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Paper No. 7
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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.

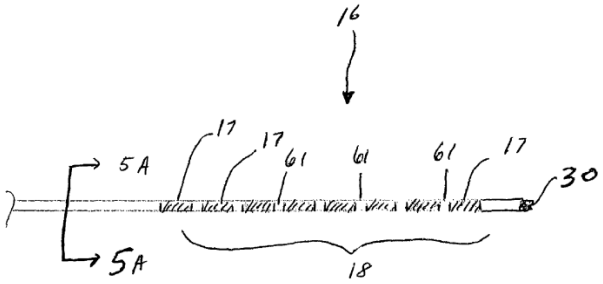

FIG.3A

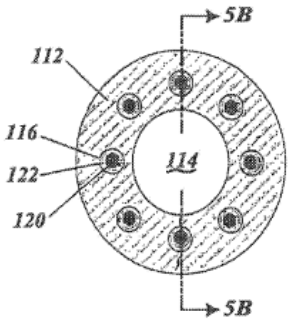

FIG.5A

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.

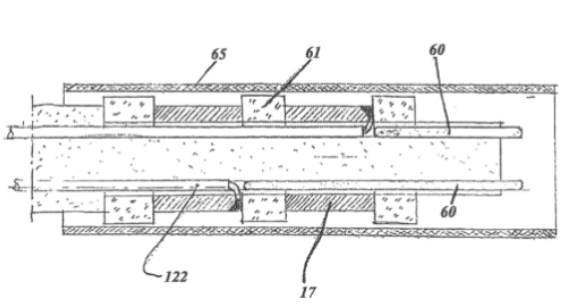

FIG.6A

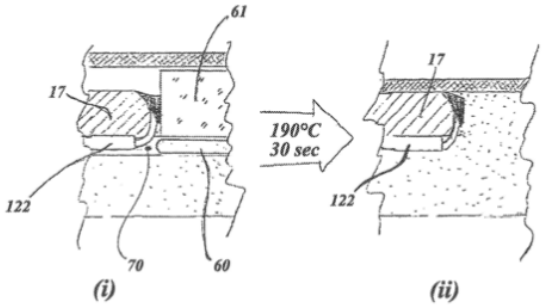

FIG.6B

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.

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–19 of the '085 patent based on the following grounds. Pet. 4.

No.	References	Basis	Claim(s) Challenged
1	"Stolz, Ormsby, Black, and the knowledge of POSA" (*see* Pet. 4)	§ 103	1–3, 6–12, and 14–17
2	Ground 1 further in view of Modern Plastics	§ 103	4, 5, and 13
3	Ground 1 further in view of Wessman	§ 103	18
4	Ground 3 further in view of Saab	§ 103	19

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, we generally give claim terms their ordinary and customary meaning, as understood by a person of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

We determine that no claim term requires express construction for purposes of this Decision. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999); *see also* Pet. 7–8; Prelim. Resp. 23.

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is

resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of elements produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

Relying on the Plishka Declaration, Petitioner contends that a person of ordinary skill in the art of the '085 patent would have had "general knowledge of implantable medical devices and various related technologies as of January 11, 2005" and, furthermore, "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." Pet. 6 (citing Ex. 1003 ¶¶ 21–24). In its Preliminary

Response, Patent Owner does not provide an express assessment of skill level. *See generally* Prelim. Resp.

On this record, we are persuaded by, and adopt, the assessment of the level of ordinary skill in the art asserted by Petitioner.

D. Obviousness over "Stolz, Ormsby, Black, and the knowledge of POSA"

Petitioner contends that claims 1–3, 6–12, and 14–17 of the '085 patent would have been obvious in light "Stolz, Ormsby, Black, and the knowledge of POSA." Pet. 4, 9, 16–59. For reasons that follow, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing as to the challenged claims.

1. Overview of Stolz (Ex. 1005)

Stolz is a U.S. Patent Publication titled "Implantable Lead with Isolated Contact Coupling." Ex. 1005, (54). Stolz explains that "[i]mplantable leads have conductors that are connected to contacts to form electrical paths." *Id.* ¶ 4. These elements should have a "solid mechanical," "low impedance electrical connection," but the prior art presented problems with respect to these connections. *Id.* Thus, Stolz discloses "an implantable lead with an isolated contact connection for connecting a conductor to a contact [that] reduces the opportunity for conductor material to migrate to a contact or into a patient." *Id.* ¶ 5.

