:6–12 (emphasis added)), but Petitioner did not follow up on that qualifying statement or independently explain *why* the use of Acker's device in a renal vessel would have been appropriate.

As the next potential reason for why one of ordinary skill in the art would have used Acker's device in Levin's renal neuromodulation method, Petitioner asserts that one of ordinary skill in the art would have expected certain advantages from using Acker's ultrasound catheter in Levin's renal neuromodulation method, including that Acker's ability to focus energy in a ring around the catheter would have allegedly 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. ¶¶ 83, 93–94, 99; Mendelson 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, 51:5–14).

We are not persuaded by this argument, however, because, for all the reasons discussed elsewhere in this subsection, the record does not support that one of ordinary skill in the art at the time of the invention would have expected advantages from performing the renal neuromodulation method in Levin using the ultrasound catheter of Acker. For example, Dr. Daft relies on Dr. Mendelsohn's testimony as to these alleged advantages (*see* Daft Pet. Decl. ¶ 99), and Dr. Mendelsohn, in turn, concludes—without adequate explanation—that the alleged advantages of Acker's device present *in the context of ablation around pulmonary veins* would also have been present if Acker's device were to have been used *in Levin's renal neuromodulation method around a renal vessel*. *See* Mendelsohn Decl. ¶ 73 (discussing how "Acker's catheter, in contrast, would have focused energy within a desired focal region, helping to avoid damage to the wall of the renal artery" even though Acker does not discuss renal arteries), *cited at* Pet. 32–33. For the reasons discussed here and elsewhere, the record does not support that one of ordinary skill in the art would have used Acker's catheter in Levin's renal neuromodulation method to arrive at these alleged advantages.

As another potential reason for why one of ordinary skill in the art would have used Acker's device in Levin's renal neuromodulation method, Petitioner states that one of ordinary skill in the art would have "understood ultrasound to be 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, 24:26–25:7; Mendelson

Decl. ¶¶ 69, 75). On this issue, Patent Owner addresses Petitioner's and Petitioner's declarants' reliance on Diederich (Ex. 1006) and Huang (Ex. 1059). *See* PO Resp. 40–41.

In presenting its case, Petitioner quotes a lengthy passage from Diederich—which is incorporated by reference into Acker (*see* Ex. 1005, 1:19–22)—as allegedly "teach[ing] that ultrasound is a known alternative to electrical current." Pet. 33–34 (quoting Ex. 1006, 24:26–25:7). The record does not support Petitioner's position, however, because Diederich's list of several "[s]uitable 'energy emitting' ablation elements" (which includes both RF current sources and ultrasonic elements) are ones "for use in the present invention," i.e., the invention of Diederich. *See* Ex. 1006, 24:31–25:8. And as highlighted by Patent Owner, Diederich "is directed to forming a 'conduction block along a circumferential region of tissue located between . . . a pulmonary vein . . . and . . . a posterior left atrial wall.'" PO Resp. 41 (quoting Ex. 1006, 3:8–12). Thus, as argued by Patent Owner, Diederich does not support that ultrasound "is a known alternative" to RF for *any* application generally (as inferred by Petitioner (Pet. 33)), or for renal neuromodulation applications (which neither Diederich nor Acker addresses). *See* PO Resp. 41 (stating that Diederich "fails to identify known substitutes of RF energy for RDN"); *id.* at 39 ("While individual methods of ablation . . . were known (*see* Pet. 33–34 (citing Daft [Pet. Decl.] ¶¶ 94, 102)), they were not known substitutes for one another across all applications or with respect to RDN in particular."). This argument by Patent Owner is supported by Dr. Tucker's cited testimony regarding Diederich. Tucker Decl. ¶ 118, *cited at* PO Resp. 41.

In testimony cited in the Petition, Dr. Daft quotes the entire passage at issue from Diederich (*see* Daft Pet. Decl. ¶ 95), but Dr. Daft does not adequately explain how that passage (which, again, is limited to the invention of Diederich) supports the *broader* proposition that "ultrasound is a known alternative to electrical current" for *other* applications, including renal neuromodulation, as recited in claim 1. Pet. 33–34 (discussing Daft Pet. Decl. ¶ 95). The same applies to similar testimony by Dr. Mendelsohn cited in the Petition. *See* Mendelsohn Decl. ¶ 69, *cited at* Pet. 33–34.

