

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,

Petitioner,

v.

EMKINETICS, INC.,

Patent Owner.

Review No. IPR2024-01375

U.S. Patent No. 11,224,742

PATENT OWNER'S RESPONSE

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PATENT OWNER'S TABLE OF EXHIBITS

Exhibit No.	Description
2001	<i>[Reserved]</i>
2002	<i>[Reserved]</i>
2003	Certified June 19, 2025, Transcript of June 5, 2025, Deposition of Dr. Brett Wingeier ¹

¹ Pin citations to the deposition transcript in this Response are made with reference to internal pagination and line numbering (*i.e.*, the pagination and line numbering of the certified transcript).

I. Introduction & Summary of Argument

Pursuant to 37 C.F.R. § 42.120 and the Board’s Scheduling Order (Paper 8 at 12; *see also* Paper 9 (Joint Stipulation to Modify Due Dates)), Patent Owner EMKinetics, Inc. (“Patent Owner”) submits this Response (Paper 12) to the Petition for *Inter Partes* Review (the “Petition,” Paper 2) filed by Petitioner Avation Medical, Inc. (“Petitioner”), setting forth reasons why the Petition fails to establish the unpatentability of claims 1-13 (the “challenged claims”) of U.S. Patent No. 11,224,742 (the “’742 Patent”). The principal reason is that Petitioner failed to carry its statutory burden of proving the unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 316(e). Specifically, Petitioner has not established unpatentability based on either of the two grounds (Grounds 1 or 2) identified in the Petition. (*See* Paper 2 at 2-3).

This Response may be summarized as follows:

1. **Grounds 1 & 2.** Petitioner has failed to carry its burden of proving that the non-patent references (Exs. 1004-05, 1008-17, 1024, 1027-28, 1030, 1035, 1037-39, 1041-43, 1085, 1088) cited in the Petition were publicly accessible before any alleged critical date and has failed to carry its attendant burden of proving that these references qualify as prior art. These references include the primary references on which both grounds in the Petition (Grounds 1 and 2) are based (Svihra, Ex. 1004; Amarenco, Ex. 1005), as well as many other references on

which these grounds are further based (Exs. 1008-17, 1024, 1027-28, 1030, 1035, 1037-39, 1041-43, 1085, 1088). Whether Petitioner has carried its burden of proving the public accessibility of these references depends on the information and evidence provided and identified by Petitioner in the Petition. Here, Petitioner has not provided additional information or evidence since the Petition was filed. Although Petitioner did not cite any evidence of public accessibility in the Petition beyond copies of the references themselves, the Board concluded that Petitioner presented a case of public accessibility sufficient for institution. (Paper 7 at 11-14). With review having been instituted, the Petition, which was not supplemented, does not satisfy the higher legal standard that now applies. *Compare* 35 U.S.C. § 314(a) *with* 35 U.S.C. § 316(e). Accordingly, Grounds 1 and 2 of the Petition have not been proven. This topic is discussed in greater detail in Part II below.

2. **Ground 1.** Ground 1 further fails because Petitioner has not demonstrated the obviousness of the challenged claims. Ground 1 is explicitly premised on the knowledge of a person of ordinary skill in the art, which Petitioner expresses as a series of appreciations that such a person supposedly would have had at the time of invention. (*See* Paper 2 at 27). However, the references that are said by Petitioner to evidence this knowledge do not teach all that Petitioner says that they teach. To the contrary, their teachings do not support many of the broad notions advanced by Petitioner in support of what a skilled artisan would have

known at the time of invention. Nor do they supply sufficient motivation to modify Svihra (Ex. 1004) to arrive at the invention recited in claim 1 of the '742 Patent. Without these teachings, Petitioner cannot and does not carry its burden of demonstrating that the claimed invention involved simple substitution, represented a known improvement, or had a reasonable expectation of success. (*See* Paper 2 at 28). This is particularly true in the case of claim 4, where the Petition fails to present any evidence on whether stimulating a different nerve would require any modification to a treatment schedule to treat overactive bladder or incontinence, as claimed. Petitioner's challenges to claims 2-3 and 5-13 fail for at least the same reasons as the challenges against claim 1.

3. **Ground 2.** Ground 2 swaps Amarenco (Ex. 1005) for Svihra (Ex. 1004) but is otherwise the same as Ground 1. For the same reasons that Ground 1 failed, Ground 2 also fails. Petitioner has not shown that a person of ordinary skill in the art would have found it obvious to modify Amarenco (Ex. 1005) as claimed. The references cited do not show, by a preponderance of the evidence, that a person of ordinary skill in the art would have possessed the knowledge on which Petitioner's obviousness assertions are based. Without having sufficiently shown this knowledge, Petitioner cannot prove the obviousness of the challenged claims under Ground 2.

Patent Owner's specific responses now follow.

II. Grounds 1 & 2 Fail Because Petitioner Did Not Provide Evidence Regarding the Public Accessibility of Non-Patent References

Petitioner fails to carry its burden of proving that the non-patent references cited in the Petition (Paper 2) – *e.g.*, Svihra (Ex. 1004) and Amarenco (Ex. 1005), among other items – qualifies as a prior art printed publication. To demonstrate that a document is a printed publication, Petitioner must show that it was “‘sufficiently accessible to the public interested in the art’ before the critical date.” *Align Tech., Inc. v. Dental Monitoring SAS*, IPR2023-01369, Paper 42 at 25 (PTAB Mar. 3, 2025) (quoting *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989)) (finding reference qualifies as printed publication based on declaration, not present in this case, setting forth personal knowledge concerning facts of publication). Here, Petitioner fails to show that any of the non-patent references was publicly accessible because, in each case, there is no record evidence of public accessibility other than the document itself.

