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Paper 10
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.

IPR2020-00715
Patent 8,036,756 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, 5, 7, 13–15, and 18 of U.S. Patent No. 8,036,756 B2 ("the '756 patent"). Paper 1 ("Pet."). Medtronic, Inc. ("Patent Owner") filed a Preliminary Response. Paper 7 ("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 '756 patent.

II. BACKGROUND

A. Real Parties in Interest

Petitioner asserts that it is the real party in interest. Pet. 69. 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 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 (Ex. 1001)

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.

According to the '756 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 2:32–36. 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 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 3:6–12. 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, though use of minimally invasive implantation techniques.” *Id.* at 5:33–38. Figure 1, reproduced below, shows a sacral nerve stimulation lead of the invention. *Id.* at 8:34–35.

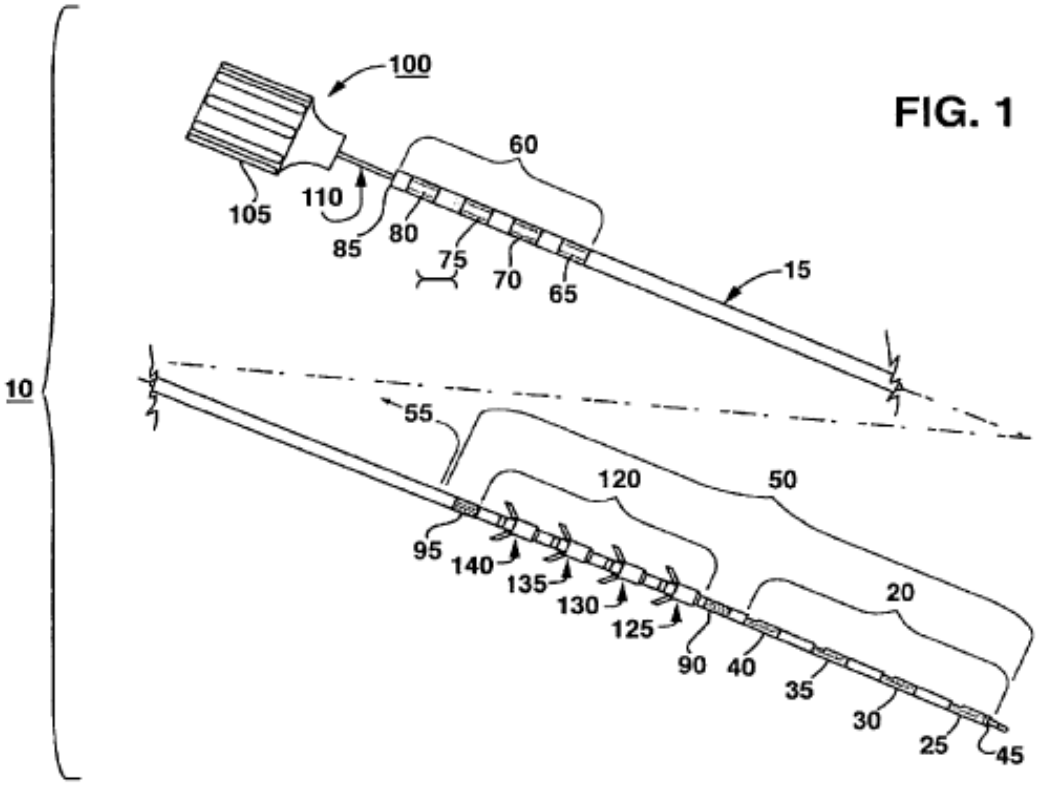


Figure 1 is a plan view showing implantable medical lead 10 for sacral nerve stimulation. *Id.* at 8:34–35, 9:7–8. Implantable medical lead 10 includes lead body 15 with electrode array 20 that extends proximally from lead distal end 45 and comprises P stimulation electrodes. *Id.* at 6:10–14, 9:7–12. 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.

Figure 3, reproduced below, shows a tine elements. *Id.* at 8:41–42.

