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Paper 10
Entered: November 30, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC NEUROMODULATION CORPORATION,
Petitioner,

v.

NEVRO CORPORATION,
Patent Owner.

Case IPR2015-01203
Patent 8,359,102 B2

Before BARRY L. GROSSMAN, MITCHELL G. WEATHERLY, and JAMES A. WORTH, *Administrative Patent Judges.*

WORTH, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner, Boston Scientific Neuromodulation Corporation ("BSNC"), filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1, 2, 11–15, 17–23, 25 and 26 of U.S. Patent 8,359,102 B2 ("the '102 patent," Ex. 1001). Patent Owner, Nevro Corporation ("Nevro"), filed a Preliminary Response (Paper 9, "Prelim. Resp.").

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition filed under section 311 and any response filed under section 313 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(a); 37 C.F.R. § 42.108. For the reasons set forth below, we conclude that the information presented in the Petition does not establish a reasonable likelihood that BSNC would prevail in showing that claims 1, 2, 11–15, 17–23, 25 and 26 of the '102 patent are unpatentable.

Accordingly, we do not institute an *inter partes* review for any of these challenged claims.

A. Related Matters

The parties state that there is no related litigation or related matters other than a co-pending petition for *inter partes* review (Case IPR2015-01204).

B. The '102 Patent (Ex. 1001)

The '102 patent is titled "Selective High Frequency Spinal Cord Modulation For Inhibiting Pain with Reduced Side Effects, and Associated Systems and Methods," and relates to a method for applying selective high frequency modulation to the dorsal column, dorsal horn, dorsal root, dorsal

root entry zone, and/or other regions of the spinal column to control pain while reducing or eliminating side effects. Ex. 1001, 1:1–4, 1:21–24, 3:1–6. Such side effects include unwanted motor stimulation or blocking, and/or interference with sensory functions other than the targeted pain. *Id.* at 2:57–60. The '102 patent describes that a problem existed in the art because electrical pulses generated sensations that masked or otherwise altered the patient's pain and created tingling or paraesthesia. *Id.* at 1:47–52.

The '102 patent addresses this problem by using electrical signals possessing waveforms with high frequency elements or components (e.g., portions having high fundamental frequencies). *Id.* at 2:55–57; 4:54–60. One embodiment employed therapeutic signals of about 3 kHz to about 10 kHz, and generally from about 1.5 kHz to about 100 kHz, and the amplitude generally from about 1mA to about 4 mA. *Id.* at 6:60–7:8.

Several embodiments of the '102 patent use an electrical signal delivery element with leads implanted in the spinal region on either side of the midline. *Id.* at 5:11–34, 6:12–37. Figure 1B is reproduced below:

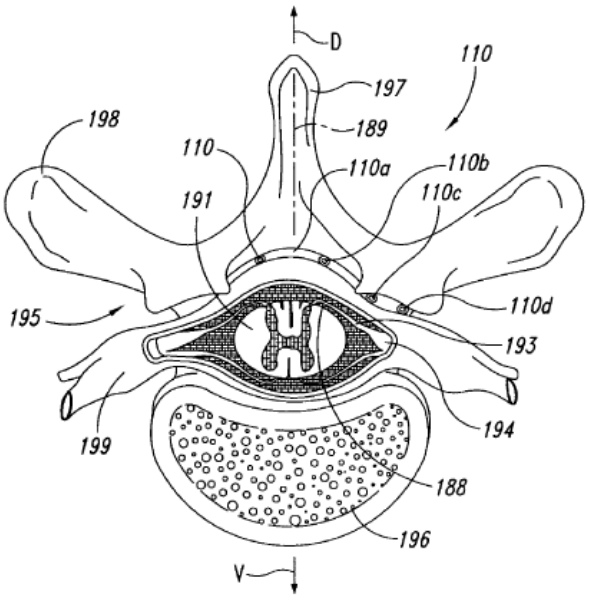

Figure 1B, above, depicts the placement of lead 110, according to one embodiment, at spinal level T7–T8. *Id.* at 6:39–40.