Neither declaration submitted with the Petition, whether the attorney declaration (Ex. 1053) or expert declaration (Ex. 1003), provides evidence concerning public accessibility. For example, the attorney declaration submitted with the Petition declares for each reference, *in toto*, that “[a] true and correct copy of [the reference, *e.g.*, Svihra, Ex. 1004] is attached” to such declaration. (Ex. 1053 ¶ 6; *see id.* ¶ 7 (same for Amarenco, Ex. 1005), ¶¶ 8-18, 21-22, 24, 29, 31-36, 44, 47 (same for other documents alleged to constitute printed publications, Ex. 1008-

17, 1024, 1027-28, 1030, 1035, 1037-39, 1041-43, 1085, 1088)). The attorney declaration does not recite any further allegations concerning Svihra (Ex. 1004), Amarenco (Ex. 1005), or any other non-patent references (Exs. 1008-17, 1024, 1027-28, 1030, 1035, 1037-39, 1041-43, 1085, 1088). It does not, for instance, declare that any of these references were publicly accessible prior to the alleged critical date. It does not, by way of further example, express any personal knowledge or explain how the copies of these documents were obtained or how they were obtained, or provide or identify any evidence tending to establish that they could have been obtained from a library, or some other qualifying public source, before the alleged critical date.

The expert declaration submitted with the Petition (Ex. 1003) similarly identifies no evidence tending to establish the public accessibility of any of the non-patent references identified in the Petition. Although the expert claims that certain items were “published,” these claims are not based on any stated personal knowledge. The expert does not claim, for example, any familiarity with any of the documents prior to these proceedings and does not claim any personal or particularized knowledge of any library or database system that would inform the numerous questions of public accessibility raised by the Petition. Like the attorney declaration (Ex. 1053), the expert declaration (Ex. 1003) does not explain why information concerning the source or publication of any of these documents could

not have been obtained by reasonable efforts and, consistent with the Rules, submitted with the Petition or at any time since then.

On this topic, the applicable statutes and rules require *inter partes* review petitions to be complete. The petition must identify, with particularity, the evidence supporting the grounds on which the challenge is based. 35 U.S.C. § 312(a)(3); 37 C.F.R. § 42.104(b). Here, the Petition (Paper 2) failed to identify any evidence supporting public availability. Even though a petition is supposed to be complete, there are opportunities for supplementation. For instance, where a preliminary response is filed, the petitioner may seek leave to file a reply with further evidence. 37 C.F.R. § 42.108(c). In this case, Patent Owned filed a Preliminary Response (Paper 6), but Petitioner did not seek leave to file a reply with further evidence concerning the public accessibility of any of the non-patent references on which the Petition relies. After institution, the petitioner may submit supplemental information in support of its petition with the Board's permission. 37 C.F.R. § 42.123. On these issues, the Decision Granting Institution of *Inter Partes* Review (Paper 7), the Board stated that "[t]he parties may develop this issue further at trial, potentially including supplemental information under 37 C.F.R. § 42.123 (as to public availability) and supplemental evidence under 37 C.F.R. § 42.64(b) (as to admissibility)." (Paper 7 at 13-14).

Since the Board’s Decision, Petitioner has not sought to develop the issue of public accessibility through supplemental information or evidence even though it bears the burden of proving the same. As a result, the evidence of record is insufficient to establish public accessibility of any of the non-patent references cited in the Petition at any relevant time. *See Medivis, Inc. Novarad Corp.*, IPR2023-00042, Paper 37 (PTAB Apr. 23, 2024) (denying request for rehearing on a finding of failure to establish public accessibility, notwithstanding “reliance on a copyright date, statements on the face of [the reference], and mere assertion that [the reference] was cited by seven publications”). In *Medivis*, the Board stated that, if a petitioner cites no evidence for public accessibility in the petition, except for the references themselves, “[t]his is insufficient and tantamount to submitting no proof of public accessibility.” *Id.* at 4.

This case is no different and, potentially, even weaker. Fundamentally, Petitioner assumes that each non-patent reference was publicly accessible and asks the Board to do the same. Yet, the Board, in other matters, has stated that there is no presumption of public accessibility, as the burden of proof always remains with the petitioner. *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 16 (PTAB Dec. 20, 2019) (precedential) (“[T]here is no presumption ... in favor of finding a reference to be a printed publication under § 42.108(c) or any other authority.”). Patent Owner respectfully submits that, in these proceedings, the

record is particularly devoid of any evidence of public accessibility and therefore does not establish unpatentability as required by statute. 35 U.S.C. § 316(e).

The consequence is that Petitioner has failed to carry its burden of proving by a preponderance of the evidence that the challenged claims are invalid based on Grounds 1 and 2 identified in the Petition. Ground 1 relies on non-patent reference Svihra (Ex. 1004) as the “primary” reference. (Paper 2 at 2). However, Petitioner has not shown that Svihra was publicly accessible prior to the critical date. Its accessibility today is irrelevant no matter how easily shown. Ground 2 similarly relies on non-patent reference Amarenco (Ex. 1005) as the “primary” reference (Paper 2 at 3); however, Petitioner has not shown that Amarenco was publicly accessible prior to the critical date. Each of Grounds 1 and 2 further relies on the “Knowledge of POSA [person of ordinary skill in the art]” (Paper 2 at 2-3), but these contentions are based almost entirely on non-patent references for which public accessibility has not been shown. (*See, e.g.*, Paper 2 at 3-11 (citing non-patent literature Exs. 1008-17, 1041, 1088); *see also id.* at 34 (citing non-patent literature Ex. 1027), 37 (Exs. 1028, 1030, 1042-43), 41 (Ex. 1035), 41 (Ex. 1037), 55 (Exs. 1038-39)).

Accordingly, the Petition, which was never supplemented by Petitioner, does not establish unpatentability of the challenged claims based on Grounds 1 or 2.

III. Claim Construction

Although a petition for *inter partes* review “must identify ... [h]ow the challenged claim is to be construed,” 37 C.F.R. § 42.104(b)(3), the Petition here asserts that “no terms require construction for purposes of this Petition.” (Paper 2 at 22).

