UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.
Petitioner

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP.
Patent Owner

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,891,085

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Petitioner Nevro Corp. requests *inter partes* review of claims 1-19 of U.S. Patent No. 7,891,085[1] (Ex. 1001), which is assigned to Boston Scientific Neuromodulation Corporation ("BSNC").

I. Introduction

The sole independent claim of the '085 patent is directed to making an implantable lead that provides electrical stimulation therapy. In its most basic form, the lead body described in the '085 patent has an electrode array at a distal end, and a plurality of corresponding conductive contacts at a proximal end. The distal-end electrodes stimulate the area where the lead is implanted, and the contacts at the proximal end are typically coupled to an implantable pulse generator. As applied herein, BSNC interprets this claim in the co-pending district court litigation to require a plurality of conductive wires that run the length of the lead body to couple the proximal end contacts to their corresponding distal end electrodes. The conductive wires run inside conductor lumens, which are hollow bores within the insulated lead body. Insulating spacers are disposed between individual adjacent distal-end electrodes and individual proximal-end contacts.

[1] The '085 patent issued on February 11, 2011 and was thus filed well-prior to the enactment of the America Invents Act ("AIA"). Accordingly this petition applies the pre-AIA versions of 35 U.S.C. §§ 102, 103, 112.

This basic and well-known structure is laid out in the first four steps of independent claim 1 of the ’085 patent:

> 1. A method of manufacturing a stimulation lead having a proximal end and a distal end, comprising:
>
> [a] providing a plurality of conductive contacts located at an end of a lead body of the stimulation lead;
>
> [b] disposing a plurality of conductor wires in a plurality of conductor lumens formed in the lead body;
>
> [c] connecting at least one of the plurality of conductor wires to each of the conductive contacts;
>
> [d] placing spacers between pairs of adjacent conductive contacts, wherein portions of the conductor lumens are located beneath the plurality of conductive contacts and the spacers. Ex. 1001, 8:10-22.

The last two steps of the ’085 patent, focus very narrowly on filling, at least partially, an empty portion of a conductor lumen. The specific steps in the ’085 patent include inserting monofilament into at least a portion of the lumen, and then heating the spacers and the monofilaments so that at least one melts or thermally reflows into the empty space of a conductor lumen. The last two steps are reproduced below:

> [e] inserting monofilament into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by the conductor wires; and
>
> [f] reflowing at least one of the spacers or monofilament into at least one portion of at least one of the conductor lumens not occupied by

> the conductive wires by heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament. Ex. 1001, 8:23-32.

* * *

By January 11, 2005 (the earliest priority date for the ’085 patent), the field of implantable leads for providing electrical stimulation to a body was already mature. Ex. 1003, ¶¶1-37. Many prior-art implantable leads at that time had the exact same basic structure as claim 1 of the ’085 patent. This is readily seen in the Stolz reference. *See e.g.*, Ex. 1005, Stolz, FIGs. 4-5. Moreover, the benefits of filling empty portions of a conductor lumen in an implantable lead were also well-known in the prior art. Indeed, Stolz itself heats and reflows thermoplastic material from its distal tip into the empty portions of its conductor lumens. Ex. 1005, [0035], [0036], [0046]. The Ormsby reference teaches why it is beneficial to fill empty conductor lumens, *see e.g.*, Ex. 1006, Ormsby, 7:3-10, while the Black reference teaches the specific technique of reflowing a spacer into the empty spaces of a conductor lumen, Ex. 1008, 7:13-24.

Nevro will thus prove in the petition below that the BSNC’s purported invention in the ’085 patent is nothing more than an incremental and obvious modification to well-known prior art leads, and lead manufacturing techniques, available by January 2005.

II. Statement of Unpatentability Grounds for Claims 1-19 of the ’085 Patent

Nevro requests *inter partes* review of claims 1-19 of the ’085 patent and a determination that those claims are unpatentable based on the following grounds:

Ground	Prior Art	Basis	Claims Challenged
1	Stolz, Ormsby, Black, and knowledge of POSA	§ 103	1-3, 6-12, and 14-17
2	Stolz, Ormbsy, Black, knowledge of POSA, and further in view of the Modern Plastics Encyclopedia	§ 103	4, 5, and 13 (time and temperature parameters for reflowing thermoplastic material)
3	Stolz, Ormbsy, Black, knowledge of POSA, and further in view of Wessman	§ 103	18 (use of heat shrink tubing)
4	Stolz, Ormbsy, Black, knowledge of POSA, Wessman, and further in view of Saab	§ 103	19 (heat shrink tubing made of PTFE)

The earliest priority date on the face of the ’085 patent is January 11, 2005. The prior art references cited for each ground above qualify as prior art to the ’085 patent under 35 U.S.C. § 102(b) for the following reasons:

- Stolz (Ex. 1005): U.S. Patent Publication No. 2003/0199950 to Stolz *et al.* qualifies as a prior art under 35 U.S.C. § 102(b) at least because its publication date is October 23, 2003, which is more than one year before January 11, 2005.
- Ormsby (Ex. 1006): WO 00/35349 to Ormsby *et al*. and qualifies as a prior art under 35 U.S.C. § 102(b) at least because its international publication date is June 22, 2000, which is more than one year before January 11, 2005.

- Black (Ex. 1008): U.S. Patent No. 6,216,045 to Black *et al*. qualifies as a prior art patent under 35 U.S.C. § 102(b) at least because it issued on April 10, 2001, which is more than one year before January 11, 2005.
- Wessman (Ex. 1009): U.S. Patent App. Pub. No. 2002/0143377 to Wessman *et al.* qualifies as prior art under 35 U.S.C. § 102(b) at least because its publication date is October 3, 2002, which is more than one year before January 11, 2005.
- Modern Plastics Encyclopedia (Ex. 1010): Modern Plastics Encyclopedia, 1986-1987, published by McGraw-Hill, Inc. in October 1986 qualifies as a prior-art printed publication under 35 U.S.C. § 102(b) because it was publically available to interested persons for more than one year before January 11, 2005.
- Saab (Ex. 1011): Using Thin-Wall Heat-Shrink Tubing in Medical Device Manufacturing, Medical Device & Diagnostic Industry Magazine (April 1, 1999), (available at https://www.mddionline.com/using-thin-wall-heat-shrink-tubing-medical-device-manufacturing) qualifies as a prior-art printed publication under 35 U.S.C. § 102(b) because it was publically available to interested persons for more than one year before January 11, 2005.

Nevro also relies on the expert opinions of Michael Plishka (Ex. 1003) to prove that the challenged claims would have been obvious to a person of ordinary skill in the art by January 2005. Mr. Plishka's qualifications are listed in his CV (Ex. 1004).

III. Level of Ordinary Skill in the Art

Patent claims must be analyzed from the perspective of a person of ordinary skill in the art (a "POSA") at the time the claimed invention was allegedly invented by the patentee. On the face of the '085 patent, this appears to be the time period shortly before January 11, 2005.

Further, in ascertaining the appropriate level of ordinary skill in the art of a patent, several factors should be considered including (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the educational level of active workers in the field of the patent. Moreover, a POSA is a person who is presumed to be aware of the pertinent art, thinks along the line of conventional wisdom in the art, and is a person of ordinary creativity.

In view of these factors, a POSA with respect to the '085 patent disclosure would have had general knowledge of implantable medical devices and various related technologies as of January 11, 2005. Further, a POSA would have had (1) at least a bachelor's degree in a relevant life sciences field, mechanical engineering, electrical engineering, biomedical engineering, or equivalent coursework, and (2) at least one year of experience researching or developing implantable medical devices, and/or methods of their manufacture. *See*, Ex. 1003, ¶¶21-24.

IV. Claim Construction

In considering the scope and meaning of the claims of an unexpired patent (such as the ’085 patent) in an *inter partes* review, the claim terms are to be given their broadest reasonable interpretation as understood by a POSA in light of the specification. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144-46 (2016); 37 C.F.R. § 42.100(b). Under this standard, absent any special definitions, claim terms or phrases are given their ordinary and customary meaning, as would be understood by a POSA in the context of the entire specification. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In this petition, Nevro challenges the claims of the ’085 patent under their broadest reasonable interpretations. The patentee did not use any unusual claim terms. Nor do any claim terms appear to be used outside their ordinary and customary meaning, as understood by a POSA and in view of the ’085 patent specification, under the broadest reasonable interpretation. The patentee did not provide a glossary, and the patentee does not appear to have acted as its own lexicographer for any term. The only term that the patentee appears to have expressly construed in the ’085 patent specification is the term “lead.” And there, the term is broadly construed as “an elongate device having any conductor or conductors, covered with an insulated sheath and having at least one electrode contact attached to the elongate device, usually at the distal portion of the elongate device." Ex. 1001, 1:31-35.

If the patent owner BSNC asserts that any other term specifically requires construction for this proceeding, Nevro reserves the right to challenge such construction, if necessary. And if the Board believes, after reviewing the patent owner's preliminary response, that any claim term requires additional briefing, Nevro is willing to provide supplemental briefing. Petitioner Nevro also reserves the right to challenge in a different forum, such as in a U.S. District Court, that a claim of the '085 patent is indefinite or has a claim scope that differs from its broadest reasonable interpretation.[2]

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[2] Specifically, the '085 patent is part of BSNC's suit against Nevro. *See* Mandatory Notices, Section XII.B. *infra*. In that case the parties are currently engaged in claim construction. *See* Final Joint Claim Chart filed September 14, 2017, *Boston Scientific Corporation et al. v. Nevro Corp.*, Case No. 1:16-cv-01163 (D.E.D.); Revised Final Joint Claim Chart filed October 6, 2017 in the same case; *see also* Nevro Corp.'s Opening Claim Construction Brief, filed on October 13, 2017 in the same case.

V. Summary of the Unpatentability Argument for Independent Claim 1.

Independent claim 1 is unpatentable under 35 U.S.C. § 103 over Stolz, Ormsby, Black, and the knowledge of a POSA. Nevro first provides a summary of its unpatentability position for independent claim 1. This summary explains the motivation to combine the key references. It also serves as an overview of substantive positions that are explained in detail in each of the four grounds below in Sections VI-IX.

Stolz (Ex. 1005) is the base reference. It discloses a stimulation lead having the same structure set forth in claim 1. Stolz is only missing the steps of (1) "*inserting monofilament*" into at least a portion of a conductor lumen that is unoccupied by the conductor wires, and (2) then heating the monofilament and the spacers to reflow material from either a monofilament or a spacer into those unoccupied spaces of the conductor lumen. Ormsby (Ex. 1006) provides the motivation to modify Stolz to fill the unoccupied portions of the conductor lumens. Black (Ex. 1008), which was considered during prosecution of the application which led to the '085 patent, teaches the technique of heating the spacers between the electrodes to reflow material into the void spaces of a conductor lumen—a teaching the Examiner did not appreciate at the time.

A. Overview of the ’085 patent

The ’085 patent is generally directed to the lead portion of an implantable system with a microstimulator 12 and a stimulation lead 18 having multiple electrodes 17 at a distal end of the lead. Figure 1 is illustrative and shows an array 18 of electrodes 17 at the distal end of lead 16:

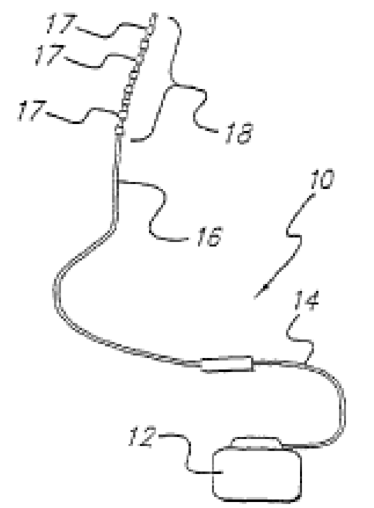
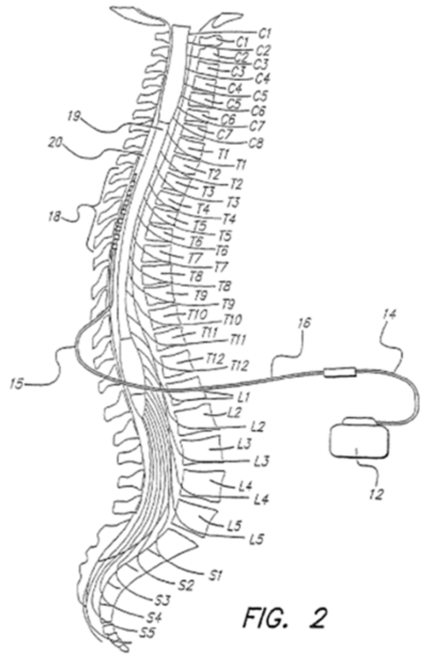


FIG. 1

Ex. 1001, FIG. 1; 3:42–53, 4:6–16.

The microstimulator 12 and stimulation lead 16 are typically implanted in a body. *Id.*, 4:6–16. In one embodiment, it provides stimulation to a spine. *Id.*



Ex. 1001, FIG. 2.