C. Illustrative Claims

Claims 1 and 26 are independent claims. Claim 1, reproduced below, is illustrative of the subject matter at issue.

> 1. A method for treating a patient, comprising: delivering or instructing delivery of an electrical signal to the patient's spinal cord via at least one implantable signal delivery device; and wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz and does not create paresthesia in the patient.

Ex. 1001, 26:2–9.

D. The Alleged Grounds of Unpatentability

Petitioner contends that claims 1, 2, 11–15, 17–23, 25 and 26 are unpatentable on the following grounds:

References	Basis	Claims challenged
MacDonald[1]	§ 102	1, 2, 11–14, 17–22, 25, and 26
Sluitjer[2]	§ 102	1, 2, 15, 17, 18, 25, and 26
Royle[3]	§ 102	1, 2, 17–23, 25, and 26

[1] MacDonald, U.S. Patent No. 5,776,170, iss. July 7, 1998 (Ex. 1002).

[2] Sluitjer, U.S. Patent No. 6,246,912 B1, iss. June 12, 2001 (Ex. 1003).

[3] Royle, U.S. Patent Application Pub. No. 2006/0009820 A1, pub. Jan. 12, 2006 (Ex. 1004).

References	Basis	Claims challenged
MacDonald, either alone or in view of De Ridder[4], Sluijter and/or Royle	§ 103	1, 2, 11–15, 17–23, 25, and 26
Sluijter, either alone or in view of De Ridder, MacDonald and/or Royle	§ 103	1, 2, 11–15, 17–23, 25, and 26
Royle, either alone or in view of De Ridder, MacDonald and/or Sluijter	§ 103	1, 2, 11–15, 17–23, 25, and 26

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); s*ee In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes constructions of "implantable signal delivery device" and "paresthesia." Pet. 10–11. Patent Owner disputes the construction of these terms. Prelim. Resp. 10–20.

[4] De Ridder, U.S. Patent Application Pub. No. 2011/0184488 Al, pub. July 28, 2011 (Ex. 1005).

We construe only claim terms relevant to issues in dispute and only to the extent necessary to resolve the issues presented by the Petition. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). For purposes of this Decision, we provide an express construction for the term "paresthesia." Paresthesia occurs in the phrase "wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz and does not create paresthesia," as recited by claims 1 and 26.

Petitioner asserts that "paresthesia" refers to a sensation perceived as tingling or prickling, and proposes a construction for "paresthesia" as "a tingling sensation induced by spinal cord stimulation." Pet. 11. Petitioner relies on a statement in the Specification's description of the prior art that "patients report a tingling or paresthesia that is perceived as more pleasant and/or less uncomfortable than the underlying pain sensation." Pet. 11 (quoting Ex. 1001, 1:50–52; citing also Ex. 1015 (McIntyre Decl.) ¶ 14).

Patent Owner requests that "paresthesia" not be limited to "tingling" and instead proposes that "paresthesia" be construed as follows: "Any abnormal sensation with no apparent cause from a corresponding physical condition. Examples of paresthesia include burning, pricking, pressure, formication, tickling, numbness, tingling, a 'pins and needles' feeling, or creeping on the skin." Prelim. Resp. 15–16. Patent Owner relies for its construction on definitions of "paresthesia" from two medical dictionaries and one general dictionary as follows: (a) DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (Ex. 2011, 0004) ("morbid or perverted sensation; an

abnormal sensation, as burning, prickling, formication[5], etc."); (b) MOSBY'S MEDICAL DICTIONARY (Ex. 2012, 0003) ("any subjective sensation, experienced as numbness, tingling, or a 'pins and needles' feeling"); (c) WEBSTER'S THIRD INTERNATIONAL DICTIONARY (Ex. 2013, 0003) ("a sensation of pricking, tingling, or creeping on the skin having no objective cause and usu. associated with injury or irritation of a sensory nerve or nerve root."). Prelim. Resp. 17.

