UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS MODULATION TECHNOLOGIES, INC.
Petitioner
v.

MEDTRONIC, INC.
Patent Owner

Case IPR2020-00679

Patent No. 8,626,314

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 8,626,314

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I. INTRODUCTION

Petitioner Axonics Modulation Technologies, Inc. ("Axonics"/"Petitioner") respectfully requests *inter partes* review of claims 1, 2, 4, 7, 10-12, 14, and 18-24 ("challenged claims") of U.S. Patent No. 8,626,314 ("'314 Patent") in accordance with 35 U.S.C. §§ 311319 and 37 C.F.R. § 42.100 *et seq*. ("Petition").

The '314 Patent is directed to a certain type of implantable medical electrical lead, in particularly to be used for stimulating the sacral nerves, and method of implanting and anchoring that lead. The '314 Patent does not disclose or cover anything new. It even admits that all the components of its system—leads with multiple electrodes and/or tines and other fixation means to anchor the lead connected to a pulse generator—were well known in the prior art. It further admits that the methods of introducing the lead using introducers and anchoring a lead using tines were both known before the '314 Patent priority date.

Due to the abundance of prior knowledge, the prosecution history is long. After many rejections, the Examiner allowed claims after amendment, requiring

that "all tine elements" are positioned between the most proximal[1] electrode … and the proximal end of the lead body. This location of tine elements is, however, obvious in view of prior art such as the Young reference (Ex. 1010), which disclosed implantation of prior tined lead and pulse generator developed by the Patent Owner Medtronic, Inc. ("Medtronic") and was notably not disclosed to the Examiner during prosecution. For the reasons explained below, the challenged claims are unpatentable and should be cancelled.

II. THE '314 PATENT AND TECHNICAL BACKGROUND

The '314 Patent is directed to a certain type of implantable medical electrical lead, in particular to be used for stimulating the sacral nerves, and method of implanting and anchoring that lead. Ex. 1001, 1:34-44. It has 24 claims, of which claims 1, 11 and 18 are independent claims. Claims 1 and 11 are system claims that describe the implantable medical lead comprising essentially (a) a plurality of electrodes that is electrically connected via conductors and connectors to a pulse generator and (b) a plurality of tines on a plurality of tine elements that are adapted

[1] Proximal direction in the '314 Patent refers to being closer to the physician who is inserting the lead percutaneously (through the skin). *See* Ex. 1001 at 5:65-6:5 (referring to "distal electrode" at a site in the body).

to fold within the lumen of the introducer and then deploy at a simulation site. The method claim 18 requires the use of an introducer through which the medical lead of claims 1 or 11 are advanced to the stimulation site. The '314 Patent was filed on July 14, 2011, but claims priority to a provisional application 60/316,582, filed on August 31, 2001.[2]

A. Technical Background

Operative neurostimulation, also known as neuromodulation, involves altering the electrical signals of nerves through the use of active implanted device to produce therapeutic effects. Ex. 1003 ¶24. Neurostimulation has been studied since the 1800s, with first theories of regulating bladder function formulated around 1864. This area continued to develop and by the late 1960s, numerous and different active implanted devices had been developed, including nerve stimulators for the heart, brain, and peripheral nerve stimulations and other applications. *Id.* ¶¶25-26. As these implantations showed therapeutic effect, there was significant research and development that led to improved neurostimulation device designs well before 2001, including in electrode designs, various fixing mechanisms to

[2] For purposes of this Petition, Axonics assumes that the '314 Patent priority date is August 31, 2001.

anchor the lead into position, and introducers to place the lead into the human body. *Id.* ¶¶27-33. Before 2001, there existed single monopolar electrodes or multiple electrodes in different arrays, linear or multilinear or in grid format. *Id.* ¶30. Similarly, there existed many different devices used to fix the lead: screws, sutures, loops, cloth, adhesive, coils, fins, tines, or combination of these. *Id.* ¶¶31-32. The use of different types of introducers, e.g. hollow tubes such as needles, cannulas, catheters, were well known before 2001. *Id.* ¶33. The material, size, spacing, and number of these devices to be used were dependent on the anatomy of the area where the lead with electrode(s) and fixing mechanism could be introduced and fixed into position. *Id.* ¶34.

B. Overview of the ’314 Patent

The ’314 Patent admits that all the components of its implantable medical lead were known in the prior art. The ’314 Patent acknowledges that many different permanent neurostimulation leads had been implanted. Ex. 1001 at 2:7-3:21. It further acknowledges:

> [C]urrent lead designs *used* for permanent implantation … have a number, e.g. *four, ring-shaped stimulation electrodes* spaced along a distal segment of the lead body…. Each distal stimulation electrode is electrically coupled to the distal end of a lead conductor within the elongated lead body that extends proximally through the lead body. The proximal ends of the

> separately insulated lead conductors are each coupled to a ring-shaped connector element in a proximal connector element array along a proximal segment of the lead body that is adapted to be coupled with the implantable neurostimulation pulse generator.

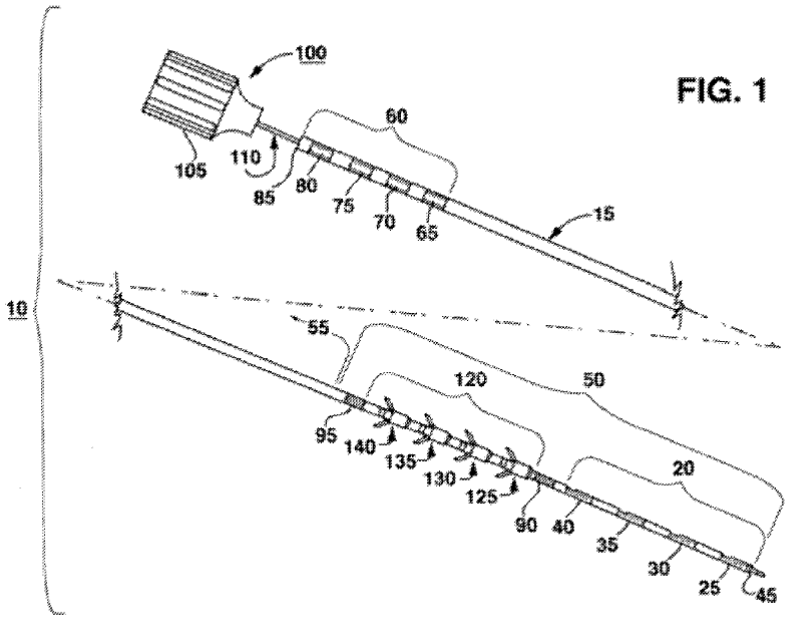
Id., 2:47-59 (emphasis added). The problem, however, with these leads according to the '314 Patent was the suturing mechanism that led to lead migration and/or dangers of general anesthesia. *Id.* 3:22-38, 3:64-67.

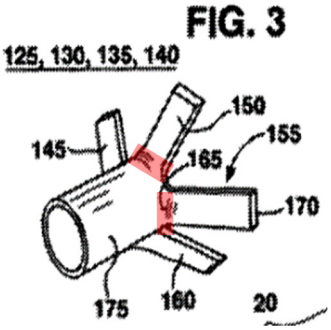
To avoid this, the '314 Patent acknowledges that prior art for sacral nerve stimulation used a percutaneous approach that had essentially nubs that increased resistance and somewhat fixed the leads into position. *Id.* at 4:4-17. The '314 Patent further admits that in the cardiac space, prior art used multiple tines on a tine element array. *Id.* at 4:28-63 (discussing patents incorporated by reference, including U.S. Patent No. 3,939,843 that was "directed to the first atrial tined leads, longitudinally extending rows of elongated tines"). It also admits these tines "fold against the introducer lumen and the vein wall after the lead distal end exits the introducer lumen." Ex. 1001 at 5:3-4.

The '314 Patent, however, states "there remains a need in the art for a permanently implantable electrical sacral nerve stimulation lead that is capable of being passed percutaneously over a guide wire, and/or through the lumen of an introducer from the patient's skin to locate stimulation electrodes in casual contact

with a sacral nerve, that provides acute fixation with muscle and tissue layers posterior to the sacrum, and that can be bent to extend subcutaneously to the neurostimulator IPG without disturbing the fixation so that the stimulation electrodes are less likely to be dislodged during the acute recovery phase and the chronic implantation period." *Id.* at 5:34-44.

The '314 Patent describes several embodiments that have implantable medical lead comprising of a lead body 15 and P number of electrodes on the distal end of the lead body, "where P=one or more" electrodes arranged in an array spaced apart from one another. Ex. 1001 at 6:26-30; 9:25-30; *see also id.* at 12:51-53 (P=one); Fig. 1. Each electrode (25, 30, 35, 40) is electrically coupled to a wire lead conductor within the lead body and the conductor is coupled to connector elements (65, 70, 75, 80) at the proximal end. *Id.* at 9:41-49; Fig. 1. Those connector elements are adapted to be coupled to an IPG, including Medtronic InterStim Neurostimulator Model 3023. *Id.* at 9:62-67.





The electrodes are affixed through "[t]he fixation mechanism compris[ing] a plurality M of tine elements [125, 130, 135, 140] arrayed in a tine element array [120]…. Each tine element comprises at least N flexible, pliant, [sic] tines [145, 150, 155, 160], each tine having a tine width and thickness and extending through a tine length from an attached tine end [165 annotated in Fig. 3] to a free tine end [170]." Ex. 1001 at 5:65-6:12; 6:42-47; 10:12-32; 10:42-52; Figs. 1, 3. While all figures show M=4 tine element and N=4 tines (*id.* at Figs. 2-4, 9), the '314 Patent also states N can be one or more tines (*id.* at 13:14-16). In contrast, M tined elements is always discussed in plural and M is never identified as 1. *Id.* at 6:5-8; 10:25-26; 12:38-40.

The ’314 Patent discloses that its lead is introduced through an introducer such that the tines are adapted to be folded inward against the lead body when constrained in the introducer lumen. Ex. 1001 at 7:1-35; 10:59-64; 11:22-28; Figs. 5-8. The lead is advanced to the stimulation site and the electrode array of the lead is “advanced distally out of the introducer lumen.” *Id.* at 7:36-43; 11:28-36. Then, the introducer is retracted proximally (and withdrawn completely) and the tines are successively released from the introducer lumen to bear against the tissue to inhibit proximal retraction. *Id.* at 7:43-55; 11:9-15; 12:6-22.

The ’314 Patent has 24 claims, with claims 1-17, 22 and 23 being system claims directed to the implanted medical lead, and claims 18-21 and 24 being method claims of introducing essentially the medical lead of earlier system claims using an introducer.

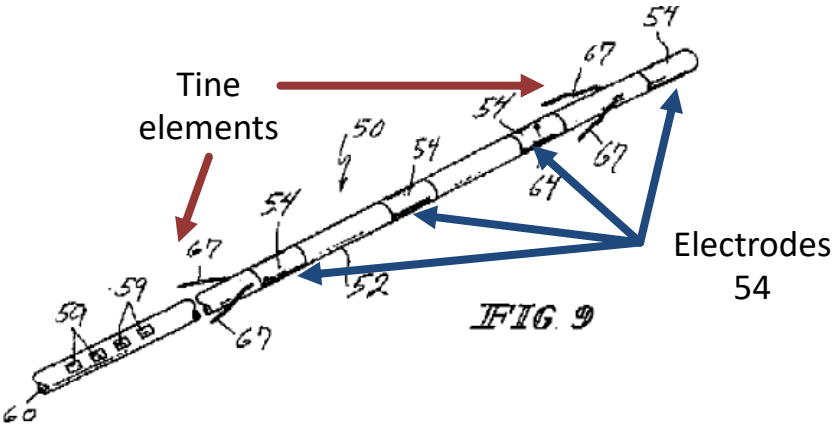
C. Prosecution History

The ’314 Patent was filed as U.S. Application No. 13/183,289 (“the ’289 Application”)[3] on July 14, 2011 with 21 claims and three independent claims—

[3] It is a grandchild continuation of the application that issued as U.S. Patent No. 8,035,756, against which Axonics is filing a concurrent *inter partes* petition. Both these patents claim a priority to the provisional application.

claims 1, 11, and 18—all of which were amended during prosecution. Issued claims 22-24 were added during prosecution.