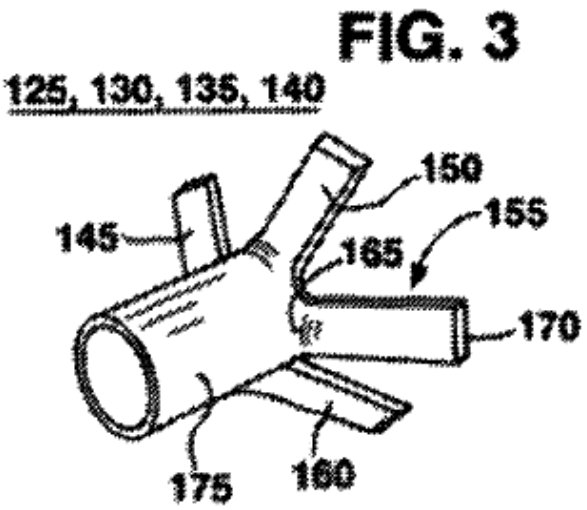
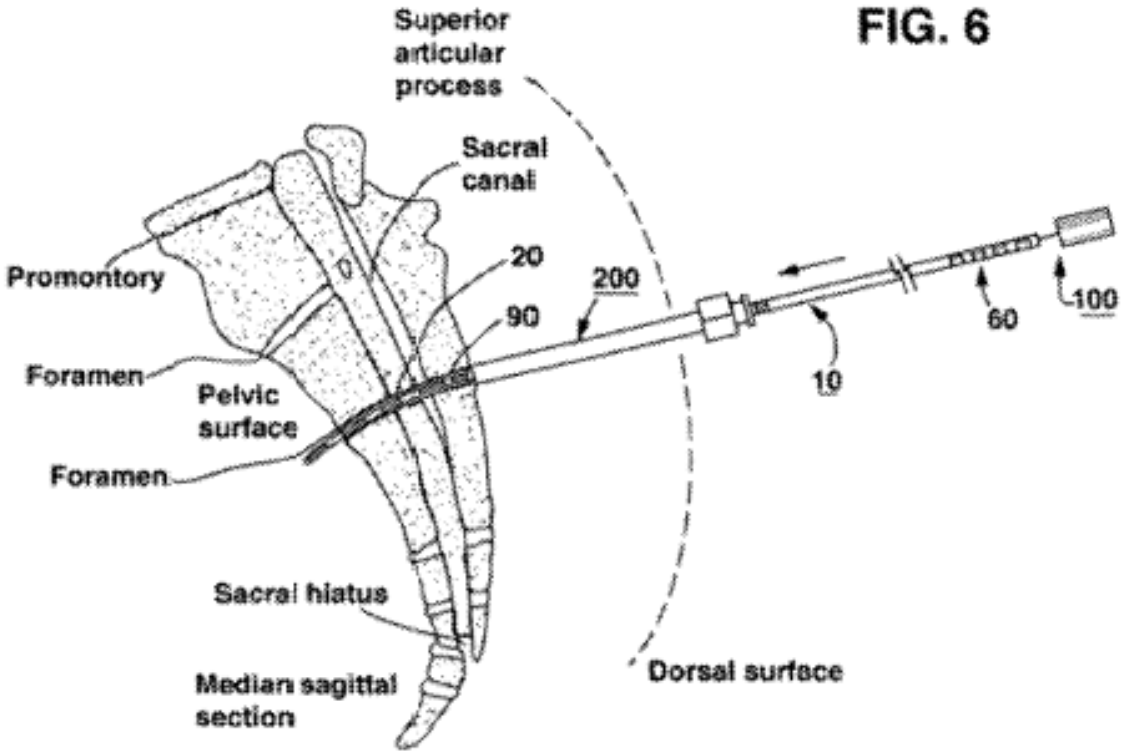
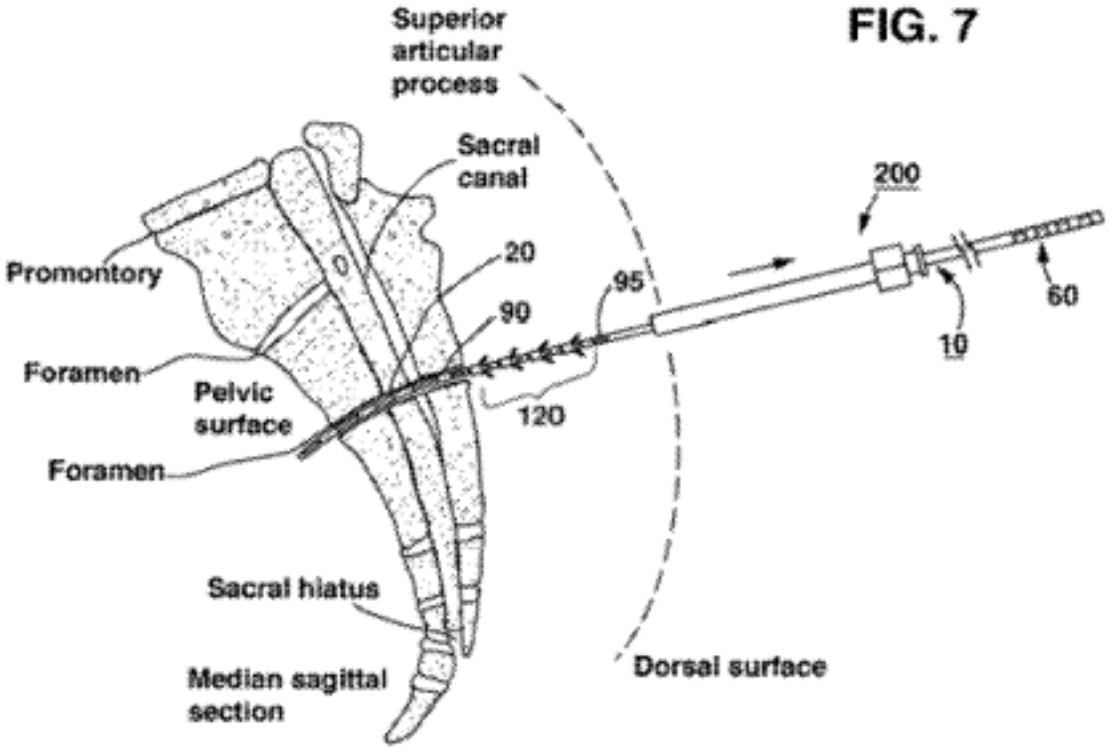


Figure 3 is an expanded perspective view showing one of tine elements 125, 130, 135, 140. *Id.* Each tine element comprises N flexible, pliant, tines. *Id.* at 5:60–61, 10:8–11. As shown in Figure 3, the tine element includes tines 145, 150, 155, 160 such that N=4. *Id.* at 10:8–11. Each tine extends 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.





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, 30–32, 36–40, 61–63, 16:7–12, 22–23.

E. Evidence

Petitioner relies on the following references in asserting that the challenged claims are unpatentable. Pet. 20.

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")	1008
Gerber, US 6,055,456, issued Apr. 25, 2000 ("Gerber")	1010
Lindegren, WO 98/20933, published May 22, 1998 ("Lindegren")	1011
Akerström, US 4,407,303, issued Oct. 4, 1983 ("Akerström")	1012
Hauser et al., US 5,052,407, issued Oct. 1, 1991 ("Hauser")	1013

Petitioner also relies on a Declaration of Mr. Benjamin Pless (Ex. 1003). Pet. 20–21.

F. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability. Pet. 20.

Claims Challenged	**35 U.S.C. §**	**References**
1, 2, 5, 7, 13–15, 18	103(a)	Young, Gerber, Lindegren, Akerström

1, 2, 5, 7, 13–15, 18	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. 15 (citing Ex. 1003 ¶ 61). 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 '756 patent and Gerber are each directed to an implantable medical electrical lead for stimulation of a bundle of sacral nerve fibers. Ex. 1001, 1:18–25, 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 "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 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, 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 is obvious over Young, Gerber, Lindegren, and Akerström. Pet. 22–47. 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 skill in the art would have been motivated to combine the teachings of the references to

arrive at the claimed invention. Prelim. Resp. 18–38. 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. 1008)

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[1] is shown in Figure 1 below. *Id.*

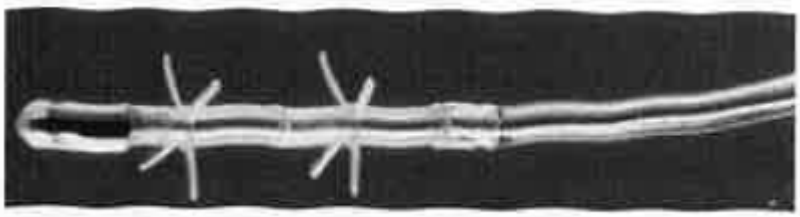


FIG. 1.

