

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 JOHN G. NEW, BARRY L. GROSSMAN, and
SEAN P. O'HANLON, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 328(a) and 37 C.F.R. § 42.73. For the reasons set forth below, we determine that Petitioner Avation Medical, Inc. (“Petitioner”) has established, by a preponderance of the evidence, that challenged claims 1–13 of Patent Owner EMKinetics, Inc.’s (“Patent Owner”) U.S. Patent No. 11,224,742 B2 (Ex. 1001, the “’742 patent”) are unpatentable.

A. *Procedural History*

On September 3, 2024, Petitioner filed its Petition (Paper 2, “Petition” or “Pet.”) seeking *inter partes* review of claims 1–13 of the ’742 patent. Patent Owner timely filed a Preliminary Response. Paper 6 (“Preliminary Response” or “Prelim. Resp.”). We instituted *inter partes* review of the challenged claims of the ’742 patent on March 18, 2025. Paper 7 (“Institution Decision” or “Inst. Dec.”).

After institution of trial, Patent Owner filed a Response (“Resp.,” Paper 12), Petitioner filed a Reply (“Reply,” Paper 15), and Patent Owner filed a Sur-Reply (“Sur-Reply,” Paper 17). A consolidated oral argument was held in this proceeding and IPR2024-01378 on January 7, 2026, and a copy of the transcript was entered into the record. (“Tr.,” Paper 27).

II. BACKGROUND

A. *Real Parties-in-Interest*

Petitioner identifies itself, Avation Medical, Inc. as the real party-in-interest. Pet. xii. Patent Owner similarly identifies itself, EMKinetics, Inc., as the real party-in-interest. Paper 5, 2, Paper 10, 2.¹

B. *Related Matters*

Petitioner identifies *Avation Medical, Inc. v. EMKinetics, Inc.*, No. 4:24-cv-01702-JST (N.D. Cal.), seeking declaratory judgment of noninfringement against the '742 patent and U.S. Patent No. 9,002,477 B2 (the "'477 patent"). The district court subsequently stayed the case pending our *inter partes* review of the patents-in-suit. *Avation Medical*, 4:24-cv-01702-JST, October 1, 2024. Petitioner also states that it has not filed any civil action challenging the validity of any claim of the '742 patent. Petitioner also identifies *Avation Medical, Inc. v. EMKinetics, Inc.*, PGR2024-00043 (PTAB) (decided January 7, 2026) and *Avation Medical, Inc. v. EMKinetics, Inc.*, IPR2024-1378 (PTAB) as related matters. Pet. xii.

Patent Owner identifies these same cases or matters relating to the '742 patent. Paper 5, 2; Paper 10, 2.

B. *The Asserted Grounds of Unpatentability*

Petitioner contends that claims 1–13 of the '742 patent are unpatentable, based upon the following grounds:

¹ We note that both Paper 2 and Paper 10 are not paginated. We assign page numbers to each these documents consecutively, beginning with the initial page.

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

Petitioner additionally relies upon the Declaration of Dr. Brett Wingeier (Ex. 1003, the “Wingeier Declaration”). We have reviewed the credentials of Petitioner’s Declarant, and consider Dr. Wingeier to be qualified to provide the opinions for which his testimony has been submitted.

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. §§ 102, 103, and 112 effective March 16, 2013. Because the application from which the ’742 patent issued has an effective filing date prior to that date, the pre-AIA versions of §§ 102, 103, and 112 apply.

³ J. Svihra et al., *Neuromodulative Treatment of Overactive Bladder — Noninvasive Tibial Nerve Stimulation*, 103(12) BRATISL LEK LISTY 480–83 (2002) (“Svihra”) Ex. 1004.

⁴ Mann et al. (US 6,941,171 B2, September 6, 2005) (“Mann”) Ex. 1084.

⁵ S.N. Ponsford, *Sensory Conduction in Medial and Lateral Plantar Nerves*, 51 J. NEUROL., NEUROSURG., PSYCHIATRY 188–91 (1988) (“Ponsford”) Ex. 1085.

⁶ G. Amarenco et al., *Urodynamic Effect of Acute Transcutaneous Posterior Tibial Nerve Stimulation in Overactive Bladder*, 169 J. UROL. 2210–15 (2003) (“Amarenco”) Ex. 1005.

C. The '742 Patent

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 col. 8, ll. 35–36. The energy may be in the form of “magnetic energy, electrical energy or ultrasound energy.” *Id.* at col. 8, ll. 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, col. 5, ll. 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 col. 5, ll. 54–59.

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

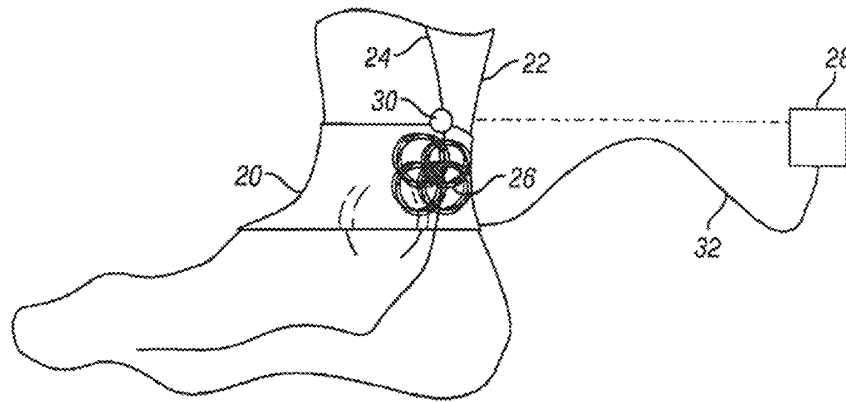


FIG. 1

Figure 1 depicts a coil wrap 20 disposed over ankle 22 circumferentially to surround a portion of tibial nerve 24.

According to the '742 patent:

Coil 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.

Ex. 1001, col. 10, ll. 32–37. A programmable logic controller 28 supplies the electrical current that flows through coils 26 and produces the magnetic field. *Id.* at col. 10, ll. 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 cols. 10–11, ll. 67–4.

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

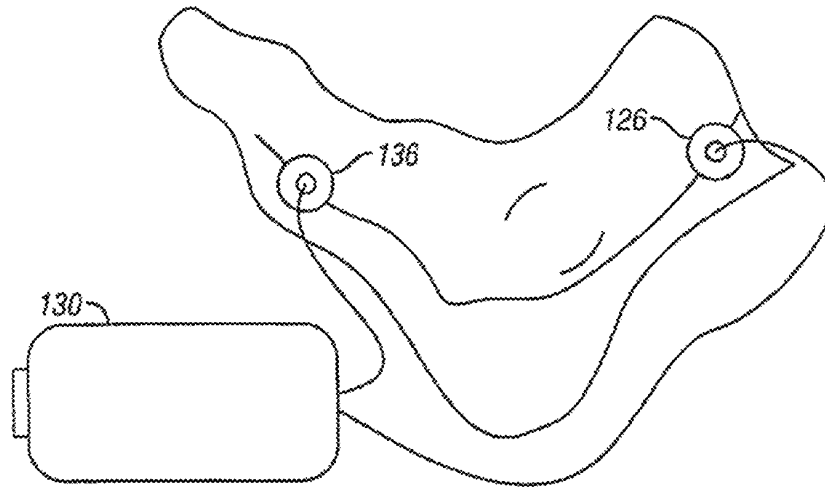


FIG. 11

Figure 11 shows electrical pulse stimulator 130 connected to electrode 126 and sensor 134.

The '742 patent discloses that “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.” Ex. 1001, col. 17, ll. 5–9.

D. Representative Claim

Challenged claim 1, the sole independent claim of the '742 patent, is representative of the challenged claims, and recites:

- [1.p]⁷ 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;

⁷ 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, col. 46, ll. 45–56.

III. 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.⁸ *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Furthermore, “there must 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).

⁸ In the present proceeding, neither party presents arguments or evidence relating to secondary considerations.

B. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 100(b) (2020). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence may also be considered, but is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

In its Petition, Petitioner states that “[e]xcept as noted below, no terms require construction for purposes of this Petition.” Pet. 22. Petitioner provides no express construction of any claim term or limitation in the Petition.

In its Response, Patent Owner nevertheless disputes the deposition testimony of Petitioner’s expert, Dr. Wingeier, that the plain and ordinary meaning of “directly,” as used in the limitation reciting “such that the branch [of the PTN] directly receives the electrical stimulation,” as recited in claim 1 of the ’742 Patent, means “stimulating with the intent of creating an effect in that structure.” Resp. 9 (citing Ex. 2003, 22). According to Patent

Owner, Dr. Wingeier contrasts this construction with “indirectly” stimulating a nerve structure, which he interprets as “stimulating the vagus nerve to have a follow-on effect on some distant brain network.” *Id.* (citing Ex. 2003, 22; also citing Ex. 1025, Fig. 2, element 60). Patent Owner therefore argues that Petitioner is construing “directly” to mean “delivering an electric stimulus to a branch of the posterior tibial nerve with the intent of creating an effect in a branch of the posterior tibial nerve.” *Id.*

Patent Owner therefore contends that Petitioner construes “direct” stimulation” such that “the branch directly receives the electrical stimulation to treat overactive bladder or incontinence,” as an element of the challenged claims, and that the prior art would need to teach this element for claim 1 to be anticipated or rendered obvious by the prior art. Resp. 9–10 (citing Ex. 2003, 20–21). In other words, Patent Owner argues, according to Petitioner’s expert, the challenged claims require treating overactive bladder or incontinence. *Id.* at 10.

Petitioner disputes Patent Owner’s construction of “directly” targeting or stimulating PTN branches. Reply. 17. According to Petitioner, the ’742 patent does not describe what “directly” targeting or stimulating a nerve means for noninvasive electrostimulation. *Id.* Rather, Petitioner argues, the ’742 patent discloses providing stimulation by placing a noninvasive device over an area of the body. *Id.* (citing, e.g., Ex. 1001, Fig. 11; Pet. 30–31, 51–52; Ex. 1003 ¶¶ 89–90, 95–96, 148–149, 154–155). Petitioner contends that simply placing electrodes over branches of the PTN therefore “directly” targets and stimulates the branches, as claimed. *See id.*

Petitioner disputes Patent Owner’s contention that “directly” targeting/stimulating means “delivering an electric stimulus to a [PTN]

branch [] with the intent of creating an effect in a [PTN] branch.” Reply 17 (alterations in original). Petitioner contends that, to the extent Patent Owner suggests this excludes “directly” stimulating PTN branches to create indirect, upstream effects, Patent Owner is incorrect. *Id.*

Petitioner further alleges that Patent Owner misquotes Dr. Wingeier’s deposition testimony. Reply 17. Petitioner asserts that Dr. Wingeier testified that “directly” stimulating means “stimulating with the intent of creating an effect in that structure and, of course, that might have its own follow-on effect.” *Id.* at 17–18 (quoting Ex. 2003, 22) (emphasis omitted). Petitioner adds that Dr. Wingeier further explained that directly stimulating a nerve could indirectly affect other structures. *Id.* (quoting Ex. 2003, 22 (“if I was stimulating the vagus nerve to have a follow-on effect on some distant brain network, then I would be directly stimulating the vagus nerve ... and I would be having an indirect effect on the brain thereby”))).

Petitioner also argues that Patent Owner’s interpretation is inconsistent with the ’742 Patent. Reply 18. The only embodiment of the ’742 patent arguably disclosing noninvasive PTN electrostimulation depicts a noninvasive device placed over the PTN to “directly” stimulate the PTN and indirectly affect other structures to treat overactive bladder (“OAB”)/urinary incontinence. *Id.* (citing Ex. 1001, 17, 29). Petitioner argues that Patent Owner’s construction improperly excludes embodiments disclosed by the Specification of the ’742 patent. *Id.* (citing *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1320 (Fed. Cir. 2005)).

We reject Petitioner’s construction that “directly” stimulating the PTN *via* noninvasive electrodes means “simply placing electrodes over branches of the PTN” as being inconsistent with both the language of the claims and

the knowledge of those of ordinary skill in the art. Claim 1 of the '742 patent recites:

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;

passing a current through the electrical stimulator; and

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, claim 1. In other words, to effectuate "direct" stimulation of the PTN nerve branch, a practitioner of the '742 patent must: (1) non-invasively position an electrical stimulator relative to a portion of a patient's body, such that a branch of a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator; (2) *passing a current through the electrical stimulator*; and (3) *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*. Merely "placing electrodes over branches of the PTN" cannot be said, in and of itself, to "directly" target and stimulate the branches, as Petitioner argues.

Svihra provides an example of the understanding of those of ordinary skill in the art as to non-invasive stimulation of the PTN. Svihra teaches:

We have used an electromyographic device Nicolet Viking II E. The patient stayed in a horizontal position on her back and 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.

