

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 PRELIMINARY RESPONSE

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No exhibits are submitted by Patent Owner with this Preliminary Response. However, Patent Owner reserves the right to submit exhibits as may be necessary and appropriate should the Board institute proceedings.

Pursuant to 37 C.F.R. § 42.107, Patent Owner EMKinetics, Inc.

(“EMKinetics” or “Patent Owner”) files this Preliminary Response setting forth reasons why the Petition for *Inter Partes* Review (Paper 2) of claims 1-13 of U.S. Patent No. 11,224,742 (the “’742 Patent”), as requested by Avation Medical, Inc. (“Avation” or “Petitioner”), should be denied and no trial instituted.¹

I. The Petition (Grounds 1 & 2) does not demonstrate a reasonable likelihood that Petitioner would prevail if trial were instituted.

Neither ground in the Petition demonstrates a reasonable likelihood that Petitioner would prevail. Accordingly, “[t]he Director may not authorize an *inter partes* review to be instituted,” as requested, pursuant to 35 U.S.C. § 314(a).

Ground 1 in the Petition fails for at least two reasons. First, Petitioner failed to carry its burden of showing that Svihra (Ex. 1004) qualifies as prior art. At most, Petitioner presents only limited hearsay in support of the critical factual proposition that Svihra was publicly accessible prior to the priority date of the challenged claims. Petitioner carries the burden on establishing the public

¹ By submitting this Preliminary Response, no waiver of any argument is intended by Patent Owner. Patent Owner will have a right to file a complete response to the Petition, should the Board institute *inter partes* review. 37 C.F.R. § 42.120(a).

accessibility of any reference at every stage of this proceeding. Petitioner has failed to carry that burden here.

Even if Svihra (Ex. 1004) were considered as prior art, Petitioner has also failed to carry its burden of showing that a person of ordinary skill in the art would have been motivated to combine Svihra (Ex. 1004) with various other references and alleged knowledge to arrive at the claimed inventions. While Petitioner cites numerous references, not one discloses a motivation to modify Svihra (Ex. 1004) to treat overactive bladder or incontinence by direct electrical stimulation of a branch of the posterior tibial nerve, as recited in each of the challenged claims of the '742 Patent. Ground 1 therefore fails.

Ground 2 fails for many of the same reasons. Ground 2 comprises a combination of references—Amarenco (Ex. 1005) and Mann (Ex. 1084)—already considered by the examiner during original prosecution. Petitioner concedes as much but claims it has found “new” prior art that supplies the teachings found missing during original prosecution. However, none of these references allow Petitioner to carry its burden of showing that a person of ordinary skill in the art would have been motivated to combine Amarenco (Ex. 1005) and Mann (Ex. 1084) and further modify the combination, as Petitioner claims. Ground 2 therefore fails as well.

A. Ground 1 of the Petition does not establish that Petitioner is likely to prevail.

1. Petitioner has not shown that Svihra qualifies as prior art.

Ground 1 of the Petition relies on Svihra (Ex. 1004). (Paper 2 at 2).

Although the Petition asserts that “Svihra (Ex. 1004) published in 2002 ... and [is] therefore prior art under pre-AIA 35 U.S.C. § 102(b)” (Paper 2 at 22), the Petition does not identify any evidence that Svihra was, in fact, publicly accessible before the alleged critical date. On its face (Ex. 1004), Svihra appears to be a document entitled, “Neuromodulative treatment of overactive bladder – noninvasive tibial nerve stimulation.” (*Id.* at 480).

However, beyond potentially looking like an article, there is no evidence cited in the Petition that Svihra was publicly accessible at any time, let alone before the alleged critical date. To be clear, “there is no presumption in favor of ... finding a reference to be a printed publication.” *Hulu, LLC v. Sound View Innovations, LLC*, Case IPR2018-01039, slip op. at 16 (PTAB Dec. 20, 2019) (Paper 29). Rather, the burden is on Petitioner “to identify with particularity evidence sufficient to establish a reasonable likelihood that the reference was publicly accessible before the critical date of the challenged patent.” *Id.*

Here, Petitioner does not identify any such evidence, with particularity or otherwise, and thus fails to meet its burden. Beginning with Svihra itself, it does

not bear a copyright notice.² It does not include a publication page. It does not have an International Standard Book Number (ISBN) on it. It does not bear the name of any known publication. And, it does not state that it was published. Accordingly, on its face, Svihra fails to provide any indicia of its own public accessibility.