In the first Non-Final Office Action dated July 16, 2012, all claims 1-21 were rejected. Ex. 1002 at 80. Claims 1-4, 6-8, 10-14, 16, 18, and 20-21 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,510,347 ("Borkan") in view of U.S. Patent No. 4,989,617 ("Memberg"). *Id.* at 81. Similarly claims 5, 9, 15, and 17 were rejected as obvious over Borkan in view of Memberg and U.S. Patent No. 5,257,634 ("Kroll"). *Id.* at 84. Claim 19 was rejected as obvious over Borkan, Memberg, and U.S. Patent No. 4,044,774 ("Corbin"). *Id.*



The Examiner stated that Borkan disclosed the claimed lead having a plurality of tine elements 67 proximal a plurality of electrodes 54 (Fig. 9 annotated above). Ex. 1002, 84-85. Since Borkan was silent on the use of an introducer, the Examiner relied on Memberg for use of an introducer, while Corbin taught

percutaneously introduction. *Id.* Kroll disclosed the use of tines that are radially offset and interleaved. *Id.* at 84.

On October 16, 2012, Medtronic responded to the rejection and added new dependent claims 22-24 requiring at least a "tine mounting band." Ex. 1002 at 113. Medtronic argued that none of the references disclosed "a plurality of tine elements positioned between a plurality of electrodes and the proximal end of the lead body." *Id.*, 115-16.

In a Final Office Action of December 21, 2012, the Examiner maintained the rejections and rejected new claims 22-24 under 35 U.S.C. §103(a) as obvious over Borkan in view of Memberg and U.S. Patent No. 4,957,118 ("Erlebacher"). Ex. 1002 at 130. Erlebacher was relied upon for teaching a tine mounting band. *Id.* In response to the original claims and Medtronic's arguments, the Examiner stated:

> … it doesn't matter if there is only a single electrode distal to the distal tine element or if there is Xn electrodes, since the electrode is part of 'the plurality', and since the tine elements is placed between the plurality, Examiner considers the disclosure of Borkan to meet the invention as claimed. It is of note that the claim as written does not claim a first plurality of electrodes distal a tine element ….

Id. at 130-31. Thus, the Examiner understood the claim language as met if any tine element existed between plurality of electrodes.

In a Response filed on February 14, 2013, Medtronic amended the independent claims 1, 11 and 18 to clarify that "all tine elements of the plurality of tine elements are positioned between the plurality of electrodes and the proximal end of the lead body." Ex. 1002 at 144-45. Medtronic argued that none of the references discloses this amended limitation.

After an interview and request for continued examination was filed, a second Non-Final Office Action issued on April 11, 2013. The Examiner maintained the previous rejections even with the new amendments:

> *Examiner has considered the newly amended claims to clearly set forth a proximal boundary with respect to the tines; however it is still unclear what the distal boundary is*. The claims as written have been interpreted for the purpose of Examination as only requiring there be a proximal end, tine elements and so long as the most distal tine element is not positioned distal the most distal electrode then the tine elements are considered to be placed between the proximal end and the electrodes. *Examiner suggest amending the claims to read, 'all of the tine elements are positioned between the most proximal electrode and the proximal end of the lead body.'* "

Ex. 1002 at 169 (emphasis added).

Medtronic complied with the Examiner's request and amended all claims. Notice of allowance issued on September 3, 2013.

D. Person of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSITA") in the field of the '314 Patent by August 31, 2001 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. Ex. 1003 ¶52.

III. PROPOSED CLAIM CONSTRUCTION

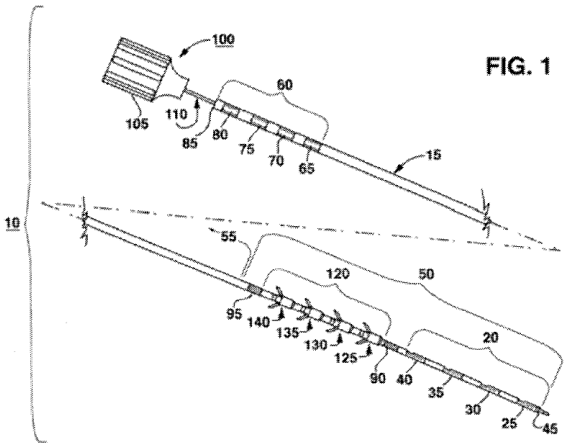
Claims in an IPR filed after November 13, 2019 shall be construed using the same claim construction standard as in a civil action, including construing the claim in accordance with the ordinary meaning as understood by a POSITA. 37 C.F.R. §42.100(b); 83 Fed. Reg. 51,358 (Oct. 11, 2018). Axonics is unaware of any prior construction for the '314 Patent.

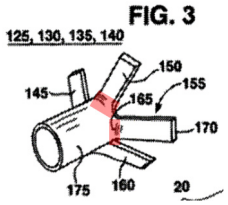
Axonics proposes the following construction under the standard espoused in *Phillips v. AWH Corp*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). The remaining terms should be given their plain and ordinary meaning and the Board need not expressly construe any other term. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

A. "a plurality of tine elements"

All of the independent claims recite "a plurality of tine elements," and thus all challenged claims require this term.

First, the ’314 Patent uses “a plurality” consistent with its plain meaning, two or more. When the specification uses “tine elements” in the plural, it consistently describes or shows multiple structures, most frequently four tine elements arranged in an array from the lead body. Ex. 1001 at 6:5-9 (“a plurality M of tine elements arrayed in a tine element array along a segment of the lead”); 10:16-18 (“four tine elements 125, 130, 135 and 140 arrayed in a tine element array 120”); *see also referring to “tine elements*; 6:20-25, 6:42-43, 10:19-26,





10:42-44, 11:16-21, 12:38-50, Figs. 1, 3, 4, 9 (all showing 4 tine elements).

Similarly, the specification conforms to the plain meaning for singular usage of nouns to mean one. For example, the ’314 Patent also mention alternative designs where the 125, 130, 135, and 140 elements form “a single structure with a common tine mounting band” or is “an integral section of the outer sheath of the lead body.” 13:5-11. Such use of the words “a single” or “an integral section” limits these designs to only one component, *i.e.* one tine element structure or one

lead body.[4] Another example is consistent use of "lead" to refer to one lead versus "leads" for plural leads. *See, e.g.*, 5:48-53 ("maintaining electrical *leads*" vs. "maintain *one* or more *lead* electrode"). When the inventors wanted to deviate from the plain meaning, the specification provides a definition, such as "P=one or more" for electrodes. *See, e.g.*, 6:26-27, 6:39-40, 12:51-52 (P=one). Notably, there is no such deviation from the plain meaning for "tine elements." Thus, a POSITA would have understood "a plurality of tine elements" to mean two or more "tine elements."

Second, both the claims and specification describe each "tine element" as a structure that has attached to it a plurality of tines. Claims 1, 11, and 18 require

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[4] These designs are not claimed in the '756 Patent, which requires "a plurality of" tine elements. *Tip Sys., LLC v. Philips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008) ("the claims of the patent need not encompass all disclosed embodiments" when doing so would contradict the claim language). Claim 1 also requires tine elements that "are separate from and axially displaced from each other," which further precludes a single or integrated design. Ex. 1003 ¶57 n.19. Claim 14 also requires "tine element*s attached* to the lead body," which similarly precludes a single or integrated design. *Id.* (italics added).

"each tine element comprising a plurality of flexible tines" where each tine has 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 …." Thus, all claims provide that there are tines attached to the tine element at the "attached tine end," which also is attached to the lead body.

The specification similarly describes multiple tine elements with each tine element having multiple tines attached to the tine element. *See, e.g.*, 6:8-12 ("Each tine element comprises at least N flexible, pliant, tines…. The attached tine end is attached to the lead body from a tine attachment site"); 10:26-33 (describing 4 tines 145, 150, 155 and 160 on each tine element with each tine having an attached tine end 165, which is attached to the lead body 15 from a tine attachment site); Figs. 1-4. The attached tine end 165 is always shown as attached to the tine element and extending from it. Figs. 3, 4. Thus, each tine element is a structure that connects multiple tines and each tine is attached to the tine element at one end and also to the lead body. Ex. 1003 ¶51.

Accordingly, a POSITA would have understood that "a plurality of [] tine elements" is at least two or more structures that mount to the lead body, each structure comprising of multiple tines attached to the structure.

IV. IDENTIFICATION OF CHALLENGED CLAIMS AND GROUNDS FOR CANCELLATION (37 C.F.R. § 42.22(a) and 42.104(b))

Since the '314 Patent claims priority to August 31, 2001, it is subject to the *pre*-America Invents Act ("AIA") provisions of 35 U.S.C. § 103. Claims 1, 2, 4, 7, 10-12, 14, and 18-24 of the '314 Patent are unpatentable under 35 U.S.C. § 103 as follows:

Ground 1. Claims 1, 2, 4, 7, 10-12, 14, 18-24 are obvious over Ronald F. Young, "Electrical Stimulation of the Trigeminal Nerve Root for the Treatment of Chronic Facial Pain," J. Neurosurg. 83:72-78 (July 1995) ("Young")(Ex. 1010) in view of U.S. Patent No. 6,055,456 ("Gerber")(Ex. 1012) and PCT Publication WO98/20933 ("Lindegren")(Ex. 1013).

Ground 2. Claims 18, 20 and 21 are obvious over Young, Gerber, Lindegren in view of U.S. Patent No. 5,052,407 ("Hauser") (Ex. 1014).

Ground 3. Claims 1, 2, 4, 7, 10-12, 14, 18-24 are obvious over Gerber in view of Hauser and U.S. Patent No. 4,407,303 ("Akerstrom") (Ex. 1015).

As further explained below, each of these references are prior art to the '314 Patent, which claims priority to August 31, 2001. This Petition is further supported by the declaration and testimony of Mr. Benjamin Pless (Ex. 1003), an expert in active, implantable medical devices with over 25 years of experience. *Id.* ¶¶5-16; Ex. 1004 (CV). Mr. Pless also has been awarded more than 160 patents by

the United States Patent & Trademark Office ("USPTO") for his inventions, more than half of which are directed to the field of neuromodulation. *Id.* ¶15.

Petitioner's patentability challenges do not advance "the same or substantially the same prior art or arguments previously … presented to the Office." *See* 35 U.S.C. § 325(d). Young, Hauser and Lindegren were not previously considered by the Examiner during prosecution of the '314 Patent. Gerber and Akerstrom were provided in an IDS, but never discussed during prosecution. The Examiner also did not have the testimony of Mr. Pless and additional evidence that may be in the record of this proceeding. Accordingly, these combinations of evidence are not the same or substantially the same as those raised during prosecution. *See, e.g.*, *ZTE (USA), Inc. v. Bell N. Research, LLC,* IPR 2019-01365, 2020 WL 698725, at *3 (PTAB Feb. 11, 2020) (finding combination different even if one reference was considered during prosecution).

A. Claims 1, 2, 4, 7, 10-12, 14, 18-24 Are Obvious over Young in view of Gerber and Lindegren

Claims 1, 2, 4, 7, 10-12, 14, 18-24 are obvious over Young in view of Gerber and Lindegren.

1. Young

Around July 1995, Journal of Neurosurgery published publicly Dr. Young's article titled "Electrical Stimulation of the Trigeminal Nerve Root for the

Treatment of Chronic Facial Pain." Exs. 1010; 1011. Published 6 years before the 2001 priority date, Young qualifies as prior art under 35 U.S.C. §102(b).

Young undertook his study to expand the knowledge of percutaneous techniques for using stimulating electrodes for treatment of chronic pain. Ex. 1010 at 72. Between March 1990 and December 1992, 23 patients were implanted with Medtronic's tined lead connected to ITREL IPG to treat their facial pain. *Id.* at 72-75. Young discloses an implanted lead "consist[ing] 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 (Fig. 1). The purpose of the tines was to prevent the electrode from becoming dislodged after implantation." *Id.* at 73. Figure 1 (below) shows the distal dip of the lead, while Figure 3 shows the complete system with the lead, IPG and an extension lead between them.

