

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

**RECOR MEDICAL, INC., OTSUKA MEDICAL
DEVICES CO., LTD.,**
Appellants

v.

**MEDTRONIC IRELAND MANUFACTURING
UNLIMITED CO.,**
Appellee

2023-2251

Appeal from the United States Patent and Trademark
Office, Patent Trial and Appeal Board in No. IPR2022-
00431.

Decided: March 27, 2025

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Before LOURIE, MAYER, and PROST, *Circuit Judges*.

PROST, *Circuit Judge*.

Recor Medical, Inc. and Otsuka Medical Devices Co. Ltd. (collectively, “Recor”) appeal the final written decision of an inter partes review (“IPR”) of U.S. Patent No. 8,845,629 (“the ’629 patent”), holding all challenged claims were not shown unpatentable. *Recor Med., Inc. v. Medtronic Ir. Mfg. Unlimited Co.*, No. IPR2022-00431, 2023 WL 5167837, at *16 (P.T.A.B. July 14, 2023) (“*Final Written Decision*”). We vacate and remand for further proceedings consistent with this opinion.

BACKGROUND

The ’629 patent is titled “Ultrasound Apparatuses for Thermally-Induced Renal Neuromodulation” and “relates to methods and apparatus[es] for achieving renal neuromodulation via thermal heating and/or cooling mechanisms.” ’629 patent col. 1 ll. 43–44. Renal neuromodulation is the process of surgically disrupting or destroying the renal nerves. The ’629 patent discusses how renal neuromodulation may be used to treat certain diseases such as heart failure, renal failure, and hypertension. *Id.* at col. 1 ll. 48 to col. 2 ll. 21.

More specifically, the ’629 patent relates to using a catheter to perform renal neuromodulation by applying thermal energy to the target neural fibers. The catheter contains a positioning element (e.g., a balloon), which may be used to center or position the electrodes that deliver the thermal energy within the blood vessel to the targeted tissue. *See id.* at col. 7 ll. 34–55. While various forms of thermal energy may be used for neuromodulation, “such as through application of a ‘thermal’ electric field, of high-

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intensity focused ultrasound, of laser irradiation, etc.,” *id.* at col. 4 ll. 61–63, the claims of the ’629 patent are directed to ultrasound. Claim 1 is illustrative:

1. An ultrasound apparatus for thermally-induced renal neuromodulation, the apparatus comprising:

a catheter sized and shaped for delivery within a blood vessel to a vicinity of neural fibers that contribute to renal function;

an ultrasound transducer carried by the catheter, 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

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

wherein the ultrasound transducer is positioned on a shaft of the catheter and within the expandable member.

Id. at claim 1.

In 2022, Recor filed a petition for IPR of the ’629 patent, challenging claims 1–4 and 8–12. Relevant here are Recor’s four grounds based on obviousness of the ’629 patent, including two grounds involving Levin¹ in view of Acker²

¹ U.S. Patent App. Pub. No. 2003/0216792 (“Levin”), J.A. 2102–26.

² U.S. Patent No. 6,669,655 (“Acker”), J.A. 2127–40.

and two grounds involving Acker in view of the knowledge of a person of ordinary skill in the art. For the Levin-Acker grounds, Recor argued that it would have been obvious to combine the renal neuromodulation method of Levin with Acker's catheter. *See* J.A. 1035 (“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.”). The Board disagreed, finding that there was no motivation to combine Levin with Acker and that it would not have been obvious to try ultrasound energy for renal neuromodulation. *See Final Written Decision*, 2023 WL 5167837, at *7–12.

As to Acker in view of the knowledge of a person of ordinary skill in the art, Recor argued that “Acker teaches an ultrasound ablation catheter,” and a person of ordinary skill in the art “would have understood from Acker that its catheter was appropriate for selectively ablating tissue, including nerve tissue.” J.A. 1069. The Board disagreed “[f]or the same reasons discussed . . . in the context of the asserted ground based on Levin and Acker”—i.e., “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.” *Final Written Decision*, 2023 WL 5167837, at *15. Based on these findings (and others), the Board held that Recor had not demonstrated by a preponderance of the evidence that the challenged claims would have been obvious.

Recor appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

“Whether a claimed invention would have been obvious is a question of law, based on factual determinations

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regarding the scope and content of the prior art, differences between the prior art and the claims at issue, the level of ordinary skill in the pertinent art, the motivations to modify or combine prior art, and any objective indicia of non-obviousness.” *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015). “We review the Board’s legal determination of obviousness de novo and its factual findings for substantial evidence.” *Outdry Techs. Corp. v. Geox S.p.A.*, 859 F.3d 1364, 1367 (Fed. Cir. 2017) (internal citation omitted). “Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1378 (Fed. Cir. 2023) (internal citation omitted).

