

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PEAKLOGIC, INC.,
Petitioner,

v.

WAVE NEUROSCIENCE, INC.,
Patent Owner.

IPR2022-01550
Patent 8,475,354 B2

Before JAMES A. WORTH, DEVON ZASTROW NEWMAN, and
DAVID COTTA, *Administrative Patent Judges*.

NEWMAN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

A. *Background and Summary*

PeakLogic, Inc., (“Petitioner”) filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claim 39 “the Challenged Claim”) of U.S. Patent No. 8,475,354 (Ex. 1001, “the ’354 patent”). Paper 1 (“Pet.”). Wave Neuroscience, Inc., (“Patent Owner”) filed a Patent Owner Preliminary Response (“Prelim. Resp.”). Paper 5. With our permission, (Ex. 3001) Petitioner filed a Reply to Patent Owner’s Preliminary Response (“Pet. Reply,” Paper 8) and Patent Owner filed Patent Owner’s Sur-Reply to Petitioner’s Reply to Patent Owner’s Preliminary Response (“PO Sur-reply,” Paper 10).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b) (2018); 37 C.F.R. § 42.4(a) (2019). An *inter partes* review may not be instituted “unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Upon consideration of the Petition, the Preliminary Response, and the evidence of record, we conclude that Petitioner has not established a reasonable likelihood of prevailing on its assertion that the challenged claims are unpatentable based on the grounds advanced here. Accordingly, we deny institution of *inter partes* review of claim 39 of the ’354 patent.

B. Real Parties in Interest

The parties identify themselves as the real parties-in-interest. Pet. 2; Paper 4, 2.¹

C. Related Matters

The parties identify *Wave Neuroscience, Inc. v. PeakLogic, Inc.*, Case No. 3:21-cv-01330-CAB-AGS (S.D. Cal.) (“the parallel district court litigation”) as a related matter.² Pet. 3; Paper 4, 2. The parties also identify IPR2022-01526 (regarding U.S. Patent No. 9,446,259 B2), IPR2022-01527 (regarding U.S. Patent No. 8,480,554 B2), and U.S. Patent Application No. 17/033,903 as related matters. Pet. 2–3; Paper 4, 2–3.

D. The ’354 Patent

The ’354 patent, titled “Systems and Methods for Neuro-EEG Synchronization Therapy,” issued July 2, 2013, from Application No. 12/237,319 (“the ’319 application”), filed September 24, 2008. Ex. 1001, codes (21), (22), (45), (54).

The ’354 patent discloses “methods and systems for novel, inexpensive, easy to use therapy for a number of mental disorders.” *Id.* at 1:32–33. The ’354 patent states that its methods and devices “gently ‘tune’ the brain and affect mood, focus, and cognition of human subjects.” *Id.* at 1:35–37. More specifically, the ’354 patent describes the use of repetitive Transcranial Magnetic Stimulation (“rTMS”), which involves placing an

¹ Paper 4 is not paginated. We cite to Paper 4 as if pagination began on the cover page.

² Petitioner also identifies *Wave Neuroscience, Inc. v. Miramar Health Physicians Grp., Inc.*, Case No. 3:21-cv-01247-CAB-BGS (S.D. Cal.) as a related matter but states that proceeding was dismissed without prejudice. Pet. 4.

electromagnet on a subject's scalp to generate "a series of magnetic field pulses roughly the strength of an MRI scan." *Id.* at 1:20–22. According to the '354 patent, "[s]ome studies have shown that rTMS can reduce the negative symptoms of schizophrenia and depression under certain circumstances." *Id.* at 1:23–25.

The '354 patent describes "altering an intrinsic frequency of a brain of a subject within a specified EEG band, comprising: (a) determining the intrinsic frequency of the subject within the specified EEG band; (b) comparing the intrinsic frequency from step (a) to an average intrinsic frequency of a healthy population database." *Id.* at 1:47–52. The '354 patent describes the intrinsic frequency as a subject's peak frequency for a given brain wave frequency band, such as the peak frequency for the alpha band. *Id.* at 14:5–11; 23:52–58; Fig. 5. The '354 patent explains that if the intrinsic frequency measured in step (a) differs from the average intrinsic frequency of the healthy population database, the subject's intrinsic frequency is altered by applying a magnetic field of a certain frequency close to the subject's head. *Id.* at 1:52–64.

In one aspect, the method comprises: "(a) adjusting output of a magnetic field for influencing an intrinsic frequency of a specified EEG band of the subject toward a pre-selected or target intrinsic frequency of the specified EEG band; and (b) applying said magnetic field close to a head of the subject." *Id.* at 1:41–45.

The '354 patent also describes "determining the Q-factor of the intrinsic frequency within the specified EEG band of the subject; comparing the Q-factor of the intrinsic frequency from step (a) to an average Q-factor of the intrinsic frequency of a healthy population database." *Id.* at 2:4–9.

The '354 patent describes the Q-factor as a ratio of the peak frequency (the intrinsic frequency) to the bandwidth for which energy is above one-half of the peak energy. *Id.* at 41:57–63, 46:40; Fig. 12. When the Q-factor measured in step (a) differs from the average Q-factor of the intrinsic frequency of the healthy population database, the subject's Q-factor is altered by applying a magnetic field with a certain frequency to the subject's head. *Id.* at 2:9–19.

The '354 patent describes using permanent magnets or electromagnets for its embodiments to produce a magnetic field that can be varied. *Id.* at 25:6–17; 26:16–30. Figure 1 of the '354 patent, reproduced below, shows an exemplary device that includes permanent magnets.

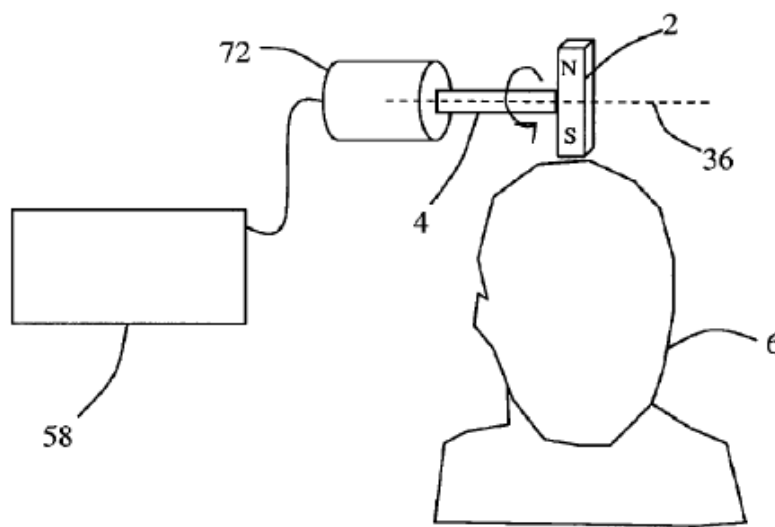


Figure 1

The '354 explains that the device includes “a magnet 2 coupled to and rotated by a motor 72” that “is coupled to the magnet 2 by a drive shaft 4, and the magnet rotation is controlled by a controller 58.” *Id.* at 18:31–38. For instance, subject 6 may experience no magnetic field when magnet 2's north and south poles have equal distances to subject 6. *Id.* at 26:20–24.

When magnet 2's south pole is closer, subject 6 experiences a negative magnetic field. *Id.* at 26:24–27. When magnet 2's north pole is closer, subject 6 experiences a positive magnetic field. *Id.* at 26:27–30.

E. Challenged Claim

Petitioner challenges claim 39 of the '354 patent. Pet. 5. Claim 39 is independent. Ex. 1001, 62:62–63:24. Claim 39 is reproduced below.

39. A device for use in treating a subject, comprising: a Transcranial Magnetic Stimulation (TMS) device comprising an electromagnet that generates a magnetic field;
- a first processor that controls a repetitive firing of the magnetic field based on at least one of: an intrinsic frequency of a brain of a subject within a specified Electroencephalography (EEG) band; and a Q subject within the specified EEG band; and
- wherein the first processor or a second processor moves
- (a) an intrinsic frequency of the brain of the subject within the specified (EEG) band to a pre-selected intrinsic frequency within the specified EEG band using the magnetic field; (b) a Q-factor of an intrinsic frequency of the brain of the subject within a specified EEG band toward a pre-selected Q-factor of the intrinsic frequency using the magnetic field; (c) a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band using the magnetic field wherein if the coherence value is higher than a pre-selected coherence value, lowering the coherence value by applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the pre-selected coherence value, raising the coherence value by applying at least one synchronized magnetic field close to the head of the subject; (d) an EEG phase between two sites in the brain of the subject of a specified EEG

frequency using the magnetic field wherein the magnetic field comprises a first magnetic field that is in-phase with a second magnetic field or a first magnetic field that is out of phase with a second magnetic field, or (e) a combination thereof.