Fig. 1:

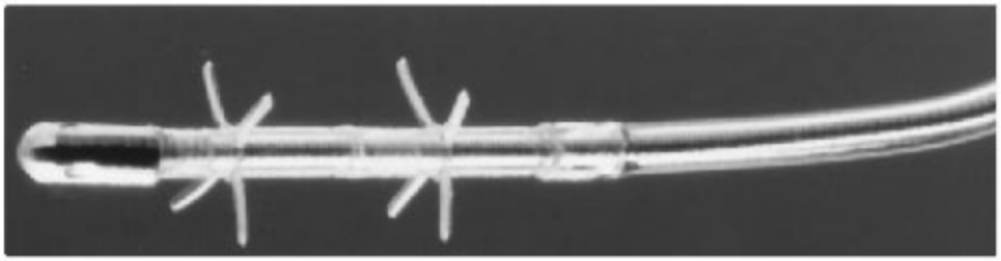
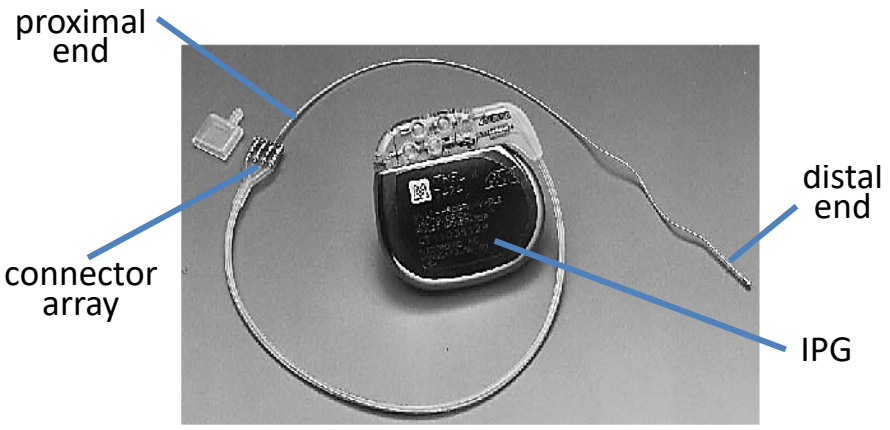


Fig. 3:



Young also discusses an implantation technique: a No. 14 Needle was first percutaneously inserted to the stimulation site, then "the electrode was inserted and advanced under fluoroscopic guidance" to the stimulation site and tested for paresthesia, and "[s]ubsequently, the introducing needle and central stylet were removed and the proximal end of the electrode [i.e. lead] was tunneled subcutaneously around the mandible and connected to the percutaneous extension lead" and proximal end of that extension lead was connected to the ITREL IPG. Ex. 1010 at 73-74. Young also teaches that a multi-contact electrode for bi-polar therapy could be used. *Id.* at 77.

2. Gerber

Gerber is a U.S. patent issued on April 25, 2000, more than a year before the August 2001 priority date, and thus qualifies as §102(b) prior art. Like the '314 Patent, Gerber discloses the problem of patients being under general anesthesia for placing the lead and "[a] problem associated with the prior art electrical

stimulation to control incontinence is positioning and maintaining the discrete electrode in casual contact or in close proximity to the nerve to provide adequate stimulation of the sacral nerves." Ex. 1012 at 1:64-2:13.

To solve that problem, Gerber discloses an implantable lead for stimulation of the sacral nerves, comprising a lead body which includes one or more electrodes in the distal end and different types of anchoring mechanisms that are located between the most proximal electrode and the proximal end of the lead. Ex. 1012, Abstract; 2:4-5 ("current lead design used for sacral nerve stimulation uses 4 electrodes"); 3:39-4:52 (disclosing two electrodes); Figs. 2-3. Gerber discloses different types of anchoring mechanisms, including "[y]et another anchoring mechanism 50 is to allow the medical lead 10 to fibrose in naturally" (*id.* at 4:27-30). Tines anchor the lead initially by engaging the body tissue and then by fibrosis. Ex. 1003 ¶¶32, 91. Gerber thus discloses the exact location for the anchoring mechanism that was required by the Examiner with the amendment during prosecution. *See id.* ¶83.

Gerber further discloses that the proximal end of the lead body can be connected to an IPG, including Medtronic's InterStim Neurostimulator Model 3023 (Ex. 1012 at 3:48-52), also identified in the '314 Patent (Ex. 1001 at 9:62-67). While Gerber does not disclose expressly an implantation method, it does teach that its medical lead with a stylet "is particularly useful for implantation

using a cannula" (Ex. 1012 at 5:16-17), which by 2001 has been well known to act as an introducer (Ex. 1003 ¶¶32-33, 84).

3. Lindegren

Lindegren is a PCT application published on May 22, 1998. Ex. 1013. Publicly available years before the 2001 priority date, Lindegren qualifies as § 102(b) prior art.

Like the '314 Patent, Lindegren acknowledges the lead migration problem. *Id.* at 1:20-27. Lindegren discloses an implantable lead with a single electrode 4 on the distal end and a tine anchoring means 10. *Id.* 4:32-5:22; Ex. 1003 ¶89. The tine-like anchoring means from a manufacturing point of view, Lindegren teaches, is preferable if its tines are "devised as an integral part of a one-piece ring-shaped means and evenly distributed around the circumference of the ring-shaped means" and made of elastic material such as silicone rubber. *Id.* at 5:17-22; 7:1-27; Ex. 1003 ¶87; Figs. 1, 3 (annotated).

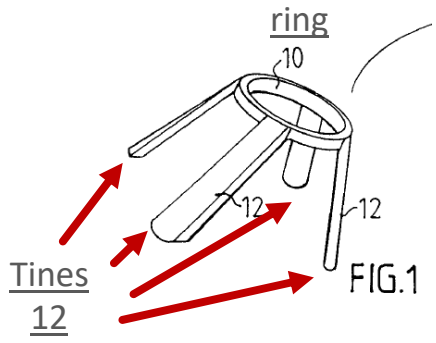


FIG.1

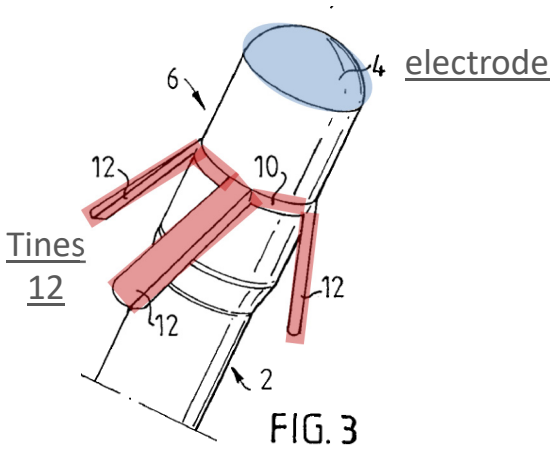


FIG. 3

4. Applying Young in view of Gerber and Lindegren

A POSITA is presumed to know the relevant prior art and is of ordinary creativity, and not an automaton, and is capable of making inferences and combining teachings in the prior art. *Gnosis S.p.A. v. South Alabama Med. Sci. Found.,* IPR2013-00116, Paper 68 at 9 (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420-21 (2007)).

A POSITA would have been motivated to combine Young, Gerber and Lindegren for several reasons. First, each prior art reasonably addresses the similar problems of leads adequately stimulating the nerves while limiting electrode migration as the '314 Patent. *See, e.g.*, Ex. 1010 at 73; Ex. 1012 at 1:64-2:13; Ex. 1013 at 1:20-27; 4:32-5:7. Second, all three references are analogous art to the '314 Patent. Each reference is from the same field as the '314 Patent of neurostimulation with implantable medical leads with electrode(s) at the distal end of the lead and a proximal anchoring mechanism. *See, e.g.* Ex. 1010 at 73; Ex. 1012 at 3:39-4:52; Ex. 1013 at 4:32-5:22. Thus, a POSITA would have been motivated to combine references that solve the same problem as the '314 Patent in the same field. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011) (finding motivation to combine references that both identify similar problem of lighter safety).

Third, there is teaching in the references themselves for the combination. Young teaches that the single electrode "could be improved to provide multiple active stimulation sites near the tip." Ex. 1010 at 77. Thus, a POSITA would have been motivated to look for multiple electrodes that provide greater flexibility for electrode placement, such as Gerber which discloses multiple electrodes on implanted leads for sacral nerve stimulation. Gerber further discloses that its lead uses anchoring means that fixes by fibrosis. Thus, a POSITA would have considered the limited number of devices available at the time to anchor via fibrosis leads; by 1990s, the predominant fixation means by fibrosis was tines. Ex. 1003 ¶91. Young discloses two sets of tines, each having multiple tines that appear connected to a cylindrical band. Lindegren discloses 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.* ¶91. Thus, a POSITA would have considered using tines mounted on bands or rings on a lead.

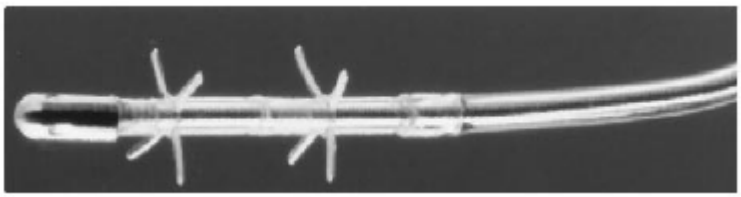
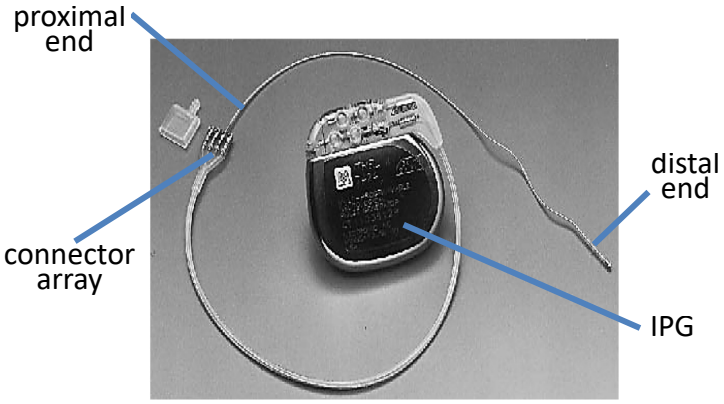
Not only is there a motivation to combine, but doing so would have been highly feasible. *Id.* ¶¶93, 108. A POSITA would have considered the combinations because of the ease in manufacturing using these references. All three references disclose relatively simple, implantable medical leads that are without curves or hooks on the distal end. Lindegren's tine-mounted rings could be easily reproduced for addition to the lead body. Accordingly, it would have

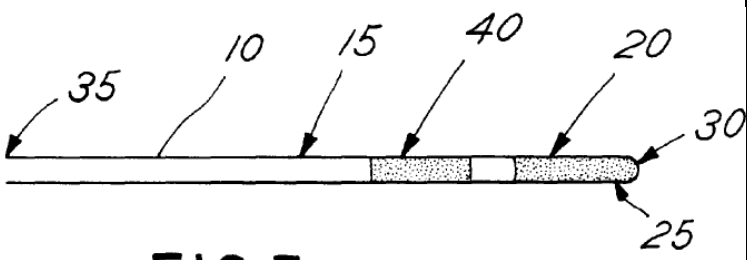
been easy to replace the one electrode of Young with multiple electrodes at the distal end distal to the anchoring mechanism, as taught in Gerber, in order to provide more flexibility in activation of a wider area and provide the possibility for bipolar electrical stimulation, as taught in Young. Also, 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. Such modifications of Young to have additional electrodes or tines facing proximally would have been simply "arrang[ing] old elements with each performing the same function it had been known to perform and yield[ing] no more than one would expect from such an arrangement" and would have been thus obvious. *KSR*, 550 U.S. at 417.

