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Paper: 65
Date: September 13, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS, INC.,
Petitioner,

v.

MEDTRONIC, INC.,
Patent Owner.

IPR2020-00715
Patent 8,036,756 B2

Before JAMES A. TARTAL, ERIC C. JESCHKE, and ALYSSA A. FINAMORE, *Administrative Patent Judges.*

FINAMORE, *Administrative Patent Judge.*

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

Petitioner, Axonics, Inc.,[1] filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1, 2, 5, 7, 13–15, and 18 of U.S. Patent No. 8,036,756 B2 ("the '756 patent") (Ex. 1001). Pet. 1. On September 15, 2020, we granted institution of an *inter partes* review. Paper 10.

During the trial, Patent Owner, Medtronic, Inc., filed a Response (Paper 30, "PO Resp."). Petitioner filed a Reply (Paper 43, "Reply"), and Patent Owner filed a Sur-reply (Paper 56, "Sur-reply"). Oral argument took place on June 17, 2021, and we have entered the transcript (Paper 64, "Tr.").

This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we conclude Petitioner has not proven by a preponderance of the evidence that claims 1, 2, 5, 7, 13–15, and 18 are unpatentable.

II. BACKGROUND

A. Real Parties in Interest

Petitioner asserts that it is the real party in interest. Pet. 69; *see also* Paper 52 (notifying the Board of the name change from Axonics Modulation Technologies, Inc. to Axonics, Inc.). Patent Owner maintains that it is the real party in interest. Paper 5, 1. Patent Owner further maintains that "Medtronic plc is the ultimate parent of Medtronic, Inc." (*id.*), and that "Medtronic, Inc. has granted certain rights with respect to the patent-at-issue

[1] During the trial, the name of Petitioner when the Petition was filed, Axonics Modulation Technologies, Inc., was changed to Axonics, Inc. *See* Paper 52.

to Medtronic Puerto Rico Operations Co., which in-turn has granted certain rights to Medtronic Logistics, LLC, which in-turn has granted certain rights to Medtronic USA, Inc." (*id.* at 1 n.1).

B. Related Matters

The parties identify *Medtronic, Inc. v. Axonics Modulation Technologies, Inc.*, No. 8:19-cv-02115 (C.D. Cal. filed Nov. 4, 2011) and *Axonics Modulation Technologies, Inc. v. Medtronic, Inc.*, IPR2020-00679 (PTAB filed Mar. 16, 2020) (challenging U.S. Patent No. 8,626,314 B2). Pet. 69; Paper 5, 1–2.

C. The '756 Patent

The invention "relates generally to a method and apparatus that allows for stimulation of body tissue, particularly sacral nerves." Ex. 1001, 1:18–20. More specifically, the invention "relates to an implantable medical electrical lead having at least one stimulation electrode adapted to be implanted near the sacral nerves for stimulation of a bundle of sacral nerve fibers and a fixation mechanism for providing chronic stability of the stimulation electrode and lead." *Id. at* 1:20–25.

Leads typically have a number of ring-shaped stimulation electrodes spaced along a distal segment of the lead body, which is adapted to be passed into the foramen along a selected sacral nerve. *Id.* at 2:32–36. Each distal stimulation electrode is coupled to a lead conductor extending proximally through the lead body. *Id.* at 2:37–39. The proximal end of each lead conductor is coupled to a connector that is adapted to be coupled with an implantable pulse generator (IPG). *Id.* at 2:39–44.

The '756 patent describes that "[a] problem associated with implantation of permanent and temporary neurostimulation leads involves

maintaining the discrete ring-shaped electrode(s) in casual contact . . . or in close proximity to the sacral nerve to provide adequate stimulation of the sacral nerve, while allowing for some axial movement of the lead body." *Id.* at 3:6–12. According to the '756 patent, "physicians spend a great deal of time with the patient under general anesthetic placing the leads due to the necessity of making an incision exposing the foramen and due to the difficulty in optimally positioning the small size stimulation electrodes relative to the sacral nerve." *Id.* at 3:13–17.

The invention of the '756 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 5:33–38. A sacral nerve stimulation lead of the invention is shown in Figure 1, reproduced below.

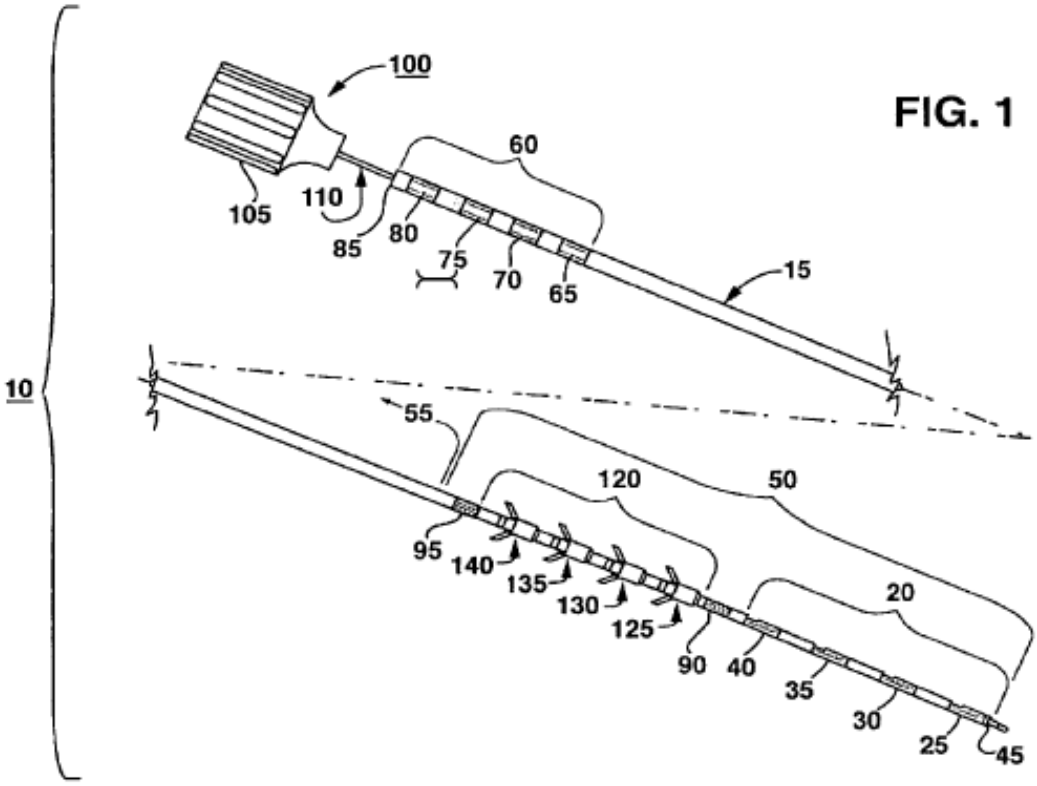


Figure 1 is a plan view showing implantable medical lead 10 for sacral nerve stimulation. *Id.* at 8:34–35, 9:7–8. Implantable medical lead 10 includes lead body 15 with electrode array 20 that extends proximally from lead distal end 45 and comprises P stimulation electrodes. *Id.* at 6:10–14, 9:7–12. As shown in Figure 1, electrode array 20 includes stimulation electrodes 25, 30, 35, 40 such that P=4. *Id.* at 9:7–12. Each stimulation electrode 25, 30, 35, 40 is electrically coupled to the distal end of a coiled wire lead conductor extending proximally through distal portion 50 and proximal portion 55 of lead body 15. *Id.* at 9:23–27. The proximal end of each lead conductor is coupled to one of P connector elements 65, 70, 75, 80 in proximal connector element array 60 along proximal portion 55 adjacent proximal end 85. *Id.* at 6:17–21, 9:27–31. Connector elements 65, 70, 75, 80 are adapted to be coupled with a neurostimulator IPG. *Id.* at 9:44–47.

To inhibit axial movement of lead body 15 and dislodgement of stimulation electrodes 25, 30, 35, 40, 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 5:50–57, 9:61–65. The fixation mechanism comprises M tine elements in tine element array 120. *Id.* at 5:57–60, 9:65–10:1. As shown in Figure 1, tine element array 120 includes tine elements 125, 130, 135, 140 such that M=4. *Id.* at 9:65–10:1.

A tine element is shown in Figure, reproduced below.

FIG. 3

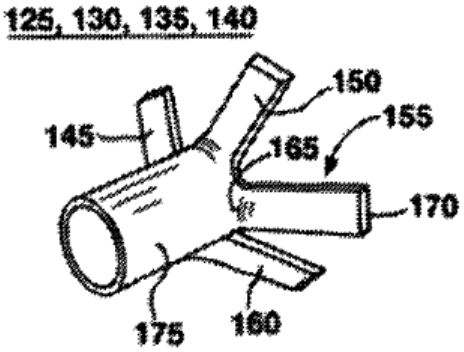


Figure 3 is an expanded perspective view showing one of tine elements 125, 130, 135, 140. *Id.* at 8:41–42. Each tine element comprises N flexible, pliant, tines. *Id.* at 5:60–61, 10:8–11. As shown in Figure 3, the tine element includes tines 145, 150, 155, 160 such that N=4. *Id.* at 10:8–11. Each tine extends through a tine length from attached tine end 165 to free tine end 170. *Id.* at 10:11–14. Attached tine end 165 is attached to lead body 15 at a tine attachment site and so that the tine extends outwardly of lead body 15 and proximally toward lead proximal end 85. *Id.* at 10:14–17. 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 5:66–6:3, 10:17–23.

Figures 6 and 7, reproduced below, illustrate steps of implanting lead 10. *Id.* at 11:4–6.

FIG. 6

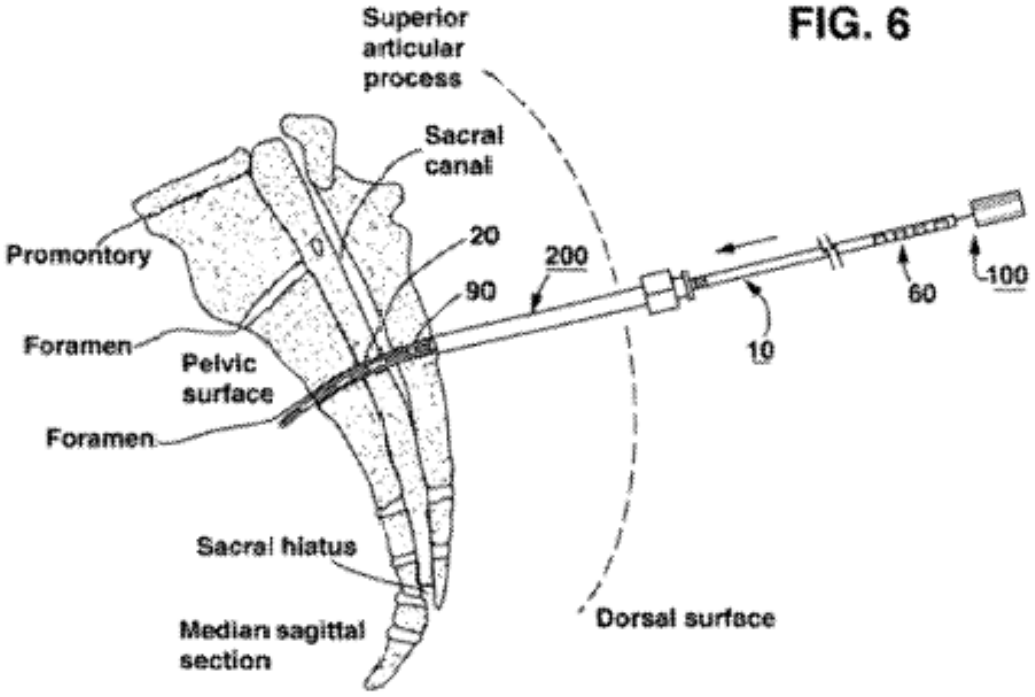
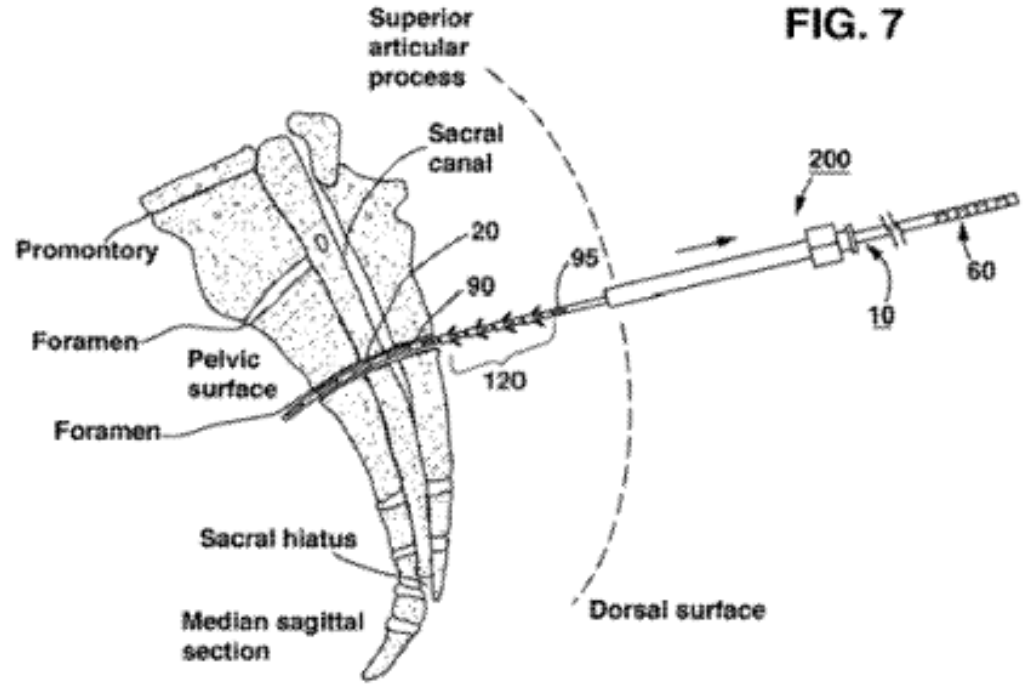