F. Prior Art and Asserted Grounds

Petitioner asserts that the Challenged Claim is unpatentable based on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	39	102 ³	Klimesch ⁴
2	39	102	Jin ⁵

Pet. 5. Petitioner alleges that “[t]he Klimesch reference was published in 2003 by the Federation of European Neuroscience Societies and is therefore prior art under pre-AIA 35 U.S.C. § 102(b).” *Id.* at 23 (citing Ex. 1005, 1129, 1133). Petitioner further asserts that “[t]he Jin reference was published on October 27, 2005, and is therefore prior art under pre-AIA

³ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. Because the ’319 application was filed prior to the effective date of these AIA amendments, we apply the pre-AIA version of 35 U.S.C. § 102. Ex. 1001, code (22).

⁴ Wolfgang Klimesch et al., *Enhancing Cognitive Performance with Repetitive Transcranial Magnetic Stimulation at Human Individual Alpha Frequency*, 17 EUR. J. OF NEUROSCIENCE 1129–33 (2003) (Ex. 1005, “Klimesch”).

⁵ Yi Jin et al., *Therapeutic Effects of Individualized Alpha Frequency Transcranial Magnetic Stimulation on the Negative Symptoms of Schizophrenia*, 32 SCHIZOPHRENIA BULL. 556–61 (2005) (Ex. 1006, “Jin”).

35 U.S.C. § 102(b). *Id.* at 36 (citing Ex. 1006, 556). Patent Owner does not challenge the prior art status of any asserted reference. *See generally* Prelim. Resp.

In support of its Petition, Petitioner relies on the supporting Declaration of Robert Silvetz, M.D., dated September 9, 2022. Ex. 1003 (“Silvetz Dec.”).

II. PETITIONER’S GROUNDS OF UNPATENTABILITY

A. *Legal Standard*

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)).

“A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Moreover, “[b]ecause the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). Whether a reference anticipates is assessed from the perspective of an ordinarily skilled artisan. *See Dayco*

Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1368 (Fed. Cir. 2003).

B. Person of Ordinary Skill in the Art

“The level of skill in the art is a factual determination” that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner asserts that “[a] person of ordinary skill in the art would have a medical degree plus at least two years of academic and/or industry experience in the field of TMS” and that “[a]dditional professional and/or technical experience could substitute for education, and vice versa.” Pet. 10 (citing Ex. 1003 ¶ 12). Patent Owner does not comment on the characterization offered by Petitioner or offer one of its own. *See generally* Prelim. Resp.

Petitioner’s definition appears to be consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the ’354 patent. Accordingly, for purposes of this Decision, we accept Petitioner’s proposed definition of the person of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (“the prior art itself [may] reflect[] an appropriate level” as evidence of the ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

C. Claim Construction

We apply the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R.

§ 42.100(b) (2019). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips*, 415 F.3d at 1317.

Both parties advanced arguments for claim construction in their initial briefs (*see* Pet. 10–22; Prelim. Resp. 10–17). Petitioner indicated in its Reply that the district court construed the claims after the Petition had been filed, and stated that “the parties to the IPRs have agreed that, for the purposes of these IPRs, the Board should accept the claim construction as adopted by the district court.”⁶ Pet. Reply 4. Patent Owner did not contradict this statement. *See generally* PO Sur-reply. As a result, we do not need to construe all proposed terms for purposes of rendering this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). For the purpose of institution, we address the sole remaining issue regarding to claim 39:

⁶ Exhibit 2001 is the district court’s claim construction order.

whether the claim phrase “wherein the first processor or a second processor moves” is limiting.

Petitioner argues that because claim 39 recites a device, its patentability can rely only the device’s structure and not the act of using the device to move parameters to distinguish over the prior art. Pet. 11–12. Petitioner argues that giving effect to the “moves” step would render the claim invalid under 35 U.S.C. § 112 for indefiniteness because the “moves” step is a method step in a claim to a device. *Id.* (citing, e.g., *IPXL Holdings v. Amazon*, 430 F.3d 1377, 1383–84 (Fed. Cir. 2005)). Petitioner argues that the recitation “wherein the first processor or a second processor moves” is non-limiting because “moves” refers to the device’s action in moving the recited parameters and because “the recited movement is a natural, inherent property of the human brain.” *Id.* at 12. Petitioner proposes that, for purposes of patentability, the entire third paragraph of the claim be read out. *Id.*

Patent Owner responds that the features in claim 39 relating to the term “moves” are limiting because they recite structural features of the first or second processor. Prelim. Resp. 15. Patent Owner cites cases supporting the concept that a device claim may recite structure capable of performing recited functions to describe and distinguish the apparatus, without reciting “capable of” as claim language, and argues that claim 39 is such a claim. *Id.* at 16 (citing, e.g., *INVT SPE LLC v. Int’l Trade Comm’n*, 46 F.4th 1361, 1372 (Fed. Cir. 2022)).

Claim 39 describes a device used to treat a subject by creating an electromagnetic field to “tune” the brain and affect mood, focus, and cognition of human subjects. Ex. 1001, 62:62–63:34. Briefly, claim 39

recites a device that creates an electromagnetic field using an electromagnet. A first processor “tunes” the brain by firing the magnetic field. The first or a second processor moves one of the recited frequency characteristics in the brain to a preselected different frequency. The term “moves” in claim 39 describes a function of the first or second processor, which provides the means by which the brain frequency is shifted. *See MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1312–1315 (reviewing cases applying and distinguishing reasoning in *IPXL Holdings*, 430 F.3d at 1383–84. Unlike *IPXL Holdings*, there is no confusion here as to when infringement of this claim would occur; infringement occurs when one makes, uses, offers to sell, or sells the claimed apparatus, which is capable of use for treatment. For this reason, we find that the recitation “wherein the first processor or a second processor moves” in claim 39 does not recite a method step, but rather describes the function of the recited structure – the first or second processor – that is capable of performing the recited (a) through (e) steps. *MasterMine*, 874 F.3d at 1315–16 (“the claims at issue here merely claim that the system ‘possess[es] the recited structure [which is] capable of performing the recited functions.’”) (alterations in original). As a result, we agree with Patent Owner that the recitation “wherein the first processor or a second processor moves” is limiting.⁷

For purposes of resolving whether to institute trial, we adopt and apply the interpretations stated in the district court’s claim construction order, Ex. 2001.

⁷ Having determined that the “moves” claim language is limiting, we need not further address Petitioner’s arguments that “the patentability of the device of claim 39 cannot be based on the act of using the device to “move[.]” certain parameters.” *See, e.g.*, Pet. 11–12.

D. Ground I – Anticipation of Claim 39 by Klimesch

1. Technology Overview

“The alpha band is the bandwidth of brain wave frequencies between about 8 and 13 Hz. Activity at these brain wave frequencies and at other brain wave frequencies outside the alpha band are readable by Electroencephalogram (EEG).” Ex. 1003 ¶ 15. Alpha frequency is the “dominant frequency in the human scalp EEG of adults.” Ex. 2002, 171. “[A]lpha frequency varies to a large extent as a function of age, neurological diseases, memory performance . . . , brain volume . . . and task demands.” *Id.* at 172. “Usually, alpha frequency is defined in terms of peak or gravity frequency within the traditional alpha frequency range.” *Id.* at 171. “Peak frequency is that spectral component within [the alpha band] which shows the largest power estimate.” *Id.* The gravity of a frequency is a mean calculated as “the weighted sum of spectral estimates, divided by alpha power.” *Id.*

Peak alpha frequency is referred to as the “intrinsic frequency,” in the ’354 patent. Ex. 1001, Figs. 5 & 6, 23:56–58 (“The vertical line drawn through the peaks [of the EEG segment shown in Figure 5] is at 9.1 Hz, the subject’s intrinsic alpha frequency.”); 46:30–32 (“The intrinsic frequency of alpha EEG is defined as the mean peak frequency (Fp) of 3 central leads (C3, C4, and Cz)”); *see also* Ex. 1003 ¶ 20 (testimony of Dr. Silvetz that “an individual subject’s peak frequency in the alpha band [is] called the ‘intrinsic frequency’ or the ‘intrinsic alpha frequency[]’”); Pet. 6 (“The intrinsic frequency is the peak in the frequency spectrum of the patient’s brain waves in the alpha band, unique to each patient.”); Prelim. Resp. 5

(“[T]he intrinsic frequency of a specified EEG band can be the frequency in a specified band having the highest energy or power estimate.”).

