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Paper 30
Date: January 7, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,

Petitioner,

v.

EMKINETICS, INC.,

Patent Owner.

PGR2024-00043
Patent 11,844,943 B2

Before BARRY L. GROSSMAN, RYAN H. FLAX, and SEAN P. O'HANLON, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Patent Owner's Motion to Exclude Evidence
35 U.S.C. § 328(a); 37 C.F.R. § 42.71

I. INTRODUCTION

Patent Owner EMKinetics, Inc. ("Patent Owner") is the owner of U.S. Patent 11,844,943 B2 (Ex. 1001, "the '943 patent"). Paper 13, 1 (Patent Owner Updated Mandatory Notices). On July 1, 2024, Avation Medical, Inc. ("Petitioner") filed a Petition for post-grant review challenging the patentability of claims 1–39 of the '943 patent. Paper 2, 1 ("Pet."). We instituted trial on January 29, 2005. Paper 8 ("Institution Decision" or "DI"). On April 23, 2005, Patent Owner filed a Response to the Petition and Institution Decision. Paper 11 ("Resp."). Petitioner responded with a Reply on July 16, 2025 (Paper 12, "Reply"), to which Patent Owner responded with a Sur-reply (Paper 15, "Sur-reply"). A hearing was conducted on December 2, 2025, where the parties presented oral argument. *See* Paper 29 ("Hr'g Tr.").

After considering the parties' arguments and supporting evidence, we conclude that Petitioner has proved by a preponderance of the evidence that claims 1–39 of the '943 patent are unpatentable. 35 U.S.C. § 326(e). Our reasoning is discussed below.

Patent Owner filed a Motion to Exclude Evidence directed to Petitioner's Exhibits 1085–1090. Paper 22 ("Motion" or "Mot."). Petitioner filed an Opposition to that Motion. Paper 23 ("Opposition" or "Mot. Opp."). Patent Owner filed a Reply to that Opposition. Paper 24 ("Opposition Reply" or "Opp. Reply"). As discussed below, we *deny* the Motion.

A. STANDING

Petitioner

> certifies that if the '943 patent is an AIA patent (see §IV.A), it is available for PGR. Petitioner is not barred or estopped from requesting PGR on the Challenged Claims on the grounds

> below. Petitioner and its privies have not filed a civil action challenging the validity of any claim of the '943 patent. This petition is timely filed because: (a) Petitioner has not been served with a complaint alleging infringement of the '943 patent as of this petition's filing; and (b) it is filed within 9 months of the patent's issuance (i.e., December 19, 2023).

Pet. 1–2. Patent Owner contests whether Petitioner has standing based on Patent Owner's argument that the '943 patent is not eligible for post-grant review. *See* Resp. 18.

We find Petitioner's certification is sufficient. We are persuaded that Petitioner's position that the '943 patent is an "AIA patent" is correct (*see* 35 U.S.C. § 100(note), and AIA § 3(n)(1) amending this section) because the patent contains "a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to [a] patent or application that contains or contained at any time [a claim to a claimed invention that has an effective filing date on or after March 16, 2013]." *See* 35 U.S.C. § 100(note), § 321(note)(1)(A). Therefore, we find that the '943 patent is eligible for post-grant review. We address this issue more fully below at Section II.A.

B. REAL PARTIES-IN-INTEREST

Petitioner identifies Avation Medical, Inc. as the real party-in-interest. Pet. x. Patent Owner identifies EMKinetics, Inc. as the real party-in-interest. Paper 5, 1; Paper 6, 1. Neither party contests the other's assertions on this.

C. RELATED MATTERS

Petitioner and Patent Owner identify *Avation Medical, Inc. v. EMKinetics, Inc.*, No. 4:24-cv-01702 (N.D. Cal.) (the "California litigation") as a related matter involving the '943 patent. Pet. x; Paper 5, 1; Paper 6, 1.

The parties also identify that U.S. Patent 9,002,477 ("the '477 patent") and U.S. Patent 11,224,742 ("the' 742 patent") are involved in the California

litigation. Pet. x; Paper 5, 1; Paper 6, 1. Patent Owner identifies the '477 patent as being also the subject of IPR2024-01378 and the '742 patent as being also the subject of IPR2024-01375. Paper 6, 1.

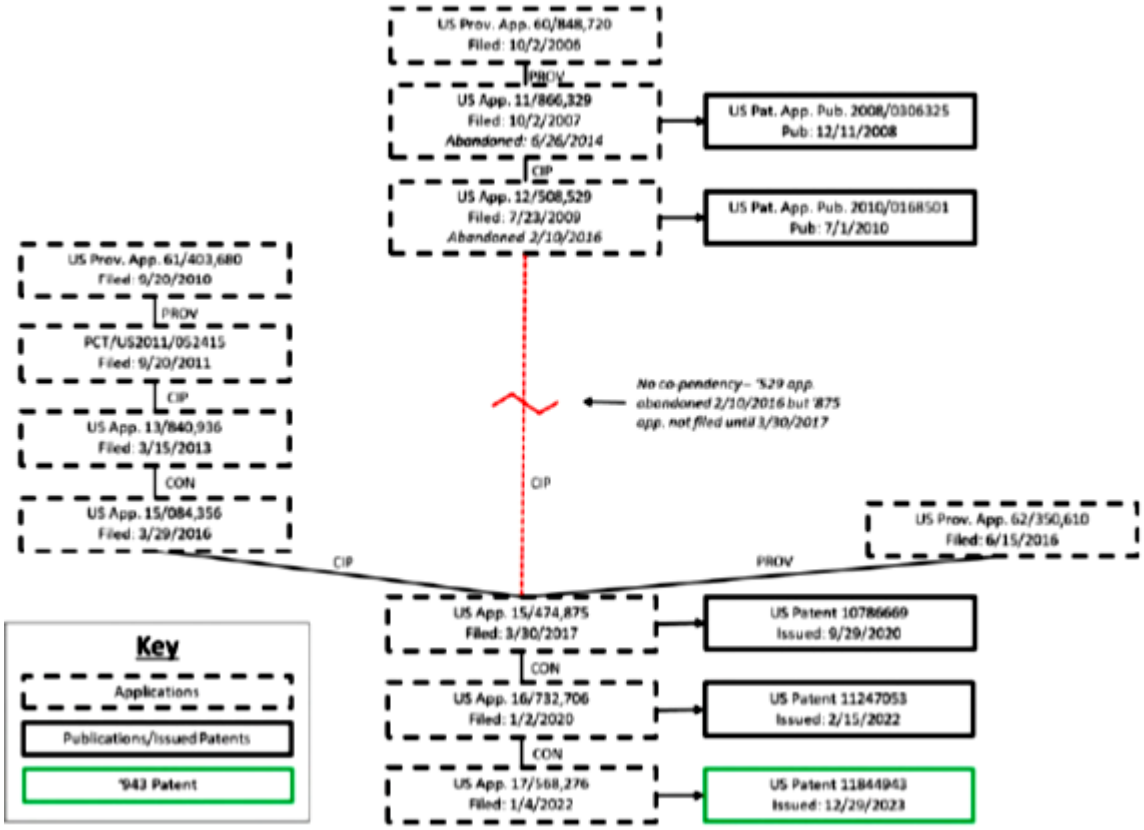
D. THE '943 PATENT AND RELEVANT BACKGROUND

The '943 patent, titled "METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES," issued on December 19, 2023, from U.S. Application 17/568,276 ("the '276 application"), which was filed on January 4, 2022. Ex. 1001, codes (10), (21), (22), (45), (54). The '943 patent indicates priority as follows:

> This application is a continuation of U.S. patent application Ser. No. 16/732,706 filed Jan. 2, 2020, which is ***a continuation of U.S. patent application Ser. No. 15/474,875 filed Mar. 30, 2017*** (now U.S. Pat. No. 10,786,669), which is a continuation-in-part of U.S. patent application Ser. No. 15/084,356 filed Mar. 29, 2016 (now U.S. Pat. No. 9,630,004), which is ***a continuation of U.S. patent application Ser. No. 13/840,936 filed Mar. 15, 2013 (now U.S. Pat. No. 9,339,641), which is a continuation in part of PCT International Patent Application Number PCT/US2011/052415 filed Sep. 20, 2011***, which claims benefit of priority to U.S. Provisional Patent Application No. 61/403,680 filed ***Sep. 20, 2010***. ***U.S. patent application Ser. No. 15/474,875 is also a continuation-in part of U.S. patent application Ser. No. 12/508,529 filed Jul. 23, 2009 (now abandoned)***, which is a continuation-in-part of U.S. patent application Ser. No. 11/866,329 filed Oct. 2, 2007 (now abandoned), which claims priority to U.S. Provisional Patent Application No. 60/848,720 filed Oct. 2, 2006. U.S. patent application Ser. No. 15/474,875 also claims priority to U.S. Provisional Patent Application No. 62/350,610 filed Jun. 15, 2016.

Id. at 1:8–28 (emphasis added to highlight highly relevant priority relationships); *see also id.* at codes (60), (63). This listing of related

applications is complex, and Petitioner provides a graphic illustrating the same in the Petition and its Reply, which we reproduce below, and which at oral argument Patent Owner confirmed is an accurate representation of how the '943 patent, on its face and in its associated Application Data Sheet filed with the '276 application, identifies the chain of priority:



See Pet. 15; Reply 19; Hr'g Tr. 21:7–22:8 (Patent Owner agreeing this diagram accurately represents the '943 patent's assertion of priority, on its face); Ex. 1001, codes (60), (63), 1:8–28; Ex. 1002, 161–64 (Filing Receipt), 188–97 (Application Data Sheet). The image above is a flow-chart identifying each application and/or patent in the priority chain listed on the face of the '943 patent for compliance with 35 U.S.C. §§ 119 and 120, and

37 C.F.R. § 1.78, naming each listed application/patent in boxes with connecting lines labeled to indicate the identified relationships therebetween.

> The '943 patent indicates it relates generally to the following:
>
> The disclosure describes devices and methods for providing transdermal electrical stimulation therapy to a subject including positioning a stimulator electrode over a glabrous[1] skin surface overlying a palm of the subject and delivering electrical stimulation via a pulse generator transdermally through the glabrous skin surface and to a target nerve or tissue within the hand to stimulate the target nerve or tissue within the hand so that pain felt by the subject is mitigated. The pulses generated during the electrical stimulation therapy may include pulses of two different magnitudes.

Ex. 1001, Abstr. (code (57)). The '943 patent relates to an apparatus or system, and methods, for central and peripheral nerve and other tissue modulation or stimulations therapies. *Id.* at 2:3–7. According to the '943 patent, these apparatus and methods may be useful in the treatment and prevention of urinary incontinence (UI), overactive bladder (OAB), and other conditions. *Id.* at 8:33–36.

As background, the '943 patent describes neuromodulation for OAB and UI patients using a posterior tibial nerve stimulator, which, according to the '943 patent is often referred to as SANS. Ex. 1001, 3:5–7. The '943 patent notes that this treatment was invasive in nature, requiring the insertion

[1] The terms "glabrous" and "non-glabrous" are not expressly defined in the '943 patent. Petitioner's witness, Dr. Wingeier, states that "a 'glabrous' surface of the body is a smooth surface that is not typically covered by hair," and a "'non-glabrous' surface, by contrast, is a non-smooth surface of the body that may be covered by hair." Ex. 1003 ¶ 54 (we omit the witness's further characterization of anatomical parts that typically may or may not be glabrous).

of a needle into the patient's ankle region in order to stimulate the posterior tibial nerve. *Id*. at 3:8–11.

The '943 patent describes an exemplary embodiment based on transdermal electrical stimulation therapy, where a stimulator electrode is positioned over a glabrous skin surface to deliver transdermal electrical stimulation through or across the skin to an underlying target nerve, resulting in stimulation of the target nerve. Ex. 1001, 3:32–39, 46:4–11. According to the '943 patent:

> Delivery of electrical stimulation through or across a glabrous surface of the body via an electrode positioned over a glabrous surface, e.g., a glabrous surface on a palmar or plantar surface, unexpectedly allows for the use of a higher frequency and/or higher amplitude electrical pulsation or electrical stimulus to deliver the electrical stimulation than would otherwise be safe and/or tolerable to deliver electrical stimulation through a non-glabrous surface of the body. For example, an electrical stimulus having a frequency of about 5 Hz to about 60 Hz (a range found to be effective for generating motor and/or sensory nerve conduction of the posterior tibial nerve) may be utilized to stimulate a target nerve (to generate motor and/or sensory nerve conduction therein) or tissue through or across a glabrous skin surface (via an electrode positioned over the glabrous skin surface) in a manner that remains safe and tolerable to the patient and avoids burns or injury.

