

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Avation Medical, Inc.,

Petitioner

v.

EMKinetics, Inc.,

Patent Owner

Case No. IPR2024-01378

U.S. Patent No. 9,002,477

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 9,002,477 (“’477 patent”)
1002	File History of U.S. Patent No. 9,002,477 (“’477 patent file history”)
1003	Declaration of Dr. Brett Wingeier in Support of Petition for Inter Partes Review of U.S. Patent No. 9,002,477 (“Wingeier Decl.”)
1004	J. Svihra <i>et al.</i> , “Neuromodulative treatment of overactive bladder – noninvasive tibial nerve stimulation,” <i>Bratisl Lek Listy</i> 103(12):480-483 (2002) (“Svihra”)
1005	G. Amarenco <i>et al.</i> , “Urodynamic Effect of Acute Transcutaneous Posterior Tibial Nerve Stimulation in Overactive Bladder,” <i>J. Urology</i> 169: 2210-2215 (2003) (“Amarenco”)
1006	[Reserved] ¹
1007	[Reserved]
1008	G. Willy Davila & Minda Neimark, “The Overactive Bladder: Prevalence and Effects on Quality of Life,” <i>Clinical Obstetrics and Gynecology</i> 45(1):173-181 (2002) (“Davila”)
1009	Alan J. Wein & Eric S. Rovner, “Definition and Epidemiology of Overactive Bladder,” <i>Urology</i> 60(Suppl 5A):7-12 (2002) (“Wein”)
1010	Paul Abrams <i>et al.</i> , “Overactive Bladder Significantly Affects Quality of Life,” <i>The American Journal of Managed Care</i> 6(11, Sup.):580-590 (2000) (“Abrams”)
1011	Neeral Kohli & Peter L. Rosenblatt, “Neuromodulation Techniques for the Treatment of the Overactive Bladder,” <i>Clinical Obstetrics and Gynecology</i> 45(1):218-232 (2002) (“Kohli”)

¹ Petitioner has reserved certain exhibit numbers in this proceeding in order to, to the extent possible, maintain consistency with the exhibits and exhibit numbering in related proceedings PGR2024-00043 and IPR2024-01375.

Exhibit No.	Description
1012	Floor van der Pal <i>et al.</i> , “Current opinion on the working mechanisms of neuromodulation in the treatment of lower urinary tract dysfunction,” <i>Current Opinion in Urology</i> 16(4):261-267 (2006) (“van der Pal”)
1013	Francisco Velasco, “Neuromodulation: An Overview,” <i>Archives of Medical Research</i> 31(3):232-236 (2000) (“Velasco”)
1014	J. Groen & J.L.H.R. Bosch, “Neuromodulation techniques in the treatment of the overactive bladder,” 87(8):723-731 (2001) (“Groen”)
1015	Marshall L. Stoller, “Afferent Nerve Stimulation for Pelvic Floor Dysfunction,” <i>Scientific Non Discussion Poster Session</i> 16(257):256 (1999) (“Stoller”)
1016	M. Queralto <i>et al.</i> , “Preliminary results of peripheral transcutaneous neuromodulation in the treatment of idiopathic fecal incontinence,” <i>International Journal of Colorectal Disease</i> 21(2006):670-672 (2006) (“Queralto”)
1017	F. Monti <i>et al.</i> , “Peripheral neuromodulation using surface electrode for treatment of overactive bladder (oab): initial experience,” <i>Clinical Neurophysiology</i> 117(2006):243 (2006) (“Monti”)
1018	[Reserved]
1019	[Reserved]
1020	[Reserved]
1021	[Reserved]
1022	[Reserved]
1023	[Reserved]
1024	[Reserved]
1025	[Reserved]
1026	[Reserved]
1027	[Reserved]

