

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IRHYTHM, INC.,

Petitioner,

v.

WELCH ALLYN, INC.,

Patent Owner.

CASE: IPR2025-00378

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

PATENT OWNER PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	SUMMARY OF THE '007 PATENT	4
III.	ORIGINAL PROSECUTION OF THE '007 PATENT	7
IV.	OVERVIEW OF THE ART.....	8
	A. Overview of <i>Matsumura</i>	8
	B. Overview of <i>Kroll</i>	10
	C. Overview of <i>Ozguz</i>	14
V.	“GENERAL KNOWLEDGE” AND CLAIM CONSTRUCTION	17
	A. The Petition Fails to Comply with 35 U.S.C. § 311(b).....	17
	B. The Petition Fails to Advance A Legally Cognizable Claim Construction Position	20
	i. The Petition is Riddled with Claim Construction Yet Fails to Propose Actual Constructions	21
	ii. The Petitioner Improperly Shifts the Burden of Clarification to the Board and Patent Owner.....	26
	iii. The Petition’s Reliance on Non-Prior Art, Outdated, and Irrelevant References Significantly Burdens the Patent Owner and the Board.....	27
VI.	THE PETITION FAILS TO SHOW A REASONABLE LIKELIHOOD THAT THE PETITIONER WILL PREVAIL ON A SINGLE CLAIM.....	30
	A. Ground 1 Fails to Render Obvious the Challenged Claims	31
	i. The Non-Obvious Combination of <i>Matsumura</i> and <i>Kroll</i> Fails to Render Obvious Claims 1 and 45.....	31
	a. Ground 1 fails to render obvious a resistor “configured to protect the communication-computation module”	31
	b. Ground 1 fails to render obvious the power source	38
	ii. The Petition Fails to Establish a Motivation to Combine <i>Matsumura</i> and <i>Kroll</i>	39
	a. A POSA Would Not Have Been Motivated to Modify <i>Matsumura</i> ’s Conductive Rods and Hooks with Screen Printed Resistors	40

b. Petitioner’s Proposed Modification to Add the Printed Resistive Traces Would Frustrate <i>Matsumura</i> ’s Goal of a Waterproof Device.....	45
c. A POSA Would Not Have Been Motivated by <i>Kroll</i> to Reduce the Size of <i>Matsumura</i> ’s Device	47
d. A POSA Would Not Have Been Motivated by <i>Kroll</i> to Add Resistive Strips to Protect the Patient	51
e. The Petition does not address any technical obstacles in designing a resistor that would function to protect <i>Matsumura</i> ’s electronics.....	54
iii. <i>Matsumura</i> Fails Under Rule 42.63(b)	56
iv. The Non-Obvious Combination of <i>Matsumura</i> , <i>Kroll</i> , and the “General Knowledge” of the POSA Fails to Render Obvious Claim 45	58
B. Ground 2 Fails to Render Obvious the Challenged Claims	58
i. The Petition Fails to Establish a Motivation to Combine <i>Matsumura</i> , <i>Ozguz</i> , and <i>Kroll</i>	60
ii. <i>Ozguz</i> is non-enabling for obviousness	63
a. A POSA would not have relied on <i>Ozguz</i> to reach the challenged claims.....	63
b. <i>Ozguz</i> ’s Infeasible Flexible Battery Technology Renders <i>Ozguz</i> ’s device non-enabled.....	68
c. The Petition’s Reliance on <i>Ozguz</i> ’s Infeasible Thin Silicon Technology is Fatal to Ground 3.....	71
iii. The Non-Obvious Combination of <i>Matsumura</i> , <i>Ozguz</i> , <i>Kroll</i> and the “General Knowledge” of the POSA Fails to Render Obvious Claim 45 ..	72
VII. Conclusion.....	73

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	Declaration of Dr. Brian Anthony for IPR2025-00378 of U.S. Patent No. 8,214,007

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 1-6, 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 that bifurcates two main components—the communication-computation module and the disposable module. Ex. 1001, Cls. 1, 45, Abstract; Ex. 2017, ¶[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, 7:50-55, Cl. 1; Ex. 2017, ¶[0045].

In challenging the ’007 Patent, the Petition does not identify a single reference that includes 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.” 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 the “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.” *Qualcomm Inc. v. Apple Inc.*, Nos. 2023-1208, -1209, 2025 WL 1174161 (Fed. Cir. Apr. 23, 2025). The “General Knowledge of a POSA”—which plagues every Ground of the Petition—is neither a patent nor printed publication. The Petition should be denied for failing to comply § 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 construction of a term (e.g., “configured to”) is critical to the required analysis. Petition, 2. Without any constructions from the 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 also fails on the merits.

In Ground 1, the Petition relies on the combination of *Matsumura*,¹ *Kroll*,² and the “general knowledge” of a POSA. *See* Petition, 19-33. First, the combination does not teach or suggest each element of Claim 1, including: (a) the power source, (b) communicating “upon determination of the predetermined physiological event, a result of the physiological analysis,” (c) the current-limiting resistor, (d) the current-limiting resistor being screened onto a flexible substrate, or (e) the current-limiting resistor being in the form of resistive traces. Further, the Petition does not consider the language of “upon determination of the predetermined event” at all in its analysis. Ground 1 also fails because the Petition does not establish a motivation to combine *Matsumura* and *Kroll*.

In Ground 2, the Petition relies on the combination of *Matsumura*, *Kroll*, and the “general knowledge” of a POSA, or *Matsumura*, *Kroll*, *Ozguz*,³ and the “general knowledge” of a POSA. *See* Petition, 49-58. The proposed combination of *Matsumura*, *Kroll*, *Ozguz*, and the so-called “general knowledge” of the POSA fails

¹ Purported Translation of Japanese Pat. Pub. JP2004/121360 to *Matsumura* (Ex. 1012).

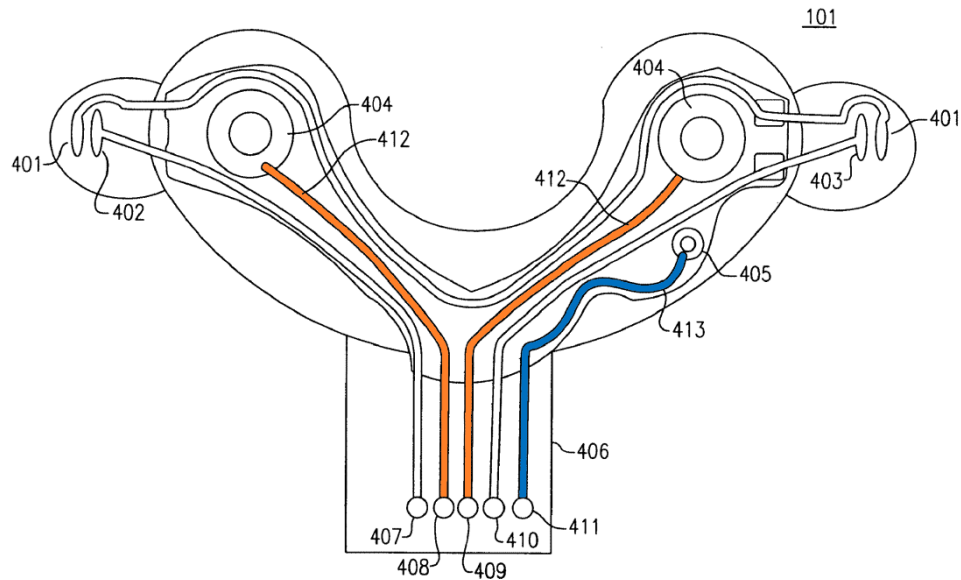
² U.S. Patent No. 4,763,660 to *Kroll* et al. (Ex. 1014).

³ U.S. Patent Publication No. 2005/0096513 to *Ozguz* et al. (“Ex. 1014”).

on numerous grounds. First, the combination does not teach or suggest each element of Claims 1 and 45 for the reasons discussed below in Section VI.A. In Ground 2, *Ozguz* does not remedy the deficiencies of *Matsumura* and *Kroll* discussed below in Section VI.B because *Ozguz* is a non-enabled reference. As such, *Ozguz* cannot be relied on for its teachings, as its disclosure includes technology that was wildly beyond what was possible at the time of the invention of the '007 Patent—2006.

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. 2017, ¶[0045]. The body-worn patient monitoring device includes a computation-communication module 102 that attaches to a disposable electrode module 110. Ex. 1001, Cl. 1, 4:58-5:4, Figure 2; Ex. 2017, ¶[0045]. In Figure 2, a retention clip 104 secures the computation-communication module to the disposable electrode module. Ex. 1001, 4:58-5:4; Ex. 2017, ¶[0045].