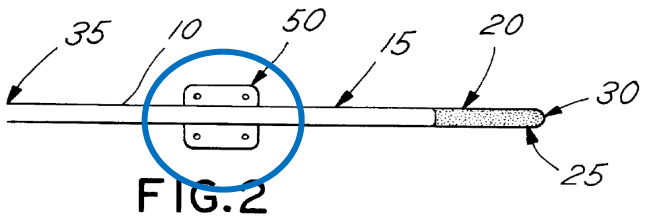
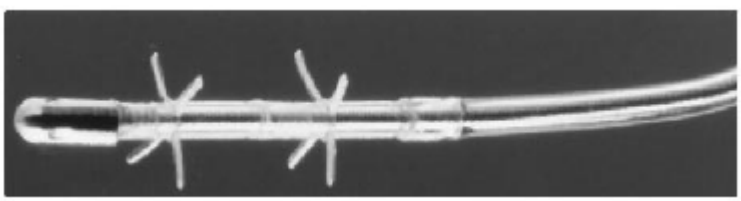
a. Invalidity Claim Chart

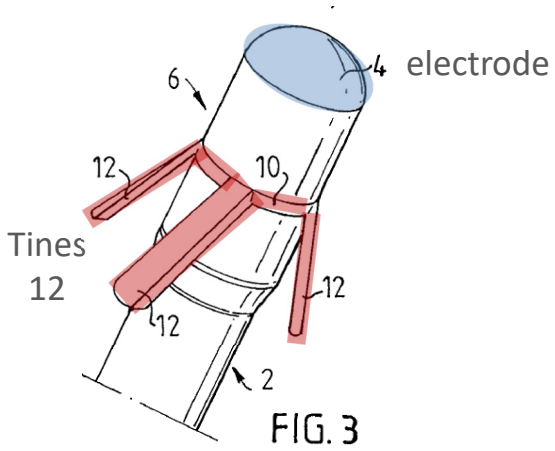
The combination of Young, Gerber and Lindegren teaches every limitation of claims 1, 2, 4, 7, 10-12, 14, 18-24, as set forth in the following charts.

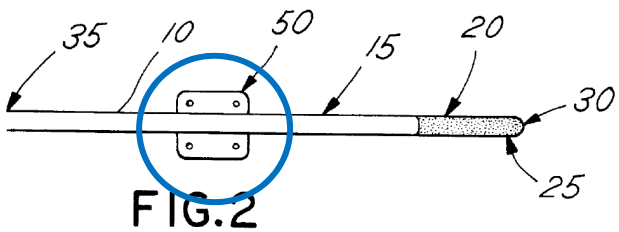
Cl.	Language	Prior Art Disclosure
1.0	1. A system comprising:	To the extent this preamble is a limitation, Young, Gerber and Lindegren discloses this system.
1.a	an implantable medical lead comprising:	Young discloses a Medtronic lead shown in Figures 1 and 2 (see below). Ex. 1010 at 73-74.
1.b	a lead body extending	Young shows a Medtronic lead with lead body

Cl.	Language	Prior Art Disclosure
	between a proximal end and a distal end;	with two ends. *Id.* at 73-74, Figs. 1 and 3. Leads also inherently have a body that extends between proximal end and a distal end. Young Fig. 1 (below showing lead distal end):  Young Fig. 3 (annotated below). 
1.c	a plurality of conductors within the lead body;	Young inherently discloses one conductor wire between the one electrode and a connector. The conductor connecting the electrode to the IPG must have existed for electrode to function and stimulate the nerve in the patients in the study. Ex. 1010 at 73-74. Young discloses an extension lead with 4 connectors, which then must have had 4 conductor wires. Ex. 1003 at 68. Gerber's "lead body 15 of the present invention comprises one or more conductor wire(s) within an insulating sheath." Ex. 1012 at 4:6-7 (emphasis added). Thus, this element is disclosed.
1.d	a plurality of	Young discloses one electrode, but states "[t]he

Cl.	Language	Prior Art Disclosure
	electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors; and	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. Gerber discloses multiple stimulation electrodes. Ex. 1012 at 1:57-58; 2:4-5 (4 electrodes); Abstract; 4:32-33 (two electrode contacts 20 and 40."); Claim 1; Fig. 3 (disclosing two electrodes 20 and 40).  FIG.3 Gerber further teaches that "[t]he stimulation pulses produced by the pulse generator are carried from the pulse generator through the proximal end 35 of the lead body 15 of the present invention toward the distal end 25 having at least one electrode contact 20." *Id.* at 3:52-56. Thus, each electrode must be electrically connected to a conductor for there to be stimulation pulses. Ex. 1003 at 68-69.
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	Young discloses at least 2 tine elements formed in a tine element which is located between the electrode and the lead proximal end: "The stimulating electrode (Quintatrigmenial, Medtronic, Inc., Minneapolis, MN) consisted 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 (Fig. 1)." Ex. 1010 at 73; see Fig. 1 above.

Cl.	Language	Prior Art Disclosure
	plurality of electrodes and the proximal end of the lead body,	Gerber does not expressly identify tines, but describes anchoring mechanisms that is located between the most proximal electrode and proximal end of lead body: "Referring to FIG. 2, the implantable medical lead 10 of the present invention may have an anchoring mechanism 50 to fixate the medical lead 10 in the desired position. … Yet another anchoring mechanism 50 is to allow the medical lead 10 to fibrose in naturally using the human body's natural reaction to a foreign body or healing." Ex. 1012 at 4:13-30; Fig. 3.  FIG.2 Thus, instead of the suturing anchoring mechanism 50 shown in Fig. 2, Gerber teaches that 50 can also be the location of an anchoring mechanism via fibrosis. Skilled artisan would know that tines anchor are a widely used fibrosing anchoring means. Ex. 1003 at 70.
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	Young discloses "two sets of four 'tines'" where each tine has a width, thickness and length. *See* Ex. 1010, Fig. 1 below.  Each tine is attached to the lead body on one end and extends outwardly from the lead body

Cl.	Language	Prior Art Disclosure
	body from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end,	towards the lead proximal end. Lindegren discloses tines mounted on rings where tines extend proximally. Ex. 1013, Fig. 3 (annotated).  FIG. 3 Tines oriented proximally was common before 2001, especially for use with introducer since the attached tine ends enter the introducer first and does not risk damaging the free tine ends. See below 1.g.
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	Young teaches percutaneously introducing "a No. 14 needle" that inherently has a lumen to allow the lead to advance to the stimulation site. *See* Ex. 1010 at 73: "The electrode was inserted percutaneously through a No. 14 needle via a puncture of the foramen ovale, under local anesthesia …. Once cerebrospinal fluid flow was obtained through the needle, the electrode was inserted and advanced under fluoroscopic guidance until paresthesias could be induced in the distribution of the patient's pain …. Subsequently, the introducing needle and central stylet were removed …" Paresthesia is only achieved if the electrode is adjacent to the

Cl.	Language	Prior Art Disclosure
	withdrawn to release the plurality of tines,	stimulation site. 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.* & 71-72. Young teaches that "[t]he purpose of the tines was to prevent the electrode from becoming dislodged after implantation." Ex. 1010 at 73. Thus, the tines are adapted to deploy outward, as shown in FIG. 1, to engage the body tissue when no longer constrained within the lumen when it is withdrawn.
1.h	wherein the plurality of tine elements is separate from and axially displaced from the plurality of electrodes.	Young Fig. 1 shows the two sets of tines, i.e. plurality of tined elements, are separate from and axially displaced from the electrode. Ex. 1010. As discussed in 1.d and 1.e above, Gerber teaches two electrodes and a more proximal anchoring mechanism 50 (Fig. 2) located separate from and spaced apart from the electrode 20. Ex. 1012.  FIG.2

Cl.	Language	Prior Art Disclosure
2.0	2. The system of claim 1, wherein the tines of the tine elements are formed of a flexible, bio-compatible plastic selected from the group consisting of medical grade polyurethane compounds and silicone rubber compounds.	See claim 1. Lindegren teaches that tines "are preferably made of an elastic material such as silicone rubber." Ex. 1013 at 5:17-22.
4.0	4. The system of claim 1, wherein the tine attachment sites of the plurality of tine elements are separated longitudinally along the lead body by a distance that is greater than or equal to the tine length so that the tines are not overlapping one another when the tines are folded against the lead body towards the proximal end of the lead body.	See claim 1. The '314 patent describes "tine attachment sites" as where the tine attaches to the tine element and lead body. Thus, if the tine length is less than the distance between the attached tine ends, then this dependent element is met. As explained with claim 1.g, Young discloses tine length that is less than the distance between the attached tine ends.
7.0	7. The system of claim 1, wherein each tine element in the plurality of tine elements comprises an equal number of tines.	See claim 1. Young discloses two sets of four tines, *i.e.* each set has an equal number of four tines. Ex. 1010 at 73; Fig. 1.
10.0	10. The system of	See claim 1.

Cl.	Language	Prior Art Disclosure
	claim 1, further comprising the introducer.	Young discloses a No. 14 needle as the introducer. Ex. 1010 at 73; Ex. 1003 ¶80.
11.0	11. A system comprising:	To the extent this preamble is a limitation, Young, Gerber and Lindegren discloses this system as provided below.
11.a	an implantable pulse generator configured to generate electrical stimulation; and	Young discloses "a lithium battery-powered completely implanted pulse generator system (ITREL, Medtronic, Inc., Minneapolis, MN) (Fig. 3). After the patient recovered from the anesthesia, the pulse generator was programmed to induce paresthesias in the distribution of the pain without producing undesirable side effects…." Ex. 1010 at 74; Fig. 3 (showing lead connected to IPG). Gerber teaches the use of implantable pulse generator: "The proximal end 35 of the lead body 15 may be coupled to a pulse generator, additional intermediate wiring, or other stimulation device. An example of such a pulse generator is the Medtronic InterStim Neurostimulator Model 3023. The stimulation pulses produced by the pulse generator are carried from the pulse generator …." Ex. 1012 at 3:49-56.
11.b	an implantable medical lead configured to be electrically coupled to the implantable pulse generator and introduced through and released into body tissue via an	As discussed in claim 11.a, both Young and Gerber discloses a lead body that may be coupled to an IPG. As discussed in claim 1.g, Young discloses "[t]he electrode [i.e. medical lead] was inserted percutaneously through a No. 14 needle via a puncture of the foramen ovale…." Ex. 1010 at 73.

Cl.	Language	Prior Art Disclosure
	introducer defining an introducer lumen, the implantable medical lead comprising:	Gerber discloses lead can be used with a cannula, which is an introducer. Ex. 1010 at 5:16-17; 5:45-6:1; Ex. 1003 ¶84 & 75.
11.c	a lead body extending between a proximal end and a distal end;	See claim 1.b
11.d	a plurality of conductors within the lead body;	See claim 1.c
11.e	a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors; and	See claim 1.d
11.f	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,	See claim 1.e
11.g	each tine element comprising a plurality of flexible, pliant tines, each tine having a tine width and thickness and extending a tine length	See claim 1.f

Cl.	Language	Prior Art Disclosure
	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,	
11.h	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 the lumen of the introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn proximally,	See claim 1.g. When the "introducer is withdrawn to release the plurality of tines" as discussed in claim 1.g, the introducer is withdrawn proximally, that is towards the doctor and out of the body. Ex. 1003 at 76.
11.i	wherein the plurality of tine elements is separate from and axially displaced from the plurality of electrodes.	See claim 1.h.
12	The system of claim 11, wherein the tines of the tine elements are formed of a flexible, bio-compatible plastic	See claim 11. See claim 2 for the dependent element for tines formed of silicone rubber.

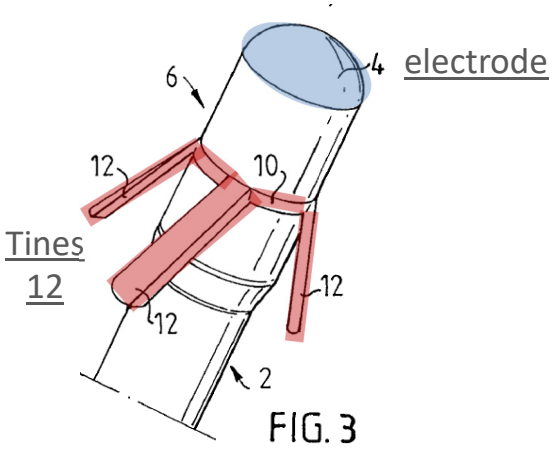
Cl.	Language	Prior Art Disclosure
	selected from the group consisting of medical grade polyurethane compounds and silicone rubber compounds.	
14	The system of claim 11, wherein the tine attachment sites of the plurality of tine elements are separated longitudinally along the lead body by a distance that is greater than or equal to the tine length so that the tines are not overlapping one another when the tines are folded against the lead body towards the proximal end of the lead body.	See claim 11 above. See claim 4 above for the dependent element "wherein the tine attachment sites … lead body."
18	18. A method comprising:	To the extent this preamble is a limitation, both Young and Gerber disclose a method for implanting medical leads.
18.a	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	Young teaches percutaneously introducing "a No. 14 needle" that inherently has a lumen to allow the lead to advance: "[t]he electrode was inserted percutaneously through a No. 14 needle via a puncture of the foramen ovale, under local anesthesia …. Once cerebrospinal fluid flow was obtained through the needle, the electrode was inserted and advanced under fluoscopic guidance …." Ex. 1010 at 73.

