

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CALA HEALTH, INC.,
Petitioner,

v.

EMKINETICS INC.,
Patent Owner.

IPR2023-00511
Patent 9,387,338 B2

Before JEREMY M. PLENZLER, JOHN G. NEW, and
JASON W. MELVIN, *Administrative Patent Judges*.

MELVIN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Cala Health, Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting institution of *inter partes* review of claims 1–8 (“the challenged claims”) of U.S. Patent No. 9,387,338 B2 (Ex. 1001, “the ’338 patent”). EMKinetics Inc. (“Patent Owner”) elected to waive a Preliminary Response. Paper 6.

An *inter partes* review may not be instituted unless “the information presented in the petition . . . and any response . . . 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) (2018). “When instituting *inter partes* review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.” 37 C.F.R. § 42.108(a) (2021).

For the reasons that follow, based on the present record, we conclude that Petitioner has shown a reasonable likelihood it will prevail with respect to at least one challenged claim, and we institute *inter partes* of the ’338 patent.

A. REAL PARTIES IN INTEREST

The parties identify themselves as real parties in interest. Pet. 88; Paper 4, 2.

B. RELATED MATTERS

The parties identify U.S. Patent No. 9,757,584, which is the subject of IPR2023-00508, as related to the ’338 patent. Pet. 88; Paper 4, 2.

C. THE ’338 PATENT (EX. 1001)

The ’338 patent is entitled “Methods and Devices for Performing Electrical Stimulation to Treat Various Conditions” and is directed to

systems and/or methods for electromagnetic induction therapy. Ex. 1001, codes (54), (57). The '338 patent describes “treating a variety of ailments by providing energy to a target nerve.” *Id.* at 8:18–19. The energy may be in the form of “magnetic energy, electrical energy or ultrasound energy.” *Id.* at 8:19–21.

The '338 patent depicts an embodiment of a system in Figure 27, which is reproduced below.

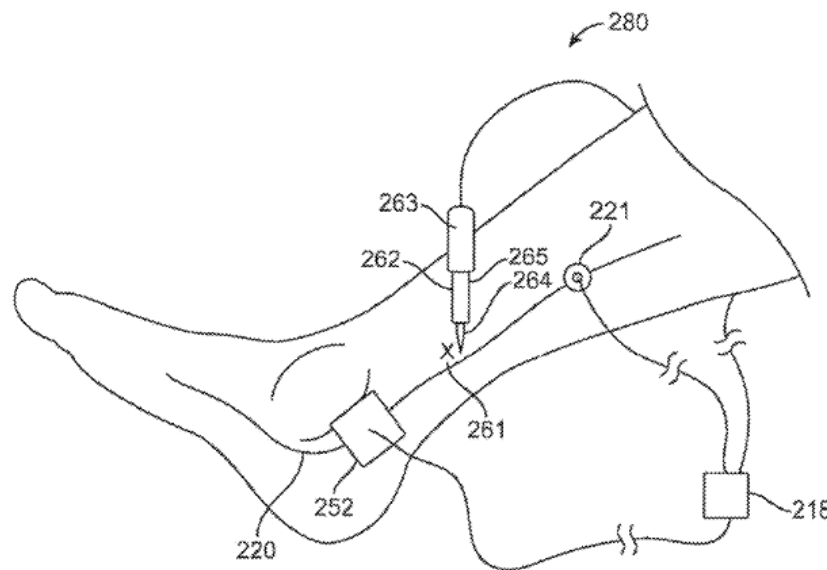


FIG. 27

Ex. 1001, Fig. 27. Figure 27 illustrates an energy emitting system that includes an electrode needle and microneedle patch to provide stimulation. *Id.* at 7:31–33. Energy emitting system 280 includes “one or more percutaneous electrode needles 262 coupled to a controller 218 and having an end insertable into a subject’s body in proximity to said target nerve.” *Id.* at 26:66–27:5. In addition, “[t]he percutaneous electrode needle 262 is inductively coupled to conductive microneedle patch 252.” *Id.* at 27:7–9.

The '338 patent explains that “[t]he percutaneous electrode needle 262 is inserted through the skin at a location and to a depth that brings the tip in close proximity to the target nerve to be stimulated.” Ex. 1001, 27:13–16. When controller 218 is activated, current passes through microneedle patch 252 and traverses internal stimulation site 261 “by passing from microneedle patch 252 to the internal percutaneous electrode needle 262.” *Id.* at 27:17–20.