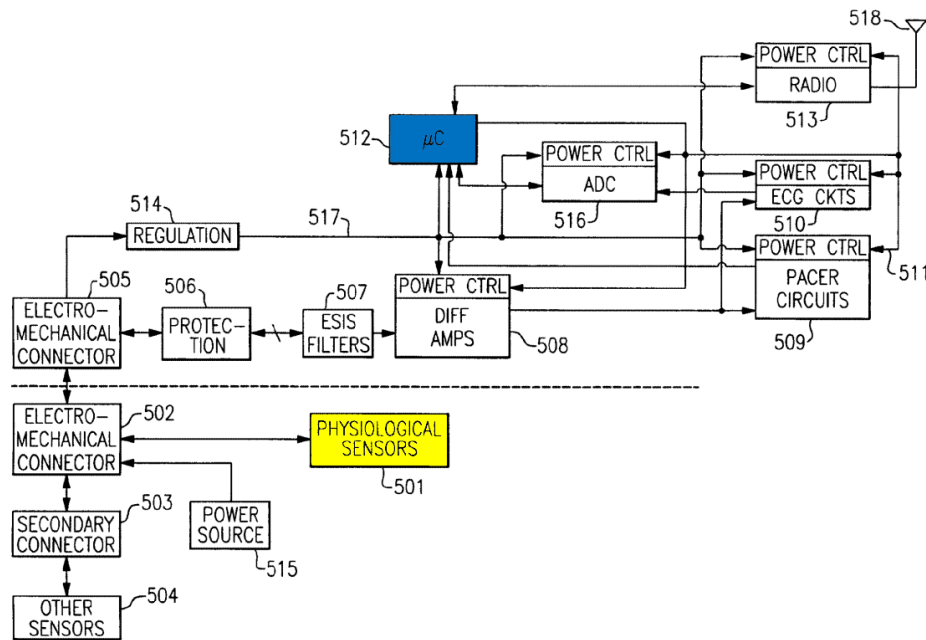


Ex. 1004, Figure 4A (annotated); Ex. 2017, ¶[0046].

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, 7:50-55, Cl. 1; Ex. 2017, ¶[0047]. In an example, the resistance is in the desirable range of “about 1 kilo ohm to about 10 kilo ohms.” Ex. 1001, 7:46-48; Ex. 2017, ¶[0047].

The pathway provided by these resistive traces is also shown in the block diagram of the Figure 5. Ex. 1003, 11:29-46, Figure 5. There, the physiological sensors (*e.g.*, electrodes) for capturing an ECG difference potential are indicated in yellow. Ex. 1003, 11:29-46, Figure 5 (annotated); Ex. 2017, ¶[0048]. The physiological sensors 501 are electrically coupled to an electromechanical connector 502, which is further connected to the processor for performing computational

analysis on the detected signals. Ex. 1003, 11:33-43, Figure 5 (annotated), Figure 4A; Ex. 2017, ¶[0048]. The computation-communication module includes a housing that contains this processor. Ex. 1003, Cl. 7; Ex. 2017, ¶[0048].



Ex. 1003, Figure 5 (annotated); Ex. 2017, ¶[0048].

III. ORIGINAL PROSECUTION OF THE '007 PATENT

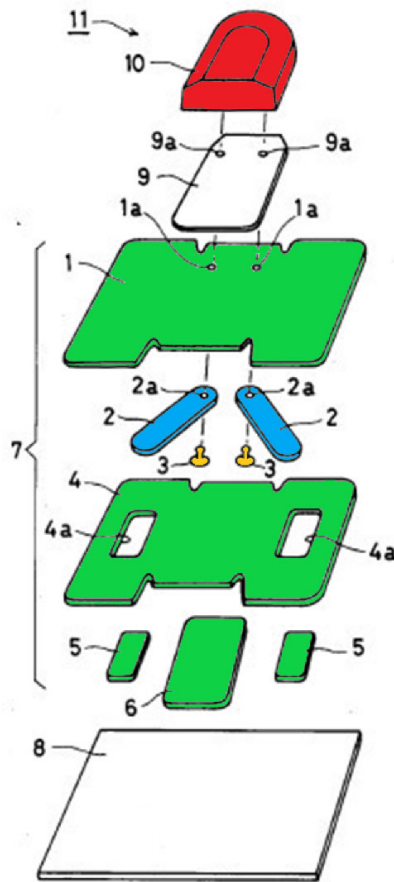
The '007 Patent was filed as U.S. Patent Application No. 11/591,619 and claims priority to application no. 11/591,619, filed on November 1, 2006. Ex. 1001, Cover. During prosecution, the Applicant distinguished the claims over several references and amended each independent claim to include a “series current-limiting resistor configured to protect the communication-computation module.” See Ex. 1002, 134. Further, the Applicant specified that the “series current-limiting resistor

configured to protect the communication-computation module” was in the form of “resistive traces.” *See* Ex. 1002, 134. Ultimately, 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 *Matsumura*

Matsumura describes a waterproof wearable monitor for detecting bioelectric potential, addressing concerns regarding water submersion of the monitor. Ex. 1012, Abstract; Ex. 2017, ¶[0049]. In reference to Figure 1, *Matsumura* provides a bioelectric potential detector 11 comprised of disposable pad 7 (green) and reusable signal processor 10 (red). Ex. 1012, ¶[0016]. Disposable pad 7 further comprises first sheet 1, conductive material 2 (blue), hooks 3 (orange), second sheet 4, conductive gels 5, and double-sided adhesive tape 9. Ex. 1012, ¶[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. 1012, ¶[0019]; Ex. 2017, ¶[0049].



Ex. 1012, Figure 1 (annotated); Ex. 2017, ¶[0049].

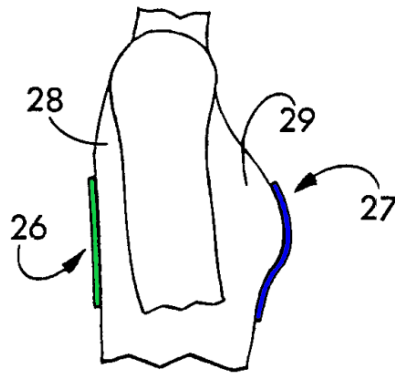
Matsumura explains “two pieces of conductive material 2 and two hooks 3 are arranged to transmit the bioelectric potential detected by the conductive gel 5, which is placed in the openings 4a of the second sheet 4.” Ex. 1012, ¶[0019]. Conductive material 2 is rod-shaped with one end that contacts conductive gel 5 and the other end that “has two holes 2a through which the protruding portions of hook 3 are inserted.” Ex. 1012, ¶[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. 1012, ¶[0019]; Ex. 2017, ¶[0050].

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. 1012, ¶[0019]; Ex. 2017, ¶[0051].

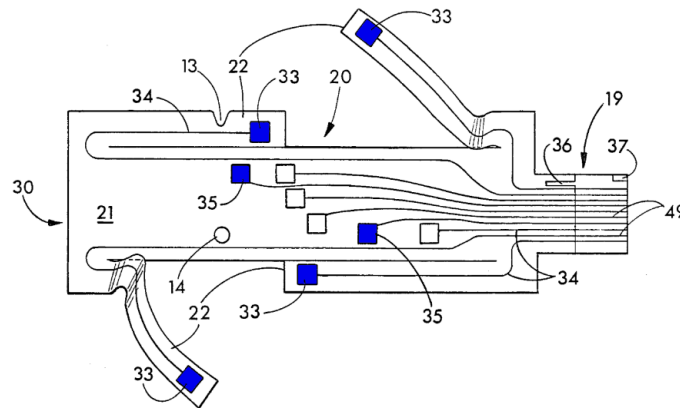
B. Overview of *Kroll*

Kroll provides a disposable electrode belt, which is a therapeutic device “for receiving and transmitting electric current and voltage.” Ex. 2017, ¶[0052]; 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. 2017, ¶[0052]; Ex. 1013, 1:27-36. For example, the device may be placed on the patient’s chest and back to deliver an electrical current through the chest of the patient. Ex. 2017, ¶[0053]; Ex. 1013, 4:44-47, Figure 3 (indicating the chest portion of the disposable electrode belt in blue and the back portion of the belt in green).



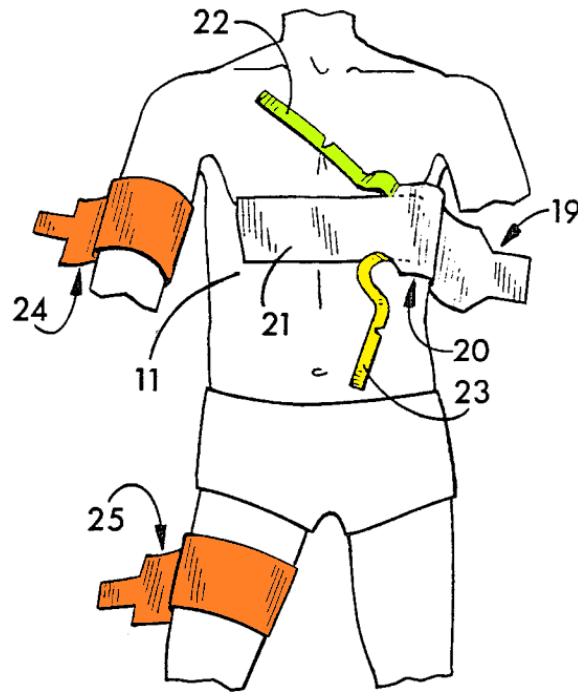
Ex. 1013, Figure 3 (annotated). Ex. 2017, ¶[0056].

Figure 4 shows the electrodes (indicated in blue) of *Kroll's* disposable electrode belt. Ex. 2017, ¶[0054]; Ex. 1013, 4:48-68, Figure 4A (annotated). Each electrode “transmit[s] and receive[s] electric signals” over lead strip 34. Ex. 2017, ¶[0054]; 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. 2017, ¶[0054]; Ex. 1013, 5:4-13. Other than protecting the patient, *Kroll* does not provide any additional functions for its resistive lead strips. Ex. 2017, ¶[0054].



Ex. 1013, Figure 4A (annotated); Ex. 2017, ¶[0054].

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. 2017, ¶[0055]; 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. 2017, ¶[0055]; 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 achieve its therapeutic effects. Ex. 2017, ¶[0055].

