UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS MODULATION TECHNOLOGIES, INC.
Petitioner
v.

MEDTRONIC, INC.
Patent Owner

Case IPR2020-00715
Patent No. 8,036,756

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 8,036,756

TABLE OF CONTENTS

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 8,626,756 (Patent at Issue)
1002	File History of U.S. Patent No. 8,626,756
1003	Declaration of Benjamin Pless
1004	CV of Benjamin Pless
1005	U.S. Patent No. 5,257,634 – "Kroll"
1006	U.S. Patent No. 4,044,774 – "Corbin"
1007	U.S. Patent No. 6,510,347 B2 – "Borkan"
1008	Ronald F. Young, "Electrical Stimulation of the Trigeminal Nerve Root for the Treatment of Chronic Facial Pain," J. Neurosurg. 83:72-78 (July 1995)
1009	Declaration of Rachel J. Watters on Authentication of Publication
1010	U.S. Patent No. 6,055,456 – "Gerber"
1011	PCT Publication No. WO 98/20933 – "Lindegren"
1012	U.S. Patent No. 4,407,303 – "Akerstrom"
1013	U.S. Patent No. 5,052,407 – "Hauser"
1014	Proof of Service, Dkt. No. 26, filed on November 5, 2019 in *Medtronic, Inc. et al. v. Axonics Modulation Techs., Inc.*, No. 8:19-cv-02115-DOC-JDE (C.D. Cal.)

I. INTRODUCTION

Petitioner Axonics Modulation Technologies, Inc. ("Axonics"/"Petitioner") respectfully requests *inter partes* review of claims 1, 2, 5, 7, 13-15, and 18 ("challenged claims") of U.S. Patent No. 8,036,756 ("'756 Patent") in accordance with 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 *et seq*. ("Petition").

The '756 Patent is directed to methods of implanting and anchoring a specific type of medical electrical lead that uses multiple sets of tines for anchoring the lead in order to stimulate a selected sacral nerve. However, none of the '756 Patent claims are limited to implantation in the sacrum area; the method claims are generic to percutaneous implantation of a specific type of medical electrical lead with tines to affix to any subcutaneous tissue. There is nothing new thus in the '756 Patent. It facially admits that the methods of introducing the lead using introducers and anchoring an implantable electrical lead using tines were all well known before the '756 Patent priority date.

It is therefore not surprising that the '756 Patent has a long prosecution history of five years. After many rejections and amendments, the Examiner finally allowed claims after requiring that all electrodes be positioned between the tine

elements and the lead distal end[1]—a limitation of the lead and not related to any method. This location of electrodes is, however, obvious and common sense to a skilled artisan in view of prior art such as the Young reference (Ex. 1008), which disclosed implantation of prior tined lead and pulse generator developed by the Patent Owner Medtronic, Inc. ("Medtronic"), and the Gerber patent (Ex. 1010), none of which were considered during prosecution. For the reasons explained below, the challenged claims are unpatentable and should be cancelled.

II. THE '756 PATENT AND TECHNICAL BACKGROUND

The '756 Patent was filed on February 13, 2006, but claims priority to a provisional application 60/316,582, filed on August 31, 2001.[2] The '756 Patent is directed to methods for implanting and anchoring a certain type of implantable medical electrical lead. Ex. 1001 at 1:33-44. It has 19 method claims, of which claims 1 and 14 are independent claims that are very similar. Claims 1 and 14 both

---

[1] Distal direction in the '756 Patent refers to being in the body farther away from the physician. *See* Ex. 1001 at 5:50-57 (referring to location of the "distal electrode" at a site in the body).

[2] For purposes of this Petition, Axonics assumes that the '756 Patent priority date is August 31, 2001.

describe percutaneously implanting a medical lead via the lumen of an introducer, wherein the implantable medical lead comprises of (a) a plurality of electrodes that is electrically connected via conductors and connectors and (b) plurality of tine elements with tines that are adapted to fold within the introducer lumen and deploy outward at the simulation site. *Compare* claim 1 *with* 14. The only essential difference between the two claims is that claim 1 additionally requires coupling the lead to the implantable pulse generator ("IPG"). *Id.* at 14:8-9. All this, however, was known before the '756 priority date of August 31, 2001. *See id.* at 1:62-3:22.

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. 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.* ¶¶23-25. 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 anchor the lead into position, and introducers to place the lead into the human

body. *Id.* ¶¶26-29. Before 2001, there existed single monopolar electrodes or multiple electrodes in different arrays, linear or multilinear or in grid format. *Id.* ¶29. Similarly, there existed many different devices used to fix the lead: screws, sutures, cloth, adhesive, coils, resilient loops, fins, or tines, or combination of these. *Id.* ¶¶30-33. The use of different types of introducers, e.g. hollow tubes such as needles, cannulas, catheters, were also 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 '756 Patent

The '756 Patent admits that all the components of its implantable medical lead were known in the prior art. The '756 Patent acknowledges that many different permanent neurostimulation leads had been implanted. *Id.* at 1:58-2:6, 2:7-3:5 (incorporating by reference four patents that support these prior leads and methods). 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 or neurostimulator IPG.

Id. at 2:32-44 (emphasis added). Thus, prior to the '756 patent, percutaneous implantation of leads were known and the lead designs used 4 electrodes along the distal segment of the lead body, each coupled to a conductor that couples to an IPG, just as claimed in the '756 patent claims 1 and 14.

The problem with these leads according to the '756 Patent was the suturing mechanism that required patient to be under general anesthesia for a lengthy time, large surgical exposure and led to lead migration. *Id.* at 3:6-22, 3:37-51. To avoid this, the '756 Patent acknowledges that prior art for sacral nerve stimulation used percutaneous approach that had essentially nubs that increased resistance and somewhat fixed the leads into position. *Id. at* 3:55-4:1. The '756 Patent further admits that in the cardiac space, prior art used multiple tines on a tine element array. *Id. at* 4:16-47 (discussing numerous patents incorporated by reference, including U.S. Patent No. 3,939,843 that '756 Patent states was "directed to the first atrial *tined leads, longitudinally extending rows* of elongated tines")(emphasis added). It also admits the use of percutaneous implantation with introducer of

leads with these tines and that tines "fold against the introducer lumen and the vein wall after the lead distal end exits the introducer lumen." *Id.* at 4:54-55.

After review of this prior art, the '756 Patent 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 5:19-29; 5:33-38. This is the problem that the '756 Patent identifies.

The solution according to the '756 Patent is an 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. *Id.* at 6:10-14; 9:7-12; *see also* 5:38-40, 5:50-52; 12:33-35 (P=one); Fig. 1. Each electrode (*e.g.* 25, 30, 35, 40) is electrically coupled to a wire lead conductor within the lead body and the conductor is coupled to connector elements (*e.g.* 65, 70, 75, 80) at the proximal end. *Id.* at 9:23-31; Fig. 1. Those connector elements are adapted to be coupled to an IPG, including Medtronic

InterStim Neurostimulator Model 3023. *Id.* at 9:44-49. The electrodes are affixed through "[t]he fixation mechanism comprises a plurality M of tine elements [*e.g.* 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 red] to a free tine end [170]." *Id.* at 5:50-63; *see also* 6:26-30; 9:61-10:14; 10:24-34; Figs. 1, 3 (below). While figures show M=4 tine element and N=4 tines (*Id.* Figs. 2-4, 9; 10:7-8; 12:20-22), the '756 Patent also states N can be one or more tines (12:63-65). In contrast, M "tined elements" is always discussed in plural and M is never identified as 1. *Id.* at 5:57-60 ("plurality M of tine elements"); *Id*. at 10:7-8 ("M=4"); 12:20-22 ("M=4").

FIG. 1

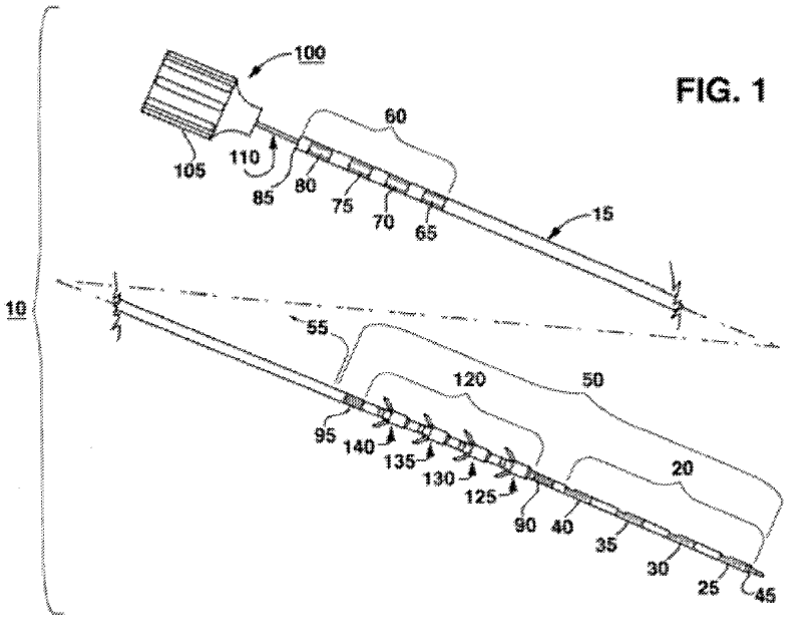
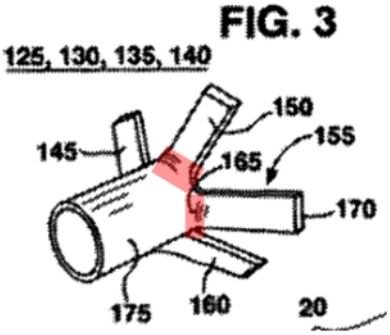


FIG. 3



The ’756 Patent discloses using an introducer to advance the lead with the tines folded inward against the lead body when constrained in the introducer lumen. *Id.* at 5:63-6:3; 6:41-43; 6:52-7:19; 10:17-23; 10:41-46; 11:4-10; Figs. 5-8. The lead is advanced to the stimulation site and the electrodes is “advanced distally out of the introducer lumen.” *Id.* at 7:20-27; 11:11-18. Then, the introducer is retracted proximally and the tines are successively released from the introducer lumen to bear against the tissue to inhibit proximal retraction. *Id.* at 7:27-39; 10:58-64; 11:55-12:4.

The ’756 Patent has 19 method claims, with independent claims 1 and 14 that are very similar as discussed above. None of the challenged dependent claims add novel methods or components. For example, claim 2 requires that the electrode comes out of the lumen at the stimulation site before withdrawal of the introducer. Claim 5 requires the introduction of the introducer before placing the lead into the introducer. Both methods describe how an introducer was commonly used before 2001 (and still is). Ex. 1003 ¶¶33, 36, 90, 114. Claims 7 and 15 state essentially that the distance between the tine elements is greater than the tine length when folded against the lead body. Claims 13 and 18 require the tines comprising of biocompatible plastic. As explained in the charts, these elements were all well known before the ’756 priority date.

C. Prosecution History

The '756 Patent was filed as U.S. Application No. 11/352,552 ("the '552 Application")[3] on February 13, 2006 with 22 claims, including three independent claims (claims 1, 10 and 19), of which claims 1-18 were system claims and the remainder were method claims 19-22. *See generally* Ex. 1002.

After Applicants had provisionally elected to pursue the methods claims 19-22, on December 11, 2007, the Examiner rejected those claims under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,257,634 ("Kroll") in view of U.S. Patent No. 4,044,744 ("Corbin"). Ex. 1002 at 76-78. Kroll disclosed then required limitations for a lead having multiple electrodes and tine elements, as shown in Figure 3 (see below) and an introducer structure. *Id.* at 77.