In deposition, Petitioner’s expert testified that the plain and ordinary meaning of “directly,” in the context of “directly” stimulating a nerve structure as recited in claim 1 of the ’742 Patent, means “stimulating with the intent of creating an effect in that structure.” (Ex. 2003 at 22:7-8). A contrasting example, that of “indirectly” stimulating a nerve structure, according to Petitioner’s expert, is “stimulating the vagus nerve to have a follow-on effect on some distant brain network.” (*Id.* at 22:11-17; *see also, e.g.*, Ex. 1025, Fig 2., elt. 60 (showing that vagus nerve 60 originates in the neck and is not part of the brain)).

Thus, according to Petitioner’s expert, “directly” in claim 1 means delivering an electric stimulus to a branch of the posterior tibial nerve with the intent of creating an effect in a branch of the posterior tibial nerve.

In deposition, Petitioner’s expert further confirmed that the language in claim 1 of the ’742 Patent, “such that the branch directly receives the electrical stimulation to treat overactive bladder or incontinence,” was an element of the challenged claims, and that the prior art would need to teach this element in order

for claim 1 to be anticipated or rendered obvious by the prior art. (Ex. 2003 at 20:15-21:7). Stated otherwise, according to Petitioner's expert, the challenged claims require treating overactive bladder or incontinence.

IV. Ground 1 Further Fails Because Petitioner Has Not Demonstrated the Obviousness of the Challenged Claims.

A. Claim 1

Petitioner has not demonstrated the obviousness of claim 1 of the '742 Patent based on Ground 1, even if the Board were to conclude that Petitioner sufficiently demonstrated the public accessibility of the cited non-patent references without any declaration averring to public accessibility before the critical date of the '742 Patent. In addition, as is now explained, Petitioner has not demonstrated the knowledge of a person of ordinary skill in the art at the time of invention or that such a person would have been motivated to modify Svihra (Ex. 1004) to arrive at the claimed invention recited in claim 1.

Claim 1 recites a method of treating overactive bladder or incontinence by, among other things, "non-invasively positioning a first portion of a patient's body relative to an electrical stimulator such that a branch of a posterior tibial nerve ... is directly targeted by the electrical stimulator" and "delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve such that the branch directly receives the electrical stimulation to treat overactive bladder or incontinence." (Paper 2 at 72).

The parties agree that Svihra (Ex. 1004) does not disclose delivering electrical stimulation directly to a branch of the posterior tibial nerve to treat overactive bladder or incontinence. (*See* Paper 2 at 24). The Petition does not identify any teaching, suggestion, or motivation in Svihra (Ex. 1004) to directly target any nerve other than the posterior tibial nerve to treat overactive bladder or incontinence.

Rather, the Petition relies on dozens of references to support at least four separate categories of knowledge a person of ordinary skill in the art is said to have possessed at the time of invention to supply the teachings missing from Svihra. (*See, e.g.*, Paper 2 at 27; *see also id.* at 24-31, 32-33). Petitioner's contentions, however, do not withstand scrutiny, and Petitioner has not carried its burden of demonstrating obviousness on Ground 1.

1. Petitioner has not shown that a POSA would have appreciated that conditions treatable via electrostimulation of the PTN can also be treated by stimulating PTN branches.

Petitioner contends, incorrectly, that “a POSA would have appreciated ... [c]onditions treatable via electrostimulation of the PTN can also be treated by stimulating ... PTN branches with similar efficacy.” (Paper 2 at 27). In principal support, Petitioner cites Grey. (*Id.* (citing Ex. 1081, 1:35-53, 2:53-60)). However, Grey does not teach that conditions treatable via electrostimulation of the posterior tibial nerve can also be treated by stimulating PTN branches with similar efficacy,

as asserted by Petitioner. Grey instead teaches that stomach symptoms associated with non-identified conditions can be treated by electro-acupuncture of traditional acupuncture points. (Ex. 1081 at 1:35-36; *see also id.*, Abstract (referring to stomach symptoms)). Specifically, Grey teaches using electro-acupuncture to emulate the “same affect [sic] as stimulation of the traditional SP and BL acupuncture points.” (*Id.* at 2:53-60). Petitioner does not explain the relevance of “traditional SP and BL acupuncture points” to this matter. (*See, e.g.*, Paper 2 at 13). Grey explains that “SP” refers to the “Spleen Channel” but does not further describe this Channel. (Ex. 1081 at 2:63). Petitioner’s expert, “[n]ot being a traditional Chinese physician” (Ex. 2003 at 67:10), could not provide any further description of the Spleen Channel. (*Id.* at 67:7-15). Grey does not define the traditional “BL” channel at all, and Petitioner’s expert could not define it either in deposition. (*Id.* at 67:16-68:6). In deposition, Petitioner’s expert further acknowledged that that persons in the field would not consult traditional Chinese medicine sources in their work. (Ex. 2003 at 69:6-70:2).

Grey teaches that stomach symptoms associated with non-specified conditions can be treated by electro-acupuncture of traditional acupuncture points, not well-defined in Grey or in the record, with the same effect of traditional acupuncture. But Grey does not support Petitioner’s claim that a person of ordinary skill in the art would have appreciated conditions treatable via electrostimulation of

the posterior tibial nerve can also be treated by stimulating PTN branches with similar efficacy, as Petitioner asserts. (*See* Paper 2 at 27). At most, such a person would have understood 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, whatever they may be. And, the only cited paragraph in the Declaration of Petitioner's expert (Ex. 1003 ¶ 83) adds nothing beyond citing the same portions of Grey as the Petition, already discussed as not supporting the broad claim (Paper 2 at 27) that a skilled artisan would have understood that conditions treatable by stimulation of the PTN could also be treated by stimulation of a branch thereof.

Grey does not support the broad notion, advanced by Petitioner (Paper 2 at 27), that a POSA would have appreciated that conditions treatable via electrostimulation of the PTN can also be treated by stimulating PTN branches. Without any other distinct support, Petitioner has not shown that POSA would have possessed this appreciation, on which Petitioner's obviousness assertions are based.

