

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Avation Medical, Inc.,

Petitioner

v.

EMKinetics, Inc.,

Patent Owner

Case No. IPR2024-01375
U.S. Patent No. 11,224,742

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 11,224,742 (“’742 patent”)
1002	File History of U.S. Patent No. 11,224,742 (“’742 patent file history”)
1003	Declaration of Dr. Brett Wingeier in Support of Petition for Inter Partes Review of U.S. Patent No. 11,224,742 (“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”)
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”)

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 IPR2024-01378.

Exhibit No.	Description
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	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 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”)

Exhibit No.	Description
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 2001”)
1039	J.L.H. Ruud Bosch, “Electrical neuromodulatory therapy in female voiding dysfunction,” <i>BJU International</i> 98(s1):43-48 (2006) (“Bosch”)
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]

Exhibit No.	Description
1045	<i>[Reserved]</i>
1046	<i>[Reserved]</i>
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	<i>[Reserved]</i>
1055	<i>[Reserved]</i>
1056	<i>[Reserved]</i>
1057	<i>[Reserved]</i>
1058	<i>[Reserved]</i>
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1075	<i>[Reserved]</i>
1076	<i>[Reserved]</i>
1077	<i>[Reserved]</i>
1078	<i>[Reserved]</i>
1079	<i>[Reserved]</i>

Exhibit No.	Description
1080	U.S. Patent Pub. App. Pub. No. 2006/0122660 to Boveja <i>et al.</i> filed Dec. 28, 2005, published Jun. 8, 2006 (“Boveja”)
1081	U.S. Patent No. 6,272,383 to Grey <i>et al.</i> (“Grey”)
1082	U.S. Patent No. 5,984,854 to Ishikawa <i>et al.</i> (“Ishikawa”)
1083	U.S. Patent No. 6,735,474 to Loeb <i>et al.</i> (“Loeb”)
1084	U.S. Patent No. 6,941,171 to Mann <i>et al.</i> (“Mann”)
1085	S N Ponsford, “Sensory conduction in medial and lateral plantar nerves,” <i>Journal of Neurology, Neurosurgery, and Psychiatry</i> 51(2):188-191 (1988) (“Ponsford”)
1086	U.S. Patent No. 5,995,873 to Rhodes (“Rhodes”)
1087	U.S. Patent No. 11,844,943 to Rajguru <i>et al.</i> (“‘943 patent”)
1088	<i>Gray’s Anatomy</i> 1123-53 (Peter L. Williams <i>et al.</i> eds., 37th ed. 1989) (“Gray’s”)
1089	[Reserved]
1090	[Reserved]
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	[Reserved]
1098	[Reserved]
1099	H. Krämer <i>et al.</i> , “Follow-up of advanced diabetic neuropathy Useful variables and possible pitfalls,” <i>J Neurol</i> 252:315-20 (2005) (“Krämer”)

Exhibit No.	Description
1100	K. Galloway <i>et al.</i> , “Clinical utility of tibial motor and sensory nerve conduction studies with motor recording from the flexor hallucis brevis: a methodological and reliability study,” <i>Journal of Foot and Ankle Research</i> 4:14 (2011) (“Galloway”)

I. INTRODUCTION

EMK's Response does not overcome the Petition's showing that claims 1-13 of the '742 Patent are unpatentable. EMK does not dispute that the primary references, Svihra (Ex.1004) and Amarenco (Ex.1005), disclose nearly all elements of the claimed inventions. Instead, EMK relies on a procedural attack that ignores evidence in the record and unsupported substantive attacks based exclusively on attorney argument that mischaracterize the prior art. None are sufficient to rebut the Petition's strong invalidity grounds.

EMK's procedural attack centers on its erroneous contention that Avation has not proven certain "non-patent references" were publicly accessible. This "argument" ignores the ample evidence submitted with the Petition demonstrating the references qualify as prior art printed publications. EMK's substantive attacks on the Petition's Grounds 1-2 fare no better. EMK contends the prior art does not disclose "directly" targeting or stimulating branches of the posterior tibial nerve ("PTN") and that a POSA would not have been motivated to modify Svihra or Amarenco, but its arguments misread (and often ignore) the prior art's teachings, mischaracterize Avation's arguments, and misquote the testimony of Avation's expert.