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

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

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.

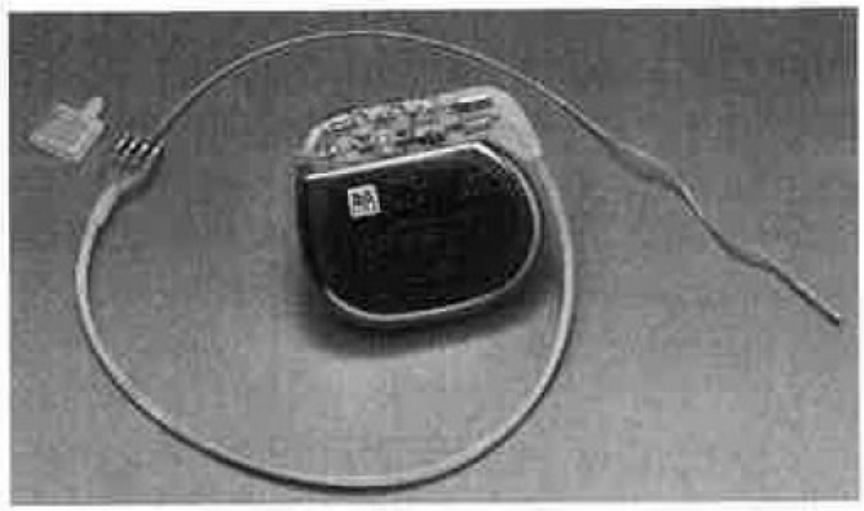


Figure 3 is a photograph of the complete component system for trigeminal stimulation, including the electrode, the implanted pulse generator, and an extension lead. *Id.*

2. Gerber (Ex. 1010)

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. Figure 1, reproduced below, shows the implantable medical lead for stimulation of the sacral nerves. *Id.* at 3:40–42.

[2] The implanted pulse generator system disclosed in Young is Patent Owner's ITREL. *Id.* at 74.

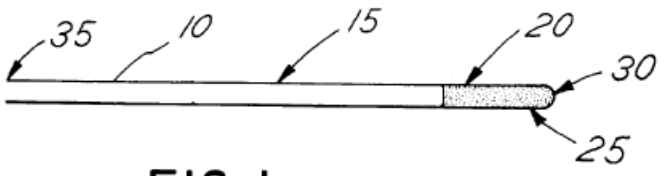


FIG. 1

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.

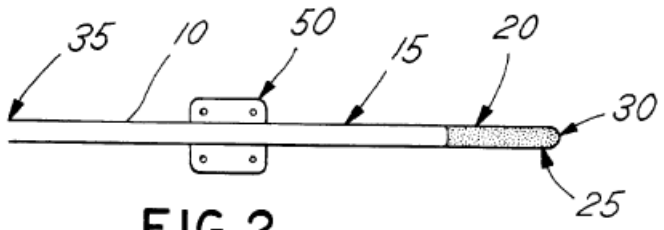


FIG. 2

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.

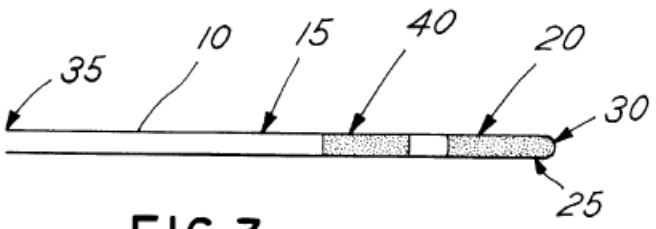


FIG.3

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. 1011)

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. *Id.* at 6:30–32.

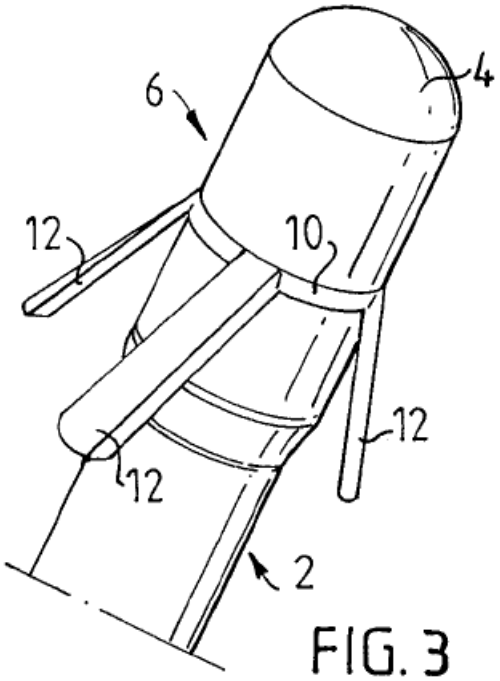


FIG. 3

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. Akerström (Ex. 1012)

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

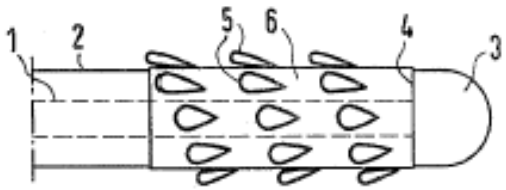


FIG 1

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.

5. *Independent claim 1*

   a. *Undisputed limitations (limitations 1.0, 1.b, 1.d, 1.e, 1.h, 1.i, and 1.k)*

The preamble of independent claim 1, i.e., 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 further 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 also 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. 1008, 77; Ex. 1003 ¶ 104). 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 next 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. 1008, 74; Ex. 1003 ¶ 106). 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 further 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. 1008, 73, Fig. 1; Ex. 1003, 75–76). 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). Per Petitioner, Akerström's loops look like tines, and a person of ordinary skill in the art could arrange 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 person of ordinary skill in the art would know that tines allow for anchoring by fibrosis and would locate the tines between all electrodes and the lead distal end. *Id.* at 38–39 (citing Ex. 1010, 4:15–30, Fig. 2; Ex. 1003, 76–77).