All of the evidence presented supports an understanding that paresthesia includes various manifestations of a "pins and needles" feeling, often described as "tingling." Patent Owner's dictionaries also refer to "pricking," "formication," and "creeping on the skin," which is consistent with Petitioner's Declarant's observation the same sensation may manifest itself as "prickling." *See* Ex. 1105 ¶ 14. Although we recognize that Patent Owner has not had the opportunity to submit any "new testimonial evidence" at this stage of the proceeding, *see* 37 C.F.R. § 42.107(c), Patent Owner does not here provide support for "pressure" as it might be understood apart from "pricking," "formication," and "creeping on the skin."

For purposes of this Decision on Institution, we determine that the broadest reasonable construction consistent with the Specification of "does not create paresthesia" is "does not create tingling." We are guided by the submitted dictionaries as well as the Specification which criticizes prior art techniques for causing "tingling or paresthesia." Ex. 1001, 1:50–52. We credit the statement of Petitioner's Declarant that the same sensation may be

[5] Formication is a hallucination in which a patient feels as if insects are crawling on his or her skin.

variously perceived. However, we do not include "pressure" itself within that construction.

B. Principles of Law

To establish anticipation, each limitation in a claim must be found in a single prior art reference, arranged as recited in the claim. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). While the limitations must be arranged or combined in the same way as in the claim, identity of terminology is not required. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009); *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). Moreover, a reference anticipates a claim "if it discloses the claimed invention such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention." *In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995) (emphasis omitted). Thus, "it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826 (CCPA 1968).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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. of Kansas City*, 383 U.S. 1, 17–18 (1966).

In that regard, an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *see also Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). A prima facie case of obviousness is established when the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. *In re Rinehart*, 531 F.2d 1048, 1051 (CCPA 1976). The level of ordinary skill in the art may be reflected by the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

C. Anticipation by MacDonald (Ex. 1002)

Relying on the Declaration of Cameron C. McIntyre, Ph.D. (Ex. 1015), Petitioner contends that MacDonald anticipates claims 1, 2, 11–14, 17–22, 25, and 26. Pet. 13–27. Patent Owner disagrees. Prelim. Resp. 23–28. We determine, on the current record, that Petitioner has not established a reasonable likelihood of prevailing on its assertion.

1. Overview of MacDonald

MacDonald discloses an electrotherapeutic apparatus "for producing analgesia through electrical stimulation wherein the apparatus comprises two or more electrodes adapted to supply electrical signals to two or more locations on the surface of a body overlying the central nervous system." Ex. 1002, at [54], [57], 2:22–26. MacDonald discloses a rapid rise and fall of the electrical signal (*id.* at 2:26–30), and in one embodiment discloses that "[t]he main features of this stimulator circuit are that it provides a high

voltage, that is up to approximately 450V, a narrow pulse width, around 1–10 μs, and that this pulse has short rise and fall times so that even under adverse output conditions a narrow pulse with short rise and fall times is maintained." *Id.* at 4:62–67.

MacDonald discloses that "the placement of the electrodes on regions overlying the spinal cord is preferred as this has not produced any known side effects." *Id.* at 3:46–48. MacDonald also discloses that electrodes may be implanted as an alternative. *Id.* at 3:49–51.