Figures 3A and 5A and 5B from the ’085 patent, annotated below in color, show the basic structure of an implantable lead made by the claimed method:

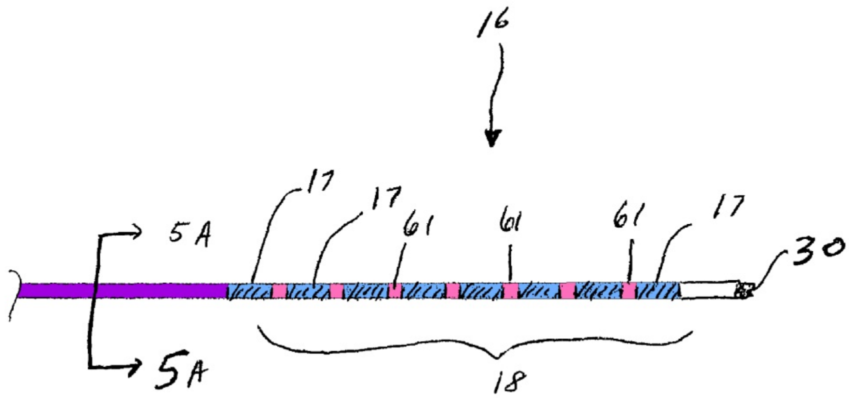
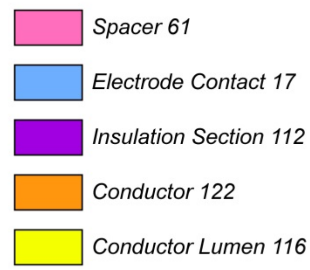


FIG. 3A



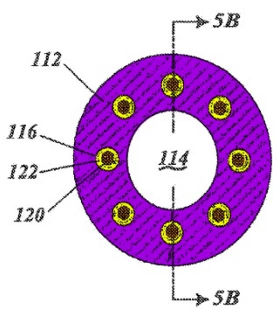


FIG. 5A

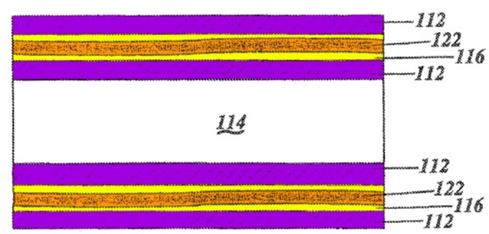


FIG. 5B

Ex. 1001 at FIGS. 3A, 5A, and 5B; *See also* Ex. 1003, ¶¶40-44.

The claimed stimulation lead 16 has an electrode array 18 at its distal end (i.e., the end furthest from the signal generator). Ex. 1001, 4:17-51. The key structural components are the conductor wires 122, the conductive contacts (i.e., electrodes) 17, and the spacers 61 placed between the conductive contacts. *See id.* Each electrode contact 17 receives the stimulation signals from an attached conductor 122 that runs through a separate conductor lumen disposed along the length of the interior of the lead body. *See* Ex. 1003, ¶¶43-45.

Figures 5A and 5B of the ’085 patent show how the conductor lumens 116 and conductors 122 are disposed in the stimulation lead body. Ex. 1001, 5:13-56. In these views, the conductors 122 run through the hollow conductor lumens 116 along the length of the lead body. The method of assembly set forth in the sole independent claim 1 of the ’085 patent puts this basic and well-known stimulation lead structure together. Ex. 1003, ¶¶40-45.

The ’085 patent specification also discloses how to fill void space where the conductors are coupled to the electrode contacts, and how to fill any empty conductor lumen[3] in the multi-lumen tube body. Ex. 1001, 7:18-20, 7:29-31. The described embodiment consists of inserting a monofilament “inside the void space as shown in FIG. 6A, and inside any empty conductor lumens 116,” and then, with the assistance of shrink wrap, heating and reflowing either the monofilament, or the spacer, into the void space.

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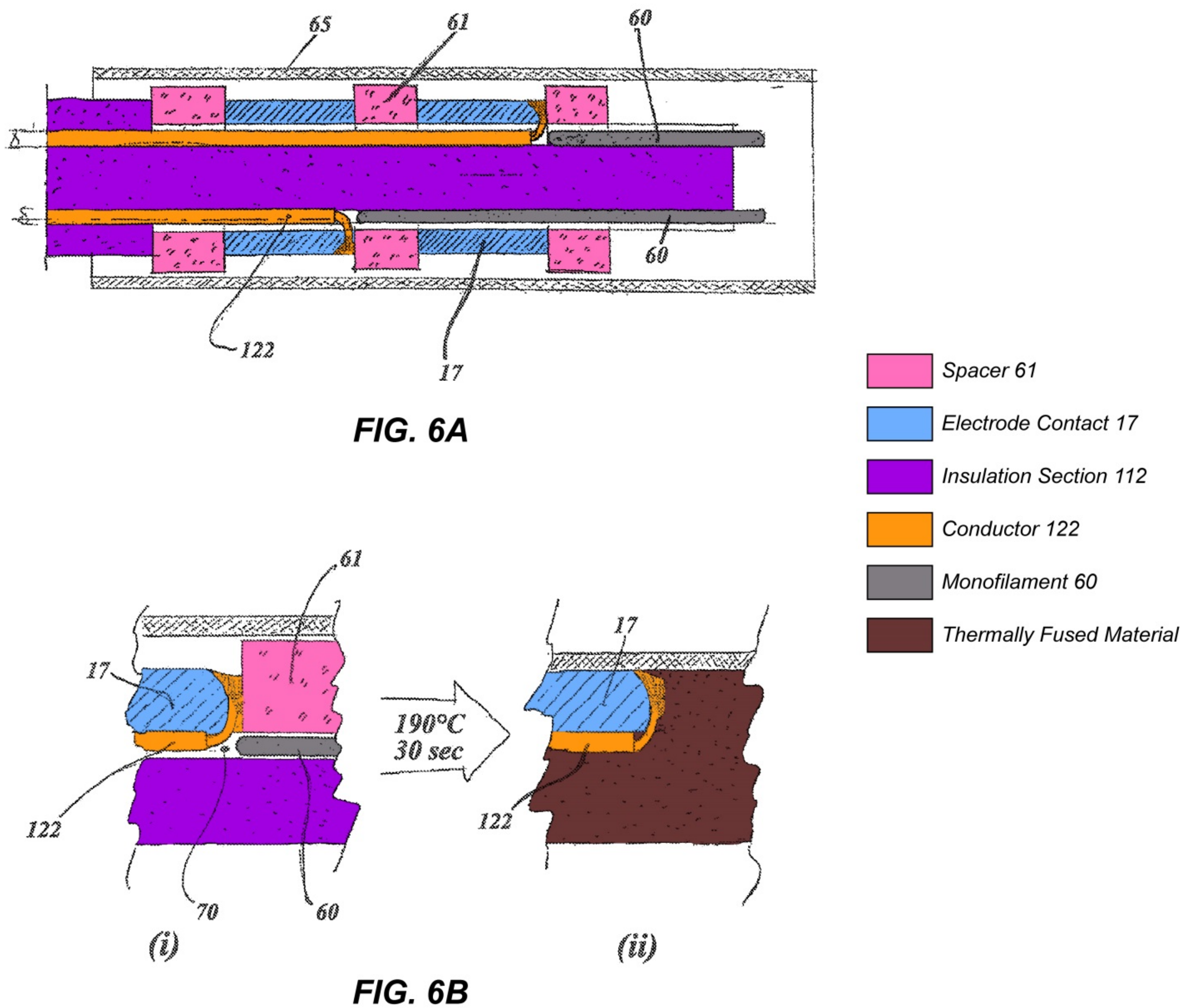
[3] In the district court litigation, the parties have agreed that the term conductor lumen be construed as “a hollow bore within the lead body for one or more conductor wires” and the term lead body as “an insulated, multi-lumen tube.” *See* Revised Final Joint Claim Chart filed October 6, 2017, *Boston Scientific Corporation et al. v. Nevro Corp.*, Case No. 1:16-cv-01163 (D.E.D.).

Figures 6A and 6B of the ’085 patent illustrate both the structure and the steps of filling the void space where the conductors are coupled to an electrode contact.



Ex. 1001 at FIGS. 6A and 6B; Ex. 1003, ¶¶55-56.

In the figures, monofilament 60 is inserted into the void space, up to the point where the conductor 122 attaches to the electrode 17 (i.e., the conductive contact). Element 70 denotes the void space near the electrode contact being at least partially filled by the monofilament 60. In the embodiment illustrated in Figure 6B, the structure of Figure 6A—including heat shrink tubing 65, spacer 61, and monofilament 60—is heated at 190 degrees Celsius for 30 seconds. This causes the spacer 61 and/or the monofilament 60 to melt or reflow, and then to fill a portion of the void space 70 near the electrode contact 17. Ex. 1001, 6:7-39, *see also* Ex. 1003, ¶¶54-67.

B. The prosecution history

The prosecution history is instructive. Prosecution claim 11 became independent claim 1. Ex. 1002, pp. 179, 163-164. Prosecution claim 11 is set forth below, with step identifiers [a]-[g] added.

The primary prior art reference during prosecution of the application that led to the ’085 patent was U.S. Patent No. 6,216,045 to Black *et al.* (Ex. 1008). Ex. 1002, p. 166. The patentee persistently focused on the monofilament and the step of reflowing material from the monofilament or the spacers, in an attempt to get around the applied art. *Id.*, pp. 149-150, 120-122, 92-93, 56-58.

After four attempts to amend and two requests for continued examination (*Id.*, pp. 113, 63), the patentee completely changed course and amended prosecution claim 11, as shown in issued claim 1 above, to add the step of “*disposing a plurality of conductor wires in a plurality of conductor lumens formed in the lead body.*” Ex. 1002, p. 52. Prior versions of prosecution claim 11 did not include the structural requirement of a plurality of "conductor lumens." *Id.*, pp. 215, 146, 116 and 88. The patentee also added the related step that the monofilament be "*inserted into at least one portion of at least one of the conductor lumen*." *Id.*, p. 52. The patentee then argued that Black did not teach the insertion of a monofilament into the unoccupied portions of those newly added conductor lumens. *Id.*, pp. 56-57. The amended claim was then allowed.

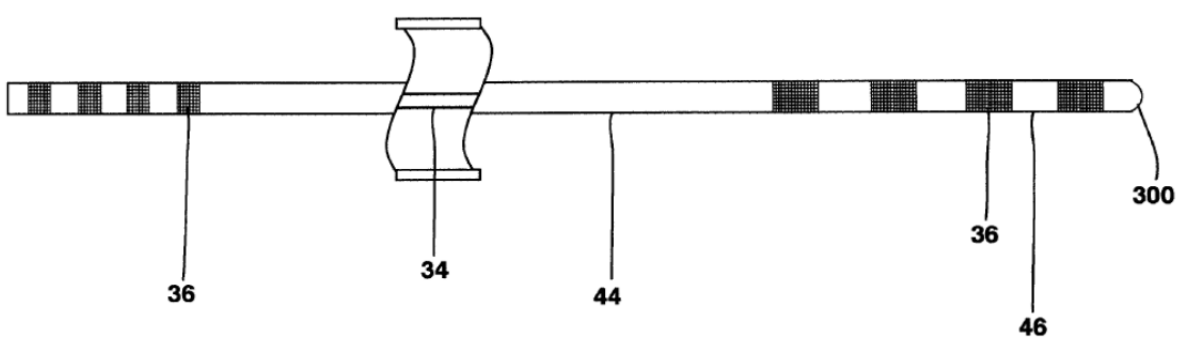
C. Independent claim 1 is unpatentable over Stolz, Ormsby, Black, and the knowledge of a POSA.

Nevro first addresses the well-known lead structure, and then the incremental and obvious steps of filling the conductor lumen by heating and then reflowing either a spacer or monofilament into the void spaces.

1. The stimulation lead structure described by the '085 patent claims was well-known.

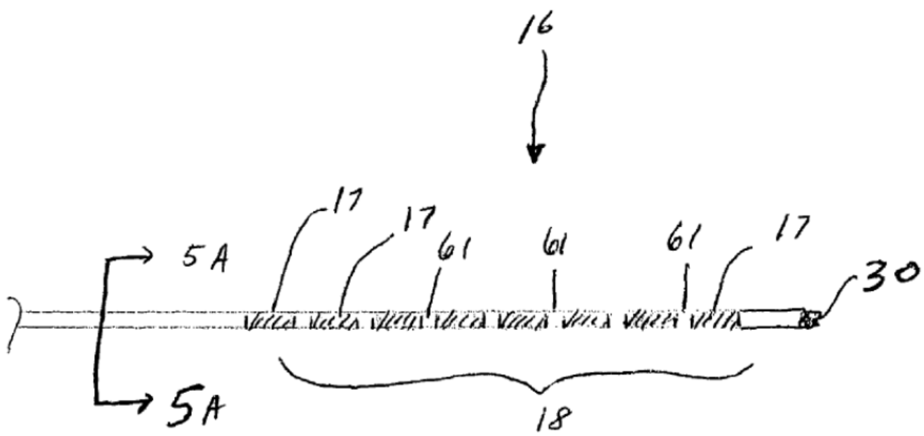
Both the Stolz (Ex. 1005) and Black (Ex. 1008) prior art references show a stimulation lead with an identical arrangement of conductive contacts—e.g., electrodes—with insulating spacers disposed in between.

Stolz's Figure 3 is exemplary:



Stolz shows a stimulation lead having a plurality of conductive contacts (e.g., electrodes) 36 with spacers 46 disposed in between. Ex. 1005, [0025]-[0027]; Ex. 1003, ¶¶73-76.

