

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,
Petitioner,

v.

EMKINETICS, INC.,
Patent Owner.

IPR2024-01375
Patent 11,224,742 B2

Before ERICA A. FRANKLIN, JOHN G. NEW, and JASON W. MELVIN,
Administrative Patent Judges.

MELVIN, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Avation Medical, Inc. (“Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting institution of *inter partes* review of claims 1–13 (“the challenged claims”) of U.S. Patent No. 11,224,742 B2 (Ex. 1001, “the ’742 patent”). Patent Owner EMKinetics, Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 6 (“Prelim. Resp.”).

An *inter partes* review may not be instituted unless “the information presented in the petition . . . and any 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(a) (2018). “When instituting *inter partes* review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.” 37 C.F.R. § 42.108(a) (2021).

For the reasons that follow, based on the present record, we conclude that Petitioner has shown a reasonable likelihood it will prevail with respect to at least one challenged claim, and we institute *inter partes* review of the ’742 patent.

A. REAL PARTIES IN INTEREST

The parties identify themselves as real parties in interest. Pet. xii; Paper 5, 2.

B. RELATED MATTERS

Petitioner and Patent Owner identify *Avation Medical, Inc. v. EMKinetics, Inc.*, No. 4:24-cv-01702 (N.D. Cal.) (“NDCA litigation”) as a related matter involving the ’742 patent. Pet. xii (citing Ex. 1051); Paper 5, 2.

The parties also identify U.S. Patent No. 11,844,943 (“the ’943 patent”), and U.S. Patent No. 9,002,477 (“the ’477 patent”) as being involved in the NDCA litigation. Pet. xii (citing Ex. 1051); Paper 5, 2. The parties further identify that the ’943 patent is the subject of PGR2024-00043, and the ’477 patent is the subject of IPR2024-01378. Pet. xii; Paper 5, 2.

C. THE ’742 PATENT (EX. 1001)

The ’742 patent is entitled “Methods and Devices for Performing Electrical Stimulation to Treat Various Conditions” and is directed to systems and/or methods for electromagnetic induction therapy. Ex. 1001, codes (54), (57). The ’742 patent describes “treating a variety of ailments by providing energy to a target nerve.” *Id.* at 8:35–36. The energy may be in the form of “magnetic energy, electrical energy or ultrasound energy.” *Id.* at 8:37–38.

The ’742 patent describes an exemplary embodiment based on electromagnetic induction therapy, wherein one or more conductive coils may be configured to generate a magnetic field focused on a target nerve, muscle, or other body tissues in proximity to the coils. Ex. 1001, 5:49–53. One or more sensors may be used to detect electrical conduction in the target nerve, to detect a muscular response caused by an electrical conduction in the target nerve, or to detect stimulation of a nerve, muscle or other body tissues, and to provide feedback about the efficacy of the applied electromagnetic induction therapy. *Id.* at 5:54–59.

The ’742 patent depicts an embodiment of a system for magnetic induction therapy in Figure 1, which is reproduced below.

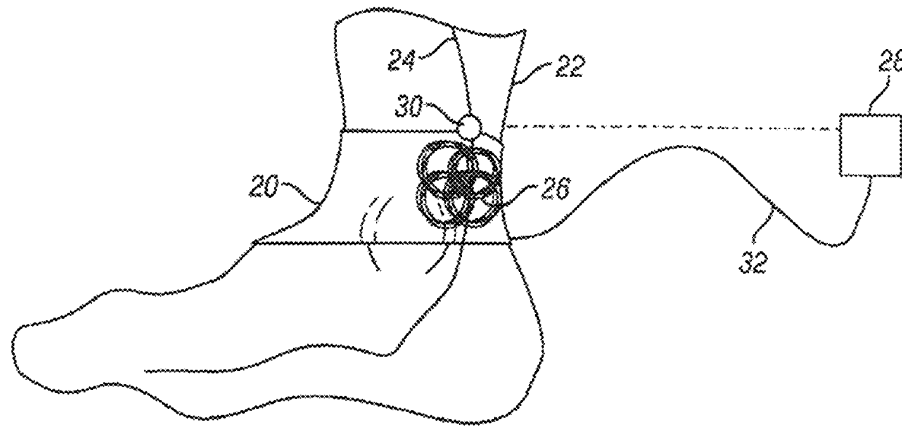


FIG. 1

Figure 1 shows a coil wrap 20 disposed over ankle 22 circumferentially to surround a portion of tibial nerve 24. Ex. 1001, 10:7–9. According to the '742 patent,

[c]oil wrap 20 contains one or more conductive coils 26 arranged to produce a pulsed magnetic field that will flow across tibial nerve 24 and generate a current that will flow along tibial nerve 24 and spread along the length of tibial nerve 24 all the way to its sacral or pudendal nerve root origins.

Id. at 10:32–37. A programmable logic controller 28 supplies the electrical current that flows through coils 26 and produces the magnetic field. *Id.* at 10:61–64. Figure 1 also shows a sensor 30, whose purpose is “to detect and record the firing of the target nerve and to provide related information to logic controller 28, so to render the intended therapy most effective.” *Id.* at 10:67–11:4.