2. Petitioner has not shown that a POSA would have appreciated that OAB/incontinence can be treated by electrically stimulating branches of the PTN.

Petitioner further contends, incorrectly, that "a POSA would have appreciated ... OAB/incontinence can be treated by electrically stimulating ... the

PTN and its branches.” (Paper 2 at 27). From Svihra (Ex. 1004), a skilled artisan could have understood that OAB/incontinence can be treated by electrically stimulating the PTN. As mentioned, the Petition does not identify any teaching, suggestion, or motivation in Svihra (Ex. 1004) to directly target any nerve other than the posterior tibial nerve to treat overactive bladder or incontinence. Thus, from Svihra (Ex. 1004), a skilled artisan would have not understood that OAB/incontinence can be treated by electrically stimulating a branch of the PTN.

This alleged understanding has not been shown to come from the secondary references cited by Petitioner. (Paper 2 at 27 (citing Ex. 1084 (Mann), 11:50-12:7; Ex. 1080 (Boveja), [0028-29], [0180], cl. 1)). Mann, in cited portions (Ex. 1084, 11:50-12:7), discloses stimulating the pudendal nerve and its branches to treat incontinence. Petitioner’s expert, “not [being] a[n] anatomist or physician,” was unable to confirm whether the pudendal nerve is the main nerve of the perineum (Ex. 2003 at 46:23-47:3) or whether the urethral branch is a branch of the pudendal nerve (*id.* at 47:10-21 (also: “I am not an expert in perineal nervous anatomy.”); 47:12-17 (also: “sounds reasonable” that the urethral branch is a branch of the pudendal nerve)). Both would show direct stimulation of the nerves that control the bladder to treat bladder conditions, which is not the claimed invention, and it is not explained how it would lead to the claimed invention.

While Mann notes that the pudendal nerve has certain sacral roots (Ex. 1084, 11:50-51), Mann does not teach that just any nerve having a sacral root can be stimulated to treat overactive bladder or incontinence. The anatomical diagram in the Petition (Paper 2 at 9) depicts the posterior tibial nerve having different origins in the sacral plexus compared to the pudendal nerve being considered in cited portions of Mann.

While Mann references the posterior tibial nerve as another potential stimulation location (Ex. 1084 at 12:41-64), it never identifies a branch of the posterior tibial nerve as another possible location. Rather, Mann suggests between the “level of the ankle” and “the level of the knee.” (*Id.*). There is seemingly no dispute that no branch of the posterior tibial nerve is located at the level of the knee. With respect to Mann’s note concerning the “level of the ankle,” Mann clarifies that she is still referring to the “tibial nerve.” (*Id.*). Another anatomical diagram in the Petition (Paper 2 at 10) depicts the tibial nerve at the level of both the knee and ankle, thus confirming that Mann is referring to the PTN and not one of its branches even when referring to the ankle. Mann identifies numerous other anatomical structures, at the level of the ankle and of the knee, none of which are nerves, let alone a branch of the posterior tibial nerve. (*Id.*; *see also* Ex. 2003 at 59:10-60:5 (Petitioner’s expert testifying and confirming that each of these anatomical structures are not nerves but rather bones, *etc.*)). Thus, Mann does not

supply the appreciation, alleged by Petitioner (Paper 2 at 27), that a skilled artisan would have understood that overactive bladder or incontinence can be treated by direct stimulation of a branch of the posterior tibial nerve.

Boveja (Ex. 1080) does not supply this appreciation either. In the paragraphs cited in the Petition, Boveja teaches “[n]euromodulation ... applies pulsed electrical stimulation to the sacral nerves.” (*Id.* at [0028]). Boveja identifies the sacral nerves as being located at the bottom of the spine. (*Id.*, Fig. 3A, elt. 54 (“sacral nerves”)). In deposition, Petitioner’s expert confirmed that the “sacral region of the spinal cord is located at the bottom of the spine.” (Ex. 2003 at 61:12-14). Thus, Boveja discloses, at most, stimulation of the nerves at the bottom of the spine to treat bladder conditions. It does not supply an appreciation that overactive bladder or incontinence could be treated by directly stimulating a branch of the posterior tibial nerve. While Boveja references other nerves having sacral roots (*e.g.*, the tibial nerve), Boveja discloses stimulation their sacral roots to treat overactive bladder or incontinence. Boveja states that, “[o]f the sacral nerve roots the S₃ root is the most practical for use in chronic pulsed electrical stimulation, although S₄ and S₂ along with S₃ may be stimulated.” (Ex. 1003 at [0029]). While the tibial nerve has sacral roots, Boveja does not disclose stimulating nerves other than the sacral roots or nerves outside of the sacral region. (Ex. 1080 (Boveja), [0028-29], [0180], cl. 1). Stated otherwise, Boveja at most teaches stimulation of

the sacral portion of the tibial nerve, not a branch of the PTN, outside the sacral region, and thus Boveja adds nothing to Svihra (Ex. 1004), which likewise lacks any teaching or suggestion to directly stimulate a PTN branch. Boveja does not teach or suggest that anything outside the sacral region, such as a branch of the posterior tibial nerve, could be directly stimulated to treat anything, such as overactive bladder or incontinence. The Declaration of Petitioner's expert adds nothing further regarding Boveja in the cited portion. (Ex. 1003 ¶ 83).

3. Petitioner has not shown that directly targeting and stimulating PTN branches causes signals to travel to the PTN and upstream to the spinal cord via the sacral nerve roots.

