

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,
Petitioner,
v.
EMKINETICS, INC.,
Patent Owner.

IPR2024-01378
Patent 9,002,477 B2

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

NEW, *Administrative Patent Judge*.

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

I. INTRODUCTION

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, we determine that Petitioner Avation Medical, Inc. (“Petitioner”) has established, by a preponderance of the evidence, that challenged claims 1–10 of Patent Owner EMKinetics, Inc.’s (“Patent Owner”) U.S. Patent No. 9,002,477 B2 (Ex. 1001, the “’477 patent”) are unpatentable.

A. *Procedural History*

On September 5, 2024, Petitioner filed its Petition (Paper 2, “Petition” or “Pet.”) seeking *inter partes* review of claims 1–10 of the ’477 patent. Patent Owner timely filed a Preliminary Response. Paper 6 (“Preliminary Response” or “Prelim. Resp.”). We instituted *inter partes* review of the challenged claims of the ’477 patent on March 18, 2025. Paper 7 (“Institution Decision” or “Inst. Dec.”).

After institution of trial, Patent Owner filed a Response (“Resp.,” Paper 12), Petitioner filed a Reply (“Reply,” Paper 15), and Patent Owner filed a Sur-Reply (“Sur-Reply,” Paper 17). A consolidated oral argument was held in this proceeding and IPR2024-01375 on January 7, 2026, and a copy of the transcript was entered into the record. (“Tr.,” Paper 27).

II. BACKGROUND

A. *Real Parties-in-Interest*

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

B. *Related Matters*

Petitioner identifies *Avation Medical, Inc. v. EMKinetics, Inc.*, No. 4:24-cv-01702-JST (N.D. Cal.), seeking declaratory judgment of noninfringement against the '477 patent and U.S. Patent No. 11,224,742 B2 (the "'742 patent"). The district court subsequently stayed the case pending our *inter partes* review of the patents-in-suit. *Avation Medical*, 4:24-cv-01702-JST, October 1, 2024. Petitioner also states that it has not filed any other civil action challenging the validity of any claim of the '477 patent. Petitioner also identifies *Avation Medical, Inc. v. EMKinetics, Inc.*, PGR2024-00043 (PTAB) (decided January 7, 2026) and *Avation Medical, Inc. v. EMKinetics, Inc.*, IPR2024-1375 (PTAB) as related matters. Pet. xii.

Patent Owner identifies no additional cases or matters relating to the '477 patent. Paper 5, 2; Paper 10, 2.¹

B. *The Asserted Grounds of Unpatentability*

Petitioner contends that claims 1–10 of the '477 patent are unpatentable, based upon the following grounds:

¹ Neither Paper 5 nor Paper 10 is paginated. We assign page numbers based upon their sequential order.

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1	102 ²	Svihra ³
2	1	103	Svihra, Mann ⁴ , DiLorenzo ⁵ , Gerber ⁶ , or Bourget ⁷
3	2–10	103	Svihra, Mann, DiLorenzo, Gerber, or Bourget
4	1	103	Amarenco ⁸ , Mann, DiLorenzo, Gerber, or Bourget
5	2–10	103	Amarenco, Mann

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. §§ 102 and 103 effective March 16, 2013. Because the application from which the ’477 patent issued has an effective filing date prior to that date, the pre-AIA versions of §§ 102 and 103 apply.

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

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

⁵ DiLorenzo (US 6,366,813 B1, April 2, 2002) (“DiLorenzo”) Ex. 1054.

⁶ Gerber et al. (US 7,515,965 B2, April 7, 2009) (“Gerber”) Ex. 1055.

⁷ Bourget et al. (US 7,853,322 B2, December 14, 2010) (Bourget”) Ex. 1056.

⁸ Amarenco et al., *Urodynamic Effect of Acute Transcutaneous Posterior Tibial Nerve Stimulation in Overactive Bladder*, 169 J. UROL. 2210–15 (2003) (“Amarenco”) Ex. 1005.