Ex. 1004, 481. In this protocol, activation of the PTN was measured indirectly by measuring the amplitude of the contractions of the abductor hallucis muscle, which is innervated by motor neurons of the PTN, which contract when the motor neurons are stimulated.

In consequence, we construe the claim term “directly receives the electrical stimulation” to mean that the passage of electrical current between the noninvasive electrodes such that a branch of the PTN is stimulated to produce a neural response in the fibers of the targeted PTN branch (i.e., “electrical stimulation”).

C. Person 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* 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 this definition, and also use the term “skilled artisan” to refer to persons with such skill at the time the invention was filed.

D. Ground 1: Obviousness of challenged claims 1–13 under 35 U.S.C. § 103 over Svihra, Mann, and Ponsford

1. Overview of Svihra (Ex. 1004)

Svihra is directed to noninvasive electrical stimulation of the posterior tibial nerve to achieve a desired therapeutic effects without inducing iatrogenic nerve damage, by the use of superficial, noninvasive electrostimulation. Ex. 1004, 480. Svihra teaches that the noninvasive stimulation “had improved subjective symptom related to overactive bladder, had no adverse events, and was well tolerated.” *Id.* (emphasis omitted)

Svihra teaches that the original invasive Stoller’s afferent nerve stimulation (“SANS”) technique used the region of medial ankle for percutaneous tibial nerve stimulation, using a needle electrode inserted in the vicinity of the nerve. Ex. 1004, 481. The aim of Svihra was to produce noninvasive stimulation to achieve a comparable effect, by the use of superficial, noninvasive electrodes, to avoid iatrogenic damage to the tibial nerve. *Id.* Svihra teaches 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. To illustrate this method, Svihra explains that:

[T]he 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 [of this technique] document good tolerance of non-invasive SANS and comparable efficacy with invasive SANS.” *Id.* at 482.

2. Overview of Mann (Ex. 1084)

Mann is entitled “Implantable Stimulator Methods for Treatment of Incontinence and Pain.” Ex. 1084, code (54). Mann teaches, *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 col. 9, ll. 48–51.

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

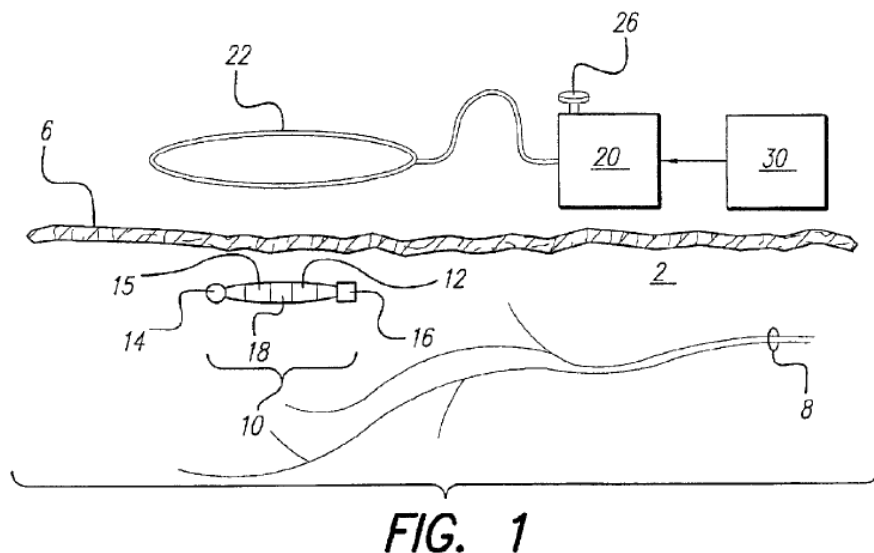


Figure 1 of Mann illustrates a battery-powered microstimulator 10 implanted under skin 6 into subcutaneous region 2, where

current pulses delivered from its electrodes 14 and 16 stimulate nerve fibers 8.

Mann teaches that 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).” Ex. 1084, cols. 14–15, ll. 63–5. 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 col. 15, ll. 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 col. 15, ll. 37–42.

Mann additionally teaches that “[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.” Ex. 1084, col. 15, ll. 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 col. 23, ll. 4–8. Mann teaches, by way of example, that “the muscle activity produced in response to stimulation may be detected, e.g., *via* recording of the associated electromyograph (EMG).” *Id.* at col. 23, ll. 8–11. Mann additionally teaches that “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 col. 26, ll.

4–7. Mann teaches that, in this manner, “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 col. 26, ll. 7–10.

3. Overview of Ponsford (Ex. 1085)

Ponsford describes a study in which sensory action potentials in the medial and lateral plantar nerve (major branches of the PTN) are recorded with surface electrodes at the ankle. Ex. 1085, 188. According to Ponsford, electrical stimulation of the medial plantar nerve 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.*

Ponsford teaches that for stimulation of the 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.” Ex. 1085, 188. 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 [sensory action potentials]” in the medial and lateral plantar nerves. Ex. 1085, 189–90.

4. Petitioner's argument

a. Challenged claim 1

i. **[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).” *Id.* at 22 (citing Ex. 1004, 480).

ii. **[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 those of ordinary skill in the art 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. *Id.* at 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). Petitioner contends that, 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. *Id.* at 24–31 (citing Ex. 1003 ¶¶ 77–91).

Petitioner reasons that Mann establishes “treating incontinence, urgency, and frequency by targeting nerves ‘emanating from the sacral nerve roots,’ including ‘sites along the tibial nerve.’” Pet. 24 (quoting Ex. 1084, code (57), cols. 10–11, ll. 65–19, cols. 11–12, ll. 43–7, col. 16, ll. 28–41). Petitioner notes that 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,” and contends that skilled artisans would recognize that the PTN and its branches are part of such nerves. *Id.* at 12, 24 (quoting Ex. 1084, cols. 11–12, ll. 15–7; and citing Ex. 1003 ¶ 77). Petitioner reinforces that view with Boveja,⁹ 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 (citing Ex. 1080, code (57), ¶¶ 2, 26, 28–29, 180, claim 1).

Petitioner also points to Grey¹⁰, which teaches electrical stimulation to treat other conditions and teaches that an equivalent therapeutic effect may

⁹ Boveja et al. (US 2006/0122660 A1, June 8, 2006) (“Boveja”) Ex. 1080.

¹⁰ Grey et al. (US 6,272,383 B1, August 7, 2001) (“Grey”) Ex. 1081.

be achieved by treating either the tibial nerve or its branches. Pet. 13, 25 (citing Ex. 1081, col. 1, ll. 35–53, col. 2, ll. 53–60). Petitioner argues that these references establish the understanding of those of ordinary skill in the art that bladder contraction could be inhibited by stimulating nerves including the PTN and that stimulating PTN branches would produce an equivalent effect to 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.” Pet. 26 (citing Ex. 1003 ¶¶ 80–81). That conclusion, in Petitioner’s view, is supported by 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). Petitioner acknowledges that Ponsford’s study did not involve therapy but rather the diagnosis of various conditions related to nerve conduction (*see* Ex. 1085, 188), but then points to Rhodes.¹¹ *Id.* Rhodes teaches treating pain and other nervous-system ailments by placing electrodes over the medial plantar nerve (a branch of the PTN). *Id.* at 26–27 (citing Ex. 1086, code (57), col. 3, ll. 1–18, cols. 3–4, ll. 57–21).

Summarizing, Petitioner contends that a person of ordinary skill in the art would have understood that the cited references teach or suggest: (1) treating overactive bladder and incontinence by stimulating nerves that reach the spinal cord *via* branches of the sacral plexus such as the PTN and its branches; (2) stimulating the medial and lateral plantar nerves (which are

¹¹ Rhodes (US 5,995,873, November 30, 1999) (“Rhodes”) Ex. 1086.

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. Pet. 27.

Petitioner additionally reasons that modifying Svihra's approach to stimulate a branch of the PTN (rather than the PTN 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. Pet. 28. As Petitioner points out, the substitution would require nothing more than "mov[ing] Svihra's surface electrodes from one location to another." *Id.* at 29.

Petitioner also argues that a skilled artisan would have been motivated to make the proposed substitution, because it would have improved patient convenience such that "the electrodes are less visible and more discre[et]." Pet. 29. With respect to the potential therapeutic impact of the substitution, Petitioner contends 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.*

iii. **[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. 1004, 481;

Ex. 1003 ¶ 93). Petitioner’s arguments that it would have been obvious to modify Svihra to directly target a PTN branch, for the reasons discussed above. *Id.*

b. Challenged claim 2

Petitioner argues that Svihra used “surface electrodes,” which a person of ordinary skill in the art would interpret as likely referring to an “electrode patch.” Pet. 33 (citing Ex. 1004, 481; Ex. 1003 ¶ 98). Petitioner asserts that such “electrode patches” for electrostimulation were well known in the art. *Id.* (citing, e.g., Ex. 1024, 234; Ex. 1025; Ex. 1026; Ex. 1027, 24; Ex. 1003 ¶ 99).

Alternatively, Petitioner argues that, even if Svihra’s surface electrodes are not an “electrode patch,” *per se*, modifying Svihra to “position[] an electrode patch in communication with the electrical stimulator” would have been obvious. Pet. 34. According to Petitioner, using an “electrode patch” in place of Svihra’s “surface electrodes” would have involved nothing more than simple substitution of known elements (*viz.*, substituting “surface electrodes” for known “electrode patches”) or the predictable use of prior art elements according to established functions (using known “electrode patches” to provide electrostimulation). *Id.* (citing Ex. 1003 ¶ 100). Furthermore, argues Petitioner, it would have been obvious to try use of known “electrode patches,” given the finite number of types of electrodes that could be used for electrostimulation. *Id.* Petitioner argues that a person of ordinary skill in the art would have expected success in modifying Svihra’s procedure, and that the results would be predictable

given the widespread and successful use of “electrode patches” throughout the art in similar procedures. *Id.*

Petitioner argues further that modifying Svihra’s procedure to directly target and deliver stimulation to a branch of the PTN, and further to use an “electrode patch” as discussed above would necessarily result in placement of the patch “upon a foot” of the patient. Pet. 34 (citing Ex. 1003 ¶ 101). Petitioner asserts that a skilled artisan would have been aware of the location of PTN branches. *Id.* Moreover, a POSA would appreciate the stimulating electrode (or “electrode patch”) would need to be positioned “upon a foot” overlaying the branch, would have been aware of techniques known in the art for doing so, and would have done so to ensure the branch directly receives stimulation from the electrode (or “electrode patch”). *Id.* at 34–35 (citing Ex. 1085, 188; Ex. 1086, col. 3, ll. 11–18, cols 3–4, ll. 57–21; Ex. 1003 ¶¶ 101–102).

c. Challenged claim 3

Petitioner argues that Svihra teaches the use of an electromyographic (“EMG”) device, which measures electrical activity and muscle response resulting from stimulation of muscle by nerves. Pet. 35 (citing Ex. 1004, 481; Ex. 1003 ¶ 103). Petitioner notes that Svihra teaches that the “[i]ntensity 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).” *Id.* (citing Ex. 1004, 481). Petitioner thus argues that Svihra measured the electrical signal emanating from the muscle as a result of

electrical stimulation, which is “detecting a muscular response.” *Id.* (citing Ex. 1003 ¶ 104).

d. Challenged claim 4

Petitioner asserts that Svihra expressly states that stimulation was applied once per week for 30 minutes. Pet. 35–36 (citing Ex. 1004, 481; Ex. 1003 ¶ 105).

e. Challenged claim 5

Petitioner argues that Svihra used an electromyogram (“EMG”) device (an “electromyographic device Nicolet Viking II E”), which measures electrical activity and muscle response resulting from stimulation of muscle by nerves. Pet. 36 (citing Ex. 1004, 481; Ex. 1003 ¶ 106). Petitioner notes that Svihra teaches that “the maximal amplitude of response was registered from the abductor hallucis muscle,” which refers to the maximum electrical signal from the patients’ muscle as a result of stimulation of the nerve. *Id.* (citing Ex. 1004, 481; Ex. 1003 ¶ 107). Petitioner argues that measurement of electrical signals from patients are a “physiological parameter detected from the patient.” *Id.*

Petitioner argues that a skilled artisan would have understood that, because Svihra determined the “maximal amplitude of response,” the results were necessarily displayed to Svihra; otherwise Svihra could not have determined the maximum electrical signal response, i.e., “maximal amplitude.” Pet. 36.

f. Challenged claim 6

Petitioner argues that a person of ordinary skill in the art would have understood that the language of claim 6 encompasses within its scope using techniques such as EMG, based on the claim language and the '742 Specification. Pet. 36–37 (citing Ex. 1003 ¶¶ 108, 109; Ex. 1042, 120–21; Ex. 1043, 174; Ex. 1084, col. 23, ll. 8–11).