Id. at 50:36–52. The '943 patent explains that similarly electrically stimulating a target nerve or tissue through a non-glabrous skin surface is intolerable and painful, resulting in burns or injury. *Id*. at 50:55–61.

In an exemplary embodiment:

> [E]nergy delivered transdermally, through, or across a patient[']s skin at about 1 Hz to about 30 Hz, or at less than 10 Hz has unexpectedly been found to stimulate or generate motor and/or sensory nerve conduction of a tibial nerve, where such

> level of stimulation may be sufficient to treat a patient suffering from urinary incontinence, overactive bladder, fecal incontinence or other conditions. The energy may be delivered through or across a glabrous skin surface or non-glabrous skin surface or any other skin surface (e.g., any skin surface overlying a tibial nerve).

Id. at 49:30–40; *see also id.* at 3:46–55, 49:8–25.

An apparatus for providing electrical stimulation is depicted at Figure 11 of the '943 patent, which is reproduced below:

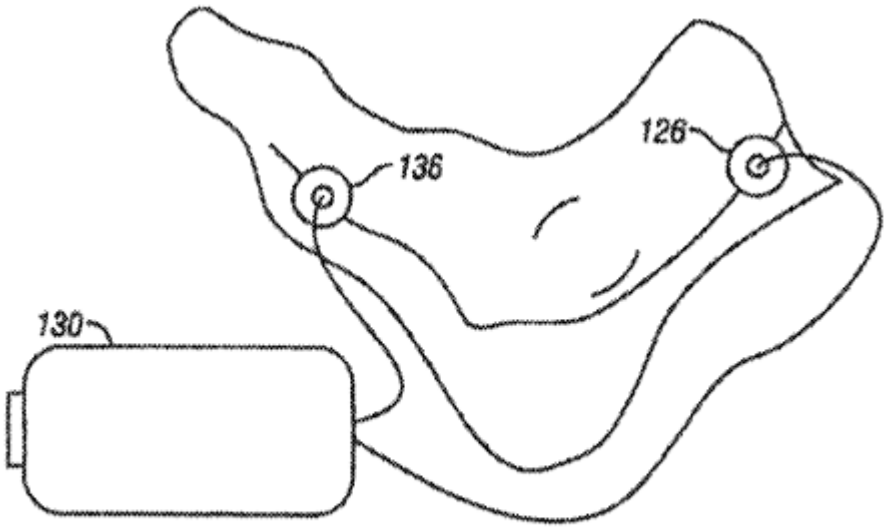


FIG. 11

Figure 11 depicts an apparatus for electrical stimulation and shows a transcutaneous stimulator, such as an electrode 126, that dispenses electrical energy for nerve stimulation. Ex. 1001, 17:9–13. Electrical pulse controller 130 is connected to electrode 126 and to sensor 136. *Id*. at 17:17–20. According to the '943 patent, "nerve conduction may be detected at a site sufficiently distant from the site of stimulation, so to enable detection of nerve conduction despite the confounding interference from the direct electrical stimuli." *Id*. at 17:20–24.

In an embodiment, conductive coils may generate a magnetic field focused on a target nerve, muscle, or other body tissues in proximity to the coils. Ex. 1001, 3:56–60. 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 3:61–66.

An apparatus for magnetic induction therapy is depicted in Figure 1 of the '943 patent, reproduced below:

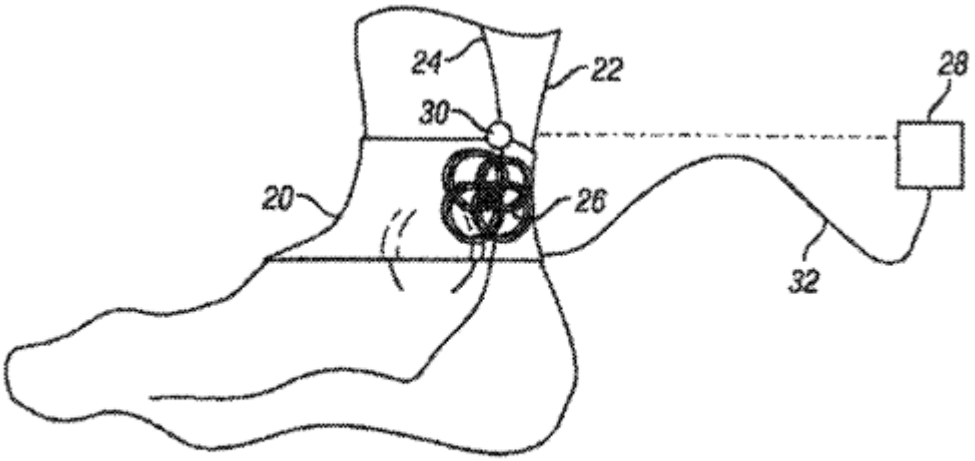


FIG. 1

Figure 1 depicts an apparatus for magnetic induction therapy and shows a coil wrap 20 disposed over ankle 22 circumferentially to surround a portion of tibial nerve 24. Ex. 1001, 10:21–23. According to the '943 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.

Id. at 10:46–51. A programmable logic controller 28 supplies the electrical current that flows through coils 26 and produces the magnetic field. *Id*. at 11:8–11. Figure 1 also shows a sensor 30, provided "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 11:14–18.

The '943 patent concludes with 39 claims. Independent claims 1, 14, and 27 are representative and are reproduced below:

> 1. A method of treating overactive bladder or incontinence, comprising:
>
> non-invasively positioning a first portion of a patient's body near an ankle 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;
>
> passing a current through the electrical stimulator; and
>
> delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive bladder or incontinence.
>
> * * *
>
> 14. A method of treating overactive bladder or incontinence, comprising:
>
> non-invasively positioning a first portion of a patient's body near an ankle relative to an electrical stimulator positioned within a sock worn upon a foot of the patient such that 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 posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive bladder or incontinence.

* * *

27. A method of treating overactive bladder or incontinence, comprising:

non-invasively positioning a first portion of a patient's body near an ankle relative to an electrical stimulator positioned upon a strap which is secured over a foot of the patient such that 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 posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive bladder or incontinence.

Ex. 1001, 70:8–19, 70:63–71:8, 71:53–72:9. Claims 2–13, 15–26, and 28–39 each depends directly or indirectly from these independent claims. *Id.* at 70:8–72:55.

E. PETITIONER'S ASSERTED GROUNDS FOR UNPATENTABILITY

Petitioner contends that claims 1–39 of the '943 patent are unpatentable, based upon the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1, 3–5	102	Svihra[2]
2	2, 6–13	103	Svihra
3	14, 16–18, 27, 29–31	103	Svihra, Johnson[3]
4	15, 19–26, 28, 32–39	103	Svihra, Johnson
5	1–3, 5	102	Amarenco[4]
6	4, 6–13	103	Amarenco
7	14–16, 18, 27–29, 31	103	Amarenco, Johnson
8	17, 19–26, 30, 32–39	103	Amarenco, Johnson
9	1–3, 5–13	102	Burnett[5]
10	4, 14–39	103	Burnett, Johnson
11	1–39	112	Lack of enablement

Pet. 2–3. Petitioner relies, *inter alia*, on the Declaration of Dr. Brett Wingeier (PhD). Ex. 1003. The qualifications of this witness to testify as to the subject matter of his declaration stand uncontested, on this record. Patent Owner submits no evidence in this proceeding.

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[2] J. Svihra et al., *Neuromodulative Treatment of Overactive Bladder – Noninvasive Tibial Nerve Stimulation*, 103(12) BRATISL LEK LISTY 480–83 (2002) ("Svihra"). Ex. 1004.

[3] J. Johnson (WO 2004/108209 A1, pub. Dec. 16, 2004) ("Johnson"). Ex. 1007.

[4] G. Amarenco et al., *Urodynamic Effect of Acute Transcutaneous Posterior Tibial Nerve Stimulation in Overactive Bladder*, 169 J. UROLOGY 2210–15 (2003) ("Amarenco"). Ex. 1005.

[5] Burnett et al. (US 2008/0306325 A1, pub. Dec. 11, 2008) ("Burnett"). Ex. 1006.

II. DISCUSSION AND ANALYSIS

A. ELIGIBILITY FOR POST-GRANT REVIEW AND STANDING

35 U.S.C. § 321(note)(1)(A) states that "[t]he post-grant review provisions of the Leahy-Smith America Invents Act (AIA) apply only to patents subject to the first inventor to file provisions of the AIA (see 35 U.S.C. 100 (note))." Under the Patent Act's § 100(note), "[t]he first inventor to file provisions of the Leahy-Smith America Invents Act (AIA) apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time—" "a claim to a claimed invention that has an effective filing date on or after March 16, 2013," such that either a claim of the subject patent has an effective date after March 16, 2013, ***or*** the subject patent includes "a specific reference under section 120, 121, 365(c), or 386(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim," meaning a prior patent or application referenced for priority purposes under, e.g., § 120, has a post-AIA claim. 35 U.S.C. § 100(note). Our rules require that a petitioner for post-grant review must certify that the challenged patent is eligible for post-grant review, which Petitioner has done, as discussed above. 37 C.F.R. § 42.204(a); *see supra* Section I.A.

Petitioner asserts, *inter alia*, that "the '943 patent contains a specific reference to patents and/or applications that 'contain[] or contained at any time' claims with an effective filing date 'after the [AIA] effective date,' *i.e.*, March 16, 2013." Pet. 9 (alterations in original). Pointing to the '943 patent's long list of priority applications/patents (*see supra* Section I.D; *see also* Ex. 1001, codes (60) and (63) ("Related U.S. Application Data") and 1:8–30 ("Cross-Reference to Related Applications)), Petitioner identifies the

following as having claims (at some point) supported under 35 U.S.C. § 112 only in post-AIA specifications and, thus, having post-AIA effective filing dates:

- U.S. Patent 10,786,669 ("the '669 patent," Ex. 1018), which was filed as U.S. Application 15/474,875 ("the '875 application," Ex. 1019), includes claims 1 and 19 reciting a method for treating tremors and stimulating the ulnar or median nerve, each of which Petitioner asserts may be accorded an effective filing date no earlier than March 30, 2017;
- The '875 application included claim 1 reciting stimulating via pulses at different first and a second amplitudes, and claim 21 reciting treating migraine pain, each of which Petitioner asserts may be accorded an effective filing date no earlier than March 30, 2017;
- U.S. Application 16/732,706 ("the 706 application," Ex. 1020) that issued as U.S. Patent 11,247,053 ("the '053 patent," Ex. 1021), included claim 1 reciting stimulating via five respective pulses at different first and second amplitudes (second set following the first set) and using a pulse width of 200 microseconds, claim 11 reciting placing an electrode in proximity to an ulnar nerve, and claim 12 reciting placing an electrode in proximity to a median nerve, each of which Petitioner asserts may be accorded an effective filing date no earlier than March 30, 2017; and
- The '053 patent includes claim 1 reciting treating migraines and positioning an electrode over a nerve in the subject's hand, which Petitioner asserts may be accorded an effective filing date no earlier than March 30, 2017.

Pet. 9–13. Petitioner asserts that for each above-identified claim and its respectively recited subject matter, the first written description disclosure thereof was in the '875 application, which was filed on March 30, 2017. *Id.*

Petitioner asserts that, "[a]ccordingly, because the '943 patent contains a 'specific reference' to the patents/applications discussed above that 'contain or contained' claims with an effective filing date after March 16, 2013, the '943 patent is a patent described in AIA §3(n)(1) and is eligible for PGR." *Id.* at 13.

Patent Owner contests Petitioner's assertion of post-grant review eligibility. Resp. 18. Patent Owner argues that "Petitioner has failed to establish that the challenged claims have an effective filing date on or after March 16, 2013. Petitioner has therefore failed to establish that the challenged claims are eligible for post-grant review." *Id.*

Patent Owner makes no mention of nor directly contests Petitioner's assertions of fact regarding the patents and applications to which the '943 patent asserts priority and the effective filing dates of their claims based on claimed subject matter (e.g., stimulating the ulnar or median nerve). Patent Owner does not challenge that the '943 patent contains a specific reference, for priority under 35 U.S.C. § 120, to patents and applications that contain or contained at any time claims with an effective filing date no earlier than March 30, 2017, which is after the AIA effective date of March 16, 2013. Thus, such arguments are waived. *See infra* Section II.G (discussing the '943 patent's priority).

