

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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IRHYTHM, INC.,

Petitioner,

v.

WELCH ALLYN, INC.,

Patent Owner.

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CASE: IPR2025-00363

U.S. PATENT NO. 10,159,422

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**PATENT OWNER PRELIMINARY RESPONSE**

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**TABLE OF PATENT OWNER EXHIBITS**

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                  |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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)                                                                                        |

| <b>Exhibit No.</b> | <b>Description</b>                                                               |
|--------------------|----------------------------------------------------------------------------------|
| 2012               | [Reserved]                                                                       |
| 2013               | Declaration of Dr. Brian Anthony for IPR2025-00363 of U.S. Patent No. 10,159,422 |
| 2014               | [Reserved]                                                                       |
| 2015               | [Reserved]                                                                       |
| 2016               | [Reserved]                                                                       |
| 2017               | [Reserved]                                                                       |

Patent Owner, Welch Allyn, Inc. (“Welch Allyn” or “Patent Owner”), submits this Patent Owner Preliminary Response (“Response”) pursuant to 37 C.F.R. § 42.107(a) to the *Inter Partes* Review petition (“Petition”) filed by iRhythm, Inc. (“Petitioner”) for Claims 1-7, 9-12, and 14-20 (the “Challenged Claims”) of U.S. Patent No. 10,159,422 (the “’422 Patent”) (Ex. 1007).

## **I. INTRODUCTION**

The ’422 Patent claims a novel method for making a body-worn physiological sensor package that adhesively attaches to a patient’s skin and measures physiological signals. Ex. 1007, Abstract, Cl. 1, Figure 2; Ex. 2013, ¶[0045]. Namely, the ’422 Patent bifurcates the two main components of the sensor package into (1) the communication-computation module and (2) a disposable substrate. Ex. 1007, 5:32-47, Cl. 1, Figure 2; Ex. 2013, ¶[0045]. As a result, a flexible printed circuit board, which is located on the disposable substrate portion, includes conductive traces defined between at least two electrodes for carrying the signal to the processor for analysis. Ex. 1007, Cls. 1, 14; Ex. 2013, ¶[0046].

In challenging the ’422 Patent, the Petition does not identify a single reference that includes this bifurcated structure with the communication-computation module and the disposable substrate having the claimed traces. With the benefit of hindsight, the Petition attempts to reconstruct the novel features of the ’422 Patent.

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.” *See 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 with § 311(b).

The Petition worsens this issue by forcing combinations (where no motivation exists) and offloading its analysis to the Board. Finally, the Petition relies extensively on Exhibit 1012, a purported English translation of Japanese Pat. Pub. JP2004/121360 to *Matsumura*, but Petitioner failed to establish that Exhibit 1012 is an accurate translation, leaving the Board and Patent Owner to guess regarding the accuracy. *See* Exs. 1065, 1066 and 1012 (all lacking any connection). The alleged attorney argument in footnote 2 cannot carry the day on this dispositive issue.

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.*, the “housing”) 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 technical merits.

In Ground 1, the Petition relies on the combination of *Matsumura*,<sup>1</sup> and the "general knowledge" of a POSA. Petition, 1-2. This challenge fails because the Petition does not establish that *Matsumura* renders obvious the claimed method of manufacture, the disposable substrate made from an insulating material, and the flexible printed circuit board layer. Because Petitioner cannot set forth a rational basis for obviousness, the Petition relies on improper claim constructions and improper motivations to modify *Matsumura* in view of the so-called "general knowledge" of a POSA. Under a proper construction, the Petition fails. Without using Claim 1 as a guide, a POSA would not have been motivated to modify

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

*Matsumura*'s three-dimensional conductive materials into printed circuitry made from insulating materials.

In Ground 2, the Petition relies on the combination of *Jensen*<sup>2</sup> and the “general knowledge” of a POSA or *Matsumura*. Petition, 1-2. However, *Jensen*, alone or in combination with *Matsumura*, or Petitioner’s amorphous “general knowledge,” fails to teach or suggest both the claimed disposable substrate or the computation-communication module. The Petition also fails to articulate a rational basis to support the Petition’s alleged modifications and combination. In view of the references’ teachings, it becomes clear that the Petition uses Claim 1 as a guide to redesign *Jensen* to arrive at the Challenged Claims. This is blatant improper hindsight reconstruction, and thus Ground 2 fails.

In Ground 3, the Petition relies on the combination of *Ozguz*<sup>3</sup> and the “general knowledge” of a POSA. Petition, 1-2. This challenge fails because the Petition does not establish that *Ozguz* renders obvious the claimed housing “retaining” or “containing” a processor, and the claimed flexible printed circuit layer. Because Petitioner cannot set forth a rational basis for obviousness, the Petition relies on

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

<sup>3</sup> U.S. Patent Publication No. 2005/0096513 to *Ozguz* et al. (Ex. 1014).

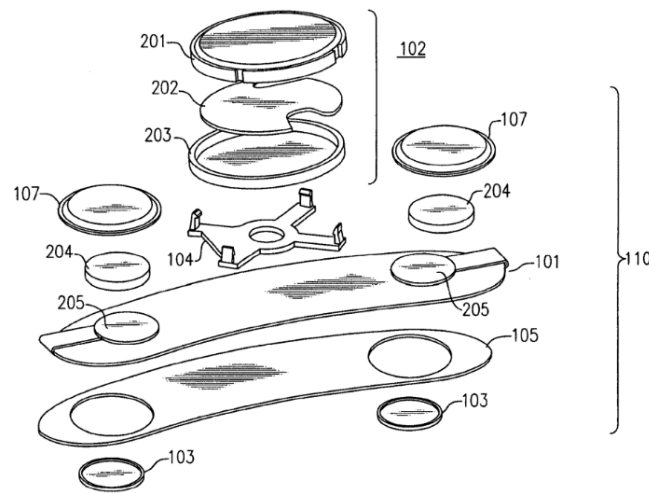
improper claim constructions and improper motivations to modify *Ozguz* in view of the so-called “general knowledge” of a POSA. Under a proper construction, the Petition fails. Even worse, the Petition relies on passages from *Ozguz* that are not enabled, as *Ozguz* is a non-enabling reference. Without using the claims as a guide, a POSA would not have been motivated to modify *Ozguz* to achieve the claimed invention, and indeed a POSA could not have achieved the claimed invention using the teachings of *Ozguz*.

In Ground 4, the Petition relies on the combination of *Ozguz* and the “general knowledge” of a POSA or *Matsumura*. This challenge fails because the Petition does not establish that *Ozguz* alone or in combination with the “general knowledge” or *Matsumura* renders obvious the “processor disposed in the housing.” The Petition also fails to articulate any plausible bases for modifying *Ozguz* with the purported “general knowledge” of a POSA or to combine *Ozguz* with *Matsumura*. Even worse, the Petition relies on passages from *Ozguz* that are not enabled. In doing so, the Petition ignores the aspirational disclosure of *Ozguz*, applies—without reason or support—its own improper claim constructions, and employs impermissible hindsight to meet the Challenged Claims. Under a proper analysis, and without using Claim 1 as a guide, a POSA would not have understood *Ozguz*, alone or in

combination with the “general knowledge” of a POSA or *Matsumura*, to disclose the limitations of the Challenged Claims.