The structural arrangement of Stolz's lead is not materially different from the structural arrangement of the claimed lead described in the '085 patent, shown in FIG. 3A below:



Ex. 1001, FIG. 3A

Stolz also has a similar arrangement for running its conductor wires in conductor lumens that run along the length of the lead body for attachment to the plurality of conductive contacts. Stolz's FIG. 5 is exemplary:

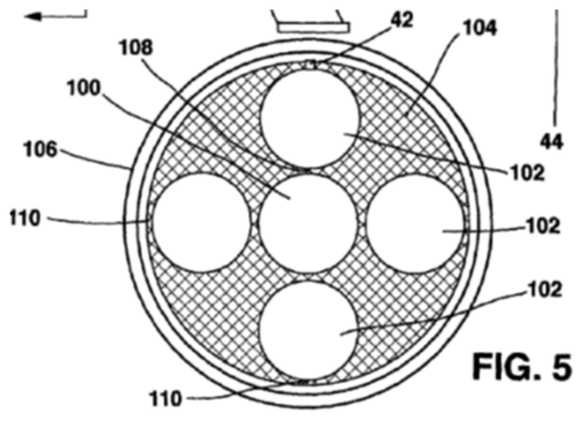


FIG. 5

In Stolz's arrangement, a plurality of conductor lumens 102 are arranged around a central stylet lumen 100, just like the '085 patent. Ex. 1005, [0028]-[0030]. Stolz's conductors run through the plurality of conductor lumens to a point where they attach to their corresponding contact. *Id.* Black has a similar configuration, but in Black's arrangement (*see* FIG. 3 above), there is a single, torus-shaped conductor lumen between the outer tubing 22,23 and the inner stylet tubing 24 within which the conductors 20 are disposed. Stolz thus unambiguously fills the gap that the patentee alleged was missing from Black during prosecution—i.e., a plurality of conductor lumens running through the lead body through which the conductors pass to reach their corresponding contacts or electrodes.

The structural arrangement of Stolz's conductors and conductor lumens is thus not materially different from the arrangement required by the '085 patent. This is readily seen by comparing FIG. 5A below from the '085 patent to Stolz's FIG 5 above.

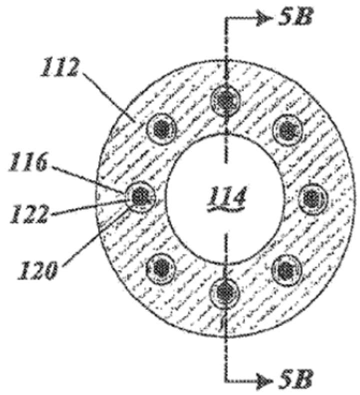


FIG.5A

Ex. 1001, FIG. 5A. *See also* Ex. 1003, ¶¶ 38–53.

* * *

With the structural overview set forth above as an introduction, Nevro will demonstrate in detail in Section VI.A., below, that there is no material difference between the structure of the stimulation lead required by the ’085 patent and the stimulation leads described by at least Stolz. Nevro now turns to the method steps.

2. The claimed method of manufacturing the lead in the ’085 patent would have been obvious by January 2005.

Claim 1 of the ’085 patent is a method of manufacturing a stimulation lead having the structure described above. The preamble and the first five steps [a]-[d], below, simply lay out a basic, prior-art lead structure that is found at least in Stolz, Ex. 1003, ¶¶71-85.

> 1. A method of manufacturing a stimulation lead having a proximal end and a distal end, comprising:
> [a] providing a plurality of conductive contacts located at an end of a lead body of the stimulation lead;

> [b] disposing a plurality of conductor wires in a plurality of conductor lumens formed in the lead body;
>
> [c] connecting at least one of the plurality of conductor wires to each of the conductive contacts;
>
> [d] placing spacers between pairs of adjacent conductive contacts, wherein portions of the conductor lumens are located beneath the plurality of conductive contacts and the spacers; …

Ex. 1001, 8:10-22.

Stolz discloses a stimulation lead that has a proximal and distal end. Ex. 1005, FIG. 3; Ex. 1003, ¶¶ 38–73. It provides a plurality of conductive contacts at an end of a lead body. Ex. 1005, FIG. 3; Ex. 1003, ¶74. Stolz also disposes a plurality of conductor wires in a plurality of conductor lumens formed in the lead body, with the lumens located beneath the plurality of conductive contacts. Ex. 1005, FIGs. 4, 5; Ex. 1003, ¶¶75–78. And, of course, Stolz connects the conductor wires to the conductive contacts. Ex. 1005, FIGs. 12, 13; Ex. 1003, ¶79.

Claim 1's final two steps [e] and [f] are directed to filling at least a portion the unoccupied spaces in the conductor lumens by inserting a monofilament from the distal end of the lead into the unoccupied portion of the conductor lumen, and then heating the spacer and the inserted monofilament to reflow the material of at least one so that it fills at least a portion of the lumen:

> [e] inserting monofilament into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by the conductor wires; and
>
> [f] reflowing at least one of the spacers or monofilament into at least one portion of at least one of the conductor lumens not occupied by the conductive wires by heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament.

Ex. 1001, 8:23-32.

Stolz discloses most of these steps. Ex. 1003, ¶¶79-81. Specifically, Stolz's method heats a distal tip on the end of its lead, and reflows material (e.g., silicone rubber, polyurethane, fluoropolymers) from the distal tip into an unoccupied portion of the conductor lumen. Ex. 1005, [0035], [0036]; Ex. 1003, ¶82. Stolz discloses that a similar method may be used to form a proximal flare on the proximal end of its lead. Ex. 1005, [0032], [0033]; Ex. 1003, ¶83. The only thing that Stolz is missing is insertion of monofilament into the unoccupied portion of the conductor lumen. Though not required by claim 1 of the '085 patent, inserting monofilament allows most or all of the empty portion of the conductor lumen to be filled, whereas in Stolz, the material from the distal tip does not flow very far into the conductor lumens. Ex. 1003, ¶¶141-144. Stolz's method thus results in a stimulation lead where a substantial portion of at least some of its conductor lumens are empty—especially for the conductor lumens that service the electrodes furthest from the distal end. *Id.*

Ormsby (Ex. 1006) provides the motivation to fill the portion of Stolz's conductor lumens that are not occupied by its conductive wires. Ex. 1003, ¶¶ 86-90, 145-157. Specifically, Ormsby teaches that it is desirable to fill lumen spaces to prevent kinking or crushing, if stressed. *See e.g.*, Ex. 1006, 7:3-10; Ex. 1007; *see also* Ex. 1003 ¶¶ 145-157. Ormsby also teaches various methods for filling a lumen, including with powder, liquid adhesive, epoxy, or resin. Ex. 1003, ¶¶88-93. For these reasons, a POSA would have been motivated to modify Stolz to fill the unoccupied portions of its conductor lumens. Ex. 1003, ¶¶144-146. A POSA would have also recognized that there are a finite and limited number of ways to fill a conductor lumen. Ex. 1003, ¶¶153, 159. Accordingly, a POSA would have at least been motivated to try filling the space with monofilament given the size and length of the space to fill—i.e., a relatively long, narrow, cylindrical space.[4] *See* Ex. 1003, ¶¶144-160.

Finally, Black discloses the technique of heating, then reflowing lead elements, like a spacer, to fill void lumen spaces. Ex. 1003, ¶¶94-101. For

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[4] Claim 1 of the '085 patent only requires monofilament to be inserted into "at least one portion of at least one of the conductor lumens."

example, Black discloses that "electrode spacers 28 and terminal spacers 30 are placed in a state of flow, which, at least in part, results in a filling of regions between terminals 16/electrodes 18 and stylet guide 24"—i.e., unoccupied portions or void spaces in the conductor lumen. Ex. 1008, 7:13-15. The Examiner during prosecution focused on Black's lead structure, but did not appear to recognize the significance of Black's technique for filling void spaces in the conductor lumen by heating and reflowing a spacer because the Examiner relied on another reference for this teaching. *See e.g.*, Ex. 1002, p. 69.

Black's previously unappreciated technique of heating the spacers so that they reflow into the void space in the conductor lumen is directly applicable to Stolz in view of Ormsby's teaching. And a POSA would have been expected to succeed in executing these steps. Ex. 1003, ¶ 174. Indeed, Stolz already discloses the technique of heating its distal tip to reflow that material into the end of the conductor lumens.

* * *

This summary of Nevro's unpatentability position for independent claim 1 of the '085 patent provides context, background, and motivation for the detailed mapping of the prior art to all of the claims in the '085 patent.

VI. Ground 1: The combination of Stolz, Ormsby, Black and the knowledge of a POSA renders obvious claims 1-3, 6-12, and 14-17 of the '085 patent.

A. Independent claim 1

1. "A method of manufacturing a stimulation lead having a proximal end and a distal end, comprising:"

Stolz describes a stimulation lead 30. It characterizes that lead as "[a]n implantable lead [comprising] a lead body 32… [with] a proximal end 38 [and] a distal end 40." Ex. 1005, [0025], FIG. 3. Stolz discloses that its lead may be part of an "implantable neurological stimulation system that can be used to treat conditions such as pain, movement disorders, pelvic floor disorders, gastroparesis, and a wide variety of other medical conditions." *Id.*, [0003], FIG. 3. Stolz provides some examples of prior devices and teaches that "[t]he implantable lead 30 can be configured as a neurological stimulation lead, a neurological sensing lead, and a combination of both as a neurological stimulation and sensing lead, a cardiac lead, and the like." *Id.*, [0024].

Thus, Stolz discloses a method of manufacturing a stimulation lead having a proximal end and a distal end. *See* Ex. 1003, ¶¶110-119.

2. "providing a plurality of conductive contacts located at an end of a lead body of the stimulation lead;"

Stolz provides conductive contacts at an end of the lead body. Ex. 1005, [0039], [0041], *see also* FIGS. 3, 12, and 13. In one embodiment, Stolz provides "at least two contacts 36" where the contacts include "at least one contact 36 carried on the lead distal end 40…and at least one contact 36 carried on the proximal end 38." *Id.*, [0027], [0039], [0054]; *see also* FIGS. 3, 12, and 13. Stolz further discloses that "[i]mplantable leads have conductors that are connected to contacts to form electrical paths." *Id.*, [0004]. Moreover, Stolz discloses that "[t]he connection between the conductors and the contacts should have a solid mechanical connection and a low impedance electrical connection for efficient operation and reliability." *Id*. Stolz's FIG. 3 is reproduced below for convenience, showing four contacts 36 on each of the proximal 38 and distal 40 end of lead body 32.

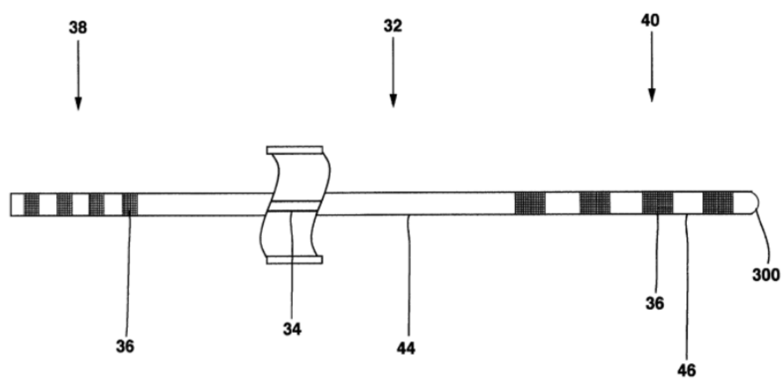


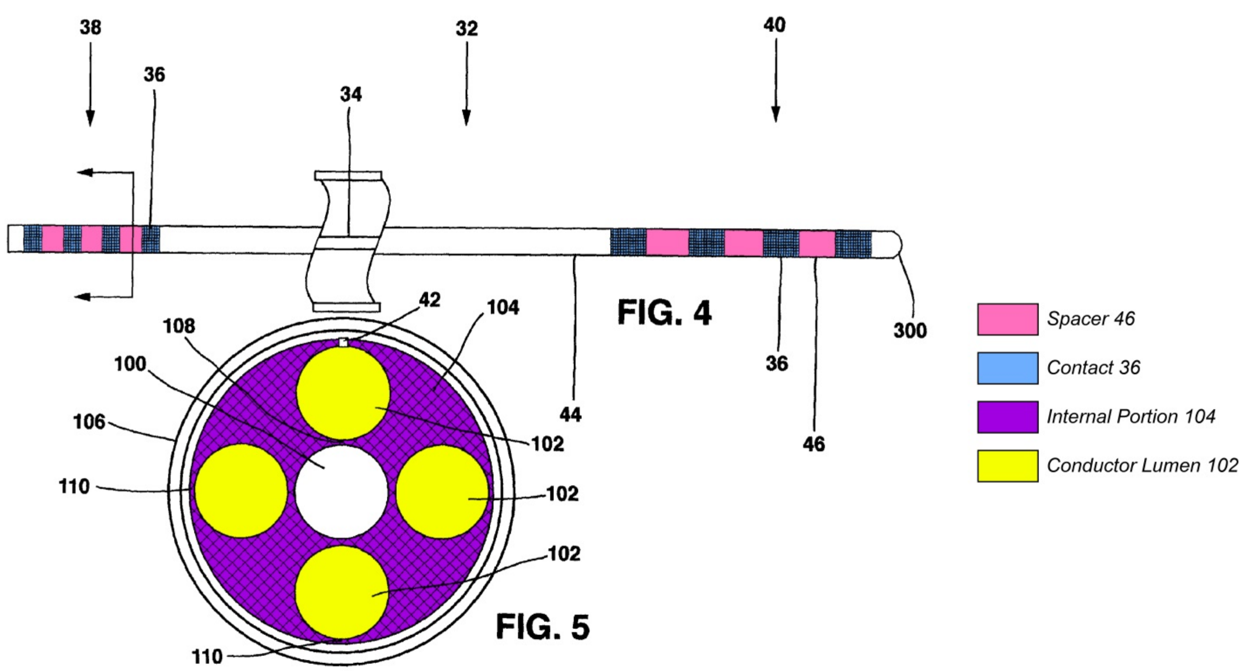
FIG. 3

Thus, Stolz provides a plurality of conductive contacts located at an end of a lead body of the stimulation lead. *See* Ex. 1003, ¶¶120-123.