We turn now to Huang, which is an excerpt from a 2000 textbook titled "Radiofrequency Catheter Ablation of Cardiac Arrhythmias." *See* Ex. 1059. Petitioner does not discuss Huang directly in the Petition, but rather, Petitioner cites to a paragraph of Dr. Daft's testimony discussing Huang. *See* Pet. 33–34 (citing Daft Pet. Decl. ¶ 102). In that paragraph, 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.*

Similar to the discussion above as to Diederich, the record as to Huang does not support Petitioner's position because—even though Table 1 of Huang shows that RF and ultrasound are substitutable energy sources *for lesion generation in the context of cardiac ablation of cardiac arrythmias* (Ex. 1059 at 3)—Table 1 does not show RF and ultrasound are substitutable energy sources *for any application generally* (as inferred by Petitioner (Pet. 33)), or, more specifically, for renal neuromodulation applications (which Huang does not even address). *See* PO Resp. 40 ("Huang lists, *inter alia*, RF heating and focused ultrasound as energy sources for lesion generation, but fails to suggest that focused ultrasound could be a substitute for RF energy in RDN."); *id.* at 39 ("While individual methods of ablation . . . were known (*see* Pet. 33–34 (citing Daft [Pet. Decl.] ¶¶ 94, 102)), they were not known substitutes for one another across all applications or with respect to RDN in particular."). This argument by Patent Owner is supported by Dr. Tucker's and Dr. van der Weide's testimony regarding Huang. Tucker Decl. ¶ 116 ("That [Table 1 of Huang] includes every single 'energy source' that has been developed 'for lesion generation,' without any rationale for discriminating between the energy sources, does not inspire confidence in applying those energy sources for denervating the fine structures of the renal nerves."), *cited at* PO Resp. 40–41; van der Weide Decl. ¶ 67 (similar statement), *cited at* PO Resp. 39 & Tucker Decl. ¶ 117.

In testimony cited in the Petition, Dr. Daft does not adequately explain how Table 1 of Huang supports the *broader* proposition that

"ultrasound is a known alternative to electrical current" for applications not disclosed in Huang, such as renal neuromodulation. Pet. 33–34 (discussing Daft Pet. Decl. ¶ 102). More specifically, paragraph 102 of the Daft Petition Declaration does not support Petitioner's assertion that "a person of ordinary skill would have understood that one could use ultrasound or electrical current *to ablate renal nerves*." Pet. 34 (emphasis added) (citing Daft Pet. Decl. ¶¶ 102, 94). For that point, Petitioner also cites to paragraph 94 of the Daft Petition Declaration, but that paragraph discusses *only Acker*, which (as noted above) does not specifically discuss renal nerves.

In the Reply, Petitioner makes only one statement regarding Huang or Diederich, stating that Patent Owner

> essentially argues that teachings in Acker, Huang, and Diederich, relating to the alternative use of RF and ultrasound for tissue ablation, would have been viewed as limited to the cardiac context. (POR 39–41). These arguments fail—Acker is broadly directed to blood vessels and tubular structures ([Pet. Reply] 12), and there were numerous other examples of ultrasound for ablation. (Ex. 2033, 23:12–24:11).

Pet. Reply 29. For many of the same reasons discussed above, we are not persuaded that Acker's use of the phrases "blood vessel" and "tubular anatomical structures" in certain disclosures (*see, e.g.*, Ex. 1005, 8:15–18) supports that one of ordinary skill in the art would have understood that Acker's ultrasound catheter could have been used effectively on *any* anatomical structures near *any* blood vessel, including, for example, renal nerves near renal vessels. For the reasons above, we determine, in light of the complete record, that Petitioner has not 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 the device of Acker in the renal neuromodulation method of Levin, as proposed.

(2) Objective Indicia of Nonobviousness

We next turn to Patent Owner's objective evidence of nonobviousness. Patent Owner alleges (1) unexpected results and skepticism, (2) copying, (3) praise, and (4) long-felt but unsolved need and failure of others. *See* PO Resp. 60–68; PO Sur-reply 25–27. Petitioner responds. *See* Pet. Reply 36–37. We have considered the evidence and argument presented by both parties, but do not address the issues in detail. *See Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365, 1373 n.9 (Fed. Cir. 2004) ("Because [patent challenger] has not made a prima facie case of obviousness, we need not address the parties' assertions regarding the district court's discussion of secondary considerations.").