In Klimesch and Klimesch II,⁸ the peak alpha frequency is referred to as the “individual alpha frequency” (“IAF”). Ex. 1005, 1132 (“The IAF was determined . . . on the basis of power spectra . . . as the peak frequency within 7 and 14 Hz”); Ex. 2002, 172 (“In order to avoid confusions with traditional measures, we use the term individual alpha frequency (IAF) to denote the individual dominant (peak or gravity) EEG frequency in the [alpha range] of a single subject.”).

Klimesch II discloses that “[i]f EEG power in a resting condition is compared with a test condition, alpha power decreases (desynchronizes).” *Id.* This can be seen in Figure 1A of Klimesch II, which is reproduced below.

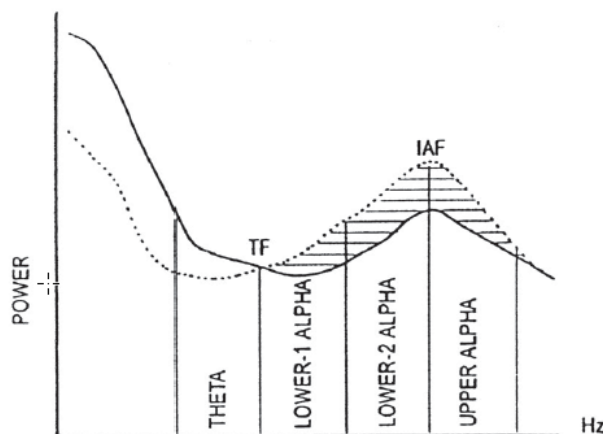


Figure 1A is a spectral analysis plotting frequency on the x-axis and power on the y-axis. *Id.* at 171, 172. Figure 1 plots the power spectra for both “a resting period in which subjects are in a state of alert wakefulness”

⁸ Wolfgang Klimesch, *EEG alpha and theta oscillations reflect cognitive and memory performance: a review and analysis*, 29 BRAIN RESEARCH REVS. 169–195 (1999) (Ex. 2002, “Klimesch II”).

(shown as a dotted line) and for a period when subject is performing a task like “memorizing visually presented words” (shown by a solid line). *Id.* at Fig. 1, 171. As can be seen, alpha power, including peak alpha power, is lower when the subjects were performing a task than when they were in a state of alert wakefulness. *Id.* This difference in power is referred to as “event-related desynchronization (ERD).” *Id.* at 172.

2. *Summary of Klimesch (Ex. 1005)*

Klimesch is an article appearing in the European Journal of Neuroscience. Ex. 1005. Petitioner contends that Klimesch is prior art under 35 U.S.C. 102(b). Pet. 20. Klimesch discloses a study in which subjects were given “rapid-rate repetitive transcranial magnetic stimulation (rTMS) at individual alpha frequency (IAF)” to determine whether that treatment would enhance cognitive performance by “influencing the dynamics of alpha desynchronization.” Ex. 1005, 1129–1130.⁹ The subjects were shown line drawings of cubes having different symbols on each side and were asked to decide which cube matched a mentally rotated target, a “mental rotation task.” *Id.* at 1130. A subject’s trial would commence with a signal, a train of twenty-four TMS pulses would then be delivered to the subject, and then the cubes would be presented after the last TMS pulse. *Id.*

Klimesch theorized that “a period of pronounced (upper) alpha activity – preceding task performance – is associated both with a large ERD (alpha suppression or reactivity) and good performance.” *Id.* To test this, Klimesch “appl[ied] rTMS at individual upper alpha frequency (IAF + 1Hz)

⁹ Petitioner cites to the page numbers of Klimesch rather than of the exhibit. We do the same for consistency.

in a period preceding task performance.” *Id.* Klimesch also applied RTMS at frequencies of IAF – 3 Hz, and 20 Hz. *Id.* at 1132. Klimesch describes using “[a] MagStim Rapid stimulator” to apply the pulses. *Id.* at 1130.

Klimesch explains that experiments would include recording an EEG to determine a subject’s individual upper alpha frequency (IAF). *Id.* at 1129–30. A first experiment would assess a subject’s cognitive performance and a second experiment would monitor changes in event-related desynchronization (ERD) and absolute band power. *Id.* at 1130–32

Klimesch reports that application of rTMS at IAF + 1 Hz “lead to a significant improvement in mental rotation performance.” *Id.* at 1132. “No significant changes in performance were induced with stimulation frequencies at IAF – 3 Hz, or 20 Hz.” *Id.* With respect to the subjects’ EEG profiles, Klimesch discloses that “[c]ompared with sham, rTMS at IAF + 1 Hz, induced a significant increase in lower-2¹⁰ and upper alpha¹¹ desynchronization (ERD) during mental rotation” and that “the increase in upper alpha ERD during rTMS stimulation is a result of both decreased poststimulus power . . . and increased reference power.” *Id.* Klimesch concludes that “[t]he influence of rTMS at IAF on EEG parameters mimicked exactly that situation which we know is typical for good performance: increased reference power, decreased test power and, consequently, a large ERD.” *Id.*

Klimesch states that “we have shown that cognitive performance is related to the extent of ERD, which in turn depends on the extent of power

¹⁰ “Lower-2-alpha” is the frequency band between IAF – 2 Hz and IAF. Ex. 1005, 1132.

¹¹ “Upper alpha” is the frequency band between IAF and IAF + 2 Hz. Ex. 1005, 1132.

in a resting or test interval” and that “large resting (or reference) alpha power and a large ERD are associated with good cognitive performance.” *Id.* at 1129–1130. Klimesch states that the experiments show a significant increase in performance but only after rTMS at IAF + 1 Hz. *Id.* at 1132.

3. *Analysis*

Petitioner asserts that Klimesch anticipates claim 39 of the '354 patent. Claim 39 recites a device including five device features recited in the alternative. Ex. 1001, 62:62–63:24 (reciting that the device comprises four differently phrased “wherein the first or second processor moves” alternative bases for adjusting the output of the magnetic field, or, as a fifth basis, “a combination thereof”). Petitioner contends that the prior art need not disclose all five of these alternatives; rather, Petitioner contends that it is sufficient for anticipation if the prior art discloses one. Pet. 11–12. Because it is dispositive with respect to Ground 1, we focus our discussion on the two alternatives that Petitioner contends are disclosed in Klimesch: 1) “moves an intrinsic frequency of the brain of the subject within the specified (EEG) band to a pre-selected intrinsic frequency within the specified EEG band using the magnetic field” (“the intrinsic frequency limitation”), and 2) “moves a Q-factor of an intrinsic frequency of the brain of the subject within a specified EEG band toward a pre-selected Q-factor of the intrinsic frequency using the magnetic field” (“the Q-factor limitation”). Ex. 1001, 63:3–9. We discuss each alternative limitation in turn.

a) The intrinsic frequency limitation

We begin by considering whether Klimesch discloses the intrinsic frequency limitation. Petitioner contends that Klimesch discloses “wherein a first or second processor moves an intrinsic frequency of the brain of the

subject within the specified (EEG) band to a pre-selected intrinsic frequency within the specified EEG band using the magnetic field” both expressly and inherently. Pet. 27–32.