Petitioner further contends, incorrectly, that “a POSA would have appreciated ... [d]irectly targeting and stimulating PTN branches causes signals to travel to the PTN and upstream to the spinal cord via the sacral nerve roots,” citing Ponsford (Paper 2 at 27 (citing Ex. 1085 at 188-89)). Ponsford discloses stimulation “applied to the sole [of the foot] just lateral to the first metatarsal, the anode level with metatarsophalangeal joint, the cathode thus overlying the first common digital nerve sub-serving contiguous surfaces of the great and second toes.” (Ex. 1085 at 188). In other words, the foot. Recordings were made to assist in the diagnosis of peripheral neuropathy. (*Id.*). Ponsford notes that some of the subjects in the study had lumbosacral lesions. (*Id.* at 189). Ponsford later notes these lesions are “associated with sensory loss in the medial plantar territory.” (*Id.*

at 191; *see also* Ex. 2003 at 72:22-23 (“You know, there’s a lot of things that can cause neural lesions.”). Meaning, according to Ponsford, sensory loss in the foot is associated with the presence to lumbosacral lesions in the spine. But, this does not establish, as Petitioner contends (Paper 2 at 27), that a skilled artisan would have appreciated directly targeting and stimulating PTN branches causes signals to travel to the PTN and upstream to the spinal cord via the sacral nerve roots, or have an effect of treating any condition. And, again, the Declaration of Petitioner’s expert does not add anything further about Ponsford in the cited paragraph. (Ex. 1003 ¶ 83).

At deposition, “asked ... about the relationship between the sacral nerves and the nerves that control bladder function,” Petitioner’s expert explained that it is “a hard question to answer,” not least because he is “not ... a neuroanatomist,” but because, even in 2025, “there’s still some scientific work that continues to be done ... on the mechanism of neuromodulation for overactive bladder.” (Ex. 2003 at 112:23-114:13). And, contradicting the simple notion expressed in the Petition that knowledge of sacral root stimulation would lead a skilled artisan to stimulation of a branch of the PTN (Paper 2 at 27), Petitioner’s expert continued, explaining that, “[s]o ... it’s hard to say upstream or downstream. It’s ... a more complicated system than that.” (Ex. 2003 at 112:23-114:13). The record evidence does not

support the simplicity with which the Petitioner views manipulation of the human nervous system.

4. Because the disclosures do not support Petitioner's view of a POSA's knowledge, Petitioner has not shown that it would have been obvious to modify Svihra (Ex. 1004) to arrive at the claimed invention.

Petitioner claims that modifying Svihra (Ex. 1004) to arrive at the invention recited in claim 1 of the '742 Patent would have been obvious "[b]ased on these disclosures on a POSA's knowledge." (Paper 2 at 27). But, as discussed above, the disclosures do not support Petitioner's contentions as to what a POSA would have appreciated at the time of invention. Grey (Ex. 1081) teaches that stomach symptoms associated with non-specified medical conditions can be treated by electro-acupuncture of traditional acupuncture points – not that conditions treatable via electrostimulation of the PTN can also be treated by stimulating PTN branches. Like Svihra (Ex. 1004), Mann (Ex. 1084) teaches treating overactive bladder by directly stimulating various points on the PTN but not any branch thereof, and Boveja (Ex. 1080) is limited to stimulation of nerves within the sacral region, even if those nerve structures may extend outside of that region. Neither Mann nor Boveja would lead a POSA to appreciate that overactive bladder could be treated by electrically stimulating a branch of the PTN, as claimed. And, Ponsford (Ex. 1085) simply observes a relationship between weak responses in the foot, when the foot is stimulated, on the one hand, and certain medical conditions, on the other. It

does not establish that any treatment modality can be achieved by stimulation of the foot, let alone treatment of a condition affecting systems controlled by remote and unrelated nerve structures.

Without having sufficiently demonstrated “a POSA’s knowledge,” Petitioner’s obviousness argument, which is based on “a POSA’s knowledge,” fails. (*See* Paper 2 at 27-28). The lack of support for Petitioner’s allegations concerning a “POSA’s knowledge” renders Petitioner’s consideration of the *KSR* factors irrelevant. (*See* Paper 2 at 28). Still, Petitioner’s consideration of *KSR* does not establish obviousness.

To begin, while Petitioner claims without further citation that substituting one nerve in the human body for another, as the target for electrical stimulation for the purposes of treating a specific disease, is “simple substitution,” the record presented by Petitioner does not support this conclusion by a preponderance of the evidence. For example, Rhodes (Ex. 1086) explains that “[m]odern animals, humans among them, have marvelously complex nervous systems.” (Ex. 1086 at 1:24-26). Petitioner’s expert, in deposition, confirmed that “the neuroanatomy is always – is always very complicated.” (Ex. 2003 at 113:4-6; *see also id.* at 62:17 (“Neuroanatomy is always complicated.”)). He testified that “the nervous system is complex” (*id.* at 54:9-10), “often in neuroanatomy ... one is surprised” (*id.* at 62:25-63:1), and that “[a] lot of this anatomy often gets, you know, very complex

and ... varied across patients.” (*Id.* at 47:7-9). Without sufficiently demonstrating “a POSA’s knowledge” and by disregarding any complexity of the human nervous system, Petitioner’s obviousness argument based on “simple substitution” fails.

The same can be said of Petitioner’s “obvious to try” argument. (*See* Paper 2 at 28). The references cited by Petitioner focus on direct stimulation of the nerve structures controlling bladder function and/or the upstream sacral nerve roots, and Petitioner never identifies any suggestion in the record to try direct stimulation of each and every nerve in the human body to treat overactive bladder or incontinence with any reasonable expectation of success.

