UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IRHYTHM, INC.,

Petitioner,

v.

WELCH ALLYN, INC.,

Patent Owner.

CASE: IPR2025-00377

U.S. PATENT NO. 8,214,007

PATENT OWNER PRELIMINARY RESPONSE

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TABLE OF PATENT OWNER EXHIBITS

Exhibit No.	Description
2001	Information Disclosure Statement dated May 18, 2015 in Application No. 13/890,144, submitted by Petitioner indicating it was aware of the '007 Patent, reference no. 67
2002	Information Disclosure Statement dated August 7, 2013 in Application No. 13/890,144, submitted by Petitioner indicating it was aware of the pre-grant publication that issued as the '007 Patent, reference no. 101
2003	iRhythm's Amended Answer alleging infringement against PO's related company, Bardy Diagnostics
2004	26(f) Report from *Bardy Diagnostics, Inc. v. iRhythm Technologies, Inc.*, 1:24-cv-01355, indicating Petitioner iRhythm's intent to assert additional patents.
2005	Scheduling order in *Welch Allyn Inc. v. iRhythm Technologies, Inc*., 1:24-cv-00224
2006	Notice of Service of Party Discovery in *Welch Allyn Inc. v. iRhythm Technologies, Inc*., 1:24-cv-00224 (ECF 26)
2007	Notice of Service of Party Discovery in *Welch Allyn Inc. v. iRhythm Technologies, Inc*., 1:24-cv-00224 (ECF 27)
2008	Notice of Service of Third-Party Discovery in *Welch Allyn Inc. v. iRhythm Technologies, Inc*., 1:24-cv-00224 (ECF 41)
2009	Notice of Service of Third-Party Discovery Responses in *Welch Allyn Inc. v. iRhythm Technologies, Inc*., 1:24-cv-00224 (ECF 47)
2010	Excerpt from Zenious et al., BIODESIGN; THE PROCESS OF INNOVATING MEDICAL TECHNOLOGIES
2011	Notice of Service of Third-Party Discovery in *Welch Allyn Inc. v. iRhythm Technologies Inc*., 1:24-cv-00224 (ECF 48)

Exhibit No.	Description
2012	[Reserved]
2013	[Reserved]
2014	[Reserved]
2015	[Reserved]
2016	Declaration of Dr. Brian Anthony for IPR2025-00377 of U.S. Patent No. 8,214,007
2017	[Reserved]

Patent Owner, Welch Allyn, Inc. ("Welch Allyn" or "Patent Owner"), submits this Patent Owner Preliminary Response ("Response") pursuant to 37 C.F.R. § 42.107(a) to the *Inter Partes* Review petition ("Petition") filed by iRhythm, Inc. ("Petitioner") for Claims 1-8, 10-15, 29, 31-35, 37-39, and 43-45 (the "Challenged Claims") of U.S. Patent No. 8,214,007 (the "'007 Patent") (Ex. 1001).

I. INTRODUCTION

The '007 Patent claims a novel body-worn patient monitoring device that bifurcates two main components—the communication-computation module and the disposable module. Ex. 1001, Cls. 1, 45, Abstract; Ex. 2016, ¶[0045]. The body-worn patient monitor further includes a current-limiting resistor designed to protect the communication-computation module from, for example, defibrillation pulses. Ex. 1001, Cl. 1, 7:34-45; Ex. 2016, ¶¶[0046]-[0047].

In challenging the '007 Patent, the Petition does not identify a single reference with this bifurcated structure having a resistor configured to protect the device's electronics. With the benefit of hindsight, the Petition attempts to reconstruct the novel features of the '007 Patent while relying on a reference that uses "lead strips" that are specifically designed to protect the patient—not the electronics, as required by the claimed resistors, which must be "configured to protect the communication-computation module." Ex. 1001, Cl. 1. This is not sufficient.

First, the Petition is fundamentally flawed. To form the basis of its challenges, the Petition gap-fills the prior art by expressly relying on "General Knowledge of a POSA." Petition, 1-2. This approach contradicts Federal Circuit law and 35 U.S.C. § 311(b), which allows challenges "***only*** on the basis of prior art consisting of patents or printing publications." *See Qualcomm Inc. v. Apple Inc.*, Nos. 2023-1208, -1209, 2025 WL 1174161 (Fed. Cir. Apr. 23, 2025). The "General Knowledge"—which plagues every Ground of the Petition—is neither a patent nor printed publication. The Petition should be denied for failing to comply with § 311(b).

Second, the Petition fails to comply with 37 C.F.R. § 42.104(b)(3) by relying on the "ordinary and customary meaning" for all claim terms, even when a term's construction (*e.g.*, "configured to") is critical to the required analysis. Petition, 2. Without any constructions from Petitioner, the Board and Patent Owner are required to speculate and analyze implied meanings that are uncovered only by sifting through Petitioner's expert declaration. Across all five petitions filed at the same time, the Petition relies on the single, 516-page omnibus declaration from Dr. Heikenfeld with confusing nested- and cross-citations between his opinions on different patents and proceedings. In addition to these procedural failures, the Petition fails on the technical merits.

In Ground 1, which is the only ground that challenges the independent claims of the '007 Patent, the Petition relies on the combination of *Jensen*,[1] *Kroll*,[2] and the alleged "General Knowledge" of a POSA. *See* Petition, 1. Ground 1 fails to establish that the combination renders obvious the current-limiting resistor or the communication-computation module being both removable and reuseable.

In yet another shortcoming in Ground 1, the Petition fails to establish a motivation to combine *Jensen* and *Kroll*, and indeed, one would not because *Kroll's* system is designed to safely administer therapeutic shocks, far removed from *Jensen's* fundamentally different system designed to simply monitor ECG signals. Without using the claims as a roadmap, a POSA would not have been motivated to remove *Jensen's* conventional resistors and replace them with *Kroll's* lead strips.

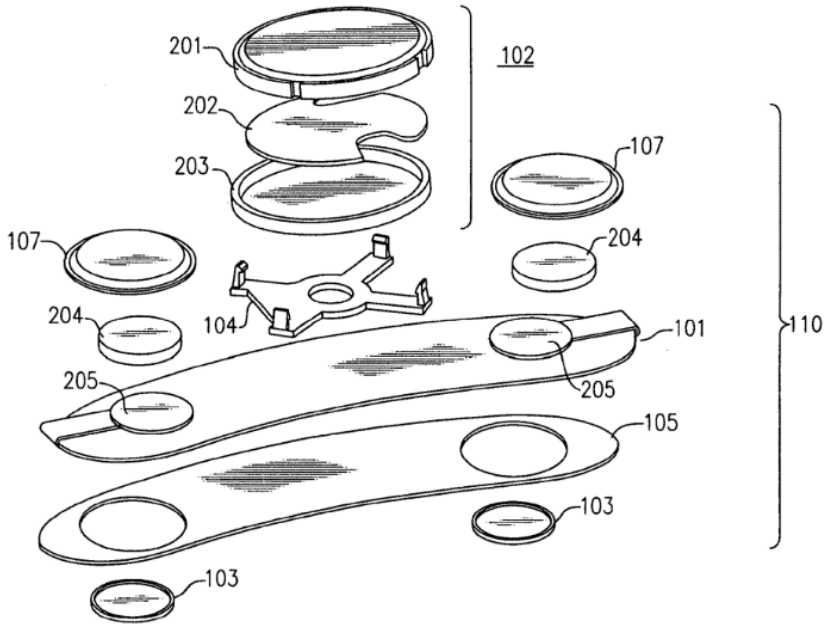
II. SUMMARY OF THE '007 PATENT

The '007 Patent provides a body-worn patient monitoring device that adhesively attaches to a patient's skin for measuring physiological signals. Ex. 1001, Abstract, Cl. 1; Ex. 2016, ¶[0045]. The body-worn patient monitoring device includes computation-communication module 102 that attaches to disposable

[1] U.S. Patent Publication No. 2003/0149349 to *Jensen* et al. (Ex. 1011).

[2] U.S. Patent No. 4,763,660 to *Kroll* et al. (Ex. 1014).

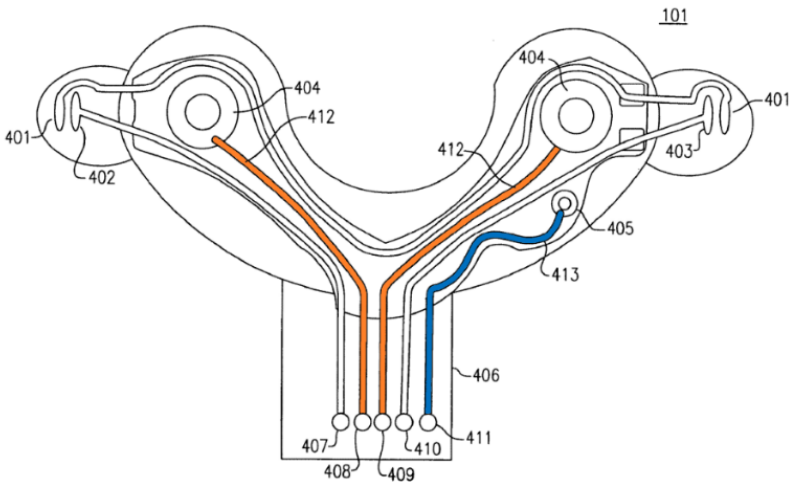
electrode module 110. Ex. 1001, Cl. 1, 4:58-5:4, Figure 2; Ex. 2016, ¶[0045]. In Figure 2, the retention clip secures the computation-communication module to the disposable electrode module. Ex. 1001, 4:58-5:4; Ex. 2016, ¶[0045].



Ex. 1001, Figure 2.

The disposable electrode module includes flexible printed circuit layer 101 made from an insulating material. Ex. 1001, 4:58-5:4; Ex. 2016, ¶[0046]. The flexible printed circuit layer transmits electrical signal via traces, which connect a connection pad and an electrode. Ex. 1001, 7:22-33; Ex. 2016, ¶[0046]. The traces 412 (orange in the annotated figure below), which are preferably printed, "extend[] between conductive surface 404 and connection pads 408 and 409." Ex. 1001, Figure 4A, 5:12-16 (defining the conductive surface as part of the electrode); Ex.

2016, ¶[0046]. Similarly, the trace 413 (blue), "extend[s] between conductive surface 405 and connection pad 411." Ex. 1001, Figure 4A, 7:28-33; Ex. 2016, ¶[0046]. The traces are made from a resistive material. Ex. 1001, 7:28-33.

