Paper No. 7

UNITED STATES PATENT AND TRADMARK 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 PRELIMINARY RESPONSE

TABLE OF CONTENTS

I. The prior art-based grounds in the Petition (Grounds 1-10) do not demonstrate a reasonable likelihood that Petitioner would prevail 1

A. Grounds 1-4 of the Petition should be denied because Petitioner has not shown that Svihra qualifies as prior art 2

B. Grounds 5-8 of the Petition should be denied under Section 325(d) because all supporting references were previously considered, including as same combinations 7

C. Grounds 9-10 of the Petition should be denied because Petitioner has not shown that Burnett qualifies as prior art 11

II. The non-prior art grounds in the Petition (Ground 11) likewise do not show a reasonable likelihood that Petitioner would prevail, as Petitioner has not shown a lack of enablement 20

III. Conclusion 23

TABLE OF AUTHORITIES

Page(s)

Cases

Amgen, Inc. v. Sanofi,
143 S. Ct. 1243 (2023) 22

Cultec, Inc. v. StormTech LLC,
Case IPR2017-00777, slip op. (PTAB Aug. 22, 2017) (Paper 7) 10

*Droplets, Inc. v. E*TRADE Bank*,
887 F.3d 1309 (Fed. Cir. 2018) 15-18

FLIR Sys., Inc. v. Leak Surveys, Inc.,
Case IPR2014-00411, slip op. (PTAB Sept. 5, 2014) (Paper 9) 3

Ford Motor Co. v. Cruise Control Techs. LLC,
Case IPR2014-00291, slip op. (PTAB June 29, 2015)..... 3

Hovlid v. Asari ,
305 F.2d 747 (9th Cir. 1962) 17

Hulu, LLC v. Sound View Innovations, LLC,
Case IPR2018-01039, slip op. (PTAB Dec. 20, 2019)..... 3

In re Vaeck,
947 F.2d 488 (Fed. Cir. 1991) 20

LG Electronics, Inc. v. Advanced Micro Devices, Inc.,
Case IPR2015-00329, slip op. (PTAB July 10, 2015) (Paper 13)..... 6

Liebel-Flarsheim v. Medrad,
481 F.3d 1371 (Fed. Cir. 2007) 22

Monolithic Power Sys., Inc. v. Volterra Semiconductor LLC,
Case IPR2020-01348, slip. op. (PTAB Mar. 4, 2021) (Paper 19)..... 9

Sampson v. Ampex Corp.,
463 F.2d 1042 (2d Cir. 1972) 17, 18

Standard Innovation Corp. v. Lelo, Inc.,
Case IPR2014-00148, slip op. (PTAB Apr. 23, 2015) (Paper 41) 5

In re Wands,
858 F.2d 731 (Fed. Cir. 1988) 20

Statutes

35 U.S.C. § 102(a)(1) 2, 11

35 U.S.C. § 112 20

35 U.S.C. § 120 ..... 11, 12, 15, 17-19

35 U.S.C. § 325(d) 2, 7, 9

Regulations

37 C.F.R. § 42.107 1

37 C.F.R. § 42.120(a) 1

37 C.F.R. § 1.78 ..... 16, 19

37 C.F.R. § 1.290 ..... 8, 10

PATENT OWNER'S TABLE OF EXHIBITS

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 Post Grant Review (Paper 2) of claims 1-39 of U.S. Patent No. 11,844,943 (the "'943 Patent"), as requested by Avation Medical, Inc. ("Avation" or "Petitioner"), should be denied and no trial instituted.[1]

I. The prior art-based grounds in the Petition (Grounds 1-10) do not demonstrate a reasonable likelihood that Petitioner would prevail

Grounds 1-10 of the Petition rely on prior art-based theories of invalidity. As discussed below, none of these grounds, either individually or collectively, demonstrates a reasonable likelihood that Petitioner would prevail. In Part I.A, Patent Owner shows that Petitioner failed to carry its burden of showing that Svihra (Ex. 1004) (Grounds 1-4) qualifies as prior art because Petitioner presents only hearsay and because such hearsay, even if admissible and considered, does not establish public accessibility. In Part I.B, Patent Owner shows that Amarenco (Ex. 1005) and Johnson (Ex. 1007) (Grounds 5-8) were both previously presented to and considered by the Office in connection with a concise Third-Party

[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 *post grant* review. 37 C.F.R. § 42.120(a).