MacDonald proceeds to disclose an experiment in which "[s]urface electrodes were attached to the stimulator that produced a square wave pulse of 4–8 μs duration, at a rate of 100 pulses per second, at various amplitudes (voltages) to see whether the phenomenon of spatial summation could be produced in the spinal cord." *Id.* at 5:33–37. MacDonald reports the findings from this experiment as follows:

> When two 4x4 cm electrodes were placed close together anywhere on the mid-line of the back over the spine from T1 downwards, a tingling sensation only was produced.
>
> However, if the electrodes were separated by a distance of 10 cms or so the levels between T1 and T12 could be perceived and described by the trained observer at a lower threshold than the tingling. It was a continuous feeling of warmth and painless, light pressure. However, this sensation is so mild in intensity that many patients distracted by their aches and pains are unable to perceive it. Nevertheless amongst those that report this sensation, the most striking observation about it is its continuity; the discrete sensations produced by each pulse are not detectable as it is when tingling is present. This new feeling may be called 'spinal cord sensation' as it is only obtained when the electrodes are placed in the immediate vicinity of the spinal cord itself.

Id. at 5:48–63.

MacDonald notes that at 600 Hz, typically up to about 250V may be employed to produce analgesia, but at higher frequencies, unwanted heated effects begin to occur, so the voltage has to be decreased. *Id.* at 8:36–44. For example, at a frequency of 5 KHz, 150V would be used, while at 150 KHz a voltage of 25V was found to be effective. *Id.*

2. Analysis

Petitioner sets forth in the Petition how each limitation of claims 1, 2, 11–14, 17–22, 25, and 26 would be understood to be disclosed by MacDonald. Pet. 13–27. The parties first dispute whether MacDonald discloses any examples of electrical stimulation that "does not create paresthesia in the patient," as recited by claims 1 and 26. *See* Pet. 14–17; Prelim. Resp. 24–25. When MacDonald discloses electronic stimulation lower than the threshold for tingling, MacDonald also discloses a "feeling of warmth and painless, light pressure." 5:51–63. Applying the above claim construction of "paresthesia," we determine, on the current record, that Petitioner has shown sufficient evidence that MacDonald discloses a lack of paresthesia in that example.

However, we agree with Patent Owner that Petitioner has not sufficiently demonstrated that MacDonald anticipates because Petitioner has not shown that MacDonald's transcutaneous therapy is applicable for an implantable signal delivery device or that MacDonald teaches the claimed frequency ranges with sufficient specificity. Prelim. Resp. 25–29. MacDonald's disclosure results from an experiment using "surface electrodes," and "at a rate of 100 pulses per second." Ex. 1002, 5:33–37. Therefore, even though Petitioner relies on a disclosure in MacDonald that

electrodes may be implanted (*id*. at 3:49–51, 8:55–57), and that frequencies of up to 150 kHz or 250 kHz may be used (*id.* at 4:9–21, 8:39–43), Petitioner does not provide evidence that the patient would feel no paresthesia under such conditions, i.e., under conditions different than those described in the first set of experiments. *See* Pet. 14–20. Nor does Petitioner direct us to persuasive evidence from Dr. McIntyre's testimony (Ex. 1015) that MacDonald discloses this claim element.

In sum, although the various disclosures relied upon by Petitioner are in the same reference, Petitioner has not sufficiently shown that the conditions were arranged together in the same way as recited in the claim. *See Net MoneyIN, Inc. v. VeriSign, Inc*., 545 F.3d 1359, 1369 (Fed. Cir. 2008). We, therefore, conclude that Petitioner has not shown a reasonable likelihood of prevailing on its assertion that claims 1, 2, 11–14, 17–22, 25, and 26 are anticipated by MacDonald.

D. Anticipation by Sluitjer (Ex. 1003)

Petitioner contends Sluitjer anticipates claims 1, 2, 15, 17, 18, 25 and 26. Pet. 27–37. Patent Owner disagrees. Prelim. Resp. 35–39. We determine, on the current record, that Petitioner has not established a reasonable likelihood of prevailing on its assertion.

