United States Court of Appeals for the Federal Circuit

AXONICS, INC.,
Appellant

v.

MEDTRONIC, INC.,
Appellee

2022-1451, 2022-1452

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2020-00715, IPR2020-00679.

Decided: July 10, 2023

WILLIAM P. NELSON, Tensegrity Law Group LLP, Redwood Shores, CA, argued for appellant. Also represented by MATTHEW D. POWERS; AZRA HADZIMEHMEDOVIC, SAMANTHA A. JAMESON, AARON MATTHEW NATHAN, McLean, VA.

CHETAN BANSAL, Paul Hastings LLP, Washington, DC, argued for appellee. Also represented by STEPHEN BLAKE KINNAIRD, NAVEEN MODI.

Before LOURIE, DYK, and TARANTO, *Circuit Judges*.

TARANTO, *Circuit Judge*.

Medtronic, Inc., owns U.S. Patent Nos. 8,626,314 and 8,036,756 (together, the Medtronic patents), which describe and claim a neurostimulation lead and a method for implanting and anchoring the lead. Axonics, Inc., having been sued by Medtronic for infringement, challenged various claims of the Medtronic patents for obviousness in inter partes reviews (IPRs) under 35 U.S.C. §§ 311–319. In both IPRs, the Patent and Trademark Office's Patent Trial and Appeal Board concluded that Axonics had failed to prove any of the challenged claims unpatentable. Axonics appeals. Because the Board erred in its obviousness analysis, and because the errors cannot be regarded as harmless, we vacate and remand.

I

A

The '314 patent is a grandchild of the '756 patent, so we hereafter cite only the '314 specification. The "Field of the Invention" section of the specification states:

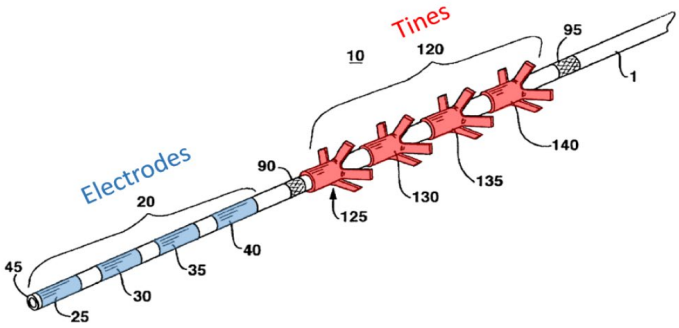
> This invention relates generally to a method and apparatus that allows for stimulation of body tissue, particularly sacral nerves. More specifically, this invention relates to an implantable medical electrical lead having at least one stimulation electrode adapted to be implanted near the sacral nerves for stimulation of a bundle of sacral nerve fibers and a fixation mechanism for providing chronic stability of the stimulation electrode and lead. Moreover, this invention relates to the method of implantation and anchoring of the medical electrical lead electrodes in operative relation to a selected sacral nerve to allow for stimulation.

'314 patent, col. 1, lines 34–44. An extended discussion of "Related Art" follows, *id.*, col. 1, line 45, through col. 5, line 44, which is focused on medical problems addressable by

electrical stimulation of the sacral nerves, *e.g.*, *id.*, col. 1, line 46, through col. 4, line 23, but includes discussion of electrostimulation devices for other parts of the body, *e.g.*, *id.*, col. 4, line 24, through col. 5, line 33. That section ends by identifying a "need in the art for a permanently implantable electrical sacral nerve stimulation lead" with certain properties. *Id.*, col. 5, lines 34–44.

In the "Summary of the Invention" section, *id.*, col. 5, line 46 (full-phrase capitalization altered), the specification then describes the "present invention" in terms that are not confined to the sacral nerves, *id.*, col. 5, line 48. "The present invention provides a solution to the problems associated with implanting and maintaining electrical leads in body tissue, particularly muscle tissue to maintain one or more lead electrode in relation to a particular body site, through use of minimally invasive implantation techniques." *Id.*, col. 5, lines 48–53; *see also*, *e.g.*, *id.*, col. 5, line 65, through col. 6, line 19. Application to "sacral nerve stimulation" is one "preferred embodiment." *Id.*, col. 5, lines 53–64.

The patents describe and show the features key to the present appeal: at least two electrodes at the distal end of the lead, with "a plurality M of tine elements arrayed . . . along a segment of the lead proximal to the stimulation electrode array." *Id.*, col. 6, lines 5–8. For example, Figure 2 shows four "ring-shaped electrodes 25, 30, 35, and 40 in an electrode array 20 extending proximally from the lead distal end 45," *id.*, col. 9, lines 25–34 (emphases omitted), and four "tine elements" (125, 130, 135, and 140) attached "proximally toward the lead proximal end," *id.*, col. 10, lines 25, 32–35:



Id., Fig. 2 (annotated version in Medtronic's Br. at 14).