Submission that included the same claim charts in the same combinations as redundantly presented in the Petition, and that discretionary denial by the Board under 35 U.S.C. § 325(d) is appropriate. And, in Part I.C, Patent Owner shows that, contrary to Petitioner's assertion, the '943 Patent specifically references, by serial number and filing date, each and every application that establishes a continuous chain of priority to a provisional patent application filed October 2, 2006, well before the alleged prior art date of the Burnett reference (Ex. 1006) (Grounds 9-10), meaning the Burnett reference is not prior art and is not properly cited in the Petition.

Each principal reason for denying the Petition is now discussed in turn.

A. Grounds 1-4 of the Petition should be denied because Petitioner has not shown that Svihra qualifies as prior art

Each of Grounds 1-4 of the Petition relies on Svihra (Ex. 1004). (Paper 2 at 2). Although the Petition asserts that "Svihra published in 2002 and is therefore prior art under AIA 35 U.S.C. § 102(a)(1)" (Paper 2 at 1, 21), 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

[2] The fact that Svihra does not contain a copyright notice distinguishes cases in which a copyright notice has been accepted as *prima facia* 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)).

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 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.* ¶ 46). 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, 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 each of Grounds 1-4 in the Petition rely on Svihra, the Petition fails to establish a likelihood of success on Grounds 1-4.

B. Grounds 5-8 of the Petition should be denied under Section 325(d) because all supporting references were previously considered, including as same combinations

Each of Grounds 5-8 of the Petition relies on Amarenco (Ex. 1005). (Paper 2 at 2-3). Each of Grounds 7-8 of the Petition further relies on Johnson (Ex. 1007) in proposed combination with Amarenco. (Paper 2 at 3).[3] Patent Owner contends that the Board should exercise its discretion under 35 U.S.C. § 325(d) to deny institution because: (i) Amarenco was previously presented and considered during prosecution of the '943 Patent; (ii) Johnson was previously presented and considered during prosecution of the '943 Patent; and (iii) the combination of Amarenco and Johnson was previously presented and considering during the prosecution of the '943 Patent. To be clear, this is *not* a case in which the

[3] As with Svihra (Ex. 1004), the Petition does not establish the public accessibility of either Amarenco (Ex. 1005) or Johnson (Ex. 1007), and the Board may conclude that Grounds 5-8 of the Petition do not establish a likelihood of success for substantially the same reasons as set forth in Part I.A of this Preliminary Response (*e.g.*, at most, only hearsay tends to establish the public accessibility of these two reference, and such hearsay is insufficient to carry Petitioner's burden on institution).

references at issue (Amarenco and Johnson) were simply disclosed on an Information Disclosure Statement.

Rather, Amarenco and Johnson—as well as the proposed combination thereof—were each presented to the Examiner during original prosecution through a Third-Party Submission under 37 C.F.R. § 1.290, which included a concise description of the relevance of Amarenco and Johnson. (Ex. 1002 at 148-53). Specifically, on May 15, 2023, the Office received a Third-Party Submission identifying Amarenco (Ex. 1005), Johnson (Ex. 1007), and one other reference not presently at issue (Rhodes, Ex. 1022). (Ex. 1002 at 148). The Third-Party Submission did not identify any other references. Although the Third-Party Submission was made anonymously through a registered patent practitioner, Petitioner does not deny having been the real party-in-interest behind such submission.

Grounds 5-8 duplicate the Third-Party Submission previously presented in this case. Like Grounds 5 and 6 of the Petition, the Third-Party Submission identified Amarenco individually as potential prior art. (*Compare* Paper 2 at 2-3 *with* Ex. 1002 at 149-50). And, like Grounds 7 and 8 of the Petition, the Third-Party Submission identified the proposed combination of Amarenco and Johnson as potential prior art. (*Compare* Paper 2 at 3 *with* Ex. 1002 at 151-53). Indeed, the Third-Party Submission includes a claim chart identifying the same portions of

Amarenco as Grounds 5-6 of the Petition. (*Compare* Paper 2 at 44-47 *with* Ex. 1002 at 149-50). Plus, the Third-Party Submission includes a second claim chart identifying the same portions of the proposed Amarenco/Johnson combination as Grounds 7-8 in the Petition. (*Compare* Paper 2 at 58-60 *with* Ex. 1002 at 151-53). The Office promptly acknowledged filing of the Third-Party Submission and noted that it was "entered." (Ex. 1002 at 109). The fact that the Third-Party Submission was "entered" indicates that the Office previously considered and rejected the exact same prior art and prior art combinations that Petitioner now seeks to assert.