On appeal, Recor makes two main arguments: (1) that the Board committed legal error by failing to consider Acker “for everything it teaches,” *Belden*, 805 F.3d at 1076 (emphasis omitted); and (2) that the Board erred in concluding that it would not have been obvious to try ultrasound energy to ablate renal nerves. We address each argument in turn.

I

“[A] reference must be considered for everything it teaches by way of technology and is not limited to the particular invention it is describing and attempting to protect.” *Id.* (emphasis omitted) (quoting *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985)). We agree with Recor that the Board violated this principle here.

Recor relied on Acker’s catheter in both its Levin-Acker grounds and its Acker-in-view-of-a-person-of-ordinary-skill grounds. The use of such a catheter in the renal neuromodulation context in all of these grounds was based on obviousness arguments, including Levin’s use of a catheter in the renal neuromodulation context and the knowledge of a person of ordinary skill in the art. One of Recor’s

arguments was that Acker itself provides a basis for using its ultrasound catheter in any “blood vessel” or “tubular anatomical structure,” which when combined with Levin or the person of ordinary skill in the art would render obvious the claimed invention of the ’629 patent. The Board disagreed, concluding that Acker primarily discloses more specific uses for ultrasound catheters in pulmonary veins. See *Final Written Decision*, 2023 WL 5167837, at *8–9.

But the Board was required to consider Acker “for everything it teaches.” *Belden*, 805 F.3d at 1076. And Acker teaches using a catheter with an ultrasonic transducer “to provide ultrasonic energy in a ring-like zone surrounding a blood vessel.” J.A. 2127 abstract (emphasis added); see also J.A. 2135 col. 2 ll. 23–25 (“[T]he catheter is positioned within a circulatory vessel with a central axis of the emitting element substantially aligned with an axis of *the circulatory vessel*.” (emphasis added)); J.A. 2139 claim 10 (“said catheter is positioned within a circulatory vessel with a central axis of the emitting element substantially aligned with an axis of the circulatory vessel”). While 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: “Although the invention has been described above with reference to ablation of blood vessel walls, the same techniques can be used to ablate ring-like regions around other tubular anatomical structures.” J.A. 2138 col. 8 ll. 15–18. These disclosures in Acker, among others, explicitly contemplate the use of Acker’s catheter in various blood vessels. And they should not be disregarded simply because Acker has a preferred embodiment involving a more specific use in pulmonary veins. *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (“In a section 103 inquiry, the fact that a specific embodiment is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.” (cleaned up)).

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And although the Board recognized that “Acker does, in certain passages cited by Petitioner, use broader phrases such as ‘blood vessel’ and ‘tubular anatomical structures,’” *Final Written Decision*, 2023 WL 5167837, at *8, the Board’s justification for disregarding these teachings was unsound: “[T]he 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.” *Id.* (emphasis altered from original). Whether the Board’s narrow interpretation of Acker is read as a requirement that the prior art actually operate to perform the claimed invention or that the prior art be enabled, neither inquiry is correct under our obviousness standard. *See, e.g., Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (“Even if a reference discloses an inoperative device, it is prior art for all that it teaches.”); *In re Etter*, 756 F.2d 852, 859 (Fed. Cir. 1985) (en banc) (explaining that the test for obviousness is “not whether the references could be physically combined but whether the claimed inventions are rendered obvious by the teachings of the prior art as a whole”).

Instead, the question is whether “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention.” *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (quoting *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007)). *KSR* explained that “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton,’ so the fact that it would take some creativity to [arrive at the claimed invention] does not defeat a finding of obviousness.” *Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1343 (Fed. Cir. 2020) (quoting *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007)). By failing to consider Acker “for everything it teaches,” the Board disregarded the

“expansive and flexible approach” to obviousness inquiries expressed in *KSR*. 550 U.S. at 415. We, therefore, conclude that the Board legally erred in dismissing Acker’s broader teachings and vacate the Board’s holdings as to all four of Recor’s obviousness grounds that rely on Acker in combination with Levin or the knowledge of a person of ordinary skill in the art.