Exhibit No.	Description
1028	Hermie J. Hermens <i>et al.</i> , “Development of recommendations for SEMG sensors and sensor placement procedures,” <i>Journal of Electromyography and Kinesiology</i> 10(5):361-374 (2000) (“Hermens”)
1029	[Reserved]
1030	S. Tahseen Hasan <i>et al.</i> , “Transcutaneous Electrical Nerve Stimulation and Temporary S3 Neuromodulation in Idiopathic Detrusor Instability,” <i>The Journal of Urology</i> 155(6):2005-2011 (1996) (“Hasan”)
1031	[Reserved]
1032	[Reserved]
1033	[Reserved]
1034	[Reserved]
1035	[Reserved]
1036	[Reserved]
1037	[Reserved]
1038	[Reserved]
1039	[Reserved]
1040	[Reserved]
1041	Edward J. McGuire <i>et al.</i> , “Treatment of Motor and Sensory Detrusor Instability by Electrical Stimulation,” <i>The Journal of Urology</i> 129(1):78-79 (1983) (“McGuire”)
1042	A.L. Hof, “EMG and Muscle Force: An Introduction,” <i>Human Movement Science</i> 3(1-2):119-153 (1984) (“Hof”)
1043	A Martens De Noordhout <i>et al.</i> , “Percutaneous electrical stimulation of lumbosacral roots in man,” <i>Journal of Neurology, Neurosurgery, and Psychiatry</i> 51(2):174-181 (1988) (“Noordhout”)
1044	[Reserved]
1045	[Reserved]
1046	[Reserved]

Exhibit No.	Description
1047	<i>[Reserved]</i>
1048	U.S. Patent App. No. 11/866,329 to Burnett <i>et al.</i> (“‘329 application”)
1049	<i>[Reserved]</i>
1050	<i>[Reserved]</i>
1051	<i>Avation Medical, Inc. v. EMKinetics, Inc.</i> No. 3:24-cv-01702 (N.D. Cal.) First Amended Complaint, Dkt. No. 5
1052	<i>[Reserved]</i>
1053	Declaration of Todd R. Tucker
1054	U.S. Patent No. 6,366,813 to DiLorenzo filed Jun. 25, 1999 (“DiLorenzo”)
1055	U.S. Patent No. 7,515,965 to Gerber <i>et al.</i> filed Apr. 28, 2005 (“Gerber”)
1056	U.S. Patent No. 7,853,322 to Bourget <i>et al.</i> filed Apr. 28, 2006 (“Bourget”)
1057	<i>[Reserved]</i>
1058	<i>[Reserved]</i>
1059	<i>[Reserved]</i>
1060	<i>[Reserved]</i>
1061	<i>[Reserved]</i>
1062	<i>[Reserved]</i>
1063	<i>[Reserved]</i>
1064	A. Shafik <i>et al.</i> , “Percutaneous Peripheral Neuromodulation in the Treatment of Fecal Incontinence,” <i>European Surgical Research</i> 35(2):103-107 (2003) (“Shafik”)
1065	Michael R. van Balken <i>et al.</i> , “Percutaneous Tibial Nerve Stimulation as Neuromodulative Treatment of Chronic Pelvic Pain,” <i>European Urology</i> 43(2):158-163 (2003) (“van Balken 2003”)

Exhibit No.	Description
1066	U.S. Patent Pub. App. Pub. No. 2005/0143789 to Whitehurst <i>et al.</i> (“Whitehurst”)
1067	U.S. Patent No. 7,610,100 to Jaax <i>et al.</i> filed Dec. 30, 2005 (“Jaax”)
1068	U.S. Patent App. Pub. No. 2005/0021103 to DiLorenzo published January 27, 2005 (“DiLorenzo ‘103”)
1069	U.S. Patent App. Pub. No. 2005/0033372 to Gerber published February 10, 2005 (“Gerber ‘372”)
1070	U.S. Patent App. Pub. No. 2005/0245989 to Davis filed April 28, 2005 (“Davis”)
1071	Jader A. De Lima et al., “A Low-Cost Neurostimulator with Accurate Pulsed-Current Control,” IEEE Transactions on Biomedical Engineering 49(5):497-500 (2002) (“De Lima”)
1072	[Reserved]
1073	[Reserved]
1074	[Reserved]
1075	[Reserved]
1076	[Reserved]
1077	[Reserved]
1078	[Reserved]
1079	[Reserved]
1080	U.S. Patent Pub. App. Pub. No. 2006/0122660 to Boveja et al. filed Dec. 28, 2005, published Jun. 8, 2006 (“Boveja”)
1081	[Reserved]
1082	[Reserved]
1083	[Reserved]
1084	U.S. Patent No. 6,941,171 to Mann et al. filed Aug. 16, 2001 (“Mann”)
1085	[Reserved]