## II. SUMMARY OF THE '422 PATENT

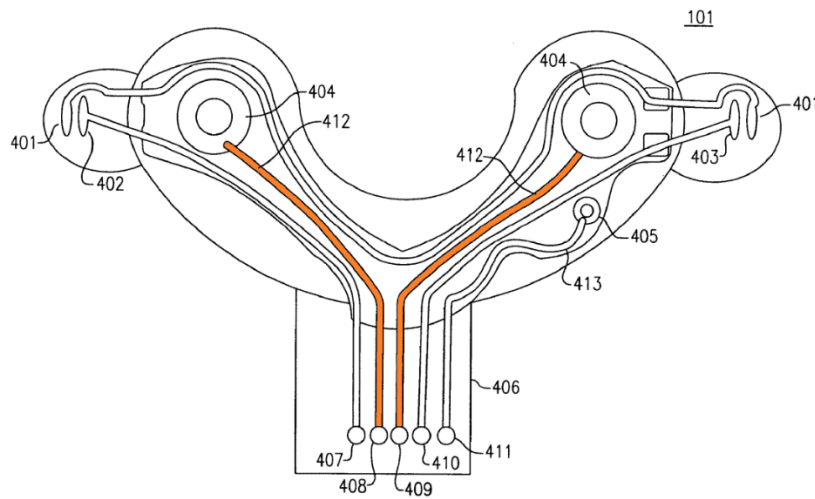
The '422 Patent provides for the making of a body-worn physiological sensor package that adhesively attaches to a patient's skin and measures physiological signals. Ex. 1007, Abstract, cl. 1, Figure 2; Ex. 2013, ¶[0045]. The body-worn sensor package includes a computation-communication module 102 and disposable electrode module 110. Ex. 1007, 5:32-47, cl. 1, Figure 2; Ex. 2013, ¶[0045].



Ex. 1007, Figure 2.

The disposable electrode module 110 includes a flexible printed circuit layer 101 made from an insulating material. Ex. 1007, Cl. 1, 8:4-16; Ex. 2013, ¶[0046]. The flexible printed circuit layer transmits electrical signal via traces, which connect a connection pad and an electrode. Ex. 1007, 8:4-17, Figure 4A; Ex. 2013, ¶[0046].

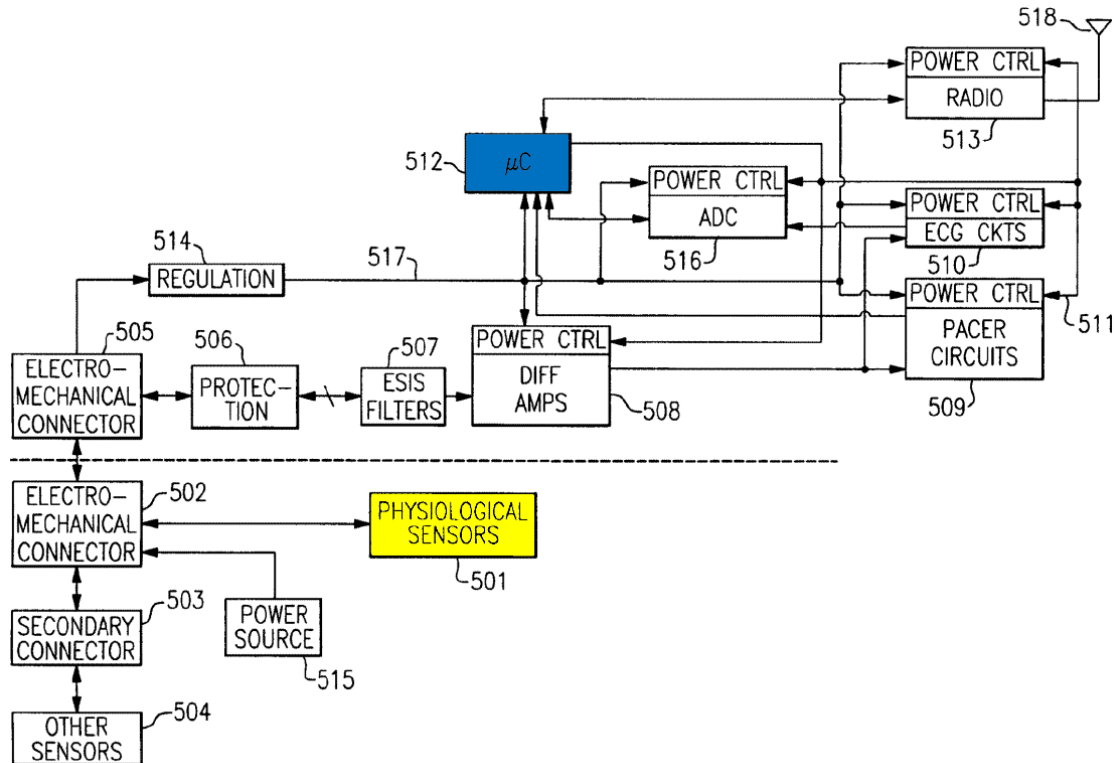
The traces 412 (orange), which are preferably printed, “extend[] between conductive surface 404 and connection pads 408 and 409.” Ex. 1007, 8:4-17, Figure 4A; Ex. 2013, ¶[0046]. This way, the traces 412, which are preferably printed onto electrically couple the signals from electrodes to the computation-communication module. Ex. 1007, 8:4-17; Ex. 2013, ¶[0046].



Ex. 1007, Figure 4A (annotated); Ex. 2013, ¶[0046].

This pathway from the electrodes to the computation-communication module is also shown in the block diagram of Figure 5. Ex. 1007, 11:62-66, Figure 5. There, the physiological sensors (*e.g.*, electrodes) for capturing an ECG difference potential of the patient are indicated in yellow. Ex. 1007, 11:64-65, Figure 5 (indicating the physiological sensors 501 in yellow); Ex. 2013, ¶[0047]. The physiological sensors 501 are electrically coupled to an electromechanical connector 502, which is further connected to a processor for performing computational analysis on the detected

signals. Ex. 1007, 11:62-66, Figure 5 (annotated, indicating the microprocessor 512 in blue), Figure 4A; Ex. 2013, ¶[0047]. The computation-communication module includes a housing that contains this processor. Ex. 1007, Cl. 1; Ex. 2013, ¶[0047].



Ex. 1007, Figure 5 (annotated); Ex. 2013, ¶[0047].

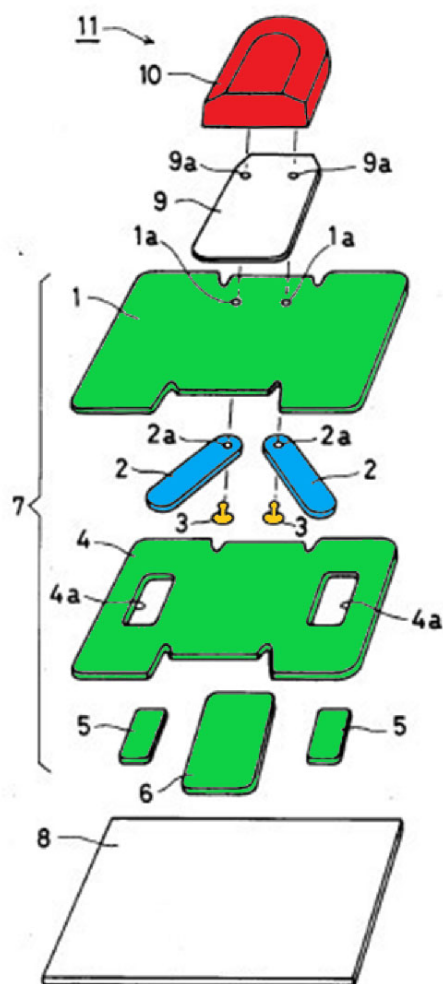
### III. ORIGINAL PROSECUTION OF THE '422 PATENT

The '422 Patent issued from U.S. Patent Application No. 15/880,712 and claims priority to Application No. 11/591,619 filed on November 1, 2006. Ex. 1001, 1-2. Applicant filed a Terminal Disclaimer to overcome a nonstatutory double patenting rejection of a subset of the claims, resulting in a Notice of Allowance for all originally filed method of manufacturing claims. Ex. 1008, 12, 125.