The Petition likewise does not identify any evidence outside the four corners of Svihra tending to establish the public accessibility of Svihra. For example, the attorney declaration submitted with the Petition declares, *in toto*, that “[a] true and correct copy of [Svihra] is attached” to such declaration. (Ex. 1053 ¶ 6). The attorney declaration does not recite any further allegations concerning Svihra. It does not, for instance, declare that Svihra was publicly accessible prior to the alleged critical date. It does not, by way of further example, express any personal knowledge or explain how the copy of Svihra was obtained or when it was obtained, or provide or identify any evidence tending to establish that Svihra could

² The fact that Svihra does not contain a copyright notice distinguishes cases in which a copyright notice has been accepted as *prima facie* evidence of publication for purposes of institution. *See, e.g., Ford Motor Co. v. Cruise Control Techs. LLC*, Case IPR2014-00291, slip op. at 7-8 (PTAB June 29, 2015) (Paper 44) (citing *FLIR Sys., Inc. v. Leak Surveys, Inc.*, Case IPR2014-00411, slip op. at 18-19 (PTAB Sept. 5, 2014) (Paper 9)).

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 Svihra. Although the expert claims that “Svihra published a study,” the expert does not allege that Svihra was publicly accessible before the alleged critical date or that Svihra was published in 2002. (*Id.* ¶ 43). Nor does the expert state, for example, that he personally recalls the publication of Svihra. And, like the attorney declaration (Ex. 1053), the expert declaration (Ex. 1003) does not explain why information concerning the source or publication of Svihra could not have been obtained by reasonable efforts.

Thus, the entirety of Petitioner’s challenge, insofar as it relies on Svihra qualifying as prior art (Ground 1), is based on the document submitted as Exhibit 1004. Accordingly, the dates in Svihra are hearsay. *See Standard Innovation Corp. v. Lelo, Inc.*, Case IPR2014-00148, slip op. at 13-16 (PTAB Apr. 23, 2015) (Paper 41) (determining that reliance on a copyright notice as evidence that a reference was a printed publication as of a particular date is inadmissible hearsay). Yet, the Petition does not acknowledge that the dates in Svihra are hearsay or even offer them as truth of the matter asserted. Nor does the Petition attempt to show that the dates in Svihra are admissible, even though hearsay, to prove any proposition, such

as the publication date, if any, of Svihra. Instead, the Petition is silent on these issues.

Even if the dates in Svihra were admissible hearsay, they do not establish the public availability of Svihra before the alleged critical date. At most, Svihra states that it was “[r]eceived” and “[a]ccepted” in 2002 in connection with some entity known as “Bratisl Lek Listy.” (Ex. 1004 at 483). As mentioned above, Svihra does not state that it was published at any time. Thus, even if this hearsay were admissible and tended to establish the proof of the matter asserted (*e.g.*, that Svihra was received and accepted in 2002 by Bratisl Lek Listy), it does *not* establish that Svihra was published or otherwise publicly accessible before the alleged critical date, as receiving and accepting a document are critically different from publishing one. In short, the hearsay at issue, even if admissible and true, does not establish public accessibility.

Moreover, even if this hearsay tended to prove publication of Svihra in 2002 (which it does not), the Board is free to conclude that the mere presence of a date, without more, is insufficient evidence of public accessibility as of a particular date, given that the burden of proof always lies with Petitioner. *See, e.g., LG Electronics, Inc. v. Advanced Micro Devices, Inc.*, Case IPR2015-00329, slip op. at 10 (PTAB July 10, 2015) (Paper 13) (also recognizing that different panels of the Board have required varying levels of evidentiary rigor on institution).

Accordingly, Petitioner has failed to carry its burden of identifying, with particularity, evidence sufficient to establish a reasonable likelihood that Svihra was publicly accessible or that there is a reasonable likelihood that Svihra qualifies as a printed publication. Because Ground 1 in the Petition relies on Svihra, the Petition fails to establish a likelihood of success on Ground 1.

