

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Avation Medical, Inc.,

Petitioner

v.

EMKinetics, Inc.,

Patent Owner

Case No. PGR2024-00043
U.S. Patent No. 11,844,943

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 11,844,943 (“’943 patent”)
1002	File History of U.S. Patent No. 11,844,943 (“’943 patent file history”)
1003	Declaration of Dr. Brett Wingeier in Support of Petition for Post Grant Review of U.S. Patent No. 11,844,943 (“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	U.S. Patent App. Pub. 2008/0306325 to Burnett <i>et al.</i> (“Burnett”)
1007	Int’l App. Pub. No. WO 2004/108209 to Johnson (“Johnson”)
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”)
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”)

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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	U. S. Patent No. 10,786,669 to Rajguru <i>et al.</i> (“‘669 patent”)
1019	U.S. Patent Application No. 15/474,875 to Rajguru (<i>as originally filed</i>) (“‘875 application”)
1020	U.S. Patent Application No. 16/732,706 to Rajguru <i>et al.</i> (<i>as originally filed</i>) (“‘706 application”)
1021	U.S. Patent No. 11,247,053 to Rajguru (“‘053 patent”)
1022	U.S. Patent No. 6,453,204 to Rhodes (“Rhodes”)
1023	U.S. Patent Application No. 15/084,356 to Rajguru <i>et al.</i> (“‘356 application”)
1024	L. Zhang & D.P. Rabussay, “Clinical evaluation of safety and human tolerance of electrical sensation induced by electric fields with non-invasive electrodes,” <i>Bioelectrochemistry</i> 56(1-2):233-236 (2002) (“Zhang”)
1025	U.S. Patent No. 6,341,236 to Osorio <i>et al.</i> (“‘236 patent”)
1026	U.S. Patent App. Pub. No. 2007/0021803 to Deem <i>et al.</i> (“US2007/0021803”)
1027	Katherine N. Moore, “Treatment of Urinary Incontinence in Men with Electrical Stimulation: Is Practice Evidence-Based?,” <i>Journal</i>

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	<i>of Wound, Ostomy and Continence Nursing</i> 27(1):20-31 (2000) (“Moore”)
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	U.S. Patent No. 8,206,312 to Farquhar (“’312 patent”)
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	U.S. Patent App. Pub. No. 2005/0075670 to Bengtsson (“’670 publication”)
1032	U.S. Patent App. Pub. No. 2007/0276449 to Gunter <i>et al.</i> (“’449 publication”)
1033	U.S. Patent No. 7,801,603 to Westlund <i>et al.</i> (“’603 patent”)
1034	U.S. Patent No. 8,712,546 to Kim <i>et al.</i> (“’546 patent”)
1035	Micael A. Crary <i>et al.</i> , “Biomechanical Correlates of Surface Electromyography Signals Obtained During Swallowing by Healthy Adults,” <i>Journal of Speech, Language, and Hearing Research</i> 49(1):186-193 (2006) (“Crary”)
1036	U.S. Patent No. 7,206,630 to Tarler (“’630 patent”)
1037	Stephen A. Koff & Evan J. Kass, “Abdominal Wall Electromyography: A Noninvasive Technique To Improve Pediatric Urodynamic Accuracy,” <i>The Journal of Urology</i> 127(4):736-739 (1982) (“Koff”)
1038	Michael R. van Balken <i>et al.</i> , “Posterior Tibial Nerve Stimulation as Neuromodulative Treatment of Lower Urinary Tract Dysfunction,” <i>The Journal of Urology</i> 166(3):914-918 (2001) (“van Balken”)

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1039	J.L.H. Ruud Bosch, “Electrical neuromodulatory therapy in female voiding dysfunction,” <i>BJU International</i> 98(s1):43-48 (2006) (“Bosch”)
1040	U.S. Patent No. 11,224,742 to Burnett (“‘742 patent”)
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	U.S. Patent App. Pub. No. 13/840,936 to Rajguru <i>et al.</i> (“‘936 application”)
1045	Int’l App. No. PCT/US2011/052415 (“‘415 application”)
1046	U.S. Provisional App. No. 61/403,680 to Rajguru <i>et al.</i> (‘680 provisional”)
1047	U.S. Patent App. No. 12/508,529 to Burnett <i>et al.</i> (“‘529 application”)
1048	U.S. Patent App. No. 11/866,329 to Burnett <i>et al.</i> (“‘329 application”)
1049	U.S. Provisional App. No. 60/848,720 to Burnett <i>et al.</i> (‘720 provisional”)
1050	File History of U.S. Patent No. 11,224,742 (“‘742 patent”/“‘742 patent file history”)
1051	<i>Avation Medical, Inc. v. EMKinetics, Inc.</i> No. 3:24-cv-01702 (N.D. Cal.) First Amended Complaint, Dkt. No. 5
1052	Notice of Abandonment for U.S. Patent App. No. 12/508,529
1053	Declaration of Todd R. Tucker
1054-1084	<i>RESERVED</i>