All told, Avation met its burden of demonstrating, by preponderance of the evidence, that claims 1-13 of the ‘742 Patent (“Challenged Claims”) are invalid. Respectfully, the Board should find the Challenged Claims unpatentable.

II. THE JOURNAL ARTICLES ARE PRIOR ART PRINTED PUBLICATIONS

Petitioner Avation Medical Inc. (“Avation”) met its burden of proving Svihra (Ex.1004), Amarenco (Ex.1005), Ponsford (Ex.1085), and the other cited non-patent references (Exs.1008-17, 1024, 1027-28, 1030, 1035, 1037-39, 1041-43, and 1088) (“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. (“EMK”) challenged the prior art status of Svihra in its Preliminary Response (“POPR”) (Paper 6, 3-7), but the Board rejected EMK’s argument and found Avation’s public accessibility evidence sufficient at that stage. Paper 7, 11-14.

EMK now retreads the publicly accessibility argument in its Patent Owner Response (“Response”), but ***offers no argument or evidence whatsoever to rebut the record evidence of public accessibility, let alone address the Board’s conclusions regarding the printed publication status of Svihra.*** Paper 12, 4-8.

The best EMK can muster is an unsupported “suggestion”—without addressing the references themselves or what they show regarding public availability—that

Avation has possibly not met its burden. *See id.* This is insufficient to overcome the record evidence of public accessibility. As Avation’s evidence stands un rebutted, the Board should find the Journal Articles qualify as prior art printed publications.

A. Avation Met Its Burden of Proving the Journal Articles Qualify as Prior Art

Avation met its burden of proving that Svihra, Amarenco, Ponsford, and the other Journal Articles 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). Public accessibility is established by demonstrating 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 consistently found articles published in scientific journals to be publicly accessible and qualify as prior art printed

publications. *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 printed publication); *Grünenthal GmbH v. Antecip Bioventures II LLC*, PGR2018-00092, Paper 31 at 16 (PTAB December 22, 2020) (finding in FWD 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 FWD “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 article’s face—including journal name, volume, number/edition, page numbers, and/or copyright/publication date—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 journal name, citation information reflecting date, volume, and page numbers, and dates article available); *Telefonaktiebolaget*, 941 F.3d at 1347 (Fed. Cir. 2019) (holding “date on the face of the journal” supported PTAB’s finding 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, for example, includes the “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 it was “Received May 30, 2002” and “Accepted December 9, 2002.” *Id.*, 483. The Board found this evidence sufficient for 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).² The Board concluded Avation “established a reasonable likelihood that *Svihra was publicly accessible before the critical date of the ’742 patent. Svihra exhibits the necessary hallmarks to support such a finding.*” *Id.* EMK’s Response provides no evidence or argument that undermine the Board’s previous findings.

Amarenco likewise contains “hallmarks” of a printed publication publicly accessible before the critical date, including the journal, volume, pages, and date of publication:

² All emphasis added unless indicated otherwise.

**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. Like Svihra, a person of ordinary skill in the art (“POSA”) would understand Amarenco’s header to indicate 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 it was “[a]ccepted for publication January 17, 2003.” *Id.* Moreover, Amarenco includes a “DOI,” or “Digital Object Identifier,” which a POSA would understand is a permanent address for digital content. *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.” Paper 7, 13. As with Svihra, EMK submits no evidence or argument to challenge the Board’s findings.

The same is true for Ponsford (Ex.1085). Ponsford’s header includes the journal, volume, pages, and date of publication:

Journal of Neurology, Neurosurgery, and Psychiatry 1988;**51**:188–191

Sensory conduction in medial and lateral plantar nerves

S N PONSFORD

From the Department of Clinical Neurophysiology, Walsgrave Hospital, Coventry, UK

Ex.1085, 188. A POSA would understand from these “hallmarks” that Ponsford appeared in volume 51 of the *Journal of Neurology, Neurosurgery, and Psychiatry* at pages 188-91, published in 1988. *Id.* Ponsford also indicates the article was “Received 24 May 1987” and “Accepted 14 August 1987,” further confirming it was published and publicly available by 1988. *Id.* EMK provides no evidence or argument suggesting otherwise.