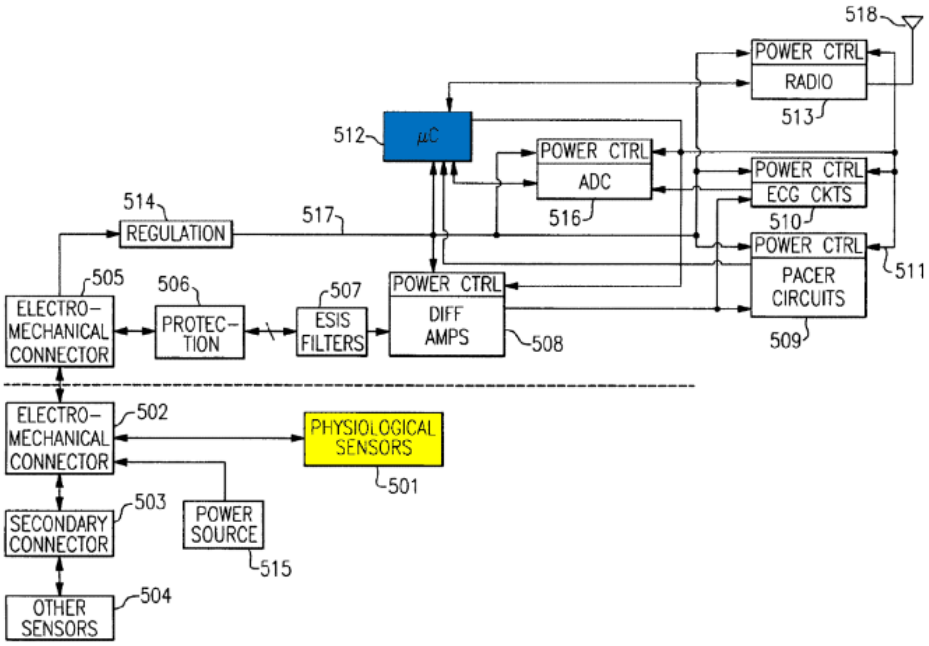


Ex. 1001, Figure 4A (annotated); Ex. 2016, ¶[0046].

Based on the resistance of the traces and design of the device, the traces are configured to protect the communication-computation module from, for example, defibrillation pulses. Ex. 1001, 7:34-45, Cl. 1; Ex. 2016, ¶[0047]. In an example, the resistance is in the desirable range of "about 1 kilo ohm to about 10 kilo ohms." Ex. 1001, 7:46-58; Ex. 2016, ¶[0047].

The pathway provided by these resistive traces is also shown in the block diagram of Figure 5. Ex. 1001, 11:7-8, Figure 5. There, the physiological sensors (*e.g.*, electrodes) for capturing an ECG difference potential are indicated in yellow. Ex. 1001, 11:9-11, Figure 5 (annotated); Ex. 2016, ¶[0048]. The physiological

sensors are electrically coupled to electromechanical connector 502, which is further connected to the processor for performing computational analysis on the detected signals. Ex. 1001, 11:7-47, Figure 5 (annotated), Figure 4A; Ex. 2016, ¶[0048]. The computation-communication module includes a housing that contains this processor. Ex. 1001, Figure 2; Ex. 2016, ¶[0048].



Ex. 1001, Figure 5 (annotated); Ex. 2016, ¶[0048].

III. ORIGINAL PROSECUTION OF THE '007 PATENT

The '007 Patent was filed as U.S. Patent Application No. 11/591,619 and claims priority to Application No. 11/591,619, filed on November 1, 2006. Ex. 1001, Cover. During prosecution, the Applicant distinguished the claims over several references and amended each independent claim to include a "series current-

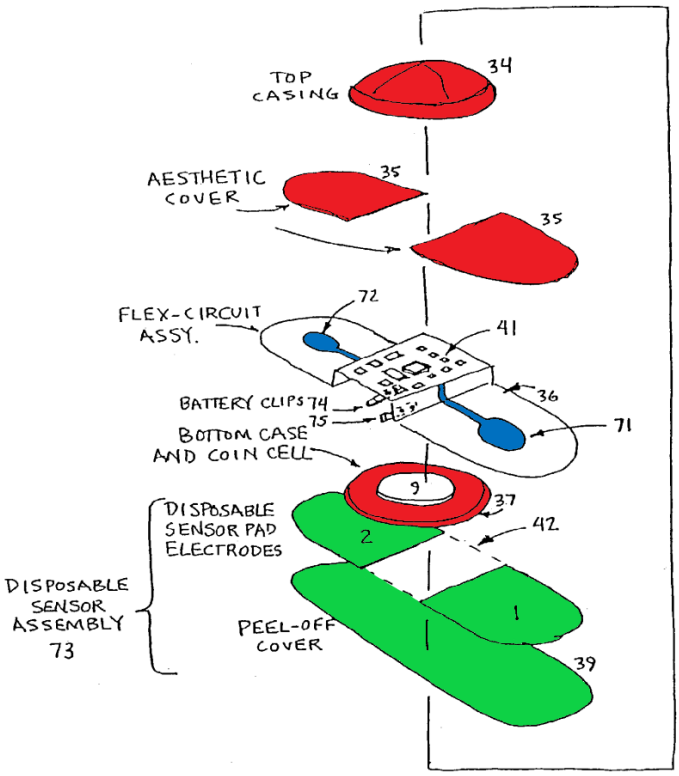
limiting resistor configured to protect the communication-computation module." *See* Ex. 1002, 134. The Applicant specified that the "series current-limiting resistor configured to protect the communication-computation module" was in the form of "resistive traces." *Id.* The Patent Office issued a Notice of Allowance, stating that the art, alone or in combination, fails to disclose the claimed resistor. *Id.* at 26.

IV. OVERVIEW OF THE ART

A. Overview of *Jensen*

Jensen provides a cardiac monitor that adheres to a patient's skin. Ex. 1011, Abstract; Ex. 2016, ¶[0049]. *Jensen's* "novelty include[s] its physical construction and method of use." Ex. 1011, ¶[0030]. Regarding the device's size, *Jensen* illustrates and describes "a totally self-contained sensor that is thin, being less than 6 or 7 mm in thickness, [and] low in mass." Ex. 2016, ¶[0049]; Ex. 1011, ¶[0030].

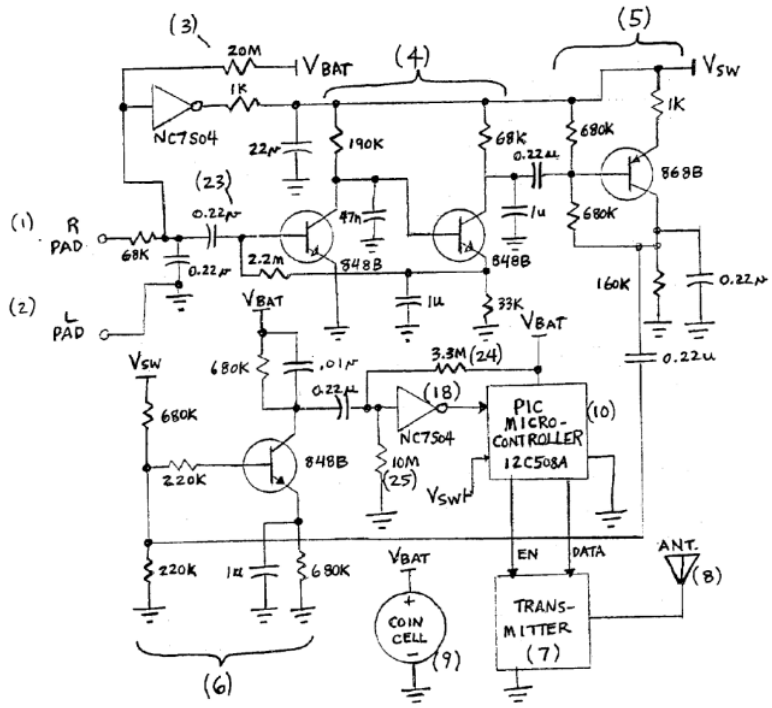
As part of the self-contained sensor, *Jensen* provides disposable sensor assembly 73, which includes cover 39, connective material 42, and pads 1 and 2. Ex. 1011, ¶[0042], Figure 5 (indicating the disposable components in green); Ex. 2016, ¶[0050]. These three components are the full extent of *Jensen's* disposable components. Ex. 2016, ¶[0050]; *see generally* Ex. 1011.



Ex. 1011, Figure 5 (annotated); Ex. 2016, ¶[0050].

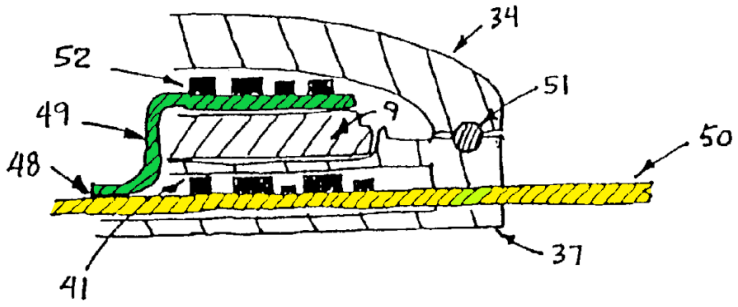
In contrast, the reusable portions, which include bottom case 37, top casing 34, and two aesthetic covers 35, are indicated in red. Ex. 1011, ¶[0043], Figure 5 (indicating the reusable components in red); Ex. 2016, ¶[0050]. *Jensen* also describes non-disposable flexible circuit assembly 36 having "traces" (annotated in blue above). Ex. 1011, ¶[0040], Figure 5; Ex. 2016, ¶[0051]. These "traces" connect electronics circuit 41 to sensor contacts 71 and 72, which in turn connect to pads 1 and 2 of disposable sensor assembly 73. Ex. 1011, ¶[0040], Figure 5; Ex. 2016, ¶[0051]. This way, the signal is transmitted to electronics circuit 41.

The electronics circuit includes a microcontroller and a transmitter. Ex. 1011, ¶[0032]; Ex. 2016, ¶[0052]. After receiving the signals, the electronics circuit processes the signals through various steps for amplification, filtering, and data extraction. Ex. 1011, ¶[0032]; Ex. 2016, ¶[0052]. The processed signal can either be (1) directly input into the transmitter or (2) input into the microcontroller for further analysis and encoding. Ex. 1011, ¶[0032]; Ex. 2016, ¶[0052]. The electronics circuit also includes various resistors for signal biasing and gain setting. Ex. 2016, ¶[0052]; Ex. 1011, ¶¶[0032], [0036]. Figure 2 is an example electronics circuit with resistors 24, 25 for signal biasing.



Ex. 1011, Figure 2.

Jensen also describes an alternative structure for its device in Figure 8. Ex. 1011, ¶[0046], Figure 8; Ex. 2016, ¶[0053]. In this alternative embodiment, *Jensen's* device includes two flexible printed circuits 49, 50. Ex. 1011, ¶[0046], Figure 8 (indicating the first circuit 50 in yellow and the second circuit 49 in green); Ex. 2016, ¶[0053]. As shown in Figure 8, *Jensen's* electronics circuit 41, which includes a transmitter and a microcontroller, is disposed on flexible circuit 50, which is closest to the skin. Ex. 1011, ¶[0046], Figure 8; Ex. 2016, ¶[0053]. The second flexible circuit assembly 49 is connected to first flexible circuit 50 via a set of pads 48. Ex. 1011, ¶[0046]; Ex. 2016, ¶[0053].

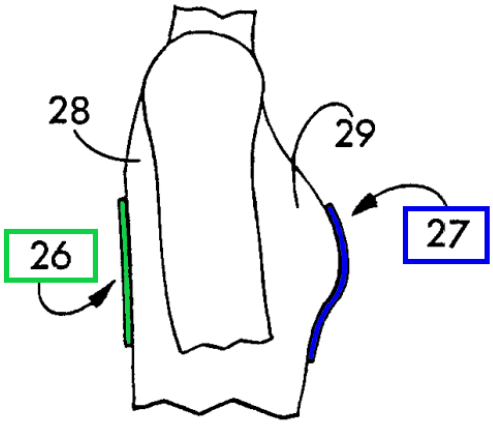


Ex. 1011, Figure 8 (annotated); Ex. 2016, ¶[0053].