Figures 8 and 9 are reproduced below.

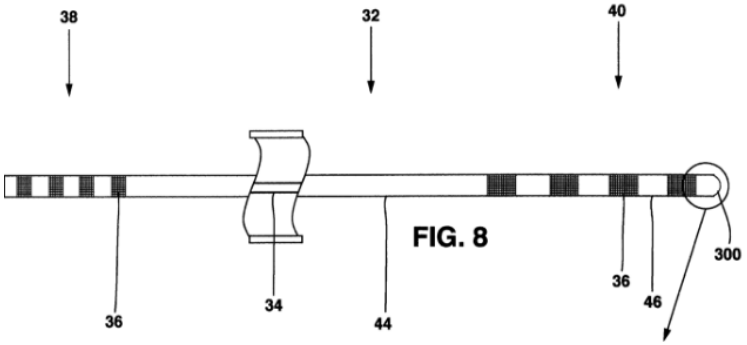

FIG. 8

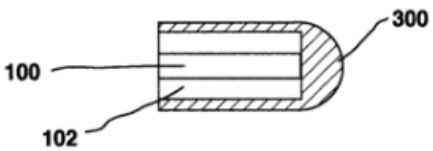

FIG. 9

Figure 8 depicts an implantable lead with a distal end enlargement, which is expanded in Figure 9. Ex. 1005 ¶¶ 14–15.

Stolz discloses that the implantable lead includes a lead body, at least two conductors 34 extending from proximal end 38 to distal end 40, contacts 36 electrically connected to the conductors 34, stylet lumen 100, conductor lumens 102, and distal tip 300. *Id.* ¶ 34. Stolz explains that distal tip 300 can be formed by molding. *Id.* ¶ 36. Specifically, "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.* In this manner,

> distal tip 300 seals the conductor lumens 102 free from adhesive or solvents. The conductor lumens 102 closed off by the formed distal tip 300 improve electrical isolation between the conductors 34. The formed distal tip 300 penetrates the lumens 100, 102 of the lead body. The material filling reaches no further into the lumens than making contact to the enclosed conductors 34.

Id. ¶ 35. Stolz also explains that forming distal tip 300 from the same material as the lead body "minimizes the possibility of separation." *Id.* ¶ 36.

2. Overview of Ormsby (Ex. 1006)

Ormsby is a PCT Publication titled "Guidewire Having Sidewise Looking Imaging Capabilities and Methods." Ex. 1006, (54). Ormsby discloses a guidewire that is deployed through a patient's vasculature to a desired location. *Id.* at (57). The guidewire includes an ultrasonic transducer, which allows a surgeon to view the desired location, while a catheter is advanced over the guidewire and placed in that location. *Id.* at (57), 3, 8–9 (discussing operation of the device).

Ormsby's Figure 3 is reproduced below.

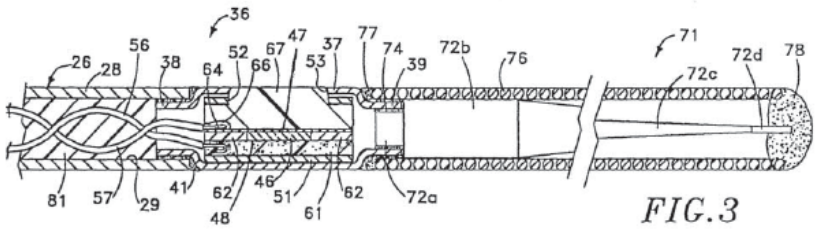

FIG.3

Figure 3 depicts an enlarged cross-sectional view of the distal extremity of a guidewire. *Id.* at 2. As shown, guidewire 11 includes tubular member 26 with lumen 29 extending therethrough. *Id.* at 3. Transducer assembly 36, with transducer element 46, is carried on the guidewire. *Id.* at 4. Conductors 56, 57 are also provided in the lumen of the guidewire. *Id.* at 5. Ormsby explains,

> In 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 such as a liquid epoxy or resin and permitted to harden. Alternatively, a polymer can be utilized in powder form and can be melt formed therein. Thus it can be seen that the filler 81 fills the void within the lumen and greatly reduces the possibility of kinking of the hypotube forming the flexible elongate tubular member 26.

Id. at 7.