Petitioner argues further that challenged claim 6 also refers to detecting lack of conduction “at a second portion of the patient’s body distant from the first portion,” which, Petitioner argues, is standard in EMG procedures in which EMG electrodes are commonly placed at locations distant from a stimulation site. Pet. 37 (citing Ex. 1003 ¶ 110; Ex. 1028, 367; Ex. 1030, 10). Petitioner further explains that claim 6 also requires detecting “a lack of presence of electrical conduction”: Petitioner asserts that EMG measurements indicate whether there is electrical conduction in the muscle, which in turn indicates the presence or absence of the induction of electrical conduction in the nerve innervating that muscle. *Id.* (citing Ex. 1003 ¶ 110).

g. Challenged claim 7

Petitioner argues that Svihra teaches the use of EMGs to measure “the maximal amplitude of response [] registered from the abductor hallucis muscle.” Pet. 41 (citing Ex. 1004, 481). Furthermore, argues Petitioner, it was well known in the art that various sensors/electrodes, including

“electrode patches,” could be used for EMG. *Id.* (citing Ex. 1003 ¶ 122; Ex. 1035, 188; Ex. 1036, col. 5, ll. 33–50; Ex. 1037, 736).

Additionally, argues Petitioner, it would have been obvious to try use known “electrode patches” in recording EMGs given the finite number of types of sensors/electrodes that could be used in EMG procedures. Pet. 42. Petitioner contends that a skilled artisan would have reasonably expected success modifying Svihra’s procedure in this manner and the results would have been predictable, given the widespread and successful use of EMG “electrode patches” used throughout the art in similar procedures. *Id.*

h. Challenged claims 8–13

Petitioner notes that Petitioner notes that challenged claims 8–13 are nearly identical, respectively, to claims 6, 7, 6, 7, 6, and 7. Pet. 42–43. Petitioner argues that claims 8–13 are similarly obvious over the cited prior art for the reasons discussed with respect to claims 6 or 7, respectively. *Id.*

5. Patent Owner’s Response

a. Challenged claim 1

Patent Owner argues that Petitioner has not demonstrated the knowledge of a person of ordinary skill in the art at the time of invention or that such a person would have been motivated to modify Svihra to arrive at the claimed invention recited in challenged claim 1. Resp. 10. We discuss in a following section of this Decision Patent Owner’s argument in its Response that “Grounds 1 and 2 fail because Petitioner did not provide evidence regarding the public accessibility of non-patent references.”

Patent Owner notes that both parties agree that Svihra does not disclose delivering electrical stimulation directly to *a branch* of the posterior tibial nerve to treat overactive bladder or incontinence. Resp. 11 (citing Pet. 24). Patent Owner asserts that Petitioner does not identify any teaching or suggestion in Svihra, or provide any motivation for a person of ordinary skill in the art to directly target any nerve other than the posterior tibial nerve to treat overactive bladder or incontinence. *Id.*

Patent Owner contends that Petitioner relies on other references to support at least four separate categories of knowledge a person of ordinary skill in the art is said to have possessed at the time of invention to supply the teachings missing from Svihra. Resp. 11 (citing, e.g., Pet. 27, 24–31, 32–33). Patent Owner addresses each of these categories in turn.

i. **Petitioner has not shown that a POSA would have appreciated that conditions treatable *via* electrostimulation of the PTN can also be treated by stimulating PTN branches.**

Patent Owner disputes Petitioner’s argument that “a POSA would have appreciated ... [c]onditions treatable via electrostimulation of the PTN can also be treated by stimulating ... PTN branches with similar efficacy.” Resp. 11 (quoting Pet. 27). Patent Owner notes that Petitioner relies upon Grey in support of this contention. *Id.* (citing Pet. 27; Ex. 1081, col. 1, ll. 35–53, col. 2, ll. 53–60). However, Patent Owner argues, Grey does not teach that conditions treatable *via* electrostimulation of the posterior tibial nerve can also be treated by stimulating PTN branches with similar efficacy. *Id.* Rather, Patent Owner contends, Grey teaches that stomach symptoms associated with non-identified conditions can be treated by electro-

acupuncture of traditional acupuncture points. *Id.* at 12 (citing Ex. 1081, code (57), col. 1, ll. 35–36). Specifically, argues Patent Owner, Grey teaches using electro-acupuncture to emulate the “same affect [sic] as stimulation of the traditional SP and BL acupuncture points.” *Id.* (quoting Ex. 1081, col. 2, ll. 53–60). Patent Owner notes that Petitioner does not explain the relevance of “traditional SP and BL acupuncture points” to this matter. *Id.* (citing, e.g., Pet. 13).

According to Patent Owner, Grey explains that “SP” refers to the “Spleen Channel” but does not further describe this channel, nor could Petitioner’s expert, Dr. Wingeier. Resp. 12 (citing Ex. 1081, col. 2, l. 63; Ex. 2003, 67). Nor, Petitioner notes, does Grey define the traditional “BL” channel. *Id.*

Patent Owner further argues that Grey teaches that stomach symptoms associated with non-specified conditions can be treated by electro-acupuncture of traditional acupuncture points, which are not well-defined in either Grey or the record, with the same effect as traditional acupuncture. Resp. 12. However, Patent Owner asserts, Grey does not support Petitioner’s claim that a person of ordinary skill in the art would have appreciated that conditions treatable *via* electrostimulation of the posterior tibial nerve can also be treated by stimulating PTN branches with similar efficacy, as Petitioner asserts. *Id.* at 12–13 (citing Pet. 27). Patent Owner argues that a skilled artisan, comprehending the teachings of Grey, would at most have understood that electro-acupuncture of the PTN and its branches would have the same effect as traditional acupunctural stimulation of the SP and BL acupuncture points. *Id.* at 13. Therefore, Petitioner argues, Grey does not support Petitioner’s argument that a person of ordinary skill in the

art would have appreciated that conditions treatable *via* electrostimulation of the PTN can also be treated by stimulating branches of the PTN. *Id.*

ii. Petitioner has not shown that a skilled artisan would have appreciated that OAB/incontinence can be treated by electrically simulating branches of the PTN

Patent Owner acknowledges that a skilled artisan would have understood from the teachings of Svihra that OAB/incontinence can be treated by electrically stimulating the PTN. Resp. 14. However, Patent Owner repeats that Petitioner does not identify any teaching or suggestion of Svihra, nor any motivation provided by Svihra, that would lead a person of ordinary skill in the art to directly target any nerve other than the posterior tibial nerve to treat overactive bladder or incontinence. *Id.*

Rather, argues Patent Owner, Petitioner relies upon secondary references. Resp. 14 (citing Pet. 27 (citing Ex. 1084, cols. 11–12, ll. 50–7; Ex. 1080 ¶¶ 28–29, 180, claim 1)). According to Patent Owner, Mann teaches stimulating the pudendal nerve and its branches to treat incontinence. *Id.* (citing (Ex. 1084, cols. 11–12, ll. 50–7). Patent Owner notes that Petitioner’s expert was unable to confirm whether the pudendal nerve is the main nerve of the perineum or whether the urethral branch is a branch of the pudendal nerve. *Id.* (citing (Ex. 2003, 46–47). Patent Owner contends that Mann does not show that direct stimulation of the nerves that control the bladder to treat bladder conditions, would lead to the claimed invention. *Id.*

Patent Owner acknowledges that Mann teaches the posterior tibial nerve as another potential location for stimulation, it does not identify a branch of the posterior tibial nerve as another possible location. Rather,

Mann suggests stimulation between the “level of the ankle” and “the level of the knee.” Resp. 14 (citing Ex. 1084, col. 12, ll. 41–64). Patent Owner contends that, with respect to Mann’s note concerning the “level of the ankle,” Mann clarifies that it is still referring to the “tibial nerve.” *Id.* (citing Ex. 1084, col. 12, ll. 41–64). Patent Owner points to Petitioner’s anatomical diagram in the Petition (citing Pet. 10), which depicts the tibial nerve at the level of both the knee and ankle, confirming that Mann is referring to the PTN and not one of its branches even when referring to the ankle. *Id.*

Patent Owner also notes that Mann identifies numerous other anatomical structures, at the level of the ankle and of the knee, none of which are nerves, let alone a branch of the posterior tibial nerve. Resp. 15–16 (citing Ex. 1084, col. 12, ll. 41–64; Ex. 2003, 59–60). Therefore, Patent Owner asserts, a skilled artisan would not have understood from the teachings of Mann that overactive bladder or incontinence can be treated by direct stimulation of a branch of the posterior tibial nerve. *Id.*

With respect to Boveja, Patent Owner argues that the reference teaches “[n]euromodulation ... applies pulsed electrical stimulation to the sacral nerves.” Resp. 16 (citing Ex. 1080 ¶ 28). According to Patent Owner, Boveja identifies the sacral nerves as being located at the bottom of the spine. *Id.* (citing Ex. 1080, Fig. 3A, element 54 (“sacral nerves”)).

Patent Owner notes that, at deposition, Petitioner’s expert, Dr. Wingeier, confirmed that the “sacral region of the spinal cord is located at the bottom of the spine.” Resp. 16 (citing Ex. 2003, 61). Patent Owner therefore concludes that Boveja teaches, at most, stimulation of the nerves at the bottom of the spine to treat bladder conditions. *Id.* Patent Owner argues that a person of ordinary skill in the art would understand from Boveja that

overactive bladder or incontinence could be treated by directly stimulating a branch of the posterior tibial nerve. *Id.* Patent Owner acknowledges that Boveja teaches other nerves having sacral roots (e.g., the tibial nerve), but argues that Boveja teaches stimulation only of their sacral roots to treat overactive bladder or incontinence. *Id.* Patent Owner points out that Boveja states that, “[o]f the sacral nerve roots, the S3 root, is the most practical for use in chronic pulsed electrical stimulation, although S4 and S2 along with S3 may be stimulated.” *Id.* (citing Ex. 1003 ¶ 29). Patent Owner also acknowledges that, whereas the tibial nerve has sacral roots, Boveja does not disclose stimulating nerves other than the sacral roots or nerves outside of the sacral region. *Id.* (Ex. 1080 ¶¶ 28–29, 180, claim 1).

iii. **Petitioner has not shown that directly targeting and stimulating PTN branches causes signals to travel to the PTN and upstream to the spinal cord *via* the sacral nerve roots**

Patent Owner contends that Ponsford discloses stimulation “applied to the sole [of the foot] just lateral to the first metatarsal, the anode level with metatarsophalangeal joint, the cathode thus overlying the first common digital nerve sub-serving contiguous surfaces of the great and second toes,” to assist in the diagnosis of peripheral neuropathy. Resp. 17 (citing Ex. 1085, 188). Patent Owner, argues that Ponsford teaches that some of the subjects in the study had lumbosacral lesions, which can be “associated with sensory loss in the medial plantar territory,” and which can result in sensory loss in the foot. *Id.* at 17–18 (citing Ex. 1085, 189).

However, Patent Owner argues that this teaching does not establish that a skilled artisan would have appreciated directly targeting and

stimulating PTN branches causes signals to travel to the PTN and upstream to the spinal cord *via* the sacral nerve roots, or have an effect of treating any condition, Petitioner’s alleged arguments to the contrary notwithstanding. Resp. 18 (citing Pet. 27).

Patent Owner also notes that Dr. Wingeier explained at deposition that it is “a hard question to answer,” not least because he is “not ... a neuroanatomist,” and because, even in 2025, “there’s still some scientific work that continues to be done ... on the mechanism of neuromodulation for overactive bladder.” Resp. 18 (citing Ex. 2003, 112–114). Patent Owner also points to Dr. Wingeier’s explanation that “[s]o ... it’s hard to say upstream or downstream. It’s ... a more complicated system than that.” *Id.* (quoting Ex. 2003, 112–114).

iv. Patent Owner contends that Petitioner has not shown that it would have been obvious to modify Svihra to arrive at the claimed invention

Finally, Patent Owner disputes Petitioner’s claims that substituting one nerve in the human body for another, as the target for electrical stimulation for the purposes of treating a specific disease, is “simple substitution.” Resp. 20. According to Patent Owner, the record presented by Petitioner does not support this conclusion by a preponderance of the evidence. *Id.* For example, Rhodes explains that “[m]odern animals, humans among them, have marvelously complex nervous systems.” *Id.* (citing Ex. 1086, col. 1, ll. 24–26). Patent Owner also points to Dr. Wingeier’s testimony, which confirmed that “the neuroanatomy is always – is always very complicated.” *Id.* (citing Ex. 2003, 113). Patent Owner argues that without sufficiently demonstrating the extent of “a POSA’s

knowledge” and by disregarding any complexity of the human nervous system, Petitioner’s obviousness argument based on “simple substitution” must fail. *Id.* at 21.