#### 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. 2013, ¶[0048]. In 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. 2013, ¶[0048].



Ex. 1012, Figure 1 (annotated); Ex. 2013, ¶[0048].

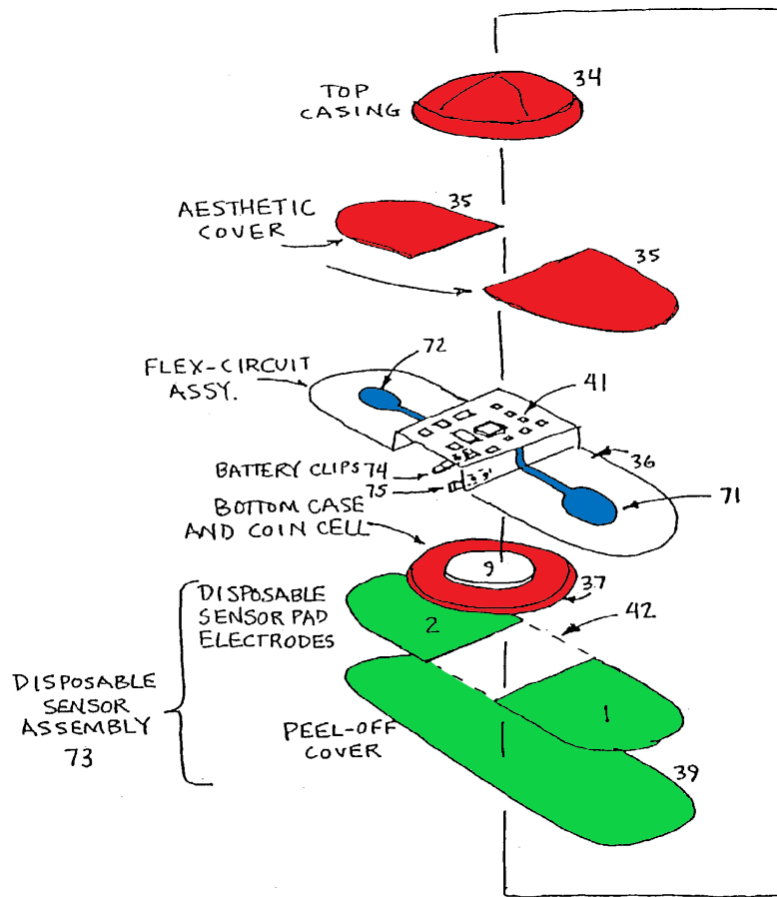
*Matsumura* explains “two pieces of conductive material 2 and two hooks 3 are arranged to transmit the bioelectric potential detected by the conductive gel 5, which is placed in the openings 4a of the second sheet 4.” Ex. 1012, ¶[0019]. Conductive material 2 is rod-shaped with one end that contacts conductive gel 5 and the other end that “has two holes 2a through which the protruding portions of hook 3 are inserted.” Ex. 1012, ¶[0019]; Ex. 2013, ¶[0049]. This configuration allows

“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. 2013, ¶[0049].

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. 2013, [0050].

**B. Overview of *Jensen***

*Jensen* provides a cardiac monitor that adheres to a patient’s skin. Ex. 1011, Abstract; Ex. 2013, ¶[0051]. *Jensen* provides disposable sensor assembly 73, which includes cover 39, connective material 42, and pads 1 and 2. Ex. 1011, ¶[0040], Figure 5 (indicating the disposable components in green); Ex. 2013, ¶[0052]. These three components are the full extent of *Jensen*’s disposable components. Ex. 2013, ¶[0052]; Ex. 1011.

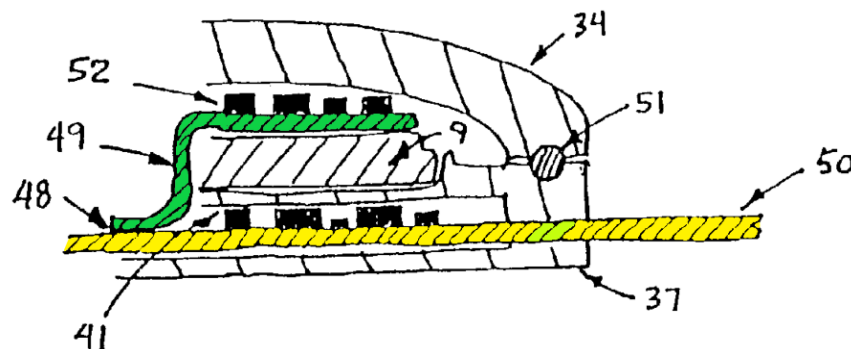


Ex. 1011, Figure 5 (annotated); Ex. 2013, ¶[0052].

*Jensen* describes an additional, non-disposable flexible circuit assembly 36 having “traces” (annotated in blue above). Ex. 1011, ¶[0040], Figure 5; Ex. 2013, ¶[0052]. These “traces” connect circuit 41 to sensor contacts 71 and 72, which in turn connect to pads 1 and 2 of disposable sensor assembly 73. Ex. 1011, ¶[0040], Figure 5; Ex. 2013, ¶[0052]. *Jensen* further discloses bottom case 37, top casing 34, and two aesthetic covers 35, which are the “re-usable (non-disposable) portion[s] of

the invention.” Ex. 1011, ¶[0040], Figure 5 (indicating the re-useable components in red); Ex. 2013, ¶[0052].

*Jensen* also describes an alternative structure for its device in Figure 8. Ex. 1011, ¶[0046], Figure 8; Ex. 2013, ¶[0055]. In this alternative embodiment, *Jensen*’s device includes two flexible printed circuits 49, 50. Ex. 1011, ¶[0046], Figure 8 (indicating the first circuit 50 in yellow and the second circuit 49 in green); Ex. 2013, ¶[0055]. The second flexible circuit assembly 49 is connected to first flexible circuit 50 via a set of pads 48. Ex. 1011, ¶[0046]; Ex. 2013, ¶[0055].

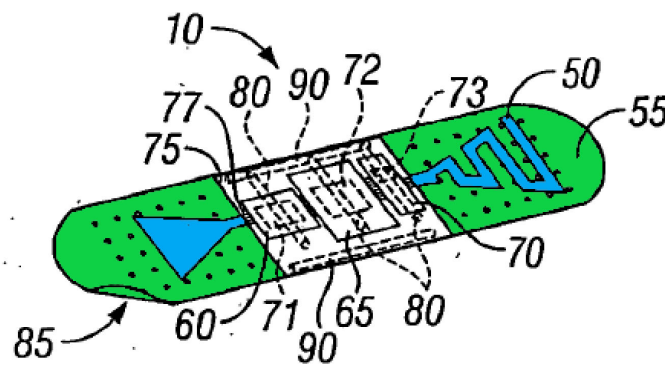


Ex. 1011, Figure 8 (annotated); Ex. 2013, ¶[0055].