Cl.	Language	Prior Art Disclosure
	introducer,	
18.b	the medical lead comprising: a lead body extending between a proximal end and a distal end; a plurality of conductors within the lead body; a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors; and a plurality of tine elements extending from the lead body, wherein all tine elements of the plurality of tine elements are positioned between a most proximal electrode of the plurality of electrodes and the proximal end of the lead body, each tine element comprising a plurality of flexible, pliant tines, each tine having a tine width and thickness and extending through a tine length from an attached tine end to a free tine end, the	See claim 1.a-1.f.

Cl.	Language	Prior Art Disclosure
	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,	
18.c	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 the lumen of the introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn proximally,	See claims 1.g and 11.h.
18.d	wherein the plurality of tine elements is separate from and axially displaced from the plurality of electrodes;	See claim 1.h.
18.e	withdrawing the introducer from the body tissue to deploy the plurality of tine elements.	See 1.e which has the same language as 18.b and here regarding "plurality of tine elements." The tines are adapted to fold towards the lead body when constrained and deploy when not constrained by the lead body. Tines, however, should not be deployed until the electrode placement is finalized because once deployed,

Cl.	Language	Prior Art Disclosure
		they engage body tissue and can be damaged if the lead is moved within the body. Ex. 1003 at 79-80. Young teaches the lead is "advanced under fluoroscopic guidance until paresthesias could be induced" and "[s]ubsequently, the introducing needle …[was] removed." Ex. 1010 at 73. In all cases but one, the lead stayed in place; therefore, the tines worked to prevent migration. *Id.* at 75. Thus, a POSITA would understand Young to disclose that doctors observed the electrode advancement to the stimulation site, the electrode was out of the Needle to stimulate the nerve and exact placement location was obtained to induce paresthesia, and once paresthesia was obtained, the Needle was withdrawn to deploy the tines so the tines did not suffer damage and lose its intended function to prevent electrode migration. Ex. 1003 at 79-80.
19	19. The method of claim 18, wherein introducing the introducer into body tissue comprises percutaneously introducing the introducer through body tissue.	See claim 18. Young teaches percutaneously introducing an introducer "a No. 14 needle" through body tissue: "The electrode was inserted percutaneously through a No. 14 needle via a puncture of the foramen ovale, under local anesthesia …." Ex. 1010 at 73.
20	20. The method of claim 18, wherein withdrawing the introducer from the body tissue to deploy the plurality of tine elements comprises withdrawing the introducer from the	See claim 18. As discussed in claim 18.e, Young discloses withdrawing the No. 14 needle from the body tissue to deploy the tines, whose entire expressed purpose is to engage with subcutaneous tissue around the trigeminal nerve to prevent the electrode from dislodgment. Ex. 1010 at 73.

Cl.	Language	Prior Art Disclosure
	body tissue to deploy the plurality of tine elements into subcutaneous tissue, wherein the plurality of tine elements engage with the subcutaneous tissue to inhibit axial movement of the lead body and dislodgement of the plurality of electrodes.	
21	21. The method of claim 18, wherein withdrawing the introducer from the body tissue to deploy the plurality of tine elements comprises anchoring, with the plurality of tine elements, the plurality of electrodes in operative relation to a selected stimulation site.	See claim 18. See claim 18.e for withdrawing of Young's Needle to deploy the tine elements for anchoring the lead. While Young does not disclose plurality of electrodes, Gerber does and it also teaches anchoring mechanim by fibrosis in order to keep the electrodes near stimulation site. See claim 1.d
22	22. The system of claim 1, further comprising a tine mounting band, wherein at least one tine element is mounted to the lead via the tine mounting band.	Lindegren discloses a ring-shaped means with a ring 10 (i.e. tine mounting band) and tines 12 attached to the ring. Ex. 1013, Abstract ("The anchoring means consist of e.g. four tine-like projections (12) devised as an integral part of a one—piece ring—shaped means (10) which bears them…") (emphasis added); 7:18-27; Figs. 1-3. Each of the Lindegren ring-shaped means shown in Figure 1 can be mounted to a lead (Fig. 3). Ex. 1003 at 81-82.

Cl.	Language	Prior Art Disclosure
		 FIG. 3
23	23. The system of claim 11, further comprising a tine mounting band, wherein at least one tine element is mounted to the lead via the tine mounting band.	See claim 11 above. See claim 22 for the "tine mounting band" dependent element.
24	24. The method of claim 18, wherein the medical lead further comprises a tine mounting band, wherein at least one tine element is mounted to the lead via the tine mounting band.	See claim 18 above. See claim 22 above for the "wherein the medical lead…band" dependent element.

B. Claims 18, 20 and 21 are Obvious over Young, Gerber, Lindegren in view of Hauser.

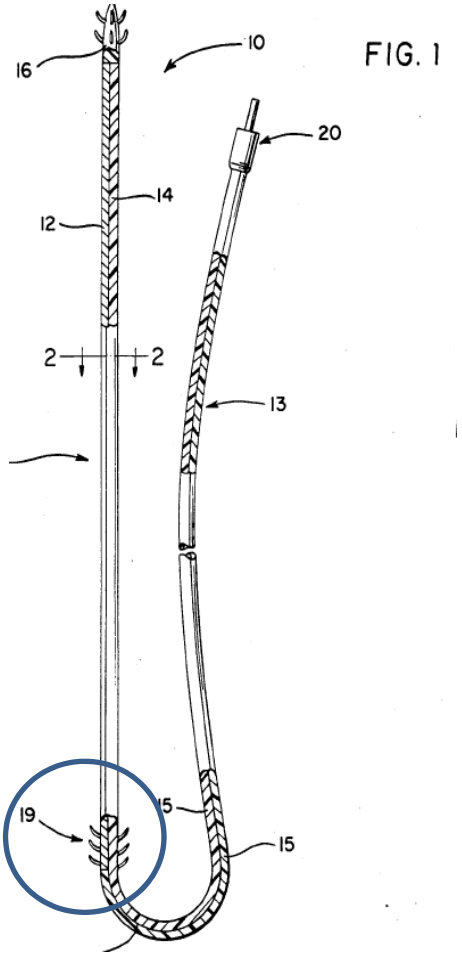
Claims 18, 20 and 21 are obvious over Young, Gerber, and Lindegren in view of Hauser. Young, Gerber, Lindegren and their combination are described in prior §IV.A.4. To the extent Young does not expressly disclose that the method of withdrawing the introducer to deploy the tines, Hauser discloses this.

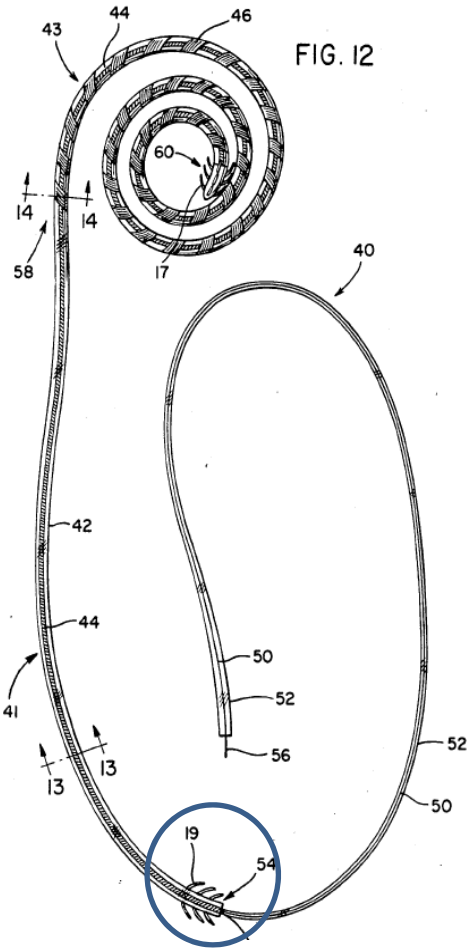
1. Hauser

Hauser is a U.S. patent issued on October 1, 1991. With a publication date years before the 2001 priority date, Hauser qualifies as prior art under 35 U.S.C. §102(b). Hauser discloses the problem of major surgeries for implantation of medical leads due in part for need of precise placement of the electrodes. Ex. 1014 at 1:26-31. Hauser discloses that its objective is to provide a simplified and non-invasive method for implanting a defibrillation/cardioversion lead and such simplified lead with sufficient electrode area for stimulation and fixation means to facilitate non-invasive implantation. *Id.* at 2:16-30.

Hauser discloses an implantable defibrillation/cardioversion lead with a non-invasive method for implantation. Hauser uses the term "electrode" to mean both the lead and the conductive elements. *Id.* at 3:46-50. The distal end of the lead has a spiral active region with conductive element. Proximal to that region is a fixation means 19 that anchors the lead at location determined by the surgeon during implantation. *Id.* at 4:3-8; 4:21-25; Fig. 12. Anchoring means 19 can be three sets

of tines as shown in Figures 1 and 12 or suture sleeve or any other means known. *Id.* at 4:8-19.





Hauser discloses an implantation method where a "catheter 21, having a cross-section only slightly larger than the cross section of the electrode 10, first is introduced through the skin and into the pericardial space; the electrode 10 then is inserted into the catheter 21, as by introducing a stylet 22 … the active region 11 of the electrode 10 is urged out of the catheter [see Fig. 4]…. Deployment then is

continued until the entire active portion 11 of the electrode 10 is in place in the pericardial space. The stylet 22 and the catheter 21 are then removed." *Id.*at 4:32-55; 7:8-12. Due to the substantial distance between the active, electrically conductive region 12 (Fig. 1) or 43 (Fig. 12) and the proximal sets of tines 19, advancement of the active region out of the catheter as shown in Figure 5 will not deploy the proximal tines. Ex. 1003 ¶99. Tines will remain constrained in the catheter until the catheter is withdrawn. *Id.*

2. Applying Young, Gerber, Lindegren in view of Hauser

As discussed in §IV.A.4, a POSITA would have been motivated to combine Young, Gerber and Lindegren for multiple reasons. Similarly, a POSITA would have been motivated to combine Hauser to those references. Hauser is also from the same field as the '314 Patent of neurostimulation with implantable medical leads with electrode(s) at the distal end of the lead and an anchoring mechanism. *See, e.g.* Ex. 1014, 2:16-30. Hauser also seeks to solve the problems regarding major surgeries and lead placement with a simplified lead. *Id.* at 1:26-29, 2:9-19. Thus, a POSITA would have been motivated to combine references that solve the same problem as the '314 Patent in the same field. *Tokai*, 632 F.3d at 1371.

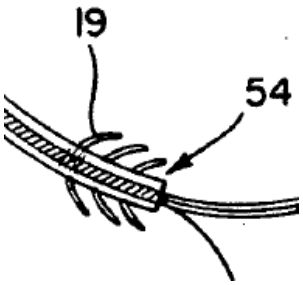
Furthermore, Hauser also uses 3 sets of tines to anchor the lead into proper position, not unlike Young, but Hauser's proximal tines are spaced much further proximally from the electrical conductive region. Both Young and Hauser

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

a. Invalidity Claim Charts

The combination of Young, Gerber, Lindegren in view of Hauser teaches every limitation of method claims 18, 20 and 21, as set forth in the following charts.