Upon review of the evidence, we find that, for example, as indicated by Petitioner, the '875 application (filed March 30, 2017, i.e., after March 16, 2013) describes stimulating the ulnar and median nerves, but the '936 application and the '529 application (each filed before March 16, 2013) do not. *See, e.g.*, Ex. 1019 ¶¶ 77–86, 365–370, 381–382, 384, 392–402; *see generally* Ex. 1044 and Ex. 1047. Furthermore, we find the Petitioner-

identified claims (listed above) recite subject matter as Petitioner asserts, and we accept Petitioner's uncontested certification that at least one of these claims is, indeed, entitled to no filing date earlier than March 30, 2017. *See* Exs. 1018–1021.

For example, because claim 19 of the '669 patent recites "at least two electrodes are positioned to stimulate an Ulnar or Median nerve," and claims 11 and 12 of the '706 application recite "positioning the stimulator in proximity to an ulnar nerve" and "positioning the stimulator in proximity to a median nerve," respectively, it appears on this record that such claims are/were entitled to only the March 30, 2017, filing date of the '875 application. Ex. 1018, 17:7–9; Ex. 1020, 102. Again, such assertions by Petitioner are not contested by Patent Owner.

For the reasons above, we find the '943 patent is eligible for post-grant review.

B. LEGAL STANDARDS ON PATENTABILITY

"In [a post-grant review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3), but also applicable to § 322(a)(3) (requiring AIA petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l*

Graphics, Inc., 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in AIA proceedings).[6]

Novelty Requirement

"[A] prior art reference will anticipate if it 'disclose[s] each and every element of the claimed invention . . . arranged or combined in the same way as in the claim.'" *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016) (quoting *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (alterations by Federal Circuit)). "However, a reference can anticipate a claim even if it 'd[oes] not expressly spell out' all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination." *Id.* (quoting *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (alteration by Federal Circuit); *In re Petering*, 301 F.2d 676, 681 (CCPA 1962)).

Non-Obviousness Requirement

The Supreme Court, in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual factors set forth in *Graham* (383 U.S. at 17–18) that are applied in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103(a) as follows: (1) determine the scope and content of the prior art; (2) ascertain the differences between the prior art and the

[6] At times, we may refer to Patent Owner's arguments as unpersuasive; however, this is in the context of the record as a whole. We do not shift the ultimate burden from Petitioner.

claims at issue; (3) resolve the level of ordinary skill in the art;[7] and (4) consider objective evidence indicating obviousness or non-obviousness.[8] *KSR*, 550 U.S. at 406.

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416. "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the answer depends on "whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.* at 417.

Enablement Requirement

35 U.S.C. § 112(a) states, *inter alia*:

> IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

Id. Our reviewing court has established that "§ 112[a] contains two separate description requirements: a 'written description [i] of the invention, and [ii] of the manner and process of making and using [the invention']." *Ariad Pharms, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344, 1351 (Fed. Cir. 2010).

Regarding the enablement requirement, at issue in this proceeding, our reviewing court has held:

> Enablement "is a legal determination of whether a patent enables one skilled in the art to make and use the claimed

[7] *See infra* Section II.C.

[8] There is no evidence of record regarding objective indicia of obviousness or non-obviousness.

> invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed.Cir.1986) (citation omitted). To be enabling, a patent's specification must "teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed.Cir.2010) (citations omitted). It is well-established, however, that a specification need not disclose what is well-known in the art. *See Hybritech*, 802 F.2d at 1384 ("[A] patent need not teach, and preferably omits, what is well known in the art."). It is true, however, that, "the rule that a specification need not disclose what is well known in the art is merely a rule of supplementation, not a substitute for a basic enabling disclosure." *ALZA*, 603 F.3d at 940–41 (quoting *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1282 (Fed.Cir.2007)).

Steck, Inc. v. Res. & Diagnostic Sys., Inc., 665 F.3d 1269, 1288 (Fed. Cir. 2012).

C. ORDINARY SKILL IN THE ART

Petitioner contends:

> A POSA at the time of the claimed invention 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. Additional work experience could substitute for a formal degree and vice versa. Ex.1003, ¶21.

Pet. 20 (citing Ex. 1003). Patent Owner does not contest this proposed definition or offer an alternative. *See generally* Resp.

We accept and use Petitioner's uncontested definition of the ordinarily skilled artisan, which appears to comport with the level of skill in the art reflected in the prior art of record and the '943 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("the prior art itself [may]

reflect[] an appropriate level" of the ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

D. CLAIM CONSTRUCTION

The Board interprets claim terms in an *inter partes* review using the same claim construction standard that is used to construe patent claims in a civil action in federal district court. 37 C.F.R. § 42.200(b). In construing claims, district courts and the Board here, by default, give claim terms their ordinary and customary meaning, which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner states that, "no terms require construction for purposes of this Petition." Pet. 21. Patent Owner presents no express position on claim construction. *See generally* Resp. We do not expressly construe any claim terms.

E. PETITIONER'S ASSERTED PRIOR ART

We review and summarize Petitioner's asserted prior art references below. The parties' dispute regarding whether Svihra, Johnson, Amarenco, and/or Burnett are prior art is addressed below at Sections II.F and II.G.

1. Svihra (Ex. 1004)

Petitioner asserts that Svihra is prior art under 37 U.S.C. § 102(a)(1). Pet. 1, 7–8, 17, 21. Svihra is a journal article from Bratisl Lek Listy (understood to be the Bratislava Medical Journal of Comenius University in Bratislava, Slovak Republic), tilted "Neuromodulative treatment of overactive bladder — noninvasive tibial nerve stimulation," and indicating

publication in 2002. Ex. 1004, 480. At its Abstract, Svihra indicates it relates to the following subject matter:

> *Background:* Conservative treatment of overactive bladder employes behavioral or invasive neuromodulatory inhibition of miction reflex and administration of anticholinergic drugs.
>
> *Main purpose:* The aim of this study was to use non-invasive stimulation of the tibial nerve with the intention to achieve desired therapeutic effects without iatrogenic nerve damage using a superficial electrostimulation.
>
> *Methods:* All patients suffered from overactive bladder (OAB) without bladder outlet obstruction. OAB was examined by the Behavioral urge score BUS (0.0 — the best and 1.0 — the worst score), the International prostate symptom score IPSS (0 — the best and 35 — the worst score) and the Incontinence quality of life questionnaire IQOL (0.0 — the worst and 1.0 — the best index). The patients were divided into 3 groups: Group I — patients with electrode attached behind the medial ankle of the left lower extremity. The intensity of stimulation corresponded to 70 % of the maximum amplitude of response from musculus abductor hallucis. Frequency of stimulation was 1 Hz and duration of the square impulse was 0.1 ms. Surface stimulation lasted 30 minutes and was repeated once a week. Group II — patients were treated by oral oxybutynin 5 mg t.i.d. Group III — patients without treatment. The BUS, IPSS, and IQOL were repeated after the treatment.
>
> *Results:* The study included 28 females of average age 54 year (range 45 to 63). Mean IPSS was 17 (range 12 to 21), mean index of quality of life IQOL was 30 (range 12 to 78) and mean BUS score was 0.68 (range 0.50 to 0.86). Group I with stimulation did achieve statistically significant changes following the treatment: decrease of mean IPSS from 1713 points to 614 points after the treatment, increase in mean IQOL from 36110 to 68120 and decrease of mean BUS from 0.6510.12 to 0.4310.16. Group II had similar statistically significant differences after the treatment of OAB. Group III noted no changes in the complaints.

> *Conclusion:* Noninvasive stimulation had improved subjective symptom related to overactive bladder, had no adverse events and was well tolerated. (Fig. 1, Tab. 1, Ref 18.)

Id.

Svihra provides a background discussion of electrical stimulation techniques for treating OAB, including invasive neuromodulation, which "gave rise to the development of minimally invasive peripheral stimulation SANS (Stoller, 1999)." *Id.* Svihra further discloses, "Stoller's stimulation belongs to minimally invasive therapeutic methods because the stimulatory electrode is placed close to the tibial nerve in the region of medial ankle." *Id.* at 481.

Svihra states:

> When using the modified non-invasive stimulation SANS it is necessary to use surface electrodes for the area of medial ankle and stimulation of tibial nerve with different values, which cannot be set by the original SANS stimulator. 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 optimalization 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. Svihra further states, "patients with non-invasive SANS tolerated the treatment very well, and we had not observed adverse events. We assume,

that non-invasive SANS is acceptable and safe conservative treatment in case of overactive bladder." *Id.* at 482.

2. Amarenco (Ex. 1005)

Petitioner asserts that Amarenco is prior art under 35 U.S.C. § 102(a)(1). Pet. 7–8, 17, 44. Amarenco is an article titled "URODYNAMIC EFFECT OF ACUTE TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION IN OVERACTIVE BLADDER," published in June 2003 in The Journal of Urology, a publication of the American Urological Association. Ex. 1005, 2210.

Amarenco states that, "[o]f the various treatments proposed for urge incontinence, frequency and urgency electrostimulation has been widely tested." *Id.* (Abstr.). Further, Amarenco discloses "peripheral electrical stimulation of the posterior tibial nerve was proposed for irritative symptoms in first intention or for intractable incontinence," and "[c]linical studies have demonstrated good results and urodynamic parameters were improved after chronic treatment." *Id.*

Amarenco discloses "posterior tibial nerve stimulation using a surface self-adhesive electrode on the ankle skin behind the internal malleolus with shocks in continuous mode at 10 Hz. frequency and 200 milliseconds wide," where "[p]osterior tibial nerve stimulation was associated with significant improvement in first involuntary detrusor contraction volume ($p < 0.0001$) and significant improvement in maximum cystometric capacity ($p < 0.0001$)." *Id.*; *see also id.* at 2211, 2214 (discussing the same testing).

Amarenco states that "[t]hese results suggest an objective acute effect of posterior tibial nerve stimulation on urodynamic parameters. Improved bladder overactivity is an encouraging argument to propose posterior tibial

nerve stimulation as a noninvasive treatment modality in clinical practice." *Id.* at 2210 (Abstr.); *see also id.* at 2214 (stating "[p]osterior tibial nerve stimulation inhibits bladder activity").

3. Burnett (Ex. 1006)

Petitioner asserts that Burnett is prior art under 35 U.S.C. § 102(a)(1). Pet. 17, 65. Burnett, titled "METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY," is the December 11, 2008, publication (US 2008/0306325 A1) of U.S. Application 11/866,329, which was filed on October 2, 2007. Burnett's application is listed on the face of the '943 patent for priority; we discuss this below at Section II.G.

Burnett states that its invention relates to:

> An energy emitting apparatus for providing a medical therapy includes one or more energy generators, a logic controller electrically connected to the one or more energy generators, and one or more sensors for detecting electric conduction in a target nerve that are connected to the logic controller. The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the energy is varied by the logic controller according to an input provided by the one or more sensors. In one embodiment, the energy emitting apparatus is an apparatus for magnetic induction therapy that includes one or more conductive coils disposed in an ergonomic housing that produce a magnetic field focused on the target nerve upon receiving an electric current from the logic controller based on an input provided by the one or more sensors.

Ex. 1006, Abstr.

Such an energy emitting apparatus, as applied to a human ankle, is illustrated in Burnett at Figure 1, reproduced below:

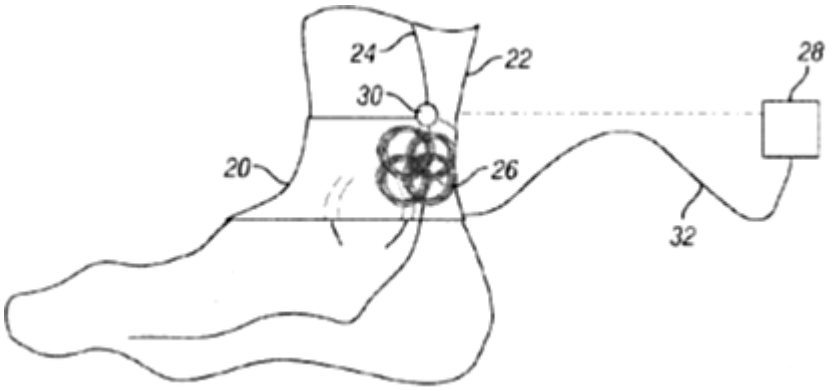

Figure 1 depicts an apparatus (a wrap) for magnetic induction therapy and shows a coil wrap 20 disposed over ankle 22 circumferentially to surround a portion of tibial nerve 24, which is "particularly suited for the treatment of OAB and UI." *Id.* ¶¶ 39, 49, 89, 97. According to the Burnett,

> 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.