D. THE CHALLENGED CLAIMS

Claims 1 and 2 are independent. Claim 1 is reproduced below:

1. A method, comprising:
applying an electrode patch to skin in proximity to a stimulation site of a patient such that the electrode patch is disposed on an outer surface of the skin and the electrode patch is electrically coupled with a controller unit, the controller unit including a pulse generator;
electrically coupling a percutaneous electrode having an end for inserting in proximity to a tibial nerve of the patient to the controller unit;
inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve of the patient; and
activating the pulse generator such that current pulses flow along the tibial nerve by passing between the electrode patch and the percutaneous electrode, the current pulses configured to treat incontinence.

Ex. 1001, 45:20–34. Claim 2 is reproduced below:

2. A method, comprising:
positioning a transcutaneous electrode on skin of a patient in proximity to a tibial nerve;
inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve, the

percutaneous needle electrode including a wire disposed opposite the end;

securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode, the controller unit including a pulse generator;

connecting the wire of the percutaneous needle electrode to the controller unit for electrically coupling the percutaneous needle electrode to the controller; and

activating the pulse generator such that current pulses flow along the tibial nerve by passing between the transcutaneous electrode and the percutaneous needle electrode, the current pulses configured to treat incontinence.

Id. at 46:1–19. The remaining claims depend directly from claim 1 or 2. *Id.* at 46:20–33.

E. PRIOR ART AND ASSERTED GROUNDS

Petitioner asserts the following unpatentability grounds:

Claims Challenged	35 U.S.C. § ¹	Reference(s)/Basis
1–3, 6	102(b)	Govier ²
1–3, 6	103(a)	Govier, Williams ³
1–3, 6	102(b)	Williams
1–3, 6	103(a)	Williams, Govier
4, 5, 7, 8	103(a)	Govier, Mumford ⁴
4, 5, 7, 8	103(a)	Govier, Williams, Mumford

¹ The '338 patent claims priority to an October 2, 2006, provisional application. Ex. 1001, codes (60), (63); *see* Pet. 9. Therefore, the pre-AIA statutes apply.

² Govier et al., *Percutaneous Afferent Neuromodulation for the Refractory Overactive Bladder: Results of a Multicenter Study*, 165 J. Urology 1193–1198 (Apr. 2001) (Ex. 1005). All citations are to the native pagination.

³ U.S. Pub. No. 2005/0171576 A1, published Aug. 4, 2005 (Ex. 1006).

⁴ U.S. Pub. No. 2005/0261559 A1, published Nov. 24, 2005 (Ex. 1019).

Claims Challenged	35 U.S.C. § ¹	Reference(s)/Basis
4, 5, 7, 8	103(a)	Williams, Mumford
4, 5, 7, 8	103(a)	Williams, Govier, Mumford
4, 5, 7, 8	103(a)	Govier, Sarwal ⁵
4, 5, 7, 8	103(a)	Govier, Williams, Sarwal
4, 5, 7, 8	103(a)	Williams, Sarwal
4, 5, 7, 8	103(a)	Williams, Govier, Sarwal

Pet. 11. Petitioner relies also on the Declaration of John Laughlin. Ex. 1002.

II. ANALYSIS

A. LEVEL OF ORDINARY SKILL IN THE ART

Petitioner contends that a person of ordinary skill in the art “would have had an undergraduate degree in the field of biomedical engineering, or a related discipline, and at least two years of experience in the design and/or analysis of biomedical devices” and that “[a]dditional work experience could serve as a substitute for a formal degree and vice versa.” Pet. 10 (citing Ex. 1002 ¶ 23).

Patent Owner has not filed a Preliminary Response and therefore does not dispute Petitioner’s proposal. Because Petitioner’s proposed level of ordinary skill in the art appears to be consistent with the challenged patent and prior art, we adopt it for purposes of this decision.

B. CLAIM CONSTRUCTION

We construe claims according to the standard used in the federal courts in civil actions under 35 U.S.C. § 282(b), which is articulated in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). See 37 C.F.R. § 42.100(b). Under *Phillips*, the “words of a claim ‘are generally given their ordinary and customary meaning,’” which is “the meaning that

