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Paper 8
Entered: September 15, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS MODULATION TECHNOLOGIES, INC.,
Petitioner,

v.

MEDTRONIC, INC.,
Patent Owner.

IPR2020-00679
Patent 8,626,314 B2

Before WILLIAM V. SAINDON, JAMES A. TARTAL, and ALYSSA A. FINAMORE, *Administrative Patent Judges.*

FINAMORE, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314; 37 C.F.R. § 42.4

I. INTRODUCTION

Axonics Modulation Technologies, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1, 2, 4, 7, 10–12, 14, and 18–24 of U.S. Patent No. 8,626,314 B2 ("the '314 patent"). Paper 1 ("Pet."). Medtronic, Inc. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority, acting under the designation of the Director, to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4(a). We may not authorize an *inter partes* review to be instituted "unless . . . the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a).

Upon consideration of the arguments and evidence presented by both parties, we determine Petitioner has demonstrated a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. Accordingly, we institute an *inter partes* review of the challenged claims of the '314 patent.

II. BACKGROUND

A. Real Parties in Interest

Petitioner asserts that it is the real party in interest. Pet. 67. Patent Owner maintains that it is the real party in interest. Paper 4, 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 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.*, IPR2020-00715 (PTAB filed Mar. 16, 2020) (challenging U.S. Patent No. 8,036,756 B2) as related matters. Pet. 67–68; Paper 4, 2.

C. The '314 Patent (Ex. 1001)

The invention "relates generally to a method and apparatus that allows for stimulation of body tissue, particularly sacral nerves." Ex. 1001, 1:34–36. 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 1:36–41.

According to the '314 patent, leads typically have a number of ring-shaped stimulation electrodes spaced along a distal segment of the lead body that is adapted to be passed into the foramen along a selected sacral nerve. *Id.* at 2:47–51. Each distal stimulation electrode is coupled to a lead conductor extending proximally through the lead body. *Id.* at 2:52–54. 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 2:54–59.

The ’314 patent describes that “[a] problem associated with implantation of permanent and temporary neurostimulation leads involves maintaining the discrete ring-shaped electrodes 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 3:22–28. According to the ’314 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 3:29–33.

The invention of the ’314 patent “provides a solution to the problems associated with implanting and maintaining electrical leads in body tissue, particularly muscle tissue to maintain one or more lead electrode in relation to a particular body site, though use of minimally invasive implantation techniques.” *Id.* at 5:48–53. Figure 1, reproduced below, shows a sacral nerve stimulation lead of the invention. *Id.* at 8:51–52.

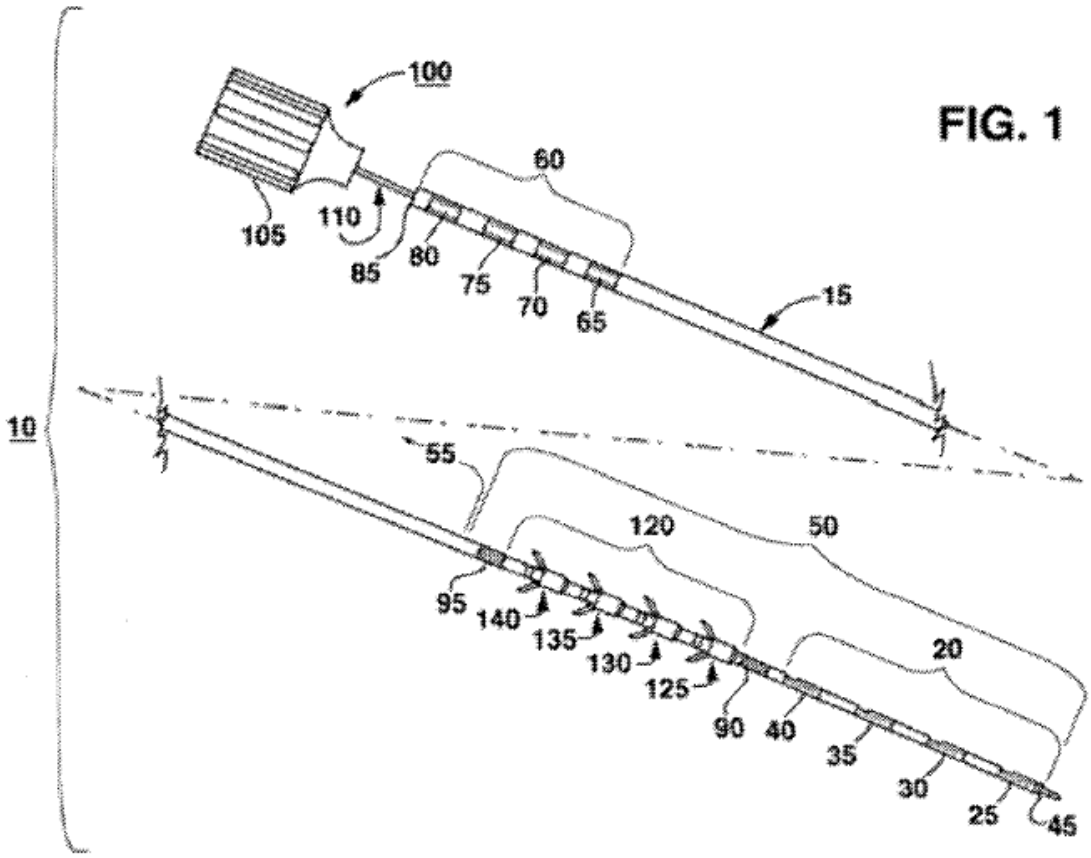


Figure 1 is a plan view showing implantable medical lead 10 for sacral nerve stimulation. *Id.* at 8:51–52, 9:25–26. Implantable medical lead 10 includes lead body 15 with electrode array 20 that extends proximally from lead distal end 45 and comprises P stimulation electrodes. *Id.* at 6:26–30, 9:25–30. As shown in Figure 1, electrode array 20 includes stimulation electrodes 25, 30, 35, 40 such that P=4. *Id.* at 9:25–30. 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 9:41–45. 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 6:33–37, 9:45–49. Connector elements 65, 70, 75, 80 are adapted to be coupled with a neurostimulator IPG. *Id.* at 9:62–65.

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 5:65–6:5, 10:12–16. The fixation mechanism comprises M tine elements in tine element array 120. *Id.* at 6:5–8, 10:16–19. As shown in Figure 1, tine element array 120 includes tine elements 125, 130, 135, 140 such that M=4. *Id.* at 10:16–19.

Figure 3, reproduced below, shows a tine element. *Id.* at 8:59–60.

FIG. 3

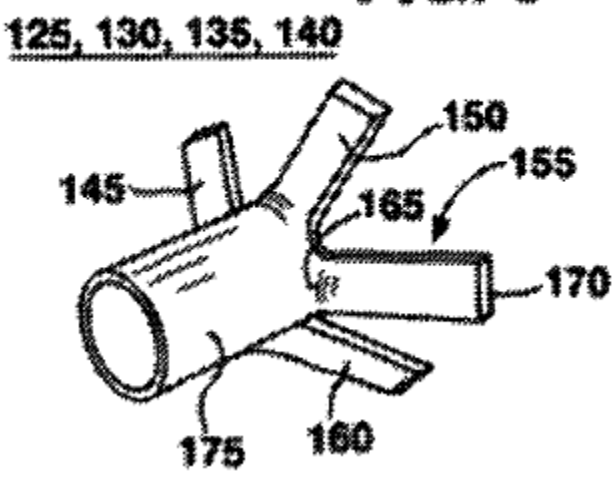
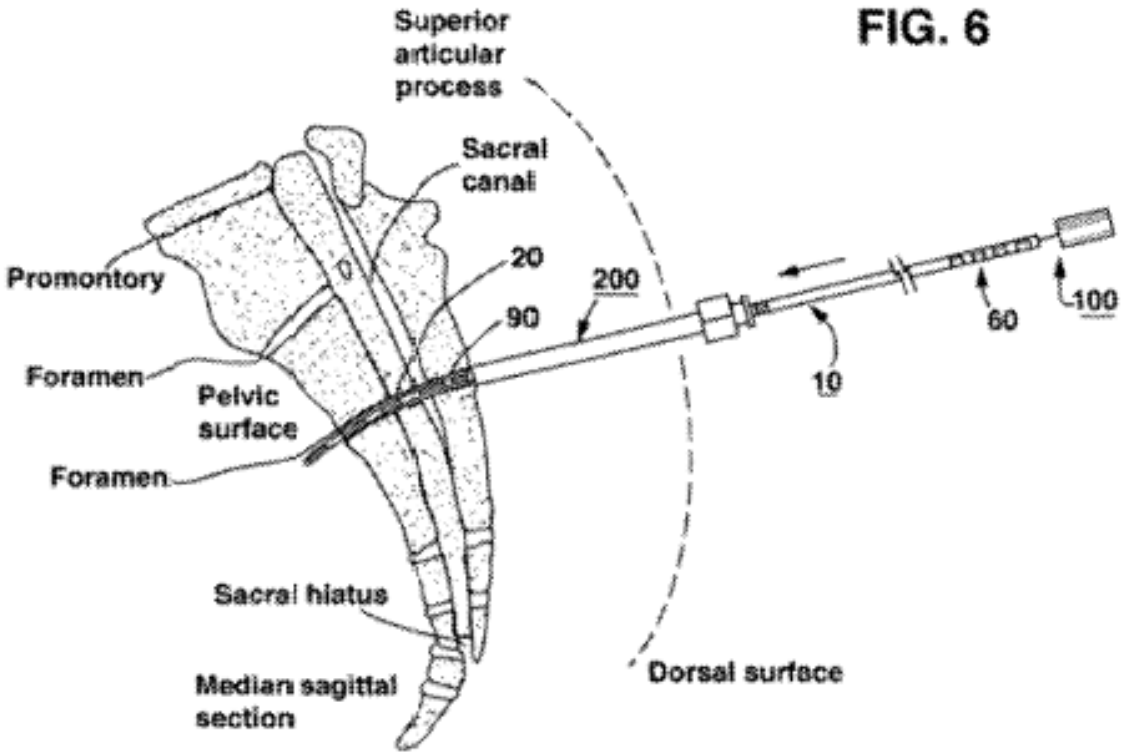


