

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IRHYTHM, INC.,

Petitioner,

v.

WELCH ALLYN, INC.,

Patent Owner.

CASE: IPR2025-01081

U.S. PATENT NO. 8,630,699

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 <i>Bardy Diagnostics, Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-01355, indicating Petitioner iRhythm's intent to assert additional patents.
2005	Scheduling order in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224
2006	Notice of Service of Party Discovery in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224 (ECF 26)
2007	Notice of Service of Party Discovery in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224 (ECF 27)
2008	Notice of Service of Third-Party Discovery in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224 (ECF 41)
2009	Notice of Service of Third-Party Discovery Responses in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 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 <i>Welch Allyn Inc. v. iRhythm Technologies Inc.</i> , 1:24-cv-00224 (ECF 48)

Exhibit No.	Description
2012	[Reserved]
2013	[Reserved]
2014	[Reserved]
2015	[Reserved]
2016	[Reserved]
2017	[Reserved]
2018	iRhythm's Third Amended Answer alleging infringement against PO's related company, Bardy Diagnostics
2019	Notice of Service of Party Discovery in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224 (ECF 58)
2020	Notice of Service of Party Discovery in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224 (ECF 61)
2021	Notice of Service of Party Discovery in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224 (ECF 63)
2022	Third-Party Discovery Request in <i>Welch Allyn Inc. v. iRhythm Technologies, Inc.</i> , 1:24-cv-00224
2023	Declaration of Dr. Brian Anthony for IPR2025-01081 of U.S. Patent No. 8,630,699
2024	<i>Curriculum Vitae</i> of Dr. Brian Anthony, Ph.D.
2025	Director's July 31, 2025 Memorandum

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 1-4 and 8 (the “Challenged Claims”) of U.S. Patent No. 8,630,699 (the “’699 Patent”) (Ex. 1001).

I. INTRODUCTION

The ’699 Patent claims a novel body-worn patient monitoring device that measures physiological signals and includes high voltage circuit protection. Ex. 1001, Abstract, Cl. 1; Ex. 2023, ¶[0045]. The ’699 Patent details the design and function of resistive traces that protect the patient monitor from multiple defibrillation cycles. Ex. 1001, 7:46-57; Ex. 2023, ¶¶[0046]-[0047]. Such design ensures that the patient monitor remains functional even after one or more attempts to restart a patient’s heart. Ex. 1001, 7:46-57; Ex. 2023, ¶[0048].

In challenging the ’699 Patent, the Petition does not identify a single reference that teaches an ECG monitor with a defibrillation protection resistor. With the benefit of hindsight, the Petition attempts to reconstruct the novel features of the ’699 Patent while relying on a reference that uses “lead strips,” but these lead strips are specifically designed to protect the patient and do not provide defibrillation protection as the ’699 Patent requires. Ex. 1001, Cl. 1.

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) (emphasis added).¹ The “General Knowledge”—which is used in every Ground—is neither a patent nor printed publication. Thus, 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.*, “current-limiting defibrillation protection resistor”) 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.

In addition to these procedural failures, the Petition fails on the technical merits.

¹ Unless otherwise indicated, all emphasis is added herein.

In Ground 1, the Petition relies on the combination of *Jensen*,² *Kroll*,³ and the alleged “General Knowledge” of a POSA. *See* Petition, 1. Ground 1 fails for two reasons. First, Ground 1 does not render obvious a current-limiting defibrillation protection resistor as required by the sole independent claim. Ex. 1001, Cl. 1. Second, the Petition does not establish a motivation to combine *Jensen* and *Kroll*.

Ground 3, which relies on the *Matsumura*,⁴ *Kroll*, and “General Knowledge,” also fails. For the same reasons as in Ground 1, Ground 3 does not render obvious a current-limiting defibrillation protection resistor. Moreover, Ground 3 does not render obvious a power source as recited by independent Claims 1. Finally, a POSA would not have been motivated to combine *Matsumura* and *Kroll*. As such, the Petition does not have a reasonable likelihood of prevailing.⁵

² U.S. Patent Publication No. 2003/0149349 to *Jensen* et al. (Ex. 1011).

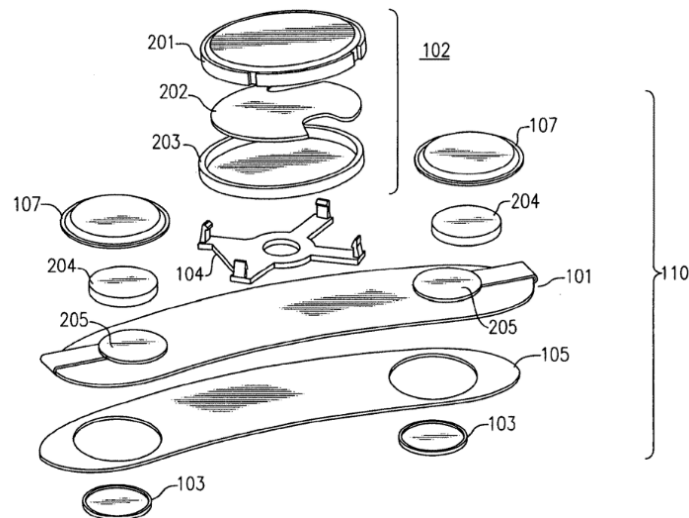
³ U.S. Patent No. 4,763,660 to *Kroll* et al. (Ex. 1014).

⁴ Purported Translation of Japanese Pat. Pub. JP2004/121360 to *Matsumura* (Ex. 1012).

⁵ Remaining Grounds 2, 4, and 5 only challenge dependent claims and therefore fail for the same reasons.

II. SUMMARY OF THE '699 PATENT

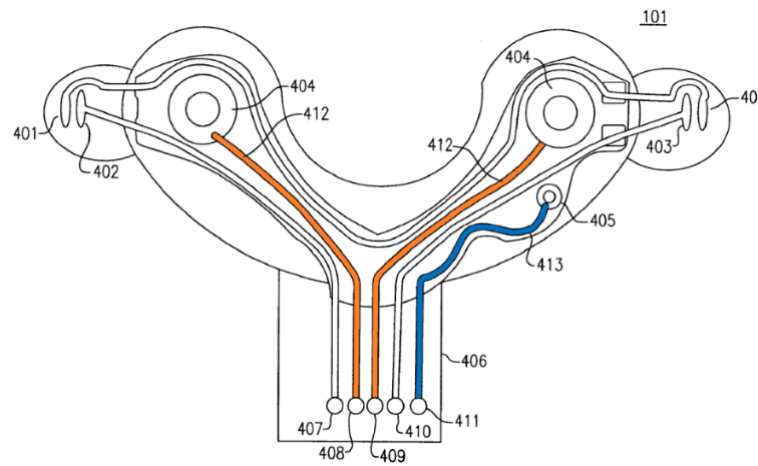
The '699 Patent provides a body-worn patient monitor that measures physiological signals and includes high voltage circuit protection. Ex. 1001, Abstract, Cl. 1; Ex. 2023, ¶[0045]. As shown in Figure 2, the computation-communication module 102 of the patient monitor attaches to disposable electrode module 110. Ex. 1001, 4:45-67, Figure 2; Ex. 2023, ¶[0045].



Ex. 1001, Figure 2.

The disposable electrode module includes flexible printed circuit layer 101, which transmits electrical signals from an electrode to a connection pad over traces. Ex. 1001, 5:1-14, 7:33-45; Ex. 2023, ¶[0046]. The traces 412 (orange in the annotated figure below) are preferably printed and “extend[] between conductive surface 404 and connection pads 408 and 409.” Ex. 1001, Figure 4A, 7:33-45 (defining the conductive surface as part of the electrode); Ex. 2023, ¶[0046].

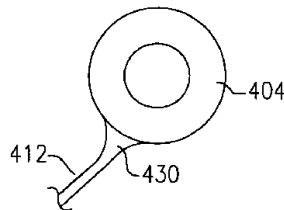
Similarly, the trace 413 (blue), “extend[s] between conductive surface 405 and connection pad 411.” Ex. 1001, Figure 4A, 7:33-45; Ex. 2023, ¶[0046]. The traces are made from a material with a resistance is in the desirable range of “about 1 kilo ohm to about 10 kilo ohms.” Ex. 1001, 7:33-45, 7:58-61.



Ex. 1001, Figure 4A (annotated); Ex. 2023, ¶[0046].

Based on the resistance and design, the traces provide high voltage circuit protection for the patient monitor. Ex. 1001, Abstract; Ex. 2023, ¶[0047]. For example, if the patient requires defibrillation, the resistors serve to protect the electronics from defibrillation cycles. Ex. 1001, 7:46-57; Ex. 2023, ¶[0047]. Moreover, the resistive traces can withstand multiple defibrillation cycles, ensuring that the body worn monitor remains functional even after more than one attempt to restart a patient’s heart. Ex. 1001, 7:46-57; Ex. 2023, ¶¶[0047]-[0048].