FIG. 7



Figures 6 and 7 are cross-section views of the sacrum schematically illustrating steps of implanting lead 10. *Id.* at 8:50–57. Introducer 200 can

be advanced into position over a guide wire previously percutaneously advanced into the foramen from a skin incision. *Id.* at 11:28–31. Lead 10 is advanced through the introducer lumen proximal end opening into the introducer lumen. *Id.* at 11:40–43. Electrode array 20 and tine element array 120 are disposed within the pre-positioned introducer lumen for implantation in relation to the sacral nerve accessed through the foramen and in the subcutaneous tissue, respectively. *Id.* at 11:43–47. As shown in Figure 6, lead 10 is advanced distally out of the introducer lumen distal end opening to advance electrode array 20 into or through the foramen from the posterior entrance into casual contact with the more anterior sacral nerve. *Id.* at 11:48–54. After electrical testing to establish optimal positioning, introducer 200 is retracted proximally, and distal-to-proximal tine elements 125, 130, 135, 140 are successively released from the introducer lumen, as shown in Figure 7. *Id.* at 11:55–60. Once introducer 200 is completely removed, lead proximal portion 55 is bent laterally and implanted through a subcutaneously tunneled path to the neurostimulator IPG. *Id.* at 12:2–7.

D. Challenged Claims

Petitioner challenges claims 1, 2, 5, 7, 13–15, and 18 of the '756 patent. Pet. 1, 20. Claims 1 and 14 are independent. Ex. 1001, 13:33–14:18, 14:64–16:6. Independent claim 1 is illustrative and reproduced below, adding Petitioner's labels for the limitations.

> 1. [1.0] A method of providing electrical stimulation of body tissue at a stimulation site employing an implantable pulse generator, the method comprising:
>
> [1.a] percutaneously introducing an introducer having an introducer lumen extending between an introducer lumen proximal end opening and an introducer lumen

distal end opening through body tissue to locate the introducer lumen distal end opening adjacent to the stimulation site;

disposing an implantable medical lead within the introducer lumen, wherein the implantable medical lead comprises:

[1.b] a lead body extending between a lead proximal end and a lead distal end;

[1.c] P connector elements formed in a connector array along a first segment of the lead body proximate to the lead proximal end;

[1.d] P stimulation electrodes arranged in an electrode array extending along a second segment of the lead body proximate to the lead distal end;

[1.e] P lead conductors extending between the P connector elements and the P stimulation electrodes; and

[1.f] a plurality of M tine elements formed in a tine element array extending along a third segment of the lead body between the second segment of the lead body and the lead proximal end, [1.g] each tine element comprising N flexible tines, each tine having a tine width and a tine thickness and extending through a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead body at a tine attachment site and supporting the tine extending outwardly of the lead body and toward the lead proximal end, whereby the MxN tines are adapted to be folded inward against the lead body when fitted into and constrained by the introducer lumen, [1.h] wherein the plurality of M tine elements are separate from and axially displaced from each other and from each of the P stimulation electrodes, and wherein all of the P stimulation electrodes are between the plurality of M tine elements and the lead distal end, and

[1.i] wherein disposing the implantable medical lead within the introducer lumen comprises disposing the implantable medical lead within the introducer lumen with the MxN tines folded inward against the lead body by constraint imposed by the introducer lumen without overlapping one another;

[1.j] withdrawing the introducer proximally from the tine element array to successively release the N tines of each of the M tine elements to deploy outward and toward the lead proximal end to engage body tissue and inhibit axial dislodgement of the P stimulation electrodes; and

[1.k] coupling the P connector elements to the implantable pulse generator.

Id. at 13:33–14:18.

Independent claim 14 recites a method similar to that of independent claim 1. *Id.* at 14:64–16:6. Claims 2, 5, 7 and 13 depend from independent claim 1, and claims 15 and 18 depend from independent claim 14. *Id.* at 14:19–23, 14:30–32, 14:36–40, 14:61–63, 16:7–12, 16:22–23.

E. Asserted Grounds of Unpatentability and Evidence

Petitioner asserts that claims 1, 2, 5, 7, 13–15, and 18 are unpatentable on the following two grounds:

Claims Challenged	35 U.S.C. §[2]	References
1, 2, 5, 7, 13–15, 18	103(a)	Young[3], Gerber[4], Lindegren[5], Akerström[6]
1, 2, 5, 7, 13–15, 18	103(a)	Gerber, Hauser[7], Akerström

Pet. 20. In support of its asserted grounds of unpatentability, Petitioner relies on Declarations of Benjamin Pless (Exs. 1003, 1023). Patent Owner deposed and cross-examined Mr. Pless and submits transcripts of these depositions (Exs. 2026, 2072).

Patent Owner proffers a Declaration of Dr. Konstantin Slavin (Ex. 2029), a Declaration of Dr. Steven Siegel (Ex. 2030), and a Declaration of Charles Thomas Bombeck (Ex. 2035). Petitioner deposed and cross-examined each of Patent Owner's declarants and submits transcripts of

[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended certain sections of this statute, including §§ 102 and 103, and the effective date of the relevant amendment is March 16, 2013. The '756 patent was filed on February 13, 2006 (Ex. 1001, code (22)), and there is no dispute that the challenged claims of the '756 patent have an effective filing date before March 16, 2013. Accordingly, we apply the pre-AIA version of the statute.
[3] 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) ("Young") (Ex. 1008).
[4] Gerber, US 6,055,456, issued Apr. 25, 2000 ("Gerber") (Ex. 1010).
[5] Lindegren, WO 98/20933, published May 22, 1998 ("Lindegren") (Ex. 1011).
[6] Akerström, US 4,407,303, issued Oct. 4, 1983 ("Akerström") (Ex. 1012).
[7] Hauser et al., US 5,052,407, issued Oct. 1, 1991 ("Hauser") (Ex. 1013).

Dr. Slavin's deposition (Ex. 1021), Dr. Siegel's deposition (Ex. 1022), and Mr. Bombeck's deposition (Ex. 1024).

Additionally, Patent Owner provides evidence of objective indicia of non-obviousness of the claimed invention. Patent Owner identifies this evidence in its briefing. PO Resp. 57–69; Sur-reply 15–30.

III. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner contends a person of ordinary skill in the art ("POSITA") would have had "(1) at least a bachelor's degree in biomedical engineering, electrical engineering, mechanical engineering, or equivalent coursework, and (2) at least two years of experience researching or developing active, implantable medical devices." Pet. 15 (citing Ex. 1003 ¶ 61). Patent Owner proposes its own level of ordinary skill in the art. PO Resp. 14. According to Patent Owner, a POSITA "would have been a physician with at least two years of experience in sacral neuromodulation" or "would have been an implantable medical lead designer with at least three years of experience designing and researching leads for use in sacral neuromodulation, and working in close collaboration with a physician having two years of experience in sacral neuromodulation." *Id.* (citing Ex. 2029 ¶¶ 21–22; Ex. 2030 ¶ 64). Patent Owner further contends "[m]ore education can substitute for practical experience and *vice versa*." *Id.* (citing Ex. 2029 ¶ 21; Ex. 2030 ¶ 64).

Patent Owner argues that we should reject Petitioner's proposed level of ordinary skill in the art because it requires no understanding of the sacral anatomy or sacral neuromodulation, which, according to Patent Owner, is

the context of the '756 patent. PO Resp. 14–15 (citing Ex. 1001, 1:17–28; Ex. 2029 ¶¶ 23–24; Ex. 2030 ¶¶ 65–66). Patent Owner further argues that Mr. Pless "does not possess the appropriate skill in sacral neuromodulation or the requisite knowledge of the sacrum, sacral nerves, and surrounding tissues" (*id.* at 15 (citing Ex. 2026, 216:12–21)), and that "Mr. Pless'[s] testimony in this proceeding is not grounded in the perspective of a POSITA" (*id.*). Petitioner replies that the challenged claims do not recite sacral anatomy or sacral neuromodulation (Reply 3 (citing Ex. 1022, 92:25–102:4; Ex. 1023 ¶¶ 9–15)), and that the '756 patent describes uses of the invention outside of sacral anatomy (*id.* (citing Ex. 1021, 27:5–29:25, 31:4–17, 35:2–37:8; Ex. 1022, 89:8–90:22, 99:25–102:4)).

The level of ordinary skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). The POSITA is a hypothetical person presumed to have known the relevant art at the time of the invention. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, we may consider certain factors, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *Id.*

The parties dispute not only the level of ordinary skill, but also the relevant art. Beginning with the relevant art, Petitioner's proposed level of ordinary skill suggests the relevant art is implantable medical devices generally (Pet. 15 (citing Ex. 1003 ¶ 61)), whereas Patent Owner's proffered level of ordinary skill indicates the relevant art is medical leads specifically for sacral neuromodulation (PO Resp. 14 (citing Ex. 2029 ¶¶ 21–22;

Ex. 2030 ¶ 64)). We find it is the latter. The Specification of the '756 patent defines the field of the invention as medical electrical leads for sacral neuromodulation:

> 1. Field of the Invention
>
> This invention relates generally to a method and apparatus that allows for stimulation of body tissue, *particularly sacral nerves*. More specifically, this invention relates to *an implantable medical electrical lead having at least one stimulation electrode adapted to be implanted near the sacral nerves* for stimulation of a bundle of sacral nerve fibers and a fixation mechanism for providing chronic stability of the stimulation electrode and lead. Moreover, this invention relates to the method of implantation and anchoring of *the medical electrical lead electrodes in operative relation to a selected sacral nerve to allow for stimulation*.

Ex. 1001, 1:17–28 (emphases added). Apart from a reference to applications outside of sacral neuromodulation (*id.* at 13:19–21), the Specification describes the invention with respect to the sacral anatomy (*see, e.g., id.* at 8:34–9:2 (describing each of the drawings as depicting a sacral nerve stimulation lead)). Moreover, the claims' lack of a recitation of sacral anatomy or sacral neuromodulation does not override the Specification's express description of the field of the invention because the claims' purpose is not to describe the subject matter of the patent but rather to define the boundary of the patent monopoly. *See, e.g.*, *PSC Comput. Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1358 (Fed. Cir. 2004) ("One important purpose of the written description is to provide notice to the public as to the subject matter of the patent, while the claim provides notice as to the scope of the invention."); *In re Vogel*, 422 F.2d 438, 442 (CCPA 1970) ("A claim is a group of words defining only the boundary of the patent monopoly.").

