UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS, INC.,
Petitioner,

v.

MEDTRONIC, INC.,
Patent Owner.

Case IPR2020-00679
Patent No. 8,626,314

PETITIONER'S NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Pursuant to 35 U.S.C. §§ 141, 142, and 319; 28 U.S.C. § 1295; 37 C.F.R. §§ 90.2–90.3; Federal Rule of Appellate Procedure 15; and Federal Circuit Rule 15, Petitioner Axonics, Inc. ("Petitioner") hereby provides notice that it appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision on Remand of the Patent Trial and Appeal Board ("Board") entered on March 21, 2024 in IPR2020-00679 (Paper No. 94) ("Final Written Decision on Remand") (Attachment 1) and from all underlying findings, determinations, rulings, opinions, orders, issues, and decisions regarding the *inter partes* review of U.S. Patent No. 8,626,314 (the "'314 Patent"). This notice is timely under 37 C.F.R. § 90.3, having been filed within 63 days after the Final Written Decision on Remand.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Petitioners state that the issues on appeal include, but are not limited to: the Board's determination that Claims 18–21 and 24 of the '314 Patent have not been shown to be unpatentable, including any underlying questions of law or fact; the Board's determination that the combination of the publications at issue (Ronald F. Young, *Electrical Stimulation of the Trigeminal Nerve Root for the Treatment of Chronic Facial Pain*, Journal of Neurosurgery 83:72–78 (July 1995), US Patent No. 6,055,456, WO 98/20933, US Patent No. 4,407,303, and US Patent No. 5,052,407) does not render obvious Claims 18-21 and 24 of the '314 Patent; the Board's consideration of the expert testimony, fact witness testimony, and other evidence in the record; and the Board's factual

findings, conclusions of law, or other determinations supporting or related to the foregoing issues, as well as all other issues decided adversely to Petitioners in any orders, decisions, rulings, or opinions.

This Notice of Appeal is being e-filed with the Clerk's Office for the United States Court of Appeals for the Federal Circuit, along with payment of the required docketing fees. In addition, a true and correct copy of this Notice of Appeal is being filed simultaneously with the Director of the United States Patent and Trademark Office.

Dated: April 15, 2024

Respectfully submitted,

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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e))

The undersigned hereby certifies that, in addition to being filed electronically with the Patent Trial and Appeal Board, copies of the **PETITIONER'S NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT** are being filed and served as described below on April 15, 2024.

Pursuant to 37 C.F.R. § 90.2(a) and 37 C.F.R. § 104.2, a copy of the **PETITIONER'S NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT** is being filed with the Director of the United States Patent and Trademark Office by Priority Mail Express addressed to the Office of the General Counsel, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Pursuant to 37 C.F.R. § 90.2, Fed. R. App. Proc. 15(a)(1), Fed. Cir. R. 15(a)(1) and 52, and Manual of Patent Examining Procedure 1216.01, the **PETITIONER'S NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT** is being electronically filed with the United States Court of Appeals for the Federal Circuit, via electronic CM/ECF, a paper copy is being sent to the Clerk of the Federal Circuit at the U.S. Court of Appeals for the Federal Circuit, 717 Madison Place, N.W., Washington, DC 20439, and the requisite fee was paid.

Copies of the **PETITIONER'S NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT** are being served electronically via e-mail upon the following:

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ATTACHMENT 1

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Paper 94
Date: March 21, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS, INC.,
Petitioner,

v.

MEDTRONIC, INC.,
Patent Owner.

IPR2020-00679
Patent 8,626,314 B2

Before JAMES A. TARTAL, ERIC C. JESCHKE, and
BRENT M. DOUGAL, *Administrative Patent Judges.*

Opinion for the Board filed by *Administrative Patent Judge* DOUGAL.

Opinion Dissenting-in-Part filed by *Administrative Patent Judge* TARTAL.

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

I. INTRODUCTION

This Final Written Decision is entered pursuant to 35 U.S.C. § 318 and pursuant to a remand from the United States Court of Appeals for the Federal Circuit in *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950 (Fed. Cir. 2023).[1] For the reasons discussed below, we determine, in view of the Federal Circuit's decision and the record, that Petitioner, Axonics, Inc., has shown by a preponderance of the evidence that claims 1, 2, 4, 7, 10–12, 14, 22, and 23 of U.S. Patent 8,626,314 B2 (Ex. 1001, "the '314 patent") are unpatentable and has not shown that claims 18–21 and 24 are unpatentable.

II. BACKGROUND

A. Procedural History

Petitioner filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of the challenged claims, which we granted (Paper 8). During trial, Patent Owner, Medtronic, Inc., filed a Response (Paper 28, "PO Resp."). Petitioner filed a Reply (Paper 47, "Reply"), and Patent Owner filed a Sur-reply (Paper 55, "Sur-reply"). An oral argument was conducted and a transcript was entered into the record. Paper 63 ("Tr."). In our Final Written Decision, we determined that Petitioner had not proven by a preponderance of the evidence that the challenged claims were unpatentable. Paper 64, 2, 59 ("FWD").

[1] The Federal Circuit's slip opinion is recorded at Paper 76.

In our Final Written Decision, we determined the following:

Claims	35 U.S.C. §[2]	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 2, 4, 7, 10–12, 14, 18–24	103(a)	Young[3], Gerber[4], Lindegren[5]		1, 2, 4, 7, 10–12, 14, 18–24
18, 20, 21	103(a)	Young, Gerber, Lindegren, Hauser[6]		18, 20, 21
1, 2, 4, 7, 10–12, 14, 18–24	103(a)	Gerber, Hauser, Akerström[7]		1, 2, 4, 7, 10–12, 14, 18–24
Overall Outcome				1, 2, 4, 7, 10–12, 14, 18–24

FWD 59.

Petitioner appealed to the United States Court of Appeals for the Federal Circuit. Paper 74. The Federal Circuit determined that we had "erred in [our] obviousness analysis" of the combination of Young and Gerber, vacated our Final Written Decision, and remanded for further consideration of the grounds based on Young and Gerber. *Axonics*, 73 F.4th at 952, 954, 959.

[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 285–88 (2011), revised 35 U.S.C. § 103 effective March 16, 2013. We refer to the pre-AIA version of § 103.
[3] Young, *Electrical Stimulation of the Trigeminal Nerve Root for the Treatment of Chronic Facial Pain*, Journal of Neurosurgery 83:72–78 (July 1995) ("Young") (Ex. 1010).
[4] Gerber, US 6,055,456, iss. Apr. 25, 2000 ("Gerber") (Ex. 1012).
[5] Lindegren, WO 98/20933, pub. May 22, 1998 ("Lindegren") (Ex. 1013).
[6] Hauser et al., US 5,052,407, iss. Oct. 1, 1991 ("Hauser") (Ex. 1014).
[7] Akerström, US 4,407,303, iss. Oct. 4, 1983 ("Akerström") (Ex. 1015).

The parties filed Post Remand Briefs (Papers 87 ("Pet. PR"), 88 ("PO PR")) and Post Remand Reply Briefs (Papers 89 ("Pet. PR Reply"), 90 ("PO PR Reply")).

First, the Federal Circuit stated that "[o]nly the Board's findings about the combination of Young and Gerber are presented for review in this appeal." *Axonics*, 73 F.4th at 954. Thus, the Federal Circuit does not address our prior determination that Petitioner has not shown, by a preponderance of the evidence, that claims 1, 2, 4, 7, 10–12, 14, and 18–24 are unpatentable over the combination of Gerber, Hauser, and Akerström. *See* FWD 38–59.

Second, the Federal Circuit summarized their holding and provided guidance as follows:

> 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.

Axonics, 73 F.4th at 957 (emphases added).

We now reevaluate our findings and determinations involving the grounds with both Young and Gerber.

B. The '314 Patent

The invention "relates generally to a method and apparatus that allows for stimulation of body tissue, particularly sacral nerves." Ex. 1001, 1:34–36. The '314 patent "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.* at 5:48–53. A sacral nerve stimulation lead of the invention is shown in Figure 1, reproduced below.

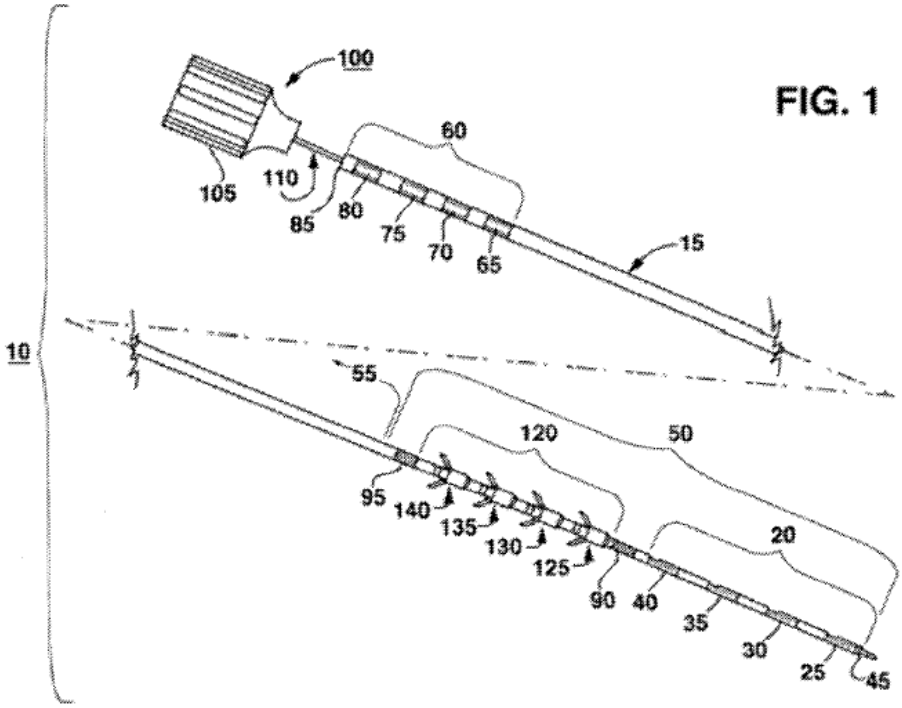


Figure 1 is a plan view showing implantable medical lead 10 for sacral nerve stimulation. *Id.* at 8:51–52, 9:25–26. Implantable medical lead 10 includes lead body 15 with electrode array 20 that extends proximally from lead distal end 45 and stimulation electrodes 25, 30, 35, 40. *Id.* at 6:26–30, 9:25–30. Each stimulation electrode is electrically coupled to the distal end of a coiled wire lead conductor extending through the lead body 15. *Id.* at 9:41–45. The proximal end of each lead conductor is coupled to one of connector elements 65, 70, 75, 80 in proximal connector element array 60 adjacent proximal end 85. *Id.* at 6:33–37, 9:45–49. Connector elements 65,

70, 75, 80 are adapted to be coupled with a neurostimulator implanted pulse generator ("IPG"). *Id.* at 9:62–65.

To inhibit axial movement of lead body 15 and dislodgement of the stimulation electrodes, a fixation mechanism adapted to engage subcutaneous tissue is formed on lead body 15 proximal to electrode array 20 in distal portion 50. *Id.* at 5:65–6:5, 10:12–16. The fixation mechanism comprises tine elements in tine element array 120. *Id.* at 6:5–8, 10:16–19.

Each tine element can include a number of flexible, pliant tines. *Id.* at 6:8–9, 10:26–27. Each tine can extend outwardly of lead body 15 and proximally toward lead proximal end 85. *Id.* at 10:32–35. The tines are adapted to be folded inward against lead body 15 when fitted into and constrained by the lumen of an introducer, and the folded tines do not overlap one another. *Id.* at 6:15–19, 10:35–41.

To implant lead 10 adjacent sacral nerves, an introducer can be advanced over a previously placed guide wire into the foramen from a skin incision. *Id.* at 11:46–48. Lead 10 is advanced through the introducer until the electrode array 20 is in casual contact with the more anterior sacral nerve. *Id.* at 11:58–12:6. After electrical testing to establish optimal positioning, the introducer is retracted proximally, and the tine elements are successively released from the introducer lumen. *Id.* at 12:6–11.

