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. 8,646,172

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Petitioner Nevro Corporation ("Nevro") requests *inter partes* review of claims 1-11 of U.S. Patent No. 8,646,172[1] ("the '172 patent") (Ex. 1001), which is assigned to Boston Scientific Neuromodulation Corporation ("BSNC").

I. Introduction

The independent claims of the '172 patent are directed to a "method of manufacturing a stimulation lead"—namely, an implantable lead that provides electrical stimulation therapy. In its most basic form, the stimulation lead described in the '172 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. A plurality of conductive wires run the length of the lead body to couple the proximal end contacts to their corresponding distal end electrodes. 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

[1] The '172 patent issued from an application filed January 25, 2011 and was thus filed 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.

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.

Part of this basic and well-known structure is set forth by the method of the ’172 patent’s independent claim 1:

> 1. A method of manufacturing a stimulation lead comprising:
>
> [a] providing a lead body comprising an insulation section, the insulation section defining a central lumen extending along the insulation section and a plurality of conductor lumens extending along the insulation section and arranged around, and external to, the central lumen,
>
> [a1] the lead body further comprising a plurality of conductive contacts located along an axial end of the lead body, and a plurality of conductor wires,
>
> [a2] wherein each of the conductor wires is disposed within one of the plurality of conductor lumens and each of the conductor lumens of the plurality of conductor lumens has at least one of the conductor wires of the plurality of conductor wires disposed therein,
>
> [a3] wherein a portion of the conductor lumens is disposed radially beneath the conductive contacts;
>
> [b] after providing the lead body, conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts;…

Ex. 1001, the ’172 patent, at 8:20-39.

The last step [c] of claim 1 of the ’172 patent, focuses very narrowly on placing non-conductive material into at least a portion of one of the conductor lumens. The last element of claim 1 is reproduced below:

> [c] after providing the lead body, placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed radially beneath the conductive contacts.

Ex. 1001 at 8:40-44.

Independent claim 6 adds only the step [d] of heating the non-conductive material at a temperature and time range to cause the non-conductive material to thermally reflow or melt. Claim 6 is reproduced for convenience below:

> 6. A method of manufacturing a stimulation lead comprising;
>
> [a] providing a lead body comprising a [sic] insulation section, the insulation section defining a central lumen extending along the insulation section and a plurality of conductor lumens extending along the insulation section and arranged around, and external to, the central lumen,
>
> [a1] the lead body further comprising a plurality of conductive contacts located along an axial end of the lead body, and a plurality of conductor wires,
>
> [a2] wherein each of the conductor wires is disposed within one of the plurality of conductor lumens and each of the conductor lumens of the plurality of conductor lumens has at least one of the conductor wires of the plurality of conductor wires disposed therein,

> [a3] wherein a portion of the conductor lumens is disposed radially beneath the conductive contacts;
>
> [b] after providing the lead body, conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts;
>
> [c] after providing the lead body, placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed radially beneath the conductive contacts; and
>
> [d] after placing the non-conductive material, heating the non-conductive material at a temperature in a range of 140 to 250 degrees Celsius for a period in a range of 15 to 120 seconds to cause the non-conductive material to thermally reflow or melt.

Ex. 1001 at 8:61-10:3.

* * *

By January 11, 2005 (the earliest possible priority date for the ’172 patent), the field of implantable leads for providing electrical stimulation to a body was already mature. Ex. 1003, Declaration of Michael Plishka, ¶¶1-33. Many prior-art implantable leads at that time had the exact same basic structure recited in independent claims 1 and 6 of the ’172 patent, including the conductor lumen structure that the patentee relied upon to distinguish the primary Black reference during prosecution. The claimed features, including the conductor lumen configuration, is readily seen in the Stolz reference. *See e.g.*, Ex. 1005, Stolz at FIGs. 4-5.

Moreover, the benefits of filling empty spaces in in an implantable lead, such as an empty conductor lumen, were also well-known in the prior art. Indeed, Stolz itself heats and reflows thermoplastic material from its distal tip into an empty portions of its conductor lumens. Ex. 1005, [0035], [0036], [0046]. Stolz also discusses filling an isolation space below its contacts with epoxy. *Id.* at [0046]. Further, the Ormsby reference teaches why it is beneficial to fill empty conductor lumens, *see e.g.*, Ex. 1006, Ormsby at 7:3-10, while the Black reference teaches the specific technique of reflowing a spacer, for example, into the spaces of a conductor lumen beneath a contact, Ex. 1008, Black at 7:12-24. Finally, the time and temperature features of independent claim 6 would have been obvious to a person of ordinary skill in the art, as confirmed by the Modern Plastics Encyclopedia, Ex. 1010, and Nevro's expert, Ex. 1003.

Nevro will thus prove in the Petition below that the '172 patent claims are nothing more than an incremental and obvious modification to well-known prior art stimulation leads, and their manufacturing techniques, available by January 2005.

II. Statement of Unpatentability Grounds for Claims 1-11 of the ’172 Patent

Nevro requests *inter partes* review of claims 1-11 of the ’172 patent and a determination that those claims are unpatentable based on the following ground:

Ground	Prior Art	Basis	Claims Challenged
1	Stolz, Ormsby, and Black	§ 103	1-5
2	Stolz, Ormbsy, and Black, further in view of the Modern Plastics Encyclopedia	§ 103	6-11 (time and temperature parameters for reflowing thermoplastic material)

The earliest possible priority date on the face of the ’172 patent is January 11, 2005. The prior art references cited for the ground above qualify as prior art to the ’172 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 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*. qualifies as 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.

- 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.

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. If given the benefit of the earliest possible priority date on the face of the '172 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 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 ’172 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, ¶¶17-20.

IV. Claim Construction

In considering the scope and meaning of the claims of an unexpired patent (such as the ’172 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 ’172 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 ’172 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 ’172 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, 1:36-40. This construction is consistent with the broadest reasonable interpretation of the claims of the ’172 patent.

If the patent owner BSNC asserts that any other claim term or phrase specifically requires construction for this proceeding, Nevro reserves the right to challenge such construction, if necessary. And if the Board believes, after reviewing the Petition or 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 '172 patent is indefinite or has a claim scope that differs from its broadest reasonable interpretation.[2]

V. Summary of the Unpatentability Argument for Independent Claim 6

The narrower independent claim 6 has every limitation of the broader independent claim 1. We thus summarize here Nevro's argument for why independent claim 6 is unpatentable under 35 U.S.C. § 103 over Stolz, Ormsby, and Black. The arguments apply equally 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 the unpatentability ground set forth in more detail below.

Stolz is the base reference. It discloses a stimulation lead having the same structure set forth in claim 1. Stolz teaches reflowing its distal tip into at least a

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[2] Specifically, the '172 patent is part of BSNC's civil action against Nevro for patent infringement. *See* Mandatory Notices, Section X.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.

portion of an unoccupied conductor lumen, and Stolz also discloses using epoxy to fill an isolation space beneath a contact.

To the extent that Stolz is missing an express teaching of "after providing the lead body, placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed radially beneath the conductive contacts," any gap is met with the Ormsby and Black references. Specifically, Ormsby (Ex. 1006) provides the motivation to modify Stolz to fill the unoccupied portions of the conductor lumens and thermally fusing the same to the lead body. And Black, which was considered during prosecution of the application which led to the '172 patent, teaches a specific technique of heating the spacers between the electrodes to reflow material into the spaces of a conductor lumen that is radially underneath a conductive contact, and thermally fusing the spacer material with the lead body—a teaching the Examiner did not appreciate at the time. The Modern Plastics Encyclopedia confirms that selecting particular ranges for temperature or time in reflowing or melting operations are well within the grasp of a POSA, as confirmed by Nevro's expert and supported by well-settled case law.

A. Overview of the '172 Patent

The '172 patent is generally directed to a method for manufacturing the lead portion 18 of an implantable system with a microstimulator 12. The lead portion has 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:

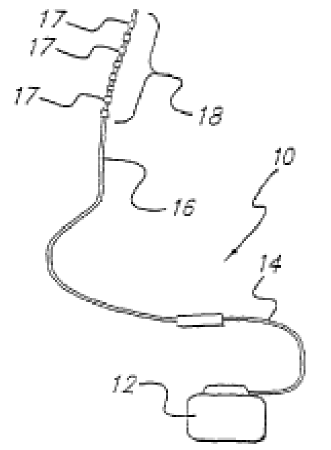

FIG. 1

Ex. 1001, FIG. 1; 3:46–57.

The microstimulator 12 and stimulation lead 16 are typically implanted in a body. *Id.*, 4:12–22. In one embodiment, it provides stimulation to a spine. *Id.*

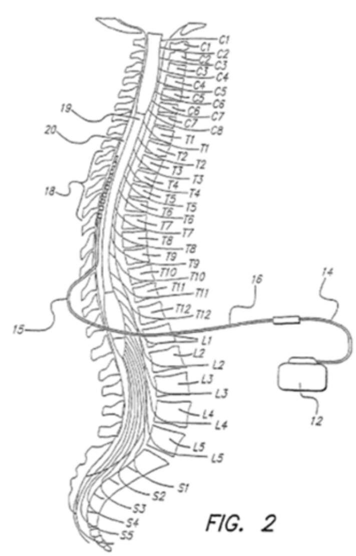

FIG. 2

Ex. 1001, FIG. 2.