3. Overview of Black (Ex. 1008)

Black is a U.S. Patent titled "Implantable Lead and Method of Manufacture." Ex. 1008, (54). Figure 5 is reproduced below.

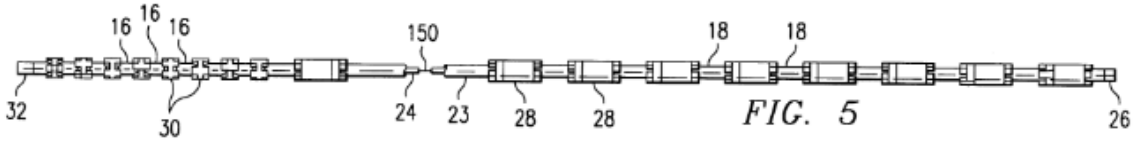

FIG. 5

Figure 5 depicts a plan view of an assembly of elements on a mandrel, prior to formation of a lead. *Id.* at 3:10–12. As shown in Figure 5, the lead produced by Black's method includes, *inter alia,* terminals 16 (separated by terminal spacers 30) and electrodes 18 (separated by electrode spacers 28). *Id.* at 6:5–10. Once

arranged as depicted in Figure 5, the assembly is "over-molded, using well known injection molding techniques." *Id.* at 7:5–10. According to Black,

> This process has the beneficial effect of unitizing the element assembly to form lead 10. Moreover, 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. Consequently, terminals 16 and electrodes 18 are partially surrounded (i.e., along an interior surface) and supported by a fused matrix of material. Importantly, as electrode spacers 28 and terminal spacers 30 are formed of a material mechanically equivalent to that of body 22/outer tubing 23, 20 the stimulation/sensing portion and terminal portion of lead 10 are stabilized and strengthened while also retaining their flexible properties.

Id. at 7:11–23.

4. Analysis of Independent Claim 1

Of particular importance to our analysis, claim 1 recites, "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." Ex. 1001, 8:23–25. Petitioner contends that Stolz discloses much of this limitation. Pet. 9, 21, 33. For example, Petitioner contends that "Stolz teaches inserting material into conductor lumens 102, e.g., to seal them." *Id.* at 33 (citing Ex. 1005 ¶¶ 35–36, 46, Figs. 8–9). In support of this position, Petitioner quotes Stolz's disclosure that "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.* (quoting Ex. 1005 ¶ 36). Thus, Petitioner contends that distal tip 300 "penetrates the lumens 100, 102 of the lead body . . . [and] reaches no further into the lumens than making contact to the enclosed conductors." *Id.* (quoting Ex. 1005 ¶ 35). According to Petitioner, "the reflowed portion of Stolz's distal tip may not penetrate very far," such that the lead "may still have a long, unoccupied

space between the distal tip and the conductor." *Id.* at 34 (citing Ex. 1003 ¶¶ 144–146).

Petitioner contends that "a POSA would have recognized that leaving long, empty portions of a conductor lumen could be an undesirable condition," because such an empty portion could lead to perforation, kinking, variable flexibility, or separation of components. Pet. 34–35 (citing Ex. 1003 ¶ 145). To avoid such outcomes, Petitioner contends that a person of ordinary skill in the art would have "searched for other known techniques for filling the unoccupied portions of the conductor lumens." *Id.* at 35. To that end, Petitioner contends that Ormsby "provides the motivation to modify Stolz to fill the unoccupied portions of the conductor lumens." Pet. 9, 22. According to Petitioner, "Ormsby teaches that it is desirable to fill lumen spaces to prevent kinking or crushing, if stressed." *Id.* at 22, 35–36 (citing Ex. 1006, 7:3–10; Ex. 1003 ¶¶ 145–157). Specifically, Petitioner contends that "Ormsby teaches various methods for filling a lumen, including with powder, liquid adhesive, epoxy, or resin." *Id.* at 22 (citing Ex. 1003 ¶¶ 88–93), 36.