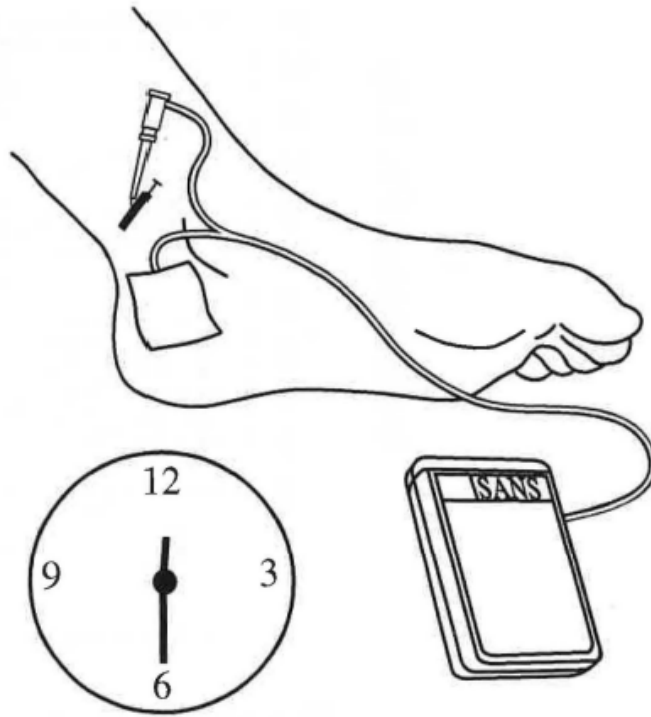
⁵ U.S. Patent No. 6,662,052 B1, issued Dec. 9, 2003 (Ex. 1020).

the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1312–13.

Petitioner argues that “no claim terms require express construction to resolve the challenges in this Petition.” Pet. 10. We agree and do not expressly construe any terms at this stage. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that “we need only construe terms ‘that are in controversy, and only 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))). Should either party believe that a position taken during trial depends on a particular claim construction, it should explain that dependence and why the asserted construction is correct.

C. ANTICIPATION BY GOVIER OR
OBVIOUSNESS OVER GOVIER AND WILLIAMS

Govier describes a study in which patients with overactive bladders were given “percutaneous electrical stimulations via a 34 gauge needle placed near the tibial nerve 3 finger breadths above the ankle.” Ex. 1005, 1193. Specifically, “[a] 34 gauge, solid stainless steel needle was advanced through the skin” and “the needle was advanced approximately 3 to 4 cm. posterior to the tibia and, if advanced further, would traverse anterior to the fibula.” *Id.* at 1194. Govier further explains that “[a]n electrocardiogram ground pad was placed over the medial aspect of the calcaneus” and “[a] stimulator was then connected to the needle and the ipsilateral ground pad.” *Id.* This arrangement is depicted in Govier’s Figure 3, which is reproduced below.



Id. at 1195. Govier describes titrating stimulation “from 0 to 10 mA. with fixed pulse 200 microseconds at frequency 20 Hz” and the patient controlling the power setting for thirty minutes. *Id.* at 1194.

Williams describes an electro-nerve stimulation system. Ex. 1006 ¶ 6. Figure 1, reproduced below, illustrates such a system.

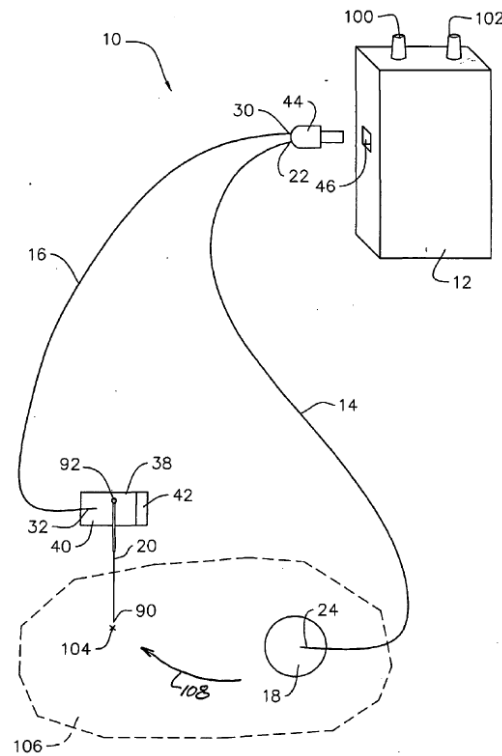


FIG. 1

Figure 1 shows an embodiment of an electro-nerve stimulation apparatus 10 that includes pulse generator 12; first electrically conductive, insulated lead wire 14; second electrically conductive, insulated lead wire 16; electrically conductive transcutaneous electrode 18; and electrically conductive percutaneous needle electrode 20. *Id.* ¶¶ 11, 23. According to Williams, pulse generator 12 “produces small electrical current pulses, preferably between 1–10 mA, which pass between the transcutaneous electrode 18 and the percutaneous needle electrode 20.” *Id.* ¶ 31. Williams states that apparatus 10 “is particularly suited for the treatment of urinary urge incontinence” by inserting percutaneous needle electrode 20 “into the patient’s skin in proximity to the tibial nerve cephalic to the medial malleolus” and adhering transcutaneous electrode 18 “to the patient’s skin distal to the percutaneous needle electrode.” *Id.* ¶ 37.