Turning to the level of ordinary skill, each party's proposed level of ordinary skill requires a combination of formal education and experience. Pet. 15 (citing Ex. 1003 ¶ 61); PO Resp. 14 (citing Ex. 2029 ¶¶ 21–22; Ex. 2030 ¶ 64). Patent Owner's proposed level is higher than Petitioner's proposed level in that Patent Owner's proposed level requires a POSITA to either be a physician with at least two years of experience in sacral neuromodulation or a sacral neuromodulation lead designer working in close collaboration with such a physician. PO Resp. 14 (citing Ex. 2029 ¶¶ 21–22; Ex. 2030 ¶ 64). Drs. Slavin and Siegel testify that this requirement for a physician with at least two years of experience in sacral neuromodulation is necessary for the knowledge of human anatomy and surgical procedures involved in sacral neuromodulation lead placement. Ex. 2029 ¶ 24; Ex. 2030 ¶ 66. Mr. Pless, however, testifies that a lead designer developing leads for sacral neuromodulation would have similar knowledge:

> [O]ne of the things that engineers who develop products for implantation in the body pay attention to is the anatomy, and we had lots of books on anatomy, both, you know, photographic depictions as well as, you know, more schematic. You know, Netter was a great resource for that. And occasionally we would do cadaver studies as well.

Ex. 2026, 24:7–15. Although a physician with at least two years of experience in sacral neuromodulation would have knowledge of human anatomy and surgical procedures involved in sacral neuromodulation lead placement, we disagree with Patent Owner that a POSITA must be a physician with at least two years of experience in sacral neuromodulation or a sacral neuromodulation lead designer working in close collaboration with such a physician to have this knowledge.

In view of the foregoing, the relevant art is medical leads for sacral neuromodulation. This art is sophisticated and requires knowledge of human anatomy of the sacral area and the surgical procedures involved in sacral neuromodulation. Both lead designers and physicians work in this field. With these considerations, we find a POSITA 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.

Regarding Patent Owner's criticism of Mr. Pless's testimony as not being grounded in the perspective of a POSITA, our Trial Practice Guide[8] explains that there is no requirement between a declarant's experience and the relevant field. TPG 34 (citing *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010)). We generally permit testimony where the declarant's scientific, technical, or other specialized knowledge will help the Board understand the evidence or to determine a fact in issue. *Id.* (citing Fed. R. Evid. 702(a)). Given his education as an electrical engineer and his experience as a medical lead designer (Ex. 1003 ¶¶ 4–10), we find Mr. Pless's testimony helpful in deciding factual issues in this proceeding. Moreover, when assigning weight to a declarant's testimony, we consider

[8] USPTO, *Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019*, https://www.uspto.gov/TrialPracticeGuideConsolidated ("TPG"); *see also* Office Patent Trial Practice Guide, November 2019 Edition, 84 Fed. Reg. 64,280 (Nov. 21, 2019) (notifying the public of the availability of the Consolidated Trial Practice Guide).

the underlying facts or data upon which the testimony is based. TPG 40–41. In our analysis of the asserted grounds of unpatentability, we weigh Mr. Pless's testimony accordingly.

B. Claim Construction

We interpret a claim "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)." 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe 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." *Id.* Furthermore, we expressly construe the claims to the extent necessary to determine whether Petitioner has proven that the challenged claims are unpatentable. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Petitioner argues "a plurality of M tine elements" recited in independent claim 1 and "a plurality of tine elements" recited in independent claim 14 should be construed as "at least two or more structures that mount to the lead body, each structure comprising multiple tines attached to it." Pet. 20. Patent Owner disagrees with Petitioner's proposed construction, and also asserts the Board can resolve the dispute in this proceeding without construing these terms. PO Resp. 16–18.

We agree with Patent Owner that an express construction of each of the claim terms "a plurality of M tine elements" and "a plurality of tine elements" is unnecessary to resolve the dispute. For the reasons set forth in

our analysis of the asserted grounds of unpatentability, we determine that no claim term requires an express construction for us to ascertain whether Petitioner has shown the challenged claims to be unpatentable.

C. Obviousness Based on Young, Gerber, Lindegren, and Akerström

Petitioner challenges claims 1, 2, 5, 7, 13–15, and 18 under 35 U.S.C. § 103(a), contending the claimed subject matter would have been obvious over Young, Gerber, Lindegren, and Akerström. Pet. 22–47; Reply 3–10. Patent Owner argues Petitioner's proposed combination of Young, Gerber, and Lindegren would not have resulted in a method comprising all of the claim limitations. PO Resp. 19–23; Sur-reply 1–5. Patent Owner also argues that there would not have been a motivation to combine the teachings of the references as Petitioner proposes. PO Resp. 23–38; Sur-reply 5–10.

We begin our analysis of this asserted ground of unpatentability with an overview of the references, and then discuss the parties' contentions for each of the claims. For the reasons below, Petitioner has not shown, by a preponderance of the evidence, that the subject matter of claims 1, 2, 5, 7, 13–15, and 18 would have been obvious over the combined teachings of Young, Gerber, Lindegren, and Akerström.

1. Young

Young details "the author's experience with 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. 1008, 73. The trigeminal stimulating electrode[9] is shown in Figure 1, reproduced below.

[9] The trigeminal stimulating electrode disclosed in Young is Patent Owner's Quintatrigeminal electrode. Ex. 1008, 73.

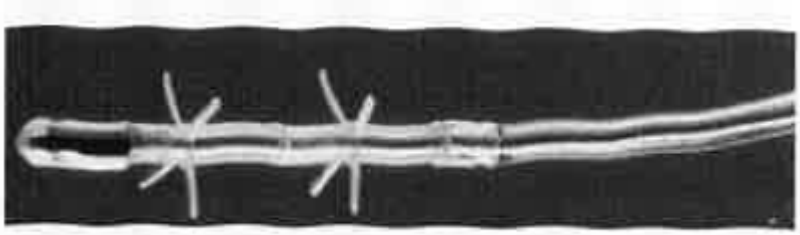


FIG. 1.

Figure 1 is a photograph of the tip of the trigeminal stimulating electrode. *Id.* The trigeminal stimulating electrode consists of a monopolar platinum-iridium 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 purpose of the tines is to prevent the electrode from becoming dislodged after implantation. *Id.*

The electrode is inserted percutaneously through a No. 14 needle via a puncture of the foramen ovale. *Id.* Subsequently, the introducing needle and central stylet are removed, and the proximal end of the electrode is tunneled subcutaneously around the mandible and connected to a percutaneous extension lead. *Id.* The distal end of the extension lead is connected to a completely implanted pulse generator system. *Id.* at 74. The implanted pulse generator system[10] is shown in Figure 3 below.

[10] The implanted pulse generator system disclosed in Young is Patent Owner's ITREL. Ex. 1008, 74.

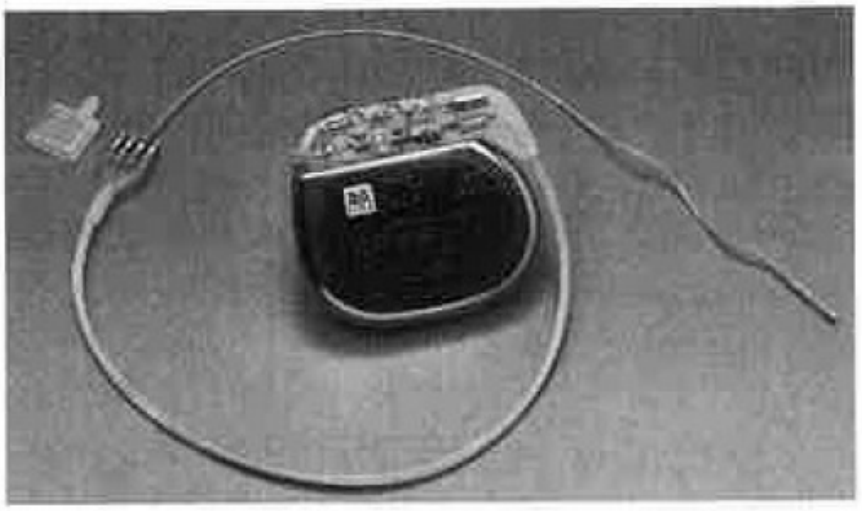


Figure 3 is a photograph of the complete component system for trigeminal stimulation, including the electrode, the implanted pulse generator, and an extension lead. *Id.*

The patients with the implanted electrode system did not have any major complications but instead only a few minor problems. *Id.* at 77. Nonetheless, "[t]he electrode could be improved to provide multiple active stimulation sites near the tip," which "would be particularly useful for achieving stimulation-induced paresthesias in patients with pain in all three trigeminal divisions." *Id.*

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. 1010, 1:9–12. An implantable medical lead for stimulation of the sacral nerves is shown in Figure 1, reproduced below.

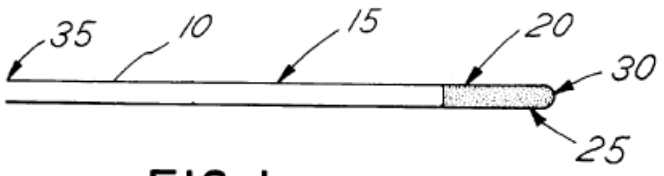


FIG. 1

Figure 1 is a plan view showing implantable medical lead 10 comprising lead body 15 having at least one electrode contact 20 at distal end 25. *Id.* at 3:21–22, 3:40–43. 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.

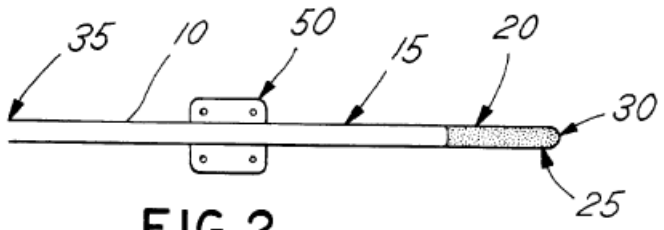


FIG. 2

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.

Implantable medical lead 10 may include two electrode contacts, as shown in Figure 3 below.

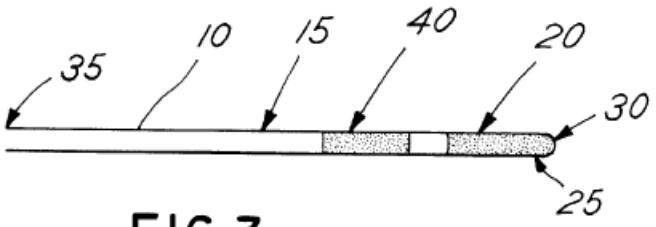


FIG.3

Figure 3 is a plan view of implantable medical lead 10 having two electrode contacts 20, 40 to provide for a bipolar configuration. *Id.* at 3:26–27, 4:32–33.

The medical lead has a smaller than typical diameter. *Id.* at 2:64–66. The smaller diameter allows for less invasive implantation techniques, such as via a cannula, imparts less trauma to the patient during implantation, and enables a physician to use local, instead of general, anesthesia. *Id.* at 2:66–3:6. When the medical lead is implanted with a cannula, a stylet is useful to straighten the medical lead for passing through the cannula. *Id.* at 5:15–17, 5:26–28.

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. 1011, 1:6–11. The position-fixation means consists of a position-fixation groove encircling the exterior of the electrode head, and the groove 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 position-fixation groove.

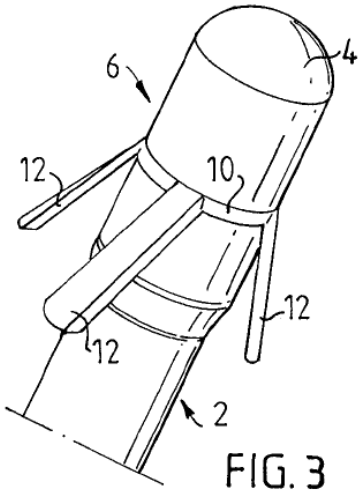


FIG. 3

Figure 3 is a perspective view of the distal end section of implantable electrode lead 2. *Id.* at 6:30–32, 7:7–8. Received in position-fixation groove 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. Furthermore, ring-shaped means 10 and projections 12 are preferably made of an elastic material such as silicone rubber. *Id.* at 5:20–22, 8:5–8.

4. Akerström

Akerström relates to an endocardial electrode arrangement having an elongated electric conductor, an electrode head conductively connected to a distal end of the conductor for applying stimulation pulses to the heart, and means for placing the conductor or the electrode head on the heart wall. Ex. 1012, 1:5–13. The distal end of the endocardial electrode arrangement is shown in Figure 1, reproduced below.