The other Journal Articles challenged by EMK (Exs. 1008-17, 1024, 1027-28, 1030, 1035, 1037-39, 1041-43, and 1088) also include sufficient publication indicia to demonstrate public accessibility before the critical date. Each reference is an article published in a scientific journal and includes “hallmarks” including journal headers identifying the journal in which it published, the volume and

edition/number, page numbers, and the publication and/or copyright date.³ See Paper 7, 13 (explaining how POSA would understand journal header information).

³ See, e.g., Ex.1028 at 361 (article published in volume 10 of *Journal of Electromyography and Kinesiology* on pages 361-74 in 2000; also including “© Elsevier Science Ltd.”); Ex.1042 at 119 (article published in volume 3 of *Human Movement Science* on pages 119-153 in 1984; also including “© 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 dates article received and accepted); Ex.1024 at 233 (article published in volume 56 of *Bioelectrochemistry* on pages 233-36 in 2002; also indicating article “Received 17 December 2001,” “accepted 28 January 2002,” and including “© 2002 Elsevier Science B.V.”); Ex. 1027 at 20 (article published in volume 27, edition 1 of *Journal of Wound Ostomy & Continence Nursing* on pages 20-31 in 2000; also including “Copyright © 2000 by the Wound, Ostomy and Continence Nurses Society”); Ex.1035 at 186 (article published in volume 49 of *Journal of Speech, Language, and Hearing Research* on pages 186-93 in February 2006; also including “©American Speech-Language-Hearing Association”); Ex.1037 at 736 (article published in volume 127 of *The Journal of Urology* on

Further, some Journal Articles also contain additional information indicative of public accessibility, including unique identifiers, such as ISSN and/or Accession numbers, or other identifying information. *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”). EMK ignores this evidence entirely.

Additionally, Avation submitted an attorney declaration attesting that true and correct copies of each Journal Article were filed. Ex.1053, ¶¶ 6-18, 21-22, 24, 29, 31-36, 44, 47. EMK also concedes Avation’s expert’s declaration states that various references were “published” (*see, e.g.*, Ex.1003, ¶¶43-44), at a minimum establishing that POSAs would understand the articles were published and publicly available as of the dates on the references.

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

pages 736-39; also indicating article “Accepted for publication July 1, 1981” and “Copyright © 1982 by The Williams & Wilkins Co.”).

B. EMK Fails to Rebut Avation’s Public Accessibility Evidence

Despite Avation’s overwhelming public accessibility evidence, EMK contends Avation did not prove the Journal Articles are printed publications. Paper 12, 4-8. ***EMK, however, provides no argument or evidence whatsoever to rebut the record evidence of public accessibility.*** For example, despite the references’ publisher/publication information, EMK never contends they were not published by an established publisher. *See Vidstream*, 981 F.3d at 1065-66. Nor does EMK argue or provide evidence that the Journal Articles contain inaccurate publication information, were ***not*** published in widely distributed scientific journals, or were not disseminated or available so a POSA could locate them. EMK never even affirmatively disputes the Journal Articles were publicly accessible before the critical date. Worse, EMK did not file objections—*e.g.*, challenging authenticity or that information such as publication dates constitute hearsay—waiving any motion to exclude on these bases. 37 C.F.R. §42.64(b)-(c).

EMK ignores the public availability evidence outright, instead generically admonishing Avation without discussing the references’ specific public accessibility information. EMK never addresses the references’ printed publication “hallmarks” or any other public accessibility indicia. Crucially, it never individually addresses any of the references at all. And EMK does not even attempt to address the Institution Decision’s findings regarding Svihra. Rather,

EMK suggests a heightened standard—one that ignores the document itself entirely—should apply. See Paper 12, 4 (“there is no record evidence of public accessibility ***other than the document itself***”). EMK effectively contends that merely ***questioning*** public accessibility—even where, as here, there is unrebutted public accessibility evidence in the record—Petitioners must automatically provide even ***further*** evidence to meet some nonexistent elevated burden. EMK provides no support for this proposition—nor could it, as it is contrary to Federal Circuit and PTAB precedent. *E.g.*, *Hulu*, IPR2018-01039, Paper 29 at 17-20 (precedential).

At most, EMK critiques Avation’s declarations, but its arguments miss the mark. Paper 12, 4-5. Personal knowledge a reference was actually accessed, however, is not necessary. *E.g.*, *Samsung Elecs. Co. v. Infobridge Pte. Ltd.*, 929 F.3d 1363, 1374 (Fed. Cir. 2019). Regardless, the declarations at minimum corroborate the otherwise ample public accessibility evidence from the references themselves.