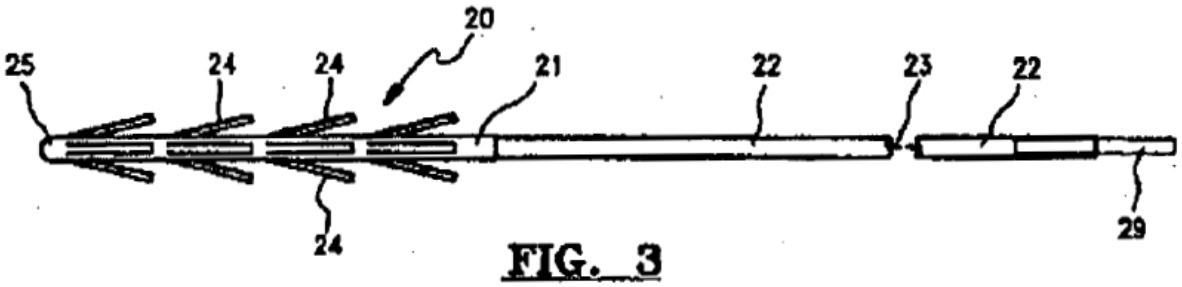


FIG. 3

[3] It is a continuation of U.S. Application No. 10/004,732 (now Patent No. 6,999,819).

Ex. 1005, Fig. 3. Corbin was relied upon for teaching the method of introducing the lead percutaneously. Ex. 1002 at 77-78.

In a Response dated June 17, 2008, Applicants amended method claim 19, including the following: "withdrawing the introducer proximally from the tine element array to successively release the N tines of each of the M tine elements ~~element array~~ to deploy outward." Ex. 1002 at 89. Applicants also amended claims 20-22 to delete the word "the step of," and added new claims 23-37. Applicants argued against the rejections noting that the "extensions 24" in Figure 3 of Kroll, cited as being tine elements, were actually conductive electrode structures and not proximal to the electrodes, whereas claim 19 recites P stimulation electrodes separate and in addition to a plurality of tine elements (*id.* at 94-96).

On October 31, 2008, the Examiner rejected claims 19-32 as "Final Action," again stating the claims were obvious over Kroll in view of Corbin. The Examiner rejected Applicants' arguments: "Applicant argues that the invention as claimed requires the P stimulation electrodes to be separate from the tine elements; however support within the claim appears to be lacking for such a limitation" (Ex. 1002 at 114), and "Applicant argues that Kroll fails to teach tine elements being disposed proximally to the lead body from the electrodes. As previously explained, Kroll discloses a distal tip electrode, 25, as well as a portion of the conductive lead body that extends from the most distal region of tine elements to

the distal tip electrode and all embodiments show tine elements located proximal to the distal tip" (*id.* at 115). In sum, the Examiner believed the claims did not require all of the electrodes to be separate from all of the tine elements.

In a Response, on December 31, 2008, the Applicants reiterated their previous arguments that the amended claims require the tine elements to be separate from and in addition to the stimulation electrodes. Ex. 1002 at 129-130. Thus, they amended independent claims 19 and 33 to add the following limitation "wherein the plurality of tine elements are separate from and axially displaced from each of the stimulation electrodes."

Like ships passing by at night, the Examiner and the Applicants continued to reiterate the same rejections and responses in the next seven communications between January 13, 2009 and October 6, 2009. In a Response filed on October 6, 2009, Applicants reiterated previously made arguments and made clear again their opinion that "neither Kroll nor Corbin discloses or suggests a medical lead that includes a plurality of stimulation electrodes and a plurality of tine elements that are separate from and axially displaced from all of the stimulation electrodes of the medical lead, as required by Applicant's [amended] claims 19 and 33." Ex. 1002 at 201.

Impasse was broken but the Examiner provided a different §103 ground for rejection on December 29, 2009, relying on the combination of U.S. Patent No. 6,510,347 ("Borkan") in view of Kroll and Corbin. The Examiner stated Borkan disclosed a lead having tine elements separate from and axially displaced from stimulation electrodes, as shown in Fig. 9 (see below); Kroll disclosed tines that are radially offset and interleaved and introduced through an introducer; and Corbin disclosed percutaneously introducing a stimulation lead.

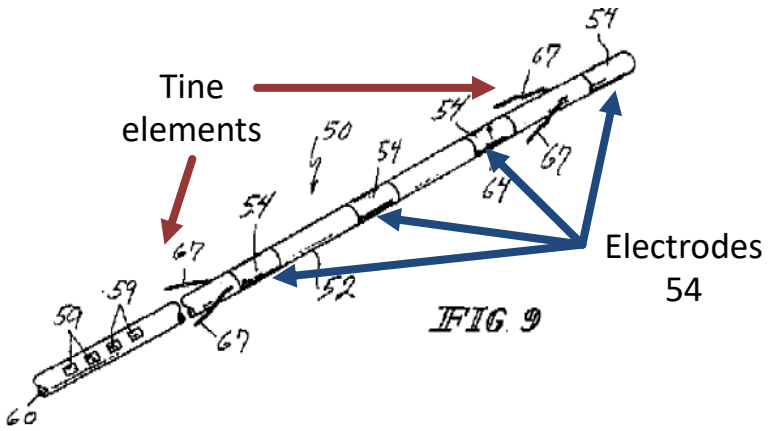


FIG. 9

On March 29, 2010, Applicants argued against the rejections without amendment to the claims and added new dependent claims 38-39. Applicants argued that: "Even if the two pairs of tine fixation devices 67 illustrated in FIG. 9 can reasonably be characterized as a plurality of M tine elements, an assertion with which Applicant does not necessarily agree, Borkan fails to disclose or suggest that the two pairs of tine fixation devices 67 are formed in a tine element array

extending through a segment of a lead proximal to an electrode array", limitations in then claims 19 and 33. Ex. 1002 at 238 (emphasis in original) .

Not persuaded, the Examiner issued a Final Office Action of July 7, 2010, again rejected claims 19-39. Specifically, claim 39 was rejected under § 112 and claims 19-39 were again rejected as obvious over Borkan in view of Kroll and Corbin. In response to Applicant's arguments, the Examiner noted that: "Applicant has failed to claim a tine element array that is not separated by an electrode." Ex. 1002 at 261. The Examiner further noted that: "Applicant further argues that the tine element array disclosed by Borkan is not proximal the electrode array. Examiner respectfully disagrees. Claim 19 only requires P stimulation electrodes and claim 30 further contains the limitation that P equals 1. Accordingly only a single distal electrode is necessary to consider the tine element array disclosed by Borkan to read on the invention as claimed." *Id.*

On September 7, 2010, Applicants responded by amending claims 19 and 33, and canceled claim 39. Specifically, to avoid Borkan, then independent claims 19 and 33 were amended to add the following: "and wherein no electrodes are positioned between adjacent tine elements of the plurality of M tine elements;" and claim 33 was amended to recite "wherein no electrodes are positioned between adjacent tine elements of the plurality of tine elements." Applicants then regurgitated their prior arguments but specifically identified that the Borkin-Kroll-

Corbin combination did not disclose these new amendments which now require no electrodes between adjacent tine elements. Ex. 1002 at 282.

In a Non-Final Office Action issued November 15, 2010, the Examiner rejected claims 19-38 under § 112, first paragraph, for failure to support the previously added amendment because figures only disclose what is in the invention and "not what is not present." Ex. 1002 at 301. A telephone interview failed to reach any agreement. Thus, on February 15, 2011, Applicants rejiggered their claims: claims 19, 25, 27, 33 and 34 were basically reformulated but kept many of the same components, claims 30 and 38 were canceled, and claims 40 and 41 were added. Of note, Applicants stated that independent claims were revised so P electrode cannot be one. Moreover, the revised independent claims identified segments of the lead body such that the segment containing electrodes and the segment containing tine elements, those two segments cannot overlap. *Id.* at 324.

Subsequently, another telephone interview occurred on April 19, 2011, in which the Examiner suggested amendments to independent claims 19 and 33 to overcome the §112, first paragraph rejections. Ex. 1002 at 345. Applicants agreed and claim 19 was amended to recite "wherein all of the P stimulation electrodes are between the plurality of M tine elements and the lead distal end" and claim 33 was amended to recite "wherein the plurality of stimulation electrodes is between the plurality of tine elements and the lead distal end." *Id.* at 341-43. In a reversal of

February 11 Response where they stated electrode has to be plural, the Applicants added dependent claim 42 where P electrodes is now equal to 1.

A Notice of Allowance issued on June 7, 2011 allowing pending claims 19-29, 31-37 and 42. The Examiner noted the Reasons for Allowance as: "The prior art of record fails to disclose/teach a set of and all tine elements being positioned between a first and second lead body marker in combination with the other claim limitations." Ex. 1002 at 356. The '552 Application issued as U.S. Patent No. 8,036,756 on October 11, 2011.

D. Person of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSITA") in the field of the '756 Patent in 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 ¶61.

III. PROPOSED CLAIM CONSTRUCTION

Claims in an IPR filed after November 13, 2019, "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by the one of ordinary skill in the art and the prosecution history pertaining to the patent." 37

C.F.R. §42.100(b); 83 Fed. Reg. 51,358 (Oct. 11, 2018). Axonics is unaware of any prior construction determination for the '756 Patent.

Axonics proposes the following one construction under the standard espoused in *Phillips v. AWH Corp*, 415 F.3d 1303, 1312-19 (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)(requiring construction only to the extent terms are in controversy and need to be construed to resolve the controversy).

A. "a plurality of M tine elements" and "a plurality of tine elements"

Claim 1 recites "a plurality of M tine elements" and claim 14 "a plurality of tine elements." Thus, all independent claims require a plurality of tine elements. Accordingly, all challenged claims require "a plurality of tine elements."

The '756 Patent is consistent in how it describes this phrase. First, both independent claims 1 and 14 require "a plurality," which means two or more based on plain meaning. The specification supports this meaning when it uses "tine elements" in the plural and consistently describes or shows multiple structures, most frequently four tine elements arranged in an array from the lead body. Ex. 1001, 5:57-59 ("The fixation mechanism comprises a plurality M of tine elements arrayed in a tine element array along a segment of the lead"); 9:65-10:1 ("The

fixation mechanism comprises four tine elements 125, 130, 135 and 140 arrayed in a tine element array 120"); *see also referring to "tine elements"* 6:4-9; 6:26-30; 10:3-11; 10:24-29; 10:65-11:3; 12:14-32; 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, it also mentions alternative designs where 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." Ex. 1001, 12:54-60. Such use of the words "a single" or "an integral section" limits these designs to where there is only one component, *i.e.* one tine element structure or one lead body.[4] Another example is consistent use of "lead" to refer to

[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) ("to construe the claim term to encompass the alternative embodiment in this case would contradict the language of the claims. Indeed, read in the context of the specification, the claims of the patent need not encompass all disclosed embodiments")(citing numerous precedents); *see also* Ex. 1003 ¶66 n.20. Claim 1 also requires tine elements that "are separate from and axially displaced

one lead versus "leads" for plural leads. *See id., e.g.*, Abstract; 5:33-38 ("maintaining electrical *leads*" v "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 id., e.g.*, Claim 19; 6:10-14 (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." Ex. 1003 ¶66.

Second, both the claims and specification describe each "tine element" as a structure that has attached to it a plurality of tines. Claim 1 requires "each tine element comprising N 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 at a tine attachment site …." Thus, claim 1 states that there are tines attached to the tine element at the "attached tine end," which also is attached to the lead body. Claim 14 explicitly states that tine elements are "attached to the lead body" and "each tine element comprising a plurality of flexible tines."

---

from each other," which further precludes a single or integrated design. *Id*. Claim 14 also requires "tine element*s attached* to the lead body," which similarly precludes a single or integrated design. *Id.* (italics added).

The specification similarly describes multiple tine elements with each tine element having multiple tines attached to the tine element. *See, e.g.*, Ex. 1001, 5:60-66 ("Each tine element comprises at least N flexible, pliant, tines, each tine having… a tine length from an attached tine end to a free tine end. The attached tine end is attached to the lead body from a tine attachment site"); *Id.* 6:4-9; 6:41-43; 10:7-34 (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); *Id.*, Figs. 1-4. The attached tine end 165 is always shown as attached to the tine element and extending from it. *Id.* Figs. 3 (annotated to show 165), and 4.