(1) *Alleged express disclosure*

The evidence of record does not support that Klimesch expressly discloses the intrinsic frequency limitation. Although Klimsech discloses treating subjects with rTMS at a frequency one Hz above the intrinsic frequency (IAF + 1 HZ), it does not disclose whether the treatment moves the intrinsic frequency. *See generally*, Ex. 1005. Petitioner asserts that stimulation at IAF + 1 Hz “triggered increased EEG output in the EEG band of that stimulation frequency (IAF to IAF + 2 Hz) directly corresponding to enhanced alpha power in that EEG band.” Pet. 27. Enhancing EEG power is, however, distinct from moving frequency. *See, e.g.*, Ex. 2002, Fig. 1A (spectral analysis plotting frequency on the x-axis and power on the y-axis). Thus, even if we were to credit Petitioner’s assertion that stimulation at IAF + 1 Hz “increased EEG output” and “enhanced alpha power,” such assertion does not support that Klimesch expressly discloses moving the frequency at which peak alpha power is observed.

Petitioner also directs us to Klimesch’s disclosure that rTMS at IAF + 1 Hz resulted in “a significant increase in lower-2 and upper alpha desynchronization (ERD) during mental rotation.” Ex. 1005, 1132 (cited at Pet. 27–28). But ERD is also distinct from frequency. *See, e.g.*, Ex. 2002, Fig. 1A (spectral analysis showing ERD as the difference in alpha power when subjects are performing a task as compared to when subjects are in a state of alert wakefulness). Thus, an increase in ERD does not support

that Klimesch discloses changing the frequency at which peak alpha power is observed.

As Petitioner does not direct us to any other disclosure in Klimesch that supports moving the intrinsic frequency, Petitioner is unlikely to prevail in establishing that Klimesch expressly discloses the intrinsic frequency limitation.¹²

(2) *Alleged inherent disclosure*

We next consider whether Klimesch inherently discloses the intrinsic frequency limitation. Petitioner asserts:

Even if the Office were to conclude that Klimesch does not *expressly* disclose that the application of rTMS at IAF + 1 Hz “move[s] the intrinsic frequency of the subject up within the specified EEG band toward a preselected intrinsic frequency,” the recited movement is nonetheless inherent in Klimesch because it is the brain’s natural response to stimulation at that frequency.

Pet. 29. As support, Petitioner cites: four passages from the ’354 patent (Ex. 1001, 23:63–24:3, 34:56–35:5, 40:6–11; 40:45–48), the testimony of Dr. Silvetz (Ex. 1003 ¶¶ 20–21), a passage from Jin (Ex. 1006, 559), a passage from U.S. Patent No. 6,488,617 (“Katz,” 2:66–3:5),¹³ and a portion of the prosecution history (Ex. 1002, WNI000626). Pet. 29–30. We discuss

¹² In addition to the disclosures of Klimesch, Petitioner supports its position that Klimesch expressly discloses the intrinsic frequency limitation by citing the testimony of Dr. Silvetz that peak alpha frequency increases in response to stimulation at a frequency above peak alpha frequency. Pet. 25 (citing Ex. 1003 ¶ 21). As this testimony is grounded in inherency, we address it in connection with Petitioner’s inherency argument.

¹³ Our rules state that “[a]ll evidence must be filed in the form of an exhibit.” 37 C.F.R. § 42.63. Petitioner does not provide Katz as an exhibit. Nonetheless, we have obtained a copy of Katz from public records and entered it into the record as Exhibit 3001.

all of the evidence cited by Petitioner in turn, beginning with Petitioner's citation of the '354 patent.

Petitioner contends (Pet. 29) that the following disclosure from the '354 patent supports that applying rTMS at a frequency of IAF + 1 Hz moves the intrinsic frequency up toward a preselected frequency:

FIG. 6 is similar to FIG. 5, except the EEG was sampled immediately following therapy. In this, it can be seen that the energy associated with the intrinsic alpha frequency has increased significantly. From the circle representation on the right, it can be seen that the distribution of energy at the intrinsic alpha frequency throughout the head is more uniform, though the majority of energy is still concentrated at the back of the brain.

Ex. 1001, 23:63–24:3. This passage does not speak to the effect of rTMS on the peak alpha frequency, disclosing only that the energy associated with the intrinsic alpha frequency has increased. But, as discussed above, EEG energy is distinct from frequency. *See, e.g.*, Ex. 2002, Fig. 1A (spectral analysis plotting frequency on the x-axis and power [equivalent to energy] on the y-axis). This passage also does not speak to what EEG changes are a direct consequence of treatment. Simply put, this passage does not support that applying rTMS at a frequency above peak alpha frequency necessarily moves the frequency at which peak alpha power is observed.

Petitioner also cites (Pet. 29) the following passage from the '354 patent to support inherency:

Provided herein is a method of altering an intrinsic frequency of a brain of a subject within a specified EEG band, comprising determining the intrinsic frequency of the subject within the specified EEG band; comparing the intrinsic frequency from step (a) to an average intrinsic frequency of a healthy population database; if the intrinsic frequency from step (a) is higher than the average intrinsic frequency of the healthy

population database, shifting down the intrinsic frequency of the subject by applying a specific magnetic field close to a head of the subject, wherein said specific magnetic field has a frequency lower than the intrinsic frequency of the subject; and if the intrinsic frequency from step (a) is lower than the average intrinsic frequency of the healthy population database, shifting up the intrinsic frequency of the subject by applying a specific magnetic field close to a head of the subject, wherein said specific magnetic field has a frequency higher than the intrinsic frequency of the subject.

Ex. 1001, 34:56–35:5. Although this disclosure supports that the intrinsic frequency can be shifted up or down by applying a “specific magnetic field close to the head,” it does not teach that the intrinsic frequency necessarily shifts every time a magnetic field above or below the patient’s peak alpha frequency is applied. *Scaltech Inc. v. Retec/Tetra L.L.C.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999) (“Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency.”). In addition, Petitioner does not direct us to disclosure in the ’354 patent supporting that stimulation at IAF + 1 Hz under the circumstances disclosed in Klimesch, will necessarily shift the intrinsic frequency. *See*, Ex. 1003 ¶ 20 (testimony of Dr. Silvetz identifying factors that impact how the brain responds to rTMS); Ex. 1001, 40:19–32 (describing “parameters that require optimization for rTMS,” including: “[f]requency, “[i]ntensity, “[d]uration,” and “[s]ite of stimulation”).

Petitioner also cites (Pet. 29) the following passage from the ’354 patent to support inherency:

The magnetic pulses generated by rTMS devices are generally believed to induce electrical charges to flow. The amount of electricity created in the brain is very small, and can not [sic] be felt by the patient. These flowing electric charges can cause the

neurons to fire or become active under certain circumstances. Typically, an objective of rTMS Therapy is to stimulate (or activate) brain cells.

Ex. 1001, 40:6–11. This passage does not speak to the effect of rTMS on the peak alpha frequency, disclosing only that rTMS is believed to cause electrical charges to flow and that such flow of electrical charges can cause neurons to fire or become active.

Petitioner also cites (Pet. 29) the following passage from the '354 patent to support inherency:

Since EEG changes can be direct consequences of treatments using the methods or devices described herein, those EEG changes can be used to clinically correlate improvement in symptoms of mental disorders.

Ex. 1001, 40:45–48. This passage does not support inherency for at least two reasons. First, the language it uses – “EEG changes *can be* direct consequences” – is not sufficiently certain to support inherency. *Scaltech*, 178 F.3d at 1384. Second, even if the language were sufficiently certain, this passage does not speak to what EEG changes are a direct consequence of treatment. Simply put, this passage does not support that applying rTMS at a frequency above peak alpha frequency necessarily moves the frequency at which peak alpha power is observed.

We next consider the cited testimony of Dr. Silvetz. Petitioner cites paragraphs 20 and 21 of Dr. Silvetz' declaration. Pet. 30. In paragraph 20, Dr. Silvetz testifies that “it was known that applying a course of rTMS treatment at or near an individual subject's peak frequency in the alpha band (called the ‘intrinsic frequency’ or the ‘intrinsic alpha frequency’) triggered a marked increase in the power of that subject's peak frequency in the alpha band, as observed using EEG.” Ex. 1003 ¶ 20 (citing Jin and Klimesch as

support). This testimony does not speak to whether rTMS stimulation at or near a subject's peak alpha frequency changes the frequency at which peak alpha power is observed because, as discussed above, power is different from frequency. Thus, this testimony does not support that rTMS at IAF + 1 Hz, as disclosed in Klimesch, inherently changes the frequency at which peak alpha power is observed.