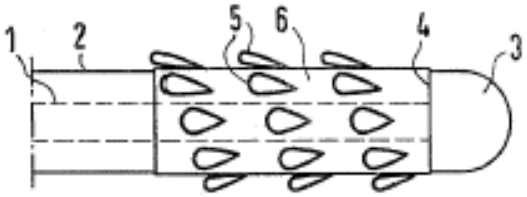


FIG 1

Figure 1 illustrates the distal end of the endocardial electrode arrangement that comprises electric conductor 1 provided with electric insulation sheath 2. *Id.* at 2:15–16, 2:34–36. At the distal end of conductor 1, electrode head 3 is disposed. *Id.* at 2:36–38.

To securely retain the electrode in its position in the heart, the electrode includes loops 5 into which heart tissue can grow. *Id.* at 2:46–49. Loops 5 are located in close proximity to electrode head 3 and mounted on sleeve 6 slipped over insulation 2 of conductor 1. *Id.* at 2:46–50. As shown in Figure 1, loops 5 are attached along a helical-shaped line. *Id.* at 2:50–51. The loops can be fabricated from a soft, thin, body-fluid-resistant material, such as polyester and polypropylene. *Id.* at 2:66–68. As loops 5 consist of a soft, thin material, they rest closely against the electrode during insertion of the electrode into a vein. *Id.* at 3:8–11.

5. Independent claim 1

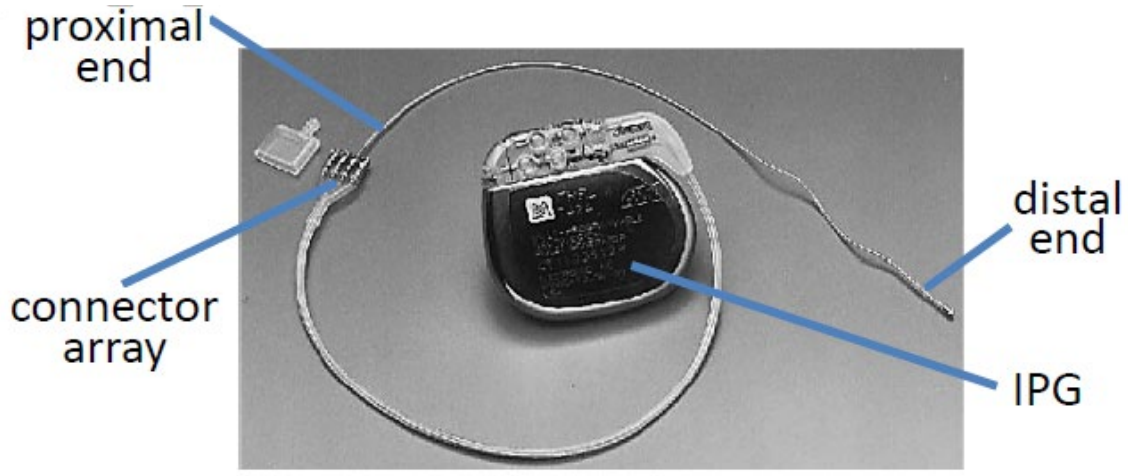
a. Undisputed limitations (limitations 1.0–1.f, 1.h, 1.i, and 1.k)

The preamble of independent claim 1, i.e., Petitioner's designated limitation 1.0, recites "[a] method of providing electrical stimulation of body tissue at a stimulation site employing an implantable pulse generator." Ex. 1001, 13:33–35. Petitioner contends that, to the extent the preamble is a limitation, Young discloses stimulating the electrode using the IPG to obtain paresthesia and pain relief. Pet. 32 (citing Ex. 1008, 73–75).

Independent claim 1 recites "percutaneously introducing an introducer having an introducer lumen extending between an introducer lumen proximal end opening and an introducer lumen distal end opening through body tissue to locate the introducer lumen distal end opening adjacent to the stimulation site," i.e., limitation 1.a. Ex. 1001, 13:36–41. Petitioner contends Young discloses percutaneous introduction of a No. 14 needle through which an electrode is passed to induce paresthesia near the trigeminal nerve. Pet. 32–33 (citing Ex. 1008, 73). According to Petitioner, "[p]aresthesia defines the stimulation site because it can only be achieved if the electrode is adjacent to the stimulation site, i.e. trigeminal nerve." *Id.* at 33 (citing Ex. 1003 ¶ 89). Petitioner further contends that Gerber teaches using a cannula to deliver the electrode into place, and that percutaneous use of a cannula as an introducer was well known prior to 2001. *Id.* (citing Ex. 1003 ¶ 96; Ex. 1010, 5:16–17, 5:26–28, 5:34–35).

Independent claim 1 also recites "a lead body extending between a lead proximal end and a lead distal end," i.e., limitation 1.b. Ex. 1001, 13:45–46. Petitioner argues that the electrode described in Young includes a lead body with two ends, and that a lead inherently has a body extending between proximal and distal ends. Pet. 33–34 (citing Ex. 1008, Figs. 1, 3).

Independent claim 1 further recites "P connector elements formed in a connector array along a first segment of the lead body proximate to the lead proximal end," i.e., limitation 1.c. Ex. 1001, 13:47–49. In support of its assertion that Young discloses this limitation, Petitioner provides an annotated version of Young's Figure 3, reproduced below. Pet. 34.



Petitioner annotated Young's Figure 3, which is a photograph of the complete component system for trigeminal stimulation, including an electrode, extension lead, and IPG (Ex. 1008, 74), to identify the distal and proximal ends of the electrode, the connector array of the extension lead, and the IPG. Petitioner argues Young discloses at least one connector along the lead proximal end because it teaches one electrode that connects to an IPG for stimulation. Pet. 34 (citing Ex. 1003, 72). Petitioner also argues Young's Figure 3 depicts a connector array with four possible connections on the extension lead that is connected to the IPG, thereby suggesting four connector elements in an array along the lead body is possible. *Id.*

Additionally, Petitioner asserts Gerber teaches existing leads have four electrodes built into the distal end of the lead to receive outputs from the IPG. *Id.* (citing Ex. 1010, 1:57–61, 3:48–50, 4:65–5:8). Per Petitioner, "in order to connect the electrodes at distal end to the IPG at the proximal end, Gerber inherently discloses up to four connectors proximate the lead proximal end, which is the first segment, between the IPG and electrodes." *Id.* (citing Ex. 1003, 72).

Independent claim 1 next recites "P stimulation electrodes arranged in an electrode array extending along a second segment of the lead body proximate to the lead distal end," i.e., limitation 1.d. Ex. 1001, 13:50–52. Petitioner argues: "Young discloses one electrode, but suggests multicontact electrodes or multiple active stimulation sites, which means there will be multiple electrodes." Pet. 34–35 (citing Ex. 1003 ¶ 104; Ex. 1008, 77). Petitioner further argues Gerber teaches leads having multiple electrodes, particularly two electrodes, arranged in an array at the distal end, which is a second segment of the lead body. *Id.* at 35 (citing Ex. 1010, Abstract, 1:57–58, 2:4–5, 4:32–45, 5:6–8, claim 1, Fig. 3).

Independent claim 1 further recites "P lead conductors extending between the P connector elements and the P stimulation electrodes," i.e., limitation 1.e. Ex. 1001, 13:53–54. Petitioner argues Young discloses one conductor wire between the electrode and a connector element for the electrode to function and provide pain relief. Pet. 35 (citing Ex. 1003 ¶ 106; Ex. 1008, 74). Petitioner also argues Gerber teaches that lead body 15 comprises at least one conductor wire within an insulating sheath, and that stimulation pulses are carried from the pulse generator through lead body 15 toward the distal end having at least one electrode contact. *Id.* at 35–36 (citing Ex. 1010, 3:52–56, 4:6–7). According to Petitioner, "where there are multiple electrodes as disclosed by Gerber, there will be multiple conductors extending between the connector elements attached to pulse generators at proximal end and the electrodes at the distal end." *Id.* at 36 (citing Ex. 1003, 73–74).

Independent claim 1 recites "a plurality of M tine elements formed in a tine element array extending along a third segment of the lead body

between the second segment of the lead body and the lead proximal end," i.e., limitation 1.f. Ex. 1001, 13:55–58. Petitioner contends Young's electrode includes at least two tine elements formed in a tine element array extending a third segment located between the electrode of the second segment and the lead proximal end. Pet. 36 (citing Ex. 1008, 73; Fig. 1). Petitioner also contends Gerber discloses multiple electrodes in the second segment. *Id.*

Independent claim 1 also recites "wherein the plurality of M tine elements are separate from and axially displaced from each other and from each of the P stimulation electrodes, and wherein all of the P stimulation electrodes are between the plurality of M tine elements and the lead distal end," i.e., limitation 1.h. Ex. 1001, 13:67–14:5. Petitioner argues Young discloses two sets of tines that are axially displaced from each other and also from the electrode. Pet. 37–38 (citing Ex. 1003, 75–76; Ex. 1008, 73, Fig. 1). Petitioner further argues that, to the extent Young does not disclose separate tine elements, Akerström teaches an arrangement of two spaced-apart series of loops. *Id.* at 38 (citing Ex. 1012, 2:56–59, Fig. 3). According to Petitioner, Akerström's loops look like tines, and a POSITA could have arranged tines as shown in Akerström. *Id.* (citing Ex. 1003, 76). Additionally, Petitioner asserts Gerber teaches two electrodes, as well as an electrode located between the anchoring mechanism and distal tip. *Id.* (citing Ex. 1010, Figs. 2–3). Per 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 allow for anchoring by fibrosis and would have located the tines between all electrodes and the lead distal end. *Id.* at 38–39 (citing Ex. 1003, 76–77; Ex. 1010, 4:15–30, Fig. 2).

Independent claim 1 further recites "wherein disposing the implantable medical lead within the introducer lumen comprises disposing the implantable medical lead within the introducer lumen with the MxN tines folded inward against the lead body by constraint imposed by the introducer lumen without overlapping one another," i.e., limitation 1.i. Ex. 1001, 14:6–11. Petitioner contends Figure 1 of Young shows each tine is shorter than the distance between the two sets of tines such that the tines cannot overlap one another. Pet. 39 (citing Ex. 1003, 78).

The last limitation of independent claim 1 recites "coupling the P connector elements to the implantable pulse generator," i.e., limitation 1.k. Ex. 1001, 14:17–18. Petitioner contends Young discloses that, after the electrode tip is within millimeters of the stimulation site, the proximal end of the electrode is tunneled subcutaneously and connected to an extension lead, which is connected to an IPG. Pet. 40–41 (citing Ex. 1008, 73–74).

Patent Owner does not dispute Petitioner's contentions with respect to what Petitioner designates as limitations 1.0–1.f, 1.h, 1.i, and 1.k. Petitioner's arguments and Mr. Pless's testimony find support in Young, Gerber, and Akerström. Young discloses a percutaneously placed electrode system for chronic electrical stimulation of the trigeminal sensory root to treat chronic facial pain. Ex. 1008, 73. Young's electrode system includes an implantable medical lead having a lead body, an electrode, and plurality of tine elements made up of a plurality of tines and located proximal to the electrode. *Id.* at 73, Fig. 1. Young's electrode system further includes an IPG connected to the end of the lead body opposite the electrode so that the lead body conducts electrical pulses from the IPG to the electrode. *Id.* at 74, Fig. 3. To implant Young's electrode, a No. 14 needle is directed toward the

center of the foramen ovale. *Id.* at 73. Once cerebrospinal fluid flows through the needle, the electrode is inserted and advanced through the needle until paresthesias could be induced. *Id.* After several days of percutaneous trial stimulation, the percutaneous extension is removed and the proximal electrode is connected to the extension lead, the distal end of which is connected to the implanted IPG. *Id.* Gerber teaches an implantable medical lead having a lead body, a plurality of conductors, a plurality of electrodes that are each electrically connected to a conductor of the plurality of conductors, a plurality of connectors for connecting the plurality of electrodes to an IPG, and an anchoring mechanism located separate and axially displaced from an electrode. Ex. 1010, Abstract, 1:57–61, 3:39–42, 3:48–50, 3:52–56, 4:6–7, 4:13–15, 4:32–33, 4:65–5:8, Figs. 2–3. Akerström teaches an electrode arrangement including flexible, proximally extending loops that are positioned on collars spaced apart from each other. Ex. 1012, 2:56–59, 3:52–59, Fig. 3. In view of the foregoing, Petitioner has persuasively identified what it designates as limitations 1.0–1.f, 1.h, 1.i, and 1.k in its proposed combination of Young, Gerber, Lindegren, and Akerström.

b. N flexible tines extending toward the lead proximal end and adapted to be folded inward against the lead body (limitation 1.g)

Independent claim 1 further recites:

> each tine element comprising N flexible tines, each tine having a tine width and a tine 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 toward the lead proximal end, whereby the MxN tines are adapted to be folded inward against the lead body when fitted into and constrained by the introducer lumen,

i.e., limitation 1.g. Ex. 1001, 13:58–67. Petitioner argues each of Young's two tine elements includes four flexible tines having a width, thickness, and length from a free tine end to an attached tine end attached to the tine element and lead body. Pet. 36–37 (citing Ex. 1008, Fig. 1). Petitioner further argues: "All 8 tines (2M x 4N) are adapted to fold inward against the lead body when constrained into the No. 14 Needle, i.e. introducer. Tines inherently fold inward against the lead body when fitted into and constrained by the introducer lumen." *Id.* at 37 (citing Ex. 1003, 74–75). Petitioner acknowledges Young's tines may not be proximally oriented, and contends Lindegren teaches four tines attached to a structure similar to that of Young and extending toward the proximal end. *Id.* (citing Ex. 1011, Fig. 3). Petitioner also contends 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.* (citing Ex. 1003, 75).