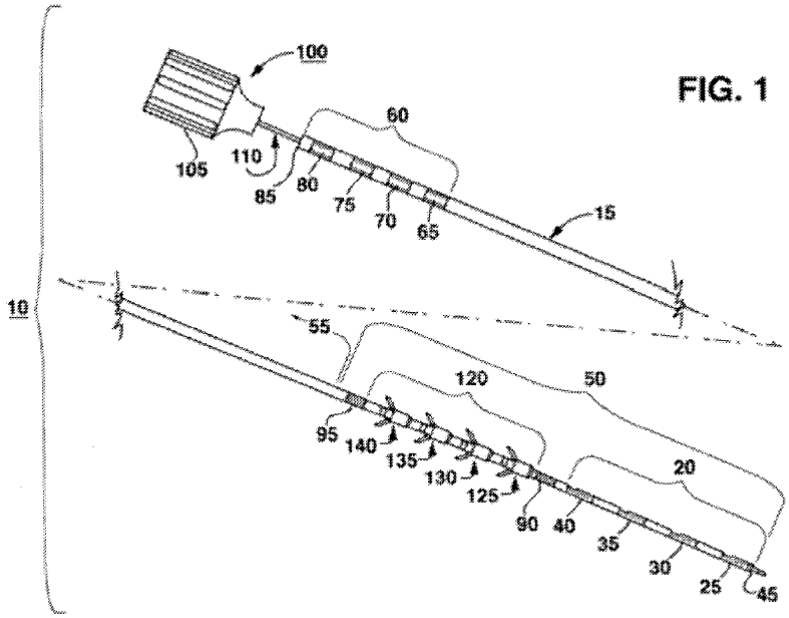


FIG. 1

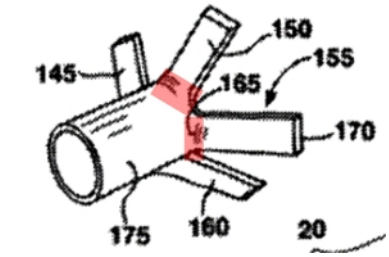


FIG. 3

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 ¶68.

Accordingly, Axonics proposes to construe "a plurality of [] tine elements" as at least two or more structures that mount to the lead body, each structure comprising multiple tines attached to it. *See id.* ¶69

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

Since the '756 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, 5, 7, 13-15, and 18 of the '756 Patent are unpatentable under 35 U.S.C. § 103 as follows:

Ground 1. Claim 1, 2, 5, 7, 13-15, and 18 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. 1008) in view of U.S. Patent No. 6,055,456 ("Gerber")(Ex. 1010), PCT Publication WO98/20933 ("Lindegren")(Ex. 1011) and 4,407,303 ("Akerstrom")(Ex. 1012).

Ground 2. Claims 1, 2, 5, 7, 13-15, and 18 are obvious over Gerber in view of U.S. Patent Nos. 5,052,407 ("Hauser")(Ex. 1013) and Akerstrom.

As further explained below, each of these references are prior art to the '756 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, 7-10, 13-14, 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.*

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). As explained above, Medtronic obtained allowance of the '756 Patent based on all tine elements being separate from all electrodes as well as located between that the most proximal electrode and the proximal end of the lead body." *See* §II.C *supra*. Young, Hauser and Lindegren were not previously considered by the Examiner during prosecution of the '756 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).

A. Ground 1. Claim 1, 2, 5, 7, 13-15, and 18 are obvious over Young in view of Gerber, Lindegren and Akerstrom

Claims 1, 2, 5, 7, 13-15 and 18 are obvious over Young in view of Gerber Lindegren and Akerstom.

1. Young

Young is an article titled "Electrical Stimulation of the Trigeminal Nerve Root for the Treatment of Chronic Facial Pain," written by Dr. Ronald F. Young and published publicly in the Journal of Neurosurgery in July 1995. Exs. 1008; 1009. With a publication date years before the 2001 priority date, Young qualifies as prior art under 35 U.S.C. §102(b).

Young discusses a study of 23 patients percutaneously implanted with a Medtronic electrical lead that had two sets of tines and Medtronic's ITREL IPG. Like the '756 Patent desire to improve existing leads, Young states its desire "to expand our knowledge of this useful technique [i.e percutaneous implantation of stimulating electrodes] and to extend the application of electrical stimulation for treatment of chronic pain." Ex. 1008 at 72. Young calls its lead "stimulating electrode" which was Medtronic's "Quintatrigeminal" lead that "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). The purpose of the

tines was to prevent the electrode from becoming dislodged after implantation." *Id.* 73.

Fig. 1 (distal tip of the lead):

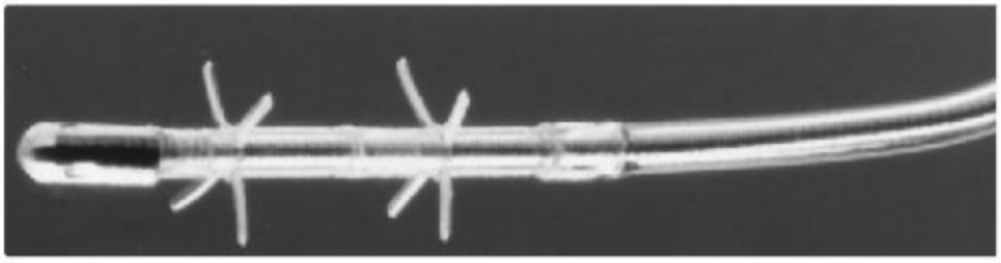
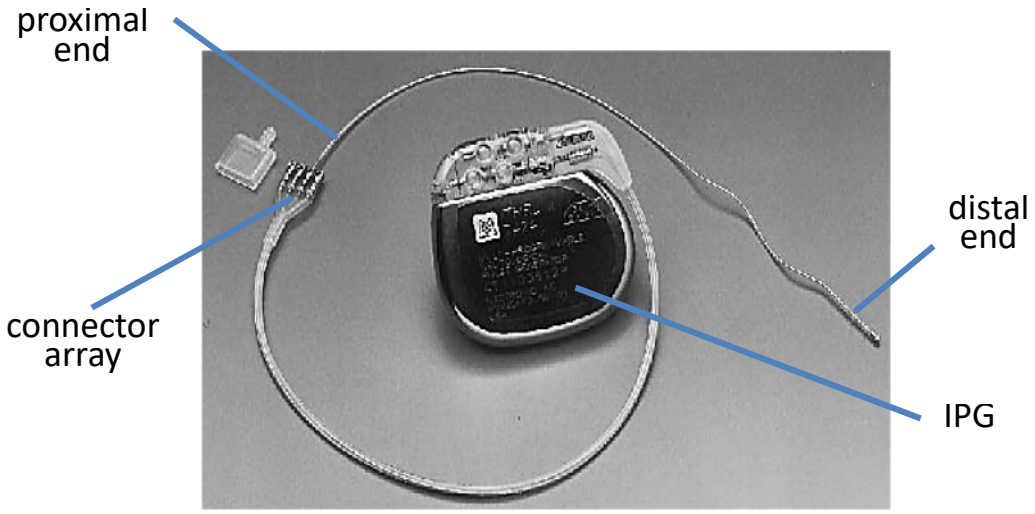


Fig. 3 (showing the complete system with the lead with distal and proximal end, connected to the connector array of the extension lead, connected to an IPG):



Young discusses an implantation technique: where 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 the distal end of that lead was connected to the ITREL IPG. Ex. 1008 at 73-74. Using this method, the lead was effective and in only one case was there lead migration. *Id.* 75-76. Young further teaches that this lead can be improved by adding electrodes "which would permit greater flexibility in activation of a wider area." *Id.* 77.

2. Gerber

Gerber is a U.S. patent issued on April 25, 2000, more than a year before the August 2001 priority date. Ex. 1010. Thus, Gerber qualifies as prior art under 35 U.S.C. §102(b).

Like the '756 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." *Id.* 1:64-2:13.

To solve that problem, Gerber discloses an implantable medical 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. *Id.*, Abstract; 2:4-5 ("current lead design used for sacral nerve stimulation uses 4

electrodes"); 3:39-4:52 (disclosing two electrodes and different anchoring means on a lead body); Figs. 2-3. Gerber discloses different types of anchoring mechanisms, including sutures, bone screws, enzyme glues (4:12-31), and "[y]et another anchoring mechanism 50 is to allow the medical lead 10 to fibrose in naturally" (4:27-30). At the time of Gerber, one of the most popular anchoring mechanisms by fibrosis was tines. Ex. 1003 ¶95. Gerber thus discloses the exact location for the anchoring mechanism that was required by the Examiner with the amendment during prosecution. *See id.* ¶95, Figs. 2 and 6 (annotated below).

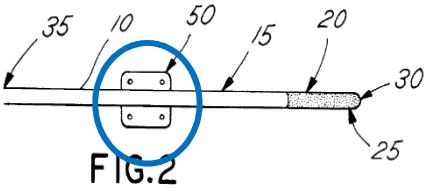


FIG.2

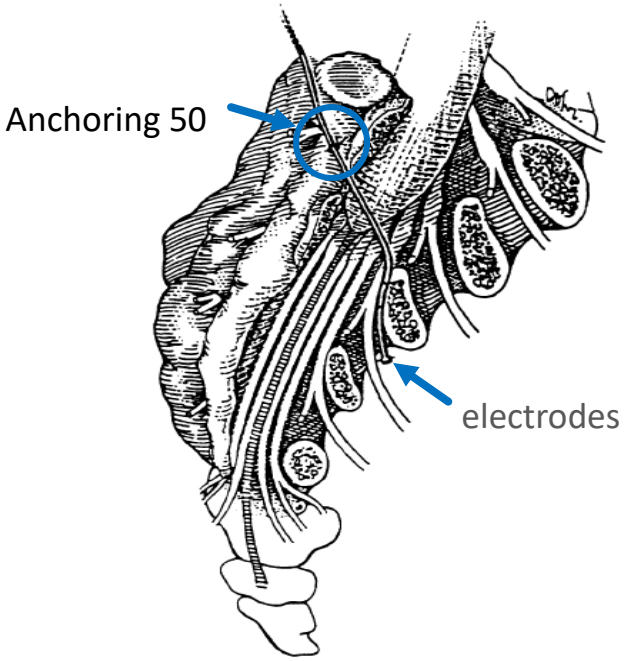


FIG.6

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. 1010, 3:48-52), which was also identified in the '756 Patent. Ex. 1001, 9:47-49. While Gerber does not disclose expressly a method for implanting the lead, it discloses that its embodiment of medical lead with a stylet "is particularly useful for implantation using a cannula." Ex. 1010, 5:16-17; 5:51-6:1 (disclosing use of needle). By 2001, a POSITA would have known well that cannula had been used as an introducer. Ex. 1003 ¶96

3. Lindegren

Lindegren is a PCT application published on May 22, 1998. Ex. 1011. Publicly available 3 years before the 2001 priority date, Lindegren qualifies as prior art under 35 U.S.C. §102(b).

Like the '756 Patent, Lindegren acknowledges a lead migration problem. *Id.* at 1:20-27. Lindegren discloses that different anchoring means, including tines (or projections) can be used and the number dependent on the level of anchoring capability desired. *Id.* at 4:32-5:7. Lindegren discloses an implantable lead with a single electrode 4 on the distal end and a tine anchoring means 10. *Id.*, Abstract, 4:32-5:22, 7:7-27. 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; *see also* 7:1-27 (describing preferred embodiments in Figs. 1-3 with electrode 4 and ring-shaped means 10 with projections 12 that "consist of tine-like position-fixation means"); Ex. 1003 ¶99.