(3) Conclusion

For the reasons discussed above (§§ II.C.3.a.1), the evidence presented by Petitioner does not indicate that claim 1 would have been obvious based on Levin and Acker. When considering all of 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 conclude Petitioner has not demonstrated by a preponderance of the evidence that claim 1 would have been obvious based on Levin and Acker.

b. Dependent Claims 2–4 and 8–11

Petitioner asserts that claims 2–4 and 8–11 would have been obvious based on Levin and Acker. Pet. 48–57; Pet. Reply 33–34. As discussed in the prior section, Petitioner has not demonstrated by a preponderance of the

evidence that independent claim 1, from which claims 2–4 and 8–11 depend, would have been obvious based on Levin and Acker. *See* § II.C.3.a. Thus, we determine, based on the complete record, that Petitioner has not demonstrated by a preponderance of the evidence that claims 2–4 and 8–11 would have been obvious based on Levin and Acker.

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

Petitioner asserts that claim 12, which depends from independent claim 1, would have been obvious under 35 U.S.C. § 103(a) based on Levin, Acker, and Yock. Pet. 12, 57–60; Pet. Reply 34–35. Petitioner's added reliance on Yock in the context of this asserted ground does not remedy the deficiencies in the asserted ground based on Levin and Acker, discussed above, regarding claim 1 (*see* § II.C.3.a). Thus, for the reasons discussed above (*see id.*), we determine, based on the complete record, that Petitioner has not 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 of the '629 patent are anticipated under 35 U.S.C. § 102(e) by Acker. Pet. 12, 60–65; Pet. Reply 35. Patent Owner provides arguments specifically addressing this asserted ground. *See* PO Resp. 56–57; PO Sur-reply 25. In this asserted ground, Petitioner relies on Acker alone (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," 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,"[11] 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) (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, in the discussion of this asserted ground based on anticipation, Petitioner has "misplaced" reliance on the section of the Petition addressing "Reasonable Expectation of Success" as to the asserted ground of obviousness based on Levin and Acker, and, in particular, that

[11] 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."

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 highlighted by Petitioner as to this asserted ground based on anticipation 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 Ground 1 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 in the section addressing element 1d for this asserted ground, especially given that (as discussed above) Acker does not 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.); *see also* *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 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 asserted 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, 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."); *see also 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"); *cf.* 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." (emphasis added)). Thus, based on the complete record, we conclude Petitioner has not demonstrated by a preponderance of the evidence that claim 1 is anticipated by Acker.

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

Petitioner asserts that claims 2, 3, 8, and 9 are anticipated under 35 U.S.C. § 102(e) 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 '629 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. Independent Claim 1

Petitioner contends that the combination of Acker and the knowledge of one of ordinary skill in the art satisfies each limitation of claim 1. Pet. 65–72; Pet. Reply 35–36. Below, we discuss the parties' positions with respect to the proposed reasons to modify Acker based on the knowledge of one of ordinary skill in the art. 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 would have been obvious based on Acker and the knowledge of one of ordinary skill in the art.

a. The Proposed Reasons to Modify Acker Based on the Knowledge of a Person of Ordinary Skill in the Art

As part of the discussion of this asserted ground, Petitioner discusses reasons that one of ordinary skill in the art would have combined Acker with the knowledge of one of ordinary skill in the art in the manner proposed (Pet. 65–70) and why one of ordinary skill in the art would have had a reasonable expectation of success in the proposed combination (Pet. 70).

As to the reasons to combine, Petitioner states that one of ordinary skill in the art at the relevant time would have known that hypertension is "problematic" for humans and that it was "well-understood that hypertension was linked to increased sympathetic renal nerve activity, and could be treated by renal denervation." Pet. 66–67 (citing Mendelsohn Decl. ¶ 97); *see also* Pet. 67–69 (further discussing why one of ordinary skill in the art would have known that renal denervation would reduce blood pressure). According to Petitioner, one of ordinary skill in the art "would have been motivated to attempt denervation of the renal nerves in the relevant timeframe in order to treat hypertension" and "[t]his would have been especially true for the portion of the hypertensive population that was resistant to treatment with pharmaceuticals." Pet. 69 (citing Mendelsohn Decl. ¶¶ 88–89, 108). Petitioner contends that, "although renal denervation had been accomplished using open surgery in the past, [one of ordinary skill in the art] would have been motivated to perform renal denervation using an intravascular catheter such as Acker's." Pet. 70 (citing Mendelsohn Decl. ¶ 109).