Petitioner contends that Govier discloses each limitation of claims 1–3 and 6 or that Govier in view of Williams renders claims 1–3 and 6 unpatentable. Pet. 16–52.

For claim 1, Petitioner asserts that, if Govier does not disclose applying an electrode patch to the outer surface of the skin, skilled artisans would have had reason to substitute Williams’s known electrode patch for Govier’s ground pad as a simple substitution of one known structure for another performing the same function—“generating a current along the tibial nerve.” *Id.* at 21–24.

Petitioner contends also that, if Govier does not disclose a controller unit including a pulse generator, skilled artisans would have had reason “to substitute Williams’s pulse generator for Govier’s stimulator.” *Id.* at 26–29. Petitioner reasons that skilled artisans would have found it obvious to try Williams’s pulse generator because of its similarities with Govier’s stimulator—“each create current pulses between 1–10 mA.” *Id.* at 28. Petitioner reasons further that using Williams’s pulse generator would have been a simple substitution. *Id.*

Finally, Petitioner contends that “[c]laim 1 does not require the current pulses to flow in a specific direction,” but submits that, to the extent that the claim language “current pulses flow . . . by passing between the electrode patch and the percutaneous electrode” requires a particular direction of current flow, skilled artisans would have had reason to use Williams’s stimulation method, in which current pulses pass “from the transcutaneous electrode 18 to the percutaneous needle electrode 20.” Pet. 34–36 (quoting Ex. 1006 ¶ 32, Fig. 1). Petitioner reasons that current pulses could flow in either of only two directions, making the claimed

configuration obvious in light of the structural similarities between Govier's and Williams's systems. *Id.*

As noted above, Patent Owner waived a Preliminary Response to the Petition. We have reviewed Petitioner's contentions and conclude that they warrant institution.

D. ANTICIPATION BY WILLIAMS OR
OBVIOUSNESS OVER WILLIAMS AND GOVIER

Petitioner contends that Williams discloses each limitation of claims 1–3 and 6 or that Williams in view of Govier renders claims 1–3 and 6 unpatentable. Pet. 52–70.

For claim 1, Petitioner asserts that both Williams and Govier disclose “activating the pulse generator such that current pulses flow along the tibial nerve by passing between the electrode patch and the percutaneous electrode” and that skilled artisans “would have been motivated to use Williams's system to produce current pulses that flow along the tibial nerve as described in Govier.” *Id.* at 60. Petitioner reasons that application would have been obvious “due to similarities between the systems.” *Id.*

As noted above, Patent Owner waived a Preliminary Response to the Petition. We have reviewed Petitioner's contentions and conclude that they warrant institution.

E. ADDITIONAL OBVIOUSNESS GROUNDS

Mumford describes “a wireless physiological monitoring system that can be used to measure a wide variety of physiological signals from a patient for monitoring the patient and/or diagnosing certain medical conditions.” Ex. 1019 ¶ 2. The system “includes, at a minimum, at least one wireless sensor and a monitoring device which are linked to one another in a wireless

fashion for measuring physiological signals from a patient for monitoring the patient.” *Id.* ¶ 6. Mumford states that the system “may also be used to perform diagnostic tests on the patient . . . such as nerve conduction velocity tests.” *Id.*

Sarwal describes “[a] system and method for remotely controlling the stimulation therapy for neurological, neuropsychiatric and urological disorders.” Ex. 1020, code (57). The system includes “an implantable lead-receiver and an external stimulator with two-way wireless communication capability, through a server.” *Id.* For instance, a physician can use a hand-held device (PDA) that can communicate remotely with a wireless server, which can then communicate with an external stimulator device that is physically attached to a patient. *Id.* at 10:30–42.

Petitioner asserts that claims 4, 5, 7, and 8 would have been obvious in view of various combinations based on Govier or Williams. Pet. 70–87.

Because we determine that the grounds discussed above warrant institution, we do not address the additional grounds at this stage. These grounds are included in the instituted review and we will address any potential deficiencies raised during trial.

III. CONCLUSION

For the reasons discussed above, we conclude that Petitioner has shown a reasonable likelihood of prevailing with respect to unpatentability of at least one claim. Accordingly, we institute *inter partes* review.

IV. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review of claims 1–8 of the '338 patent is instituted on the grounds raised in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), notice is hereby given of the institution of trial, which will commence on the entry date of this Decision.

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