Rather than contend with Avation’s evidence directly, EMK vaguely asserts Avation failed to meet its burden. This is plainly insufficient to overcome the record evidence demonstrating public accessibility. *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”); *Telefonaktiebolaget*, 941 F.3d at 1347 (noting that while Patent Owner did not bear ultimate burden of proving article’s availability date, Patent Owner “provided no evidence to counter” the record evidence of public accessibility).

EMK’s legal arguments are similarly unavailing. EMK faults Avation for not seeking a reply to EMK’s POPR and not submitting supplemental information. Paper 12, 6-7. The Board, however, rejected EMK’s public accessibility arguments for purposes of institution (Paper 7, 13) and EMK filed no objections to the evidence. Avation had no reason to submit supplemental information at that time.

EMK’s reliance on the non-precedential *Medivis* decision is similarly misplaced. There, one panel determined a Petitioner did not provide sufficient public accessibility evidence and noted Petitioner’s reliance on the references was insufficient. *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. Instead, the panel may have relied on decisions regarding non-journal articles (*e.g.*, user manuals, software documentation), which do not have known, established publishers or printed publication “hallmarks” as do the Journal Articles here. *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 case's particular facts is dubious. And notably, *Medivis* is currently on appeal. See *Medivis, Inc. v. Novarad Corp.*, No. 24-1794 (Fed. Cir.).

Additionally, other panels have distinguished *Medivis*. In *Parse*, the Board found *Medivis* "inapposite" because there was additional record evidence corroborating the article's publication date, including other references that identified the article as a cited reference. *Parse*, IPR2023-00958, Paper 48 at 22 n.10. The same is true here. *Infra*, §II.A.3. *Medivis* is therefore not controlling and distinguishable from this case.

The **only evidence** in the record is that the Journal Articles were publicly accessible before the critical date. EMK provides no evidence or argument to rebut this. The evidence thus demonstrates the Journal Articles were publicly available printed publications.

C. To Avoid Doubt, Avation Submits Further Evidence of Public Accessibility of Svihra, Amarenco, Hasan, and Ponsford

Although the record evidence is alone sufficient to establish the Journal Articles are prior art printed publications, Avation provides additional evidence responsive to EMK's arguments that corroborates Avation's record evidence. This evidence further demonstrates Svihra (Ex.1004), Amarenco (Ex.1005), Hasan

(Ex.1030), and Ponsford (Ex.1085) were published in established journals and were publicly available before the critical date.

Svihra: Sherif, Slovak, and Garcia corroborate that Svihra is a journal article published in 2002. Each reference includes a citation to Svihra in its list of references cited. Ex.1091, 135 (reference [5]); Ex.1092, 100 (reference [17]); Ex.1093, 1340 (reference 25).

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

Additionally, Queralto (previously submitted), as well as Sherif, Slovak, Garcia, and Guo corroborate that Amarenco is a journal article published in 2003. Each reference includes a citation to Amarenco in its list of references cited. 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 listed in the References Cited in the ‘742 Patent itself and the related

‘943 Patent, further demonstrating it published in 2003. Ex.1001, [56]; Ex.1087, [56].

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

Ponsford: Krämer and Galloway corroborate that Ponsford is a journal article published in 1988. Each reference includes a citation to the Ponsford article in its list of references cited. Ex.1099, 320 (reference 23); Ex.1100, 9 (reference 33).

This additional evidence corroborates the record evidence and confirms Svihra, Amarenco, Hasan, and Ponsford were published and publicly accessible. *See Parse*, IPR2023-00958, Paper 48 at 22 (relying on citations in non-contemporaneous publications to corroborate reference’s publication date). Accordingly, the Board should find that Avation met its burden of proving the Journal Articles were publicly accessible printed publications.

III. GROUNDS 1-2 DEMONSTRATE THE CHALLENGED CLAIMS ARE OBVIOUS

EMK’s substantive challenge to Grounds 1-2 fares no better. Relying solely on attorney argument, EMK contends the Challenged Claims are not obvious because the prior art does not disclose “directly” targeting or stimulating PTN branches and a POSA would not be motivated to modify Svihra (Ground 1) or

Amarenco (Ground 2). Paper 12, 10-11, 30-32.⁴ None of EMK’s attacks are, however, sufficient to overcome Avation’s strong showing of obviousness.

