

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,

Petitioner,

v.

EMKINETICS, INC.,

Patent Owner.

Review No. PGR2024-00043

U.S. Patent No. 11,844,943

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 7).

I. Introduction & Summary of Argument

Pursuant to 37 C.F.R. § 42.220 and the Board’s Scheduling Order (Paper 9 ¶ 8), Patent Owner EMKinetics, Inc. (“Patent Owner”) submits this Response (Paper 11) to the Petition for Post-Grant Review (Paper 2) filed by Petitioner Avation Medical, Inc. (“Petition”), setting forth reasons why the Petition fails to establish the unpatentability of claims 1-39 (the “challenged claims”) of U.S. Patent No. 11,844,943 (the “’943 Patent”). The principal reason is that Petitioner has failed to carry its statutory burden of proving the unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 326(e). Specifically, Petitioner has not established unpatentability based on any of the eleven grounds identified in the Petition. (Paper 2 at 2-3).

This Response may be summarized as follows:

1. **Grounds 1-8 & 10.** 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) 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, for which public accessibility has not been established by a preponderance of the evidence, include the primary references on which Grounds 1-8 are based (Svihra & Amarenco, Exs. 1004-05), as well as the secondary references on which Ground 10 is based (Exs. 1008-17,

1024, 1027-28, 1030, 1035, 1037-39, 1041-43). Whether Petitioner has carried its burden of proving the public accessibility of these references depends on the information and evidence provided and cited by Petitioner. 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 10 at 16-17). With post-grant 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. § 324(a) *with* 35 U.S.C. § 326(e). Accordingly, Grounds 1-8 and 10 of the Petition have not been proven. This topic is discussed in greater detail in Part II below.

2. **Grounds 9 & 10.** Petitioner has failed to carry its burden of proving that Burnett (Ex. 1006) published prior to the earliest effective filing date of the challenged claims, which is October 2, 2006. The Petition does not contend that the claimed inventions are not enabled by any earlier filed application referenced in the priority claims of the application leading to the '943 Patent (U.S. Application No. 17/568,276). Rather, the Petition observes that the priority claims in such application, as set forth on the Application Data Sheet (Ex. 1002 at 190-91), incompletely state all the relationships among and between the applications

specifically referenced therein. To clarify, the application leading to the '943 Patent, in the domestic priority claims (35 U.S.C. § 120) portion of the Application Data Sheet, references a set of patent applications by series code, serial number, and filing date (all completely and accurately) that were successively co-pending back to October 2, 2006. The Petition thus overlooks at least one other “branch” in the family that satisfies Section 120. Patent Owner contends that Section 120, by its terms, is satisfied if an application, in its Section 120 priority claims, references successively co-pending applications by series code, serial number, and filing date. Stated alternatively, Patent Owner contends that Section 120 does not require an applicant to identify *all* familial relationships among those applications. The Petition cites no law to the contrary. Rather, the Petitioner cites just one case, *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309 (Fed. Cir. 2018), which supports Patent Owner’s contention that its priority claims sufficiently notify the public, including Petitioner, of its priority claim to October 2, 2006. Rather than carry its burden of showing enablement or non-enablement by earlier filed applications, Petitioner challenges the completeness of the Application Data Sheet, where the standard should be whether Section 120 has been satisfied, which Patent Owner respectfully submits has been satisfied in this case. This topic is discussed in greater detail in Part III below.

3. ***All Grounds.*** Because the earliest effective filing date of the challenged claims, based on the record presented with the Petition, is October 2, 2006, the '943 Patent is ineligible for post-grant review, as requested by the Petition. *See* AIA § 6(f)(2)(A). This topic is discussed in greater detail in Part IV below.

4. ***Ground 11.*** Petitioner has not shown that the challenged claims of the '943 Patent lack enablement under 35 U.S.C. § 112. The specification of the '943 Patent does not teach away from the claimed inventions, contrary to Petitioner's contention. Even if it did, teaching away is not sufficient to establish a lack of enablement, as Petitioner seeks to do here. The Petition does not provide or cite any other evidence or information on enablement, such as undue experimentation, and Petitioner has therefore failed to carry its burden of proving lack of enablement of the challenged claims. This topic is discussed in greater detail in Part V below.

Patent Owner's specific responses now follow.