C. Challenged Claims

Of the challenged claims, 1, 11, and 18 are independent, and claim 1 is illustrative (Petitioner's labels added in [brackets]):

[1.0] A system comprising:
[1.a] an implantable medical lead comprising:

> [1.b] a lead body extending between a proximal end and a distal end;
> [1.c] a plurality of conductors within the lead body;
> [1.d] a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors; and
> [1.e] 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, [1.f] 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, [1.g] 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, [1.h] wherein the plurality of tine elements is separate from and axially displaced from the plurality of electrodes.

Id. at 13:51–14:11.

Independent claim 11 is similar to claim 1, but also includes an implantable pulse generator, and the implantable medical lead is configured to be introduced through and released into body tissue via an introducer defining an introducer lumen. *Id.* at 14:54–15:20. Independent claim 18 recites a method with similar limitations to claims 1 and 11. *Id.* at 15:55–16:31.

III. ANALYSIS

A. Level of Ordinary Skill in the Art

In the Final Written Decision, we found that:

> the relevant art is medical leads for sacral neuromodulation. . . . With these considerations, we find a POSITA[8] would have had at least the following two qualifications: (1) a bachelor's degree, or coursework equivalent, in biomedical engineering, electrical engineering, or mechanical engineering, or a medical degree, and (2) at least two years of experience researching and developing medical leads for sacral neuromodulation. We further find that more education can substitute for practical experience and vice versa.

FWD 15.

As noted above, the Federal Circuit found that the relevant art is "not limited to the sacral-nerve context." *Axonics*, 73 F.4th at 957. The court came to this conclusion based on the language of the claims and the '314 patent disclosure. *Id.* at 958–59. For example, the court stated that the "patent claims make no reference to sacral anatomy or sacral neuromodulation, and [thus] they cannot be properly construed as so limited." *Id.* at 958. The court also pointed to the title, Field of Invention, Summary of the Invention, and discussion of different embodiments to support its finding that the art is not limited to the sacral-nerve context. *Id.* at 958–59 (citing, or with reference to, Ex. 1001, code (54), 1:34–44, 5:34–44, 5:46–6:19, 13:32–39, 13:51–16:59).

Reviewing these sections of the Specification, the title, and the claims, we find that the focus of the '314 patent is medical leads, not limited to any specific area of the body. *See* Ex. 1001, code (54), 1:34–44, 5:34–44, 5:46–

[8] A person of ordinary skill in the art.

6:19, 13:32–39, 13:51–16:59. This is because each identifies medical leads, and their use, as the focus of the invention. *Id.* Further, most discuss medical leads generally, and then only certain embodiments are directed to specific areas of the body. *See*, *e.g.*, *id.* at 13:32–39. But the disclosure, and the claims in particular, are not limited to any particular area of the body.[9] As noted by the Federal Circuit, the '314 patent discusses medical leads implanted at the sacral nerve, but it does not limit the disclosure to that one area, and includes discussion of other areas of the body. *Axonics*, 73 F.4th at 958–59.

Petitioner essentially agrees that this is the focus of the '314 patent: "The relevant art must be the broader field . . . of implantable medical leads - what the 314 Patent claims are directed to." Pet. PR 4; *see also* Pet. PR Reply 4.

Patent Owner argues that "[t]here is no indication the Board's view of the 'relevant art' had any impact on its analysis." PO PR 5 n.4.[10] Patent Owner does not otherwise address the relevant art.

In view of the above, and the evidence of record, we find on remand that the relevant art is medical leads.

We previously found that the level of ordinary skill in the art requires "experience researching and developing medical leads for sacral

[9] Independent claims 1, 11, and 18 all discuss "body tissue." Ex. 1001, 14:8, 14:59, 15:56. Claim 19 requires "percutaneously introducing the introducer through body tissue" and claim 20 requires "deploy[ing] the plurality of tine elements into subcutaneous tissue." *Id.* at 15:33–34, 15:38–39.

[10] This appears to be in disagreement with the Federal Circuit's statement that "[t]he Board relied on . . . [its 'relevant art' finding] in rejecting Axonics's argument for the asserted motivation to combine Young with Gerber." *Axonics*, 73 F.4th at 959.

neuromodulation." FWD 15. Consistent with the Federal Circuit decision and our finding of the relevant art, the experience of one of ordinary skill is not limited to "sacral neuromodulation." Rather, the level of ordinary skill in the art requires experience in the relevant art, which is medical leads.

Petitioner argues that one of ordinary skill in the art should not be limited to the art of "implantable medical leads," but should include the broader area of "active, implantable medical devices." Pet. PR 4. Petitioner explains that this is because this broader area is "not . . . limited to [the] constraints of specific anatomies," consistent with the Federal Circuit's decision. *Id.* However, this is also true for the relevant art of medical leads. A person of ordinary skill in the art of medical leads will have knowledge of specific anatomies, but knowledge of any one particular anatomy is not required.

We see no reason to expand the required experience to areas related to, but outside of, the relevant field. As noted above, Petitioner essentially agrees with what we have found to be the relevant field. *Id.*; Pet. PR Reply 4. However, Petitioner does not provide any convincing argument explaining why one of ordinary skill in the art should not be required to have skill in the defined art. We also note that Petitioner does not argue that such a finding would impact any aspect of our decision.

Patent Owner argues that anatomy matters when considering lead implantation and fixation. PO PR Reply 1; PO PR 6–9. However, Patent Owner does not provide express argument concerning the particular level of skill. Further, Patent Owner argues that its declarants' testimony (Drs. Slavin and Siegel) "remain[s] the same" under Petitioner's definition. PO PR Reply 1 (citing Exs. 2029 ¶ 25; 2030 ¶ 67).

In conclusion, and in view of the above and the evidence of record, we find that the relevant art is medical leads. We also find that the level of ordinary skill in the art requires experience in medical leads, and more specifically, at least two years of experience researching and developing medical leads.

Thus, the revised level of ordinary skill in the art is: (1) a bachelor's degree, or coursework equivalent, in biomedical engineering, electrical engineering, or mechanical engineering, or a medical degree, and (2) at least two years of experience researching and developing medical leads. Further, more education can substitute for practical experience and vice versa.

B. Claim Construction

In an *inter partes* review, we construe claims using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.100(b).

No terms require express construction. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) ("The Board is required to construe 'only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

C. Obviousness Based on Young, Gerber, and Lindegren

Petitioner challenges claims 1, 2, 4, 7, 10–12, 14, and 18–24 under 35 U.S.C. § 103(a), contending the claimed subject matter would have been obvious over Young, Gerber, and Lindegren. Pet. 17–39; Reply 3–10.

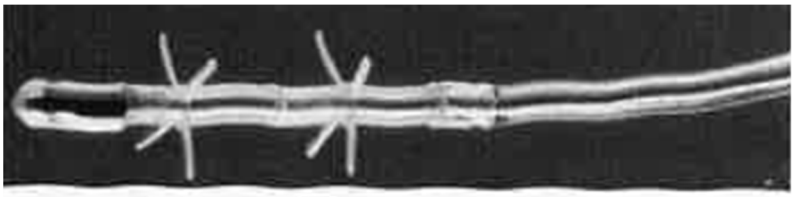
In the below sections, we first summarize the cited prior art. We then analyze the parties' arguments with respect to the specific limitations of claim 1 and motivations to combine Young, Gerber, and Lindegren. We then address the parties' arguments as to the secondary considerations. We then address the other claims in the present ground.

As previously noted, the Federal Circuit reversed our prior determination that Young and Gerber would not have been combined. *Axonics*, 73 F.4th at 957–58. Thus, we review the parties' arguments and evidence of record in view of the Federal Circuit's specific guidance.

For the reasons below, we determine that Petitioner has shown, by a preponderance of the evidence, that the subject matter of claims 1, 2, 4, 7, 10–12, 14, 22, and 23 would have been obvious over the combined teachings of Young, Gerber, and Lindegren. We further determine that Petitioner has not shown claims 18–21 and 24 unpatentable under this ground.

1. Young

Young details "the placement of a totally implanted, percutaneously placed electrode system for chronic electrical stimulation of the trigeminal sensory root for treatment of chronic facial pain in 23 patients between 1990 and 1993." Ex. 1010, 73. The trigeminal stimulating electrode[11] is shown in Figure 1, reproduced below.



[11] The trigeminal stimulating electrode disclosed in Young is Patent Owner's Quintatrigeminal electrode. Ex. 1010, 73.

Figure 1 is a photograph of the trigeminal stimulating electrode. *Id.* The trigeminal stimulating electrode "consisted of a monopolar . . . lead with two sets of four 'tines' located 5 and 10 mm from the distal tip of the electrode and a central stylet." *Id.* The tines are used "to prevent the electrode from becoming dislodged after implantation." *Id.*

An introducer needle is inserted through an incision and advanced to the treatment location. *Id.* The electrode is then advanced through the introducer needle. *Id.* The electrode is used to obtain paresthesias in the patient's pain, after which the introducing needle and central stylet are removed. *Id.* The electrode is connected to an extension lead which is connected to a pulse generator system. *Id.* at 74. The implanted pulse generator system[12] is shown in Figure 3 below.

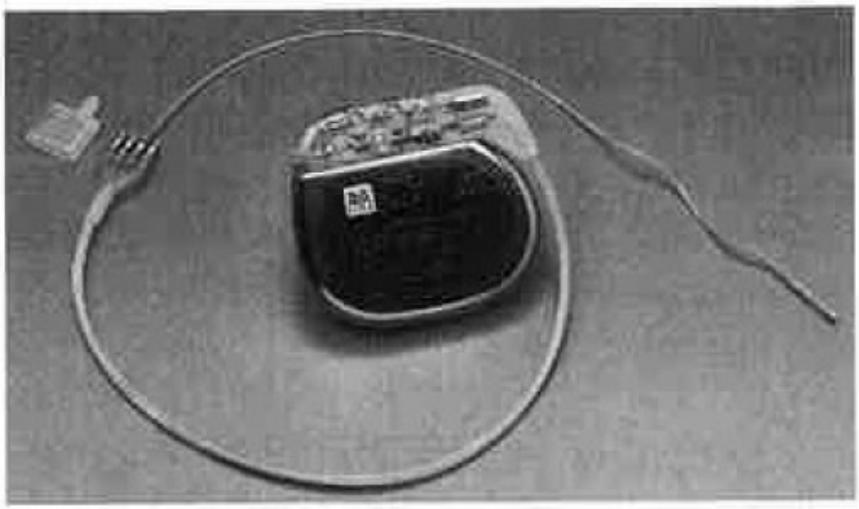


Figure 3 is a photograph of the complete component system for trigeminal stimulation, including the electrode, the implanted pulse generator, and an extension lead. *Id.*

[12] The implanted pulse generator system disclosed in Young is Patent Owner's ITREL. Ex. 1010, 74.

2. Gerber

Gerber discloses "an implantable medical lead having at least one electrode contact wherein the lead is implanted near the sacral nerves for stimulation of a bundle of nerve fibers." Ex. 1012, 1:9–12. An implantable medical lead for stimulation of the sacral nerves is shown in Figure 3, reproduced below.

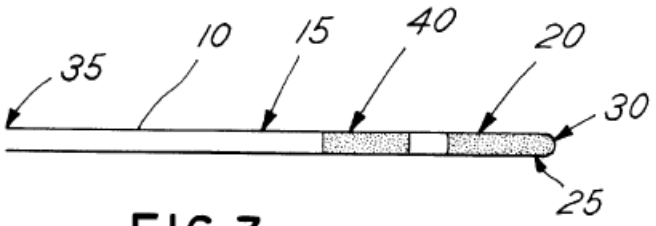


FIG.3

Figure 3 is a plan view showing implantable medical lead 10 comprising lead body 15 having two electrode contacts 20, 40 at distal end 25. *Id.* at 3:26–27, 4:32–33. Proximal end 35 of lead body 15 may be coupled to a pulse generator, and lead body 15 includes at least one conductor wire within an insulating sheath. *Id.* at 3:49–51, 4:6–7.