A. EMK’s Attempt to Redefine “Directly” Targeting/Stimulating PTN Branches Fails

At the outset, EMK’s attempt to redefine “directly” targeting or stimulating PTN branches in claim 1 fails. The ‘742 Patent does not describe what “directly” targeting or stimulating a nerve means for noninvasive electrostimulation. Instead, it discloses providing stimulation by placing a noninvasive device over an area of the body. *E.g.*, Ex.1001, Fig. 11; Paper 2, 30-31, 51-52; Ex.1003, ¶¶89-90, 95-96, 148-49, 154-55. Simply placing electrodes over branches of the PTN therefore “directly” targets and stimulates the branches, as claimed. *See id.*

EMK contends, however, that “directly” targeting/stimulating means “delivering an electric stimulus to a [PTN] branch [] with the intent of creating an effect in a [PTN] branch.” Paper 12, 9. To the extent EMK suggests this excludes “directly” stimulating PTN branches to create indirect, upstream effects, EMK’s redefinition is plainly incorrect. First, EMK misquotes Dr. Wingeier’s deposition testimony. Dr. Wingeier testified that “directly” stimulating means “stimulating with the intent of creating an effect in that structure ***and, of course, that might***

⁴ EMK’s arguments regarding Grounds 1-2 are substantially the same and are discussed together herein. Paper 12 at 10-30 (Ground 1), 30-38 (Ground 2).

have its own follow-on effect.” Ex.2003, 22:7-9. Further, Dr. Wingeier explained that *directly* stimulating a nerve could indirectly affect other structures. *Id.*, 22:11-17 (“if I was stimulating the vagus nerve to have a follow-on effect on some distant brain network, then I would be *directly stimulating* the vagus nerve . . . and I would be having an *indirect effect* on the brain thereby”). Second, EMK’s interpretation is inconsistent with the ‘742 Patent. The only embodiment arguably disclosing noninvasive PTN electrostimulation (Fig.11) depicts a noninvasive device placed over the PTN to “directly” stimulate the PTN and indirectly affect other structures to treat OAB/incontinence. Ex.1001, 17:2-15, 17:36-38, 29:39-47. EMK’s new construction would thus improperly exclude embodiments. *See Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1320 (Fed. Cir. 2005). EMK’s attempt to redefine “directly” targeting/stimulating should be rejected.

B. Grounds 1-2 Demonstrate Claim 1 Is Obvious

Avation met its burden of proving claim 1 is unpatentable in both Grounds 1-2. Paper 2, 22-33, 44-53. EMK does not contest Svihra and Amarenco disclose nearly every limitation of claim 1. *E.g.*, Paper 12, 14 (“[f]rom Svihra (Ex.1004), a skilled artisan could have understood that OAB/incontinence can be treated by electrically stimulating the PTN”). Instead, EMK contends the art does not teach or suggest “directly” targeting/stimulating PTN branches and that modifying

Svihra/Amarenco would not have been obvious. *Id.*, 10, 30-31. EMK is wrong on both accounts.

1. The Prior Art Discloses “Directly” Targeting/Stimulating PTN Branches

As described in detail in the Petition and supported by Dr. Wingeier, a POSA—informed by the prior art such as Mann, Boveja, Grey, Ponsford, and Rhodes (*see* Paper 2, 24-27, 46-48; Ex.1003, ¶¶77-83, 136-42)—would have found it obvious to modify Svihra/Amarenco to arrive at the “invention” of claim 1. Paper 2, 27-31, 48-52; Ex.1003, ¶¶84-91, 143-50. Instead of addressing the Svihra and Amarenco combinations head on, EMK largely focuses on improperly attacking prior art references in isolation. Paper 12, 11-19; *see In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (“Non-obviousness cannot be established by attacking references individually”). But more fundamentally, EMK misinterprets (and frequently ignores) the references’ teachings and how a POSA would have understood them.