II. Grounds 1-8 and 10 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), ¶¶ 10-19, 26, 29-30, 32, 37, 39-41, 43-45 (same for other documents alleged to constitute printed publications, Ex. 1008-17, 1024, 1027-28, 1030, 1035, 1037-39, 1041-43)). 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). 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 post-grant 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. § 322(a); 37 C.F.R. § 42.204(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. § 42.208(c). In this case, Patent Owned filed a Preliminary Response (Paper 7), 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. § 42.223. Here, Petitioner has not filed a motion with the Board to permit supplementation of the Petition.

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, even on institution, 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.”); *see also* 37 C.F.R. § 42.208(c). 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. § 326(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 1-8 and 10 identified in the Petition. Grounds 1-5 rely on non-patent reference Svihra (Ex. 1004), either alone or as the “primary” reference in combination with other references (Paper 2 at 2).; however, Petitioner has not shown that Svihra was publicly accessible prior to the critical date. Grounds 6-8 rely on non-patent reference Amarenco (Ex. 1005), either alone or as the “primary” reference in combination with other references (Paper 2 at 2-3); however, Petitioner has not shown that Amarenco was publicly accessible prior to the critical date. Grounds 10 relies on the “knowledge of POSA” (Paper 2 at 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 4-8 (citing non-patent literature Exs. 1008-17); *see also id.* at 70-79 (referencing “knowledge of a POSA” in support of Ground 11)).

Accordingly, the evidentiary record does not establish unpatentability of the challenged claims based on Grounds 1-8 or 10.

III. Grounds 9 & 10 Fail Because Burnett Does Not Qualify as Prior Art

Petitioner has not carried its burden of proving that Burnett (Ex. 1006) qualifies as prior art to the challenged claims of the '943 Patent. As discussed below, Burnett published no earlier than December 11, 2008, which is after the priority date to which the challenged claims are entitled based on the evidentiary record in these proceedings. Burnett therefore does not qualify as prior art to the challenged claims, and the Petition therefore fails to show that the challenged claims are invalid based on Grounds 9 and 10.

35 U.S.C. § 120 provides, in relevant part:

An application for patent for an invention disclosed in the manner provided by section 112(a) ... in an application previously filed in the United States, or as provided by section 363 or 385, which names an inventor or joint inventor in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 120. Based on the Petition (Paper 2) and the evidentiary record, the application leading to the '943 Patent (U.S. Application No. 17/568,276) satisfies the requirements of Section 120 and is therefore entitled to the priority date claimed, *i.e.*, October 2, 2006, *i.e.*, before Burnett published.

As required by Section 120 in part, the application leading to the '943 Patent contains specific references to earlier filed applications. In fact, the '943 Patent contains multiple specific references to multiple earlier filed applications. The Petition does not contend otherwise. For example, the Application Data Sheet filed with the application leading to the '943 Patent, in the section for “claim[ing] benefit under 35 U.S.C. ... 120,” references multiple applications, all earlier filed, by series code, serial number, and filing date, among other identifying information, including the following applications:

- U.S. Application No. 16/732,706, filed 1/2/2020
- U.S. Application No. 15/474,875, filed 3/30/2017
- U.S. Application No. 15/084,356, filed 3/29/2016
- U.S. Application No. 13/840,936, filed 3/15/2013
- U.S. Application No. 12/508,529, filed 7/23/2009
- U.S. Application No. 11/866,329, filed 10/2/2007
- U.S. Provisional Application No. 60/848,720, filed 10/2/2006

(Ex. 1002 at 190-91). The same specific references to these same earlier filed applications are contained elsewhere in the application leading to the '943 Patent. By way of further example, the application leading to the '943 Patent also references the above-listed applications in the same manner (*i.e.*, by series code, serial number, and filing date) in the first paragraph of the written description of the '943 Patent, both as filed and as issued, under the heading, "Cross-Reference to Related Applications" (Ex. 1002 at 198 ¶ 0001; Ex. 1001 at 79, 1:8-32). Accordingly, there can be no dispute that the application leading to the '943 Patent contains, in its Section 120 priority claims as filed, a specific reference to each of the above-listed applications, each of which was earlier filed.¹

Moreover, as required by Section 120 in remaining part, each of the above-listed applications was filed before the patenting, abandonment, or other termination of the first application (U.S. Provisional Application No. 60/848,720, filed 10/2/2006) or of an application similarly entitled to the benefit of the filing date of the first application (*i.e.*, every other application listed above). As shown in the table below, an application similarly entitled to the benefit of the filing date of

¹ The Petition does not contend that any of the earlier filed applications do not name an "inventor or joint inventor," as further required by Section 120.