Exhibit No.	Description
1086	<i>[Reserved]</i>
1087	U.S. Patent No. 11,844,943 to Rajguru <i>et al.</i> filed January 4, 2022 (“’943 Patent”)
1088	<i>[Reserved]</i>
1089	<i>[Reserved]</i>
1090	<i>[Reserved]</i>
1091	H. Sherif <i>et al.</i> , “Posterior tibial nerve stimulation as treatment for the overactive bladder,” <i>Arab J Urol</i> 11(2):151-35 (2013) (“Sherif”)
1092	M. Slovak <i>et al.</i> , “Non-invasive transcutaneous electrical stimulation in the treatment of overactive bladder,” <i>Asian J Urology</i> 2: 92-101 (2015) (“Slovak”)
1093	M. Garcia <i>et al.</i> , “Electrostimulation of the posterior tibial nerve in individuals with overactive bladder: a literature review,” <i>J. Phys. Ther. Sci.</i> 30:1333-40 (2018) (“Garcia”)
1094	G. Amarenco <i>et al.</i> , “Urodynamic Effect of Acute Transcutaneous Posterior Tibial Nerve Stimulation in Overactive Bladder,” <i>J. Urology</i> 169: 2210-2215 (2003) (“Amarenco II”)
1095	Z. Guo <i>et al.</i> , “Transcutaneous electrical nerve stimulation in the treatment of patients with poststroke urinary incontinence,” <i>Clinical Interventions in Aging</i> 9:851-56 (2014) (“Guo”)
1096	Declaration of Todd R. Tucker in Support of Petitioner’s Reply to Patent Owner’s Response
1097	<i>[Reserved]</i>
1098	U.S. Patent No. 11,224,742 to Burnett <i>et al.</i> filed July 31, 2017 (“’742 Patent”)

I. INTRODUCTION

EMK's Patent Owner Response does not substantively challenge any of the grounds set forth in Avation's Petition. EMK does not, for example, refute that the prior art cited by Avation discloses each and every limitation of claims 1-10 of the '477 Patent, nor does EMK contest that the prior art renders the claims obvious. Rather than confront these substantive positions, EMK instead merely challenges the Petition's strong invalidity grounds based on procedural issues alone. EMK's total failure to mount substantive challenges to Avation's invalidity grounds is undoubtably a tacit admission that claims 1-10 of the '477 Patent are unpatentable.

Setting this aside, EMK's procedural attacks nevertheless fail. EMK erroneously contends Grounds 1-5 do not render the claims unpatentable because Avation has not proven certain "non-patent references" relied on in those grounds were publicly accessible. This "argument" ignores the ample evidence submitted with the Petition demonstrating the references qualify as prior art printed publications. All told, Avation has met its burden of demonstrating, by preponderance of the evidence, that claims 1-10 of the '477 Patent ("Challenged Claims") are invalid. Respectfully, the Board should find the Challenged Claims of the '477 Patent unpatentable.

II. THE CHALLENGED CLAIMS OF THE ‘477 PATENT ARE UNPATENTABLE

Petitioner Avation Medical Inc. (“Avation” or “Petitioner”) has met its burden of proving that Svihra (Ex.1004), Amarenco (Ex.1005), and the other cited non-patent references (Exs.1008-17, 1028, 1030, 1041-43, and 1064-65) (collectively, “Journal Articles”) were publicly accessible and qualify as prior art printed publications. Avation submitted ample evidence with the Petition that the Journal Articles were publicly accessible before the critical date. Patent Owner EMKinetics, Inc. (“PO” or “EMK”) challenged the prior art status of at least once reference (Svihra) in its Preliminary Response (“POPR”) (Paper 6, 2-6), but the Board rejected EMK’s argument in its decision on institution and found Avation’s evidence of public accessibility sufficient for institution. *See* Paper 7, 11-14.

EMK now retreads the public accessibility argument in its Patent Owner Response (“Response”), but ***EMK offers no argument or evidence whatsoever to rebut the record evidence of public accessibility, let alone even address the Board’s conclusions regarding the status of Svihra as a printed publication.*** *See* Paper 12, 2-7. The best EMK can muster is an unsupported “suggestion”—without even addressing the references themselves or what they show regarding public availability—that Avation has not met its burden. *See id.* This is insufficient to overcome the record evidence of public accessibility. Avation’s evidence of public accessibility stands un rebutted in this proceeding, so accordingly, the Board should

find that the Journal Articles, including Svihra (Ex.1004) and Amarenco (Ex.1005), qualify as prior art printed publications.