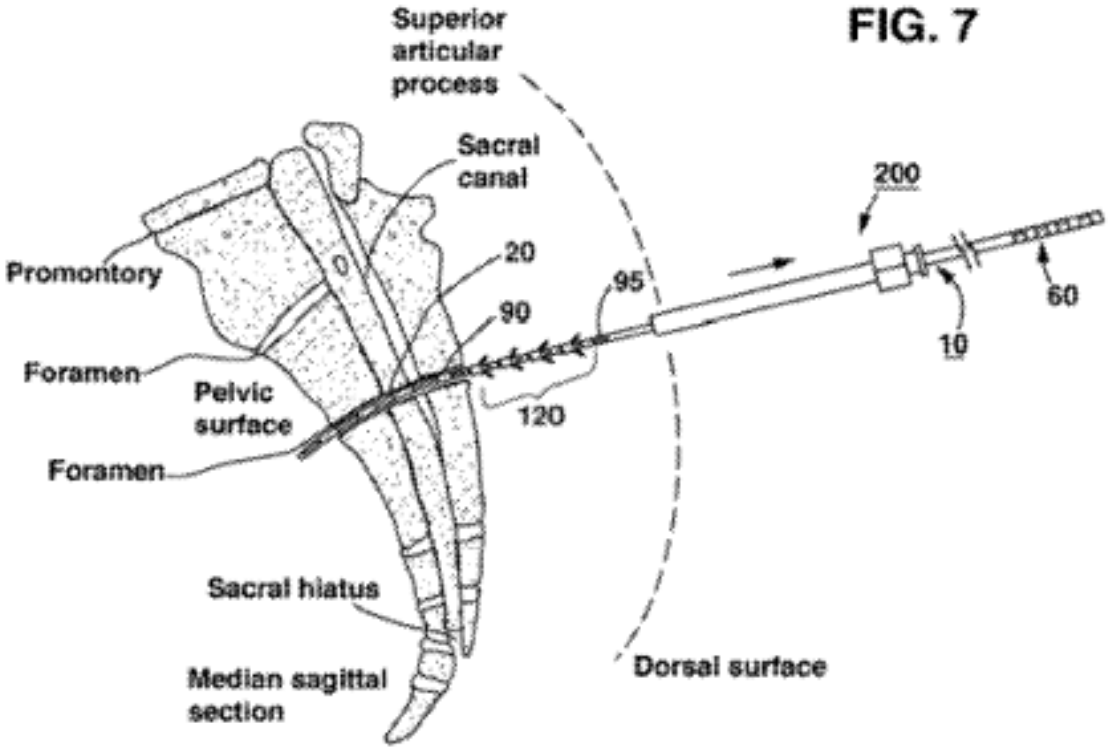
Figure 3 is an expanded perspective view showing one of tine elements 125, 130, 135, 140. *Id.* Each tine element comprises N flexible, pliant tines. *Id.* at 6:8–9; 10:26–27. As shown in Figure 3, the tine element includes tines 145, 150, 155, 160 such that N=4. *Id.* at 10:26–29. Each tine extends through a tine length from attached tine end 165 to free tine end 170. *Id.* at 10:29–32. Attached tine end 165 is attached to lead body 15 at a tine attachment site so that the tine extends outwardly of lead body 15 and

proximally toward lead proximal end 85. *Id.* at 10:32–35. The tines are adapted to be folded inward against lead body 15 when fitted into and constrained by the lumen of an introducer, and the folded tines do not overlap one another. *Id.* at 6:15–19, 10:35–41.

Figures 6 and 7, reproduced below, illustrate steps of implanting lead 10. *Id.* at 11:22–24.

FIG. 6





Figures 6 and 7 are cross-section views of the sacrum schematically illustrating steps of implanting lead 10. *Id.* at 9:1–9. Introducer 200 can be advanced into position over a guide wire previously percutaneously advanced into the foramen from a skin incision. *Id.* at 11:46–48. Lead 10 is advanced through the introducer lumen proximal end opening into the introducer lumen. *Id.* at 11:58–61. 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 11:61–65. 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 11:66–12:6. 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 12:6–11. Once introducer 200 is completely removed, proximal portion 55 of lead body 15 is bent laterally and implanted through a subcutaneously tunneled path to the neurostimulator IPG. *Id.* at 12:20–25.

D. Challenged Claims

Petitioner challenges claims 1, 2, 4, 7, 10–12, 14, and 18–24 of the '314 patent. Pet. 1, 16. Claims 1, 11, and 18 are independent. Ex. 1001, 13:51–14:11, 14:54–15:20, 15:55–16:31. Independent claim 1 is illustrative and reproduced below, adding Petitioner's labels for the limitations.

> 1. [1.0] A system comprising:
> [1.a] an implantable medical lead comprising:
> [1.b] a lead body extending between a proximal end and a distal end;[1.c] a plurality of conductors within the lead body;[1.d] a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors; and[1.e] a plurality of tine elements extending from the lead body, wherein all tine elements of the plurality of tine elements are positioned between a most proximal electrode of the plurality of electrodes and the proximal end of the lead body, [1.f] each tine element comprising a plurality of flexible, pliant tines, each tine having a tine width and thickness and extending a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead body from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end, [1.g] wherein the plurality of tines of the plurality of tine elements are adapted to be folded inward against the lead body when fitted into and constrained by a lumen of an introducer without overlapping one another and deploy outward

> to engage body tissue when the introducer is withdrawn to release the plurality of tines, [1.h] wherein the plurality of tine elements is separate from and axially displaced from the plurality of electrodes.

Id. at 13:51–14:11.

Like independent claim 1, independent claim 11 recites a system comprising an implantable medical lead having a lead body, a plurality of conductors, a plurality of electrodes, and a plurality of tine elements. *Id.* at 14:54–15:20. Independent claim 11 additionally recites that the system comprises an implantable pulse generator, and that the implantable medical lead is configured to be introduced through and released into body tissue via an introducer defining an introducer lumen. *Id.* Independent claim 18 recites a method that is similar to the systems of independent claims 1 and 11. *Id.* at 15:55–16:31.

Claims 2, 4, 7, 10, and 22 depend from independent claim 1. *Id.* at 14:12–16, 20–25, 37–38, 52–53, 16:49–51. Claims 12, 14 and 23 depend from independent claim 11 (*id.* at 15:21–24, 28–33, 16:52–54), and claims 19–21 and 24 depend from independent claim 18 (*id.* at 16:32–48, 56–59).

E. Evidence

Petitioner relies on the following references in asserting that the challenged claims are unpatentable. Pet. 16.

Reference	**Exhibit No.**
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")	1010

Gerber, US 6,055,456, issued Apr. 25, 2000 ("Gerber")	1012
Lindegren, WO 98/20933, published May 22, 1998 ("Lindegren")	1013
Hauser et al., US 5,052,407, issued Oct. 1, 1991 ("Hauser")	1014
Akerström, US 4,407,303, issued Oct. 4, 1983 ("Akerström")	1015

Petitioner also relies on a Declaration of Mr. Benjamin Pless (Ex. 1003). Pet. 16.

F. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability. Pet. 16.

Claims Challenged	**35 U.S.C. §**	**References**
1, 2, 4, 7, 10–12, 14, 18–24	103(a)	Young, Gerber, Lindegren
18, 20, 21	103(a)	Young, Gerber, Lindegren, Hauser
1, 2, 4, 7, 10–12, 14, 18–24	103(a)	Gerber, Hauser, Akerström

III. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner contends a person of ordinary skill in the art 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. 12 (citing Ex. 1003 ¶ 52). Patent Owner disagrees

with Petitioner's proffered level of ordinary skill in the art, but does not provide its own explanation of the level of ordinary skill. Prelim. Resp. 16.

Based on our review of the record at this stage of the proceeding, we find the evidence generally supports Petitioner's proposed level of ordinary skill. The '314 patent and Gerber are each directed to an implantable medical electrical lead for stimulation of a bundle of sacral nerve fibers. Ex. 1001, 1:36–41, Figs. 1, 5–8; Ex. 1012, 1:9–12, Figs. 2, 3, 6. Young regards an implanted, percutaneously placed electrode system for chronic stimulation of the trigeminal nerve root for treatment of chronic facial pain. Ex. 1010, 73, Fig. 1. Accordingly, for purposes of this decision on institution, we adopt Petitioner's explanation of the level of ordinary skill in the art.

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). 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, at this stage in the proceeding, we expressly construe the claims to the extent necessary to determine whether to institute *inter partes* review. *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 the claim term "a plurality of tine elements" should be construed as "at least two or more structures that mount to the lead body, each structure comprising of multiple tines attached to the structure." Pet. 15. Patent Owner cursorily disagrees with Petitioner's proposed construction, but does not proffer a construction. Prelim. Resp. 16–17. On this record, we determine that no claim term requires an express construction for the purpose of determining whether to institute *inter partes* review.

C. Obviousness Based on Young, Gerber, and Lindegren

Petitioner challenges claims 1, 2, 4, 7, 10–12, 13 and 18–24 under 35 U.S.C. § 103(a), contending the claimed subject matter is obvious over Young, Gerber, and Lindegren. Pet. 17–39. In contrast, Patent Owner argues Petitioner fails to demonstrate that the cited references disclose each claim limitation, and also fails to establish that a person of ordinary skill in the art would have been motivated to combine the teachings of the references to arrive at the claimed invention. Prelim. Resp. 18–36. 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.

1. Young (Ex. 1010)

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. 1010, 73. The trigeminal stimulating electrode[1] is shown in Figure 1 below. *Id.*

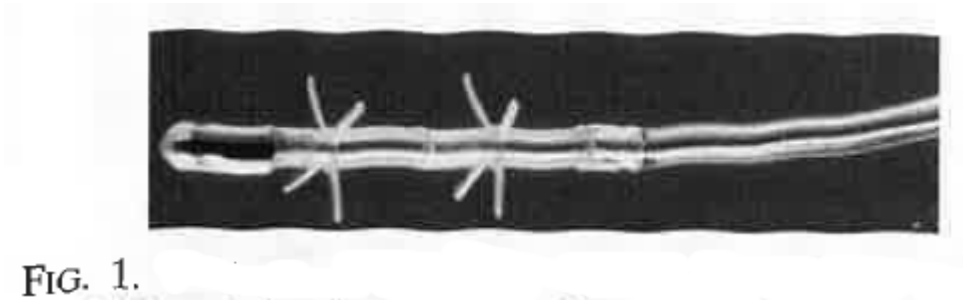


FIG. 1.

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[2] as shown in Figure 3 below. *Id.* at 74.

[1] The trigeminal stimulating electrode disclosed in Young is Patent Owner's Quintatrigeminal electrode. Ex. 1010, 73.
[2] The implanted pulse generator system disclosed in Young is Patent Owner's ITREL. *Id.* at 74.

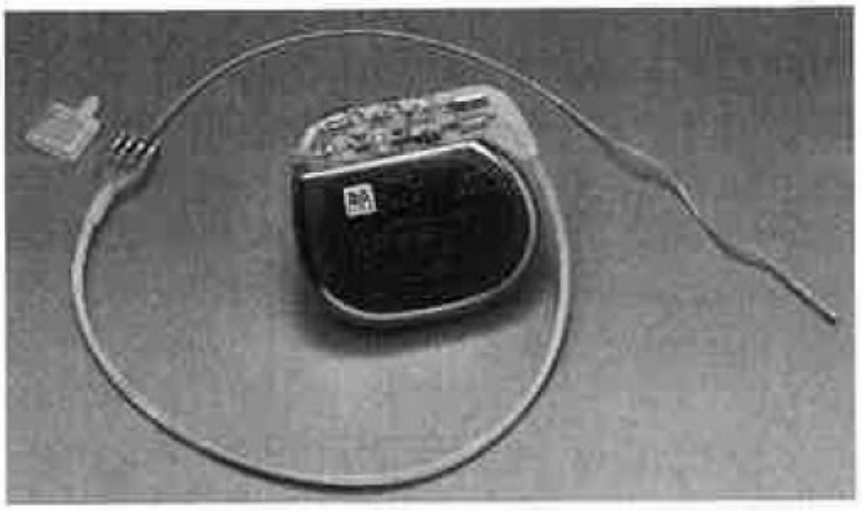


Figure 3 is a photograph of the complete component system for trigeminal stimulation, including the electrode, the implanted pulse generator, and an extension lead. *Id.*

2. *Gerber (Ex.1012)*

Gerber discloses "an implantable medical lead having at least one electrode contact wherein the lead is implanted near the sacral nerves for stimulation of a bundle of nerve fibers." Ex. 1012, 1:9–12. Figure 1, reproduced below, shows the implantable medical lead for stimulation of the sacral nerves. *Id.* at 3:40–42.

