

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC NEUROMODULATION CORPORATION,
Petitioner,

v.

NEVRO CORPORATION,
Patent Owner.

Case IPR2015-01204
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. 1101). 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 IPR2015-01203).

B. The ’102 Patent (Ex. 1101)

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. 1101, 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 where 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 these problems with 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, with the width of the applied pulses about 30–35 μ sec, and the amplitude generally from about 1mA to about 4 mA. *Id.* at 6:60–7:8.

Several embodiments of the '102 patent use 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:

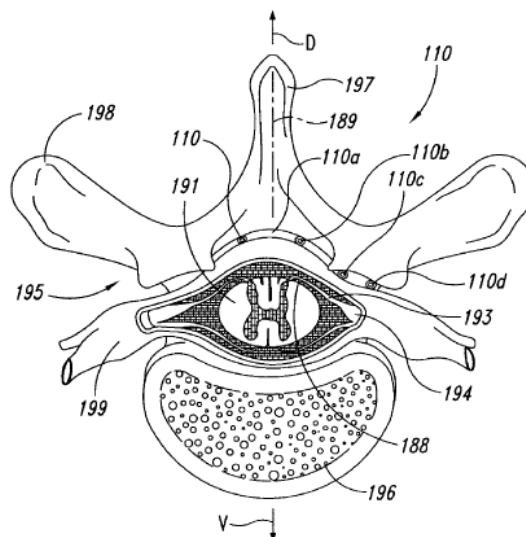


Figure 1B, above, depicts the placement of lead 110, according to one embodiment, at spinal level T7–T8. *Id.* at 6:39–40.

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. 1101, 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
Knudson ¹	§ 102	1, 2, 17–22, 25, and 26
Knudson, either alone or in view of De Ridder ² and/or MacDonald ³	§ 103	1, 2, 11–15, 17–23, 25, and 26

¹ Knudson, U.S. Patent Application Pub. No. US 2007/0073354 A1, pub. Mar. 29, 2007 (Ex. 1102).

² De Ridder, U.S. Patent Application Pub. No. 2011/0184488 A1, pub. July 28, 2011 (Ex. 1103).

³ MacDonald, U.S. Patent No. 5,776,170, iss. July 7, 1998 (Ex. 1104).

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); see *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,” “paresthesia,” “spinal cord,” and “nociceptive pain.” Pet. 11–15. Patent Owner disputes the construction of these terms. Prelim. Resp. 20–25.

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. 1101, 1:50–52; citing also Ex. 1115 (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, 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. 22.

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. 1115 ¶ 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. 1101, 1:50–52. We credit the statement of Petitioner’s Declarant that the same sensation may be 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 Knudson (Ex. 1102)

Relying on the Declaration of Cameron C. McIntyre, Ph.D. (Ex. 1115), Petitioner contends that Knudson anticipates claims 1, 2, 17–22, 25, and 26. Pet. 16–27. Patent Owner disagrees. Prelim. Resp. 26–32. We

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

1. Overview of Knudson

Knudson discloses a neural blocking therapy for treating a tissue sensation or for treating a condition associated with neural activity of a spinal cord by placing an electrode near the target area to at least partially block neural activity. Ex. 1102, at [54], [57], ¶ 36. In particular, Knudson discloses that application of a blocking signal to the electrode blocks signals such as pain signals from the dorsal root of the spinal cord. *Id.* ¶ 83. Knudson discloses the use of frequencies in excess of 3,000 Hz and more preferably about 5,000 Hz or more. *Id.*

2. Analysis

Petitioner sets forth in the Petition how each limitation of claims 1, 2, 17–22, 25, and 26 would be understood to be disclosed by Knudson. Pet. 16–27. Petitioner states that the mechanism of action of Knudson’s nerve block is to “block the propagation of action potentials along the nerve” (*id.* at 20 citing Ex. 1102 ¶ 11), and relies on the Declaration of Dr. McIntyre for the understanding that if no action potentials are traveling along a nerve, the patient will not feel paresthesia. Pet. 20 (citing Ex. 1115 ¶ 45).