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

C. The ’477 Patent

The ’477 patent is entitled *Methods and Devices for Performing Electrical Stimulation to Treat Various Conditions* and is directed to systems and/or methods for electromagnetic induction therapy. Ex. 1001, codes (54), (57). The ’477 patent describes “treating a variety of ailments by providing energy to a target nerve.” *Id.* at col. 8, ll. 13–14. The energy may be in the form of “magnetic energy, electrical energy or ultrasound energy.” *Id.* at col. 8, ll. 15–16.

The ’477 patent describes an exemplary embodiment based on electromagnetic induction therapy, wherein “one or more conductive ... coils may be configured to generate a magnetic field focused on a target nerve, muscle[,] or other body tissues in proximity to the coil[s].” Ex. 1001, col. 5, ll. 32–36. One or more sensors may be used to detect electrical conduction in the target nerve, to detect a muscular response caused by an electrical conduction in the target nerve, or to detect stimulation of a nerve, muscle or other body tissues, and to provide feedback about the efficacy of the applied electromagnetic induction therapy. *Id.* at col. 5, ll. 36–42.

The ’477 patent depicts an embodiment of a system for magnetic induction therapy in Figure 1, which is reproduced below:

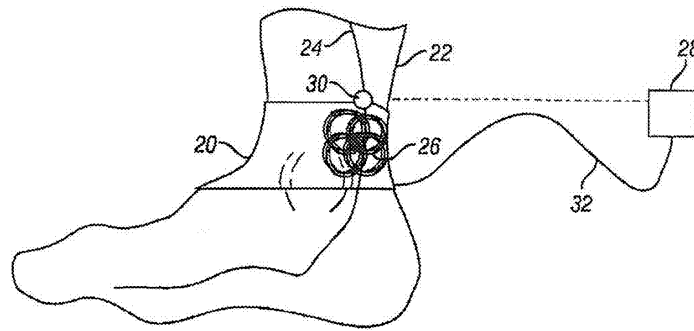


FIG. 1

Figure 1 of the '477 patent depicts “a coil wrap 20 . . . disposed over ankle 22 circumferentially to surround a portion of tibial nerve 24.”

Ex. 1001, 9:50–52. According to the '477 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 col. 10, ll. 8–13. A programmable logic controller 28 supplies the electrical current that flows through coils 26 and produces the magnetic field. *Id.* at col. 10, ll. 37–40. Figure 1 also shows a sensor 30, whose purpose is “to detect and record the firing of the target nerve and to provide related information to logic controller 28, so to render the intended therapy most effective.” *Id.* at col. 10, ll. 43–46.

The '477 patent also depicts an embodiment of a system for providing electrical stimulation in Figure 11, which is reproduced below:

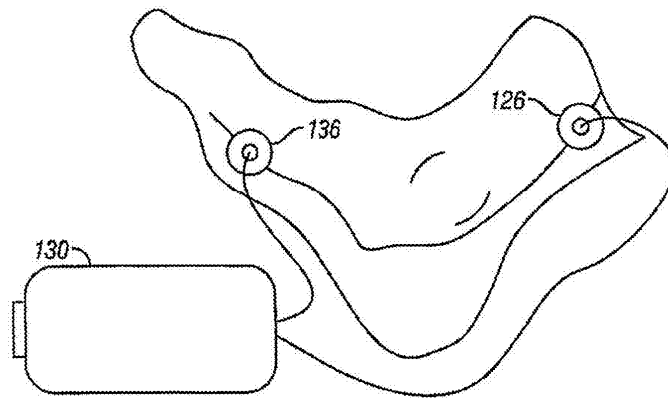


FIG. 11

Figure 11 depicts “a transcutaneous stimulator, such as an electrode 126”, that dispenses electrical energy for nerve stimulation. Ex. 1001, col. 16, ll. 25–29. Electrical pulse controller 130 is connected to electrode 126 and to sensor 136. *Id.* at col. 16, ll. 33–35. According to the ’477 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 col. 16, ll. 36–40.