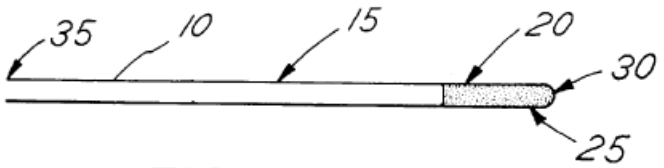


FIG. 1

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, 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.

As shown in Figure 2 below, implantable medical lead 10 may have an anchoring mechanism to fixate the lead in the desired position. *Id.* at 4:13–15.

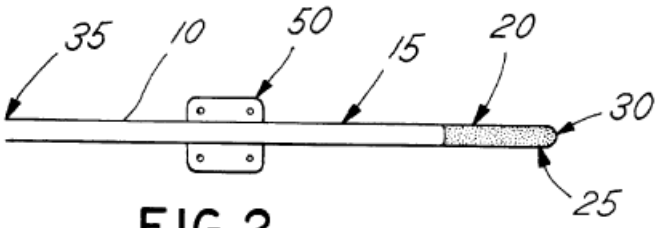


FIG.2

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. *Id.* at 4:32–33.

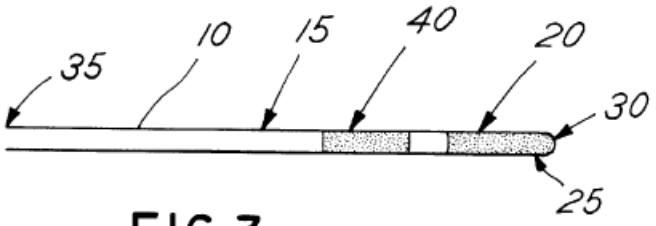


FIG.3

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, 26–28.

3. Lindegren (Ex. 1013)

Lindegren discloses an implantable electrode lead with "an electrode head equipped with external anchoring means, such as tine-like position-fixation means." Ex. 1013, 1:6–11. The position-fixation means 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. *Id.* at 6:30–32.

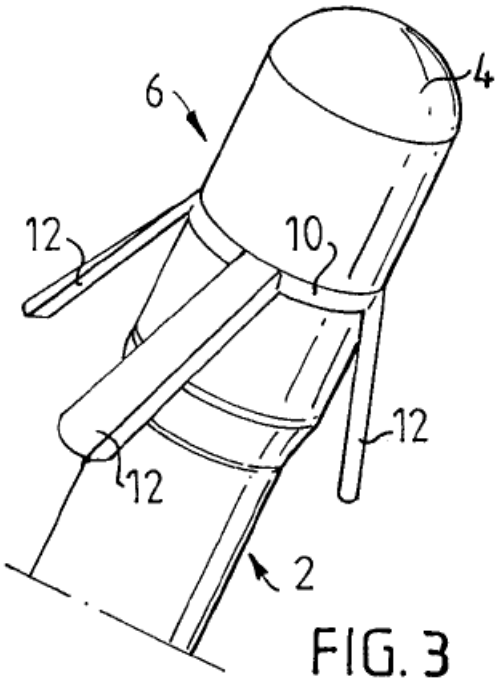


FIG. 3

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. Independent claim 1

a. Rationale

Petitioner argues a person of ordinary skill in the art would have been motivated to combine the teachings of Young, Gerber, and Lindegren for several reasons. Pet. 22–24. In particular, Petitioner contends a person of ordinary skill in the art 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.'" *Id.* at 23 (quoting Ex. 1010, 77). Petitioner also contends a person of ordinary skill in the art would have modified Young's electrode system to include Lindegren's tine-mounted rings because Lindegren teaches that it would be preferable for manufacturing to have tines mounted on a ring-shaped means like a rubber band encircling the lead body. *Id.* at 23 (citing Ex. 1003 ¶ 91). Petitioner further asserts "it would have been easy and feasible to utilize Lindegren's tine-mounted rings with tines extending proximally and spaced apart as shown in Young to further prevent dislodgement after implantation, which is a purpose of the tines stated in Young." *Id.* at 24. Additionally, Petitioner argues a person of ordinary skill in the art would have combined the

teachings of Young, Gerber, and Lindegren because each of these references addresses the problem of adequately stimulating nerves while limiting electrode migration. *Id.* at 22 (citing Ex. 1010, 73; Ex. 1012, 1:64–2:13; Ex. 1013, 1:20–27, 4:32–5:7; *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011)).

In contrast, Patent Owner argues Petitioner fails to establish that it would have been obvious to combine Young with Gerber and Lindegren. Prelim. Resp. 34–36. Patent Owner contends a person of ordinary skill in the art would not have looked to Young to securely fix a lead because Young's tines fail to prevent lead migration. *Id.* at 34 (citing Ex. 2012[3], 1558, 1563). Patent Owner's evidence, however, shows the electrode disclosed in Young is at least somewhat effective in preventing lead migration. Ex. 2012, 1563 (teaching the electrode disclosed in Young, i.e., the 3981 electrode, dislocated in 30 percent of patients), Fig. 157-12 (showing the 3981 electrode has fewer incidents of dislocation than the 3483 S electrode). Regardless of whether the lead was later found to dislocate in some percentage of patients, Young nonetheless discloses that the tines address the problem of lead migration. Ex. 1010, 73 ("The purpose of the tines was to prevent the electrode from becoming dislodged after implantation."). Moreover, in addition to the Young, Gerber, and Lindegren references describing the problem of lead migration, Petitioner's reasons for the proposed combination also include reliance on Young's disclosure of the desire for more multiple active stimulation sites and Lindegren's teaching of

[3] *Textbook of Stereotactic and Functional Neurosurgery* (Philip L. Gildenberg & Ronald R. Tasker eds., 1998) (Ex. 2012).

manufacturing efficiencies associated with tines mounted on a ring-shaped means. Pet. 23.

Patent Owner also contends that Petitioner makes no attempt to reconcile the differences in the anatomy at issue in Young, Gerber, and Lindegren, and that it was incumbent upon Petitioner to accord the different uses, i.e., applications with different anatomies, for the leads disclosed in the references. Prelim. Resp. 35–36. The Supreme Court, however, has held "familiar items may have obvious uses beyond their primary purposes, and in many cases, a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007).

At this stage of the proceeding, Petitioner has shown sufficiently that Young suggests an electrode system having multiple electrode contacts. Ex. 1010, 77 ("The electrode could be improved to provide multiple active stimulation sites near the tip."). Petitioner also has demonstrated sufficiently that Lindegren suggests an electrode system with tine-mounted rings. Ex. 1013, 5:17–20 ("From the manufacturing point of view, having the projections devised as an integral part of a one-piece ring-shaped means and evenly distributed around the circumference of the ring-shaped means, should be preferable."). Accordingly, on the current record, Petitioner has provided persuasive reasoning why a person of ordinary skill would have combined the teachings of Young, Gerber, and Lindegren in the manner set forth in the Petition.

b. Undisputed claim limitations (limitations 1.0–1.d and 1.h)

The preamble of independent claim 1, i.e., limitation 1.0, recites "[a] system." Ex. 1001, 13:51. Petitioner contends that, to the extent the

preamble is a limitation, Young, Gerber, and Lindegren disclose a system. Pet. 24.

Independent claim 1 further recites "an implantable medical lead comprising: a lead body extending between a proximal end and a distal end," i.e., limitations 1.a–1.b. Ex. 1001, 13:52–54. Petitioner argues the electrode described in Young discloses these limitations. Pet. 24–25 (citing Ex. 1010, 73–74).

Independent claim 1 next recites "a plurality of conductors within the lead body," i.e., limitation 1.c. Ex. 1001, 13:55. Petitioner contends Young inherently discloses one conductor connecting the electrode to the IPG so that the electrode can function and stimulate a patient's nerve. Pet. 25 (citing Ex. 1010, 73–74). Petitioner further contends Gerber teaches "lead body 15 of the present invention comprises one or more conductor wire(s) within an insulating sheath." *Id.* (quoting Ex. 1012, 4:6–7).

Independent claim 1 also recites "a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors," i.e., limitation 1.d. Ex. 1001, 13:56–58. Petitioner argues: "Young discloses one electrode, but states '[t]he electrode could be improved to provide multiple active stimulation sites near the tip.' Ex. 1010 at 77. Multiple active stimulation sites mean that there will be multiple electrodes. Ex. 1003 at 68." Pet. 25–26. Petitioner further argues Gerber teaches multiple electrodes that are each electrically connected to a conductor for carrying stimulation pulses from the IPG to the electrode. *Id.*

at 26 (citing Ex. 1012, Abstract, 1:57–58, 2:4–5, 3:52–56, 4:32–33, claim 1, Fig. 3; Ex. 1003, 67–68[4]).

The last limitation of independent claim 1 recites "wherein the plurality of tine elements is separate from and axially displaced from the plurality of electrodes," i.e., limitation 1.h. Ex. 1001, 14:9–11. Petitioner argues Young discloses two sets of tines that are separate from and axially displaced from the one electrode. Pet. 29 (citing Ex. 1010, Fig. 1). Petitioner also argues Gerber teaches two electrodes, as well as an anchoring mechanism located separate from and spaced apart from an electrode. *Id.* (citing Ex. 1012, Fig. 2).

At this stage of the proceeding, Patent Owner does not dispute Petitioner's contentions for claim limitations 1.0–1.d and 1.h. On the current record, our review of the cited references is consistent with Petitioner's arguments and Mr. Pless's testimony. For example, Petitioner has shown sufficiently for purposes of this Decision that Young discloses an implantable medical lead having a lead body, one electrode electrically connected to a conductor for carrying electrical pulses from an IPG to the electrode, and a plurality of tine elements separate from and axially displaced from the electrode. Ex. 1010, 73–74, Figs. 1, 3. Petitioner also has demonstrated sufficiently that Gerber discloses an implantable medical

[4] In arguing that Gerber teaches limitation 1.d, Petitioner cites to pages 68–69 of Mr. Pless's Declaration (Ex. 1003). Pet. 26. Mr. Pless, however, discusses this limitation on pages 67–68 of his Declaration. Thus, we understand that the citation to pages 68–69 of Exhibit 1003 is a typographical error, and that Petitioner is relying on pages 67–68 of Mr. Pless's Declaration to support its argument that Gerber teaches limitation 1.d. Moreover, as we note throughout this Decision, many of Petitioner's citations to Mr. Pless's Declaration are off by one page.

lead having a lead body, a plurality of conductors, a plurality of electrodes each electrically connected to a conductor of the plurality of conductors, and an anchoring mechanism located separate from and axially displaced from an electrode. Ex. 1012, Abstract, 3:39–42, 52–56, 4:6–7, 13–15, 32–33, Figs. 2–3. Based on the record at this stage of the proceeding and for purposes of this Decision, Petitioner has shown sufficiently how it contends the cited references disclose these claim limitations.

c. Plurality of tine elements (limitation 1.e)

Independent claim 1 recites "a plurality of tine elements extending from the lead body, wherein all tine elements of the plurality of tine elements are positioned between a most proximal electrode of the plurality of electrodes and the proximal end of the lead body," i.e., limitation 1.e. Ex. 1001, 13:59–62. Petitioner contends the electrode described in Young discloses at least two tine elements located between the electrode and the lead proximal end. Pet. 26 (citing Ex. 1010, 73; Fig. 1). Petitioner further contends Gerber teaches an anchoring mechanism located between the most proximal electrode and the proximal end of the lead body. *Id.* at 27. According to Petitioner, Gerber teaches the anchoring mechanism allows the medical lead to fibrose naturally into the human body, and a skilled artisan would know that tines are a widely used fibrosing anchoring means. *Id.* (citing Ex. 1012, 4:13–30, Fig. 3; Ex. 1003, 69[5]).