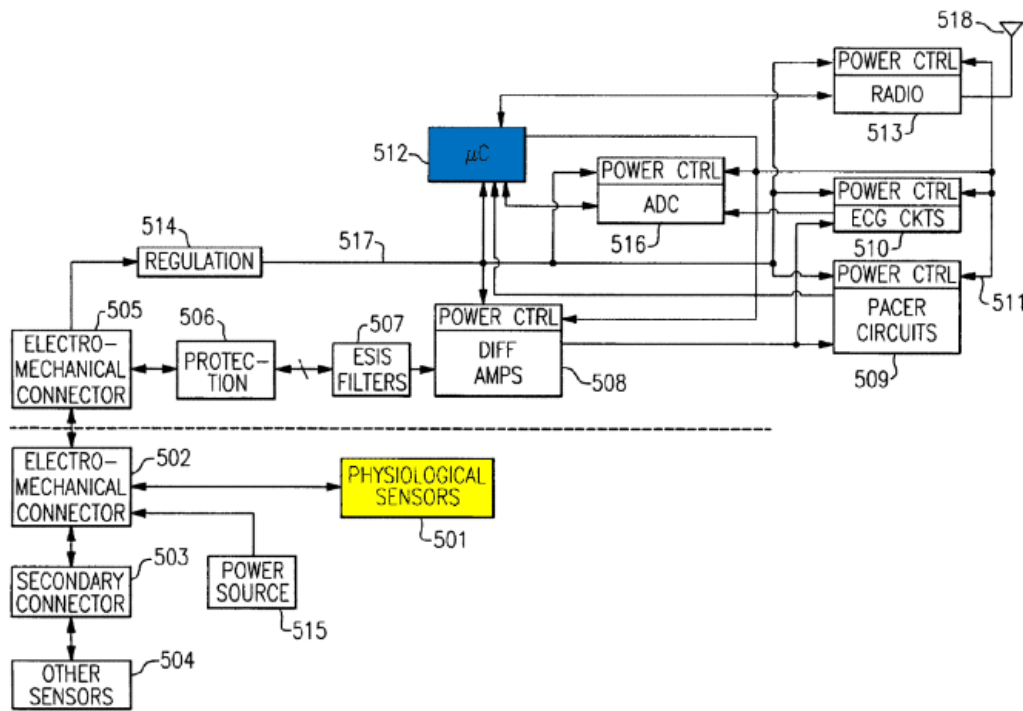
The resistive traces protect the patient monitor from defibrillation by dissipating the damaging, high voltage defibrillation energy that enters through the electrodes. Ex. 1001, 7:46-57; Ex. 2023, ¶[0048]. The '699 Patent extensively details the design options, materials, and obstacles that were overcome to provide such protection. Ex. 1001, 7:46-11:17; Ex. 2023, ¶[0048]. In one example, carbon resistive traces could be used, but they presented arcing issues at the interface between the carbon trace and the conductive surface. Ex. 1001, 8:10-55; Ex. 2023, ¶[0048]. As shown in Figure 4B, fillet shape 430 helped relieve electrical stress at the interface. Ex. 1001, 8:49-55, Figure 4B, Cl. 3; Ex. 2023, ¶[0048].



Ex. 1001, Figure 4B.

Additionally, the pathway provided by these resistive traces is shown in the block diagram of Figure 5. Ex. 1001, 11:18-19, Figure 5. There, the physiological sensors (*e.g.*, electrodes) for capturing an ECG difference potential are indicated in yellow. Ex. 1001, 11:18-22, Figure 5 (annotated); Ex. 2023, ¶[0049]. 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, 11:18-35, Figure 5 (annotated), Figure 4A; Ex. 2023, ¶[0049]. The computation-communication module includes a housing that contains this processor. Ex. 1001, Figure 2; Ex. 2023, ¶[0049].



Ex. 1001, Figure 5 (annotated); Ex. 2023, ¶[0049].

III. ORIGINAL PROSECUTION OF THE '699 PATENT

The '699 Patent was filed as U.S. Patent Application No. 13/488,520 and claims priority to Application No. 11/591,619, filed on November 1, 2006. Ex. 1001, Cover. During prosecution, the Applicant distinguished the claims and explained that the present invention relates to an ECG monitor. Ex. 1002, 580-83.

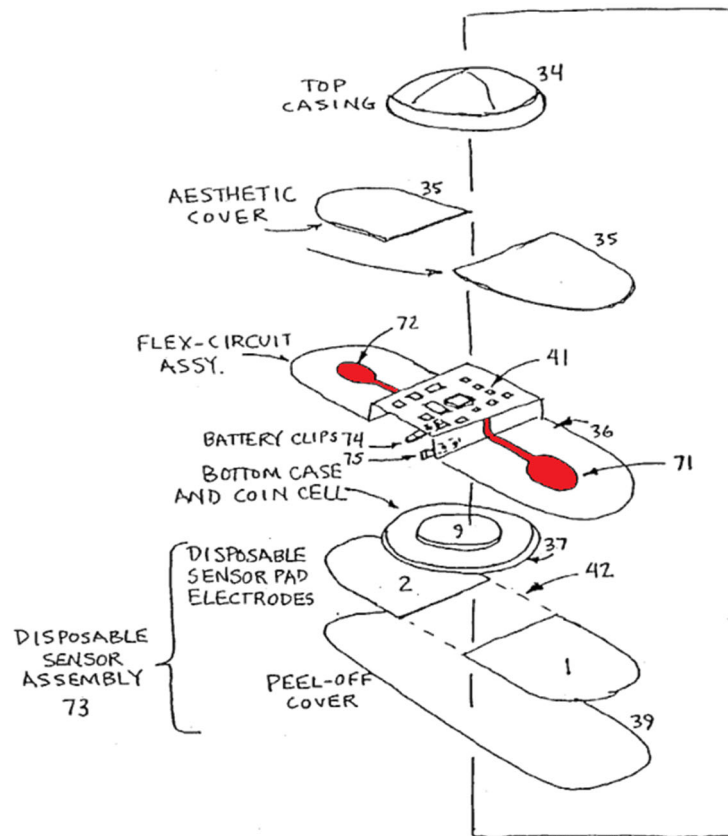
The cited art, on the other hand, “relate[d] to an electrocautery device used for promoting the flow of blood through vessels or to connective tissue of a patient.” Ex. 1002, 580. In response, the Examiner agreed with the Applicant and issued a Notice of Allowance. Ex. 1002, 572, 593-94.

IV. OVERVIEW OF THE ART

A. Overview of *Jensen*

Jensen provides a cardiac monitor that adheres to a patient’s skin. Ex. 1005, Abstract; Ex. 2023, ¶[0050]. *Jensen*’s “novelty include[s] its physical construction and method of use.” Ex. 1005, ¶[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. 2023, ¶[0050]; Ex. 1005, ¶[0030].

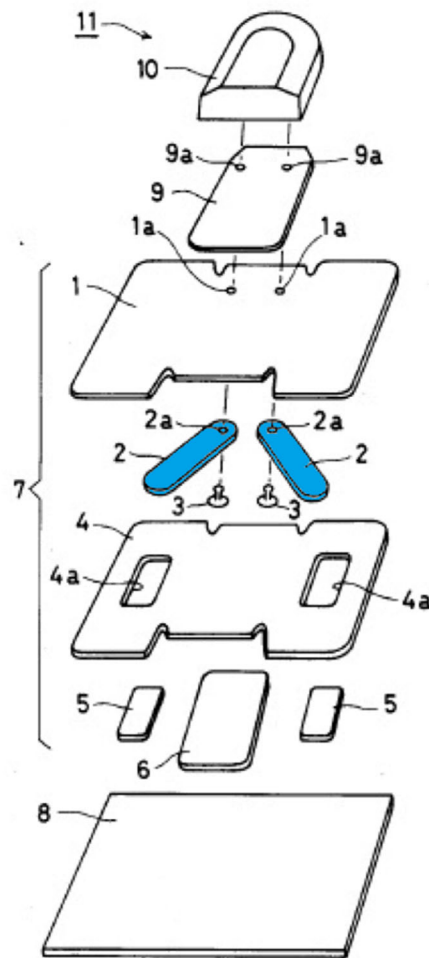
As part of the self-contained sensor, *Jensen* provides disposable sensor assembly 73, which includes cover 39, connective material 42, and pads 1 and 2. Ex. 1005, ¶[0042], Figure 5. *Jensen* also describes non-disposable flexible circuit assembly 36 having “traces” (annotated in red below). Ex. 1005, ¶[0040], Figure 5; Ex. 2023, ¶[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. 1005, ¶[0040], Figure 5; Ex. 2023, ¶[0051]. This way, the signal is transmitted to electronics circuit 41. Ex. 2023, ¶[0051].



Ex. 1005, Figure 5 (annotated); Ex. 2023, ¶[0051].

The electronics circuit includes a microcontroller and a transmitter. Ex. 1005, ¶[0032]; Ex. 2023, ¶[0052]. After receiving the signals, the electronics circuit processes the signals through various steps for amplification, filtering, and data extraction. Ex. 1005, ¶[0032]; Ex. 2023, ¶[0052]. The processed signal can either (1) be directly input into the transmitter or (2) be input into the microcontroller for further analysis and encoding. Ex. 1005, ¶[0032]; Ex. 2023, ¶[0052]. The electronics circuit also includes various resistors for signal biasing and gain setting.

conductive material 2 (blue), hooks 3, second sheet 4, conductive gels 5, and double-sided adhesive tape 9. Ex. 1006, ¶[0016]. Conductive material 2 creates a conductive path between conductive gel 5 and hooks 3 and hooks 3 provide a conductive path upwards through first sheet 1 and double-sided adhesive tape 9 to processor 10. Ex. 1006, ¶[0019]; Ex. 2023, ¶[0053].



Ex. 1006, Figure 1 (annotated); Ex. 2023, ¶[0053].