D. Representative Claim

Independent claim 1 of the ’477 patent is representative of the challenged claims, and recites:

- [1.p]⁹ 1. A method of performing electrical stimulation therapy, comprising:
 - [1.a] non-invasively positioning a first portion of a patient's body relative to an electrical stimulator such that a posterior tibial nerve or branch thereof within the first

⁹ We adopt the bracketed identifiers added by Petitioner.

portion of the body is in proximity to the electrical stimulator;

- [1.b] passing a current through the electrical stimulator;
- [1.c] delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve or branch thereof;
- [1.d] detecting electrical conduction through the posterior tibial nerve or branch thereof or detecting a muscular response caused by an electrical conduction through the posterior tibial nerve or branch thereof via at least one sensor positioned along a second portion of the body;
- [1.e] receiving a signal from the at least one sensor indicative of the detected electrical conduction or muscular response thereby providing feedback about the efficacy of the applied electrical stimulation therapy; and
- [1.f] adjusting the current via a controller in communication with the electrical stimulator based on the feedback.

Ex. 1001, cols. 45–46, ll. 20–6. The remaining challenged claims depend directly from claim 1. *Id.* at col. 46, ll. 7–33.

III. ANALYSIS

A. *Legal Standards*

1. Anticipation

A claim is unpatentable as anticipated under 35 U.S.C. § 102 only when “every element and limitation of the claim was previously described in a single prior art reference, either expressly or inherently, so as to place a person of ordinary skill in possession of the invention.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1082 (Fed. Cir. 2008). However, a reference may inherently anticipate if a claim limitation that is not expressly disclosed “is necessarily present, or inherent, in the single anticipating reference.” *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1337 (Fed.

Cir. 2010). The “very essence of inherency is that one of ordinary skill in the art would recognize that a reference unavoidably teaches the property in question.” *Agilent Technologies, Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1383 (Fed. Cir. 2009).

2. Obviousness

A claim is unpatentable “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a). The question of obviousness involves resolving underlying factual determinations including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and when presented (4) objective evidence of nonobviousness, i.e., secondary considerations.¹⁰ See *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Furthermore, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

B. Person of Ordinary Skill in the Art

Petitioner argues that a person of ordinary skill in the art at the time of filing “would have had at least an undergraduate degree in the field of biomedical engineering, or a related discipline, such as electrical

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

engineering, and at least two years of experience in the design and/or analysis of biomedical devices” and that “[a]dditional work experience could substitute for a formal degree and vice versa.” Pet. 14 (citing Ex. 1003 ¶ 21).

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

C. *Claim Construction*

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

1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

Petitioner argues that “no terms require construction for purposes of this Petition.” Pet. 14. Patent Owner does not contest Petitioner’s argument. *See generally* Resp. We agree with Petitioner’s position and do not expressly construe any terms in a manner beyond that defined by the *Phillips* standard. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that “we need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

D. Grounds 1–5: General Considerations

In its Response and Sur-Reply, Patent Owner does not address the merits of Petitioner’s challenges for Grounds 1–5. *See generally* Resp.; Sur-Reply. Rather, Patent Owner argues only that Petitioner has failed to demonstrate that the non-patent references upon which Petitioner relies are not “printed publications” for the purposes of Sections 102 and 103, because Petitioner has failed to adequately show that the references were publicly available. *See, e.g.*, Resp. 2. Mindful of the fact that the burden of showing that the challenged claims are unpatentable is always on Petitioner (*see, e.g.*, *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 278 (2016) (citing 35 U.S.C. § 318(e); recognizing that Petitioner bears the ultimate burden of proving unpatentability)), we first turn to Petitioner’s arguments that the challenged claims are anticipated and/or obvious over the cited prior art

before addressing Patent Owner’s arguments concerning the public accessibility of the non-patent references.