The '742 patent also depicts an embodiment of a system for providing electrical stimulation in Figure 11, which is reproduced below:

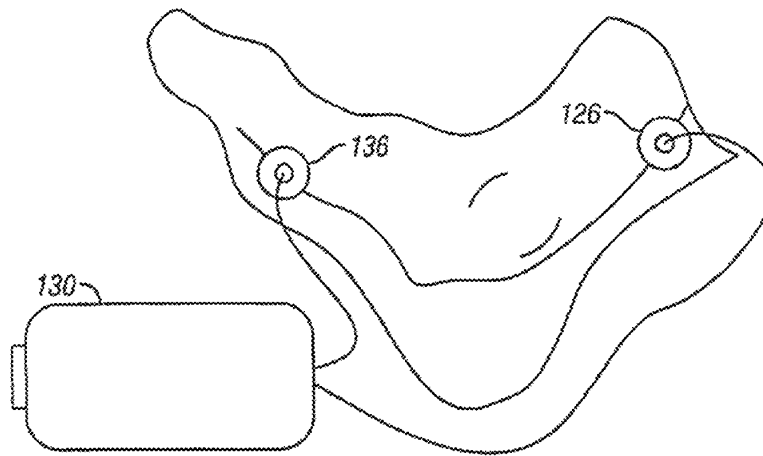


FIG. 11

Figure 11 shows electrical pulse stimulator 130 connected to electrode 126 and sensor 134. Ex. 1001, 16:61–17:5. According to the '742 patent, “nerve conduction may be detected at a site sufficiently distant from the site of stimulation, so to enable detection of nerve conduction despite the confounding interference from the direct electrical stimuli.” *Id.* at 17:5–9.

D. THE CHALLENGED CLAIMS

Petitioner challenges claims 1–13 of the '742 patent. Pet. 2–3. Claim 1 is independent and is reproduced below¹:

- [1.p] 1. A method of treating overactive bladder or incontinence, comprising:
 - [1.a] non-invasively positioning a first portion of a patient's body relative to an electrical stimulator such that a branch of a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator;

¹ We adopt the bracketed identifiers added by Petitioner.

- [1.b] passing a current through the electrical stimulator; and
- [1.c] delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve such that the branch directly receives the electrical stimulation to treat overactive bladder or incontinence.

Ex. 1001, 46:45–56. The remaining claims depend directly or indirectly from claim 1. *Id.* at 46:57–48:16.

E. PRIOR ART AND ASSERTED GROUNDS

Petitioner asserts the following unpatentability grounds:

Claim(s) Challenged	35 U.S.C. §²	Reference(s)/Basis
1–13	103(a)	Svihra, ³ Mann, ⁴ Ponsford, ⁵
1–13	103(a)	Amarenco, ⁶ Mann, Ponsford

² The '742 patent claims priority to an October 2, 2006, provisional application. Ex. 1001, codes (60), (63); *see* Pet. 21. Therefore, the pre-AIA statutes apply.

³ Svihra et al., *Neuromodulative Treatment of Overactive Bladder – Noninvasive Tibial Nerve Stimulation*, 103(12) Bratisl Lek Listy 480–83 (2002) (Ex. 1004). All citations are to the native pagination.

⁴ U.S. Patent No. 6,941,171 B2, issued Sept. 6, 2005 (Ex. 1084).

⁵ Ponsford, *Sensory Conduction in Medial and Lateral Plantar Nerves*, 51(2) J. Neurology, Neurosurgery, & Psychiatry 188–191 (1988) (Ex. 1085). All citations are to the native pagination.

⁶ Amarenco et al., *Urodynamic Effect of Acute Transcutaneous Posterior Tibial Nerve Stimulation in Overactive Bladder*, 169 J. Urology 2210–15 (June 2003) (Ex. 1005). All citations are to the native pagination.

Pet. 2–3. In addition to the references identified above, Petitioner relies on Boveja,⁷ Grey,⁸ and Rhodes⁹. *See id.* at 12–15, 25–31, 48–52. Further, Petitioner relies on the notion that an obviousness analysis always considers the perspective and knowledge of ordinarily skilled artisans. *Id.* at 2 n.3; *see KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (one considers “the background knowledge possessed by a person having ordinary skill in the art”). Petitioner relies also on the Declaration of Dr. Brett Wingeier. Ex. 1003.

II. ANALYSIS

A. LEGAL STANDARDS

A claim is unpatentable “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.” 35 U.S.C. § 103(a). The question of obviousness involves resolving 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 ordinary skill in the art; and when presented (4) objective evidence of nonobviousness, *i.e.*, secondary considerations.¹⁰ *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Further, “there must

⁷ U.S. Pub. No. 2006/0122660 A1, published Jun. 8, 2006 (Ex. 1080).

⁸ U.S. Patent No. 6,272,383 B1, issued Aug. 7, 2001 (Ex. 1081).

⁹ U.S. Patent No. 5,995,873, issued Nov. 30, 1999 (Ex. 1086).