As to direct stimulation of a branch of the posterior tibial nerve to treat overactive bladder or incontinence being “an obvious design choice,” as asserted by Petitioner (Paper at 29), Petitioner has not demonstrated as much. While Petitioner claims that “the ’742 patent specification does not ascribe any significant or criticality to targeting a branch of the PTN” (*id.*), 35 U.S.C. § 112 does not require any such ascribing in the patent specification, and in any event, Section 112 is not at issue in these *inter partes* proceedings. In support of its “design choice” contention, Petitioner observes only that one “could” have directly stimulated a branch of the posterior tibial nerve. (Paper 2 at 49). Petitioner does not assert that a POSA would have been motivated to do so as an obvious design choice. Although

Petitioner asserts that “similar results” could have been expected, there is no explanation provided for that assertion. (*Id.*)

And while Petitioner claims without further citation that modifying Svihra’s technique to target a branch of the posterior tibial nerve would have simply involved applying known techniques to “improve” a known process (Paper 2 at 28), the record does not support the conclusion that a POSA would have considered directly stimulating PTN branches to constitute an improvement on stimulating the PTN itself. The only improvement alleged by Petitioner’s expert, offered without citation, is that patient convenience would have been improved if Svihra’s (Ex. 1004) electrodes were “placed in the patient’s shoe, where they could be concealed more easily than if the electrodes were on the patient’s ankle.” (Ex. 1003 ¶ 87). Petitioner’s expert does not explain why a patient would consider it more convenient to walk on electrodes or to otherwise squeeze electrodes into their shoes or given these questions why this would be an obvious design choice when the purpose of the invention is treating a medical condition. Petitioner’s expert does not, for example, explain any relationship between the patient’s convenience and therapeutic efficacy. And Petitioner’s expert does not offer any other alleged improvement.

Petitioner also incorrectly claims that a POSA would have expected success in modifying Svihra (Ex. 1004). (Paper 2 at 28). Petitioner notes the “successful

use of electrical stimulation directly targeting sacral nerves.” (*Id.*). But the use of electrical stimulation to directly targeting sacral nerves at the base of the spine (*e.g.*, Boveja) does not lead to, or otherwise suggest, directly stimulating any nerve structure outside the sacral region. Boveja teaches sacral root stimulation by stimulating the sacral region, and Mann focuses on the same thing, while permitting stimulation of the posterior tibial nerve between the ankle and knee. These two disclosures, alone or in combination, do not show that a POSA would have had a reasonable expectation of success in treating overactive bladder or incontinence by stimulating a branch of the PTN.

Regarding Petitioner’s final contention about what a skilled artisan would have appreciated – namely, “how to directly target and deliver stimulation directly to PTN branches” (Paper 2 at 27 (1085 (Ponsford), 188-89; Ex. 1086 (Rhodes), 3:11-18, 3:57-4:21; Ex. 1003, ¶ 83)) – does not supply any motivation to arrive at the claimed invention or a reasonable expectation of success in treating overactive bladder or incontinence. That one knew how to stimulate a branch of the PTN does not establish that one would have motivated to do so to treat overactive bladder or incontinence, as claimed. It does not establish that a skilled artisan would have had any expectation of success in treating overactive bladder or incontinence upon direct stimulation of a PTN branch, as claimed.

Petitioner’s obviousness challenge to claim 1, in Ground 1, fails.

B. Claim 2

Petitioner has not shown by a preponderance of the evidence that claim 2 of the '742 Patent would have been obvious under Section 103 based on Ground 1 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103 based on Ground 1. (*See* Part IV.A). Any additional arguments made by Petitioner do not support the invalidity of claim 2 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 2.

C. Claim 3

Petitioner has not shown by a preponderance of the evidence that claim 3 of the '742 Patent would have been obvious under Section 103 based on Ground 1 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103 based on Ground 1. (*See* Part IV.A). Any additional arguments made by Petitioner do not support the invalidity of claim 3 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 3.

D. Claim 4

Petitioner has not shown by a preponderance of the evidence that claim 4 of the '742 Patent would have been obvious under Section 103 based on Ground 1 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section

103 based on Ground 1. (*See* Part IV.A). Any additional arguments made by Petitioner do not support the invalidity of claim 4 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 4.

In addition, Petitioner has not demonstrated that a POSA would have found it obvious to modify Svihra (Ex. 1004) to apply direct stimulation to a branch of the PTN to treat overactive bladder or incontinence by “activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient” for overactive bladder or incontinence, as recited in claim 4. While Svihra (Ex. 1004) may disclose “activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient” for overactive bladder or incontinence, the Petition makes no attempt to show that Svihra (Ex. 1004) – as modified in hindsight to directly target a branch of the posterior tibial nerve – would be successful in treating overactive bladder or incontinence with no modification to the treatment schedule. Although the proposed modification of Svihra (Ex. 1004) would directly target a different nerve more remote from the sacral plexus, the spine, the bladder, *etc.* than the one disclosed, the Petition does not provide any evidence or argument that the same treatment schedule would have had a reasonable expectation of success in treating overactive bladder or incontinence, as claimed, or any success at all.

It might stand to reason that more or less stimulation would need to be applied to achieve the claimed therapeutic effect because different nerves were involved. Indeed, Petitioner's expert acknowledged that "you know, the – the nervous system is complex. There – there may be cases where – where the undesired effects actually – actually decrease the effect of stimulation." (Ex. 2003 at 54:9-12). Even if the treatment would have been the same, the Petition makes no such showing, and Petitioner's expert agreed that distance alone may eliminate any therapeutic effect. (*Id.* at 25:1-6 (explained that "[i]f the field strength was too low, for instance, or if you were too distant from it, it would be possible to have – it would be *possible to not have the intended therapeutic effect.*" (emphasis added))); *id.* at 26:16-23 ("if you are too distant ... such that the energy that's received by the structure is too little to have the intended neuromodulatory effect, then – then, indeed, you would be trying to stimulate but – but not having the intended effect.")). Accordingly, Petitioner has not demonstrated the invalidity of claim 4 by a preponderance of the evidence because Petitioner asks the Board to assume, incorrectly and contrary to the testimony of Petitioner's expert, that all stimulation locations are the same and would be similarly effective.

E. Claim 5

Petitioner has not shown by a preponderance of the evidence that claim 5 of the '742 Patent would have been obvious under Section 103 based on Ground 1 for

at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103 based on Ground 1. (*See* Part IV.A). Any additional arguments made by Petitioner do not support the invalidity of claim 5 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 5.