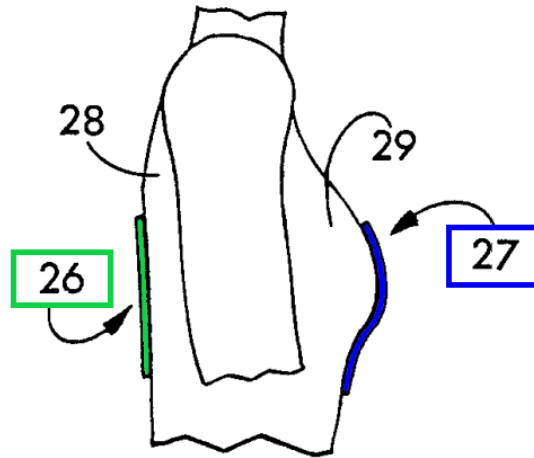
Matsumura explains “two pieces of conductive material 2 and two hooks 3 are arranged to transmit the bioelectric potential detected by the conductive gel 5, which is placed in the openings 4a of the second sheet 4.” Ex. 1006, ¶[0019]. Conductive material 2 is rod-shaped with one end that contacts conductive gel 5 and the other end that “has two holes 2a through which the protruding portions of hook 3 are inserted.” Ex. 1006, ¶[0019]. This configuration allows the “the bioelectric potential detected by the conductive gel 5 [to be] transmitted through the conductive material 2 and the hooks 3.” Ex. 1006, ¶[0019]; Ex. 2023, ¶[0054].

Hooks 3 play a vital electrical and mechanical role in preserving the device’s electrical and structural integrity by securely, but releasably, attaching disposable pad 7 to signal processor 10, while also transmitting bioelectric potential signals received from conductive material 2 to the signal processor for processing. Ex. 1006, ¶[0019]; Ex. 2023, ¶[0055].

C. Overview of *Kroll*

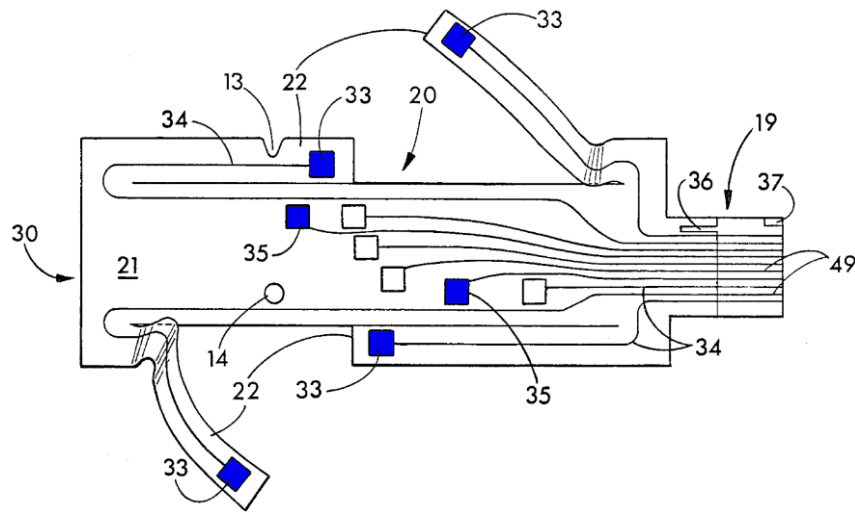
Kroll provides a disposable electrode belt, which is a therapeutic device “for receiving and transmitting electric current and voltage.” Ex. 2023, ¶[0056]; Ex. 1007, 2:41-47. To achieve its therapeutic effect, *Kroll*’s disposable electrode belt transmits current “to specific anatomical locations” of the patient. Ex. 2023, ¶[0056]; Ex. 1007, 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. 2023, ¶[0057]; Ex. 1007, 4:44-47, Figure 3 (indicating the chest portion of the belt in blue and the back portion of the belt in green).



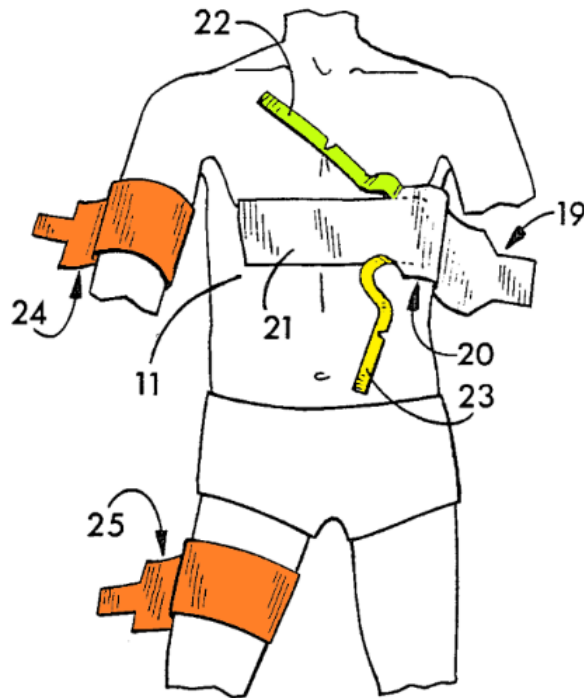
Ex. 1007, Figure 3 (annotated); Ex. 2023, ¶[0057].

Figure 4 shows the electrodes (blue) of *Kroll's* disposable electrode belt. Ex. 2023, ¶[0058]; Ex. 1007, 4:48-68, Figure 4A (annotated). Each electrode “transmit[s] and receive[s] electric signals” over lead strip 34. Ex. 2023, ¶[0058]; Ex. 1007, 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. 2023, ¶[0058]; Ex. 1007, 5:4-13. Other than protecting the patient, the lead strips do not provide any additional function. Ex. 2023, ¶[0058].



Ex. 1007, Figure 4A (annotated); Ex. 2023, ¶[0058].

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. 2023, ¶[0059]; Ex. 1007, 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. 2023, ¶[0059]; Ex. 1007, 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. 2023, ¶[0059].



Ex. 1007, Figure 3 (annotated); Ex. 2023, ¶[0059].

In addition to the extendable side members, *Kroll's* electrode belt relies on a “shielding layer” to safely administer therapeutic shocks. Ex. 2023, ¶[0060]; Ex. 1007, 6:17-24. This shielding layer prevents “interference from the device 10 with other medical diagnostic and therapeutic devices.” Ex. 2023, ¶[0060]; Ex. 1007, 6:17-24. The electrode belt may include more than one shielding layer “to further shield the device from interference.” Ex. 2023, ¶[0060]; Ex. 1007, 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. 2023, ¶[0060]; Ex. 1007, 7:3-13.

V. “GENERAL KNOWLEDGE” AND CLAIM CONSTRUCTION

A. The Petition Fails to Comply with 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 5. 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 5, relies on “Jensen, Kroll, 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, 21 (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: <u>Applicants Admitted Prior Art (AAPA)</u> in view of Majcherczak
Ground 2b	7	§103: <u>AAPA in view of Majcherczak and Matthews</u>

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 5.

Proposed Grounds of Unpatentability	
<u>Ground 1</u>	Claims 1-4 are obvious under pre-AIA § 103 over Jensen, Kroll, and <u>General Knowledge of a POSA</u>
<u>Ground 2</u>	Claim 8 is obvious under pre-AIA § 103 over Jensen, Kroll, Thompson, and <u>General Knowledge of a POSA</u>
<u>Ground 3</u>	Claims 1, 2, 4 are obvious under pre-AIA § 103 over Matsumura, Kroll, and <u>General Knowledge of a POSA</u>
<u>Ground 4</u>	Claim 3 is obvious under pre-AIA § 103 over Matsumura, Kroll, Khandpur, and <u>of a POSA</u>
<u>Ground 5</u>	Claim 8 is obvious under pre-AIA § 103 over Matsumura, Kroll, Thompson, and <u>General Knowledge of a POSA</u>

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.

The Director’s recent guidance confirms this conclusion. In a memorandum issued July 31, 2025, the Director states, “a petition for inter partes review (IPR) ‘must specify where each element of the claim is found in the prior art patents or printed publications relied upon.’” Ex. 2025, 1 (citing 37 C.F.R. § 42.104(b)(4)). Accordingly, “applicant admitted prior art (AAPA), expert testimony, common sense, and other evidence that is not ‘prior art consisting of patents or printed publications’ (collectively, ‘general knowledge’) may not be used to supply a missing claim limitation.” Ex. 2025, 1 (citing Rule 104(b)(4)).

In view of Federal Circuit law, a plain reading of § 311(b), and the Director’s recent guidance, 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. Egregiously, the Petition fails to articulate its construction, why such a construction is necessary, or properly apply any such construction, consistently throughout the Petition. 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.⁶

⁶ The Petition's reliance on non-prior art documents is also covered in Patent Owner's Argument for Discretionary Denial but is equally applicable as to the merits of the Petition analyzed here. *See* Paper 6 at 12-17.

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

Under 37 C.F.R. § 42.104(b)(3), Petitioner has an affirmative burden to articulate how the challenged claims should be construed so the parties and the Board have a clear understanding of the scope of the challenge. *See, e.g., Orthopediatrics Corp. v. K2M, Inc.*, IPR2018-01548, Paper 9 at 10 (P.T.A.B. Mar. 1, 2019).

Where the Petitioner sets forth arguments or observations of the meaning or interpretation of a claim term, 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 v. 511 Innovations, Inc.*, No. IPR2016-01792, 2017 WL 1052498 (P.T.A.B. Mar. 16, 2017) (denying institution) (“[U]nder the circumstances discussed above, including that the parties disagree over whether the prior art discloses or suggests the claimed ‘minimal height,’ 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.”).

The Petition violates this rule because: (a) a facial examination of Petitioner’s expert declaration shows that Petitioner is attempting to implicitly construe claims without providing any actual claim construction analysis; and (b) there is no claim

construction analysis, Petitioner shifts the burden to the Patent Owner and the Board to identify and construe relevant claim terms.

a. The Petition implicitly construes claim terms

The Petition’s entire discussion of claim construction is: “Claims are interpreted according to their ordinary and customary meaning as understood from the perspective of a person of ordinary skill in the art (“POSA”).” Petition, 2. The expert declaration provides no further analysis: “For purposes of this Petition, the Challenged Claims are interpreted according to their plain and ordinary meaning.” Ex. 1003, ¶50. However, throughout the Petition, there are multiple elements that are implicitly construed through a reliance on Petitioner’s expert declaration in an effort to force the Petition’s “art” to meet the claims.