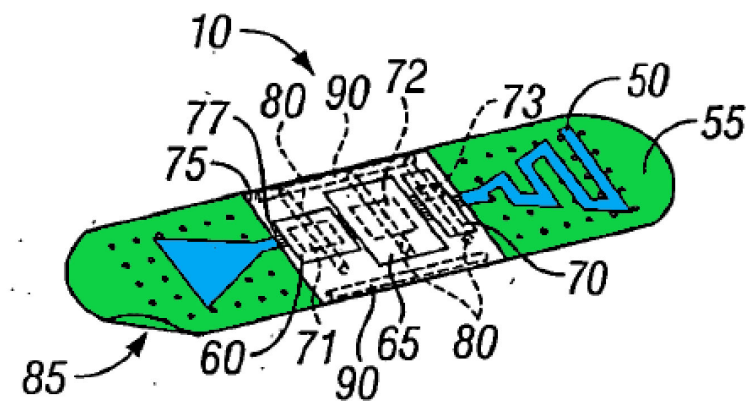


Ex. 1013, Figure 3 (annotated); Ex. 2017, ¶[0055].

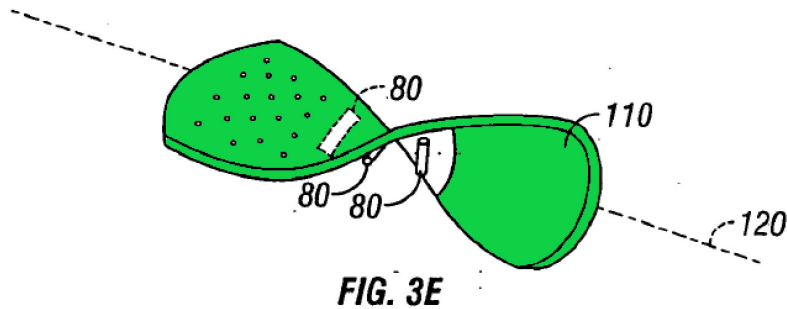
In addition to the extendable side members, *Kroll's* electrode belt relies on a “shielding layer” to safely administer therapeutic shocks. Ex. 2017, ¶[0056]; Ex. 1013, 6:17-24. This shielding layer prevents “interference from the device 10 with other medical diagnostic and therapeutic devices.” Ex. 2017, ¶[0056]; Ex. 1013, 6:17-24. The electrode belt may include more than one shielding layer “to further shield the device from interference.” Ex. 2017, ¶[0056]; 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. 2017, ¶[0056]; Ex. 1013, 7:3-13.

C. Overview of *Ozguz*

Ozguz aspirationally describes a wearable sensor module, or sensor bandage, for monitoring physiological characteristics. Ex. 2017, ¶[0057]; Ex. 1014, ¶[0003]. The alleged module is described as having a “form similar to an adhesive bandage[,]” both in appearance and application to a patient’s skin. Ex. 2017, ¶[0057]; Ex. 1014, ¶[0003], [0007]. *Ozguz* purports to “overcome[] the need for [a] stiff substrate material that is normally used to support thin silicon to prevent breaking of the silicon and destruction of any micro-circuitry thereon.” Ex. 2017, ¶[0057]; Ex. 1014, ¶[0019]. The resulting device is described as a module that is approximately 30 to 60 mm in length and 10 to 20 mm in width, approximately the size of a Band-Aid. Ex. 2017, ¶[0057]; Ex. 1014, ¶[0052].



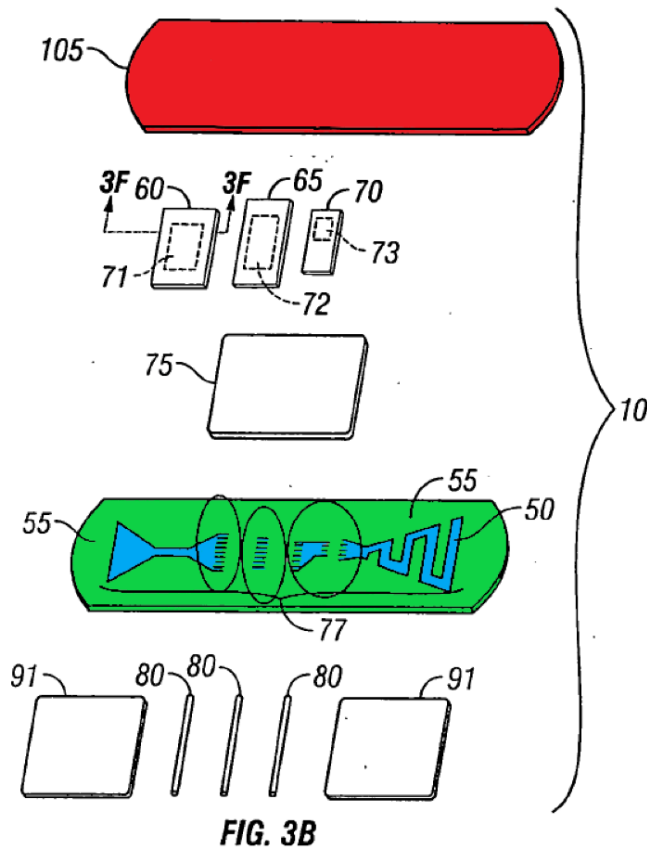
Ex. 1014, Figure 1 (in-part); Ex. 2017, ¶[0057].



Ex. 1014, Figure 3E (annotated); Ex. 2017, ¶[0057].

Ozguz further states that its sensor module is either entirely disposable (*i.e.*, the entire sensor module is discarded) or entirely reusable. Ex. 2017, ¶[0058]; Ex. 1014, ¶[0049] (“The sensor module can be sterilized in an autoclave, for example, between uses. Alternatively, the sensor modules are made disposable and are discarded after monitoring a particular subject body 20 for purposes of good hygiene.”).

Ozguz describes a sensor module including a flexible battery 105. Ex. 1014, ¶[0046]; Ex. 2017, ¶[0059]. The flexible battery 105 is described as laying atop silicon substrates 60, 65, 70 and their respective integrates circuits (“ICs”) 71, 72, 73. Ex. 2017, ¶[0059]; Ex. 1014, ¶[0048]. Additionally, the flexible battery 105 (red) may lay on top of and/or cover the flexible substrate 55 (green) and the metallization 77 (blue). Ex. 2017, ¶[0059]; Ex. 1014, ¶[0048].



Ex. 1014, Figure 3B (annotated); Ex. 2017, ¶[0059].

Further, metallization 77 connects electrodes 80 to the ICs, and the metallization is generally “integral with and forms part of the layer of the flexible substrate.” Ex. 2017, ¶[0060]; Ex. 1014, ¶¶[0047]-[0048]. The described sensor module is a single unit, and none of the components are intended to be detached from the module except for adhesive pads 91. Ex. 2017, ¶[0060]; Ex. 1014, ¶[0049]. Otherwise, the “sensor modules are made disposable and are discarded after monitoring a particular subject body 20.” Ex. 2017, ¶[0060]; Ex. 1014, ¶[0049].

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 “Matsumura, 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, 19 (listing “General Knowledge” in the subheading for Ground 1’s challenge).

The Federal Circuit’s holding in *Qualcomm Inc. v. Apple Inc.*, Nos. 2023-1208, -1209, 2025 WL 1174161 (Fed. Cir. Apr. 23, 2025) is instructive. There, the petitioner provided a chart and expressly listed AAPA (*i.e.*, applicant admitted prior art) for one 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, 2, 4-6, 8, 10-15, 29, 31, 37, 38, and 43-45 are obvious under pre-AIA § 103 over Matsumura, Kroll, and <u>General Knowledge of a POSA</u>
<u>Ground 2</u>	Claims 1, 2, 4, 5, 10, 14, 15, and 43-45 are obvious under pre-AIA § 103 over Matsumura, Kroll, and <u>General Knowledge of a POSA</u> or Matsumura, Kroll, Ozguz, and <u>General Knowledge of a POSA</u>
<u>Ground 3</u>	Claims 32-35 are obvious under pre-AIA § 103 over Matsumura, Ozguz, Kroll, DeLuca, and <u>General Knowledge of a POSA</u>
<u>Ground 4</u>	Claims 2 and 3 are obvious under pre-AIA § 103 over Matsumura, Ozguz, Kroll, Harland, and <u>General Knowledge of a POSA</u>
<u>Ground 5</u>	Claim 39 is obvious under pre-AIA § 103 over Matsumura, Ozguz, 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 a basis for one of the grounds. *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 is instead 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. The Petition’s flaws are exacerbated by its extensive reliance on non-prior art references, as well as significantly outdated and non-relevant references.

i. 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 (P.T.A.B. 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 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 (P.T.A.B. 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, Inc.* 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., 23-24	Ex. 1009, ¶¶483-486
Claim 1(h)/45(f): “microprocessor”	Pet., 27-28, 47-48	Ex. 1009, ¶501
Claim 1(n)/45(l): “traces”	Pet., 33, 49	Ex. 1009, ¶524
Claim 1(l)/45(j): “configured to”	Pet., 31-32, 49	Ex. 1009, ¶515

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*, 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.

In one notable example, and as discussed further below in Section VI.A.i.a.i-ii, the Petition improperly construes the claim term “configured to” because it provides no evidence, support, or argument that “show[] a reasonable likelihood that it would prevail in its challenge asserted as Grounds [1-5].” *See Vicor Corp.*, IPR2024-00704 at 9. *See* Section VI.A.i.a.i-ii. While the Patent Owner and the Board can only speculate based on this failure, the Petition seemingly construes

“configured to” as “capable of.” *See infra* Section VI.A.i.a.i-ii. For this reason alone, the Petition cannot “show[] a reasonable likelihood that it would prevail in its challenge asserted as Grounds [1-5].” *See Vicor Corp.*, IPR2024-00704 at 9.