¹⁰ In the present record, neither party presents arguments or evidence relating to secondary considerations.

be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

B. DISCRETIONARY DENIAL UNDER § 325(d)

Patent Owner proposes that we discretionarily deny institution under 35 U.S.C. § 325(d) because Amarenco and Mann previously were presented to the Office during prosecution of the '742 patent. *See* Prelim. Resp. 17–18. According to Patent Owner, Petitioner has identified additional references that “supposedly teach[] only some of what was missing—stimulation of a branch of the posterior tibial nerve but not to treat overactive bladder or incontinence.” *Id.* at 18. Patent Owner’s argument is flawed for two reasons. First, neither Svihra nor Ponsford were previously presented to the Office. Because Patent Owner does not argue that we should deny institution of Petitioner’s Svihra-based ground under § 325(d), and because that ground relies on a combination of art not previously presented, Patent Owner’s § 325(d) argument is unpersuasive. In that regard, we determine that even if we were to conclude the Amarenco-based ground warranted discretionary denial, the Svihra-based ground would not be subject to such denial and may alone justify institution. *See* USPTO, *SAS Q&As* (June 5, 2018) at D1.¹¹

Additionally, for the Amarenco-based ground, Petitioner relies on a combination including prior art that was not previously presented, and Patent Owner does not show that additional prior art is cumulative to art presented during prosecution. We determine that Petitioner’s Amarenco-based ground

¹¹ *Available at:* https://www.uspto.gov/sites/default/files/documents/sas_qas_20180605.pdf

is not substantially the same as one previously presented to the Office. Thus, we decline to discretionarily deny institution under § 325(d).

C. LEVEL OF ORDINARY SKILL IN THE ART

Petitioner contends that a person of ordinary skill in the art at the time of filing “would have had an undergraduate degree in the field of biomedical engineering or a related discipline, such as electrical engineering, and at least two years of experience in the design and/or analysis of biomedical devices” and that “[a]dditional work experience could substitute for a formal degree and vice versa.” Pet. 21 (citing Ex. 1003 ¶¶ 20–21).

Patent Owner does not dispute Petitioner’s proposal. *See generally* Prelim. Resp. Because Petitioner’s proposed level of ordinary skill in the art appears to be consistent with the challenged patent and prior art, we adopt it, and use “skilled artisans” to refer to people with such skill at the time the invention was filed.

D. CLAIM CONSTRUCTION

We construe claims according to the standard used in the federal courts in civil actions under 35 U.S.C. § 282(b), which is articulated in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). *See* 37 C.F.R. § 42.100(b). Under *Phillips*, the “words of a claim ‘are generally given their ordinary and customary meaning,’” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1312–13.

Petitioner argues that “no terms require construction for purposes of this Petition.” Pet. 22. Patent Owner does not contest Petitioner’s position.

See generally Prelim. Resp. We agree and do not expressly construe any terms at this stage. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that “we need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Should either party believe that a position taken during trial depends on a particular claim construction, it should explain that dependence and why its asserted construction is correct.

E. OBVIOUSNESS OVER SVIHRA, MANN, AND PONSFORD¹²

Petitioner contends that claims 1–13 are unpatentable as obvious over Svihra, Mann, Ponsford, and skilled artisans’ knowledge as shown through additional references discussed below. *See* Pet. 2, 22–44.

1. Svihra (Ex. 1004)

a. *Summary*

Svihra is directed to noninvasive stimulation of the tibial nerve to achieve desired therapeutic effects without introgenic nerve damage using a superficial electrostimulation. Ex. 1004, 480. According to Svihra, the

¹² The Petition additionally refers to “the Knowledge of a POSA [Person of Ordinary Skill in the Art].” Pet. 21 (defining “POSA”), 22 (including a POSA’s knowledge in the asserted combination). When explaining the ground, Petitioner relies on teachings from additional references to explain why skilled artisans would have found the claimed subject matter obvious. *See id.* at 25–30. We consider the asserted teachings from those additional references to the extent justified by Petitioner.

noninvasive stimulation “had improved subjective symptom related to overactive bladder, had no adverse events, and was well tolerated.” *Id.*

According to Svihra, the original invasive Stoller’s afferent nerve stimulation (SANS) uses the region of medial ankle for percutaneous tibial nerve stimulation using a needle electrode inserted in the vicinity of the nerve. Ex. 1004, 481. Svihra aims to produce noninvasive stimulation achieving comparable effect by superficial electrode without iatrogenic damage to the tibial nerve. *Id.* Svihra describes a modified noninvasive stimulation SANS by using surface electrodes for the area of medial ankle and stimulation of tibial nerve with values different from those set by the original SANS stimulator. *Id.* In this method, Svihra describes that:

the electrodes were placed behind the medial ankle of the left lower extremity. Cathode was placed proximally and anode distally. After a control stimulation accompanied by optimization of the electrode position and set intensity of stimulation we had proceeded on with a therapeutic stimulation of tibial nerve. Intensity of the surface SANS was equal to 70 % of intensity, at which the maximal amplitude of response was registered from the abductor hallucis muscle (stimulation by a constant voltage and regulated intensity of direct current). Frequency of stimulation was 1 Hz and duration of square impulse was 0.1 ms. Surface stimulation of 30 minutes duration was repeated once a week for a period of 5 weeks.

Id. According to Svihra, its “results document good tolerance of non-invasive SANS and comparable efficacy with invasive SANS.” *Id.* at 482.

b. Svihra’s Availability as Prior Art

Petitioner asserts that Svihra published in 2002 and is therefore prior art under at least pre-AIA 35 U.S.C. § 102(b). Pet. 22. Petitioner assumes an

October 2, 2006, effective filing date for the '742 patent. *Id.* at 21. Patent Owner argues that “the Petition does not identify any evidence that Svihra was, in fact, publicly accessible before the alleged critical date.” Prelim. Resp. 3.