For example, at least two claim elements, found in the sole independent claim of the ’699 Patent, have these implicit claim constructions, found only in the declaration. These deficiencies infect the entire Petition.

Claim Element + Term	Petition	Expert Declaration
Claim 1(d), 1(g): “current-limiting defibrillation protection resistor”	Pet., 24-27, 30-32	Ex. 1009, ¶¶135-145, 156-162, 222-228, 237-243

Petitioner purports to apply the ordinary and customary meaning of the terms (*see* Petition, 2); however, the Petition includes implicit claim constructions that lack

support or explanation. *See ams AG*, IPR2016-01792, Paper 15 at 8, 13 (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.

b. The Petition’s implicit construction negatively impacts the merit of its challenges

As an example of the Petition’s failings, independent Claim 1 of the ’699 Patent expressly requires “at least one current-limiting defibrillation protection resistor.” Ex. 1001, Cl. 1. The Petition improperly construes the claim term “current-limiting defibrillation protection resistor” because it provides no evidence, support, or argument that “show[] a reasonable likelihood that it would prevail in its challenge.” *See Vicor Corp.*, IPR2024-00704 at 9. The Petition, through its reliance on Dr. Heikenfeld, seemingly construes “current-limiting defibrillation protection resistor” to include any resistor that provides resistance for any purpose and pays no heed to the claim’s requirement that at least one current-limiting defibrillation protection resistor must protect the device from defibrillation. *See* Ex. 1003, ¶46 (“[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.”), ¶¶140-42.

In support of this dubious interpretation, the Petition cites no supporting evidence, and Dr. Heikenfeld 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[.]” *InfoBionic, Inc. v. Braemer Manuf., LLC*, IPR2015-01704, Paper 11 at 6 (P.T.A.B. Feb. 16, 2016) (denying institution).

Dr. Heikenfeld’s allegation that “[i]t would be obvious to place Kroll’s resistive traces over, or alternatively in place of, the copper wiring traces disclosed by Jensen. Thus, the modified traces would be disposed between at least one of the plurality of electrical connections (*i.e.*, the ECG electrode) and the ECG electronics module.” Ex. 1003, ¶160. 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 (P.T.A.B. 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.”). This leaves the reader to decipher the actual scope of claims that the Petition is challenging.

As discussed in greater detail below in Section I.A.1, the Petition’s approach is not only deficient, but it is incorrect.

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

In addition to the issues outlined above, the Petition also relies extensively on non-prior art, outdated, and irrelevant documents. The Petition seemingly agrees that no combination of the actual prior art references identified in the specific Grounds of alleged unpatentability actually teaches the independent claim of the ’699 Patent. Instead, it resorts to reliance on amorphous “General Knowledge” for *each* ground, leaving the reader to guess which limitations this “General Knowledge” purportedly teaches, how to interpret this “General Knowledge,” or how a POSA would have applied this “General Knowledge” in the prior art period.

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” through the use of 44 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.

As described above, of the 56 exhibits submitted with the Petition, the Petitioner relies on 44 references (Exs. 1005 through 1045) as supporting its unpatentability theories. Of these 44 references, at least nine are decidedly not prior art, being from *after* the November 2006 priority date of the '699 Patent. For example, Exhibits 1008 (dated in 2006); 1010 (dated in 2008); 1011 (dated in 2013); 1017 (dated in 2012); 1018 (dated in 2023); 1021 (dated in 2025), 1024 (dated in 2022), and 1039 (dated in 2019), were all dated anywhere from months to **19 years** *after* the priority date of the '699 Patent (November 1, 2006). Dr. Heikenfeld's reliance on these non-prior art documents is extensive—collectively citing these references approximately 27 times in his declaration, not including any internal cross references that further incorporate these references. He further relies on Exhibits 1010, 1011, 1017, 1018, 1021, and 1024 in his “background sections” which are cross-referenced repeatedly throughout his declaration including his 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 '699 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. It weakens the Petition's challenge.

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 priority of the '699 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 1012 (dated in 1979); 1020 (dated in 1960); 1025 (dated in 1985); and 1026 (dated in 1984). Nothing about these references from decades before the priority date of the '699 Patent suggests how a POSA would understand the problems facing the industry in 2006.

In light of the Petition's failure to establish the relevancy of these ancient references, one can only assume they are irrelevant, unreliable, and inapplicable to the field of the invention as of 2006. 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.

As another example, because the Petition hides behind the “ordinary and customary meaning” for all claim terms, the Board is left to guess the Petition’s actual position on “current-limiting defibrillation protection resistor.”⁷ *See* Petition, 2. Rather than articulate a construction for “current-limiting defibrillation protection resistor,” the Petition seemingly construes this term to include *any* resistor, without requiring the resistor to provide defibrillation protection.

For example, the Petition identifies *Kroll’s* lead strips and argues that “Kroll teaches a current-limiting defibrillation protection resistor in the form ‘of a flexible conductive ink compound . . . of a preselected conductivity to provide a certain total lead strip resistance so that each strip [] serves as a current limiter to protect a patient from shock due to malfunction of the device [] or of a complementary medical device.’” Petition, 26. That *Kroll’s* lead strips serve to protect the patient does not somehow mean that the lead strips are also “current-limiting defibrillation protection resistors” that protect the device from defibrillation, as required by Claim 1.

A proper claim construction analysis considers the intrinsic evidence of the ’699 Patent, which the Petition ignores. The ’699 Patent explains that the “resistive

⁷ This term appears in Grounds 1 and 3 and is discussed in an exemplary way with regard to Ground 1 here.

traces should survive multiple defibrillation cycles such that body worn monitor 100 remains functional even after one or more attempts to re-start a patient's heart. In order to survive defibrillation, the resistive traces should dissipate that portion of the potentially damaging defibrillation energy that is coupled into the monitor.” Ex. 1001, 7:48-54. The '699 Patent is clear that the use of circuit protection including the current-limiting defibrillation protection resistors, which “are typically in the form of resistive traces 412,” allow “a body worn device [to] survive multiple defibrillation cycles of at least 360 joules.” Ex. 1001, 15:19-24.

The only way to reconcile the '699 Patents express disclosure (explaining that current-limiting defibrillation protection resistors must *protect the device* from defibrillation) and the Petition's argument (the current-limiting defibrillation protection resistors *protect the patient* from defibrillation) is to broadly construe “current-limiting defibrillation protection resistors” to capture any resistor that provides any resistance for any purpose. The Petition's application of this broad construction without actually construing “current-limiting defibrillation protection resistors,” is improper and should be ignored.

The Petition, recognizing the limits of the art it elected for its challenge, disregards the teachings of the '699 Patent in an effort to render its claims obvious. But this attempt should be denied because it fails to both (1) present a cognizable

claim construction theory, and (2) if proper would vitiate the actual claim language, rendering the claim element moot, which cannot be correct.

Therefore, the Petition’s implicit and improperly broad construction of “current-limiting defibrillation protection resistors” fails.

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 to render obvious a current-limiting defibrillation protection resistor. Ex. 2023, ¶¶[0061]-[0062]. Moreover, the Petition does not establish a motivation to combine *Jensen* and *Kroll*. Ex. 2023, ¶[0066]. Ground 3 also fails. The combination of *Matsumura*, *Kroll*, and “general knowledge” fails to render obvious a current-limiting defibrillation protection resistor or a power source. Ex. 1001, Cl. 1; Ex. 2023, ¶[0063]. Moreover, a POSA would not have been motivated to combine *Matsumura* and *Kroll*. Ex. 2023, ¶[0063]. As such, the Petition does not have a reasonable likelihood of prevailing.

A. Ground 1 Fails to Render Obvious the Challenged Claims

1. Ground 1 Fails to Render Obvious the Claimed Current-Limiting Defibrillation Protection Resistor

The non-obvious combination of *Jensen* and *Kroll* cannot succeed because it fails to render obvious the “current-limiting defibrillation protection resistor.” Ex.

1001, Cl. 1; Ex. 2023, ¶¶[0064]-[0065]. In an attempt to teach this element, the Petition relies only on *Kroll*; however, *Kroll* discloses a lead strip that “protect[s] **a patient** from shock.” Ex. 1007, 5:4-13. *Kroll* does not teach or suggest that its lead strips **for patient protection** provide any defibrillation protection for its device. Ex. 2023, ¶¶[0067]-[0069].

To bridge this gap, the Petition contends that *Kroll*’s lead strips would protect a device from outside shocks simply because, based on Dr. Heikenfeld’s alleged theories, resistors limit current flow in both directions. Petition, 11; *see* Ex. 1003, ¶46. The Petition’s maze of cross-nested citations does not provide any explanation as to why *Kroll*’s lead strips **would** provide this function based on anything more than the inherent property that resistors limit current. 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 defibrillation protection. Ex. 2023, ¶¶[0070]-[0072]; *see also* Ex. 2023, ¶¶[0070]-[0072]; *see also* ¶¶[0041]-[0044] (detailing the level of ordinary skill in the art). The Petition did not address any of these design considerations.