Id. ¶ 51. A programmable logic controller 28 supplies the electrical current that flows through coils 26 and produces the magnetic field. *Id.* ¶¶ 49–53; *see also id.* ¶ 102 (treatment may include daily, 15–30 minute sessions). Figure 1 also shows a sensor 30, provided "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.* ¶ 53. Burnett discloses using the sensor to detect and measure conduction in nerves, as well as concomitant muscle contraction to confirm stimulation. *Id.* ¶¶ 58, 88.

1. Johnson (Ex. 1007)

Petitioner asserts that Johnson is prior art under 35 U.S.C. § 102(a)(1). Pet. 17. Johnson (WO 2004/108209 Al), titled "ELECTRICAL

STIMULATOR AND GARMENT ELECTRODE CONNECTION SYSTEM," is the December 16, 2004, publication of international Application PCT/US2004/018198, which was filed under the PCT on June 4, 2004. Ex. 1007, codes (10), (21), (22), (43), (54). Johnson states that its invention relates to:

> An electronic stimulator for delivery of energy to a treated body portion through a garment or other form of electrode, and a method of treatment using said stimulator. A connector strap comprising diode bridge circuitry maintains proper polarity on the electrodes regardless of the orientation of connection between the stimulator and the electrode.

Id. at Abstr.

Johnson illustrates such an electronic stimulator garment at Figure 1, which is reproduced below:

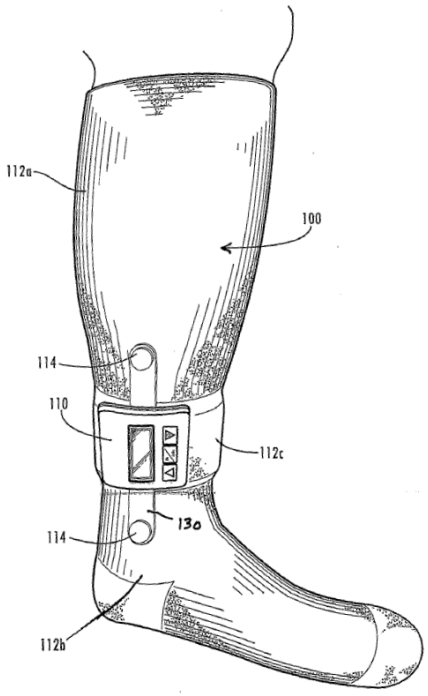

Fig. 1

According to Johnson,

> Figure 1 shows a system according to an example form of the present invention, including a garment electrode 100 having an electrical stimulator 110 directly attached thereto by a connector strap. The garment electrode is depicted as a stocking, but other embodiments of the invention include a sleeve, wrap, glove, or other type of garment electrode to be worn over one or more body parts of a human or animal subject.

Id. at 6:18–23. Figure 1 shows garment 100 has electrical stimulator 110, conductive regions 112a, 112b, non-conductive region 112c, contacts 114, and connector strap 130. *Id.* at 6:18–7:16.

F. THE PRIOR ART STATUS OF SVIHRA AND AMARENCO

The parties dispute whether Svihra and Amarenco qualify as prior art in this proceeding. As discussed below, we find on this unique record that they do qualify as printed publications and prior art.

Patent Owner argues that neither Svihra nor Amarenco have been shown to be printed publications, accessible to the interested public, and therefore cannot be considered as prior art in this proceeding. Resp. 4–9 (citing Ex. 1003; Ex. 1004; Ex. 1005; Exs. 1008–1017; Ex. 1024; Exs. 1027–1028; Ex. 1030; Ex. 1037–1039; Exs. 1041–1043; Ex. 1053 ¶¶ 6–7, 10–19, 26, 29–30, 32, 39–41, 43–45).[9] Patent Owner argues that, "in each case, there is no record evidence of public accessibility" for these exhibits, "other than the document itself." *Id.* at 5. Patent Owner acknowledges that there is witness testimony as to the authenticity (i.e., each

[9] Patent Owner makes a general accusation against "other documents alleged [by Petitioner] to constitute printed publications" (*see* Resp. 5) without discussing these other exhibits in detail. In any event, the rationale for finding Svihra and Amarenco to be printed publication applies generally to these other references as well, as discussed further, below.

reference is a true and correct copy of what it is asserted to be) in the Declaration of Todd R. Tucker, submitted with the evidence as Exhibit 1053, but argues there is no personal knowledge of record establishing the public availability, e.g., in a library or some other source, for the evidence. *Id.* at 5–6.

Petitioner, in the Petition, asserts that Svihra was published "[i]n the early 2000's," and similarly asserts that Amarenco was published "[l]ong before 2006." Pet. 7–8. The Petition also states that "***all references relied on by Petitioner herein other than Burnett*** were published before [October 2, 2006,] and thus qualify as prior art under AIA §102(a)(1) or (2)." *Id.* at 17 (emphasis in original). The Petition states, "Svihra published in 2002 and is therefore prior art," and "Amarenco published in 2003 and is therefore prior art." *Id.* at 21, 44. The Petition also identifies that Amarenco (as well as Johnson (Ex. 1007) and Rhodes (Ex. 1022)) is of record in the prosecution of the '943 patent; it is listed on the face thereof as considered by the Office. *Id.* at 20; *see also* Ex. 1001, code (56) (references cited, listing Amarenco as the fourth non-patent reference).

Contesting Patent Owner's argument in the Response, Petitioner argues that Svihra and Amarenco, and the other cited non-patent references, were publicly accessible and qualify as prior art printed publications. Reply 2 (citing Ex. 1004; Ex. 1005; Exs.1008–1017; Ex. 1024; Exs. 1027–1028; Ex. 1030; Ex. 1035; Exs. 1037–1039; Exs. 1041–1043). Regarding Svihra and Amarenco, Petitioner argues that each identifies, on its face, "an established publisher," thus, "there is a presumption of public accessibility as of the publication date," Svihra's being Bratisl Lek Listy, i.e., the well-established Bratislava Medical Journal published (103 times) by the Faculty

of Medicine at Comenius University in Bratislava, Slovakia, and Amarenco's being The Journal of Urology (published 169 times). *Id.* at 4–9 (citing, *inter alia*, *VidStream LLC v. Twitter, Inc.*, 981 F.3d 1060, 1065–66 (Fed. Cir. 2020)).

Petitioner also argues that Svihra and Amarenco bear hallmarks of publication, including these journal names, identification of publication dates, identification of journal receipt and accepted dates, volume and edition numbers, and page numbers, and, in Amarenco's case, copyright notice and digital object identifier number.[10] *Id.* (citing, *inter alia*, *Telefonaktiebolaget LM Ericsson v. TCL Corp.*, 941 F.3d 1341, 1344, 1347 (Fed. Cir. 2019) and *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 17–20 (PTAB Dec. 20, 2019) (precedential)). And, although Petitioner does not supply any testimonial personal knowledge as to the publication or public accessibility of the references, Petitioner does argue that several other scientific journal articles cite these references, indicating that they could be and were accessed publicly by interested persons. *Id.* at 15–18 (citing Ex. 1001, code (56); Exs. 1085–1090).

We agree with Petitioner that the evidence of record supports that Svihra and Amarenco (as well as the other identified non-patent references, barring, possibly, Stoller—Ex. 1015) are printed publications, published on the dates identified on the faces of the references.

Two precedential cases are instructive on the presented circumstances: *VidStream*, 981 F.3d 1060, and *Hulu*, 2021 WL 487622. In *VidStream*, the Federal Circuit identified that whether a reference is prior art is a legal

[10] Petitioner also points out that the other non-patent references at issue also bear similar hallmarks of publication. Reply 9–10.

question, based on factual findings. *VidStream*, 981 F.3d at 1063–64. 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. *Id.* at 1065. Particularly pertinent here is that "[w]hen there is an established publisher there is a presumption of public accessibility as of the publication date." *Id.*

Hulu (which cites *VidStream* on this issue) concerned, *inter alia*, whether certain asserted references were shown to be publicly available and could be considered as prior art. *Hulu*, 2021 WL 487622. Hulu holds that, although testimonial evidence is one way to prove public accessibility, there are also a variety of hallmarks 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 *10–13, 21. 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, and whether the reference's "purpose of publishing . . . was 'dialogue with an intended audience.'" *Id.* at *10–21 (citing *Valve Corp. v. Ironburg Inventions Ltd.*, 8 F.4th 1364, 1374 (Fed. Cir. 2021)).

Here, we find the totality of evidence supports Petitioner's position that Svihra and Amarenco (as well as the other identified non-patent references, possibly barring Stoller (Ex. 1015)) were printed publications

prior to the '943 patent's priority date. We note at the outset that Patent Owner does not allege that any contested reference is a fabricated forgery or counterfeit document, but only that Petitioner has not set forth sufficient facts establishing that such references were published and available. Hr'g Tr. 24:4–10.

Svihra bears sufficient hallmarks 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 the 103rd issue (No. 12) of Bratisl Lek Listy, aka, the Medical Journal of Comenius University in Bratislava, Slovakia, an established publication; it identifies 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 hallmarks supports that Svihra was published and publicly available in 2002. *See, e.g.*, Hr'g Tr. 32:12–17 (Patent Owner agreeing that things like a journal title, an issue number, a volume number, and a copyright date are hallmarks of publication.). There is no *direct* evidence that Svihra was publicly accessed as of this date, but it is cited as a reference in each of Exhibits 1085–1087, which supports that Svihra was, generally, publicly available to interested ordinarily skilled people, which corroborates that it was published and publicly accessible. Having an established publisher also creates a presumption of publication for Svihra, which has not been rebutted by Patent Owner.

Amarenco, too, bears sufficient hallmarks 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, an established 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. Ex. 1005, 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. 1088, 1–8. Each of these hallmarks supports 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 the '943 patent (*see* Ex. 1001, code (56)), which supports that Amarenco was, generally, 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.

As for the "other items" mentioned by Patent Owner (*see* Resp. 5) 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, and

Exhibits 1041–1043; we find these references are similar in most ways to Svihra and Amarenco in bearing hallmarks of publication. For example, Exhibit 1008 is a journal article in the Clinical Obstetrics and Gynecology journal's volume 45, it has a copyright date, and correspondence information. Ex. 1008. As another example, Exhibit 1009 is a journal article from the journal Urology's 60th volume, 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 publisher/provider of scientific journal articles. Ex. 1009. We could go on and enumerate the details of the hallmarks for each reference, but they are basically the same as these examples.[11] Thus, we find each of these "other items" to be printed publications as of their indicated publication dates.

G. PRIORITY OF THE '943 PATENT AND BURNETT AS PRIOR ART

The parties dispute the effective filing date and priority date that can be accorded the claims of the '943 patent. This dispute is of primary importance regarding Petitioner's Grounds 9 and 10, which rely on Burnett. Burnett's publication date is December 11, 2008, and its filing date is October 2, 2007, which makes its status as prior art dependent on the priority date accorded the claims of the '943 patent. As discussed below, we find that, on this unique record, the '943 patent's claims can be accorded a

[11] Exhibit 1015, Stoller, is less clear than the others because it does not on its face include a publication date, an identified publisher, contact information, etc. Stoller, however, is cited in the Petition (*see* Pet. 6) as mere background on techniques for treating incontinence with electrical stimulation; it is not critical to any issue of patentability presented here and we do not rely on it in this Decision in rendering our conclusions on patentability.

priority date no earlier than September 20, 2010, which makes Burnett prior art under 37 U.S.C. § 102(a)(1).