To create this connection, *Jensen* explains that "pads of tinned-copper exposed on the bottom side of circuit 49 and the top side of circuit 50" are matched. Ex. 1011, ¶[0046], Figure 8A; Ex. 2016, ¶[0054]. Then, pads 48 "are heat re-flowed together, melting the tinning metal, to connect the two circuits." Ex. 1011, ¶[0046], Figure 8, 8A; Ex. 2016, ¶[0054].

B. Overview of *Kroll*

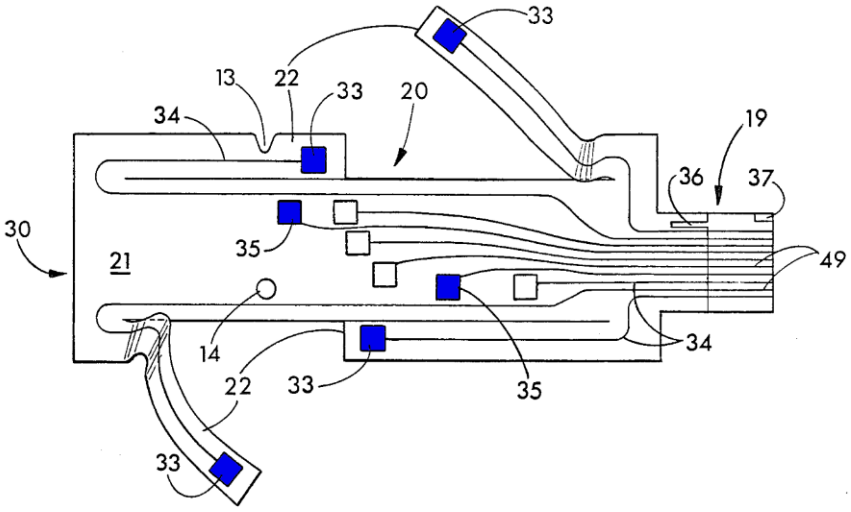
Kroll provides a disposable electrode belt, which is a therapeutic device "for receiving and transmitting electric current and voltage." Ex. 2016, ¶[0055]; Ex. 1013, 2:41-47. To achieve its therapeutic effect, *Kroll's* disposable electrode belt transmits current "to specific anatomical locations" of the patient. Ex. 2016, ¶[0055]; Ex. 1013, 1:27-36. *Kroll* sizes its belt to allow for the device to be placed on the patient's chest and back concurrently to deliver an electrical current through the chest of the patient. Ex. 2002, ¶[0056]; Ex. 1013, 4:44-47, Figure 3 (indicating the chest portion of the belt in blue and the back portion of the belt in green).



Ex. 1013, Figure 3 (annotated); Ex. 2016, ¶[0056].

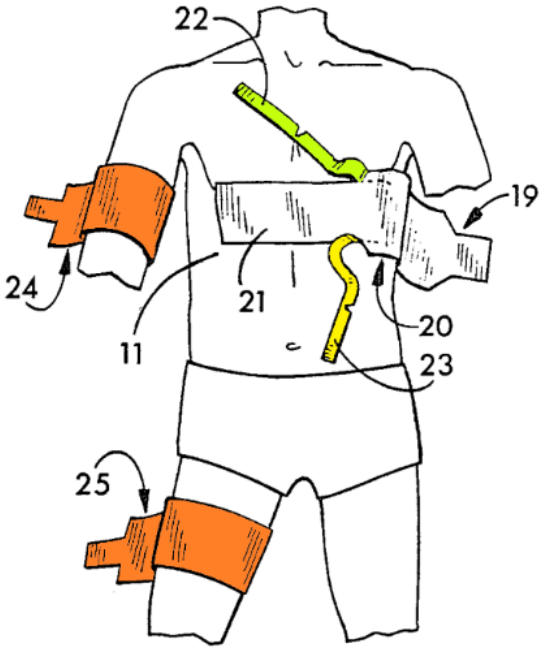
Figure 4 shows the electrodes (indicated in blue) of *Kroll's* disposable electrode belt. Ex. 2016, ¶[0057]; Ex. 1013, 4:48-68, Figure 4A (annotated). Each electrode "transmit[s] and receive[s] electric signals" over lead strip 34. Ex. 2016, ¶[0057]; Ex. 1013, 5:1-4. "[T]o ***protect a patient*** from shock due to malfunction of

the device 20 or of a complementary medical device," the lead strips may provide a "certain total lead strip resistance," thereby serving as a current limiter for charge being fed ***to*** the patient. Ex. 2016, ¶[0057]; Ex. 1013, 5:4-13. Other than protecting the patient, the lead strips do not provide any additional function. Ex. 2016, ¶[0057].



Ex. 1013, Figure 4A (annotated); Ex. 2016, ¶[0057].

The disposable electrode belt also includes extendable side members 22 that extend from the electrode belt's main body for placement outside of the precordial region. Ex. 2016, ¶[0058]; Ex. 1013, 4:37-47, Figure 4A, Figure 2 (indicating the side members in yellow). *Kroll's* electrode belt may also be placed around the patient's limbs. Ex. 2016, ¶[0058]; Ex. 1013, 4:37-47, Figure 2 (indicating the embodiments placed around the limbs in orange). Each embodiment is a specific size and structure to provide a desired therapeutic effect to a specific portion of the human body. Ex. 2016, ¶[0058].



Ex. 1013, Figure 3 (annotated); Ex. 2016, ¶[0058].

In addition to the extendable side members, *Kroll's* electrode belt relies on a "shielding layer" to safely administer therapeutic shocks. Ex. 2016, ¶[0059]; Ex. 1013, 6:17-24. This shielding layer prevents "interference from the device 10 with other medical diagnostic and therapeutic devices." Ex. 2016, ¶[0059]; Ex. 1013, 6:17-24. The electrode belt may include more than one shielding layer "to further shield the device from interference." Ex. 2016, ¶[0059]; Ex. 1013, 6:17-24. "[T]o minimize the risk of electrical shorting and patient shock in the event of device 10 failure," the shielding layer is "recessed inwardly at its outer boundaries." Ex. 2016, ¶[0059]; Ex. 1013, 7:3-13.

V. "GENERAL KNOWLEDGE" AND CLAIM CONSTRUCTION[3]

A. The Petition Fails to Comply with to 35 U.S.C. § 311(b)

The Petition does not satisfy 35 U.S.C. § 311(b) because the Petition relies on the "General Knowledge of Person of Ordinary Skill in the Art" as a basis in all Grounds. *See* Petition, 1-2; 35 U.S.C. § 311(b) (permitting challenges "only on the basis of prior art consisting of patents or printing publications"). Petitioner's strategy, summarized in its proposed grounds of unpatentability, is improper.

This conclusion, which is supported by Federal Circuit law, is established by two principles. First, § 311(b) only permits challenges on the "basis of prior art consisting of patents or printing publications." 35 U.S.C. § 311(b). And second, the Petition expressly relies on "General Knowledge" as a basis for its challenges in Grounds 1 to 4. Petition, 1-2. Specifically, the Petition opens with a table, prominently labeled: "Proposed Grounds of Unpatentability." Petition, 1-2. In one example, Ground 1, which applies equally to Grounds 2 to 4, relies on "Jensen, Kroll,

[3] The claim construction issues discussed in this Section are also covered in Patent Owner's Argument for Discretionary Denial. *See* Paper 7 at 11-19. However, Patent Owner includes similar arguments with this Response to show how Petitioner's failure to construe key terms impacts the merits of the Petition.

and ***General Knowledge of a POSA***." Petition, 1. This combination and listing of "General Knowledge" is repeated throughout the Petition. *See* Petition, 3 (listing "General Knowledge" in the overview of challenges), Petition, 16 (listing "General Knowledge" in the subheading for Ground 1's challenge).

The Federal Circuit's holding in *Qualcomm Inc. v. Apple Inc.*, No. 2023-1208, 2025 WL 1174161 (Fed. Cir. Apr. 23, 2025) is instructive. There, the petitioner provided a table outlining its challenge to the claims and listed AAPA (*i.e.*, applicant admitted prior art) for two of its grounds. *Id.* at *9. The court held that this listing was an "express statement[]" that AAPA is part of the basis of its ground. *Id.*

Ground	'674 Patent Claims	Basis for Rejection
Ground 1	**1, 2, 5-7**	§103: Steinacker in view of Doyle and Park
Ground 2a	**1, 2, 5, and 6,**	§103: Applicants Admitted Prior Art (AAPA) in view of Majcherczak
Ground 2b	**7**	§103: AAPA in view of Majcherczak and Matthews

Id. at *4.

Just as the petition's listing of AAPA was viewed as an express statement in *Qualcomm*, the Petition's listing of "General Knowledge" is likewise an express statement that "General Knowledge" is part of the basis of Grounds 1 to 4.

Proposed Grounds of Unpatentability	
Ground 1	Claims 1, 2, 4-8, 10-15, 29, 31, 37, 38, and 43-45 are obvious under pre-AIA § 103 over Jensen, Kroll, and General Knowledge of a POSA
Ground 2	Claims 32-35 are obvious under pre-AIA § 103 over Jensen Kroll and General Knowledge of a POSA, and/or Jensen, Kroll, DeLuca, and General Knowledge of a POSA.
Ground 3	Claims 2 and 3 are obvious under pre-AIA § 103 over Jensen, Kroll, Harland and General Knowledge of a POSA
Ground 4	Claim 39 is obvious under pre-AIA § 103 over Jensen, Kroll, Thompson, and General Knowledge of a POSA

Petition, 1-2 (annotated).

In *Qualcomm*, the Federal Circuit ultimately held that the petition failed to comply with § 311(b) by including AAPA as part of its ***basis*** for its challenge. *Id.* at *11. The same conclusion should follow here. Like the petitioner in *Qualcomm*, the Petitioner chose not to limit its challenges to "patents or printing publications." 35 U.S.C. § 311(b). Instead, the Petition relies on "General Knowledge" to teach elements missing from the references themselves.

Thus, in view of Federal Circuit law and a plain reading of § 311(b), the Petition cannot advance "General Knowledge" as the basis for its challenges.

B. The Petition Fails to Advance A Legally Cognizable Claim Construction Position

When construing claims, the Board applies the principles set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-17 (Fed. Cir. 2005) (en banc). The *Phillips*

Standard establishes that the words of a claim are generally given their plain and ordinary meaning, which is the meaning the term would have to a POSA at the time of the invention, in the context of the entire patent. *Phillips*, 415 F.3d at 1312-13. Although Petitioner claims to apply the ordinary and customary meaning of the terms (*see* Petition, 2), the Petition advances implicit claim constructions that lack support or explanation. This failure renders the Petition fundamentally defective, as it leaves the Board without a clear and reasoned basis to evaluate claim scope, thereby shifting the burden of claim clarification to the Patent Owner and the Board. The Petition's flaws are exacerbated by its extensive reliance on non-prior art references, as well as significantly outdated and non-relevant references.[4]

1. The Petition is Riddled with Claim Construction Yet Fails to Propose Actual Constructions

According to 37 C.F.R. § 42.104(b)(3), Petitioner has an affirmative burden to set forth how the challenged claims should be construed. *See, e.g.*, *Orthopediatrics Corp. v. K2M, Inc.*, IPR2018-01548, Paper 9 at 10 (PTAB Mar. 1, 2019). A petition for *inter partes* review must clearly articulate a rationale for "[h]ow the challenged claim is to be construed." 37 CFR § 42.104(b)(3). If the

[4] The Petition's reliance on non-prior art documents is also covered in Patent Owner's Argument for Discretionary Denial. *See* Paper 7 at 26-29.

petitioner construes a claim term, but "does not establish that such interpretations are appropriate[,]" it is fatal to the petitioner's ground. *Vicor Corp. v. Delta Elecs., Inc.*, IPR2024-00704, Paper 11, at 8 (PTAB Oct. 2, 2024). Controlling law mandates that claim terms in an IPR be construed using the same standard as in a civil action under 35 U.S.C. § 282(b), including "construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*; *see also* 37 C.F.R. § 42.100(b) (2021). Thus, to determine the meaning of a disputed claim term, one must "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).