It has long been recognized that the touchstone as to whether an asserted reference qualifies as prior art is public accessibility. *See In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986). “[A]t the institution stage, the petition must identify, with particularity, evidence sufficient to establish a reasonable likelihood that the reference was publicly accessible before the critical date of the challenged patent and therefore that there is a reasonable likelihood that it qualifies as a printed publication.” *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29, 13 (PTAB Dec. 20, 2019) (precedential).

Patent Owner argues that “beyond potentially looking like an article, there is no evidence cited in the Petition that Svihra was publicly accessible at any time, let alone before the alleged critical date.” Prelim. Resp. 3. Patent Owner notes that the reference does not bear a copyright notice, does not include a publication page or an International Standard Book Number (ISBN), and does not “state that it was published.” *Id.* at 3–4. Patent Owner asserts that Svihra does not “bear the name of any known publication.” *Id.*

Patent Owner recognizes that Svihra states that it was “[r]eceived” and “[a]ccepted” in 2002 in connection with “some entity known as ‘Bratisl Lek Listy.’” *Id.* at 6 (citing Ex. 1004, 483). In Patent Owner’s view, however, dates listed in the exhibit itself—(“2002,” “Received May 30, 2002,” “Accepted December 9, 2002”)—are hearsay, absent further information regarding “the source or publication of Svihra.” *Id.* at 5. Thus,

Patent Owner argues that Petitioner lacks any evidence tending to establish that Svihra was a publicly accessible reference prior to the critical date. *Id.* at 4–5.

Patent Owner’s arguments at this stage are not persuasive. A simple internet search reveals that “Bratisl Lek Listy,” which appears on the header of Svihra, is an abbreviation for Bratislavské lekárske listy—the Bratislava Medical Journal—an international medical journal founded in 1921, published monthly in English, and currently in its 126th volume. *See* Ex. 3001.¹³ Svihra’s header states, in full: “Bratisl Lek Listy 2002; 103 (12): 480-483,” which we find skilled artisans would understand to mean that Svihra appeared as an article appearing in volume 103, number 12, of the Bratislava Medical Journal at pages 480–483 and was published in December 2002 (i.e., number 12). *See* Ex. 1004, 480. Thus, on its face, the reference supports Petitioner’s assertion under § 102(b).

Based on the present record, Petitioner has established a reasonable likelihood that Svihra was publicly accessible before the critical date of the ’742 patent. Svihra exhibits the necessary hallmarks to support such a finding. Indeed, it exhibits many of the same hallmarks as Amarenco and Ponsford—*e.g.*, journal title and volume number, page numbers, date of acceptance for publication—and Patent Owner does not dispute those references are applicable prior art. *See* Ex. 1005; Ex. 1085. We conclude that Petitioner has established the public accessibility of Svihra sufficiently for purposes of institution. The parties may develop this issue further at trial, potentially including supplemental information under 37 C.F.R. § 42.123 (as

¹³ Available at <https://link.springer.com/journal/44411/aims-and-scope>.

to public availability) and supplemental evidence under 37 C.F.R. § 42.64(b) (as to admissibility).

2. Mann (Ex. 1084)

Mann is titled, “Implantable stimulator methods for treatment of incontinence and pain.” Ex. 1084, code (54). Mann discloses, *inter alia*, “the injection, direct implantation, endoscopic, or laparoscopic implantation of one or more battery- or radio-frequency-powered microstimulators on or near the tibial nerve.” *Id.* at 9:48–51.

Mann depicts an embodiment of a system in Figure 1, which is reproduced below.

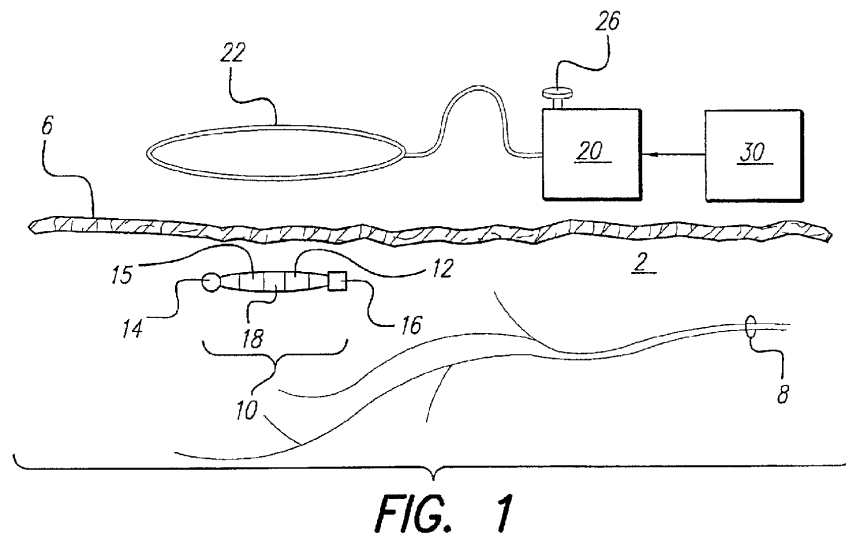


Figure 1 illustrates a battery-powered microstimulator 10 implanted under skin 6 into subcutaneous region 2, where current pulses delivered from its electrodes 14 and 16 stimulate nerve fibers 8. *Id.* at 14:53–57. According to Mann, microstimulator 10 contains electronic circuitry 12, which includes, for example, “an inductive coil for receiving and transmitting RF data and/or power, [and] an integrated circuit (IC) chip for decoding and storing