Paragraph 21 of Dr. Silvetz' declaration does speak to whether rTMS stimulation at or near a subject's peak alpha frequency changes the frequency at which peak alpha power is observed. In that paragraph, Dr. Silvetz testifies:

As the power of a subject's peak alpha frequency increases in response to rTMS at or near the subject's peak alpha frequency, this naturally alters the shape of the patient's brain wave frequency spectrum, as observed using EEG. First, the peak alpha frequency itself changes. In response to stimulation at a frequency in the alpha band that is higher than the patient's peak alpha frequency, the peak alpha frequency increases in the alpha band – meaning, the peak alpha frequency moves from one frequency to a higher frequency. In response to stimulation at a frequency in the alpha band that is lower than the patient's peak alpha frequency, the peak alpha frequency decreases in the alpha band – meaning, the peak alpha frequency moves from one frequency to a lower frequency. These are natural responses of the typical human brain to such stimulation.

Id. ¶ 21. If we were to credit this testimony, it would lend support to Petitioner's assertion that stimulation at IAF + 1 Hz, as disclosed in Klimesch, can move the intrinsic frequency to a higher frequency.

Importantly, however, Dr. Silvetz does not cite anything to support his opinion that stimulation at a frequency above the peak alpha frequency moves the peak frequency. *Id.* Nor does Dr. Silvetz explain why such stimulation moves the peak frequency. *Id.* Accordingly, Dr. Silvetz'

testimony is entitled to little weight. *Xerox Corp. v. Bytemark, Inc.*, IPR 2022-00624, Paper 9 at 15–16 (PTAB August 24, 2022)) (Decision Denying Institution) (precedential) (finding that expert’s conclusory assertions that repeat the proposition for which they are offered without “any additional supporting evidence or provide any technical reasoning” in support are “conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight”); *see also*, 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”); *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1311 (Fed. Cir. 2000) (“Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination.”) (quoting *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985)); *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986) (“Although in some circumstances unsupported oral testimony can be sufficient to provide prior knowledge or use, it must be regarded with suspicion and subjected to close scrutiny.”).

In addition, Dr. Silvetz’ testimony that rTMS at frequencies above peak alpha frequency moves the peak frequency to a higher frequency is not specific to the conditions under which rTMS was administered in Klimesch. This is problematic because Dr. Silvetz also testifies that the brain’s response to rTMS varies depending on the conditions under which it was administered. Ex. 1003 ¶ 20 (“The brain’s natural response varies depending on factors such as: a) the location of the electromagnet; b) the frequency of stimulation; c) the duration of stimulation; d) the number of

stimulation pulses administered; e) the amplitude of the pulses administered; and f) the patient's physiology.”).

In summary, given that it not accompanied by supporting evidence, does not provide any technical reasoning, is not specific to Klimesch, and does not offer perspective on the understanding of an ordinary artisan at the time of the invention, we give little weight to Dr. Silvetz' testimony in determining whether Petitioner has established a reasonable likelihood that Klimesch inherently discloses the intrinsic frequency limitation. We do not determine here that Dr. Silvetz' testimony is incorrect, only that it is not insufficiently supported by evidence and technical reasoning and lacks relevant information regarding the perspective of the ordinary artisan to be accorded substantial weight.

We turn now to Petitioner's citation of Jin as supporting inherency. Petitioner describes Jin as teaching that “that rTMS applied at subjects' intrinsic (α TMS) frequency produced clinical improvement¹⁴ ‘highly correlated ($r = 0.86, p = .001$) with increases (34%) in front alpha amplitude.” Pet. 29–30 (citing Ex. 1006, 559).¹⁵ Jin's disclosure that there is a correlation between clinical improvement and increased front alpha amplitude does not speak to what effect stimulation with a frequency above peak alpha frequency has on the frequency at which peak alpha power is observed. Accordingly, Petitioner's citation of Jin does not support that

¹⁴ The “clinical improvement” referenced in the quoted passage from Jin is in “negative symptoms of schizophrenia.” Ex. 1006, 556 (Abstract).

¹⁵ This citation appears to be incorrect. Although page 559 of Jin includes a disclosure similar to that quoted in the Petition, the quoted passage appears in Jin's abstract. See Ex. 1006, 556. For completeness, we consider both disclosures.

rTMS at IAF + 1 Hz, as disclosed in Klimesch, inherently meets the intrinsic frequency limitation.

We next consider whether Katz supports Petitioner's position. The cited portion of Katz includes the disclosure that "[t]he ability to produce a localized magnetic field, which in turn triggers localized electrical activity in the brain, has enabled TMS to be successful in the treatment of depression." Ex. 3002, 3:2–5. This disclosure does not support Petitioner's inherency position because the teaching that TMS triggers electrical activity in the brain does not speak to whether the triggered electrical activity causes the frequency at which peak alpha power is observed to move. The remaining content in the cited portion of Katz is similarly unhelpful to Petitioner's inherency position, including disclosures that TMS can treat depression, that TMS is a less dangerous way to stimulate the brain, and that the type of magnetic coil used in TMS is disclosed in a prior art patent. *Id.* at 2:66–3:1.

Finally, we consider whether Petitioner's citation to the prosecution history of the '354 patent supports inherency. Petitioner contends that the cited passage "discuss[es] how the application of TMS in Katz ***“move the brain waves* from one band to another.”** Pet. 30. As an initial matter, the cited portions of the prosecution history are all attorney argument, and thus not evidence. *Id.*; *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989) (“Attorneys’ argument is no substitute for evidence.”); *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974).

Moreover, even if moving frequency between bands supports that it is possible to move peak frequency within the alpha band, Petitioner does not provide a persuasive evidentiary basis to support a conclusion that the circumstances under which TMS was applied in Katz are comparable to

circumstances under which rTMS was applied in Klimesch, much less that the rTMS in Klimesch would necessarily move the frequency at which peak alpha power is observed. *Scaltech Inc.*, 178 F.3d at 1384; *In re Rijckaert*, 9 F.3d 1531, 1534, (Fed. Cir. 1993) (reversing rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art).

(3) *Conclusion with respect to the intrinsic frequency limitation*

For the reasons discussed above, Petitioner has not established a reasonable likelihood that it will prevail in showing that Klimesch expressly or inherently discloses the intrinsic frequency limitation.

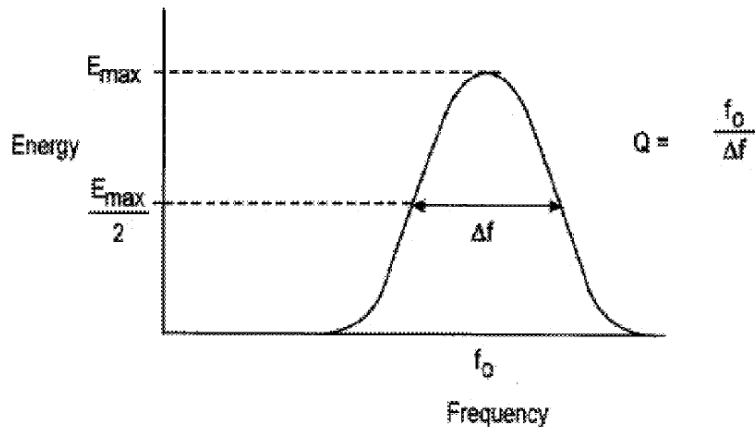
b) The Q-factor limitation

Petitioner contends that Klimesch expressly and inherently discloses “wherein a first or second processor moves a Q-factor of an intrinsic frequency of the brain of the subject within a specified EEG band toward a pre-selected Q-factor of the intrinsic frequency using the magnetic field” both expressly and inherently. Pet. 32–36.

(1) *Alleged express disclosure*

According to Petitioner, Klimesch satisfies the Q-factor limitation because it “expressly discloses that stimulation at IAF + 1 Hz triggered increased EEG output in the EEG band of that stimulation frequency (IAF to IAF + 2 Hz).” Pet. 33. Petitioner explains that the “increased energy in the EEG band of the subject’s intrinsic frequency causes the Q-factor of the intrinsic frequency to increase,” and thus Klimesch expressly discloses moving the Q-factor. *Id.* We do not agree for the reasons discussed below.