Figures 3A, 5A, and 5B from the '172 patent, annotated below in color, show the basic structure of an implantable lead made by the claimed method:

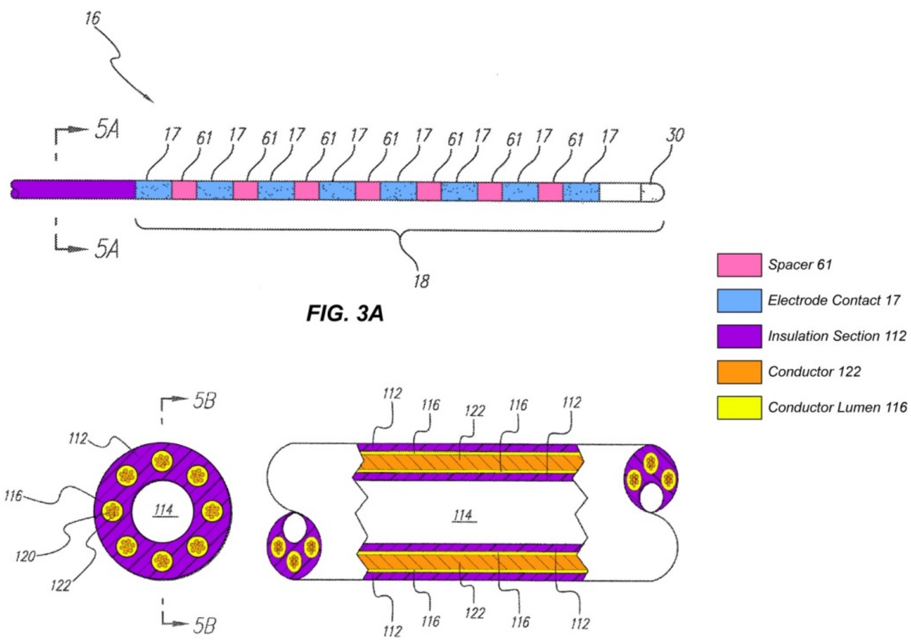

FIG. 3A

FIG. 5A FIG. 5B

Ex. 1001 at FIGS. 3A, 5A, and 5B (annotated); *See also* Ex. 1003, ¶¶27-40.

Figures 5A and 5B of the '172 patent show how the conductor lumens 116 (yellow) and conductors 122 (orange) are disposed in the stimulation lead body. Ex. 1001, 5:36-62. In the disclosed embodiment, the claimed stimulation lead 16 has an electrode array 18 (blue) at its distal end (*i.e.*, the end furthest from the signal generator). Ex. 1001, 4:12-66. The basic structural components are the conductor wires 122 (orange), the conductive contacts (*i.e.*, electrodes) 17 (blue), and the spacers 61 (pink) 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 116 (yellow) disposed along the length of the interior of the lead body. *See* Ex. 1003, ¶41.

The ’172 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 insulated multi-lumen tube body. For example, the described embodiment consists of placing 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. *See* Ex. 1001, 7:37-46.

The specific embodiment in Figures 6A and 6B of the ’172 patent illustrate both the structure and the steps of filling the void space where the conductors are coupled to an electrode contact.

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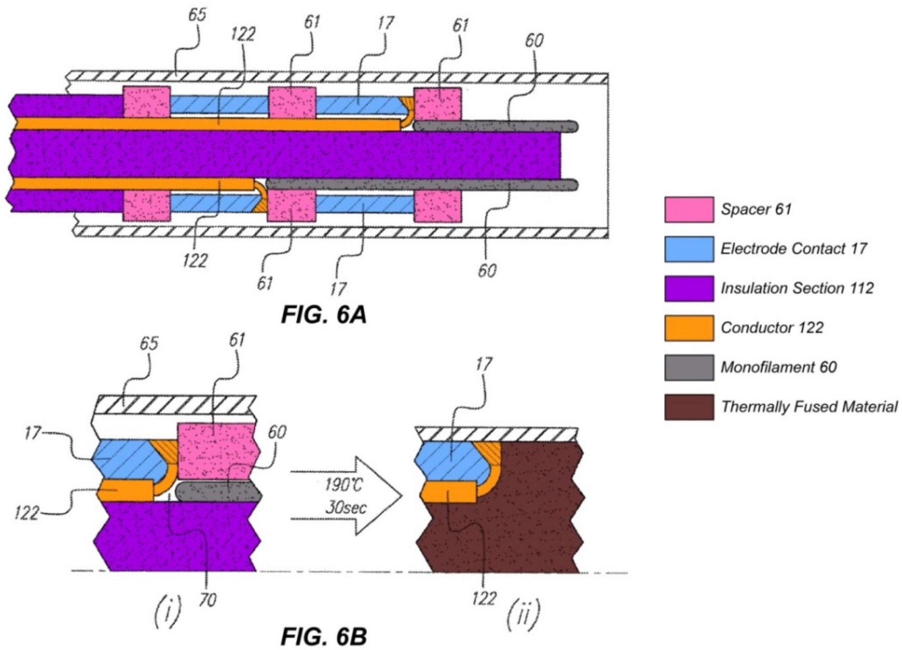
[3] In the district court litigation, the parties have agreed that the term conductor lumen be construed as “a hollow bore within the lead body for one or more conductor wires” and the term lead body as “an insulated, multi-lumen tube.” *See* Revised Final Joint Claim Chart filed October 6, 2017, *Boston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



Ex. 1001, FIGS. 6A and 6B (annotated); Ex. 1003, ¶¶41-51.

In the figures, monofilament 60 (which may be made from non-conductive material) 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, 6:14-47, *see also* Ex. 1003, ¶¶ 52-103.

Claim 1 of the ’172 patent is broader than the embodiment set forth in Figures 6A and 6B. For example, it does not require monofilament. All it requires is that some sort of “non-conductive material” is “placed” in “into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed radially beneath the conductive contacts.” Ex. 1001, 8:40-44. On its face, claim 1 puts no restrictions on *how* the non-conductive material is placed, nor does it require any heating of the non-conductive material.

Independent claim 6 is narrower than claim 1. It has the same structural features, but claim 6 further specifies the step of, after the non-conductive material is placed, heating the non-conductive material at a specific temperature range for a specific time, to cause the non-conductive material to thermally reflow or melt. This feature is obvious, incremental, and non-critical as discussed, *infra*.

The dependent claims cover additional obvious and incremental features. For example, dependent claim 2, restates the general reflowing step already discussed with reference to independent claim 6, but without any temperature or time specification. Dependent claims 3 and 8 further specify that the material fills the unoccupied portion of each of the conductor lumens, instead of only at least one. Dependent claims 4 and 9 further define spacers placed between pairs of adjacent conductive contacts. This feature is well known and disclosed by both Stolz and Black. Dependent claims 5 and 10 further specify that the heating of the non-conductive material and spacers cause them to thermally fuse together—which is obvious in view of the applied art. Dependent claim 7 further defines that there is exactly eight conductor lumens. This falls within a range that Stolz discloses. Finally, dependent claim 11 specifies that the non-conductive material comprises polyurethane, which is also disclosed and rendered obvious by the applied art. Material selection is obvious and the ’172 patent does not ascribe any importance or unexpected results to material selection.

B. The Prosecution History

The prosecution history is instructive. The last amendment made prior to allowance included the “radially beneath” descriptor along with the specification that each of the conductor wires is disposed within one of the conductor lumens. Ex. 1002, 53-57. The amendment was apparently made to satisfy the Examiner’s objection to the claim as being indefinite under § 112 and to overcome the prior art anticipation rejection based on U.S. Patent No. 6,249,708 to Nelson *et al. See* Ex. 1002 at 058. The features related to the particular time and temperature features were not substantively treated on the record, as they were rejoined from previously withdrawn claims at the time of the Notice of Allowance.

One of the primary prior art references during prosecution of the application that led to the ’172 patent was U.S. Patent No. 6,216,045 to Black *et al.* Ex. 1002 at 096-098. The other primary prior art reference used was U.S. Patent No. 6,249,708 to Nelson *et al. See* Ex. 1002 at 069-070.

The prosecution history reveals that to distinguish Black, the patentee focused primarily on the claimed lumen structure—namely, a central lumen surrounded by a plurality of conductor lumens disposed external to the central lumen. The patentee also focused on the step of placing the non-conductive material in at least one of the conductor lumens. Ex. 1002, 085-086. But as discussed below, Stolz discloses and renders obvious these features.