Claim 1 of the '314 patent is illustrative of the claims at issue here:

> 1. A system comprising:
>
> an implantable medical lead comprising:
>
> a lead body extending between a proximal end and a distal end;
>
> a plurality of conductors within the lead body;
>
> a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors; and
>
> a plurality of tine elements extending from the lead body, wherein all tine elements of the plurality of tine elements are positioned between a most proximal electrode of the plurality of electrodes and the proximal end of the lead body, each tine element comprising a plurality of flexible, pliant tines, each tine having a tine width and thickness and extending a tine

> length from an attached tine end to a free tine end, the attached tine end attached to the lead body from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end, wherein the plurality of tines of the plurality of tine elements are adapted to be folded inward against the lead body when fitted into and constrained by a lumen of an introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn to release the plurality of tines, wherein the plurality of tine elements is separate from and axially displaced from the plurality of electrodes.

Id., col. 13, line 51, through col. 14, line 11. No claim of the two patents either mentions or is limited to sacral nerves. The same is true of the titles of the two patents: "Implantable Medical Lead Including a Plurality of Tine Elements," '314 patent, col. 1, lines 1–3 (capitalization removed); "Implantable Medical Electrical Stimulation Lead Fixation Method and Apparatus," '756 patent, col. 1, lines 1–3 (capitalization removed).

B

On March 16, 2020, Axonics petitioned for IPRs of claims 1, 2, 4, 7, 10–12, 14, and 18–24 of the '314 patent and of claims 1, 2, 5, 7, 13–15, and 18 of the '756 patent. The Board instituted both IPRs on September 15, 2020—IPR2020-00679 for the '314 patent and IPR2020-00715 for the '756 patent. On September 13, 2021, the Board issued final written decisions in both IPRs.

1

In its petition concerning the '314 patent, Axonics argued, among other things, that the challenged claims of the '314 patent are unpatentable under 35 U.S.C. § 103 for obviousness over Young (Ronald F. Young, M.D., *Electrical Stimulation of the Trigeminal Nerve Root for the Treatment of Chronic Facial Pain*, 83 Journal of Neurosurgery 72 (1995)) in view of Gerber (U.S. Patent No. 6,055,456) and Lindegren (PCT App. No. WO 98/20933).[1] Axonics specifically argued that a relevant artisan would have been motivated "to replace the one electrode of Young with multiple electrodes at the distal end distal to the anchoring mechanism, as taught in Gerber, in order to provide more flexibility in activation of a wider area and provide the possibility for bipolar electrical stimulation, as taught in Young." J.A. 208 (Axonics's petition). Only the Board's findings about the combination of Young and Gerber are presented for review in this appeal.

Young describes a clinical study of patients who received percutaneous implantations of an electrical neurostimulator to treat chronic facial pain resulting from injury to the trigeminal nerve or nerve root. J.A. 2405–06 (Young at 72–73). The "study was undertaken . . . to extend the application of electrical stimulation," which had previously "been used successfully with spinal cord and deep brain stimulation, to the trigeminal system and chronic facial pain." *Id.* The implanted neurostimulator used in the study "consisted of a monopolar . . . lead with two sets of four 'tines' located" a short distance proximal to the single electrode at the distal tip of the lead. J.A. 2406 (Young at 73). The tines "prevent[ed] the electrode from

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[1] The version of 35 U.S.C. § 103 applicable to both patents at issue here is the one pre-dating the amendments made by the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011).

becoming dislodged after implantation." *Id.* Young states that the neurostimulator "could be improved" by adding "multiple active stimulation sites," *i.e.*, additional electrodes, "near the tip[,] . . . which would permit greater flexibility in activation of a wider area of the trigeminal nerve root" and would "provide the possibility for bipolar electrical stimulation, which in other neurostimulation settings (such as [those] involving spinal cord and brain) has proved to be more effective than monopolar stimulation." J.A. 2410 (Young at 77).