EMK’s first argument—that Grey teaches “[a]t most . . . that electro-acupuncture of the PTN and its branches would have the same effect as traditional acupunctural stimulation of the SP and BL acupuncture points”—plainly misses the point. Paper 12, 12-13. Grey discloses noninvasive electrical nerve stimulation for treating certain conditions and explicitly states “***the tibial nerve [] and its branches (e.g., the medial plantar nerve [] and lateral plantar nerves [] under the***

foot, generally traveling inside the ankle) . . . can be stimulated to cause the same affect as stimulation of the traditional SP and BL acupuncture points.” Ex.1081, 2:53-60. In other words, *stimulating the PTN or PTN branches would cause the same therapeutic effect*. Paper 2, 25; Ex.1003, ¶¶79, 83. EMK’s focus on Grey’s statements regarding acupuncture is a red herring—the key point is Grey’s explicit teaching that the PTN *or* PTN branches can be stimulated to treat conditions *with the same efficacy*. See *id.*

Further, EMK suggests Mann (Ex.1084) merely discloses “stimulating the pudendal nerve and its branches to treat incontinence.” Paper 12, 13-16. Not only does EMK concede Mann discloses PTN stimulation (see *id.*, 15), EMK apparently ignores Mann’s explicit statement that OAB/incontinence can be treated by stimulating nerves emanating from the sacral roots:

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

Ex.1084, 11:50-12:7. Given the PTN and its branches are “[o]ther somatic nerves emanating from the sacral nerve roots,” Mann clearly teaches treating OAB/incontinence by electrically stimulating the PTN or PTN branches. Paper 2,

24-25; Ex.1003, ¶¶ 77, 83. EMK additionally asserts Mann does not suggest stimulating “just any nerve having a sacral root” (Paper 12, 15), but EMK does not—because it cannot—dispute that both the PTN and pudendal nerve emanate from sacral nerve roots and share common origination points including S2, S3, and S4. Ex.1084, 11:50-12:7; Paper 2, 9. EMK next argues Mann does not disclose stimulating PTN branches. Paper 12, 15. Wrong again—on top of the above disclosures, Mann states explicitly that “[o]ther sites along tibial nerve . . . are acceptable stimulator locations,” which a POSA would understand includes the PTN and its branches. Ex.1084, 16:28-41; Ex.1003, ¶77. Notably, the Examiner agreed with Avation’s interpretation of Mann during prosecution. Paper 2, §IV.B.

EMK’s attempt to distinguish Boveja (Ex.1080) fares no better. EMK claims Boveja “discloses, at most, stimulation of the nerves at the bottom of the spine to treat bladder conditions” and “at most teaches stimulation of the sacral portion of the tibial nerve.” Paper 12, 16. But Boveja discloses electrically stimulating “sacral nerves and/or its branches,” including the PTN and branches, to treat OAB/incontinence. Ex.1080, Abstract, [0002], [0026], [0028-29], [0180], cl.1; Ex.1003, ¶78. Boveja lists various nerves to be stimulated, many of which branch from the sacral nerves and are outside the sacral region. *Id.*, [0180], cl.1, 3. In other words, Boveja teaches treating OAB/incontinence by stimulating nerves and branches that **emanate** from the sacral nerve roots (such as the PTN and PTN

branches), not simply those at the base of the spine as EMK contends. Ex.1003, ¶¶ 78, 83.

Finally, while EMK concedes Ponsford (Ex.1085) directly targeted/stimulated PTN branches, EMK asserts Ponsford does not teach that stimulating PTN branches causes signals to travel upstream to the spinal cord via sacral nerve roots. Paper 12, 17-18. But Ponsford recorded SAPs—signals propagating from stimulation sites (PTN branches) upstream to the recording site (the ankle). Paper 2, 25-26; Ex.1080, 188-89; Ex.1003, ¶¶80-81. A POSA would understand Ponsford’s study teaches that stimulating PTN branches causes signals to travel upstream to the PTN and propagate to the sacral nerve roots. Ex.1003, ¶¶80-81. Dr. Wingeier’s deposition testimony cited by EMK does not show otherwise. Paper 12, 18-19. Asked whether sacral nerves are upstream or downstream of nerves that control bladder function, Dr. Wingeier merely noted the upstream/downstream distinction depends on signal direction. Ex.2003, 112:23-114:13. Additionally, he explained that one mechanism of neuromodulation for OAB is stimulating nerves “that ultimately come back up to the sacral roots.” *Id.* Dr. Wingeier’s testimony is therefore entirely consistent with his prior opinions. Ex.1003, ¶81.