Exhibit No.	Description
1085	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”)
1086	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”)
1087	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”)
1088	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”)
1089	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”)
1090	Declaration of Todd R. Tucker in Support of Petitioner’s Reply to Patent Owner’s Response

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 1-39 of the '943 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 1-39 of the '943 Patent are unpatentable.

Setting this aside, each of EMK's procedural attacks nevertheless fail. EMK erroneously contends Grounds 1-8 and 10 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. EMK next asserts that for Grounds 9-10, Avation has not shown Burnett (Ex.1006) qualifies as prior art. EMK's argument, however, fundamentally misunderstands the law and rules regarding priority and the '943 Patent's priority chain itself. Regarding Ground 11, EMK incorrectly contends the Challenged Claims do not lack enablement, but misreads the specification of the '943 Patent, which plainly teaches away from the claimed invention. Finally, EMK belatedly

asserts that the ‘943 Patent is not PGR eligible, but once again misinterprets the law and Avation’s PGR eligibility arguments in the Petition.

All told, Avation has met its burden of demonstrating, by preponderance of the evidence, that claims 1-39 of the ‘943 Patent (“Challenged Claims”) are invalid. Respectfully, the Board should find the Challenged Claims of the ‘943 Patent unpatentable.

II. THE CHALLENGED CLAIMS OF THE ‘943 PATENT ARE UNPATENTABLE

A. Grounds 1-8 and 10 Demonstrate the Challenged Claims Are Unpatentable Because the Journal Articles Qualify as Prior Art Printed Publications

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, 1024, 1027-28, 1030, 1035, 1037-39, and 1041-43) (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 one reference (Svihra) in its Preliminary Response (“POPR”) (Paper 7 at 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 8 at 14-17. EMK now retreads the publicly 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 11 at 4-9. 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 possibly met its burden. See *id.* This is insufficient to overcome the record evidence of public accessibility. Avation’s evidence of public accessibility stands unrebutted in this proceeding, so accordingly, the Board should find 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 1-8 and 10. See Paper 11 at 4-9. EMK does not contest that Svihra teaches the limitations of Claims 1 and 3-5 (Ground 1) or that Amarenco teaches the limitations of Claims 1-3 and 5 (Ground 5). See *id.* 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 2-4, 6-8, 10). 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 Journal Articles are publicly accessible. As such, the Challenged Claims of the '943 Patent are unpatentable for the reasons set forth in Grounds 1-8 and 10 of Avation's Petition.

1. 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):

TREATMENT

Neuromodulative treatment of overactive bladder – noninvasive tibial nerve stimulation

Svihra J, Kurca E, Luptak J, Kliment J

Department of Urology, Jessenius Faculty of Medicine, Comenius University, Martin, Slovakia. svihra@jfmmed.uniba.sk

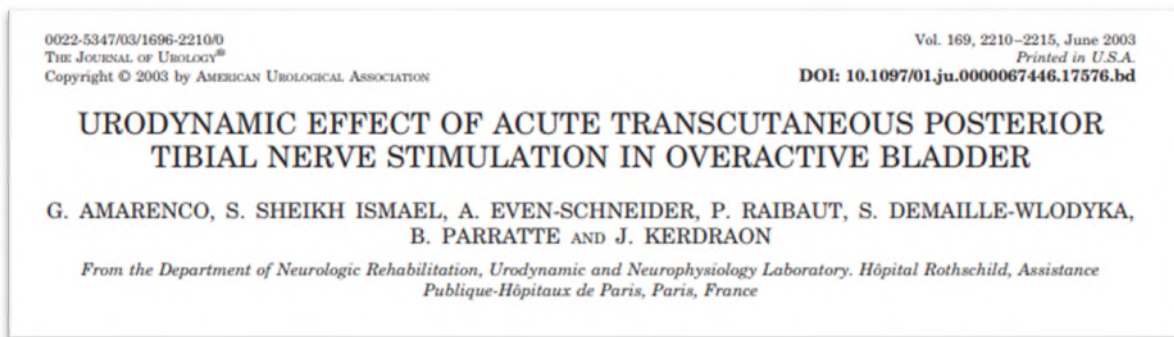
Ex.1004 at 480. Svihra further indicates the article was “Received May 30, 2002” and “Accepted December 9, 2002.” *Id.* at 483. The Board found this information to be sufficient evidence that Svihra qualifies as a printed publication for purposes of institution:

We do not find persuasive Patent Owner’s argument that Petitioner has failed to establish that Svihra was not either publicly accessible or a printed publication as of the critical date of September 20, 2010. A cursory internet search reveals that “Bratisl Lek Listy,” which appears on the header of Svihra, is, in fact, an abbreviation for Bratislavské lekárske listy, the Bratislava Medical Journal, an international medical journal founded in 1919, published monthly in English, and currently in its 125th volume. ***The header of the Svihra reference states, in full: “Bratisl Lek Listy 2002; 103 (12): 480-483,” which we find, based on the current record, that a person of ordinary skill in the art would understand to mean that the Svihra reference appeared as an article appearing in volume 103, number 12, of the Bratislava***

Medical Journal at pages 480–483, and which was published in December 2002 (i.e., number 12), which antedates the critical date of the '943 patent. See Ex. 1004, 480.

Paper 8 at 16 (emphasis added). The Board concluded that “for the purposes of this Decision and on the record as presently developed, ***the Svihra reference more likely than not exhibits the necessary hallmarks of a printed publication that would have been publicly accessible as of the critical date of the '943 patent.***” *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 ‘943 Patent. Amarenco’s header includes the journal, volume, pages, and date of publication:



Ex.1005 at 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 printed publication,” including “journal title and volume number, page numbers, date of acceptance for publication.” *See* Paper 8 at 16. 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, 1024, 1027-28, 1030, 1035, 1037-39, and 1041-43) also include sufficient indicia of publication to demonstrate they were public accessibly printed publications before the critical date of the ‘943 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 at 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 at 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 at 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”); see also Paper 8 at 16 (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 at 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”). 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 at ¶¶6-7, 10-19, 26, 20-30, 32, 37, 40-41, 43-45. And as EMK concedes, the declaration of Avation’s expert states that various references were “published” (see, *e.g.*, Ex.1003 at ¶46 (“Svihra published a study...”), ¶47 (“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.

2. 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 11 at 4-9. 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. Curiously, EMK never even affirmatively disputes that any of the Journal Articles were publicly accessible before the critical date.

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 11 at 5 (“there is no record evidence of public accessibility ***other than the document itself.***”) (emphasis added). 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 11 at 5-6. But personal knowledge that a reference was actually accessed is not necessary to prove public accessibility. Regardless, at a minimum 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 instead 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 11 at 6-7. The Board, however, rejected EMK’s public availability arguments regarding Svihra for purposes of institution. Paper 8 at 16. 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.A.3. *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.

3. 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.¹

Svihra: Sherif (Ex.1085), Slovak (Ex.1086), and Garcia (Ex.1087) 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 references cited. *See* Ex.1085 at 135 (reference [5]); Ex.1086 at 100 (reference [17]); Ex.1087 at 1340 (reference 25).

Amarenco: Amarenco II (Ex.1088) 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.1088 at 4-6. The cover page, copyright page, and table of contents confirm that this volume/edition of the journal, including the Amarenco article

¹ 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.

itself, published in June 2003. *Id.* at 1-4. The text of the article within Ex.1088 matches that of the Amarenco article submitted with Avation’s Petition. *See* Ex.1088 at 9-14; Ex.1005 at 2210-15.

Additionally, Queralto (Ex.1016) (previously submitted with Avation’s Petition), as well as Sherif (Ex.1085), Slovak (Ex.1086), Garcia (Ex.1087), and Guo (Ex.1089) 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 at 672 (reference 5); Ex.1085 at 135 (reference [29]); Ex.1086 at 100 (reference [37]); Ex.1087 at 1340 (reference 5); Ex.1089 at 856 (reference 11). Finally, Amarenco is included in the References Cited list in the ‘943 Patent itself, further demonstrating it was published in 2003. Ex.1001, [56] (listing Amarenco under “Other Publications” cited).

Hasan: Slovak (Ex.1086) and Guo (Ex.1089) 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.1086 at 100 (reference 12); Ex.1089 at 856 (reference 24).