Petitioner asserts that the earliest possible effective filing date of the '943 patent, if not the actual filing date, is September 20, 2010, which is the date U.S. Provisional 61/403,680 was filed, to which the '943 patent asserts priority via the following intervening, related applications, in chronological order: International Application PCT/US2011/052415 filed on September 20, 2011; U.S. Application 13/840,936 filed on March 15, 2013; U.S. Application 15/084,356 filed on March 29, 2016; U.S. Application 15/474,875 filed on March 30, 2017; and U.S. Application 16/732,706 filed on January 2, 2020. Pet. 14–17; *see supra* Section I.D. (reproducing Petitioner's diagram of the '943 patent's priority claim, which Patent Owner conceded at oral argument is an accurate representation (*see* Hr'g Tr. 21:7–22:8)). Although Petitioner acknowledges there are several other and earlier-filed applications listed by the '943 patent for priority purposes, Petitioner argues that, because of defects in the '943 patent's identification of these applications and their relationships, there is no continuity of pendency in any other line of applications than the one just listed above. Pet. 14–17.

The problem, as identified by Petitioner, is that the '943 patent identifies that the '875 application is a continuation-in-part of both the '356 application and the '529 application, but the '529 application was abandoned on February 10, 2016, and the '875 application was not filed until after that abandonment date, i.e., on March 30, 2017, meaning there was no co-pendency along that branch of the priority chain. *Id.* And, none of the above-listed applications (importantly, not the '936 application) is identified

on the '943 patent (or its Application Data Sheet) as directly related to the '529 application so as to connect the separate branches of the priority chain and preserve requisite co-pendency with the '592 application. *Id.*; *see also* Reply 18–21 (addressing the issue).

Petitioner cites *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309 (Fed. Cir. 2018), and argues that the Federal Circuit has held that, under the strict requirements for identifying a priority claim on a patent, mistakes in accurately listing applications and identifying their relationships may break co-pendency in the chain of priority and, so, defeat a priority claim. Pet. 16 n.3; Reply 20–22. Petitioner argues that Patent Owner did not meet the "strict compliance" with the rules for indicating priority that the Federal Circuit held to be "essential," meaning "the earliest effective filing date of the '943 Patent is September 20, 2010 (i.e., the filing date of the '680 provisional)." Reply 21–22.

In response to this, Patent Owner argues that 35 U.S.C. § 120 does not require "an applicant to identify 'all familial relationships,'" but only requires "a 'specific reference,' to priority. Sur-reply 12. Patent Owner argues that listing all the prior applications on the '943 patent, as noted above at Section I.D., is all that is needed to perfect a priority claim. *Id.* at 12–13. Patent Owner argues that,

> [e]ven though the Federal Circuit noted in *Droplets* that USPTO regulations require the identification of familial relationships, the Federal Circuit did not state that Section 120 requires such an identification or that the specific identification of patent applications by series code, serial number, and filing

> date (all completely and accurately), but without certain familial relationships, is insufficient.

Id. at 13. Patent Owner states the '943 patent (and its Application Data Sheet at filing) "identified 'the relationship of the applications' to which priority was claimed, consistent with 37 C.F.R. § 1.78(d)(2), just not all the relationships," and so concedes this is a technical problem.[12] *Id.* at 14.

Having considered the undisputed facts of record concerning how the priority claim was made on and for the '943 patent, we find that the Petitioner is correct and the *Droplets* case compels our conclusion that the '943 patent is entitled to priority no earlier than September 20, 2010.

In *Droplets*, the Federal Circuit held that merely mentioning, or incorporating by reference, a prior application, e.g., a provisional application, cannot satisfy the statutory requirement under § 120 for claiming priority. *Droplets*, 887 F.3d at 1312. In *Droplets*, a challenged patent identified priority to and incorporated by reference a copending prior application, which itself identified priority to a provisional application, which the challenged patent also identified for priority; however, the challenged patent failed to expressly identify an intervening patent application slotted between the identified provisional and prior application necessary for continuity of copendency. *Id.* at 1313.

Although it was true that a continuous familial relationship actually existed so as to link the challenged patent continuously to the provisional application for priority purposes, the Federal Circuit held that 35 U.S.C.

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[12] Patent Owner has identified that the deficient assertion of priority could be corrected, if necessary, with a reissue application under 35 U.S.C. § 251. Resp. 14 n.2. At oral argument, however, Patent Owner confirmed that no such corrective measures have been taken. Hr'g Tr. 32:23–33:5.

§§ 119 and 120 require specific reference to earlier filed applications for priority claims, and that 37 C.F.R. § 1.78 requires that this specific reference include identification of the numbers of and the familial relationships for prior applications to establish copendency throughout the entire chain of prior applications—and the failure to meet the requirements is not a mere hypertechnical violation, but an important error that defeats priority. *Id.* at 1315–16.

The Federal Circuit held that this identification requirement serves "an important public policy" that the public be able to determine a patent's priority with minimum effort, which requires strict procedural adherence, where the burden is on the patent owner to provide a clear, unbroken chain of priority. *Id.* at 1316–17. That the priority chain was, in fact, unbroken, did not matter without proper identification by the challenged patent because, "[t]o require the public to search for an unstated priority claim through incorporated materials would create uncertainty and would require the type of guess-work that the statute is meant to avoid." *Id.* at 1320. Thus, the mistake in listing the relationships between all prior related application doomed the patent's priority claim.

Patent Owner has the same problem here as did the patent owner in *Droplets* — Patent Owner's challenged '943 patent fails to provide a complete identification of prior related applications and familial relationships to establish linked copendency of applications and, thereby, priority. *See* Resp. 13 ("The only thing 'missing' is a statement that U.S. Application No. 13/840,936 was also a continuation-in-part of [application] 12/508,529."); Hr'g Tr. 22:4–8 (Patent Owner agreeing that neither the '943

patent nor its Application Data Sheet identify the necessary prior application relationships for priority purposes).

Patent Owner acknowledges that the '943 patent fails to accurately identify "all the relationships" of the priority application, and so concedes the technical problem. Reply 13; Sur-reply 14. The technical problem is the failure to identify the relationship between application 15/474,875, application 13/840,936, and application 12/508,529. *See* Ex. 1001, code (63), 1:8–30 ("U.S. patent application Ser. No. 15/474,875 filed Mar. 30, 2017 (now U.S. Pat. No. 10,786,669), which is a continuation-in-part of U.S. patent application Ser. No. 15/084,356 filed Mar. 29, 2016 (now U.S. Pat. No. 9,630,004), which is a continuation of U.S. patent application Ser. No. 13/840,936 filed Mar. 15, 2013 (now U.S. Pat. No. 9,339,641), which is a continuation in part of PCT International Patent Application Number PCT/US2011/052415 filed Sep. 20, 2011, which claims benefit of priority to U.S. Provisional Patent Application No. 61/403,680 filed Sep. 20, 2010. U.S. patent application Ser. No. 15/474,875 is also a continuation-in part of U.S. patent application Ser. No. 12/508,529 filed Jul. 23, 2009 (now abandoned)"); *see also* Ex. 1002, 188–97 (Application Data Sheet with same omission).

As sufficiently illustrated by Petitioner's flow chart graphic (*see supra* Section I.D (reproduced); *see also* Pet. 15 (original)), which Patent Owner agrees accurately depicts how the '943 patent identifies its priority claim (Hr'g Tr. 21:7–22:8), the '529 application was abandoned before the '875 application was filed; the '875 application also links to another branch of this family tree including the '936 application, but that branch begins with the filing of provisional application 61/403,680 on September 20, 2010, and

there is no identified familial relationship with the '529 application so as to connect with the earliest-filed applications. This is the defect in Patent Owner's claim of priority and it defeats the earlier possible priority, as in the *Droplets* case.

Thus, September 20, 2010, is the earliest possible effective filing date for the '943 patent, as argued by Petitioner. Burnett was published on December 11, 2008, and it is, therefore, prior art under 35 U.S.C. § 102(a)(1).

H. GROUNDS 1–4 — UNPATENTABILITY OF CLAIMS 1–39 AS ANTICIPATED BY SVIHRA, OR AS OBVIOUS OVER SVIHRA INDIVIDUALLY OR COMBINED WITH JOHNSON

Each of Petitioner's unpatentability Grounds 1–4 is foundationally based on the disclosure of Svihra, therefore, we analyze these Grounds together as a group.

Under Ground 1, Petitioner asserts that Svihra anticipates claims 1 and 3–5, under Ground 2 asserts that claims 2 and 6–13 would have been obvious over Svihra, and under Grounds 3 and 4 asserts that claims 14–39 would have been obvious over Svihra and Johnson. Pet. 2, 21–44 (citing Ex. 1001, 3:2–4, 6:18–20, 20:54–62, 25:5–8, 26:61–64, 36:15–27, 46:28–39; Ex. 1003 ¶¶ 59–73, 75–100, 102–119, 121–138; Ex. 1004, 480–82; Ex. 1024, 234; Ex. 1007, 1:11–15, 2:9–20, 3:2–15, 3:26–28, 6:18–20, claim 4; Ex. 1022, 4:25–51; Ex. 1025; Ex. 1026; Ex. 1027, 24; Ex. 1028, 361–62, 367; Ex. 1029, 1:45–63; Ex. 1030, 3, 7, 10; Ex. 1031 ¶ 24; Ex. 1032 ¶ 5; Ex. 1033, 1:41–48; Ex. 1034, 12:28–45; Ex. 1035, 188; Ex. 1036, 5:33–50; Ex. 1037, 736; Ex. 1041, 119; Ex. 1042, 120–21; Ex. 1043, 174).

Patent Owner does not expressly contest any of Grounds 1–4 on the merits, i.e., it does not argue that Svihra fails to anticipate any claim or that

Svihra individually or Svihra and Johnson combined would not have rendered the claims obvious, and thus unpatentable. *See generally* Resp.; *see also* Hr'g Tr. 26:18–21 ("JUDGE FLAX: So your opposing counsel mentioned at the very beginning of their argument that you have not challenged the merits of the patentability arguments being made in the petition; is that accurate? MR. GERASIMOW: It's accurate for this proceeding."). Patent Owner argues that Petitioner has not established that Svihra is a prior art publication and that "[t]he consequence is that Petitioner has failed to carry its burden of proving by a preponderance of the evidence that the challenged claims are invalid based on Grounds 1-[4] identified in the Petition." *Id.* at 8.

We addressed this issue above, finding that, on this record, Svihra (as well as Amarenco) is a prior art publication. *See supra* Section II.F. Patent Owner has no remaining arguments contesting Grounds 1–4. In fact, Patent Owner has conceded that if the Board "concludes that they're prior art, Svihra and Amarenco, then [Patent Owner] agree[s] Petitioner will win on . . . most grounds, if not all." Hr'g Tr. 26:25–27:6. Nevertheless, the ultimate burden here is Petitioner's, so we analyze these Grounds below.

Petitioner addresses each of claims 1–39 of the '943 patent and maps their limitations to the disclosure of Svihra and/or Johnson to show anticipation and obviousness. Where modification or combination of the prior art is asserted to have been obvious, Petitioner addresses why the ordinarily skilled artisan would have done so and had a reasonable expectation of success. We first address the independent claims.

Petitioner asserts that Svihra anticipates (under 35 U.S.C. § 102(a)(1)) independent claim 1 in disclosing using non-invasive stimulation of a

patient's posterior tibial nerve to treat overactive bladder, where the therapy includes attaching surface electrodes behind the patient's median ankle, and applying controlled electrical stimulation (in frequency and intensity) targeting the tibial nerve, which resulted in successfully improving patients' overactive bladder symptoms. Pet. 21–24 (citing Ex. 1003 ¶¶ 59–68; Ex. 1004, 480–82).