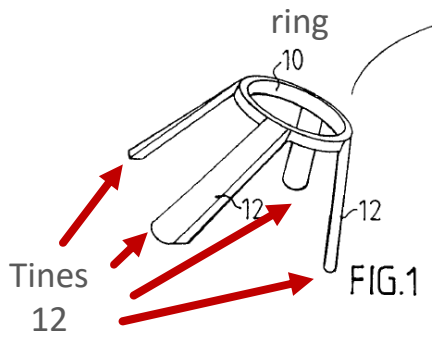


FIG.1

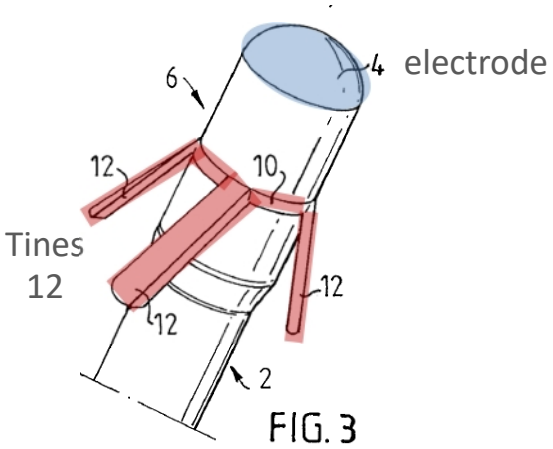


FIG. 3

4. Akerstrom

Akerstrom is a U.S. patent issued on October 4, 1983. Ex. 1012. Publicly available years before the 2001 priority date, Akerstrom qualifies as prior art under 35 U.S.C. §102(b).

Akerstrom wanted a small lead that applies stimulation pulses to the heart with a good emplacement mechanism. *Id.* 1:5-14, 35-39 (stating invention's objective). It also focused on addressing prior endocardial leads with stiff tines that were too big for delivery through a small vein and having limited tissue area to

anchor in the heart wall.[5] *Id.* 1:19-31. To solve this problem, Akerstrom discloses a lead with a distal electrode and multiple proximal anchors, each comprising resilient loops mounted on collars or sleeves to anchor the lead. *Id.* 1:6-14; 2:34-61; Figs. 1-3. These loops are used to secure the lead. *Id.* 2:46-49. They are of sufficient stiffness as to project above the surface of the electrode. *Id.* 3:6-8; 3:29-36; 3:52-55; Fig. 7. Loops of Akerstrom when viewed only by the POSITA look like form of tines. Ex. 1003 ¶101.

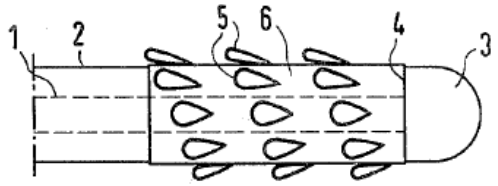


FIG 1

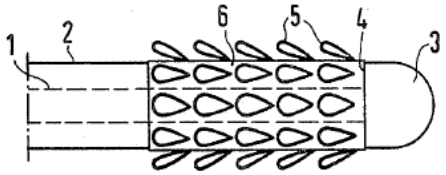


FIG 2

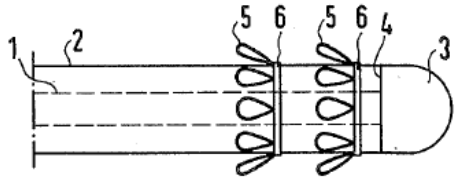


FIG 3

[5] While Ackerstrom had concerns of inserting tined leads in a vein, those 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 of the anchor. Ex. 1003 ¶101. Plus, skilled artisans knew before 2001 that tines could be made as pliant as loops and vice versa. *Id.*

5. Applying Young in view of Gerber, Lindegren and Akerstrom

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, Final Written Decision (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, Lindegren and Akerstrom for several reasons. First, each prior art reasonably addresses similar problems of leads adequately stimulating the nerves while limiting dislodgment as the '756 Patent. *See, e.g.*, Ex. 1008 at 73; Ex. 1010 at 1:64-2:14; Ex. 1011 at 1:20-27; Ex. 1013 at 1:5-14. Second, all four references are analogous art to the '756 Patent. Each reference is from the same field as the '756 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. 1008 at 73; Ex. 1010 at 3:39-4:52; Ex. 1011 at 4:32-5:9; Ex. 1013 at 2:34-59. Thus, a POSITA would have been motivated to combine references that solve the same problem as the '756 Patent in the same field. *Tokai Corp. v. Easton Enterp., Inc.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011) (finding motivation to combine art addressing the similar problem).

Third, there is teaching in the references themselves to combine these. Young teaches that the single electrode "could be improved to provide multiple active stimulation sites near the tip" and that "patients who discontinued stimulation due to ineffective pain relief might have benefited from a multicontact electrode [i.e. lead with multiple electrodes], which would permit greater flexibility in activation of a wider area." Ex. 1008 at 77; Ex. 1003 ¶104. Thus, a POSITA would have been motivated to look for multiple electrodes that provide greater flexibility for electrode placement, such as Gerber's lead that discloses multiple electrodes for implanted leads for sacral nerve stimulation. Gerber further discloses that its lead could use various anchoring means that fixes by fibrosis. Thus, a POSITA would have considered the limited number of devices available at the time to anchor by fibrosis leads; by 1990s, the predominant fixation means by fibrosis was tines. Ex. 1003 ¶105. 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. Akerstrom's loops also anchor by fibrosis, and look like tines in the figures of Young and Lindegren. Akerstrom also provides different arrangements of loops that could similarly have been used with tines. *Id.* Thus, a POSITA would have considered using tines mounted on bands or rings on a lead.

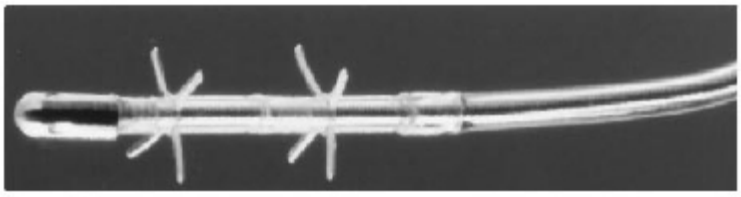
Not only is there a motivation to combine, but doing so would have been highly feasible. *Id.* ¶¶107, 117. A POSITA would have considered the combinations because of the ease in manufacturing using these references. All three references disclose relatively simple, implantable medical leads with the distal end without curves or hooks. 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 for activating a wider area. Furthermore, Lindegren's tine-mounted rings could be easily reproducible and added to the simple, linear lead. Akerstrom's arrangement of loops in Figure 3 with a collar 6 look very similar to Lindegren's tine-mounted rings and that Akerstrom arrangement allows for easy manufacturing and adaptation to the needs of the stimulation site. *Id.* Thus, in order to improve anchoring within the soft tissue near the sacrum, it would have been obvious to a POSITA to use multiples of tines mounted on collars (i.e. tine elements) extending proximally and spaced them apart as shown in Young and Akerstrom to further prevent dislodgment after implantation, i.e. a purpose of tines taught by Young. Such modifications of Young to have the additional electrodes or tines facing proximally and separate from each other 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

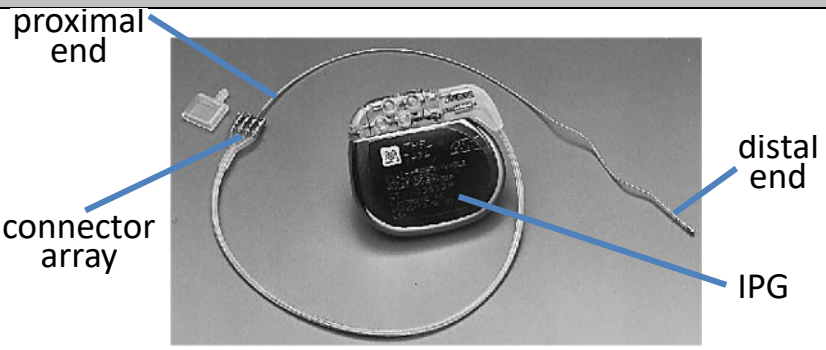
function it had been known to perform and yields no more than one would expect from such an arrangement" and would have been obvious. *Id.*

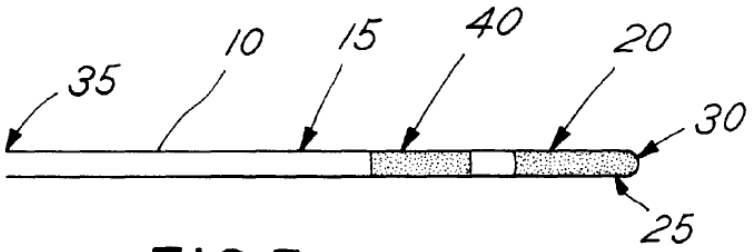
a. Invalidity Chart for Ground 1 Combination

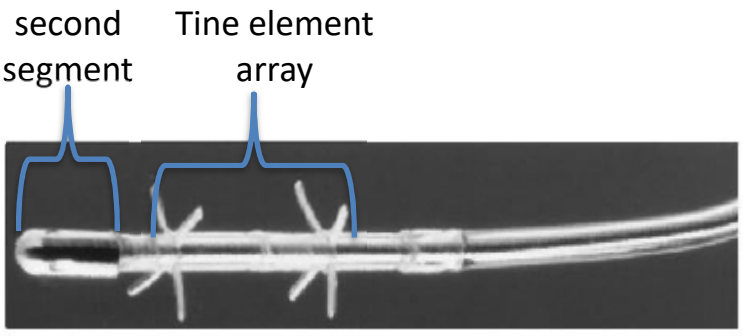
The combination of Young, Gerber, Lindegren and Akerstrom teaches every limitation of claims 1, 2, 5, 7, 13-15 and 18, as set forth in greater detail in the following charts.

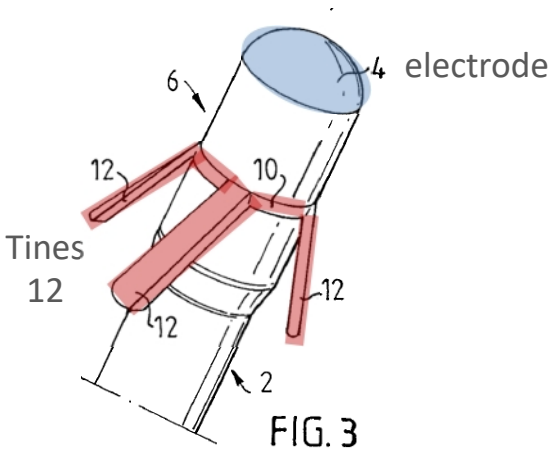
Cl.	Language	Prior Art Disclosure
1.0	1. A method of providing electrical stimulation of body tissue at a stimulation site employing an implantable pulse generator, the method comprising:	To the extent this preamble is a limitation, Young, discloses stimulating its electrode to obtain paresthesia and pain relief while using Medtronic's ITREL IPG. Ex. 1008 at 73-75 (see below for details).
1.a	percutaneously introducing an introducer having an introducer lumen extending between an introducer lumen proximal end opening and an introducer	Young teaches: "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 fluoscopic guidance until paresthesias could be induced in the distribution of the patient's pain by monopolar electrical stimulation…." Ex. 1008 at 73. Thus, Young discloses percutaneous introduction of a No. 14 needle, which acts as an introducer with a lumen with a distal opening for the electrode to be inserted, and a proximal opening for the electrode advanced out for paresthesia to be induced near the trigeminal nerve, i.e. stimulation

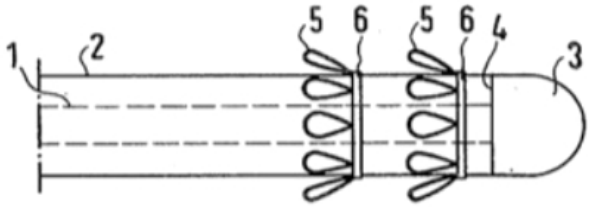
Cl.	Language	Prior Art Disclosure
	lumen distal end opening through body tissue to locate the introducer lumen distal end opening adjacent to the stimulation site; disposing an implantable medical lead within the introducer lumen, wherein the implantable medical lead comprises:	site. Paresthesia defines the stimulation site because it can only be achieved if the electrode is adjacent to the stimulation site, i.e. trigeminal nerve. Ex. 1003 ¶89. Gerber also teaches that "lead 10 is inserted by first making an incision" (Ex. 1010 at 5:34-35) and the use of cannula for delivery (5:16-17, 26-28). Percutaneous use of cannula as introducer were well known prior to 2001. Ex. 1003 ¶96.
1.b	a lead body extending between a lead proximal end and a lead distal end;	Young shows a Medtronic lead with a lead body with two ends. See Ex. 1008, Figs. 1 and 3. Leads also inherently have a body that extends between proximal end and a distal end. Young Fig. 1 (showing lead distal end):  Young Fig. 3 (annotated):