Moreover, a failure to explain such a 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.i.a.i-ii. In *Acclarent, Inc. 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.*

Besides the Petitioner’s failure to address any case law supporting this 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.i.a.iii. Specifically, at least four separate terms, found in ***all*** independent claims of the '007 Patent (see table below), appear to be improperly 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., 23-24	Ex. 1009, ¶¶483-486
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Claim 1(n)/45(l): "traces"	Pet., 33, 49	Ex. 1009, ¶524
Claim 1(l)/45(j): "configured to"	Pet., 31-32, 49	Ex. 1009, ¶515

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. Here, Dr. Heikenfeld simply alleges, without support in the prior art, that *Kroll's* lead strips "would help to" protect *Matsumura's* device because resistors limit current in both directions. Ex. 1009, ¶¶467-470. 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 (P.T.A.B. Aug. 24, 2022) (precedential) (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 plainly wrong. *See* Section VI.A.i.a.

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 disclosure of the ’007 Patent (although the Petition did not address either). Finally, as set forth in Section VI.A.i.a.iii, the Petition fails to establish that the art renders the claim term obvious even when applying its impermissibly broad construction.

ii. 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, 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 VI.A.i.a.i-ii. Where 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 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.”).

iii. 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” through the use of 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.

As described above, 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. 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 '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, or the problems facing a POSA, 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). For example, 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.

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.

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 *Matsumura*, *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 or Claim 45, including: (a) a resistor "configured to protect the communication-computation module," (b) the power source, (c) the current-limiting resistor, (d) the current-limiting resistor being screened onto a flexible substrate, and (e) the current-limiting resistor being in the form of resistive traces. Further, the Petition does not address the language of "upon determination of the predetermined event" in its analysis.

Ground 1 also fails because the Petition does not establish a motivation to combine *Matsumura* and *Kroll*. As such, the Petition does not have a reasonable likelihood of prevailing on Ground 1. Finally, fatal to the Petition's arguments is that Petitioner has not established that *Matsumura* (Ex. 1012) is an accurate

translation reflecting the Japanese language version (Ex. 1065) or, therefore, that Ex. 1012 is actually prior art. As a result, the Board should not rely on Exhibit 1012, fatal to all grounds of the Petition.

A. Ground 1 Fails to Render Obvious the Challenged Claims

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

The non-obvious combination of *Matsumura* and *Kroll* fails to render obvious several elements of Claims 1 and 45, including the power source, the current-limiting resistor “configured to protect the communication-computation module,” and the current-limiting resistor being screen printed and in the form of resistive traces. In an attempt to teach certain of these elements, 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.

First, both *Matsumura* and *Kroll* are silent with regard to any power source in their devices. Second, *Matsumura*’s device does not include a current-limiting resistor, much less a current-limiting resistor in the form of resistive traces that are screened on a flexible substrate, and *Kroll* fails to remedy this deficiency.

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

The Petition does not rely on *Matsumura* for the claimed resistor, only *Kroll*. Petition, 31-32. However, Neither *Matsumura* nor *Kroll* disclose a resistor “configured to *protect the communication-computation module*,” and the Petition fails to render this element obvious. Ex. 1001, Cl. 1; Petition, 31-32.

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, Claims 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 the Petition therefore fails in entirety. 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., v. Ford Albritton, IV*, IPR2017-00498, Paper 40 at 13 (P.T.A.B. July 9, 2018) (citing *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d. 1335, 1349 (Fed. Cir. 2012)). The Board has recognized 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, Inc. et al v. Ford Albritton*, IPR2017-00498, Paper 40 at 11 (P.T.A.B. July 9, 2018). 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” connotes 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 completely 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 at 31-32.

- 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. 2017, ¶¶[0072]-[0073]; 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 “in the event of a patient being defibrillated.” *See* Petition, 31 (“[A] POSA would have known that the “resistive trace” of Kroll on a flexible, wearable medium **would ensure** the viability of Matsumura’s communication-computation module on a flexible printed medium in the event of a patient being defibrillated.”).

In interpreting “configured to” as merely “capable of,” the Petition cuts against this settled law without making any argument as to the sufficiency of this interpretation. *See* Petition, 31-32. These cases are a death knell to the Petition and are unaddressed.

In addition to the case law, which the Petition did not analyze, the disclosure of the ’007 Patent 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. 2017, ¶[0069]. 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. 2017, ¶[0069]; 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. 2017, ¶[0069]; Ex. 1001, 7:48-58. Additionally, the ’007 Patent provides a detailed analysis regarding the structure, requirements, and issues in designing its resistor over several columns of disclosure. Ex. 2017, ¶[0069]; *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, the “configured to” is properly construed using the narrower meaning of “design to” or “made to.” Applying this proper constructing, the conclusion logically follows. The Petition’s proposed combination of *Matsumura* and *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. For this reason, the analysis ends here, and each of Grounds 1-5 should be denied.

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 *Matsumura*’s electronics simply because, based on Dr. Heikenfeld’s alleged theories, resistors limit current flow

bidirectionally. Petition, 31; *see* Ex. 1009, ¶514. The Petition's maze of cross-nested citations does not provide any explanation on why *Kroll's* lead strips **would** protect *Matsumura'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 *Matsumura's* electronics. *Infra* Section VI.B.ii.e. The Petition did not address any of these design considerations.

Instead, to support its position, the Petitioner first points to its motivation to combine *Matsumura* and *Kroll* arguments. *See* Petition, 31. Specifically, the Petition cites to its motivation to combine section, Section VII.A.1, and to Dr. Heikenfeld for the same conclusion. *See* Petition, 17 (“To help protect patients from potential shock, ensure the long-term viability of *Matsumura's* reusable module against potential defibrillation, and reduce the size of *Matsumura's* device, a POSA would have been motivated to incorporate *Kroll's* teaching of resistive “lead strips” to protect the circuitry in *Matsumura*.”) (citing Ex. 1009, ¶¶467-470). Dr. Heikenfeld repeats the same conclusion and cites to a non-prior art reference (Ex. 1035). *See* Ex. 1009, ¶468. The Petition fails to acknowledge that modifying *Matsumura* to include *Kroll's* printed lead strips render *Matsumura* inoperable for

its intended purposes, as *Matsumura* cannot plausibly be modified to have printed electronics. See Section VI.A.ii.

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 *Matsumura's* electronics.

b. Ground 1 fails to render obvious the power source

Each independent claim, Claims 1 and 45, require a power source. Because *Matsumura* does not itself teach or suggest a power source for *Matsumura's* device, the Petition fails to render claim element 1[e] obvious. 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. 1012, ¶[0004]. *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. 1012, ¶[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. 1012, ¶[0012] (“the 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. 2017, ¶[0076]. 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, it relies on expert testimony to teach an element that is not actually disclosed in *Matsumura*.

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

The Petition fails to establish that a POSA would 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. *See* Petition, 19-20. 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* and would actually

frustrate *Matsumura's* goal of waterproofing. Second, “reducing the size of *Matsumura's* device” likewise fails to provide a motivation to otherwise modify *Matsumura* to include the specifically claimed resistors. Petition, 20. *Matsumura* already achieves its size goals. 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) (“Conclusory expert testimony does not qualify as substantial evidence.”). Accordingly, the Petition fails to establish a motivation to combine and thus cannot render obvious any of the Challenged Claims in Ground 1.

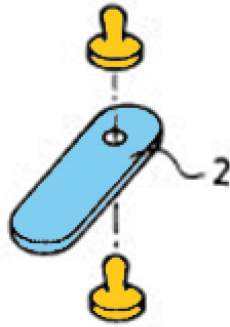
a. A POSA Would Not Have Been Motivated to Modify
Matsumura's Conductive Rods and Hooks with Screen
Printed Resistors

Atop admitting that *Matsumura* fails to teach or suggest the claimed resistors (*see* Section), *Matsumura*, in fact, affirmatively ***requires*** teachings that are at odds with the claimed invention.

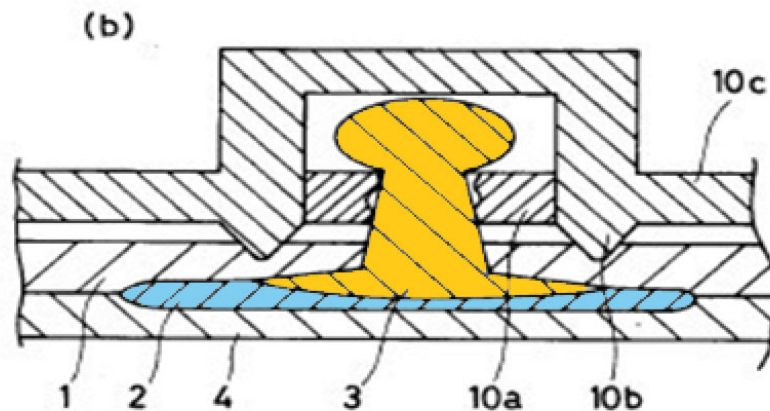
Matsumura is clear that its bioelectrode pad comprises “conductive material 2,” conductive “hook 3,” and “conductive gel 5.” Ex. 1012, ¶[0016]. These conductive materials are essential to the operation of *Matsumura's* waterproof design. *See, e.g.,* Ex. 1012, ¶[0006] (“In order to enable hospitalized or home-bound patients/subjects to measure electrocardiograms while showering or bathing, a

waterproof bioelectric potential detector is first required. [And] [t]he present invention was made in order to achieve these objectives.”).