The '354 patent uses Figure 12, which is reproduced below, to illustrate Q-factor.



Ex. 1001, Fig. 12. Figure 12 is a graph showing “the frequency distribution of the energy of an EEG signal.” *Id.* at 14:50–51. The x-axis of the graph is the “frequency” of the EEG signal and the y-axis is the “energy” of the signal. The graph labels the intrinsic frequency – i.e., the peak frequency – “ f_0 ” and labels “the frequency bandwidth for which the energy is above one-half the peak energy” “ Δf .” *Id.* at 14: 52–53. The '354 patent defines “Q-factor” as “the ratio of $f_0/\Delta f$.” *Id.* at 41:62–64.

Petitioner asserts that Klimesch discloses “increased energy in the EEG band of the subject’s intrinsic frequency” (Pet. 33) but does not explain how that increased energy is distributed across the EEG band. Absent information about how energy is distributed across the EEG band, we can only speculate as to whether the Q-factor changed. Pet. 33. As Patent Owner explains, “even if Klimesch’s peak energy changes, Q-factor will not change so long as the ratio of $f_0/\Delta f$ stays the same.” Prelim. Resp. 34.

As Petitioner does not direct us to any other disclosure in Klimesch that supports changing the Q-factor, Petitioner is unlikely to prevail in

establishing that Klimesch expressly discloses the intrinsic frequency limitation.

(2) *Alleged inherent disclosure*

Petitioner contends that Klimesch “inherently discloses moving the subjects’ Q-factor of the intrinsic frequency within the specified EEG band (IAF to IAF + 2 Hz) to a different Q-factor of the intrinsic frequency in the same specified EEG band, because that is the brain’s natural response.” Pet. 33–34. As support, Petitioner cites: two passages from the ’354 patent (Ex. 1001, 35:15–20, 35:20–25) and the testimony of Dr. Silvetz (Ex. 1003 ¶¶ 20, 21, 23). Pet. 32. We discuss each source of alleged evidentiary support in turn.

Petitioner quotes the ’354 patent as teaching: “[i]nherently, “the Q-factor will increase . . . when the peak energy E_{max} of the signal increases.”” Pet. 34 (quoting Ex. 1001, 46:50–60). But considered in full context, the ’354 patent clearly uses language of possibility not necessity:

The Q-factor is defined as the ratio of $f_0/\Delta f$. As can be seen [discussing Figure 12, reproduced above], when Δf decreases for a given f_0 , the Q-factor will increase. ***This can occur*** when the peak energy E_{max} of the signal increases or when the bandwidth of the EEG signal decreases.

Ex. 1001, 46:56–61 (emphasis added). This passage supports that one possible effect of increasing peak energy is to increase the Q-factor, but it does not support that such effect is inherent.

Petitioner also alleges the ’354 disclosure acknowledges that “applying a magnetic field at IAF + 1 Hz, as taught in Klimesch, inherently causes the Q-factor of the subject’s intrinsic frequency to tune up.” Pet. 32,

34–35 (citing Ex. 1001, 35:1–20).¹⁶ Although this passage supports that the Q-factor can be tuned by applying a preselected magnetic frequency, the cited portion of the '354 patent does not identify what that frequency is. *See* Ex. 1001, 35:1–20. And Petitioner does not direct us to disclosure in the '354 patent supporting that stimulation at IAF + 1 Hz, as in Klimesch, will necessarily tune the Q-factor up, much less that it will do so under the circumstances disclosed in Klimesch. *See* Ex. 1003 ¶ 20 (testimony of Dr. Silvetz identifying factors that impact how the brain responds to rTMS); Ex. 1001, 40:19–32 (describing “parameters that require optimization for rTMS,” including: “[f]requency, “[i]ntensity, “[d]uration,” and “[s]ite of stimulation”). Accordingly, the disclosure of the '354 patent does not support Petitioner’s inherency position.

We turn now to the testimony of Dr. Silvetz on inherency. Dr. Silvetz testifies that Q-factor increases as a natural response to stimulation at or near a subject’s peak alpha frequency, explaining:

In response to stimulation at or near the subject’s peak alpha frequency, as the amplitude of the subject’s peak alpha frequency increases, the peak takes on a sharper, tighter, more defined shape in the frequency spectrum observed using EEG, where the ratio corresponding to the peak’s amplitude divided by the peak’s bandwidth increases. This effect also often accompanies a reduction in the “noise” attributable to brain waves at frequencies other than the peak alpha frequency. This reduction in noise is part of the natural response of the human brain to rTMS at or near the subject’s peak alpha frequency. As the power of the noise decreases and the power of the peak alpha frequency increases, the peak naturally takes on a tighter,

¹⁶ The cited portion of the '354 patent includes a similar disclosure on tuning the Q-factor down. Ex. 1001, 35:9–27. We focus our discussion on tuning the Q-factor up because Petitioner asserts that the stimulation in Klimesch has the effect of tuning the Q-factor up not down.

more defined shape in the frequency spectrum observed using EEG. A known measurement of the peak's tightness is the quality factor, or "Q-factor," which the patents define as $f_0/\Delta f$, where Δf is the frequency bandwidth for which the energy of the peak is above one-half the peak energy. This increase in Q-factor in response to rTMS at or near the subject's peak alpha frequency is a natural response of the typical human brain to such stimulation.

Ex. 1003 ¶ 23. If we were to credit this testimony, it would lend support to Petitioner's assertion that stimulation at IAF + 1 Hz, as disclosed in Klimesch, can increase in Q-factor.

Importantly, however, Dr. Silvetz does not cite anything to support his opinion that stimulation at a frequency above the peak alpha frequency causes the Q-factor to increase. *Id.* Nor does Dr. Silvetz explain why such stimulation causes the Q-factor to increase. *Id.* Accordingly, Dr. Silvetz' testimony is entitled to little weight. *Xerox Corp.* IPR2022-00624, Paper 9, at 15–16; *see also*, 37 C.F.R. § 42.65(a); *Upjohn Co.*, 225 F.3d at 1311; *Carella*. 804 F.2d at 138.

In addition, Dr. Silvetz' cited testimony that rTMS at frequencies above peak alpha frequency causes the Q-factor to increase is not specific to the conditions under which rTMS was administered in Klimesch. This is problematic because Dr. Silvetz also testifies that the brain's response to rTMS varies depending on the conditions under which it was administered. Ex. 1003 ¶ 20 ("The brain's natural response varies depending on factors such as: a) the location of the electromagnet; b) the frequency of stimulation; c) the duration of stimulation; d) the number of stimulation pulses administered; e) the amplitude of the pulses administered; and f) the patient's physiology.").

In testimony not cited in the portion of the Petition that asserts that the Q-factor is inherent in Klimesch (Pet. 33–34), Dr. Silvetz testifies that the increased ERD disclosed in Klimesch “would appear on an EEG of the upper alpha band as the expected change in the amplitude of the peak alpha frequency, and the corresponding change in shape of that peak would cause a change in the Q-factor of that peak, since the shape of the peak and its Q-factor are, by definition, related” (Ex. 1003 ¶ 25). Dr. Silvetz may well be correct. But his testimony on this point is conclusory and no better supported by evidence and technical reasoning than the testimony discussed above.

In summary, given that it not accompanied by supporting evidence, does not provide any technical reasoning, we give little weight to Dr. Silvetz’ testimony in determining whether Petitioner has established a reasonable likelihood that Klimesch inherently discloses the Q-factor limitation. We do not determine here that Dr. Silvetz’ testimony is incorrect, only that it is not insufficiently supported by evidence and technical reasoning to support institution.

E. Ground II - Anticipation of Claim 39 by Jin

1. Summary of Jin (Ex. 1006)

Jin is an article appearing in Schizophrenia Bulletin. Ex. 1006. Petitioner contends that Jin is prior art under 35 U.S.C. § 102(b). Pet. 37.

Jin describes a study on the effect of rTMS upon negative symptoms of schizophrenia. Ex. 1006, 556–557.¹⁷ Subjects diagnosed with

¹⁷ Petitioner cites to the page numbers of Jin rather than of the exhibit. We do the same for consistency.

schizophrenia who presented predominantly negative symptoms were given four rTMS treatments with three different frequencies or a sham stimulus.