Implantable medical lead 10 may have an anchoring mechanism to fixate the lead in the desired position, as shown in Figure 2, reproduced below.

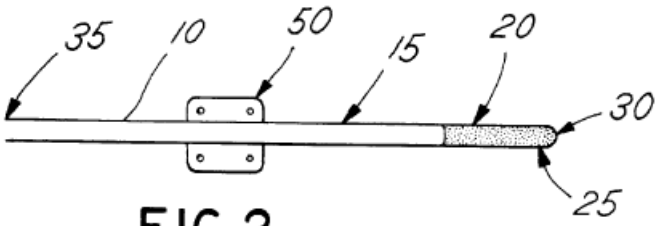


FIG.2

Figure 2 is a plan view of implantable medical lead 10 having anchoring mechanism 50, which is a molded part, integral to medical lead 10. *Id.* at 3:23–25, 4:13–17. A physician can pass sutures through the molded part

to attach medical lead 10 to the human anatomy. *Id.* at 4:17–19. Alternatively, anchoring mechanism 50 allows medical lead 10 to fibrose in naturally using the human body's natural reaction to a foreign body or healing. *Id.* at 4:27–30.

3. Lindegren

Lindegren discloses an implantable electrode lead with "an electrode head equipped with external anchoring means, such as tine-like position-fixation means." Ex. 1013, 1:6–11. The position-fixation means includes a groove encircling the exterior of the electrode head, which is sized to receive a ring-shaped tine-bearing means. *Id.* at 5:11–15. Figure 3, reproduced below, shows the ring-shaped means mounted in the groove.

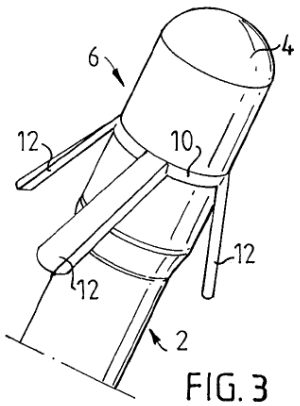


FIG. 3

Figure 3 is a perspective view of the distal end section of implantable electrode lead 2. *Id.* at 6:30–32, 7:7–8. Ring-shaped means 10 encircles electrode head 6 and includes four projections 12 extending at an angle outward and to the rear. *Id.* at 7:18–23. From a manufacturing point of view, it is preferable to have projections 12 integral with ring-shaped means 10 and evenly distributed around the circumference of ring-shaped means 10. *Id.* at 5:17–22, 7:30–8:1.

4. Independent claim 1

a. Claim Limitations 1.0–1.b

Claim 1 requires:
[1.0] A system comprising:
[1.a] an implantable medical lead comprising:
[1.b] a lead body extending between a proximal end and a distal end.

Id. at 13:51–54.

Petitioner contends that, to the extent the preamble is a limitation, Young discloses a system. Pet. 24. Petitioner also contends that Young's lead discloses "an implantable medical lead comprising: a lead body extending between a proximal end and a distal end." Pet. 24–25 (citing Ex. 1010, 73–74, Figs. 1–3).

Patent Owner does not contest that Young teaches these limitations. *See generally*, PO Resp. 18–36.

We determine that Petitioner has shown, by a preponderance of the evidence, that Young teaches or suggests claim limitations 1.0–1.b.

b. Plurality of Tine Elements Between a Plurality of Electrodes and the Proximal End of the Lead Body

Claim 1 also requires:

[1.c] a plurality of conductors within the lead body;
[1.d] a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors; and
[1.e] 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,
…

> [1.h] wherein the plurality of tine elements is separate from and axially displaced from the plurality of electrodes.

Ex. 1001, 13:55–14:12.

Petitioner contends that Young's lead includes at least two tine elements located between an electrode and the lead proximal end. Pet. 26 (citing Ex. 1010, 73, Fig. 1). Petitioner argues that Young's tines are separate from and axially displaced from the electrode. *Id.* at 29. Petitioner contends that Young inherently discloses one conductor connecting the electrode to the implanted pulse generator ("IPG") so that the electrode can function and stimulate a patient's nerve. *Id.* at 25 (citing Ex. 1010, 73–74; Ex. 1003, 66–67[13]).

Petitioner further argues: "Young discloses one electrode, but states '[t]he electrode could be improved to provide multiple active stimulation sites near the tip.' Ex. 1010 at 77. Multiple active stimulation sites mean that there will be multiple electrodes. Ex. 1003 at 68." Pet. 25–26. Petitioner's declarant, Mr. Pless, also testifies that "[a] POSITA would understand this suggestion applicable to other nerves than trigeminal, since it had been a common practice and understanding that greater the number of electrodes or electrode regions lead to greater flexibility in placement and in activation of a wider area for stimulation." Ex. 1003 ¶ 79.

Moving to Gerber, Petitioner argues that Gerber teaches multiple electrodes, each electrically connected to a conductor for carrying

[13] In arguing that Young teaches limitation 1.c, Petitioner cites to page 68 of Mr. Pless's Declaration. Pet. 25. Mr. Pless, however, discusses this limitation on pages 67–68 of his Declaration. Thus, we understand the citation to be a typographical error. Moreover, we note that many of Petitioner's citations to Mr. Pless's Declaration are off by one page.

stimulation pulses from the IPG to the electrode. Pet. 26 (citing Ex. 1012, Abstr., 1:57–58, 2:4–5, 3:52–56, 4:6–7, 4:32–33, claim 1, Fig. 3; Ex. 1003, 67–68[14]). Petitioner further contends that Gerber teaches an anchoring mechanism located between the most proximal electrode and the proximal end of the lead body. *Id.* at 27. Petitioner argues that Gerber's anchoring mechanism is separate from and axially displaced from the electrodes. *Id.* at 29. According to Petitioner, Gerber teaches the anchoring mechanism allows the medical lead to fibrose naturally into the human body, and a POSITA would have known that tines are a widely used fibrosing anchoring means. *Id.* (citing Ex. 1003, 69[15]; Ex. 1012, 4:13–30, Fig. 3).

Patent Owner does not contest the teachings of Young and Gerber as relied on by Petitioner. However, Patent Owner does contest the reasons to combine these two references.

- *Reasons to Combine*

Petitioner contends a POSITA would have modified Young's electrode system to include a lead with multiple electrodes, as Gerber teaches, because Young expressly teaches that the single electrode could be improved to provide multiple active stimulation sites near the tip. Pet. 23 (citing Ex. 1010, 77); Reply 7–8; Pet. PR 5. Young further teaches that its tines are positioned between the electrode and the proximal end of the lead body, and thus, the combined teachings would result in the claimed limitations. Pet. 23–24, 26–27; Reply 7–8; Pet. PR 5.

[14] Mr. Pless's related testimony is on page 69 of his Declaration. Thus, Petitioner's citation to page 70 is a typographical error.
[15] Mr. Pless's related testimony is on page 69 of his Declaration. Thus, Petitioner's citation to page 70 is a typographical error.

Petitioner also argues that "it would have been easy 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." Pet. 23–24. Similarly, Mr. Pless testifies in support of the above that:

> it had been a common practice to add electrodes at the distal tip of the lead for percutaneous implantations before 2001, because it is easier to place the distal tip of the lead to the desired neural target than for example, a place in the middle of the lead to be adjacent to a neural target. A POSITA would further want to minimize the damage to the body tissue and thus would avoid excess amount of entry into the body with a medical device. Consequently, based on the suggestion of Young, a POSITA would have replaced the single electrode at the distal tip with multiple electrodes.

Ex. 1003 ¶ 90.

Finally, both Petitioner and Mr. Pless state that "[s]uch modifications of Young to have additional electrodes . . . would have been simply 'arrang[ing] old elements with each performing the same function it had been known to perform and yield[ing] no more than one would expect from such an arrangement' and would have been thus obvious." Pet. 24 (citing *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398 at 417 (2007); Ex. 1003 ¶ 94.

In its Response, Patent Owner argues that the combination of Young and Gerber would not be feasible in the trigeminal nerve region of Young. PO Resp. 23–26. The Federal Circuit reversed our prior determination that Young and Gerber would not have been combined based on this reasoning. *Axonics*, 73 F.4th at 957–58. The court faulted our analysis, finding that it was improper to "confin[e] 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." *Id.* at 957.

Patent Owner argues on remand that our prior findings included that "Young does not suggest adding electrodes distal to the tines," and so there is not a motivation to combine. PO PR 5 (citing Dec. 34–35). However, Patent Owner did not make such an argument in their briefs (*see generally*, PO Resp.; Sur-reply), and we did not make such a finding that was not limited to the trigeminal nerve region of Young. Our prior findings in this regard were predicated on the feasibility of the modification in the trigeminal nerve region. *See* Dec. 35. As noted by the Federal Circuit, the claims are not limited to any particular treatment area, and Patent Owner does not argue that multiple electrodes on the device of Young, as suggested by Young, would not be effective in other treatment areas.

We did find that Young does not explicitly specify a relationship between the multiple electrodes and the tines. Dec. 35 ("Young discloses multiple active sites *near* the tip, not at the tip or distal to the tines"). Young is in fact silent on this relationship. Young states that "[t]he electrode could be improved to provide multiple active stimulation sites near the tip. [This could allow treatment of] . . . patients with pain in all three trigeminal divisions." Ex. 1010, 10. At the same time, Young shows two tine elements separate and distal of the electrode in Figure 1.

Further, Petitioner relies on Gerber for teaching multiple electrodes at the distal end and distal to the anchoring mechanism. *See* Pet. 23–24. We find that Gerber teaches or at least suggests multiple electrodes distal to the anchoring devices. *See* Ex. 1012, 3:39–48, 4:13–52, 5:33–50, Figs. 1–3, 6.

Still further, Mr. Pless's testimony is uncontroverted that "it had been a common practice to add electrodes at the distal tip of the lead for percutaneous implantations before 2001." Ex. 1003 ¶ 90. In view of the teachings of Young, Gerber, and the testimony of Mr. Pless, Petitioner has shown that one of skill in the art would have been motivated to add electrodes to the distal end of Young, distal to the tines.

In addition to the above arguments, Patent Owner argues that "what works in one part of the body will not necessarily work in other parts of the body." PO Resp. 26–27 (citing Ex. 2029 ¶¶ 30–35). Patent Owner's declarant, Dr. Slavin, testifies that there are specific requirements for different treatment areas, and that different treatment areas of the body are even considered different fields. Ex. 2029 ¶¶ 30–35.

However, as the claims are not limited to any particular treatment area, the significance of these facts and testimony is limited. For example, though Dr. Slavin states that the invention is "specifically designed for sacral neuromodulation" (*id.* ¶ 30), neither Dr. Slavin nor Patent Owner identifies any aspect of the claims that is specific to any particular treatment area, or that requires features that are relevant only to specific types of treatments.

Patent Owner also avers that because Gerber discloses a different anchoring mechanism than Young's tines, one of skill in the art would not have combined the two.[16] PO Resp. 27–28. However, Petitioner is not

[16] Patent Owner also argues that none of the cited references solve the same problem as the '314 patent. PO Resp. 35 (citing Ex. 2029 ¶¶ 76–83). Based on the other reasons to combine discussed herein, it is unnecessary to consider whether the cited references addressing a similar problem to the '314 patent is a sufficient additional reason to combine the references.

relying on Gerber for teaching tines. Patent Owner does not explain why one of ordinary skill would not have considered the electrodes of Gerber because of a difference in the anchoring mechanism with Young. We likewise see no reason why it would exclude consideration of Gerber.