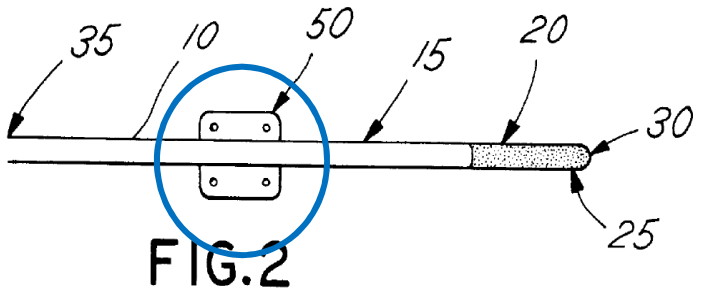
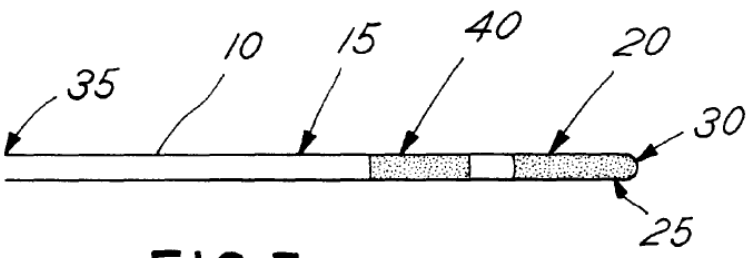
Cl.	Language	Prior Art Disclosure
		
1.c	P connector elements formed in a connector array along a first segment of the lead body proximate to the lead proximal end;	The '756 Patent describes "connector elements" as receiving conductor wires and "adapted to be coupled with a neurostimulator IPG …." Ex. 1001 at 9:27-31, 9:44-47. Young discloses at least one connector along the lead proximal end (shown in annotated Figure 3 above), because it teaches one electrode that connects to an IPG for stimulation. Ex. 1003 at 72 (claim 1.c). Young displays a connector array with 4 possible connections on the extension lead that ultimately connects to the IPG in Figure 3. Thus, Young suggests that 4 connector elements in an array along the lead body is possible. Gerber teaches that "[t]ypically, existing leads have four small discrete electrodes built into the distal end of the lead. During implantation, the physician steers the implantable pulse generator outputs to the electrodes to provide the most efficacious therapy." Ex. 1010 at 1:57-61; 3:48-50 ("The proximal end 35 of the lead body 15 may be coupled to a pulse generator"); *id.* at 4:65-5:8. Thus, in order to connect the electrodes at distal end to the IPG at the proximal end, Gerber inherently discloses up to four connectors proximate the lead proximal end, which is the first segment, between the IPG and electrodes. Ex. 1003 at 72 (claim 1.c).
1.d	P stimulation electrodes	Young discloses one electrode, but suggests multicontact electrodes or multiple active stimulation

Cl.	Language	Prior Art Disclosure
	arranged in an electrode array extending along a second segment of the lead body proximate to the lead distal end;	sites, which mean there will be multiple electrodes. Ex. 1008 at 77; Ex. 1003 ¶104. Gerber discloses "[t]ypically, existing leads have four small discrete electrodes built into the distal end of the lead." Ex. 1010 at 1:57-58; 2:4-5. Gerber teaches using two larger electrodes arranged in an array at the distal end, *i.e.* second segment. *Id.,* Abstract; Claim 1; 4:32-45 ("The length of the first and the second electrode contacts 20 and 40 extend longitudinally from the distal end 25 toward the proximal end 35. … The first electrode contact and the second electrode contact do not overlap."); 5:6-8; Fig. 3. Gerber Fig. 3:  FIG.3 Arranged linearly as part of the lead body in Figure 3, the electrodes are in an array that extend along the lead distal end, which is a second segment of the lead body. *See* Ex. 1010 at 4:36-45; 5:6-8.
1.e	P lead conductors extending between the P connector elements and the P stimulation electrodes;	Young discloses one conductor wire between the one electrode and a connector element for electrode to function and provide pain relief. Ex. 1008 at 74; Ex. 1003 ¶106. Gerber discloses that "[t]he lead body 15 of the present invention comprises one or more conductor wire(s) within an insulating sheath." Ex. 1010 at 4:6-7. It further teaches that "[t]he stimulation pulses produced

Cl.	Language	Prior Art Disclosure
		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.* 3:52-56. Thus, where there are multiple electrodes as disclosed by Gerber, there will be multiple conductors extending between the connector elements attached to pulse generators at proximal end and the electrodes at the distal end. Ex. 1003 at 73-74 (claim 1.3).
1.f	and a plurality of M tine elements formed in a tine element array extending along a third segment of the lead body between the second segment of the lead body and the lead proximal end,	The '756 Patent specification discusses "a plurality M of tine elements arrayed in a tine element array." Ex. 1001 at 5:57-58. Young discloses at least 2 tine elements formed in a tine element array extending along a third segment, which is located between the electrode, i.e. second segment, 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. 1008 at 73 (emphasis added). Young Fig. 1 is annotated below.  As discussed above, Gerber discloses multiple electrodes in the second segment.
1.g	each tine	Young discloses each tine element with 4 flexible tines

Cl.	Language	Prior Art Disclosure
	element comprising N flexible tines, each tine having a tine width and a tine thickness and extending through a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead body at a tine attachment site and supporting the tine extending outwardly of the lead body and toward the lead proximal end, whereby the MxN tines are adapted to be folded inward against the lead body when fitted into and constrained by the introducer lumen,	each with a width, thickness and length from an attached tine end and free end and attached tine end attached to the tine element and lead body (see Fig. 1 above). All 8 tines (2M x 4N) are adapted to fold inward against the lead body when constrained into the 14 Needle, i.e. introducer. Tines inherently fold inward against the lead body when fitted into and constrained by the introducer lumen. Ex. 1003 at 74-75 (claim 1.g). Young's tines extends outwardly from the lead body, but may not be proximally oriented. Lindegren, however, shows 4 tines attached to a structure similar to Young, but where the tines extend toward the proximal end. Ex. 1011 at 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. Ex. 1003 at 75.
1.h	wherein the plurality of M	Young's two sets of identical tine elements that are axially displaced from each other and also from the

Cl.	Language	Prior Art Disclosure
	tine elements are separate from and axially displaced from each other and from each of the P stimulation electrodes, and wherein all of the P stimulation electrodes are between the plurality of M tine elements and the lead distal end,	stimulation electrode. Young describes "two sets of four 'tines' located 5 and 10 mm from the distal tip of the electrode …." Ex. 1008 at 73, Fig. 1. If the two sets were connected, then the second tine element would be 5 mm in length, and so should the first tine element. However, the first tine element is located 5 mm from the distal tip, with 5 mm including the electrode. Consequently, each tine element must be less than 5 mm in length, which means the first tine element is separate from the second tine element. Ex. 1003 at 75-76 (claim 1.h). To the extent Young does not disclose separate tine elements, Akerstrom teaches arrangement of the same anchor twice but spaced apart. *See* Ex. 1012 at 2:56-59; Fig. 3.  FIG 3 Loops look like tines and a POSITA could arrange tines as shown in Akerstrom. Ex. 1003 at 76. Gerber does not expressly teach tine elements but suggests their use and location in describing "another anchoring mechanism 50 is to allow the medical lead 10 to fibrose in naturally using the human body's natural reaction to a foreign body or healing." Ex. 1010 at4:15-30; Fig. 2. Figure 2 shows an electrode located between the anchoring mechanism 50 and distal tip 30, just like in Young. As discussed for element 1.d and shown in Figure 3, Gerber also discloses plurality of electrodes at distal end. Skilled artisan would know that tines allow

Cl.	Language	Prior Art Disclosure
		for anchoring by fibrosis and would be obvious to locate tines at 50, *i.e.* between all electrodes and the lead distal end. Ex. 1003 at 76-77.  FIG.2  FIG.3
1.i	and wherein disposing the implantable medical lead within the introducer lumen comprises disposing the implantable medical lead within the introducer lumen with the MxN tines folded inward	See 1.a for disposing the implantable medical lead within the introducer lumen. See 1.g for tines folded inward against the lead body by constraint imposed of being in the introducer lumen. As can be seen in Figure 1 of Young above, 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. Ex. 1003 at 78 (claim 1.i).

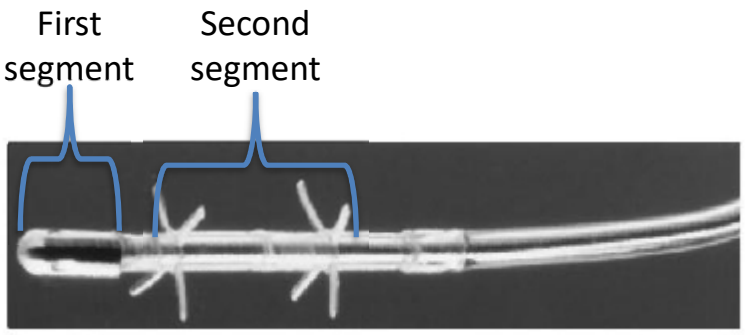
Cl.	Language	Prior Art Disclosure
	against the lead body by constraint imposed by the introducer lumen without overlapping one another;	
1.j	withdrawing the introducer proximally from the tine element array to successively release the N tines of each of the M tine elements to deploy outward and toward the lead proximal end to engage body tissue and inhibit axial dislodgement of the P stimulation electrodes;	Tines should not be deployed until the electrode placement is finalized because once deployed, they engage body tissue and can be damaged if the lead is moved within the body. Ex. 1003 ¶32. Young teaches the lead is "advanced under fluoroscopic guidance until paresthesias could be induced" and "[s]ubsequently, the introducing needle …[was] removed." Ex. 1008 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 proximally towards the lead proximal end by the physician to deploy the tines successively so the tines did not suffer damage and lose its intended function to prevent electrode migration. Ex. 1003 at 78-79. Tines inherently release when no longer constrained. *Id.*
1.k	and coupling the P connector elements to the implantable pulse	See claim 1.c for connector elements. Young further teaches that after the electrode tip is within millimeters of the stimulation site, "the proximal end of the electrode was tunneled subcutaneously … and connected to a percutaneous extension lead" and after trial stimulation was successful, "[t]he distal end of

Cl.	Language	Prior Art Disclosure
	generator.	the extension lead was connected to a lithium battery-powered completely implanted pulse generator system (ITREL, Medtronic, Inc., Minneapolis, MN) (Fig. 3)." Ex. 1008 at 73-74.
2.0	The method of claim 1, further comprising advancing the implantable medical lead from the introducer lumen distal end opening to dispose the P electrodes in operative relation to body tissue to be stimulated prior to withdrawing the introducer proximally.	See claim 1. Young teaches: "the electrode was inserted and advanced under fluoscopic guidance until paresthesias could be induced in the distribution of the patient's pain by monopolar electrical stimulation. … Subsequently, the introducing needle and central stylet were removed…." Removal occurs by withdrawing the introducer proximally towards the physician. Ex. 1003 at 79.
5.0	The method of claim 1, wherein percutaneously introducing the introducer precedes disposing the implantable medical lead within the introducer	See claim 1. See also claim 1.a for dependent element.