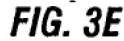
To create this connection, pads 48 on each circuit are matched; “the matched pads of tinned-copper exposed on the bottom side of circuit 49 and the top side of circuit 50.” Ex. 1011, ¶[0046], Figure 8A; Ex. 2013, ¶[0056]. Then, the pads 48 “are heat re-flowed together, melting the tinning metal, to connect the two circuits.” Ex. 1011, ¶[0046], Figure 8, 8A; Ex. 2013, ¶[0056].

**C. Overview of Ozguz**

*Ozguz* aspirationally describes a wearable sensor module for monitoring physiological characteristics. Ex. 1014, ¶[0003]; Ex. 1013, ¶[0057]. 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. 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. 1014, ¶[0019]; Ex. 2013, ¶[0057]. 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. 1014, ¶[0052]; Ex. 2013, ¶[0057].



Ex. 1014, Figure 1 (in-part); Ex. 2013, ¶[0057].



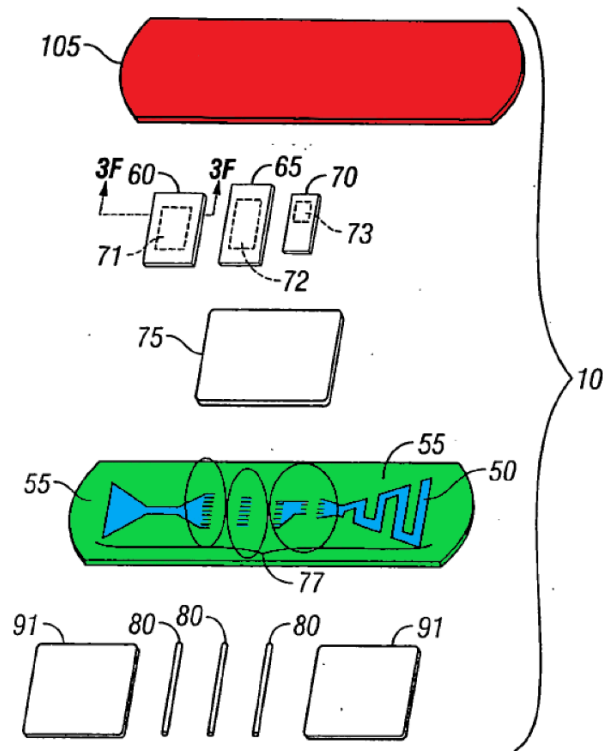


**FIG. 3B**

Ex. 1014, Figure 3B (annotated); Ex. 2013, ¶[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. 1014, ¶¶[0047]-[0048]. *Ozguz*’s sensor module is a single unit, and none of its components are detachable from the module except for adhesive pads 91. Ex. 1014, ¶[0049]; Ex. 2013, ¶[0060]. Otherwise, the “sensor modules are made disposable and are discarded after monitoring a particular subject body 20.” Ex. 1014, ¶[0049]; Ex. 2013, ¶[0060].

## V. “GENERAL KNOWLEDGE” AND CLAIM CONSTRUCTION<sup>4</sup>

### 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. 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 3. 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 and 3, relies on

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<sup>4</sup> The claim construction issues discussed in this Section are also covered in Patent Owner’s Argument for Discretionary Denial. *See* Paper 7 at 13-19. However, Patent Owner includes similar arguments with this Response to show how Petitioner’s failure to construe key terms impacts the merits of the Petition.

“Matsumura, Kroll, and ***General Knowledge of a POSA.***” Petition, 1. This combination and listing of “General Knowledge” is repeated throughout the Petition. Petition, 2-3 (listing “General Knowledge” in overview of challenges), Petition, 15 (listing “General Knowledge” in 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 table outlining its challenge to the claims and listed AAPA (*i.e.*, applicant admitted prior art) for two of its grounds. *Id.* at \*9. The court held that this listing was an “express statement[]” that AAPA is part of the basis of its ground. *Id.*

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

*Id.* at \*4.

Just as the petition’s listing of AAPA was viewed as an express statement in *Qualcomm*, the Petition’s listing of “General Knowledge” is likewise an express statement that “General Knowledge” is part of the basis of Grounds 1 to 3.

| Proposed Grounds of Unpatentability |                                                                                                                                                                                   |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ground 1                            | Claims 1-7, 9-11, and 14-20 are obvious under pre-AIA § 103 over Matsumura in view of the <u>General Knowledge of Person of Ordinary Skill in the Art</u>                         |
| Ground 2                            | Claims 1-7, 9, 11, 12, and 14-20 are obvious under pre-AIA § 103 over Jensen and the <u>General Knowledge of Person of Ordinary Skill in the Art</u> or Matsumura                 |
| Ground 3                            | Claims 1-3, 5, 6, 9, 11, 12, 14-18, and 20 are obvious under pre-AIA § 103 over Ozguz in view of the <u>General Knowledge of Person of Ordinary Skill in the Art</u> or Matsumura |

Petition, 1-2 (annotated).

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

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

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

When construing claims, the Board applies the principles set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-17 (Fed. Cir. 2005) (en banc). The *Phillips* Standard establishes that the words of a claim are generally given their plain and

ordinary meaning, which is the meaning the term would have to a POSA at the time of the invention, in the context of the entire patent. *Phillips*, 415 F.3d at 1312-13. Although Petitioner claims to apply the ordinary and customary meaning of the terms (*see* Petition, 2), the Petition is instead filled with implicit claim constructions that lack support or explanation. *See ams AG v. 511 Innovations, Inc.*, IPR2016–01792, Paper 15, 8 and 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.<sup>5</sup>

**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.*,

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<sup>5</sup> The Petition’s reliance on non-prior art documents is also covered in Patent Owner’s Argument for Discretionary Denial. *See* Paper 7 at 26-29.

*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). 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).

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 three separate terms, found in *all* independent claims of the '422 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[d]/14[d]: “trace”                   | Pet., 18, 28    | Ex. 1009 ¶1398                             |
| Claim 1[f]/14[f]: “housing”                 | Pet., 20, 29    | Ex. 1009 ¶¶1406-09; Ex. 1009 ¶¶1467-1468   |
| Claim 1[g]/14[g]: “disposed in the housing” | Pet., 20-21, 29 | Ex. 1009 ¶¶1411-1413; Ex. 1009 ¶¶1469-1470 |

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, the Petition implicitly and improperly construes the claim terms “housing” and “disposed in the housing” because it provides no

evidence, support, or argument that “show[] a reasonable likelihood that it would prevail in its challenge asserted as Ground [3].” *See Vicor Corp.*, IPR2024-00704, Paper 11 at 9. The Petition construes “housing” so broadly that it includes anything that merely touches or rests atop another component, disregarding the claim’s requirement that the housing contains other components inside of it. Ex. 2013, ¶¶[0141]-[0142]. Likewise, the Petition appears to construe “disposed in the housing” just as loosely—suggesting that “disposed in” simply means physical contact, completely vitiating the concept of “in.” Under this flawed reasoning, a microprocessor that merely touches the outer wall of a flexible battery would somehow be “disposed in” that battery, thereby transforming the battery into a housing. This interpretation is plainly unreasonable in view of the claim language and the ’422 Patent’s disclosure.

In support of this dubious interpretation, the Petition cites no supporting evidence, and Dr. Heikenfeld’s Declaration merely 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). Neither the Petition nor Dr. Heikenfeld “disclose the underlying facts or data on which the opinion is based” and his opinion

is therefore “entitled to little or no weight.” *See Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (P.T.A.B. Aug. 24, 2022) (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.”).