Instead, to support its position, the Petitioner first cites to Dr. Heikenfeld. *See* Petition, 21 (citing Ex. 1002, ¶¶111-12). Dr. Heikenfeld repeats the same conclusion and cites to a different section of his declaration. *See* Ex. 1003, ¶¶111-12 (citing

Sections IV.E-F) (“[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.E, Dr. Heikenfeld again repeats the Petition’s insufficient conclusion that *Kroll’s* lead strips would protect *Jensen’s* electronics because resistors limit current in both directions. *See* Ex. 1003, ¶46 (“[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 1039, which is a **2019 reference** that was published **thirteen years** after the priority date of the ’699 Patent. *See* Ex. 1003, ¶46 (citing Ex. 1039 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 would provide defibrillation protection for *Jensen’s* device. Dr. Anthony’s analysis shows that *Kroll’s* lead strips would not necessarily provide such function, directly contrary to the Petition’s argument. Ex. 2023, ¶¶[0068]-[0069].

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

The Petition fails to establish a motivation to combine *Jensen* and *Kroll* based on either a desire to limit current or a desire to make *Jensen*'s device smaller. *See* Petition, 21-22; Ex. 2023, ¶[0073]. First, a POSA would not have been motivated to incorporate *Kroll*'s lead strips into *Jensen*'s device to “limit the current” because a POSA would have recognized that this would provide no benefit to *Jensen*. Petition, 21; Ex. 2023, ¶[0080]. Indeed, this alleged argument ignores the fact that the only reason *Kroll* includes such resistors is because *Kroll*'s device discharges electrical pulses *into* the wearer. Ex. 2023, ¶[0077]. This is not possible in *Jensen*'s device or contemplated in the proposed combination. *Jensen*'s device monitors the patient without transmitting any current. Ex. 2023, ¶¶[0079]-[0080].

“Jensen's goal of reducing the size of the device” likewise fails to provide a motivation to modify *Jensen* by including the specifically claimed resistors. Petition, 22. *Jensen* already achieves its size goals with conventional resistors. Ex. 2023, ¶¶[0100]-[0102]. 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

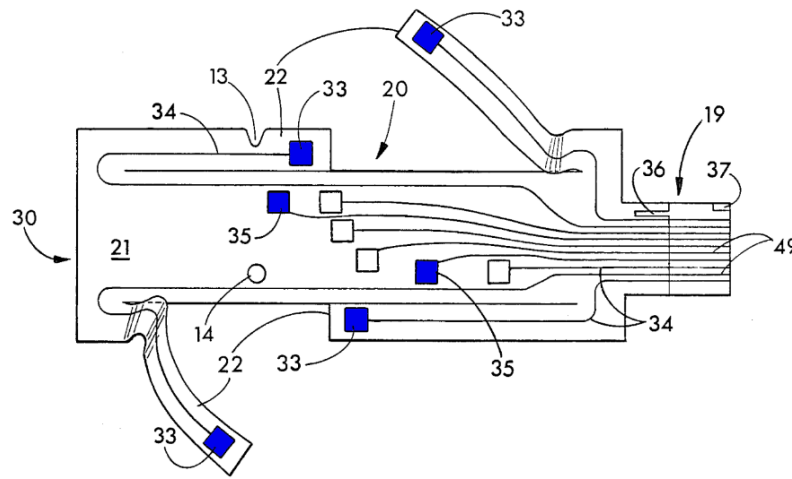
A POSA would not have been motivated to incorporate *Kroll*'s lead strips into *Jensen*'s device to limit the current between *Jensen*'s device and the patient. *See* Petition, 21-22. *Jensen*'s device only monitors the patient and does not transmit any current to the patient. Thus, there would be no motivation for a POSA to limit current (as there is none) from the device to the patient. Ex. 2023, ¶[0075]. 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, 21-22; Ex. 2023, ¶[0074]. *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. Ex. 2023, ¶[0082].

- 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. 2023, ¶¶[0079]-[0080]. Thus, contrary to the Petition's argument, a POSA would not have been motivated to limit

the current from *Jensen's* device to the patient—because there is no current from *Jensen's* device to the patient. Ex. 2023, ¶¶[0079]-[0080]; see Petition, 21-22 (arguing that it would be beneficial to limit the current transmitted from *Jensen's* device to the patient to protect the patient from shock due to electricity from the device).

As introduced in Section IV.C, *Kroll* provides a disposable electrode belt “for receiving and transmitting electric current and voltage.” Ex. 2023, ¶[0076]; Ex. 1007, 2:41-47. Figure 4 shows the electrodes (indicated in blue) of *Kroll's* disposable electrode belt. Ex. 2023, ¶[0076]; Ex. 1007, 4:48-68, Figure 4A (annotated). Each electrode “transmit[s] and receive[s] electric signals” over its respective lead strips. Ex. 2023, ¶[0076]; Ex. 1007, 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. 2023, ¶[0076]; Ex. 1007, 5:4-13.



Ex. 1007, Figure 4A (annotated); Ex. 2023, ¶[0076].

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. 2023, ¶[0077]. This same understanding does not apply to *Jensen* because *Jensen* only monitors the patient. Ex. 2023, ¶[0080]. *Jensen* provides a patch that “sense[s] the heart-rate voltage differential across [its] sensors.” Ex. 2023, ¶[0078]; Ex. 1005, Abstract. These signals are then amplified, converted to an output format, and transmitted to receiving equipment. Ex. 2023, ¶[0078]; Ex. 1005, Abstract; *see also* Ex. 1005, ¶[0054] (describing the advantages “for monitoring of heart-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. 2023, ¶[0079]; *see generally* Ex. 1005. Neither

does *Jensen* provide a reason to transmit electrical signals or disclose components that would allow such function. *Id.* Consistent with this disclosure, the Petition itself repeatedly characterizes *Jensen's* device as a “monitoring device.” *See* Petition, 22, 26 (“*Jensen*...discloses a medical monitoring device.”).

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. 2023, ¶¶[0080]-[0081]. 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. 2023, ¶¶[0080]-[0081]; *see* Petition, 21 (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, 21.

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 the sensitive electronics.” Petition, 21; Ex. 1007, 5:8-13; Ex. 2023, ¶[0082]. A POSA would have understood that the design of the resistors corresponds to the

function. Ex. 2023, ¶[0082]. 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 aligns with *Kroll’s* disclosure

Kroll’s leads strips are designed “to ***protect a patient*** from shock” rather than “protect the sensitive electronics.” Petition, 21; Ex. 1007, 5:8-13; Ex. 2023, ¶[0083]. This disclosure, which the Petition identifies (Petition, 11, 26), aligns with *Kroll’s* consistent goal of patient safety. Ex. 2023, ¶[0083].

Kroll provides a therapeutic electrode belt “for receiving and transmitting electric current and voltage.” Ex. 2023, ¶[0084]; Ex. 1007, 2:41-47. To safely administer such therapy, *Kroll’s* device includes several features for patient protection. Ex. 2023, ¶[0084]. 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. 2023, ¶[0084]; Ex. 1007, 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. 2023, ¶[0085]; Ex. 1007, 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. 2023, ¶[0085]. 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. 2023, ¶[0086]; Ex. 1007, 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. 2023, ¶[0086]; Ex. 1007, 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. 2023, ¶[0086].

Finally, *Kroll* details the integrated layers of its 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. 2023, ¶[0087]; Ex. 1007, 6:17-24. In other embodiments, the belt may include more than one shielding layer “to further shield the device from interference.” Ex. 2023, ¶[0087]; Ex. 1007, 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. 2023, ¶[0087]; Ex. 1007, 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. 2023, ¶[0087]. *Jensen's* device only monitors ECG signals and does not have these same safety concerns as in *Kroll*. Ex. 2023, ¶[0087].

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

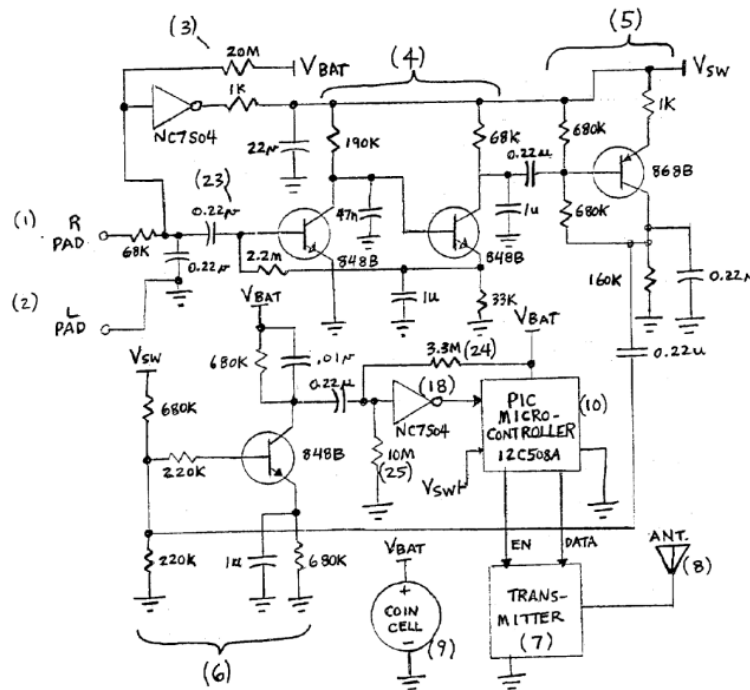
To the extent that *Kroll*'s lead strips are used in *Jensen*'s device, the Petition fails to establish that *Kroll*'s lead strips would protect *Jensen*'s electronics. Ex. 2023, ¶[0088]. The Petition highlights this failure, stating that the combination would use “the resistive lead strips of Kroll... instead of the conventional resistors on Jensen’s circuit assembly.” Petition, 22. This would do nothing to protect *Jensen*'s electronics. Ex. 2023, ¶[0089].

As the Petition identifies, *Jensen*'s electronics circuit provides several resistors, including gain setting resistors, feedback resistors, and resistors for signal biasing. Ex. 2023, ¶[0091]; Ex. 1005, ¶¶[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. 2023, ¶¶[0090]-[0091]. 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. 2023, ¶[0092]. The same is true for both the feedback resistors and the resistors for signal biasing. Ex. 2023, ¶[0092]. Here, the Petition and Dr. Heikenfeld conflate a resistor's ***form*** with its ***function***. Ex. 2023, ¶[0092].