Gerber describes "an implantable medical lead having at least one electrode contact wherein the lead is implanted near the sacral nerves for stimulation" and a "method of implantation and anchoring of the medical lead near the sacral nerve." Gerber, col. 1, lines 9–14. Gerber also discloses that existing leads for sacral nerve stimulation "have four small discrete electrodes built into the distal end of the lead." *Id.*, col. 1, lines 57–58. Gerber's implantable lead includes "a distal end" (25) with "at least one electrode contact" (20) and "a proximal end" (35), *id.* col. 3, lines 21–22, 42–46, and may include an "anchoring mechanism" (50) to keep the lead near the targeted sacral nerve, *id.*, col. 4, lines 13–31, as shown in Figure 2:

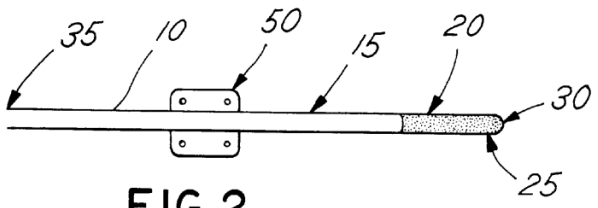

FIG.2

The anchoring mechanism may have holes for suture fixation (50 in Figure 2) or may "allow the medical lead . . . to fibrose in naturally using the human body's reaction to a foreign body or healing." *Id.*, col. 4, lines 13–31.

In arguing that a relevant artisan would have been motivated to combine the teachings of Young and Gerber, Axonics asserted that Young and Gerber "reasonably

address[] the similar problems of leads adequately stimulating the nerves while limiting electrode migration"—a problem that Axonics contended the '314 patent also addresses. J.A. 206 (Axonics's petition, citing Young at 73; Gerber, col. 1, line 64, through col. 2, line 13). Young, Gerber, and the '314 patent, according to Axonics, are also "from the same field": "neurostimulation with implantable medical leads with electrode(s) at the distal end of the lead and a proximal anchoring mechanism." *Id.* (citing Young at 73; Gerber, col. 3, line 39, through col. 4, line 52). Axonics argued that a relevant artisan "would have been motivated to combine references that solve the same problem as the '314 [p]atent in the same field." *Id.* (citing *Tokai Corp. v. Easton Enterprises, Inc.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011)). Axonics also argued that Young expressly provides a motivation to make the asserted combination when it states that the neurostimulator used in the clinical study "could be improved to provide multiple active stimulation sites near the tip." J.A. 207 (quoting Young at 77). Gerber, urged Axonics, "discloses multiple electrodes on implanted leads for sacral nerve stimulation" and an "anchoring means that fixes by fibrosis." *Id.* Axonics added that, at the priority date, there were a "limited number of devices available . . . to anchor by fibrosis," tines being the predominant one. *Id.*

In its final written decision, the Board held all the challenged claims of the '314 patent not unpatentable for obviousness. J.A. 2. The Board began by defining the relevant art and a relevant artisan, in agreement with Medtronic on the point of relevance here, as focused on sacral-nerve stimulation specifically. The Board found that "the relevant art is medical leads specifically for sacral neuromodulation," J.A. 13; *see* J.A. 15, relying on the "field of the invention" statements to narrow the field in that way even though the claims are not limited to sacral nerves. J.A. 13–14. The Board then concluded that, because the relevant art "is sophisticated and requires knowledge of human anatomy of

the sacral area and the surgical procedures involved in sacral neuromodulation," a relevant artisan is someone with, among other experience, "at least two years of experience researching and developing medical leads for sacral neuromodulation." J.A. 15.

The Board then addressed Axonics's argument that the claims would have been obvious over Young in view of Gerber and Lindegren. The Board agreed with Axonics that it had "demonstrated each limitation of independent claim 1 in its proposed combination"—including, as relevant here, a plurality of electrodes distal to all tines. J.A. 36. Nevertheless, the Board found that Axonics had not demonstrated that a relevant artisan would have had a motivation to combine "Young's lead with Gerber's plurality of electrodes so the plurality of electrodes is distal to all of the lead's tines." *Id.* This failure of proof, the Board said, defeated the challenge to all identified claims, as Axonics "relie[d] on the same reasoning for combining" the teachings of Young and Gerber for all three independent claims (1, 11, 18). *Id.*

In making its decisive determination, the Board first found that, contrary to the argument of Axonics, Young, Gerber, and the '314 patent do not solve the same problem. The Board reasoned that the '314 patent "addresses the need for a percutaneously implantable lead that is properly and securely positioned to provide *sacral* nerve stimulation," J.A. 31 (emphasis added), and Gerber addresses "the positioning and securement of an electrode that is implanted in the sacral area via a non-percutaneous surgical procedure," *id.*, but "Young addresses placement of an implanted, percutaneously placed electrode system for . . . stimulation of the *trigeminal* sensory root for treatment of chronic facial pain," *id.* (emphasis added).