1. Overview of Sluitjer

Sluitjer, titled "Modulated High Frequency Tissue Modification," discloses a method of applying high frequency electromagnetic fields for modifying neural function or achieving pain relief without burning tissue. Ex. 1003, [54], [57], 1:10–17, 2:40–52. Sluitjer discloses inserting electrodes into the body near or in neural tissue, and applying RF (radiofrequency) waveforms with bursts of RF power, interposed with off-

time, to prevent the average temperature from exceeding approximately 45 °C. *Id.* at 2:57–66. Sluitjer further discloses the use of a variety of frequencies, i.e., in the 0 to about 300 to 400 Hertz range, or as high as 50 kilohertz to many megahertz. *Id.* at 15:47–53, 19:4–6.

2. Analysis

Petitioner sets forth in the Petition how each limitation of claims 1, 2, 15, 17, 18, 25, and 26 would be understood to be disclosed by Sluitjer. Pet. 21–34. We determine that this proposed ground of unpatentability is deficient for similar reasons as for the ground based on MacDonald, i.e., that Petitioner has not sufficiently shown that the desired lack of paresthesia would occur under the recited conditions.

To meet the limitation "without causing paresthesia in the patient," Petitioner relies on the following disclosure in Sluitjer: "In addition, the high frequency waveform from the generator may or may not be free from substantial stimulative components in the 0 to about 300 to 400 Hertz range, which is lower than radiofrequencies. If the waveform is without stimulative frequencies, it will avoid the stimulation effects that are typical for stimulator system applications as described above." *Id.* at 15:47–53.

Petitioner argues based, *inter alia*, on the above passage, that Sluitjer discloses lack of paresthesia at high frequencies. *See* Pet. 29. First, Patent Owner persuades us that Sluitjer is ambiguous about the type of "stimulative effects" to which it refers, and we agree with Patent Owner that "stimulative effects" does not clearly and necessarily refer to paresthesia. *See In re Hughes*, 345 F.2d 184 (CCPA 1965) (an ambiguous reference cannot serve as an anticipation).

Further, in context, Sluitjer simply states that "[I]f the waveform is without stimulative frequencies, it will avoid the stimulation effects that are typical for stimulator system applications as described above." *Id.* at 15:47–53. Sluitjer's disclosure is thus somewhat circular, i.e., that if the frequencies are not "stimulative frequencies," it will "avoid the stimulation effects that are typical."[6] We agree with Patent Owner that Sluitjer does not contain a clear disclosure that Sluitjer's method "does not create paresthesia in the patient" in the range of 1.5 kHz to about 50 kHz, as recited by independent claims 1 and 26. *See* Prelim. Resp. 35–36.

Petitioner's Declarant relies on technical articles describing testing performed using Sluijter's methodologies to "confirm" the nature of the results disclosed in the Sluitjer reference. Pet. 30 (citing Ex. 1015 ¶ 35; Ex. 1016, 113; Ex. 1017, 438). However, Patent Owner asserts that one of these articles states that patients did experience "some slight tingling." Prelim. Resp. 36 (quoting Ex. 1016, 114). We agree with Patent Owner that, even to the extent Petitioner's additional evidence may shed light on the question of anticipation, it does not serve to confirm Petitioner's reading of Sluitjer. We conclude, on this record, that Petitioner has not adequately shown the Sluitjer reference discloses lack of paresthesia at the recited frequencies so as to anticipate claims 1, 2, 15, 17, 18, 25, and 26.

[6] There is a teaching in Sluitjer to avoid physiologic frequencies in the range of 0 to 300 Hz. *Id.* at 15:47–53, 17:13–19. At the same time, Sluitjer teaches that one may purposefully use a mixture of frequencies, including those in the range of 0 to about 300 Hz. *Id.* at 19:11–29.

E. Anticipation by Royle (Ex. 1004)

Petitioner contends Royle anticipates claims 1, 2, 17–23, 25, and 26. Pet. 37–45. Patent Owner disagrees. Prelim. Resp. 29–35. We determine, on the current record, that Petitioner has not established a reasonable likelihood of prevailing on its assertion for claims 1, 2, 17–23, 25, and 26.