F. Claim 6

Petitioner has not shown by a preponderance of the evidence that claim 6 of the '742 Patent would have been obvious under Section 103 based on Ground 1 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103 based on Ground 1. (*See* Part IV.A). Any additional arguments made by Petitioner do not support the invalidity of claim 6 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 6.

G. Claim 7

Petitioner has not shown by a preponderance of the evidence that claim 7 of the '742 Patent would have been obvious under Section 103 based on Ground 1 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claims 1 and 6 of the '742 Patent would have been obvious under Section 103 based on Ground 1. (*See* Part IV.A). Any additional arguments made

by Petitioner do not support the invalidity of claim 7 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 7.

H. Claim 8

Petitioner has not shown by a preponderance of the evidence that claim 8 of the '742 Patent would have been obvious under Section 103 based on Ground 1 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103 based on Ground 1. (*See* Part IV.A). Any additional arguments made by Petitioner do not support the invalidity of claim 8 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 8.

I. Claim 9

Petitioner has not shown by a preponderance of the evidence that claim 9 of the '742 Patent would have been obvious under Section 103 based on Ground 1 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claims 1 and 8 of the '742 Patent would have been obvious under Section 103 based on Ground 1. (*See* Part IV.A). Any additional arguments made by Petitioner do not support the invalidity of claim 9 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 9.

J. Claim 10

Petitioner has not shown by a preponderance of the evidence that claim 10 of the '742 Patent would have been obvious under Section 103 based on Ground 1 for

at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103 based on Ground 1. (*See* Part IV.A). Any additional arguments made by Petitioner do not support the invalidity of claim 10 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 10.

K. Claim 11

Petitioner has not shown by a preponderance of the evidence that claim 11 of the '742 Patent would have been obvious under Section 103 based on Ground 1 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claims 1 and 10 of the '742 Patent would have been obvious under Section 103 based on Ground 1. (*See* Part IV.A). Any additional arguments made by Petitioner do not support the invalidity of claim 11 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 11.

L. Claim 12

Petitioner has not shown by a preponderance of the evidence that claim 12 of the '742 Patent would have been obvious under Section 103 based on Ground 1 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103 based on Ground 1. (*See* Part IV.A). Any additional arguments made by

Petitioner do not support the invalidity of claim 12 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 12.

M. Claim 13

Petitioner has not shown by a preponderance of the evidence that claim 12 of the '742 Patent would have been obvious under Section 103 based on Ground 1 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claims 1 and 12 of the '742 Patent would have been obvious under Section 103 based on Ground 1. (*See* Part IV.A). Any additional arguments made by Petitioner do not support the invalidity of claim 13 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 13.

V. Ground 2 Further Fails Because Petitioner Has Not Demonstrated the Obviousness of the Challenged Claims.

A. Claim 1

Ground 2 of the Petition is the same as Ground 1, but instead of modifying Svihra (Ex. 1004), Petitioner suggests modifying Amarenco (Ex. 1005) in the same manner based on the same alleged knowledge of a person of ordinary skill in the art, which in turn is based on the same secondary references. (*Compare* Ground 1 with Ground 2, Paper 2 at 2-3). The parties agree that Amarenco does not disclose directly stimulating a branch of the posterior tibial nerve to treat overactive bladder or incontinence as claimed. (Paper 2 at 46 (“Amarenco targeted the PTN”)). As with Svihra (Ex. 1004), and as explained above (*see* Part IV.A), the Petition fails to

demonstrate that a POSA would have appreciated all the things they are said to have appreciated or that claim 1 would have been obvious for the reasons stated.

As with Ground 1, the disclosures do not support Petitioner's view of a POSA's knowledge. (*See* Paper 2 at 46-48, 52-53; *see* Part IV.A.1-3). To reiterate, Grey (Ex. 1081) teaches that stomach symptoms associated with non-specified medical conditions can be treated by electro-acupuncture of traditional acupuncture points – not that conditions treatable via electrostimulation of the PTN can also be treated by stimulating PTN branches. (*See* Part IV.A.1). Like Svihra (Ex. 1004) and Amarenco (Ex. 1005), Mann (Ex. 1084) teaches treating overactive bladder by directly stimulating the PTN but not any branch thereof, and Boveja (Ex. 1080) is limited to stimulation of nerves within the sacral region. Neither Mann nor Boveja would lead a POSA to appreciate that overactive bladder could be treated by electrically stimulating a branch of the PTN. (*See* Part IV.A.2). And, Ponsford (Ex. 1085) simply observes an associative relationship between weak responses in the foot, when the foot is stimulated, on the one hand, and other conditions, on the other. Ponsford does not establish that any treatment modality can be achieved by stimulation of the foot, let alone treatment of a condition affecting systems controlled by remote and unrelated nerve structures. Even if Ponsford or Rhodes (Ex. 1086) were to show that one could have stimulated a branch of the PTN, they

do not motivate a person of skill in the art to do so to treat overactive bladder or incontinence. (*See* Part IV.A.3).

Without having sufficiently demonstrated “a POSA’s knowledge,” Petitioner’s obviousness argument, which is based on “a POSA’s knowledge,” fails. (*See* Paper 2 at 46-48). The lack of support for Petitioner’s allegations concerning a “POSA’s knowledge” renders Petitioner’s consideration of the *KSR* factors on Ground 2 irrelevant and unsupported. (*See* Paper 2 at 48-50). As explained above (*see* Part IV.A.4), the claimed invention does not involve simple substitution or a known improvement. It was not obvious to try nor was it an obvious design choice, and Petitioner has not demonstrated that a skilled artisan would have possessed a reasonable expectation of success in modifying Amarenco (Ex. 1005) to arrive the invention recited in claim 1 of the ’742 Patent. (*See* Part IV.A.4). Thus, Ground 2 as to claim 1 fails.

B. Claim 2

Petitioner has not shown by a preponderance of the evidence that claim 2 of the ’742 Patent would have been obvious under Section 103 based on Ground 2 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the ’742 Patent would have been obvious under Section 103 based on Ground 2. (*See* Part V.A). Any additional arguments made by

Petitioner do not support the invalidity of claim 2 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 2.