Petitioner acknowledges that "Stolz in view of Ormsby still does not expressly disclose 'inserting a monofilament' to fill the void within the conductor lumen." Pet. 36. However, Petitioner relies upon the Plishka Declaration to support Petitioner's contention that "a POSA would have found it obvious to use monofilament to fill the empty spaces in Stolz's conductor lumens instead of the powder of Ormsby," because "a POSA would have naturally looked for a filling option that would match the size, shape, and configuration of the lumen it would be designed to fill—such as monofilament." *Id.* at 36–37 (citing Ex. 1003 ¶¶ 151–157). Petitioner alleges that "a POSA would have recognized that there are a limited number of ways to fill a lumen," such that it would have been "at least

obvious to try and fill the lumen with a non-powder, solid material, like a monofilament." *Id.* at 37–38 (citing Ex. 1003 ¶¶ 153–161).

Patent Owner disputes Petitioner's contentions regarding claim 1. Prelim. Resp. 23–30, 32–43. Patent Owner argues, *inter alia*, that Ormsby does not disclose filling an empty, void space within a conductor lumen, as claimed, but rather discloses a fill material that surrounds the conductor wires within the lumen. *Id.* at 27–28. Patent Owner also argues that "the Petition, as well as its accompanying expert declaration, still fails to establish that one skilled in the art would have [been] motivated to substitute monofilament for the epoxy or powdered fill materials disclosed in [Ormsby]." *Id.* at 39.

We agree with Patent Owner on both points. First, we are not persuaded by Petitioner's contention that "Ormsby . . . provides the motivation to fill the portion of Stolz's conductor lumens that are not occupied by its conductive wires." Pet. 22; *see also id.* at 9. Ormsby's Figure 3 is reproduced below.

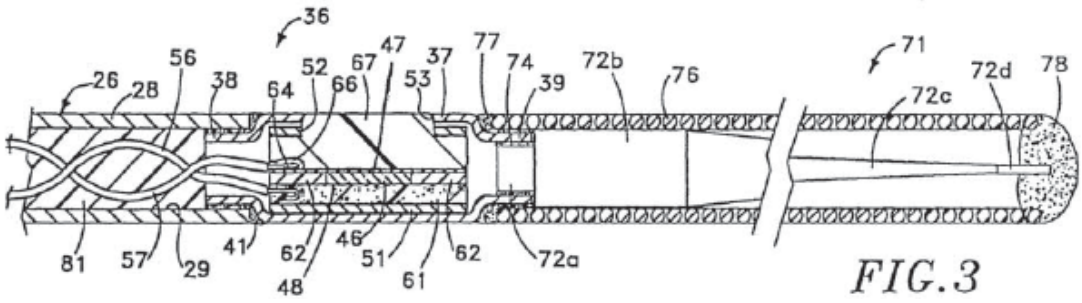

FIG.3

Figure 3 is an enlarged cross-sectional view of the distal extremity of a guidewire. Ex. 1006, 2. As seen in Figure 3, lumen 29 includes conductors 56, 57. *Id.* at 5. Ormsby explains that "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 suitable material." *Id.* at 7. Thus, Ormsby discloses that material 81 fills the portion of conductor lumen 29 that *is occupied* by conductive wires 56, 57.

In light of these teachings, Petitioner has not explained persuasively why or how Ormsby would have motivated a person of ordinary skill in the art to, nonetheless, "fill the portion of Stolz's conductor lumens that are *not occupied* by its conductive wires." Pet. 22 (emphasis added), 35–36. Ormsby is silent as to any benefit associated with filling portions of the conductor lumen that are *not* occupied by conductor wires, and Petitioner does not demonstrate sufficiently that any benefits of kink resistance also would be realized if fill material were utilized in a portion of the lumen that lacks the conductor wires present in Ormsby's lumen. Thus, because Ormsby does not address using a fill material in a "portion of at least one of the conductor lumens of the lead body *that is not occupied by the conductor wires*," as claimed, we find Petitioner's contention that Ormsby would have motivated such a modification to lack sufficient support in Ormsby's disclosure.

Moreover, the cited portions of the Plishka Declaration fail to support Petitioner's contention. *Id.* at 35–36 (citing Ex. 1003 ¶¶ 78, 146–150). Cited paragraph 78 concerns Stolz and, as such, does not support Petitioner's contention regarding the motivation purportedly offered by Ormsby. Ex. 1003 ¶ 78. Cited paragraph 146 states, "Ormsby, in addition to explaining why a POSA would fill long, unoccupied lumen spaces, also provides alternative methods for filling a lumen." *Id.* ¶ 146. However, this statement is not supported by Ormsby, which does not fill "unoccupied lumen spaces." *See* Ex. 1006, 7 (addressing how to fill lumen spaces occupied by conductor wires 56, 57); *compare* Ex. 1003 ¶ 146, *with id.* ¶¶ 147–148 (acknowledging conductors 56, 57 occupy lumen). Additionally, cited paragraph 149 states that "filling Stolz's empty conductor lumens would provide the benefit, as taught by Ormsby, of reducing the possibility of kinking in Stolz's lead, while improving axial stability." This paragraph, however, fails to