Again, EMK mounts no substantive, merits-based arguments in response to the Petition's Grounds 1-5. *See* Paper 12, 2-7. EMK does not contest that Svihra teaches the limitations of Claim 1 (Ground 1). *See id.*² Nor does EMK contest that the Journal Articles, in combination, teach all limitations of the Challenged Claims, that a person of ordinary skill would have been motivated to combine references, or that the Challenged Claims would have been obvious (Grounds 2-5). *See id.* Rather, EMK's sole argument is speculation that Avation did not meet its burden of proving the Journal Articles were publicly accessible. *See id.* In other words, ***EMK effectively admits that if the Journal Articles, including Svihra (Ex.1004) and/or Amarenco (Ex.1005), qualify as prior art, the Challenged Claims are invalid.*** Without issue, Avation has met its burden of proving the

² Notably, despite having had an opportunity to do so, EMK does not substantively challenge that Svihra discloses limitation 1.f ("adjusting the current via a controller...") or address the Board's comments in the Institution Decision regarding this limitation. *See* Paper 2, 20; Paper 7, 18-19. Petitioner's arguments on this ground, supported by its expert Dr. Wingeier, thus stand unrebutted. *See* Paper 2, 20; Ex.1003, ¶ 78.

Journal Articles are publicly accessible. As such, the Challenged Claims of the ‘477 Patent are unpatentable for the reasons set forth in Grounds 1-5 of Avation’s Petition.

A. Avation Met Its Burden of Proving the Journal Articles, Including Svihra (Ex.1004) and Amarenco (Ex.1005), Qualify as Prior Art

Avation has met its burden of proving that the Journal Articles, including Svihra (Ex.1004) and Amarenco (Ex.1005), are prior art printed publications. To qualify as a printed publication, a reference “must have been sufficiently accessible to the public interested in the art.” *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989). Public accessibility is “the touchstone in determining whether a reference constitutes” a printed publication under § 102. *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1348 (Fed. Cir. 2016). A petitioner establishes public accessibility by demonstrating that a reference was “disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.” *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347, 1355–56 (Fed. Cir. 2018). Importantly, “[w]hen there is an established publisher there is a presumption of public accessibility as of the publication date.” *Vidstream LLC v. Twitter, Inc.*, 981 F.3d 1060, 1065-66 (Fed. Cir. 2020).

The Courts and PTAB have, time and time again, found articles published in scientific journals to be publicly accessible and qualify as prior art printed

publications. *See, e.g., Telefonaktiebolaget LM Ericsson v. TCL Corp.*, 941 F.3d 1341, 1344, 1347 (Fed. Cir. 2019) (affirming PTAB ruling that journal article qualified as prior art printed publication); *Grünenthal GmbH v. Antecip Bioventures II LLC*, PGR2018-00092, Paper 31 at 16 (PTAB December 22, 2020) (finding in final written decision that “information pertaining to the publication of [journal article] on the face of the document is sufficient to establish [article] as a printed publication”); *Parse Biosciences, Inc. v. 10X Genomics, Inc.*, IPR2023-00958, Paper 48 at 19-20 (PTAB February 3, 2025) (finding in final written decision “ample evidence in the record demonstrating [journal article] is a prior art printed publication,” including publication date, journal name, volume, and copyright notice on reference itself).

Commonly, “hallmarks” of printed publications on the face of an article—including journal name, volume, number/edition, page numbers, and/or copyright/publication date—are used to establish the article as a printed publication. *See, e.g., Grünenthal*, PGR2018-00092, Paper 31 at 16-17 (noting reference “bears several hallmarks” of publication “as part of a regularly distributed medical journal,” including name of journal, citation information reflecting date, volume, and page numbers, and dates article available); *Telefonaktiebolaget*, 941 F.3d at 1347 (Fed. Cir. 2019) (holding that “date on the face of the journal” was part of substantial evidence supporting PTAB’s finding

that journal article was prior art); *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 17-20 (PTAB Dec. 20, 2019) (precedential) (“[T]he indicia on the face of a reference, such as printed dates and stamps, are considered as part of the totality of the evidence.”).