Id. at 557. The rTMS treatments were administered via a coil that was placed on the subject's forehead at frequencies of "3 Hz, individualized alpha (8–13 Hz) and 20 Hz," with sham treatment as a control. *Id.* The "[r]ate for the alpha frequency stimulation was determined at the nearest integer of each patient's average alpha peak frequency, obtained from 5 frontal EEG leads." *Id.*

Jin states that the subjects receiving TMS at a mean stimulus rate of $8.6 \text{ Hz} \pm 0.8$, "individualized α TMS," had a significantly greater reduction of negative symptoms¹⁸ than for sham, low and high frequency rTMS treatments. *Id.* at 558.

With respect to the subjects' EEG profiles, Jin discloses that "[t]he individualized α TMS produced a marked increase . . . in power of the alpha EEG activity, primarily in the frontal area, while there were no significant EEG changes in sham . . . , low-frequency . . . , or high-frequency treatment groups." *Id.* at 559. Jin teaches that "[c]orrelational analyses demonstrated that improvements in negative symptoms following α TMS treatment were highly associated with the degree of alpha EEG power increment in the frontal lobe." *Id.* According to Jin, these results support that "the resonant 'tuning' of the peak alpha oscillations would serve to increase the power density in this frequency range and thereby improve the negative symptoms" of schizophrenia. *Id.* at 560.

¹⁸ Symptoms were evaluated on the Positive and Negative Syndrome Scale (PANSS) used to evaluate the severity of schizophrenia symptoms. Ex. 1006, 557.

2. *Analysis*

Petitioner asserts that Jin anticipates claim 39 of the '354 patent. Pet. 36–47. As discussed above, claim 39 recites a device including five device features recited in the alternative. Ex. 1001, 62:62–63:24 (reciting that the device comprises four differently phrased “wherein the first or second processor moves” alternative bases for adjusting the output of the magnetic field, or “a combination thereof”). Petitioner argues that “[b]ecause the intrinsic frequency and Q-factor are recited as two alternative bases for adjusting the output of the magnetic field, a prior art reference only needs to disclose one to anticipate this element of the claim.” Pet. 8, 40.

Patent Owner’s responsive arguments dispute only whether Jin teaches these two alternative bases, directly or inherently. Prelim. Resp. 40–54. Because it is dispositive to Ground 2, we focus our discussions on the two alternative bases that Petitioner contends are disclosed in Jin: 1) a processor that “moves” an intrinsic frequency of the brain to a “pre-selected intrinsic frequency” (the “intrinsic frequency” limitation) and 2) a processor that “moves” a Q-factor of an intrinsic frequency of the brain toward a “pre-selected Q-factor” (“the Q-factor limitation”). Ex. 1001, 63:3–9. We discuss each alternative limitation in turn.

1. The intrinsic frequency limitation

We begin by considering whether Jin discloses the intrinsic frequency limitation. Petitioner contends that Jin expressly discloses this limitation. Pet. 40–47.

The evidence of record does not support that Jin expressly discloses the intrinsic frequency limitation. Under the agreed-upon claim construction for “pre-selected intrinsic frequency,” Jin would need to have identified a

“targeted intrinsic frequency chosen before treatment.” Ex. 2001, 2. Jin makes no mention of a such a frequency, or disclose that a targeted frequency was reached.¹⁹

Jin discloses applying rTMS at “3Hz, individualized alpha (8–13 Hz), and 20 Hz [to patients]. Rate for the alpha frequency stimulation was determined at the nearest integer of each patient’s average alpha peak frequency.” Ex. 1006, 557. A sham stimulation was given as a control. *Id.*

Jin discloses collecting EEG recordings of the patients “at screening, baseline (immediately prior to first treatment), immediately following the fifth and tenth treatments, and after 2 weeks of washout for each condition.” *Id.* at 558. Jin discloses that the raw EEG data were edited to remove artifact, followed by data analysis of the results to calculate “[p]eak frequency and power density of each band.”²⁰ *Id.* However, Jin does not disclose what effect the applied rTMS treatment has on the intrinsic frequency, which would be necessary in order for Jin to disclose that its processor “moves” an intrinsic frequency of the brain to a “pre-selected intrinsic frequency.” *See generally, id.*

Petitioner argues, with no cited declarant support, that the ordinarily skilled artisan would have understood that applying rTMS at the nearest integer frequency to the subject’s internal alpha frequency would have

¹⁹ We acknowledge Petitioner’s argument that the ’354 patent contemplates that the pre-selected intrinsic frequency may be the same as the subject’s intrinsic frequency. Pet. 40–41. However, Petitioner has not identified anything in Jin showing that Jin identified or otherwise acknowledged the existing frequency as the “targeted intrinsic frequency” prior to its application of rTMS.

²⁰ Jin also discloses clinical data on changes in patients’ negative symptoms pertaining to e.g., schizophrenia, but those data are not relevant to this case.

caused Jin’s applied magnetic field to be “higher than the subject’s intrinsic frequency in some cases, equal to the subject’s intrinsic frequency in some cases, and lower than the subject’s intrinsic frequency in some cases.” Pet. 41. Petitioner cites the disclosure of the ’354 patent as teaching that “the human brain’s natural response [to stimulation at a frequency higher than the subject’s intrinsic frequency] is for the intrinsic frequency in the alpha EEG band to shift up.” *Id.* (citing Ex. 1001, 34:61–35:5).

We are not persuaded. The test for anticipation is what the reference plainly discloses. *See In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009) (“Anticipation requires that all of the claim elements and their limitations are shown in a single prior art reference.”). For this reason, Petitioner’s citation to certain disclosures of the ’354 patent is unpersuasive to explain *what Jin teaches*; Petitioner has cited no disclosure of Jin showing that the patients’ peak frequency was changed to a previously identified targeted frequency by the application of rTMS.²¹

To the extent Petitioner seeks to invoke principles of inherency, as discussed *supra* § II.D.2.a(2) the cited disclosure from the ’354 patent supports only that the intrinsic frequency *can* be shifted up or down by applying a “specific magnetic field close to the head.” It does not teach that

²¹ To the extent Petitioner appears to argue that citation to the method claimed in the ’354 patent can be used to explain the knowledge of an ordinary skilled artisan, we disagree. *See Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985) (“The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.”) Petitioner’s contentions largely consist of non-evidentiary attorney argument. *See Johnston.*, 885 F.2d at 1581 (attorney argument not evidence).

the intrinsic frequency necessarily shifts every time a magnetic field above or below the patient's peak alpha frequency is applied. In addition, Petitioner does not direct us to disclosure in the '354 patent supporting that stimulation at the nearest integer frequency to the subject's intrinsic alpha frequency under the circumstances disclosed in Jin will necessarily shift the intrinsic frequency. *See*, Ex. 1003 ¶ 20 (testimony of Dr. Silvetz identifying factors that impact how the brain responds to rTMS); Ex. 1001, 40:19–32 (describing “parameters that require optimization for rTMS,” including: “[f]requency, “[i]ntensity, “[d]uration,” and “[s]ite of stimulation”).

Finally, Petitioner asserts that “[t]he individualized α TMS produced a marked increase (34% +/- 0.3) in power of the alpha EEG activity.” Pet. 41. But increasing EEG power is distinct from moving frequency. *See e.g.*, Ex. 2002, Fig. 1A (spectral analysis plotting frequency on the x-axis and power on the y-axis). Thus, even if we were to credit Petitioner's assertion that the α TMS produced a large increase in power of the alpha EEG activity, this assertion does not support that Jin expressly discloses changing the frequency at which peak alpha power is observed as recited in claim 39. As Petitioner does not direct us to any other disclosure in Jin that supports moving the intrinsic frequency, Petitioner is unlikely to prevail in establishing that Jin expressly discloses the intrinsic frequency limitation.

2. The Q-factor limitation

Petitioner contends that Jin expressly and inherently discloses “wherein the first processor or a second processor moves . . . a Q-factor of an intrinsic frequency of the brain of the subject within a specified EEG band toward a pre-selected Q-factor of the intrinsic frequency using the magnetic field” (the “Q-factor limitation”). Pet. 42–47.

a) Alleged express disclosure

The evidence of record does not support that Jin expressly discloses the Q-factor limitation.