Cl.	Language	Prior Art Disclosure
18	18. A method comprising:	See §IV.A.4.a chart claim 18.
18.a	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,	See §IV.A.4.a chart claim 18.a.
18.b	the medical lead	See §IV.A.4.a chart claim 1.a-1.f.

Cl.	Language	Prior Art Disclosure
	comprising: a lead body extending between a proximal end and a distal end; a plurality of conductors within the lead body; a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors; and a plurality of tine elements extending from the lead body, wherein all tine elements of the plurality of tine elements are positioned between a most proximal electrode of the plurality of electrodes and the proximal end of the lead body, each tine element comprising a plurality of flexible, pliant tines, each tine having a tine width and thickness and extending through a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead	Hauser also discloses flexible tines, each tine having a tine width and 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 from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end. See excerpt of Ex. 1014, Fig. 12: 

Cl.	Language	Prior Art Disclosure
	body from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end,	
18.c	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 the lumen of the introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn proximally,	See §IV.A.4.a chart claim 1.g and 11.h.
18.d	wherein the plurality of tine elements is separate from and axially displaced from the plurality of electrodes;	See §IV.A.4.a chart claim 1.h.
18.e	withdrawing the introducer from the body tissue to deploy the plurality of tine elements.	See §IV.A.4.a chart claim 18.e. To the extent Young does not disclose this element, Hauser discloses it. Hauser discloses: "Deployment then is continued until the entire active portion 11 of the electrode 10 is in place in the pericardial space. The stylet 22 and the catheter 21 are then removed…." Ex. 1014 at 4:49-55. Thus, Hauser discloses that deployment continues until the active electrode region is at

Cl.	Language	Prior Art Disclosure
		the stimulation site. Figure 5 with only the active electrode region outside the catheter, as compared to Figure 12, shows that the proximal sets of tines 19 will remain inside the catheter, i.e. introducer. Thus, only when the catheter is removed will the proximal tines 19 deploy. Hauser also teaches its electrode "can be implanted percutaneously" (see *Id.* 2:61). Ex. 1003 at 85.
20	20. The method of claim 18, wherein withdrawing the introducer from the body tissue to deploy the plurality of tine elements comprises withdrawing the introducer from the body tissue to deploy the plurality of tine elements into subcutaneous tissue, wherein the plurality of tine elements engage with the subcutaneous tissue to inhibit axial movement of the lead body and dislodgement of the plurality of electrodes.	See claim 18. As discussed in claim 18.e, to the extent Young does not disclose the idea of withdrawal of the introducer deploying the tines, Hauser discloses that it is the withdrawal of the introducer (i.e. catheter in Hauser) deploys the tines to engage with body tissue to inhibit axial movement and dislodgement of the electrode. Young discloses tine elements and Gerber discloses the use of anchoring means by fibrosis to prevent dislodgment of multiple electrodes. Ex. 1003 at 85-86.
21	21. The method of claim 18, wherein withdrawing the introducer from the body tissue to deploy the plurality of tine	See claim 18. As discussed in claim 18.e, to the extent Young does not disclose the idea of withdrawal of the introducer deploying the tines, Hauser discloses that it is the withdrawal of the introducer (i.e.

Cl.	Language	Prior Art Disclosure
	elements comprises anchoring, with the plurality of tine elements, the plurality of electrodes in operative relation to a selected stimulation site.	catheter in Hauser) deploys the tines to anchor the lead. Ex. 1003 at 86. While Young does not disclose plurality of electrodes, Gerber does and it also teaches anchoring mechanism by fibrosis in order to keep the electrodes near stimulation site. See §IV.A.4.a chart claim 1.d.

C. Claims 1, 2, 4, 7, 10-12, 14, 18-24 are obvious over Gerber in view of Hauser and Akerstrom

Claims 1, 2, 4, 7, 10-12, 14, 18-24 are obvious over Gerber in view of Hauser and Akerstrom. Gerber and Hauser have previously been described. §IV.A.2 and §IV.B.1

1. Akerstrom

Akerstrom is a U.S. patent issued on October 4, 1983. Publicly available years before the 2001 priority date, Akerstrom qualifies as prior art under 35 U.S.C. §102(b).

Akerstrom focused on the problem of prior endocardial leads with stiff tines being too big for delivery through a small vein and having limited tissue area to

anchor in the heart wall.[5] Ex. 1015 at 1:19-31. To solve this problem, Akerstrom discloses a lead with an electrode and loops mounted on collars or sleeves to anchor the lead. *Id.* at 1:6-14; 2:34-59; Figs. 1-3. Similar to tines, the loops extend outward when deployed and anchor by fibrosis, and the loops somewhat resemble the form of tines. Ex. 1003 ¶105.

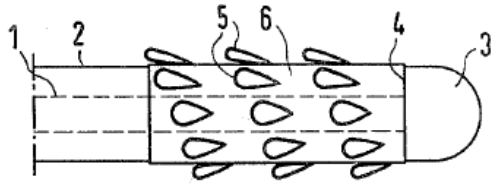


FIG 1

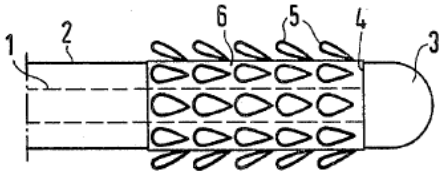


FIG 2

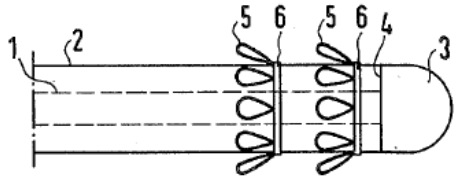


FIG 3

2. Applying Gerber, Hauser and Akerstrom

A POSITA would have been motivated to combine Gerber, Hauser and Akerstrom for several reasons. First, all three references are analogous art to the '314 Patent. Each reference is from the same field as the '314 Patent of

[5] These concerns are not applicable to percutaneous delivery of a sacral lead where there is more space than a small vein and soft tissues are present along the entire proximal length for anchoring. Ex. 1003 ¶105, fn. 23.

neurostimulation with implantable medical leads with electrode(s) at the distal end of the lead and an anchoring mechanism. *See, e.g.*, Ex. 1010, 3:39-4:52; Ex. 1014, 2:16-30; Ex. 1015, 2:34-59; *see also Tokai*, 632 F.3d at 1371; Ex. 1003 ¶106.

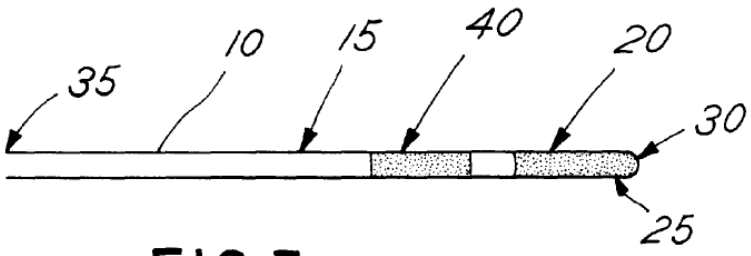
Second, Gerber provides a motivation to combine. *Id.* ¶107. Gerber discloses a multi-electrode lead with a proximal anchoring mechanism that anchors by fibrosis instead of the depicted suture sleeve (Fig. 2). The depicted suture sleeve with 4 holes affirms the need for multiple fixing areas along the lead within the tissue around the sacrum. Thus, a POSITA would have considered tines, a leading candidate among the limited number of devices that anchor by fibrosis. *Id.* While Akerstrom discloses various arrangements of loops that anchors by fibrosis, those arrangements could be used for tines. *Id.* ¶105. In particular, the arrangement in Figure 3 with repeated sets of multiple loops extending from collar 6 allows for easy manufacturing and adaptation to the needs of the stimulation site. *Id.* That arrangement with non-overlapping loops that fold to the lead body due to the collars being spaced apart also has the advantage of a smaller profile, which is suited to percutaneous delivery. *Id.* Thus, it would have been obvious to a POSITA to improve anchoring within the soft tissue near the sacrum to use multiples tined anchors, each mounted on collars (i.e. tine elements) to affix by fibrosis. A POSITA would have positioned the tine elements in a region proximal to the most proximal electrode, as shown and described in Gerber. *Id.* ¶107.

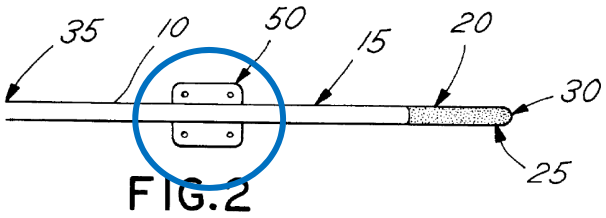
Not only is there strong motivation to combine, but doing so would have been highly feasible. *Id.* ¶108. A POSITA would have considered these combinations because of the ease in manufacturing using these references. *Id.* All three references disclose relatively simple, implantable medical leads. Hauser provides multiple tined anchors that are spaced apart while Akerstrom's collar design (Fig. 3) for fibrosing anchors is easily reproducible for use with tines to allow for desired spacing between the sets of tines as required by the anatomy and physicians. Accordingly, it would have been easy to replace Gerber's anchoring mechanism with multiple tined anchors, as taught in Hauser, and further to arrange such tines in accordance with the array design taught in Akerstrom in regard to its fibrosing fixation means. *Id.* Such modifications of Gerber would have been simply rearrangement of old elements with each performing substantially the same function it had been known to perform and yielding predictable results that would have been obvious. *KSR*, 550 U.S. at 417.

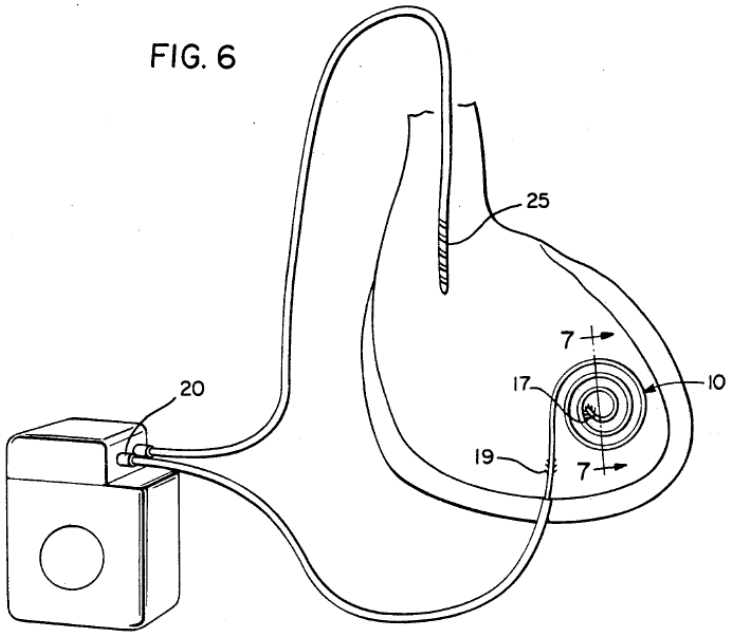
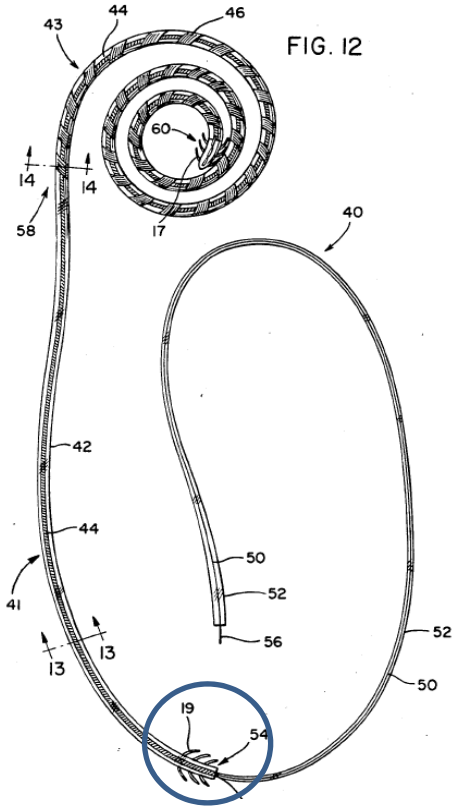
a. Invalidity Claim Charts

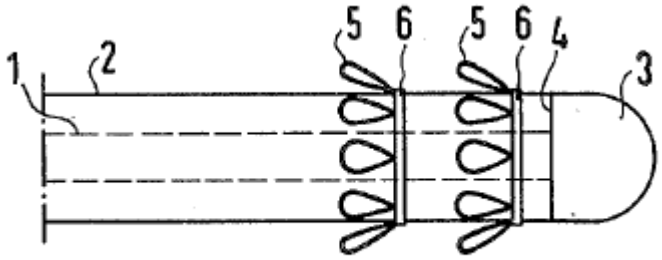
The combination of Gerber, Hauser and Akerstrom teaches every limitation of claims 1, 2, 4, 7, 10-12, 14, 18-24, as set forth in the following charts.