[5] Mr. Pless's testimony regarding a skilled artisan's understanding that tines are a known fibrosing anchoring means is on page 69 of his Declaration. We consider Petitioner's citation to page 70 for this testimony to be a typographical error, and we understand Petitioner to have intended to cite page 69.

Patent Owner argues Petitioner fails to demonstrate how the prior art discloses the recited "plurality of tine elements" under its proposed construction. Prelim. Resp. 20–23. We disagree. Pursuant to its definition, Petitioner argues that the electrode described in Young discloses an electrode consisting of a lead body with two sets of four tines, i.e., two structures each comprising four tines. *Id.* at 26 (citing Ex. 1010, 73, Fig. 1).

On the current record, Mr. Pless's testimony provides support for Petitioner's arguments regarding this limitation, and our review of Young and Gerber is consistent with Petitioner's contentions. In particular, Figure 1 of Young shows the electrode having a lead body with two tine structures each composed of four tines. Ex. 1010, 73, Fig. 1. Figure 2 of Gerber shows an anchoring mechanism located between an electrode and the proximal end of the lead body, and Gerber expressly teaches that the anchoring mechanism allows the medical lead to fibrose in the human body. Ex. 1012, 4:27–30, Fig. 2. On this record and for purposes of institution, Petitioner demonstrates sufficiently that Young and Gerber disclose limitation 1.e.

d. Plurality of flexible, pliant tines extending outwardly and proximally (limitation 1.f)

Independent claim 1 recites:

> each tine element comprising a plurality of flexible, pliant tines, each tine having a tine width and thickness and extending a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead body from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end,

i.e., limitation 1.f. Ex. 1001, 13:63–14:3. Petitioner argues each of Young's tines has a width, thickness and length, and is attached to the lead body so

that one end extends outwardly from the lead body towards the lead proximal end. Pet. 27–28 (citing Ex. 1010. Fig. 1). Petitioner also argues Lindegren teaches a plurality of proximally-extending tines mounted on rings. *Id.* at 28 (citing Ex. 1013, Fig. 3). Petitioner further asserts that proximally-oriented tines were common before 2001, especially for use with an introducer into which the tine ends enter first, because such an orientation does not risk damaging the free tine ends. *Id.*; Ex. 1003 ¶ 32.

Patent Owner argues Petitioner has not demonstrated the cited references disclose flexible and pliant tines, as limitation 1.f requires. Prelim. Resp. 18–20. Per Patent Owner, "Petitioner does not even allege, let alone demonstrate, that the tines in Young are 'flexible' and 'pliant.'" *Id.* at 19 (citing Pet. 27–28). Patent Owner further contends Petitioner relies on Lindegren for teaching only the orientation of tines and provides no evidence to show Lindegren's tines are flexible or pliant. *Id.* at 20.

We disagree that Petitioner is relying on Lindegren for only the orientation of the tines. Instead Petitioner proposes to modify the electrode described in Young to include Lindegren's tine-mounted rings, which are made of an elastic material such as silicone rubber and include evenly distributed projections, i.e., tines, extending outward and to the rear. Pet. 23–24; Ex. 1013, 5:17–22, 7:21–23, 8:5–8. Per Petitioner, "it would be preferable for manufacturing to have tines mounted on a ring-shaped means like a rubber band encircling the lead body" (*id.* at 23 (citing Ex. 1003 ¶ 91)), and "it would have been easy and feasible to utilize Lindegren's tine-mounted rings with tines extending proximally" (*id.* at 24).

Moreover, on the current record, Petitioner has demonstrated persuasively that a person of ordinary skill in the art would have understood

Young discloses flexible and pliant tines. "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). Although Young does not explicitly describe the tines as flexible or pliant, Mr. Pless testifies that tines are formed from compliant materials, such as silicone rubber and polyurethane. Ex. 1003 ¶ 32 (citing Citron[6] 3:5–7; Smyth[7] 3:28–32). In addition to Citron and Smyth, Mr. Pless's testimony finds support in Lindegren, which teaches tines made from an elastic material such as silicone rubber. Ex. 1013, 5:20–22; 8:5–8.

Patent Owner also argues Young and Lindegren do not render obvious tines that extend "proximally toward the lead proximal end" as recited in limitation 1.f. Prelim. Resp. 23–28. In regard to Young, Patent Owner contends Figure 1 of Young shows the tines extending toward the lead distal end, not proximally toward the lead proximal end. *Id.* at 23–24. With respect to Lindegren, Patent Owner does not refute that Lindegren teaches proximally-extending tines, but maintains Petitioner's obviousness analysis is deficient. *Id.* at 25–28. According to Patent Owner, Petitioner's allegation that both Young and Lindegren disclose proximally-extending tines "is a 'catch-all' 'ground [that] is not reasonably bounded in scope,' is factually inaccurate at least with respect to Young, and 'unduly burdensome for both Patent Owner and the Board to address.'" *Id.* at 25–26 (alteration in original) (quoting *Adaptics Ltd. v. Perfect Co.*, IPR2018-01596, Paper 20 at 21 (PTAB Mar. 6, 2019) (informative)). Patent Owner also asserts

[6] Citron et al., US 3,902,501, issued Sept. 2, 1975 ("Citron").
[7] Smyth, US 3,939,843, issued Feb. 24, 1976 ("Smyth").

Petitioner has not provided a legally sufficient reason for the proposed combination. *Id.* at 26–28.

At the outset, we disagree Petitioner's reliance on both Young and Lindegren to disclose proximally-extending tines places an excessive burden on Patent Owner. Relying on two references to teach a claim element hardly results in an unbridled ground of unpatentability. *Cf. Adaptics*, Paper 20 at 20 ("[C]ontrary to Petitioner's argument, Petitioner's third obviousness ground does not rely on a small set of secondary references to teach 'the final "trigger" element.'"). Furthermore, as evidenced by Patent Owner's arguments, there is no uncertainty that Petitioner contends Young and Lindegren both disclose proximally-extending tines.

We also disagree that Petitioner's reasons for combining the teachings of Young and Lindegren are insufficient at this stage of the proceeding because Petitioner's reasons find support in Lindegren. Petitioner argues a person of ordinary skill in the art would have modified Young's electrode system to include Lindegren's tine-mounted rings to enhance manufacturing (Pet. 23), and indeed Lindegren teaches its tine-mounted rings, which include proximally-extending tines, are preferable from a manufacturing point of view (Ex. 1013, 5:17–20, 7:21–23, Fig. 3). Petitioner also argues a person of ordinary skill in the art would have made the proposed combination of Young and Lindegren to prevent dislodgement of the lead after implantation (Pet. 24), and Lindegren explicitly teaches that the task of the proximally-extending tines is "to anchor the electrode head 6 in the interior of heart muscle" (Ex. 1013, 7:23–24).

On the current record, Petitioner's arguments regarding limitation 1.f are consistent with our review of Young and Lindegren. On this record and

for purposes of institution, Petitioner demonstrates sufficiently that Young and Gerber disclose limitation 1.f.

e. Tines that are adapted to fold inward and deploy outward (limitation 1.g)

Independent claim 1 recites

> wherein the plurality of tines of the plurality of tine elements are adapted to be folded inward against the lead body when fitted into and constrained by a lumen of an introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn to release the plurality of tines,

i.e., limitation 1.g. Ex. 1001, 14:3–9. In view of Young's teaching of the electrode being inserted into a No. 14 needle, Petitioner contends Young discloses this limitation. Pet. 28–29. In particular, Petitioner asserts:

> Since Young's electrode is "inserted and advanced" in the needle, the tines are adapted to and do fold inward against the lead body without overlapping one another. Tines are purposefully designed to fold inward when constrained in a lumen because if they did not, they are likely damaged when the lead is advanced. Ex. 1003 ¶32. In Young Figure 1, the length of each tine is shorter than the distance between the two sets, i.e. two tine elements. Thus, the tines cannot overlap one another. *Id.* [at 70–71].[8]

Id. at 29.

Patent Owner argues that Petitioner fails to explain where and how Young discloses tines that are constrained by an introducer lumen such that the tines fold inwardly against the lead body and then deploy outwardly, as

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

limitation 1.g. requires, and that Petitioner improperly incorporates by reference arguments from expert testimony rather than explain in sufficient detail why the limitation is met. Prelim. Resp. 29–31. Patent Owner also contends that, to the extent Petitioner is asserting Young inherently discloses limitation 1.g, neither Petitioner nor Mr. Pless provides any evidence to establish Young's tines necessarily fold inward against the lead body when they are constrained by the lumen and then deploy outwardly when the introducer is removed. *Id.* at 32.

We disagree with Patent Owner. Petitioner's contention that Young discloses this limitation is based on Young's teaching of the tined electrode being introduced into a No. 14 needle, as well as paragraph 32 of Mr. Pless's Declaration. Pet. 28–29. In paragraph 32, Mr. Pless testifies that "[t]o deliver such leads having expandable tines to the stimulation site, tines are constrained during delivery by a constraining structure with a lumen (e.g., cannula, needle, sheath, shroud) so that when released from the lumen of the constraining structure, the tines resiliently deploy outward." Ex. 1003 ¶ 32 (citing Citron 5:13–21). Indeed, Young discloses that the tined electrode is inserted percutaneously through a No. 14 needle (Ex. 1010, 73), and Mr. Pless's testimony finds support in Citron. Petitioner has demonstrated persuasively, at this stage of the proceeding, that a person of ordinary skill in the art would have understood from Young's teaching of using a No. 14 needle to introduce the tined electrode that Young's tines fold inward against the lead body when they are constrained in the needle and then deploy outwardly when the needle is removed. *See supra In re Preda*, 401 F.2d at 826. Thus, for purposes of institution, Petitioner demonstrates sufficiently that Young discloses limitation 1.g.

f. Conclusion for independent claim 1

In view of the foregoing, Petitioner has shown sufficiently how it contends each limitation of independent claim 1 is found in Young, Gerber, and Lindegren. Petitioner also has articulated sufficient reasoning for why a person of ordinary skill would have combined the teachings of Young, Gerber, and Lindegren in the manner set forth in the Petition for purposes of this Decision. Based on this record, Petitioner has shown a reasonable likelihood that Petitioner would prevail in demonstrating independent claim 1 is unpatentable under 35 U.S.C. § 103(a) based on the combination of Young, Gerber, and Lindegren.