Patent Owner argues that the same can be said of Petitioner’s “obvious to try” argument. Resp. 21 (citing Pet. 28). Patent Owner contends that the references cited by Petitioner focus on direct stimulation of the nerve structures controlling bladder function and/or the upstream sacral nerve roots, but Petitioner never identifies any suggestion in the record to try direct stimulation of each and every nerve in the human body to treat overactive bladder or incontinence with any reasonable expectation of success. *Id.*

Similarly, with respect to direct stimulation of a branch of the posterior tibial nerve to treat overactive bladder or incontinence being “an obvious design choice,” as asserted by Petitioner, Patent Owner contends that Petitioner has not demonstrated as much. Resp. 21 (citing Pet. 29). Patent Owner asserts that, although Petitioner claims that “the ’742 patent specification does not ascribe any significant or criticality to targeting a branch of the PTN,” 35 U.S.C. § 112 does not require any such ascribing in the patent specification, and in any event, Section 112 is not at issue in these *inter partes* proceedings. *Id.* (quoting Pet. 29). According to Patent Owner, Petitioner does not assert that a person of ordinary skill in the art would have been motivated to do so as an obvious design choice. *Id.* Although

Patent Owner also disputes Petitioner’s contention that modifying Svihra’s technique to target a branch of the PTN would have simply involved applying known techniques to “improve” a known process. Resp. 22 (citing Pet. 28). According to Patent Owner, the record does not

support the conclusion that a skilled artisan would have considered directly stimulating PTN branches to constitute an improvement on stimulating the PTN itself. *Id.*

Patent Owner additionally argues that, contrary to Petitioner’s position, a person of ordinary skill in the art would not have reasonably expected success in modifying Svihra. Resp. 22 (citing Pet. 28). Patent Owner argues that the use of electrical stimulation to directly targeting sacral nerves at the base of the spine (e.g., as in Boveja¹²) does not lead to, or otherwise suggest, directly stimulating any nerve structure outside the sacral region. *Id.* Patent Owner acknowledges that Boveja teaches sacral root stimulation by stimulating the sacral region, and Mann focuses on the same thing, while additionally teaching stimulation of the posterior tibial nerve between the ankle and knee. *Id.* at 23. However, Patent Owner argues, these two disclosures, alone or in combination, do not show that a person of ordinary skill in the art would have had a reasonable expectation of success in treating overactive bladder or incontinence by stimulating a branch of the PTN. *Id.*

Finally, Patent Owner argues, Petitioner’s argument that a skilled artisan would have understood “how to directly target and deliver stimulation directly to PTN branches” does not supply any motivation to arrive at the claimed invention or a reasonable expectation of success in treating overactive bladder or incontinence. Resp. 23 (quoting Pet. 27). Patent Owner argues that because those of ordinary skill in the art would have known how to stimulate a branch of the PTN does not establish that

¹² See, e.g., Ex. 1080 ¶¶ 28–29.

one would have motivated to do so to treat overactive bladder or incontinence. *Id.*

b. Dependent claims 2, 3, and 5–13

Patent Owner contends that Petitioner’s arguments with respect to dependent claims 2, 3, and 5–13 fail for the same reasons as claim 1, as described in Section III.D.5.a–d, above. *See* Resp. 24–30.

c. Dependent claim 4

Patent Owner contends that Petitioner’s arguments with respect to dependent claims 4 fails for the same reasons as claim 1, as described in Section III.D.5.a–d, above. Resp. 24.

Patent Owner additionally argues, with respect to claim 4, that Petitioner has not demonstrated that a person of ordinary skill in the art would have found it obvious to modify Svihra to apply direct stimulation to a branch of the PTN to treat overactive bladder or incontinence by “activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient” for overactive bladder or incontinence, as recited in claim 4. Resp. 25.

Patent Owner acknowledges that Svihra teaches “activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient” for overactive bladder or incontinence, but argues that Petitioner makes no attempt to show that the treatment taught by Svihra would be successful in treating overactive bladder or incontinence without any modification to the treatment schedule. Resp. 25. Patent Owner asserts that although the proposed modification of Svihra would directly target a

different nerve remote from the sacral plexus, the spine, the bladder, etc. than the one disclosed, the Petition does not provide any evidence or argument that the same treatment schedule would have had a reasonable expectation of success in treating overactive bladder or incontinence, as claimed, or any success at all.

6. Petitioner's Reply

Petitioner replies that Patent Owner misinterprets (and frequently ignores) the references' teachings and how a skilled artisan would have understood them. Reply 19.

With respect to Patent Owner's contention that Grey teaches "that electroacupuncture of the PTN and its branches would have the same effect as traditional acupunctural stimulation of the SP and BL acupuncture points" (*see* Resp. 12–13), Petitioner argues that Grey teaches noninvasive electrical nerve stimulation for treating certain conditions and explicitly states "the tibial nerve [] and its branches (e.g., the medial plantar nerve [] and lateral plantar nerves [] under the foot, generally traveling inside the ankle) . . . can be stimulated to cause the same [e]ffect as stimulation of the traditional SP and BL acupuncture points." Reply 19–20 (quoting Ex. 1081, col. 2, ll. 53–60). In other words, argues Petitioner, stimulating the PTN or PTN branches would cause the same therapeutic effect. *Id.* at 20 (citing Pet. 25; Ex. 1003 ¶¶ 79, 83). Therefore, Petitioner contends, the relevant teaching of Grey is its express teaching that the PTN or PTN branches can be stimulated to treat conditions with the same efficacy. *Id.*

Similarly, with respect to Patent Owner's contention that Mann discloses "stimulating the pudendal nerve and its branches to treat

incontinence” (*see* Resp. 13–16), Petitioner notes that Patent Owner acknowledges that Mann discloses PTN stimulation, but apparently ignores Mann’s express teaching that OAB/incontinence can be treated by stimulating nerves emanating from the sacral roots:

The pudendal nerve and its branches are somatic nerves that originate from the sacral nerve roots S2, S3, and S4. These and other somatic nerves emanating from the sacral nerve roots are preferably stimulated to treat dysfunctions of perineal structures, such as urinary and/or bowel incontinence, urgency, frequency, and/or pain.

Reply 20 (quoting Ex. 1084, cols. 11–12, ll. 50–7). Petitioner argues that, given the PTN and its branches are “[o]ther somatic nerves emanating from the sacral nerve roots,” Mann teaches treating OAB/incontinence by electrically stimulating the PTN or PTN branches. *Id.* (citing Pet. 24–25; Ex. 1003 ¶¶ 77, 83). Petitioner asserts that Patent Owner cannot dispute that both the PTN and pudendal nerve emanate from sacral nerve roots and share common origination points including S2, S3, and S4. *Id.* at 21 (citing Ex. 1084, col. 11–12, ll. 50–7; Pet. 9).

Petitioner also notes that Mann additionally teaches that “[o]ther sites along tibial nerve ... are acceptable stimulator locations,” which Petitioner interprets to mean that a person of ordinary skill in the art would understand includes the PTN and its branches. Reply 21 (citing Ex. 1084, col. 16, ll. 28–41; Ex. 1003 ¶ 77). Petitioner also notes that, during prosecution of the application, the Examiner agreed with Petitioner’s interpretation of Mann. *Id.* (citing Pet. § IV.B).

With respect to Patent Owner’s contention that Boveja “discloses, at most, stimulation of the nerves at the bottom of the spine to treat bladder conditions” and “at most teaches stimulation of the sacral portion of the

tibial nerve,” (*see* Resp. 16), Petitioner argues that Boveja discloses electrically stimulating “sacral nerves and/or its branches,” including the PTN and branches, to treat OAB/incontinence. Reply 21 (quoting Ex. 1080, code (57), ¶¶ 2, 26, 28–29, 180, claim 1; Ex. 1003 ¶ 78). Petitioner asserts that Boveja lists various nerves that may be stimulated, many of which branch from the sacral nerves and are outside the sacral region. *Id.* (citing Ex. 1080 ¶ 180, claims 1, 3). Petitioner asserts that Boveja thus teaches treating OAB/incontinence by stimulating nerves and branches that emanate from the sacral nerve roots (such as the PTN and its branches), not simply those at the base of the spine. *Id.* at 21–22 (citing Ex. 1003 ¶¶ 78, 83).

With respect to Ponsford, Petitioner notes that Patent Owner acknowledges that the reference directly targeted/stimulated PTN branches, but contends that it does not teach that stimulating PTN branches causes signals to travel upstream to the spinal cord *via* sacral nerve roots. Reply 22 (citing Resp. 17–18). However, Petitioner argues, Ponsford recorded SAPs—signals propagating from stimulation sites (PTN branches) upstream to the recording site (the ankle). *Id.* (citing Pet. 2, 25–26; Ex. 1085, 188–89; Ex. 1003 ¶¶ 80–81). According to Petitioner, a skilled artisan would have understood that Ponsford teaches that stimulating PTN branches causes signals to travel upstream to the PTN and propagate to the sacral nerve roots. *Id.* (citing Ex. 1003 ¶¶ 80–81).

Petitioner argues that Dr. Wingeier’s deposition testimony, cited by Patent Owner, does not show otherwise. Reply 22 (citing Resp. 18–19). Petitioner notes that, when asked whether sacral nerves are upstream or downstream of nerves that control bladder function, Dr. Wingeier merely noted the upstream/downstream distinction depends on signal direction. *Id.*

(citing Ex. 2003, 112–114). Petitioner points out that Dr. Wingeier also explained that one mechanism of neuromodulation for OAB is stimulating nerves “that ultimately come back up to the sacral roots.” *Id.* (citing Ex. 2003, 112–114).

With respect to whether a person of ordinary skill in the art would have been motivated to modify Svihra, with a reasonable expectation of success, Petitioner argues that targeting and stimulating one nerve (PTN branches) in place of another closely related one (the PTN) is simple substitution of one known element for another. Reply 23. Petitioner asserts that this is particularly true given the teachings in the cited prior art concerning electrically stimulating the PTN and PTN branches to treat OAB/incontinence, which would have provided sufficient motivation to substitute PTN branches for the PTN. *Id.* at 23–24 (citing Pet. 24–28, 46–48). Petitioner argues that Patent Owner’s arguments regarding the complexity of the nervous system overall are irrelevant to substituting one closely related sacral nerve for another. *Id.* at 24.

Petitioner also disputes Patent Owner’s argument that a person of ordinary skill in the art would not have considered stimulation of a branch of the PTN an “improvement.” Reply 24 (citing Resp. 22). Petitioner argues that evidence of record teaches that targeting/stimulating PTN branches rather than the PTN would improve patient convenience. *Id.* at 25 (citing Pet. 28–29, 48–50; Ex. 1003 ¶¶ 87, 146). Petitioner additionally points out that the law does not require showing an actual improvement, only that applying a known technique to a known process would be suitable. *Id.* (citing, e.g., *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1381 (Fed. Cir. 2023)).

With regards to a skilled artisan’s reasonable expectation of success, Petitioner contends that Patent Owner’s argument that “sacral root stimulation by stimulating the sacral region” would not provide an expectation of success in stimulating PTN branches. Reply 25 (citing Resp. 22–23). Petitioner argues that Patent Owner misinterprets Mann and Boveja, which both teach electrical stimulation of sacral nerves and branches (including the PTN and PTN branches), and not merely the sacral nerves themselves. *Id.* Petitioner also points out that it does not rely on Ponsford and Rhodes alone as teaching that knowledge of how to stimulate PTN branches would not have provided motivation or an expectation of success in treating OAB/incontinence. *Id.* Rather, Petitioner argues that it relies on the prior art’s combined teachings, including Mann, Boveja, and Grey in addition to Ponsford and Rhodes. *Id.* (citing Pet. 27–31, 48–52; Ex. 1003 ¶¶ 84–91, 143–150).

7. Patent Owner’s Sur-Reply

Patent Owner replies that the references cited by Petitioner do not show, by a preponderance of the evidence, that a person of ordinary skill in the art would have possessed the knowledge on which Petitioner’s obviousness assertions are based. Sur-Reply 16 (citing, e.g., Resp. 11–19). For example, Patent Owner argues, Grey teaches that stimulating the PTN or its branches, has the same effect as traditional acupunctural stimulation, but does not provide that the “swapability” of the PTN and its branches in the context of traditional acupuncture can be further extended, contrary to Petitioner’s suggestion. *Id.* at 17.