The secondary argument advanced by the patentee in the prosecution history that the applied art (namely Nelson) did not disclose non-conductive material in a portion of at least one of the conductor lumens, "disposed radially beneath the conductive contacts." But Stolz and the previously applied Black reference discloses such a feature, even if the Examiner did not appreciate the disclosure at that time. As discussed below, Stolz also discloses and renders obvious these features in combination with at least Black and Ormsby.

C. Independent Claim 6 is Unpatentable Over Stolz, Ormsby, and Black

Nevro first addresses the well-known steps of making a lead structure having the claimed features. It then addresses the incremental and obvious step of placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, where at least a portion of the non-conductive material is disposed radially beneath the conductive contacts, and further heating the non-conductive material in order to reflow or melt it.

1. The steps of manufacturing the stimulation lead assembly described by the ’172 patent claims were well-known by January 2005.

Claim 6 of the ’172 patent is a method of manufacturing a stimulation lead having the structure described above. The preamble and the elements [a]-[c], below, simply lay out a few of the most basic parts of a stimulation lead—namely, the lead body with conductor lumens, a plurality of contacts (*e.g.*, electrodes), and conductor wires:

> 6. A method of manufacturing a stimulation lead comprising;
> [a] providing a lead body comprising a [sic] insulation section, the insulation section defining a central lumen extending along the insulation section and a plurality of conductor lumens extending along the insulation section and arranged around, and external to, the central lumen,
>
> [a1] the lead body further comprising a plurality of conductive contacts located along an axial end of the lead body, and a plurality of conductor wires,
>
> [a2] wherein each of the conductor wires is disposed within one of the plurality of conductor lumens and each of the conductor lumens of the plurality of conductor lumens has at least one of the conductor wires of the plurality of conductor wires disposed therein,

[a3] wherein a portion of the conductor lumens is disposed radially beneath the conductive contacts;

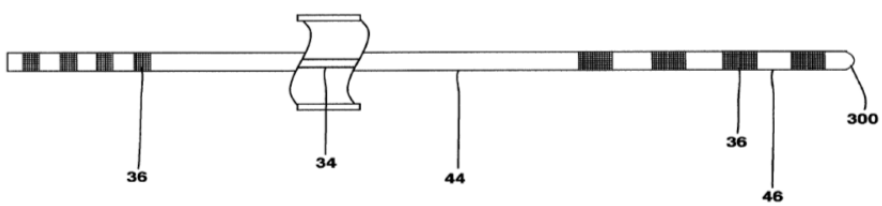
[b] after providing the lead body, conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts;

[c] after providing the lead body, placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed radially beneath the conductive contacts; and

[d] after placing the non-conductive material, heating the non-conductive material at a temperature in a range of 140 to 250 degrees Celsius for a period in a range of 15 to 120 seconds to cause the non-conductive material to thermally reflow or melt.

Ex. 1001 at 8:61-10:3.

Stolz discloses a stimulation lead with an identical arrangement of conductive contacts as claimed in the ’172 patent. Stolz’s Figure 3 is exemplary:



Stolz, FIG. 3.

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, ¶¶69-85. The distal end of the lead described in the ’172 patent is shown in Figure 3A below for comparison:

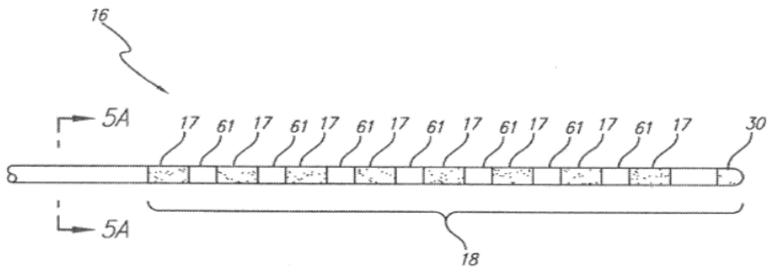


FIG. 3A

Ex. 1001, FIG. 3A. There is no material difference between the ’172 patent’s claimed lead and Stolz’s lead vis-à-vis the lead body and the conductive contacts.

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 Figure 5 is exemplary:

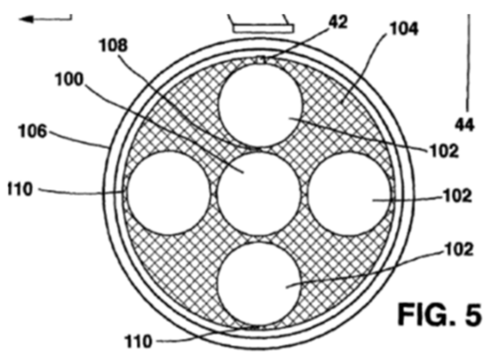
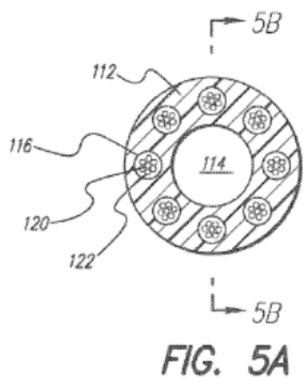


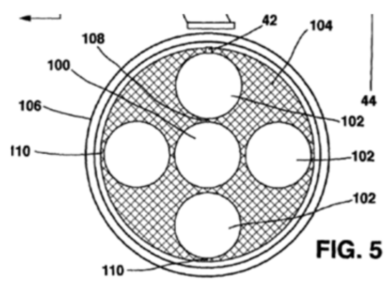
FIG. 5

Ex. 1005, FIG. 5.

In Stolz’s arrangement, a plurality of conductor lumens 102 are arranged around a central stylet lumen 100, just like the ’172 patent. Ex. 1005, [0028]-[0030]. And like the ’172 patent, Stolz’s conductors run through the plurality of conductor lumens to a point where they attach to their corresponding conductive contacts. *Id.* Thus, Stolz unambiguously fills the gap that the patentee alleged was missing from Black[4] 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 claimed by the '172 patent. This is readily seen by comparing the '172 patent's Figure 5A with Stolz's Figure 5 below.





'172 patent **Stolz**

Ex. 1001, FIG. 5A; Ex. 1005, FIG. 5. *See also* Ex. 1003, ¶ 73.

Stolz also discloses a plurality of conductor wires disposed in the conductor lumens as set forth in independent claim 1. Ex. 1005, [0026], [0028]-[0031],

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[4] In Black's arrangement (*see* Ex. 1008, FIG. 3), 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.

[0034], [0045], [0058], 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 '172 patent. *Id.*, [0026].

To summarize, Stolz discloses disposing a plurality of conductor wires in a plurality of conductor lumens formed in the lead body, with each of the conductor lumens having at least one of the conductor wires disposed therein. *See* Ex. 1003, ¶¶69-85.

* * *

Nevro now turns to the specific steps of disposing non-conductive material, radially underneath the contacts, and heating the non-conductive material to cause the non-conductive material to thermally reflow or melt.

2. Placing non-conductive material in empty portions of a conductor lumen, including radially beneath conductive contacts, and then heating and reflowing the non-conductive material would have been obvious by January 2005.

The final elements [d]-[f] in claim 6 are directed to placing non-conductive material into a portion of at least one of the conductor lumens, radially beneath the conductive contacts, and then heating the non-conductive material at a particular range of time and temperature to cause the non-conductive material to thermally reflow or melt. These claim features are reproduced below:

> [d] after providing the lead body, placing non-conductive material into a portion of at least one of the conductor lumens of the lead body,
> [e] wherein at least a portion of the non-conductive material is disposed radially beneath the conductive contacts; and
> [f] after placing the non-conductive material, heating the non-conductive material at a temperature in a range of 140 to 250 degrees Celsius for a period in a range of 15 to 120 seconds to cause the non-conductive material to thermally reflow or melt.

Ex. 1001, 9:15-10:3.

Stolz discloses most of what is recited in these steps. Ex. 1003, ¶¶104-105. Specifically, Stolz discloses heating a distal tip on the end of its lead, and reflowing non-conductive material (*e.g.*, silicone rubber, polyurethane, and fluoropolymers) from the distal tip into an unoccupied portion of the conductor lumen. Ex. 1005, [0035], [0036]; Ex. 1003, ¶ 106-107. A similar method may be used to form a proximal flare on the proximal end of its lead. Ex. 1005, [0032], [0033]; Ex. 1003, ¶ 106-107. Further, Stolz discloses that the isolation space 506, which is directly beneath each conductive contact, can include a "fill material," such as non-conductive epoxy. Ex. 1005, [0046], *see also* FIG. 13.

In Stolz, however, the material from the distal tip may not flow very far into the conductor lumens. Ex. 1003, ¶ 106. Stolz thus results in a stimulation lead where a substantial portion of at least some of its conductor lumens may be empty—especially for the conductor lumens that service the electrodes furthest from the distal end. *Id.* Ormsby and Black provide motivation to fill empty portions of a conductor lumen, including radially beneath the conductive contacts, and heating and reflowing the non-conductive material.