In this regard, *Matsumura*’s processor and housing are located separate and apart from the bioelectric pad. Ex. 1012, ¶[0016], Figures 1-2. To accomplish the waterproof design, there must be a vertical conductive protrusion that allows for the electrical flow of signals from the bio-pad to the processor. Ex. 1012, ¶¶[0024], [0027], Figures 4-5; Ex. 2017, ¶[0081]. It is clear from Figures 4 and 5 that to provide this waterproof design, the rigid nature of conductive rods 2 provides a stable support for hook 3 to clamp. Ex. 2017, ¶[0081]; Ex. 1012, ¶¶[0019], [0021], Figures 4-5. Specifically, “the protruding portions of the hook 3” extend upwards “from the back side of the conductive material 2,” clamping both sides of conductive rod 2. Ex. 2017, ¶[0081]; Ex. 1012, ¶[0021], Figures 4(b) (annotated), 8 (annotated). The organization of these components was not by accident but rather provides the electro-mechanical connection essential to *Matsumura*’s device. Ex. 2017, ¶[0081]; Ex. 1012, ¶[0019].



Ex. 1012, Figure 8 (annotated); Ex. 2017, ¶[0081].



Ex. 1012, Figure 4(b) (annotated); Ex. 2017, ¶[0081].

In the face of *Matsumura*'s express teachings, the Petition proposes adding screen printed resistive traces to “*Matsumura*'s flexible substrate [that] includes electrical connections (*i.e.*, traces)” for no other reason than to reach the claims. Ex. 2017, ¶[0082]; Petition, 32. For example, the Petitioner and Dr. Heikenfeld both conveniently (for Petitioner) bypass the fact that *Matsumura* includes non-printed circuitry. Instead, Dr. Heikenfeld alleges that “[a] POSA would understand Kroll's disclosure of ‘lead strips’ as referring to a ‘trace’ as recited by the '007 patent” and

that “the terms ‘lead’ and ‘trace’ are often used interchangeably.” Ex. 1009, ¶524 (citing Ex. 1035 at 642).

Petitioner’s own concessions regarding the understanding of a POSA severely undermine its argument that the printed circuitry of *Kroll* would reasonably be combined with the definitively non-printed circuitry of *Matsumura*. Ex. 2017, ¶[0083]. *Matsumura*’s electrical connections are three-dimensional conductive rods and hooks. Ex. 1012, ¶[0019]. Nothing in *Matsumura* suggests the replacement of these rigid conductive rods and hooks or their compatibility with *Kroll*’s screen printed resistive traces, nor how *Matsumura*’s waterproof goals would be accomplished without the structural support from the conductive rods. Ex. 2017, ¶[0084].

Instead, the Petition and its expert simply allege that “[i]t therefore would have been obvious to a POSA to combine *Matsumura*’s teaching of a communication-computation module on a flexible printed medium with *Kroll*’s teaching of resistive traces on flexible printed mediums.” Petition, 33. This is nothing more than hindsight driven efforts to arrive at the claim. Ultimately, Petitioner’s challenge amounts to nothing more than “different technology was independently known.” This fails. *See Virtek Vision Int’l ULC v. Assembly Guidance Sys. Inc.*, 97 F.4th 882, 888 (Fed. Cir. 2024) (explaining arguments

“grounded in the fact that the claim elements are known in the prior art” without more “does not show a motivation to combine” (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.”))).

In support of this substantial modification, Dr. Heikenfeld provides no explanation or support for *why* a POSA would have been motivated to modify *Matsumura* to include printed resistors, and simply concludes that “it would have been obvious to a POSA to combine Matsumura’s teaching of a communication-computation module on a flexible printed medium with Kroll’s teaching of resistive traces on a flexible printed medium.” Ex. 1009, ¶783. Without the “*why*,” Dr. Heikenfeld’s opinion, and the Petitioner’s arguments are fatally deficient. The PTAB has long held that conclusory expert testimony is to be given little weight. *See TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1358-59 (Fed. Cir. 2021); *Virtek Vision*, 97 F.4th at 889 (characterizing expert’s testimony as conclusory where expert argued a POSA “would have known to use a camera with a multi megapixel sensor” without “address[ing] why or whether a skilled artisan would have been motivated” to do so).

b. Petitioner’s Proposed Modification to Add the Printed Resistive Traces Would Frustrate *Matsumura*’s Goal of a Waterproof Device

Petitioner ignores that *Matsumura*’s electronics are three-dimensional, non-printed, protruding conductive materials (*i.e.*, conductive material 2 and hooks 3). Instead, the Petition characterizes *Matsumura* as including a “flexible substrate [that] includes electrical connections (*i.e.*, traces).” Petition, 32. Because of Petitioner’s misrepresentation of *Matsumura*’s electronics, the Petition alleges that because *Kroll* discloses a “conductive ink compound” that comprises its resistive trace is applied to a base layer “by means of a silk screen process[,]” “It therefore would have been obvious to a POSA to combine *Matsumura*’s teaching of a communication-computation module on a flexible printed medium with *Kroll*’s teaching of resistive traces screened on a flexible, wearable medium, which would meet this limitation.” Petition, 32 (citing Ex. 1009, ¶¶517-520).

However, *Matsumura*’s conductive rods 2 and hooks 3 necessarily do not comprise printed traces, and Petitioner’s apparent assumption—or additional instances of improper claim construction (*see supra* Section V)—appears to consider *Matsumura*’s circuitry as printed and therefore easy to combine with *Kroll*’s printed electronics. Petition, 32. This modification, however, would directly undermine the

waterproof functionality central to *Matsumura's* device. Ex. 2017, ¶¶[0085]-[0087].

Matsumura discloses:

By using the structure described above, the housing of the signal processor 10, the part that transmits bioelectric potential from the bioelectrode pad 7 to the signal processor 10, i.e. engagement portion between the protruding part of the hook 3 and the hook engagement portion 10a is waterproofed, thus the entire bioelectric potential detector 11 is waterproofed.

Ex. 1012, ¶[0027]. A POSA would not have been motivated to replace the conductive rods 2, to which the hook “clamps” onto both sides, with printed circuitry. Ex. 2017, ¶[0087]; Ex. 1012, ¶[0021]. This is because the POSA would have known that the hooks are necessary for waterproofing “the entire bioelectric potential detector” as described above. Ex. 2017, ¶[0087]; Ex. 1012, ¶¶[0027]-[0030]. The Petition is silent with regard to the device being waterproof and fails to recognize or address the hooks’ electrical and mechanical role altogether. Ex. 2017, ¶¶[0086]-[0087]. For these same reasons, and because *Matsumura's* device has achieved its desired dimensions, a POSA would not have been motivated to reduce *Matsumura's* size in view of the much larger device disclosed in *Kroll*. Ex. 2017, ¶[0087].

It is clear that to arrive at the Challenged Claims, the Petitioner uses Claim 1 as a guide to modify *Matsumura*, seemingly removing its conductive rods and conductive protruding hooks and replacing the same with *Kroll's* printed resistors.

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

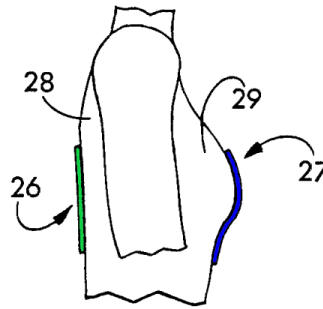
c. A POSA Would Not Have Been Motivated by *Kroll* to
Reduce the Size of *Matsumura*'s Device

Replacing *Matsumura*'s conductive rods and conductive hooks with printed electronics destroys the electro-mechanical structure of *Matsumura* necessary for the device to function as intended. For this element, the Petition identifies *Matsumura*'s modified conductive material 2 and hooks 3 that can purportedly be combined with *Kroll*'s "printed (ink) electrical traces." Petition, 23 (citing Section V.II.A.2.ii of Petition). The Petition relies on *Kroll*'s "printed ink leads" to further modify *Matsumura*, arguing that "a POSA would have understood [ink lead strips] as traces made in least in part of resistive material." Petition, 23-24 (citing Ex. 1013, 5:4-13; Ex. 1009, ¶¶798, 803). The proposed combinations ((1) *Matsumura* in view of the "general knowledge" of a POSA to obtain a printed circuit layer, and (2) *Matsumura* in view of *Kroll* to further modify the printed circuit layer to be made of resistive ink) are two critical steps removed from *Matsumura*'s device, and a POSA would not have been motivated to make these modifications. Ex. 2017, ¶¶[0088]-[0089], [0094].

Even if a POSA would be motivated to replace Matsumura's conductive material 2 with a printed insulating sheet and replace hooks 3 to be a printed resistive trace, *Matsumura* is explicit that “**conductive** material 2” and hooks 3 are indeed conductive—not resistive. Ex. 1012, ¶¶[0019]-[0021]; Ex. 2017, ¶[0095]. Although all conductive materials (indeed, all materials generally) have some resistance, this does not mean that conductors and resistors are interchangeable or functionally equivalent. Ex. 2017, ¶[0095]. *Matsumura* specifically discloses two options for the makeup of conductive material 2, both requiring conductive material 2 to be entirely covered in a conductive material, and neither option resulting in a predominantly resistive material, let alone a resistive lead strip. Ex. 2017, ¶[0095]; Ex. 1012, [0020] (“The conductive material 2 can be a carbon sheet or a PET sheet coated with conductive Ag/AgCl.”).