Petitioner also asserts that independent claim 14 would have been obvious over Svihra and Johnson. Pet. 35–36. Claim 14 is substantially similar to independent claim 1, but adds that the "electrical stimulator [is] positioned within a sock worn upon a foot of the patient." *See supra* Section I.D (reproducing the independent claims). Petitioner cites the same teachings of Svihra as for its anticipation of independent claim 1, and further cites Johnson, which teaches that electrical stimulators, like Svihra's surface electrodes, can be provided in a patient-worn garment such as a sock, stocking, sleeve, wrap, glove, strap, etc., which Petitioner asserts teaches claim 14's "sock." Pet. 35–36 (citing Ex. 1003 ¶¶ 102–107; Ex. 1004, 480–82; Ex. 1007, 1:11–15, 3:2–15, 3:26–28, 6:18–20, claim 4; Ex. 1022, 4:25–51 (another sock-electrode example)). Petitioner asserts it would have been obvious to the ordinarily skilled artisan to combine Svihra and Johnson and modify Svihra's electrodes to be in a sock (for example), with a reasonable expectation of success, because it would have been a predictable, more comfortable and convenient option for providing electrodes at a patient's ankle for Svihra's therapy. *Id.*

Regarding independent claim 27, it is also substantially similar to independent claim 1, but adds that the "electrical stimulator [is] positioned upon a strap which is secured over a foot of the patient." *See supra* Section

I.D (reproducing the independent claims). Petitioner asserts that claim 27 would have been obvious over Svihra and Johnson for essentially the same reasons as for claim 14, pointing to Johnson's disclosure of, for example, sleeves, wraps, and straps (as teaching the recited "strap") for predictably, comfortably, and conveniently providing electrodes, like Svihra's, to a patient's ankle and tibial nerve, with a reasonable expectation of success. Pet. 37–39 (citing Ex. 1003 ¶¶ 111–116; Ex. 1004, 480–482; Ex. 1007, 1:11–15, 2:9–20, 3:2–15, 3:26–28, 6:18–20, claim 4; Ex. 1022 4:25–51).

Concerning these independent claims, we find no gaps in Petitioner's analysis or assertions of unpatentability for anticipation or obviousness, which stand uncontested by Patent Owner on the merits. We are persuaded that these independent claims are unpatentable, as asserted by Petitioner. We now turn to the dependent claims and address substantially similar claims together.

Claims 2, 15, and 28 depend from claims 1, 14, and 27, respectively, and add that an electrode is part of a "patch." Ex. 1001, 70:20–23, 71:9–12, 72:10–14. Petitioner asserts that Svihra teaches this in disclosing surface electrodes, akin to well-known TENS patches—Petitioner asserts the ordinarily skilled artisan would have found it obvious to apply Svihra's surfaced electrodes as patches because doing so was a well-known way to apply surface electrodes with a reasonable expectation of success. Pet. 26–27, 40 (citing Ex. 1001, 46:28–39 (TENS was well known); Ex. 1003 ¶¶ 75–78, 121; Ex. 1004, 480–482; Ex. 1024, 234; Ex. 1025; Ex. 1026; Ex. 1027).

Claims 3, 16, and 29 depend from claims 1, 14, and 27, respectively, and add "detecting a muscular response caused by" the electrical

stimulation. Ex. 1001, 70:24–26, 71:13–15, 72:15–17. Petitioner asserts that Svihra discloses using an electromyographic (EMG) device to measure electrical activity and muscle response during stimulation of nerves, where muscular responses indicate stimulation intensity, which anticipates (and also renders obvious) this limitation. Pet. 24–25, 36, 39 (citing Ex. 1003 ¶¶ 69–70, 108, 117; Ex. 1004, 481).

Claims 4, 17, and 30 depend from claims 1, 14, and 27, respectively, and add "activating the electrical stimulator for a duration of about 30 minutes per week." Ex. 1001, 70:27–29, 71:16–19, 72:18–21. Petitioner asserts that Svihra discloses applying electrical stimulation for 30 minutes once a week, for five weeks. Pet. 25, 37, 39 (citing Ex. 1003 ¶¶ 71, 109, 118; Ex. 1004, 480–82).

Claims 5, 18, and 31 depend from claims 1, 14, and 27, respectively, and add "displaying physiological parameters detected." Ex. 1001, 70:30–31, 71:20–21, 72:22–23. Petitioner asserts that Svihra teaches using the EMG (a Nicolet Viking II E machine) to measure electrical activity and muscle response, registering the results on a display, as reported by Svihra's results. Pet. 25, 37, 39 (citing Ex. 1003 ¶¶ 72–73, 110, 119; Ex. 1004, 481).

Claims 6, 19, and 32 depend from claims 1, 14, and 27, respectively, and add "detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode migration from the first portion." Ex. 1001, 70:32–35, 71:22–25, 72:24–27. Claims 7, 20, and 33 depend from claims 6, 19, and 32, respectively, and add that the "detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion." *Id.* at 70:36–38, 71:26–28, 72:28–31. Petitioner asserts

that Svihra discloses measuring muscle responses to electrical stimulation using EMG, which detects electrical conduction in the tissue, typically using physically separated EMG electrode patches to do so, where the presence or lack of conduction would indicate electrode migration, malfunction, or proper/improper placement. Pet. 27–32, 40, 42 (citing Ex. 1001, 4:66–5:7, 17:9–30, 20:54–62, 25:5–8, 26:61–64, 36:15–27, 57:23–36, 57:53–58:3, 58:39–50, 58:66–59:5, 61:13–14, 65:35–62, 67:14–59; Ex. 1003 ¶¶ 79–94, 122–123, 131–132; Ex. 1004, 480–82; Ex. 1028, 361–62, 367; Ex. 1029, 1:45–63; Ex. 1034, 12:28–45; Ex. 1035, 188; Ex. 1037, 736; Ex. 1041, 119; Ex. 1042, 120–121; Ex. 1043, 174; Ex. 1028, 367; Ex. 1030, 3, 7, 10). Petitioner asserts that such a use of EMG equipment would be a conventional, known, and obvious use thereof. *Id.*

Claims 8, 21, and 34 depend from claims 1, 14, and 27, respectively, and are quite similar to, e.g., claim 6, but add "detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode malfunction from the first portion." Ex. 1001, 70:39–42, 71:29–32, 72:32–34. Claims 9, 22, and 35 depend from claims 8, 21, and 34, respectively, and, like claim 7, add that the "detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion." *Id.* at 70:43–45, 71:33–35:72, 35–37. Petitioner asserts that, for the same reasons Svihra teaches the limitations of claims 6 and 7, it also teaches the limitations of these claims because detecting the lack of electrical conduction would have been known as an indicator of electrode migration, malfunction, and placement. Pet. 32–33, 40–43 (citing, *inter alia*, Ex. 1003 ¶¶ 95–96, 124–125, 133–134).

Claims 10, 23, and 36 depend from claims 1, 14, and 27, respectively, and, similarly to claim 6, add "detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement upon the first portion." Ex. 1001, 70:46–50, 71:36–40, 74:38–43. Claims 11, 24, and 37 depend from claims 10, 23, and 36, respectively, and, like claim 7, add that the "detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion." *Id.* at 70:51–53, 71:41–43, 72:44–46. Petitioner asserts that, for the same reasons Svihra teaches the limitations of claims 6 and 7, it also teaches the limitations of these claims because detecting the lack of electrical conduction is an indicator of electrode migration, malfunction, and placement. Pet. 33–34, 41, 43 (citing, *inter alia*, Ex. 1003 ¶¶ 97–98, 126–127, 135–136).

Claims 12, 25, and 38 depend from claims 1, 14, and 27, respectively, and, similarly to claim 6, add "detecting for a lack of presence of electrical conduction through tissue at a second portion of the patient's body distant from the first portion as an indicator of electrode placement upon the first portion." Ex. 1001, 70:54–58, 71:44–48, 72:46–51. Claims 13, 26, and 39 depend from claims 12, 25, and 38, respectively, and, like claim 7, add that the "detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion." *Id.* at 70:59–62, 71:49–52, 72:52–55. Petitioner asserts that, for the same reasons Svihra teaches the limitations of claims 6 and 7, it also teaches the limitations of these claims because detecting electrical conduction is an indicator of electrode migration, malfunction, and

placement. Pet. 34, 41–44 (citing, *inter alia*, Ex. 1003 ¶¶ 99–100, 128–129, 137–138).

Again, none of the above-reviewed assertions of Petitioner are contested by Patent Owner. We are persuaded by Petitioner's arguments and evidence that dependent claims 2–13, 15–26, and 28–39 are unpatentable over Svihra as anticipated or obvious, or obvious over Svihra and Johnson. We find no gaps in Petitioner's identification of each limitation as disclosed, taught, or suggested by the prior art and, where any combination or modification would have been needed, we agree there was a reason with rational underpinning for the ordinarily skilled artisan to have done so, with a reasonable expectation of success.

In summary, we find Petitioner has proven by a preponderance of the evidence that, under Grounds 1–4, claims 1–39 are unpatentable.

I. GROUNDS 5–8 — UNPATENTABILITY OF CLAIMS 1–39 AS ANTICIPATED BY AMARENCO, OR AS OBVIOUS OVER AMARENCO INDIVIDUALLY OR COMBINED WITH JOHNSON

Each of Petitioner's unpatentability Grounds 5–8 is foundationally based on the disclosure of Amarenco (thus, we address them together), where, under Ground 5 Petitioner asserts that Amarenco anticipates claims 1–3 and 5, under Ground 6 asserts that claims 4 and 6–13 would have been obvious over Amarenco, and under Grounds 7 and 8 asserts that claims 14–39 would have been obvious over Amarenco and Johnson. Pet. 2–3, 44–65 (citing Ex. 1001, 3:2–4, 25:5–8, 25:61–64; Ex. 1003 ¶¶ 140–149, 151–175, 177–194, 196–213; Ex. 1004, 481; Ex. 1005, 2210–11, 2214, Figs 3–4; Ex. 1007, 1:11–15, 2:9–20, 3:2–15, 3:26–28, 4:25–51, 6:18–20, claim 4; Ex. 1022, 4:25–51; Ex. 1028, 367; Ex. 1030, 3, 7, 10; Ex. 1031 ¶ 24; Ex. 1032 ¶ 5; Ex. 1033, 1:41–48; Ex. 1034, 12:28–45; Ex. 1035, 188;

Ex. 1036, 5:33–50; Ex. 1037, 736; Ex. 1038, 915; Ex. 1039, 44; Ex. 1042, 120–21).

Again, Patent Owner does not expressly contest any of Grounds 5–8 on the merits. *See generally* Resp.; *see also* Hr'g Tr. 26:18–21. Patent Owner argues that Petitioner has not established that Amarenco is a prior art publication and that "[t]he consequence is that Petitioner has failed to carry its burden of proving by a preponderance of the evidence that the challenged claims are invalid based on Grounds [5]-8 . . . identified in the Petition." *Id.* at 8. As discussed above, we find that, on this record, Amarenco is a prior art publication. *See supra* Section II.F. Patent Owner has no remaining arguments contesting Grounds 5–8. In fact, Patent Owner has conceded that if the Board "concludes that they're prior art, Svihra and Amarenco, then [Patent Owner] agree[s] Petitioner will win on . . . most grounds, if not all." Hr'g Tr. 26:25–27:6. Nevertheless, the ultimate burden here is Petitioner's, so we analyze these Grounds below.

Petitioner addresses each of claims 1–39 of the '943 patent and maps their limitations to the disclosure of Amarenco and/or Johnson. Where modification or combination of the prior art is asserted to have been obvious, Petitioner addresses why the ordinarily skilled artisan would have done so with a reasonable expectation of success. We first address the independent claims.

As noted above, independent claim 1, 14, and 27 are very similar. Beginning with claim 1, Petitioner asserts that it is anticipated by Amarenco because the reference discloses noninvasive tibial nerve stimulation to treat incontinence and overactive bladder symptoms by adhering electrodes to a patient's ankle and continuously administering 10Hz electrical shocks at a

pulse width of 200 ms, which produced successful results by suppressing instability and improving bladder capacity. Pet. 44–47 (citing Ex. 1003 ¶¶ 140–146; Ex. 1005, 2210–11).

As for independent claims 14 and 27, Petitioner asserts that it would have been obvious over Amarenco and Johnson, combined, because Amarenco teaches the claimed system and method (as with claim 1) and Johnson teaches providing electrodes, like Amarenco's, in a garment such as a sock (claim 14) or strap/wrap/sleeve (claim 27), which the ordinarily skilled artisan would have recognized would have provided a comfortable, convenient, and predictable way to apply Amarenco's electrodes for Amarenco's therapy with a reasonable expectation of success. *Id.* at 56–60 (citing, *inter alia*, Ex. 1003 ¶¶ 178–182, 187–191; Ex. 1005, 2211; Ex. 1007, 1:11–15, 2:9–20, 3:2–15, 3:26–28, 4:25–51, 6:18–20, claim 4).