5. Independent claims 11 and 18

Independent claim 11 recites a system similar to that of independent claim 1, and additionally recites "an implantable pulse generator configured to generate electrical stimulation," i.e., limitation 11.a, and "an implantable medical lead configured to be electrically coupled to the implantable pulse generator and introduced through and released into body tissue via an introducer defining an introducer lumen," i.e., limitation 11.b. Ex. 1001, 14:54–15:20. The remaining limitations of independent claim 11, i.e., limitations 11.c–i, are similar to limitations 1.b–h. *Id.*

Petitioner's arguments for independent claim 11 are similar to its arguments for independent claim 1. *Compare* Pet. 31–33, *with id.* at 24–29. Additionally, for limitation 11.a, Petitioner argues both Young and Gerber teach a pulse generator.[9] *Id.* at 31 (citing Ex. 1010, 74, Fig. 3; Ex. 1012, 3:49–56). For limitation 11.b, Petitioner relies on Young's No. 14 needle

[9] The pulse generator disclosed in Gerber is Patent Owner's InterStim Neurostimulator Model 3023. Ex. 1012, 3:51–52.

and Gerber's cannula. *Id.* at 31–32 (citing Ex. 1003 ¶¶ 75, 84; Ex. 1010, 73; Ex. 1012, 5:16–17, 5:45–6:1).

Independent claim 18 recites a method employing a medical lead similar to that recited in independent claims 1 and 11, and the method comprises the steps of "introducing an introducer into body tissue, the introducer defining a lumen extending between a lumen proximal end and a lumen distal end; advancing a medical lead through the lumen of the introducer," i.e., limitation 18.a, and "withdrawing the introducer from the body tissue to deploy the plurality of tine elements," i.e., limitation 18.e. Ex. 1001, 15:55–16:31. The remaining limitations of independent claim 18, i.e., limitations 18.b–d, describe the medical lead and are similar to limitations 1.b–1.h and 11.c–11.i. *Id.*

Petitioner's arguments for independent claim 18 are similar to its arguments for independent claims 1 and 11. *Compare* Pet. 34–37, *with id.* at 24–29, 31–33. Additionally, for limitation 18.a, Petitioner contends Young discloses inserting the electrode through a No. 14 needle via puncture of the foramen ovale. *Id.* at 34–35 (citing Ex. 1010, 73). In regard to limitation 18.e, Petitioner argues Young discloses that a needle is used to implant the tined electrode, and that the tines prevent migration of the electrode after implantation. *Id.* at 37 (citing Ex. 1010, 73, 75). Per Petitioner, "a [person of ordinary skill in the art] would understand Young to disclose . . . the [n]eedle was withdrawn to deploy the tines so the tines did not suffer damage and lose [their] intended function to prevent electrode migration." *Id.* (citing Ex. 1003, 78–79[10]).

[10] Mr. Pless's testimony regarding limitation 18.e is on pages 78–79 of his Declaration. We consider Petitioner's citation to pages 79–80 for this

Patent Owner's arguments regarding independent claims 11 and 18 are similar to its arguments for independent claim 1. Prelim. Resp. 18–36. We address these arguments above in section III.C.4. Furthermore, on the current record, our review of Young is consistent with Petitioner's arguments and Mr. Pless's testimony for limitations 11a, 11.b, 18.a, and 18.e. We thus determine that Petitioner has shown a reasonable likelihood it would prevail in demonstrating independent claims 11 and 18 are unpatentable under 35 U.S.C. § 103(a) based on the combination of Young, Gerber, and Lindegren.

6. Dependent claims

Petitioner argues Young, Gerber, and Lindegren disclose the limitations of claims 2, 4, 7, 10, 12, 14, and 19–24. Pet. 30–31, 33–34, 37–39. At this stage of the proceeding, Patent Owner does not raise arguments for these claims apart from its arguments for the independent claims. Prelim. Resp. 17–36.

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

Petitioner challenges claims 18, 20, and 21 of the '314 patent under 35 U.S.C. § 103(a) as unpatentable over Young, Gerber, Lindegren, and Hauser. Pet. 39–47. As we discuss Young, Gerber, and Lindegren in sections III.C.1–3, we begin our analysis of this asserted ground with an overview of Hauser, and then turn to the parties' contentions for each of the claims.

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testimony to be a typographical error, and we understand Petitioner to be citing pages 78–79.

1. Hauser (Ex. 1014)

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. 1014, 1:12–16. Figure 1, reproduced below, shows the electrode.

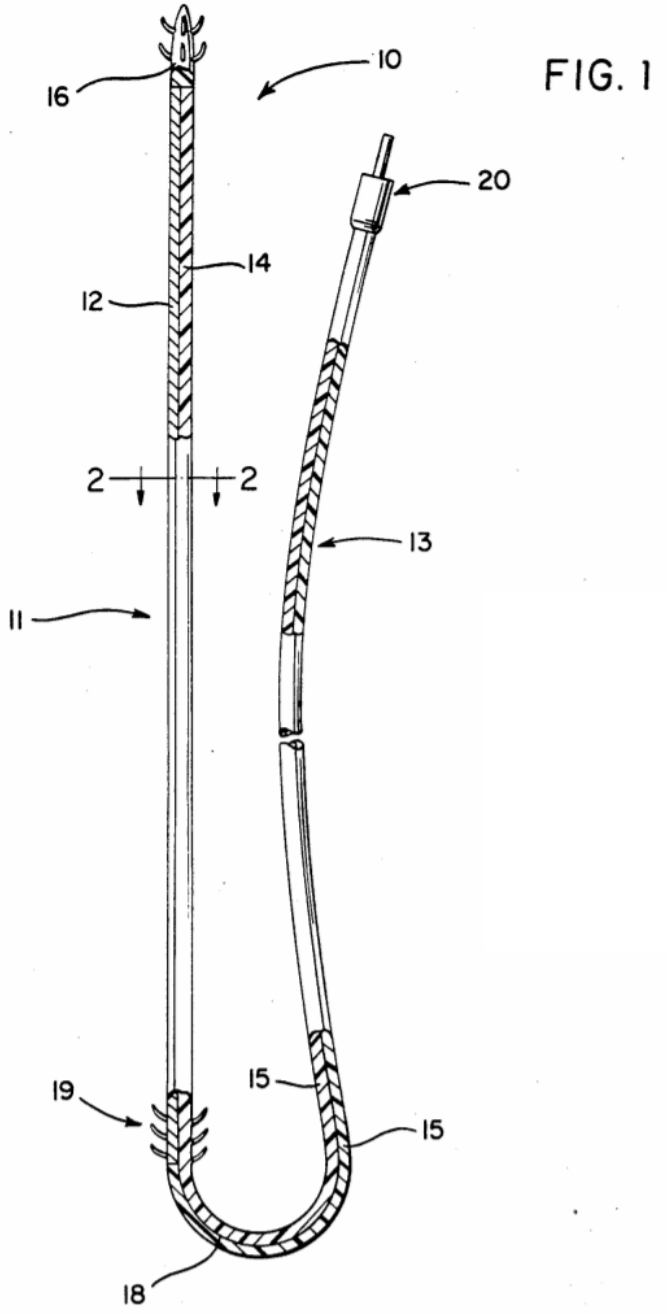
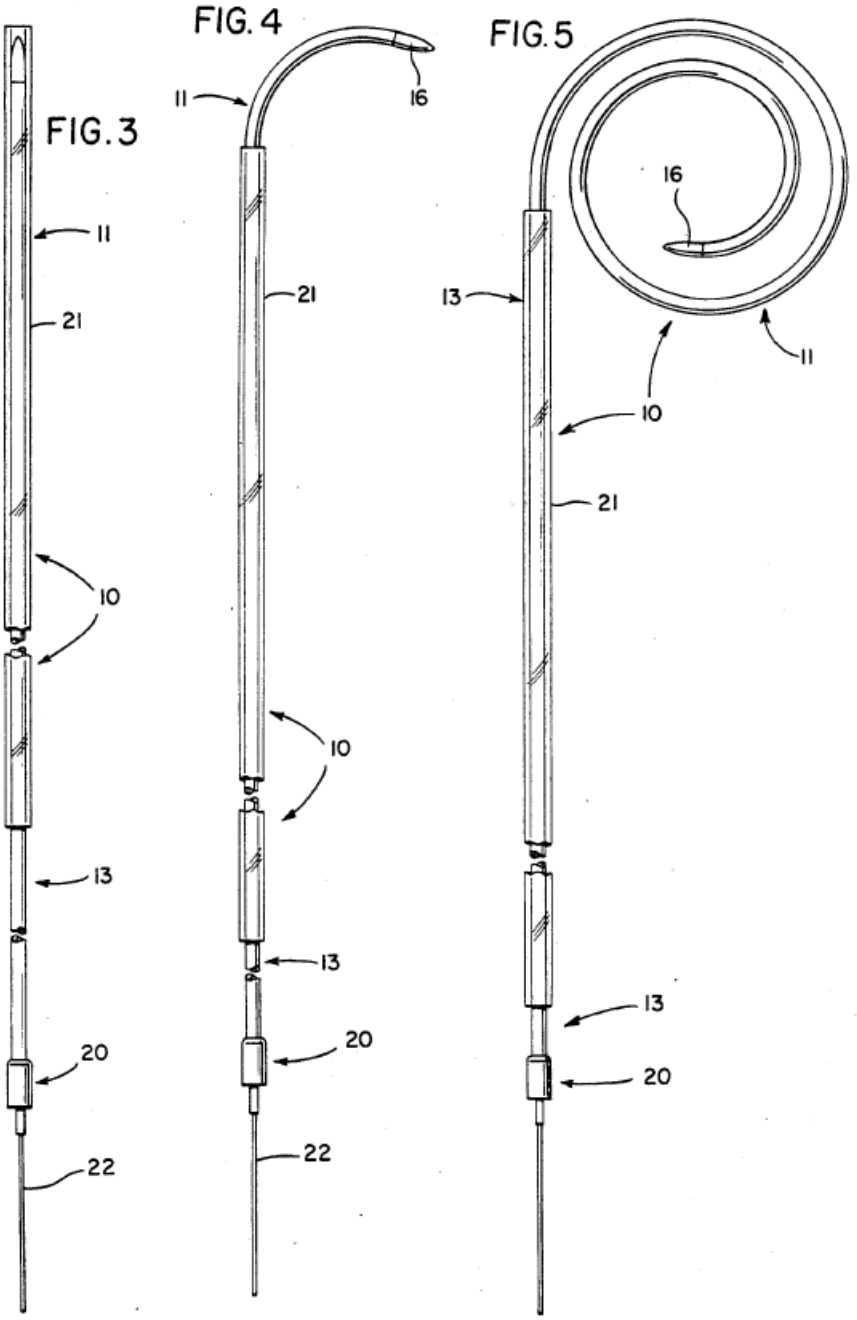


Figure 1 is a perspective view of the electrode in a partially straightened position. *Id.* at 3:9–10. Electrode 10 is thin and elongated, and includes distal active region 11 and proximal lead region 13. *Id.* at 3:50–52. Conductive discharge surface 12 and insulative surface 14 define and extend the 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 which anchors electrode 10 at the location of entrance into the pericardial space. *Id.* at 4:3–8.