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, ¶¶ 104-111. 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; *see also* Ex. 1003 ¶¶86-90, 130-147. Ormsby also teaches various methods for filling a lumen, including with powder, liquid adhesive, epoxy, or resin. Ex. 1003, ¶¶ 86-90, 130-147. For these reasons, a POSA would have been motivated to modify Stolz to fill the unoccupied portions of its conductor lumens. Ex. 1003, ¶¶ 86-90, 130-147. A POSA would have also recognized that there are a finite and limited number of ways to fill a conductor lumen. Ex. 1003, ¶¶86-90, 130-147. Accordingly, a POSA and would have at least been motivated to try filling the space with one of powder (and subsequently reflowing the same), liquid adhesive, epoxy, or resin, as taught by Ormsby. *See* Ex. 1003, ¶¶ 86-90, 130-147.

Moreover, Black discloses a specific technique of heating, then reflowing solid, non-conductive lead elements, like a spacer, to fill lumen spaces. Ex. 1003, ¶¶94-101, 154. For 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 spaces in the conductor lumen. Ex. 1008, 7:12-15 (emphasis added). Black further discloses "an isodiametric lead is obtained, which is further free of any gaps or voids between insulative material and conductive material that may otherwise exist in conventional devices,"—*i.e.*, Black teaches complete filling of its conductor lumen space, and the space beneath the contacts. Ex 1008, 7:29-33.

The Examiner during prosecution did not appear to recognize the significance of Black's technique for filling spaces in the conductor lumen by heating and reflowing a spacer, and did not address those features during the rejoinder of claims containing such features. *See e.g.*, Ex. 1002 at 040. Nevro thus uses Black in a way that is different from the prosecution below.

Black's previously unappreciated technique of heating its non-conductive spacers so that they reflow into the space in its conductor lumen is directly applicable to Stolz in view of Ormsby's motivation to fill empty lumen spaces. And a POSA would have been expected to succeed in executing these steps. Ex.

1003 at ¶¶133-156; ¶¶187-202. Indeed, Stolz, Ormsby, and Black all indicate that the applicable techniques were well-known in the art.

Here, the ’172 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. 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 processing 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, ¶¶187-202.

Independent claim 1 is nearly identical, substantively, to independent claim 6, and is addressed, *infra* at Section VII.A.

* * *

This summary of Nevro’s unpatentability position for independent claim 6 of the ’172 patent provides context, background, and motivation for the detailed mapping of the prior art to all of the claims in the ’172 patent.

VI. Ground 1: The Combination of Stolz, Ormsby, and Black Renders Obvious Claims 1-5 of the ’172 Patent

A. Independent Claim 1

1. “a method of manufacturing a stimulation lead comprising”

Stolz describes a method of manufacturing 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].

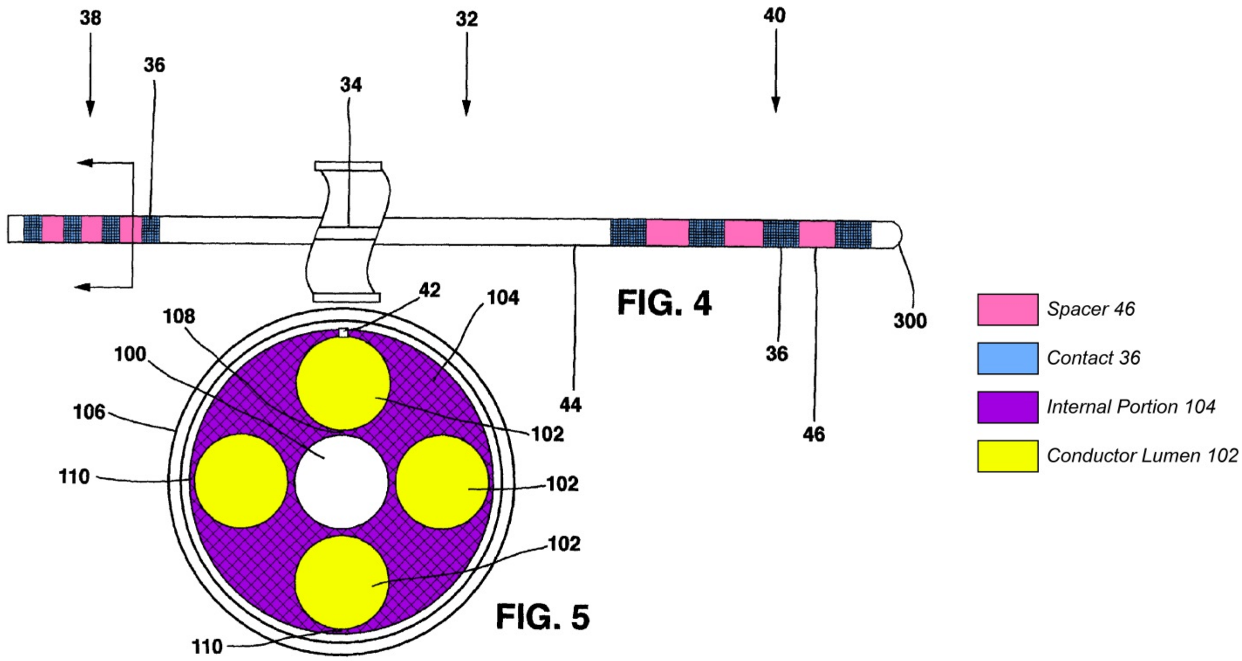
Thus, Stolz discloses a method of manufacturing a stimulation lead. *See* Ex. 1003, ¶¶112-115.

2. “providing a lead body comprising an insulation section, the insulation section defining a central lumen extending along the insulation section and a plurality of conductor lumens extending along the insulation section and arranged around, and external to, the central lumen,”

Stolz also shows a substantially cylindrical lead body with a central lumen and a plurality of conductor lumens. *See, e.g.*, Ex. 1005 at FIG. 12; *see also* Ex.

1003, ¶¶116-119. The conductor lumens 102 are shown within the substantially cylindrical body and disposed around a central lumen (*i.e.*, stylet lumen 100), and extend along the lead body as shown (e.g, in Stolz Figure 4). Ex. 1003, ¶116-119. Specifically, Stolz discloses that "the conductor lumens 102 electrically insulate each conductor 34 and physically separate each conductors [sic] 34 to facilitate identification of the conductor 34 that is appropriate for its single corresponding contact 36," the conductor lumens being formed in internal portion 104. Ex. 1005, [0029], [0039].

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 annotated below for convenience:



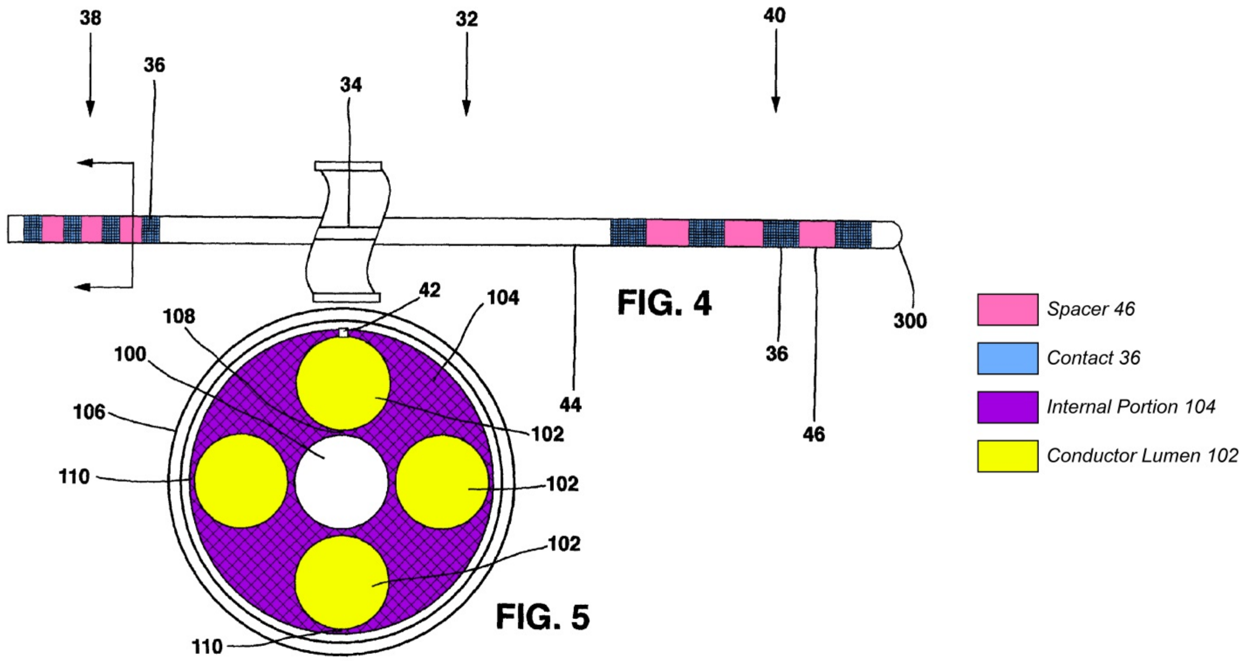
Ex. 1005 at FIGs. 4 and 5 (annotated).