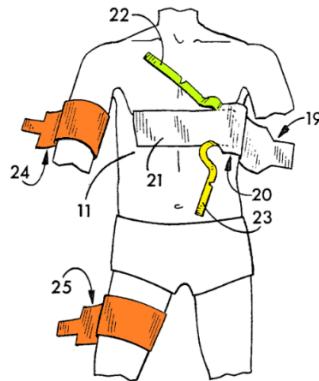
Further, *Kroll* provides a device that wraps around the patient's body to administer therapeutic shocks. Ex. 2017, ¶[0103]. Specifically, *Kroll* provides an “electrode belt...for receiving and transmitting electric current or voltage for use on the body of a patient.” Ex. 2017, ¶[0103]; Ex. 1013, Abstract, Figure 1. Such electrical current may be transmitted “to specific anatomical locations for therapeutic purposes.” Ex. 2017, ¶[0103]; Ex. 1013, 1:27-36. In one example, *Kroll's* electrode belt is placed on the patient's chest and back. Ex. 2017, ¶[0104];

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. 2017, ¶[0104]; Ex. 1013, 4:44-47, Figure 3.



Ex. 1013, Figure 3 (annotated); Ex. 2017, ¶[0104].

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. 2017, ¶[0105]; Ex. 1013, 4:37-47, Figure 2 (indicating side members in yellow). *Kroll's* electrode belt may also be placed around the patient's limbs. Ex. 2017, ¶[0105]; Ex. 1013, 4:37-47, Figure 2 (indicating embodiments placed around the limbs in orange).



Ex. 1013, Figure 3 (annotated); Ex. 2017, ¶[0105].

Contrary to the Petition arguments, a POSA would not have looked to any embodiments of *Kroll's* therapeutic electrode belt to “reduce the size of Matsumura’s monitoring device.” Ex. 2017, ¶[0106]; Petition, 19. This is especially true for *Kroll's* lead strips. Ex. 2017, ¶[0106]; see Petition, 19 (arguing that a POSA would use *Kroll's* lead strips to reduce the size of *Matsumura's* device). *Kroll's* lead strips are used on the “extendable side members,” which are specifically designed to make the electrode belt **larger**. Ex. 2017, ¶[0106]; Ex. 1013, 4:37-47. The extendable side members are used for placement outside of the precordial region. Ex. 2017, ¶[0106]; Ex. 1013, 4:37-47. Based on this disclosure, a POSA would not have been motivated to make *Matsumura* smaller by adding *Kroll's* traces. Ex. 2017, ¶[0107].

It is clear that to arrive at the Challenged Claims, the Petitioner uses Claim 1 as a guide to modify *Matsumura*, removing its conductive rods and conductive

protruding hooks and replacing the same with *Kroll's* insulating material and printed ink traces, respectively. This is blatant hindsight reconstruction. In view of the actual teachings of *Matsumura* and *Kroll*, it becomes clear that a POSA would not have been motivated to make this modification, and the Petition offers these modifications solely to reconstruct the Challenged Claims.

d. A POSA Would Not Have Been Motivated by *Kroll* to Add Resistive Strips to Protect the Patient

The Petition's suggestion to incorporate *Kroll's* resistive ink strips into *Matsumura's* design does not arise from the teachings of either reference. Ex. 2017, ¶¶[0095]-[0101]. *Kroll's* ink lead strips are intended for different purposes—to protect the patient (*i.e.*, current from the device to the patient). Ex. 2017, ¶¶[0110]-[0113]. There is no motivation provided to suggest that these resistive materials would enhance *Matsumura's* waterproofing or bioelectric signal transmission, and the Petition fails to establish any compelling reason why a POSA would seek to replace *Matsumura's* conductive material with resistive lead strips. Ex. 2017, ¶[0115]. 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 *Matsumura* or contemplated in the proposed combination.

Moreover, the combination of *Matsumura* and *Kroll* is two steps removed from the original invention and is artificially constructed to mirror the Challenged Claims. The Petition first assumes that a POSA would be motivated to modify *Matsumura*'s conductive material 2 and conductive hook 3 into an insulating sheet and printed traces, respectively, and then alter them further with resistive ink—a combination of modifications that is not naturally suggested by either reference. Ex. 2017, ¶¶[0094]-[0095].

Additionally, as discussed above in Section VI.A.ii.c, *Matsumura* itself is explicit about the conductive nature of its materials, specifically stating that the conductive materials are either carbon or PET with conductive coatings like Ag/AgCl. Ex. 2017, ¶[0095]; Ex. 1012, ¶[0020]. There is no suggestion in *Matsumura* that the conductive rods should or could be replaced with resistive ink, nor does the reference provide any indication that resistive materials would function equivalently in this context. Ex. 2017, ¶[0095]. Thus, any proposed modification based on *Kroll*'s resistive ink strips would contradict *Matsumura*'s explicit teachings. Ex. 2017, ¶[0095]; *supra* Section VI.A.ii.c.

The Petition's reliance on *Kroll* to suggest a modification to *Matsumura* is not only unmotivated but also illogical. The two-step modification (first, replacing conductive material with printed conductive material and second, modifying that

material to include resistive properties) is unsupported by the references and is purely hindsight reconstruction. Ex. 2017, ¶[0094]. This is particularly glaring given that the Petition improperly injects a motivation add *Kroll*'s resistive strips to replace “conventional resistors in [*Matsumura*'s] signal processor” even though *Matsumura* does not teach or suggest, in any way, that it relies on conventional resistors in its signal processor. Ex. 2017, ¶¶[0096]-[0101]. 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” further with *Kroll*'s resistive ink strips, as doing so would undermine the device's core functionality and mechanical structure. Ex.

2017, ¶¶[0107]-[0108]. Therefore, the Petition’s proposed modification fails to render the Challenged Claims obvious. Ex. 2017, ¶[0108].

- e. 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. 2017, ¶[0110]; Petition, 17-18; Ex. 1013, 5:8-13. In contrast, *Matsumura* provides a “compact” biopotential detector that is worn on the patient’s chest. Ex. 2017, ¶[0118]; Ex. 1012, ¶¶[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. 2017, ¶[0118].

Neither the Petition nor Dr. Heikenfeld address any of the design variables below, which are critical to the function of the resistor. Ex. 2017, ¶[0118].

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. 2017, ¶[0119].

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. 2017, ¶[0120].

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. 2017, ¶[0121]. This analysis requires an understanding of detailed aspects related to transient response, resistance change and variability, and safety margins. Ex. 2017, ¶[0121].

Fourth, a POSA would have to design contact pads to reduce arcing. Ex. 2017, ¶[0122]. This design and solution is crucial when implementing resistors in small devices, as the Petition attempts to do so here. Ex. 2017, ¶[0122].

Fifth, a POSA would have to manage the space between traces to minimize arcing potential. Ex. 2017, ¶[0123]. Again, a POSA would recognize this as a key consideration in implementing traces on a small device. Ex. 2017, ¶[0123]. Further, a POSA would have to develop insulative dielectric coating methods to reduce spacing requirements significantly. Ex. 2017, ¶[0123].

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. 2017, ¶[0124].

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. 2017, ¶[0125]. 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. 2017, ¶[0126].

iii. Matsumura Fails Under Rule 42.63(b)

Each of the grounds presented in the Petition rely on *Matsumura*, which has not been established to be prior art. Specifically, the Petition is procedurally defective because Petitioner failed to establish that the alleged translation for *Matsumura* (Ex. 1012) is accurate or reflects the Japanese version (Ex. 1065). The Board should not rely on Exhibit 1012 as it has not been established to be prior art and Grounds 1-5 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 1066 is a certified translation of the document submitted as Exhibit 1065 (the Japanese Pat. Pub. JP2004/121360 to *Matsumura*), (*see* Petition, viii), Exhibit 1066 does not identify or even refer to the document submitted as Exhibit 1065, nor does Exhibit 1066 identify or refer to the purported English language version of *Matsumura* submitted as Exhibit 1012. 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. 1066. Petitioner did not submit in this proceeding any document that is titled or referred to as “403-45924_JP2004121360A_JA.” There is nothing in Exhibit 1066 that links the certification to *Matsumura* (either the Japanese language version (Ex. 1065) or the English language version (Ex. 1012)). *See* Exs. 1001-1065.

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 1-5 should be denied.

iv. The Non-Obvious Combination of *Matsumura*, *Kroll*, and the “General Knowledge” of the POSA Fails to Render Obvious Claim 45

As described above with respect to Claim 1, the Petition fails to render obvious Claim 45. *Supra* VI.A.i-iii; Ex. 2017, ¶¶[0062]-[0065].

B. Ground 2 Fails to Render Obvious the Challenged Claims

The Petition fails to establish a reasonable likelihood of success on a single claim. As an initial matter, Ground 2 is facially duplicative of Ground 1. *See* Petition, 49 (setting forth Ground 2 as certain claims being “obvious over *Matsumura*, *Kroll*, and General Knowledge of a POSA”).⁴ The proposed combination of *Matsumura*, *Kroll*, *Ozguz*, and the so-called “general knowledge” of the POSA fails on numerous grounds. First, the combination does not teach or suggest each element of Claims 1 or 45 for the reasons discussed above in Section VI.A. For many elements, the Petition does nothing more than point back to the

⁴ While the Petition appears to have a two-part ground, it is unclear from the Petition which of the two theories separated by an “or” are the actual challenge of Ground 2.

analysis for Ground 1. Petition at 52-55. The Petition does not rely on *Ozguz* at all for claim element 1(l), the “configured to” element addressed above. For element 1(e), the Petition provides nothing more than conclusory statements regarding the alleged power source (despite relying on a pie-in-the-sky disclosure regarding a thin flexible battery of *Ozguz*).

Moreover, *Ozguz* does not remedy the deficiencies of *Matsumura* and *Kroll* discussed above because *Ozguz* is a non-enabled reference. As such, *Ozguz* cannot be relied on for its teachings, as its disclosure includes technology that was wildly beyond what was possible at the time of the invention—2006.