**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, the Petitioner improperly shifts the burden of claim clarification to the Patent Owner and the Board. As discussed, the Petition fails to adequately articulate a construction of the claim terms “housing” and “disposed in the housing,” despite applying impermissibly broad interpretations of the claim language throughout the Petition. *Supra* Section V.B.i.; *infra* Section VI.C.i. Where the Petitioner sets forth arguments or observations of what a claim term means, but does not provide an explicit construction for the claim term, the “Petitioner improperly attempts to shift the burden of construing the claim term . . . to the Board[,]” and institution should be denied. *ams AG*, No. IPR2016–01792, Paper 15, at 8, 13 (“[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 ’422 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 '422 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 '422 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 '422 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. *See, e.g.*, Exs. 1022, 1026, 1031, 1032, 1037, 1038, 1048-1052, 1059, 1060-1061.

The Petition fails to allege, let alone establish, the relevancy of these ancient references to the problems facing the field of the invention as of 2006. 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 THAT THERE IS A REASONABLE LIKELIHOOD TO PREVAIL ON A SINGLE CLAIM**

### **A. Ground 1 Fails to Render Obvious the Challenged Claims**

Ground 1, which is based on the modification of *Matsumura* in view of the general knowledge of a POSA, fails to render the Challenged Claims obvious. Petition 14-30. "An obvious determination generally requires [1] a finding that all claimed limitations are disclosed in the prior art, and [2] that a person of ordinary skill in the art would have been motivated to combine or modify the teachings in the prior art." *Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 160 (Fed. Cir. 2021) (citations omitted). Ground 1 does not satisfy either requirement.

First, the Petition is silent with regard to any method of manufacturing despite the '422 Patent's claims being method claims. Second, the Petition's proposed modification of *Matsumura* in view of the so-called "general knowledge" of a POSA fails to render obvious the claimed disposable substrate made from an insulating material. Third, the Petition's proposed modification likewise fails to render obvious the flexible printed circuit board layer of Claim 1.

Finally, the Petition does not provide a sufficient motivation to modify *Matsumura* in view of the general knowledge of a POSA, and in fact, presents a modification that renders *Matsumura*'s device completely inoperable for its intended purpose of providing a waterproof wearable monitor.

i. The Non-Obvious Combination of *Matsumura* and the General Knowledge of the POSA Fails to Render Obvious Claim 1

The Petition is silent with regard to any method of manufacturing despite the '422 Patent's claims being method claims. Second, the Petition's proposed modification of *Matsumura* in view of the so-called "general knowledge" of a POSA fails to render obvious the claimed disposable substrate made from an insulating material. Third, the Petition's proposed modification likewise fails to render obvious the flexible printed circuit board layer of Claim 1. Finally, the Petition does not provide a sufficient motivation to modify *Matsumura* in view of the general

knowledge of a POSA, and in fact, presents a modification that prevents *Matsumura*'s device from achieving its primary goal: waterproofing.

- a. Ground 1 fails to render obvious the claimed method of manufacturing

The independent claims of the '422 Patent are directed towards a process, and the claim elements require steps be performed. *Matsumura* does not describe any method, only a resulting product. Petitioner relies on *Kamstrup AS v. Axioma Metering UAB*, 43 F.4th 1374 (Fed. Cir. 2022), which addressed a product claim, not a method claim. *Id.* at 1377-78. Petitioner also relies on *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345 (Fed. Cir. 2016), which also addressed a product claim, not a method claim. *Id.* at 1352 n.2 (“All of the asserted claims are product claims”). Both cases are directed towards product-by-process claims; the '422 Patent claims, including independent Claim 1, include method claims. Petitioner has entirely failed to identify any method steps in *Matsumura*.

- b. Ground 1 fails to render obvious a disposable substrate made from an insulating material

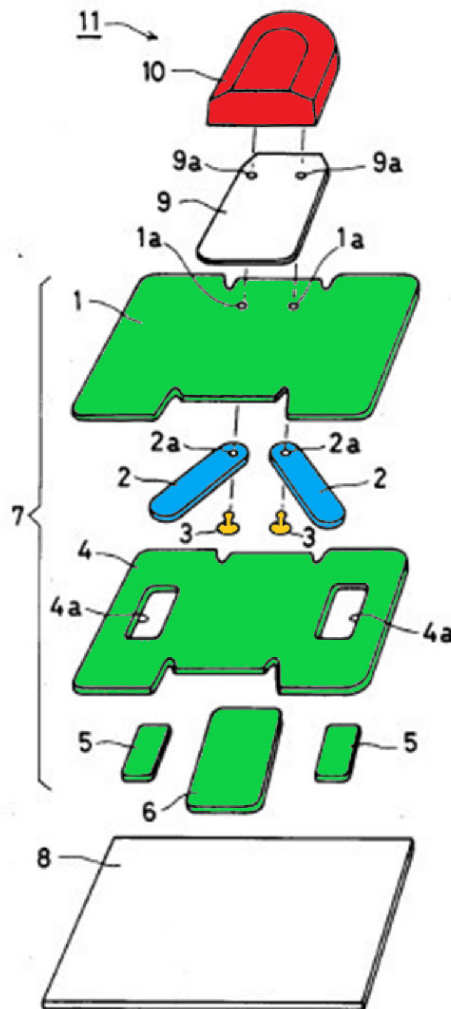
The Petition concedes that *Matsumura* does not disclose a disposable substrate made from an insulating material. *See* Petition, 15. The Petition does not rely on any other references to teach this limitation in Ground 1. *Id.* The Trial Practice Guide is clear that “Expert testimony, however, cannot take the place of a

disclosure in a prior art reference, when that disclosure is required as part of the unpatentability analysis.” PTAB Consolidated Trial Practice Guide at 36 (Nov. 2019). This ground necessarily fails by Petitioner’s own admission.

c. *Matsumura* does not disclose the flexible printed circuit board layer

*Matsumura* does not teach any flexible **printed** circuit board. Rather, *Matsumura* discloses a “bioelectric pad” composed of (1) a first sheet, (2) a conductive material, (3) a hook, (4) a second sheet, (5) a conductive gel, (6) a third sheet, and (7) double-sided adhesive tape. Ex. 1012, ¶[0016]. The Petition, while alleging *Matsumura* teaches a printed circuit board, concedes that there are no disclosures of printing or a PCB in *Matsumura*. Petition, 16-17.

*Matsumura* rather discloses that the conductive material is rod-shaped and that the hooks (orange) are studs that protrude through the back side of conductive material 2 (blue). Ex. 1012, ¶[0019]; Figure 1 (annotated below).