The evidence provided with Avation’s Petition proves the Journal Articles were publicly accessible. Svihra (Ex.1004), for example, includes all these necessary “hallmarks” of a publicly accessible printed publication, including the journal name (“Bratisl Lek Listy,” *i.e.*, the well-established international medical journal *Bratislava Medical Journal* published by the Faculty of Medicine at Comenius University in Bratislava, Slovakia), publication year (2002), volume (103), number/edition (12), and page numbers (480-83):



Ex.1004, 480. Svihra further indicates the article was “Received May 30, 2002” and “Accepted December 9, 2002.” *Id.*, 483. The Board found this information to

be sufficient evidence that Svihra qualifies as a printed publication for purposes of institution:

A simple internet search reveals that “Bratisl Lek Listy,” which appears on the header of Svihra, is an abbreviation for Bratislavské lekárske listy—the Bratislava Medical Journal—an international medical journal founded in 1921, published monthly in English, and currently in its 126th volume. See Ex. 3001. ***Svihra’s header states, in full: “Bratisl Lek Listy 2002; 103 (12): 480-483,” which we find skilled artisans would understand to mean that Svihra appeared as an article appearing in volume 103, number 12, of the Bratislava Medical Journal at pages 480–483 and was published in December 2002 (i.e., number 12). See Ex. 1004, 480. Thus, on its face, the reference supports Petitioner’s assertion under § 102(b).***

Paper 7, 13 (footnote omitted, emphasis added). The Board concluded that “Petitioner has established a reasonable likelihood that ***Svihra was publicly accessible before the critical date of the ‘477 patent. Svihra exhibits the necessary hallmarks to support such a finding.***” *Id.* (emphasis added). EMK submits no evidence or argument in its Response that undermine or alter the Board’s previous findings regarding Svihra.

Amarenco (Ex.1005) likewise includes “hallmarks” of a printed publication that was publicly accessible before the critical date of the ‘477 Patent. Amarenco’s header includes the journal, volume, pages, and date of publication:

URODYNAMIC EFFECT OF ACUTE TRANSCUTANEOUS POSTERIOR
TIBIAL NERVE STIMULATION IN OVERACTIVE BLADDER

G. AMARENCO, S. SHEIKH ISMAEL, A. EVEN-SCHNEIDER, P. RAIBAUT, S. DEMAILLE-WLODYKA,
B. PARRATTE AND J. KERDRAON

*From the Department of Neurologic Rehabilitation, Urodynamic and Neurophysiology Laboratory. Hôpital Rothschild, Assistance
Publique-Hôpitaux de Paris, Paris, France*

Ex.1005, 2210. As with Svihra, a person of ordinary skill in the art would understand Amarenco's header to indicate that the reference appeared as an article in volume 169 of *The Journal of Urology* at pages 2210-15, which published June 2003. *Id.* Amarenco further includes copyright information ("Copyright © 2003 by American Urological Association") and indicates the article was "[a]ccepted for publication January 17, 2003." *Id.* Moreover, Amarenco includes a "DOI," or "Digital Object Identifier," which a person of ordinary skill in the art would understand is a permanent address for digital content like online articles. *Id.* In the Institution Decision, the Board noted that Amarenco included "hallmarks" of a publicly accessible printed publication, including "journal title and volume number, page numbers, date of acceptance for publication." *See* Paper 7, 13. As with Svihra, EMK submits no evidence or argument to challenge the Board's previous findings concerning Amarenco.

Like Svihra and Amarenco, the other Journal Articles identified by EMK (Exs. 1008-17, 1028, 1030, 1041-43, and 1064-65) also include sufficient indicia

of publication to demonstrate they were public accessibly printed publications before the critical date of the '477 Patent. Each reference is an article published in a scientific journal and each includes the “hallmarks” of a printed publication, such as a journal header identifying the name of the journal in which it was published, the volume and edition/number, page numbers, and the publication and/or copyright date. *See, e.g.*, Ex.1028, 361 (article published in volume 10 of the *Journal of Electromyography and Kinesiology* on pages 361-74 in 2000; also including copyright information “© Elsevier Science Ltd.”); Ex.1042, 119 (article published in volume 3 of *Human Movement Science* on pages 119-153 in 1984; also including copyright information “© 1984, Elsevier Science Publishers B.V.”); Ex.1043, 174 (article published in volume 51 of *Journal of Neurology, Neurosurgery, and Psychiatry* on pages 174-81 in 1988; also indicating article “Received 1 May 1987 and in revised form 20 July 1987” and “Accepted 27 July 1987”); Ex.1016, 670 (article published in volume 21 of the *International Journal of Colorectal Disease* on pages 670-72 in 2006; also including “Accepted: 1 November 2005,” “Published online: 6 December 2005,” and copyright information “© Spring-Verlag 2005”); Ex.1064, 103 (article published in volume 35 of *European Surgical Research* on pages 103-07 in 2003; also including “Received: June 18, 2002,” “Accepted after revision: August 19, 2002,” and copyright information “© 2003 S. Karger AG, Basel”); Ex.1065, 158 (article