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 Grounds 5-8 of the Petition, within the meaning of 35 U.S.C. § 325(d). On this record, it is "difficult to suggest that the Examiner merely 'overlooked'" the Third-Party Submission. *See Monolithic Power Sys., Inc. v. Volterra Semiconductor LLC*, Case IPR2020-01348, slip. op. at 12 (PTAB Mar. 4, 2021) (Paper 19). Petitioner's boilerplate assertion that "[t]he art and arguments presented in this petition are not the same or substantially the same as those presented to the Office during prosecution" (Paper 2 at 84) is unhelpful, if not patently false. Although Petitioner alleges in conclusory fashion that "the Examiner plainly erred in a manner material to the patentability of the Challenged

Claims," Petitioner does not identify any such error. (*Id.*) Section 325(d) denial is therefore appropriate.

The facts of this case are strikingly similar to other cases in which the Board has denied institution under Section 325(d) where the same prior art or arguments were previously presented to the Office by way of third-party submission under 37 C.F.R. § 1.290. For example, in *Cultec, Inc. v. StormTech LLC*, Case IPR2017-00777, slip op. at 10 (PTAB Aug. 22, 2017) (Paper 7), the Board denied institution of *inter partes* review because, as here, the same or substantially the same prior art or arguments were said to have been previously presented to the Office during prosecution of the challenged patent by way of a third-party submission under 37 C.F.R. § 1.290. The Board denied institution in the *Cultec* case even though the *Cultec* petition presented secondary references not presented in the third-party submission. *Cultec, Inc. v. StormTech LLC*, Case IPR2017-00777, slip op. at 10 (PTAB Aug. 22, 2017) (Paper 7). Rather, the Board found that "[t]he claim charts submitted with the Petition are an expanded version of the claim chart submitted with the Third Party Submission" and denied institution because the petitioner's arguments were substantially based on arguments and prior art previously before the Office in such Submission. (*Id.* at 10-11.). Here, in this case, the claim charts do not merely expand on the claim charts submitted with the Third-Party Submission. They are, in many cases, the exact same.

Section 325(d) denial is therefore appropriate.

C. Grounds 9-10 of the Petition should be denied because Petitioner has not shown that Burnett qualifies as prior art

Each of Grounds 9-10 of the Petition rely on Burnett (Ex. 1006). In addition to being named an inventor on the Burnett reference (Ex. 1006 at 1, Item 75 ("Inventors")), Mr. Daniel Burnett is also named as an inventor on the '943 Patent being challenged (Ex. 1001 at 1, Item 72 ("Inventors")). Petitioner asserts that Burnett (Ex. 1006) is prior art under AIA 35 U.S.C. § 102(a)(1) because, according to Petitioner, the earliest effective filing date of the '943 Patent claims is September 10, 2010. (Paper 2 at 65). However, as discussed below, the earliest effective filing date of the '943 Patent claims is October 2, 2006, and Burnett (Ex. 1006) is therefore not prior art to the '943 Patent claims.

To clarify, the '943 Patent, in its priority claims under 35 U.S.C. § 120, specifically and explicitly identifies the application (U.S. Application Serial No. 11/866,329), by serial number and filing date, that later published as the Burnett reference (Ex. 1006, publication of U.S. Application Serial No. 11/866,329). (*See, e.g.*, Ex. 1001 at 1-2, Item 63 ("Related U.S. Application Data")). In the same priority claims under 35 U.S.C. § 120, the '943 Patent specifically and explicitly identifies, by serial number and filing date, several other applications that establish a continuous claim of priority to October 2, 2006. (Ex. 1001 at 1-2, Item 63

("Related U.S. Application Data")). By identifying such earlier-filed applications in its priority claims by serial number and file number, Patent Owner complied with 35 U.S.C. § 120, as explained by the Federal Circuit. Thus, the Burnett reference (Ex. 1006) is not prior art to the '943 Patent, at least not because the '943 Patent has defective priority claims, as Petitioner asserts.