We determine that Petitioner has shown, by a preponderance of the evidence, that the combination of Young and Gerber renders obvious claim limitations 1.c–1.e and 1.h.

c. Tine Elements

Claim 1 also requires:

> [1.f] 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.

Ex. 1001, 13:63–14:3.

Petitioner argues that each of Young's tines has a width, thickness, and length, and is attached to the lead body so that one end extends outwardly from the lead body towards the lead proximal end. Pet. 27–28 (citing Ex. 1010, Fig. 1).

Patent Owner contests that Young teaches proximally extending tines, stating that Petitioner's position is based solely on Young Figure 1, which does not clearly illustrate the angle of the tines. PO Resp. 29 n.6. Patent Owner argues that Petitioner does not explain why it believes Young teaches proximally extending tines, and provides citation to another IPR where Petitioner took a more open approach, that "Young's tines . . . may not be proximally oriented." *Id.* (quoting Ex. 2014, 37). Neither party provides

declaratory evidence of what one of skill in the art would have understood from Young Figure 1.

We agree with Patent Owner that Petitioner's showing based on Young, alone, is insufficient. Based solely on Young Figure 1 (reproduced above at § III.C.1), a single picture taken from an unspecified angle, and without further explanation, Petitioner has not met its burden to show by a preponderance of the evidence that Young teaches proximally extending tines. Petitioner's own declarant, Mr. Pless testified that "it's difficult to be sure what direction [Young's tines are] bent in" based on the photograph of Young's Figure 1. Ex. 2026, 114:18–24. However, Petitioner also relies on Lindegren for teaching this feature.

Petitioner argues that Lindegren teaches a plurality of proximally extending tines mounted on rings. Pet. 28 (citing Ex. 1013, Fig. 3). Petitioner further asserts that proximally oriented tines were common before 2001, especially for use with an introducer into which the tine ends enter first, because such an orientation does not risk damaging the free tine ends. *Id.*; Ex. 1003 ¶ 32.

Patent Owner does not contest the teachings of Lindegren, but does contest the reasons to combine Young and Lindegren. PO Resp. 28–32; Sur-reply 8.

- *Reasons to Combine*

Petitioner contends a POSITA would have modified Young's electrode system to include Lindegren's tine-mounted rings because Lindegren teaches that it would be preferable for manufacturing to have tines mounted on a ring-shaped means, like a rubber band encircling the lead body. Pet. 23 (citing Ex. 1003 ¶ 91); Reply 8. Petitioner further asserts "it

would have been easy and feasible to utilize Lindegren's tine-mounted rings with tines extending proximally and spaced apart as shown in Young to further prevent dislodgement after implantation, which is a purpose of the tines stated in Young." Pet. 24; *see also* Ex. 1003 ¶ 92 (Mr. Pless argues that proximal tines better withstand dislodgment of the lead given that the "dislodgement of the lead occurs towards the proximal direction, the path in which the lead was introduced."). Finally, both Petitioner and Mr. Pless state that "[s]uch modifications of Young to have . . . tines facing proximally would have been simply 'arrang[ing] old elements with each performing the same function it had been known to perform and yield[ing] no more than one would expect from such an arrangement' and would have been thus obvious. *KSR*, 550 U.S. at 417." Pet. 24; Ex. 1003 ¶ 94.

Patent Owner provides multiple arguments why there would not have been a motivation to combine the teachings of Young's lead with Lindegren's proximally extending tines. PO Resp. 28–32; Sur-reply 8.

Patent Owner first argues that even if proximally facing tines were common, "commonality" itself is not a reason to combine the references. PO Resp. 30. However, the Petition does not rely on "commonality" as a reason to combine. Lindegren teaches proximally facing tines (Ex. 1013, Fig. 3; Pet. 28), which is not contested by Patent Owner. *See also* Ex. 1003 ¶ 32 (discussing multiple references with proximally facing tines). Thus, there is no question whether Lindegren teaches proximally facing tines or whether they were known. Petitioner argues that proximally facing tines were common in support of the reason to combine. Pet. 24. In other words, Petitioner argues that a POSITA would have understood that proximally facing tines prevent migration in the proximal direction. *See id.* at 23–24.

Patent Owner argues that there is "no evidence" in the trigeminal nerve region of Young "that Young's lead would better withstand dislodgment if the tines were oriented proximally like in Lindegren." PO Resp. 31. As previously discussed, the Federal Circuit rejected our prior determinations specific to the trigeminal nerve region of Young because the present claims are not limited to any particular treatment area. *Axonics*, 73 F.4th at 957–58. Thus, though there may be treatment areas where proximally extending tines may not be as effective as other configurations, that does not negate Petitioner's evidence and testimony that proximally extending tines are especially useful for a treatment device that has been advanced distally to its treatment location. *See, e.g.*, Pet. 24; Ex. 1003 ¶¶ 32, 92.

Patent Owner's own declarant, Dr. Slavin, provides support for Petitioner's position when he states that if anything, one of ordinary skill would have wanted to prevent migration in the distal direction (towards the brain) in Young and thus would have pointed the tines distally. Ex. 2029 ¶ 72. Thus, one of skill in the art would have understood that the direction the tines point is an important consideration when one does not want the lead to experience movement in a particular direction.

We determine that Petitioner has persuasively identified a reason to combine Young and Lindegren in arguing that a person of ordinary skill in the art would have known that using proximally extending tines would have been beneficial to prevent dislodgement in the direction of implantation. Pet. 24. As noted above, this argument is supported by Petitioner's declarant, and Patent Owner's declarant testimony also supports the general concept behind Petitioner's argument.

Moving to Patent Owner's final argument in the Patent Owner Response, Patent Owner correctly identifies that ease of manufacturing the tines on a ring is not a reason to make the tines proximally facing. PO Resp. 32. However, we determine that the other reasoning discussed above is persuasive.

We determine that Petitioner has shown, by a preponderance of the evidence, that the combination of Young and Lindegren renders obvious claim limitation 1.f.

d. Adapted to Fold Inward

Claim 1 further recites:

> [1.g] 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,

Ex. 1001, 14:3–9.

In view of Young's teaching of the electrode being inserted into a No. 14 needle, Petitioner contends that Young discloses this limitation. Pet. 28–29. In particular, Petitioner asserts:

> Since Young's electrode is "inserted and advanced" in the needle, the tines are adapted to and do fold inward against the lead body without overlapping one another. Tines are purposefully designed to fold inward when constrained in a lumen because if they did not, they are likely damaged when the lead is advanced. Ex. 1003 ¶32. In Young Figure 1, the length of each tine is shorter than the distance between the two sets, i.e.

> two tine elements. Thus, the tines cannot overlap one another. *Id.* [at 70–71].[17]

Pet. 29.

Patent Owner argues "[Petitioner's] assertion that Young discloses this limitation, in effect, amounts to an unsupported and legally improper inherency argument that should be rejected because there is no evidence that Young's tines necessarily fold inward against the lead body." PO Resp. 19 (internal quotation omitted). Patent Owner maintains that even if inserting Young's lead into a needle causes the tines to fold inwardly, the tines would not necessarily touch the lead body. *Id.* at 19–20; Sur-reply 3–5. According to Patent Owner, Dr. Slavin testifies that whether Young's tines fold inwardly against the lead body depends on multiple factors, including the diameter of the electrode, length and diameter of the tines, diameter of the needle through which the tined electrode is introduced, and the material of the tines (PO Resp. 19 (citing Ex. 2029 ¶¶ 48–52)), and Dr. Slavin provides an example of how a tine can fold inwardly without being against the lead body (Sur-reply 3–4 (citing Ex. 2029 ¶ 50)). Patent Owner also contends Mr. Pless admits that he could not say for sure whether Young's tines would touch the lead body. PO Resp. 19–20 (citing Ex. 2026, 112:14–113:11); Sur-reply 4.

Petitioner replies that limitation 1.g recites tines adapted to be folded against the lead body and thus does not require the tines to actually be folded against the lead body but simply tines capable of being folded against the

[17] Mr. Pless's testimony regarding limitation 1.g is on pages 70–71 of his Declaration. We consider Petitioner's citation to pages 71–72 for this testimony to be a typographical error, and we understand Petitioner to be citing pages 70–71.

lead body. Reply 3–4. Petitioner further replies that Mr. Pless's opinion regarding Young's tines being adapted to be folded against the lead body is based on his measurements of Young's tines and the inner diameter of a No. 14 needle. *Id.* at 4 (citing Ex. 1023 ¶ 24; Ex. 2029, 109:14–110:16).

We agree with Petitioner that limitation 1.g recites tines adapted to be folded against the lead body and does not require the tines to actually be folded against the lead body. Consequently, Dr. Slavin's testimony that there is insufficient evidence to conclude Young's tines touch the lead body when constrained by the needle's lumen (Ex. 2029 ¶¶ 49–51) and Mr. Pless's admission that he could not say for sure whether Young's tines would touch the lead body (Ex. 2026, 112:25–113:11) are not commensurate with the scope of limitation 1.g and thus not probative.

Moreover, contrary to Patent Owner's argument, Petitioner is not alleging it is inherent that Young's tines fold inwardly against the lead body when fitted into a No. 14 needle. Rather, Petitioner argues that, given the disclosed dimensions of Young's tined lead relative to the inner diameter of a No. 14 needle and Young's disclosure of inserting the tined lead into a No. 14 needle, a POSITA would have understood that Young teaches tines capable of folding against the lead body. Pet. 28–29; Reply 4. In particular, Mr. Pless testifies:

> I did look up the size of a No. 14 needle and compared that against Young's disclosed dimensions, which were that the tines were 5 mm apart. Using that as a scale, the diameter of the tines (tip to tip) appears to be about 4mm. While I couldn't recall the dimensions during my deposition, I looked up the size of a No. 14 needle afterwards. I confirmed that inner diameter of a No. 14 needle is typically around 1.6 mm. Thus, when the lead is advanced through the No. 14 needle, it is difficult to see how that could happen without the tines (which have a considerably

> larger span than the inside diameter of the needle) being adapted to be folded against the lead body.

Ex. 1023 ¶ 24 (footnote omitted).

In view of Young's disclosure of its tines being spaced 5 mm apart (Ex. 1010, 73), we credit Mr. Pless's testimony that, based on the photograph of the lead shown in Figure 1, the tines extend, tip to tip, approximately 4 mm. *See In re Aslanian*, 590 F.2d 911, 914 (CCPA 1979) (holding that drawings must be evaluated for what they reasonably disclose and suggest to a POSITA); *cf. Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000) (holding that arguments based on measurements taken from a reference's drawings are of little value when the reference does not disclose the drawings are to scale and is silent as to dimensions). We also credit Mr. Pless's uncontested testimony that the inner diameter of a No. 14 needle is approximately 1.6 mm. Given Young's disclosure of its tined electrode being inserted through a No. 14 needle, which has an inner diameter that is less than half the length of the tines measured tip to tip, Young's tines must be flexible and bend significantly to fit in the No. 14 needle and therefore capable of folding inwardly against the lead body.

Accordingly, Petitioner has persuaded us that Young discloses tines adapted to be folded inwardly against the lead body, and we further determine that Petitioner has shown, by a preponderance of the evidence, that the combination of Young and Lindegren renders obvious claim limitation 1.g.

e. Secondary Considerations

Based on the evidence of record and findings discussed above, we determine that any evidence of secondary considerations would need to be

given substantial weight in order to determine that claim 1 has not been shown to be unpatentable by a preponderance of the evidence.

In order for secondary considerations to be awarded "substantial weight" "in an obviousness analysis," the Federal Circuit has advised that the "secondary considerations must have a nexus to the claims." *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (internal quotations omitted). The Federal Circuit has further instructed that "[t]he patentee bears the burden of showing that a nexus exists." *Id.* (quoting *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999)). Finally, the Federal Circuit instructs that "[t]o determine whether the patentee has met that burden, we consider the correspondence between the objective evidence and the claim scope." *Id.* (quoting *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019)).