Petitioner contends that the disclosure of the '354 patent supports its position that Jin expressly discloses the Q-factor limitation by teaching that “when the peak energy of the EEG signal in the specified band of the intrinsic frequency increases, the Q-factor of the intrinsic frequency will increase.” Pet. 42 (citing Ex. 1001, 46:50–60 (referring to peak energy $E_{\max}$ of the signal) and 35:20–25 (describing “tuning up” the Q-factor)). According to Petitioner, Jin discloses the Q-factor limitation because Jin observes and discloses that, following stimulation at each subject’s individualized intrinsic peak alpha frequency, a “marked increase (34% +/- 0.3) in power of the alpha EEG activity” resulted and corresponded to improvements in negative symptoms. *Id.* at 42–43 (quoting Ex. 1006, 558–59). Petitioner asserts that “Jin observed this increase in the power of EEG activity in the specified EEG alpha band between 8 and 13 Hz” and cites the '354 patent at 46:50–60, Fig. 12 “(defining the Δf component of Q-factor as a ‘frequency range’ or ‘frequency bandwidth’).” Petitioner argues that this observation is an express disclosure of the Q-factor limitation. *Id.* at 43. Petitioner further argues that Jin’s attempt to reduce the negative symptoms of schizophrenia through rTMS stimulation “discloses ‘tuning up’ the Q-factor of the subjects’ intrinsic frequency toward that of a healthy population.” *Id.* at 43–44.

We do not agree for the reasons discussed below. Once again, we refer to Figure 12, illustrated above with regard to the discussion of Klimesch’s alleged teachings of the Q-factor limitation. Figure 12 is a graph

showing “the frequency distribution of the energy of an EEG signal.” *Id.* at 14:50–51. The x-axis of the graph is the “frequency” of the EEG signal and the y-axis is the “energy” of the signal. The graph labels the intrinsic frequency – i.e., the peak frequency – “ f_0 ” and “labels the frequency bandwidth for which the energy is above one-half the peak energy” “ Δf .” *Id.* at 14: 53–53. The ’354 patent defines “Q-factor” as “the ratio of $f_0/\Delta f$.” *Id.* at 41:62–64.

Petitioner asserts that Jin discloses a “marked increase (34% +/- 0.3) in power of the alpha EEG activity” but does not explain how that increased energy is distributed across the EEG band. Absent information about how energy is distributed across the EEG band, we can only speculate as to whether the Q-factor changed. As Patent Owner explains, “even if Jin’s peak energy changes, Q-factor will not change so long as the ratio of $f_0/\Delta f$ stays the same.” Prelim. Resp. 48–49.

Petitioner’s evidence of record, including its reliance on the ’354 patent’s disclosure to explain an anticipated shift in the Q-factor of the intrinsic frequency at high energy, is insufficient on this record to show that Jin discloses the Q-factor limitation. Moreover, under the agreed-upon claim constructions for “pre-selected Q-factor of the intrinsic frequency,” Jin would need to have identified a “targeted Q-factor chosen before treatment” to anticipate all limitations of claim 39. Ex. 2001, 2. Jin makes no mention of a targeted Q-factor or disclose that a targeted Q-factor had been reached or approached. As Petitioner does not direct us to any other disclosure in Jin that supports changing the Q-factor toward a pre-selected Q-factor, Petitioner is unlikely to prevail in establishing that Jin expressly discloses the intrinsic frequency limitation.

b) Alleged inherent disclosure

The evidence of record does not support that Jin inherently discloses the Q-factor limitation.

Petitioner again relies on the disclosure of the '354 patent for the definition of the Q-factor and asserts that this definition shows Jin's inherent disclosure of an increase in the Q-factor of the intrinsic frequency. Pet. 45. Petitioner argues that Jin inherently discloses the Q-factor limitation as a natural result of the increase in power of the alpha EEG activity in the subject's alpha band caused by rTMS. *Id.* (citing Ex. 1006, 558–59). Petitioner argues the property is inherent in the brain's natural response to stimulation and in the definition of the Q-factor, and that the '354 patent acknowledges that applying a magnetic field causes the subject's Q-factor of the intrinsic frequency to tune up. *Id.* at 45–46 (citing Ex. 1003 ¶¶ 20, 23).

With respect to the disclosure of the '354 patent, Petitioner cites to the same disclosures it cited in connection with its assertion that Klimesch inherently discloses the Q-factor limitation. As discussed *supra* § II.D.2.b(2), the cited disclosure at 69:53–59 of the '354 patent – which includes a definition of Q-factor – uses language of possibility not necessity:

The Q-factor is defined as the ratio of $f_0/\Delta f$. As can be seen [discussing Figure 12, reproduced above], when Δf decreases for a given f_0 , the Q-factor will increase. ***This can occur*** when the peak energy E_{max} of the signal increases or when the bandwidth of the EEG signal decreases.

Ex. 1001, 46:56–61 (emphasis added). This passage supports that one possible effect of increasing peak energy is to increase the Q-factor, but it does not support that such effect is inherent.

Petitioner also cites the disclosure in the '354 teaching that “applying a magnetic field at a subject’s intrinsic frequency, as taught in Jin, inherently causes the Q-factor of the subject’s intrinsic frequency to tune up.” Pet. 46 (citing Ex. 1001, 35:20–25). Although this passage supports that the Q-factor can be tuned by applying a preselected magnetic frequency, the cited portion of the '354 patent does not identify what that frequency is. *See* Ex. 1001, 35:20–25. And Petitioner does not direct us to disclosure in the '354 patent supporting that stimulation at the individualized alpha frequency (8–13 Hz), as disclosed in Jin, without an understanding of the direction in which the frequency is to be shifted to via identification of a pre-selected frequency, will inherently lead to tuning up of the Q-factor, much less that it will do so under the circumstances disclosed in Jin. *See* Ex. 1003 ¶ 20 (testimony of Dr. Silvetz identifying factors that impact how the brain responds to rTMS). Accordingly, the disclosure of the '354 patent does not support Petitioner’s inherency position.

We now turn to the testimony of Dr. Silvetz, cited by Petitioner in support of its position that Jin inherently discloses the Q-factor limitation. Petitioner cites the same testimony from Dr. Silvetz that it relied upon to support its opinion that Klimesch inherently discloses the Q-factor limitation. Pet. 34 (Klimesch discussion citing Ex. 2003 ¶¶ 20, 23), 45 (Jin discussion citing Ex. 2003 ¶¶ 20, 23). For the reasons discussed *supra* § II.G.2.b, we give little weight to Dr. Silvetz’ testimony because it is not accompanied by supporting evidence and does not provide any technical reasoning. We do not determine here that Dr. Silvetz’ testimony is incorrect, only that it is not insufficiently supported by evidence and technical reasoning to support institution.

In addition, Dr. Silvetz' declaration identified six factors that affect the brain's natural response to rTMS (Ex. 1003 ¶ 20) but neglects to explain how those would apply in Jin's methods, which makes it difficult to extend his broad statement regarding inherency to the specific factual circumstances under which rTMS was applied in Jin. Nor does Dr. Silvetz address whether Jin – expressly or inherently – identified a pre-selected Q-factor of the intrinsic frequency of the brain or moving the Q-factor to that pre-selected frequency with application of a magnetic field.

As Petitioner does not direct us to any other disclosure in Jin that supports moving the intrinsic frequency, Petitioner is unlikely to prevail in establishing that Jin expressly discloses the intrinsic frequency limitation.

III. CONCLUSION

Based on the evidence before us, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing in showing that at least one of the challenged claims is unpatentable based on the grounds advanced in the Petition.

IV. ORDER

Upon consideration of the record before us, it is hereby:

ORDERED that an *inter partes* review of claim 39 is not instituted in this proceeding.

FOR PETITIONER:

Allen Sokal
Arthur Steiner
asokal@dcpatent.com
asteiner@dcpatent.com

FOR PATENT OWNER:

Rick Tache
Benjamin Deming
Robert Sterne
James R. Hietala
David W. Haars
rtache@buchalter.com
bdeming@buchalter.com
rsterne-ptab@sternekessler.com
jhietala-ptab@sternekessler.com
dhaars-ptab@sternekessler.com