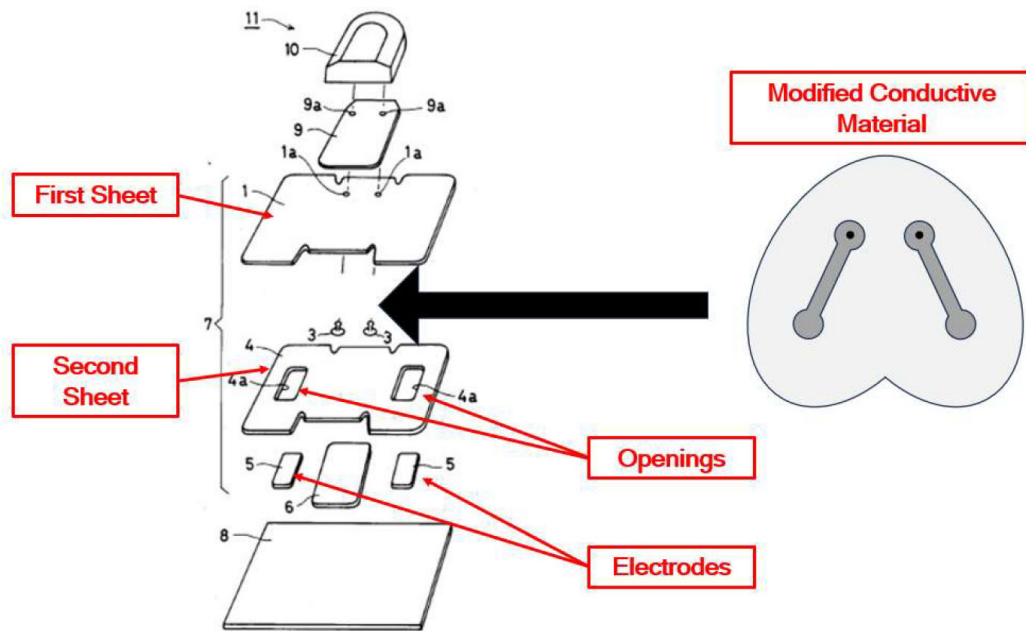
Ex. 1012, Figure 1 (annotated); Ex. 2013, ¶[0069].

A POSA would understand that neither conductive material 2 nor hooks 3 are printed, and therefore *Matsumura* does not disclose or suggest a printed circuit board layer. Ex. 2013, ¶¶[0069]-[0071]. It is not disputed that *Matsumura* lacks a printed circuit board. Ex. 2013, ¶[0069]. Additionally, a POSA would have known that replacing the conductive rods and hooks with insulating material and printed

conductive traces, respectively, would “render[] [*Matsumura*] inoperable for its intended purpose.” *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984); Ex. 2013, ¶[0071]. This is because without *Matsumura*’s specific conductive material, the bioelectric signals could not be transmitted from the conductive gel, through the conductive material, to the hooks, and the bioelectric signals could not reach the signal processor. Ex. 2013, ¶¶[0071]-[0072].

In some instances, the Petition identifies the hooks alone as traces. Petition, 35 (“sensor contacts (conductive material 2), and *traces (hooks 3)*” (emphasis added)). Yet, the Petition concludes that a POSA would have modified *Matsumura* to replace the conductive material with a sheet of insulating material with printed conductive traces, thereby eliminating the hooks as the “trace” as defined by the Petition. Ex. 2013, ¶[0072]. A POSA would not have made such a modification because the hooks are essential for carrying bioelectric signals to the processor. Ex. 2013, ¶¶[0071]-[0072], [0075].

The Petitioner uses clip art of “modified conductive material,” which it inserts in a self-serving location within Figure 1 to baselessly suggest that a POSA would have known that conductive rods 2 could be replaced with a flexible printed circuit layer made from insulating material.



Petition, 16-17.

The Petitioner identifies no disclosure within *Matsumura* nor any knowledge of a POSA suggesting the replacement of conductive rods with a sheet of insulating material and printed traces and placing it in the middle of Figure 1. Instead, the Petition relies on four paragraphs of the expert declaration, which in turn relies on a non-prior art reference as support for this modification. Petition, 16 (citing Ex. 1009, ¶¶1387-88, which in turn cites Ex. 1035, a non-prior art reference). Therefore, the Petition's illustration of Figure 1 is merely the application of hindsight—unsupported by any disclosure in the reference itself—to meet the claim limitation. Ex. 2013, ¶¶[0073]-[0075].

At base, the Petition ignores the express teachings of *Matsumura*. Ex. 2013, ¶[0075]. *Matsumura*'s disclosure is explicit: “two pieces of conductive material 2 and two hooks 3 are arranged to transmit the bioelectric potential detected by the conductive gel 5.” Ex. 1012, ¶[0019]; Ex. 2013, ¶[0075]. Further, *Matsumura* is clear that “[t]he bioelectric pad 7 and the signal processor 10 are detachable with hooks.” Ex. 1012, ¶[0016]; Ex. 2013, ¶[0075]. Accordingly, the three-dimensional structures of both conductive rod 2 and hook 3 are necessary for the electrical and mechanical connections, and a POSA would not have been motivated to replace them with printed circuitry. Ex. 2013, ¶[0075].

ii. The Petition Fails to Establish a Motivation to Modify *Matsumura* in view of the “General Knowledge” of a POSA

i. A POSA Would Not Have Been Motivated to Replace *Matsumura*'s Conductive Material with Insulating Material and Printed Traces

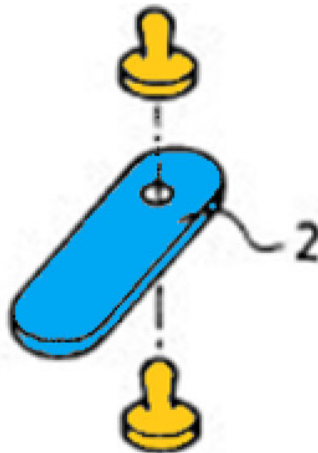
Atop admitting that *Matsumura* fails to teach or suggest the claimed printed circuit board layer, *Matsumura* affirmatively **requires** teachings that are at odds with the claimed method of manufacturing. Ex. 1012, ¶[0019]; Ex. 2013, ¶[0075].

*Matsumura* is clear that its bioelectrode pad comprises “a conductive material 2,” a conductive “hook 3,” and “a conductive gel 5.” Ex. 1012, ¶[0016]. Conductive material 2 is a rigid “rod-shaped” piece of material through which the “protruding” hook 3 vertically protrudes through. Ex. 1012, ¶[0019]. Despite *Matsumura*'s

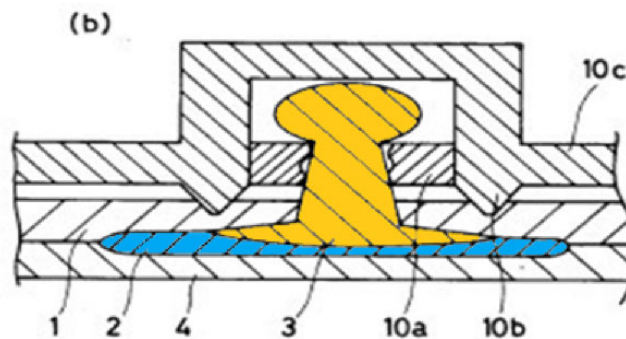
express teachings, Petitioner somehow concludes that “a POSA would have been motivated to modify Matsumura’s disposable bioelectrode pad 7, to replace conductive material 2 with another sheet of insulating material with printed conductive traces (*i.e.*, lines of conductive ink).” Petition, 15. To Petitioner, “[t]his modification would result in three sheets of insulating material bonded together, forming the claimed disposable substrate made from an insulating material. Accordingly, Matsumura discloses providing a disposable substrate made from an insulating material.” Petition, 15. Not so.

The Petition fails to acknowledge that *Matsumura’s* rigid, 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 from the bioelectric pad. Ex. 1012, ¶[0016], Figures 1-2; Ex. 2013, ¶[0079]. To accomplish the waterproof design, there must be a vertical conductive protrusion that allows for the electrical flow of signals from the bio-pad upwards to the processor. Ex. 1012, ¶¶[0024], [0027], Figures 4-5; Ex. 2013, ¶[0079]. It is clear from Figures 4 and 5 that to provide this waterproof design, the

rigid nature of conductive material 2 provides a stable support for hook 3. Ex. 1012, ¶[0019], Figures 4-5; Ex. 2013, ¶[0080]. Specifically, “the protruding portions of the hook 3” extend upwards “from the back side of the conductive material 2,” clamping both sides of conductive material 2. Ex. 1012, ¶[0021], Figures 4(b) (annotated), 8 (annotated). The organization of these components was not by accident but rather provides the electrical and mechanical connection essential to *Matsumura’s* device. Ex. 1012, ¶[0019]; Ex. 2013, ¶[0080].