2. A POSA Would Have Been Motivated to Modify Svihra and/or Amarenco and Expected Success

The Petition demonstrates based on evidence in the record that a POSA would have been motivated to modify Svihra/Amarenco and reasonably expected success. Paper 2, 27-31, 48-52; Ex.1003, ¶¶ 84-91, 143-50. The ‘742 Patent’s prosecution history underscores this point—the Examiner determined a POSA would have been motivated to modify Amarenco to target and stimulate PTN branches based on Mann, and the only reason the claims were allowed was the Examiner’s apparent view that the art did not disclose “directly” targeting/stimulating PTN branches. Paper 2, §IV.B. Grounds 1-2 fill that narrow gap and render claim 1 obvious. EMK argues otherwise—based on unsupported attorney argument alone—but its attacks do not withstand scrutiny. *Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1359 (Fed. Cir. 2018) (“‘[a]ttorney argument is not evidence’ and cannot rebut other admitted evidence”).

EMK first contends targeting/stimulating PTN branches is not “simple substitution” (Paper 12, 20-21), but this falls flat. Targeting and stimulating one nerve (PTN branches) in place of another closely related one (the PTN) is just that—simple substitution of one known element for another. This is particularly true here given teachings in the art regarding electrically stimulating the PTN and PTN branches to treat OAB/incontinence, which provide clear motivation to

substitute PTN branches for the PTN. *See supra*, § III.B.1; Paper 2, 24-28, 46-48. EMK’s selective citations regarding the complexity of the nervous system ***overall*** are thus irrelevant to substituting one closely related sacral nerve for another.

EMK’s “obvious to try” argument is a strawman. Paper 12, 21. Avation never suggested trying “direct stimulation of each and every nerve in the human body.” Paper 2, 28, 48-49. The Petition instead explains that the number of nerves emanating from sacral nerve roots and locations along those nerves are finite. *Id.* As such, it would have been obvious to try targeting/stimulating other locations along the PTN, including PTN branches. *Id.*

EMK’s dismissal of Avation’s “obvious design choice” argument likewise fails. Paper 12, 21-22. EMK’s critique of the Petition’s wording (“could” versus “would”) is semantics—the point is that a POSA would have motivation to modify Svihra/Amarenco based on obvious design choices such as improving patient convenience. Paper 2, 29, 49-50. And contrary to EMK’s assertion, the Petition states a POSA would have expected similar results “based on knowledge of the art” as discussed in the Petition at length and supported by Dr. Wingeier. *See id.* (citing Ex.1003, ¶87).

Next, EMK contends a POSA would not have considered PTN branch stimulation an “improvement.” Paper 12, 22. EMK’s attorney argument, however, does not overcome the only evidence in the record that targeting/stimulating PTN

branches rather than the PTN would improve patient convenience. Paper 2, 28-29, 48-50; Ex.1003, ¶¶87, 146. In any event, the law does not require showing actual improvement, only (as here) that applying a known technique to a known process would be suitable. *E.g.*, *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1381 (Fed. Cir. 2023) (known-technique rationale does not require showing improvement).

EMK's attacks regarding reasonable expectation of success are also easily dispatched. Paper 12, 22-23. Based again on attorney argument alone, EMK asserts that teachings regarding "sacral root stimulation by stimulating the sacral region" would not provide an expectation of success in stimulating PTN branches. Paper 12, 22-23. The premise of EMK's argument is, however, based on its flawed interpretation of Mann and Boveja. As discussed above, both disclose electrical stimulation of sacral nerves **and branches** (including the PTN and PTN branches), not merely the sacral nerves themselves. *See supra*, §III.B.1. EMK's final contention—that knowledge of how to stimulate PTN branches would not have provided motivation or an expectation of success in treating OAB/incontinence (Paper 12, 23)—is equally flawed. Avation does not rely on Ponsford and Rhodes alone for these points, but rather on the art's combined teachings (including Mann, Boveja, and Grey in addition to Ponsford and Rhodes). Paper 2, 27-31, 48-52; Ex.1003, ¶¶ 84-91, 143-50.

EMK's unsupported attorney argument mischaracterizes the record, ignores the teachings of the prior art and how a POSA would have understood them, and misinterprets the Petition. This is insufficient to overcome obviousness.

Respectfully, the Board should find claim 1 unpatentable.