3. "disposing a plurality of conductor wires in a plurality of conductor lumens formed in the lead body;"

Stolz discloses disposing conductor wires in a plurality of conductor lumens formed in the lead body Ex. 1005, [0026], [0028]–[0031], [0034], [0045], [0059], FIGS. 1–15. Specifically, Stolz discloses conductors 34 in the form of conductor wires "contained in the conductor lumens 102 extending from the lead proximal end 38 to the distal end 40." *Id.*, [0031], FIGS. 4, 5, 13. The conductors 34 can be wires. *Id.*, [0026], [0034]. Stolz teaches that the conductors 34 can be manufactured from a wide range of materials that are electrically conductive, such as MP35N, platinum, and the like, as in the '085 patent. *Id.*, [0026].

Stolz's FIG. 4 shows an implantable lead embodiment, and FIG. 5 shows a cross section of the implantable lead in FIG. 4 (reproduced below).



As illustrated, Stolz's implantable lead comprises a lead body 32, a stylet lumen 100, at least one conductor lumen 102. *Id.*, [0028]. The conductors 34 are contained in the conductor lumens 102, which extend from the lead's proximal end 38 to its distal end 40. *Id*., [0031]. The conductor lumens 102 are formed in the internal portion 104 and positioned near an outer surface of the internal portion 104. *Id.*, [0029]. Stolz discloses a plurality of conductor lumens 102, in the range from about two to sixteen. *Id.* Stolz teaches that conductor lumens 102 electrically insulate each conductor 34 and physically separate each conductor 34 to facilitate identification of the conductor 34 that is appropriate for its single corresponding contact 36. *Id.*

Thus Stolz discloses disposing a plurality of conductor wires in a plurality of conductor lumens formed in the lead body. *See* Ex. 1003, ¶¶124-130.

4. "connecting at least one of the plurality of conductor wires to each of the conductive contacts;"

In a concurrent patent infringement suit in Delaware, the patent owner BSNC is construing the "connecting" step as "connecting at least one conductor wire to one conductive contact, such that the conductive contacts are connected to the plurality of conductor wires."[56] For purposes of this proceeding, Nevro does

[5] *See* C.A. No. 16-1163 (GMS) Defendant Nevro Corp.'s Opening Claim Construction Brief, filed on October 13, 2017.

not dispute that BSNC's proposed construction under the narrower *Phillips* standard applicable to the district court action also falls within the broader BRI standard that the Board must apply in this proceeding. Under BSNC's broad construction, this step would be met by a process that connects each conductive contact to at least one of the plurality of conductor wires. This step is met by at least Stolz.

In the embodiment shown in Stolz's figures, there are four distal end electrodes, four conductor lumens, and four proximal end contacts. Ex. 1003, ¶ 131; *see also* Ex. 1005, Figures 4, 5. Stolz thus naturally discloses connecting four conductor wires to their respective conductive contacts in a one-conductor-wire-to-

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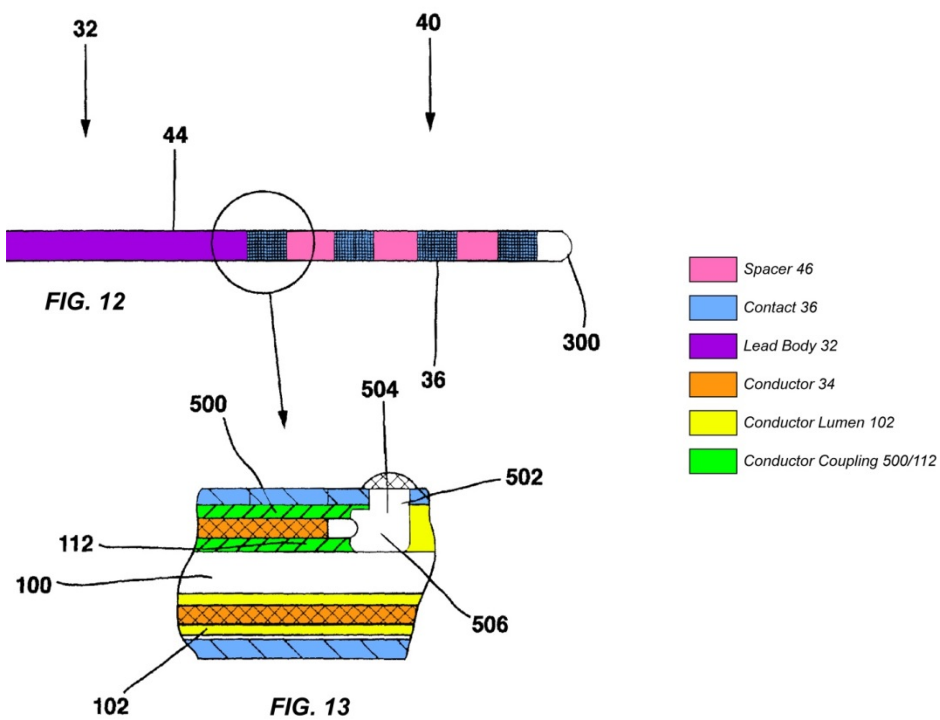
[6] BSNC's construction is broader than the construction Nevro has proposed in the district court, where Nevro is advocating a plain reading of the connecting clause under the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). Under Nevro's narrower construction, the connecting clause requires at least one single conductor that is connected to each of the plurality of conductive contacts. This narrower configuration, too, was known in the prior art. *See, e.g.*, Schallhorn, Ex. 1016, 3:17-4:9, 5:63-6:12, 8:13-33, FIGS. 1, 2, 6, 14-15. Nevro's narrower, *Phillips*, construction also falls within the scope of the broadest reasonable interpretation.

one-conductive-contact configuration. Ex. 1005, [0026], [0028]–[0031], [0034], [0045], [0059], FIGS. 1–15. Specifically, Stolz discloses that "the conductor lumens 102 electrically insulate each conductor 34 and physically separate each conductors 34 to facilitate identification of the conductor 34 that is appropriate for its single corresponding contact 36." Ex. 1005, [0029].

Stolz's figure 13, annotated below, shows the conductor 34 (orange) coupled to the electrical contact 36 (blue) via electrical coupling 112 in the conductor to conductor coupling 500/112 (green):



Stolz explains that "[t]he coupling 112 has a conductor coupling 500 and a contact coupling 502." Ex. 1005, [0045]. The conductor coupling 500 is made from "a material with good mechanical and electrical properties such as MP35N and the like." *Id.* The "coupling 112 is attached … to a conductor 34 so that the conductor 34 extends into a first coupling region 500 of the coupling 112." *Id.*, [0048]. "The first coupling region 500 is mechanically attached to the conductor 34 in a crimping process that … engages the conductor 34 firmly." *Id.* [0049]. Then, Stolz teaches that "[t]he coupling 112 attached to the conductor 34 is exited through the axial slit 42 in the lead body distal end … [which] permits the coupling 112 to pass through to mate to the contact 36 with the minimum amount of movement of the conductor 34 assembly within the lead body." *Id.*, [0051].

Thus, as this step is construed by the patent owner BSNC and under any broadest reasonable interpretation of the claim, Stolz discloses connecting the conductor wires to the conductive contacts. *See* Ex. 1003, ¶¶131-133. Black also discloses this step. *See* Ex. 1008, 5:29-39, 6:56-65.

5. "placing spacers between pairs of adjacent conductive contacts,"

Stolz discloses placing spacers between pairs of adjacent conductive contacts. Ex. 1005, [0027], FIGS. 3, 4, 6, 7, 10, 12, 13. Specifically, Stolz discloses that "spacers 46 are inserted between contacts 36." *Id.*, [0027]; *see also* FIGS. 3, 4, 6, 8, 10, 12, 13. Stolz's figure 3 below is illustrative.

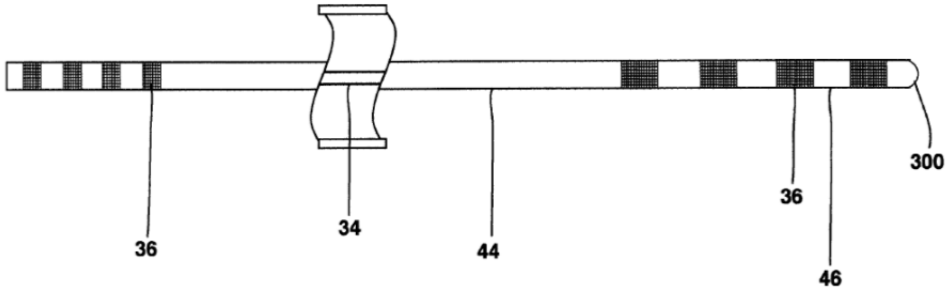


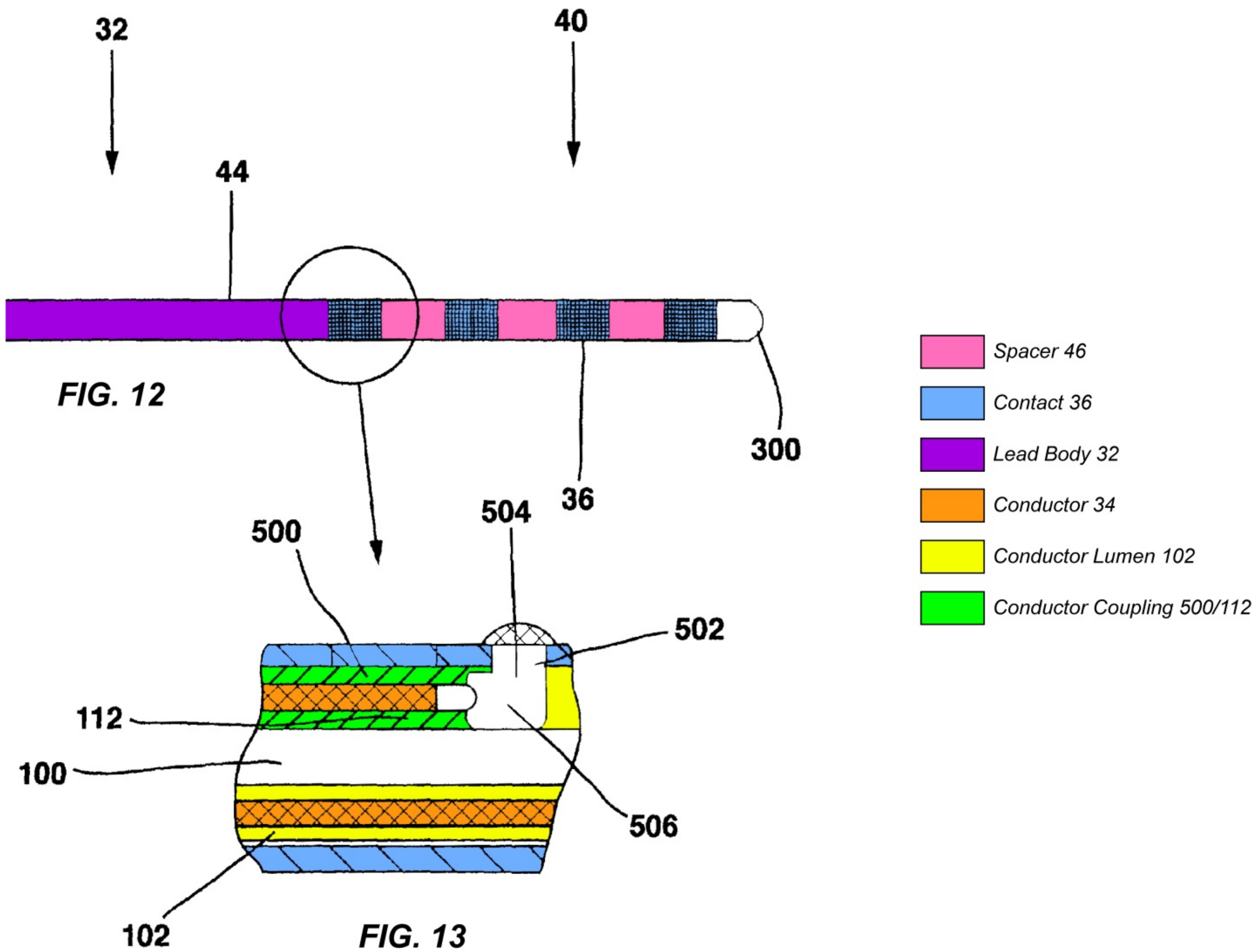
FIG. 3

Thus Stolz discloses placing spacers between pairs of adjacent conductive contacts. *See* Ex. 1003, ¶¶134-135. Black also discloses this step. *See* Ex. 1008, FIG. 7, 6:19-36.

6. "wherein portions of the conductor lumens are located beneath the plurality of conductive contacts and the spacers;"

Stolz discloses portions of the conductor lumens being located beneath the conductive contacts and the spacers *See, e.g.*, Ex. 1005, FIGS. 6–9, 12, and 13. Specifically, Stolz's conductor lumens 102 extend through Stolz's lead body from the proximal end to the distal end. *See, e.g.*, FIGS. 6–9. Additionally, Stolz's figures 6–9, and 13 show the conductor lumens 102 located beneath the conductive contacts 36 and spacers 46.