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, 21; *see* Ex. 1003, ¶46. Applying this same blanket conclusion—that does not consider a single variable of the resistor—*Jensen*'s conventional resistors, as resistors, limit current flow in both directions and thus would protect *Jensen*'s electronics. Ex. 2023, ¶¶[0092]-[0096]. But they do not. *Jensen*'s resistors are specifically designed as part of the electronics circuit to correspond to their function. Ex. 2023, ¶[0096].

Jensen provides example embodiments of its electronics circuit. Ex. 2023, ¶[0097]; Ex. 1005, ¶[0036]. Figure 2 includes resistors 24, 25 for signal biasing while resistors 20, 21 in Figure 3 function as gain setting resistors. Ex. 2023, ¶[0097], Ex. 1005, ¶¶[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. 2023, ¶[0097].



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. 2023, ¶¶[0096]-[0099]. 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.

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. Petition, 21; Ex. 1007, 5:8-13; Ex. 2023, ¶[0082]. 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. 2023, ¶[0102]; Ex. 1005, ¶[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. 2023, ¶[0112].

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. 2023, ¶[0113].

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. 2023, ¶[0114].

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. 2023, ¶[0115]. This analysis requires an understanding of

detailed aspects related to transient response, resistance change and variability, and safety margins. Ex. 2023, ¶[0115].

Fourth, a POSA would have to design contact pads to reduce arcing. Ex. 2023, ¶[0116]. This design and solution is crucial when implementing resistors in small devices, as the Petition attempts to do so here. Ex. 2023, ¶[0116].

Fifth, a POSA would have to manage the space between traces to minimize arcing potential. Ex. 2023, ¶[0117]. Again, a POSA would recognize this as a key consideration in implementing traces on a small device. Ex. 2023, ¶[0117]. Further, a POSA would have to develop insulative dielectric coating methods to reduce spacing requirements significantly. Ex. 2023, ¶[0117].

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. 2023, ¶[0118].

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. 2023, ¶[0119]. 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, 21 (citing Ex. 1003, ¶¶108-12). 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. 1003, ¶110 (citing Section IV.E). 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. 1003, ¶46 (citing Ex. 1039 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. 1003, ¶¶46 (citing Ex. 1039 at 816-17), 110. As Dr. Anthony’s analysis makes clear, resistors are designed corresponding to their function. Ex. 2023, ¶¶[0088]-[0099]. And Dr. Heikenfeld is wrong; it is not the case that “any resistor...would protect the body-worn device from excess electrical current.” Ex. 2023, ¶¶[0088]-[0099]; Ex. 1003, ¶46. This issue is worsened by Dr. Heikenfeld’s citation to Exhibit 1039, which is a 2019 reference that published

thirteen years after the priority date of the '699 Patent. *See* Ex. 1003, ¶46 (citing Ex. 1039 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. 2023, ¶¶[0088]-[0099].

- 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, 22-23. 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. 2023, ¶[0101]. 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. 2023, ¶[0101]. Finally, the Petition fails to show how the combination of *Jensen* and *Kroll* would further *Jensen's* size goals. Ex. 2023, ¶[0101].

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

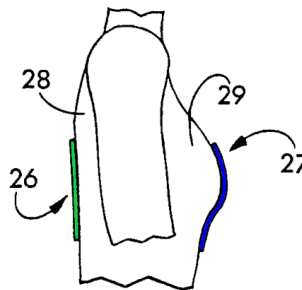
A POSA would not have been motivated to replace *Jensen's* conventional resistors to reduce the size of *Jensen's* device because *Jensen* already achieves this goal. Ex. 2023, ¶[0102]; see Petition, 22. *Jensen's* “novelty include[s] its physical construction.” Ex. 2023, ¶[0102]; Ex. 1005, ¶[0030]. 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. 2023, ¶[0102]; Ex. 1005, ¶[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. 2023, ¶[0102]; Ex. 1005, ¶¶[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. 2023, ¶[0103]. This is because *Jensen* achieves its desired physical dimensions. Ex. 2023, ¶[0103]; Ex. 1005, ¶[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 '699 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. 2023, ¶[0104].

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

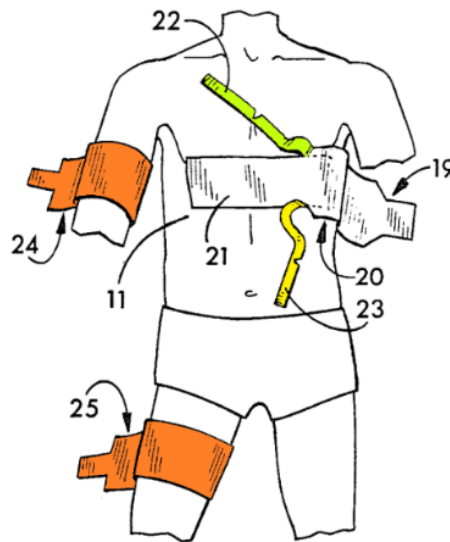
Kroll provides a device that wraps around the patient's body to administer therapeutic shocks. Ex. 2023, ¶[0106]. The Petition ignores this disclosure to argue that a POSA, motivated to make *Jensen's* device smaller, would look to *Kroll's* much larger device. See Petition, 22-23; Ex. 2023, ¶[0105].

Specifically, *Kroll* provides an “electrode belt...for receiving and transmitting electric current or voltage for use on the body of a patient.” Ex. 2023, ¶[0106]; Ex. 1007, Abstract, Figure 1. Such electrical current may be transmitted “to specific anatomical locations for therapeutic purposes.” Ex. 2023, ¶[0106]; Ex. 1007, 1:27-36. In one example, *Kroll's* electrode belt is placed on the patient's chest and back. Ex. 2023, ¶[0107]; Ex. 1007, 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. 2023, ¶[0107]; Ex. 1007, 4:44-47, Figure 3.



Ex. 1007, Figure 3 (annotated); Ex. 2023, ¶[0107].

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. 2023, ¶[0108]; Ex. 1007, 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. 2023, ¶[0108]; Ex. 1007, 4:37-47, Figure 2 (indicating the embodiments placed around the limbs in orange).



Ex. 1007, Figure 3 (annotated); Ex. 2023, ¶[0108].

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. 2023, ¶[0109]; Petition, 22. This is especially true for *Kroll's* lead strips. Ex. 2023, ¶[0109]; see Petition, 22 (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. 2023, ¶[0109]; Ex. 1007, 4:37-47. The extendable side members are used for placement outside of the precordial region. Ex. 2023, ¶[0109]; Ex. 1007, 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. 2023, ¶[0111].

iii. The Petition combination would not lead to any size benefits in *Jensen*’s device

A POSA would have known that replacing *Jensen*’s copper wiring with *Kroll*’s traces would not decrease the size of *Jensen*’s device. Ex. 2023, ¶[0110]; *see* Petition, 27 (arguing that “a POSA would have replaced the copper wiring traces disclosed by Jensen”). Instead, the size of *Jensen*’s device would remain the same with this substitution. Ex. 2023, ¶[0110]. Beyond its unsupported conclusion, the Petition does nothing to explain how replacing *Jensen*’s copper wiring with printed traces would decrease the size of the device. Ex. 2023, ¶[0110]; *see* Petition, 22 (“Using the resistive lead strips of Kroll, formed with ink deposits, instead of the conventional resistors on Jensen’s circuit assembly, would further Jensen’s goal.”) (citing Ex 1003, ¶115), 27. Thus, contrary to the Petition’s argument, a POSA would not have been motivated to combine *Jensen* and *Kroll* based on size concerns. Ex. 2023, ¶[0120].

B. Grounds 2 Fails to Render Obvious the Challenged Claims

Ground 2 challenges dependent Claim 8 using the base of Ground 1 and fails to provide any independent argument for independent Claim 1 addressed with respect to Ground 1. Thus, Ground 2 should be similarly rejected.

C. Ground 3 Fails to Render Obvious Challenged Claims

Ground 3 fails to render obvious the Challenged Claims. Ex. 2023, ¶[0121]. First, the combination of *Matsumura* and *Kroll* fail to render obvious a power source as recited by independent Claim 1. Ex. 1001, Cl. 1; Ex. 2023, ¶[0122]. Instead, *Matsumura* and *Kroll* are silent with regard to any power source in their devices. Second, for the same reasons as in Section I.A.1, Ground 3 fails to render obvious a current-limiting defibrillation protection resistor. Ex. 1001, Cl. 1; *see* Section I.A.1; Ex. 2023, ¶[0123]. Third, a POSA would not have been motivated to combine *Matsumura* and *Kroll* based on either a desire to protect *Matsumura*'s circuitry or a desire to make *Matsumura*'s device smaller. Ex. 2023, ¶[0124]; *see* Petition, 42-44.

1. Ground 3 Fails to Render Obvious a Power Source

Independent Claim 1 requires a power source. Because *Matsumura* does not teach or suggest a power source for its device, the Petition fails to render obvious claim element 1[c]. The Petition only relies on one paragraph in *Matsumura* describing an entirely different prior art monitor that was “comprised of a conduction portion (equivalent to an electrode element), *a power source*, a potential difference

detection portion, and a wireless transmitting/receiving portion.” Ex. 1006, ¶[0004]; Ex. 2023, ¶¶[0125]-[0126]. *Matsumura* further describes that these prior art monitors’

[P]ower source, []potential difference detection portion, and wireless transmitting/receiving portion are embedded in a sealing material. However, they are not detachable from the conduction portion, which is equivalent to the electrode element. Therefore, it is unhygienic to reuse a device that has been used once, and, conversely, it is uneconomical to use it as a disposable device.