Patent Owner provides evidence of secondary considerations limited to the use of the product in claim 1 in the treatment of sacral neuromodulation. PO Resp. 64–71; Sur-reply 16 ("All of Medtronic's proffered objective indicia of obviousness relates to what is known in the sacral neuromodulation art as the 'tined lead.'"). Patent Owner argues that there is a nexus to the claims "because each independent claim recites the structure of the Medtronic 'tined lead.'" PO PR 11. Patent Owner further argues that "[s]acral neuromodulation is an application of the claimed invention and the 'tined lead' was a revolutionary invention in that field." PO PR Reply 6.

As previously noted, the Federal Circuit determined that the claims are not limited to sacral neuromodulation. *Axonics*, 73 F.4th at 957 ("[T]he . . . claims are not limited to the sacral-nerve context and the shared

specification, properly read, is not so limited either."). Patent Owner, who bears the burden to establish nexus (*Fox Factory*, 944 F.3d at 1373), does not explain why claim 1 should be entitled to nexus when the claim is not limited to the same field of use as addressed in the evidence of secondary considerations.

When we consider "the correspondence between the objective evidence [provided by Patent Owner] and the claim scope" of claim 1 (*Fox Factory*, 944 F.3d at 1373), we cannot say that they are coextensive. *See also* Pet. PR 11–12. The Federal Circuit has instructed that the claims are not limited to sacral neuromodulation and Patent Owner only provides evidence of secondary considerations drawn to sacral neuromodulation. *See* PO Resp. 64–71; Sur-reply 16; PO PR 11. Patent Owner has not identified why evidence relevant to a single subset of use of the claimed invention should be sufficient evidence to establish nexus for the claimed device in general.[18]

This is not to say the Patent Owner's evidence is not entitled to any weight. However, as Patent Owner has not established nexus between the evidence and the claims, that evidence is not entitled to substantial weight, which requires a showing of nexus. Thus, at best, Patent Owner's evidence is entitled to minimal weight, which under the present facts is insufficient to outweigh the other evidence of obviousness.

f. Conclusion of independent claim 1

After review of the evidence and argument, we determine that Petitioner has shown by a preponderance of the evidence that the subject

[18] Similarly, for the method of independent claim 18, Patent Owner does not address the breadth of the claimed method as compared to the unclaimed use in the sacral-nerve context.

matter of independent claim 1 would have been obvious over the combined teachings of Young, Gerber, and Lindegren.

5. Claims 2, 4, 7, 10–12, 14, 22, 23

Petitioner argues that the combination of Young, Gerber, and Lindegren renders obvious independent claim 11 for similar reasons to those discussed above. Pet. 31–33. Patent Owner argues for the patentability of claim 11 together with claim 1, as discussed above. PO Resp. 18–36.

Petitioner also argues that the combination of Young, Gerber, and Lindegren renders obvious dependent claims 2, 4, 7, 10, 12, 14, 22, and 23. Pet. 30–31, 33–34, 38–39. Patent Owner does not separately contest Petitioner's assertions regarding these dependent claims. *See generally*, PO Resp. 18–39.

After review of the arguments and evidence, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 2, 4, 7, 10–12, 14, 22, and 23 are unpatentable over the combination of Young, Gerber, and Lindegren.

6. Claims 18–21, 24

Petitioner argues that the combination of Young, Gerber, and Lindegren renders obvious independent claim 18 and its dependents, claims 19–21, and 24. Pet. 34–39. Patent Owner argues that the Petition fails to show that the cited references suggest all of the limitations in claims 18 and 20. PO Resp. 36–39.

After review of the arguments and evidence, we determine that Petitioner has not shown that claims 18–21 and 24 are unpatentable over the combination of Young, Gerber, and Lindegren.

a. Claim 18

Independent claim 18 recites a method where a medical lead is implanted in body tissue. Ex. 1001, 15:55–16:31. The structure of the medical lead is similar to that in claims 1 and 11, but the method steps are not recited in those claims. Petitioner argues that the combination of Young, Gerber, and Lindegren renders obvious independent claim 18 largely for similar reasons to claim 1. Pet. 34–37. Petitioner relies on Young to teach the method steps (*id.* at 34–35, 36–37)[19], and on the combination of Young, Gerber, and Lindegren for the structural features of the medical lead (*id*. at 22–24, 34–37).

Patent Owner argues that Young does not teach or suggest "withdrawing the introducer from the body tissue to deploy the plurality of tine elements," as required by claim 18. PO Resp. 36–38.

Claim 18 first discusses the structure of "the plurality of tine elements [ ] adapted to . . . deploy outward to engage body tissue when the introducer is withdrawn proximally" at 18.c, and then, claim 18 later actively claims "withdrawing the introducer from the body tissue to deploy the plurality of tine elements" at 18.e. Ex. 1001, 16:1–31; *see also* Pet. 36.

Thus, the Petition discusses deployment of the tines by withdrawal of the introducer at both sections. Pet. 36–37. The Petition also points to the discussion of the similar limitation 1.g which discusses the "adapted to . . . deploy" language. *Id.* In these sections, Petitioner discusses the teachings of

[19] The Petition does state that Gerber also teaches "a method for implanting medical leads" (Pet. 34), but provides no citations to Gerber and then does not identify any specific aspect of Gerber as teaching any of the method steps of claim 18 (*see id.* at 34–37).

Young and also cites to its declarant, Mr. Pless. Pet. 28–29, 34–37. Petitioner does not cite to any other reference in the record in support of the method steps of claim 18. *Id.*

Concerning this limitation, Petitioner argues:

> The tines [in Young] are adapted to fold towards the lead body when constrained and deploy when not constrained by the lead body. Tines, however, should not be deployed until the electrode placement is finalized because once deployed, they engage body tissue and can be damaged if the lead is moved within the body.

Id. at 36–37 (citing Ex. 1003 ¶¶ 79–80); *see also*, *id.* at 28–29 (citing Ex. 1003 ¶ 32).

Patent Owner takes issue with Petitioner's position on preventing damage when using the tines of Young. PO Resp. 37. Patent Owner argues that "[t]he tines of Young do not 'engage body tissue' once 'deployed.' (Ex. 2029, ¶55.) Instead, the tines are placed within the fluid[20] cavity of the trigeminal cistern, which does not contain tissue for the tines to 'engage' with. (*Id.*)." PO Resp. 37. As a result, Young's tines would not have been damaged if moved within the trigeminal cistern. *Id.* (citing Ex. 2029 ¶ 55).

Patent Owner further argues that it is possible, based on the small size of Young's device, that "the tines could extend outside the needle (while it is in place) as the lead is advanced to induce paresthesia." *Id.* at 36–37 (citing Ex. 2029 ¶ 53).

Young does not teach at what point the tines are exposed from the introducer sheath. *See* Ex. 1010, 73. Young does not teach whether the tines

[20] Young teaches that this area contains "cerebrospinal fluid." Ex. 1010, 73.

are advanced forward and deployed with the electrode[21], or are not deployed until the introducer sheath is removed. *Id.*

Petitioner does not contest Patent Owner's argument and evidence that Young does not teach that the tines engage with body tissue and that the tines would not have been damaged if moved within the trigeminal cistern. *See* Reply 10. This is the only reason in the Petition provided for why one of ordinary skill in the art would not have deployed the tines in Young until the electrode was placed. *See* Pet. 36–37.

We credit Dr. Slavin's testimony that the trigeminal cistern is a fluid-filled cavity that does not contain tissue for the tines to "engage" with, or be damaged by. Ex. 2029 ¶¶ 55–56. Dr. Slavin testifies that he is "a board certified neurosurgeon and [has] been in active clinical practice that includes all aspects of neuromodulation, spinal surgery and surgery for pain, including implantation of electrical stimulation devices, surgery on vertebral column including sacrum, trigeminal nerve surgery and so forth." Ex. 2029 ¶ 5. Thus, Dr. Slavin has extensive knowledge of the areas around the trigeminal nerve. In contrast, Mr. Pless, an electrical engineer and product designer for electrical stimulations device in various areas of the body (Ex. 1003 ¶¶ 3–16), testifies that he believes there is tissue in the area of implantation in Young, but states "I'm not exactly sure what that tissue would be." Ex. 2026, 123:21–23. Thus, we do not credit Mr. Pless's testimony that Young's tines can be damaged because of the body tissue

[21] Hauser, discussed in the next ground, teaches tines on the distal most end which impliedly would be advanced out of the introducer, before advancement and placement of the electrode. Ex. 1014, 4:1–3, 4:26–51, Figs. 1, 6.

present in the area of implantation of Young. As noted previously, the Petition relies exclusively on Young for teaching the method steps of claim 18. We further note that the Petition does not present evidence as to methods of use of Young's modified device in other parts of the body. *See* Pet. 34–37.

In the Reply, Petitioner argues that Young's tines deploy when the introducer is withdrawn because the procedure is done under fluoroscopy:

> a POSITA would understand Young to teach that the doctors observed advance of the electrode under fluoroscopy until paresthesia was obtained and "[s]ubsequently, the introducing needle …[was] removed". Petition, 37. Young also teaches that tines prevent the electrode from dislodging. *Id.,* 18, 37. Thus, a POSITA would understand that the tines should *not* deploy until after doctors correctly placed the electrode and obtained paresthesia. The emphasis on sequence of "[s]ubsequently, the introducing needle …[was] removed" would have been understood to mean that tined elements deploy only after exact placement of electrode is obtained. *Id.*

Reply 10; *see also* Ex. 1023 ¶ 25 (Mr. Pless making a similar statement).

This reasoning is largely conclusory, and seems to imply that the only use of the introducer is to deploy the tines. The mere fact that the procedure is done under fluoroscopy is not persuasive evidence that one of ordinary skill in the art would have deployed the electrode in Young first before deploying the tines.

Young teaches that "[t]he purpose of the tines was to prevent the electrode from becoming dislodged *after implantation*." Ex. 1010, 73 (emphasis added). Petitioner provides no evidence concerning what impact the tines within the fluid cavity of the trigeminal cistern would have on placing the electrode. As noted above, Petitioner does not contest Patent

Owner's evidence that the tines within the fluid of the trigeminal cistern can move without damage. This would seem to limit the importance that Petitioner is placing on positioning the tines after final placement of the electrode. *See* Reply 10 ("[A] POSITA would understand that the tines should not deploy until after doctors correctly placed the electrode and obtained paresthesia."); *see also* Ex. 1023 ¶ 25 (Mr. Pless making a similar assertion).

Petitioner's argument is insufficient. Though Young's tines are ultimately used to prevent the electrode from dislodging "after implantation" (Ex. 1010, 73), Petitioner relies solely on the teachings of Young for the method steps, and yet Petitioner does not respond to Patent Owner's argument and evidence concerning what impact the tines within the *fluid* cavity of the trigeminal cistern would have on placing the electrode. *See* Reply 10. Petitioner asserts in Reply that preventing movement is why one of ordinary skill would not have deployed the tines during the placement procedure; yet, there is no non-conclusory evidence on this point as discussed above. *See id.*; Ex. 1023 ¶ 25. Thus, Petitioner fails to show that Young teaches or suggests "withdrawing the introducer from the body tissue to deploy the plurality of tine elements" as required by claim 18. As such, Petitioner fails to show by a preponderance of the evidence, that claim 18 is unpatentable.

b. Claim 20

Claim 20 depends from claim 18 and requires, inter alia: "withdrawing the introducer from the body tissue to deploy the plurality of tine elements into subcutaneous tissue." Ex. 1001, 16:35–43.

Petitioner argues that Young teaches this claim element. Pet. 37–38 (citing Ex. 1010, 73).

Patent Owner argues that "the tines of Young do not engage with *subcutaneous tissue* given they are located in the trigeminal cistern, which is distal to the foramen ovale (one of the entrances to the human skull)." PO Resp. 38–39 (citing Ex. 2029 ¶ 57). Mr. Slavin further explains that

> The tines in Young do not engage with subcutaneous tissue given that the tines have already crossed the entrance to the skull (namely, the foramen ovale). "Subcutaneous" generally means under the skin and in the '314 patent context, it includes the muscle under the skin. (Ex. 1001, 6:3.) But the trigeminal cistern or its surrounding area is not "subcutaneous" given that those areas are beyond the bone (i.e., the skull).