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 the tines in Young necessarily fold inward against the lead body." PO Resp. 20 (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 20–21; 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. 20 (citing Ex. 2029 ¶¶ 45–51)), 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 ¶ 49)). 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. 21 (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 adapted to be folded against the lead body. Reply 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. 2029, 109:14–110:16).

We agree with Petitioner that limitation 1.g recites tines adapted to be folded against the lead body and therefore 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 ¶¶ 48–50) 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 understand that Young teaches tines capable of folding against the lead body. Pet. 36–37; 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. 1008, 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.

In view of the foregoing, Petitioner has persuaded us that Young discloses tines adapted to be folded inwardly against the lead body. Petitioner also has persuaded us that Lindegren teaches tines extending toward the proximal end of the lead, as shown in Figure 3. Petitioner has shown limitation 1.g in its proposed combination of Young, Gerber, Lindegren, and Akerström.

c. Withdrawing the introducer to successively release the N tines to deploy outward to engage body tissue (limitation 1.j)

Independent claim 1 recites "withdrawing the introducer proximally from the tine element array to successively release the N tines of each of the M tine elements to deploy outward and toward the lead proximal end to engage body tissue and inhibit axial dislodgement of the P stimulation electrodes," i.e., limitation 1.j. Ex. 1001, 14:12–16. Petitioner argues that "[t]ines 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." Pet. 40 (citing Ex. 1003 ¶ 32). Petitioner also argues that, in view of Young's disclosure of the lead being advanced into place in the body and the tines working to prevent migration of the lead after the introducing needle was removed, a POSITA would have understood Young discloses withdrawing the needle deploys the tines successively so that the tines do not suffer damage and lose the ability to prevent electrode migration. *Id.* (citing Ex. 1003, 78–79; Ex. 1008, 73, 75).

Patent Owner argues that Young merely discloses advancing the lead and subsequently withdrawing the needle through which the lead was advanced, and that there is no evidence that withdrawing the needle deploys

the tines as limitation 1.j requires. PO Resp. 22 (citing Ex. 1008, 73; Ex. 2029 ¶¶ 34–41, 52–55); Sur-reply 2. According to Patent Owner, "[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." PO Resp. 22 (citing Ex. 2029 ¶ 52). Patent Owner also argues the tines of Young do not engage body tissue once deployed because the tines are placed in the fluid cavity of the trigeminal cistern, which does not contain tissue. *Id.* at 22–23 (citing Ex. 2029 ¶ 54); Sur-reply 3.

Petitioner replies that Young discloses the tines prevent the electrode from dislodging. Reply 5. Petitioner further replies that a POSITA would have understood the tines deploy only after exact placement of the electrode is obtained. *Id.*

Beginning with whether Young discloses withdrawing the introducer to deploy the tines, Young's electrode is implanted by directing a No. 14 needle toward the center of the foramen ovale until cerebrospinal fluid flows through the needle, then inserting and advancing the electrode through the needle until paresthesias is induced, and subsequently removing the needle. Ex. 1008, 73. Petitioner's argument is based on Mr. Pless's testimony that

> a POSITA 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 proximally towards the lead proximal end and the physician to deploy the tines successively so the tines did not suffer damage and lose its intended function to prevent electrode migration.

Ex. 1003, 78–79. Patent Owner's argument is based on Dr. Slavin's opinion that "[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 ¶ 52. Dr. Slavin's opinion, however, ignores Young's express disclosure that "[t]he purpose of the tines was to prevent the electrode from becoming dislodged after implantation." Ex. 1008, 73. If the tines came out of the needle before the electrode was properly placed at the stimulation site to induce paresthesias, the tines would cause the electrode to be secured at the inexact location. In view of Young's disclosure that the tines are intended to prevent the electrode from becoming dislodged, we find credible Mr. Pless's testimony that a POSITA would understand Young's tines are deployed by withdrawing the introducer, which occurs after the electrode is positioned in the stimulation site by advancing the electrode through the needle.

Turning to whether Young's tines engage body tissue, Patent Owner's argument that Young's tines do not engage body tissue is based on Dr. Slavin's testimony regarding the anatomy of the trigeminal cistern into which Young's electrode is placed. According to Dr. Slavin:

> [Young's] needle is inserted until reaching cerebrospinal fluid. This signals to the physician that the needle has reached the trigeminal cistern which is filled with cerebrospinal fluid and that the needle should not be advanced further. (Ex. 1008, 73.) The lead is then fed through the needle and the tip is advanced deeper into the cistern. (*Id.*) The tines, being just behind the electrode, are thus placed within this fluid cavity of the trigeminal cistern. So contrary to the assertion that the tines engage body tissue like the '756 patent, Young's tines float among nerve rootlets. The trigeminal cistern simply does not contain tissue for the tines to "engage."

Ex. 2029 ¶ 54. Dr. Slavin's testimony, however, is contrary to Young's express disclosure that the tines prevent dislodgement of the electrode. Tines must engage body tissue to secure the electrode. Although Young's electrode is inserted into the trigeminal cavity, which is filled with fluid, the

trigeminal cavity itself is surrounded by body tissue and includes nerve rootlets therein. *See* Ex. 2029 ¶ 38 (Dr. Slavin's depiction of the anatomy of the trigeminal nerve area showing the trigeminal cistern being formed within body tissue and enclosing nerve rootlets therein).

After considering the parties' arguments and evidence, Petitioner has persuaded us that Young discloses withdrawing the introducer to deploy the tines to engage body tissue, as limitation 1.j requires. Petitioner has shown limitation 1.j in its proposed combination of Young, Gerber, Lindegren, and Akerström.

d. Reasons for combining the teachings

Petitioner argues a POSITA would have been motivated to combine the teachings of Young, Gerber, Lindegren, and Akerström. Pet. 29–32. Petitioner contends a POSITA would have modified Young's electrode system to include a lead with multiple electrodes, as taught by Gerber, because "Young teaches that the single electrode 'could be improved to provide multiple active stimulation sites near the tip' and that 'patients who discontinued stimulation due to ineffective pain relief might have benefitted from a multicontact electrode [i.e. lead with multiple electrodes], which would permit greater flexibility in activation of a wider area.'" *Id.* at 30 (alteration in original) (quoting Ex. 1008, 77) (citing Ex. 1003 ¶ 104). Petitioner also contends that Gerber teaches its lead could use various anchoring means that affix by fibrosis, and that Young's tines and Akerström's loops secure via fibrosis. *Id.* Petitioner further contends that Lindegren teaches it would be preferable for manufacturing to have tines mounted on a ring-shaped means like a rubber band encircling the lead body (*id.*), and that Akerström's arrangement of loops shown in Figure 3 looks

very similar to Lindegren's tine-mounted rings and allows for easy manufacturing and adaptation to the needs of the stimulation site (*id.* at 31 (citing Ex. 1003 ¶¶ 107, 117)). Per Petitioner,

> in order to improve anchoring within the soft tissue near the sacrum, it would have been obvious to a POSITA to use multiples of tines mounted on collars (i.e. tine elements) extending proximally and spaced them apart as shown in Young and Akerstr[ö]m to further prevent dislodgment after implantation, i.e., a purpose of tines taught by Young.

Id. Additionally, Petitioner argues a POSITA would have combined the teachings of Young, Gerber, Lindegren, and Akerström because each of these references solve the same problem as the '756 patent in the same field. *Id.* at 29 (citing Ex. 1008, 73; Ex. 1010, 1:64–2:14; Ex. 1011, 1:20–27; Ex. 1013, 1:5–14; *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011)).

Patent Owner maintains Petitioner's proposed combination of the references is based on impermissible hindsight. PO Resp. 23–25. Patent Owner argues there would not have been a motivation to modify Young's lead to include Gerber's multiple electrodes so that the electrodes are distal to all of the lead's tines, as independent claim 1 requires. *Id.* at 25–32; Sur-reply 6–8. Patent Owner also argues there would not have been a motivation to combine the teachings of Young's lead with Lindegren's proximally extending tines, as recited in limitation 1.g. PO Resp. 32–35; Sur-reply 8. Patent Owner additionally argues Petitioner's general reasons for combining the teachings of the references are insufficient. PO Resp. 35–38.

Beginning with Petitioner's reasoning premised on the references solving the same problem as the '756 patent, Patent Owner argues none of

these references solve the same problem as the '756 patent. PO Resp. 37 (citing Ex. 2029 ¶¶ 74–81). We agree with Patent Owner. Petitioner characterizes the problem addressed in the '756 patent as "leads adequately stimulating the nerves while limiting dislodgement" (Pet. 29), but the '756 patent describes a more specific problem. According to the '756 patent:

> [T]here remains a need in the art for *a permanently implantable electrical sacral nerve stimulation lead that is capable of being passed percutaneously over a guide wire, and/or through the lumen of an introducer from the patient's skin to locate stimulation electrodes in casual contact with a sacral nerve*, that provides acute fixation with muscle and tissue layers posterior to the sacrum, and that can be bent to extend subcutaneously to the neurostimulator IPG without disturbing the fixation so that the stimulation electrodes are less likely to be dislodged during the acute recovery phase and the chronic implantation period.

Ex. 1001, 5:19–29 (emphasis added). The '756 patent addresses the need for a percutaneously implantable lead that is properly and securely positioned to provide sacral nerve stimulation, whereas the references do not. Young addresses placement of an implanted, percutaneously placed electrode system for electrical stimulation of the trigeminal sensory root for treatment of chronic facial pain. Ex. 1008, 73. Gerber contemplates the positioning and securement of an electrode that is implanted in the sacral area via a non-percutaneous surgical procedure. Ex. 1010, 2:9–13. Lindegren addresses the need for a cardiac lead that can be easily detached from the anchoring means and allow the lead to be replaced despite the anchoring means being stuck in the heart. Ex. 1011, 4:16–22. Akerström addresses the difficulties of inserting an endocardial lead with a voluminous electrode head into a vein. Ex. 1012, 1:20–28. Moreover, the nature of the problem to be solved is typically pertinent to the motivation for combining the teachings

of simpler mechanical technologies. *Tokai*, 632 F.3d at 1371 ("We have consistently stated that courts may find a motivation to combine prior art references in the nature of the problem to be solved, and that [t]his form of motivation to combine evidence is particularly relevant with simpler mechanical technologies." (alternation in original) (citations and internal quotations omitted)). The technologies in this proceeding involve medical devices implanted in the body for neurostimulation, not simple mechanical technologies. *See, e.g.*, Ex. 1001, 1:20–25 (describing the field of the invention for '756 patent as "an implantable medical electrical lead having at least one stimulation electrode adapted to be implanted near the sacral nerves for stimulation of a bundle of sacral nerve fibers and a fixation mechanism for providing chronic stability of the stimulation electrode and lead"). Accordingly, Petitioner's reasoning premised on Young, Gerber, Lindegren, and Akerström solving the same problem as the '756 patent does not persuade us that a POSITA would have had a reason to combine the teachings of the references.