Figures 3–5, reproduced below, depict the implantation procedure of electrode 10. *Id.* at 3:12–13, 4:30–32.



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 18

a. Rationale

Petitioner contends a person of ordinary skill in the art would have combined the teachings of Young, Gerber, Lindegren, and Hauser because, similar to Young, Gerber, and Lindegren, Hauser seeks to solve the problems regarding lead placement. Pet. 42 (citing Ex. 1014, 1:26–29, 2:9–19; *Tokai*, 632 F.3d at 1371). Petitioner further asserts "Hauser also uses 3 sets of tines to anchor the lead into proper position, not unlike Young, but Hauser's proximal tines are spaced much further proximally from the electrical conductive region." *Id.* Per Petitioner, a person of ordinary skill in the art would have modified Young's electrode system to have tines facing proximally and spaced further proximally on the lead, as taught by Hauser, as "applications of a known technique to a piece of prior art ready

for the improvement," where the proposed combination "arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement." *Id.* at 43 (quoting *KSR*, 550 U.S. at 417).

On the other hand, Patent Owner argues Petitioner fails to establish that it would have been obvious to combine Young with Hauser. Prelim. Resp. 40–41. In particular, Patent Owner maintains Petitioner ignores the different anatomies at issue in the references and provides no explanation why a person of ordinary skill in the art would have been motivated to use Hauser's fixation mechanism for an endocardial lead anchoring with Young's trigeminal lead. *Id.* at 41.

Although the electrodes of Young and Hauser are used to stimulate different parts of the body, the Supreme Court has instructed that "familiar items may have obvious uses beyond their primary purposes." *KSR*, 550 U.S. at 420. As Petitioner correctly argues, both Young and Hauser disclose using tines to secure the electrode within the body. Pet. 42; Ex. 1010, 73 ("The purpose of the tines was to prevent the electrode from becoming dislodged after implantation."); Ex. 1014, 4:3–9 ("In addition, a proximal fixation means 19 is provided which . . . anchors the electrode 10 at the location of entrance into the pericardial space . . . ."); Fig. 1 (showing proximal fixation 19 as a plurality of tines). Given both Young and Hauser disclose using tines for securement, Petitioner, at this stage of the proceeding, has shown sufficiently that a person of ordinary skill in the art would have modified Young's electrode to include Hauser's tines as an application of a known electrode fixation technique to a known electrode system in need of electrode fixation and as an arrangement of old elements

with each performing the same function it had been known to perform and without more than one would expect from such an arrangement. Petitioner has, on the current record, provided persuasive reasoning why a person of ordinary skill would have combined the teachings of Young, Gerber, Lindegren, and Hauser in the manner set forth in the Petition.

b. Claim limitations

Petitioner's arguments identifying the limitations of independent claim 18 in Young, Gerber, Lindegren, and Hauser with respect to this asserted ground of unpatentability are similar to its arguments for independent claims 1, 11 and 18 in regard to the asserted ground of unpatentability based on Young, Gerber, and Lindegren. Pet. 43–45. Additionally, Petitioner further argues Hauser teaches flexible tines, each having a tine width, thickness, and length, and being attached to a tine attachment site so that tine extends outwardly and proximally. *Id.* at 44 (citing Ex. 1014, Fig. 12). Petitioner also argues that, to the extent Young does not disclose "withdrawing the introducer from the body tissue to deploy the plurality of tine elements," i.e., limitation 18.e, Hauser teaches that proximal tines 19 remain in catheter 21 until catheter 21 is removed. *Id.* at 45–46 (citing Ex. 1003 ¶ 84[11]; Ex. 1014, 2:61, 4:49–55, Figs. 5, 12).

Patent Owner maintains Hauser does not remedy the deficiencies in its asserted ground of unpatentability premised on Young, Gerber, and Lindegren relating to Young's inadequate disclosure of the recited "flexible,

[11] Mr. Pless's testimony regarding limitation 18.e is on page 84 of his Declaration. We consider Petitioner's citation to page 85 for this testimony to be a typographical error, and we understand Petitioner to be citing page 84.

pliant tines," Petitioner's failure to demonstrate the prior art discloses "tine elements" under its proffered construction, and the lack of explanation as to why it would have been obvious to modify Young's tines to extend proximally. Prelim. Resp. 38. Yet, for the reasons above in sections III.C.4–5, Petitioner has shown a reasonable likelihood it would prevail in demonstrating independent claims 11 and 18 are unpatentable under 35 U.S.C. § 103(a) based on the combination of Young, Gerber, and Lindegren such that, for purposes of institution, there are no deficiencies in that asserted ground of unpatentability.

Patent Owner also asserts that Petitioner provides no details as to how and why Young would be modified in view of Hauser's teachings to include any features missing from Young in regard to the limitation of independent claim 18 reciting "the plurality of tines of the plurality of tine elements are adapted to be folded inward against the lead body when fitted into and constrained by the lumen of the introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn proximally," i.e., limitation 18.c. Prelim. Resp. 39. Petitioner, however, is not relying on Hauser for disclosing this limitation. *See* Pet. 45 (referring to arguments for the asserted ground of unpatentability based on Young, Gerber, and Lindegren).

On the current record, Petitioner has demonstrated sufficiently that Hauser teaches advancing an electrode through a catheter to implant the electrode in the body. Ex. 1014, 4:39–55, Figs. 3–5. Petitioner also has shown sufficiently that Hauser teaches the proximal fixation means anchors the electrode at the location of entrance into the pericardial space. *Id.* at 4:3–9, 4:65–5:1, Fig. 6. As our review of Hauser is consistent with

Petitioner's arguments and Mr. Pless's testimony, and for the reasons set forth in sections III.C.4–5, Petitioner demonstrates persuasively, on the record at this stage of the proceeding and for purposes of this Decision, that the cited references disclose the limitations of independent claim 18.

c. Conclusion for independent claim 18

In view of the foregoing, Petitioner has shown sufficiently how it contends each limitation of independent claim 18 is found in Young, Gerber, Lindegren, and Hauser. Petitioner also articulates sufficient reasoning for why a person of ordinary skill would have combined the teachings of Young, Gerber, Lindegren, and Hauser in the manner set forth in the Petition for purposes of this Decision. Based on this record, Petitioner shows a reasonable likelihood that Petitioner would prevail in demonstrating independent claim 18 is unpatentable under 35 U.S.C. § 103(a) based on the combination of Young, Gerber, Lindegren, and Hauser.

3. Dependent claims

Petitioner argues Young, Gerber, Lindegren, and Hauser disclose the limitations of claims 20 and 21. Pet. 46–47. At this stage of the proceeding, Patent Owner does not raise arguments for claims 20 and 21 apart from its arguments for independent claim 18. Prelim. Resp. 37–41.

E. Obviousness Based on Gerber, Hauser, and Akerström

As an alternative to its assertion that claims 1, 2, 4, 7, 10–12, 14, and 18–24 are unpatentable under 35 U.S.C. § 103(a) based on the combination of Young, Gerber, and Lindegren, Petitioner challenges these claims under 35 U.S.C. § 103(a) as unpatentable over Gerber, Hauser, and Akerström. Pet. 47–67. As we discuss Gerber and Hauser in sections III.C.2 and D.1,

we turn to Akerström, and thereafter discuss the parties' contentions with respect to this asserted ground of unpatentability.

1. Akerström (Ex. 1015)

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. 1015, 1:5–13. Figure 1, reproduced below, shows the distal end of the endocardial electrode arrangement. *Id.* at 2:15–16.

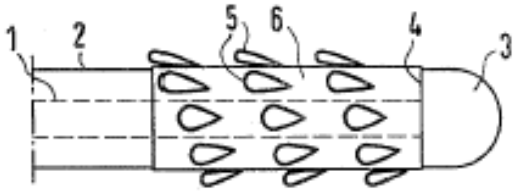


FIG 1

Figure 1 shows the electrode arrangement comprising electric conductor 1 provided with electric insulation sheath 2. *Id.* at 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.

2. Independent claim 1

a. Rationale

Petitioner contends a person of ordinary skill in the art 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, to affix by fibrosis and improve anchoring within the soft tissue near the sacrum. Pet. 49. Petitioner further contends Gerber provides a motivation for the proposed combination. *Id.* Per Petitioner, Gerber discloses a multi-electrode lead with a proximal anchoring mechanism that anchors by fibrosis instead of the suture sleeve depicted in Figure 2. *Id.* Petitioner argues "a [person of ordinary skill in the art] would have considered tines, a leading candidate among the limited number of devices that anchor by fibrosis." *Id.* (citing Ex. 1003 ¶ 107). Petitioner also argues that Akerström's arrangements of loops for anchoring by fibrosis are applicable to tines, and that Akerström's arrangement 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 ¶ 105).

Patent Owner argues Petitioner fails to demonstrate that it would have been obvious to combine the teachings of Gerber, Hauser, and Akerström in the manner set forth in the Petition. Prelim. Resp. 42–50. According to Patent Owner, "Petitioner and its declarant simply offer no evidence to provide that tines were an obvious choice whenever fibrosis was involved." *Id.* at 44. Patent Owner further asserts "[e]ven assuming *arguendo* that Hauser's 'fixation means 19' are tines, Petitioner does not provide any

evidence that a [person of ordinary skill in the art] would consider such fixation means 19 an appropriate mechanism for use as the anchoring mechanism 50 in Gerber." *Id.* at 47. We disagree with Patent Owner that Petitioner's reasoning lacks evidentiary support. Gerber discloses an anchoring mechanism that allows the medical lead to fibrose naturally into the body, and both Hauser and Akerström teach that tines provide anchoring via fibrosis. Ex. 1012, 4:27–30 ("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. 1014, 2:39–49 ("In addition, the electrode may be provided with preformed insulative or conductive discharge wings attached along its active region. . . . The similarly designed conductive discharge wings provide additional discharge surface area and a degree of fixation of the electrode via tissue ingrowth after implantation."), Fig. 12 (showing fixation means 17, 19 as tines); Ex. 1015, 1:28–32 ("The tines also hardly permit subsequent corrections of the position; their growth into the heart wall is rendered difficult, since the connective tissue is offered a small space for growth around said tines."); *see also KSR*, 398 U.S. at 416 ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.").

Patent Owner also argues Akerström teaches away from tines and instead teaches loops. Prelim. Resp. 44–45 (citing Ex. 1015, 1:28–32, 52–55, Fig. 6). Akerström teaches the use of tines is problematic in the delivery of an electrode through a vein, in particular because the connective tissue is offered a small space for growth around the tines, making growth

onto the heart wall difficult. Ex. 1015, 1:15–32. Petitioner, however, is proposing to add tines to Gerber's electrode (Pet. 49), which is for sacral nerve stimulation and not introduced venously (Ex. 1012, 1:9–12, 5:33–39), so we disagree with Patent Owner that Akerström's criticism of tines would have led a person of ordinary skill in the art away from Petitioner's proposed combination. Moreover, Hauser teaches tines for securing the electrode to the heart. Ex. 1014, 3:67–4:8, Fig. 6.