II

Recor also argues that the Board erred in concluding that it had not shown that it would have been obvious to try ultrasound to ablate renal nerves.³ Recor frames its argument as a legal error, but we agree with Medtronic that the question here is one of fact reviewed for substantial evidence under the circumstances before us.⁴

“To prove obviousness under an obvious to try theory, [Recor] must show (1) a design or market need to solve a particular problem, and (2) that ‘there are a finite number of identified, predictable solutions’ that would lead to an expectation of success.” *Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1345 (Fed. Cir. 2019) (emphasis omitted) (quoting *KSR*, 550 U.S. at 421). Here, Recor argues that it would have been obvious to combine Levin’s method of renal neuromodulation with Acker’s ultrasound catheter because both Levin and Acker use thermal energy, and a

³ Medtronic argues that Recor forfeited this argument. Appellee’s Br. 47. We disagree. Recor’s petition raised and preserved this issue. *See* J.A. 1037–38.

⁴ There may be circumstances where obvious-to-try arguments are rooted in a legal question. For example, if there are no underlying facts in dispute regarding the “finite number of identified, predictable solutions,” the application of the obvious-to-try rationale may be purely a question of law. *See Uber Techs. Inc. v. X One, Inc.*, 957 F.3d 1334, 1341 (Fed. Cir. 2020). That is not the case here.

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person 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.” J.A. 1037.⁵ Specifically, Recor asserts that there are a finite number of thermal energy sources for ablation, including electrical, ultrasound, radiofrequency, cryogenics, microwave, laser, chemical, induction, radiation, and mechanical methods. *See* Appellant’s Br. 36–39.

Aside from its forfeiture argument, Medtronic responds that on the merits “Acker’s particular ultrasound transducer that forms a ring-shaped lesion was not a predictable source of thermal energy for [renal neuromodulation],” Appellee’s Br. 47, and “while several sources list ultrasound as a thermal source, it is among many different options and none of the references suggests ultrasound is an option for renal denervation,” *id.* at 51 (emphasis omitted). In other words, Medtronic argues that ultrasound catheters were not part of a finite number of predictable solutions for renal neuromodulation.

“Absolute predictability . . . is not required.” *Valeant Pharms. Int’l, Inc. v. Mylan Pharms. Inc.*, 955 F.3d 25, 34 (Fed. Cir. 2020). “Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *KSR*, 550 U.S. at 420. The Board should therefore have considered, under the obvious-to-try rationale, whether “a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.” *Id.* at 421. On that question, Recor provided ample

⁵ Based on Recor’s argument in its petition and its opening brief, we understand its obvious-to-try argument to apply only to the two Acker-Levin grounds raised in its petition. *See* J.A. 1036–38; Appellant’s Br. 36.

evidence, including Levin, Acker, Diederich,⁶ and Huang.⁷ For example, Levin teaches renal neuromodulation, including ablation, using a catheter with electrical energy. J.A. 2114, ¶ 2; J.A. 2119 ¶ 64 (“Ablation can be performed by introduction of a catheter into the venous system in close proximity of the sympathetic renal nerve subsequent ablation of the tissue.”). And Acker teaches ablation of tissue using an ultrasound catheter. J.A. 2127 abstract. Both Diederich and Huang teach a limited universe of thermal energy sources for the ablation of tissues. See J.A. 2164–65 (Diederich) (listing DC current, AC current, radiofrequency, microwave, heating elements, light emitting elements, and ultrasound as possible “energy emitting” ablation elements); J.A. 3962 (Huang) (listing a similar and overlapping list as Diederich of ten thermal energy sources). This is a sufficiently finite universe of options to support an obvious-to-try theory. See *Valeant Pharms.*, 955 F.3d at 34 (concluding a set of ten variables was finite). And these thermal energy sources’ known use for ablation renders them reasonably predictable. See *In re Copaxone Consol. Cases*, 906 F.3d 1013, 1025–27 (Fed. Cir. 2018). Based on these prior-art references, “a person of ordinary skill [would have] good reason to pursue [these] known options.” *KSR*, 550 U.S. at 421. We therefore conclude that substantial evidence does not support the Board’s rejection of Recor’s obvious-to-try theory.

⁶ PCT App. No. WO 99/02096 (“Diederich”), J.A. 2141–2257.

⁷ S. Huang & D. Wilber, *Radiofrequency Catheter Ablation of Cardiac Arrhythmias, Basic Concepts and Clinical Applications* (Futura Publishing Co. 2d ed. 2000) (“Huang”), J.A. 3959–70.

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CONCLUSION

For the reasons above, we vacate and remand to the Board for further proceedings consistent with this opinion.

VACATED AND REMANDED

COSTS

Costs to Appellants.