Annotated figure 13 of Stolz is illustrative:



Thus Stolz discloses that portions of the conductor lumens are located beneath the plurality of conductive contacts and the spacers. *See*, Ex. 1003, ¶¶ 136-139.

7. “inserting monofilament into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by the conductor wires;”

The claimed step of “inserting monofilament into at least one portion of at least one of the conductor lumens of the lead body that is not occupied by the conductor wires" would have been obvious over Stolz in view of the teachings in Ormsby (Ex. 1006).

Stolz discloses most of this step. Stolz teaches inserting material into the conductor lumens 102, e.g., to seal them. Ex. 1005, [0035], [0036], [0046]. In the described embodiment, "the formed distal tip 300 seals the conductor lumens 102 free from adhesive or solvents." *Id.*, [0035]. This is accomplished when "[t]he heat conducted from the mold to the lead distal tip 300 melts the surrounding material into the conductor lumen 102 and into the stylet lumen 100, completely sealing them from the outside." *Id.*, [0036]. The distal tip 300 thus "penetrates the lumens 100, 102 of the lead body… [and] reaches no further into the lumens than making contact to the enclosed conductors." *Id.*, [0035]. Further, Stolz discloses that the isolation space 506 (shown above) can include a "fill material such as epoxy," further filling an unoccupied portion of the conductor lumen. *Id.* [0046].

Stolz's figures 8 and 9 (below) are illustrative of the location of the distal tip 300 relative to the stylet lumen 100, and conductor lumens 102.

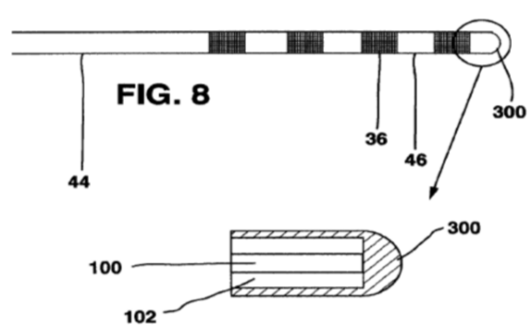


FIG. 9

Accordingly, in Stolz "at least one portion of at least one of the conductor lumens of the lead body that is not occupied by the conductor wires," is filled with the distal tip material when Stolz's distal tip is melted or thermally reflowed into the end of the lead body.

However, Stolz's method for sealing the end of the implantable lead with its distal tip does have some disadvantages. Ex. 1003, ¶¶140-145. Specifically, the reflowed portion of Stolz's distal tip may not penetrate very far into the stylet lumen or the conductor lumens. Specifically, Stolz teaches that the distal tip material "penetrates the most distal end of the stylet lumen 100 by about 0.15 cm (0.059 inch) into the stylet lumen 100 of the lead beginning from the most distal end of the hemi-spherical distal tip 300." Ex. 1005, [0038]. Stolz discloses that the distal tip may make contact with the enclosed conductors *see, e.g.*, *id.*, [0035]. But given the distance that the distal tip material penetrates the stylet lumen, some conductor lumens—e.g., especially those that service electrodes that are furthest from the distal tip—may still have a long, unoccupied space between the distal tip and the conductor. *See* Ex. 1003, ¶¶144-146.

By January 2005, a POSA would have recognized that leaving long, empty portions of a conductor lumen could be an undesirable condition, depending on the application. Ex. 1003, ¶145. For example, as Nevro's expert explains, a long and empty conductor lumen would be more susceptible to perforation, kinking, or other material damage, such as during insertion into a human body. Further, having empty conductor lumens of varying lengths could cause variations in the flexibility of the implantable lead. *Id.* Finally, empty conductor lumens could increase the chance of separation of components of the lead body from one another. *Id.*

To prevent these potential problems, a POSA would therefore have searched for other known techniques for filling the unoccupied portions of the conductor lumens. And to do so, a POSA would have thus considered other medical device references to identify suitable methods for filling lumens and other voids within elongate structures having conductive wires therein. The prior-art Ormsby reference (Ex. 1006) meets that need. Ex. 1003, ¶146.

Ormsby discloses a catheter with a lumen extending from the proximal end to the distal end. Ex. 1006, Abstract. Ormsby's FIG. 3 is shown below for reference:

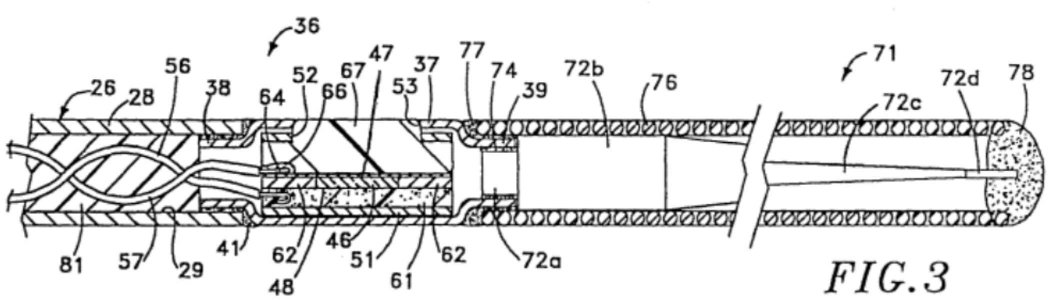


FIG. 3

Conductor members 56 and 57 extend through Ormbsy's conductor lumen from the proximal end to connect to a transducer element at the distal end. *Id.*, 5:10–16, FIG. 3. Ormsby teaches that "[i]n order to substantially increase the kink resistance of the flexible elongate tubular member 26, the lumen 29 therein can be filled with a filler 81 of a suitable material." *Id.*, 7:3–5. This process ensures that material "fills the void within the lumen and greatly reduces the possibility of kinking of the hypotube forming the flexible elongate tubular member." *Id.*, 7:8–10. Filling the portions of Stolz's conductor lumens not occupied by conductor wires would provide the benefit, as taught by Ormsby, of reducing the possibility of kinking in Stolz's lead, while also improving axial stability. *See* Ex. 1003, ¶¶147-149.

In addition to the "prior method" of using epoxy to fill voids in the lead body as taught in the '085 patent itself (Ex. 1001, 7:52-54), Ormsby discloses inserting a liquid epoxy or resin that then hardens, or a polymer powder that may be melt formed or reflowed inside the lead body to form a non-powder solid polymer. Ex. 1006, 7:3-10. These methods increase "kink resistance." *Id.*; *see also,* Ex. 1003, ¶150. They also facilitate formation of an isodiametric lead, which Stolz itself teaches is beneficial. Ex. 1003, ¶78.

However, Stolz in view of Ormsby still does not expressly disclose "inserting a monofilament" to fill the void within the conductor lumen. But given the orientation of the lumen voids and the conductors, and for ease of manufacturing, a POSA would have found it obvious to use monofilament to fill the empty spaces in Stolz's conductor lumens instead of the powder of Ormsby.

Ex. 1003, ¶¶151-157. That is, when faced with a straight, narrow, cylindrical void of a multi-lumen body such as in Stolz, a POSA would have naturally looked for a filling option that would match the size, shape, and configuration of the lumen it would be designed to fill—such as monofilament. *Id.* In this way, a POSA would have viewed a monofilament simply as a way to plug and seal the lumens, similar to the reflowing of the distal tip and proximal flare in Stolz. *Id*.

Moreover, while a powder may have been preferred in Ormsby because of the need to fill the empty spaces in between Ormsby's twisted conductor pair, the same obstacle does not exist in Stolz's device. *See* Ex. 1006, FIG. 3. Stolz's conductor lumen portions (where the monofilament would be inserted) are straight, empty, and relatively small in diameter. For this reason as well, it would have been obvious to consider using a monofilament—corresponding to the interior shape of the conductor lumen portions—instead of a powder. *See* Ex. 1003, ¶152.

Finally, a POSA would have recognized that there are a limited number of ways to fill a lumen. *See* Ex. 1003, ¶153. A POSA thus would have found it at least obvious to try and fill the lumen with a non-powder, solid material, like a monofilament, to determine the best of a limited number of options. *Id.* Specifically, given the state of the prior-art, it would be obvious to insert a non-powder solid material having the same shape as the portion of the lumen to be filled – i.e., a long, thin and straight solid like monofilament. *Id.* A POSA would have appreciated that monofilament was a known solution in related arts and would have had reasonable expectation of success. Ex. 1003, ¶¶153-161; *see also* Ex. 1012, 1013, 1014.

* * *

For the reasons explained above, a POSA would have found it obvious to at least try various techniques to fill the spaces in Stolz's conductor lumens that are unoccupied by the conductor wire to enhance the reliability of Stolz's stimulation lead. Ex. 1003, ¶¶141-158. Ormsby confirms this. *Id.* Though Ormsby does not specifically disclose inserting a monofilament to fill a void space in Stolz's conductor lumen, that choice would have been obvious to a POSA given both the shape of Stolz's conductor lumen and the limited number of ways to fill it. *See* Ex. 1003, ¶¶140-158.

Finally, a POSA also would have had a reasonable expectation that the teachings of Stolz and Ormsby would have been compatible. A POSA would have understood Stolz and Orbmsy disclose several, alternate, interchangeable methods of backfilling and sealing empty lumen space. And a POSA would have had a reasonable expectation of success using Stolz and Ormsby's processes, but modified to include inserting monofilament element to bond the elements. Ex. 1003, ¶160.

Thus Stolz's stimulation lead, as modified by the above teachings of Ormsby and the knowledge of a POSA, would disclose the method of manufacturing a stimulation lead that includes all of the elements as arranged in the claims of the '085 patent, including a monofilament being inserted into a portion of the lumen during manufacturing. *See* Ex. 1003, ¶¶140-161.

8. "reflowing at least one of the spacers or monofilament into at least one portion of at least one of the conductor lumens not occupied by the conductive wires by heating the spacers and monofilament to a temperature to cause thermal flow or melting of at least one of the spacers or monofilament."

Finally, the '085 patent includes the step of "reflowing" of at least one of the spacers or monofilament into at least one portion of at least one of the conductor lumens not occupied by the conductive wires by heating the spacers and monofilament. Stolz discloses reflowing material into at least one of the conductor lumens not occupied by the conductive wires by applying heat to cause thermal reflow. Ex. 1005, [0035], [0036], [0046]. Although Stolz does not explicitly disclose that the material comes from either an inserted monofilament, or a spacer (unless the distal tip is construed to be the last spacer), the prior-art Black patent (Ex. 1008) fills that gap.

Prior versions of prosecution claim 11—issued claim 1 in the '085 patent—did not include the structural requirement of a plurality of "conductor lumens." *Id.*, pp. 215, 146, 116 and 88. Black was the primary reference cited by the Examiner during this prosecution. Ex. 1002, p. 156. In addition to a plurality of "conductor lumens," the patentee also added the related step that the monofilament be "*inserted into at least one portion of at least one of the conductor lumens*." The patentee then argued that Black did not teach the insertion of a monofilament into the unoccupied portions of those newly added conductor lumens. *Id.*, pp. 56-57. The amended claim was then allowed.

But the Examiner did not appear to appreciate that Black taught the feature of heating and reflowing spacers because the Examiner relied on other art to teach that step. *Id.*, 167-168. Nevro thus relies on Black for different teachings than the Examiner below.

Black renders obvious the step of heating and reflowing at least one of the spacers or monofilament into at least one portion of at least one of the conductor lumens not occupied by the conductive wires. Black does this by heating the spacers to a temperature to cause thermal flow of at least one of the spacers or inserted monofilament (as suggested above). Like Ormsby, Black recognizes the utility of filling the void spaces in a conductor lumen of an implantable stimulation lead. Ex. 1003, ¶164. Specifically, Black discloses reflowing its spacers into the conductor lumen voids to stabilize and strengthen the structural elements therein within "a fused matrix of material" that is "free of gaps and voids." *See* Ex. 1008, 6:19–34, 7:5-23, 7:29-34, FIG. 5; *see also* Ex. 1003, ¶¶162-164.

And like the ’085 patent, Black teaches a method for filling a conductor lumen by putting a spacer between adjacent conductive contacts into a state of flow, thus filling the void spaces. Ex. 1003, ¶165. Figure 3 illustrates Black’s conductor lumen:

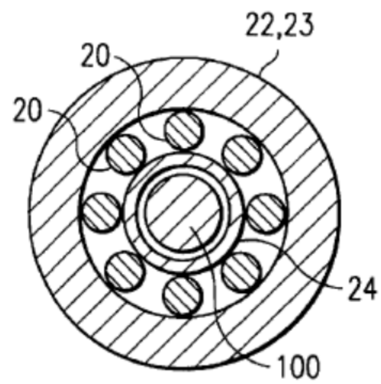


FIG. 3

The conductors 20 are disposed around a center stylet 100, and stylet tubing 24. (Ex. 1008, 5:28-45, 6:5-10.) The conductor lumen is the cylindrical (toriodal- or donut-shaped) space between the stylet tubing 24 and the outer tubing 22, 23 in which the conductors 20 are disposed. There are void spaces between the conductors at this stage of manufacture. Like the ’085 patent, Black uses spacers 28 that are disposed between electrodes 18.