provide any support for the conclusion that benefits associated with filling lumen spaces in which conductor wires are present would also apply when filling *empty* lumen spaces. Ex. 1003 ¶ 149. For these reasons, we are not persuaded by Petitioner's contention that Ormsby would have motivated a person of ordinary skill in the art to fill Stolz's empty conductor lumen portions.

Second, even if Ormsby would have provided a motivation to fill the empty portions of Stolz's conductor lumens, we are not persuaded by Petitioner's contention that it would have been obvious to "insert[ ] monofilament" to fill such voids. Petitioner contends that this modification would have been obvious to try because there are a limited number of ways to fill a lumen that has the specific shape, size, and configuration disclosed by Stolz, e.g., "a straight, narrow, cylindrical void." Pet. 37. To support this position, Petitioner relies on Mr. Plishka's testimony that "a POSA would have naturally looked for a filling option that would match the size, shape, and configuration of the lumen." Ex. 1003 ¶ 151. Mr. Plishka's testimony appears to be conclusory, in that he does not provide any evidence, or much supporting analysis, as to why this statement is correct. However, even if true, Petitioner has additionally not shown that "there are a limited number" of options, such that it would have been obvious to try monofilament.

As an initial matter, neither the Petition nor Mr. Plishka identify the specific shape, size, and configuration of the lumen, to which the filling material must match. Petitioner characterizes this shape as "a straight, narrow, cylindrical void" (Pet. 37) and Mr. Plishka explains that it is "a straight, cylindrical space" (Ex. 1003 ¶ 151). However, neither specific nor relative dimensions are discussed in any manner. As such, any comparison of potential filling materials to this purported

shape is necessarily vague, approximate, imprecise, and insufficient to demonstrate that a limited number of options would have existed.

Furthermore, Mr. Plishka testifies that the only options available to fill the empty portions of Stolz's conductor lumens would have been "liquids, powdered solids, and non-powder solids (gasses not being an attractive option)." *Id.* ¶ 153. However, this testimony establishes that the options would have been quite numerous, and certainly not "limited." Indeed, Mr. Plishka testifies that the potential options would have included *any material* that is "straight" and "cylindrical," and that comes from the general classes of liquids, powders, or solids. *Id.* According to Mr. Plishka, gases are the only materials *excluded* from consideration as a filling material. *Id.* Thus, we are not persuaded by Petitioner's contention that monofilament is merely one of a "limited number" of options. *See, e.g.*, Prelim. Resp. 39–40 ("The Petition does not identify these finite possibilities other than by reference to the general categories of liquids, powdered solids, and non-powdered solids. By this rationale, using uranium (non-powdered solid), gasoline (liquid), or sand (powdered solid) would be just as 'obvious' as using monofilament.").

Moreover, the Petition and Mr. Plishka fail to explain sufficiently why or how it would have been obvious to choose monofilament specifically, out of all possible filling materials. Even accepting Mr. Plishka's opinion that a person of ordinary skill in the art would have selected a material having the same shape as the lumen, *see* Ex. 1003 ¶ 151, the Petition does not explain why monofilament would have been chosen over other materials that have, or are capable of having, the same shape, e.g., a liquid epoxy or resin as taught by Ormsby (which would conform to the straight, narrow, cylindrical shape of the lumen), a polymer powder as taught by Ormsby (which would also conform to the straight, narrow,

cylindrical shape of the lumen), or even a solid birthday candle (which would match the straight, narrow, cylindrical shape of the lumen). Without sufficient articulated support, grounded in evidence of record, Petitioner's choice of monofilament appears to be driven by hindsight. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 n.3 (Fed. Cir. 2008) ("We must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention."); *W.L. Gore & Assocs, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teache[s].").