Independent claim 1 next 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).

At this stage of the proceeding, Patent Owner does not dispute Petitioner's contentions for claim limitations 1.0, 1.b, 1.d, 1.e, 1.h, 1.i, and 1.k. On the current record, our review of the cited references is consistent with Petitioner's arguments and Mr. Pless's testimony. For example, 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, a plurality of tine elements separate from and axially displaced each other and from the electrode, and a proximal end that is connected to an extension lead, which is connected to the IPG. Ex. 1008, 73–74, Figs. 1, 3. Gerber discloses an implantable medical lead having a lead body, conductors, electrodes, and an anchoring mechanism located separate from and axially displaced from an electrode. Ex. 1010,

Abstract, 3:39–42, 52–56, 4:6–7, 13–15, 32–33, Figs. 2–3. Akerström teaches an arrangement of two spaced-apart series of loops. Ex. 1012, 2:56–59, Fig. 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.

b. Introducing an introducer (limitation 1.a)

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. 1010, 5:16–17, 26–28, 34–35; Ex. 1003 ¶ 96).

Patent Owner argues Petitioner fails to present evidence that the needle, i.e., introducer, is placed near the stimulation site, as limitation 1.a requires. Prelim. Resp. 32–33. We disagree. Given Young's express disclosure of guiding the needle toward the foramen ovale and receiving cerebrospinal fluid flow therein (Ex. 1008, 73), Petitioner has persuaded us, on the current record, that a person of ordinary skill in the art would have

understood Young discloses locating the distal end of the needle lumen opening adjacent the foramen ovale, i.e., stimulation site.

Patent Owner further asserts that Petitioner's reliance on Gerber cannot cure Young's deficiency in regard to this limitation because Petitioner has not explained how Gerber meets this limitation. Prelim. Resp. 33–34. Yet, for purposes of institution, Petitioner has persuaded us that Young discloses the limitation.

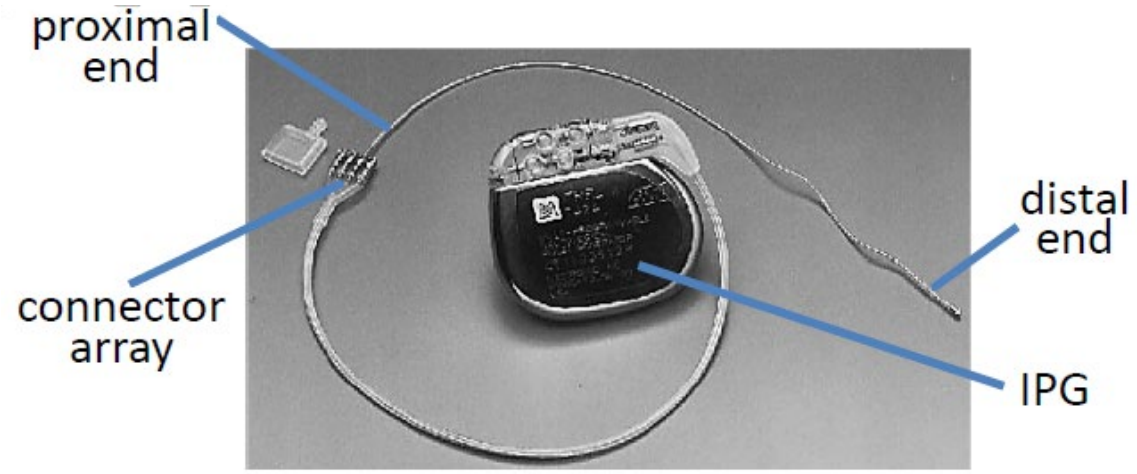
Patent Owner also argues Petitioner provides no details regarding which aspect of the claim limitation is missing from Young, for what Gerber is being relied upon, and how and why Young would have been modified based on Gerber. *Id.* at 34. Per Patent Owner, Petitioner's failure to specify which reference is relied upon for which aspect of the limitation "is a 'catch-all' 'ground [that] is not reasonably bounded in scope and unduly burdensome for both Patent Owner and the Board to address' and fails to perform the proper analysis under the *Graham* factors. *Id.* (alteration in original) (quoting *Adaptics Ltd. v. Perfect Co.*, IPR2018-01596, Paper 20 at 21 (PTAB Mar. 6, 2019) (informative)). Contrary to Patent Owner's argument, Petitioner's reliance on both Young and Gerber to disclose limitation 1.a does not place 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.'").

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

purposes of institution, Petitioner persuasively identifies limitation 1.a in the cited references.

c. P connector elements (limitation 1.c)

Independent claim 1 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).

In contrast, Patent Owner contends that, under Petitioner's mapping of the limitation to Young's disclosure, Young does not disclose the connector array is part of the lead body, as the limitation requires. Prelim. Resp. 27. According to Patent Owner, Petitioner's annotated version of Young's Figure 3 shows the alleged connector array located proximal to the lead proximal end, and anything proximal of the lead proximal end cannot be part of the lead. *Id.* at 27–28. Patent Owner also contends Young does not suggest four connector elements in an array along the same lead body is possible, but instead discloses a port having four parallel slots with the lead body inserted into one of the slots such that the remaining three slots would each receive an independent lead therein. *Id.* at 29. In regard to Gerber, Patent Owner argues there is no support for Petitioner's assertion that the plurality of electrodes at the distal end inherently corresponds to a plurality of connector elements on the proximal end at least because Petitioner does not explain why a single connector could not deliver electrical signals to the plurality of electrodes. *Id.* at 29–30. Patent Owner additionally argues that Petitioner does not adequately describe its proposed combination of Young and Gerber with respect to limitation 1.c, and that Petitioner's description of

the proposed combination relates to a modification of the distal end of Young's lead, not the proximal end pertinent to this limitation. *Id.* at 30–32.