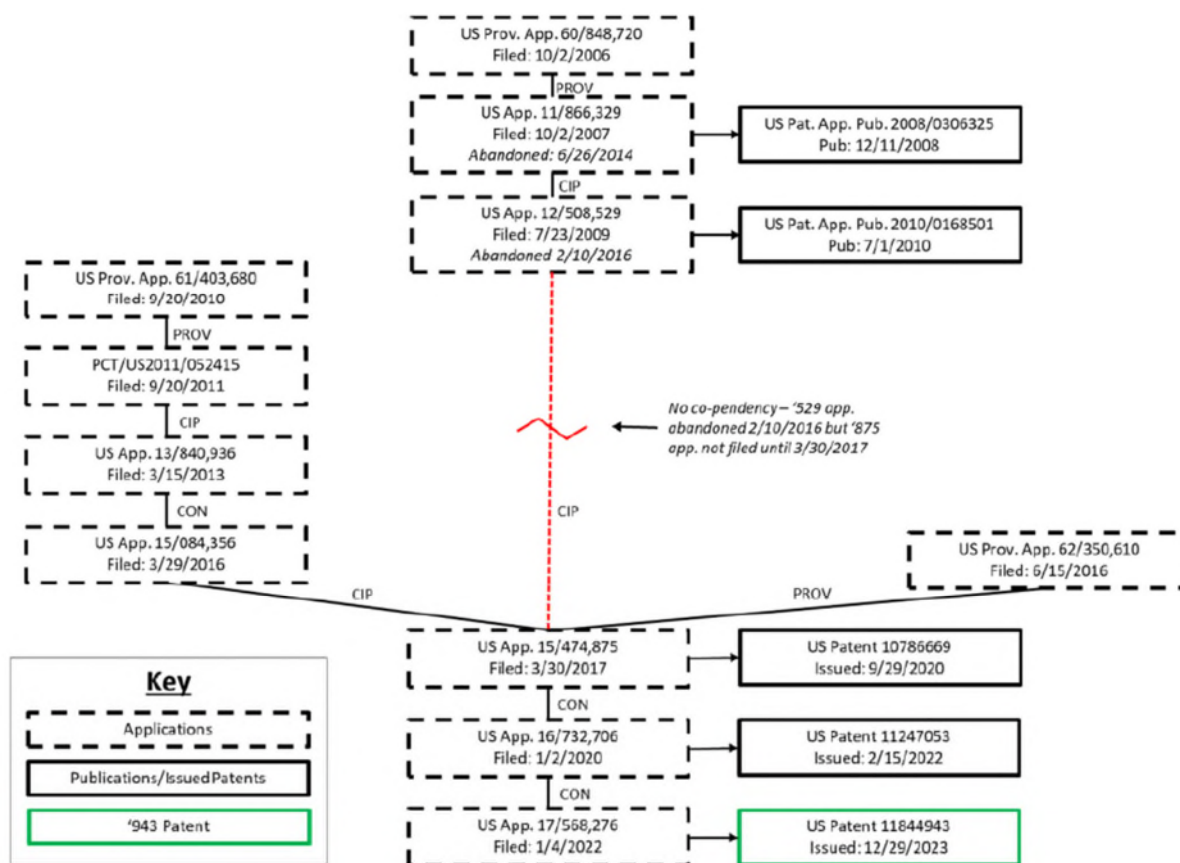
This additional evidence—while not necessary to prove the references are printed publications—corroborates the evidence submitted with Avation’s Petition and confirms Svihra (Ex.1004), Amarenco (Ex.1005), and Hasan (Ex.1030) were published and publicly accessible. *See Parse*, IPR2023-00958, Paper 48 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.

B. Grounds 9-10 Demonstrate the Challenged Claims Are Unpatentable Because Burnett (Ex.1006) Is Prior Art to the '943 Patent

EMK further contends, incorrectly, that Avation has not carried its burden of proving that Burnett (Ex.1006) qualifies as prior art. Paper 11 at 9. EMK's argument is based on a fundamental misunderstanding of the law and the '943 Patent's priority chain.

As explained in the Petition, due to defects in the '943 Patent's priority chain, the earliest possible effective filing date for the patent is September 20, 2010 (*i.e.*, the filing date of the '680 provisional). Paper 2 at 14-17. As shown in the figure below from the Petition, there is a break in co-pendency in the priority chain. In particular, the applicant abandoned the '529 application by February 10, 2016, but did not file the '875 application until March 30, 2017.