Paragraph 153 of the Plishka Declaration cites three publications which purportedly "confirm [Mr. Plishka's] understanding of the state of the art." Ex. 1003 ¶ 153. We do not find these citations to cure the deficiencies discussed above. For example, the cited Huepenbecker publication discloses a monofilament tensile member that is inserted into a lumen, so as to communicate traction forces from one end of the lead to another. Ex. 1012, 4–5. However, as seen in Figure 4, tensile member 50 does not fill the lumen and, as such, does not support Mr. Plishka's opinion that monofilament would have been one of a limited number of options to try, when seeking to fill voids in Stolz's lumens. *Id.* at Fig. 4. Similarly, the cited Mahurkar patent discloses a catheter with nylon reinforcing strip 50, which also transmits forces through the catheter and prevents collapse. Ex. 1014, 6:43–53, 7:25–31. This element, however, is not located in a lumen and is not a monofilament. *Id.* at Figs. 2, 4–6. Although not referred to explicitly in

Mr. Plishka's Declaration, we note that Mahurkar also discloses spiral 70, which may be a monofilament. *Id.* at 8:3–14. However, spiral 70 is not located in a lumen and, as such, does not support Mr. Plishka's opinion that monofilament would have been one of a limited number of options to try, when seeking to fill voids in Stolz's lumens. *See id.* at Fig. 2. Finally, the cited Whitfill patent discloses a logging cable, in which strands 20 are twisted around monofilament 21, such that the strands embed in the monofilament when subjected to heat. Ex. 1014, 1:52–58, 2:62–3:10, Fig. 2. Whitfill, however, does not disclose a lumen. *Id.* As such, Whitfill does not support Mr. Plishka's opinion that monofilament would have been one of a limited number of options to try, when seeking to fill voids in Stolz's lumens.

The Plishka Declaration also cites a patent to Verness, which "has a similar disclosure to Ormsby . . . [and] teaches that filling the conductor lumen increases its perforation resistance, minimizes the possibility of separation of components of the lead body, and better supports components within a fused matrix support." Ex. 1003 ¶ 154 (citing Ex. 1007 ¶¶ 1, 6–10, 12–15). However, Verness does not disclose a monofilament, and, thus, does not support Mr. Plishka's opinion that monofilament would have been one of a limited number of options to try, when seeking to fill voids in Stolz's lumens. Moreover, cited paragraph 13 suggests that reinforced conductor lumens may cause problems, e.g., reinforcement "can stiffen the lead body unduly and may increase the likelihood of stress-related fracture." Ex. 1007 ¶ 13. Similarly, cited paragraph 15 suggests that filling void spaces within a lumen "may or may not reduce the possibility of lead conductor fracture through abrasion or crushing." *Id.* ¶ 15. As such, this disclosure does not support Mr. Plishka's opinion that monofilament would have been one of a limited number

of options to try, when seeking to fill voids in Stolz's lumens, and, indeed, suggests *against* the proposed modification to Stolz's lumens.

Therefore, on the record before us, we determine that Petitioner has not provided persuasive reasoning, with sufficient rational underpinnings, to support its contention that it would have been obvious to have "insert[ed] monofilament into at least one portion of at least one of the conductor lumens of [Stolz's] lead body that is not occupied by the conductor wires," as required by claim 1. *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[Unpatentability based on] obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."). As such, Petitioner has not demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of challenged claim 1.

5. Dependent Claims 2, 3, 6–12, and 14–17

Claims 2, 3, 6–12, and 14–17 all depend, directly or indirectly, from claim 1. Therefore, for the same reasons discussed above with respect to claim 1, Petitioner has not demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of these challenged claims.

E. Remaining Asserted Grounds of Unpatentability

Petitioner contends that claims 4, 5, 13, 18, and 19 would have been obvious over Stolz, Ormsby, Black, and the knowledge of a POSA, in further combination with Modern Plastics (for claims 4, 5, and 13), Wessman (for claim 18), or Wessman and Saab (for claim 19). Pet. 4.

Each of these claims depend, directly or indirectly, from claim 1. Petitioner does not rely on Modern Plastics, Wessman, or Saab to cure the deficiencies discussed above with respect to claim 1. Pet. 59–71. Therefore, for the same

reasons discussed above with respect to claim 1, Petitioner has not demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of these challenged claims.

III. CONCLUSION

For the foregoing reasons, we determine Petitioner has not demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of challenged claims 1–19 of the ’085 patent.

IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that the Petition is *denied* as to all challenged claims, and no trial is instituted.

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