Turning to Petitioner's reasoning for modifying Young's lead to include Gerber's multiple electrodes so that the electrodes are distal to all of the lead's tines, Petitioner's reasoning is premised on Young, which discloses "[t]he electrode could be improved to provide multiple active stimulation sites near the tip." Ex. 1008, 77. Petitioner argues this disclosure suggests multiple electrodes arranged distal to all of the tines because "[t]he tip referenced here is the distal tip where Young's original electrode was located, which is distal to all of the tines of Young." Reply 8; *see also* Ex. 2026, 168:12–21 (Mr. Pless testifying "I think a person of ordinary skill in the art would see that Young is recommending multiple

distal electrodes, and at least to me the natural thing would be to add the electrodes where the current electrode in Young is, which is distal to the tines").

Patent Owner argues Young's disclosure of improving its lead to provide multiple active stimulation sites, i.e., electrodes, near the tip would not have suggested to a POSITA to modify Young's lead to include a plurality of electrodes distal to all of the tines because such an arrangement would not be feasible in the complex anatomy of the trigeminal nerve region. PO Resp. 26 (citing Ex. 2029 ¶¶ 56–63); *see also* Sur-reply 6–8 (arguing that adding electrodes distal to all of the tines would render Young's tines inoperable for their intended purpose). Patent Owner's argument is based on Dr. Slavin's testimony:

> If, as Mr. Pless appears to assume, that Young is suggesting adding electrode(s) distal to the tines in figure 1, then the tines would have to get pushed back in the proximal direction (i.e., towards the foramen ovale) to accommodate the additional electrode(s). This means the tines would be out of the cistern, but moving the tines outside the cistern would result in them being in contact with, for example, the hard tissue of the trigeminal ganglion. But tines cannot anchor in such hard tissue, which would have prevented the tines from performing their intended function of stabilizing the lead electrode within the cistern.

Ex. 2029 ¶ 60 (footnote omitted). Patent Owner also argues that we should give no weight to Mr. Pless's opinion that a POSITA would have been motivated to combine the teachings of Young with other references because Mr. Pless lacks an understanding of the trigeminal nerve anatomy pertinent to Young's disclosure. PO Resp. 28–29. Patent Owner further argues that "[e]ven if a POSITA were motivated to try to improve the lead in Young—they would look to modify Young's lead to *remove* tines and would certainly

not consider rearranging them to arrive at the claimed invention." *Id.* at 29 (citing Ex. 2029 ¶ 63).

Petitioner replies that it is incorrect for Patent Owner to require Young's lead, as modified to include Gerber's multiple electrodes, to operate as intended in the trigeminal area. Reply 6–7. According to Petitioner, the proper inquiry is whether the proposed combination would achieve what is in the '756 patent claims. *Id.* at 7.

Petitioner, however, conflates the obviousness requirements of motivation to combine and reasonable expectation of success, which are distinct inquiries. *See, e.g.*, *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (explaining "two different legal concepts—reasonable expectation of success and motivation to combine"). Reasonable expectation of success contemplates the likelihood of success in combining the references to meet the limitations of the claimed invention, and failure to consider the appropriate scope of the claimed invention in evaluating a reasonable expectation of success constitutes a legal error. *Id.* In contrast, motivation to combine considers whether there would have been a suggestion or motivation to make the proposed combination of references. *Id.* at 1368. Although an unclaimed purpose is irrelevant to reasonable expectation of success, it may be pertinent to motivation to combine. *Id.* ("While [the deblocking of the prior art's azidomethyl group] is irrelevant to a finding that there was no reasonable expectation of success in meeting the claims of the '537 patent, which do not require quantitative deblocking at all, it is central to a finding of no motivation to combine."); *see also In re Gordon*, 733 F.2d 900, 902 Fed. Cir. 1984) (reversing a determination of obviousness because the proposed modification would have rendered the

prior art device inoperable for its intended purpose); *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) ("We find no error in the Board's rejection of TriVascular's argument that it would have been obvious to substitute the recessed barbs of Samuels '851 with the protuberances of Todd, since TriVascular's proposed substitution would destroy the basic objective of the barbs, which is to *penetrate* surrounding tissue.").

As the purpose of Young's lead, which is electrical stimulation of the trigeminal sensory root (Ex. 1008, 73), is relevant to assessing whether there would have been a motivation to combine, we credit Dr. Slavin's testimony that Young's disclosure of improving its lead to provide multiple active stimulation sites near the tip would not have suggested to a POSITA to modify Young's lead to include a plurality of electrodes distal to all of the tines because such an arrangement would not be feasible in the trigeminal nerve region. Moreover, contrary to Petitioner's argument, Young discloses multiple active sites *near* the tip, not at the tip or distal to the tines. In view of Young simply disclosing multiple active sites near the tip, without any relation to the tines, and Dr. Slavin's testimony that a POSITA would not understand Young to suggest multiple electrodes distal to all of the tines, Petitioner has not persuaded us that Young's disclosure of improving its lead to provide multiple active stimulation sites near the tip would have suggested to a POSITA to modify Young's lead to include a plurality of electrodes distal to all of the tines.

e. Conclusion for independent claim 1

Petitioner has demonstrated each limitation of independent claim 1 in its proposed combination of Young, Gerber, Lindegren, and Akerström. Petitioner, however, has not persuaded us that a POSITA would have had a

reason to combine Young's lead with Gerber's plurality of electrodes so the plurality of electrodes is distal to all of the lead's tines, as Petitioner proposes. Even without Patent Owner's proffered objective indicia of non-obviousness (PO Resp. 57–69; Sur-reply 15–30), Petitioner has not shown, by a preponderance of the evidence, that the subject matter of independent claim 1 would have been obvious over the combined teachings of Young, Gerber, Lindegren, and Akerström.

6. Independent claim 14

Petitioner relies on the same reasoning for combining the teachings of Young, Gerber, Lindegren, and Akerström to result in the subject matter of independent claim 14 as for combining the teachings of these references to result in the subject matter of independent claim 1. Pet. 29–32. As discussed above in section III.C.5.d, Petitioner's reasoning is not persuasive. Even without Patent Owner's proffered objective indicia of non-obviousness (PO Resp. 57–69; Sur-reply 15–30), Petitioner has not shown, by a preponderance of the evidence, that the subject matter of independent claim 14 would have been obvious over combined teachings of Young, Gerber, Lindegren, and Akerström.

7. Dependent claims

For the reasons discussed above in sections III.C.5.d and III.C.6, Petitioner has not persuaded us that a POSITA would have had a reason to combine the teachings of Young, Gerber, Lindegren, and Akerström to result in the subject matter of independent claims 1 and 14, from which claims 2, 5, 7, 13, 15, and 18 depend. Even without Patent Owner's proffered objective indicia of non-obviousness (PO Resp. 57–69; Sur-reply 15–30), Petitioner has not shown, by a preponderance of the evidence, that the

subject matter of dependent claims 2, 5, 7, 13, 15, and 18 would have been obvious over combined teachings of Young, Gerber, Lindegren, and Akerström.

D. Obviousness Based on Gerber, Hauser, and Akerström

As an alternative to its assertion that claims 1, 2, 5, 7, 13–15, and 18 are unpatentable over Young, Gerber, Lindegren, and Akerström, Petitioner challenges these claims under 35 U.S.C. § 103(a) as unpatentable over Gerber, Hauser, and Akerström. Pet. 48–68; Reply 10–14. Patent Owner argues that Petitioner's proposed combination of Gerber, Hauser, and Akerström would not have resulted in all of the claim limitations. PO Resp. 39–43; Sur-reply 10–11. Patent Owner also argues that there would not have been a motivation to combine the teachings of the references as Petitioner proposes. PO Resp. 43–57; Sur-reply 12–15.

As we discuss Gerber and Akerström above in sections III.C.2 and III.C.4, respectively, we begin our analysis of this asserted ground of unpatentability with an overview of Hauser. We then turn to the parties' contentions for each of the claims. For the reasons below, Petitioner has not shown, by a preponderance of the evidence, that the subject matter of claims 1, 2, 5, 7, 13–15, and 18 would have been obvious over the combined teachings of Gerber, Hauser, and Akerström.

1. Hauser

Hauser is directed to "an implantable defibrillation or cardioversion electrode and a method for placing the electrode on or about the heart to deliver electrical energy to the heart." Ex. 1013, 1:12–16. An electrode is shown in Figure 1, reproduced below.

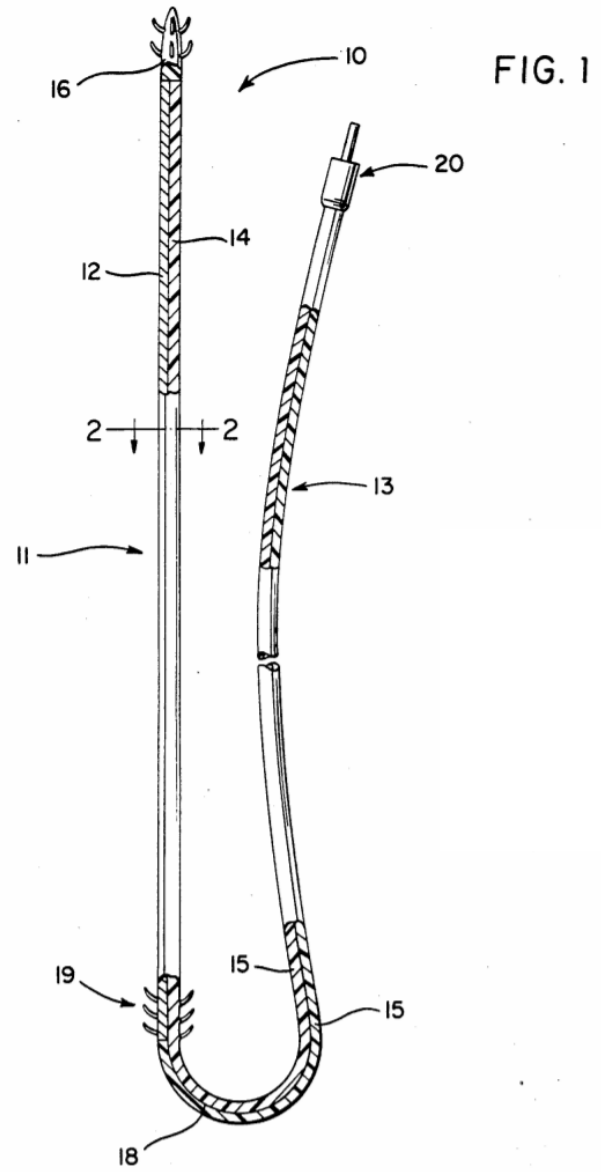
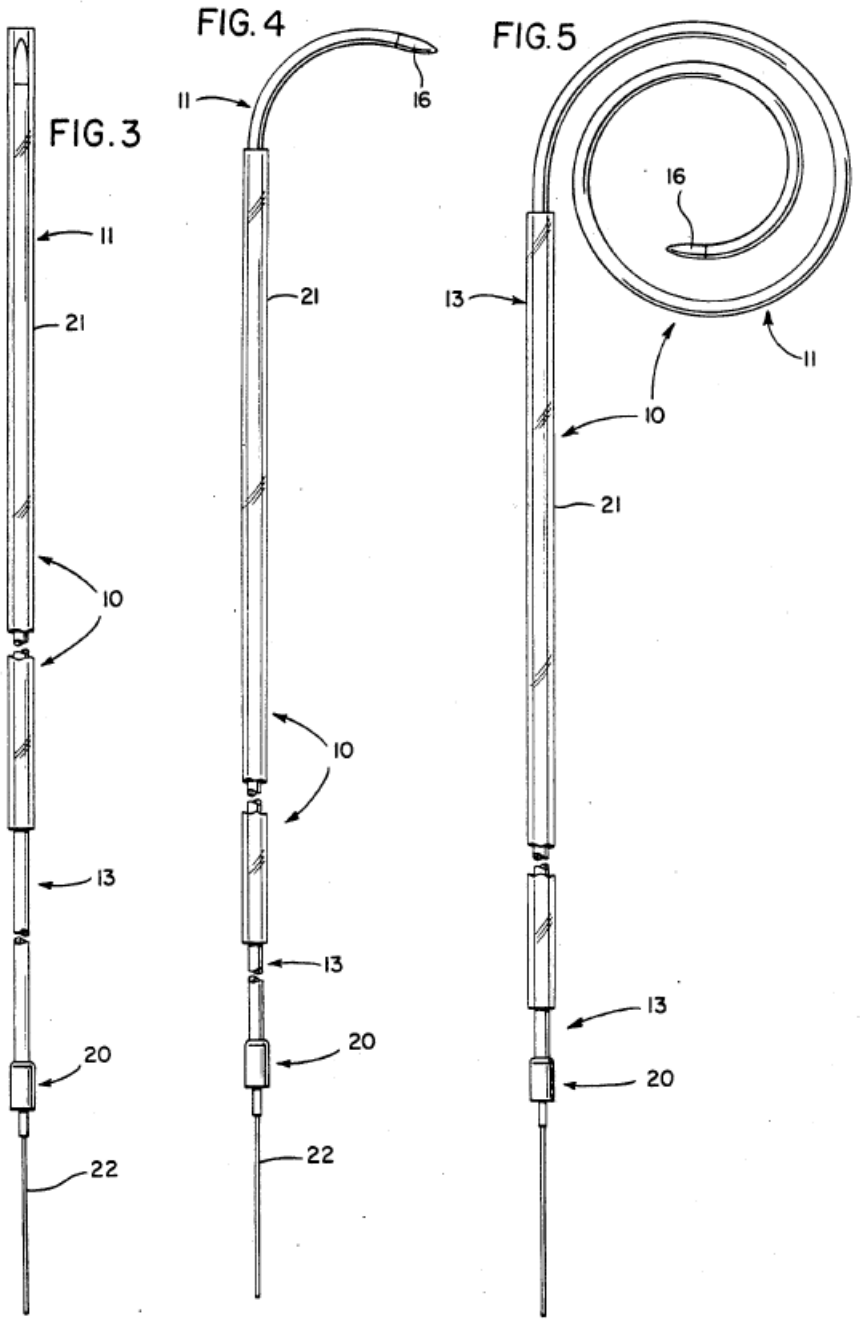