With respect to Mann, Patent Owner argues that neither Petitioner nor its expert, Dr. Wingeier, point to any teaching of the reference that teaches direct stimulation of a branch of the posterior tibial nerve. Sur-Reply 18. Patent Owner maintains that its contention that Mann would not have supplied a skilled artisan with an understanding that overactive bladder or incontinence can be treated by direct stimulation of a branch of the posterior tibial nerve. *Id.* at 18–19. Similarly, Patent Owner notes that Petitioner does not identify any teaching or suggestion of Boveja in which a branch of the PTN is directly stimulated to treat OAB/incontinence. *Id.* at 19.

Finally, with respect to Ponsford, Patent Owner again argues that Petitioner fails to establish that a skilled artisan would have appreciated from Ponsford that directly targeting and stimulating PTN branches would treat any condition. Sur-Reply 20.

8. Analysis

a. Introduction

Both parties appear to agree with Dr. Wingeier’s assertion that “neuroanatomy is ... very complicated.” *See, e.g.*, Resp. 20 (quoting Ex. 2003, 113). Indeed it is, nevertheless, we believe it would be useful to the reader, before beginning our analysis proper, to set forth a few basic principles of neuroanatomy that would have been well known to those of

ordinary skill in the art at the time of filing of the application that issued as the '742 patent.¹³

A *nerve* consists principally of a bundle of nerve fibers, also known as axons, located outside of the central nervous system (i.e., the brain and spinal cord). In most nerves, including the PTN, the nerve fibers consist of both fibers that send signals *from* the central nervous system to muscles and other effector organs (“motor” or “efferent” nerve fibers) and fibers transmitting information from sensory receptors (touch, pain, temperature, etc.) *to* the central nervous system (“sensory” or “afferent” nerve fibers). In other words, a nerve such as the PTN consists of a collection of individual nerve fibers transmitting information either to or from the central nervous system.

Furthermore, a branch of a nerve comprises a subset of the nerve fibers of the larger nerve from which it diverges. Thus, the nerve fibers constituting the medial and lateral plantar nerves are continuous with, and form a subset of, the nerve fibers of the PTN, from which the two branches diverge. *See, e.g.*, Ex. 1085, 188–189. Similarly, the nerve fibers of the PTN constitute a subset of the fibers of the sciatic nerve, from which the PTN branches. Thus, a nerve and its branches form a continuum of both sensory and nerve fibers.

¹³ This introductory portion of our analysis is generally drawn from the following sources: Ex. 1088, 1123–53; Ex. 1005, 2214; Butler, A.B and W. Hodos, *The Vertebrate Central Nervous System*, 39–47 in COMPARATIVE VERTEBRATE NEUROANATOMY: EVOLUTION AND ADAPTATION (1996) Ex. 3001; and Northcutt, R.G., *The Comparative Anatomy of the Nervous System and Sense Organs: A. General Considerations*, 615–31 in HYMAN’S COMPARATIVE VERTEBRATE ANATOMY, 3D ED. (M.H. Wake, ed.) (1979) Ex. 3002.

It directly follows from this that, as a nerve divides and subdivides as it branches into the various subsets of its constituent fibers, the resultant targets of those nerve fibers become more and more limited and circumscribed. That is to say, the number of muscles, sensory receptors, etc., that are innervated by a small nerve branch in the periphery is much more limited than those that are innervated by the large nerve trunk as it emerges from the central nervous system.

Furthermore, when electrically stimulating a nerve, the applied electrical current excites both sensory and motor nerve fibers alike, sending electrical nerve signals (“action potentials” or “impulses”) in both directions from the site of stimulation: both peripherally towards the muscles and centrally towards the central nervous system. Indeed, this phenomenon is often exploited in studies in which the contraction of muscles by electrical stimulation of the motor nerve fibers is used as an indicator of the overall effectiveness of the stimulation of the nerve sending signals in both directions. As Svihra teaches;

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).

Ex. 1004, 481.

Bearing this summary of very basic principles of neuroanatomy in mind, we now turn to our analysis.

b. Challenged claim 1

Challenged claim 1 relates to a method of treating overactive bladder or incontinence, and requires: (1) non-invasively positioning an electrical stimulator relative to a portion of a patient's body relative, such that a branch of a posterior tibial nerve is directly targeted by the electrical stimulator; (2) passing a current through the electrical stimulator; and (3) 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, col. 46, ll. 45–56.

Svihra teaches non-invasive stimulation of the tibial nerve with the intention to achieve desired therapeutic effects, principally OAB and urinary incontinence without iatrogenic nerve damage. Ex. 1004, Abstr. Svihra teaches that its non-invasive, superficial, stimulating electrodes are placed on the skin in the area of the medial ankle, thus targeting the PTN. *Id.* at 481; *see also* Ex. 1014¹⁴, Fig. 4, 728; Ex. 1088, 1146. Svihra confirms the accurate positioning of the superficial electrodes such that it electrically stimulates the PTN *via* measuring contractions of the abductor hallucis muscle in the foot. Ex. 1004, 481. Svihra teaches that non-invasive, superficial electrical stimulation of the PTN achieved a significant measure of success in the treatment of OAB/urinary incontinence. *Id.* at 481–82.

Mann teaches the use of electrical stimulation of nerves to relieve, among other maladies, incontinence. Ex. 1084, Abstr. Mann teaches the use

¹⁴ J. Groen, et al., *Neuromodulation Techniques in the Treatment of the Overactive Bladder*, 87 BJU INT'L 723–31 (2001) (“Groen”) Ex. 1014.

of implanted electrodes to stimulate the pudendal nerve, which receives fibers from sacral nerves S2, S3, and S4. However, Mann also expressly teaches:

Another preferred stimulation location for purposes of the present invention is the tibial nerve. The tibial nerve is relatively easily accessible (i.e., relatively near the overlying skin with no muscle between the nerve and the skin) at two sites in the leg: at the level of the ankle, immediately posterior to the medial malleolus and posterior tibial artery and vein; and at the level of the knee, in the popliteal fossa (i.e., the back of the knee), immediately lateral to the popliteal artery and vein. Other sites along the tibial nerve, although not as easily accessible, are acceptable stimulation sites.

Id. at col. 12, ll. 41–52. From Mann’s description of a tibial nerve stimulation site “at the level of the ankle, immediately posterior to the medial malleolus and posterior tibial artery and vein,” it is evident that Mann is teaching stimulation of the PTN at approximately the same location taught by Svihra. *See* Ex. 1004, 481.

Importantly, Mann also teaches, with respect to stimulation of the sacral nerves:

An advantage of directly stimulating the pudendal nerve and/or its branches is the resulting recruitment of sacral nerves S2, S3, and S4. In addition, the stimulation of the present invention leads to less side effects than, e.g., sacral nerve stimulation. For instance, Stimulating the pudendal nerve and/or its branches *avoids recruitment of nerves unrelated to the desired treatment, such as the sciatic nerve.*

Ex. 1084, col. 12, ll. 33–40 (emphasis added). We emphasize this passage because it establishes an important point that would have been well understand by those of ordinary skill in the art, *viz.*, that stimulating more peripherally results in the recruitment and stimulation of fewer fibers,

especially motor fibers, which minimizes the adverse side effects of nerve stimulation (e.g., the contraction of large groups of muscles).

Ponsford teaches electrical stimulation of the medial and lateral plantar nerves, which are major branches of the PTN innervating the sensory receptors and muscles of the inferior surface of the foot. Ex. 1085, 188; *see also* Ex. 1088, 1148. Ponsford describes a study in which the medial and lateral plantar nerves are electrically stimulated from the surface of the sole, and the response of sensory (afferent) nerve fibers was measured in the PTN at the location “posterior to the medial malleolus, using the posterior tibial artery as a landmark.” Ex. 1085, 188. The purpose of Ponsford’s study is to develop methods for the “the diagnosis of peripheral neuropathy and investigation of root or individual nerve lesions involving the leg or foot”; essentially, Ponsford’s study examines the efficiency of neural conduction along the plantar nerves into the PTN in patients with potential peripheral nerve damage (neuropathy). *Id.*

However, what is important with respect to the teachings of Ponsford is that superficial stimulation of the medial and lateral plantar nerve branches of the PTN results in the electrical stimulation of sensory (afferent) nerve fibers that travel within those nerves and into the PTN and, from there, ascending to the central nervous system. Put simply, stimulation of the plantar nerves constitutes stimulation of a subset of those nerve fibers that constitute the PTN.

We conclude that Petitioner has established, by a preponderance of the evidence of record, that a person of ordinary skill in the art would have found it obvious to modify the teachings of Svihra by non-invasively stimulating a nerve branch of the PTN, e.g., the medial or lateral plantar

nerves, as taught by Ponsford, to treat OAB/urinary incontinence. A skilled artisan would have understood that the fibers of a given branch of the PTN necessarily constitute a subset of the PTN fibers, stimulation of which is known to be effective in the treatment of OAB/urinary incontinence. *See* Ex. 1004, 480–481. Just as it was known in the art that stimulation of the much larger sacral nerve, of which the fibers of the PTN form a part, could have beneficial effects in the treatment of incontinence, and that stimulation of the PTN itself could have a similar effect (*see* Ex. 1084, col. 12, ll. 33–52), so, a skilled artisan could reason, might electrical stimulation of a branch of the PTN exert a similar effect.

We also agree that a person of ordinary skill in the art would have been motivated to stimulate a smaller nerve branch of the PTN, rather than the entire PTN itself, so as to minimize undesirable side effects of stimulating the entire PTN, i.e., the recruitment of downstream muscular contraction, as taught by Mann.

With respect as to whether a person of ordinary skill in the art would have had a reasonable expectation of success in the treatment of OAB/incontinence *via* stimulation of a branch of the PTN, rather than the entire PTN itself, we agree with Petitioner that a person of ordinary skill in the art, would understand from Mann that electrical stimulation of the larger, more central sacral nerve could be employed to treat OAB/urinary incontinence, and that a subset of those PTN fibers could be electrically stimulated to achieve a similar effect. *See* Ex. 1084, col. 12, ll. 33–52. Such a skilled artisan could similarly reason that a subset of those PTN fibers, i.e., a branch of the PTN, particularly major branches such as the plantar nerves, could also be similarly electrically stimulated to treat OAB/urinary

incontinence. Although success in such an experiment would not be guaranteed, “only a reasonable expectation of success, not absolute predictability, is necessary for a conclusion of obviousness.” *In re Longi*, 759 F.2d 887, 897 (Fed. Cir. 1985).

We note here that, contrary to Patent Owner’s assertions (*see, e.g.*, Resp. 12), nothing in the language of the claims requires that electrical stimulation of a branch of the PTN have the same efficacy in the treatment of OAB/urinary incontinence, as stimulation of the entire PTN.

We do not find that Patent Owner’s arguments overcome Petitioner’s case that the challenged claims are obvious over the cited prior art. Patent Owner argues that Petitioner has not shown that: (1) a skilled artisan would have appreciated that conditions treatable *via* electrical stimulation of the PTN can also be treated by stimulating PTN branches; (2) a person of ordinary skill in the art would have appreciated that OAB/incontinence can be treated by electrically stimulating branches of the PTN; (3) directly targeting and stimulating PTN branches causes signals to travel to the PTN and upstream to the spinal cord *via* the sacral nerve roots; and (4) it would have been obvious to modify Svihra to arrive at the claimed invention. *See* Resp. 11–23.

With respect to (1) and (2), we have explained why, although none of the cited prior art references expressly teaches the electrical stimulation of a branch of the PTN to treat OAB/urinary incontinence, a person of ordinary skill in the art, comprehending the teachings of the cited prior art, would have found it obvious to do so, because a skilled artisan would understand that the nerve fibers in a branch of the PTN constitute a subset of the nerve fibers of the PTN, just as the fibers of the PTN constitute a subset of the

sacral nerve, both of which can be stimulated to treat OAB/incontinence.
See Ex. 1084, col. 12, ll. 33–52.

With respect to (3), we disagree with Patent Owner’s assertion. Ponsford expressly demonstrates that electrical stimulation of the medial and lateral plantar nerves, which are branches of the PTN, results in signals (sensory action potentials) that could be measured in or near where those fibers merge into the PTN. *See* Ex. 1085, 188. Such signals must normally travel along those fibers to the sacral nerve (of which the PTN is itself a branch because *they are the same fibers*). That is, sensory nerve fibers travel from the plantar nerve fibers into the tibial nerve, then ascend into the sacral nerve, and from thence into the dorsal portion of the spinal cord *via* the dorsal roots of the spinal nerves. *See* Ex. 1088, 1123–27.