1. Overview of Royle

Royle, is disclosed as relating to "apparatus and methods suitable for, but not limited to, the application of electricity to the skin so as to modulate nerves electronically." Ex. 1004, at [54], [57], ¶ 1. In particular, Royle discloses the use of both positive and negative impulses in series, referred to as "Electronic Nerve Modulation" or "ENM," having a spacing preferably of 4 μs or 6 μs. *Id.* ¶¶ 61, 63. Royle states that the skin is "less likely to burn" at high voltages of 100–400 V with the use of both positive and negative voltage pulses. *Id.* ¶¶ 73–74.

Royle further discloses that "[t]he use of a fast rise time (the transition time from 0 volts to the peak voltage) of the pulses is preferable, as it is understood to lower the electrical resistance of the skin without stimulating the peripheral nerves, so that the subject (i.e. patient) feels no sensation. Further, this enables a relatively large quantity of electrical charge to pass through the skin and tissues." *Id.* ¶ 75. Conversely, Royle notes that a fast decay of the voltage prevents stimulation of the peripheral nerves. *Id.* ¶ 76. Royle, however, states the use of both positive and negative voltage allows longer pulse widths to be "comfortably utilised on a patient." *Id.* ¶ 78.

Royle states that ". . . the electrodes are normally applied to the surface of a body overlying the central nervous system, such that analgesic effects tend to be effected in the central nervous system whilst stimulating

peripheral nerves that lie between the electrodes and the central nervous system to a lesser extent or not at all. If desired, the electrodes could be implanted within the body, including within the skin, but it is more preferable that they are designed to simply be placed in contact with the skin surface." *Id.* ¶ 104.

2. Analysis

Petitioner sets forth in the Petition how each limitation of claims 1, 2, 17–23, 25, and 26 would be understood to be disclosed by Royle. Pet. 37–45. Although Petitioner relies on paragraphs 75, 76, and 78 of Royle for meeting the limitation "does not create paresthesia in the patient" (Pet. 39), the context of these paragraphs indicates that Royle is referring to skin electrodes such that "[f]urther, this enables a relatively large quantity of electrical charge to pass through the skin and tissues." *Id.* ¶ 75. We agree with Patent Owner that Petitioner has not adequately shown that Royle achieves "no sensation," however, in the context of an implantable signal delivery device, e.g., as referred to in paragraph 104 of Royle. *See* Prelim. Resp. 33–35. We, therefore, determine that Petitioner has not established a reasonable likelihood of prevailing on its assertion of anticipation by Royle for similar reasons as set forth for its assertion of anticipation by MacDonald above.

F. Obviousness over MacDonald, either alone or in view of De Ridder (Ex. 1005), Sluijter and/or Royle

Petitioner contends the combination of MacDonald, either alone or in view of De Ridder, Sluijter and/or Royle renders obvious claims 1, 2, 11–15, 17–23, 25, and 26. Pet. 45–50. Patent Owner disagrees. Prelim. Resp. 41–

53. We determine, on the current record, that Petitioner has not established a reasonable likelihood of prevailing on its assertion.

1. Overview of De Ridder

De Ridder discloses a system and method for treating pain without paresthesia by spinal cord stimulation. Ex. 1005, at [54], [57]. De Ridder discloses paresthesia as a side effect of high frequency electrode stimulation. *Id.* ¶ 4. De Ridder discloses that treatment with "burst stimulation" resulted in "complete pain suppression" and that one patient experienced a "complete suppression of both pain and paresthesia with burst [spinal cord stimulation] treatment." *Id.* ¶ 44. De Ridder performed experiments with an "inter-burst" frequency of 40 Hz and an "intra-burst" frequency of 500 Hz. *Id.* ¶ 41–42; Table 1.