E. Ground 1: Anticipation of Challenged Claims 1 under 35 U.S.C. § 102 by Svihra

We have carefully reviewed Petitioner’s arguments presented in its Petition, as well as the evidence of record challenging claim 1 as being anticipated by Svihra. *See* Section II.B *supra*. We have also reviewed Dr. Wingeier’s cited declaration testimony in support of Petitioner’s asserted unpatentability. *See* Ex. 1003 ¶¶ 63–78. We need not fully repeat here Petitioner’s detailed analysis of the limitations of claim 1 and the references, as well as the mapping of the references to the challenged claim. Through this mapping, Petitioner provides specific citations to Svihra, as well as to applicable citations to Dr. Wingeier’s testimony. *See* Pet. 15–20.

For example, Petitioner asserts that Svihra discloses limitations: [1p] “us[ing] non-invasive stimulation of the tibial nerve with the intention to achieve desired therapeutic effects . . . using a superficial electrostimulation” in patients “suffer[ing] from overactive bladder (OAB)”: [1a] “non-invasive stimulation of the tibial nerve” *via* “electrode[s] attached behind the medial ankle of the left lower extremity”; [1b] “stimulation by a constant voltage and regulated intensity of direct current” *via* “surface electrodes” behind the patients’ medial ankle; [1c] “stimulation by a constant voltage and regulated intensity of direct current”; [1d] “detecting electrical conduction through the posterior tibial nerve or branch thereof or detecting a muscular response” using techniques such as EMG; and [1e, 1f] determining the “[i]ntensity of the surface SANS was equal to 70% of intensity, at which the maximal

amplitude of response was registered from the abductor hallucis muscle” (stimulation by a constant voltage and regulated intensity of direct current). Pet. 15–20 (citing Ex. 1004, 480, 481; Ex. 1003 ¶¶ 63, 64., 70, 71 72, 77, 78).

Based on our careful review of the evidence and arguments, we determine that Petitioner has established, by a preponderance of the evidence of record, that the Svihra discloses all of the limitations of, and thus anticipates, challenged claim 1.

As explained above, Patent Owner does not address the merits of any of the Petition’s challenges to the claims, but argues only that Grounds 1–5 fail because Petitioner did not provide sufficient evidence regarding the public accessibility of non-patent references, including Svihra (*see* Resp. 2–7). We address below the party’s arguments concerning whether the non-patent references of record were publicly available as of the effective filing date, and are thus printed publications under 35 U.S.C. § 102(a)(1). Consequently, there is no contrary argument or evidence rebutting Petitioner’s assertions on the merits.

F. Ground 2: Obviousness of Challenged Claim 1 Under 35 U.S.C. § 103 over Svihra, Mann , DiLorenzo, Gerber, or Bourget

We have carefully reviewed Petitioner’s arguments presented in the Petition that challenged claim 1 would have been obvious over the cited prior art, as well as the evidence of record. *See* Pet. 20–28. We have also reviewed Dr. Wingeier’s cited testimony in support of Petitioner’s asserted unpatentability. *See* Ex. 1003 ¶¶ 79–114. We need not repeat here Petitioner’s analysis of Ground 2, or Petitioner’s mapping of the references to challenged claim 1. *See* Pet. 20–28. Through this mapping of claim 1

against the cited references, Petitioner provides specific citations to the cited references as well as applicable citations to Dr. Wingeier's testimony. *Id.*

Petitioner also explains why a person of ordinary skill would have been motivated to combine the cited references, again citing specific disclosures from the references, and the supporting testimony of Dr. Wingeier. *See Pet. at 27–28.*

Based on our review of Petitioner's arguments and the evidence of record, we determine that Petitioner has established, by a preponderance of the evidence, that the cited references teach or suggest all of the limitations of challenged claim 1, and that Petitioner has established why a person of ordinary skill would have been motivated to combine the references, as proposed, with a reasonable expectation of success, for the reasons advocated by Petitioner with respect to Ground 2.

As stated above, Patent Owner does not address the merits of any of the challenged claims. Thus, there is no contrary evidence rebutting Petitioner's assertions with respect to the merits of Petitioner's obviousness arguments.