stimulation parameters and generating stimulation pulses (either intermittent or continuous).” *Id.* at 14:63–15:5. Electronic circuitry 12 also includes “a programmable memory 18 for storing a set(s) of data, stimulation, and control parameters,” which “allows electrical and/or drug stimulation to be adjusted to settings that are safe and efficacious with minimal discomfort for each individual.” *Id.* at 15:11–15. Electronic circuitry 12 receives power and data to be stored in memory 18 by inductive coupling from external controller and its associated antenna coil 22. *Id.* at 15:37–42. According to Mann, “[e]ach time stimulator(s) 10 are recharged by controller 20, the stimulation parameters required from each stimulator 10 are transmitted via coil 22, along with the power required for recharging.” *Id.* at 15:46–50.

Mann describes an embodiment for sensing “a patient’s response to and/or need for treatment” “to help determine the strength and/or duration of electrical stimulation . . . required to produce the desired therapeutic effect.” *Id.* at 23:4–8. For example, “the muscle activity produced in response to stimulation may be detected, *e.g.*, via recording of the associated electromyograph (EMG).” *Id.* at 23:8–11. According to Mann, “the sensed information is transmitted to the stimulating stimulator(s)” and “the parameters used by the stimulator(s) are automatically adjusted based on the sensed information.” *Id.* at 26:4–7. In this way, “the electrical and/or drug stimulation parameters are adjusted in a closed-loop manner to provide stimulation tailored to the need for and/or response to the electrical and/or drug stimulation.” *Id.* at 26:7–10.

3. Ponsford (Ex. 1085)

Ponsford describes a study in which medial and lateral plantar nerve sensory action potentials (SAPs) are recorded with surface electrodes at the

ankle. Ex. 1085, 188. According to Ponsford, medial plantar stimulation was “applied to the sole just lateral to the first metatarsal, the anode level with metatarsophalangeal joint, the cathode thus overlying the first common digital nerve subserving contiguous surfaces of the great and second toes.” *Id.* For lateral plantar stimulation, “the stimulator was placed between the fourth and fifth metatarsals, the anode-again level with the metatarsophalangeal joint, overlying the fourth common digital nerve supplying contiguous surfaces of the fourth and fifth toes.” *Id.* Recording electrodes were “placed posterior to the medial malleolus, using the posterior tibial artery as a landmark.” *Id.* Based on the results of the study, Ponsford concludes that this “technique of stimulating the sole (rather than the big toe) provides a simple, reliable method of measuring the plantar SAP.” *Id.* at 189–90.

4. Claim 1

a. *[1.p] A method of treating overactive bladder or incontinence, comprising:*

Petitioner argues that “[p]rior art need only disclose treating overactive bladder or incontinence, not both, to invalidate the claim.” Pet. 23 n.5. Petitioner contends that Svihra discloses “us[ing] non-invasive stimulation of the tibial nerve with the intention to achieve desired therapeutic effects” in patients “suffer[ing] from overactive bladder (OAB).” Pet. 22 (citing Ex.1004, 480). Patent Owner does not dispute that Svihra discloses a method of treating overactive bladder or incontinence. *See* Prelim. Resp. 7–14. We agree with Petitioner that Svihra’s disclosure satisfies the preamble, regardless of whether it is limiting.

Notably, Patent Owner argues that the other references “lack any specific teaching about branches of the posterior tibial nerve or the stimulation of same to treat overactive bladder or incontinence.” Prelim. Resp. 8. But that position does not consider the combination Petitioner asserts, and would only impact an anticipation challenge. Thus, it is not persuasive.

b. [1.a] non-invasively positioning a first portion of a patient's body relative to an electrical stimulator such that a branch of a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator;

Petitioner argues that Svihra performed “non-invasive stimulation of the tibial nerve” via “electrode[s] attached behind the medial ankle of the left lower extremity,” where “surface electrodes” provided “stimulation by a constant voltage and regulated intensity of direct current” and “tibial nerve” is the PTN. Pet. 23–24 (citing Ex.1004, 480–481; Ex. 1003 ¶ 76). Petitioner contends that skilled artisans would have understood that “surface electrodes” are a noninvasive procedure because they do not break the skin and that electrostimulation would necessarily require connecting the electrodes to an electrical stimulator source. Pet. 23 (citing Ex. 1003 ¶ 74).