2. Even if Svihra (Ex. 1004) were considered, Petitioner has not shown the obviousness of claim 1-13 of the '742 Patent.

Claims 1-13 recite methods of noninvasively treating overactive bladder or incontinence through direct electrical stimulation of a branch of the posterior tibial nerve. Petitioner concedes that Svihra (Ex. 1004) does not disclose such a method because it does not disclose the claim element, present in all challenged claims, of “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 24). Petitioner nonetheless asserts that “it would have been obvious to modify Svihra’s method to directly target and deliver stimulation to a branch of the PTN.” (*Id.*). Patent Owner disagrees.

Petitioner claims that a person of ordinary skill in the art, to achieve this modification of Svihra (Ex. 1004), would have needed to appreciate at least four additional teachings. (Paper 2 at 27). In support, Petitioner cites several references that are said to supply these teachings. (*Id.*). However, the references do not in fact

supply all the teachings claimed. Notably, they lack any specific teaching about branches of the posterior tibial nerve or the stimulation of same to treat overactive bladder or incontinence. Further, the record does not establish that a person of ordinary skill in the art would have appreciated all that Petitioner believes that they would have known, or that a person of ordinary skill in the art would have been motivated, as Petitioner claims, to make the modifications asserted.

As shown below, the references identified by Petitioner to supply the teachings used in the Ground 1 obviousness combination do not relate to directly stimulating a branch of the posterior tibial nerve and providing and receiving such stimulation to treat overactive bladder or incontinence. Petitioner's failure to identify any secondary references that relate to treating overactive bladder or incontinence by directly or indirectly stimulating the posterior tibial nerve or branch thereof is particularly problematic where Petitioner has not shown that the primary reference (Svihra, Ex. 1004) qualifies as prior art accessible and available to a person of ordinary skill in the art.

With respect to these secondary references, Petitioner first claims that a person of ordinary skill in the art "would have appreciated. . . OAB/incontinence can be treated by electrically stimulating nerves and branches that reach the spinal cord. . . including the PTN and its branches." (Paper 2 at 27). The references cited by Petitioner—Mann (Ex. 1080) and Boveja (Ex. 1084)—at most support only the first

part of this proposition, not the second. Mann and Boveja are evidence that a person of ordinary skill in the art would have appreciated overactive bladder and incontinence can be treated by electrically stimulating nerves and branches that reach the spinal cord. They also teach that the nerves targeted for electrical stimulation were located around the bladder region. But they do not teach overactive bladder and incontinence can be treated by electrically stimulating any other nerves such as a branch of the posterior tibial nerve.

In the portion cited by Petitioner (Paper 2 at 27), Mann focuses on the “pudendal nerve and its branches” and, at most, refers only broadly to “nerves emanating from the sacral nerve roots.” (Ex. 1084, 11:50-12:7). Mann does not reference direct or indirect stimulation of the posterior tibial nerve or a branch thereof. Rather, Mann describes invasive direct stimulation of the pudendal nerve and its branches via the pelvic floor. (*Id.* at 11:43-49). There is no teaching in Mann of direct or indirect electrical stimulation of a branch of the posterior tibial nerve or of any relationship between such stimulation and the treatment of overactive bladder or incontinence. Given that Mann encourages direct stimulation of the nerves most immediately involved in these conditions, Petitioner has not shown that a person of ordinary skill in the art would have appreciated from Mann that overactive bladder can be treated by direct electrical stimulation of a branch of the posterior tibial nerve.