Id. at 15. Thus, the ‘329 application—which published as Burnett (Ex.1006) on December 11, 2008, as conceded by EMK—constitutes prior art to the ‘943 Patent.

EMK contends that there is no “break in the chain” of priority to October 2, 2006 because each of the applications in the family were “specifically referenced in the application at issue.” Paper 11 at 12. EMK, however, concedes the ‘943 Patent is “missing [] a statement that U.S. Application No. 13/840/936 was also a continuation-in-part of 12/508,529.” *Id.* at 13. EMK effectively asks the Board to excuse this “missing” statement and find that the ‘943 Patent’s simple listing of

applications in the priority chain is sufficient. The Board should not indulge EMK's request.

In *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309 (Fed. Cir. 2018), the Federal Circuit affirmed the Board's decision that the claims of a patent were invalid because the patent "failed to enumerate a priority claim sufficient to avoid fully-invalidating prior art." *Id.* at 1311. The patent (the '115 Patent) properly claimed priority to an earlier filed, co-pending patent (the '838 Patent), but did not identify any earlier applications in the family or the '838 Patent's familial relationships to the earlier applications. *Id.* at 1313. The Board determined the earliest effective filing date of the '115 Patent was the filing date of the '838 Patent and therefore, earlier applications in the family qualified as prior art. *Id.* at 1314.

The Federal Circuit agreed. According to the Court, 35 U.S.C. § 120 "requires that the patent application 'contain a specific reference to the earlier filed application' to which it purports to claim priority." *Id.* at 1315. The Court also noted that USPTO regulations require "that the application claiming the benefit of one or more prior-filed copending nonprovisional applications must include 'a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number)' **and indicating 'the relationship of the applications (i.e., whether the later-filed application is a continuation, divisional, or continuation-in-part of the prior-filed nonprovisional application**

or international application).” *Id.* (citing 37 C.F.R. § 1.78(d)(3)) (emphasis added). Thus, the Court held that the Board correctly found the ‘115 Patent’s earliest effective filing was the filing date of the ‘838 Patent. *Id.* at 1319.

Contrary to EMK’s assertions, the Federal Circuit did not simply find that “no reference whatsoever cannot be the ‘specific reference’ required by Section.” Paper 11 at 15. Rather, the Federal Circuit found that strict compliance with the applicable patent laws and rules is essential to proper priority claims and that failure to provide the required “specific reference” (including both a reference to the earlier filed applications and the relationship of the applications) will break the chain of priority and render prior applications in the family as prior art.

The Federal Circuit’s decision in *Droplets* is analogous to the present case. Here, although the ‘943 Patent provides a listing of applications in the chain, it does not identify all familial relationships—indeed, it does not indicate that the ‘936 application is a CIP of the ‘529 application. EMK admits this. *See* Paper 11 at 13. The ‘943 Patent thus cannot rely on this relationship for purposes of priority. *See, e.g.*, 37 C.F.R. § 1.78(d)(3).

Given the break in co-pendency between the ‘529 application and the ‘875 application, the earliest effective filing date of the ‘943 Patent is September 20, 2010 (*i.e.*, the filing date of the ‘680 provisional). *See* Paper 2 at 14-17. As such,

Burnett (Ex.1006), which published on December 11, 2008, qualifies as prior art to the '943 Patent.

C. Ground 11 Demonstrates the Challenged Claims Lack Enablement

EMK erroneously asserts that the specification does not teach away from the claimed inventions. According to EMK, although “the specification states that one treatment modality (electrical stimulation) in one frequency range (about 5 Hz to about 60 Hz or greater) applied to one skin type (non-glabrous) may cause pain and injury to the patient,” the claims “do not require a frequency range or a skin type.” Paper 11 at 20-21. This is incorrect.

Contrary to EMK’s argument, the claims **do** require a particular skin type—“non-glabrous” skin. All the Challenged Claims of the '943 Patent require positioning an electrical stimulator “near an ankle” of the patient. *See* Ex.1001, cls.1-39. The skin “near an ankle” of the patient is “non-glabrous” skin. *See* Ex.1003, ¶271. This is distinct from “glabrous” skin, such as the palm of the hand or bottom of the foot. *Id.* Thus, while the claims do not explicitly refer to skin type, every claim of the '943 Patent implicitly requires the electrical stimulator to be placed on “non-glabrous” skin because every claim requires the electrical stimulator to be placed “near an ankle” of the patient.