Like the petition in *Vicor Corp.*, the Petition does not even purport to apply the controlling law of *DePuy Spine* and *Phillips*. The Petition's singular reference to claim construction states: "Claims are interpreted with their ordinary and customary meaning as understood from the perspective of a person of ordinary skill in the art." Petition, 2 (citing *Phillips*, 415 F.3d at 1303). Despite this, the Petition repeatedly engages in improper claim construction, deviating significantly from the "ordinary and customary meaning" of the construed terms without providing any

rationale for doing so, often treating an amalgamation of non-contemporaneous, unhelpful, irrelevant documents as if they were helpful to the *Phillips* inquiry.

For example, at least four separate terms, found in ***all*** independent claims of the '007 Patent (see table below), appear to be implicitly construed in Petitioner's expert declaration and incorporated by reference into the Petition:

Claim Element + Term	**Petition**	**Expert Decl.**
Claim 1(c): "half cell"	Pet., 21-22	Ex. 1009, ¶¶237-38
Claim 1(h)/45(f): "microprocessor"	Pet., 26, 45	Ex. 1009, ¶256
Claim 1(n)/45(*l*): "traces"	Pet., 31, 48	Ex. 1009, ¶290
Claim 1(*l*)/45(j): "configured to"	Pet., 29-30, 48	Ex. 1009, ¶277

Petitioner purports to apply the ordinary and customary meaning of the terms (*see* Petition, 2); however, the Petition is filled with implicit claim constructions that lack support or explanation. *See ams AG v. 511 Innovations, Inc.*, IPR2016-01792, Paper 15 at 8, 13 (P.T.A.B. Mar. 16, 2017) (denying institution where "Petitioner improperly attempts to shift the burden of construing the claim term 'minimal height' to the Board. *See* 37 C.F.R. § 42.104(b)(3)."). This failure renders the Petition fundamentally defective, as it leaves the Board without a clear and reasoned basis to evaluate claim scope thereby shifting the burden of claim clarification to the Patent Owner and the Board.

In one notable example, the Petition implicitly construes the claim term "configured to" without providing its position, let alone citing to any case law, intrinsic evidence, or extrinsic evidence. *See* Section VI.A.1.a. While the Patent Owner and the Board can only speculate based on this failure, the Petition seemingly construes "configured to" as "capable of." *Id.* For this reason alone, the Petition cannot "show[] a reasonable likelihood that it would prevail in its challenge asserted as Ground [2]." *See Vicor Corp.*, IPR2024-00704, Paper 11 at 9.

Moreover, a failure to explain such broadening construction is especially concerning because the Federal Circuit and the Board have issued a line of cases directly pertinent to the construction of "configured to." *See* Section VI.A.1.a.i. In *Acclarent, Inc. et al v. Ford Albritton*, IPR2017-00498, Paper 40 at 13 (P.T.A.B. July 9, 2018), the Board took issue with the petitioner's failure to "cite to any controlling case law where either 'configured to' or 'adapted to' was construed in the broad manner." This failure to address key case law, including *Giannelli* or *Aspex Eyewear*, "sp[oke] volumes regarding Petitioner's ability to distinguish those cases and escape their holdings, and supports applying the narrower construction." *Id.* Ultimately, the Board explained that "configured to" is "synonymous with the narrower 'made to' and 'designed to' phrases." *Id.* (citing *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d. 1335, 1349 (Fed. Cir. 2012)).

This difference between "configured to" and "capable of" is important to this proceeding because both independent claims of the '007 Patent, and thus all Challenged Claims, expressly require "at least one series current-limiting resistor ***configured to*** protect the communication-computation module." Ex. 1001, Cl. 1, 45. As further detailed in Section VI.A.1.a, the Petition relies on *Kroll's* lead strips, which "***protect a patient*** from shock." Ex. 1013, 5:4-13; Ex. 1001, Cl. 1. In this regard, *Kroll's* lead strips are decidedly not "designed to" protect a communication-computation module. The Petition neither advances this argument nor identifies any disclosure in *Kroll* that shows its lead strips are designed to function as required by the independent claims of the '007 Patent. Accordingly, each of the Petition's ground fail under the proper construction of "configured to."

Besides the Petitioner's failure to address any case law supporting its unreasonably broad interpretation, the Petition also cites no supporting evidence from the '007 Patent itself, and Dr. Heikenfeld's Declaration substantially parrots the Petition, which is not "persuasive or helpful as it repeats the Petitioner's arguments and offers little or no elaboration as to how one of ordinary skill in the art would understand the term[.]" *See InfoBionic, Inc. v. Braemer Manuf., LLC*, IPR2015-01704, Paper 11, 6 (P.T.A.B. Feb. 16, 2016) (denying institution). Continuing with this line of failures, the Petition fails to establish how the art renders

the claim obvious even under its improperly broad claim construction. *See* Section VI.A.1.a.iii. Here, Dr. Heikenfeld simply alleges, without support in the prior art, that *Kroll's* lead strips "would protect" *Jensen's* electronics because resistors "function to limit current in either direction." Ex. 1009, ¶211.

However, Dr. Heikenfeld "does not disclose the underlying facts or data on which the opinion is based" and his opinion is therefore "entitled to little or no weight." *See Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (Aug. 24, 2022) (designated precedential Feb. 10, 2023) (citing 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 to factual determinations, however, may render the testimony of little probative value in a validity determination."). Furthermore, Patent Owner's expert, Dr. Anthony, details how Dr. Heikenfeld's conclusion is wrong. *See* Section VI.A.2.a.ii(c).

In sum, the Petition's reliance on the "ordinary and customary meaning" of critical terms is riddled with issues. The Petition does not provide its position, leaving the Patent Owner and Board to speculate on the Petition's construction. And based on the Petition's arguments, it appears to apply a construction that is contrary

to settled law and the '007 Patent (although the Petition did not address either). Finally, the Petition fails to establish that the art renders the claim term obvious even when applying its impermissibly broad construction. *See* Section VI.A.1.a.iii.

2. The Petitioner Improperly Shifts the Burden of Clarification to the Board and Patent Owner

As a result of the Petition's improper and unclear claim constructions, the Petitioner improperly shifts the burden of claim clarification to the Patent Owner and the Board. As discussed, the Petition fails to adequately articulate a construction of "configured to" despite applying an impermissibly broad interpretation throughout the Petition. *See supra* Section V.B.1. Where the petitioner sets forth arguments or observations of what a claim term means, but does not provide an explicit construction for the claim term, the "Petitioner improperly attempts to shift the burden of construing the claim term…to the Board[,]" and institution should be denied. *See ams AG*, IPR2016–01792, Paper 15 at 8, 13 (denying institution) ("[U]nder the circumstances discussed above…Petitioner fails to meet its burden under 37 C.F.R. § 42.104(b)(3) of providing a claim construction for the term 'minimal height.' Therefore, we decline to institute an *inter partes* review of the challenged claims.").

3. The Petition's Reliance on Non-Prior Art, Outdated, and Irrelevant References Significantly Burdens the Patent Owner and the Board

The Petition's reliance on non-prior art, outdated, and irrelevant references is an aggravating factor that undermines its obviousness theories. Specifically, the Petition claims to establish the "state of the art" using 55 references. However, many of these references are not actually prior art, and the Petition fails to distinguish which references qualify as valid art for the state-of-the-art determination.

For example, of the 66 exhibits submitted with the Petition, the Petitioner relies on 55 references (Exs. 1011 through 1065) as supporting its unpatentability theories. Of these 55 references, eight are decidedly not prior art, being from ***after*** the November 2006 priority date of the '007 Patent. For example, Exhibits 1020 (dated in 2008); 1021 (dated in 2013); 1024 (dated in 2023); 1025 (dated in 2012); 1027 (dated in 2025), 1030 (dated in 2022), 1043 (dated in 2019), and 1035 (dated in 2006), are all dated anywhere from months to ***19 years after*** the priority date of the '007 Patent (November 1, 2006). Dr. Heikenfeld's reliance on these non-prior art documents is extensive: He cites Ex. 1035 approximately 62 times in his declaration and Exhibit 1043 approximately ten times in his declaration, not including any internal cross references that incorporate these references. He further relies on Exhibits 1020, 1021, 1024, 1025, 1027, and 1030 in his "background

sections," which are cross-referenced repeatedly throughout his declaration including his actual analysis of claim elements and explanations for why the alleged combinations would be made.

That the Petition relies on references from after the priority date of the '007 Patent as alleged evidence of the "state of the art" at the time of the invention–2006– creates confusion, undermines the foundation of the obviousness challenge, and distorts the obviousness inquiry making it difficult for both the Patent Owner and the Board to decipher the proper state of the art at the time of the claimed invention.

Moreover, many of the other cited references are significantly outdated, lack contextual explanations, and are presented without sufficient clarity as to their relevance to the technology at issue. For example, the Petition does not explain why some very old references (some 50+ years prior to the '007 Patent) are relevant to the problems facing the ***state of the art*** in 2006 or provide any insight into how they would contribute to a POSA's understanding of the technology at the time of the claimed invention. For example, the Petition relies on numerous ancient references, including: Exhibits 1022 (dated in 1979); 1026 (dated in 1960); 1031 (dated in 1985); 1032 (dated in 1984); 1037 (dated in 1969); 1038 (dated in 1989); 1048 (dated in 1956); 1049 (dated in 1985); 1050 (dated in 1985); 1051 (dated in 1980); 1052 (dated in 1977); 1059 (dated in 1986); 1060 (dated in 1917); and 1061 (dated in

1978). Dr. Heikenfeld uses Exhibit 1038, from 1989, as alleged evidence that in 2006, a POSA would have had problems properly cleaning medical devices. Ex. 1009, ¶32. Nothing about these references from decades before the '007 Patent was filed suggests how a POSA would understand the problems facing the industry in 2006.

The Petition fails to allege, let alone establish, the relevancy of these ancient references to the problems facing the field of the invention as of 2006. If the Petitioner can establish the state of the art using references spanning over a century, it would render the requirement to assess the state of the art ***at the time of the invention*** a nullity. As such, there is no rational basis for relying on the references, as they lack the modern technological relevance necessary for a POSA to reasonably combine them.

VI. THE PETITION FAILS TO SHOW A REASONABLE LIKELIHOOD THAT THE PETITIONER WILL PREVAIL ON A SINGLE CLAIM

The Petition fails to establish a reasonable likelihood of success on a single claim. In Ground 1, the proposed combination of *Jensen*, *Kroll*, and the Petition's amorphous "general knowledge" fails on numerous grounds. First, the combination does not teach or suggest each element of Claim 1, including the current-limiting resistor or the communication-computation module being both removable and reuseable. Second, Ground 1 fails because the Petition does not establish a

motivation to combine *Jensen* and *Kroll*. As such, the Petition does not have a reasonable likelihood of prevailing on Ground 1.