Petitioner further points to two scientific publications (discussed during the prosecution of a related application) for evidence that Knudson’s disclosure of “blocking” peripheral nerves is consistent with, and inherently means, “without causing paresthesia.” See Pet. 20–23 (citing K. Kilgore et al., *Reversible Nerve Conduction Block Using Kilohertz Frequency Alternating Current*, 17 NEUROMODULATION: TECHNOLOGY AT THE NEURAL

INTERFACE 242–255 (International Neuromodulation Society, 2013–14) (Ex. 1116) and C. Perruchoud et al., *Analgesic Efficacy of High-Frequency Spinal Cord Stimulation: A Randomized Double-Blind Placebo-Controlled Study*, 16 NEUROMODULATION: TECHNOLOGY AT THE NEURAL INTERFACE 363–369 (International Neuromodulation Society, 2013) (Ex. 1117)). In this connection, Petitioner, *inter alia*, quotes Kilgore as explaining that “[i]n true nerve conduction block, action potentials are arrested as they pass under the blocking electrode.” Pet. 21 (discussing Ex. 1116). Petitioner asserts that Perruchoud utilizes a 5kHz signal but does not refer to blocking. See Pet. 23 (discussing Ex. 1117).

We are persuaded by Patent Owner that Knudson does not disclose a paresthesia-free therapy, either explicitly or inherently. Prelim. Resp. 10–13. We have reviewed Kilgore and Perruchoud and do not find that they support a reading that Knudson’s nerve blocking necessarily resulted in the patient feeling no paresthesia. The Petition relies primarily on the testimony of Dr. McIntyre for the proposition that Knudson’s method of nerve blocking inherently discloses an application “without causing paresthesia in the patient.” See Pet. 16–24. However, Dr. McIntyre offers no support for the proffered testimony that “one of ordinary skill would have understood that by describing his therapy signal as applying a ‘blocking’ signal, Knudson was teaching application of a signal that would not cause the patient to perceive paresthesia.” Ex. 1115 ¶ 44. To the extent that Petitioner and Petitioner’s Declarant rely on a mechanism of nerve block as blocking a nerve action potential, Petitioner has not adduced persuasive evidence as to what a patient would necessarily have perceived or sensed in the Knudson experiment. See 37 C.F.R. § 42.65 (“Expert testimony that does not

disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”).

We conclude that Petitioner has not adequately shown that Knudson discloses application of electricity “without causing paresthesia in the patient,” as required by independent claims 1 and 26. *See In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999) (“Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”). We, therefore, determine that Petitioner has not established a reasonable likelihood of prevailing on its assertion with respect to claims 1, 2, 17–22, 25, and 26.

D. Obviousness over Knudson, either alone or in view of De Ridder (Ex. 1103) and/or MacDonald (Ex. 1104)

Petitioner contends the combination of Knudson, either alone or in view of De Ridder and/or MacDonald renders obvious claims 1, 2, 11–15, 17–23, 25, and 26. Pet. 27–35. Patent Owner disagrees. Prelim. Resp. 33–52. We determine, on the basis of the record before us, 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. 1103, 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. 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. 1104, at [54], [57], 2:22–26. 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 μ s 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 that “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.” *Id.* at 5:48–63.

3. Analysis

Petitioner contends the combination of Knudson, either alone or in view of De Ridder and/or MacDonald renders obvious claims 1, 2, 11–15, 17–23, 25, and 26. Pet. 27–36. Petitioner asserts that it would have been an obvious design choice for one of ordinary skill in the art to implement Knudson’s therapy in a way that does not cause paresthesia, and that De Ridder and MacDonald disclose treatment of pain without causing paresthesia. Pet. 27–30 (citing Ex. 1103 ¶¶ 41–44; Ex. 1104, 6:33–48, 7:65–8:35; Ex. 1115 ¶¶ 67–71; *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 De Ridder teaches paresthesia was undesirable. Pet. 28–29.

However, we agree with Patent Owner that De Ridder discloses that high frequency stimulation causes, rather than avoids, paresthesia. Prelim. Resp. 37–39 (citing Ex. 1103 ¶ 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. *Id.* ¶ 41–42; Table 1.

With respect to MacDonald, we determine that Petitioner has not established that MacDonald indicates how a person of ordinary skill would deliver an electric signal, without causing paresthesia, at the frequencies of about 1.5 kHz to about 50 kHz, as recited by claims 1 and 26. See Pet. 27–36.

We also agree with Patent Owner that the Petition does not articulate the obviousness ground inasmuch as the Petition does not explain which aspects of Knudson would have been retained and which aspects of De Ridder or MacDonald would have been the basis for a modification, and the rationale for the choice of any such elements. See Prelim. Resp. 39–42; Pet. 27–36; 37 C.F.R. § 42.104(b)(4), (b)(5); *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

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 Knudson, either alone or in view of De Ridder and/or MacDonald.

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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