published in volume 43 of *European Urology* on pages 158-63 in 2003; also including copyright information “© 2002 Elsevier Science B.V.”); *see also* Paper 7, 13 (explaining how person of ordinary skill would understand information in journal header). In addition to these “hallmarks,” some Journal Articles also contain additional information indicative of public accessibility, including ISSN numbers (*i.e.*, unique identifier for journals and other periodicals), Accession numbers (*i.e.*, unique identifier for records such as articles in database), or other identifying information. *See, e.g.*, Ex.1030, 1 (article published in volume 155(6) of *The Journal of Urology* on pages 2005-11 in June 1996, further identifying “ISSN: 0022-5347” and “Accession: 00076734-199606000-00055”); Ex.1064, 103 (including “DOI” number); Ex.1065, 158 (same); Ex.1016, 670 (same). EMK ignores this evidence entirely.

On top of the Journal Articles themselves, Avation also submitted an attorney declaration attesting that true and correct copies of each exhibit, including each Journal Article, were filed with the Petition. *See* Ex.1053, ¶¶ 6-22, 28-29. And as EMK concedes, the declaration of Avation’s expert states that various references were “published” (*see, e.g.*, Ex.1003, ¶44 (“Svihra published a study...”), ¶45 (“Amarenco published a similar study...”), at a minimum establishing that persons of ordinary skill in the art would understand from the

“hallmarks” of the references themselves that they were published and publicly available as of the dates on the references.

Avation provided ample evidence with the Petition that the Journal Articles were publicly accessible and qualify as printed publications. And crucially, as explained below, Avation’s evidence is unrebutted by EMK.

B. EMK Fails to Rebut Avation’s Evidence of Public Accessibility of the Journal Articles

Despite Avation’s overwhelming evidence of public accessibility, EMK nonetheless contends that Avation failed to meet its burden to prove the Journal Articles are printed publications. *See* Paper 12, 2-7. EMK, however, fails to provide any argument or evidence whatsoever to rebut the evidence of public accessibility in the record. As indicated above, “[w]hen there is an established publisher there is a presumption of public accessibility as of the publication date.” *Vidstream*, 981 F.3d at 1065-66. Despite publisher/publication information in the record from the documents themselves, EMK never contends that any of the Journal Articles were not published by an established publisher. Nor does EMK argue or provide evidence that any of the publication information on the references (*e.g.*, publication date) is inaccurate, that the Journal Articles were **not** published in scientific journals, or that the Journal Articles were not disseminated or made available so that persons interested and ordinarily skilled in the art could locate them. EMK curiously never even affirmatively disputes that any of the Journal

Articles were publicly accessible before the critical date. And on top of all that, EMK did not even file objections to any of the Journal Articles—*e.g.*, to challenge the authenticity of the references or argue that any reliance on information such as publication date in the references constitutes hearsay—and therefore waived its right to move to exclude these references on any such basis in this proceeding.. See 37 C.F.R. § 42.64(b)-(c).

Instead, EMK effectively ignores the public availability evidence provided with Avation’s Petition. EMK never addresses any of the printed publication “hallmarks” in the Journal Articles or any other indicia of public accessibility, and at the same time, never individually addresses any of the references at all. EMK merely generically admonishes Avation without discussing any specific information demonstrating public accessibility in any of the references. And EMK does not even attempt to address the findings regarding Svihra in the Institution Decision. Rather, EMK suggests that a heightened standard of public accessibility—one that ignores the document itself entirely—should apply. See Paper 12, 2 (“there is no record evidence of public accessibility ***other than the document itself.***”) (emphasis added). Effectively, EMK contends that by merely ***questioning*** the printed publication status of a reference—even where, as here, there is already unrebutted evidence of publicly accessible in the record—Petitioners should automatically be obligated to provide even ***further*** evidence to

meet some nonexistent elevated public accessibility burden. EMK provides no support for this proposition; nor could it, as it is directly contrary to Federal Circuit and PTAB precedent. *E.g.*, *Hulu*, IPR2018-01039, Paper 29 at 17-20 (precedential) (“[T]he indicia on the face of a reference, such as printed dates and stamps, are considered as part of the totality of the evidence.”).

