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Paper No. 7
Entered: May 2, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.,
Petitioner,

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP.,
Patent Owner.

Case IPR2018-00143
Patent 7,891,085 B1

Before HUBERT C. LORIN, MICHAEL W. KIM, and AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Nevro Corp. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–19 ("the challenged claims") of U.S. Patent No. 7,891,085 B1 (Ex. 1001, "the '085 patent"). Paper 2 ("Pet."). Boston Scientific Neuromodulation Corp. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition and the Preliminary Response shows that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see also* 37 C.F.R § 42.4(a) ("The Board institutes the trial on behalf of the Director."). Taking into account the arguments presented in the Preliminary Response, we conclude that the information presented in the Petition does not establish a reasonable likelihood that Petitioner would prevail with respect to the challenged claims.

Accordingly, we decline to institute an *inter partes* review.

B. Related Proceedings

The parties identify the following matter related to the '085 patent (Pet. 72; Paper 4, 2):

> *Boston Scientific Corp. et al. v. Nevro Corp.*, Case No. 1:16-cv-01163 (D. Del.).

C. The '085 Patent

The '085 patent is titled "Electrode Array Assembly and Method of Making Same" and issued on February 22, 2011, from U.S. Application No. 11/329,907, which was filed on January 11, 2006. Ex. 1001, (21), (22), (54).

The ’085 patent discloses a percutaneous lead, as shown in Figures 3A and 5A, which are reproduced below.

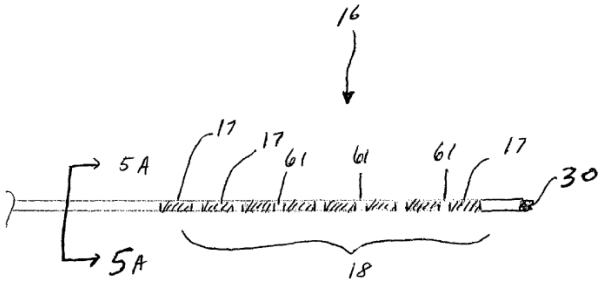

FIG.3A

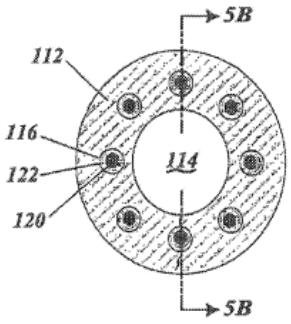

FIG.5A

Figure 3A depicts a side view of the distal end of a percutaneous lead, and Figure 5A depicts a cross-sectional view of the lead. *Id.* at 3:12–13, 3:21–22.

Lead 16 delivers electrical stimulation to, e.g., neural tissue, through electrode contacts 17. *Id.* at 4:17–21. As shown in Figure 3A, electrode contacts 17 are separated by spacers 61, which serve to insulate contacts 17 from each other. *Id.* at 4:17–23. Each electrode contact 17 is connected to conductor wire 122, which is made up of individual strands 120, as shown in Figure 5A. *Id.* at 5:15–18, 5:35–39, 5:42–45. Each conductor wire is located within individual conductor lumen 116, wherein conductor lumens 116 encircle central stylet lumen 114. *Id.* at 5:40–41, 5:47–49, Fig. 5A.

The ’085 patent also discloses a method of making such a lead. Figures 6A–B are reproduced below.

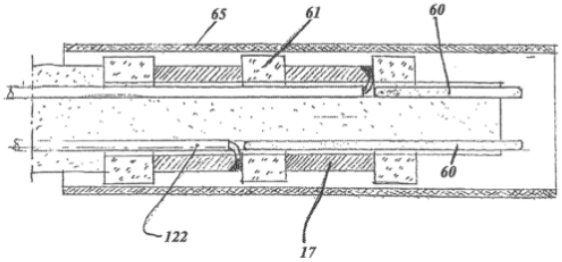

FIG.6A

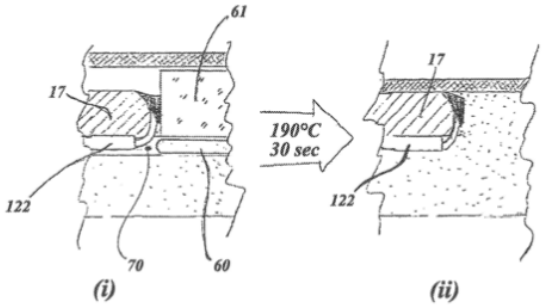

FIG.6B

Figure 6A depicts a longitudinal view of the distal portion of a lead assembly, and Figure 6B depicts how voids within that lead are filled. Ex. 1001, 3:26–30.

During manufacture, monofilament 60 is inserted into void spaces 70 within conductor lumens 116. *Id.* at 5:66–6:2, 6:10–12, Figs. 6A, 6B(i). The distal portion of the lead is then heated to a temperature just below the melting temperature of spacer 61 and/or monofilament 60, e.g., 190° Celsius for thirty seconds. *Id.* at 6:12–19. The '085 patent explains that "[a]t this just-below-melting temperature, the spacer and monofilament will reflow and thermally fuse together," as shown in Figure 6B(ii). *Id.* at 6:19–21, 6:35–38 (explaining that the heating temperature is chosen to ensure reflow of either, or both, spacer 61 and/or monofilament 60). According to the '085 patent, this process minimizes or eliminates tooling and molding, is faster than using epoxy, ensures more uniform stiffness, and yields a better bond within the lead. *Id.* at 7:45–63.

D. Illustrative Claim

Of the challenged claims, claim 1 is independent. Claim 1 is illustrative and is reproduced below.

> 1. A method of manufacturing a stimulation lead having a proximal end and a distal end, comprising:
>
> providing a plurality of conductive contacts located at an end of a lead body of the stimulation lead;
>
> disposing a plurality of conductor wires in a plurality of conductor lumens formed in the lead body;

> connecting at least one of the plurality of conductor wires to each of the conductive contacts;
>
> 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;
>
> *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
>
> 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, 8:11–31 (emphasis added).

E. Applied References

Petitioner relies upon the following references:

> Stolz et al., U.S. Patent Publication No. 2003/0199950 A1, filed April 22, 2002, published October 23, 2003 (Ex. 1005, "Stolz");
>
> Ormsby et al., PCT Publication No. WO 00/35349, filed December 16, 1999, published June 22, 2000 (Ex. 1006, "Ormsby");
>
> Black et al., U.S. Patent No. 6,216,045 B1, filed April 26, 1999, issued April 10, 2001 (Ex. 1008, "Black");
>
> Wessman et al., U.S. Patent Publication No. 2002/0143377 A1, filed March 30, 2001, published October 3, 2002 (Ex. 1009, "Wessman");
>
> Modern Plastics Encyclopedia 1986–1987, October 1986, Vol. 63, No. 10A (Ex. 1010, "Modern Plastics"); and
>
> Mark Saab, *Using Thin-Wall Heat-Shrink Tubing in Medical Device Manufacturing*, Medical Device & Diagnostic Industry April 1, 1999, 54–62 (Ex. 1011, "Saab").

Pet. 4–5. Petitioner also relies upon the Declaration of Michael Plishka ("the Plishka Declaration," Ex. 1003). *Id.* at 5.

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