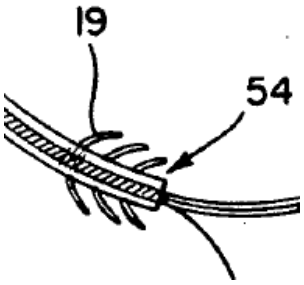
Cl.	Language	Prior Art Disclosure
1.0	1. A system comprising:	To the extent this preamble is a limitation, Gerber, Hauser and Akerstrom discloses this system below.
1.a	an implantable	Gerber discloses a "Single and Multi-Polar

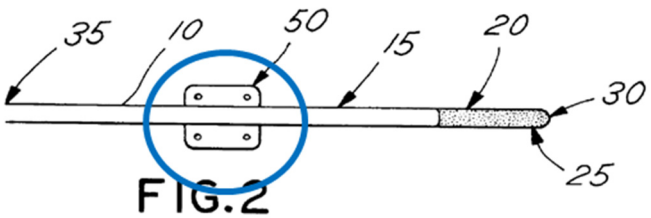
Cl.	Language	Prior Art Disclosure
	medical lead comprising:	Implantable Lead for Sacral Nerve Electrical Stimulation." Ex. 1012, Title, Abstract.
1.b	a lead body extending between a proximal end and a distal end;	Gerber discloses: "An implantable medical lead for stimulation of the sacral nerves comprises a lead body which includes a distal end and a proximal end …." *Id.,* Abstract.
1.c	a plurality of conductors within the lead body;	Gerber's "lead body 15 of the present invention comprises one or more conductor wire(s) within an insulating sheath." *Id.* at 4:6-7. Gerber discloses multiple electrodes connected to conductors. See 1.d below.
1.d	a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors; and	Gerber discloses multiple stimulation electrodes. Gerber acknowledges "[t]ypically, existing leads have four small discrete electrodes built into the distal end of the lead." Ex. 1012 at 1:57-58; 2:4-5. Gerber teaches the use of two electrodes. *Id.*, Abstract; 4:32-33; Claim 1; Fig. 3 (disclosing two electrodes 20 and 40).  FIG.3 Gerber further teaches that "[t]he stimulation pulses produced by the pulse generator are carried from the pulse generator through the proximal end 35 of the lead body 15 of the present invention toward the distal end 25 having at least one electrode contact 20." *Id.* at 3:52-56. Thus, each electrode must be electrically connected to a conductor for there to be stimulation pulses. Ex. 1003 at 87-88.

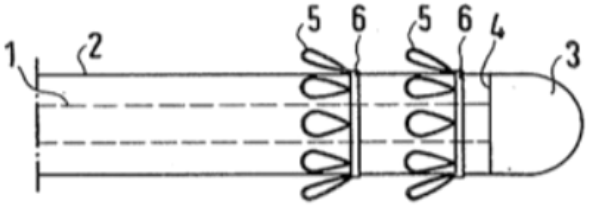
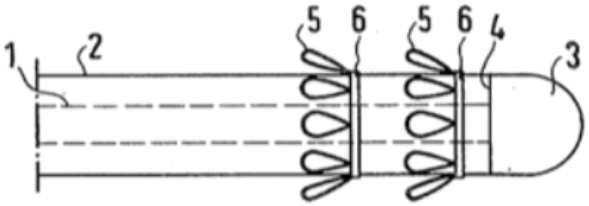
Cl.	Language	Prior Art Disclosure
1.e	a plurality of tine elements extending from the lead body, wherein all tine elements of the plurality of tine elements are positioned between a most proximal electrode of the plurality of electrodes and the proximal end of the lead body,	While Gerber does not teach tine elements, it does describe anchoring mechanisms that are located between the most proximal electrode and proximal end of lead body: "Referring to FIG. **2,** the implantable medical lead **10** of the present invention may have an anchoring mechanism **50** to fixate the medical lead **10** in the desired position.… Yet another anchoring mechanism 50 is to allow the medical lead 10 to fibrose in naturally using the human body's natural reaction to a foreign body or healing." Ex. 1012 at 4:13-30 (emphasis added); Fig. 2; Ex. 1003 at 88.  FIG.2 Thus, Gerber teaches that 50 can be an anchoring mechanism via fibrosis. A POSITA knows tines affix by fibrosis. Ex. 1003 at 88. Hauser discloses fixation means 17 and 19, depicted as multiple sets of tines. Ex. 1003 at 88-89.

Cl.	Language	Prior Art Disclosure
		FIG. 6  FIG. 12 

Cl.	Language	Prior Art Disclosure
		Hauser states the proximal fixation means 19 can be placed at other locations on the lead as determined by the surgeon. *Id.* Akerstrom teaches various arrangements of fixation means using loops 5 mounted on collars 6, but notable is Figure 3 arrangement: • "several collars 6, which are provided with loops 5, are slipped on the insulation 2 of the conductor 1, which collars are spaced apart from one another" (*id.* at 2:56-59; Fig. 3).  FIG 3 The loops are of sufficient stiffness as to project above the surface of the electrode. *Id.* at 3:6-8; 3:29-36; 3:52-55; Fig. 7. Loops look like tines and a skilled artisan could arrange tines as shown in Akerstrom. Ex. 1003 at 91.
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	As shown below excerpts of tined elements from Ex. 1014, Figure 12 of Hauser, the tined elements includes a plurality of tines, each having a tine width and thickness, and extending a tine length from an attached end to a free end and extend outwardly from the lead body in a proximal direction. Ex. 1003 at 91-92.

Cl.	Language	Prior Art Disclosure
	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,	 While Akerstrom does not teach the use of tines, it does disclose flexible, pliant loops that extend outwardly from the lead body in a proximal direction and anchor by fibrosing. Ex. 1003 at 92.
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,	As seen above in Ex. 1014, Figure 12 of Hauser, the 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 would deploy laterally outward when released from the catheter. However, Hauser does not explicitly teach that the tines do not overlap each other. Akerstrom, however, teaches a design arrangement where the set of loops on the first collar 6, as can be seen above in Ex. 1015, Figure 3, fold inward against the lead body without overlapping each other or against the loops of the second collar if constrained within an lumen of an introducer. Thus, Akerstrom design from Figure 3 can be applied to Hauser's tine sets. Ex. 1003 at 92.
1.h	wherein the plurality of tine elements is separate from and axially displaced from	See claim 1.e for plurality of tine elements. As seen below in Ex. 1012, Figure 2 of Gerber, the region at which anchoring mechanism 50 is

Cl.	Language	Prior Art Disclosure
	the plurality of electrodes.	located is separate from and spaced apart from the electrode. Ex. 1003 at 93.  FIG.2 As discussed in claim 1.d, Gerber teaches multiple electrodes.
2.0	2. The system of claim 1, wherein the tines of the tine elements are formed of a flexible, bio-compatible plastic selected from the group consisting of medical grade polyurethane compounds and silicone rubber compounds.	See claim 1. Akerstrom discloses that prior art tines, which were necessary part of tine elements, were made of silicone rubber. Ex. 1003 at 93.
4.0	4. The system of claim 1, wherein the tine attachment sites of the plurality of tine elements are separated longitudinally along the lead body by a distance that is greater than or equal to the tine length so that the tines are not overlapping one another when the tines	See claim 1. Akerstrom teaches an arrangement where the collars 6, which are provided with loops, are spaced apart from one another and the loops do not overlap when folded against the lead body. Ex. 1003 at 93-94.

Cl.	Language	Prior Art Disclosure
	are folded against the lead body towards the proximal end of the lead body.	 FIG 3 The tines in Hauser can be rearranged to the spacing arrangement of Akerstrom. *Id.*
7.0	7. The system of claim 1, wherein each tine element in the plurality of tine elements comprises an equal number of tines.	See claim 1. Hauser discloses fixation means 19, showing 3 sets of tines where each set comprise of at least two tines, and thus comprise an equal number of tines. See Ex. 1014, Fig. 12. Akerstrom Ex. 1015, Fig. 3:  FIG 3 Akerstrom shows arrangement of using the same anchor twice but spaced apart, such that each collar 6 would have an equal number of tines (loops). This arrangement can be used with tines. Ex. 1003 at 94.
10.0	10. The system of claim 1, further comprising the introducer.	Gerber discloses its lead can be used with a cannula, which is an introducer. Ex. 1012 at 5:16-17; 5:45-6:1; Ex. 1003 ¶84. Hauser discloses a catheter, i.e. introducer, that "first is introduced through the skin and into the pericardial space; the electrode 10 [i.e. medical

Cl.	Language	Prior Art Disclosure
		lead] then is inserted into the catheter 21, as by introducing a stylet 22 (or smooth plastic coated guidewire) through terminal pin 20…. With the catheter 21 containing the electrode 10 and in position in the pericardial space surrounding the heart, the active region 11 of electrode 10 is urged out of the catheter with the aid of the stylet 22." Ex. 1014 at 4:32-43.
11.0	11. A system comprising:	To the extent this preamble is a limitation, Gerber, Hauser and Akerstrom discloses this system.
11.a	an implantable pulse generator configured to generate electrical stimulation; and	Gerber teaches this: "The proximal end 35 of the *lead body 15 may be coupled to a pulse generator*, additional intermediate wiring, or other stimulation device. An example of such a pulse generator is the Medtronic InterStim Neurostimulator Model 3023. *The stimulation pulses produced by the pulse generator* are carried from the pulse generator through the proximal end 35 of the lead body 15 of the present invention toward the distal end 25 having at least one electrode contact 20." Ex. 1003 at 95.
11.b	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, the implantable medical lead comprising:	As discussed in claim 11.a, Gerber discloses a lead body that may be coupled to a pulse generator. Gerber also discloses its lead can be used with a cannula, which is an introducer. Ex. 1012 at 5:16-17; 5:45-6:1; Ex. 1003 ¶84. Hauser discloses a catheter, i.e. introducer, that "ha[s] a cross section only slightly larger than the cross section of the electrode 10 …; the electrode 10 [i.e. medical lead] then is inserted into the catheter 21, as by introducing a stylet 22 (or smooth plastic coated guidewire) through terminal pin 20…. With the catheter 21

Cl.	Language	Prior Art Disclosure
		containing the electrode 10 and in position in the pericardial space surrounding the heart, the active region 11 of electrode 10 is urged out of the catheter with the aid of the stylet 22." Ex. 1014 at 4:32-43. Hauser also discloses "the proximal lead region 13 of electrode 10 is tunneled to the location where it will be connected to the pulse generator of the defibrillation/cardioversion system." *Id.* at 4:51-55. Thus, Hauser discloses that lead is introduced via lumen of the introducer defining and is configured to be electrically connected to the implantable pulse generator. Ex. 1003 at 95-96.
11.c	a lead body extending between a proximal end and a distal end;	See claim 1.b
11.d	a plurality of conductors within the lead body;	See claim 1.c
11.e	a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors; and	See claim 1.d
11.f	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	See claim 1.e

Cl.	Language	Prior Art Disclosure
	and the proximal end of the lead body,	
11.g	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,	See claim 1.f
11.h	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 the lumen of the introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn proximally,	See claim 1.g. When the "introducer is withdrawn to release the plurality of tines" as discussed in claim 1.g, the tines deploy outward to engage with body tissue, and this occurs when the introducer is withdrawn proximally, that is towards the doctor and out of the body. Ex. 1003 at 97.
11.i	wherein the plurality of tine elements is separate from and	See claim 1.h.