By way of background, Petitioner erroneously asserts that "the earliest effective filing date of the '943 Patent is September 20, 2010." (Paper 2 at 14). Based on this erroneous assertion, Petitioner incorrectly concludes that the Burnett reference (Ex. 1006) is prior art to the '943 Patent (Paper 2 at 65) even though the '943 Patent specifically cites, by serial number and filing date, the application published as the Burnett reference in its Section 120 priority claims. As explained below and contrary to Petitioner's assertions, the earliest effective filing date of the '943 Patent is well prior to the December 11, 2008, publication date of the Burnett reference asserted by Petitioner. (*Id.*). Thus, the Burnett reference (Ex. 1006) does not qualify as prior art against the '943 Patent. In fact, the earliest effective filing date of the '943 Patent is October 2, 2006, the filing date of a provisional patent application.

Starting with the '943 Patent, which is the patent under challenge, the parties agree, as Petitioner asserts, that the '943 Patent properly claims priority to U.S. Application No. 13/840,936 (the "'936 Application"):

> [T]he ’943 patent claims benefit to the ‘706 application filed January 2, 2020, which is a continuation of the ‘875 application filed March 30, 2017. Ex.1001, 1:8-30. The ‘875 application is a CIP of the ‘356 application filed on March 29, 2016, which is a continuation of the ’936 application filed on March 15, 2013. *Id.*

(Paper 2 at 15). The parties also agree, as Petitioner asserts, that the ’936 Application claims priority to at least September 20, 2010:

> The ’936 application is a CIP of the ’415 PCT application filed on September 20, 2011. *Id.* Finally, the ’415 PCT application claims priority to the ’680 provisional filed on September 20, 2010. *Id.*

(Paper 2 at 15-16). However, Petitioner fails to note, but never disputes, that the ’936 Application also claims priority to several other applications. Specifically, the ’936 Application claims priority, through two intervening continuation-in-part applications (including the Burnett reference), to a provisional patent application filed October 2, 2006, as shown in the following reproduction of the first paragraph of the ’936 Application as filed:

> The present application [U.S. Application No. 13/840,936] is also a continuation-in-part of U.S. Patent Application Serial No. 12/508,529 filed July 23, 2009, which is a continuation-in-part of U.S. Patent Application Serial No. 11/866,329 filed October 2, 2007, which claims priority to U.S. Provisional Patent Application Serial No. 60/848,720 filed October 2, 2006.

(Ex. 1044 ¶ 0001). U.S. Provisional Patent Application Serial No. 60/848,720 was filed October 2, 2006. (Ex. 1044 at 1). One year later, U.S. Patent Application Serial No. 11/866,329 was filed on October 2, 2007, explicitly claiming priority to U.S. Provisional Patent Application Serial No. 60/848,720 in the first paragraph.

(Ex. 1048 at ¶ 0001). While U.S. Patent Application Serial No. 11/866,329 was still pending, U.S. Patent Application Serial No. 12/508,529 was filed July 23, 2009, explicitly claiming priority to both U.S. Patent Application Serial No. 11/866,329 and U.S. Provisional Patent Application Serial No. 60/848,720. (Ex. 1047 ¶ 0001). Thus, it is indisputable that the ’936 Application, to which the ’943 Patent being challenged explicitly and properly claims priority (as the parties agree), further explicitly and properly claims priority a provisional patent application filed on October 2, 2006, which is well before the alleged prior art date of the Burnett reference (Ex. 1006).

This provisional patent application, as well as each and every intervening patent application establishing a continuous chain of priority to such provisional patent application, are specifically referenced multiple times in the ’943 Patent, and in the application leading to the ’943 Patent. For example, each of the following applications:

(i) U.S. Patent Application Serial No. 12/508,529 filed July 23, 2009;

(ii) U.S. Patent Application Serial No. 11/866,329 filed October 2, 2007; and

(iii) U.S. Provisional Patent Application Serial No. 60/848,720 filed October 2, 2006

was and is specifically referenced, by serial number and filing date, in at least the following places:

(1) the face of the '943 Patent, as issued, under the heading, "Related U.S. Application Data" (Ex. 1001 at 1-2, Items 60 & 63);

(2) 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); and

(3) the Application Data Sheet submitted with the application leading to the '943 Patent (Ex. 1002 at 191).