Finally, with respect to (4), we have explained above why we have concluded that it would have been obvious to a person of ordinary skill in the art to modify Svihra to arrive at the claimed invention, *viz.*, by stimulating a branch of the PTN rather than the PTN itself to treat OAB/urinary incontinence. Patent Owner argues, *inter alia*, that Petitioner claims without further citation that substituting one nerve in the human body for another, as the target for electrical stimulation for the purposes of treating a specific disease, is “simple substitution.” However, and as we have explained at length, modifying of Svihra to electrically stimulate a branch of the PTN, rather than the PTN itself, is not simply stimulating a “different nerve” but is rather the stimulation of a subset of the fibers that constitute the PTN. Moreover, we have explained why a person of ordinary skill in the art would have been motivated to modify Svihra by electrically stimulating a branch of the PTN, *viz.*, to minimize the recruitment of nerve

fibers innervating muscles and to minimize the resultant contractions of those muscles.

In summary, we conclude that Petitioner has demonstrated, by a preponderance of the evidence, that a person of ordinary skill in the art would have found it obvious to modify the teachings of Svihra, in view of the teachings of Mann and Ponsford, to arrive at the invention of challenged claim 1.

c. Challenged dependent claims 2, 3, and 5–13

Having carefully reviewed the parties' arguments both in their briefs and at oral argument, and the evidence of record, we conclude that Petitioner has demonstrated, by a preponderance of the evidence, that challenged claims 2, 3, and 5–13 are obvious over the cited prior art.

Patent Owner relies upon the same arguments with respect to these challenged dependent claims that it employed with respect to challenged claim 1. *See* Resp. 24–30. We have explained above why we conclude that Patent Owner's arguments are not sufficient to overcome Petitioner's showing that challenged claim 1 is obvious over the cited prior art, and we adopt the same reasoning in concluding that Patent Owner has failed to overcome Petitioner's demonstration, by a preponderance of the evidence, that dependent claims 2, 3, and 5–13 are obvious over the cited prior art.

d. Challenged dependent claim 4

Challenged claim 4 recites: "wherein delivering the electrical stimulus comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient." Ex. 1001, col. 46, ll. 64–67.

Petitioner argues that Svihra expressly states that stimulation was applied once per week for 30 minutes. *See* Pet. 35 (citing Ex. 1004, 481; Ex. 1003 ¶ 105).

Patent Owner acknowledges that Svihra teaches “activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient” for overactive bladder or incontinence, but asserts that although the proposed modification of Svihra would directly target a different nerve remote from the sacral plexus, the spine, the bladder, etc. than the one disclosed, the Petition does not provide any evidence or argument that the same treatment schedule would have had a reasonable expectation of success in treating overactive bladder or incontinence, as claimed, or any success at all. *See* Resp. 24–25.

Svihra expressly teaches that “[s]urface stimulation of 30 minutes duration was repeated once a week for a period of 5 weeks” and that this stimulation regime was successful in the treatment of OAB/urinary incontinence. Ex. 1004, 481–482. We agree with Petitioner that a person of ordinary skill in the art would have found it obvious to employ the same successful stimulus regime as Svihra when electrically stimulating a branch of the PTN, because Svihra, in stimulating the PTN was necessarily stimulating those ascending (afferent) nerve fibers from branches of the PTN located distal to the site of stimulation, e.g., nerve fibers of the lateral and medial plantar nerves. For this same reason, and for the reasons we have explained above, a skilled artisan would have had a reasonable expectation of success in using Svihra’s stimulus regime because in successfully stimulating the PTN to treat OAB/urinary incontinence, Svihra was electrically stimulating those nerve fibers from branches distal to the

stimulation site that make up a subset of the nerve fibers of the PTN.¹⁵ Patent Owner’s argument that stimulating a nerve branch of the PTN is somehow stimulating a “different nerve” is therefore not sufficiently persuasive to overcome Petitioner’s demonstration, by a preponderance of the evidence, that challenged claim 4 is obvious over the cited prior art.

e. Summary

For the reasons set forth above, we conclude that Petitioner has established, by a preponderance of the evidence that claims 1–13 of the ’742 patent would have been obvious over the combination of Svihra, Mann, and Ponsford, as set forth in Ground 1. Furthermore, we conclude that Patent Owner’s arguments fail to overcome Petitioner’s showing of obviousness under 35 U.S.C. § 103.

E. Ground 2: Obviousness of challenged claims 1–13 under 35 U.S.C. § 103 over Amarenco, Mann, and Ponsford

The arguments of Ground 2 of the Petition are largely the same with respect to the teachings of Mann and Ponsford, with Amarenco substituted for Svihra. *See* Pet. 3, 44. In our analysis below, then, we focus principally on the teachings of Amarenco, and incorporate our findings and conclusions above with respect to Mann and Ponsford herein.

¹⁵ We note here that Svihra teaches stimulation of the distal PTN near the medial malleolus bone of the ankle. However, Gann teaches successful stimulation of the PTN, for the treatment of incontinence, at more proximal sites (e.g., at “the back of the knee”), which would also include fibers of more proximal branches of the PTN than the plantar nerves. *See* Ex. 1084, col. 12, ll. 48–50.

1. Overview of Amarenco

Amarenco relates to urodynamic changes during acute posterior tibial nerve stimulation. Ex. 1005, 2210. In view of its results demonstrating 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 PTN stimulation is a minimally invasive technique that can suppress detrusor instability or hyperreflexia and that the finding of improved bladder capacity further supports its use as a noninvasive treatment modality in clinical practice. Ex. 1005, 2214.

2. Petitioner's arguments

a. Challenged claim 1

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

Petitioner argues that Amarengo teaches “acute tibial nerve stimulation in a population presenting with symptoms (urge incontinence and frequency) secondary to [OAB].” Pet. 45 (quoting Ex. 1005, 2210; and citing Ex. 1003 ¶ 131).

ii. **[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 Amarengo discloses a noninvasive procedure by which “[s]timulation was done using a self-adhesive surface stimulation electrode without an implanted needle electrode.” Pet. 45 (citing Ex. 1005, 2211) (alteration in original) (emphasis omitted). Petitioner argues that a person of ordinary skill in the art would have understood that the use of “self-adhesive surface stimulation electrode[s]” constitutes a noninvasive procedure because the electrodes do not break the skin, and electrostimulation would necessarily require connecting the electrodes to an electrical stimulator source. *Id.* (alteration in original) (citing Ex. 1003 ¶¶ 132–133). Petitioner further contends that a skilled artisan “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).

Although Amarenco’s method directly targets the PTN, Petitioner asserts 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, 2210–11; Ex. 1003 ¶¶ 135–142; Ex. 1084, code (57), cols. 10–11, ll. 65–19, cols. 11–12, ll. 43–7, col. 12, ll. 26–41, col. 16, ll. 28–41; Ex. 1080, code (57), ¶¶ 2, 26, 28–29, 180, claim 1; Ex. 1081, col. 1, ll. 35–53, col. 2, ll. 53–60; Ex. 1085, 188–189; Ex. 1086, code (57), col. 3, ll. 1–18, cols. 3–4, ll. 57–21).

Petitioner’s explanation mirrors that explained above regarding modifying Svihra. *See* Section III.D.4.a.ii *supra*. Petitioner’s proposed modification is to apply Amarenco’s stimulation to a branch of the PTN rather than to the PTN. 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 to the PTN. *Id.* at 49. Furthermore, and in view of the teachings of the prior art, Petitioner contends that those of ordinary skill in the art would have 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).

Petitioner notes that Amarenco further 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.” Pet. 46 (citing Ex. 1005, 2210, 2211).

- iii. **[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 “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, 2210–11).

b. Challenged claim 2

Petitioner’s argues that Amarenco teaches the use of a “self-adhesive surface stimulation electrode” that was placed “on the ankle skin with the negative electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode.” Pet. 53–54 (quoting Ex. 1005, 2211). Petitioner asserts that a “self-adhesive surface stimulation electrode,” as taught by Amarenco is an “electrode patch.” *Id.* at 54 (quoting Ex. 1003 ¶ 156).

Petitioner argues that modifying Amarenco’s method to directly target and deliver stimulation to a branch of the PTN would necessarily result in placement of the electrode patch “upon a foot” of the patient. Pet. 54. Petitioner argues that a person of ordinary skill in the art would have been aware of the location of PTN branches. *Id.* Furthermore, argues Petitioner,

a skilled artisan would appreciate that Amarenco's stimulating electrode (or "electrode patch") would need to be positioned "upon a foot" overlaying the branch, and would have been aware of techniques known in the art for doing so, and would have done so to ensure the branch directly receives the stimulation from the electrode patch. *Id.* (citing, e.g., Ex. 1085, 188; Ex. 1086, col. 3, ll. 11–8, cols. 3–4, ll. 57–21; Ex. 1003 ¶¶ 157–158).

c. Challenged claim 3

Petitioner argues that Amarenco teaches "[t]he 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." Pet. 54 (citing Ex. 1005, 2211). According to Petitioner, "[f]lexion of the toes" and "muscle contractions" are muscular responses caused by Amarenco's electrical stimulation of the PTN. *Id.* (citing Ex. 1003 ¶ 159).

d. Challenged claim 4

Petitioner acknowledges that Amarenco does not teach or suggest multiple 30-minute treatment sessions, but argues that it would have been obvious to those of ordinary skill in the art to modify Amarenco to apply electrostimulation in 30-minute, weekly treatment sessions, because such stimulus regimes were known in the art. Pet. 55 (citing Ex. 1003 ¶ 162). According to Petitioner, modifying Amarenco in this manner would have involved applying known techniques to improve known processes and/or combining prior art elements to known methods—namely, using Amarenco's method in known, successful weekly 30-minute treatment

sessions. *Id.* Petitioner asserts that a person of ordinary skill in the art would have found results to be predictable, based on the knowledge in the art, given that this precise treatment duration and frequency was known and used successfully to treat OAB/incontinence. *Id.*

e. Challenged claim 5

Petitioner asserts that Amarenco teaches performing cystometry both before and after PTN stimulation, with computerized analysis of results. Pet. 55 (citing Ex. 1005, 2211). Petitioner points to Amarenco's Figures 3- and 4, as illustrating that Amarenco also performed an electromyogram ("EMG"), which measures electrical activity and response to muscle stimulation by a nerve. *Id.* at 56 (citing Ex. 1005, Figs. 3, 4; Ex. 1003 ¶ 163). According to Petitioner, cystometry and EMG are "physiological parameters" detected from Amarenco's patients and displayed in Figures 3 and 4. *Id.* (citing Ex. 1003 ¶ 163).

f. Challenged claim 6

Petitioner argues that Amarenco used EMGs to measure the electrical activity and muscle response from patients. Pet. 58 (citing Ex. 1005, Figs. 3-4; Ex. 1003 ¶ 170). Petitioner acknowledges that Amarenco does not expressly teach that the EMG results were used to detect for the presence or lack of presence of electrical conduction, but argues that a person of ordinary skill in the art would have found it obvious to detect for the electrical conduction at a second portion of a patient's body as an indicator of possible electrode migration, electrode malfunction, or proper electrode placement. *Id.* at 58-59 (citing Ex. 1003 ¶¶ 170, 175).

g. Challenged claim 7

Petitioner argues that Amarenco teaches the use of EMG measurements. Pet. 60 (citing Ex. 1005, Figs. 3–4; Ex. 1003 ¶ 177). Petitioner contends that various sensors/electrodes, including “electrode patches,” were known in the art for use in measuring EMGs. *Id.* (citing, e.g., Ex. 1003 ¶ 178; Ex. 1035, 188 (electrode “patch” for surface EMG); Ex. 1036, col. 5, ll. 33–50 (“electrode patch” for detecting physiological signal such as EMG); Ex. 1037, 736 (“sticky surface patch electrodes” for EMG)).

h. Challenged claims 8–13

Petitioner notes that challenged claims 8–13 are nearly identical, respectively, to claims 6, 7, 6, 7, 6, and 7. Pet. 61–63. Petitioner argues that claims 8–13 are similarly obvious over the cited prior art for the reasons discussed with respect to claims 6 or 7, respectively. *Id.*

3. Patent Owner’s Response

a. Challenged claim 1

Patent Owner responds that, as with Ground 1, the teachings of the cited prior art do not support Petitioner’s view of the knowledge of a person of ordinary skill in the art. Resp. 31 (citing Pet. 46–48, 52–53). Briefly, Patent Owner repeats that Grey teaches that stomach symptoms associated with non-specified medical conditions can be treated by electro-acupuncture of traditional acupuncture points – not that conditions treatable *via* electrostimulation of the PTN can also be treated by stimulating PTN

branches. *Id.* Patent Owner contends that Amarenco, like Svihra and Mann, teaches treating overactive bladder by directly stimulating the PTN, and Boveja teaches electrical stimulation of nerves within the region of the sacral plexus. *Id.* Patent Owner argues that neither Mann nor Boveja would have led a skilled artisan to appreciate that overactive bladder could be treated by electrically stimulating a branch of the PTN. *Id.*

Furthermore, argues Patent Owner, Ponsford teaches an associative relationship between weak responses in the foot, when the foot is stimulated and other conditions. According to Patent Owner, Ponsford does not establish that any treatment modality can be achieved by stimulation of the foot, let alone treatment of a condition affecting systems controlled by remote and unrelated nerve structures. Resp. 31.