Thus, Stolz unambiguously discloses a lead body 32 with an insulation section (*e.g.*, internal portion 104) defining a central, stylet lumen 100 extending along the lead body and insulation section, and a plurality of conductor lumens 102 extending along the lead body and insulation section and arranged around, and external to (*e.g.*, separate from) the central stylet lumen 100. Ex. 1003, ¶¶116-120.

3. "the lead body further comprising a plurality of conductive contacts located along an axial end of the lead body, and a plurality of conductor wires, wherein each of the conductor wires is disposed within one of the plurality of conductor lumens and each of the conductor lumens of the plurality of conductor lumens has at least one of the conductor wires of the plurality of conductor wires disposed therein, wherein a portion of the conductor lumens is disposed radially beneath the conductive contacts"

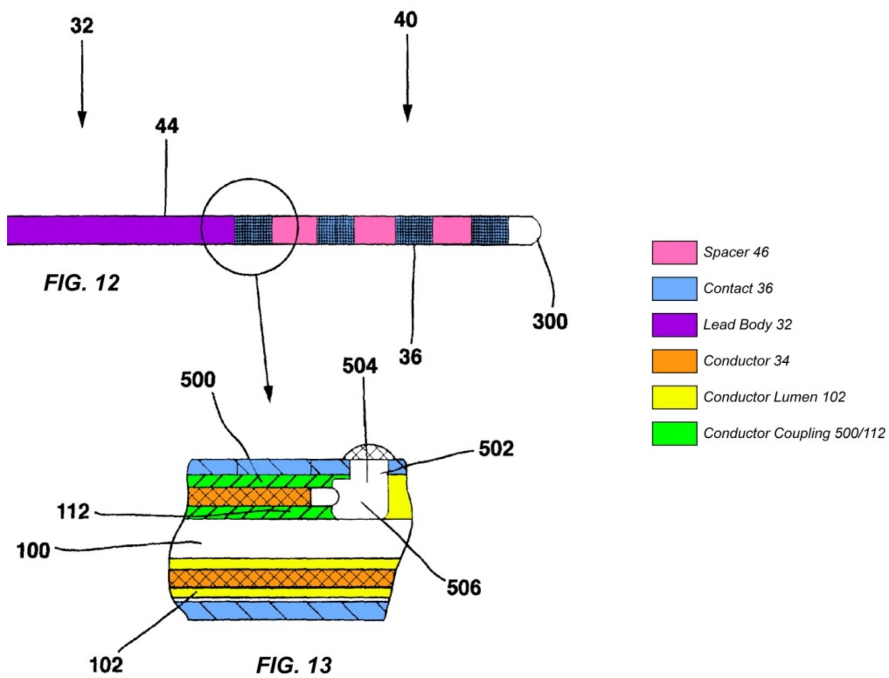
In the embodiment shown in the figures, Stolz provides four conductive contacts (*e.g.*, distal end electrodes) located along an axial end of the lead body. Ex. 1005, [0039], [0041], *see also* FIGS. 3, 12, and 13. Those contacts have corresponding conductive contacts on a proximal end. For example, Stolz discloses "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 Figures 4 and 5 are annotated below for convenience showing four contacts 36 on each of the proximal 38 and distal 40 end of lead body 32. Figure 5 shows a cross section of the implantable lead in Figure 4.



Ex. 1005 at FIGs. 4 and 5 (annotated).

As illustrated, Stolz's four conductor lumens 102 are formed in the internal portion 104 and positioned near an outer surface of the internal portion 104, with a web 110 between the conductor lumen 102 and the outer surface of internal portion 104. *Id.*, [0029]. Stolz's four conductor lumens are each designed to carry one of four conductors that electrically couple the distal end electrodes to the proximal end contacts. Ex. 1003, ¶¶121-125; *see* Ex. 1005, [0026], [0028]-[0031], [0034], [0045], [0059], FIGS. 1-15. Stolz's Figure 13, annotated below, shows a conductor 34 (orange) coupled to an electrical contact 36 (blue) via electrical coupling 112 in the conductor to conductor coupling 500/112 (green):

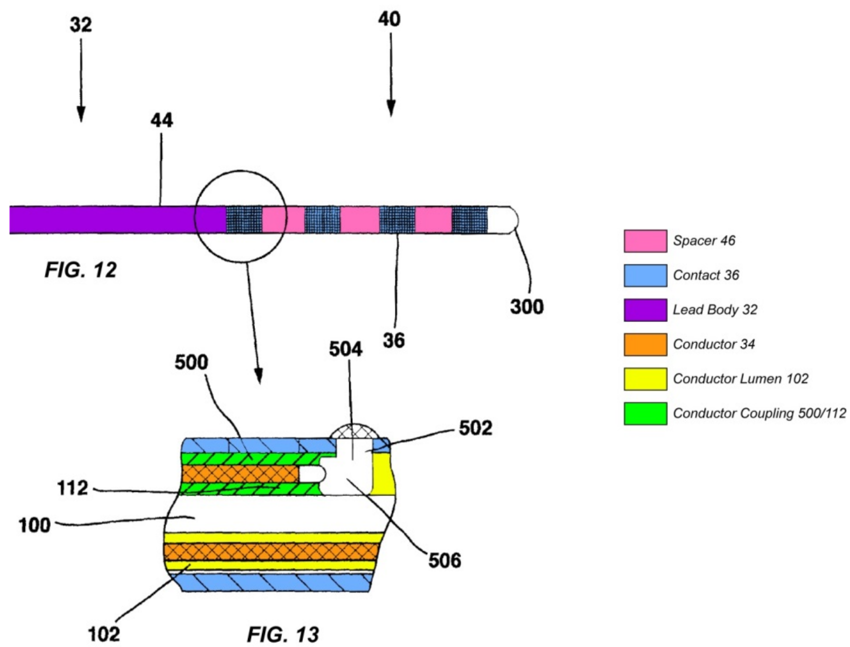


Ex. 1005, FIGs. 12 and 13 (annotated). Figure 13 shows a second conductor (orange) at the bottom that extends to the next conductive contact (*e.g.*, distal end electrode) as one moves towards the distal tip 300. Ex. 1003, ¶¶121-126. It is also clear that the conductor lumens 102 (yellow) are disposed radially underneath their respective conductive contacts (blue), on the outer surface of the lead. *See also* Ex. 1005, FIGS. 6-9; [0028] ("The stylet lumen 100 and conductor lumen 102 are formed in the internal portion 104. The internal portion 104 is a continuous material that has a proximal end 38 and a distal end 40…. This structure can be extruded and its configuration can be substantially the same at any longitudinal cross section.").

Thus Stolz discloses the lead body further comprising a plurality of conductive contacts located along an axial end of the lead body, and a plurality of conductor wires, wherein each of the conductor wires is disposed within one of the plurality of conductor lumens and each of the conductor lumens of the plurality of conductor lumens has at least one of the conductor wires of the plurality of conductor wires disposed therein, wherein a portion of the conductor lumens is disposed radially beneath the conductive contacts. *See* Ex. 1003, ¶¶121-127.

4. "after providing the lead body, conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts"

Stolz discloses electrically connecting the conductor wires to the each of the conductive contacts, after the lead body is provided. Ex. 1005 at [0026], [0028]-[0031], [0034], [0045], [0059], FIGS. 1-15. 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):



Ex. 1005, FIGs. 12 and 13 (annotated).

Stolz explains that "[t]he coupling 112 has a conductor coupling 500 and a contact coupling 502." Ex. 1005 at [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]. Stolz further 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, Stolz unambiguously discloses connecting the conductor wires to the conductive contacts, *after* the lead body is provided. *See* Ex. 1003, ¶¶128-133. Black also discloses this step. *See* Ex. 1008, 5:29-39, 6:56-65.

In a concurrent patent infringement suit in Delaware, the patent owner BSNC is construing the recited feature "conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts," as "connecting at least one conductor wire to one conductive contact, such that the conductive contacts are connected to the plurality of conductor wires."[5][6] For purposes of this

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

[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.

proceeding, Nevro does 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, ¶¶128-133; *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-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].

5. "after providing the lead body, placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed radially beneath the conductive contacts"

Stolz further discloses placing non-conductive material disposed in a conductor lumen 102 (*e.g.*, to seal it). Ex. 1005, [0025], [0032], [0035], [0036],

[0046]. Stolz thus fills, at least in part, an unoccupied portion of at least one of the conductor lumens. 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 solid 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]. This material may be a wide range of electrically isolative (*i.e.*, non-conductive) materials and configurations such as silicone rubber, polyurethane, fluoropolymers and the like. *Id.* [0025], [0032], [0035]. 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.