Thus, the '943 Patent "contains … a specific reference to the earliest filed application[s]" to which priority is claimed, 35 U.S.C. § 120, and the earliest effective filing date of the claims is October 2, 2006.

In a footnote to the Petition (Paper 2 at 16 n.3), Petitioner misapplies Federal Circuit law concerning Section 120, as well as the factual record, to assert that "[b]enefit/priority claims to earlier-filed applications in either of the '356 or '936 applications that are not enumerated in the '943 patent cannot be relied on to give the '943 patent an earlier effective filing date." (*Id.*). In *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309 (Fed. Cir. 2018), cited by Petitioner in sole support of their priority date assertions, the Federal Circuit affirmed a final written decision by the Board in which the patent being challenged *contained no reference whatsoever* to

the earlier-filed application to which priority was claimed. *Id.* at 1315-16. Although the patent being challenged in *Droplets* contained specific reference to an earlier-filed application (thus properly establishing priority to this earlier-filed application), the Federal Circuit affirmed the Board's decision not to extend these priority claims to even earlier-filed applications because those other applications were not explicitly referenced (*e.g.*, by number) in the patent being challenged. (*Id.*)

The Federal Circuit did *not* hold, as Petitioner now seems to suggest, that a patent, which in fact identifies, by correct serial number and filing date, all earlier-filed applications through which priority may be properly claimed to an earlier date, must completely identify *all familial relationships* between the earlier-filed applications that were specifically identified in order to maintain priority claims. The facts of *Droplets* were different, and its comments relative to the present situation are *dicta*. Here, as mentioned, each and every patent application establishing a continuous chain of priority was cited by name and filing date on the face of the '943 Patent, as issued, and in both in the first paragraph of the written description and the Application Data Sheet of the application leading to the '943 Patent, as filed. In other words, these claims were enumerated, and this is not the *Droplets* case. As opposed to the *Droplets* case, where there existed a complete failure to comply with 37 C.F.R. § 1.78, here, Patent Owner has provided a citation

to a serial number and filing date to each reference for claiming priority. Indeed, each time those specific citations were made, they were made in the context of a priority claim under Section 120. This fact distinguishes other cases in which the complete failure to state a serial number and filing date deprived the patent owner of an otherwise proper priority claim.[4]

This fact also distinguishes the *Droplets* case, cited by Petitioner, as well as the policy on which the Court decided such case. In *Droplets*, unlike here, the patent being challenged did not identify (*e.g.*, by serial number and filing date) all the applications to which priority was claimed. Given that, in *Droplets*, there was no identification of applications to which priority was claimed, the Court was

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[4] *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 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.").

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 applications." (*Id.* at 1316-17 (quoting *Sampson*, 463 F.2d at 1045) (internal quotation omitted).) On this point, Petitioner never alleges that any burden was required to identify the earlier-filed applications.

At most, Petitioner can point only to an incomplete yet accurate statement of familial relationships between the intervening patent applications that were specifically referenced. Section 120, by its terms, requires no such thing, and *Droplets* does not hold otherwise. Because the '943 Patent, in its priority claims, specifically identifies each and every application, by serial number and filing date, Patent Owner provided more than enough information to enable a person searching the records of the Patent Office to determine with a minimum of effort that the '943 Patent claims priority to a provisional application filed October 2, 2006. In

fact, it takes little or no effort at all because this provisional application is referenced by serial number and filing date in the priority claims section of the '943 Patent.

Furthermore, the priority claims in '943 Patent substantially comply with the Office's regulations in addition to Section 120. For claiming benefit to a prior-filed provisional application, the Office requires the application to "contain … a reference to each such prior-filed provisional application, identifying it by the provisional application number (consisting of series code and serial number)." 37 C.F.R. § 1.78(a)(1)(3). Here, the '943 Patent identifies U.S. Provisional Patent Application Serial No. 60/848,720, filed October 2, 2006, "by the provisional application number (consisting of series code and serial number)," 37 C.F.R. § 1.78(a)(1)(3), in the written description and in the Application Data Sheet.