Moreover, the specification does not merely state that electrical stimulation causes pain and injury to a patient “in one frequency range (about 5 Hz to about 60

Hz or greater),” as EMK contends. For example, the specification explicitly states that “delivering electrical stimulation through a non-glabrous surface of the body, for example, ***by stimulating a site overlying a nerve near the medial malleolus [i.e., “near an ankle”]*** 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, 50:35-51:3 (emphasis added). This statement from the specification does not specify a frequency range, but instead merely indicates that electrically stimulating “near an ankle” is painful and intolerable to the patient.

Accordingly, there is no “variation between the teachings [in the specification] and the claims in question” as EMK suggests. See Paper 11 at 21. Rather, the specification teaches away from electrically stimulating “non-glabrous” skin (regardless of frequency range). The claims all require electrically stimulating “near an ankle” (*i.e.*, “non-glabrous” skin) of the patient (without specifying frequency range). The specification therefore teaches away from the claimed invention. See *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1379 (Fed. Cir. 2007) (“where the specification teaches against a purported aspect of an invention, such a teaching ‘is itself evidence that at least a significant amount of experimentation would have been necessary to practice the claimed invention.’”)

(quoting *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003)). As such, undue experimentation would have been required to practice the invention and the claims are invalid for lack of enablement.

D. The ‘943 Patent Is Eligible for PGR

EMK’s argument that the ‘943 Patent is not PGR eligible (*see* Paper 11 at 18) misinterprets both the law and the reasons the ‘943 Patent is eligible for PGR set forth in Avation’s Petition. *See* Paper 2 at 8-13. As explained in the Petition and the Board’s Institution Decision, patents described in AIA §3(n)(1) are eligible for PGR. *See* AIA §6(f)(2)(A), 125 Stat. at 311. According to §3(n)(1), AIA patents include:

any application for patent, and [] any patent issuing thereon, that contains or contained at any time—

(A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after the effective date [i.e., March 16, 2013]; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

AIA §3(n)(1), 125 Stat. at 293; Paper 2 at 8; Paper 8 at 10. Importantly, this includes both: (A) patents that issue from applications that contain or contained at any time a claim to a claimed invention with an effective filing date on or after

March 16, 2013 (§3(n)(1)(A)); **and** (B) patents that issue from applications that contain or contained any time a specific reference under 35 U.S.C. §§ 120, 121, or 365(c) to any patent or application that contains or contained at any time such a claim (§3(n)(1)(B)).

EMK's argument that the '943 Patent is not PGR eligible is based on a misunderstanding of the law regarding PGR eligibility. EMK's summary of the legal standard omits Subsection B (Paper 11 at 18), which clearly indicates that patents subject to the first-inventor-to-file provisions also include patents that issue from applications that contain or contained any time a specific reference to any patent or application that contains or contained at any time such a claim.

AIA §3(n)(1)(B).

Moreover, EMK misinterprets the reasons for PGR eligibility set forth in Avation's Petition. See Paper 11 at 18. Avation does not rely on a "break in the chain" to establish PGR eligibility. Rather, the Petition provides multiple reasons why the '943 Patent is eligible for PGR, none of which relate to the break in EMK's priority chain. As the Petition explains, 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. See Paper 2 at 9. In other words, the '943 Patent claims the benefit of the filing date of various patents or applications (as continuations and/or CIPs), at least

several of which—including the ‘669 Patent, ‘875 Application, ‘706 Application, and ‘053 Patent—“contain[] or contained at any time” claims with an effective filing date after March 16, 2013. *Id.* at 9-13. Moreover, the ‘943 patent is also eligible for PGR because it contains claims with an effective filing date after March 16, 2013, *i.e.*, the ‘943 Patent’s claims do not enable “positioning a first portion of a patient's body near an ankle relative to an electrical stimulator” and therefore the earliest effective filing date for the claims is the filing date of the ‘943 Patent, January 4, 2022. *Id.* at 13.

The Board agreed with Avation’s analysis and found the ‘943 Patent was eligible for PGR on institution. Paper 8 at 10-12. EMK’s Response—which is wrong on the law and fails to even address Avation’s actual PGR eligibility arguments—are insufficient to disrupt the Board’s previous PGR eligibility determination.

III. CONCLUSION

For the reasons set forth in Avation’s Petition (Paper 2) and above, the Board should respectfully find Challenged Claims 1-39 of the ‘943 Patent are unpatentable and cancel the claims.

Dated: July 16, 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 5,567 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: July 16, 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**

(Ex.1085-90) were served by email to Patent Owner by serving the email correspondence addresses of record as follows in accordance with 37 C.F.R.

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