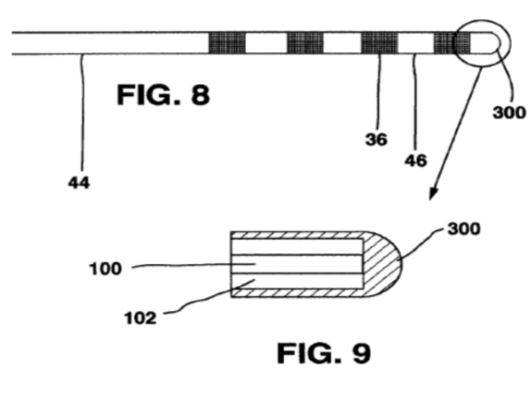
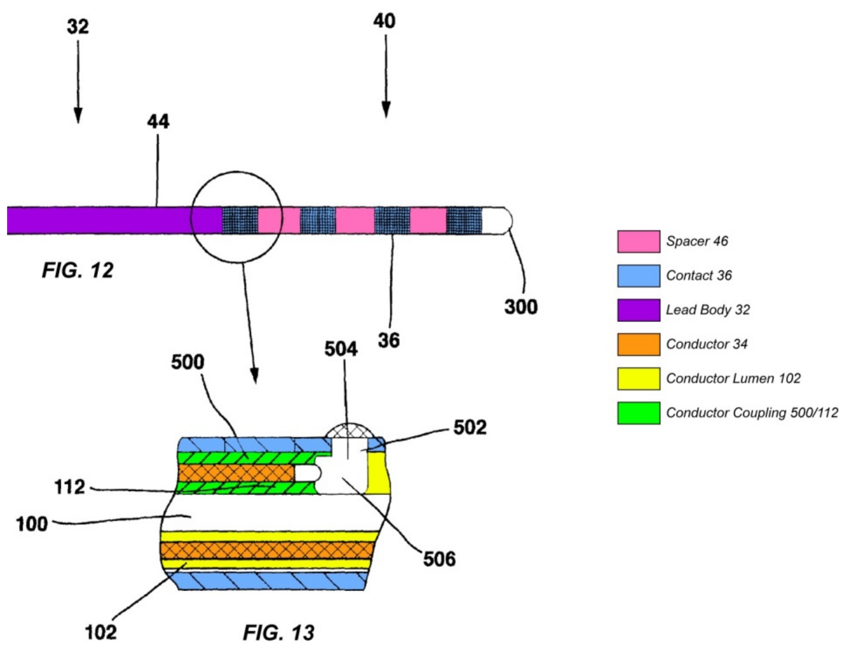


FIG. 9

Further, Stolz discloses that the isolation space 506 can include a "fill material" (such as epoxy)—which a POSA would have understood to be non-conductive Ex. 1003, ¶¶134-137—further filling an unoccupied portion of the conductor lumen that is radially beneath the conductive contacts. *Id.* [0046]. Stolz's Figure 13 annotated below shows the isolation space 506 is radially beneath Stolz's conductive contacts.



Ex. 1005 at FIGs. 12 and 13 (annotated).

Accordingly, Stolz discloses after the lead body is provided, "placing non-conductive material into a portion of at least one of the conductor lumens of the lead body." Stolz also discloses placing non-conductive material "wherein at least a portion of the non-conductive material is disposed radially beneath the conductive contacts."

However, Stolz's sealing the end of the implantable lead with its distal tip does have some potential disadvantages. Ex. 1003, ¶¶138-139. 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, ¶¶138-140.

By January 2005, however, 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, ¶142. 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 considered other medical device references to identify suitable methods for filling lumens and other spaces within elongate structures having conductive wires therein. Ormsby meets that need and confirms Nevro's expert's assertion that a POSA would have been motivated to fill the unoccupied lumen spaces. Ex. 1003, ¶¶141-151.

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

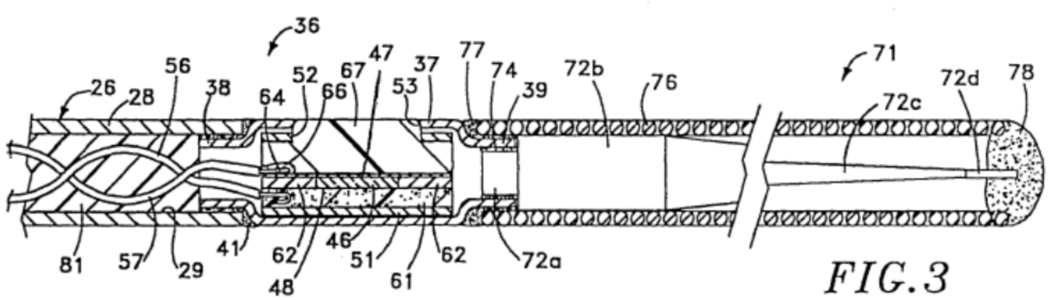


FIG.3

Ex. 1006 at 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 a similar benefit, as taught by Ormsby, of reducing the possibility of kinking in Stolz's lead, while also improving axial stability. *See* Ex. 1003, ¶144.

In addition to using epoxy to fill spaces in the lead body, which the '172 patent itself describes as a "prior method," Ex. 1001, 7:4-10, 57-67; 8:1-4, Ormsby discloses inserting other non-conductive materials like 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 at 7:3-10; *see also*, Ex. 1003 at ¶145. These methods increase "kink resistance." Ex. 1006 at 7:3-10; *see also*, Ex. 1003 at ¶145. They also facilitate formation of an isodiametric lead, which Stolz itself teaches is beneficial. Ex. 1003 at ¶145.

Black also discloses filling the unoccupied portion of a conductor lumen, and also the space beneath its conductive contacts, and it provides a different technique for doing so. *See* Ex. 1002, ¶¶152-157. Figure 3 illustrates Black's conductor lumen:

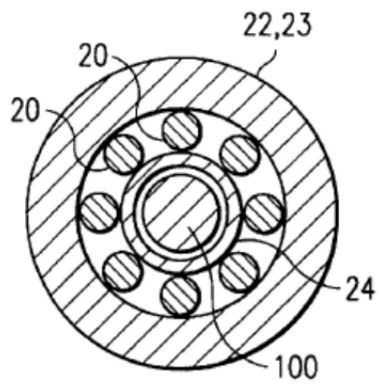


FIG. 3

Ex. 1008 at 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 spaces between the conductors at this stage of manufacture.

Black discloses the technique of heating, then reflowing non-conductive lead elements, like its spacers, to fill its empty space in the conductor lumen, and beneath the conductive contacts. Ex. 1008, 5:28-45, 6:5-10, 7:12–23. Specifically, 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 spaces in the conductor lumen. Ex. 1008, 7:13-16 (emphasis added). Black further discloses "an isodiametric lead is obtained, which is further free of any gaps or spaces between the insulative material and conductive material that may otherwise exist in conventional devices,"—*i.e.*, Black teaches complete filling of its conductor lumen space including beneath its conductive contacts. *Id.* at 7:29-33. As described above, Black uses spacers 28 that are disposed between electrodes 18.

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

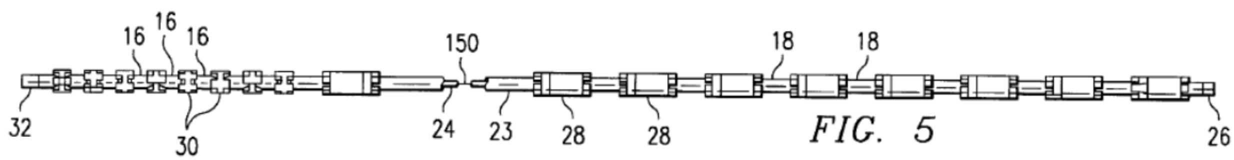


FIG. 5

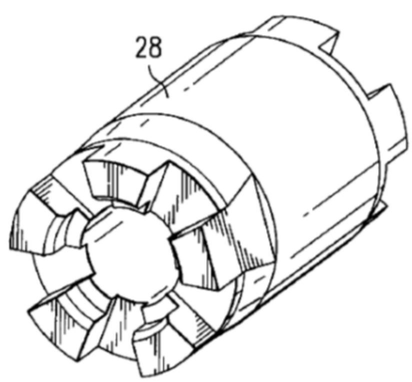


FIG. 7

Finally, a POSA would have recognized that there are a limited number of ways to fill a lumen. *See* Ex. 1003, ¶¶156-157. A POSA thus would have found it at least obvious to try and fill the lumen with a non-powder, solid material, as Ormsby describes, or to fill the lumen with reflowed, non-conductive spacer material, as Black describes, to determine the best of a limited number of options. *Id.* A POSA would have appreciated that these types of filling were known solutions in related arts, and would have had reasonable expectation of success. *Id.*

* * *

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, and the space radially beneath the conductive contacts that are unoccupied by the conductor wire to enhance the reliability of Stolz's stimulation lead. Ex. 1003, ¶¶156-157. Ormsby and Black confirm this. *Id.* Thus Stolz's stimulation lead, as modified by the above teachings of Ormsby, would disclose the method of manufacturing a stimulation lead that includes all of the steps as arranged in the claims of the '172 patent. *See* Ex. 1003, ¶¶156-157.