Even if Ponsford or Rhodes were to show that one could have stimulated a branch of the PTN, argues Patent Owner, the references would not have motivated a person of skill in the art to do so to treat overactive bladder or incontinence. Resp. 31–32.

Patent Owner contends that, having failed to sufficiently demonstrate the knowledge of a skilled artisan, Petitioner’s obviousness argument, which is based upon that knowledge, is insufficient. Resp. 32. Patent Owner asserts that the claimed invention does not involve simple substitution or a known improvement, nor was it obvious to try or an obvious design choice. *Id.* Furthermore, argues Patent Owner, Petitioner has failed to adequately demonstrate that a skilled artisan would have possessed a reasonable expectation of success in modifying Amarenco to arrive the invention recited in claim 1 of the ’742 Patent. *Id.*

b. Challenged claims 2, 3, 5–13

Patent Owner contends that, with respect to Ground 2, Petitioner’s arguments concerning dependent claims 2, 3, and 5–13 fail for the same reasons as claim 1, as described in Section III.E.3.a above. *See* Resp. 32–38.

c. Challenged claim 4

Patent Owner argues that Petitioner has not demonstrated that a person of ordinary skill in the art would have found it obvious to modify Amarenco to apply direct stimulation to a branch of the PTN to treat overactive bladder or incontinence by “activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient,” as recited in claim 4. Resp. 33–34. Patent Owner notes that Petitioner acknowledges that Amarenco does not disclose multiple 30-minute treatment sessions. *Id.* at 34 (citing Pet. 55). Patent Owner contends that, although Petitioner’s expert, Dr. Wingeier, states that multiple 30-minute treatment sessions were known in the art, Petitioner makes no attempt to show that Amarenco – as modified to directly target a branch of the posterior tibial nerve – would be successful in treating overactive bladder or incontinence on such a treatment schedule. *Id.* Patent Owner asserts that whereas the proposed modification of Amarenco would directly target a different nerve more remote from the sacral plexus than the one disclosed, the Petition does not provide any evidence or argument that the same treatment schedule would have had a reasonable expectation of success in treating overactive bladder or incontinence, as claimed. *Id.* Patent Owner also notes that Petitioner’s expert conceded at deposition that such distance would affect or potentially eliminate therapeutic efficacy. *Id.* (citing Ex. 2003, 24–25). Absent any

such analysis, argues Patent Owner, Petitioner has not demonstrated the invalidity of claim 4 by a preponderance of the evidence, for the reasons and for the same reasons that Ground 1 does not show the invalidity of claim 4. *Id.*

4. Analysis

a. Challenged claim 1

Ground 2 is the same as Ground 1, with the exception of the substitution of Amarenco for Svihra. Give our reasoning and conclusion in Section III.D.8 above, the question before us is whether Petitioner has demonstrated, by a preponderance of the evidence, that Amarenco teaches or suggests those limitations of the challenged claims for which Petitioner relies upon Svihra in Ground 1. We also look as to whether Petitioner has demonstrated that it would have been obvious to modify the teachings of the cited prior art to electrically stimulate a branch of the PTN, rather than stimulating the PTN itself.

Amarenco teaches that it was known in the art that electrical stimulation of the PTN as treatment for OAB/urinary incontinence: “More recently posterior tibial nerve stimulation has been used as a chronic treatment to improve urge [urinary] incontinence and frequency.” Ex. 1005, 2210. The stated purpose of Amarenco’s study was to determine “by urodynamic investigation possible detrusor activity modifications during acute tibial nerve stimulation in a population presenting with symptoms (urge incontinence and frequency) secondary to overactive bladder.” *Id.* Amarenco thus teaches the limitations of claim 1 reciting “[a] method of treating overactive bladder or incontinence.”

Amarenco teaches that electrical stimulation of the PTN was performed

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.

Ex. 1005, 2211 (emphases added). Amarenco thus teaches: “non-invasively positioning a first portion of a patient’s body relative to an electrical stimulator such that a ... posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator,” as recited in claim 1. Amarenco’s teaching of a “surface stimulation electrode without an implanted needle electrode” corresponds to claim 1’s requirement that the electrical stimulator be “non-invasively position[ed].” “Direct[] targeting” of the PTN was confirmed in Amarenco by flexion of the plantar muscles, indicating electrical stimulation of the plantar nerves, which are branches of (and thus continuations of) the PTN. *Id.* This satisfies the claim 1’s requirement of “delivering an electrical stimulus from the electrical stimulator ... such that the [PTN] directly receives the electrical stimulation.” We emphasize that Amarenco does *not* expressly teach or suggest electrical stimulation of “a branch of a posterior tibial nerve,” as recited in challenged claim 1; we address this issue below.

Amarenco teaches that “[s]timulation frequency during cystometry was then applied at 10 Hz. and a pulse width of 200 milliseconds in continuous mode,” (Ex. 1005, 2211), which corresponds to challenged claim 1’s requirement that “passing a current through the electrical stimulator; and

delivering an electrical stimulus from the electrical stimulator to the ... posterior tibial nerve.”

Finally, Amarenco teaches that “[p]osterior tibial nerve stimulation is a minimally invasive technique that can suppress detrusor instability or hyperreflexia. Improved bladder capacity is an encouraging finding that further supports its use as a noninvasive treatment modality in clinical practice.” Ex. 1005, 2214. Amarenco thus teaches that the PTN “directly receives the electrical stimulation to treat overactive bladder or incontinence,” as recited in challenged claim 1.

We conclude, therefore, that Petitioner has sufficiently demonstrated, by a preponderance of the evidence, that Amarenco teaches or suggests the limitations of challenged claim 1, with the exception of the limitation reciting direct electrical stimulation of *a branch of* the PTN. The question before us is whether it would have been obvious to a person of ordinary skill in the art to modify Amarenco to stimulate a branch of the PTN, rather than the PTN itself. As with this same issue with respect to Svihra in Ground 1 of this proceeding, we conclude that it would have been obvious to modify Amarenco in this manner.

As we explained in Section III.D.8 above, the various branches of the PTN are each continuous with, and consist of, a subset of those nerve fibers (both sensory and motor) constituting the PTN. That is, the nerve fibers of the PTN branches are continuations of a portion of the fibers constituting the PTN. Stimulation of a branch of the PTN results in the stimulation of the sensory fibers that extend into the PTN and travel from thence to the spinal cord. *See, e.g.*, Ex. 1005, 2214 (“Posterior tibial nerve stimulation inhibits bladder activity by depolarizing somatic sacral and lumbar afferent fibers.

Afferent stimulation provides central inhibition of the preganglionic bladder motor neurons through a direct route in the sacral cord”) (reference omitted).

As we explained in Section II.D.8 above, stimulation of the PTN thus stimulates the nerve fibers of the branches of the PTN that are distal to the site of electrical stimulation. For example, stimulation of the PTN at the site employed in both Svihra and Amarenco (the medial ankle) would also at least stimulate the sensory and motor nerve fibers of the medial and lateral plantar nerve branches of the PTN, because the fibers of those branches are a subset of the nerve fibers of the PTN, just as the fibers of the PTN form a portion of the sacral nerve branches as they enter the spinal cord.

Consequently, a person of ordinary skill in the art would understand that stimulating a branch of the PTN would necessarily stimulate those same fibers as they travel from the branch into and through the PTN, and from there extend through the sacral nerves to the spinal cord. We have also explained, in our analysis of Ground 1, why we agree with Petitioner that a person of ordinary skill in the art would have been motivated to stimulate a branch of the PTN, rather than the PTN itself, *viz.*, to minimize the recruitment of motor nerve fibers, and the resulting involuntary muscular contractions resulting from stimulation of the motor fibers. *See* Pet. 50. We additionally conclude again that a person of ordinary skill in the art would have had a reasonable expectation of success in stimulating a branch of the PTN to treat OAB/urinary incontinence for the reason that we explained in Section III.D.8 above, *viz.*, that by stimulating a branch of the PTN, a skilled artisan would understand that she is stimulating at least a subset of the same fibers that are stimulated by direct electrical stimulation of the PTN itself.

Patent Owner’s arguments with respect to Amarenco and Ground 2 are essentially the same as they were for Svihra and Ground 1. For the reasons we explained in our analysis in Section III.D.8 above, we do not find that Patent Owner’s arguments are sufficiently persuasive to overcome the Petitioner’s demonstration, by a preponderance of the evidence, that it would have been obvious to a person of ordinary skill in the art to modify the teachings of the cited prior art to arrive at the invention recited in challenged claim 1 of the ’742 patent.

b. Challenged claims 2, 3, and 5–13

Having carefully reviewed the parties’ arguments both in their briefs and at oral argument, and the evidence of record, we conclude that Petitioner has demonstrated, by a preponderance of the evidence, that challenged claims 2, 3, and 5–13 are obvious over the cited prior art.

Patent Owner relies upon the same arguments with respect to these challenged dependent claims that it employed with respect to challenged claim 1. *See* Resp. 32–38. We have explained in Section III.D.8 above, and in the immediately preceding Section, why we conclude that Patent Owner’s arguments are not sufficient to overcome Petitioner’s showing that challenged claim 1 is obvious over the cited prior art, and we adopt the same reasoning in concluding that Patent Owner has failed to overcome Petitioner’s demonstration, by a preponderance of the evidence, that dependent claims 2, 3, and 5–13 are obvious over the cited prior art.

c. Challenged claim 4

The parties do not dispute that Amarenco fails to expressly teach or suggest the limitation of claim 4 reciting “wherein delivering the electrical

stimulus comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient.”

Petitioner argues that that it would have been obvious to those of ordinary skill in the art to modify Amarenco to apply electrostimulation in 30-minute, weekly treatment sessions, because such stimulus regimes were known in the art. Pet. 55 (citing Ex. 1003 ¶ 162). Patent Owner contends that, although Petitioner’s expert, Dr. Wingeier, states that multiple 30-minute treatment sessions were known in the art, Petitioner makes no attempt to show that Amarenco – as modified to directly target a branch of the posterior tibial nerve – would be successful in treating overactive bladder or incontinence on such a treatment schedule. Resp. 34.

Dr. Wingeier’s testimony, and the evidence of record, show that it was known in the art to apply electrical stimulation for 30 minutes per week to treat OAB/urinary incontinence. For example, Svihra¹⁶ teaches “[s]urface stimulation of 30 minutes duration was repeated once a week for a period of 5 weeks.” Ex. 1004, 481. Another prior art reference of record, van Balken,¹⁷ teaches percutaneous electrostimulation *via* “12 weekly outpatient treatment sessions, each lasting for 30 minutes.” Ex. 1038, 915.

¹⁶ We acknowledge that Svihra is not one of the prior art references cited as the basis of Ground 2. Nevertheless, it remains prior art to the ’742 patent and would have been presumptively familiar to those of skill in the art at the time of filing. *See Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) (holding that a person of ordinary skill in the art “thinks along the line of conventional wisdom in the art,” and that they are also “presumed to be aware of all the pertinent prior art”).

¹⁷ M.R. van Balken et al., *Posterior Tibial Nerve Stimulation as Neuromodulative Treatment of Lower Urinary Tract Dysfunction*, Vol. 166 J. UROLOGY 914–18, (2001) (“van Balken”) Ex. 1038.

Bosch¹⁸ teaches electrical stimulation of the PTN for treatment of “urge frequency syndrome, urge incontinence and unobstructive urinary retention” via 30-minute, weekly treatments for 10–12 weeks and showing statistically significant improvement. Ex. 1039, Abstr., 44. And Boveja teaches a stimulation regime for the direct stimulation of sacral nerves (which contain ascending PTN sensory nerve fibers) for treatment of “urinary/fecal incontinence and other urological disorders” of 3.0 mA current output, 0.50 msec pulse width, a pulse frequency of 30 Hz, and a stimulus duration of 30 minutes. Ex. 1080 Abstr., ¶ 222; *see also* Ex. 1003 ¶ 161.

We conclude that Petitioner has demonstrated that, based upon a preponderance of the evidence of record, a person of ordinary skill in the art would have found it obvious, based upon the teachings and suggestions of the prior art, to “activate the electrical stimulator for a duration of about 30 minutes per week to treat the patient, as recited in claim 4. Furthermore, we conclude that a person of ordinary skill in the art would have been motivated to electrically stimulate a branch of the PTN for about 30 minutes per week, with a reasonable expectation of success, based upon the teachings of the prior art, that a similar electrical stimulation duration had proven successful in the treatment of OAB/urinary incontinence in previous prior art studies in patients.