Ex. 2029 ¶ 57.

Petitioner does not respond to this argument. *See generally*, Pet. Reply.[22]

As Patent Owner's uncontested evidence of record shows that Young does not teach deploying tine elements into subcutaneous tissue, this is another reason why Petitioner has not met its burden with respect to claim 20.

c. Claims 19, 21, 24

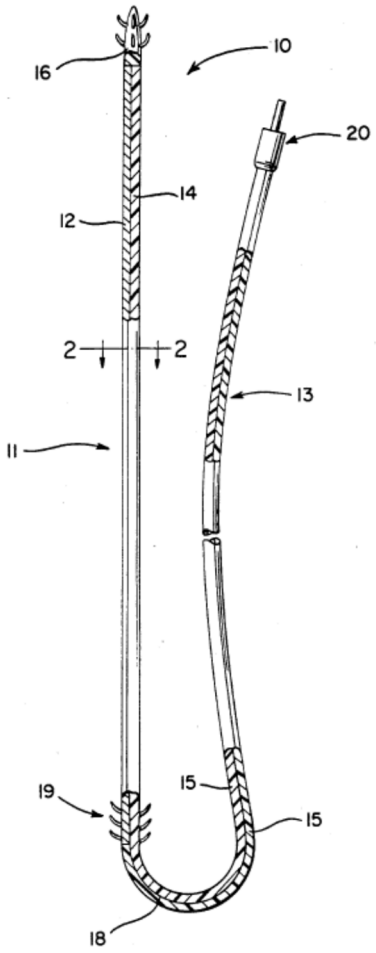
Claims 19, 21, and 24 depend from claim 18. As such, Petitioner fails to show that claims 19, 21, and 24 are unpatentable under this ground, at least because of their dependency from claim 18.

[22] Mr. Pless gives lengthy testimony in support of Petitioner's Reply discussing "body tissue," but also does not address Patent Owner's argument that the foramen ovale would not be understood to be subcutaneous tissue. *See* Ex. 1023 ¶¶ 11–14.

D. Obviousness Based on Young, Gerber, Lindegren, and Hauser

Petitioner argues that the combination of Young, Gerber, Lindegren, and Hauser renders obvious claims 18, 20, and 21. Pet. 39–47; Reply 11–12. Patent Owner argues this asserted ground of unpatentability fails for the same reasons as the asserted ground based on Young, Gerber, and Lindegren. PO Resp. 39. Patent Owner also argues that there would not have been a motivation to combine the teachings of Young, Gerber, Lindegren, and Hauser as Petitioner proposes. *Id.* at 40–42; Sur-reply 10.

Hauser, Figure 1, showing an electrode is reproduced below.



Hauser, Figure 1 illustrates an electrode (10) with distal tines (16), an active region (11), and proximal tines (19). Ex. 1014, 3:50–52, 3:67–4:8.

Hauser teaches that the electrode is implanted in the body with the use of a catheter through which the electrode can be advanced until the entire active region is positioned as desired adjacent body tissue. *Id.* at 4:26–51. The catheter can then be removed. *Id.* at 4:51–55.

Petitioner argues that Hauser overcomes the shortcomings of Young and teaches, among other things, "the method of withdrawing the introducer to deploy the tines," as required by claim 18, deploying the plurality of tine elements into subcutaneous tissue, as required by claim 20, and anchoring the lead with the tines, as required by claim 21. Pet. 40, 45–47.

Petitioner further argues that

> Due to the substantial distance between the active, electrically conductive region 12 (Fig. 1) . . . and the proximal sets of tines 19, advancement of the active region out of the catheter . . . will not deploy the proximal tines. Ex. 1003 ¶99. Tines will remain constrained in the catheter until the catheter is withdrawn. *Id.*

Pet. 42.

Concerning the reason to combine, Petitioner argues that

> Both Young and Hauser describe similar implantation techniques of using a form of a tube, e.g. needle or catheter, and a stylet to introduce its lead. Such modifications of Young to have the tines facing proximally and spaced further proximally on the lead would have been "applications of a known technique to a piece of prior art ready for the improvement." *See KSR*, 550 U.S. at 417. It simply "arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement" and would have been obvious. *Id.*

Pet. 42–43.

Patent Owner argues that the Petition "offers no reason why a POSITA would have modified Young's procedure so that its tines deploy

upon the needle's withdrawal." PO Resp. 40. Patent Owner further argues that Petitioner "does not even propose any modification of Young's procedure to arrive at the claimed step of withdrawing the introducer to deploy the tines. *Id.*

In response, Petitioner argues that "a POSITA would have been motivated to address [the closeness of Young's electrode to its tines] . . . to allow movement of the electrode to allow proper placement without inhibiting movement." Reply 12. Petitioner does not explain its reasoning or support the reason to combine with evidence of the understanding of one of ordinary skill in the art. Further, Petitioner does not provide a reason why one would have been concerned with the closeness of Young's electrode to its tines.[23]

For these reasons, Petitioner has not met its burden with respect to the present ground.

E. Obviousness Based on Gerber, Hauser, and Akerström

As previously mentioned, the Federal Circuit stated that "[o]nly the Board's findings about the combination of Young and Gerber are presented for review in this appeal." *Axonics*, 73 F.4th at 954. Both parties agree that the Federal Circuit's decision does not impact our prior determination that Petitioner has not shown, by a preponderance of the evidence, that claims 1, 2, 4, 7, 10–12, 14, and 18–24 are unpatentable over the combination of

[23] Hauser also does not appear to be concerned with this issue. Hauser teaches tines (16) that are distal of the active electrode region (11). Ex. 1014, Fig. 1. The distal tines would move with the active electrode region as it is advanced out of the introducer in the circular motion disclosed. *Id.* at 4:31–55, Figs. 1, 3–6. Thus, Hauser would suggest that tines next to the electrode does not necessarily inhibit movement or prevent proper placement of the electrode.

Gerber, Hauser, and Akerström. *See* Pet. PR 2 ("[T]he following challenged claims and grounds are before the Board: Claims 1, 2, 4, 7, 10-12, 14, and 18-24 under Ground 1 (Young in view of Gerber and Lindegren) and Ground 2 (Young, Gerber, and Lindegren in view of Hauser)"); PO PR 1–2.

For the sake of completeness, we incorporate by reference FWD 38–59, and include the verbatim analysis of the "Reasons for combining the teachings" from claim 1 in the Final Written Decision. *See* FWD 51–58. We also reiterate that Petitioner has not shown, by a preponderance of the evidence, that claims 1, 2, 4, 7, 10–12, 14, and 18–24 are unpatentable over the combination of Gerber, Hauser, and Akerström.

1. *Independent claim 1*

a. Reasons for combining the teachings

Petitioner maintains a POSITA would have modified Gerber's multi-electrode lead to have Hauser's tined anchors arranged on collars according to Akerström's array design. Pet. 49–50. Petitioner argues that Gerber discloses a multi-electrode lead with a proximal anchoring mechanism that anchors by fibrosis, and that a POSITA would have considered tines a leading candidate among the limited number of devices that anchor by fibrosis. *Id.* at 49 (citing Ex. 1003 ¶ 107). Petitioner also argues that Akerström's arrangements of loops for anchoring by fibrosis are applicable to tines, and that Akerström's arrangement shown in Figure 3, which has repeated sets of multiple loops extending from a collar without overlap, allows for easy manufacturing, adaptation to the needs of the stimulation site, and a smaller profile which is suited to percutaneous delivery. *Id.* (citing Ex. 1003 ¶ 105). Petitioner further maintains "it would have been obvious to a POSITA to improve anchoring within the soft tissue

near the sacrum to use multiple[] tined anchors, each mounted on collars (i.e. tine elements) to affix by fibrosis." *Id.*

Patent Owner contends Petitioner's reasoning for combining the teachings of Gerber, Hauser, and Akerström "is based on a hindsight driven compilation of claim elements from the prior art references that a POSITA would have had no reason to combine." PO Resp. 46 (citing Ex. 2030 ¶¶ 101–132). In particular, Patent Owner argues Petitioner has not shown that a POSITA would have replaced Gerber's anchoring mechanism with a plurality of tines as recited in limitation 1.e, much less proximally extending tines that are adapted to be folded inwardly against the lead body without overlap as recited in limitations 1.f and 1.g. *Id.* at 45–46, 48–60; Sur-reply 12–16.

Regarding the reasoning for replacing Gerber's anchoring mechanism with tines, such as those in Hauser, Patent Owner argues Petitioner fails to provide evidence that the use of tines would improve anchoring of Gerber's lead. PO Resp. 49; Sur-reply 14. According to Patent Owner, Gerber's disclosure of an implantable electrical lead that allows for some movement after implantation obviates the need for improved anchoring. PO Resp. 49 (citing Ex. 1012, 2:4–6, 2:9–17, 2:56–63, 3:39–58; Ex. 2030 ¶¶ 70–73); Sur-reply 15. Patent Owner also argues: "Gerber is not suggesting fibrosis as a standalone fixation mechanism; it is instead suggesting that the other disclosed anchoring mechanisms (namely, the bone screws or sutures; *see* Ex. 1012, 4:12-31) would become more fixated in the body over time due to fibrosis." PO Resp. 50 (citing Ex. 2030 ¶¶ 77–80, 111). Patent Owner further argues there is no factual support for Petitioner's allegation that tines were a leading candidate among the limited number of devices that anchor

by fibrosis. *Id.*; Sur-reply 14. Per Patent Owner, introducing any foreign body into a place where fibrosis can occur will result in fibrosis, and Akerström teaches that loops are better at allowing tissue ingrowth than tines. PO Resp. 50–51 (citing Ex. 1012, 4:27–30; Ex. 2030 ¶ 108). Patent Owner additionally contends Petitioner provides no evidence that a POSITA would have expected tines to work in Gerber's anatomy. *Id.* at 51–52; Sur-reply 14–15. Rather, according to Patent Owner, a POSITA would not have expected tines to work with Gerber's implantation procedure because the periosteum and the soft tissues surrounding the implantation site are dissected during the procedure, leaving them compromised of structural integrity and unsuitable for tines to affix thereto. PO Resp. 52 (citing Ex. 1012, 5:32–6:1, Fig. 6; Ex. 2030 ¶¶ 81, 105–107, 114–115); Sur-reply 14–15.

In regard to the reasoning for arranging Hauser's tines according to Akerström's arrangement so that the tines extend proximally and are adapted to be folded inwardly against the lead body without overlap, Patent Owner argues there would have been no motivation to include, in Gerber's lead, such an arrangement of tines. PO Resp. 55–58 (citing Ex. 2030 ¶¶ 123–126); Sur-reply 15–16. Patent Owner contends that Petitioner's reasoning for applying Akerström's arrangement—i.e., ease of manufacturing and a smaller profile for the lead—does not explain why a POSITA would have combined the teachings of the references to result in tines that are adapted to be folded inward against the lead body without overlap. PO Resp. 45–46, 56–57. Patent Owner also contends that Hauser illustrates fixation means projecting in both the proximal and distal directions (PO Resp. 58 (citing Ex. 1014, Figs. 1, 12)), and that Hauser provides no guidance to a POSITA

regarding the appropriate orientation for the tines (*id.* (citing Ex. 2030 ¶¶ 127–132)).

Petitioner replies that it is incorrect for Patent Owner to consider the intended purpose of Gerber's lead. Reply 14. This assertion is similar to Petitioner's argument that it is incorrect to consider the intended purpose of Young's lead when determining motivation to combine because the proper inquiry is whether the proposed combination would achieve what is in the '314 patent claims. *See id.* (referencing the arguments regarding the motivation to combine to the teachings of Young, Gerber, and Lindegren). As we explain above, Petitioner conflates the separate requirements of motivation to combine and reasonable expectation of success. Although an unclaimed purpose is irrelevant to reasonable expectation of success, it may be pertinent to motivation to combine. *See Intelligent Bio–Sys*., 821 F.3d at 1367–68 (explaining that, unlike reasonable expectation of success, motivation to combine does not contemplate the scope of the claimed invention).