Similarly, for claiming benefit to a prior-filed non-provisional application, the Office likewise requires the application to "contain … a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number)." 37 C.F.R. § 1.78(d)(2). Here again, the '943 Patent identifies U.S. Patent Application Serial Nos. 12/508,529 and 11/866,329 "by application number (consisting of series code and serial number)," 37 C.F.R. § 1.78(d)(2), in the written description and in the Application Data Sheet. For claiming benefit to a prior-filed non-provisional application, the Office also

requires that "[t]he reference must also identify the relationship of the applications." There is no dispute that Patent Owner stated correctly, though not necessarily completely, the relationship of all applications identified specifically in the '943 Patent.

Thus, Petitioner has failed to establish that the Burnett reference (Ex. 1006) is likely prior art against the challenged claims of the '943 Patent, and Petitioner is unlikely to succeed on Grounds 9-10 of the Petition, each of which rely on Burnett.

II. The non-prior art grounds in the Petition (Ground 11) likewise do not show a reasonable likelihood that Petitioner would prevail, as Petitioner has not shown a lack of enablement

Lastly, Petitioner has failed to show a likelihood of succeeding on Ground 11 in the Petition, in which Petitioner asserts that all 39 challenged claims of the '943 Patent are putatively invalid for lack of enablement under 35 U.S.C. § 112. (Paper 2 at 79-81). Petitioner's enablement challenge fails because Petitioner has not shown that practicing the claimed inventions would require "undue experimentation," as required by law. *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991). Disregarding the "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), Petitioner focuses exclusively on portions of the specification of the '943 Patent, which supposedly discourage utilizing purely

electrical stimuli within a certain frequency range (*e.g.*, "about 5 Hz to about 60 Hz or greater") to stimulate nerves through certain skin surfaces (*e.g.*, "non-glabrous skin surfaces"). Yet, no claim of the '943 Patent recites particular frequency ranges or particular types of skin surfaces and, furthermore, the '943 Patent claims on their face, absent claim construction, do not preclude the application of electromagnetic stimuli,[5] which the specification explicitly contemplates as being acceptable within and with these frequencies and skin types.

Fundamentally, neither Petitioner nor Petitioner's expert attempts to show that undue experimentation would be required to practice the challenged claims, which is fatal to its enablement challenge. There seems to be no genuine dispute that one of ordinary skill in the art could, based on the specification, practice the claimed inventions, even the embodiments that Petitioner asserts are inadvisable.

[5] According to the Petition, "no terms require construction for purposes of this Petition." (Paper 2 at 21). A "comprising" claim, like the claims at issue here, which recites "an electrical stimulus" could cover an electromagnetic stimulus (being the combination of electrical and magnetic stimuli), which would be entirely consistent with the teachings relied upon by Petitioner. The Petition's failure to set forth a proper claim construction analysis does not support its enablement challenges.

For example, Petitioner's expert never alleges that he tried, but failed, to practice the claims with the frequencies and skin types supposedly discouraged in the specification.

This is not a case in which a patent claims a genus but teaches only limited species, as for example 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 v. Medrad*, 481 F.3d 1371, 1378 (Fed. Cir. 2007).

Rather, it is a case in which a patent claims methods of treatment that do not recite particular frequency ranges or skin types and may therefore be practiced with various frequency ranges and with various skin types, all of which are disclosed in the specification. At most, certain frequency ranges and skin types that could be used to practice the invention are discouraged in the specification. Notably, the record in fact suggests that the inventors of the '943 Patent were the very first to recognize the advantages and disadvantages of certain frequency ranges for certain stimuli as applied to certain skin types. Neither Petitioner nor its expert says otherwise. Although Petitioner reads portions of the specification of the '943 Patent to discourage certain embodiments, Petitioner never shows that undue

experimentation would be required to practice such embodiments, even if discouraged. Petitioner's enablement challenge (Ground 11) therefore fails.

III. Conclusion

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

Respectfully submitted,

Date: October 30, 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 5,195 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 October 30, 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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