Figure 1 is a perspective view of the electrode in a partially straightened position. *Id.* at 3:9–10. Electrode 10 is thin and elongated, and includes distal active region 11 and proximal lead region 13. *Id.* at 3:50–52.

Conductive discharge surface 12 and insulative surface 14 define and extend the entire length of distal active region 11, and tapered, soft, insulative tip 16 terminates the distal end of distal active region 11. *Id.* at 3:52–55. Conductive discharge surface 12 and insulative surface 14 are preformed so that distal active region 11 adopts a planar spiral patch shape when in its relaxed state. *Id.* at 3:62–66, Fig. 6. Conductive element 18 surrounded by insulator 15 extends the entire length of proximal lead region 13. *Id.* at 3:55–57. Conductive element 18 is a lead electrically connecting at one end with conductive discharge surface 12. *Id.* at 3:57–60.

Distal insulative tip 16 includes fixation means 17 to anchor and stabilize electrode 10 relative to the heart. *Id.* at 3:67–4:1. Electrode 10 is also provided with proximal fixation means 19 to anchor electrode 10 at the location of entrance into the pericardial space. *Id.* at 4:3–8.

The implantation procedure of electrode 10 is shown in Figures 3–5, reproduced below.



Figures 3–5 are views during various stages of implantation of the electrode. *Id.* at 3:12–13, 4:30–32. First, catheter 21, having a cross section only

slightly larger than the cross section of electrode 10, is introduced through the skin and into the pericardial space, and electrode 10 is inserted into catheter 21 using stylet 22 through a lumen in the body of electrode 10, thereby straightening distal active region 11, as shown in Figure 3. *Id.* at 4:32–39. With catheter 21 containing electrode 10 and in position in the pericardial space, distal active region 11 is urged out of catheter 21 with stylet 22. *Id.* at 4:39–43. Distal active region emerges from catheter 21 as stylet 22 is withdrawn, and begins to take a relaxed, coiled shape, as shown in Figure 4. *Id.* at 4:41–47. As distal active region 11 continues to emerge from catheter 21, it assumes more of its relaxed planar spiral shape, as shown in Figure 5, and deployment continues until the entire distal active region 11 of electrode 10 is in place in the pericardial space. *Id.* at 4:47–51. Stylet 22 and catheter 21 are then removed, and proximal lead region 13 of electrode 10 is tunneled to the location where it will be connected to a pulse generator of the defibrillation/cardioversion system. *Id.* at 4:51–55.

2. *Independent claim 1*

a. Undisputed limitations (limitations 1.0–1.f, 1.h, 1.j, and 1.k)

In regard to what Petitioner designates as limitation 1.0, Petitioner contends that, to the extent the preamble is a limitation, Gerber discloses stimulating an electrode near the sacral nerve with pulses produced by an IPG[11]. Pet. 52 (citing Ex. 1010, Abstract, 2:31–36, 3:48–56). For limitation 1.a, which recites percutaneously introducing an introducer having an introducer lumen and disposing an implantable medical lead within the introducer lumen, Petitioner argues Gerber discloses the lead is inserted by

[11] The pulse generator disclosed in Gerber is Patent Owner's InterStim Neurostimulator Model 3023. Ex. 1010, 3:51–52.

first making an incision and using a cannula. *Id.* at 53 (citing Ex. 1010, 5:16–17, 5:26–28, 5:34–37). Petitioner further argues "[p]ercutaneous use of cannula as introducer [was] well known prior to 2001." *Id.* (citing Ex. 1003, 87[12], ¶ 96). Petitioner also contends Hauser teaches introducing a catheter through the skin and into the pericardial space, inserting the electrode into the catheter, and, when the catheter containing the electrode is in position in the pericardial space, urging the active region of the electrode out of the catheter. *Id.* (citing Ex. 1013, 4:32–43). Per Petitioner, Hauser's catheter inherently has proximal and distal ends, and the distal end is adjacent the heart, i.e., the stimulation site. *Id.* (citing Ex. 1003, 87[13]).

For limitation 1.b reciting a lead body, Petitioner argues "Gerber discloses: 'An implantable medical lead for stimulation of the sacral nerves comprises a lead body which includes a distal end and a proximal end . . . .'" *Id.* (quoting Ex. 1010, Abstract). For limitations 1.c–1.e, which respectively recite P connector elements, P stimulation electrodes, and P lead conductors, Petitioner relies on its arguments regarding Gerber's disclosure of these limitations with respect to its asserted ground of unpatentability premised on Young, Gerber, Lindegren, and Akerström. *Id.* at 53–54.

For limitation 1.f reciting a plurality of M tine elements, Petitioner argues Gerber discloses that an anchoring mechanism is located between the most proximal electrode and the proximal end of the lead body, and that the anchoring mechanism can provide for fibrosis. *Id.* at 54–55 (citing

[12] Mr. Pless's identification of limitation 1.a in the cited references is on page 87 of his Declaration. We consider Petitioner's citation to page 86 for this testimony to be a typographical error, and we understand Petitioner to be citing page 87.
[13] *See supra* note 12.

Ex. 1010, 4:13–30, Figs. 2, 6). Petitioner further argues a POSITA would turn to tines to affix by fibrosis. *Id.* at 55 (citing Ex. 1003, 89–90). Petitioner also contends Hauser teaches fixation means 19, which is made up of three sets of tines and located between the electrode region and the lead proximal end. *Id.* at 55–57 (citing Ex. 1013, 4:1–25, Figs. 6, 12). Per Petitioner, Hauser teaches fixation means 19 can be placed at other locations on the lead as determined by the surgeon, and a POSITA would have understood to place tine elements proximal for sacral lead implantation where there are soft tissues near the sacrum. *Id.* at 57 (citing Ex. 1003, 90–92). Additionally, Petitioner asserts Akerström teaches various arrangements of loops, including an arrangement where the loops are on collars in an array. *Id.* at 57–58 (citing Ex. 1012, 2:56–59, Fig. 3). According to Petitioner, a POSITA would have considered loops a variation of tines, and instead of loops, tines can be as easily attached to collars, arranged in an array, and mounted on a lead. *Id.* at 58 (citing Ex. 1003, 92–94).

In regard to limitation 1.h, which recites the plurality of M tine elements are separate from and axially displaced from each other and from the P stimulation electrodes such that all of the P stimulation electrodes are between the plurality of M tine elements and the lead distal end, Petitioner argues Hauser teaches three tine elements separate from and axially displaced from each other and from the stimulation electrodes. *Id.* at 59 (citing Ex. 1013, Figs. 1, 12). Petitioner further argues that, to the extent Hauser does not disclose tine elements separate and axially displaced from each other, Akerström teaches an arrangement, which can be easily adapted to tine elements, of several spaced-apart collars 6 provided with loops 5 and

slipped on insulation 2 of conductor 1. *Id.* at 60 (citing Ex. 1003, 95–96; Ex. 1013, 2:56–59, Fig. 3). Additionally, Petitioner asserts Gerber discloses the electrodes are between anchoring mechanism 50, which can anchor via fibrosis, and the lead distal end. *Id.*

With respect to limitation 1.j, which recites withdrawing the introducer to successively release the N tines to deploy outwardly, Petitioner contends Hauser teaches that tined fixation means 19 remains in catheter 21 until catheter 21 is removed. *Id.* at 61–62 (citing Ex. 1003, 96–97, ¶ 113; Ex. 1013, 4:3–8, 4:49–52, Figs. 5, 12). Petitioner further contends "[i]t is inherent that tines adapted to engage body tissue would successively deploy when no longer constrained by the catheter lumen upon withdrawal of the catheter." *Id.* at 61 (citing Ex. 1003, 96).

For limitation 1.k reciting coupling the P connector elements to the IPG, Petitioner argues that Gerber discloses this limitation because it discloses carrying stimulation pulses from the IPG toward the distal end having at least one electrode contact. *Id.* at 62 (citing Ex. 1003, 97–98; Ex. 1010, 3:52–56). Petitioner also argues Hauser inherently teaches the IPG is connected to the lead at the connector elements. *Id.* (citing Ex. 1003, 97).

Patent Owner does not dispute Petitioner's contentions with respect to what Petitioner designates as limitations 1.0–1.f, 1.h, 1.j, and 1.k. Petitioner's arguments and Mr. Pless's testimony find support in Gerber, Hauser, and Akerström. Gerber teaches an implantable medical lead having a lead body, a plurality of conductors, a plurality of electrodes that are each electrically connected to a conductor of the plurality of conductors, a plurality of connectors for connecting the plurality of electrodes to an IPG,

and an anchoring mechanism located separate and axially displaced from an electrode. Ex. 1010, Abstract, 1:57–61, 3:39–42, 3:48–50, 3:52–56, 4:6–7, 4:13–15, 4:32–33, 4:65–5:8, Figs. 2–3. Gerber discloses the lead is inserted by first making an incision and using a cannula. *Id.* at 5:16–17, 5:26–28, 5:34–37. Hauser teaches an electrode with proximal fixation means 19 made up of multiple sets of tines extending outwardly and proximally. Ex. 1013, 4:3–8, Fig. 12. Hauser's electrode is implanted by introducing a catheter through the skin and into the pericardial space, inserting the electrode into the catheter, urging the active region of the electrode out of the catheter until the active region is in place in the pericardial space, and then removing the catheter. *Id.* at 4:32–55. Akerström teaches an electrode arrangement including flexible, proximally extending loops that are positioned on collars spaced apart from each other. Ex. 1012, 2:56–59, 3:52–59, Fig. 3. In view of the foregoing, Petitioner has persuasively identified what it designates as limitations 1.0–1.f, 1.h, 1.j, and 1.k in its proposed combination of Gerber, Hauser, and Akerström.

b. N flexible tines extending toward the lead proximal end and adapted to be folded inward against the lead body (limitation 1.g)

For limitation 1.g reciting N flexible tines extending proximally and adapted to be folded inwardly against the lead body, Petitioner argues Hauser's fixation means 19 include flexible tines such that placement of the lead constrained within catheter 21 would fold all of the tines inwardly against the lead body. Pet. 58–59 (citing Ex. 1003, 94; Ex. 1012, Figs. 3, 12). Petitioner further argues that, to the extent Hauser does not teach a tine end directly attached to the lead body, Akerström teaches flexible loops extending outwardly from both the lead body and the tine element in a proximal direction. *Id.* at 59 (citing Ex. 1013, Fig. 7). Per Petitioner, a

POSITA would have considered loops to be a variation of tines, and tines can be similarly mounted to a collar and lead body, as shown in Akerström's Figure 7. *Id.* (citing Ex. 1003, 94–95; Ex. 1013, 2:26–28).