Cl.	Language	Prior Art Disclosure
	lumen.	
7.0	The method of claim 1, wherein the tine attachment sites are separated longitudinally along the lead body in the tine element array by a distance that is substantially equal to or exceeds the tine length when folded toward the lead proximal end against the lead body.	See claim 1. The '756 patent describes "tine attachment sites" as where the tine attaches to the tine element and lead body. Claim 1.g; §III.A. Thus, if the tine length is less than the distance between the attached tine ends, then this dependent element is met. As seen with element 1.i, Young and Akerstrom discloses tine length that is less than the distance between the attached tine ends. Fig. 1. Ex. 1003 at 80.
13	The method of claim 1, wherein at least one of the plurality of M tine elements comprises a biocompatible plastic.	See claim 1. The '756 Patent provides: "the tine elements 125, 130, 135 and 140 are formed of a bio-compatible plastic, e.g., medical grade silicone rubber or polyurethane." Ex. 1001, 10:65-67. Lindegren describes its ring-shaped means (i.e. tine element) "are preferably made of an elastic material such as silicone rubber" (Ex. 1011, 5:20-22). Akerstrom describes tines consisting of silicone rubber (Ex. 1012, 1:14-19), and tines are part of tine elements. Ex. 1003 at 81.
14.0	A method comprising:	To the extent this preamble is a limitation, the combination below discloses a method.

Cl.	Language	Prior Art Disclosure
14.a	percutaneously introducing an introducer comprising an introducer lumen extending between an introducer lumen proximal end opening and an introducer lumen distal end opening through body tissue to locate the introducer lumen distal end opening adjacent to a stimulation site; disposing an implantable medical lead within the introducer lumen, wherein the implantable medical lead comprises:	See claim 1.a since the language is identical except claim 1.a uses "having" and 14.1 uses "comprising." This difference is not material here. Ex. 1003 at 81.
14.b	a lead body extending between a lead	See claim 1.b.

Cl.	Language	Prior Art Disclosure
	proximal end and a lead distal end;	
14.c	a plurality of connector elements formed in a connector array adjacent the lead proximal end;	See claim 1.c. since the language is identical except claim 1.c uses "P connector elements" and 14.c uses "a plurality of connector elements." This difference is not material here. Ex. 1003 at 82.
14.d	a plurality of stimulation electrodes arranged in an electrode array extending along a first segment of the lead body proximate to the lead distal end;	See claim 1.d since the language is identical in substance. Claim 1.d recites "P stimulation electrodes" along a second segment, while this element cites "plurality of stimulation electrodes" along a first segment. Both require plural electrodes and the location of "second segment" and "first segment" is the same, i.e. "proximate to the lead distal end." Prior art described in claim 1.d is thus applicable here. Ex. 1003 at 82.
14.e	a plurality of lead conductors extending between the connector elements and the stimulation electrodes;	See claim 1.e. since the language is identical with only difference between claim 1 using "P" instead of "plurality" used in claim 14.e. This difference is not material here. Ex. 1003 at 83.
14.f	and a plurality of tine elements attached to the	See claim 1.h Gerber disclosure for location of plurality of electrodes, i.e. first segment, in relation to the anchoring mechanism 50, i.e. second segment of the body.

Cl.	Language	Prior Art Disclosure
	lead body along a second segment of the lead body between the first segment of the lead body and the lead proximal end,	Young discloses "two sets [i.e tine elements] of four 'tines'" attached to the lead body along a second segment between the electrode, i.e. first segment, and the lead proximal end. Ex. 1008 at 73; Fig. 1 (annotated)  Ex. 1003 at 83.
14.g	each tine element comprising a plurality of flexible tines that are adapted to be folded inward against the lead body when fitted into and constrained by the introducer lumen and adapted to deploy outward to engage body tissue when the introducer	See claims 1.g for "each tine element comprising a plurality of flexible tines that are adapted to be folded inward against the lead body when fitted into and constrained by the introducer lumen." See claim 1.i. for tines "adapted to deploy outward to engage body tissue when the introducer is withdrawn."

Cl.	Language	Prior Art Disclosure
	is withdrawn,	
14.h	wherein the plurality of tine elements are separate from and axially displaced from each of the stimulation electrodes, and wherein the plurality of stimulation electrodes is between the plurality of tine elements and the lead distal end; and	See claim 1.h since 1.h encompasses all the elements of 14.h and the difference between claim 1 using "M" and "P" instead of "plurality" used in claim 14.h is not material. Ex. 1003 at 84.
14.i	withdrawing the introducer toward the lead proximal end from the plurality of tine elements to release the plurality of tines.	See claim 1.j since 1.j encompasses all the elements of 14.i.
15	The method of claim 14, wherein each tine of each tine element has a tine length, and the	See claim 14. For dependent element, see claim 1.g for the element "wherein each tine … the lead body at tine attachment sites." See claim 7 dependent element for the remaining language of this claim since the language is identical.

Cl.	Language	Prior Art Disclosure
	tine elements are attached to the lead body at tine attachment sites, wherein the tine attachment sites are separated longitudinally along the lead body by a distance that is substantially equal to or exceeds the tine length when folded against the lead body.	
18	The method of claim 14, wherein at least one of the plurality of tines comprises a biocompatible plastic.	See claim 14. The '756 Patent provides that "bio-compatible plastic [comprise], e.g., medical grade silicone rubber or polyurethane." Ex. 1001, 10:65-67. Lindegren describes its one-piece ring-shaped means, which includes tines, are made of silicone rubber (Ex. 1011, 5:20-22). Akerstrom describes tines consisting of silicone rubber. Ex. 1012, 1:14-19.

B. Ground 2. Claims 1, 2, 5, 7, 13-15, and 18 are obvious over Gerber in view of Hauser and Akerstrom.

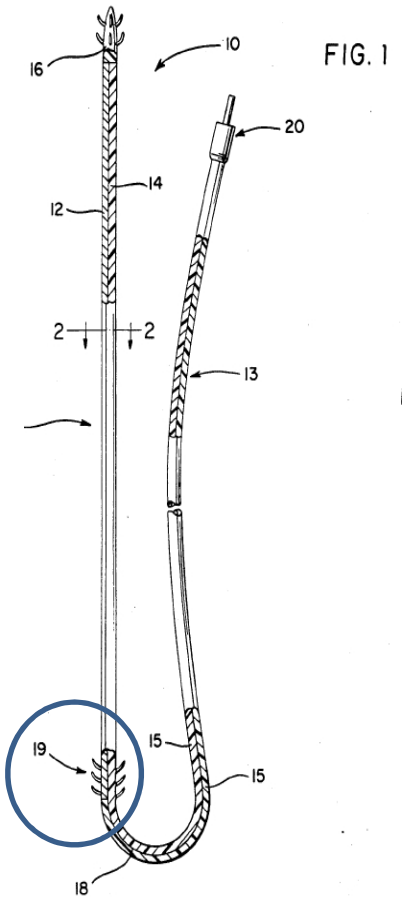
Claims 1, 2, 5, 7, 13-15, and 18 are obvious over Gerber in view of Hauser and Akerstrom. Gerber and Akerstrom have been described in §IV.A.2 and §IV.A.4 respectively.

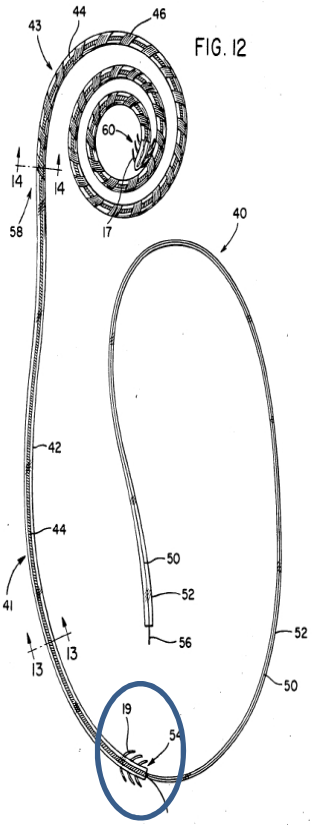
1. Hauser

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). Like the '765 Patent, Hauser discloses the problem of major surgeries for implantation of medical leads due in part for need of precise placement of the electrodes. Ex. 1013 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 uses the term "electrode" to mean both the lead and the conductive elements. Ex. 1013 at 3:48-49. It describes the distal end of the lead to have a spiral active region with a conductive element. Proximal to that region is a fixation means 19 (shown as 3 sets of tines) that anchors the lead at locations determined by the surgeon during implantation. *Id.* at 4:3-8; 4:21-25; Fig. 12. While Hauser does not identify to what structure the tines attach, it teaches "the fixation anchors

19 can be replaced by other anchoring means" and at any locations determined by the surgeon. *Id.,* 4:17-21, 4:21-25.[6]





[6] Hauser also discloses a distal fixation means 17, but that location is specific to cardiac leads that needs to snag the trabecula or atrial/ventricular walls. *See* Ex. 1013 at 3:67-4:1; Ex. 1003 ¶112 n.22. To stimulate the sacral nerve, a POSITA would know from the anatomy to avoid placing tines on the distal tip which can injure the sacral nerves. *Id*.

Hauser further teaches an implantation method where a "catheter 21, having a crosssection 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 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." Ex. 1013 at 4:32-4:55; 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 ¶113. Tines will remain constrained in the catheter until the catheter is withdrawn. *Id.*

2. Applying Gerber, Hauser and Akerstrom

A POSITA would have been motivated to combine Gerber, Hauser and Akerstrom for several reasons. First, as discussed above, like the '756 Patent, Hauser seeks to solve the same problem of open surgery and lead placement and is also from the same field of implantable leads with stimulation electrode(s) and an anchoring mechanism. Thus, a POSITA would have been motivated to combine these references. *Tokai*, 632 F.3d at 1371.

Second, Gerber provides a motivation to combine. Gerber teaches that its anchoring means can be by fibrosis and discloses a wide and multiple areas for strong fixation with sutures by a suture sleeve with 4 holes. Ex. 1010, Fig. 2. Thus, a POSITA would have considered tines, a leading candidate among the limited number of devices that anchor by fibrosis. Ex. 1003 ¶115. Hauser's 3 sets of proximal tined anchor is spaced much further proximally from the electrode region. While Akerstrom discloses various arrangements of loops that anchors by fibrosis, those arrangements could be used for tines. *Id.* ¶116. 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. Thus, it would have been obvious to a POSITA in order to improve anchoring within the soft tissue near the sacrum to use multiples of tines mounted on collars (i.e. tine elements) to affix by fibrosis. A POSITA would have positioned the tine elements in a region proximal to the most proximal electrode, as shown and described in Gerber. *Id.*

Not only is there a motivation to combine, but doing so would have been highly feasible. *Id.* ¶¶107, 115, 117. 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. Hauser provides a series of tines that overlap however Akerstrom's collar design (Fig. 3) is easily reproducible to allow for any spacing between the sets of tines as required by the anatomy and desired by physicians, like Hauser teaches to apply known fixation means in locations according to surgeon's desires. Accordingly, it would have been easy to replace Gerber's anchoring mechanism with Hauser's tines arranged in Akerstrom's array design. Such modifications of Gerber would have been simply rearrangement of old elements with each performing the same function it had been known to perform and yielding predictable results and would have been obvious. *KSR*, 550 U.S. at 417.