G. Ground 3: Obviousness of Challenged Claims 2–10 Under 35 U.S.C. § 103 over Svihra, Mann, DiLorenzo, Gerber, or Bourget

We have carefully reviewed Petitioner's arguments presented in the Petition that challenged claims 2–10 would have been obvious over the cited prior art, as well as the evidence of record. *See Pet. 28–43.* We have also reviewed Dr. Wingeier's cited testimony in support of Petitioner's asserted unpatentability. *See Ex. 1003 ¶¶ 115–162.* We need not repeat here all of Petitioner's analysis of Ground 3, or Petitioner's mapping of the references to challenged claims 2–10. *See Pet. 28–43.* Through this mapping of claims

2–10 against the cited references, Petitioner provides specific citations to the cited references as well as applicable citations to Dr. Wingeier’s testimony. *Id.*

Petitioner also explains why a person of ordinary skill would have been motivated to combine the cited references, again citing specific disclosures from the references, and the supporting testimony of Dr. Wingeier. *See* Pet. 42–43.

Based on our review of Petitioner’s arguments and the evidence of record, we determine that Petitioner has established, by a preponderance of the evidence, that the cited references teach or suggest all of the limitations of challenged claim 1, and that Petitioner has established why a person of ordinary skill would have been motivated to combine the references, as proposed, with a reasonable expectation of success, for the reasons advocated by Petitioner with respect to Ground 3.

As stated above, Patent Owner does not address the merits of any of the challenged claims. Thus, there is no contrary evidence rebutting Petitioner’s assertions with respect to the merits of Petitioner’s obviousness arguments.

H. Ground 4: Obviousness of Challenged Claim 1 Under 35 U.S.C. § 103 over Amarenco, Mann, DiLorenzo, Gerber, or Bourget

We have carefully reviewed Petitioner’s arguments presented in the Petition that challenged claim 1 would have been obvious over the cited prior art, as well as the evidence of record. *See* Pet. 43–50. We have also reviewed Dr. Wingeier’s cited testimony in support of Petitioner’s asserted unpatentability. *See* Ex. 1003 ¶¶ 163–194. We need not repeat here

Petitioner's analysis of Ground 4, or Petitioner's mapping of the references to challenged claim 1. *See* Pet. 43–50. Through this mapping of claim 1 against the cited references, Petitioner provides specific citations to the cited references as well as applicable citations to Dr. Wingeier's testimony. *Id.*

For example Petitioner argues that the references teach or suggest the limitations of claim 1, including : [1p] “left [PTN] stimulation using a surface self-adhesive electrode on the ankle skin behind the internal malleolus with shocks in continuous mode at 10Hz. frequency and 200 milliseconds wide”; [1a] “[s]timulation was done using a self-adhesive surface stimulation electrode without an implanted needle electrode”; [1b] stimulation *via* “surface self-adhesive electrode[s]” “at 10 Hz. and a pulse width of 200 milliseconds in continuous mode”; [1c] delivering a “[s]timulation frequency during cystometry was then applied at 10 Hz. and a pulse width of 200 milliseconds in continuous mode”; and [1d–1f] “detecting ...,” “receiving...,” and “adjusting...” *via* measured EMGs. Pet. 43–48 (citing, e.g., Ex. 1005, 2211, 2212, Ex. 1055, col. 3, ll. 19–49; Ex. 1054, cols. 3–4, ll. 35–3; Ex. 1056, cols. 3–4, ll. 52–14, col. 4, ll. 41–51; Ex. 1084, cols. 10–11, ll. 65–19, Figs. 3–4; Ex. 1003 ¶¶ 165, 166–167, 168, 169, 170, 171–178, 190).

Petitioner also explains why a person of ordinary skill would have been motivated to combine the cited references, again citing specific disclosures from the references, and the supporting testimony of Dr. Wingeier. *See* Pet. 48–50.

Based on our review of Petitioner's arguments and the evidence of record, we determine that Petitioner has established, by a preponderance of the evidence, that the cited references teach or suggest all of the limitations

of challenged claim 1, and that Petitioner has established why a person of ordinary skill would have been motivated to combine the references, as proposed, with a reasonable expectation of success, for the reasons advocated by Petitioner with respect to Ground 4.