Petitioner further argues that skilled artisans would have understood placing electrodes behind the medial ankle of the left lower extremity for PTN stimulation necessarily indicates a portion of the patients’ bodies were positioned relative to an electrical stimulator, as claimed. Pet. 23–24 (citing Ex. 1003 ¶ 75). Although Svihra’s method directly targets the PTN, Petitioner submits that it would have been obvious to modify Svihra’s method to directly target and deliver stimulation to a branch of the PTN. Pet. 24–31 (citing Ex. 1003 ¶¶ 77–91)

Petitioner reasons first that Mann establishes “treating incontinence, urgency, and frequency by targeting nerves ‘emanating from the sacral nerve roots,’ including ‘sites along the tibial nerve.’” *Id.* at 24 (quoting Ex.1084, code (57), 10:65–11:19, 11:43–12:7, 16:28–41). Where Mann discloses targeting the pudendal nerve and instructs that “other somatic nerves emanating from the sacral nerve roots” may be targeted to treat “urinary and/or bowel incontinence, urgency, frequency, and/or pain,” Petitioner contends that skilled artisans would recognize that the PTN and its branches are part of such nerves. *Id.* at 12, 24 (quoting Ex. 1084, 11:50:12:7; citing Ex. 1003 ¶ 77). Petitioner reinforces that view with Boveja, which describes that bladder contraction is inhibited by stimulating “branches and fibers [that] reach the spinal cord via the dorsal roots of the sacral nerves” and specifically mentions the tibial nerve *Id.* at 13, 25 (quoting Ex. 1080 ¶ 29; citing Ex. 1080, code (57), ¶¶ 2, 26, 28–29, 180, cl. 1). Additionally, Petitioner points to Grey, which teaches electrical stimulation to treat other conditions and teaches that an equivalent therapeutic effect may be achieved by treating either the tibial nerve or its branches. *Id.* at 13, 25 (citing Ex. 1081, 1:35–53, 2:53–60). For the reasons Petitioner explains, these references establish skilled artisans’ understanding that bladder contraction could be inhibited by stimulating nerves including the PTN and that stimulating PTN branches would produce the same effect as stimulating the PTN itself.

Petitioner further contends that skilled artisans understood that stimulating PTN branches would “cause signals to travel ‘upstream’ to the PTN and propagate to the sacral nerve roots in the same manner as signals induced by stimulating the PTN itself.” *Id.* at 26 (citing Ex. 1003 ¶¶ 80–81).

That conclusion, in Petitioner’s view, comes from Ponsford’s study of stimulating plantar nerves (which are tibial-nerve branches) and measuring potentials in the ankle. *Id.* at 25–26 (citing Ex. 1085, 188–189; Ex. 1003 ¶¶ 80–81). Although Ponsford’s study did not involve therapy but instead diagnosis of various conditions (*see* Ex. 1085, 188), Petitioner points to Rhodes, which discloses treating pain and other nervous-system ailments and teaches placing electrodes over the medial plantar nerve (a branch of the PTN). *Id.* at 26–27 (citing Ex. 1086, code (57), 3:1–18, 3:57–4:21).

In light of the foregoing, reasons Petitioner, skilled artisans would have known: (1) to treat overactive bladder and incontinence by stimulating nerves that reach the spinal cord via the sacral nerve roots such as the PTN and its branches; (2) that stimulating the medial and lateral plantar nerves (which are branches of the PTN) would provide the same effect as stimulating the PTN itself; (3) that stimulating PTN branches would cause signals to travel to the PTN and upstream to the spinal cord via the sacral nerve roots; and (4) methods for noninvasively stimulating the PTN branches. *Id.* at 27.

Further, Petitioner reasons that modifying Svihra’s approach to stimulate a branch of the PTN (rather than the tibial nerve itself, as in Svihra) would have been a simple substitution of a PTN branch for the PTN itself, or would have required applying the known technique of directly targeting a branch of the PTN to Svihra’s approach targeting the PTN. *Id.* at 28. As Petitioner points out, the change would require nothing more than “mov[ing] Svihra’s surface electrodes from one location to another.” *Id.* at 29. Skilled artisans had reason to make the change, in Petitioner’s view, because it would have improved patient convenience such that “the

electrodes are less visible and more discre[et].” *Id.* at 29. As to the therapeutic impact, Petitioner submits that the change was an obvious design choice because “[t]he ’742 patent specification does not ascribe any significance or criticality to targeting a PTN branch.” *Id.*

Patent Owner challenges Petitioner’s reasoning, arguing that no reference teaches treating overactive bladder or incontinence by stimulating a branch of the PTN. Prelim. Resp. 9. That argument, however, ignores Petitioner’s asserted combination, which relies on modifying Svihra based on skilled artisans’ knowledge that stimulating a branch of the PTN would produce the same effect as stimulating the PTN itself. Thus, Petitioner need not identify a single reference that discloses the entire claim.

In other aspects, Patent Owner criticizes some of Petitioner’s references as relating to invasive stimulation, rather than noninvasive stimulation as claimed. *Id.* at 9 (regarding Mann), 10 (regarding Boveja). But Petitioner relies on Svihra for the noninvasive nature of the stimulation in the asserted combination (Pet. 23), so that argument is inapposite. Likewise, Patent Owner notes that Grey does not discuss treating overactive bladder. Prelim. Resp. 11; *accord id.* at 14 (arguing the same for Ponsford and Rhodes). But Petitioner relies on Svihra for that aspect of the claim. Pet. 22–23. Thus, Patent Owner’s argument fails to address the asserted combination. Although Patent Owner argues that Petitioner does not show how skilled artisans “would make the leap” from, for example, Grey’s teachings to the claimed subject matter (Prelim. Resp. 11), we view Petitioner’s contentions as logically connecting the prior art’s teachings as described above.

Patent Owner claims that Petitioner has not shown that skilled artisans would have had a reasonable expectation of success with the asserted combination. Prelim. Resp. 13. But as discussed above, the combination involves nothing more than changing the location of Svihra's electrode based on teachings in other references. We agree with Petitioner that such a change was amply within the ordinary skill in the art at the time (Pet. 28), and conclude that Petitioner has sufficiently justified institution.