Petitioner also replies that we should give Dr. Siegel's testimony, on which Patent Owner's arguments are based, very little, if any, weight. Reply 13–14. Per Petitioner, Dr. Siegel never analyzed the claims of the '314 patent, and his entire Declaration rests on the incorrect premise that the claims are limited to sacral neuromodulation. *Id.* (citing Ex. 1022, 94:2–13, 99:5–22, 111:14–19). Petitioner further alleges that Dr. Siegel's independence is questionable because he has been a consultant for Patent Owner in many other proceedings. *Id.* at 13–14 n.7.

Beginning with Dr. Siegel's independence, we take into account that Dr. Siegel has consulted for Patent Owner, but we disagree that Dr. Siegel's

relationship with Patent Owner depreciates his testimony. Patent Owner retained Dr. Siegel to testify regarding Petitioner's asserted obviousness based on Gerber, Hauser, and Akerström (Ex. 2030 ¶ 1), and Gerber is assigned to Patent Owner (Ex. 1012, code (73)). Patent Owner also retained Dr. Siegel to testify regarding Patent Owner's InterStim system. Ex. 2030 ¶ 1. Dr. Siegel's familiarity with Patent Owner's technologies is pertinent to the nature of his testimony. Moreover, Dr. Siegel testifies that "[m]y compensation is not contingent upon the outcome of this matter or the specifics of my testimony." *Id.* ¶ 2. We also disagree with Petitioner that we should grossly discount his testimony for lacking an understanding of the claims of the '314 patent. Dr. Siegel's testimony on which Patent Owner relies regards whether a POSITA would have added tines to Gerber's lead as Petitioner proposes. As we explain above, motivation to combine is a question disparate from the claimed invention. *See Intelligent Bio–Sys*., 821 F.3d at 1367–68 (explaining that, unlike reasonable expectation of success, motivation to combine does not contemplate the scope of the claimed invention).

With this, we turn to Petitioner's reasoning for combining the teachings of Gerber, Hauser, and Akerström. With respect to Petitioner's reasoning for replacing Gerber's anchoring mechanism with tines, contrary to Patent Owner's arguments regarding improved anchoring, Petitioner does not contend that a POSITA would have added tines to Gerber's lead to more securely affix the lead within the body. Rather, Petitioner contends a POSITA would have added tines to Gerber's lead because Gerber suggests anchoring its lead by fibrosis, for which tines are a leading candidate. *See* Pet. 49 ("Gerber discloses a multi-electrode lead with a proximal anchoring

mechanism that anchors by fibrosis instead of the depicted suture sleeve (Fig. 2). . . . [A] POSITA would have considered tines, a leading candidate among the limited number of devices that anchor by fibrosis."); *see also* Tr. 13:11–14 (Petitioner arguing "Gerber expressly suggests fixation mechanism by fibrosis and the most predominant use or the common use of that to actually fixate implantable medical leads by fibrosis was tines by the late 1990s").

Gerber indeed suggests anchoring its lead by fibrosis. Namely, Gerber discloses: "Yet another anchoring mechanism 50 is to allow the medical lead 10 to fibrose in naturally using the human body's natural reaction to a foreign body or healing." Ex. 1012, 4:27–30. Moreover, there is no dispute that tines secure via fibrosis. Petitioner, however, acknowledges that any foreign object introduced into the body will cause fibrosis. Tr. 12:8–13.

Nonetheless, Petitioner maintains that Gerber's disclosure of securing its lead by fibrosis would have led a POSITA to choose tines because tines were *a leading candidate* among the devices that anchor by fibrosis. Pet. 49 (citing Ex. 1003 ¶ 107) (emphasis added). Petitioner's argument relies on Mr. Pless's opinion that tines were a leading candidate for securement via fibrosis, and Mr. Pless's opinion is based his review of the conventional uses of tines. Tr. 12:18–24 (Petitioner explaining that pages 13–16 of Mr. Pless's Declaration provide support for his opinion that tines were most commonly used for fixation via fibrosis). According to Mr. Pless, "[b]efore 2001, tines were the most commonly used passive fixation, especially due to the predominant usage of tines in the cardiac space. Tines help to anchor the

lead immediately after implantation by engaging with the body tissue, and then by fibrosis." Ex. 1003, 15.

Gerber's lead, however, is for sacral nerve stimulation and is implanted in the sacral area via an open surgical procedure. Ex. 1012, 1:7–15, 5:32–39. We find credible Dr. Siegel's testimony that Gerber's device is implanted via an open surgical procedure in which the periosteum and soft tissues surrounding the implantation site are dissected, compromising their structural integrity and rendering tines, which initially anchor by engaging body tissue, ineffective. Thus, despite the prevalent use of tines in the cardiac space to secure leads by engaging body tissue and then by fibrosis, Petitioner has not persuaded us that Gerber's disclosure of securing its lead by fibrosis would have led a POSITA to replace Gerber's anchoring mechanism with tines.

Regarding Petitioner's reasoning for positioning tines according to Akerström's arrangement, Lindegren attributes a manufacturing preference to tines integrally formed and evenly spaced on rings, not proximally extending tines that are adapted to be folded inwardly against the lead body without overlap. Ex. 1013, 5:17–20 ("From the manufacturing point of view, having the projections devised as an integral part of a one-piece ring-shaped means and evenly distributed around the circumference of the ring-shaped means, should be preferable."). Moreover, according to Petitioner, a smaller profile is suited to percutaneous delivery (Pet. 49), but Gerber's lead is implanted via an open surgical procedure (Ex. 1012, 1:7–15, 5:32–39). Accordingly, Petitioner has not persuaded us that a POSITA would have had a reason to include, in Gerber's lead, Hauser's tines situated according to Akerström's arrangement.

b. Conclusion of independent claim 1

Petitioner has not persuaded us that a POSITA would have had a reason to combine the teachings of these references as Petitioner proposes. Even without Patent Owner's proffered objective indicia of non-obviousness (PO Resp. 60–71; Sur-reply 16–30), Petitioner has not shown, by a preponderance of the evidence, that the subject matter of independent claim 1 would have been obvious over combined teachings of Gerber, Hauser, and Akerström.

2. Independent claims 11 and 18

Petitioner relies on the same reasoning for combining the teachings of Gerber, Hauser, and Akerström to result in the subject matter of independent claims 11 and 18 as for combining the teachings of these references to result in the subject matter of independent claim 1. Pet. 48–50. For the reasons discussed above, Petitioner's reasons are not persuasive. Even without Patent Owner's proffered objective indicia of non-obviousness (PO Resp. 60–71; Sur-reply 16–30), Petitioner has not shown, by a preponderance of the evidence, that the subject matter of independent claims 11 and 18 would have been obvious over combined teachings of Gerber, Hauser, and Akerström.

3. Dependent claims

For the reasons discussed above, Petitioner has not persuaded us that a POSITA would have had a reason to combine the teachings of Gerber, Hauser, and Akerström to result in the subject matter of independent claims 1, 11, and 18, from which claims 2, 4, 7, 10, 12, 14, and 19–24 depend. Even without Patent Owner's proffered objective indicia of non-obviousness (PO Resp. 60–71; Sur-reply 16–30), Petitioner has not

shown, by a preponderance of the evidence, that the subject matter of dependent claims 2, 4, 7, 10, 12, 14, and 19–24 would have been obvious over combined teachings of Gerber, Hauser, and Akerström.

IV. CONCLUSION

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 2, 4, 7, 10–12, 14, 18–24	103(a)	Young, Gerber, Lindegren	1, 2, 4, 7, 10–12, 14, 22, 23	18–21, 24
18, 20, 21	103(a)	Young, Gerber, Lindegren, Hauser		18, 20, 21
1, 2, 4, 7, 10–12, 14, 18–24	103(a)	Gerber, Hauser, Akerström		1, 2, 4, 7, 10–12, 14, 18–24
Overall Outcome			1, 2, 4, 7, 10–12, 14, 18, 20–23	18–21, 24

V. ORDER

In consideration of the foregoing, it is:

ORDERED that claims 1, 2, 4, 7, 10–12, 14, 22, and 23 of the ’314 patent have been shown to be unpatentable,

FURTHER ORDERED that claims 18–21 and 24 of the ’314 patent have not been shown to be unpatentable, and

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

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS, INC.,
Petitioner,

v.

MEDTRONIC, INC.,
Patent Owner.

IPR2020-00679
Patent 8,626,314 B2

Before JAMES A. TARTAL, ERIC C. JESCHKE, and BRENT M. DOUGAL, *Administrative Patent Judges.*

TARTAL, *Administrative Patent Judge*, Dissenting-in-Part.

I respectfully dissent from the determination in the Majority Opinion ("Maj. Op.") that Petitioner has not shown by a preponderance of the evidence the unpatentability of claims 18–21 and 24 of the '314 patent over the asserted combination of Young, Gerber, and Lindegren.

Petitioner contends the subject matter of claims 1, 2, 4, 7, 10–12, 14, and 18–24 would have been obvious over the combination of Young, Gerber, and Lindegren. Pet. 16. The Majority Opinion determines, and I agree, that Petitioner has shown by a preponderance of the evidence that

claims 1, 2, 4, 7, 10–12, 14, 22 and 23 would have been obvious over Young, Gerber, and Lindegren. *See* Maj. Op. 50. The Majority Opinion further determines that Petitioner failed to make the necessary showing as to claim 18, as well as to claims 19–21 and 24, which depend from claim 18. *See id.* As explained below, in my view Petitioner has shown by a preponderance of the evidence that the subject matter of claims 18–21 and 24 would have been obvious to a person of ordinary skill in the art over Young, Gerber, and Lindegren.

I begin with a comparison of the relevant claim language between claim 1, which the Majority Opinion determines was shown to be obvious over Young, Gerber, and Lindegren, and claim 18, which the Majority Opinion determines was not shown to be obvious over the same asserted prior art. Claim 1 recites, in relevant part, a "system" comprising "a plurality of tine elements . . . adapted to . . . deploy outward to engage body tissue when the introducer is withdrawn to release the plurality of tines." Claim 18 recites, in relevant part, a "method" comprising "advancing a medical lead" through the "lumen" of an "introducer," where the "medical lead" includes "a plurality of tine elements" that are "adapted to . . . deploy outward to engage body tissue when the introducer is withdrawn proximally," and further recites "withdrawing the introducer from the body tissue to deploy the plurality of tine elements." The Majority Opinion finds that Petitioner has shown by a preponderance of the evidence that the asserted art renders obvious tine elements "adapted to . . . deploy outward to engage body tissue when the introducer is withdrawn," as required by both claims 1 and 18. Maj. Op. 26–29 (discussing limitation "1.g," which recites tine elements adapted to "deploy outward to engage body tissue when the

introducer is withdrawn to release the plurality of tines"). In regard to claim 18, however, the Majority Opinion determines the evidence was insufficient to show that "withdrawing the introducer from the body tissue to deploy the plurality of tines" (the "Withdrawing Limitation") would have been obvious to a person of ordinary skill in the art. *Id.* at 32–37. In light of the arguments addressed below, it is important to note that the Withdrawing Limitation does not require, as part of the recited method, tines that engage body tissue. The Withdrawing Limitation is the only limitation upon which the Majority Opinion bases its determination that claim 18 was not shown to be obvious over Young, Gerber, and Lindegren. *Id.* at 33–37.