Ex. 1012, Figure 8 (annotated); Ex. 2013, ¶[0080].



Ex. 1012, Figure 4(b) (annotated); Ex. 2013, ¶[0080].

In the face of this express teaching of *Matsumura*, the Petition proposes removing conductive material 2 and replacing them with “traces,” for no other reason than to reach the claims. Nothing in *Matsumura*, the single reference used in this ground, suggests the replacement of these rigid conductive rods.

Instead, the Petition and its expert simply allege that “a POSA would have been motivated to combine conductive material 2 onto a single, printed sheet” and add traces. Petition, 18. This is nothing more than hindsight driven efforts to arrive at the claim. In support of this argument, Petitioner relies on five paragraphs of its expert declaration. Petition at 17, (citing Ex. 1009, ¶¶1386-90) which itself incorporates by reference another section (*see* Ex. 1009, ¶1387 (citing “Section XIX.A.6.iii,” which is in turn paragraphs 1068-74, yet again incorporating yet another section, “Section XIX.A.1.iii” in paragraph 1069, which in turn is paragraphs 1027-1031)). Once a reader deciphers the seventeen paragraphs that are actually cited here, including the multiple references and different opinions across different challenged patents, Petitioner’s ultimate opinion begins to appear: “at the time of the invention of the Challenged Patents, it was well-known that silver and/or silver paste could be applied using the screen-printing technique.” Ex. 1009, ¶1387. 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, Petitioner’s expert simply concludes, without any basis, that this alleged change would be made “to reduce the manufacturing costs associated with manufacturing the parts.” Ex. 1009, ¶1388. Dr. Heikenfeld provides no evidence of this “cost savings” opinion. *Id.* 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).

ii. The Implementation of a Printed Circuit Board Layer Would Frustrate *Matsumura’s* Goal of a Waterproof Device

Replacing *Matsumura’s* conductive rods and conductive hooks with a sheet of insulating material and printed electrical traces destroys the electrical and mechanical structure of *Matsumura* necessary for the device to function as intended. *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 hooks with a printed conductive trace because the POSA would have known that the hooks are necessary for waterproofing “the entire bioelectric potential detector” as described above. Ex. 1012, ¶¶[0027]-[0030]; Ex. 2013, ¶¶[0083]-[0084]. The Petition is silent with regard to the device being waterproof and fails to recognize or address the hooks’ electrical and mechanical role altogether.

Instead, the Petition proposes replacing *Matsumura*’s non-printed electronic circuitry with a printed circuit board layer including printed conductive traces; however, the Petition’s combination frustrates *Matsumura*’s goal of providing a waterproof device. *See, e.g.*, Ex. 1012, ¶¶[0001], [0006], [0025]-[0032]; Ex. 2013, ¶[0085]. Accordingly, a POSA would not have been motivated to modify *Matsumura* in this way, and Ground 1 fails.

**iii. Matsumura Fails Under Rule 42.63(b)**

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 and 3 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. 1065, 1066 and 1012

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 and 3 should be denied.

**iv. The Non-Obvious Combination of *Matsumura* and the General Knowledge of the POSA Fails to Render Obvious Claim 14**

Claim 14, like Claim 1, requires “a disposable substrate made from an insulating material” as well as “a flexible printed circuit board layer.” As described above with respect to Claim 1, the Petition fails to render obvious Claim 14. *Supra* Section V.A.i-iii; Ex. 2013, ¶¶[0065]-[0086].

**B. Ground 2 Fails to Render Obvious the Challenged Claims**

*Jensen*, alone or in combination with *Matsumura*, or Petitioner’s amorphous “general knowledge,” fails to teach or suggest both the claimed disposable substrate and computation-communication module. Further, there is simply no rational basis articulated to support the Petition’s alleged modifications. Rather, the Petition uses Claim 1 as a guide to redesign *Jensen*, eschewing the actual teachings of *Jensen*, to arrive at the Challenged Claims. This is blatant improper hindsight reconstruction.

Starting with two circuits in *Jensen*’s device, the Petition argues that a POSA would have been motivated to make “the circuit closest to the patient’s skin”

disposable. Petition, 38 (citing Ex. 1009, ¶1499). But then, to “avoid[] the cost of disposing of valuable electronic circuitry”—a bi-product of the modification that the Petition proposed, not present in *Jensen* to begin—the Petition argues without support that a POSA would further redistribute *Jensen’s* already redistributed electronics. Petition, 39. These alleged movements of circuitry and redesigning of *Jensen’s* device is supported by nothing more than the conclusory statements of Petitioner’s expert regarding the state of the art (which often include references to non-prior art, e.g., Ex. 1009, ¶¶17, 19); *see also* Section V.B.iii.

In view of the actual teachings of *Jensen* and *Matsumura*, it becomes clear that the Petition offers these modifications solely to reconstruct the Challenged Claims while relying on the general knowledge of a POSA to fill gaps along the way. Thus, Ground 2 is legally flawed and fails to render obvious the Challenged Claims.

i. The Non-obvious Combination of *Jensen* and *Matsumura* Fails to Teach or Suggest Every Element of Claim 1

Even assuming a POSA would have combined *Jensen* and *Matsumura* (they would have not), the alleged combination fails to teach at least two elements of Claim 1. *Infra* Section VI.B.ii (explaining the failure to establish a motivation to combine *Jensen* and *Matsumura*). First, the combination does not disclose the “disposable substrate” of Claim 1. Seemingly recognizing this shortcoming, the

Petition posits nothing more than a cursory gap-filling theory that fails to establish a POSA would have been motivated to modify *Jensen* to include such a feature.

Second, the combination fails to render obvious the “computation-communication module.” *See* Section VI.B.i.b. To reconstruct the claimed computation-communication module, the Petition ignores the explicit location of *Jensen*’s electronics; provides no explanation for its modifications to *Jensen*’s electronics; and then contradicts its own position. *See* Section VI.B.i.b.

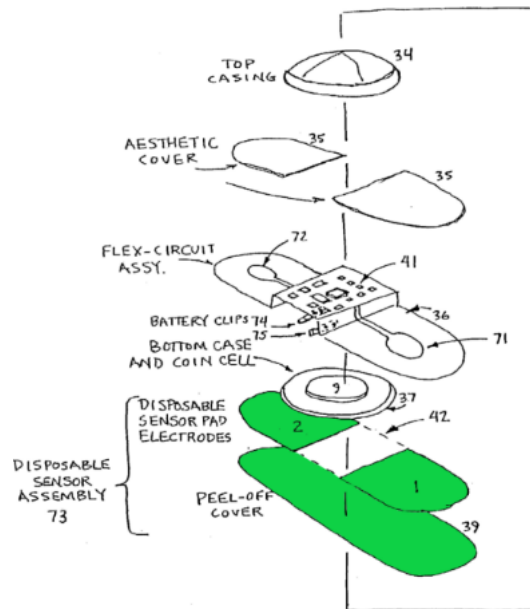
a. Ground 1 fails to render obvious “a disposable substrate”

The Petition fails to render obvious the disposable substrate of claim element 1[a]. First, *Jensen* does not disclose a disposable substrate, and the Petition does not identify one. Ex. 1011, ¶¶[0041]-[0042]; Ex. 2013, ¶[0088]; Petition, 37-40. Second, a POSA would not have been motivated to modify *Jensen* to include the disposable substrate. Ex. 2013, ¶[0089]; Petition, 30, 37-41. Finally, “hygiene and waterproofing” do not provide a sufficient motivation for the Petition’s further modification to redistribute *Jensen*’s electronics from their original location, as the problem does not exist in *Jensen*. Ex. 2013, ¶[0090]; Petition, 39.

i. The Petition Concedes that *Jensen* Does Not Disclose a Disposable Substrate

*Jensen* does not disclose a disposable substrate. The only disposable portion of *Jensen* is the “disposable sensor assembly,” which includes (1) sensor pad

electrodes 1 and 2 and (2) peel-off cover 34, each shown below in Figure 5. Ex. 1011, ¶¶[0041]-[0042], Figure 5; Ex. 2013, ¶[0092].