Concerning these independent claims, we find no gaps in Petitioner's analysis or assertions of unpatentability for anticipation or obviousness, which are uncontested on their merits. We are persuaded that these independent claims are unpatentable, as asserted by Petitioner. We now turn to the dependent claims and address substantially similar claims together.

Regarding claims 2, 15, and 28, which add that an electrode is part of a "patch," Petitioner asserts that Amarenco teaches this in disclosing self-adhesive surface electrode patches for patients' ankles. Pet. 47, 58, 60 (citing, *inter alia*, Ex. 1003 ¶¶ 147, 183, 192; Ex. 1005, 2211).

As for claims 3, 16, and 29, which add "detecting a muscular response caused by" the electrical stimulation, Petitioner asserts that Amarenco discloses this in teaching "[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," where these are muscular responses caused by Amarenco's stimulation. Pet. 47, 58, 60 (citing, *inter alia*, Ex. 1003 ¶¶ 148, 184, 193; Ex. 1005, 2211).

Claims 4, 17, and 30 add "activating the electrical stimulator for a duration of about 30 minutes per week," which Petitioner asserts have been obvious to the ordinarily skilled artisan over Amarenco's teaching of applying electrostimulation treatments, where weekly 30 minute applications would have been a predictable, already well known way to perform such electrical stimulation treatments. Pet. 49 (citing, *inter alia*, Ex. 1003 ¶¶ 151–153; Ex. 1004, 481; Ex. 1038, 915; Ex. 1039, 44).

As for claims 5, 18, and 31, which add "displaying physiological parameters detected," Petitioner asserts that Amarenco teaches computerized analysis of electrical stimulation results using EMG data, which is a measure of electrical activity and muscular response to nerve stimulation. Pet. 47–48, 58, 60 (citing, *inter alia*, Ex. 1003 ¶¶ 149, 185, 194; Ex. 1005, 2211, Figs. 3–4).

Claims 6, 19, and 32 add "detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode migration from the first portion," and claims 7, 20, and 33 then add that the "detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion," which Petitioner asserts would have been obvious over Amarenco's teaching of using EMG (utilizing sensors, e.g., electrode patches) to analyze electrical stimulation, thus detecting the presence or lack of electrical conduction through the tissue/nerve, thereby analyzing whether the electrodes were properly positioned, migrate, and/or malfunction; all

well-known techniques, obvious to use in Amarenco's therapy. Pet. 49–53, 61, 63 (citing, *inter alia*, Ex. 1001, 3:2–4, 25:5–8, 26:61–64; Ex. 1003 ¶¶ 154–169, 197–198, 206–207; Ex. 1005, Figs. 3–4; Ex. 1028, 361–62, 367; Ex. 1029, 1:45–63; Ex. 1030, 3, 7, 10; Ex. 1031 ¶ 24; Ex. 1032 ¶ 5; Ex. 1033, 1:41–48; Ex. 1034, 12:28–45; Ex. 1035, 188; Ex. 1036, 5:33–50; Ex. 1037, 736; Ex. 1041, 119; Ex. 1042, 120–21). Petitioner asserts that such a use of EMG equipment would be a conventional, known, and obvious use thereof. *Id.*

Claims 8, 21, and 34 add "detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode malfunction from the first portion," and claims 9, 22, and 35 add that the "detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion." Similarly, claims 10, 23, and 36 add "detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement upon the first portion," and claims 11, 24, and 37 add that the "detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion." And, also similarly, claims 12, 25, and 38 add "detecting for a lack of presence of electrical conduction through tissue at a second portion of the patient's body distant from the first portion as an indicator of electrode placement upon the first portion," and claims 13, 26, and 39 add that the "detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion." This recited subject matter is quite similar to that of claims 6, 7, 19, 20, 32, and 33, just discussed, and

Petitioner asserts that, for the same reasons, Amarenco teaches or suggests the limitations of claims 8–13, 21–26, and 34–39. Pet. 53–55, 61–65 (citing, *inter alia*, Ex. 1003 ¶¶ 170–175, 199–204, 208–213).

Again, none of the above-reviewed assertions of Petitioner are contested by Patent Owner. We are persuaded by Petitioner's arguments and evidence that dependent claims 2–13, 15–26, and 28–39 are unpatentable over Amarenco as anticipated or obvious, or obvious over Amarenco and Johnson. We find no gaps in Petitioner's identification of each limitation as disclosed, taught, or suggested by the prior art and, where any combination or modification would have been needed, we agree there was a reason with rational underpinning for the ordinarily skilled artisan to have done so with a reasonable expectation of success.

In summary, we find Petitioner has proven by a preponderance of the evidence that, under Grounds 5–8, claims 1–39 are unpatentable.

J. GROUND 9 AND 10 — UNPATENTABILITY OF CLAIMS 1–39 AS ANTICIPATED BY BURNETT, OR AS OBVIOUS OVER BURNETT COMBINED WITH JOHNSON

Petitioner's Grounds 9 and 10 assert that claims 1–3 and 5–13 are anticipated by Burnett and that claims 4 and 14–39 would have been obvious over Burnett and Johnson (covering all claims of the '943 patent). Pet. 3, 65–79 (citing Ex. 1001; Ex. 1003 ¶¶ 215–229, 231–269; Ex. 1004, 481; Ex. 1006 ¶¶ 2, 35–36, 49, 58, 67, 80, 82, 88–90, 102; Ex. 1007, 1:11–15, 2:9–20, 3:2–15, 3:26–28, 4:25–51, 6:18–20, claim 4; Ex. 1038, 915; Ex. 1039, 44).

As with Petitioner's Grounds 1–8, Patent Owner does not expressly contest either of Grounds 9 and 10 on its merits. *See generally* Resp. Patent Owner argues that "Petitioner has not carried its burden of proving that

Burnett (Ex. 1006) qualifies as prior art" because "Burnett published no earlier than December 11, 2008, which is after the priority date" of "October 2, 2006," i.e., the filing date of Provisional Application 60/848,720. *Id.* at 9–17. As discussed above, we find that, on this record, Burnett is a prior art publication because the '943 patent is entitled to an effective filing date no earlier than September 20, 2010. *See supra* Section II.G.

Patent Owner has no remaining arguments contesting Grounds 9 and 10. Nevertheless, the ultimate burden here is upon Petitioner, so we analyze these Grounds below. As above, we begin with the independent claims.

Petitioner asserts that Burnett anticipates independent claim 1 because the reference discloses treating overactive bladder and/or incontinence using non-invasive electrodes provided at a patient's ankle to electrically stimulate the posterior tibial nerve. Pet. 65–66 (citing, *inter alia*, Ex. 1003 ¶¶ 215–218; Ex. 1006 ¶¶ 2, 49, 88–90, Fig. 11). Similarly, Petitioner asserts that independent claims 14 and 27 would have been obvious over Burnett and Johnson combined because Johnson teaches that electrodes, as taught in Burnett, can be provided in a sock or sleeve/wrap/strap and the ordinarily skilled artisan would have known that doing so would be a comfortable, convenient, and predictable way to provide Burnett's therapy with a reasonable expectation of success. *Id.* at 70–72, 75–76 (citing, *inter alia*, Ex. 1003 ¶¶ 234–239, 252–257; Ex. 1006 ¶ 88; Ex. 1007, 1:11–15, 2:9–20, 3:2–15, 3:26–28, 4:25–51, 6:18–20, claim 4).

Concerning these independent claims, we find no gaps in Petitioner's analysis or assertions of unpatentability for anticipation or obviousness, which are uncontested on their merits. We are persuaded that these

independent claims are unpatentable, as asserted by Petitioner. We turn to the dependent claims below.

Regarding claims 2, 15, and 28, which add that an electrode is part of a "patch," Petitioner asserts that Burnett teaches this in disclosing transcutaneous stimulator electrodes (reference number 126). Pet. 67, 72, 76 (citing, *inter alia*, Ex. 1003 ¶¶ 219, 240, 258; Ex. 1006 ¶ 88).

As for claims 3, 16, and 29, which add "detecting a muscular response caused by" the electrical stimulation, Petitioner asserts that Burnett discloses this in teaching "detection of muscle contraction may also confirm that the target nerve is being stimulated and provide an indication to the patient or to a healthcare provider as to whether stimulation has been applied at an excessive level in view of the anatomical and physiological characteristics of the patient." Pet. 67, 72, 77 (citing, *inter alia*, Ex. 1003 ¶¶ 220, 241, 259; Ex. 1006 ¶¶ 35, 58).

Claims 4, 17, and 30 add "activating the electrical stimulator for a duration of about 30 minutes per week," which Petitioner asserts have been obvious to the ordinarily skilled artisan over Burnett's teaching of applying electrostimulation treatments for, e.g., "15–30 minutes," where weekly 30 minute applications would have been a predictable, already well known way to perform such electrical stimulation treatments. Pet. 70, 73, 77 (citing, *inter alia*, Ex. 1003 ¶¶ 231–233, 242, 260; Ex. 1004, 481; Ex. 1006 ¶102; Ex. 1038, 915; Ex. 1039, 44).

As for claims 5, 18, and 31, which add "displaying physiological parameters detected," Petitioner asserts that Burnett teaches "detect[ing] a variety of physiologic changes, including neural impulses, muscular contraction, twitching, etc. that may occur with neural or muscular

stimulation," using EKG-type patches attached to the body, where results of such detecting would be displayed to enable "the correct level of stimulation." Pet. 67–68, 73, 77 (citing, *inter alia*, Ex. 1003 ¶¶ 221, 243, 261; Ex. 1006 ¶¶ 80, 82).

Claims 6, 19, and 32 add "detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode migration from the first portion," and claims 7, 20, and 33 then add that the "detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion," which Petitioner asserts would have been obvious over Burnett's teaching of detecting nerve conduction at a site distant from the stimulation site to detect nerve conduction, which enables the user to provide optimal therapy, detect electrode migration or malfunction, and identify lack of body tissue stimulation. Pet. 68–69, 73, 77 (citing, *inter alia*, Ex. 1001, 3:2–4, 25:5–8, 26:61–64; Ex. 1003 ¶¶ 222–223, 244–245, 262–263; Ex. 1006 ¶¶ 36, 67, 88).

Claims 8, 21, and 34 similarly add "detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode malfunction from the first portion," and claims 9, 22, and 35 similarly add that the "detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion." Moreover, claims 10, 23, and 36 similarly add "detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement upon the first portion," and claims 11, 24, and 37 similarly add that the "detecting for the presence of electrical

conduction comprises detecting via an electrode patch positioned upon the second portion." Furthermore, claims 12, 25, and 38 similarly add "detecting for a lack of presence of electrical conduction through tissue at a second portion of the patient's body distant from the first portion as an indicator of electrode placement upon the first portion," and claims 13, 26, and 39 similarly add that the "detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion." This recited subject matter is quite similar to that of claims 6, 7, 19, 20, 32, and 33, just discussed, and Petitioner asserts that, for the same reasons, Burnett teaches or suggests the limitations of claims 8–13, 21–26, and 34–39. Pet. 69, 73–74, 78–79 (citing, *inter alia*, Ex. 1003 ¶¶ 224–229, 246–251, 264–269).

Again, none of the above-reviewed assertions of Petitioner are contested by Patent Owner. We are persuaded by Petitioner's arguments and evidence that dependent claims 2–13, 15–26, and 28–39 are unpatentable over Burnett as anticipated or obvious, or obvious over Burnett and Johnson. We find no gaps in Petitioner's identification of each limitation as disclosed, taught, or suggested by the prior art and, where any combination or modification would have been needed, we agree there was a reason with rational underpinning for the ordinarily skilled artisan to have done so, with a reasonable expectation of success.

In summary, we find Petitioner has proven by a preponderance of the evidence that, under Grounds 9 and 10, claims 1–39 are unpatentable.

K. GROUND 11 — UNPATENTABILITY FOR LACK OF ENABLEMENT

Under Ground 11, Petitioner asserts that claims 1–39 are unpatentable because the Specification fails under the enablement requirement. Pet. 3,

79–81 (citing Ex. 1001, 50:35–51:3, claims 1, 14, 27; Ex. 1003 ¶¶ 271–273). Petitioner's position is that the claims require positioning the electrical stimulator near the patient's ankle, that the '943 patent's written description describes that electrical stimulation at a non-glabrous surface of the body is painful to the patient and should be avoided, that an ankle is such a non-glabrous skin surface, and, therefore, the '943 patent's disclosure teaches against the claimed subject matter. *Id.*

Patent Owner presents no arguments specifically contesting this Ground. *See generally* Resp. Nevertheless, the ultimate burden here is Petitioner's, so we analyze this Ground below.