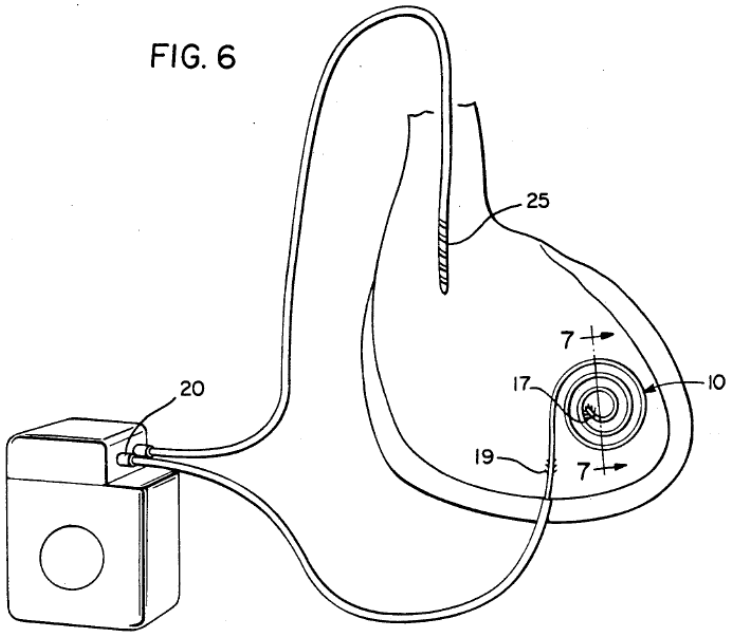
Cl.	Language	Prior Art Disclosure
	axially displaced from the plurality of electrodes.	
12	12. The system of claim 11, wherein the tines of the tine elements are formed of a flexible, bio-compatible plastic selected from the group consisting of medical grade polyurethane compounds and silicone rubber compounds.	See claim 11 above. See claim 2 above for the element "wherein the tines…silicone rubber compound."
14	14. The system of claim 11, wherein the tine attachment sites of the plurality of tine elements are separated longitudinally along the lead body by a distance that is greater than or equal to the tine length so that the tines are not overlapping one another when the tines are folded against the lead body towards the proximal end of the lead body.	See claim 11 above. See claim 4 above for the element "wherein the tine attachment sites…lead body."
18	18. A method comprising:	To the extent this preamble is limiting, Gerber, Hauser and Akerstrom combined discloses this method for implanting medical lead.

Cl.	Language	Prior Art Disclosure
18.a	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,	Gerber discloses lead can be used with a cannula, which is an introducer with a lumen, proximal end and a distal end. Ex. 1012 at 5:16-17; 5:45-6:1; Ex. 1003 ¶32. Hauser discloses a catheter, i.e. introducer, that "first is introduced through the skin and into the pericardial space; the electrode 10 [i.e. medical lead] then is inserted into the catheter 21, as by introducing a stylet 22 (or smooth plastic coated guidewire) through terminal pin 20…. With the catheter 21 containing the electrode 10 and in position in the pericardial space surrounding the heart, the active region 11 of electrode 10 is urged out of the catheter with the aid of the stylet 22." Ex. 1014 at 4:32-43. The catheter inherently has a proximal and a distal end. Ex. 1003 at 99.
18.b	the medical lead comprising: a lead body extending between a proximal end and a distal end; a plurality of conductors within the lead body; a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors; and a plurality of tine elements extending from the lead body, wherein all tine elements of the plurality of tine	See claim 1.a-1.f.

Cl.	Language	Prior Art Disclosure
	elements are positioned between a most proximal electrode of the plurality of electrodes and the proximal end of the lead body, each tine element comprising a plurality of flexible, pliant tines, each tine having a tine width and thickness and extending through 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,	
18.c	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 the lumen of the introducer without overlapping one another and deploy outward to engage	See claims 1.g and 11.h.

Cl.	Language	Prior Art Disclosure
	body tissue when the introducer is withdrawn proximally,	
18.d	wherein the plurality of tine elements is separate from and axially displaced from the plurality of electrodes;	See claim 1.h.
18.e	withdrawing the introducer from the body tissue to deploy the plurality of tine elements.	See claim 1.e for plurality of tine elements. Hauser discloses: "Deployment then is continued until the entire active portion 11 of the electrode 10 is in place in the pericardial space. The stylet 22 and the catheter 21 are then removed…." Ex. 1014 at 4:49-55. Thus, Hauser discloses that deployment continues until the active electrode region is at the stimulation site. Figure 5 with only the active electrode region outside the catheter, as compared to Figure 12, shows that the proximal sets of tines 19 will remain inside the catheter, i.e. introducer. Thus, only when the catheter is removed will the proximal tines 19 deploy. Ex. 1003 at 101.
19	19. The method of claim 18, wherein introducing the introducer into body tissue comprises percutaneously introducing the introducer through body tissue.	See claim 18. Hauser further discloses a catheter, i.e. introducer, that "first is introduced through the skin and into the pericardial space…." Ex. 1014 at 4:32-39; *see also id.* at 2:58-62; 7:51-55. Thus, Hauser teaches percutaneous introduction. Ex. 1003 at 101.
20	20. The method of claim 18, wherein withdrawing the introducer from the	See claim 18. As discussed in claim 18.e, Hauser teaches that the removal of the catheter will deploy the

Cl.	Language	Prior Art Disclosure
	body tissue to deploy the plurality of tine elements comprises withdrawing the introducer from the body tissue to deploy the plurality of tine elements into subcutaneous tissue, wherein the plurality of tine elements engage with the subcutaneous tissue to inhibit axial movement of the lead body and dislodgement of the plurality of electrodes.	proximal tines of the fixation means 19. Hauser teaches that "a proximal fixation means 19 is provided which is illustrated as being similar to fixation means 17 but anchors the electrode 10 at the location of entrance into the pericardial space as will be explained hereinafter." Ex. 1014 at 3:67-4:8; 4:65-5:1. Accordingly, the tines shown in 19 deploy and engage with the subcutaneous tissue to inhibit axial movement of the lead body and dislodgment. Ex. 1003 at 102.
21	21. The method of claim 18, wherein withdrawing the introducer from the body tissue to deploy the plurality of tine elements comprises anchoring, with the plurality of tine elements, the plurality of electrodes in operative relation to a selected stimulation site.	See claim 18. As discussed in claim 18.e, Hauser teaches that withdrawing the catheter deploys the three sets of tines on proximal fixation means 19. Hauser discloses that proximal fixation means 19 "anchors the electrode 10 at the location of entrance into the pericardial space." Ex. 1014 at 4:3-8. Hauser discloses removal only occurs after the active region of the lead is at the stimulation site: "With the catheter 21 containing the electrode 10 and in position in the pericardial space surrounding the heart, the active region 11 of electrode 10 is urged out of the catheter with the aid of the stylet 22." *Id.* at 4:39-43; *see also id.* at 4:63-5:7; Fig. 6.

Cl.	Language	Prior Art Disclosure
		
22	22. The system of claim 1, further comprising a tine mounting band, wherein at least one tine element is mounted to the lead via the tine mounting band.	See claim 1 above. Akerstrom discloses a collar 6, i.e. a mounting band, that attaches all the loops (Ex. 1015, Fig. 3) and the collar 6 is mounted to the lead (*id.* at Fig. 7). As discussed in § IV.C.2, it would have been obvious to apply the arrangement of Akerstrom to Hauser's proximal fixation means 19 with three sets of tines.
23	23. The system of claim 11, further comprising a tine mounting band, wherein at least one tine element is mounted to the lead via the tine mounting band.	See claim 11 above. See claim 22 above for the "further comprising" dependent element of claim 23.
24	24. The method of claim 18, wherein the	See claim 18 above.

Cl.	Language	Prior Art Disclosure
	medical lead further comprises a tine mounting band, wherein at least one tine element is mounted to the lead via the tine mounting band.	See claim 22 above for the "wherein the medical lead" dependent element of claim 24.

D. No Secondary Considerations Exist

Petitioner is unaware of any assertion by Medtronic that secondary indicia of non-obviousness exists having any nexus to any invention of the '314 Patent. Petitioner reserves its right to respond to any assertions of secondary considerations by Medtronic.

V. MANDATORY REQUIREMENTS

A. Grounds for Standing

Axonics certifies that the '314 Patent is available for IPR and Axonics is not barred or estopped from requesting an IPR of the challenged claims. This petition is timely filed within one year of the service of Medtronic's complaint alleging infringement of the '314 Patent. Ex. 1016.

B. Mandatory Notices (37 C.F.R. § 42.8)

1. Real Parties in Interest

Axonics is the real party in interest for this Petition.

2. Related Matters

The '314 Patent is at issue in *Medtronic, Inc. et al. v. Axonics Modulation*

Technologies, Inc., No. 8:19-cv-02115-DOC-JDE (C.D. Cal.).

The '314 Patent is related to U.S. Patent No. 8,036,756, against which Axonics is filing a separate petition for IPR concurrently with this Petition.

3. Fees

This Petition requests review of fifteen (15) claims of the '314 Patent and is accompanied by a payment of $30,500.00, which includes the $15,500.00 *inter partes* review request fee, and the $15,000 post-institution fee. *See* 37 C.F.R. § 42.15(a). Thus, this Petition meets the fee requirements under 35 U.S.C. § 312(a)(1). The Board is hereby authorized to charge any additional fees required by this action to Deposit Account No. 20-1430.

4. Power of Attorney

Powers of attorney are filed herewith pursuant to 37 C.F.R. § 42.10(b)

5. Designation of Lead and Back-Up Counsel and Service Information

Axonics serves this Petition and exhibits to the correspondence address of record for the '314 Patent pursuant to 37 C.F.R. § 42.105(a) and the Certificate of Service. Axonics consents to be served via lead and back-up counsel identified below at the mailing and e-mail addresses below.

Respectfully submitted,

By: */s/ A. James Isbester*
A. James Isbester
Registration No. 36,315
Lead Counsel for Petitioner

Lead Counsel	Back-Up Counsel
A. James Isbester Registration No. 36,315 jisbester@kilpatricktownsend.com Postal and Hand-Delivery Address: Kilpatrick Townsend & Stockton LLP Two Embarcadero Center, Suite 1900 San Francisco, CA 94111 Telephone: (415) 576-0200 Facsimile: (415) 576-0300	Babak S. Sani Registration No. 37,495 bssani@kilpatricktownsend.com Postal and Hand-Delivery Address: Kilpatrick Townsend & Stockton LLP Two Embarcadero Center, Suite 1900 San Francisco, CA 94111 Telephone: (415) 576-0200 Facsimile: (415) 576-0300

CERTIFICATE OF WORD COUNT

The undersigned certifies pursuant to 37 C.F.R. § 42.24(d) that the foregoing Petition for *Inter Partes* Review excluding any table of contents, table of authorities, certificates of service or word count, or appendix of exhibits or claim listing, contains 13,648 words according to the word-processing program used to prepare this paper (Microsoft Word). Petitioner certifies that this Petition for *Inter Partes* Review does not exceed the applicable type-volume limit of 37 C.F.R. § 42.24(a).

Dated: March 16, 2020

/s/ *A. James Isbester*
Counsel for Petitioner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of this Petition for *Inter Partes* Review of U.S. Patent No. 8,626,314, including its supporting Exhibits (1001-1016) has been served via USPS Priority Mail Express on March 16, 2020 upon Patent Owner's correspondence address of record for U.S. Patent No. 8,626,314:

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 100
Woodbury, MN 55125

The Petition has also been served via email and USPS Priority Mail Express to lead trial counsel for litigation at the following address:

George C. Lombardi
glombard@winston.com
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, IL 60601-9703

For the additional litigation counsel of record, the Petition has been served via email to the following email addresses:

Nimalka Wickramasekera: nwickramasekera@winston.com
Samantha M. Lerner: slerner@winston.com
J.R. McNair: jmcnair@winston.com

[Additional counsel identified on next page]

Vivek V. Krishnan: vkrishnan@winston.com
Joe S. Netikosol: jnetikosol@winston.com

Respectfully,

Dated: March 16, 2020

By: */s/ A. James Isbester*
A. James Isbester
Registration No. 36,315
Counsel for Petitioner

73048167