Beginning with Young, Figure 3 is a photograph of the complete component system, including the electrode, IPG, and extension lead connecting the electrode and the IPG. Ex. 1008, 74, Fig. 3. Even if we agree with Patent Owner that the port, i.e., connection between the electrode and the extension lead, is proximal to the proximal end of the electrode and therefore not located along the lead body, the proximal end of the electrode is nonetheless connected to the port. Put simply, as shown in Young's Figure 3, the proximal end of the electrode is connected to the extension lead such that the proximal end of the lead body has a connector element.

To the extent Young does not disclose a plurality of connectors, Petitioner persuasively argues, at this stage of the proceeding, that Gerber inherently discloses up to four connectors proximate the lead proximal end. Gerber teaches up to four electrodes connected to the IPG. Ex. 1010, 1:57–61. Gerber also supports Mr. Pless's testimony that this connection between the four electrodes and the IPG inherently discloses four connectors, as opposed to a single connector, because Gerber teaches the electrodes have different polarities. *Id.* at 4:65–5:6. Furthermore, in view of the corollary between Gerber's plurality of electrodes and a plurality of connectors, modifying the distal end of Young's electrode to include Gerber's plurality of electrodes would have necessitated a plurality of connectors.

In view of the foregoing, Petitioner's arguments and Mr. Pless's testimony find support in Young and Gerber. On this record and for

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

d. Plurality of M tine elements (limitation 1.f).

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 the electrode described in Young discloses 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.*

Patent Owner argues Petitioner fails to demonstrate how the prior art discloses the recited "tine elements" under its proposed construction. Prelim. Resp. 24–25. We disagree. Pursuant to its definition, Petitioner argues 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 36 (citing Ex. 1008, 73, Fig. 1).

On the current record, 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, and formed in a tine element array located between the electrode and the lead proximal end. Ex. 1008, 73, Fig. 1. On this record and for purposes of institution, Petitioner demonstrates sufficiently that Young and Gerber disclose limitation 1.e.

e. N flexible tines adapted to be folded inward and deploy outward (limitations 1.g and 1.j)

Independent claim 1 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 proximally 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. For this limitation, 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 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).

Independent claim 1 additionally 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. For this limitation, 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 person of ordinary skill in the art 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. 1008, 73, 75; Ex. 1003, 78–79).

Patent Owner argues Petitioner fails to establish Young expressly or inherently discloses tines that are flexible and adapted to fold inwardly, as limitation 1.g requires. Prelim. Resp. 19–22. Patent Owner also argues that Petitioner's reliance on Lindegren does not remedy Young's failure to disclose flexible tines adapted to fold inwardly because Petitioner's reliance on Lindegren is limited to its teaching of proximally-extending tines. *Id.* at 22–23. Patent Owner further argues Petitioner fails to show Young inherently discloses tines that deploy outwardly when no longer constrained, in accordance with limitation 1.j. *Id.* at 23–24.

At the outset, we disagree Petitioner is relying on Lindegren for teaching only proximally-extending tines. Rather, Petitioner proposes to modify the electrode 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. 30–31; Ex. 1011, 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 30), and "in order to improve anchoring within the soft tissue near the sacrum, it would have been obvious to a [person of ordinary skill in the art] to use multiples of tines mounted on collars (i.e. tine elements) extending proximally" (*id.* at 31).

We further disagree Petitioner has not demonstrated persuasively that Young discloses flexible tines that are adapted to fold inwardly and that deploy outwardly, as limitations 1.g. and 1.j require. "[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). 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[3] 5:13–21). Given Mr. Pless's testimony, which finds support in Citron, Petitioner has shown persuasively, on the current record, that a person of ordinary skill in the art would have understood from Young's teaching of using a No. 14 needle to implant the tined electrode that Young's tines are flexible and adapted to fold inwardly against the lead body when they are constrained in the needle and deploy outwardly when the needle is

[3] Citron et al., US 3,902,501, issued Sept. 2, 1975 ("Citron").

removed. Accordingly, for purposes of institution, Petitioner sufficiently identifies limitations 1.g and 1.j in the prior art.

f. Rationale

Petitioner argues a person of ordinary skill in the art would have been motivated to combine the teachings of Young, Gerber, Lindegren, and Akerström for several reasons. Pet. 29–32. 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' 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)). Additionally, Petitioner argues a person of ordinary skill in the art would have combined the teachings of Young, Gerber, Lindegren, and Akerström because each of these references addresses the problem of adequately stimulating nerves while limiting

dislodgement. *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)).

In contrast, Patent Owner argues Petitioner fails to establish that it would have been obvious to combine Young with Gerber, Lindegren, and Akerström. Prelim. Resp. 35–38. More particularly, Patent Owner contends "Petitioner reproduces portions of various references in its claim charts without providing a comprehensible mapping between the prior art and the claim limitations." *Id.* at 36. We disagree for the reasons stated above in sections III.C.5.a–e.

Patent Owner also contends that Petitioner makes no attempt to reconcile the differences in the anatomy at issue in Young and Gerber, 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. 36–37. 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).

Patent Owner additionally maintains 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 37–38 (citing Ex. 2012[4], 1558, 1563). Patent Owner's evidence, however, shows the electrode disclosed in Young is at least somewhat effective in preventing lead migration.

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

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. 1008, 73 ("The purpose of the tines was to prevent the electrode from becoming dislodged after implantation."). Moreover, in addition to the Young, Gerber, Lindegren, and Akerström references describing the problem of lead dislodgement, Petitioner's reasons for the proposed combination also include reliance on Young's disclosure of the desire for more multiple active stimulation sites, Lindegren's teaching of manufacturing efficiencies associated with tines mounted on a ring-shaped means, and similarities between Lindegren's tine-mounted rings and Akerström's loop-mounted collars. Pet. 30–31.