Black’s Figures 5 (lead) and 7 (spacer) are illustrative:

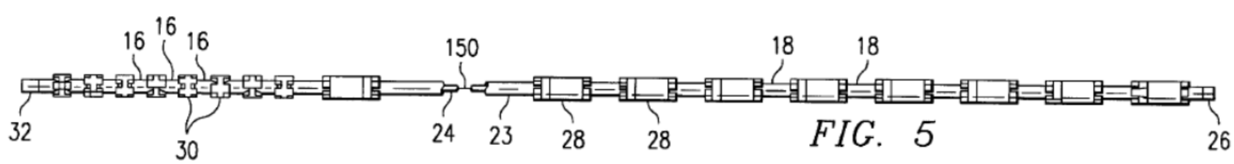


FIG. 5

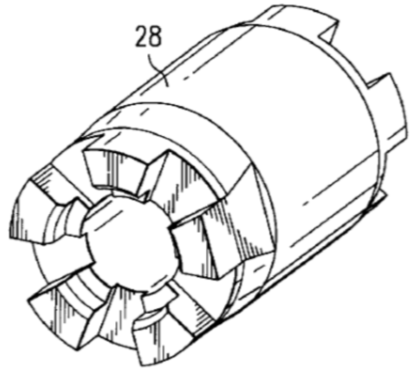


FIG. 7

Black teaches that "spacer[s] 28 … are preferably formed of the same material as the outer tubing 23." Ex. 1008, 6:23-26. As one example, Black teaches spacers made of polyurethane material. *Id.*, 6:32-34. Black goes on to teach that the completed assembly in Figure 5 is "over-molded using well known injection molding techniques, using a material having mechanical properties consistent with a material(s) used to form outer tubing 23, electrode spacer 28, and terminal spacer 30… [and that in] a preferred embodiment," all of the materials are the same. *Id.*, 7:5-11; *see also*, Ex. 1003, ¶¶166-167.

Stolz and Black also employ a similar structure with respect to the arrangement of the conductors around a central stylet. Black's figure 3 and Stolz's figure 5 below show the similarity:

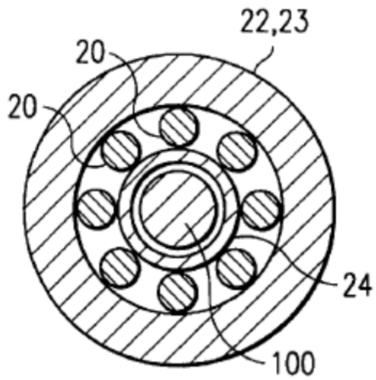


FIG. 3

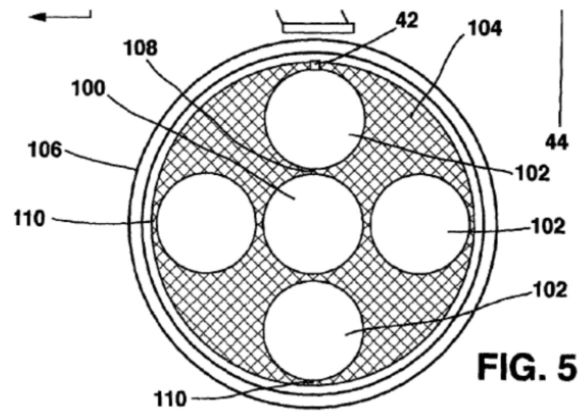


FIG. 5

The principal difference between these figures is that Black's conductor lumen is a donut-, or toriodal-shaped space between the stylet tube 24 and outer tube 22, 23 where the conductors 20 are disposed, while in Stolz, each of the conductors has its own conductor lumen 102, disposed in a web 110 around the stylet lumen 100. Ex. 1003, ¶¶168-169.

Both Stolz and Black also use a similar arrangement of spacers and electrodes, as Black's figure 5 and Stolz's figure 3 below illustrate.

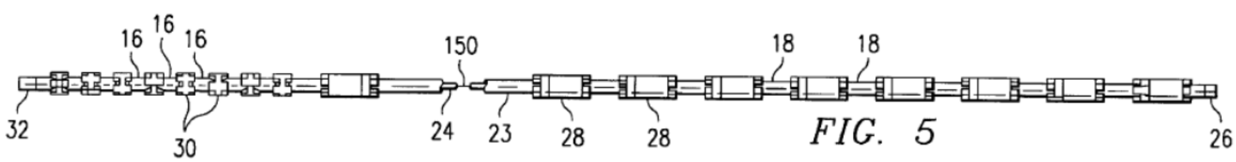


FIG. 5

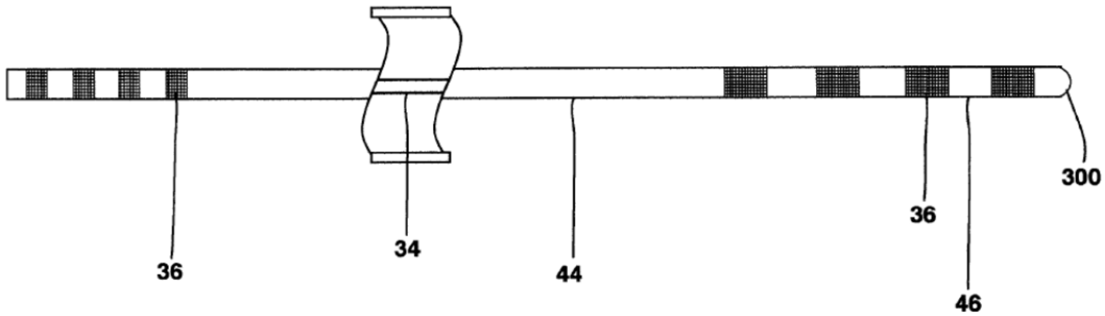


FIG. 3

It would have been within the skill of a POSA to apply the technique taught in Black of reflowing spacers to fill void spaces in the conductor lumen to Stolz to achieve the desired benefits, discussed immediately below, of filling void spaces in the conductor lumen. *See* Ex. 1003, ¶¶168-171.

Black itself teaches the benefits. Specifically, Black teaches that "[t]his process has the beneficial effect of unitizing the element assembly to form lead 10." Ex. 1008, 7:11-12. That occurs because, as Black teaches, "electrode spacers 28 … are placed in a state of flow, which, at least in part, results in a filling of regions between … electrodes 18 and stylet guide 24"—i.e., the conductor lumen. *Id.*, 7:13-16. The result is that electrode 18 is "partially surrounded (i.e., along an interior surface) and supported by a fused matrix of material," which "stabilize[s] and strengthen[s] while also retaining their flexible properties." (*Id.*, 7:16-24.) The completed lead assembly, which Black does not show in a figure, is "isodiametric" and "free of any gaps or voids between insulative material and conductive material that may otherwise exist in conventional devices." *Id.*, 7:29-33; *see* Ex. 1003, ¶172.

*   *   *

For the reasons explained above, a POSA would have been motivated to take advantage of this type of either reflowing of the spacers of Black in combination with Stolz's method of forming the distal tip (and proximal flare, as well). Both processes operate based on the same principles of material joining by applying heat. For the same reasons, a POSA would have appreciated that the method would be successful, especially for reflowing at least one of the spacers or monofilament into a portion of at least one of the conductor lumens. *See*, Ex. 1003, ¶¶162-175.

CONCLUSION FOR CLAIM 1

Stolz's stimulation lead 30, as modified by the teachings of Ormsby and Black and the knowledge of a POSA, discloses and renders obvious the method of manufacturing a stimulation lead that includes all of the elements and steps as arranged in independent claim 1 of the '085 patent. *See generally*, Ex. 1003, ¶¶116-175.

B. Claim 2

1. "The method of claim 1,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein either the spacers or monofilament is polyurethane."

It is well recognized that the selection of a known material based on its suitability for its intended use may support a *prima facie* obviousness determination. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327 (1945). Put simply, "[r]eading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." *Id*. at 335; *see also In re Leshin*, 277 F.2d 197 (C.C.P.A. 1960) (selection of a known plastic to make a container of a type made of plastics prior to the invention was held to be obvious).

Stolz generally discloses that lead body components may include those made from polyurethane. Ex. 1005, [0025] ("The lead body 32 can be composed of a wide variety of electrically isolative materials and configurations. Materials may include, but are not limited to, silicone rubber, *polyurethane*, fluoropolymers and the like.") (emphasis added); *see also* Ex. 1003 ¶¶176–177. Black also discusses full flexibility in specifying materials, and expressly discloses use of "polyurethane material." Ex. 1008, 6:24-42. And Black discusses that its spacers may specifically be polyurethane, and that they may be of the same material (or different material) as Black's lead body. *Id.*, 6:19-42. A POSA generally would have appreciated that these types of devices may be fabricated from polyurethane, and a POSA would have thus found it obvious to have selected polyurethane as the material for either the spacers or monofilament. Ex. 1003, ¶¶177-181.

C. Claim 3

1. "The method of claim 2,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein the monofilament is a thermoplastic material."

This feature would have been obvious to a POSA in view of the material filling options described above. *See, e.g.*, Sections VI.A.7, VI.A.8., and VI.B. *See also* Ex. 1003, ¶¶182-183. Specifically, polyurethanes that are capable of being melted and reflowed, as described in the prior art, are by definition thermoplastic material. *Id.*

D. Claim 6

1. "The method of claim 1,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein the spacers are oversized in diameter, relative to a predetermined final diameter of the lead."

While Stolz and Ormsby do not expressly disclose particular sizing of spacers relative to a predetermined final diameter, their combination with Black renders such feature obvious. Ex. 1003, ¶184-189.

Black discloses a lead with spacers disposed between its electrode contacts and proximal end contacts. *See* Ex. 1008, 6:19–23, FIG. 5. Black's "spacers [ ] have an outer diameter greater than lead 10." *Id.*, 6:34–35. The spacers are then "placed in a state of flow, which, at least in part, results in a filling of the regions between the [proximal end contacts] 16 and electrodes 18…Consequently, [they] are partially surrounded…and supported by a fused matrix of material." *Id.*, 7:12–18.

A POSA would have found it obvious to modify Stolz's spacers so that they have larger diameters than the diameter of the lead. Ex. 1003, ¶187. With this configuration, the Stolz's spacers would have the extra material needed for melting to better surround Stolz's terminal and electrode contacts. As modified, the melted material surrounding Stolz's terminal and electrode contacts would give the lead more support, as taught by Black. *Id.* As discussed previously in the context of the monofilament limitation of claim 1, because of Stolz's desire for an isodiametric lead, there would have been a reason to provide strengthening support at the distal end of the leads, something a POSA would have readily appreciated. *Id.* Additionally, the otherwise empty spaces between Stolz's contacts and spacers would be filled out by the spacer material, leading to a more even and isodiametric lead throughout its length. *Id.*, ¶¶188-189.

Thus, a person of ordinary skill in the art would have had a reason to use Black's larger diameter spacers, with reasonable expectation of success due to the interchangability of the processes of Stolz, Ormsby, and Black. *Id.*

E. Claim 7

1. "The method of claim 1,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein conductive contacts are in the form of rings."

Stolz's contacts 36 are ring-shaped. *See*, *e.g.*, Ex. 1005, FIGS. 13–15, [0020], [0047]; *see also* Ex. 1003, ¶¶190-191. Stolz's figure 14, which illustrates a ring-shaped conductive contact, is shown below for reference.

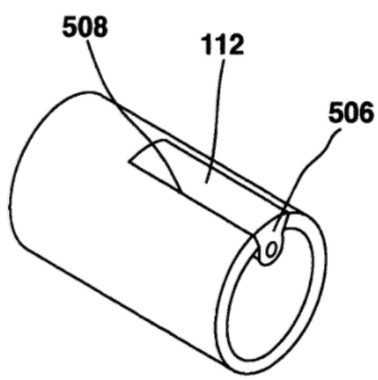


FIG. 14

F. Claim 8

1. "The method of claim 1,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein the conductive contacts are electrode contacts on the lead."

Stolz discloses that its lead may be a neurological stimulation lead, and it discloses the use of its lead in a person, with the distal end inserted next the tissue to be stimulated. *Id.*, FIGs. 1-3, [0024]-[0027]; *see also* Ex. 1003, ¶¶192-194. Stolz further discloses that "[t]he neurostimulator is typically connected to a stimulation lead that has one or more electrodes to deliver electrical stimulations to a specific location in the patient's body." Ex. 1005, [0003]. Thus, Stolz discloses distal contacts that are electrode contacts. Ex. 1003, ¶195.

G. Claim 9

1. "The method of claim 1,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein the conductive contacts are connector contacts on the proximal end of the lead."

Stolz provides "at least two contacts 36" where "the contacts 36 includes at least one contact 36 carried on the lead distal end 40…and at least one contact 36 carried on the proximal end 38." Ex. 1005, [0024], 0025], [0027], [0034], FIGs. 1-

3, 13; *see also* Ex. 1003, ¶¶196-200. The proximal contacts, "are typically manufactured from a material with good mechanical strength…and the like to withstand interaction with mating devices such as an implantable neurological extension." Ex. 1005, [0027]. These proximal contacts serve as "connector contacts," e.g., between the proximal end 38 and an implantable neurological extension, or neurostimulator 22. *See* Ex. 1005, [0024], 0025], [0027], [0034], FIGs. 1-3, 13. Thus, Stolz discloses that the contacts on the proximal end of the lead are connector contacts that are used to couple the lead to the implantable pulse generator. Ex. 1003, ¶200.

H. Claim 10

1. "The method of claim 1,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein the step of connecting a conductor wire to each of the electrode contacts is accomplished by welding each conductor wire to each respective contact."

The term "the electrode contacts" is introduced for the first time in this claim. Notwithstanding the lack of antecedent basis for this claim term, Stolz teaches welding as a technique for coupling the conductor 34 to contact (electrode) coupling 502. Specifically, Stolz discloses that "[t]he contact coupling 502 exits the lead body and has a weld 504 to connect the contact coupling 502 to the contact 36." Ex. 1005, [0045] [0054], FIGS. 13, 16. But in Stolz, the conductor wire is not welded directly to the contact. According to Stolz, such a direct weld may be inappropriate for some applications, as the weld may lack structural integrity, for example. *Id.*, [0046]; *see also* Ex. 1003, ¶¶201-203.