Patent Owner argues that Petitioner assumes Hauser's fixation means 19 are tines. PO Resp. 39; Sur-reply 10–11. Patent Owner further argues that one cannot draw any conclusions about fixation means 19 from Figures 3–5 because these figures do not show fixation means 19. PO Resp. 39–40 (citing Ex. 2030 ¶¶ 96–99); Sur-reply 11.

We disagree with Patent Owner that Petitioner assumes Hauser's fixation means 19 are tines. Rather, Petitioner's argument is based on Mr. Pless's testimony that fixation means 19 are tines. Pet. 58–59 (citing Ex. 1003, 94). Moreover, Hauser's fixation means 19 have a similar shape to tine elements 125, 130, 135, 140 in the '756 patent and other tines, such as Lindegren's tine-like projections 12. *Compare* Ex. 1013, Fig. 12, *with* Ex. 1001, Figs. 1–2; Ex. 1011, Fig. 3. Like tine elements 125, 130, 135, 140 in the '756 patent and Lindegren's tine-like projections 12, Hauser's fixation means 19 secure a lead in place in the body. Ex. 1001, 9:61–10:1; Ex. 1011, 7:18–27; Ex. 1013, 4:3–8. We also disagree with Patent Owner that a POSITA would not draw inferences regarding Hauser's fixation means 19 from Figures 3–5. According to Hauser, Figures 3–5 are "views during various stages of implantation of the electrode illustrated in F[igure] 1" (Ex. 1013, 3:12–13), and Figure 1 shows an electrode with fixation means 19 (*id.* at 4:3–8, Fig. 1). *See also* Reply 10–11 (citing Ex. 1022, 126:1–24 (Dr. Siegel testifying that Hauser's Figures 3–5 are views of the electrode of Figure 1)).

Patent Owner argues Petitioner's proposed combination of the references would not result in tines adapted to fold inward against the lead body, as recited in limitation 1.g. PO Resp. 40–42. According to Patent Owner, Hauser's lead, which is equipped with fixation means 19 and fits inside catheter 21, does not suggest that fixation means 19 are "adapted to be folded inward against the lead body when fitted into and constrained by a lumen of an introducer," as recited in limitation 1g. *Id.* at 40 (citing Ex. 2030 ¶¶ 96–99). Patent Owner also maintains that Hauser's fixation means would overlap, not fold against the lead body. *Id.* (citing Ex. 2030 ¶ 100). Regarding Akerström, Patent Owner contends that, in the Petition, Petitioner does not rely on Akerström for teaching flexible loops that fold inwardly against the lead body. *Id.* at 41. Nonetheless, Patent Owner alleges that loops and tines are very different structures, and that loops folding against the lead body is not the same thing as tines folding against the lead body. *Id.* at 42 (citing Ex. 1012, 1:15–32; Ex. 2030 ¶¶ 94–95); Sur-reply 11.

We agree with Patent Owner that Hauser's fixation means 19 are not adapted to be folded inwardly against the lead body because the tines would overlap and thus be folded inwardly against each other, not the lead body. *See* Ex. 1013, Fig. 12 (showing the length of the tines of fixation means 19 being longer than the proximal spacing between the tines). In view of Hauser's Figure 12, we credit Dr. Siegel's testimony that "if fixation means 19 were bent or folded, they could not lie against the lead body because (except for the last two projections) the adjacent projections would interfere with folding against the lead body." Ex. 2030 ¶ 100.

Nonetheless, Patent Owner's argument that Hauser's fixation means 19 are not adapted to be folded inwardly against the lead body and its remaining arguments address Hauser and Akerström individually, whereas Petitioner is relying on their combined teachings to result in the subject matter of limitation 1.g. "[T]he test for obviousness is what the *combined teachings* of the references would have suggested to those having ordinary skill in the art." *See In re Mouttet*, 686 F.3d 1322, 1333 (Fed. Cir. 2012) (emphasis added) (citing *In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981)). It matters not whether either Hauser's fixation means 19 or Akerström's loop arrangement teaches tines that are adapted to fold inwardly against the lead body because Petitioner is relying on its proposed combination of Hauser and Akerström in which Hauser's fixation means 19 are arranged like Akerström's loops. Contrary to Patent Owner's argument, Petitioner proposes to modify Hauser's tines to be arranged according to Akerström's arrangement of flexible loops that fold inwardly against the lead body. *See* Pet. 51–52 (arguing that "[Akerström's] arrangement of non-overlapping loops that fold to the lead body due to the collars being spaced apart also has the advantage of a smaller profile, which is suited to percutaneous delivery," and that "it would have been easy to replace Gerber's anchoring mechanism with Hauser's tines arranged in Akerstr[ö]m's array design"); Reply 11 ("[The] Petition discloses Akerstr[ö]m for teaching a design arrangement where the loops are adapted to be folded inward against the lead body without overlapping each other, and that tines of Hauser could be arranged in Akerstr[ö]m's design array." (citations omitted)). Hauser's fixation means 19 include a plurality of tine elements. Ex. 1013, Fig. 12. Akerström teaches an arrangement of loops that rest against the surface of an electrode

during insertion of the electrode in a vein. Ex. 1012, 3:8–11, 3:52–59, Fig. 3. Petitioner has shown that combining the teachings of Hauser's fixation means 19 and Akerström's loop arrangement would result in a plurality of tine elements that are adapted to be folded inward against the lead body when the lead is fitted into an introducer, as limitation 1.g requires.

After considering the parties' arguments and evidence, Petitioner has persuaded us that its proposed combination of Gerber, Hauser, and Akerström would result in a plurality of tines that are adapted to fold inwardly against the lead body, as limitation 1.g requires. Petitioner has shown limitation 1.g was reasonably suggested by its proposed combination of Gerber, Hauser, and Akerström.

c. Disposing the implantable medical lead within the introducer lumen with the MxN tines folded inward against the lead body without overlapping one another (limitation 1.i)

For limitation 1.i, which requires the MxN tines folded inward against the lead body without overlap, Petitioner acknowledges Hauser does not teach non-overlapping tines, and asserts Akerström's arrangement in Figure 3 includes loops each having a length that is shorter than the distance between the two sets of loops. Pet 60–61. Per Petitioner, a POSITA could have used Akerström's arrangement for tine elements with no overlapping tines. *Id.* at 60 (citing Ex. 1003, 96).

Patent Owner argues that Petitioner's proposed combination of the references would not result in non-overlapping tines, as limitation 1.i requires, because no reference teaches non-overlapping tines. PO Resp. 52. Patent Owner, however, addresses the references individually when Petitioner relies on their combined teachings. Hauser's fixation means 19

include a plurality of tine elements (Ex. 1013, Fig. 12), and Akerström teaches an arrangement of loops that rest against the surface of an electrode without overlap (Ex. 1012, 3:8–11, 3:52–59, Fig. 3). Accordingly, Petitioner has persuaded us that its proposed combination of Gerber, Hauser, and Akerström would result in a plurality of non-overlapping tines, as limitation 1.i requires. Petitioner has shown limitation 1.i was reasonably suggested by its proposed combination of Gerber, Hauser, and Akerström.

d. Reasons for combining the teachings

Petitioner argues a POSITA would have combined the teachings of Gerber, Hauser, and Akerström to modify Gerber's multi-electrode lead to have Hauser's multiple tined anchors, each mounted on collars, as taught by Akerström. Pet. 51. Petitioner contends 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.* (citing Ex. 1003 ¶ 115). Petitioner also argues that Akerström's arrangements of loops for anchoring by fibrosis are applicable to tines, and that Akerström's arrangement with 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. 1015, Fig. 3; Ex. 1003 ¶ 116). Petitioner further maintains "it would have been obvious to a POSITA in order to improve anchoring within the soft tissue near the sacrum to use multiples of tines 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. 43 (citing Ex. 2030 ¶¶ 101–131). 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.f, much less proximally extending tines that do not overlap as recited in limitations 1.g and 1.i. *Id.* at 42–43, 45–57; Sur-reply 12–15.

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. 45–46; Sur-reply 13. 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. 46 (citing Ex. 1010, 2:4–6, 2:9–17, 2:56–63, 3:39–58; Ex. 2030 ¶¶ 70–73); Sur-reply 14. 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. 1010, 4:12-31) would become more fixated in the body over time due to fibrosis." PO Resp. 47 (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. 47–48 (citing Ex. 1010, 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 48–49; Sur-reply 14. 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. 49 (citing Ex. 1010, 5:32–6:1, Fig. 6; Ex. 2030 ¶¶ 81, 105–107, 114–115); Sur-reply 14.

In regard to the reasoning for arranging Hauser's tines according to Akerström's arrangement so that the tines extend proximally and do not overlap, Patent Owner argues there would have been no motivation to include, in Gerber's lead, such an arrangement of tines. PO Resp. 52–56 (citing Ex. 2030 ¶¶ 122–124); Sur-reply 15. 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. 42–43, 54. Patent Owner also contends that Hauser illustrates fixation means projecting in both the proximal and distal directions (PO Resp. 56 (citing Ex. 1013, Figs. 1, 12)), and that Hauser provides no guidance to a POSITA regarding the appropriate orientation for the tines (*id.* (citing Ex. 2030 ¶¶ 125–131)).

Petitioner replies that it is incorrect for Patent Owner to consider the intended purpose of Gerber's lead. Reply 13. 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 '756 patent claims. *See id.* (referencing the arguments regarding the motivation to combine to the teachings of Young, Gerber, Lindegren, and Akerström). As we explain above in section III.C.5.d, 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 11–13. Per Petitioner, Dr. Siegel never analyzed the claims of the '756 patent, and his entire Declaration rests on the incorrect premise that the claims are limited to sacral neuromodulation. *Id.* at 11–12 (citing Ex. 1022, 100:17–24, 103:6–16, 104:1–10, 109:7–14, 109:24–110:6, 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 12 n.6.

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. 1010, 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 '756 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. 51 ("Gerber teaches that its anchoring means can be by fibrosis. . . . [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. 1010, 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. 51 (citing Ex. 1003 ¶ 115) (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, 15–16.

Gerber's lead, however, is for sacral nerve stimulation and is implanted in the sacral area via an open surgical procedure. Ex. 1010, 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. 1011, 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. 51), but Gerber's lead is implanted via an open surgical procedure (Ex. 1010, 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.

e. Conclusion for independent claim 1

Petitioner has demonstrated each limitation of independent claim 1 in its proposed combination of Gerber, Hauser, and Akerström. Petitioner, however, 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. 57–69; Sur-reply 15–30), 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.

3. Independent claim 14

Petitioner relies on the same reasoning for combining the teachings of Gerber, Hauser, and Akerström to result in the subject matter of independent claim 14 as for combining the teachings of these references to result in the subject matter of independent claim 1. Pet. 50–52. For the reasons discussed above in section III.D.2.d, Petitioner's reasons are not persuasive. Even without Patent Owner's proffered objective indicia of non-obviousness (PO Resp. 57–69; Sur-reply 15–30), Petitioner has not shown, by a preponderance of the evidence, that the subject matter of independent claim 14 would have been obvious over combined teachings of Gerber, Hauser, and Akerström.

4. Dependent claims

For the reasons discussed above in sections III.D.2.e and III.D.3, 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 and 14, from which claims 2, 5, 7, 13, 15, and 18 depend. Even without Patent Owner's proffered objective indicia of non-obviousness (PO Resp. 57–69; Sur-reply 15–30), Petitioner has not shown, by a preponderance of the evidence, that the subject matter of dependent claims 2, 5, 7, 13, 15, and 18 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, 5, 7, 13–15, 18	103(a)	Young, Gerber, Lindegren, Akerström		1, 2, 5, 7, 13–15, 18
1, 2, 5, 7, 13–15, 18	103(a)	Gerber, Hauser, Akerström		1, 2, 5, 7, 13–15, 18
Overall Outcome				1, 2, 5, 7, 13–15, 18

V. ORDER

In consideration of the foregoing, it is:

ORDERED that claims 1, 2, 5, 7, 13–15, and 18 of the '756 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.

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