C. Grounds 1-2 Demonstrate Claims 2-13 Are Obvious

EMK's half-hearted arguments regarding dependent claims 2-13 likewise fail. Grounds 1-2 demonstrate, in detail and supported by Avation's expert, that claims 2-13 are obvious. Paper 2, 33-44, 53-63. The best EMK can muster in response is, for nearly every dependent claim, to refer to its deficient arguments regarding claim 1. Paper 12, 24-30, 32-38. But because claim 1 is unpatentable, dependent claims 2-13 fail for the same reasons.

Beyond simply pointing to its claim 1 arguments, the only dependent claim EMK further addresses is claim 4, but these arguments are likewise without merit. *Id.*, 24-26, 33-35. Although EMK concedes a 30-minute/week treatment regimen was disclosed in the art (including in Svihra itself), EMK suggests a POSA would not have expected success using that schedule for PTN branch stimulation. *Id.* The record evidence, however, shows a POSA would have expected success because ***this precise treatment duration and frequency*** was known and successfully used to treat OAB/incontinence. Paper 2, 35-36, 55; Ex.1003, ¶¶160-62. Moreover, other teachings in the art—such as Grey's disclosure that conditions treatable via

PTN electrostimulation could also be treated via PTN branch electrostimulation ***with similar efficacy***, along with others discussed at length above and in the Petition (*e.g.*, Mann, Boveja, Ponsford, Rhodes)—would have given a POSA a reasonable expectation that a treatment schedule effective for PTN stimulation would be equally effective for PTN branch stimulation. *E.g.*, Paper 2, 27; Ex.1003, ¶¶83, 142. Contrary to EMK’s suggestion otherwise, no more is required. *E.g.*, *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1333 (Fed. Cir. 2018) (“conclusive proof of efficacy” not required for obviousness).

Deposition testimony of Dr. Wingeier’s cited by EMK shows nothing to the contrary. Paper 12, 26. None of Dr. Wingeier’s cited testimony cited by EMK relates to treatment schedules, PTN versus PTN branch stimulation, or whether different efficacy would be expected using a given treatment schedule to stimulate one nerve versus another. *See* Ex.2003, 24:22-25:23⁵ (testimony regarding improper electrode placement and stimulation intensity), 53:15-54:12 (testimony regarding unintentional recruitment of other nerve groups). EMK’s attempt to twist Dr. Wingeier’s wholly-unrelated testimony to fit its unsupported argument is a tacit admission that claim 4 is invalid.

⁵ EMK citation to page 26, lines 16-23 of Ex.2003 appears to be a typographical error. The quoted language appears on page 25.

IV. CONCLUSION

For the reasons set forth in Avation's Petition (Paper 2) and above, the Board should respectfully find Challenged Claims 1-13 of the '742 Patent unpatentable and cancel the claims.

Dated: September 26, 2025

Respectfully submitted,

/s/ Todd R. Tucker

Todd R. Tucker (Reg. No. 40,850)

ttucker@calfee.com

Kyle Deighan (Reg. No. 75,525)

kdeighan@calfee.com

CALFEE, HALTER & GRISWOLD LLP

The Calfee Building

1405 East Sixth Street

Cleveland, Ohio 44114

P: 216-622-8200

F: 216-241-0816

*Attorneys for Petitioner Avation Medical,
Inc.*

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 5,513 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

/s/ Todd R. Tucker

Todd R. Tucker (Reg. No. 40,850)

ttucker@calfee.com

Kyle Deighan (Reg. No. 75,525)

kdeighan@calfee.com

CALFEE, HALTER & GRISWOLD LLP

The Calfee Building

1405 East Sixth Street

Cleveland, Ohio 44114

P: 216-622-8200

F: 216-241-0816

*Attorneys for Petitioner Avation Medical,
Inc.*

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing **PETITIONER’S REPLY TO PATENT OWNER’S RESPONSE** and **ACCOMPANYING EXHIBITS (Exs.1091-1096, 1099-1100)** 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):

David Gerasimow
dave@gerasimowlaw.com
The Law Offices of David A. Gerasimow, P.C.
211 W. Wacker Dr., Ste. 1717
Chicago, IL 60606
Tel: (312) 919-4254

Eran Steinberg
venture@erasteinberg.com
137 Granville Way
San Francisco, CA 94127
Tel: (415) 902-7026

Dated: September 26, 2025

/s/ Kyle Deighan

*Attorney for Petitioner Avation Medical,
Inc.*