At this stage of the proceeding, Petitioner has demonstrated sufficiently that Young suggests an electrode system that includes multiple electrode contacts to provide greater flexibility in activation of a wider area, and Gerber's electrode system includes multiple electrode contracts. Ex. 1010, 77; Ex. 1013, Abstract, 4:32–45, Fig. 3. Petitioner also has shown sufficiently that Lindegren suggests modifying the electrode system to include tine-mounted rings for manufacturing efficiencies, and that, like Lindegren's tines, Akerström's loops are mounted on collars and anchor via fibrosis. Ex. 1011, 5:17–20, Fig. 3; Ex. 1012, 2:46–20, Fig. 3. On the current record, Petitioner has provided persuasive reasoning why a person of ordinary skill would have combined the teachings of Young, Gerber, Lindegren, and Akerström in the manner set forth in the Petition.

g. Conclusion for independent claim 1

In view of the foregoing, Petitioner has shown sufficiently how each limitation of independent claim 1 is found in Young, Gerber, Lindegren, and Akerström. Petitioner also has articulated sufficient reasoning why a person of ordinary skill would have combined the teachings of Young, Gerber, Lindegren, 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 Young, Gerber, Lindegren, and Akerström.

6. Independent claim 14

Like independent claim 1, independent claim 14 recites a method, and limitations 14.0–14.i are similar to limitations 1.0–1.h and 1.j, respectively. Ex. 1001, 14:64–16:6. Petitioner's arguments for independent claim 14 are similar to its arguments for independent claim 1. *Compare* Pet. 42–46, *with id.* at 32–41.

Patent Owner's arguments regarding independent claim 14 are similar to its arguments for independent claim 1. Prelim. Resp. 18–38. We address these arguments above in section III.C.5. Patent Owner additionally contends that Petitioner's analysis of limitation 14.g is defective because Petitioner refers to its arguments for limitation 1.i, which do not address how or why Young's tines deploy outwardly when the introducer is withdrawn. Prelim. Resp. 23. Limitation 14.g, however, does not require tines that deploy outwardly, and instead recites "a plurality of flexible tines . . . adapted to deploy outward." Ex. 1001, 15:20–23. Nonetheless, as discussed above in section III.C.5.e, Petitioner has persuaded us, at this stage of the

proceeding, that Young discloses flexible tines that deploy outwardly when the introducer is withdrawn. For these reasons, to include those set forth in section III.C.5, Petitioner has shown a reasonable likelihood that it would prevail in demonstrating independent claim 14 is unpatentable under 35 U.S.C. § 103(a) based on the combination of Young, Gerber, Lindegren, and Akerström.

7. Dependent claims

Petitioner argues Young, Gerber, Lindegren, and Akerström disclose the limitations of claims 2, 5, 7, 13, 15, and 18. Pet. 41–42, 46–47. At this stage of the proceeding, Patent Owner does not raise arguments for these claims apart from its arguments for independent claims 1 and 14. Prelim. Resp. 17–38.

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. As we discuss Gerber and Akerström in sections III.C.2 and 4, respectively, 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.

1. Hauser (Ex. 1013)

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. Figure 1, reproduced below, shows the electrode.

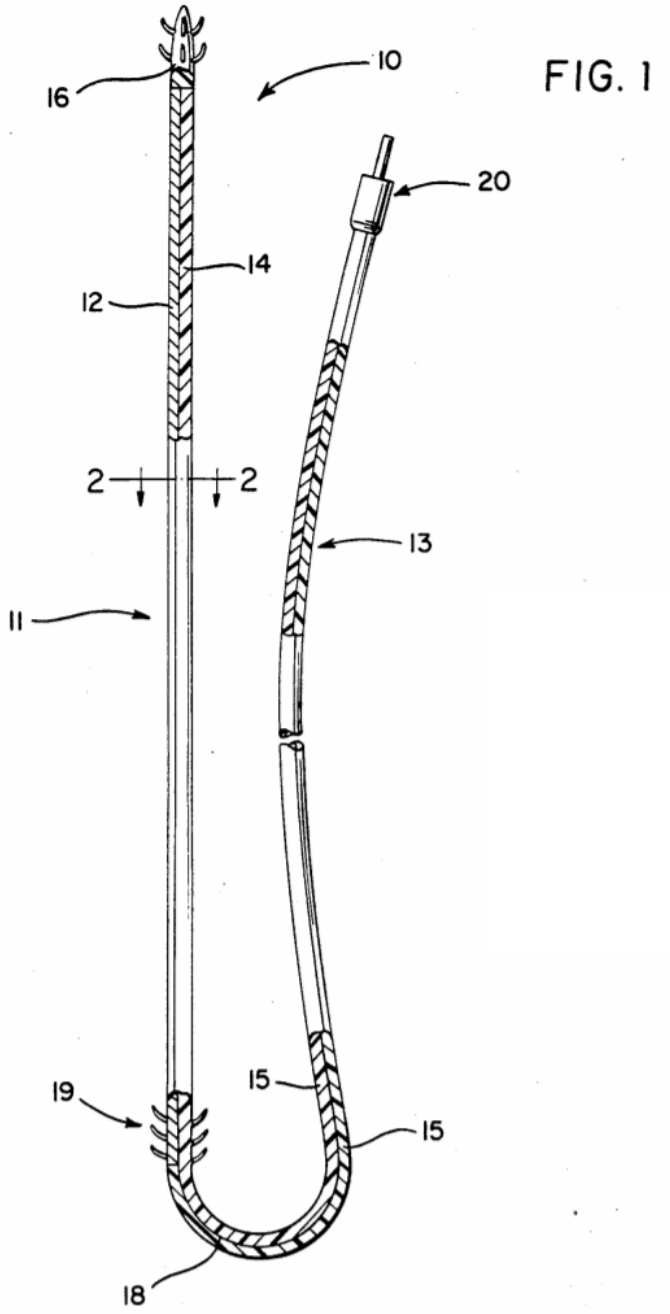
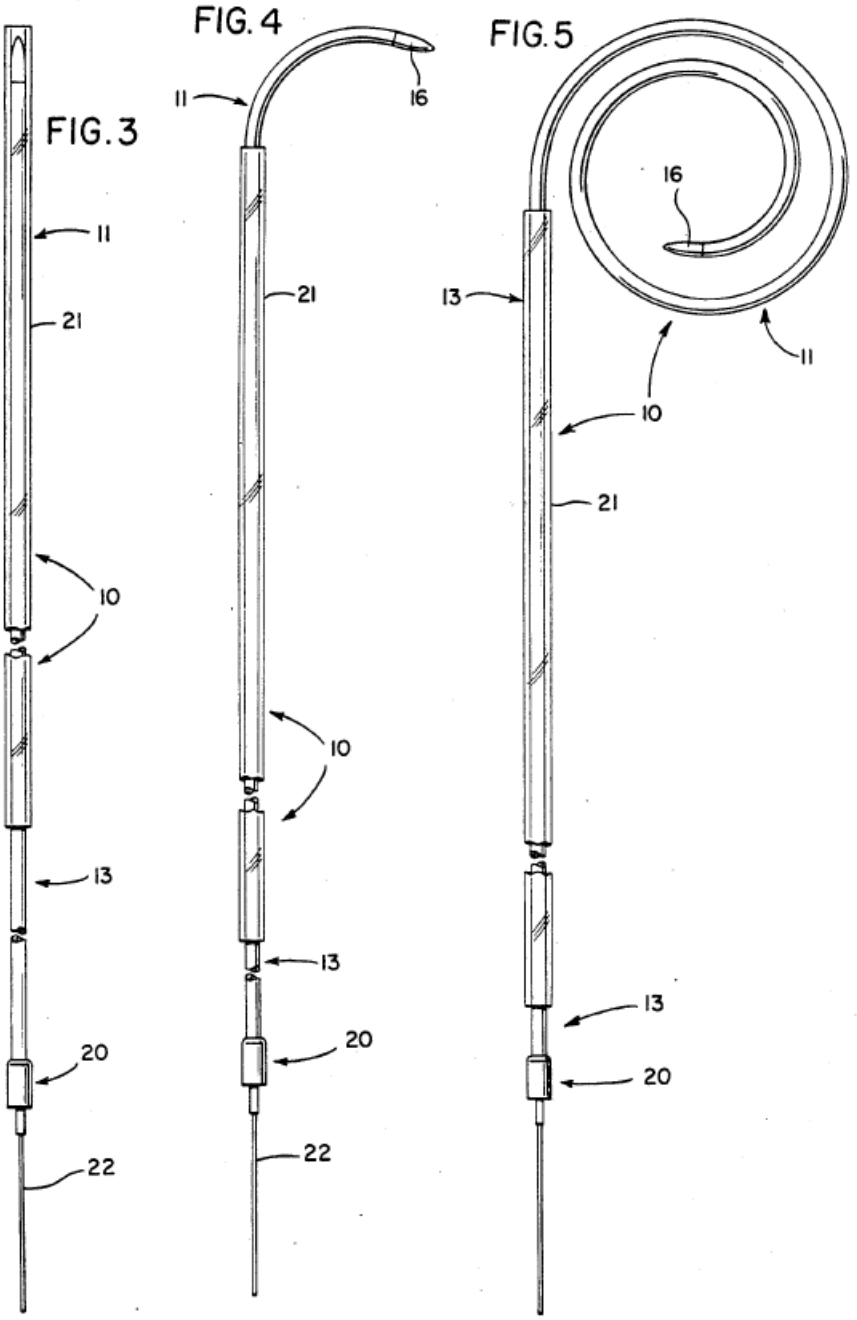