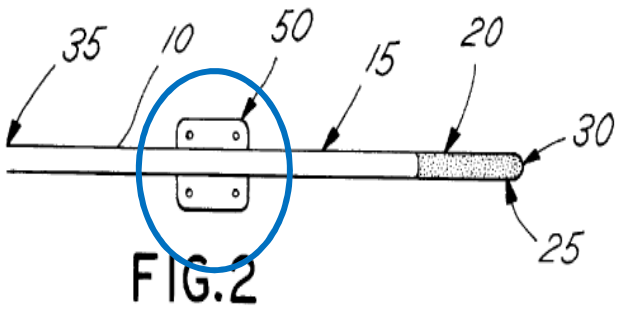
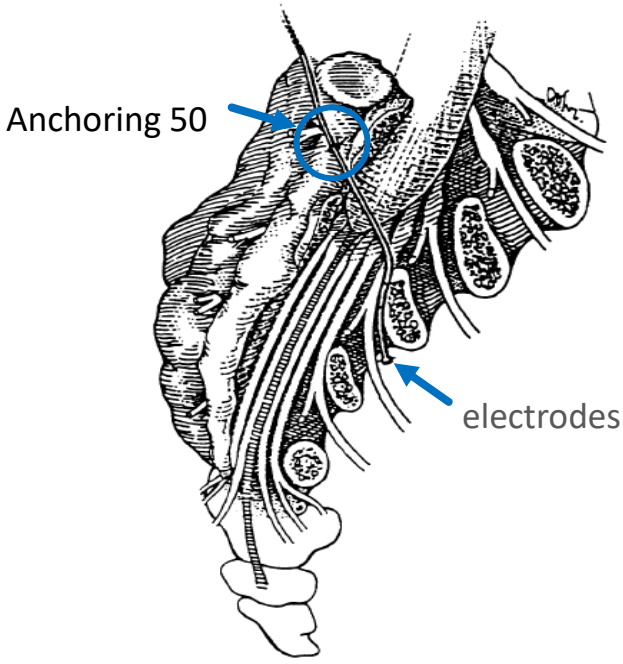
a. Invalidity Chart for Ground 2 Combination

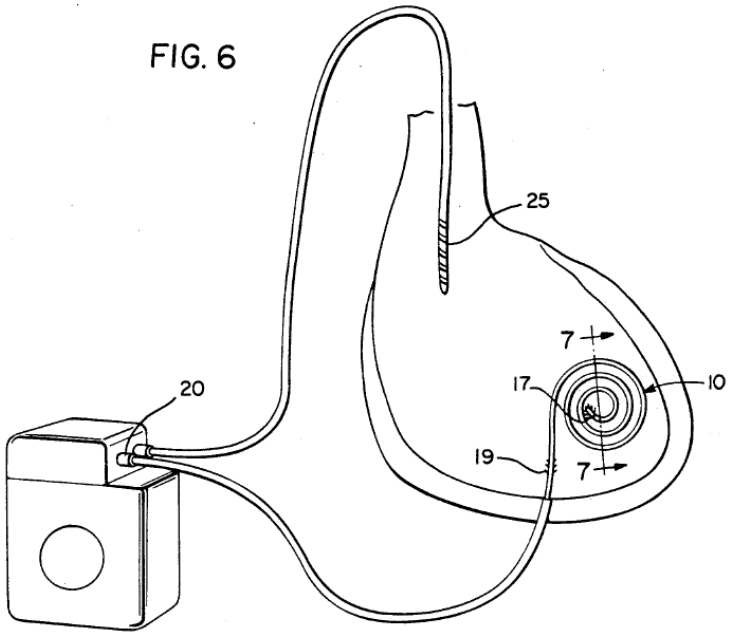
The combination of Gerber, Hauser and Akerstrom teaches every limitation of claims 1, 2, 5, 7, 13-15, and 18, as set forth in the following charts.

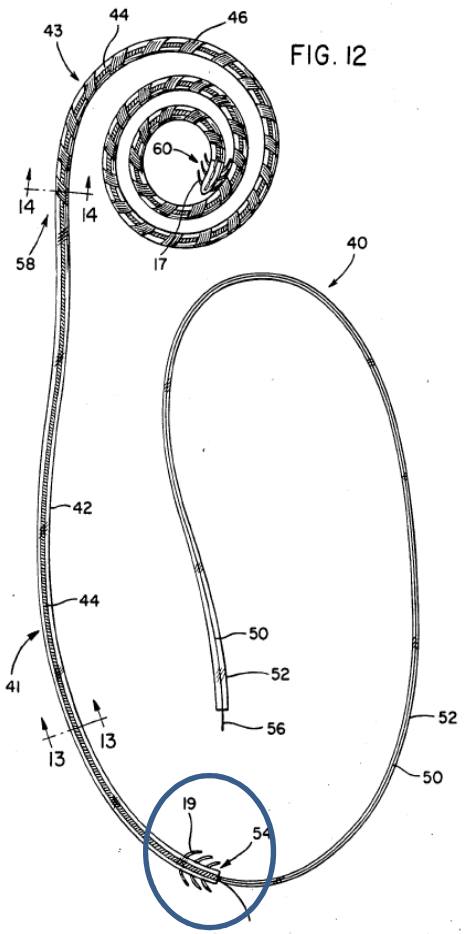
Cl.	Language	Prior Art Disclosure
1.0	1. A method of providing electrical stimulation of body tissue at a stimulation site employing an implantable pulse generator, the method comprising:	To the extent this preamble is a limitation, Gerber discloses stimulating its electrode near sacral nerve with pulses produced by the pulse generator such as Medtronic InterStim Neurostimulator Model 3023. Ex. 1010 at Abstract; 2:31-36; 3:48-56.

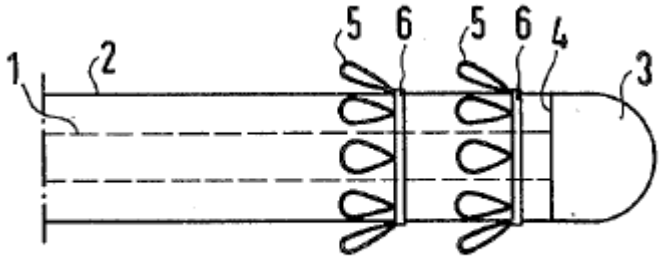
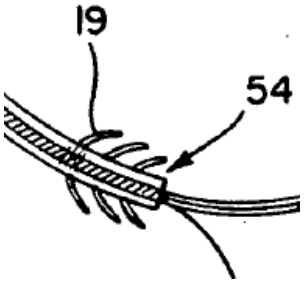
Cl.	Language	Prior Art Disclosure
1.a	percutaneously introducing an introducer having an introducer lumen extending between an introducer lumen proximal end opening and an introducer lumen distal end opening through body tissue to locate the introducer lumen distal end opening adjacent to the stimulation site; disposing an implantable medical lead within the introducer lumen, wherein the implantable medical lead comprises:	Gerber also teaches that "lead 10 is inserted by first making an incision" (Ex. 1010 at 5:34-37) and the use of cannula (*id.* at 5:16-17, 5:26-28). Percutaneous use of cannula as introducer were well known prior to 2001. Ex. 1003 ¶96; *id.* at 86. Hauser discloses a catheter, i.e. introducer, that "ha[s] a cross section only slightly larger than the cross section of the electrode 10, *first* is introduced through the skin [i.e. percutaneously] and into the pericardial space; *the electrode 10 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. 1013 at 4:32-43 (emphasis added). The catheter inherently has a proximal and distal ends. The distal end adjacent to the stimulation site—heart. *Id.* at 86.
1.b	a lead body extending between a lead proximal end and a lead 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 …." Ex. 1010 at Abstract (emphasis added).
1.c	P connector elements formed	See claim 1.c in §IV.A.5.a for Gerber disclosure.

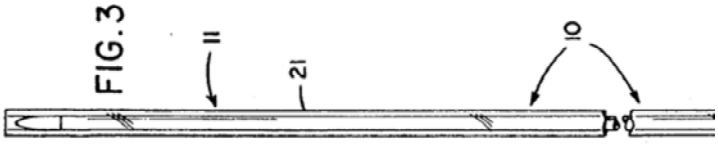
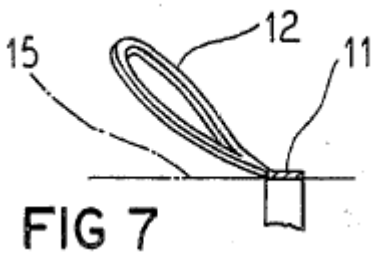
Cl.	Language	Prior Art Disclosure
	in a connector array along a first segment of the lead body proximate to the lead proximal end;	
1.d	P stimulation electrodes arranged in an electrode array extending along a second segment of the lead body proximate to the lead distal end;	See claim 1.c in §IV.A.5.a for Gerber disclosure.
1.e	P lead conductors extending between the P connector elements and the P stimulation electrodes;	See claim 1.e in §IV.A.5.a for Gerber disclosure.
1.f	and a plurality of M tine elements formed in a tine element array extending along a third segment of the lead body between the second segment of the lead body and the lead proximal end,	The '756 Patent specification discusses "a plurality M of tine elements arrayed in a tine element array." Ex. 1001 5:57-58. While Gerber does not teach tine elements, it does describe anchoring mechanisms that allows medical lead to fibrose naturally at location 50 between the second segment, i.e. electrode location, and proximal end of lead body. Ex. 1010, 4:13-30; Figs. 2 and 6 (annotated).

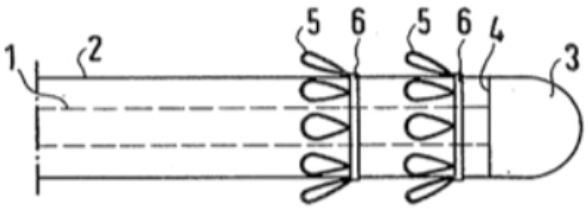
Cl.	Language	Prior Art Disclosure
		 FIG.2  FIG.6 Thus, Gerber teaches that mechanism 50 can anchor via fibrosis in the location between electrode and the lead proximal end. Skilled artisan would turn to tines to affix by fibrosis. Ex. 1003 at 89-90. Hauser discloses 3 sets of tine elements 19, extending from the lead body and proximal to the electrode region [i.e. second segment] and lead proximal end. Ex. 1013, 4:1-4:25 ("a proximal fixation means 19 is

Cl.	Language	Prior Art Disclosure
		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. Other fixation means are within the spirit and scope of this invention. … The proximal anchoring means also can be placed at locations other than as specifically illustrated, and the precise placement of the anchor even can be determined by the surgeon during implantation."); Figs. 6, 12. 

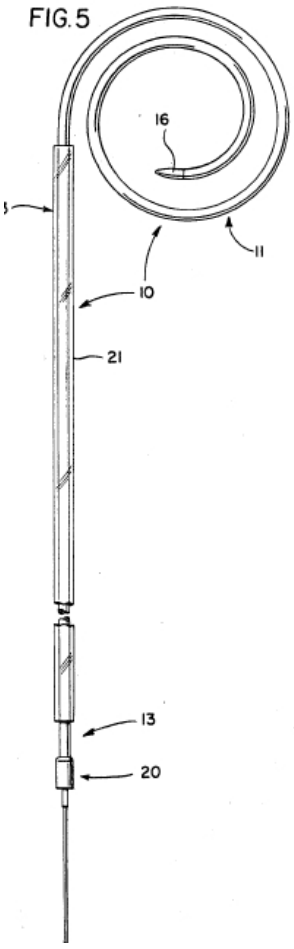
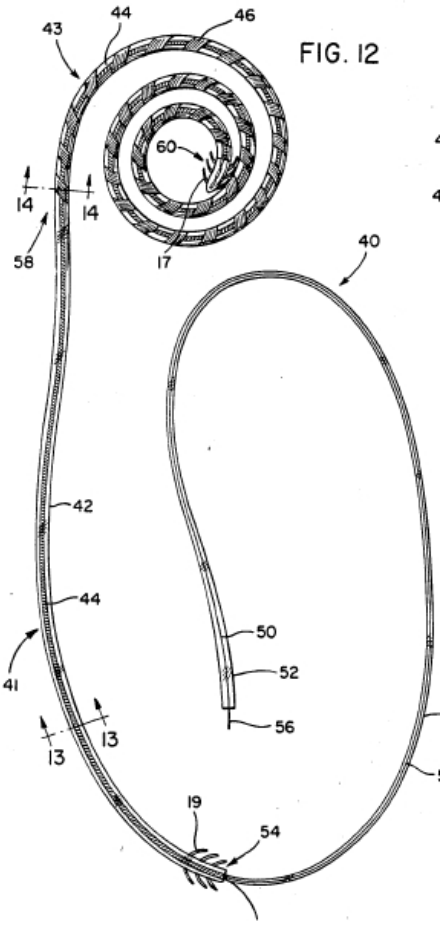
Cl.	Language	Prior Art Disclosure
		 Hauser teaches that the proximal tines 19 can be placed at other locations on the lead as determined by the surgeon. Skilled artisan would understand to place tine elements proximal for sacral lead implantation where there are soft tissues near the sacrum. Ex. 1003 at 90-92. To the extent Hauser's disclosure is not considered express disclosure of tine element array, Akerstrom teaches various arrangements, but in particular Figure 3 disclosing loops 5 mounted on collars 6 in an array: • "several collars 6, which are provided with loops 5, are slipped on the insulation 2 of the