A. Ground 1 Fails to Render Obvious the Challenged Claims

1. The Non-Obvious Combination of *Jensen* and *Kroll* Fails to Render Obvious Claims 1 and 45

The non-obvious combination of *Jensen* and *Kroll* cannot succeed because it fails to render obvious the current-limiting resistor "configured to protect the communication-computation module." In an attempt to teach this element, the Petition relies on an implicit construction of "configured to" that is improper. When construing "configured to" consistent with settled precedent and the disclosure of the '007 Patent, the Petition fails.

Further, the combination of *Jensen* and *Kroll* fails to render obvious the communication-computation module "being removable and reuseable." While *Jensen's* device includes reusable components, none of these components are the communication-computation module. Further, *Jensen's* electronics, which the Petition identifies as the communication-computation module, are not "removable"; they are located on a circuit that is ***heat re-flowed*** with another circuit. Thus, the Petition fails to establish a reasonable likelihood of success in Ground 1.

a. Ground 1 fails to render obvious a resistor "configured to protect the communication-computation module"

The Petition does not rely on *Jensen* for the claimed resistor, only *Kroll*. *See* Petition, 29-30. However, *Kroll* does not disclose a resistor "configured to ***protect the communication-computation module***," and therefore, the Petition fails to render this element obvious. Ex. 1001, Cl. 1; Petition, 29-30.

The Petition hides behind the alleged "ordinary and customary meaning" to avoid construing this term yet relies on an unreasonably broad interpretation of "configured to" when conducting its analysis. Under the proper construction, Claim 1 requires a resistor "specifically designed" or "made to"—not merely "capable of"—performing the function of protecting the communication-computation module. The Petition's attempt to implicitly construe "configured to" as "capable of" is improper and should be ignored. But the Petition fails even under its unreasonably broad interpretation. Thus, the Petition does not render this element obvious. Claim 45 recites the same language, and thus Ground 1, along with the entire Petition, fails to show a reasonable likelihood of success. Ex. 1001, Cl. 45.

i. The Petition fails to construe "configured to" beyond its "ordinary and customary meaning"

The Petition hides behind the "ordinary and customary meaning" to avoid construing any claim terms, including "configured to." *See* Petition, 2. While the Petition could have applied the proper framework or explained the "ordinary and customary meaning" of this term, the Petition chose not to. The plain meaning of

"configured to" has been repeatedly and consistently confirmed by the Federal Circuit. "[C]onfigured to" is "synonymous with the narrower 'made to' and 'designed to' phrases." *Acclarent, Inc. et al v. Ford Albritton*, IPR2017-00498, Paper 40 at 13 (P.T.A.B. July 9, 2018) (citing *Aspex Eyewear*, 672 F.3d. at 1349 (Fed. Cir. 2012)). The Board recognizes that "precedent makes clear that the 'configured to' phrase itself connotes the narrower meaning" of "designed to" or "constructed to" rather than the broader meaning of "capable of" or "suitable for." *Id.* at 11, 14 (citing *Aspex Eyewear*, 672 F.3d. at 1349).

In one example, a petitioner argued that the phrases "adapted to" and "configured to" should be broadly construed as "capable of." *Acclarent*, IPR2017-00498, Paper 40 at 11. The Board explained that the "[p]etitioner did not cite to any controlling case law" to support its position. *Id.* at 13. And because courts "simply presume[]" that "configured to" connotates the narrower meaning of "designed for," the Board agreed with the patent owner, construing "configured to" as "designed to accomplish the claimed objectives." *Id.* at 13.

The Board also applied this general rule in *Simpson Strong-Tie Company Inc. v. Columbia Insurance Company*, PGR2019-00063, Paper 52 at 43 (P.T.A.B. Mar. 11, 2011). There, the petitioner (like Petitioner here) "does not adequately explain how 'configured to' can be construed as requiring a mere capability" under current

precedent. *Id.* at 43. Thus, the Board construed "configured to" as "requir[ing] additional structure configured or designed to accomplish the claimed function." *Id.* at 44; *see also ParkerVision, Inc. v. Qualcomm, Inc.*, 903 F.3d 1354, 1361 (Fed. Cir. 2018) (explaining that Federal Circuit "cases distinguish between claims with language that recites capability, and those that recite configuration"); *In re Giannelli*, 739 F.3d 1375, 1379 (Fed. Cir. 2014).

The Petition fails to allege that any prior art teaches a resistor that is "designed to" or "constructed to" "protect the communication-computation module," as is required by the independent claims of the '007 Patent. *See* Petition, 29-30, 48.

ii. The Petition improperly construes "configured to" under the broader construction of "capable of"

To remedy the deficiency of its art, the Petition presents a theory based on an allegation of what the prior art might be capable of doing, not how it was specifically designed.

Kroll's lead strip "protect[s] ***a patient*** from shock" while the resistor of Claim 1 is "configured to protect ***the communication-computation module***." Ex. 2016, ¶¶[0067]-[0071]; Ex. 1013, 5:4-13; Ex. 1001, Cl. 1. To bridge this gap, the Petition implicitly interprets "configured to" as "capable of." *See* Petition, 29-30. The Petition argues that *Kroll* renders obvious the current-limiting resistor because *Kroll's* lead strips are capable of protecting the communication-computation

module. *See* Petition, 29-30 ("[A] POSA would have known that the 'resistive trace' of Kroll ***would help*** safeguard Jensen's communication-computation.").

In interpreting "configured to" as merely "capable of," the Petition cuts against settled law without making any argument as to the sufficiency of this interpretation. *See* Petition, 29-30. The cases discussed in Section VI.A.1.a.i are a death knell to the Petition and are unaddressed.

In addition to the case law, the disclosure of the '007 Patent, which the Petition did not analyze, shows that the correct construction of "configured to" is "designed for." Claim 1 requires "at least one series current-limiting resistor configured to protect the communication-computation module." Ex. 1001, Cl. 1. The disclosure corresponding to this claim language details the design and features required to achieve this function. Ex. 2016, ¶¶[0072]-[0074]. Namely, the '007 Patent states that the "protective resistive traces be in a range between about 1 kilo ohm to about 10 kilo ohms." Ex. 2016, ¶[0070]; Ex. 1001, 7:46-48. The '007 Patent goes on to explain the need for this range as it relates to "successive defibrillation pulses" and signal to noise ratio. Ex. 2016, ¶[0070]; Ex. 1001, 7:48-58. Also, the '007 Patent details the structure, requirements, and issues in designing its resistor over several columns of disclosure. Ex. 2016, ¶[0070]; *see* Ex. 1001, 7:46-11:6.

In view of both the case law and the disclosure of the '007 Patent, neither of which the Petition addresses, "configured to" is properly construed using the narrower meaning of "design to" or "made to." Applying this proper construction, the conclusion logically follows: *Kroll* does not render this element obvious because *Kroll's* lead strips are only described as designed to protect the patient; they are not "configured to" protect the communication-computation module as required by Claim 1 and 45. For this reason, the analysis ends here.

iii. The Petition fails even under its improperly broad construction of "configured to"

Even applying the improperly broad construction, the Petition still fails because it does not establish that *Kroll's* lead strips are even capable of "protect[ing] the communication-computation module." Ex. 1001, Cl. 1. Instead, the Petition contends that *Kroll's* lead strips would protect *Jensen's* electronics simply because, based on Dr. Heikenfeld's alleged theories, resistors limit current flow in both directions. Petition, 29-30; *see* Ex. 1009, ¶277. The Petition's maze of cross-nested citations does not provide any explanation on why *Kroll's* lead strips ***would*** protect *Jensen's* electronics based on anything more than the inherent property that resistors limit current. Moreover, as Dr. Anthony makes clear, a POSA would have recognized various design considerations that would determine whether *Kroll's* lead

strips would even be capable of protecting *Jensen's* electronics. Ex. 2016, ¶¶[0125]-[0133]. The Petition did not address any of these design considerations.

Instead, to support its position, the Petitioner first points to Section VII.A.1 of the Petition, which is related to the motivation to combine *Jensen* and *Kroll*. *See* Petition, 29-30. In Section VII.A.1, the Petition provides the same conclusion and cites to Dr. Heikenfeld. *See* Petition, 17 ("A POSA would have understood that it would be beneficial to limit the current transmitted in either direction (whether towards or away from the patient's body).") (citing Ex. 1009, ¶¶209-212). Dr. Heikenfeld repeats the same conclusion and cites to a different section of his Declaration. *See* Ex. 1009, ¶211 (citing Section IV.F, *supra*) ("[R]esistive materials which limit the current transmitted would function to limit current in either direction (*i.e.*, either towards or away from the patient's body) and thus would protect both the patient and the device, depending on the source of the excess electrical current.").

In finally reaching Section IV.F, Dr. Heikenfeld again repeats the insufficient conclusion as the Petition that *Kroll's* lead strips would protect *Jensen's* electronics because resistors limit current in both directions. *See* Ex. 1009, ¶47 ("[A]ny approach to limiting current using resistive material to protect the patient from shock would also protect the body-worn device from excess electrical current because the electrical resistance operates to limit the flow of current in either direction."),

("[A]ny resistor that simply has the proper range of resistance would protect the body-worn device from excess electrical current."). Even more, Dr. Heikenfeld only cites Exhibit 1043 here, which is a ***2019 reference*** that published ***thirteen years*** after the priority date of the '007 Patent. *See* Ex. 1009, ¶47 (citing Ex. 1043 at 816–17). With a fulsome review of the Petition's layered citations, it becomes clear that the Petition fails to demonstrate that *Kroll's* lead strips are capable of protecting *Jensen's* electronics. Moreover, Dr. Anthony's straight-forward analysis demonstrates that *Kroll's* lead strips would not necessarily protect *Jensen's* electronics, directly contrary to the Petition's argument. Ex. 2016, ¶[0074].

b. The Petition fails to consistently rely on the same structure for the "communication-computation module"

At the outset, the Petition fails to advance a coherent challenge because it provides competing positions on the "communication-computation module." For claim element 1[f], which first recites the communication-computation module, the Petition identifies the transmitter and microcontroller in *Jensen's* electronics circuit. Petition, 24 ("Jensen teaches a 'transmitter' for communication and a 'microcontroller' for computation.") (citing Ex. 1011, ¶[0032]). The Petition further states that "the electronic circuit ***contain[s]*** the communication-computation module." Petition, 24 (citing Ex. 1011, ¶¶[0042]-[0043]). Here, the Petition

identifies the transmitter and microcontroller of *Jensen's* electronics circuit as the claimed "communication-computation module." Petition, 24.

i. *Jensen's* transmitter and microcontroller cannot teach the communication-computation module

This is important because Claim 1 requires the communication-computation module to be coupled directly to the disposable module. Ex. 1001, Cl. 1 (requiring the disposable module to be "mechanically and electrically coupled directly to the communication-computation module"). Because the Petition identifies *Jensen's* "disposable sensor assembly" as the disposable module (Petition, 19), and neither the transmitter or microcontroller are directly coupled to the disposable sensor assembly, the communication-computation module cannot only be *Jensen's* transmitter and microcontroller. The Petition does not advance this theory but instead identifies a different theory.

ii. *Jensen's* flexible circuit assembly cannot teach the communication-computation module

Elsewhere, the Petition identifies *Jensen's* entire "flexible circuit assembly" as the communication-computation module. For example, the Petition states that the "adhesive acts as the claimed 'disposable module connector,' connecting…the disposable module to the reusable communication-computation module (*i.e.*, Jensen's 'flexible circuit assembly')." Petition, 22. The Petition also states that

"Jensen's disposable sensor pad electrodes…are coupled to the flexible circuit assembly, which is Jensen's communication-computation module." Petition, 27-28. Based on these competing positions, Patent Owner relies on the Petition's explicit identification of the entire "flexible circuit assembly" (rather than only the transmitter and microcontroller) as the communication-computation module.