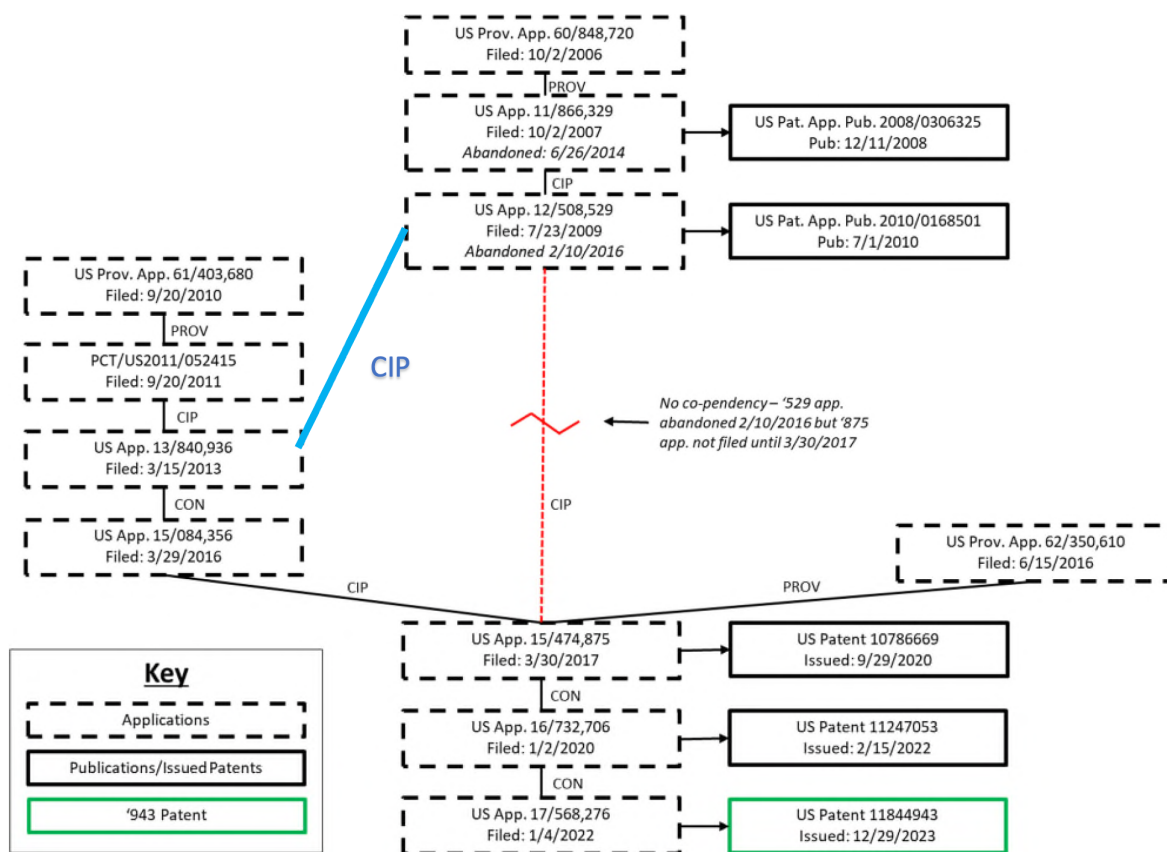
the first application was pending at the time each such next application was filed, up to and including the application leading to the '943 Patent:

Application	Filing Date	Disposition	Disposition Date	Co-Pending Application	Co-Pendency?
17/568,276	1/4/22	Patented	12/19/23	16/732,706	Yes
16/732,706	1/2/20	Patented	2/15/22	15/474,875	Yes
15/474,875	3/30/17	Patented	9/29/20	15/084,356	Yes
15/084,356	3/29/16	Patented	4/25/17	13/840,936	Yes
13/840,936	3/15/13	Patented	5/17/16	12/508,529	Yes
12/508,529	7/23/09	Abandoned	2/10/16	11/866,329	Yes
11/866,329	10/2/07	Abandoned	6/26/14	60/848,720	Yes
60/848,720	10/2/06	Expired	10/2/07	No	Not req'd

Thus, the application leading to the '943 Patent (U.S. Application No. 17/568,276) was “filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application,” *i.e.*, U.S. Provisional Application No. 60/848,720, filed October 2, 2006. Combined with the fact that each of these applications was specifically referenced in the application at issue, the requirements of Section 120 have been satisfied. Stated otherwise, there is no “break in the chain” of priority to October 2, 2006.

