

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,

Petitioner,

v.

EMKINETICS, INC.,

Patent Owner.

Review No. IPR2024-01378

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

PATENT OWNER'S RESPONSE

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No exhibits are submitted by Patent Owner with this Response. Patent Owner did not submit any exhibits with its Preliminary Response (Paper 6).

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 1-10 (the “challenged claims”) of U.S. Patent No. 9,002,477 (the “’477 Patent”).

Petitioner has failed to carry its burden of proving that the non-patent references (Exs. 1004-05, 1008-17, 1028, 1030, 1041-43, 1064-65) 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 all grounds in the Petition (Grounds 1-5) are based (Svihra, Ex. 1004; Amarenco, Ex. 1005), as well as many other references on which these grounds are based (Exs. 1008-17, 1028, 1030, 1041-43, 1064-65). 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 1-5 of the Petition have not been proven.

II. Grounds 1-5 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), ¶¶ 8-22, 28-29 (same for other documents alleged to constitute printed publications, Ex. 1008-17, 1028, 1030, 1041-43, 1064-65)). 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, 1028, 1030, 1041-43, 1064-65). 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 1-5 identified in the Petition. Grounds 1-3 rely on non-patent reference Svihra (Ex. 1004) as the “primary” reference. (Paper 2 at 3). 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. Grounds 4-5 similarly rely 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 2-5 further rely on non-patent secondary references or non-patent references said to show a skilled artisan’s knowledge at the time of invention (*id.*), 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 5-8 (citing non-patent Exs. 1008-17, 1041), 17-18 (Ex. 1028, 1030, 1042-43), 30 (Ex. 1064), 34 (Ex. 1065)).

Accordingly, the Petition, which was never supplemented by Petitioner, does not establish unpatentability of the challenged claims based on Grounds 1-5.

III. 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 1-10 of U.S. Patent No. 9,002,477.

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 1,554 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a).

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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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