As stated above, Patent Owner does not address the merits of any of the challenged claims. Thus, there is no contrary evidence rebutting Petitioner's assertions with respect to the merits of Petitioner's obviousness arguments.

I. Ground 5: Obviousness of Challenged Claims 2–10 Under 35 U.S.C. § 103 over Amarengo and Mann

We have carefully reviewed Petitioner's arguments presented in the Petition that challenged claims 2–10 would have been obvious over the cited prior art, as well as the evidence of record. *See* Pet. 51–61. We have also reviewed Dr. Wingeier's cited testimony in support of Petitioner's asserted unpatentability. *See* Ex. 1003 ¶¶ 195–242. We need not repeat here all of Petitioner's analysis of Ground 5, or Petitioner's mapping of the references to challenged claims 2–10. *See* Pet. 51–61. Through this mapping of claims 2–10 against the cited references, Petitioner provides specific citations to the cited references as well as applicable citations to Dr. Wingeier's testimony. *Id.*

Petitioner also explains why a person of ordinary skill would have been motivated to combine the cited references, again citing specific disclosures from the references, and the supporting testimony of Dr. Wingeier. *See* Pet. 59–61.

Based on our review of Petitioner’s arguments and the evidence of record, we determine that Petitioner has established, by a preponderance of the evidence, that the cited references teach or suggest all of the limitations of challenged claim 1, and that Petitioner has established why a person of ordinary skill would have been motivated to combine the references, as proposed, with a reasonable expectation of success, for the reasons advocated by Petitioner with respect to Ground 3.

As stated above, Patent Owner does not address the merits of any of the challenged claims. Thus, there is no contrary evidence rebutting Petitioner’s assertions with respect to the merits of Petitioner’s obviousness arguments.

J. Evidence Concerning the Public Accessibility of the Non-patent References Relied upon by Petitioner

1. Patent Owner’s Argument

Finally, we turn to Patent Owner’s argument that Grounds 1–5 fail because Petitioner has failed to carry its burden of proving that the non-patent references cited in the Petition (e.g., Svihra and Amarenco) qualify as prior art printed publications. Resp. 2. Patent Owner asserts that, to demonstrate that a document is a printed publication, Petitioner must show that it was “‘sufficiently accessible to the public interested in the art’ before the critical date.” *Id.* (citing *Align Tech., Inc. v. Dental Monitoring SAS*, IPR2023-01369, Paper 42 at 25 (PTAB Mar. 3, 2025) (quoting *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989)). According to Patent Owner, Petitioner has failed to demonstrate that any of the non-patent references was

publicly accessible because, in each case, there is no record evidence of public accessibility other than the document itself. *Id.*

Patent Owner argues that neither Dr. Wingeier's expert Declaration, submitted with the Petition, nor the subsequently-filed attorney declaration, provides any probative evidence concerning public accessibility of the non-patent references relied upon by Petitioner. Resp. 3 (citing Ex. 1003; Ex. 1053). In particular, Patent Owner points to the attorney declaration, which does not aver that any of the references were publicly accessible prior to the alleged critical date. *Id.* (citing Ex. 1035). Nor does it express any personal knowledge of how the copies of these documents were obtained, or provide or identify any evidence tending to establish that they could have been obtained from a library, or some other qualifying public source, before the alleged critical date. *Id.*

With respect to Dr. Wingeier's Declaration, Patent Owner points out that Dr. Wingeier identifies no evidence tending to establish the public accessibility of any of the non-patent references identified in the Petition. Resp. 3. Patent Owner acknowledges that Dr. Wingeier testifies that certain items were "published," but argues that these claims are not based on any stated personal knowledge. *Id.* at 3–4. By way of example, Patent Owner notes that Dr. Wingeier does not claim, for example, any familiarity with any of the documents prior to this *inter partes* review, and does not claim any personal or particularized knowledge of any library or database system that would inform the numerous questions of public accessibility raised by the Petition. *Id.* at 4.