2. Analysis

Petitioner asserts that it would have been an obvious design choice for one of ordinary skill in the art to implement MacDonald's therapy in a way that does not cause paresthesia, and De Ridder describes tests that were performed on patients using spinal cord stimulation parameters that successfully treated pain without causing paresthesia. Pet. 46–47 (citing Ex. 1005 ¶¶ 41–44; Exhibit 1115 ¶¶ 138–141; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007) ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.")). Petitioner also reasons that it was known from such references as De Ridder that paresthesia was undesirable. Pet. 47 and n.3.

However, we agree with Patent Owner that De Ridder teaches that high frequency stimulation causes, rather than avoids, paresthesia. Prelim. Resp. 43 (citing Ex. 1005 ¶ 4). Further, De Ridder's data reporting suppression of paresthesia was conducted at an "inter-burst" frequency of 40 Hz and an "intra-burst" frequency of 500 Hz, rather than the recited frequencies. Ex. 1005 ¶ 41–42; Table 1.

With respect to Sluitjer and Royle, we address these references individually in the sections above. Further, we agree with Patent Owner that the Petition does not articulate the obviousness ground inasmuch as the Petition does not explain which aspects of MacDonald would have been retained and which aspects of De Ridder, Sluitjer, and Royle would have been the basis for a modification, and the rationale for the choice of any such elements. *See* Prelim. Resp. 45; Pet. 45–50; 37 C.F.R. §§ 42.104(b)(4), (b)(5), 42.108(c); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

We determine, on the current record, that Petitioner has not established a reasonable likelihood of prevailing on its assertion that claims 1, 2, 11–15, 17–23, 25, and 26 are rendered obvious by the combination of MacDonald, either alone or in view of De Ridder, Sluijter and/or Royle.

G. Obviousness over Sluijter, either alone or in view of De Ridder, MacDonald and/or Royle

Petitioner contends the combination of Sluijter, either alone or in view of De Ridder, MacDonald and/or Royle renders obvious claims 1, 2, 11–15, 17–23, 25 and 26. Pet. 21–37. Patent Owner disagrees. Prelim. Resp. 41–53. We determine, on the current record, that Petitioner has not established a reasonable likelihood of prevailing on its assertion for similar reasons as

for the proposed ground of obviousness over MacDonald in view of De Ridder, Sluijter and/or Royle.

Petitioner states that "a person of ordinary skill would reasonably have expected that use of Sluijter's system to treat such sources of pain would have had similar success to MacDonald's system." Pet. 53. However, for similar reasons as set forth above with respect to the individual references, the Petition has not adequately shown a reasonable likelihood of success of providing therapy "without causing paresthesia in the patient" at the recited frequencies.

Further, we agree with Patent Owner that the Petition does not articulate the obviousness ground inasmuch as the Petition does not explain which aspect of Sluitjer would have been retained and which aspects of De Ridder, MacDonald, or Royle would have been the basis for a modification of Sluijter, and the rationale for the choice of any such elements. *See* Prelim. Resp. 50–55; Pet. 45–50; 37 C.F.R. §§ 42.104(b)(4), (b)(5), 42.108(c); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

H. Obviousness over Royle, either alone or in view of De Ridder, MacDonald and/or Sluijter

Petitioner contends the combination of Royle, either alone or in view of De Ridder, MacDonald and/or Sluijter renders obvious claims 1, 2, 11–15, 17–23, 25, and 26. Pet. 21–37. Patent Owner disagrees. Prelim. Resp. 41–53. For similar reasons as for the other proposed grounds of unpatentability based on obviousness, we determine that Petitioner has not established a reasonable likelihood of prevailing on its assertion that claims 1, 2, 11–15, 17–23, 25, and 26 are rendered obvious by the combination of Royle, either alone or in view of De Ridder, MacDonald and/or Sluijter.

III. CONCLUSION

We conclude that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claims 1, 2, 11–15, 17–23, 25, and 26 of the '102 patent are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is not instituted.

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