Cl.	Language	Prior Art Disclosure
		conductor 1, which collars are spaced apart from one another" (Ex. 1012, 2:56-59; Fig. 3).  FIG 3 Though Akerstrom teach the use of loops, skilled artisan would consider loops a variation of tines. Ex. 1003 ¶116. Thus, instead of loops, tines can be as easily attached to collars and arranged in an array as taught by Akerstrom and mounted on Gerber's lead for percutaneous delivery. *Id.* at 92-94.
1.g	each tine element comprising N flexible tines, each tine having a tine width and a tine thickness and extending through a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead body at a tine attachment site and supporting the tine	3 tine element from Figure 12 of Hauser (shown below), each include at least 2 tines, each having a tine width and thickness, and extending from an attached end to a free end, the attached end attached to the lead body and support the tine extend outwardly from the lead body in a proximal direction. Ex. 1003 at 94. Ex. 1012, Fig. 12 Excerpt:  The fixation means 19 includes flexible tines such

Cl.	Language	Prior Art Disclosure
	extending outwardly of the lead body and toward the lead proximal end, whereby the MxN tines are adapted to be folded inward against the lead body when fitted into and constrained by the introducer lumen,	that placement of the lead constrained within a catheter 21, i.e. introducer, would fold all of the tines of both tine elements inward against the lead body. *Id.* See Ex. 1012, Fig. 3 Excerpt:  To the extent Hauser does not disclose a tine end directly attached to the lead body, Akerstrom discloses flexible, pliant loops that extend outwardly from both the lead body and tine element in a proximal direction. Ex. 1013 at 93-94; Fig. 7 (shown below).  FIG 7 Skilled artisan would consider loops 12 a variation of tines and tines can be as easily and similarly be attached to collar 11 and lead body 15 as shown in Akerstrom Fig. 7, which is a sectional view of Fig. 3 (Ex. 1013, 2:26-28). Ex. 1003 at 94-95.
1.h	wherein the plurality of M tine elements are separate from and axially displaced from each other and	Hauser discloses 3 tine elements separate from and axially displaced from the stimulation electrodes, and apparently from each other, as show in Figures 1 and 12 above. To the extent Hauser does not disclose tine elements separate form and axially displaced from each other,

Cl.	Language	Prior Art Disclosure
	from each of the P stimulation electrodes, and wherein all of the P stimulation electrodes are between the plurality of M tine elements and the lead distal end,	Akerstrom teaches this element with an arangement that can be easily adapated to tine elements. Ex. 1013 at 2:56-59 ("In the electrode of FIG. 3, 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*.") (emphasis added); Fig. 3. Ex. 1003 at 95-96.  FIG 3 As discussed above in §IV.A.5.a claim 1.h, Gerber discloses that the electrodes are between the anchoring mechanism 50 (e.g. fibrosis inducing tine elements) and the lead distal end.
1.i	and wherein disposing the implantable medical lead within the introducer lumen comprises disposing the implantable medical lead within the introducer lumen with the MxN tines folded inward against the lead body by constraint	See 1.a for disposing the implantable medical lead within the introducer lumen. See 1.g for tines folded inward against the lead body by constraint imposed of being in the introducer lumen. While Hauser does not disclose tines that do not overlap one another, Akerstrom's arrangement in Figure 3 discloses the length of the loops being shorter than the distance between the two sets, i.e. two tine elements. Thus, skilled artisan could have used Akerstrom's arrangement for tine elements such with no overlapping tines. Ex. 1003 at 96.

Cl.	Language	Prior Art Disclosure
	imposed by the introducer lumen without overlapping one another;	
1.j	withdrawing the introducer proximally from the tine element array to successively release the N tines of each of the M tine elements to deploy outward and toward the lead proximal end to engage body tissue and inhibit axial dislodgement of the P stimulation electrodes;	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. 1013 at 4:49-52. Hauser further teaches that its proximal tine elements 19 "anchors the electrode 10 at the location of entrance into the pericardial space," *i.e.* engages body tissue to inhibit axial dislodgment. *Id.* 4:3-8. Thus, Hauser discloses that deployment continues until the active electrode region is at the stimulation site, as shown in Figure 5. Ex. 1003 at 96-97. 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 ¶113; *id.* at 96. It is inherent that tines adapted to engage body tissue would successively deploy when no longer constrained by the catheter lumen upon withdrawal of the catheter. *Id.* at 96.

Cl.	Language	Prior Art Disclosure
		 
1.k	and coupling the P connector elements to the implantable pulse generator.	See claim 1.c for connector elements. Gerber further teaches that "[t]he stimulation pulses produced by the pulse generator are carried from the pulse generator … toward the distal end 25 having at least one electrode contact 20." Ex. 1010 at 3:52-56. Thus, Gerber teaches coupling of the connector element to the pulse generator. Ex. 1003 at 97-98. Hauser also teaches that IPG is connected to the lead inherently at the connector elements. Ex. 1003 at 97.
2.0	The method of claim 1, further	See claim 1.

Cl.	Language	Prior Art Disclosure
	comprising advancing the implantable medical lead from the introducer lumen distal end opening to dispose the P electrodes in operative relation to body tissue to be stimulated prior to withdrawing the introducer proximally.	Hauser discloses "[w]ith the catheter 21 [i.e. introducer] containing the electrode 10 …, *the active region 11 of electrode 10 is urged out of the catheter* with the aid of the stylet 22. The active region 11 then emerges from the catheter 21, with the stylet 22 being withdrawn as appropriate…. 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. 1013, 4:32-55 (emphasis added). Thus, Hauser teaches the electrode is advanced through the catheter and urged out at distal end opening near the heart, i.e. body tissue to be stimulated and then afterwards the catheter is removed. Ex. 1003 at 98.
5.0	The method of claim 1, wherein percutaneously introducing the introducer precedes disposing the implantable medical lead within the introducer lumen.	See claim 1. See claim 1.a for dependent element.
7.0	The method of claim 1, wherein the tine attachment sites are separated longitudinally along the lead body in the tine element array by	See claim 1. The '756 patent describes "tine attachment sites" as where the tine attaches to the tine element and lead body. Claim 1.g; §III.A. Thus, if the tine length is less than the distance between the attached tine ends, then this dependent element is met. Ex. 1003 at 98. As seen with element 1.i, Akerstrom discloses loop length that is less than the distance between the

Cl.	Language	Prior Art Disclosure
	a distance that is substantially equal to or exceeds the tine length when folded toward the lead proximal end against the lead body.	attached ends at collar 6. Thus, skilled artisan could have used Akerstrom's arrangement in Figure 3 with tines instead of loops, and then the tine attachment sites would be separated longitudinally by a distance that exceeds the tine length when folded against lead body. Ex. 1003 at 99.
13	13. The method of claim 1, wherein at least one of the plurality of M tine elements comprises a biocompatible plastic.	See claim 1. The '756 Patent provides: "the tine elements … are formed of a bio-compatible plastic, e.g., medical grade silicone rubber or polyurethane." Ex. 1001, 10:65-67. Akerstrom discloses tines, which are necessary parts of tine elements, consisting of silicone rubber. Ex. 1003 at 99.
14.0	14. A method comprising:	To the extent this preamble is a limitation, Gerber in view of Hauser and Akerstrom disclose this method.
14.a	percutaneously introducing an introducer comprising an introducer lumen extending between an introducer lumen proximal end opening and an introducer lumen distal end opening through body tissue to	See claim 1.a since the language is identical except claim 1.a uses "having" and 14.1 uses "comprising." This difference is not material here. Ex. 1003 at 99-100.

Cl.	Language	Prior Art Disclosure
	locate the introducer lumen distal end opening adjacent to a stimulation site; disposing an implantable medical lead within the introducer lumen, wherein the implantable medical lead comprises:	
14.b	a lead body extending between a lead proximal end and a lead distal end;	See claim 1.b.
14.c	a plurality of connector elements formed in a connector array adjacent the lead proximal end;	See claim 1.c. since the language is identical except claim 1.c uses "P connector elements" and 14.c uses "a plurality of connector elements." This difference is not material here. Ex. 1003 at 101.
14.d	a plurality of stimulation electrodes arranged in an electrode array extending along a first segment of the lead body proximate to the	See claim 1.d since the language is identical in substance. Claim 1.d recites "P stimulation electrodes" along a second segment, while this element cites "plurality of stimulation electrodes" along a first segment. Both require plural electrodes and the location of "second segment" and "first segment" is the same, i.e. "proximate to the lead distal end." Prior art described in claim 1.d is thus applicable here. Ex. 1003 at 101.

Cl.	Language	Prior Art Disclosure
	lead distal end;	
14.e	a plurality of lead conductors extending between the connector elements and the stimulation electrodes;	See claim 1.e. since the language is identical except for claim 1 using "P" instead of "pluarality" used in claim 14.e. This difference is not material here. Ex. 1003 at 101.
14.f	and a plurality of tine elements attached to the lead body along a second segment of the lead body between the first segment of the lead body and the lead proximal end,	See claim 1.f for plurality of tine elements. See claim 1.g for Akerstrom disclosing arrangement whereby tine elements can be attached to the lead body. Hauser also discloses tine elements 19 that is attached to the lead body proximal to the electrodes. See Fig. 12. See §IV.A.5.a claim 1.h for Gerber teaching the location of the anchoring mechanism between the electrodes, i.e. first segment, and the lead proximal end.
14.g	each tine element comprising a plurality of flexible tines that are adapted to be folded inward against the lead body when fitted into and constrained by the introducer lumen and adapted to deploy outward	See claims 1.g for "each tine element comprising a plurality of flexible tines that are adapted to be folded inward against the lead body when fitted into and constrained by the introducer lumen." See claim 1.i. for tines "adapted to deploy outward to engage body tissue when the introducer is withdrawn."

Cl.	Language	Prior Art Disclosure
	to engage body tissue when the introducer is withdrawn,	
14.h	wherein the plurality of tine elements are separate from and axially displaced from each of the stimulation electrodes, and wherein the plurality of stimulation electrodes is between the plurality of tine elements and the lead distal end; and	See claim 1.h. since 1.h encompasses all the elements of 14.h and the difference between claim 1 using "M" and "P" instead of "plurality" used in claim 14.h is not material. Ex. 1003 at 102.
14.i	withdrawing the introducer toward the lead proximal end from the plurality of tine elements to release the plurality of tines.	See claim 1.j since 1.j encompasses all the elements of 14.i.
15	The method of claim 14, wherein each tine of each tine element has a	See claim 14. For dependent element, see claim 1.g for the element "wherein each tine … are attached to the lead body at tine attachment sites." See claim 7 dependent

Cl.	Language	Prior Art Disclosure
	tine length, and the tine elements are attached to the lead body at tine attachment sites, wherein the tine attachment sites are separated longitudinally along the lead body by a distance that is substantially equal to or exceeds the tine length when folded against the lead body.	element for the remaining language of this claim since the language is identical.
18	The method of claim 14, wherein at least one of the plurality of tines comprises a biocompatible plastic.	See claim 14. The '756 Patent provides: "the tine elements … are formed of a bio-compatible plastic, e.g., medical grade silicone rubber or polyurethane." Ex. 1001, 10:65-67. For dependent element, Akerstrom discloses tines consisting of silicone rubber. Ex. 1012, 1:16-20.

C. 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 '756 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 '756 Patent is available for IPR and Axonics is not barred or estopped from requesting an IPR of the challenged. This petition is timely filed within one year of the service of Medtronic's complaint alleging infringement of the '756 Patent. Ex. 1014.

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 '756 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 '756 Patent is related to U.S. Patent No. 8,626,314, against which Axonics is filing a separate petition for IPR concurrently with this Petition.

3. Fees

This Petition requests review of eight (8) claims of the '756 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 '756 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 13,841 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. 8,036,756, including its supporting Exhibits (1001-1014) 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. 8,036,756:

Medtronic, Inc. (CVG)
8200 Coral Sea Street NE
MS: MVC22
Minneapolis, MN 55112

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