It is also important to note that the Majority Opinion correctly recognizes that "the Federal Circuit rejected our prior determinations specific to the trigeminal nerve region of Young because the [challenged] claims [of the '314 patent] are not limited to any particular treatment area." Maj. Op. 25 (citing *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957–58 (Fed. Cir. 2023); *see also Axonics*, 73 F.4th at 957 (finding that "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"). Thus, in my view, when analyzing the arguments directed to whether the Withdrawing Limitation would have been obvious to a person of ordinary skill, it is necessary to consider the teachings of Young not in isolation to applications in the trigeminal cistern, but in the context of the asserted combination with Gerber and Lindegren and with the recognition that the challenged claims are not limited to any particular treatment area.

In my view, Petitioner has shown by a preponderance of the evidence that the recited step of the Withdrawing Limitation would have been obvious to a person of ordinary skill in the art based on the asserted combination of Young, Gerber, and Lindegren. *See* Pet. 45–46; Reply 10. Young describes the results of a study involving the placement of a trigeminal electrode and explains in general terms how the study was conducted. Ex. 1010, 73–74. There is no dispute that Young teaches an introducer, a plurality of tines, and withdrawing the introducer. *See id.* at 72–74. As relevant here, Young also states that "the electrode was positioned" and "[s]ubsequently, the introducing needle [i.e., an "introducer"]" was removed. *Id.* at 73. Further, Young expressly states that the "purpose of the tines was to prevent the electrode from becoming dislodged after implantation." *Id.* In this proceeding, the crux of the dispute is whether it would have been obvious to a person of ordinary skill in the art, based on the teachings of Young (as well as the other asserted refences, Gerber and Lindgren) to withdraw the introducer from body tissue to deploy the plurality of tines, as required by the Withdrawing Limitation of the method of claim 18.

In regard to the Withdrawing Limitation, Petitioner argues in the Petition as follows:

> Young teaches the lead is "advanced under fluoroscopic guidance until paresthesias could be induced" and "[s]ubsequently, the introducing needle …[was] removed." Ex. 1010 at 73. In all cases but one, the lead stayed in place; therefore, the tines worked to prevent migration. *Id.* at 75. Thus, a [person of ordinary skill in the art] would understand Young to disclose that doctors observed the electrode advancement to the stimulation site, the electrode was out of the Needle to stimulate the nerve and exact placement location was obtained to induce paresthesia, and once paresthesia was obtained, the Needle was

> withdrawn to deploy the tines so the tines did not suffer damage and lose its intended function to prevent electrode migration. Ex. 1003 at 79–80.

Pet. 37. Mr. Pless provides testimony supporting Petitioner's contentions. *See* Ex. 1003, Ex. B, pp. 78–80 (providing a claim chart as reproduced in the Petition). Mr. Pless also explains in discussing the prior art involving tines, in general, that "[t]ines should not deploy until the electrode placement is finalized, because once deployed, they engage body tissue and the higher force required to move the lead after the tines deploy may damage the tines and/or the tissue." Ex. 1003 ¶ 32. Based on both Young's express disclosures and the testimony of Mr. Pless, Petitioner, in my view, has shown that a person of ordinary skill in the art would have understood from Young that it would have been obvious, as part of the procedure described in Young, to have withdrawn Young's needle, an "introducer," to deploy Young's plurality of tines, corresponding to what is recited in the Withdrawing Limitation.

Patent Owner's arguments in opposition directed to the Withdrawing Limitation are not persuasive and the evidence relied upon by Patent Owner does not rebut Petitioner's contentions. PO Resp. 36–38; Sur-reply 1–2. The entirety of Patent Owner's argument turns on speculation by Dr. Slavin about how the procedure described in Young could possibly have been performed. According to Dr. Slavin, "[t]here is nothing in Young that prevents the tines from also coming out of the needle while the needle distal tip is maintained in the trigeminal cistern." Ex. 2029 ¶ 53. Dr. Slavin does not suggest Young teaches forcing the tines out with the needle, or even that a person of ordinary skill in the art would have understood Young to disclose such a procedure. Instead, Dr. Slaving speculates that because the

tines "are only 5mm from the distal tip of the lead [citing Ex. 1010, 73], the tines could extend outside the needle . . . as the lead is advanced." *Id.* Such speculation as to what "could" happen sheds no persuasive light on how a person of ordinary skill in the art would have under the procedure described in Young to have been conducted. Dr. Slavin's opinions are equivocal and rely on what he contends is not expressly disclosed in Young, not on what Young would have taught to a person of ordinary skill in the art. Dr. Slavin states that "[t]here is nothing in Young which suggests that the lead could not be advanced (by physically pushing the lead) once the tines exit the needle," from which he reasons "there is no evidence in Young that the deployment of the tines would occur as a result of the withdrawal of the needle." *Id.* at ¶ 54. Dr. Slavin faults Mr. Pless for assuming "that the implantation procedure in Young must operate in the same way as the claimed invention," but directs us to no evidence to suggest that a person of ordinary skill in the art would have understood Young's procedure to operate differently. *Id.* at ¶ 55. Dr. Slavin further suggests that Mr. Pless misunderstands the "trigeminal anatomy," because when deployed the tines in the procedure of Young "float among nerve rootlets," not "body tissue." *Id.* From this, Dr. Slavin opines that "there is no reason why movement in the cistern would somehow damage the tines." *Id.* at ¶ 56. Dr. Slavin, however, does not address whether movement of the tines in the cistern would damage the "nerve rootlets" that the tines are floating around, as described by Dr. Slavin. *See id.*; *compare to* Ex. 1010 ¶ 32 (Mr. Pless explaining that "the higher force required to move the lead after the tines deploy may damage . . . the tissue").

In my view, the testimony of Mr. Pless in regard to the Withdrawing Limitation deserves greater weight than the testimony of Dr. Slavin because Dr. Pless's testimony is supported by Young. Dr. Slavin does not explain how or why a person of ordinary skill in the art would have understood Young in the manner that Dr. Slavin suggests the procedure in Young "could" have been performed. Given the purpose of the tines expressly disclosed in Young was "to prevent the electrode from becoming dislodged after implantation," Dr. Slavin offers no plausible reason why the tines would have been intentionally deployed in Young's procedure before withdrawing the introducer.

To be clear, I acknowledge the burden is on Petitioner to show unpatentability, however, where Mr. Pless's opinions are supported by sound reasoning, and Dr. Slavin's are not, I find Mr. Pless's testimony is entitled to the greater weight as between the two. Moreover, even if potential damage to the tines and surrounding "nerve rootlets" may be reduced or eliminated when deployed in a fluid filled cistern in the procedure described in Young, the method of claim 18 is not limited to a particular area of treatment and Young is not asserted alone, but in combination with Gerber and Lindegren. *See* Ex. 1003 ¶¶ 83, 86 (reflecting that the asserted art includes treatment of regions beyond the treatment region of Young and explaining that Gerber teaches an implantable medical lead for stimulation of the sacral nerves and that Lindegren teaches an implanted endocardiac electrode and expressly identifies the importance of anchoring the electrode "to the heart muscle in some suitable fashion").

In regard to the analysis of claim 18 in the Majority Opinion, in my view, it imposes burdens on Petitioner that are unnecessary to show the

asserted art renders claims 18 obvious and credits the testimony of Dr. Slavin over Mr. Pless for reasons that have no bearing on the patentability of claim 18. Maj. Op. 33–37. For example, the Majority Opinion faults Petitioner for not contesting "Patent Owner's argument and evidence that Young does not teach that the tines engage with body tissue and that the tines would not have been damaged if moved within the trigeminal cistern." Maj. Op. 35; *see also* Maj. Op. 37 (stating that "Petitioner does not respond to Patent Owner's argument and evidence concerning what impact the tines within the *fluid* cavity of the trigeminal cistern would have on placing the electrode." First, claim 18 does not require as part of the recited method that "tines engage with body tissue." Second, there is no persuasive evidence that the tines would not have been damaged if moved within the trigeminal cistern, no evidence to rebut Mr. Pless's testimony that damage to the surrounding tissue was also a concern with movement of the tines, and no consideration given to the fact that claim 18 is not limited to tines in the trigeminal cistern. *See Axonics*, 73 F.4th at 957 (finding that "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").

The Majority Opinion concludes that "Petitioner fails to show that Young teaches or suggests 'withdrawing the introducer from the body tissue to deploy the plurality of tine elements' as required by claim 18." Maj. Op. 37. I disagree, for the reasons above, and, in my view, even if all of the evidence relied upon by the Majority Opinion is credited, it is insufficient to support the conclusion reached with regard to the Withdrawing Limitation. The analysis in the Majority Opinion is premised on the finding that "Young

does not teach whether the tines are advanced forward and deployed with the electrode, or are not deployed until the introducer sheath is removed." *Id.* at 34–35 (footnote omitted). The Majority Opinion, therefore, recognizes only two possible ways the tines would have been deployed in Young's procedure. There is no dispute that in Young's procedure the introducer must be withdrawn and the tines, to function, must be deployed. Setting aside the fact that, in my view, Young, itself, at least suggests that the tines are not deployed until the introducer sheath is removed (*see* Ex. 1010, 6), even if there is some ambiguity in Young as to when the needle was removed relative to when the tines were deployed, the evidence shows that withdrawing the introducer to deploy the tines would have been obvious to a person of ordinary skill in the art, as explained by Mr. Pless. *See* Ex. 1003, 78–80. In particular, to the extent the tines could be deployed in Young by advancing the tines forward (in a manner not suggested or taught in Young or in any other identified reference), rather than by withdrawing the introducer, the mere fact that Young does not *exclude* deploying the tines before withdrawing the needle fails to rebut Petitioner's evidence that it would have been obvious to a person of ordinary skill in the art based on Young to withdraw the needle to deploy the tines. There is no persuasive evidence to the contrary, only speculation by Patent Owner that "deploying the tines before withdrawing the needle may very well have been how Young's procedure was conducted." PO Sur-reply 2 (citing Ex. 2029 ¶¶ 53–56). While Young does not expressly exclude this possibility, the ground asserted is obviousness and, in my view, the evidence demonstrates that a person of ordinary skill in the art would have found the only identified alternative to deploying the tines before withdrawing the needle, i.e.,

withdrawing the needle to deploy the tines, obvious based on the teachings of Young.

Because a preponderance of the evidence makes clear that "withdrawing the introducer from the body tissue to deploy the plurality of tines," as required by claim 18, would have been obvious over Young, Gerber, and Lindegren, I dissent from the majority's contrary determination. For the same reasons discussed above, I also disagree with the determination in the Majority Opinion that claims 19–21 and 24 were not shown to be unpatentable for the same reasons claim 18 was not shown to be unpatentable.

Additionally, as to claim 20, the Majority Opinion determines that "Young does not teach deploying tine elements into subcutaneous tissue." Maj. Op. 38. In my view, the focus on claim 20 in this regard in the Majority Opinion only considers placement in the trigeminal cistern in the context of Young, when Petitioner has shown based on the combination of Young, Gerber, and Lindegren that it would have been obvious to a person of ordinary skill in the art to deploy tines into subcutaneous tissue, even if the particular study described in Young was concerned with the specific application of tines in the context of the trigeminal cistern. *See* Pet. 37–38. For the foregoing reasons, in my view, Petitioner has shown by a

preponderance of the evidence the unpatentability of claims 18–21 and 24 of the '314 patent over the combination of Young, Gerber, and Lindegren.[24]

[24] Petitioner also contends that claims 18, 20, and 21 would have been obvious over Young, Gerber, Lindegren, and Hauser, and asserts that "to the extent Young does not expressly disclose . . . the method of withdrawing the introducer to deploy the tines, Hauser discloses this." Pet. 40. In my view, the teachings of Hauser are unnecessary, because Petitioner has shown by a preponderance of the evidence that the subject matter of claims 18, 20, and 21 would have been obvious over Young, Gerber, Lindegren. Further, I agree with the Majority Opinion that Petitioner fails to show sufficient evidence supporting a persuasive reason a person of ordinary skill in the art would have applied the features of Hauser relied upon by Petitioner to the asserted combination with Young, Gerber, and Lindegren. *See* Maj. Op. 42.

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