Ex. 1006, ¶[0004]. The only time “power source” is mentioned in *Matsumura* is in a device that *Matsumura* effectively teaches away from, in the form of a prior art monitor that is intentionally distinguished by the remainder of *Matsumura*’s disclosure. Specifically, the sole power source recited in *Matsumura* is fundamentally different than the invention disclosed in *Matsumura*, which itself requires the bio-pad to be detachable from the signal processor. *See, e.g.*, Ex. 1006, ¶[0012] (“[T]he bioelectric potential detector is hygienic because the ***bioelectrode pad is disposable***, the ***signal processor is economical because it is reusable***, and the ***reusable signal processor and the disposable bioelectrode can be easily attached and detached*** before and after use and are waterproofed.”); Ex. 2023, ¶[0127]. This single mention of a “power source” is expressly taught away from by *Matsumura*, and the Petition does not point to any other reference to support its argument that *Matsumura* implicitly discloses a power source.

Instead, the Petition relies on expert testimony and “general knowledge” to teach an element that is not actually disclosed in the teachings of *Matsumura*. Contrary to the recent Guidance from the PTAB, which states that “evidence that is not ‘prior art consisting of patents or printed publications’...may not be used to supply a missing claim limitation,” the Petition relies not on the prior art reference (*Matsumura*) for this element but rather relies on the “General Knowledge.” Ex. 2025, 1 (citing Rule 104(b)(4)); *see* Petition, 48 (“A POSA would have understood *Matsumura*’s ECG monitor must include an onboard power source.”). This is exactly the type of behavior the Board’s recent guidance seeks to prevent.

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

The Petition fails to establish that a POSA would not have been motivated to combine *Matsumura* and *Kroll*. *See* Petition, 42-44; Ex. 2023, ¶[0128]. First, a POSA would not have been motivated to incorporate *Kroll*’s lead strips into *Matsumura*’s device to protect *Matsumura*’s circuitry because a POSA would have recognized that this would provide no benefit to *Matsumura*. Ex. 2023, ¶[0142]. Second, “reducing the size of *Matsumura*’s device” likewise fails to provide a motivation because *Matsumura* already achieves its size goals and the Petition provides no explanation as to how its modifications would reduce the size of the device. Petition, 44; Ex. 2023, ¶[0129]. These cursory alleged motivations are

exactly the type that the Board regularly rejects as under-developed and not rooted in the actual references. *See, e.g., TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019). Because the Petition fails to establish a motivation to combine *Matsumura* and *Kroll*, Ground 3 cannot render obvious any of the Challenged Claims.

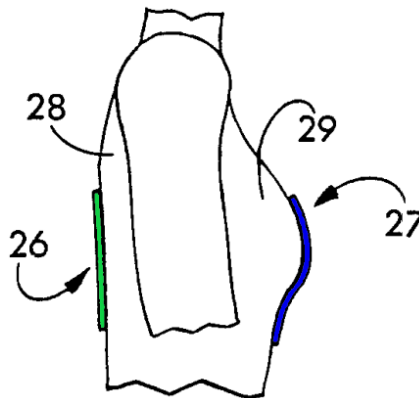
- a. A POSA would not have been motivated by *Kroll* to reduce the size of *Matsumura*'s device

A POSA would not have been motivated to combine *Matsumura* and *Kroll* to reduce the size of *Matsumura*'s device. First, the Petition does not establish that its combination provides any size decrease of *Matsumura*'s device. Ex. 2023, ¶[0129]. The Petition conclusively states that a POSA “would have known that Kroll’s resistive lead strips would also lead to the additional benefits of helping...reducing the size of Matsumura’s device.” Petition, 43-44. This is sole reference to *Matsumura*'s size—the Petition provides no explanation as to why its modification would reduce the device’s size. Ex. 2023, ¶¶[0129]-[0130].

Additionally, a cursory review of the Petition’s combination demonstrates that there would be ***no change*** to the size of the device. Ex. 2023, ¶[0130]. Instead, the Petition simply contends that “a POSA would have replaced the Ag/AgCl ink disposed on Matsumura’s conductive material 2 with Kroll’s resistive ink.” Ex. 2023, ¶[0130]. Even if a POSA would make this non-obvious substitution, using a

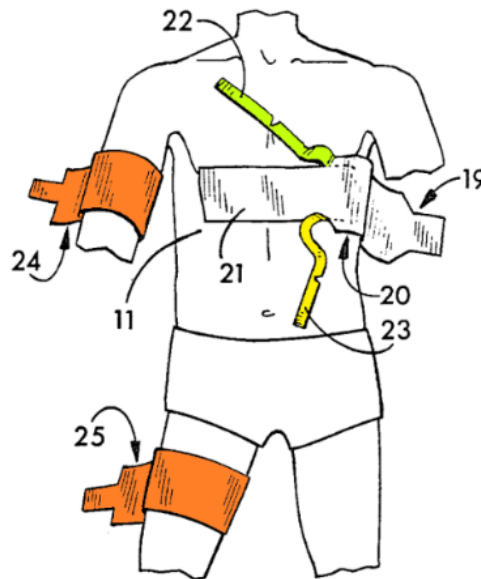
different ink would not “reduc[e] the size of Matsumura’s device.” Petition, 43-44; Ex. 2023, ¶[0130]. Relying on hindsight reconstruction, the Petition manufacturers this motivation to arrive at the Challenged Claims.

Second, a POSA would not have looked to the much larger device of *Kroll* to reduce the size of *Matsumura*’s device. Ex. 2023, ¶[0131]. *Kroll* provides a device that wraps around the patient’s body to administer therapeutic shocks. Ex. 2023, ¶[0131]. Specifically, *Kroll* provides an “electrode belt...for receiving and transmitting electric current or voltage for use on the body of a patient.” Ex. 2023, ¶[0131]; Ex. 1007, Abstract, Figure 1. Such electrical current may be transmitted “to specific anatomical locations for therapeutic purposes.” Ex. 2023, ¶[0131]; Ex. 1007, 1:27-36. In one example, *Kroll*’s electrode belt is placed on the patient’s chest and back. Ex. 2023, ¶[0132]; Ex. 1007, 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 is transmitted through the chest to the back to target specific areas for therapeutic purposes. Ex. 2023, ¶[0132]; Ex. 1007, 4:44-47.



Ex. 1007, Figure 3 (annotated); Ex. 2023, ¶[0132].

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. 2023, ¶[0133]; Ex. 1007, 4:37-47, Figure 2 (indicating side members in yellow). *Kroll's* electrode belt may also be placed around the patient's limbs. Ex. 2023, ¶[0133]; Ex. 1007, 4:37-47, Figure 2 (indicating embodiments placed around the limbs in orange).



Ex. 1007, Figure 3 (annotated); Ex. 2023, ¶[0133].

Contrary to the Petition’s conclusory position, a POSA would not have looked to *Kroll’s* therapeutic electrode belt to “reduc[e] the size of Matsumura’s device.” Ex. 2023, ¶[0134]; Petition, 44. This is especially true for *Kroll’s* lead strips. Ex. 2023, ¶[0134]. *Kroll’s* lead strips are used on the “extendable side members,” which are specifically designed to make the electrode belt **larger**. Ex. 2023, ¶[0134]; Ex. 1007, 4:37-47. The extendable side members are used for placement outside of the precordial region. Ex. 2023, ¶[0134]; Ex. 1007, 4:37-47. Based on this disclosure, a POSA would not have been motivated to make *Matsumura* smaller by adding *Kroll’s* traces. Ex. 2023, ¶¶[0134]-[0135]. Nor would the Petition’s proposed modification lead to any actual reduction in the size of *Matsumura*.

In view of the actual teachings of *Matsumura* and *Kroll*, it becomes clear that a POSA would not have been motivated to make such modification, and the Petition offers this motivation and modifications solely to reconstruct the Challenged Claims.

- b. A POSA would not have been motivated by *Kroll* to add resistive strips to protect the patient

The Petition's suggestion to implement *Kroll's* resistive strips into *Matsumura* to "help[] protect patients from potential shock from the monitor itself" does not arise from the teachings of either reference. Petition, 43-44; Ex. 2023, ¶¶[0136]-[0137]. Indeed, this alleged argument ignores the fact that the only reason *Kroll* includes such resistors is because *Kroll's* device discharges electrical pulses *into* the wearer. Ex. 2023, ¶¶[0138]-[0139]. This is not something possible in *Matsumura* or contemplated in the proposed combination. Ex. 2023, ¶¶[0140]-[0143]. Accordingly, a POSA would not have been motivated to limit current from *Matsumura's* device to the patient with *Kroll's* resistive strips because there is *no current* that travels from *Matsumura's* device to the patient. Ex. 2023, ¶¶[0140]-[0143].

Matsumura's disclosure regarding its design further undermines the Petition's proposed combination. Specifically, *Matsumura* is explicit about the conductive nature of its materials, stating that the conductive materials are either carbon or PET with conductive coatings like Ag/AgCl. Ex. 2023, ¶[0144]; Ex. 1006, ¶[0020].

There is no suggestion in *Matsumura* that its **conductive** material should be replaced with *Kroll's* **resistive** traces, nor does either reference provide any indication that resistive materials would function equivalently in this context. Ex. 2023, ¶¶[0144]-[0145]. Thus, any proposed modification based on *Kroll's* resistive ink strips would contradict *Matsumura's* explicit teachings. Ex. 2023, ¶¶[0144]-[0145]

The Petition's reliance on *Kroll* to suggest a modification to *Matsumura* is not only unmotivated but also illogical. This modification (implementing *Kroll's* resistive ink on *Matsumura's* conductive material) is unsupported by the references and is purely hindsight reconstruction. Ex. 2023, ¶[0158].