Patent Owner asserts that the Petition must identify, with particularity, the evidence supporting the grounds on which the challenge is based.

Resp. 4 (citing 35 U.S.C. § 312(a)(3); 37 C.F.R. § 42.104(b)). Patent Owner argues that, in the case presently before us, the Petition failed to identify any evidence supporting public availability. *Id.* at 4–5. Even though a petition is supposed to be complete, Petitioner argues that there exist, during the course of an *inter partes* review, opportunities for supplementation of the evidence concerning the public availability of the references, which Petitioner did not do. *Id.* at 5.

Patent Owner additionally asserts that Petitioner has not sought to develop the issue of public accessibility through supplemental information or evidence even though it bears the burden of proving public accessibility. Resp. 5. As a result, argues Patent Owner, the evidence of record is insufficient to establish public accessibility of any of the non-patent references cited in the Petition at any relevant time. *Id.* (citing *Medivis, Inc. Novarad Corp.*, IPR2023-00042, Paper 37 (PTAB Apr. 23, 2024)). Patent Owner points out that, in *Medivis*, the Board held that, if a petitioner cites no evidence for public accessibility in the petition, except for the references themselves, “[t]his is insufficient and tantamount to submitting no proof of public accessibility.” *Id.* (quoting *Medivis*, IPR2023-00042, Paper 37 at 4).

Patent Owner also points out that the Board has also held that there is no presumption of public accessibility, as the burden of proof remains always with the petitioner. Resp. 6 (citing *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 16 (PTAB December 20, 2019) (precedential)).

2. Analysis

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

We find that the evidence of record supports the conclusion that Svihra and Amarenco (as well as the other identified non-patent references) are printed publications, published on the dates identified on the faces of the references, and were publicly accessible.

Two precedential cases are instructive on the presented circumstances: *VidStream LLC v. Twitter, Inc.*, 981 F.3d 1060 (2020), and *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 (PTAB December 20, 2019) (precedential)).¹¹ In *VidStream*, the Federal Circuit identified that whether a reference is prior art is a legal question, based on factual findings. 981 F.3d at 1063–64; *see also Nobel Biocare Servs. AG v. Intradent USA, Inc.*, 903 F.3d 1365, 1375 (Fed. Cir. 2018) (citing *Jazz Pharm., Inc. v. Amneal Pharm., LLC*, 895 F.3d 1347, 1356 (Fed. Cir. 2018)). Moreover, public accessibility is the touchstone in determining whether a reference is a printed publication and such depends on whether the reference was available to interested, ordinarily skilled persons exercising reasonable diligence, which is determined on a case-by-case basis. *VidStream*, 981 F.3d at 1065; *see also Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1380 (Fed. Cir. 2018)

¹¹ *See also Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, 2021 WL 4876224 (PTAB, October 5, 2021)

(citing *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004)). Of particular relevance to the case presently before us is the *VidStream* court's holding that "[w]hen there is an established publisher there is a presumption of public accessibility as of the publication date." *VidStream*, 981 F.3d at 1065.

Hulu addressed, *inter alia*, whether certain asserted references were shown to be publicly available and could be considered as prior art. IPR2018-01039, Paper 29 at 8. In *Hulu*, the Board held that, although testimonial evidence is one way to prove public accessibility, there are also various indicia of publication and other evidence that may be considered as a totality of the evidence to determine if an asserted reference was publicly accessible and prior art. *Id.* at 18. Facts to be considered in analyzing the issue, other than testimonial evidence, include, for example, whether there is an established publisher, a copyright date/notice, other publication-related dates (impression, printing, etc.), an ISBN number, citations to the reference before (and to a lesser degree, after) the priority date at issue corroborating its availability and/or that the publisher was established. *Id.* at 19–20 (*see Valve Corp. v. Ironburg Inventions Ltd.*, 8 F.4th 1364, 1374 (Fed. Cir. 2021)).