CONCLUSION FOR CLAIM 1

Stolz's stimulation lead 30, as modified by the teachings of Ormsby and Black, and as explained and confirmed by Nevro's expert, discloses and renders obvious the method of manufacturing a stimulation lead that includes all of the steps as arranged in independent claim 1 of the '172 patent *See generally*, Ex. 1003, ¶¶112-157.

B. Claim 2

1. "The method of claim 1"

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

2. "further comprising heating the non-conductive material to cause the non-conductive material to thermally reflow or melt"

The '172 patent specifically describes in an embodiment "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. *See, e.g.*, Ex. 1001, 6:31–67.

Stolz discloses thermally fusing at least the distal tip and proximal flare by 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]. Ormsby discloses inserting other non-conductive materials like liquid epoxy or resin that then hardens, or a polymer powder that may be melt formed or reflowed therein to form a non-powder solid polymer. Ex. 1006, 7:3-10; *see also*, Ex. 1003, ¶¶158-161. These methods increase "kink resistance." Ex. 1006, 7:3-10; *see also*, Ex. 1003, ¶161. They also facilitate formation of an isodiametric lead, which Stolz itself teaches is beneficial. Ex. 1003, ¶161. And the prior-art Black patent further emphasizes this feature, along with complete filling of the lumens and portions radially beneath the contacts with reflowed, non-conductive spacer material. *See* Ex. 1008 at 6:19-34, 7:5-23, 7:29-34; FIG. 5; Sections VI.A.4 and VI.A.5, *supra*; *see also* Ex. 1003 at ¶161.

As described in detail above, Black discloses reflowing its spacers into the conductor lumen spaces to stabilize and strengthen the structural elements therein within "a fused matrix of material" that is "free of gaps and voids." *See* Ex. 1008 at 6:19-34; 7:11-24; 7:29-34; FIG. 5; *see also* Ex. 1003 at ¶¶161-162. This disclosure renders obvious the feature of heating the non-conductive material to cause the non-conductive material to thermally reflow or melt. Ex. 1003 at ¶162.

A POSA would have found it obvious to apply to Stolz the technique taught in Black of reflowing spacers to fill spaces in the conductor lumen to achieve the desired benefits, as taught by Ormsby and Black, of filling spaces in the conductor lumen, as well as spaces beneath the conductive contacts. *See* Ex. 1003 at ¶¶162-165. 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. *See,* Ex. 1003 at ¶¶ 162-165.

Stolz's stimulation lead 30, as modified by the teachings of Ormsby and Black, and as explained and confirmed by Nevro's expert, discloses and renders obvious the further comprising heating the non-conductive material to cause the non-conductive material to thermally reflow or melt. *See generally*, Ex. 1003, ¶¶162-165.

C. Claim 3

1. "The method of claim 1"

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

2. "wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material in each of the conductor lumens is disposed radially beneath the conductive contacts"

This feature adds that instead of *at least one* conductor lumen having non-conductive material placed inside of it, *each* of the conductor lumens has non-conductive material placed into a portion, such that it is disposed, at least partially, radially beneath the conductive contacts. *See supra*, Sections VI.A.4 and VI.A.5.

Specifically, a POSA would have recognized from Ormsby, for instance, that leaving long, empty portions of a conductor lumen would be an undesirable condition, depending on the application. Ex. 1003, ¶¶166-168. 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 thus not have stopped at filling only one of Stolz's empty lumen spaces, but would have filled every empty lumen space. Ex. 1003, ¶¶166-169. And in Stolz, the conductor lumens, as explained in detail above at Section VI.A., are disposed radially beneath the conductive contacts. Again, as explained above in Section VI.A. and B., a POSA would therefore have searched for known techniques for filling the unoccupied portions of the conductor lumens. And to do so, a POSA would have considered other medical device references to identify suitable methods for filling lumens and other spaces within elongate structures having conductive wires therein. Again, Ormsby and Black meet that need and confirm Nevro's expert's assertion that a POSA would have been motivated to fill the unoccupied lumen spaces, and spaces radially beneath the conductive contacts, with non-conductive material, and would have succeeded in doing so. Ex. 1003 at, ¶¶165-170.

D. Claim 4

1. "The method of claim 1"

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

2. "further comprising placing spacers between pairs of adjacent conductive contacts"

Stolz discloses spacers disposed 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.

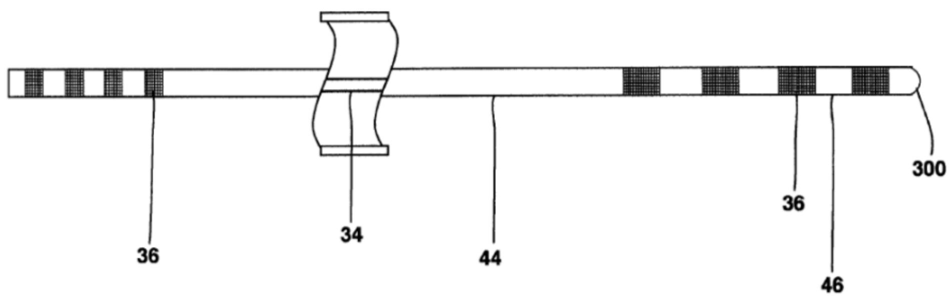


FIG. 3

Ex. 1005 FIG. 3.

Thus Stolz discloses placing spacers between pairs of adjacent conductive contacts. *See* Ex. 1003, ¶¶171-172. Black also discloses the feature of placing spacers between pairs of adjacent conductive contacts. *See* Ex. 1008, FIGs. 5, 7; 6:19-36.

E. Claim 5

1. "The method of claim 4"

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

2. "further comprising heating the non-conductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together"

This feature would have been obvious to a POSA in view of the material filling options described above. Ex. 1003 at ¶¶69-101, 134-177. Specifically, Black's spacers, as reflowed or melted above with heat applied to the lead assembly, would become thermally fused together with the material in Stolz (*e.g.*, the distal tip, proximal flare, or fill material in the isolation space). *Id.; see also supra,* Section VI.A.5. Black's process creates a "fused matrix of material" that stabilize and strengthen the lead's terminals and electrodes, "while also retaining their flexible properties." Ex. 1008 at 7:13–24. This is possible because Black's spacers are formed of a material mechanically equivalent to the other components such as the body of the lead. *Id.* Ormbsy teaches similar concepts. Ex. 1003 at ¶¶174–176; *see also supra,* Sections VI.A.5. So as applied to Stolz, any material that is used to fill the isolation space below Stolz's electrodes, like a plastic fill, would be fused into a matrix with the surrounding lead body, as taught by Black.

Ormsby also discloses a polymer powder that may be melt formed or reflowed therein to form a non-powder solid polymer. Ex. 1006 at 7:3-10; *see also*, Ex. 1003 ¶¶174-175. This too would be fused into a matrix with the surrounding lead body, as taught by Black.

As such, the combination of Stolz, Ormsby, and Black, as described in the prior art, disclose and render obvious the heating of the non-conductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together (*e.g.*, Stolz's spacers, with the lead body and any similar non-conductive, fill material). Ex. 1003, ¶¶174-177; *see also supra* Sections VI.A.5, and VI.B.2.

VII. Ground 2: The Combination of Stolz, Ormsby, Black, and Modern Plastics Encyclopedia Renders Obvious Claims 6-11 of the '172 Patent

A. Independent Claim 6

Independent claim 6 is nearly identical, substantively, to independent claim 1. It is narrower in that it further defines details of the temperature applied, along with the duration of application, in a step where heat is applied to melt or thermally reflow the non-conductive material. It recites that heat is applied between 140 to 250 degrees Celsius for approximately 15 to 120 seconds.

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 to 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, and environmental temperatures, etc. *See*, *e.g.*, Ex. 1003 ¶¶187-202. The '172 patent appears to appreciate these additional factors, stating particularly wide ranges, and leaving it to a POSA to perform experimentation with an expectation that they will succeed 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 '172 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. 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 processing 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, ¶¶187-202.

Nevro's expert 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, 003; *see also* Ex. 1003, ¶190. For example, polyurethane thermoplastics may melt or reflow in a range of between about 120 and 160 degrees Celsius. Ex. 1010, 003.

A POSA would thus appreciate that these ranges are determined through standardized testing processes. *See* Ex. 1003, ¶191. 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, ¶192. A POSA designing a manufacturing process with such a material would have been well equipped, both with prior designs as well as experimentation and iterations produced in a laboratory, 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 ’172 patent and would have been obvious to a POSA. *Id.*, ¶¶178-202.

1. “A method of making a stimulation lead, comprising”

There is no material difference between the preamble in claim 6 and the preamble in claim 1, and this feature would have been obvious for the same reasons. *See supra*, Section VI.A.1.