Nor would have a person of ordinary skill in the art appreciated the same based on Boveja (Ex. 1080), the other reference cited by Petitioner for this proposition. (Paper 2 at 27). Like Mann (Ex. 1084), Boveja (Ex. 1080) encourages invasive direct stimulation of the nerves most immediately involved in the condition of overactive bladder or incontinence, *i.e.*, the nerves immediately surrounding the pelvic floor. (Ex. 1080 ¶¶ 0028-29). Boveja does not disclose electrically stimulating a branch of the posterior tibial nerve, directly or indirectly. Accordingly, a person of ordinary skill in the art would not have appreciated from Boveja that overactive bladder can be treated by direct electrical stimulation of a branch of such nerve, contrary to Petitioner's suggestion. (Paper 2 at 27). The mere listing of the "tibial nerve" as one of many known sacral nerves (Ex. 1080 ¶ 0180) would not have caused a person of ordinary skill in the art to understand from Boveja the potential role its branches might play in treating any condition such as overactive bladder or incontinence. In short, Petitioner identifies at most teachings that electrical stimulation of certain co-located nerves can be useful in treating overactive bladder or incontinence.

Petitioner next claims, incorrectly, that a person of ordinary skill in the art would have appreciated that "[c]onditions treatable via electrostimulation of the PTN can also be treated be treated by stimulating the... PTN branches." (Paper 2 at 27). But the sole reference cited by Petitioner (Grey, Ex. 1081) does not say as much. Grey describes invasive electro-acupuncture techniques involving electrical

stimulation of traditional acupuncture points, such as the “kun lun” or “fu yang” points on the body, in the calf and ankle to treat a variety of conditions. (Ex. 1081 at 1:35-53, 2:53-60). Overactive bladder or incontinence is not among these conditions. Petitioner’s expert does not provide any further explanation as to how a person of ordinary skill in the art would make the leap from electro-acupuncture to treat co-located pain (Grey) to treating overactive bladder or incontinence via direct electrical stimulation of a branch of the posterior tibial nerve (Claims 1-13).

Thus, contrary to Petitioner’s suggestion, a person of ordinary skill in the art would not have appreciated at the time of invention that overactive bladder or incontinence could be treated by electrically stimulating a branch of the posterior tibial nerve, directly or indirectly. (Paper 2 at 27, Item No. 1). Moreover, and also contrary to Petitioner’s suggestion, a person of ordinary skill in the art would not have appreciated at the time of invention that conditions treatable via electrical stimulation of the posterior tibial nerve were likewise treatable via electrical stimulation of one of its branches. (Paper 2 at 27, Item No. 2). From Mann and Boveja, a person of ordinary skill in the art would have understood, at most, that overactive bladder or incontinence could be treated by direct electrical stimulation of the nerves immediately surrounding the bladder, *i.e.*, neither the posterior tibial nerve nor a branch thereof. And, from Grey, a person of ordinary skill in the art would have understood, at most, that some conditions could be treated by electro-

acupuncture stimulation of certain “points” in the calf and ankle, generally co-located with these nerves. But Petitioner does not show that a person of ordinary skill in the art would have been motivated to move Svihra’s direct electrical stimulation of the posterior tibial nerve to one of its branches or would have had any reasonable expectation of success in doing so. Petitioner has therefore failed to establish that it would have been “obvious to try” direct stimulation of a branch of the posterior tibial nerve to treat overactive bladder or incontinence.

Likening the human body to a machine, Petitioner asserts that “[t]here are a finite number of nerves” and “a finite number of locations along such nerves” that could be tried. (Paper 2 at 28). Yet, neither Petitioner nor its expert explicitly state this “finite number.” The *Gray’s Anatomy* excerpts (Ex. 1088) submitted by Petitioner suggest that the number of nerves in the human body is effectively uncountable, and that there are, at a minimum, thousands of named nerves in the human body.

Petitioner does not show that it would have been “obvious to try” a branch of the posterior tibial nerve to treat overactive bladder or incontinence, particularly where the cited references either do not reference overactive bladder or incontinence or a branch of the posterior tibial nerve, other than one reference (Grey, Ex. 1081) that at least seems to acknowledge the existence of such branches in the context of invasive electro-acupuncture.

Nor has Petitioner shown a reasonable expectation of success with this nerve compared to the thousands of other choices that the art seems to suggest could have been available but were never tried for lack of motivation. From the collection of references cited, a person of ordinary skill in the art, to increase convenience and reduce pain, would have tried noninvasive stimulation of the same nerves targeted by invasive stimulation, if possible, not noninvasive stimulation of some other unidentified nerves. None of the references cited by Petitioner provide the alleged motivations of increasing convenience and reducing pain (Paper 2 at 29), which may have more to do with the method of stimulation (*e.g.*, direct stimulation via the pelvic floor, invasive electro-acupuncture needles) than the nerve in question.