Here, we find the totality of evidence supports the conclusion that Petitioner has made a sufficient showing that Svihra and Amarenco (as well as the other identified non-patent references) were printed publications, and publicly accessible, prior to the '477 patent's priority date. We note at the outset that Patent Owner does not allege that any contested reference is fabricated, or a counterfeit document, but only that Petitioner has not set

forth sufficient facts establishing that such references were published and available. Resp. 4.

Svihra bears sufficient indicia of publication to conclude it was a printed publication and publicly accessible as of 2002. Ex. 1004. First, it appears on its face to be a legitimate scientific journal article; it indicates it was included at pages 480–83 in volume 103 (No. 12) of Bratisl Lek Listy, the Bratislava Medical Journal, which was established in 1921. The article identifies that it was received for publication on May 30, 2002, and accepted for publication on December 9, 2002; and multiple means of contact for the author and publisher are provided. *Id.* at 480, 483. Each of these indicia supports the contention that Svihra was published and publicly available in 2002. There is no direct evidence that Svihra was publicly accessed as of this date, but the article is cited as a reference in each of Exhibits 1085–1087, which further supports that Svihra was, generally, publicly available to interested individuals of ordinary skill in the art, which further corroborates that it was a published and publicly accessible publication. Having an established publisher also creates a presumption of publication for Svihra, which has not been rebutted by Patent Owner. *VidStream*, 981 F.3d at 1065.

Amarenco, too, bears sufficient indicia of publication to conclude it was a printed publication and publicly accessible as of 2003. Ex. 1005. Amarenco appears on its face to be a legitimate scientific journal article; it indicates it was included at pages 2210–15 in the 169th volume of The Journal of Urology, a highly-reputed publication of the American Urological Association (creating a presumption of publication); it bears a publication date of June 2003; it states it was “Printed in U.S.A.”; a copyright notice is

included indicating a 2003 copyright date; a DOI (Digital Object Identifier) number is provided; and it indicates it was accepted for publication on January 17, 2003. 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. 1094, 1–8. Each of these indicia supports our finding that Amarenco was published and publicly available in 2003. There is no direct evidence that Amarenco was publicly accessed on this date, but it is cited as a reference in each of Exhibits 1016, 1085–1087, and 1089, as well as listed on the face of US 11,844,943 B2 (December 19, 2023)¹² (*see* Ex. 1087, code (56)), all of which support the conclusion that Amarenco was publicly available to interested ordinarily skilled people, which corroborates that it was published and publicly accessible. The presumption of publication created by Amarenco having an established publisher has not been rebutted by Patent Owner. *VidStream*, 981 F.3d at 1065

¹² Claims 1–39 of Patent Owner's closely-related US 11,844,943 B2 (the "'943 patent") were challenged by Petitioner in PGR2024-00043. *See generally* PGR2024-00043, Paper 2 (PTAB July 1, 2024). Both the '477 patent and the '943 patent descend through various applications from US App. Ser. No. application No. 15/474,875, filed on March 30, 2017, which issued as US 10,786,669 B2 (September 29, 2020). Patent Owner made essentially the same argument in PGR2024-00043 as it now presents in this *inter partes* review. *See id.*, Paper 11 at 4–9

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

IV. CONCLUSION

For the reasons we have explained, we conclude that Petitioner has demonstrated, by a preponderance of the evidence, that challenged claims 1–10 of the ’477 patent are unpatentable as being anticipated by, or obvious over, the cited prior art. Furthermore, Patent Owner’s argument that

the cited non-patent prior art references are not printed publications is insufficient to overcome the reference's indicia of public accessibility.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that based on a preponderance of the evidence, claims 1–10 of the '477 patent are unpatentable;

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

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1	102	Svihra	1	
1	103	Svihra, Mann, DiLorenzo, Gerber, or Bourget	1	
2–10	103	Svihra, Mann, DiLorenzo, Gerber, Bourget	2–10	
1	103	Amarenco, Mann, DiLorenzo, Gerber, or Bourget	1	
2–10	103	Amarenco, Mann	2–10	

Overall Outcome			1–10	
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