That distinction also was central to the Board's rejection of Axonics's reliance, for motivating the combination with Gerber, on Young's statement that "[t]he electrode

could be improved to provide multiple active stimulation sites near the tip." J.A. 30, 34–35; *see* J.A. 2410 (Young at 77). Medtronic and its expert, Dr. Slavin, asserted that this sentence in Young did not suggest to a relevant artisan "to include a plurality of electrodes distal to all of the tines" in the Young neurostimulator "because such an arrangement would not be feasible in the complex anatomy of the trigeminal nerve region." J.A. 33. The Board agreed, stating that the purpose of Young's lead "is electrical stimulation of the trigeminal sensory root," so Young's sentence on improvement by adding electrodes would not have motivated a relevant artisan to combine Young's lead with a plurality of electrodes distal to all of the tines (as taught in Gerber), because "such an arrangement would not be feasible in the trigeminal nerve region" given the tight tissue-related spacing constraints of that particular nerve region. J.A. 35 (relying on Dr. Slavin's testimony, reproduced at J.A. 33). The Board further found that Young "discloses multiple active sites *near* the tip, not at the tip or distal to the tines." *Id.* This finding similarly depended entirely on Dr. Slavin's testimony regarding the space constraints of the trigeminal-nerve region. *Id.* The Board therefore concluded that Axonics failed to prove that a relevant artisan would have been motivated to combine the teachings of Young and Gerber. *Id.*

2

In its petition concerning the '756 patent, Axonics argued obviousness over Young in view of Gerber, Lindegren, and Akerström (U.S. Patent No. 4,407,303). This challenge relied on the same combination of Young and Gerber as was decisive for the '314 patent. J.A. 291 (Axonics's petition). The Board rejected the asserted motivation to combine for the '756 patent—and hence the obviousness challenge—for the same reasons it did for the '314 patent. J.A. 103–04.

3

Axonics timely appealed from both final written decisions on February 4, 2022, within the 63 days allowed by 35 U.S.C. § 142 and 37 C.F.R. § 90.3(a)(1). We have jurisdiction under 35 U.S.C. §§ 141(c), 319 and 28 U.S.C. § 1295(a)(4)(A).

II

Obviousness is an issue of law decided based on numerous factual findings, including the scope and content of the prior art, the level of ordinary skill, and whether a relevant artisan would have had a motivation to combine references in the way required to achieve the claimed invention. *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1331 (Fed. Cir. 2019) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)); *PAR Pharmaceutical, Inc. v. TWI Pharmaceuticals, Inc.*, 773 F.3d 1186, 1196–97 (Fed. Cir. 2014). Factual findings are reviewed for substantial-evidence support, which exists when, on the whole record, "a reasonable fact finder could have arrived at" the finding on review. *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000). Whether the decision on review rests on a failure to apply the correct legal standards is determined de novo on appeal. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015).

The Board in this case rejected Axonics's obviousness challenge because it found that Axonics failed to show that a relevant artisan would have had a motivation to combine the teachings of Young with those of Gerber, and the Board rested that finding on its determination that the proposed combination "would not be feasible in the trigeminal nerve region." J.A. 35. We conclude that this rationale is doubly infected by error. First, even if the Board was correct to treat the Medtronic patents at issue as limited in the problem they address to the sacral-nerve context, the Board committed a fundamental legal error in confining the motivation inquiry to whether a motivation would exist to make the proposed combination for use in the Young-

specific trigeminal-nerve context—to which the Medtronic patents are not limited. Second, the Board was incorrect in its view that "the relevant art is medical leads specifically for sacral neuromodulation," J.A. 13, as the Medtronic patents' claims are not limited to the sacral-nerve context and the shared specification, properly read, is not so limited either. Unable to characterize these errors as harmless, we vacate the Board's decisions and remand.

A

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*.'" *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (internal citations omitted) (emphasis added); *see also Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). The inquiry is not whether a relevant artisan would combine a first reference's feature with a second reference's feature to meet requirements of the first reference that are not requirements of the claims at issue. A contrary view would run counter to established principles, including that the claim defines the invention whose obviousness is being assessed and that a skilled artisan may be motivated to combine particular features of different references, *e.g.*, to secure some benefits at the expense of others, even when bodily incorporation would be impossible or inadvisable. *See*, *e.g.*, *In re Yamamoto*, 740 F.2d 1569, 1573 (Fed. Cir. 1984); *In re Urbanski*, 809 F.3d 1237, 1243–44 (Fed. Cir. 2016). As Medtronic states, "[t]he real question is 'why a person of ordinary skill in the art would have combined elements from specific references *in the way the claimed invention does*.'" Medtronic's Br. at 66 (quoting *ActiveVideo Networks, Inc. v. Verizon Communications, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (emphasis in original)).