We are not persuaded that the challenged claims of the '943 patent are not enabled by the disclosure of the Specification. It is a fact that the Specification discourages the presentation of electrical stimuli, at certain intensities and frequencies, upon non-glabrous (i.e., hairy) skin:

> In contrast, utilizing an electrical stimulus having a frequency of about 5 Hz to about 60 Hz or greater to stimulate a target nerve or tissue through a non-glabrous skin surface (via an electrode positioned over the non-glabrous skin surface) is intolerable and painful, resulting in burns or injury, and thus making such a procedure impractical and not feasible.
>
> For example, delivering electrical stimulation through a non-glabrous surface of the body, for example, by stimulating a site overlying a nerve near the medial malleolus to elicit a motor response of the abductor hallucis longus, generates a painful shock to the patient. While at a single pulse, such as in the use for EMG diagnostics, such electrical stimulation may be tolerable, as the frequency increases, the shocking sensation builds and quickly becomes painful and intolerable.

Ex. 1001, 50:55–51:3.

However, the '943 patent Specification also describes, for example:

> Energy delivered transdermally, through, or across a patient's skin at a frequency from about 1 Hz to about 30 Hz, or at a frequency of less than 10 Hz has unexpectedly been found to stimulate or generate motor and/or sensory conduction in a target nerve. For example, energy delivered transdermally, through, or across a patient[']s skin at about 1 Hz to about 30 Hz, or at less than 10 Hz has unexpectedly been found to stimulate or generate motor and/or sensory nerve conduction of a tibial nerve, where such level of stimulation may be sufficient to treat a patient suffering from urinary incontinence, overactive bladder, fecal incontinence or other conditions. *The energy may be delivered through or across a glabrous skin surface or non-glabrous skin surface or any other skin surface (e.g., any skin surface overlying a tibial nerve)*.

Id. at 49:26–40 (emphasis added). The source of the "energy" recited in the quoted passage is described by the '943 patent Specification as "an electrode or applicator for delivering electrical stimulation." *Id.* at 49:10–17. Thus, the '943 patent describes that transdermal electrical, electromagnetic, or magnetic stimulation or induction therapy can be applied safely across *glabrous or non-glabrous* skin in the vicinity of tibial nerve near a patient's ankle.

Petitioner's position that the Specification does not teach those skilled in the art how to make and use the full scope of the claimed inventions without undue experimentation is not persuasive. We conclude that, on the evidence of record, Petitioner has failed to establish that any claim is unpatentable for lack of enablement.

III. PATENT OWNER'S MOTION TO EXCLUDE

As noted above, with its Reply, Petitioner filed Exhibits 1085–1090, which are journal articles citing Svihra and/or Amarenco, a more complete version of Amarenco, and a declaration by Todd R. Tucker on behalf of

Petitioner testifying that each exhibit is a true and correct copy. Patent Owner filed a Motion to Exclude Evidence directed to these exhibits. Paper 22 (again, "Motion" or "Mot."). Petitioner filed an Opposition to the Motion (Paper 23, again, "Opposition" or "Opp."), to which Patent Owner responded with a Reply (Paper 24, again, "Opp. Reply").

Having considered the parties' arguments and support therefore, we *deny* the Motion. Our reasoning is set forth below.

A. LEGAL STANDARDS

Petitioners may file reply briefs to respond to issues raised in a patent owner's response and the institution decision. 37 C.F.R. § 42.23; PTAB Consolidated Trail Practice Guide, 84 Fed. R. 64280 (Nov. 21, 2019) at 73 ("CTPG"). A party may submit rebuttal evidence in support of a reply, but may not submit new evidence with or argument in reply that it could have presented earlier, e.g. to make out a prima facie case of unpatentability. *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1077–78 (Fed. Cir. 2015); CTPG at 73–75. For example, "gap-filling" for facts necessary to a prima facie case for unpatentability using new evidence is inappropriate. *See Genzyme Therapeutic Prods. Ltd. v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1365–69 (Fed. Cir. 2016).

As expressed in our Consolidated Trial Practice Guide,

> A motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay) but may not be used to challenge the sufficiency of the evidence to prove a particular fact. A motion to exclude is not a vehicle for addressing the weight to be given evidence—arguments regarding weight should appear only in the merits documents. ***Nor should a motion to exclude address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply***.

CTPG at 79 (emphasis added). Moreover, "[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or otherwise exceeds the proper scope of reply or sur-reply, it may request authorization to file a motion to strike." *Id.* at 80. "In most cases, the Board is capable of identifying new issues or belatedly presented evidence when weighing the evidence at the close of trial, and disregarding any new issues or belatedly presented evidence that exceeds the proper scope of reply or sur-reply." *Id.*

"The moving party has the burden of proof to establish that it is entitled to the requested relief." 37 C.F.R. § 42.20(c).

B. ANALYSIS

Petitioner asserts in the Petition that Svihra and Amarenco were published in 2002 and 2003, respectively, and are each prior art to the challenged claims under 35 U.S.C. § 102(a)(1), regardless of the effective filing date and/or priority date accorded those claims. *See* Pet. 1, 7–8, 14, 17, 21, 44; *see also* Ex. 1003 ¶¶ 46–47, 59–60 (Dr. Wingeier testifying that the references were published).

In our Institution Decision, we first addressed the issue of whether, under the record at that point, Svihra and Amarenco were prior art publications. DI 14–17. In the Institution Decision, we identified that

> It has long been recognized that the touchstone as to whether an asserted reference qualifies as prior art is public accessibility. *See In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986). "[A]t the institution stage, the petition must identify, with particularity, evidence sufficient to establish a reasonable likelihood that the reference was publicly accessible before the critical date of the challenged patent and therefore that there is a reasonable likelihood that it qualifies as a printed publication."

> *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29, 13 (PTAB Dec. 20, 2019) (precedential).

Id. at 15–16. At Institution, we preliminarily found that the record supported that each of Svihra and Amarenco bore the hallmarks of printed publications and public accessibility before the earliest possible critical date for the '943 patent's claims and, therefore, that Petitioner had established, for purposes of institution, each was prior art. *Id.* at 16–17.

In its Response, Patent Owner argues that Petitioner failed to prove that Svihra and Amarenco qualify as printed publications. *See* Resp. 4–9. Patent Owner argues that Petitioner has not proven that these references were "sufficiently accessible to the public interested in the art' before the critical date." *Id.* at 4–5 (citing *Align Tech., Inc. v. Dental Monitoring SAS*, IPR2023-01369, Paper 42 at 25 (PTAB March 3, 2025)). Patent Owner cites the lack of direct evidence and personal knowledge of public accessibility as a primary fault. *Id.* at 5–9.

Petitioner directly responds to these arguments in its Reply. Reply 1–18. As a part of this response, Petitioner argues that it submits Exhibits 1085–1089 as corroborating evidence that Svihra and Amarenco were published and publicly available. *Id.* at 15–18. Petitioner argues that Exhibits 1085–1087 and 1089 include citations to Svihra and/or Amarenco by other journal articles, demonstrating that the primary references were published and publicly available. *Id.* Petitioner compares these Exhibits to Exhibit 1016, filed with the Petition, which similarly cites Amarenco. *Id.* at 17. Petitioner asserts that Exhibit 1088 is another copy of Amarenco, further including the publishing journal's cover page, copyright notice, and table of contents listing Amarenco, which provide additional hallmarks of publication. *Id.* at 16–17.

We have addressed the parties' arguments on whether Svihra and Amarenco are prior art above at Section II.F, finding that they are printed publications as of 2002 and 2003, respectively, and are prior art to the challenged claims.

In its Motion, Patent Owner argues that Petitioner's filing of Exhibits 1085–1090 was not authorized by the Board and the circumstances do not warrant the filing of such "additional evidence." Mot. 2. Patent Owner argues these exhibits are "'late' supplemental information" under 37 C.F.R. § 42.223(b), which required Petitioner to show that the evidence could not reasonably have been obtained and submitted earlier and that late submission is in the interest of justice. *Id.* at 2–8; *see also* Opp. Reply 1–3.

Petitioner argues that Exhibits 1085–1090 are not supplemental information evidence, but constitute rebuttal evidence supporting its Reply under 37 C.F.R. § 42.23(b). Opp. 1–2. Petitioner argues that these exhibits respond to Patent Owner's Response arguments that Svihra and Amarenco (and other references) were not proven to be publicly available publications and prior art, and that the objected-to exhibits corroborate Petitioner's initial positions that these references were publicly available. *Id.* at 2–4. Petitioner argues that Exhibits 1085–1090 do not, and were not intended to, bolster Petitioner's patentability arguments on the merits. *Id.* at 6–7. Petitioner also argues that Patent Owner has had an opportunity to address the contents of Exhibits 1085–1090 in its Sur-reply and, so, is not prejudiced by the evidence. *Id.* at 8.

We determine Petitioner has the better position.

We find that Exhibits 1085–1090 are submitted by Petitioner in direct response to specific arguments presented in Patent Owner's Response,

which is proper. *Genzyme Therapeutic Prods. Ltd. P'ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1366 (Fed. Cir. 2016) ("[T]he introduction of new evidence in the course of the [PTAB] trial is to be expected in *inter partes* review trial proceedings and, as long as the opposing party is given notice of the evidence and an opportunity to respond to it, the introduction of such evidence is perfectly permissible under the APA.").

None of Exhibits 1085–1090 were required for Petitioner's prima facie case for anticipation or obviousness over Svihra or Amarenco on the merits, but constitute corroborating rebuttal evidence against Patent Owner's argument that these references are not prior art. This is the type of evidence contemplated to be filed with a reply brief. Patent Owner has identified no gaps in Petitioner's prima facie case on the merits allegedly sought to be filled by Exhibits 1085–1090. Upon review of the Reply, we do not discern that Petitioner cites any portions of Exhibits 1085–1090 as teaching or suggesting any challenged claim limitations or as necessary evidence that any prior art would have been combined with a reasonable expectation of success. This objected-to evidence was filed by Petitioner solely in response to Patent Owner's arguments in the Response, to corroborate Petitioner's original assertions and evidence that Svihra and Amarenco were published and were prior art to the challenged claims.

C. SUMMARY AND CONCLUSION

For the reasons above, we find that Exhibits 1085–1090 are each proper rebuttal evidence and we are not persuaded by Patent Owner's arguments for excluding these Exhibits. The Motion is, therefore, *denied*.

IV. CONCLUSION

On the record here Petitioner demonstrates by a preponderance of the evidence that claims 1–39 of the '943 patent are unpatentable under Grounds 1–10, and does not demonstrate that any claim is unpatentable under Ground 11. We deny Patent Owner's motion to exclude. In summary, our conclusions on Petitioner's unpatentability challenges are as follows:[13]

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 3–5	102	Svihra	1, 3–5	
2, 6–13	103	Svihra	2, 6–13	
14, 16–18, 27, 29–31	103	Svihra, Johnson	14, 16–18, 27, 29–31	
15, 19–26, 28, 32–39	103	Svihra, Johnson	15, 19–26, 28, 32–39	
1–3, 5	102	Amarenco	1–3, 5	
4, 6–13	103	Amarenco	4, 6–13	
14–16, 18, 27–29, 31	103	Amarenco, Johnson	14–16, 18, 27–29, 31	
17, 19–26, 30, 32–39	103	Amarenco, Johnson	17, 19–26, 30, 32–39	
1–3, 5–13	102	Burnett	1–3, 5–13	
4, 14–39	103	Burnett, Johnson	4, 14–39	
1–39	112	Enablement		1–39

[13] Should Patent Owner wish to pursue amendment of the challenged claim in a reissue or reexamination proceeding subsequent to the issuance of this decision, see the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, Patent Owner has a continuing obligation to notify the Board in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
Overall Outcome			1–39	

ORDER

Accordingly, it is hereby:

ORDERED that Petitioner has demonstrated by a preponderance of the evidence that claims 1–39 of U.S. Patent 11,844,943 B2 are *unpatentable*;

FURTHER ORDERED that, because this is a Final Written Decision, any party to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2; and

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence is *denied*.

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