The Petition observes that U.S. Application No. 12/508,529 was abandoned before 15/474,875 was filed. The Application Data Sheet at issue makes the same observation. (Ex. 1002 at 191). But it is of no moment to the question of whether the claims meet the requirements of the 35 U.S.C. § 120. They do. As just discussed, the application leading to the '943 Patent (U.S. Application No. 17/568,276) satisfies the requirements of Section 120 by containing specific reference to earlier filed applications, each of which satisfies the co-pendency requirement back to the first provisional filing on October 2, 2006. In other words, that the Application Data Sheet correctly and specifically identifies all patent applications required to state a sufficient priority claim under Section 120.

The only thing “missing” is a statement that U.S. Application No. 13/840,936 was also a continuation-in-part of 12/508,529. There can be no dispute on the record that the '936 application was in fact filed as a continuation-in-part of the '529 application prior to the latter's abandonment (March 15, 2013 versus February 10, 2017). (*See* Ex. 1044 at 1 (priority claim of '936 application stating that “[t]he present application is also a continuation-in-part of U.S. Patent Application Serial No. 12/508,529”). To clarify, both U.S. Application Nos. 13/840,936 and 12/508,529 were identified in the Application Data Sheet for the application leading to the '943 Patent. (Ex. 1002 at 191). For reference, the “missing link” is identified below in below:



(Paper 2 at 15 (blue line and text added); *see* Ex. 1041 at 1). As shown, U.S. Application No. 13/840,936 was filed on March 15, 2013, before 12/508,529 was abandoned, and there is a continuous chain of priority back to October 2, 2006.²

² Pursuant to 35 U.S.C. § 251, if necessary, Patent Owner may file an application to reissue the '943 Patent with additional priority claims stating additional familial relationships, such that U.S. Application No. 13/840,936 was filed as a continuation-in-part of 12/508,529, without citing any additional applications.

Petitioner agrees that the priority claim in the '943 Patent to the '936 application was entirely proper. (Paper 2 at 15).

Petitioner identifies no statute, regulation, or case for the authority that these specific references were not specific enough to satisfy Section 120. In a footnote (Paper 2 at 16 n.3), the Petition cites the sole legal authority in support of its challenge to the priority date of the challenged claims of the '943 Patent, namely, *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309 (Fed. Cir. 2018). In *Droplets*, the Federal Circuit affirmed the Board's conclusion that no reference whatsoever cannot be the "specific reference" required by Section 120. But this case is different, and the facts of *Droplets* are distinguishable. As discussed above, the application leading to the '943 Patent specifically references, in its priority claims, patent applications that were co-pending to October 2, 2006, by series code, serial number, and filing date. Other cases in which priority claims were denied are likewise distinguishable because, in those case, as in *Droplets*, there was no reference at all, let alone a specific reference.³

³ See, e.g., *Sampson v. Ampex Corp.*, 463 F.2d 1042, 1044-45 (2d Cir. 1972) (finding that the appellant could not claim the benefit of the 1961 filing date because the 1964 application did not contain a reference to it, "to say nothing of the 'specific reference' to serial number, and filing date, and a statement of the

In *Droplets*, the Federal Circuit did not hold, and based on Patent Owner’s research, the Federal Circuit has never held, that an application must completely identify all actual familial relationships between the earlier-filed applications to sustain priority claims under Section 120. In *Droplets*, as there was no identification whatsoever of an application to which priority was later claimed, unlike here, the appeals court was justifiably concerned about “the burden on the public to engage in long and expensive search of previous applications in order to determine the filing date of a later patent.” *Droplets*, 887 F.3d at 1317 (quoting *Sticker Indus. Supply Corp. v. Blaw-Knox Co.*, 405 F.2d 90, 93 (7th Cir. 1968)) (internal quotation omitted). Based on this policy, the court reasoned that “the information that must be disclosed is information that would enable a person searching the records of the Patent Office to determine with a minimum of effort the exact filing date upon which a patent applicant is relying to support the validity of his application or the validity of a patent issued on the basis of one of a series of

relationship between the two applications”); see *Hovlid v. Asari*, 305 F.2d 747, 751-52 (9th Cir. 1962) (“Having failed to state the serial number, filing date and the relationship of the second patent to the abandoned application, there seems to be a complete failure to comply with Rule 78 and Section 120, and consequently, a waiver of the benefits afforded by the latter section.”).