C. Claim 3

Petitioner has not shown by a preponderance of the evidence that claim 3 of the '742 Patent would have been obvious under Section 103 based on Ground 2 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103 based on Ground 2. (*See* Part V.A). Any additional arguments made by Petitioner do not support the invalidity of claim 3 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 3.

D. Claim 4

Petitioner has not shown by a preponderance of the evidence that claim 4 of the '742 Patent would have been obvious under Section 103 based on Ground 2 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103 based on Ground 2. (*See* Part V.A). Any additional arguments made by Petitioner do not support the invalidity of claim 4 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 4.

In addition, Petitioner has not demonstrated that a POSA would have found it obvious to modify Amarenco (Ex. 1005) to apply direct stimulation to a branch

of the PTN to treat overactive bladder or incontinence by “activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient,” as recited in claim 4. Petitioner acknowledges that Amarenco (Ex. 1005) does not disclose multiple 30-minute treatment sessions. (Paper 2 at 55). While Petitioner’s expert states that multiple 30-minute treatment sessions were known (Ex. 1003 ¶¶ 162-63), the Petition makes no attempt to show that Amarenco (Ex. 1005) – as modified to directly target a branch of the posterior tibial nerve – would be successful in treating overactive bladder or incontinence on such a treatment schedule. Although the proposed modification of Amarenco (Ex. 1005) would directly target a different nerve more remote from the sacral plexus than the one actually disclosed, the Petition does not provide any evidence or argument that the same treatment schedule would have had a reasonable expectation of success in treating overactive bladder or incontinence, as claimed, or any success at all. The Petition makes no such showing. Petitioner’s expert conceded at deposition that such distance would affect or potentially eliminate therapeutic efficacy. (*See* Ex. 2003 at 24:22-25:23). Without any such analysis, Petitioner has not demonstrated the invalidity of claim 4 by a preponderance of the evidence, for the reasons and for the same reasons that Ground 1 does not show the invalidity of claim 4. (*See also* Part IV.D).

E. Claim 5

Petitioner has not shown by a preponderance of the evidence that claim 5 of the '742 Patent would have been obvious under Section 103 based on Ground 2 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103 based on Ground 2. (*See Part V.A*). Any additional arguments made by Petitioner do not support the invalidity of claim 5 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 5.

F. Claim 6

Petitioner has not shown by a preponderance of the evidence that claim 6 of the '742 Patent would have been obvious under Section 103 based on Ground 2 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103. (*See Part V.A*). Any additional arguments made by Petitioner do not support the invalidity of claim 6 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 6.

G. Claim 7

Petitioner has not shown by a preponderance of the evidence that claim 7 of the '742 Patent would have been obvious under Section 103 based on Ground 2 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claims 1 and 6 of the '742 Patent would have been obvious under

Section 103. (*See Part V.A*). Any additional arguments made by Petitioner do not support the invalidity of claim 7 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 7.

H. Claim 8

Petitioner has not shown by a preponderance of the evidence that claim 8 of the '742 Patent would have been obvious under Section 103 based on Ground 2 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103. (*See Part V.A*). Any additional arguments made by Petitioner do not support the invalidity of claim 8 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 8.

I. Claim 9

Petitioner has not shown by a preponderance of the evidence that claim 9 of the '742 Patent would have been obvious under Section 103 based on Ground 2 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claims 1 and 8 of the '742 Patent would have been obvious under Section 103 based on Ground 2. (*See Part V.A*). Any additional arguments made by Petitioner do not support the invalidity of claim 9 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 9.

J. Claim 10

Petitioner has not shown by a preponderance of the evidence that claim 10 of the '742 Patent would have been obvious under Section 103 based on Ground 2 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section 103 based on Ground 2. (*See Part V.A*). Any additional arguments made by Petitioner do not support the invalidity of claim 10 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 10.

K. Claim 11

Petitioner has not shown by a preponderance of the evidence that claim 11 of the '742 Patent would have been obvious under Section 103 based on Ground 2 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claims 1 and 10 of the '742 Patent would have been obvious under Section 103 based on Ground 2. (*See Part V.A*). Any additional arguments made by Petitioner do not support the invalidity of claim 11 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 11.

L. Claim 12

Petitioner has not shown by a preponderance of the evidence that claim 12 of the '742 Patent would have been obvious under Section 103 based on Ground 2 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claim 1 of the '742 Patent would have been obvious under Section

103 based on Ground 2. (*See* Part V.A). Any additional arguments made by Petitioner do not support the invalidity of claim 12 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 12.

M. Claim 13

Petitioner has not shown by a preponderance of the evidence that claim 12 of the '742 Patent would have been obvious under Section 103 based on Ground 2 for at least the same reasons that Petitioner has not shown by a preponderance of the evidence that claims 1 and 12 of the '742 Patent would have been obvious under Section 103 based on Ground 2. (*See* Part V.A). Any additional arguments made by Petitioner do not support the invalidity of claim 13 because they remain premised on flawed arguments as to claim 1, which is incorporated into claim 13.

VI. Conclusion

For at least the foregoing reasons, Patent Owner EMKinetics, Inc. respectfully requests that the Board issue a Final Written Decision determining that Petitioner Avation Medical, Inc. has not carried its burden of establishing the unpatentability of claims 1-13 of U.S. Patent No. 11,224,742.

Respectfully submitted,

Date: July 11, 2025

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CERTIFICATE OF WORD COUNT

The undersigned certifies that the foregoing PATENT OWNER'S RESPONSE complies with the type-volume limitation in 37 C.F.R. § 42.24(b)(1). According to the word-processing system's word count, this Response contains 9,351 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a).

Date: July 11, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e)(4), the undersigned certifies that on July 11, 2025, a complete and entire copy of this Patent Owner's Response was provided via email to the Petitioner by serving the email correspondence addresses of record as follows:

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