To the extent that BSNC asserts that claim 10 requires a direct connection, Black fills that gap and discloses an alternate welding technique for connecting the conductor wire directly to the electrode. Ex. 1003, ¶204. Specifically, Black discloses that "each terminal 16 (and each electrode 18) is positioned relative to exposed conductive material 20a and 20b of a conductor 20 and is joined in a manner that facilitates a transfer of electrical energy, for example, resistance weld or laser weld." Ex. 1008, 6:56-62.

As modified above, the void spaces in Stolz's conductor lumens are filled by reflowing either the spacers or the inserted monofilament. Ex. 1003, ¶205. This would increase the structural integrity around any direct weld, and avoid the need for a separate conductor coupling, or creating an isolation space, as Stolz teaches. *Id.* So a POSA would have been motivated to use Black's welding technique in place of Stolz's welding technique to couple the conductor wires to the electrode contact. *Id.*

Stolz and Black thus show that it would have been obvious to a POSA to use welding as a means of connecting a conductor wire to an electrode contact. *Id.*, ¶206.

I. Claim 11

1. "The method of claim 1"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein the monofilament is a different material than the spacers."

This feature would have been obvious to a POSA in view of the material filling options described above. Ex. 1003, ¶¶207-208. Specifically, the obviousness of material selection, particularly differing materials for the monofilament and spacers would have been appreciated by a POSA. "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." *Sinclair*, 325 U.S. at 335; *see also In re Leshin*, 277 F.2d 197, 125 USPQ 416 (C.C.P.A. 1960) (selection of a known plastic to make a container of a type made of plastics prior to the invention was held to be obvious). Thus, as discussed above, a POSA would have appreciated that selecting different materials would allow one to select end physical properties of the device, as well as drive manufacturing processes. Ex. 1003, ¶176–183, 209-210.

Black provides at least one example of joining dissimilar materials, For example, Black expressly discloses that spacers may be formed of the same material as an outer tubing *or a different material*, as long as they are compatible for a particular application, e.g., non-reactive to the environment of the human body, flexible and durable. Ex. 1008, 6:24-32; *see also* Ex. 1003, ¶209. Black thus shows that it is well within the ambit of a POSA to select materials for the lead, including monofilament filler, depending on the desired physical characteristics such as strength, hardness and stiffness. Thus, this feature would have been obvious to a POSA. Ex. 1003, ¶210. *See also* discussion of claim 2, *supra*.

J. Claim 12

1. "The method of claim 1,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein the monofilament is the same material as the spacers."

This feature would have been obvious to a POSA in view of the material filling options described above. Specifically, the obviousness of material selection, particularly using the same materials for the monofilament and spacers, would have been appreciated by a POSA. Ex. 1003, ¶176–183, 211-212. Doing so would additionally take advantage of Stolz's disclosure that the lead body 32 can be composed of polyurethane, and that other components such as the distal tip and proximal flare may be made of the same material. Ex. 1005, [0035], *see also* Ex. 1003, ¶176–183, 211-212. Moreover, Stolz discloses that selecting the same materials for lead components would minimize the possibility of separation from the lead body. Ex. 1005, [0025], [0033], and [0036]; *see also* Ex. 1003, ¶212; discussion of claims 2 and 11, *supra*. A POSA would have thus found it obvious to select the same material for both the monofilament (as Stolz has been modified above) and the spacer.

K. Claim 14

1. "The method of claim 1,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein the plurality of electrically conductive contacts are located on the proximal end of the stimulation lead."

Stolz discloses a plurality of electrically conductive contacts at both the proximal and distal ends of the lead. For example, Stolz provides "at least two contacts 36" where "the contacts include at least one contact 36 carried on the lead distal end 40…and at least one contact 36 carried on the proximal end 38." Ex. 1005, [0031], [0034]. Stolz's figure also disclose a plurality of conductive contacts at the proximal and distal ends of the lead. *See, e.g.*, *id.*, FIG. 3. *See also* discussion of claim 9, *supra*; Ex. 1003, ¶¶213-214.

L. Claim 15

1. "The method of claim 1,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein the plurality of electrically conductive contacts are located on the distal end of the stimulation lead."

Stolz discloses a plurality of electrically conductive contacts at both the proximal and distal ends of the lead. For example, Stolz provides "at least two contacts 36" where "the contacts 36 include at least one contact 36 carried on the lead distal end 40…and at least one contact 36 carried on the proximal end 38." Ex. 1005, [0025], [00027], [0031], [0034]; *see also* Ex. 1003, ¶¶215-216. Stolz's figure also discloses a plurality of conductive contacts at both the distal and proximal ends of the lead. *See, e.g.*, Ex. 1005, FIG. 3; Ex. 1003, ¶216. *See also* discussion of claim 8, *supra*.

M. Claim 16

1. "The method of claim 1,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein the plurality of electrically conductive contacts and the spacers form a substantially cylindrical body and wherein the conductor lumens are defined within the substantially cylindrical body."

Stolz expressly discloses that "spacers 46 are inserted between contacts 36 so the proximal end 38 and distal end 40 are substantially iso-diametric." Ex. 1005,[0027]. Stolz also shows a lead body that is substantially cylindrical near the portion of the distal end and proximal end. *See, e.g., id.*. FIG. 12; *see also* Ex. 1003, ¶¶217-219.

The conductor lumens 102 are shown within the substantially cylindrical body, e.g., in Stolz figure 4. Ex. 1003, ¶220. Stolz states that "FIG. 4 shows an implantable lead embodiment, and FIG. 5 shows a cross section of the implantable lead in FIG. 4. An implantable lead with improved conductor lumens comprises a lead body 32, a stylet lumen 100, at least one conductor lumen 102, and at least one axial slit 42." Ex. 1005, [0028]. Figures 4 and 5 of Stolz are shown below for convenience:

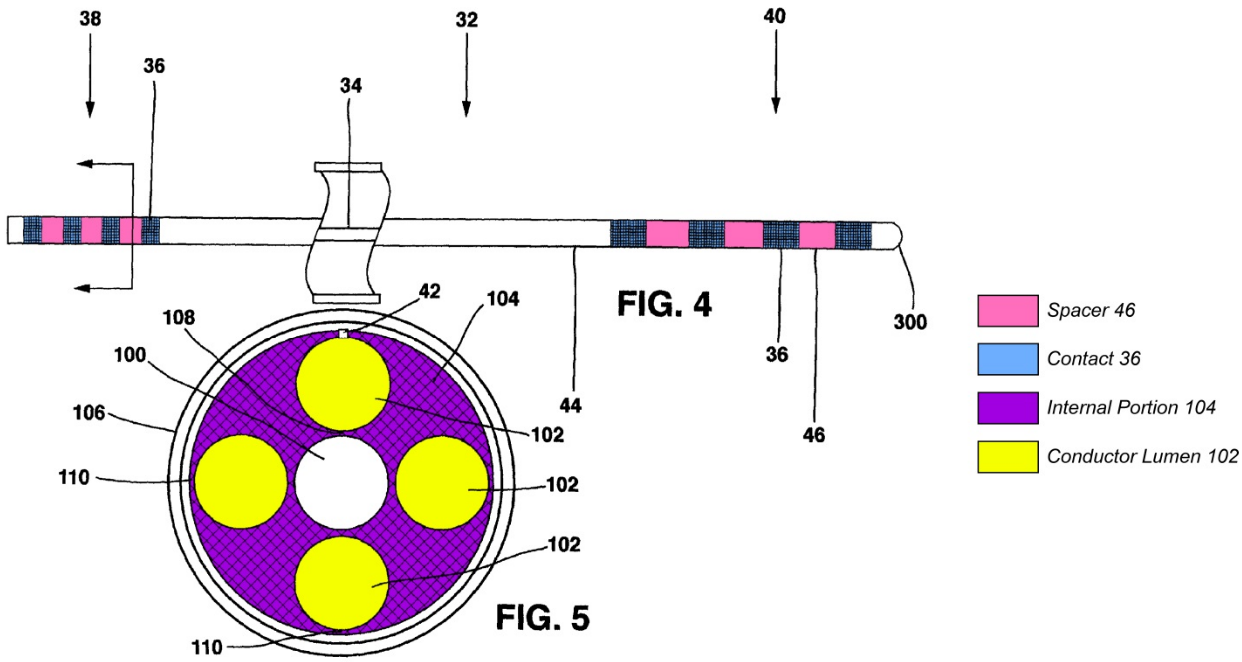


FIG. 4

FIG. 5

Thus, Stolz discloses the plurality of electrically conductive contacts and the spacers form a substantially cylindrical body and wherein the conductor lumens are defined within the substantially cylindrical body. Ex. 1003, ¶¶220-221.

N. Claim 17

1. "The method of claim 1,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "wherein the monofilament is disposed in an orientation parallel to the conductor wires."

As discussed above in the context of claim 1, a POSA considering Stolz, in view of the teachings of Ormsby and Black, would have modified Stolz by inserting a monofilament into at least one portion of the conductor lumens not occupied by the conductor to fill the lumen void and obtain well-known benefits. *See, e.g.*, Ex. 1003, ¶¶140–161, 222-224.

Stolz's conductors run inside its conductor lumens. *Id.* As an extension of these features, because the monofilaments that would be present in Stolz's modified method would also run inside the conductor lumens, monofilament *must* be disposed in an orientation parallel to the conductor wires 34. *See id.* There is simply no other logical way for a POSA to produce such a structure, or effect such a placement of monofilament in the conductor lumen. *See id.*, ¶224.

Thus, Stolz, as modified by a POSA in view of Ormsby, and Black render obvious the feature of disposing monofilament (in the modified method) in an orientation parallel to the conductor wires. *Id.*, ¶225.

VII. Ground 2: The combination of Stolz, Ormsby, Black, and the knowledge of a POSA, further in view of the Modern Plastics Encyclopedia, renders obvious claims 4, 5, and 13 of the '085 patent.

Claims 4, 5, and 13 depend from independent claim 1 and further define details of the temperature applied, along with the duration of application, in the step where heat is applied to reflow the spacers or monofilament. Those dependent claims require that the heat applied is between about 140 to 250 degrees Celsius (claim 4), the heat is applied for between about 15 to 120 seconds (claim 5), and that heat applied is about 160 degrees Celsius for about 40 seconds (claim 13).

Generally, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 269-271 (C.C.P.A. 1976); *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990). Moreover, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955). In *Aller*, for example, the claimed process was performed at a temperature between 40 degrees Celsius and 80 degrees Celsius and an acid concentration between 25% and 70%. The Court found that teaching sufficient show *prima facie* obviousness over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100 degrees Celsius and an acid concentration of 10%.

Further, as a POSA would readily recognize, the process of melting or thermally reflowing a thermoplastic material is affected by variables other than time and temperature, such as where and how the heat is applied, the thickness through which heat must penetrate, whether and how much pressure is applied, environmental temperatures, etc. *See, e.g.*, Ex. 1003, ¶¶226-228. The '085 patent appears to appreciate these additional factors, stating particularly wide ranges, and leaving it to a POSA to experiment within these ranges in producing a completed lead. *See id.* For this reason, "[t]he law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff* at 1578; *see also In re Aller* at 456.

Here, the '085 patent specification does not ascribe any criticality to the claimed temperature and time ranges. It does not describe any unexpected results, nor does it describe any difficulty in arriving at the claimed ranges. The '085 patent also does not define the relative qualifier "about." This does not matter, however, at least because at the time of the alleged invention, a POSA would have understood that the level of heat applied along with the duration of its application varies when utilizing thermal methods, and varies depending upon the physical properties desired (e.g., tensile strength, resilience, etc.), and is driven by the dimensional qualities of the leads, varying the type of thermoplastic or other material used, etc. *See* Ex. 1003, ¶229.

Nevro's expert testimony finds support in "The Modern Plastics Encyclopedia," which discloses several temperature ranges for a glass transition (e.g., reflowing) for several polymers, including polyurethane. *See* Ex. 1010 at 3;

see also Ex. 1003, ¶¶106-107, 230-239. For example, polyurethane thermoplastics may melt or reflow in a range of between about 120 and 160 degrees Celsius. Ex. 1010, p. 3.

A POSA would thus appreciate that these ranges are determined through standardized testing processes. *See* Ex. 1003, ¶¶230-241. For example, one such testing process uses a polymer specimen of standardized dimensions, and determines the ranges for glass transition temperature/reflow temperature/melt temperature based upon measurements of the properties of the plastic while under known temperature conditions. *Id.* Optimizing such result effective variables provides the motivation for modification. *See, e.g., In re Antonie,* 559 F.2d 618, 195 USPQ 6 (C.C.P.A. 1977).

These ranges are well documented by polymer manufacturers and suppliers, and are not surprising. Ex. 1003, ¶¶230-241. A POSA designing a manufacturing process with such a material would have been well equipped based on prior designs to select an appropriate temperature range, time the heat is applied, whether pressure should be applied by a heat shrink tubing, etc., based on component part dimensions/thicknesses and material selection. *Id.* A POSA would have therefore appreciated that the transition of thermoplastic polymers, such as polyurethane, is a spectrum where a given amount of material under applied heat may either reflow or melt depending in part on the level of temperature applied and the elapsed time it is applied. *Id.*

As such, the features related to the temperature applied along with the duration of application in the method of manufacturing the lead produced by the methods of the claims of the ’085 patent would have been obvious to a POSA. *Id.*

A. Claim 4

1. “The method of claim 3,”

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. “wherein the heat applied is between about 140 to 250 degrees Celsius.”