At most, EMK critiques the declarations submitted with Avation’s Petition, but its arguments miss the mark. According to EMK, the declarations are insufficient because they do not express personal knowledge of publication, source, or that the documents could have been obtained before the critical date. *See* Paper 12, 3-4. But personal knowledge that a reference was actually accessed is not necessary to prove public accessibility. Regardless, the declarations corroborate the otherwise ample evidence of public accessibility from the Journal Articles themselves.

Rather than contend with Avation’s public availability evidence head on, EMK vaguely asserts, with no evidence or persuasive argument responsive to the evidence, that Avation failed to meet its burden. This is plainly insufficient to overcome the record evidence demonstrating the Journal Articles are printed publications. *See, e.g.*, *Grünenthal*, PGR2018-00092, Paper 31 at 17 (finding article qualified as printed publication and noting “lack of evidence supporting Patent Owner’s position that [article] is not a printed publication” including “that

Patent Owner provides no evidence to counter the indicia on the face of [reference]”); *Parse*, IPR2023-00958, Paper 48 at 17 (finding article qualified as printed publication where “Patent Owner does not explain how Petitioner allegedly failed to prove [reference] is prior art” and instead merely implied Petitioner failed to prove reference “is what it has been represented to be and/or that it was actually published”); *Telefonaktiebolaget*, 941 F.3d at 1347 (noting that while Patent Owner did not bear ultimate burden of proving availability date of article, Patent Owner “provided no evidence to counter” the evidence of public accessibility in the record).

EMK’s legal arguments are similarly unavailing. EMK faults Avation for not seeking leave to file a reply to EMK’s POPR and not submitting supplemental information to address the public accessibility of Svihra. Paper 12, 4-5. The Board, however, rejected EMK’s public availability arguments regarding Svihra for purposes of institution. Paper 7, 13. There was thus no reason for Avation to move to submit supplemental information at that time.

EMK’s reliance on *Medivis* is similarly misplaced. In the non-precedential *Medivis* decision, one Board panel determined that the Petitioner did not provide sufficient evidence of public accessibility of several references and noted Petitioner’s reliance on the references themselves “is insufficient and tantamount to submitting no proof of public accessibility.” *See Medivis, Inc. v. Novarad Corp.*,

IPR2023-00042, Paper 37 at 3-4 (PTAB April 23, 2024). The panel did not provide a citation for this proposition. It appears, however, that the panel may have relied on decisions related to non-journal article publications (*e.g.*, user manuals and software documentation), which do not have known, established publishers and do not contain “hallmarks” of a printed publication as do journal articles. *See Medivis, Inc. v. Novarad Corp.*, IPR2023-00042, Paper 35 at 29-30 (PTAB March 6, 2024) (citing *Microsoft Corp. v. Corel Software, LLC*, IPR2016-01083, Paper 14 at 13-14 (PTAB December 1, 2016)). Despite the *Medivis* panels’ findings, the applicability of that decision beyond the particular facts of that case is dubious. And it is also worth noting that the *Medivis* decision is currently on appeal at the Federal Circuit. *See Medivis, Inc. v. Novarad Corp.*, No. 24-1794 (Fed. Cir).

Notably, other Board panels have distinguished *Medivis*. For example, in *Parse*, the Board found *Medivis* “inapposite” because there was additional record evidence corroborating the article’s publication date, including several other references in the record that identified the article as a cited reference. *Parse*, IPR2023-00958, Paper 48 at 22 n.10. The same is true here. *See infra*, § II.C. *Medivis* is therefore not controlling and distinguishable from the present case.

The only evidence in the record is that the Journal Articles, including Svihra (Ex.1004) and Amarenco (Ex.1005), were publicly accessible before the critical date. EMK provides no argument or evidence to rebut this. Absent any meaningful

rebuttal from EMK, Avation's evidence is sufficient to demonstrate, by a preponderance of the evidence, that the Journal Articles were publicly available before the critical date and therefore qualify as prior art printed publications.