5. Summary

For the reasons set forth above, we conclude that Petitioner has established, by a preponderance of the evidence that claims 1–13 of the ’742

¹⁸ J.L.H.R. Bosch, *Electrical Neuromodulatory Therapy in Female Voiding Dysfunction*, 98 (Supp. 1) BJU INT’L 43–48 (2008) (“Bosch”) Ex. 1039.

patent would have been obvious over the combination of Amarenco, Mann, and Ponsford, as set forth in Ground 2. Furthermore, we conclude that Patent Owner's arguments fail to overcome Petitioner's showing of obviousness under 35 U.S.C. § 103.

F. Evidence concerning the public accessibility of the non-patent references relied upon by Petitioner

1. Patent Owner's argument

Finally, we turn to Patent Owner's argument that both Grounds 1 and 2 fail because Petitioner has failed to carry its burden of proving that the non-patent references cited in the Petition (e.g., Svihra and Amarenco) qualify as prior art printed publications. Resp. 4. Patent Owner asserts that, to demonstrate that a document is a printed publication, Petitioner must show that it was "sufficiently accessible to the public interested in the art" before the critical date." *Id.* (citing *Align Tech., Inc. v. Dental Monitoring SAS*, IPR2023-01369, Paper 42 at 25 (PTAB Mar. 3, 2025) (quoting *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989)). According to Patent Owner, Petitioner has failed to demonstrate that any of the non-patent references was publicly accessible because, in each case, there is no record evidence of public accessibility other than the document itself. *Id.*

Patent Owner argues that neither Dr. Wingeier's expert Declaration, submitted with the Petition nor the subsequently-filed attorney declaration, provides any probative evidence concerning public accessibility of the non-patent references relied upon by Petitioner. Resp. 4 (citing Ex. 1003; Ex. 1053). In particular, Patent Owner points to the attorney declaration, which does not aver that any of the references were publicly accessible prior

to the alleged critical date. *Id.* at 5 (citing Ex. 1053). Nor does it express any personal knowledge of how the copies of these documents were obtained, or provide or identify any evidence tending to establish that they could have been obtained from a library, or some other qualifying public source, before the alleged critical date. *Id.*

With respect to Dr. Wingeier's Declaration, Patent Owner points out that Dr. Wingeier identifies no evidence tending to establish the public accessibility of any of the non-patent references identified in the Petition. Resp. 5. Patent Owner acknowledges that Dr. Wingeier testifies that certain items were "published," but argues that these claims are not based on any stated personal knowledge. *Id.* By way of example, Patent Owner notes that Dr. Wingeier does not claim, for example, any familiarity with any of the documents prior to this *inter partes* review, and does not claim any personal or particularized knowledge of any library or database system that would inform the numerous questions of public accessibility raised by the Petition. *Id.*

Patent Owner asserts that the Petition must identify, with particularity, the evidence supporting the grounds on which the challenge is based. Resp. 6 (citing 35 U.S.C. § 312(a)(3); 37 C.F.R. § 42.104(b)). Patent Owner argues that, in the case presently before us, the Petition failed to identify any evidence supporting public availability. *Id.* Even though a petition is supposed to be complete, Petitioner argues that there exist, during the course of an *inter partes* review, opportunities for supplementation of the evidence concerning the public availability of the references, which Petitioner did not do. *Id.*

Patent Owner additionally asserts that Petitioner has not sought to develop the issue of public accessibility through supplemental information or evidence even though it bears the burden of proving public accessibility. Resp. 7. As a result, argues Patent Owner, the evidence of record is insufficient to establish public accessibility of any of the non-patent references cited in the Petition at any relevant time. *Id.* (citing *Medivis, Inc. Novarad Corp.*, IPR2023-00042, Paper 37 (PTAB Apr. 23, 2024)). Patent Owner points out that, in *Medivis*, the Board held that, if a petitioner cites no evidence for public accessibility in the petition, except for the references themselves, “[t]his is insufficient and tantamount to submitting no proof of public accessibility.” *Id.* (quoting *Medivis*, IPR2023-00042, Paper 37 at 4).

Patent Owner also points out that the Board has also held that there is no presumption of public accessibility, as the burden of proof remains always with the petitioner. Resp. 7 (citing *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 16 (PTAB December 20, 2019) (precedential)).

2. Analysis

Patent Owner has made essentially this same argument in the closely-related *Avantis Medical, Inc. v. EMKinetics, Inc.*, PGR2024-00043, Paper 11 at 4–9 (PTAB, April 23, 2025) (the “’043 PGR”). A Final Written Decision was entered in the ’043 PGR on January 7, 2026 (*see Avantis*, PGR2024-00043, Paper 30) and our analysis in the present *inter partes* review closely mirrors the panel’s analysis in the ’043 PGR.

We find that the evidence of record supports the conclusion that Svihra and Amarenco (as well as the other identified non-patent references)

are printed publications, published on the dates identified on the faces of the references, and were publicly accessible.

Two precedential cases are instructive on the presented circumstances: *VidStream LLC v. Twitter, Inc.*, 981 F.3d 1060 (Fed. Cir. 2020), and *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 (PTAB December 20, 2019) (precedential)).¹⁹ In *VidStream*, the Federal Circuit identified that whether a reference is prior art is a legal question, based on factual findings. 981 F.3d at 1063–64; *see also Nobel Biocare Servs. AG v. Intradent USA, Inc.*, 903 F.3d 1365, 1375 (Fed. Cir. 2018) (citing *Jazz Pharm., Inc. v. Amneal Pharm., LLC*, 895 F.3d 1347, 1356 (Fed. Cir. 2018)). Moreover, public accessibility is the touchstone in determining whether a reference is a printed publication and such depends on whether the reference was available to interested, ordinarily skilled persons exercising reasonable diligence, which is determined on a case-by-case basis. *VidStream*, 981 F.3d at 1065; *see also Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1380 (Fed. Cir. 2018) (citing *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004)). Of particular relevance to the case presently before us is the *VidStream* court’s holding that “[w]hen there is an established publisher there is a presumption of public accessibility as of the publication date.” *VidStream*, 981 F.3d at 1065.

Hulu addressed, *inter alia*, whether certain asserted references were shown to be publicly available and could be considered as prior art. IPR2018-01039, Paper 29 at 8. In *Hulu*, the Board held that, although testimonial evidence is one way to prove public accessibility, there are also

¹⁹ *See also Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, 2021 WL 4876224 (PTAB, October 5, 2021).

various indicia of publication and other evidence that may be considered as a totality of the evidence to determine if an asserted reference was publicly accessible and prior art. *Id.* at 18. Facts to be considered in analyzing the issue, other than testimonial evidence, include, for example, whether there is an established publisher, a copyright date/notice, other publication-related dates (impression, printing, etc.), an ISBN number, citations to the reference before (and to a lesser degree, after) the priority date at issue corroborating its availability and/or that the publisher was established. *Id.* at 19–20 (*see also Valve Corp. v. Ironburg Inventions Ltd.*, 8 F.4th 1364, 1374 (Fed. Cir. 2021)).

Here, we find the preponderance of the evidence supports the conclusion that Petitioner has made a sufficient showing that Svihra and Amarenco (as well as the other identified non-patent references) were printed publications, and publicly accessible, prior to the '742 patent's priority date. We note at the outset that Patent Owner does not allege that any contested reference is fabricated, or a counterfeit document, but only that Petitioner has not set forth sufficient facts establishing that such references were published and available. Resp. 4; *see also, e.g.*, PGR2024-00043, Paper 29 at 24, ll. 4–10 (transcript of hearing held on December 2, 2025, making the same argument in related case).

Svihra bears sufficient indicia of publication to conclude it was a printed publication and publicly accessible as of 2002. Ex. 1004. First, it appears on its face to be a legitimate scientific journal article; it indicates it was included at pages 480–83 in volume 103 (No. 12) of Bratisl Lek Listy, the Bratislava Medical Journal, which was established in 1921. The article identifies that it was received for publication on May 30, 2002, and accepted

for publication on December 9, 2002; and multiple means of contact for the author and publisher are provided. *Id.* at 480, 483. Each of these indicia supports the contention that Svihra was published and publicly available in 2002. There is no direct evidence that Svihra was publicly accessed as of this date, but the article is cited as a reference in each of Exhibits 1085–1087, which further supports that Svihra was, generally, publicly available to interested individuals of ordinary skill in the art, which further corroborates that it was a published and publicly accessible publication. Having an established publisher also creates a presumption of publication for Svihra, which has not been rebutted by Patent Owner. *VidStream*, 981 F.3d at 1065.

Amarenco, too, bears sufficient indicia of publication to conclude it was a printed publication and publicly accessible as of 2003. Ex. 1005. Amarenco appears on its face to be a legitimate scientific journal article; it indicates it was included at pages 2210–15 in the 169th volume of *The Journal of Urology*, a highly-reputed publication of the American Urological Association (creating a presumption of publication); it bears a publication date of June 2003; it states it was “Printed in U.S.A.”; a copyright notice is included indicating a 2003 copyright date; a DOI (Digital Object Identifier) number is provided; and it indicates it was accepted for publication on January 17, 2003. *Id.* at 2210. A second copy of Amarenco was filed as Exhibit 1088, and that copy includes the cover page of Volume 169 of *The Journal of Urology*, which also indicates publication in June 2003, and bears what appears to be a collection sticker of the Shawnee Mission Medical Center Medical Library indicating it was received at that library; this exhibit also includes the journal’s list of editors pages with contact information, a table of contents listing Amarenco, and the Amarenco article itself.

Ex. 1094, 1–8. Each of these indicia supports our finding that Amarenco was published and publicly available in 2003. There is no direct evidence that Amarenco was publicly accessed on this date, but it is cited as a reference in each of Exhibits 1016, 1085–1087, and 1089, as well as listed on the face of related U.S. Patent No. 11,844,943 B2, a closely-related patent challenged in PGR2024-00043 (*see* PGR2024-00043, Ex. 1001, code (56)), which supports the conclusion that Amarenco was publicly available to interested ordinarily skilled people, which corroborates that it was published and publicly accessible. The presumption of publication created by Amarenco having an established publisher has not been rebutted by Patent Owner. *VidStream*, 981 F.3d at 1065.

As for the “other items” mentioned by Patent Owner (*see* Resp. 4) as allegedly not proven to be publications, Patent Owner does not discuss these other items in detail, but lists them as Exhibits 1008–1017, Exhibit 1024, Exhibits 1027–1028, Exhibit 1030, Exhibit 1035, Exhibits 1037–1039, Exhibits 1041–1043, and Exhibit 1088. *Id.* at 8. We find these references are similar in most ways to Svihra and Amarenco in bearing indicia of publication. For example, Exhibit 1008 is a journal article by J.W. Davila et al., published in volume 45 of the journal *Clinical Obstetrics and Gynecology*; it has a copyright date, and correspondence information. Ex. 1008. As another example, Exhibit 1009 is a journal article by A.J. Wein et al., published in volume 60 (supplement 5A) of the journal *Urology*, it indicates it was published in November 2002, provides contact information for the University of Pennsylvania School of Medicine (the journal’s publisher) and its authors, and indicates it is available from Elsevier Science Inc.—a well-known publishing house of scientific journals

and monographs. Ex. 1009. We could continue to enumerate the details of the indicia for each reference, but they are essentially the same as these examples. We therefore conclude that Petitioner has made a sufficient showing that each of these “other items” are printed publications as of their indicated publication dates.

IV. CONCLUSION

For the reasons we have explained, we conclude that Petitioner has demonstrated, by a preponderance of the evidence, that challenged claims 1–13 of the ’742 patent are unpatentable under 35 U.S.C § 103 as being obvious over the cited prior art. Furthermore, Patent Owner’s argument that the cited non-patent prior art are not printed publications is insufficient to overcome the reference’s indicia of public accessibility.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that based on a preponderance of the evidence, claims 1–13 of US Patent 11,224,742 B2 patent are unpatentable;

FURTHER ORDERED that because this is a final written decision, the parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–13	103	Svihra, Mann, Ponsford	1–13	
1–13	103	Amarenco, Mann, Ponsford	1–13	
Overall Outcome			1–13	

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For PETITIONER:

Todd Tucker
Kyle Deighan
CALFEE, HALTER & GRISWOLD LLP
ttucker@calfee.com
kdeighan@calfee.com

For Patent Owner:

David Gerasimow
Eran Steinberg
The Law Offices of David A. Gerasimow, P.C.
dave@gerasimowlaw.com
venture@eransteinberg.com