Patent Owner further contends Petitioner's rationale is deficient given the lack of explanation as to why using Hauser's fixation means in Gerber's electrode would result in an ease in manufacturing. Prelim. Resp. 48–49. Petitioner, however, relies on manufacturing efficiencies as a reason for modifying tines to include Akerström's arrangement, not as a basis for adding Hauser's tines to Gerber's electrode. Pet. 49. Moreover, Petitioner's assertion that modifying tines to include Akerström's arrangement of repeated sets extending from a collar would facilitate manufacturing finds support at least in Lindegren, which teaches having tine-mounted rings is preferable from a manufacturing point of view. Ex. 1013, 5:17–20.

Patent Owner also argues Petitioner ignores the different anatomies at issue in the references and provides no explanation why a person of ordinary skill in the art would have been motivated to use Hauser's fixation mechanism for an endocardial lead anchoring with Gerber's sacral lead. Prelim. Resp. 49. Although the electrodes of Gerber and Hauser are used to stimulate different parts of the body, the Supreme Court has instructed that "familiar items may have obvious uses beyond their primary purposes." *KSR*, 550 U.S. at 420. As Petitioner correctly argues, both Gerber and Hauser disclose securing the electrode within the body by fibrosis. Pet. 49;

Ex. 1012, 4:27–30 ("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. 1014, 2:39–49 ("In addition, the electrode may be provided with preformed insulative or conductive discharge wings attached along its active region. . . . The similarly designed conductive discharge wings provide additional discharge surface area and a degree of fixation of the electrode via tissue ingrowth after implantation."), Fig. 12 (showing fixation means 17, 19 as tines). As both Gerber and Hauser disclose securing the electrode via fibrosis, Petitioner, on the present record, has persuaded us that a person of ordinary skill in the art would have modified Gerber's electrode to include Hauser's tines as an arrangement of old elements with each performing the same function it had been known to perform and without more than one would expect from such an arrangement.

In view of the foregoing, Petitioner has, on the current record, provided persuasive reasoning why a person of ordinary skill would have combined the teachings of Gerber, Hauser, and Akerström in the manner set forth in the Petition. Based on the record at this stage of the proceeding and for purposes of this Decision, Petitioner sufficiently demonstrates a motivation for combining the references.

b. Undisputed limitations (limitations 1.0–1.d, 1.h)

In regard to limitation 1.0, Petitioner contends that, to the extent the preamble is a limitation, Gerber, Hauser, and Akerström disclose a system. Pet. 50. For limitation 1.a, which recites an implantable medical lead, Petitioner argues Gerber discloses a single and multi-polar implantable lead for sacral nerve electrical stimulation. *Id.* at 51 (citing Ex. 1012, Title, Abstract).

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. 1012, Abstract). In regard to limitation 1.c, which recites a plurality of conductors within the lead body, Petitioner argues Gerber's lead body comprises at least one conductor wire within an insulating sheath. *Id.* (citing Ex. 1012, 4:6–7).

Regarding limitation 1.d, which requires a plurality of electrodes, each electrically connected to a conductor of the plurality of conductors, Petitioner argues Gerber discloses multiple stimulation electrodes, particularly two electrodes. *Id.* (citing Ex. 1012, Abstract, 1:57–58, 2:4–5, 4:32–33, claim 1, Fig. 3). Petitioner also argues that Gerber discloses stimulation pulses are carried from the pulse generator through the lead body to the distal having at least one electrode contact, and that each electrode must be electrically connected to a conductor for there to be stimulation pulses. *Id.* (citing Ex. 1012, 3:52–56; Ex. 1003, 86–87[12]).

For limitation 1.h, which recites the plurality of tine elements are separate from and axially spaced from the plurality of electrodes, Petitioner argues Hauser teaches a plurality of tine elements. *Id.* at 55 (citing *id.* at 52–53). Petitioner also argues Gerber's anchoring mechanism is located

[12] Mr. Pless's testimony regarding limitation 1.d is on pages 86–87 of his Declaration. We consider Petitioner's citation to pages 87–88 for this testimony to be a typographical error, and we understand Petitioner to be citing pages 86–87.

separate from and spaced apart from an electrode. *Id.* at 55–56 (citing Ex. 1012, Fig. 2; Ex. 1003, 92[13]).

At this stage of the proceeding, Patent Owner does not dispute Petitioner's contentions with respect to limitations 1.0–1.d and 1.h. On the current record, our review of the cited references is consistent with Petitioner's arguments and Mr. Pless's testimony. In particular, Petitioner has shown sufficiently for purposes of this Decision that Gerber discloses an implantable medical lead having a lead body, a plurality of conductors, a plurality of electrodes each electrically connected to a conductor of the plurality of conductors, and an anchoring mechanism located separate from and axially displaced from an electrode. Ex. 1012, Abstract, 3:39–42, 52–56, 4:6–7, 13–15, 32–33, Figs. 2–3. Based on the record at this stage of the proceeding and for purposes of this Decision, Petitioner demonstrates persuasively that the cited references disclose these limitations.

c. Plurality of tines elements (limitation 1.e)

In regard to limitation 1.e, which requires a plurality of tine elements positioned between a most proximal electrode and the proximal end of the lead body, 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.

[13] Mr. Pless's testimony regarding limitation 1.h is on page 92 of his Declaration. We consider Petitioner's citation to page 93 for this testimony to be a typographical error, and we understand Petitioner to be citing page 92.

Pet. 52 (citing Ex. 1012, 4:13–30, Fig. 2; Ex. 1003, 87[14]). Petitioner further argues a person of ordinary skill in the art knows tines affix by fibrosis. *Id.* (citing Ex. 1003, 87[15]). Petitioner also contends Hauser teaches fixation means 17, 19, which are made up of multiple sets of tines and can be placed at various locations on the lead as determined by the surgeon. *Id.* at 52–54 (citing Ex. 1014, Figs. 6, 12; Ex. 1003, 87–89[16]). Additionally, Petitioner asserts Akerström teaches various arrangements of fixation loops, including an arrangement where the loops are on several collars slipped on the insulation of the conductor and spaced apart from each other. *Id.* at 54 (citing Ex. 1015, 2:56–59, Fig. 3). Per Petitioner, Akerström teaches the loops are of sufficient stiffness to project above the surface of the electrode, and, as the loops look like tines, a person of ordinary skill in the art could arrange tines as shown in Akerström. *Id.* (citing Ex. 1015, 3:6–8, 29–36, 52–55, Fig. 7; Ex. 1003, 90[17]).

Patent Owner contends that Petitioner does not explain how the prior art discloses "tine elements" under Petitioner's construction. Prelim. Resp. 54–55. According to Patent Owner, under Petitioner's proffered

[14] Mr. Pless's testimony regarding Gerber's disclosure of limitation 1.e is on page 87 of his Declaration. We consider Petitioner's citation to page 88 for this testimony to be a typographical error, and we understand Petitioner to be citing page 87.
[15] *See supra* note 12.
[16] Mr. Pless's testimony regarding Hauser's disclosure of limitation 1.e is on pages 87–89 of his Declaration. We consider Petitioner's citation to pages 88–89 for this testimony to be a typographical error, and we understand Petitioner to be citing pages 87–89.
[17] This testimony is on page 90 of Mr. Pless's Declaration, not page 91. We consider Petitioner's citation to page 91 to be a typographical error, and we understand Petitioner to be citing page 90.

construction, "tines" and "tine elements" are different, and Petitioner argues Hauser's fixation means are "tines" without any explanation as to how the prior art discloses "tine elements." *Id.* at 54. We disagree with Patent Owner. Pursuant to its construction, Petitioner argues Hauser's fixation means 17, 19 are depicted as "multiple sets of tines." Pet. 52 (citing Ex. 1003, 87–89[18]). To wit, each set of tines is a structure comprising multiple tines, and, therefore, a "tine element" under Petitioner's construction. Additionally, both Petitioner and Mr. Pless explicitly identify collars as "tine elements." Pet. 49; Ex. 1003 ¶ 107.

On this record, our review of Gerber, Hauser, and Akerström is consistent with Petitioner's arguments and Mr. Pless's testimony. In particular, Petitioner has demonstrated sufficiently that Hauser's fixation means 19 teaches a plurality of tine elements located between an electrode and the proximal end of a lead body. Ex. 1014, Fig. 1. Petitioner also has shown sufficiently that Akerström teaches a plurality of spaced collars each having multiple loops thereon. Ex. 1015, 2:56–59, Fig. 3. On this record and for purposes of institution, Petitioner identifies persuasively limitation 1.e in Gerber, Hauser, and Akerström.

d. Plurality of flexible, pliant tines adapted to be folded inward without overlap and deploy outward (limitations 1.f and 1.g)

In regard to limitation 1.f, which requires that each tine element comprises a plurality of flexible, pliant tines extending outwardly of the lead body and proximally toward the lead proximal end, Petitioner argues Hauser's fixation means 19 includes a plurality of tine elements each made up of a plurality of tines extending outwardly and proximally. Pet. 54 (citing

[18] *See supra* note 14.

Ex. 1014, Fig. 12, Ex. 1003, 90–91[19]). Petitioner also argues Akerström teaches flexible, pliant loops extending outwardly and proximally. *Id.* at 55 (citing Ex. 1003, 91[20])

For limitation 1.g, which requires that the plurality of tines are adapted to fold inwardly against the lead body without overlap when constrained by a lumen of an introducer and deploy outwardly upon withdrawal of the introducer, Petitioner contends Hauser's "fixation means 19 includes pliant tines such that placement of the lead constrained within the catheter would fold the tines inward against the lead body (Fig. 3) and [the tines] would deploy laterally outward when released from the catheter." Pet. 55. Petitioner acknowledges Hauser does not explicitly teach that the tines do not overlap, and contends Akerström teaches an arrangement where the set of loops on the first collar fold inward against the lead body without overlap. *Id.* (citing Ex. 1015, Fig. 3).

Patent Owner argues there is no evidence that Hauser's tines are flexible or pliant in accordance with limitation 1.f. Prelim. Resp. 50. Patent Owner similarly argues "nowhere in Hauser is there a description of the fixation means being folded inward, constrained, or deployed outward," as limitation 1.g requires. *Id.* at 51. We disagree with Patent Owner. Hauser's Figure 3 shows a stage of implantation of the electrode illustrated in Figure 1

[19] Mr. Pless's testimony regarding Hauser's disclosure of limitation 1.f is on pages 90–91 of his Declaration. We consider Petitioner's citation to pages 91–92 for this testimony to be a typographical error, and we understand Petitioner to be citing pages 90–91.