Accordingly, Petitioner has not shown that it is likely to prevail on Ground 1 of the Petition. Critically, Petitioner's claim that it has supplied the teachings found absent during original prosecution (Paper 2 at 31) is false or at least incomplete. Petitioner claims that Ponsford (Ex. 1085) and Rhodes (Ex. 1086) disclose direct stimulation of a branch of the posterior tibial nerve. However, more was found to be missing during original prosecution than mere disclosure of direct stimulation of a branch of the posterior tibial nerve. Specifically, the examiner concluded that "the closest prior art of record fails to disclose or fairly render unpatentable the combination of elements in claim 5 [now claim 1] including direct stimulation of a posterior tibial nerve branch to treat overactive bladder or incontinence." (Paper 2 at

20 (citing Ex. 1005 at 46)). While Ponsford (Ex. 1085) and Rhodes (Ex. 1086) may disclose direct stimulation of a branch of the posterior tibial nerve, they do not disclose doing so “to treat overactive bladder or incontinence,” as claimed and as recognized by the examiner during original prosecution. (Ex. 1005 at 46). Thus, Petitioner has not supplied the teachings found absent from the prior art during original prosecution and has not presented sufficient grounds to disturb the examiner’s original findings.

B. Ground 2 of the Petition does not establish that Petitioner is likely to prevail either.

Ground 2 fails for many of the same reasons as Ground 1. Ground 2 combines Amarenco (Ex. 1005) and Mann (Ex. 1084) with Ponsford (Ex. 1085) and further with various points of knowledge of a person of ordinary skill in the art. (Paper 2 at 3). As Petitioner acknowledges (Paper 2 at 44), the combination of Amarenco (Ex. 1005) and Mann (Ex. 1084) was already considered at length and overcome during original prosecution. In allowing the challenged claims over the combination of Amarenco (Ex. 1005) and Mann (Ex. 1084), the examiner stated that “the closest prior art of record fails to disclose or fairly render unpatentable the combination of elements in claim 5 [now independent claim 1] including direct stimulation of a posterior tibial nerve branch to treat overactive bladder or incontinence.” (Paper 2 at 20 (citing Ex. 1005 at 46)).

In Ground 2, Petitioner asserts that it has found new art (*i.e.*, Ponsford, Ex. 1085) disclosing what was found to be missing from Amarenco (Ex. 1005) and Mann (Ex. 1084) during original prosecution. However, Ponsford (Ex. 1085) does not disclose direct or indirect stimulation of any nerve to treat any condition. At most, Ponsford (Ex. 1085) discloses direct stimulation of a nerve branch to measure activity in the nerve branch. (*Id.* at 188). It does not disclose direct or indirect stimulation of a branch of the posterior tibial nerve to treat overactive bladder or incontinence, which is never mentioned or suggested in Ponsford (Ex. 1085). While a person of ordinary skill in the art might recognize that nerve signals propagate along certain pathways, there is no suggestion in Ponsford that the propagation of nerve signals from a branch of the posterior tibial nerve could be used to treat any condition, let alone a condition such as overactive bladder or incontinence for which the nerves most closely associated with the condition are not co-located with the nerves being stimulated.

Petitioner has not, therefore, shown it would have been obvious to modify the already-considered combination of Amarenco (Ex. 1005) and branch of the posterior tibial nerve using Ponsford (Ex. 1085) or any other reference. Petitioner erroneously claims that this modification would have involved substituting “known” elements and known techniques to a “finite” numbers of nerves and nerve locations. (Paper 2 at 48-49). While the elements and techniques of Ponsford (Ex.

1085) and Rhodes (Ex. 1086) might have been known, Petitioner provides no evidence that such techniques were known to represent methods of improving treatment for any condition.