applications.” *Id.* at 1316-17 (quoting *Sampson*, 463 F.2d at 1045) (internal quotation omitted),

Here, a person searching the records of the Patent Office, such as Petitioner, could determine with a minimum of effort the exact filing date upon which Patent Owner relies: October 2, 2006. On this topic, Petitioner seemingly expended little or no effort in determining the exact filing date upon which Patent Owner would rely to support the validity of the challenged claims of the '943 Patent. The Petition challenges the October 2, 2006, priority date for the '943 Patent precisely because the '943 Patent clearly claims priority to October 2, 2006, and thus, the “long and expensive search” that concerned the Federal Circuit is not present here. The reality is that Petitioner, being on notice of Patent Owner’s priority claims, did not consider them beyond a literal and limited reading of the Application Data Sheet. Petitioner does not, for example, provide any evidence on the question of whether these earlier filed applications enable the claimed inventions or concerning any other branch of the “family tree.” Given that Petitioner bears the burden of proof in these post-grant proceedings, Patent Owner respectfully submits that the Petitioner has not shown the challenged claims are not entitled to the priority date claimed, or that Burnett qualifies as prior art against the challenged claims.

IV. All Grounds Fail Because Petitioner Has Not Shown the Challenged Claims are Eligible for Post-Grant Review

The post-grant review provisions set forth in Section 6(d) of the AIA apply only to patents subject to the first-inventor-to-file provisions of the AIA. *See* AIA § 6(f)(2)(A) (“The amendments made by subsection (d) ... shall apply only to patents described in section 3(n)(1).”). Patents subject to the first-inventor-to-file provisions are those that issue from applications “that contain[] or contained at any time ... a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after” March 16, 2013. *Id.* § 3(n)(1). As discussed in the preceding section, Petitioner has failed to establish that the challenged claims have an effective filing date on or after March 16, 2013. Petitioner has therefore failed to establish that the challenged claims are eligible for post-grant review. Petitioner’s claim to the contrary is based on the claim that a “break in the chain” precludes a claim of priority to an application filed before October 6, 2013. As discussed above, in Part III of this Response, Patent Owner’s Section 120 priority claims were sufficient under the law and put the public on notice of its priority claims for the challenged claims. The Petition does not offer any contentions about whether any of these earlier filed applications enable, or do not enable, the challenged claims. Accordingly, Petitioner has not carried its burden of establishing the eligibility of the challenged claims for post-grant review.

V. Ground 11 Fails Because Petitioner Has Not Shown the Challenged Claims Lack Enablement

Ground 11 challenges all claims of the '943 Patent for lack of enablement under 35 U.S.C. § 112, which “requires that the patent specification enable those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation in order to extract meaningful disclosure of the invention and, by this disclosure, advance the technical arts.” *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1070 (Fed. Cir. 2005) (internal quotations omitted). In its Decision Granting Institution (Paper 8), the Board determined that, “[a]gainst the[] disclosures [in the specification], and on the record as presently developed, we find that, for the purpose of this [Institution] Decision, Petitioner’s argument that the Specification [of the '943 Patent] does not teach those skilled in the art how to make and use the full scope of the claimed inventions without undue experimentation would likely not be persuasive at trial.” (Paper 8 at 65). Since the time the Petition was filed, Petitioner has not provided any supplemental information in support thereof.

Patent Owner respectfully submits that the Petition does not demonstrate a lack of enablement of any claim in the '943 Patent. The Petition summarizes its sole Section 112 contention as follows: “The claims of the '943 patent lack enablement because the specification teaches against a key aspect of all the claims—positioning an electrical stimulator ‘near an ankle’ of the patient.” (Paper

2 at 80). To clarify, the Petition does *not* contend that the specification does *not* disclose how to position an electrical stimulator near an ankle of the patient. It does. Rather, the Petition contends that, even though the specification discloses how to position an electrical stimulator near an ankle of the patient, undue experimentation would still have been required to so position an electrical stimulator, and that the challenged claims are thus invalid under Section 112.