Ground 2 also fails because the Petition does not establish a motivation to combine *Matsumura*, *Kroll*, and *Ozguz*. As such, the Petition does not have a reasonable likelihood of prevailing on Ground 2. Grounds 3-5 simply challenge certain dependent claims using the base of Ground 2 and fail to provide any independent argument for the independent Claims of addressed with respect to Ground 2.⁵ The entirety of each of Grounds 3-5 should be similarly rejected.

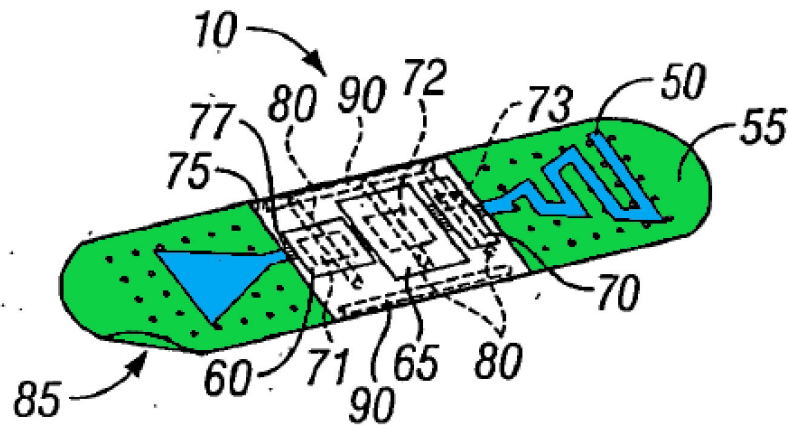
⁵ Ground 3 challenged Claims 32 to 35; Ground 4 challenges Claims 2 and 3; and Ground 5 challenges Claim 39. Petition, 1-2. Each of Claims 2, 3, 32-35, and 39 depend from independent Claim 1. *See* Ex. 1001, Cls. 1-39.

i. The Petition Fails to Establish a Motivation to Combine *Matsumura*, *Ozguz*, and *Kroll*

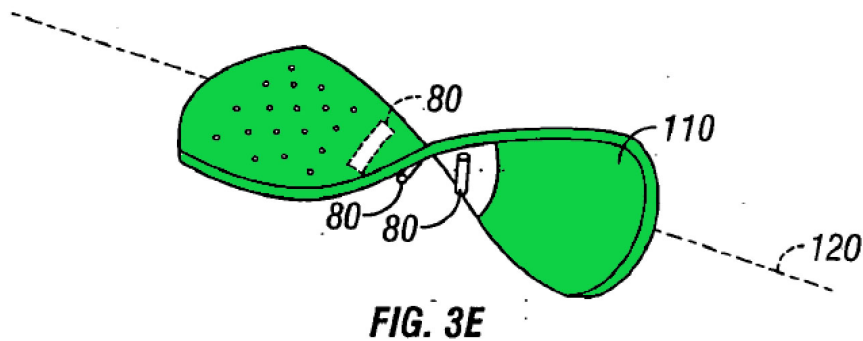
The Petition fails to establish that a POSA would have been motivated to modify *Matsumura* based on either *Kroll* or *Ozguz*. Ex. 2017, ¶[0128]. In reality, a POSA would have actively avoided looking to *Ozguz* to combine with references like *Matsumura* and *Kroll* because *Ozguz* teaches away from the Petition’s proposed combination and completely refutes the Petition’s purported reasons for combining the references. Ex. 2017, ¶[0129]. Specifically, Petitioner and Dr. Heikenfeld allege that “[a] POSA combining these teachings of *Matsumura*, *Ozguz*, and *Kroll* would have had a reasonable expectation of success in doing so because it would involve using well known *screen-printing techniques for printed circuit board manufacture*.” Petition, 51 (citing Ex. 1009, ¶635). Contrary to Petitioner’s assertion, *Ozguz* specifically teaches away from using printed circuit board materials. Ex. 2017, ¶[0129]. In particular, *Ozguz* states:

Use of rigid circuitry is due to the rigid nature of conventional microcircuit materials such as silicon and printed circuit board materials. The result is that the circuitry is inflexible, if not bulky, and is *unsuitable for comfortably adhering and conforming to a localized portion of a human body*.

Ex. 1014, ¶[0004]; Ex. 2017, ¶[0129]. *Ozguz*’s specification corroborates this. *Ozguz* is entirely devoted to describing a thin, flexible monitor as thin as a bandage:



Ex. 1014, Figure 1 (in-part); Ex. 2017, ¶[0130].



Ex. 1014, Figure 3E (annotated); Ex. 2017, ¶[0130].

Moreover, the Petition admits that *Matsumura* does not disclose “a specific circuit design or architecture to perform” functions including using a wireless transmitted to detect, process, and wirelessly transmit bioelectric signals. Petition, 50. For several reasons, a POSA would not have looked to *Ozguz* “to incorporate the specific design and structure of circuits and electronic components taught by *Ozguz*.” Petition, 50; Ex. 2017, ¶¶[0131]-[0132]. First, *Ozguz* includes printed electronic traces, and as discussed above in Section VI.A, a POSA would

unequivocally not have been motivated to replace *Matsumura*'s conductive rods and hooks with printed circuitry. *See supra* Section VI.A.ii; Ex. 2017, ¶[0133].

Second, when considered in combination with *Matsumura* and *Kroll*, *Ozguz* provides no motivation for a POSA to combine these references in a way that would lead to the claimed invention. *Ozguz*'s concepts, as discussed further below, are speculative and futuristic, lacking the practical enablement required for a POSA to build upon them in a meaningful way. The combination of *Matsumura*'s rigid conductive rods and hooks with *Ozguz*'s speculative flexible technology is not suggested by any of the cited references. Ex. 2017, ¶¶[0133]-[0134]. A POSA would not have been motivated to replace *Matsumura*'s rigid, waterproof components with speculative, non-enabling flexible electronics as proposed by *Ozguz*. Ex. 2017, ¶[0134]; *infra* Section VI.B.ii.

Similarly, integrating *Kroll*'s resistive traces with the teachings of *Ozguz* would not be a logical step for a POSA, as *Ozguz*'s reference does not provide practical details on integrating such technologies in a biomonitor device. Ex. 2017, ¶[0135]. The challenges associated with flexible power systems, wireless communication, and environmental protection make any combination with *Matsumura* and *Kroll* unworkable. Ex. 2017, ¶[0135]. Thus, the combination of

these references lacks the motivation necessary to support an obviousness rejection. Ex. 2017, ¶[0135].

ii. *Ozguz is non-enabling for obviousness*

Ozguz discloses speculative and unrealistic features that were not achievable at the time of the invention. Ex. 2017, ¶[0136]. There are several critical technical and practical barriers that prevent *Ozguz* from being an enabling reference at the time of its publication, making it an unsuitable basis for an obviousness rejection. Ex. 2017, ¶[0137]. As a result, a POSA would not have been motivated to modify *Ozguz* to reach the Challenged Claims with a reasonable expectation of success. *See In re Stepan Co.*, 868 F.3d 1342, 1345-46 (Fed. Cir. 2017) (“An obviousness determination requires finding both ‘that a skilled artisan would have been motivated to combine the teachings of the prior art ... and that the skilled artisan would have had a reasonable expectation of success in doing so.’” (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367-68 (Fed. Cir. 2016))); Ex. 2017, ¶[0137].

- a. A POSA would not have relied on *Ozguz* to reach the challenged claims

Ozguz describes the use of futuristic flexible batteries as part of the device. Ex. 1014, ¶[0048]. However, at the time of the invention, flexible batteries were not viable or commercially available in the form described in *Ozguz*. Ex. 2017, ¶[0136].

While the concept of flexible batteries may have been proposed or theoretically envisioned, the technology to implement such a feature in a real-world, working device was still in its infancy, and its commercial availability was far from practical. Ex. 2017, ¶[0137]. A POSA, relying on the state of the art at the time of the invention, would not have considered it possible to use a flexible battery as described in the reference. Ex. 2017, ¶[0137].

Ozguz suggests the use of integrated flexible batteries to power the biomonitor. *See, e.g.*, Ex. 1014, ¶[0019]. However, at the time of the invention, flexible batteries were not capable of supporting extended use without frequent recharging or replacement. Ex. 2017, ¶[0138]. The reference oversimplifies the real-world constraints on battery capacity, longevity, and energy efficiency, overlooking the fact that flexible battery technologies at that time were not sufficiently advanced to support the sustained, low-power requirements of continuous physiological monitoring. Ex. 2017, ¶[0138]. These batteries lacked the reliability and durability needed to power such a device over extended periods, and in the context of a patient wearable medical device where patient safety is of the utmost importance, a flexible battery would not have been considered a suitable option. Ex. 2017, ¶[0138]. Importantly, the miniature size and layered structure of *Ozguz*'s device would significantly increase the risk of thermal overheating in the

flexible battery, making the design impractical for real-world use. Ex. 2017, ¶[0138].

Further, a POSA, understanding the technological and economic landscape at the time of the invention, would have recognized that incorporating a flexible battery as described in *Ozguz* would be inconsistent with the cost-effective solution sought by the inventors of the '007 Patent. Ex. 1007, 1:50-52; Ex. 2017, ¶[0139].

Importantly, the use of flexible batteries for a patient wearable device, particularly one designed for continuous monitoring, would have faced significant challenges regarding user comfort and practicality. A wearable device would need to offer long-term battery life, ideally without frequent recharging or the discomfort of bulky or frequently replaced batteries. Ex. 2017, ¶[0140]. In the context of a medical or patient-monitoring device, the battery's reliability and longevity are critical not only for user convenience but also for ensuring accurate and consistent monitoring. Ex. 2017, ¶[014]. Flexible batteries of the time were not capable of achieving this, making them impractical for the intended use in wearable devices designed for patient care. Ex. 2017, ¶[0140]. The failure to address these technical and practical limitations in *Ozguz* renders the reference non-enabling, as the proposed device could not have been practically implemented with the technology available at the time. Ex. 2017, ¶[0140].