But this other interpretation also fails. As detailed below in Section VI.A.1.b.ii(a), Claim 1 requires that communication-computation module to be both "removable and reuseable." Ex. 1001, Cl. 1. The Petition fails to establish that *Jensen's* flexible circuit assembly is either removable or reuseable.

(a) *Jensen's* flexible circuit assembly is not removable or reuseable

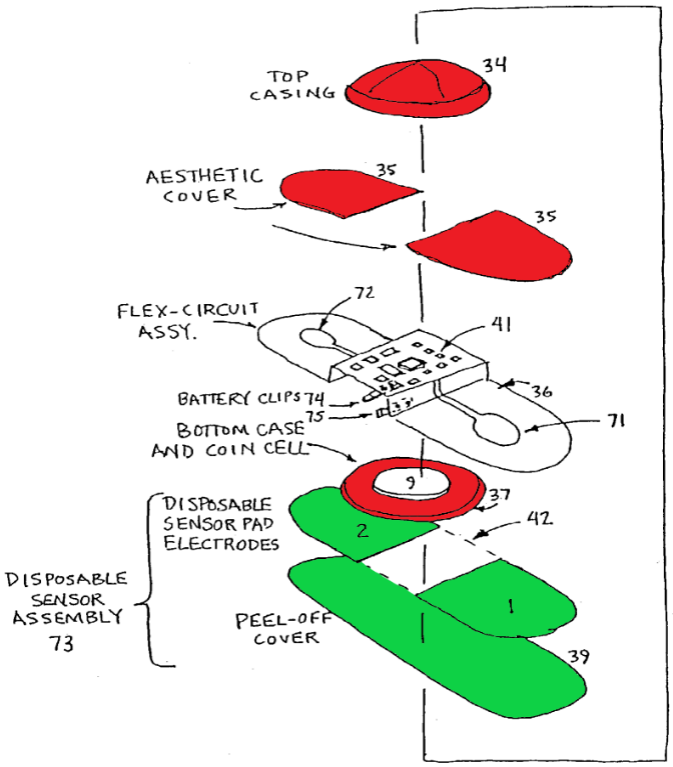
The Petition's single conclusory statement does not render obvious a communication-computation module being "removable and reuseable." *See* Petition, 24 (*Jensen's* "communication-computation module is a 're-usable' component, which is separable and removable from the 'disposable sensor assembly.'"); *see* Ex. 2016, ¶¶[0075]-[0077]. First, *Jensen* discloses specific reusable components—which are components that are ***not*** what the Petition identifies as the communication-computation module. Ex. 2016, ¶¶[0083]-[0086]; *see* Petition, 24 (identifying *Jensen's* transmitter and microcontroller as the "communication-computation module"). Second, the Petition does not explain how

Jensen renders obvious a ***removable*** communication-computation when its circuits are "heat re-flowed together." Ex. 2016, ¶¶[0078]-[0082]; Ex. 1011, ¶[0046]. For each of these reasons, the Petition fails.

(1) *Jensen's* disclosure does not support the Petition's argument of reusability

Jensen is silent as to whether its transmitter or microcontroller are reuseable. Ex. 2016, ¶[0083]; *see* Petition, 24 (identifying *Jensen's* transmitter and microcontroller as the communication-computation module). The Petition attempts to hide this gap and cherry-picks the word "re-usable" to misrepresent *Jensen* and incorrectly conclude that "the communication-computation module is a 're-usable' component." Petition, 24 (citing Ex. 1011, ¶¶[0042]-[0043]). But *Jensen* is clear.

Jensen states that its reusable portion is "comprised of bottom case 37, top casing 34 and two aesthetic covers 35." Ex. 2016, ¶[0084]; Ex. 1011, ¶[0042], Figure 5 (identifying the "re-useable" components of *Jensen* in red).



Ex. 1011, Figure 5 (annotated); Ex. 2016, ¶[0084].

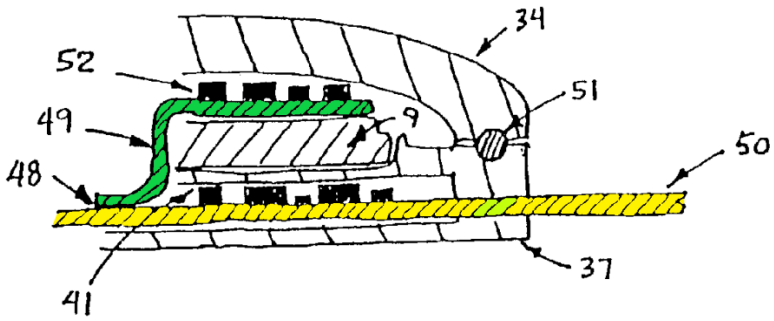
Neither *Jensen's* transmitter or microcontroller are one of these reusable components, and *Jensen* does not suggest otherwise. Ex. 2016, ¶[0085]; Ex. 1011, ¶[0042], Figure 5. Beyond a single citation to the word "re-useable"—which is not describing *Jensen's* transmitter or microcontroller—the Petition does not explain how the transmitter or microcontroller are reusable or how *Jensen's* electronics circuit is reusable. Ex. 2016, ¶[0085]; *see* Ex. 1011, ¶[0042]. Dr. Heikenfeld's analysis fares no better. Like the Petition, Dr. Heikenfeld concludes, without explaining ***why***, or identifying any evidence, *Jensen's* electronics circuit is part of *Jensen's* reusable portion. Ex. 2016, ¶¶[0085]-[0086]; *see* Ex. 1009, ¶249.

In sum, *Jensen's* only disclosure regarding reusable components ***excludes*** the transmitter and microcontroller. Rather than directly address *Jensen's* disclosure, the Petition deceptively cites to *Jensen* as if its "re-useable" portion included the transmitter and microcontroller. The Petition provides no explanation for its position; therefore, the Petition suffers from a failure of proof.

(2) *Jensen's* flexible circuit assembly is not removable

For this element, the Petition's analysis fares no better than its previously cherry-picked disclosure of "re-usable." *See* Petition, 24. *Jensen* does not provide a "removable" communication-computation module. Ex. 2016, ¶[0078]. To conclude otherwise, the Petition misrepresents *Jensen's* disclosure and selectively ignores other disclosure that contradicts its position. *See* Petition, 24.

Contrary to the Petition's argument, *Jensen* does not use "separable" or "removable" to describe any of its components. Ex. 2016, ¶[0079]; *see* Petition, 24 (*Jensen's* "communication-computation module is a 're-usable' component, which is separable and removable from the 'disposable sensor assembly.'"); *see also* Ex. 1009, ¶249 (repeating the same conclusion without pointing to support in *Jensen*). Instead, *Jensen's* description of Figure 8, which the Petition does not address, shows that the transmitter and microcontroller are not removable or separable from the device. Ex. 2016, ¶[0080]; *see* Ex. 1011, ¶[0046], Figure 8.



Ex. 1011, Figure 8 (annotated); Ex. 2016, ¶[0080].

As introduced in Section VI.A.1.b.ii(a)(1), the transmitter and microcontroller are part of *Jensen's* electronics circuit 41. Ex. 2016, ¶[0080]; Ex. 1011, ¶¶[0032], [0040]. The electronics circuit is disposed on circuit 50 (yellow), which is "heat re-flowed together" with circuit 49 (green). Ex. 2016, ¶[0080]; Ex. 1011, ¶[0046], Figure 8, Figure 8A; *see also* Petition, 45 (acknowledging that *Jensen's* circuits are heat re-flowed together). With this process, *Jensen* secures its circuits 49, 50 to each other, providing additional space. Circuits that undergo this heat re-flowed process are not removable as the Petition contends. Ex. 2016, ¶[0080]; Petition, 24.

A POSA would have understood that heat reflow process is a form of permanent bond, like a weld. Ex. 2001, ¶[0081]. And rather, separating the circuits 49, 50 would damage (if not destroy) *Jensen's* device if the two welded-together circuits were separated. Ex. 2001, ¶[0081]. Thus, *Jensen's* device includes circuit 50 that could not be detached (and thus is not removable) from *Jensen's* other circuit 49. Ex. 2001, ¶¶[0081]-[0082]. Neither the Petition nor Dr. Heikenfeld explain how

the communication-computation module is "removable," given the permanent welded nature of this bond between the two circuits. Petition, 38.

In sum, the Petition's entire support for "removable" is a single conclusory statement with no explanation; no clear disclosure from the cited reference; and no expert support. The Petition compounds these issues by failing to address *Jensen's* disclosure of Figure 8, showing that the transmitter and microcontroller are welded, which is decidedly not "removable." For these reasons, the Petition fails to render obvious the "removable" communication-computation module.

2. The Petition Fails to Establish a Motivation to Combine *Jensen* and *Kroll*

The Petition fails to establish that a POSA would have been motivated to combine *Jensen* and *Kroll* based on either a desire to limit current or a desire to make *Jensen's* device smaller. *See* Petition, 17-19; Ex. 2016, ¶[0087]. First, a POSA would not have been motivated to incorporate *Kroll's* lead strips into *Jensen's* device to limit current because a POSA would have recognized that this would provide no benefit to *Jensen*. Ex. 2016, ¶[0088]. Indeed, this alleged argument ignores the fact that the only reason *Kroll* includes such resistors is because it is discharging electrical pulses ***into*** the wearer. This is not something possible in *Jensen* or contemplated in the proposed combination.

"Jensen's goal of reducing the size of the device" likewise fails to provide a motivation to otherwise modify *Jensen* to include the specifically claimed resistors. Petition, 18. *Jensen* already achieves its size goals with conventional resistors. Ex. 2016, ¶¶[0114]-[0115]. These cursory and alleged motivations are exactly the type that the Board regularly rejects as under-developed and not rooted in the references. *See, e.g.*, *TQ Delta, LLC v. CISCO Sys.*, Inc., 942 F.3d 1352, 1359 (Fed. Cir. 2019) ("Conclusory expert testimony does not qualify as substantial evidence.").