Figure 1 is a perspective view of the electrode in a partially straightened position. *Id.* at 3:9–10. Electrode 10 is thin and elongated, and includes distal active region 11 and proximal lead region 13. *Id.* at 3:50–52. Conductive discharge surface 12 and insulative surface 14 define and extend the 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 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. 51. 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 ¶ 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).

On the other hand, 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. 39–46. 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 40. 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 43. 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. 1010, 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. 1013, 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. 1012, 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. 41–42 (citing Ex. 1012, 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. 1012, 1:15–32. Petitioner, however, is proposing to add tines to Gerber's electrode (Pet. 51), which is for sacral nerve stimulation and not introduced venously (Ex. 1010, 1:9–12, 5:33–39), so we disagree 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. 1013, 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. 44. 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. 51. 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. 1011, 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. 45. 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. 51; Ex. 1010, 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. 1013, 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.

For the foregoing reasons, 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 rationale for combining the references.

b. Undisputed limitations (limitations 1.0, 1.b–1.e, 1.h, 1.i, and 1.k)

In regard to 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[5]. Pet. 52 (citing Ex. 1010, Abstract, 2:31–36, 3:48–56). 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.* at 53 (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.

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

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

displaced from the 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. 1013, 2:56–59, Fig. 3; Ex. 1003, 95–96). Additionally, Petitioner asserts Gerber discloses the electrodes are between anchoring mechanism 50, which can anchor via fibrosis, and the lead distal end. *Id.*

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. *Id.* Per Petitioner, a person of ordinary skill in the art could have used Akerström's arrangement for tine elements with no overlapping tines. *Id.* (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. 1010, 3:52–56; Ex. 1003, 97–98). Petitioner also argues Hauser inherently teaches the IPG is connected to the lead at the connector elements. *Id.* (citing Ex. 1003, 97).

At this stage of the proceeding, Patent Owner does not dispute Petitioner's contentions with respect to limitations 1.0, 1.b–1.e, 1.h, 1.i, and 1.k. 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 sufficiently shown for purposes of this Decision that Gerber discloses an implantable medical lead having a lead body, connectors, electrodes, conductors, and an anchoring mechanism that is located separate from and axially displaced from an electrode and that can anchor via fibrosis, as well as carrying pulses from the IPG to the distal end of the lead body having at least one electrode. Ex. 1010, Abstract, 3:39–42, 52–56, 4:6–7, 13–15, 27–30, 32–33, Figs. 2–3. Petitioner also has demonstrated sufficiently that Hauser teaches fixation means retained within a catheter during deployment of the electrode. Ex. 1013, 4:30–55, Figs. 1, 3–5, 12. Petitioner has further demonstrated sufficiently that Akerström teaches an arrangement of two spaced-apart series of loops. Ex. 1012, 2:56–59. Based on the record at this stage of the proceeding and for purposes of this Decision, Petitioner demonstrates persuasively that Gerber, Hauser, and Akerström disclose these claim limitations.

c. Introducing an introducer (limitation 1.a)

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 first making an incision and using a cannula. Pet. 53 (citing Ex. 1010, 5:16–17, 26–28, 34–37). Petitioner further argues "[p]ercutaneous use of cannula as introducer [was] well known prior to 2001." *Id.* (citing Ex. 1003, 87[6], ¶ 96). Petitioner also contends Hauser teaches introducing a

[6] 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.