We conclude that Petitioner's contentions adequately support that the asserted combination would practice limitation 1.a and that skilled artisans had reason to make the asserted combination.

c. [1.b] passing a current through the electrical stimulator; and

Petitioner contends that Svihra's application of electrical stimulation through "surface electrodes" necessitates connection "to an electrical stimulator source through which current was passed." Pet. 31–32 (citing Ex. 1004, 481; Ex. 1003 ¶ 92). Patent Owner's preliminary response does not specifically address limitation 1.b. We agree with Petitioner that Svihra discloses limitation 1.b.

d. [1.c] delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve such that the branch directly receives the electrical stimulation to treat overactive bladder or incontinence.

Petitioner contends that "Svihra delivered electrical stimulus from an electrical stimulator through the electrodes to the PTN" and that the study included patients with overactive bladder. Pet. 32 (citing Ex.1003, ¶ 93; Ex. 1004, 481). Petitioner's arguments that it would have been obvious to modify Svihra to directly target a PTN branch and Patent Owner's reasons

for disagreeing are discussed above. *See supra* at 17 (§ II.E.4.b). We agree with Petitioner that the asserted combination discloses limitation 1.c.

e. Summary

We conclude that Petitioner has identified sufficient reason that skilled artisans would have modified Svihra's approach to target a branch of the PTN and that the asserted combination renders obvious claim 1's limitations. Accordingly, this ground supports institution.

5. Claims 2–13

Other than as discussed above, Patent Owner does not contest Petitioner's showing regarding obviousness of claims 2–13 over Svihra, Mann, Ponsford, and skilled artisans' knowledge. We have reviewed Petitioner's contentions, including the uncontested aspects, and conclude that Petitioner has adequately supported institution. *See* Pet. 33–44.

F. OBVIOUSNESS OVER AMARENCO, MANN, PONSFORD

Petitioner contends that claims 1–13 are unpatentable as obvious over Amarenco, Mann, Ponsford, and skilled artisans' knowledge as shown through additional references discussed below. Pet. 3, 44–63.

1. Amarenco (Ex. 1005)

Amarenco relates to urodynamic changes during acute posterior tibial nerve stimulation. Ex. 1005, 2210. In view of the result of improved bladder overactivity, Amarenco proposes posterior tibial nerve stimulation as a noninvasive treatment modality in clinical practice. *Id.*

Amarenco describes posterior tibial nerve stimulation used in the study as follows:

Stimulation was done using a self-adhesive surface stimulation electrode without an implanted needle electrode. Contact electrodes were placed with electrode gel on the ankle skin with the negative electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode. The correct position of the negative electrode was determined by visualization of rhythmic flexion of the toes secondary to plantar muscle contraction during stimulation delivered at 1 hz. The intensity level was then chosen as the intensity immediately under the threshold determining motor contraction. In addition, no pain was to be noted during the stimulation procedure, which necessarily had to be comfortable for the patient. Stimulation frequency during cystometry was then applied at 10 Hz. and a pulse width of 200 milliseconds in continuous mode.

Ex. 1005, 2211. Amarenco concludes that posterior tibial nerve stimulation is a minimally invasive technique that can suppress detrusor instability or hyperreflexia and the finding of improved bladder capacity further supports its use as a noninvasive treatment modality in clinical practice. *Id.* at 2214.

2. Claim 1

- a. *[1.p] A method of treating overactive bladder or incontinence, comprising:*

Petitioner argues that “[p]rior art need only disclose treating overactive bladder *or* incontinence, not both, to invalidate the claim.” Pet. 23 n.5. Petitioner contends that Amarenco studied “acute tibial nerve stimulation in a population presenting with symptoms (urge incontinence and frequency) secondary to [OAB].” *Id.* at 45 (citing Ex.1005, 2210; Ex.1003, ¶ 131). Patent Owner does not dispute that Amarenco studied a method of treating overactive bladder or incontinence. *See* Prelim. Resp. 14–

18. We agree with Petitioner that Amarenco's disclosure satisfies the preamble, regardless of whether it is limiting.

b. [1.a] non-invasively positioning a first portion of a patient's body relative to an electrical stimulator such that a branch of a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator;

Petitioner argues that Amarenco discloses a noninvasive procedure where “[s]timulation was done using a self-adhesive surface stimulation electrode without an implanted needle electrode.” Pet. 45 (citing Ex. 1005, 2211). Petitioner contends that skilled artisans would have understood that “self-adhesive surface stimulation electrode[s]” are a noninvasive procedure because they do not break the skin and that electrostimulation would necessarily require connecting the electrodes to an electrical stimulator source. Pet. 45 (citing Ex.1003 ¶¶ 132–133). Petitioner further contends that skilled artisans “would appreciate providing electrostimulation in this way would necessarily require electrodes connected to an electrical stimulator source” and that “the electrodes and/or the electrical stimulator source are an ‘electrical stimulator,’ as claimed.” *Id.* at 45-46 (citing Ex.1003, ¶¶ 133–134; Ex. 1005, 2211).