2. “providing a lead body comprising a [sic] insulation section, the insulation section defining a central lumen extending along the insulation section and a plurality of conductor lumens extending along the insulation section and arranged around, and external to, the central lumen”

There is no material difference between this feature in claim 6, and this feature in claim 1, and this feature would have been obvious for the same reasons. *See supra*, Section VI.A.2.

3. "the lead body further comprising a plurality of conductive contacts located along an axial end of the lead body, and a plurality of conductor wires, wherein each of the conductor wires is disposed within one of the plurality of conductor lumens and each of the conductor lumens of the plurality of conductor lumens has at least one of the conductor wires of the plurality of conductor wires disposed therein, wherein a portion of the conductor lumens is disposed radially beneath the conductive contacts"

There is no material difference between this feature in claim 6, and this feature in claim 1, and this feature would have been obvious for the same reasons. *See supra*, Section VI.A.3.

4. "after providing the lead body, conductively coupling at least one of the plurality of conductor wires to each of the conductive contacts"

There is no material difference between this feature in claim 6, and this feature in claim 1, and this feature would have been obvious for the same reasons. *See supra*, Section VI.A.4.

5. "after providing the lead body, placing non-conductive material into a portion of at least one of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material is disposed radially beneath the conductive contacts"

There is no material difference between this feature in claim 6, and this feature in claim 1, and this feature would have been obvious for the same reasons. *See supra*, Section VI.A.5.

6. "after placing the non-conductive material, heating the non-conductive material at a temperature in a range of 140 to 250 degrees Celsius for a period in a range of 15 to 120 seconds to cause the non-conductive material to thermally reflow or melt"

Claim 6 includes the additional features of placing the non-conductive material, heating the non-conductive material at a temperature in a range of 140 to 250 degrees Celsius for a period in a range of 15 to 120 seconds to cause the non-conductive material to thermally reflow or melt. These features were rejoined at the end of prosecution as a result of the withdrawal of a Restriction/Election Requirement. Stolz as modified below, discloses and renders these features obvious.

Stolz does not expressly disclose the temperature of heat applied or the duration of its application. It did not need to because, as described above, it would have been well within the skill of the POSA to figure it out. It is well-known that factors such as temperature and time applied impact the thermal process differently for any given material. *See* Ex. 1003, ¶¶187–202. For example, the Modern Plastics Encyclopedia teaches several ranges for a glass transition (*e.g.*, reflowing) temperature for several different polymers. Ex. 1010 at 003; *see also* Ex. 1003, ¶190. More specifically, the Modern Plastics Encyclopedia teaches that polyurethane thermoplastics have a glass transition temperature range of between

120 and 160 degrees Celsius, overlapping with the claimed temperature range with reasonable specificity. *Id*.

The selection of these parameters was known and a POSA would have looked to the Modern Plastics Encyclopedia as a reference for selecting process temperatures. Ex. 1003, ¶198. A POSA would have reasonably expected success due to at least the standardized measurements of the ranges and the known nature of the experimentation. *Id.*

The ’172 patent does not indicate that the selection of temperature was in any way special. *Id.* For example, the specification explains that thermal fusing may be accomplished by reflowing or melting and that both appear to be acceptable techniques. *See, e.g.*, Ex. 1001 at 6:27–39; *see also* Ex. 1003, ¶200. This reinforces that the selection of these parameters was known. Ex. 1003, ¶200.

Stolz does not expressly disclose the time that heat is applied. But this feature would have been obvious to a POSA, in view of the material filling options described above. Ex. 1003 at ¶¶187-202. It is generally well-known that factors such as temperature and time impact the thermal process depending upon any given material. *Id.* Nevro’s expert confirms that the temperature required to thermally reflow or melt varies depending on factors such as time and the material used. Ex. 1003, ¶¶187-202.

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 have different stages of reflowing, melting, or solid material, depending in part on the temperature and the elapsed time it is applied. *Id.*, ¶197. 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, ¶198.

Moreover, as Nevro's expert explains, a POSA would have also appreciated that general 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 area. *Id.*, ¶199. 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 to 120 seconds due to the standardized measurements of the ranges, component configuration and assembly, and the known nature of the experimentation. *Id.*; *see also* Ex. 1015, at 3:9–32; 5:53–66; 6:25–30.

As with the selection of temperature, the specification of the '172 patent does not indicate that the selection of time was in any way special (or selection of both at the same time). Indeed, the specification explains that thermal fusing may be accomplished by reflowing or melting and that both are acceptable techniques, which reinforces that the selection of these parameters was known. *See, e.g.*, Ex. 1001, 6:27–39; Ex. 1003, ¶200.

Thus, it would have been obvious for one of ordinary skill in the art to determine the amount of heat needed and amount of time needed to apply the heat in order to optimize the thermal processing of the assembly. Ex. 1003, ¶187-202.

B. Claim 7

1. "The method of claim 6"

As discussed above, the combination of Stolz, Ormsby, Black, and Modern Plastics Encyclopedia disclose and render obvious this limitation; *see* Ex. 1003, ¶203.

2. "wherein the plurality of conductor lumens is exactly eight conductor lumens"

Stolz discloses a plurality of conductor lumens 102, in the range from about two to sixteen. Ex. 1005 at [0029]. This range includes exactly eight conductor lumens. Thus Stolz discloses the feature of having exactly eight conductor lumens. *See* Ex. 1003 at ¶¶203-204.

C. Claim 8

1. "The method of claim 6"

As discussed above, the combination of Stolz, Ormsby, Black, and Modern Plastics Encyclopedia disclose and render obvious this limitation; *see* Ex. 1003, ¶205.

2. "wherein placing non-conductive material comprises placing the non-conductive material into a portion of each of the conductor lumens of the lead body, wherein at least a portion of the non-conductive material in each of the conductor lumens is disposed radially beneath the conductive contacts"

There is no material difference between this feature in claim 8, and this feature in claim 3, and this feature would have been obvious for the same reasons. *See supra*, Section VI.C.2; *see also* Ex. 1003, ¶206.

D. Claim 9

1. "The method of claim 6"

As discussed above, the combination of Stolz, Ormsby, Black, and Modern Plastics Encyclopedia disclose and render obvious this limitation; *see* Ex. 1003, ¶207.

2. "further comprising placing spacers between pairs of adjacent conductive contacts"

There is no material difference between this feature in claim 9, and this feature in claim 4, and this feature would have been obvious for the same reasons. *See supra*, Section VI.D.2; *see also* Ex. 1003, ¶208.

E. Claim 10

1. "The method of claim 9"

As discussed above, the combination of Stolz, Ormsby, Black, and Modern Plastics Encyclopedia disclose and render obvious this limitation; *see* Ex. 1003, ¶209.

2. "wherein heating the non-conductive material comprises heating the non-conductive material and spacers to cause the non-conductive material to thermally reflow or melt and to cause the non-conductive material and spacers to thermally fuse together"

There is no material difference between this feature in claim 10, and this feature in claim 5, and this feature would have been obvious for the same reasons. *See supra*, Section VI.E.2; *see also* Ex. 1003, ¶210.

F. Claim 11

1. "The method of claim 6"

As discussed above, the combination of Stolz, Ormsby, Black, and Modern Plastics Encyclopedia disclose and render obvious this limitation; *see* Ex. 1003, ¶211.

2. "wherein the non-conductive material comprises 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 non-conductive materials, such as 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, ¶¶211-216. 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 thus 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 the non-conductive material. Ex. 1003, ¶¶211-216.

VIII. 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 '172 patent. Nevro is not aware of any such evidence or information that could have any nexus to the claims of the '172 patent. Ex. 1003 at ¶¶217-218. Nevro, however, reserves its right to respond to any assertion of secondary indicia of non-obviousness advanced by BSNC.

IX. Standing (37 C.F.R. § 42.104(a))

Nevro certifies that the '172 patent is available for *inter partes* review, and that Nevro is not barred or estopped from requesting an *inter partes* review of the '172 patent.

The assignee of the '172 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 '172 patent. The present Petition is being filed within one year of Nevro being served with the complaint.

X. 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 ’172 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; IPR2017-01899, challenging the claims of U.S. Patent No. 7,587,241, filed July 31, 2017; IPR2018-00143, challenging the claims of U.S. Patent No. 7,891,085, filed November 2, 2017; and IPR2018-00147, challenging the claims of U.S. Patent No. 8,650,747, filed on November 2, 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.

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D. Service Information

Petitioner consents to electronic service by email at: **jwright-PTAB@skgf.com**, **rcoller-PTAB@skgf.com**, **ndesai-PTAB@skgf.com ,** **isoule-PTAB@skgf.com, PTAB@skgf.com, clfukuda@sidley.com, sde@sidley.com,** and **bhuh@sidley.com**.

Respectfully submitted,
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/Jon E. Wright/

Date: November 3, 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 3, 2017, true and correct copies of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,646,172**, 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 12,799 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,

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

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Date: November 3, 2017

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