Although Stolz does not expressly disclose the temperature of heat applied, as described above, it did not need to because, as described, it would have been well within the skill of the POSA to figure it out. It is known that factors such as temperature and time applied affects the thermal process depending upon a given material. *See* Ex. 1003, ¶¶226–244. For example, the Modern Plastics Encyclopedia teaches several ranges for a glass transition (e.g., reflowing) temperature for several polymers. Ex. 1010, p. 0003; *see also* Ex. 1003, ¶239. More specifically, Modern Plastics Encyclopedia teaches that polyurethane thermoplastics have a glass transition temperature range of between about 120 and 160 degrees Celsius, overlapping with the claimed temperature range with reasonable specificity. Ex. 1010, p. 0003. The selection of these parameters was thus known, and a POSA would have looked to the Modern Plastics Encyclopedia as a reference for selecting the claimed process temperatures. Ex. 1003, ¶239.

The ’085 patent does not indicate that the selection of temperature was in any way special. *Id.* For example, the specification explains that thermal processing may be accomplished by either reflowing or melting. *See, e.g.*, Ex. 1001, 6:27–39; *see also* Ex. 1003, ¶239. This reinforces that the selection of these parameters was known. Ex. 1003, ¶240.

Thus, it would have been obvious for one of ordinary skill in the art to determine the amount of heat needed to optimize either melting or reflowing of the spacers or monofilament and temperature applied. *Id.*, ¶241.

B. Claim 5

1. “The method of claim 4,”

As discussed above, the combination of Stolz, Ormsby, Black, the knowledge of a POSA, and the Modern Plastics Encyclopedia disclose and render obvious this limitation.

2. “wherein the heat is applied for between about 15 to 120 seconds.”

Although Stolz does not expressly disclose the time that heat is applied, this feature would have been obvious to a POSA in view of the material filling options described above. Ex. 1003, ¶¶242-249. It is generally well-known that factors such as temperature and time impact the thermal process depending upon a given material. *Id.* Nevro's expert confirms that the temperature required to thermally reflow or melt something varies depending on factors such as time and material used. Ex. 1003, ¶244.

Specifically, Nevro's expert confirms that the transition of thermoplastic polymers, such as polyurethane, is a spectrum where a given amount of material under applied heat may either reflow or melt depending in part on the temperature applied and the elapsed time it is applied. *Id.*, ¶245. The Modern Plastics Encyclopedia supports this knowledge, in supplying a glass transition temperature range of polyurethane between about 120 and 160 degrees Celsius, which reinforces that the selection of these parameters was known. Ex. 1010, p. 3; *see also* Ex. 1003, ¶¶244-248.

Thus, a POSA would have looked to the Modern Plastics Encyclopedia as a reference for selecting process temperatures and optimizing the time the heat would be applied based on the knowledge that the effect of heat flow along a distance increases as time elapses. *See, e.g.*, Ex. 1003, ¶246.

Moreover, as Nevro's expert explains, POSA would have also appreciated that heat transfer principles, such as Fourier's Law, which states that the time rate of heat transfer through a material is proportional to the negative gradient in the temperature and to the area. *Id.*, ¶247. Fourier's Law also states that depending on the temperature gradient the rate of heat transfer would vary through the material. *Id.* Given these known physical principles, a POSA would have reasonably expected success at the claimed range of 15-120 seconds due at least to the standardized measurements of the ranges, component configuration and assembly, and the known parameters. *Id.*; *see also* Ex. 1015, 3:9–32; 5:53–66; 6:25–30.

As with dependent claim 4, the specification of the ’085 patent does not indicate that the selection of temperature or time was in any way special. Indeed, the specification explains that thermal processing may be accomplished by reflowing or melting either spacers or monofilament, which reinforces that the selection of these parameters was known. *See, e.g.*, Ex. 1001, 6:27–39; Ex. 1003, ¶248.

Thus, it would have been obvious for one of ordinary skill in the art to determine the amount of time needed to apply the heat in order to optimize the thermal bonding of the assembly. Ex. 1003, ¶249.

C. Claim 13

1. “The method of claim 5,”

As discussed above, the combination of Stolz, Ormsby, Black, the knowledge of a POSA, and the Modern Plastics Encyclopedia disclose and render obvious this limitation.

2. "wherein the heat applied is about 160 degrees Celsius for about 40 seconds."

This feature would have been obvious to a POSA for at least the same reasons discussed above with reference to claims 4 and 5, discussed *supra*. *See* Ex. 1003, ¶¶250-251. Moreover, "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955). The '085 patent specification does ascribe any particular important to the temperature or time limitations set forth in dependent claim 5.

VIII. Ground 3: The combination of Stolz, Ormsby, Black, and the knowledge of a POSA, further in view of Wessman, render obvious claim 18 of the '085 patent.

Dependent claim 18 additionally defines a lead produced by claim 1 using heat shrink tubing around the spacers, conductive contacts, and monofilament. The heat shrink tubing is then removed after reflowing at least one of the spacers or monofilament. A POSA would have understood that by January 2005, use of heat shrink tubing was well-known to facilitate heat bonding processes. Ex. 1003, ¶¶102-105, 252.

A. Claim 18

1. "The method of claim 1,"

As discussed above, the combination of Stolz, Ormsby, Black, and the knowledge of a POSA disclose and render obvious this limitation.

2. "placing a heat shrink tubing around the spacers, conductive contacts, and monofilament and removing the heat shrink tubing after reflowing at least one of the spacers or monofilament."

While Stolz , Ormsby, and Black do not expressly disclose use of heat shrink tubing, their combination with Wessman (Ex. 1009) renders such features obvious. Wessman, like Stolz and Black, is directed to a method for lead body manufacture. Ex. 1009, Abstract; *see also* Ex. 1003, ¶¶253-255. Specifically, Wessman discloses a lead body having at least one conductor positioned between an inner insulator and an outer insulator wherein the outer insulator is fused to the inner insulator by heating. Ex. 1009, Abstract.

Further, Wessman teaches that to fuse the materials, a shrink-wrap, a vacuum or other method may be used. *Id.*, [0021], [0024]. Specifically, a shrink-wrap material is disposed about the outermost layer of insulating material, and the entire assembly is then heated to shrink the shrink-wrap and reflow the insulating material sufficiently to facilitate fusing of the inner insulating material with the outer insulating material, or alternatively between the insulator layers and the non-conductive spacer. *Id.*; *see also* Ex. 1003, ¶256. After heating, the assembly is typically allowed to cool before the shrink-wrap material and the mandrel are removed. Ex. 1009, [0021], [0024]; *see also* Ex. 1003, ¶257.

Using a heat shrink tube in view of Stolz (as modified) would have been obvious to a POSA, at least because the heat shrink material would have been useful to secure the components together during the thermal fusing. Ex. 1003, ¶258. Further, A POSA would have been motivated to take advantage of this type of method in view of the reflowing of the spacers, as suggested in Black. *Id.* These processes operate based on the same principles—namely, material joining by applying heat. *Id.*, ¶259.

To be more specific, a POSA would have appreciated the benefits of using heat shrink tubing with Black's spacers, which have larger initial diameters, because the pressure imparted by the heat shrink tubing would effectively squeeze the melted or reflowed material inward, promoting the more substantially isodiametric lead desired by Stolz, but with the requirement for fewer post-processing steps. Ex. 1003, ¶259; *see also* discussion of claim 6, *supra*. For the same reasons, a POSA would have appreciated that the method would be successful, especially for reflowing at least one of the spacers or monofilament into a portion of at least one of the conductor lumens while the assembly is held in place during the thermal process. *See* Ex. 1003, ¶259.

Thus, a person of ordinary skill in the art would have had a reason to use Wessman's heat shrink tubing, and to remove it in order to expose the electrode contacts after final assembly, due to the interchangability and processing techniques taught by Stolz, Ormsby, and Black, in view of Wessman. *Id.*, ¶260.

IX. Ground 4: The combination of Stolz, Ormsby, Black, the knowledge of a POSA, and Wessman, further in view of Saab, render obvious claim 19 of the ’085 patent.

Dependent claim 19 additionally defines a lead that is produced by claim 18, and further requires that the heat shrink tubing be made from a material selected from the group consisting of PTFE or polyester heat shrink material. This would have been obvious to a POSA by January 2005.

A. Claim 19

1. “The method of claim 18,”

As discussed above, the combination of Stolz, Ormsby, Black, the knowledge of a POSA, and Wessman disclose this limitation.

2. “wherein the heat shrink tubing is made from a material selected from the group consisting of PTFE or polyester heat shrink material.”

Saab confirms that it was well known during the relevant timeframe that PTFE and polyesters such as PET were common materials for heat shrink material in medical device applications. Ex. 1011, pp. 3-11; *see also* Ex. 1003, ¶¶108-109, 261-263. As discussed above, Saab gives details related to various uses of heat-shrink tubing in medical devices including catheters, bundling of components, tube joining and transitioning, tip forming, *etc*. *See* Ex. 1011, pp. 3-11. Additionally, Saab gives common types of shrink tubing used in medical device manufacturing operations including reflowing components together, such as polyolefin, fluropolymers such as PTFE, polyvinyl chloride (PVC), and polyester (such as polyethylene terephthalate (PET)). *Id.*, Ex. 1003, ¶264.

More specifically, Saab specifically describes advantages in utilizing polyester as a heat shrink tubing material, such as high tensile strength, superior flex-fatigue properties, and a relatively low shrink temperature of about 85 degrees Celsius to about 190 degrees Celsius. Ex. 1011, pp. 3-11. Thus, in selecting a material to use in a heat shrink operation, a POSA would have looked to Saab, for example, to aid in known material selection. Ex. 1003, ¶¶263-267. A POSA would have known to use any of the mentioned materials, including PTFE or polyester heat shrink material, based on the discussion by Saab. *Id.*

Thus, it would have been obvious to one of ordinary skill in the art at the time of the alleged invention to make the heat shrink tubing from PTFE or polyester (such as PET). *Id.*

X. Nevro is unaware of any secondary considerations of non-obviousness

It is BSNC's affirmative burden to come forth with evidence of secondary indicia of non-obviousness as to the claims of the '085 patent. Nevro is not aware of any such evidence or information that could have any nexus to the claims of the '085 patent. Ex. 1003, ¶¶268-270. Nevro, however, reserves its right to respond to any assertion of secondary indicia of non-obviousness advanced by BSNC.

XI. Standing (37 C.F.R. § 42.104(a))

Nevro certifies that the ’085 patent is available for *inter partes* review, and that Nevro is not barred or estopped from requesting an *inter partes* review of the ’085 patent.

The assignee of the ’085 patent, BSNC, filed and served a complaint against Nevro in the District of Delaware (case no. 1:16-cv-01163) on **December 9, 2016**, alleging infringement of the ’085 patent. The present petition is being filed within one year of Nevro being served with the complaint.

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

A. Real Party In Interest

The real party-in-interest of this petition is Nevro Corp.

B. Related Matters

The ’085 patent is the subject of one civil action: *Boston Scientific Corporation et al. v. Nevro Corp.*, Case No. 1:16-cv-01163 (D.E.D.), filed December 9, 2016. Nevro has filed several other IPR petitions on other patents involved in that suit, including: IPR2017-01811 and IPR2017-01812, challenging the claims of U.S. Patent No. 6,895,280, filed July 21, 2017; IPR2017-01920, also challenging the claims of the ’280 patent, filed August 11, 2017; IPR2017-01831, challenging the claims of U.S. Patent No. 7,437,193, filed July 21, 2017; and

IPR2017-01899, challenging the claims of U.S. Patent No. 7,587,241, filed July 31, 2017.

C. Lead and Back-up Counsel

Pursuant to 37 C.F.R. § 42.8(b)(3) and 42.10(a), Petitioner Nevro appoints the following counsel:

Jon E. Wright (Reg. No. 50,720, jwright-PTAB@skgf.com) as its lead counsel; and **Richard D. Coller III** (Reg. No. 60,390, rcoller-PTAB@skgf.com), **Ian Soule** (Reg. No. 74,290, isoule-PTAB@skgf.com), and **Nirav Desai** (Reg. No. 69,105, ndesai-PTAB@skgf.com), as its back-up counsel, all at the address: STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C., 1100 New York Avenue, N.W., Washington, D.C., 20005, phone number (202) 371-2600, and facsimile (202) 371-2540.

Additional back-up counsel include:

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Benjamin H. Huh (Reg. No. 61,207, bhuh@sidley.com, 202-736-8342), at the address: Sidley Austin LLP, 1501 K Street N.W., Washington, DC 20005.

D. Service Information

Petitioner consents to electronic service by email at:

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Respectfully submitted,
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Jon E. Wright/

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Date: November 2, 2017

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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

The undersigned hereby certifies that on November 2, 2017, true and correct copies of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,891,085**, Petitioner's Power of Attorney, and all associated exhibits were served in their entireties on the following parties via FedEx Express® or Express Mail:

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This Petition complies with the type-volume limitation of 14,000 words, comprising 13,997 words, excluding the parts exempted by 37 C.F.R. § 42.24(a).

2. This Petition complies with the general format requirements of 37 C.F.R. § 42.6(a) and has been prepared using Microsoft® Word 2010 in 14 point Times New Roman.

Respectfully submitted,

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Date: November 2, 2017

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