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, 4:23–43). 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[7]).

On the other hand, Patent Owner asserts there is no evidence that Gerber's cannula is located adjacent to a stimulation site. Prelim. Resp. 50. Patent Owner further asserts Petitioner does not explain how Hauser is being relied upon such that Petitioner's arguments for limitation 1.a are not reasonably bounded in scope and unduly burdensome to address. *Id.* at 50–51. Patent Owner also maintains Petitioner's obviousness analysis for this limitation is deficient. According to Patent Owner, Petitioner does not explain why a person of ordinary skill in the art would have combined the teachings of Gerber and Hauser to result in limitation 1.a, nor does Petitioner make an attempt to reconcile the different anatomies in Gerber and Hauser. *Id.* at 51–53.

At the outset, we disagree that Petitioner's arguments for limitation 1.a are not reasonably bounded in scope. Petitioner relies on Gerber and Hauser for this limitation, and two is a reasonable number of references.

Moreover, Patent Owner's criticisms of Petitioner's obviousness analysis for this limitation are inapposite, as, at this stage of the proceeding, Petitioner has persuasively identified this limitation in Gerber. Although

[7] *See supra* note 4.

Gerber does not expressly disclose placing the cannula adjacent to the stimulation site, we also consider the inferences a person of ordinary skill in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d at 826. Mr. Pless testifies that Gerber's teaching of implanting the electrode with a cannula discloses this limitation. Ex. 1003, 87 (citing Ex. 1010, 5:16–17, 26–28, 34–37). Mr. Pless's understanding that Gerber's cannula would be placed adjacent to the stimulation site finds support in Hauser, which teaches placing a catheter at the stimulation site during implantation of the electrode. Ex. 1013, 4:32–43. Thus, Petitioner has shown persuasively, on the current record, that a person of ordinary skill in the art would have understood from Gerber's teaching of using a cannula to implant the electrode that Gerber discloses introducing an introducer having an introducer lumen through body tissue to locate the introducer lumen distal end opening adjacent to the stimulation site and disposing an implantable medical lead within the introducer lumen, in accordance with limitation 1.a.

d. Plurality M tine elements (limitation 1.f)

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. Pet. 54–55 (citing Ex. 1010, 4:13–30, Figs. 2, 6). Petitioner further argues a person of ordinary skill in the art 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 person of ordinary skill in the art would understand 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 person of ordinary skill in the art would consider 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).

Patent Owner contends that Petitioner does not explain how the prior art discloses "tine elements" under Petitioner's construction. Prelim. Resp. 48–50. According to Patent Owner, under Petitioner's proffered construction, "tines" and "tine elements" are different, and Petitioner argues Hauser's fixation means are both "tines" and "tine elements" without any explanation as to how the prior art discloses "tine elements." *Id.* We disagree. Pursuant to its construction, Petitioner argues Hauser's fixation means 19 is made up of "3 sets of tine elements." Pet. 55 (citing Ex. 1013, 4:1–25, Figs. 6, 12). 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. 51; Ex. 1003 ¶ 115.

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 shown 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. 1012, 2:56–59, Fig. 3. On this record and for purposes of institution, Petitioner identifies persuasively limitation 1.f in Gerber, Hauser, and Akerström.

e. N flexible tines adapted to be folded inward and deploy outward (limitations 1.g and 1.j)

For limitation 1.g reciting N flexible tines adapted to be folded inwardly against the lead body when fitted into and constrained by the introducer lumen, Petitioner argues Hauser's fixation means 19 includes 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. 1012, Fig. 3). 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 person of ordinary skill in the art would consider 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. 1013, 2:26–28; Ex. 1003, 94–95).

In regard 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. 1013, 4:3–8, 49–52, Figs. 5, 12; Ex. 1003, 96–97, ¶ 113). 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).

Patent Owner argues there is no evidence that Hauser's tines are flexible. Prelim. Resp. 46. Patent Owner similarly argues "nowhere in Hauser is there a description of the fixation means 19 being folded inward, constrained, or deployed outwardly." *Id.* at 47. We disagree with Patent Owner. Hauser's Figure 3 shows a stage of implantation of the electrode illustrated in Figure 1 where the electrode is introduced into the catheter. Ex. 1013, 3:12–13, 4:32–39. As Figure 1 shows electrode 10 with fixation means 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 19 are flexible 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. 59 (Ex. 1013, Fig. 7).

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. 47 (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, and Akerström expressly teaches away from the use of tines. *Id.* (citing Ex. 1013, 1:15–32)). We, however, disagree with Patent Owner's alleged lack of explanation for modifying Gerber's electrode to include 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 naturally into the body, and a person of ordinary skill in the art understanding tines anchor by fibrosis. Pet. 51. Petitioner also argues 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. 1013, Fig. 3; Ex. 1003 ¶ 116). As set forth above in section III.D.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. 1013, 1:15–32), Petitioner is proposing to add tines to Gerber's electrode, which is for sacral nerve stimulation and not introduced venously (Ex. 1010, 1:9–12, 5:33–39).

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.g and 1.j.

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 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 it 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 claim 14

Petitioner's arguments regarding independent claim 14 are similar to its arguments for independent claim 1. *Compare* Pet. 64–67, *with id.* at 52–62. Patent Owner's arguments for independent claim 14 are similar to its arguments for independent claim 1. *See* Prelim. Resp. 38–53. For the reasons discussed in section III.D.2., Petitioner has shown a reasonable likelihood that it would prevail in demonstrating independent claim 14 is 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, 5, 7, 13, 15, and 18. Pet. 62–64, 67–68. At this stage of the proceeding, Patent Owner does not raise arguments for these claims apart from its arguments for independent claim 1. Prelim. Resp. 38–53.

E. Secondary Considerations

Patent Owner cites to a paper touting Patent Owner's tined electrode. Prelim. Resp. 42 (citing Ex. 2004[8], 24). Patent Owner also argues the invention set forth in the '756 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 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.

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

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 '756 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 '756 patent is hereby instituted with respect to claims 1, 2, 5, 7, 13–15, and 18 of the '756 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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