The Board adopted a legally incorrect framing of the motivation-to-combine question when it confined the inquiry to whether a motivation would exist to make the Gerber-Young combination for use in the Young-specific trigeminal-nerve context. That context is not part of the Medtronic patents' claims. The proper inquiry is whether the relevant artisan would be motivated to make the combination to arrive at the claims' actual limitations, which are not limited to the trigeminal-nerve context. And the Board made no finding, and the parties have not pointed to evidence, that the space constraints of that context, on which the Board relied for finding no motivation to make the combination for trigeminal-nerve stimulation, are applicable to other nerve-stimulation contexts covered by the claims at issue, which include sacral-nerve stimulation.

The Board's contrary view makes particularly little sense given the Board's definition of the relevant artisan providing the perspective that governs the obviousness analysis and of the problem addressed by the Medtronic patents here. The Board, in agreement with Medtronic's own position, defined the relevant artisan as a person in "the relevant art" of "medical leads specifically for sacral neuromodulation," J.A. 13, and the Board, while accepting that Young was prior art that the relevant artisan would consider, identified the problem addressed by the Medtronic patents as sacral-nerve stimulation, J.A. 31. Such an artisan, focused on such a problem, would hardly be reading Young only for what it taught or suggested about, or only how features of Young's teachings might be combined with Gerber for, the trigeminal-nerve context. Rather, such an artisan would be considering what Young taught or suggested about, or how features of Young's teachings might be combined with Gerber for, at least the sacral-nerve context.

The Board thus improperly limited the Young-Gerber combination analysis to what would work in the trigeminal-nerve area. That legally incorrect framing of its

motivation inquiry was not harmless. The Board did not find that the critical space limitations of the trigeminal-nerve area are present elsewhere, including the sacral-nerve area. And the Board did not rely on any ground for rejecting the motivation argument of Axonics that is independent of the legally erroneous framing. Vacatur and remand is necessary for this reason.

B

Relatedly, we also conclude that the Board erred in its definition of "the relevant art" as limited to medical leads for sacral-nerve stimulation. J.A. 31. The parties have treated this issue as a factual one, subject to substantial-evidence review. Even under that standard of review, we conclude that the Board's ruling on the issue cannot stand.

The Medtronic patent claims make no reference to sacral anatomy or sacral neuromodulation, and they cannot be properly construed as so limited. Neither the Board nor Medtronic has cited any authority for treating the relevant art as limited to a narrow subset of what the claims of a patent cover—a conclusion that would risk curtailing prior-art analysis of a claim to less than its exclusive-rights-protecting scope. And we have repeatedly ruled that what constitutes "analogous art" for section 103 purposes is tied to "the claimed invention." *See Sanofi-Aventis Deutschland GmbH v. Mylan Pharmaceuticals Inc.*, 66 F.4th 1373, 1377–78 (Fed. Cir. 2023) (citing and quoting cases).

In any event, the only reasonable reading of the specification is contrary to the Board's narrow definition. The Board relied on the "Field of the Invention" paragraph, J.A. 13 (quoted *supra* p. 2), but the language of that paragraph can readily be understood as identifying examples, not narrowing, even if read alone. And it must be so understood when not read in isolation. The "Summary of the Invention," '314 patent, col. 5, line 46 (capitalization altered), like the title of each patent, states the invention in general terms, not limited to the sacral-nerve context, *e.g.*, *id.*, col.

5, lines 48–53; *id.*, col. 5, line 65, through col. 6, line 19, and the Summary labels the sacral-nerve stimulation application as one "preferred embodiment," *id.*, col. 5, lines 53–64. *See also id.*, col. 13, lines 32–39 (stating application to specific other areas). The expressly broad scope of what was identified as invented is not negated by the fact that the specification notes a "need" in the sacral-nerve context that may have supplied the inventor's starting point. *Id.*, col. 5, lines 34–44.

We therefore conclude that substantial evidence does not support the Board's limitation of "the relevant art" to sacral-nerve stimulation. The Board relied on this limitation in rejecting Axonics's argument for the asserted motivation to combine Young with Gerber. We are unable to say that this error was harmless.

III

For the foregoing reasons, we vacate the Board's final written decisions and remand for further proceedings consistent with this opinion.

Costs awarded to Axonics.

VACATED AND REMANDED