Finally, *Ozguz*'s discussion of waterproofing and environmental protection is overly simplistic wishful thinking and fails to account for the technical challenges of protecting flexible electronics from moisture and sweat—two critical environmental factors for a wearable monitor. Ex. 2017, ¶[0141]. The reference assumes that basic waterproofing techniques, such as standard skin adhesion methods, would suffice to ensure the device's operation under real-world conditions. Ex. 2017, ¶[0141]. However, this assumption overlooks the complexity of waterproofing flexible materials, which was not feasible with the available materials and methods at the time. Ex. 2017, ¶[0141].

Waterproofing such a device requires the integration of specialized coatings or barriers that can protect sensitive electronic components from moisture without compromising the flexibility or comfort of the device. Ex. 2017, ¶[0141]. At the time of the invention, the technology for achieving long-term environmental resistance in flexible electronics was still in its infancy, and there was no reliable method for ensuring the longevity and durability of such devices when exposed to sweat, moisture, or other environmental conditions. Ex. 2017, ¶[0141].

Specifically, a critical and overlooked challenge in *Ozguz*'s design is the incompatibility between the flexibility of the flexible battery and the flexibility of the thin silicon layers of the device. Ex. 2017, ¶[0142]. The incompatibility of

flexible components would create significant waterproofing issues, particularly at the edges where the battery meets the flexible layers. Ex. 2017, ¶[0142]. For example, the incompatible flexible components would allow moisture to seep into the device due to poor sealing around the edges of the device. Ex. 2017, ¶[0142]. The unreliable seal would expose the internal electronics to water damage, particularly in environments where sweat, moisture, or even rain could compromise the device's integrity. Ex. 2017, ¶[0142]. This issue further highlights the unrealistic nature of *Ozguz's* proposal, as a practical, wearable device could not afford to risk water damage, especially when used in environments that are prone to moisture exposure. Ex. 2017, ¶[0142].

Given these challenges, the proposed device in *Ozguz* would have been highly susceptible to failure upon exposure to moisture or sweat, undermining its viability as a continuous-use wearable monitor. Ex. 2017, ¶[0142]. The failure to address these concerns in *Ozguz's* reference renders the device impractical and speculative. Ex. 2017, ¶[0143]. Therefore, a POSA at the time would not have been motivated to combine *Ozguz's* teachings with the intention of creating a functional, reliable, sterilizable, wearable monitor and would not have had any expectation of success in making the Petition's proposed combination. Ex. 2017, ¶[0143]. The lack of consideration for long-term environmental resistance and the durability and

sterilizability of flexible materials significantly diminishes the relevance of *Ozguz* as prior art, as its teachings do not provide an enabling disclosure for creating a viable wearable monitor that could withstand the rigors of real-world use. Ex. 2017, ¶[0143]. A POSA would have recognized that these barriers could not be overcome with the materials and technologies available at the time, making the combination of *Ozguz*'s teachings with other prior art unrealistic and impractical. Ex. 2017, ¶[0143].

b. *Ozguz*'s Infeasible Flexible Battery Technology Renders
Ozguz's device non-enabled

Ozguz's flexible battery technology was infeasible at the time of *Ozguz*'s purported priority date (2005), infeasible at the time of the priority date of the '422 Patent (2006), and still infeasible up to at least 2015 for at least four reasons. Ex. 2017, ¶[0144].

First, in 2005 there was limited mechanical flexibility of commercially available batteries. Ex. 2017, ¶[0145]. While several battery technologies—such as lithium polymer (Li-poly), thin-film batteries, and printed primary cells—were theoretically flexible by 2005, none could achieve the mechanical flexibility described in the *Ozguz* patent, particularly the repeated bending and twisting needed for a wearable “adhesive bandage” form factor. Ex. 2017, ¶[0145]. Specifically, commercially available Li-poly pouch cells could slightly bend to conform to curved surfaces, but were neither repeatedly flexible nor stretchable without risking internal

short circuits or physical damage. Ex. 2017, ¶[0145]. Similarly, thin-film lithium-ion cells developed by Oak Ridge National Laboratory (ORNL) demonstrated limited bending capabilities and were typically fabricated on rigid substrates, severely constraining their real-world flexibility and practical use in dynamic, wearable applications. Ex. 2017, ¶[0145].

Second, as of 2005 there were significant energy density and power delivery constraints that would have precluded using a flexible battery in *Ozguz*'s device. Ex. 2017, ¶[0146]. Printed thin-film zinc-based batteries, like those from Power Paper Ltd. and Enfucell, were indeed thin and highly flexible but had severely limited energy storage (tens of milliamp-hours at best). Ex. 2017, ¶[0146]. Such batteries were adequate only for low-power, short-duration tasks (like RFID tags or greeting cards), insufficient for continuous physiological monitoring devices that require sustained power delivery for data collection, digitization, and wireless data transmission. Ex. 2017, ¶[0146]. Rechargeable technologies like NEC's Organic Radical Battery (ORB), while flexible and seemingly promising, were only experimental prototypes with very limited energy density (~ 1 mWh/cm²). Ex. 2017, ¶[0146]. Hence, by 2005, flexible battery technologies simply could not offer sufficient power density and durability required by the *Ozguz* device specification. Ex. 2017, ¶[0146].

Third, incorporating flexible battery technology into *Ozguz*'s device would not have been feasible from a manufacturing standpoint, nor would it have provided reliable performance in such a device. Ex. 2017, ¶[0147]. As of 2005, flexible battery manufacturing was either experimental or limited to niche applications. Ex. 2017, ¶[0147]. Mass-scale production processes (roll-to-roll printing) of thin-film batteries remained in pilot stages, with limited reliability and inconsistent quality. Ex. 2017, ¶[0147]. The flexible, thin-film silicon-based integrated circuit described in *Ozguz* specifically highlights a degree of integration and complexity requiring robust, reliable power delivery. Ex. 2017, ¶[0147]. None of the battery technologies available prior to or in 2005 were manufactured with the reliability, consistency, and volume required to power such an integrated wearable monitoring device. Ex. 2017, ¶[0147].

Fourth, integrating the flexible battery into *Ozguz*'s device would have presented significant challenges. Ex. 2017, ¶[0148]. *Ozguz* explicitly describes integrating a thin, flexible battery layer with equally flexible silicon circuitry and substrates. Ex. 1014, ¶[0048]. Further, *Ozguz* emphasizes significant mechanical flexibility—such as twisting about the longitudinal axis (Ex. 1014, Figure 3E) and bending along multiple axes (Ex. 1014, Figs. 3C, 3D). Ex. 2017, ¶[0148]. Achieving this degree of flexibility with battery technologies available by 2005 was

not only impractical but posed significant risks for battery failure, leakage, or structural breakdown. Ex. 2017, ¶[0148]. The delicate thin-silicon layers and sensitive integrated circuitry required extremely uniform and mechanically stable battery technology. Ex. 2017, ¶[0148]. The available battery solutions could not satisfy this stringent mechanical integration requirement (without compromise in structural integrity, operational lifetime, or safety). Ex. 2017, ¶[0148].

c. The Petition's Reliance on *Ozguz*'s Infeasible Thin Silicon Technology is Fatal to Ground 2

The Petition relies on *Ozguz*'s thinned silicon substrates for its motivation to combine argument and for at least four of the claim elements in independent Claim 1. Petition, 49-52, (claim elements 1[a], 1[c]-1[e]). However, this thin silicon technology was infeasible in 2005 (*Ozguz*'s purported priority date), 2006 (the '007 Patent's filing date), and still infeasible up to at least 2015. Ex. 2017, ¶¶[0147]-[0150].

First, in 2005, flexible thinned silicon technology was confined to experimental development and use, and suffered from low yield, high fragility, and inadequate scalability for everyday use purposes (e.g., wearable monitors). Ex. 2017, ¶[0150]. This prevented the technology from achieving consistency, reliability, and high throughput manufacturing necessary for practical use. Ex. 2017, ¶[0150].

Second, in 2005, flexible thin silicon could not be reliably assembled or packaged, and therefore could not support a wearable patient monitor as described by *Ozguz*. Ex. 2017, ¶[0151]. Particularly, not as disclosed in *Ozguz*, which requires complex integration: flexible silicon circuitry, flexible battery, electrodes, wireless transmission capability, and adhesives into a thin, bendable form factor. Ex. 2017, ¶[0151]; Ex. 1014, Figures 2a, 3a, 3b.

Indeed, there were no off-the-shelf flexible integrated circuits or thin silicon chips available in 2005 outside of research-based contexts. Ex. 2017, ¶[0150]. However, even the research-based developments of flexible thinned silicon devices suffered from difficulties with power and wireless communication interoperability. Ex. 2017, ¶¶[0150]-[0154]. The U.S. government, in 2015, recognized these inadequacies, which underscores the depth and persistence of these technical and manufacturing challenges. Ex. 2017, ¶[0155]. Thus, the wearable, flexible device as described by *Ozguz* was not realizable by a POSA in 2005. Ex. 2017, ¶[0155].

iii. The Non-Obvious Combination of *Matsumura*, *Ozguz*, *Kroll* and the “General Knowledge” of the POSA Fails to Render Obvious Claim 45

As described above with respect to Claim 1, the Petition fails to render obvious Claim 45. *Supra* Sections VI.A, VI.B.i-ii; Ex. 2017, ¶¶[0062]-[0065], [0127].

VII. CONCLUSION

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

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