Amarenco discloses that stimulation was applied to the “left posterior tibial nerve” by using “[c]ontact electrodes . . . placed . . . on the ankle skin with the negative electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode.” Ex. 1005, 2210, 2211. Petitioner submits that skilled artisans would have understood that disclosure indicates that such stimulation of the PTN necessarily indicates a portion of the patients’ bodies was positioned relative to an electrical stimulator, as claimed. Pet. 46 (citing Ex.1003, ¶ 133; Ex. 1005, 2211).

Although Amarenco's method directly targets PTN, Petitioner submits that it would have been obvious to modify the procedure to directly target and deliver stimulation to PTN branches as taught by Mann, Ponsford, Boveja, and Grey. Pet. 46–53 (citing Ex. 1005, 2210–2211; Ex.1003 ¶ 135–142; Ex.1084, code (57), 10:65–11:19, 11:43–12:7, 12:26–12:41, 16:28–16:41; Ex.1080, code (57), [0002], [0026], [0028–29], [0180], cl.1; Ex.1081, 1:35–53, 2:53–60; Ex.1085, 188–189; Ex.1086, code (57), 3:1–18, 3:57–4:21).

Petitioner's explanation mirrors that explained above regarding modifying Svihra. *See supra* at 17 (§ II.E.4.b). In that regard, the proposed modification is applying Amarenco's stimulation to a branch of the PTN rather than the PTN itself. Pet. 46. Petitioner reasons that such a change would have involved a simple substitution of stimulation sites or applying the known technique of stimulating a PTN branch to Amarenco's method that stimulates the PTN. *Id.* at 48. Petitioner contends that the change from Amarenco is an obvious design choice because the '742 patent does not ascribe any significance or criticality to targeting a branch of the PTN rather than the PTN. *Id.* at 49. Additionally, in light of the prior art's teachings, Petitioner submits that skilled artisans had reason to modify Amarenco's approach "to avoid recruiting other nerves near Amarenco's original stimulation site." *Id.* at 50 (citing Ex. 1003 ¶ 147).

Patent Owner does not dispute Amarenco's teachings¹⁴ but argues we should discretionarily deny institute under 35 U.S.C. § 325(d). *See Prelim.*

¹⁴ Indeed, Patent Owner acknowledges that skilled artisans "knew that they could treat overactive bladder or incontinence by applying direct electrical

Resp. 14–18. We determine that argument is not persuasive as discussed above. *See supra* at 8 (§ II.B).

Patent Owner contends also that the record does not support Petitioner’s asserted reasons justifying the combination. Prelim. Resp. 14–18. Patent Owner does not, however, address Petitioner’s assertion that the modification would have avoided recruiting other nerves near Amarenco’s original stimulation site. In other regards, Patent Owner arguments repeat those discussed above regarding the Svihra-based ground, and we find the arguments unpersuasive for the reasons discussed above. *See supra* at 20 (§ II.E.4.b).

We conclude that Petitioner’s contentions adequately support that the asserted combination would practice limitation 1.a and that skilled artisans had reason to make the asserted combination.

c. [1.b] passing a current through the electrical stimulator; and

Petitioner contends that “Amarenco applied stimulation via ‘surface self-adhesive electrode[s]’ ‘at 10 Hz. and a pulse width of 200 milliseconds in continuous mode,’” and further asserts that said electrical stimulation through electrodes necessitates connection “to an electrical stimulator source through which current was passed.” Pet. 52 (citing Ex.1005, 2211). Patent Owner’s preliminary response does not specifically address limitation 1.b. We agree with Petitioner that Amarenco discloses limitation 1.b.

d. [1.c] delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve such that the branch directly

stimulation to the posterior tibial nerve itself.” *Id.* at 18 (emphasis omitted).

receives the electrical stimulation to treat overactive bladder or incontinence.

Petitioner contends that “Amarenco delivered electrical stimulus from an electrical stimulator through the electrodes to the PTN” and that the study included patients “presenting with symptoms (urge incontinence and frequency) secondary to overactive bladder.” Pet. 52–53 (citing Ex.1003, ¶ 152; Ex. 1005, 2210–2211). Petitioner’s arguments that it would have been obvious to modify Amarenco to directly target a PTN branch and Patent Owner’s reasons for disagreeing are discussed above. *See supra* at 24 (§ II.F.2.b). We agree with Petitioner that the asserted combination discloses limitation 1.c.

e. Summary

We conclude that Petitioner has identified sufficient reason that skilled artisans would have modified Amarenco’s approach to target a branch of the PTN and that the asserted combination renders obvious claim 1’s limitations. Accordingly, this ground supports institution.

3. Claims 2–13

Other than as discussed above, Patent Owner does not contest Petitioner’s showing regarding obviousness of claims 2–13 over Amarenco, Mann, Ponsford, and skilled artisans’ knowledge. We have reviewed Petitioner’s contentions, including the uncontested aspects, and conclude that Petitioner has adequately supported institution. *See* Pet. 53–63.

III. CONCLUSION

For the reasons discussed above, we conclude that Petitioner has shown a reasonable likelihood of prevailing with respect to unpatentability

of at least one claim. Furthermore, we decline to exercise our discretion to deny institution under § 325(d). Accordingly, we institute *inter partes* review.

IV. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review of claims 1–13 of the '742 patent is instituted on the grounds raised in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), notice is hereby given of the institution of trial, which will commence on the entry date of this Decision.

IPR2024-01375
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