Accordingly, the Petition fails to establish a motivation to combine *Jensen* and *Kroll* and cannot render obvious any of the Challenged Claims in Ground 1.

a. A POSA would not have been motivated to combine *Jensen* and *Kroll* to limit the current

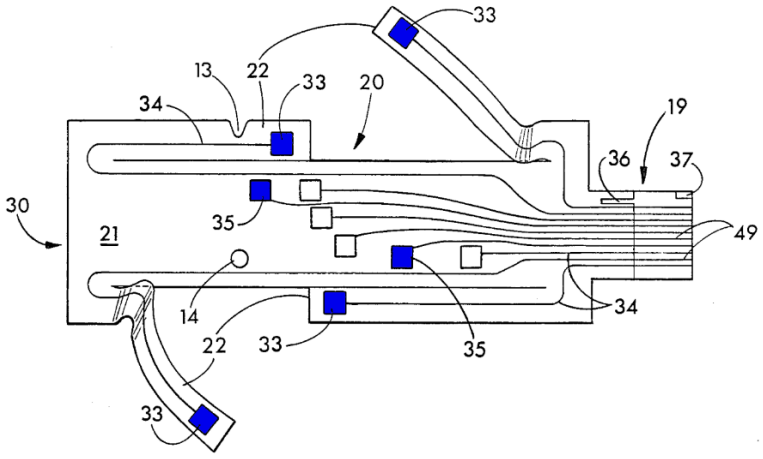
A POSA would not have been motivated to incorporate *Kroll's* lead strips into *Jensen's* device to limit the current between *Jensen's* device and the patient. *See* Petition, 17-18. *Jensen's* device only monitors the patient and does not transmit any current to the patient. Thus, there would be no motivation for a POSA to limit current (as there is none) from the device to the patient. Neither would a POSA be motivated to incorporate *Kroll's* lead strips into *Jensen's* device to limit current between the patient and the device to protect *Jensen's* electronics. Petition, 17-18. *Kroll's* lead strips are designed to protect the patient (*i.e.*, current from the device to

the patient), and a POSA would have understood that *Kroll's* lead strips would not protect *Jensen's* electronics.

i. A POSA would not have been motivated to limit the current from *Jensen's* device to the patient

Unlike *Kroll's* therapeutic device, *Jensen's* device only monitors ECG signals; it ***does not*** transmit current to the patient. Ex. 2016, ¶[0089]. Thus, contrary to the Petition's argument, a POSA would not have been motivated to limit the current (as there is none) from *Jensen's* device to the patient. Ex. 2016, ¶[0089]; *see* Petition, 17-18 (arguing that it would be beneficial to limit the current transmitted from *Jensen's* device to the patient to protect the patient from shock).

As introduced in Section IV.B, *Kroll* provides a disposable electrode belt "for receiving and transmitting electric current and voltage." Ex. 2016, ¶[0090]; Ex. 1013, 2:41-47. Figure 4 shows the electrodes (indicated in blue) of *Kroll's* disposable electrode belt. Ex. 2016, ¶[0090]; Ex. 1013, 4:48-68, Figure 4A (annotated). Each electrode "transmit[s] and receive[s] electric signals" over its respective lead strips. Ex. 2016, ¶[0090]; Ex. 1013, 5:1-4. "[T]o protect a patient from shock due to malfunction of the device 20 or of a complementary medical device," the lead strips may provide a "certain total lead strip resistance," thereby serving as a current limiter. Ex. 2016, ¶[0090]; Ex. 1013, 5:4-13.



Ex. 1013, Figure 4A (annotated); Ex. 2016, ¶[0090].

Because *Kroll* provides a therapeutic device that transmits electrical current to the patient, a POSA would have understood that lead strips may protect the patient from shock by limiting the current from the device to the patient. Ex. 2016, ¶[0091]; Petition, 17. This same understanding does not apply to *Jensen* because *Jensen* only monitors the patient. Ex. 2016, ¶[0092]. *Jensen* provides a patch that "sense[s] the heart-rate voltage differential across [its] sensors." Ex. 2016, ¶[0092]; Ex. 1011, Abstract. These signals are then amplified, converted to an output format, and transmitted to receiving equipment. Ex. 2016, ¶[0092]; Ex. 1011, Abstract; *see also* Ex. 1011, ¶[0054] (describing the advantages "for monitoring of heat-rate and other physiological and environmental data").

Jensen does not provide any disclosure on transmitting an electrical signal from its device to the patient. Ex. 2016, ¶[0093]; *see generally* Ex. 1011. Neither

does *Jensen* provide a reason to transmit electrical signals or disclose components that would allow such function. Ex. 2016, ¶[0093]; *see generally* Ex. 1011. Consistent with this disclosure, the Petition itself repeatedly characterizes *Jensen's* device as a "monitoring device." *See* Petition, 11, 17, 18.

Because *Jensen's* device only monitors the patient and does not transmit electrical signals to the patient, a POSA would not have been motivated to limit current from *Jensen's* device to the patient. Ex. 2016, ¶[0094]. For the same reason, a POSA would not have seen any benefit from the Petition's incorporation of *Kroll's* lead strips into *Jensen's* device. Ex. 2016, ¶¶[0094]-[0095]; *see* Petition, 36 (arguing that a POSA would have understood that limiting current from *Jensen's* device to the patient as "beneficial"). Therefore, the Petition fails to establish a motivation to combine *Jensen* and *Kroll* based on a desire to "protect the patient from shock due to electricity from the device." Petition, 17-18.

ii. *Kroll's* lead strips would not protect *Jensen's* electronics

A POSA would not have been motivated to incorporate *Kroll's* lead strips, which are designed "to ***protect a patient*** from shock," into *Jensen's* device to "protect sensitive electronics." Ex. 2016, ¶[096]; Petition, 17-18; Ex. 1013, 5:8-13. A POSA would have understood that the design of the resistors corresponds to the

function. Ex. 2016, ¶[0096]. And the Petition's confusing, layered citations do not outweigh the technical analysis of Dr. Anthony.

(a) *Kroll's* lead strips are designed to protect the patient, which align with *Kroll's* disclosure

Kroll's leads strips are designed "to ***protect a patient*** from shock" rather than "protect sensitive electronics." Ex. 2016, ¶[0097]; Petition, 17-18; Ex. 1013, 5:8-13. This disclosure, which the Petition identifies (Petition, 29-30), aligns with *Kroll's* consistent goal of patient safety. Ex. 2016, ¶[0097].

Kroll provides a therapeutic electrode belt "for receiving and transmitting electric current and voltage." Ex. 2016, ¶[0098]; Ex. 1013, 2:41-47. To safely administer such therapy, *Kroll's* device includes several features for patient protection. Ex. 2016, ¶[0098]. These features include *Kroll's* lead strips which "serve[] as a current limiter to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device." Ex. 2016, ¶[0098]; Ex. 1013, 5:8-13. Thus, these strips further *Kroll's* goal of patient safety.

Moreover, *Kroll's* device transmits current "to specific anatomical locations" of the patient. Ex. 2016, ¶[0099]; Ex. 1013, 1:27-36. This is important because, without delivering the shock to a precise location, the therapeutic effects would not be achieved and delivering a shock to an unintended location may injure the patient. Ex. 2016, ¶[0099]. To ensure delivery to the correct location, *Kroll* provides (1)

several electrodes, all of which can transmit and receive electrical signals, and (2) extendable side members 22. Ex. 2016, ¶[0100]; Ex. 1013, 4:37-47, 5:1-4. The side members extend from the electrode belt's main body for placement outside of the precordial region. Ex. 2016, ¶[0100]; Ex. 1013, 4:37-47, Figure 4A. Like *Kroll's* lead strips, the number, location, and adjustability of *Kroll's* electrodes all further its goal of ensuring patient safety during therapy. Ex. 2016, ¶[0100].

Finally, *Kroll* details the integrated layers of the belt, which include a "shielding layer" to prevent outside electrical interference, including "interference from the device 10 with other medical diagnostic and therapeutic devices." Ex. 2016, ¶[0101]; Ex. 1013, 6:17-24. In other embodiments, the belt may include more than one shielding layer "to further shield the device from interference." Ex. 2016, ¶[0101]; Ex. 1013, 6:17-24. These safety considerations are also shown in the design of the shielding layer itself. Namely, "[t]he shielding layer 46 is preferably recessed inwardly at its outer boundaries to minimize the risk of electrical shorting and patient shock in the event of device 10 failure." Ex. 2016, ¶[0101]; Ex. 1013, 7:3-13. Reading this disclosure, a POSA would have understood that *Kroll*, as a therapeutic device designed to shock a patient, is concerned with patient safety. Ex. 2016, ¶[0101]. *Jensen's* device only monitors ECG signals and does not have these same safety concerns as in *Kroll*. Ex. 2016, ¶[0101].

(b) The Petition fails to establish that *Kroll's* lead strips would protect *Jensen's* electronics

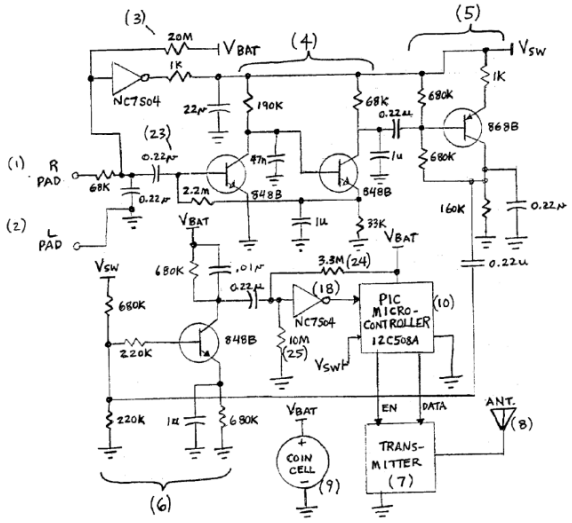
To the extent that *Kroll's* lead strips are used in *Jensen's* device, the Petition fails to establish that *Kroll's* lead strips would protect *Jensen's* electronics. Ex. 2016, ¶¶[0102]-[0113]. The Petition highlights this failure, stating that the combination would use "the resistive leads strips of Kroll…instead of conventional resistors on Jensen's circuit assembly." Petition, 18. This would do nothing to protect *Jensen's* electronics. Ex. 2016, ¶¶[0102]-[0103].

As the Petition identifies, *Jensen's* electronics circuit provides several resistors, including gain setting resistors, feedback resistors, and resistors for signal biasing. Ex. 2016, ¶¶[0105]-[0109], [0112]; Ex. 1011, ¶¶[0032], [0036], [0049]. Replacing *Jensen's* "conventional" resistors with *Kroll's* lead strips formed with ink deposits does ***nothing*** to change the function of these resistors. Ex. 2016, ¶¶[0105]-[0109]. In other words, the gain setting resistor would still have the same resistance, with the same placement on the circuit, and still functioning as a gain setting resistor. Ex. 2016, ¶[0106]. The same is true for both the feedback resistors and the resistors for signal biasing. Ex. 2016, ¶[0106]. Here, the Petition and Dr. Heikenfeld conflate a resistor's ***form*** with its ***function***. Ex. 2016, ¶[0106].

Moreover, the Petition's own arguments highlight this issue. The Petition contends that *Kroll's* lead strips would protect *Jensen's* electronics simply because

resistors limit current flow in both directions. Petition, 29-30; *see* Ex. 1009, ¶277. Applying this same blanket conclusion—that does not consider a single variable of the resistors—*Jensen's* conventional resistors, as resistors, limit current flow in both directions and thus would protect *Jensen's* electronics. Ex. 2016, ¶[0110]. But they do not. Ex. 2016, ¶[0110]. *Jensen's* resistors are specifically designed as part of the electronics circuit to correspond to their function. Ex. 2016, ¶[0110].

Jensen provides example embodiments of its electronics circuit. Ex. 2016, ¶[0111]; Ex. 1011, ¶[0036]. Figure 2 includes resistors 24, 25 for signal biasing while resistors 20, 21 in Figure 3 function as gain setting resistors. Ex. 2016, ¶[0111], Ex. 1011, ¶¶[0032], [0036], Figure 2, Figure 3. A POSA would have readily understood that these resistors are specifically designed and located on *Jensen's* electronics circuit to achieve their function. Ex. 2016, ¶[0111].



Ex. 1011, Figure 2.

The Petition does not explain how *Kroll's* lead strips would protect *Jensen's* electronics. Instead, the Petition grossly oversimplifies its combination, overlooking how a POSA would have understood the design and use of resistors in an electronics circuit. Ex. 2016, ¶[0113]. In sum, the Petition fails to establish that *Kroll's* lead strips would protect *Jensen's* electronics and thus a POSA would not have been motivated to combine *Kroll* and *Jensen* as the Petition contends.