Patent Owner challenges these reasons to combine, arguing that the "purported motivations to use Acker's catheter to perform RDN based on the knowledge of [one of ordinary skill in the art] are . . . also unavailing" because "[w]hether it was well known that hypertension could be treated through RDN (Pet. 65–69), that is not sufficient evidence that [one of ordinary skill in the art] would have been motivated to use Acker's specific catheter, which produces an entire ring of ablated tissue around the catheter, to perform RDN." PO Resp. 58. Patent Owner adds that Petitioner "provide[s] no motivation in [the context of this asserted ground] to use a catheter with ultrasound to perform RDN" and repeats the argument from the asserted ground based on Levin and Acker that "ultrasound was not a known substitute of RF for neuromodulation." *Id.* at 58–59 (citing PO Resp. 38–41); *see also* PO Sur-reply 25 (arguing that one of ordinary skill in the art "would not have used Acker's catheter or teachings for RDN"). Petitioner refers to its arguments in the Reply as to the ground based on Levin and Acker. *See* Pet. Reply 35–36.

For the same reasons discussed above in the context of the asserted ground based on Levin and Acker (*see* § II.C.3.a(1)), the complete record does not support that one of ordinary skill in the art at the time of the invention in the '629 patent would have been motivated to use Acker's ultrasound catheter for renal neuromodulation applications, as recited in claim 1. The additional knowledge of one of ordinary skill in the art discussed in the context of this asserted ground does not address this deficiency or otherwise change that conclusion. Thus, we determine, in light of the complete record, that Petitioner has not 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 the device of Acker for renal neuromodulation applications, as recited in claim 1, based on the knowledge of one of ordinary skill in the art.

b. Objective Indicia of Nonobviousness

As noted above (*see* § II.C.3.a(2)), we have considered the objective evidence and argument presented by both parties, but do not address the issues in detail. *See Alza Corp.*, 391 F.3d at 1373 n.9.

c. Conclusion

For the reasons discussed above (*see* § II.F.1.a), the evidence presented by Petitioner does not indicate that claim 1 would have been obvious based on Acker and the knowledge of one of ordinary skill in the art. When considering all of the evidence of obviousness and nonobviousness together (*see In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d at 1079), we conclude Petitioner has not demonstrated by a preponderance of the evidence that claim 1 would have been obvious based on Acker and the knowledge of one of ordinary skill in the art.

2. Dependent Claims 2–4 and 8–11

Petitioner asserts that claims 2–4 and 8–11 would have been obvious based on Acker and the knowledge of one of ordinary skill in the art. Pet. 72–75; Pet. Reply 35–36. As discussed in the prior section, Petitioner has not demonstrated by a preponderance of the evidence that independent claim 1, from which claims 2–4 and 8–11 depend, would have been obvious based on Acker and the knowledge of one of ordinary skill in the art. *See* § II.F.1. Thus, we determine, based on the complete record, that Petitioner has not demonstrated by a preponderance of the evidence that claims 2–4

and 8–11 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 under 35 U.S.C. § 103(a) based on Acker, the knowledge of one of ordinary skill in the art, and Yock. Pet. 12, 75; Pet. Reply 35–36. Petitioner's added reliance on Yock in the context of this asserted ground does not remedy the deficiencies in the asserted ground based on Acker and the knowledge of one of ordinary skill in the art, discussed above, regarding claim 1 (*see* § II.F.1). Thus, for the reasons discussed above (*see id.*), we determine, based on the complete record, that Petitioner has not demonstrated by a preponderance of the evidence that claim 12 would have been obvious based on Acker, the knowledge of one of ordinary skill in the art, and Yock.

III. CONCLUSION

Upon consideration of the briefing and the evidence of record, we determine that Petitioner has not proven, by a preponderance of the evidence, the unpatentability of any of the challenged claims.

In summary:

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

IV. ORDER

Accordingly, it is hereby:

ORDERED that Petitioner has not proven, by a preponderance of the evidence, that claims 1–4 and 8–12 are 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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