C. For the Avoidance of Doubt, Avation Submits Further Evidence of Public Accessibility of Svihra (Ex.1004), Amarenco (Ex.1005), and Hasan (Ex.1030)

Although the evidence submitted with Avation's Petition is sufficient, standing alone, to establish the Journal Articles qualify as prior art printed publications, Avation provides additional evidence in response to the arguments in EMK's Response that corroborates Avation's record evidence. This corroborating evidence further demonstrates that the Journal Articles—specifically, Svihra (Ex.1004), Amarenco (Ex.1005), and Hasan (Ex.1030)—were published in established journals and were publicly available before the critical date.³

Svihra: Sherif (Ex.1091), Slovak (Ex.1092), and Garcia (Ex.1093) corroborate that Svihra is a journal article that published in 2002. Each corroborating reference includes a citation to the Svihra article in its list of

³ Many Journal Articles are relied on for background information in Avation's Petition. Therefore, Avation provides further corroborating evidence for only a subset of the Journal Articles challenged by EMK.

references cited. See Ex.1091, 135 (reference [5]); Ex.1092, 100 (reference [17]); Ex.1093, 1340 (reference 25).

Amarenco: Amarenco II (Ex.1094) is a copy of the Amarenco article, which includes the journal cover page, copyright page, and table of contents, and the Amarenco article itself. The table of contents confirms that the Amarenco article appeared in volume 169, number 6 of the *Journal of Urology* beginning on page 2210. Ex.1094, 4-6. The cover page, copyright page, and table of contents confirm that this volume/edition of the journal, including the Amarenco article itself, published in June 2003. *Id.*, 1-4. The text of the article within Ex.1094 matches that of the Amarenco article submitted with Avation's Petition. See Ex.1094, 9-14; Ex.1005, 2210-15.

Additionally, Queralto (Ex.1016) (previously submitted with Avation's Petition), as well as Sherif (Ex.1091), Slovak (Ex.1092), Garcia (Ex.1093), and Guo (Ex.1095) corroborate that Amarenco is a journal article that published in 2003. Each corroborating reference includes a citation to the Amarenco article in its list of references cited. See Ex.1016, 672 (reference 5); Ex.1091, 135 (reference [29]); Ex.1092, 100 (reference [37]); Ex.1093, 1340 (reference 5); Ex.1095, 856 (reference 11). Finally, Amarenco is included in the References Cited list in several patents related to the '477 Patent, including U.S. Patent Nos. 11,844,943 (Ex.1087) and 11,224,742 (Ex.1098), further demonstrating Amarenco was

published in 2003. Ex.1087 [56] (listing Amarenco under “Other Publications” cited); Ex.1098, [56] (same).

Hasan: Slovak (Ex.1092) and Guo (Ex.1095) corroborate that Hasan is a journal article that published in 1996. Each corroborating reference includes a citation to the Hasan article in its list of references cited. *See* Ex.1092, 100 (reference 12); Ex.1095, 856 (reference 24).

This additional evidence—while not necessary to prove the references are printed publications—corroborates the evidence submitted with Avation’s Petition and confirms Svihra (Ex.1004), Amarenco (Ex.1005), and Hasan (Ex.1030) were published and publicly accessible. *See Parse*, IPR2023-00958, Paper 48 at 22 (relying on citations to reference in non-contemporaneous publications to corroborate reference’s publication date). Accordingly, the Board should find that Avation has met its burden of proving the Journal Articles, including Svihra (Ex.1004), Amarenco (Ex.1005), and Hasan (Ex.1030), were publicly accessible and qualify as prior art printed publications.

III. CONCLUSION

For the reasons set forth in Avation’s Petition (Paper 2) and above, the Board should respectfully find Challenged Claims 1-10 of the ‘477 Patent are unpatentable and cancel the claims.

Dated: September 26, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that the foregoing **Petitioner's Reply to Patent Owner's Response** complies with the type-volume limitations of 37 C.F.R. §42.24 because it contains 3,788 words (as determined by the Microsoft Word word-processing system used to prepare the document), excluding the parts of the brief exempted by 37 C.F.R. §42.24.

Dated: September 26, 2025

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing **PETITIONER’S REPLY TO PATENT OWNER’S RESPONSE** and **ACCOMPANYING EXHIBITS (Exs.1087, 1091-1096, 1098)** were served by email to Patent Owner by serving the email correspondence addresses of record as follows in accordance with 37 C.F.R. §42.105(a):

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