(c) The Petition does not address any technical obstacles in designing a resistor that would function to protect *Jensen's* electronics

Solely relying on the bi-directional nature of resistors, the Petition fails to consider any design variables that would affect whether *Kroll's* leads strips would protect *Jensen's* electronics. *Kroll's* lead strips are designed "to ***protect a patient*** from shock" while administering therapy via the electrode belt. Ex. 2016, ¶[0096]; Petition, 17-18; Ex. 1013, 5:8-13. In contrast, *Jensen* provides "a totally self-contained sensor that is thin, being less than 6 or 7 mm in thickness, [and] low in mass." Ex. 2016, ¶[0049]; Ex. 1011, ¶[0030]. Based on this difference, a POSA would have recognized many design hurdles that must be overcome to implement *Kroll's* lead strips in *Jensen's* device to protect the electronics.

Neither the Petition nor Dr. Heikenfeld address any of the design variables below, which are critical to the function of the resistor. Ex. 2016, ¶[0125].

First, a POSA would have to select a resistive material for the trace while also considering the specific resistivity requirements to achieve reliable signal transmission and safety. Ex. 2016, ¶[0126].

Second, a POSA would have to determine the structure of the trace, including the layered or overlapping structure and the length to precisely achieve the necessary resistance while considering the various materials. Ex. 2016, ¶[0127].

Third, a POSA would need to balance the size and resistance of the trace, which is relevant to minimizing noise, safely discharging power during high-voltage events, and compensating for variations in trace resistance following potential high-voltage occurrences. Ex. 2016, ¶[0128]. This analysis requires an understanding of detailed aspects related to transient response, resistance change and variability, and safety margins. Ex. 2016, ¶[0128].

Fourth, a POSA would have to design contact pads to reduce arching. Ex. 2016, ¶[0129]. This design and solution is crucial when implementing resistors in small devices, as the Petition attempts to do so here. Ex. 2016, ¶[0129].

Fifth, a POSA would have to manage the space between traces to minimize arcing potential. Ex. 2016, ¶[0130]. Again, a POSA would recognize this as a key consideration in implementing traces on a small device. Ex. 2016, ¶[0130]. Further,

a POSA would have to develop insulative dielectric coating methods to reduce spacing requirements significantly. Ex. 2016, ¶[0130].

Sixth, a POSA would have recognized the complexity of validating the design through simulations and experimental verification. Such process underscores the unpredictable experimentation required. Ex. 2016, ¶[0131].

The only evidence of record is from Dr. Anthony, who concludes that the ability to address these considerations requires expert knowledge spanning across multiple disciplines—far beyond a POSA's capabilities. Ex. 2016, ¶[0132]. Without addressing these issues, the Petition fails to establish that *Kroll's* lead strips would function to protect *Jensen's* electronics, even if the combination was made.

(d) The Petition's nested citations fail to overcome Dr. Anthony's analysis

The Petition's nested citations do not outweigh Dr. Anthony's analysis. To conclude that *Kroll's* lead strips would protect the electronics, the Petition cites Dr. Heikenfeld. *See* Petition, 35-36 (citing Ex. 1009, ¶¶211-214). But Dr. Heikenfeld repeats the same conclusion, stating that resistive materials "would function to limit current in either direction…and thus would protect both the patient and the device." Ex. 1009, ¶211 (citing Section IV.F). Turning to Dr. Heikenfeld's citation, he concludes that "***any approach*** to limiting current using resistive material to protect

the patient from shock would also protect the body-worn device from excess electrical current." Ex. 1009, ¶47 (citing Ex. 1043 at 816-17).

In other words, at the center of the Petition's layered citations is the position that *Kroll's* traces would protect *Jensen's* electronics because resistors limit flow in both directions. *See* Ex. 1009, ¶¶47 (citing Ex. 1043 at 816-17), 211-214. As Dr. Anthony's analysis makes clear, resistors are designed corresponding to their function. Ex. 2016, ¶[0103]. But Dr. Heikenfeld is wrong; it is not the case that "any resistor…would protect the body-worn device from excess electrical current." Ex. 2016, ¶[0103]; Ex. 1009, ¶47. This issue is worsened by Dr. Heikenfeld's citation to Exhibit 1043, which is a 2019 reference that published ***thirteen years*** after the priority date of the '007 Patent. *See* Ex. 1009, ¶47 (citing Ex. 1043 at 816–17).

In view of Dr. Anthony's proper analysis and the Petition's unsupported conclusions, a POSA would not have been motivated to incorporate *Kroll's* patient-protective resistors to protect the electronics in *Jensen's* device. Ex. 2016, ¶[0125].

b. A POSA would not have been motivated to combine *Jensen* and *Kroll* to address size concerns

A POSA would not have been motivated to replace *Jensen's* conventional resistors with *Kroll's* lead strips based on size concerns. *See* Petition, 18. First, *Jensen* already achieves its desired size, and the Petition does not identify any disclosure that the size of *Jensen's* device is an issue or that *Jensen* intends to further

limit the size. Ex. 2016, ¶¶[0114]-[0115]; *see* Section VI.A.ii.b.i. Second, *Kroll* provides a therapeutic device that wraps around the patient's body; a POSA would not have looked to this device, let alone combined it with *Jensen*, to make *Jensen's* device smaller. Ex. 2016, ¶[0115]; *see* Section VI.A.ii.b.ii.

i. *Jensen's* design already addresses its size concerns with conventional resistors

A POSA would not have been motivated to replace *Jensen's* conventional resistors to reduce the size of *Jensen's* device because *Jensen* already achieves this goal. Ex. 2016, ¶[0116]; *see* Petition, 18. *Jensen's* "novelty include[s] its physical construction." Ex. 2016, ¶[0116]; Ex. 1011, ¶[0030]. As the Petition acknowledges, *Jensen* provides "a totally self-contained sensor that is thin, being less than 6 or 7 mm in thickness, [and] low in mass." Ex. 2016, ¶[0116]; Ex. 1011, ¶[0030]. *Jensen* already achieves its goals concerning its physical dimensions with several conventional resistors, including gain setting resistors, feedback resistors, resistors for signal biasing. Ex. 2016, ¶[0116]; Ex. 1011, ¶¶[0032], [0036], [0049].

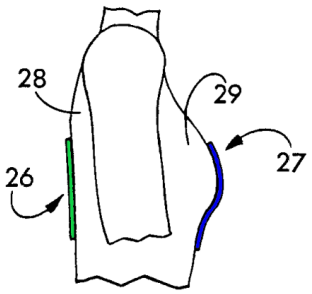
Neither the Petition nor Dr. Heikenfeld provide a single citation to establish that the size of *Jensen's* device is an issue, or that *Jensen* intends to further limit the size of its device. Ex. 2016, ¶[0117]. This is because *Jensen* achieves its desired physical dimensions. Ex. 2016, ¶[0116]; Ex. 1011, ¶[0030]. The Petition manufactures *Jensen's* need for a smaller device as a motivation to replace *Jensen's*

conventional resistors with *Kroll's* lead strips. This shows that the Petition uses Claim 1 of the '007 Patent as a roadmap to create its combination. A POSA would not have been motivated to replace *Jensen's* resistors with *Kroll's* lead strips to further a goal that *Jensen* already achieves. Ex. 2016, ¶[0118].

ii. *Kroll's* device wraps around a patient, confirming the Petition's hindsight approach

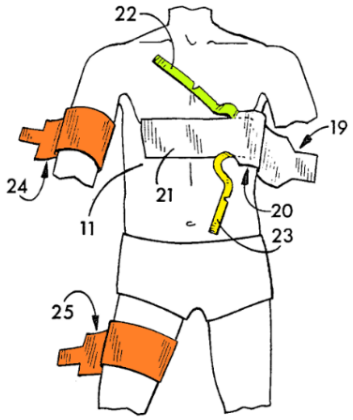
Kroll provides a device that wraps around the patient's body to administer therapeutic shocks. Ex. 2016, ¶[0120]. The Petition ignores this disclosure to argue that a POSA, motivated to make *Jensen's* device smaller, would look to *Kroll's* much larger device. *See* Petition, 36; Ex. 2016, ¶[0119].

Specifically, *Kroll* provides an "electrode belt…for receiving and transmitting electric current or voltage for use on the body of a patient." Ex. 2016, ¶[0121]; Ex. 1013, Abstract, Figure 1. Such electrical current may be transmitted "to specific anatomical locations for therapeutic purposes." Ex. 2016, ¶[0120]; Ex. 1013, 1:27-36. In one example, *Kroll's* electrode belt is placed on the patient's chest and back. Ex. 2016, ¶[0121]; Ex. 1013, 4:44-47, Figure 3 (indicating the chest portion of the belt in blue and the back portion of the belt in green). With this placement, electrical current can be transmitted through the chest to the back to target specific areas for therapeutic purposes. Ex. 2016, ¶[0121]; Ex. 1013, 4:44-47, Figure 3.



Ex. 1013, Figure 3 (annotated); Ex. 2016, ¶[0121].

In another embodiment, the electrode belt includes extendable side members that extend from the electrode belt's main body for placement outside of the precordial region. Ex. 2016, ¶[0122]; Ex. 1013, 4:37-47, Figure 2 (indicating the side members in yellow). *Kroll's* electrode belt may also be placed around the patient's limbs. Ex. 2016, ¶[0122]; Ex. 1013, 4:37-47, Figure 2 (indicating the embodiments placed around the limbs in orange).



Ex. 1013, Figure 3 (annotated); Ex. 2016, ¶[0122].

Contrary to the Petition arguments, a POSA would not have looked to any embodiments of *Kroll's* therapeutic electrode belt to "reduce the overall size of

Jensen's monitoring device." Ex. 2016, ¶[0123]; Petition, 18. This is especially true for *Kroll's* lead strips. Ex. 2016, ¶[0123]; *see* Petition, 18 (arguing that a POSA would use *Kroll's* lead strips to reduce the size of *Jensen's* device). *Kroll's* lead strips are used on the "extendable side members," which are specifically designed to make the electrode belt ***larger***. Ex. 2016, ¶[0123]; Ex. 1013, 4:37-47. The extendable side members are used for placement outside of the precordial region. Ex. 2016, ¶[0123]; Ex. 1013, 4:37-47. Based on this disclosure, a POSA would not have been motivated to make *Jensen* smaller by replacing *Jensen's* resistors with *Kroll's* traces. Ex. 2016, ¶[0124].

B. Grounds 2 to 4 Fail to Render Obvious the Challenged Claims

Grounds 2 to 4 simply challenge certain dependent claims using the base of Ground 1 and fail to provide any independent argument for the independent Claims addressed with respect to Ground 1.[5] The entirety of each of Grounds 2 to 4 should be similarly rejected.

[5] Ground 2 challenges Claims 32 to 35; Ground 3 challenges Claims 2 and 3; and Ground 4 challenges Claim 39. Petition, 1-2. Each of Claims 2, 3, 32-35, and 39 depend from independent Claim 1. *See* Ex. 1001, Cls. 1-39.

VII. CONCLUSION

As each of the Grounds fail, the Petition should be denied.

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Respectfully submitted,

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Certification of Word Count Under 37 C.F.R. § 42.24(d)

The undersigned hereby certifies that the foregoing contains 11,062 words according to the word count of the word-processing software used to prepare the foregoing and accounting for the words in the figures as required by the Trial Practice Guide.

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