Yet, the Petition does not try to show directly that undue experimentation would have been required. Rather, the Petition contends that the specification teaches away from the challenged claims, and that this automatically means that undue experimentation would have been required. (Paper 2 at 80). Here, the Petition is incorrect on both counts. First, the specification does not teach away from the challenged claims, contrary to the assertion in the Petition. And second, teaching away, even if it were present, which it is not, is not tantamount to a lack of enablement or a finding of undue experimentation, which the Petition does not otherwise address.

The Petition contends, more precisely, that the specification teaches away from positioning an electrical stimulator near an ankle of the patient because the specification states that positioning an electrical stimulator on non-glabrous skin surfaces and delivering electrical stimulation to such surfaces in one frequency range may cause pain or injury. (Paper 2 at 80 (quoting Ex. 1001, 50:35-51:3)).

Most precisely, the specification states that one treatment modality (electrical stimulation) in one frequency range (about 5 Hz to about 60 Hz or greater) applied to one skin type (non-glabrous) may cause pain and injury to the patient. By contrast, the challenged claims do not require a frequency range or a skin type. No challenged claim recites a frequency range, and further, no challenged claim recites a skin type. No claim construction requiring a frequency range or skin type has been proposed.

Thus, even if the specification were said to teach away from one frequency range-skin type combination for electrical stimulation, it does not teach against the claimed inventions, as might support a finding of undue experimentation combined with other evidence, also not present here. The teachings in the specification about frequency ranges or skin types do not limit the claims. Given the variation between the teachings and claims in question, the cited portion of the specification does not teach away from the claimed inventions.

But, even if it could be said that the specification teaches away from the claimed inventions, such a finding is not tantamount to the undue experimentation required for lack of enablement, as required by law. *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991). The case law cited by Petitioner at most provides that teaching away is evidence of undue experimentation. (Paper 2 at 80 (citing *Liebel-Flarsheim v. Medrad*, 481 F.3d 1371, 1378 (Fed. Cir. 2007))). Such case law does

not provide, however, that teaching away proves undue experimentation *per se*, as is attempted here. *Id.* Rather, the law provides, as the Petition acknowledges, there are “many factual considerations” that go into whether undue experimentation would be required to practice the claimed invention, *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factual considerations include: “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *Id.* (citing *In re Foreman*, 230 U.S.P.Q. 546 (B.P.A.I. 1986)).

Despite acknowledging the many factual considerations surrounding questions of undue experimentation, the Petition does not address any of them, instead relying on a relatively tangential portion of the specification, as discussed and addressed above. Fundamentally, the Petition does not attempt to show that undue experimentation, based on the *Wands* factors or not, would have been required to practice the challenged claims, which is fatal to the enablement challenge, as presented in the Petition. There is no genuine dispute that one of ordinary skill in the art could, based on the specification, practice the claimed inventions. For example, the Petition does not identify any expert testimony

concerning failed attempts to practice the claims with the frequencies and skin types supposedly discouraged in the specification.

The Petition cites no law providing that a patent claim covering a method of treatment must exclude all embodiments that could cause pain or discomfort to the patient, even if those embodiments effectively provide treatment, for such a patent claim to be enabled within the meaning of Section 112. This is not, for example, a case in which a patent claims a genus but teaches only limited species, as in *Amgen, Inc. v. Sanofi*, 143 S. Ct. 1243, 1256 (2023) (affirming lack of enablement finding where “claims sweep much broader than the 26 exemplary antibodies” identified in the specification). Nor is this a case in which a patent claims an invention covering multiple embodiments, only one of which is taught in the specification. *See, e.g., Liebel-Flarsheim*, 481 F.3d at 1378.

Rather, it is a case in which a patent claims methods of treatment that do not recite frequency ranges or skin types and, in the absence of claim construction not requested or sought by Petitioner, may therefore be practiced with various frequency ranges and with various skin types, all of which are disclosed in the specification. At most, the specification cautions against practicing the claimed inventions at one frequency range with one skin type because of the risk of pain or injury, not because such an invention could not be made or used as claimed. The Petition does not demonstrate that undue experimentation would be required to

practice the challenged claims, even if certain embodiments could cause pain or injury, and therefore fails to show a lack of enablement by a preponderance of the evidence of record.

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 1-39 of U.S. Patent No. 11,844,943 and/or that such claims are not eligible for post-grant review.

Respectfully submitted,

Date: April 23, 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 5,388 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 April 23, 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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