The Petition is impermissibly “defining the problem” *Kroll* addresses “in terms of [the] solution” *Kroll* discloses, which constitutes improper hindsight reasoning. See *Shenzhen Buxiang Network Tech. Co., Ltd. v. Sun Pleasure Co. Ltd.*, No. 2022-1912, 2024 WL 3451830, at *6 (Fed. Cir. July 18, 2024) (explaining petitioner's reliance on Wu for “known *disadvantages* of a *discontinuous* wall, band, or beam” is “impermissibly ‘defin[ing] the problem’ Wu addresses by ‘in terms of [the] solution’ Wu discloses” where petitioner's expert explained “Wu disclosed that the solution to existing flaws was a continuous band or wall” (emphasis in original) (citing *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 859 (Fed. Cir. 2015))).

A POSA would not have been motivated to combine *Matsumura*'s teachings with the "general knowledge" with *Kroll*'s resistive ink strips, as doing so would undermine the device's core functionality by replacing *Matsumura*'s conductive material with *Kroll*'s resistive traces. Ex. 2023, ¶[0152]. Therefore, the Petition's proposed modification fails to render obvious the Challenged Claims.

- c. The Petition does not address any technical obstacles in designing a resistor that would function to protect *Matsumura*'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 *Matsumura*'s electronics. *Kroll*'s lead strips are designed "to **protect a patient** from shock" while administering therapy via the electrode belt. Ex. 2023, ¶[0083]; Petition, 19; Ex. 1007, 5:8-13. In contrast, *Matsumura* provides a "compact" biopotential detector that is worn on the patient's chest. Ex. 2023, ¶[0140]; Ex. 1006, ¶¶[0006], [0024]. Based on this difference, a POSA would have recognized many design hurdles that must be overcome to implement *Kroll*'s lead strips in *Matsumura*'s device to protect the electronics. Ex. 2023, ¶[0145].

Neither the Petition nor Dr. Heikenfeld address any of the design variables below, which are critical to the function of the resistor. Ex. 2023, ¶[0145].

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. 2023, ¶[0146].

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. 2023, ¶[0147].

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. 2023, ¶[0148]. This analysis requires an understanding of detailed aspects related to transient response, resistance change and variability, and safety margins. Ex. 2023, ¶[0148].

Fourth, a POSA would have to design contact pads to reduce arcing. Ex. 2023, ¶[0149]. This design and solution is crucial when implementing resistors in small devices, as the Petition attempts to do so here. Ex. 2023, ¶[0149].

Fifth, a POSA would have to manage the space between traces to minimize arcing potential. Ex. 2023, ¶[0150]. Again, a POSA would recognize this as a key consideration in implementing traces on a small device. Ex. 2023, ¶[0150]. Further,

a POSA would have to develop insulative dielectric coating methods to reduce spacing requirements significantly. Ex. 2023, ¶[0150].

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. 2023, ¶[0151].

Moreover, the Petition and Dr. Heikenfeld fail to address several design considerations that are specific to the proposed combination of *Matsumura* and *Kroll*. Ex. 2023, ¶[0152]. Like the general design variables discussed above, the specific design of the Petition's proposed combination are critical to the function of the resistor. And, in view of such considerations, a POSA would not have been motivated to combine *Matsumura* and *Kroll* as proposed in Ground 3.

First, the geometry of *Matsumura's* rods would have motivated a POSA against replacing *Matsumura's* conductive material with *Kroll's* resistive ink. Ex. 2023, ¶[0153]. Specifically, coating *Matsumura's* rods with resistive ink would not provide defibrillation protection. Ex. 2023, ¶¶[0153]-[0154]. Rather, the combination would yield a resistance in the hundreds of ohms, far below the kilohm range that current limiters generally target for defibrillation immunity. Ex. 2023, ¶[0153].

To achieve defibrillation protection, a POSA would have understood that the coating (unlike *Kroll's* resistive ink) would need to be high sheet resistance inks, which are drift prone and fragile on flex. Ex. 2023, ¶[0154]. Alternatively, a POSA would have understood that a significant change to the geometry of *Matsumura's* rods may provide added protection. Ex. 2023, ¶[0154]. Neither design variables are considered by the Petition or Dr. Heikenfeld, and such modification goes far beyond a simple substitution as proposed in the Petition's combination.

Second, the electrode chemistry at the interface of *Matsumura's* electrode and the conductive rod would have motivated a POSA against replacing *Matsumura's* conductive material with *Kroll's* resistive ink. Ex. 2023, ¶[0155]. *Matsumura* discloses a carbon sheet, or a PET sheet coated that is Ag/AgCl as the conductive material. Ex. 2023, ¶[0155]; Ex. 1006, ¶ [0020]. Here, the Ag/AgCl interfaces with the gel contact at the electrode to provide a low-polarization, stable half-cell. Ex. 2023, ¶[0155]. The Petition's proposed combination replaces the Ag/AgCl coating with *Kroll's* resistive ink; however, resistive inks are formulated for resistance elements, not for electrode-gel interfaces. Ex. 2023, ¶[0155].

To the extent the Petition's non-obvious combination is made, *Kroll's* resistive ink at the electrode-gel interface would lead to higher polarization, drift, noise, and variability, especially in a wet, chloride-rich environment where

Matsumura is specifically designed to function. Ex. 2023, ¶[0156]. A POSA would have recognized these issues and instead designed a device that isolates any resistors from electrolytes. Ex. 2023, ¶[0156]. Directly contrary to the Petition's combination, a POSA would not be motivated to create an electrode interface with resistive ink. Ex. 2023, ¶[0156]. The Petition fails to consider this design variable that goes beyond a simple substitution as proposed.

Third, a POSA would not have been motivated to combine *Matsumura* and *Kroll* in view of *Matsumura*'s structure. Ex. 2023, ¶[0157]. By passing through holes 2a in the rod-shaped conductive material, *Matsumura*'s hooks act as a stress concentrator. Ex. 2023, ¶[157]. A POSA would have understood that resistive materials, like *Kroll*'s resistive ink, are brittle compared to an Ag/AgCl layer. Ex. 2023, ¶[0157]. The Petition's proposed resistive layer would micro-crack from forces introduced by the hooks and the handling of the device. Ex. 2023, ¶[0157].

Matsumura's electrode gel, which is subject to moisture, would introduce further issues with an interface to the conductive rods. Ex. 2023, ¶[0158]. Namely, the proposed design would lead to resistance drift, hot spots, and potential burn-through. Ex. 2023, ¶[0158]. Neither the Petition nor Dr. Heikenfeld consider such issues. Again, the Petition's combination goes far beyond a simple substitution and a POSA would be motivated against such combination.

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. 2023, ¶[0159]. Without addressing these issues, the Petition fails to establish that *Kroll’s* lead strips would function to protect *Matsumura’s* electronics, even if the combination was made. Ex. 2023, ¶¶[0159]-[0160].

d. *Matsumura* fails under rule 42.63(b)

Grounds 3 to 5 rely on *Matsumura*. However, the Petition fails to establish *Matsumura* as prior art. Specifically, the Petition is procedurally defective because Petitioner failed to establish that the alleged translation for *Matsumura* (Ex. 1006) is accurate or reflects the Japanese version (Ex. 1046). The Board should not rely on Exhibit 1006 as it has not been established to be prior art and Grounds 3 to 5 relying thereon, should be denied. A complete translation of a foreign language document must be submitted. *See Toyota Motor N. Am., Inc. v. Cruise Control Techs., LLC*, IPR2014-00280, Paper 17 at 6-7 (P.T.A.B. July 2, 2014). Rule 42.63(b) applies to this proceeding and states: “When a party relies on a document or is required to produce a document in a language other than English, a translation of *the document* into English and an affidavit attesting to the accuracy of *the translation* must be

filed with the document.” *See Toyota Motor N. Am., Inc.*, IPR2014-00280, Paper 17 at 6 (quoting 37 C.F.R. § 42.63(b) (2017)) (emphasis in original).

While the Petition alleges that Exhibit 1047 is a certified translation of the document submitted as Exhibit 1046 (the Japanese Pat. Pub. JP2004/121360 to *Matsumura*), Exhibit 1047 does not identify or even refer to the document submitted as Exhibit 1046, nor does Exhibit 1047 identify or refer to the purported English language version of *Matsumura* submitted as Exhibit 1006. Instead, the translation states, “This is to certify that the above-referenced document 403-45924_JP2004121360A_JA into EN has been translated from Japanese into English.” Ex. 1047. Petitioner did not submit any document that is titled or referred to as “403-45924_JP2004121360A_JA.” There is nothing in Exhibit 1047 that links the certification to *Matsumura* (either the Japanese language version (Ex. 1046) or the English language version (Ex. 1006)). *See* Exs. 1001-1054.

As a result, the Petition does not comply with 37 C.F.R. § 42.63(b) because there is no certified translation of *Matsumura*. Therefore, *Matsumura* should be stricken from the record and Grounds 3 through 5 should be denied.

D. Grounds 4 and 5 Fail to Render Obvious the Challenged Claims

Ground 4 challenges dependent Claim 3 using the base of Ground 2 and fails to provide any independent argument for independent Claim 1 addressed with

respect to Ground 3. Ground 5 challenges dependent Claim 8 using the base of Ground 1 and fails to provide any independent argument for independent Claim 1 addressed with respect to Ground 3. Thus, for the reasons outlined in with respect to Ground 3, Grounds 4 and 5 should be similarly rejected.

VII. CONCLUSION

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

Dated: September 23, 2025

Respectfully submitted,

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