[20] Mr. Pless's testimony regarding Akerström's disclosure of limitation 1.f is on page 91 of his Declaration. We consider Petitioner's citation to page 92 to be a typographical error, and we understand Petitioner to be citing page 91.

where the electrode is introduced into the catheter. Ex. 1014, 3:12–13, 4:32–39. As Figure 1 shows electrode 10 with fixation means 17, 19, Petitioner, on this record, has persuaded us that a person of ordinary skill in the art would have understood from Figure 3 that the tines of fixation means 17, 19 are flexible and pliant so as to fold inwardly when electrode 10 is introduced into catheter 21 and deploy outwardly when catheter 21 is withdrawn. Moreover, Petitioner also relies on Akerström's teaching of flexible loops that fold inwardly against the lead body. Pet. 55 (citing Ex. 1003, 91[21]; Ex. 1015, Fig. 3).

Patent Owner additionally argues "Petitioner provides no analysis why a [person of ordinary skill in the art], after choosing tines for Gerber's anchoring mechanism 50, would also ensure that the tines are 'flexible' and fold inwards against the lead body when constrained by the introducer lumen in Gerber." Prelim. Resp. 51 (emphasis omitted). According to Patent Owner, Petitioner's reasoning for modifying Gerber based on Hauser is limited to conclusory allegations such as ease in manufacturing (*id.*), and Akerström expressly teaches away from the use of tines (*id.* at 51–52 (citing Ex. 1015, 1:15–32)). We, however, disagree with Patent Owner's argument alleging a lack of explanation for modifying Gerber's electrode to include flexible tines that fold inwardly and deploy outwardly. To the extent Petitioner is relying on Hauser for teaching flexible tines that fold inwardly and deploy outwardly, Petitioner contends it would have been obvious to modify Gerber's electrode to include Hauser's tines in view of Gerber's disclosure of an anchoring mechanism allowing the medical lead to fibrose

[21] *See supra* note 18.

naturally into the body, and a person of ordinary skill in the art understanding tines anchor by fibrosis. Pet. 49. Petitioner also argues Akerström teaches an arrangement of flexible loops that fold inwardly and deploy outwardly, and maintains a person of ordinary skill in the art would have modified tines to include Akerström's arrangement to allow 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 ¶ 105). As set forth above in section III.E.2.a, Petitioner's rationale for modifying tines to include Akerström's arrangement to facilitate manufacturing finds support at least in Lindegren, which teaches having tine-mounted rings is preferable from a manufacturing point of view. Ex. 1013, 5:17–20. Furthermore, and as also set forth section III.E.2.a, Akerström does not teach away from Petitioner's proposed combination. Although Akerström teaches the use of tines is problematic in the delivery of an electrode through a vein (Ex. 1015, 1:15–32), Petitioner is proposing to add tines to Gerber's electrode, which is for sacral nerve stimulation and not introduced venously (Ex. 1012, 1:9–12, 5:33–39).

Patent Owner also asserts Petitioner has not demonstrated that the prior art discloses non-overlapping tines, as limitation 1.g requires. Prelim. Resp. 52–54. Patent Owner maintains Akerström teaches loops, not tines. *Id.* at 53. Patent Owner further contends "Petitioner's analysis lacks the necessary explanation regarding why a [person of ordinary skill in the art] would have been motivated to modify Hauser's 'fixation means 19' based on Akerstr[ö]m so that they do not overlap one another when constrained by a lumen." *Id.* According to Patent Owner, Petitioner's reasoning does not answer the fundamental question—why a person of ordinary skill in the art

would have modified Hauser's fixation means to include non-overlapping tines, and Petitioner ignores that Akerström teaches away from tines. *Id.* at 53–54.

Although Akerström teaches loops, it further teaches the loops secure the electrode in the body via fibrosis. Ex. 1015, 2:46–29. As tines also provide securement by fibrosis (*id.* at 1:28–32; Ex. 1014, 2:46–49, Fig. 12), Petitioner, on the current record, has shown sufficiently that Akerström's arrangement of loops would have been applicable to Hauser's tines. Turning to Petitioner's rationale for including Akerström's non-overlapping arrangement, as set forth above in section 2:III.E.2.a, Petitioner reasons a person of ordinary skill in the art would have modified the tined-electrode to include Akerström's non-overlapping arrangement to provide a smaller profile, which is suited to percutaneous delivery, and, on the current record, Petitioner has demonstrated sufficiently that a non-overlapping arrangement would result in a smaller profile. Pet. 49 (citing Ex. 1003 ¶ 105); *see also* Ex. 1015 ("Due to the fact that the loops 5 consist of a very soft and thin material, independently of number and size, they rest close against the electrode during insertion of the electrode in a vein."). As also set forth section III.E.2.a, we disagree with Patent Owner that Akerström teaches away from Petitioner's proposed combination.

Accordingly, on this record, Petitioner's arguments and Mr. Pless's testimony are consistent with our review of Hauser and Akerström. On the record at this stage of the proceeding and for purposes of institution, Petitioner shows persuasively that the cited references disclose limitations 1.f and 1.g.

e. Conclusion for independent claim 1

In view of the foregoing, Petitioner has shown sufficiently how it contends each limitation of independent claim 1 is found in Gerber, Hauser, and Akerström. Petitioner also articulates sufficient reasoning for why a person of ordinary skill would have combined the teachings of Gerber, Hauser, and Akerström in the manner set forth in the Petition for purposes of this Decision. Based on this record, Petitioner shows a reasonable likelihood that Petitioner would prevail in demonstrating independent claim 1 is unpatentable under 35 U.S.C. § 103(a) based on the combination of Gerber, Hauser, and Akerström.

3. Independent claims 11 and 18

Petitioner's arguments regarding independent claim 11 are similar to its arguments for independent claim 1. *Compare* Pet. 58–61, *with id.* at 50–56. Additionally, for limitation 11.a, which recites an implantable pulse generator, Petitioner relies on Gerber's disclosure of coupling the proximal end of the lead body to a pulse generator. *Id.* at 58 (citing Ex. 1003, 94[22]). Regarding limitation 1.b, which requires an implantable medical lead configured to be electrically coupled to the implantable pulse generator and introduced into the body through an introducer defining an introducer lumen, Petitioner contends Gerber discloses the lead has a lead body coupled to the pulse generator and is used with a cannula. *Id.* (citing Ex. 1012, 5:16–17, 5:45–6:1; Ex. 1003 ¶ 84). Petitioner also contends Hauser teaches that electrode 10 is inserted into the body via catheter 21,

[22] Mr. Pless's testimony regarding limitation 11.a is on page 94 of his Declaration. We consider Petitioner's citation to page 95 to be a typographical error, and we understand Petitioner to be citing page 94.

and that proximal lead region 13 of electrode 10 is connected to the pulse generator. *Id.* at 58–59 (citing Ex. 1014, 4:32–43, 51–55; Ex. 1003, 94–95[23]).

Petitioner's arguments regarding independent claim 18 are similar to its arguments for independent claims 1 and 11. *Compare* Pet. 61–64, *with id.* at 50–56, 58–61. In addition, for limitation 18.a, which requires introducing an introducer into body tissue and advancing a medical lead through the lumen of the introducer, Petitioner contends Gerber discloses that the lead is used with a cannula. *Id.* at 62 (citing Ex. 1012, 5:16–17, 5:45–6:1; Ex. 1003 ¶ 32). Petitioner also argues Hauser teaches that electrode 10 is inserted into the body via catheter 21, and that the catheter inherently has a proximal and a distal end. *Id.* (citing Ex. 1014, 4:32–43; Ex. 1003, 98[24]). Regarding limitation 18.e, Petitioner argues Hauser teaches the proximal fixation means 19 remain inside the catheter during implantation of the electrode and deploy once the catheter is removed. *Id.* at 64 (citing Ex. 1014, 4:49–55, Figs. 5, 12; Ex. 1003, 100[25]).

Patent Owner's arguments for independent claims 11 and 18 are similar to its arguments for independent claim 1. Prelim. Resp. 42–55. We

[23] Mr. Pless's testimony regarding Hauser's disclosure of limitation 11.b is on pages 94–95 of his Declaration. We consider Petitioner's citation to pages 95–96 for this testimony to be a typographical error, and we understand Petitioner to be citing pages 94–95.
[24] Mr. Pless's testimony regarding limitation 18.a is on page 98 of his Declaration. We consider Petitioner's citation to page 99 to be a typographical error, and we understand Petitioner to be citing page 98.
[25] Mr. Pless's testimony regarding limitation 18.e is on page 100 of his Declaration. We consider Petitioner's citation to page 101 to be a typographical error, and we understand Petitioner to be citing page 100.

address these arguments in section III.E.2. Furthermore, on the present record, our review of Gerber and Hauser is consistent with Petitioner's arguments and Mr. Pless's testimony for limitations 11a, 11.b, 18.a, and 18.e. We, therefore, determine Petitioner has shown a reasonable likelihood it would prevail in demonstrating independent claims 11 and 18 are unpatentable under 35 U.S.C. § 103(a) based on the combination of Gerber, Hauser, and Akerström.

4. Dependent claims

Petitioner argues Gerber, Hauser, and Akerström teach the limitations of claims 2, 4, 7, 10, 12, 14, and 19–24. Pet. 56–58, 61, 64–66. At this stage of the proceeding, Patent Owner does not raise arguments for these claims apart from its arguments for the independent claims. Prelim. Resp. 42–55.

F. Secondary Considerations

Patent Owner cites a paper touting Patent Owner's tined electrode. Prelim. Resp. 45–46 (citing Ex. 2004[26], 24). Patent Owner also argues the invention set forth in the '314 patent solved a massive problem in sacral neurostimulation. *Id.* at 10–16.

Evidence of secondary considerations, when present, must always be considered in determining obviousness. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983). Petitioner, however, has not yet had an opportunity to respond to Patent Owner's evidence and arguments for secondary considerations. Arguments and evidence of secondary

[26] Sutherland et al., *Sacral Nerve Stimulation for Voiding Dysfunction: One Institution's 11-Year Experience*, 26 Neurology and Urodynamics 19 (2007).

considerations are better evaluated in the context of a completed trial, when the record has been fully developed and the ultimate determination regarding patentability is made. That notwithstanding, we have reviewed Patent Owner's arguments and evidence regarding secondary considerations and evaluated the arguments and evidence of nonobviousness with Petitioner's arguments and evidence of obviousness. Whenever this Decision states that Petitioner has demonstrated a reasonable likelihood of showing a claim is unpatentable, that statement indicates we have determined Petitioner's evidence is sufficient to meet the evidentiary burden for institution, notwithstanding Patent Owner's arguments and evidence regarding nonobviousness, including secondary considerations.

IV. CONCLUSION

For the reasons set forth above, Petitioner demonstrates a reasonable likelihood of prevailing with respect to at least one of the challenged claims of the '314 patent, and we institute an *inter partes* review based on the asserted grounds of unpatentability set forth in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (indicating that a decision whether to institute an *inter partes* review "require[s] a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition"). At this stage of the proceeding, however, we have not made a final determination as to the patentability of any challenged claim or any underlying factual or legal issue.

V. ORDER

In consideration of the foregoing, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a) and 37 C.F.R. § 42.4, an *inter partes* review of the '314 patent is hereby instituted with respect to claims 1, 2, 4, 7, 10–12, 14, and 18–24 of the '314 patent, on all grounds presented in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), notice is hereby given of the institution of a trial, which will commence on the entry date of this Decision.

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