Ponsford (Ex. 1085) does not disclose that “targeting a PTN branch” was a known improvement over targeting the PTN itself. (Paper 2 at 48). While it may disclose stimulating a PTN branch, Ponsford (Ex. 1085) does not teach or suggest that stimulating the branch of a nerve represents any sort of improvement over targeting the nerve itself, for any purpose, let alone for the purpose of treating a condition such as overactive bladder or incontinence.

Nor does Rhodes (Ex. 1086) disclose that “targeting a PTN branch” was a known improvement over targeting the PTN itself. (Paper 2 at 48). Like Ponsford (Ex. 1085), Rhodes (Ex. 1086) may disclose stimulating a PTN branch, but it does not teach or suggest that stimulating the branch of a nerve represents any sort of improvement over targeting the nerve itself, only that it can be done. (Ex. 1086 at 3:57-4:21).

Thus, the “new” art of record identified in the Petition does not provide the motivation to combine these various known elements to arrive at direct electrical stimulation of a branch of the posterior tibial nerve to treat overactive bladder or incontinence, as claimed in the ’742 Patent. Neither Ponsford (Ex. 1085) nor Rhodes (Ex. 1086) discloses techniques for improving treatment by stimulating a

branch of the posterior tibial nerve. Without such teachings, a person of ordinary skill in the art would not have appreciated, as Petitioner claims, that the combination of Amarenco (Ex. 1005) and Mann (Ex. 1084) could be modified to target a branch of the posterior tibial nerve to treat overactive bladder or incontinence. And, neither Amarenco (Ex. 1005) nor Mann (Ex. 1084) provides such motivation itself.

In asserting obviousness via Ground 2, Petitioner otherwise reduces the human nervous system to “known” and “finite” elements. Yet the number of nerves in the human body is practically infinite, and Petitioner does not show that a person of ordinary skill in the art would have been motivated to combine the cited references and further modify them with their own skill to arrive at the claimed inventions, including “the branch [of the posterior tibial nerve] directly receiv[ing] the electrical stimulation to treat overactive bladder or incontinence,” as recited in the challenged claims. While a person of ordinary skill in the art “could [have] simply move[d]” the electrodes disclosed in Amarenco (Ex. 1005) (Paper 2 at 49), Petitioner fails to establish a motivation for doing so or for any reasonable expectation of success in doing so.

Amarenco (Ex. 1005) and Mann (Ex. 1084) were already considered at length and rejected in the same combination as proposed by Petitioner. There can be no genuine dispute, on this record, that “the same or substantially the same prior

art or arguments previously were presented to the Office” as Ground 2 of the Petition, within the meaning of 35 U.S.C. § 325(d). That Petitioner has identified additional references supposedly teaching only some of what was missing—stimulation of a branch of the posterior tibial nerve but not to treat overactive bladder or incontinence—during original prosecution does not change this result.

For the same reason, Ground 2 does not establish that Petitioner is likely to prevail, within the meaning of 35 U.S.C. § 314(a). Petitioner has not shown that a person of ordinary skill in the art *would have been motivated* to treat overactive bladder or incontinence by applying direct electrical stimulation to a branch of the posterior tibial nerve *simply because they knew that they could* treat overactive bladder or incontinence by applying direct electrical stimulation to the posterior tibial nerve itself. And, just because it may have been known that direct electrical stimulation could be applied to a branch of the posterior tibial nerve, or to any nerve for that matter, that does not establish that a person of ordinary skill in the art would have been motivated to do so to treat overactive bladder or incontinence, or that any treatment or improvement in treat would be achieved. Petitioner has not pointed to any specific teaching in the prior art providing such a motion or expectation of success.

Accordingly, Petitioner has not shown that it is likely to prevail on Ground 1 of the Petition.

II. Conclusion

For at least the foregoing reasons, the Petition (Paper 2) should be denied and no trial instituted.

Respectfully submitted,

Date: December 20, 2024

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CERTIFICATE OF WORD COUNT

The undersigned certifies that the foregoing PATENT OWNER'S PRELIMINARY 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, the brief contains 4,447 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a).

Date: December 20, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e)(4), the undersigned certifies that on December 20, 2024, a complete and entire copy of this Patent Owner's Preliminary Response was provided via email to the Petitioner by serving the email correspondence addresses of record as follows:

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