Ex. 1011, Figure 5 (annotated); Ex. 2013, ¶[0092].

Besides these components—none of which are a disposable substrate—*Jensen* does not disclose or suggest that any components are disposable. Ex. 2013, ¶[0093]. The Petition fails to identify (nor can it) a printed circuit board, electrodes, or conductive traces (the components of the claimed disposable substrate) in *Jensen* that are disposable. Instead, the portions of *Jensen* that the Petition relies on for these elements are all disposed on a non-disposable layer.

Thus, the Petition relies on the general knowledge of a POSA to fill *Jensen*'s gaps. Petition, 37-41. This argument also fails.

ii. The Petition's Disposable Substate Theory Fails

The Petition fails to establish that a POSA would have modified *Jensen* to include a disposable substrate. A POSA would not have been motivated to make *Jensen's* circuit disposable because the circuit is “heat re-flowed together” with another circuit, and *Jensen* provides no basis to make a portion of the circuit disposable, when it already is isolated from the patient's skin. Ex. 2013, ¶¶[0099]-[0102]. A POSA would have recognized that this modification would not create a disposable circuit because removal of the circuit would damage *Jensen's* device. Ex. 2013, ¶[0102].

(a) The Petition Fails to Establish *Why* a POSA Would Have Modified *Jensen* to Include a Disposable Substrate

The Petition fails to explain *why* a POSA would have modified *Jensen* to include a disposable substrate. Petition, 38 (“[A] POSA would have been motivated to make the *circuit* closest to the patient's skin, flexible circuit 50, disposable.”). This ignores the fact that the only layer that contacts the patient's skin *already is* disposable. *Jensen* has already taken the alleged motivation of the Petition to the extreme and preserved all metallic conductive components in the reusable portion of *Jensen*. Ex. 2013, ¶[0094]. Instead, the Petition identifies two circuits in Figure 8 and simply concludes that “a POSA would have been motivated to make the circuit

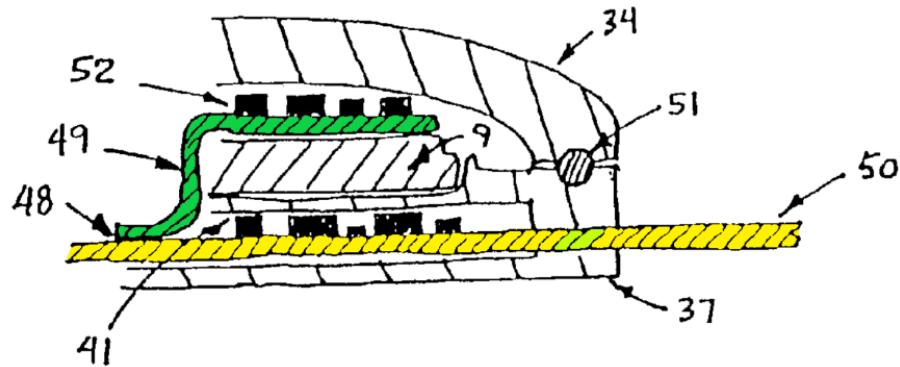
closest to the patient's skin, flexible circuit 50, disposable.” Petition, 38 (citing Ex. 1009, ¶1499). But this conclusory language fails to explain why, given the already optimized construction of *Jensen*. Ex. 2013, ¶¶[0099]-[0102].

The Petition's single citation to Dr. Heikenfeld fares no better. Dr. Heikenfeld concludes that the modification would “promot[e] hygiene generally” by ensuring components closest to the skin were disposable. Ex. 1009, ¶1499. This half-hearted motivation (which could be applied to the entire field of medical devices) is insufficient to support major changes to *Jensen*. Ex. 2013, ¶[0102].

The deficient motivation also highlights the Petition's hindsight bias. The Petition uses the '422 Patent as a roadmap to reconstruct Claim 1 while distorting *Jensen* along the way. A POSA reading *Jensen*'s actual disclosures would not have been motivated to modify *Jensen* as the Petition suggests.

(b) A POSA Would Not Have Been Motivated to  
Modify *Jensen* to Include a Disposable  
Substrate

A POSA would not have been motivated to make the circuit closest to skin (*i.e.*, circuit 50) disposable because this circuit is “heat re-flowed together” with *Jensen*'s other circuit. Ex. 1011, ¶[0046]; Ex. 2013, ¶[0100]. *Jensen* provides two flexible printed circuits in Figure 8 embodiment, annotated in green and yellow below. Ex. 1011, ¶[0046], Figure 8; Ex. 2013, ¶[0100].



Ex. 1011, Figure 8 (annotated); Ex. 2013, ¶[0100].

The circuit 49 is connected to the circuit 50 via “a set of pads 48.” Ex. 1011, ¶[0046]; Ex. 2013, ¶[0100]. The pads from each circuit are matched and “*heat re-flowed together*, melting the tinning metal, to connect the two circuits.” Ex. 1011, ¶[0046], Figure 8A; Ex. 2013, ¶[0100]; *see also* Petition, 45 (acknowledging that *Jensen’s* circuits are heat re-flowed together). A POSA would have understood that heat reflow is a form of permanent bond, like a weld. Ex. 2013, ¶[0100]. With this process, *Jensen* secures its circuits 49, 50 to each other, providing space for additional components. Ex. 1011, ¶[0046]; Ex. 2013, ¶[0100].

While the Petition concludes that a POSA would make the circuit 50 disposable, neither the Petition nor Dr. Heikenfeld explain why a POSA would make this change or how, given the permanent nature of the bond between the two circuits. Ex. 2013, ¶¶[0101]-[0102]; Petition, 38. This is worsened by the Petition’s and Dr.

Heikenfeld's failure to address the circuit 50 being heat re-flowed together with the circuit 49. Ex. 2013, ¶¶[0101]-[0102]; Petition, 38.

A POSA would not make circuit 50 disposable in view of *Jensen's* disclosure. Ex. 2013, ¶[0102]. A POSA would have recognized that there would be no advantages in making the circuit 50 disposable when it is fixed to the reuseable circuit 49. Ex. 2013, ¶[0102]. Rather, separating the circuits 49, 50 would damage (if not destroy) *Jensen's* device when a lab technician would try to dispose of the "disposable" circuit 50. Ex. 2013, ¶[0102]. If this modification was made, *Jensen's* device would include one "disposable" circuit 50 that could not be detached (and thus not disposable) from *Jensen's* other circuit 49. Ex. 2013, ¶[0102]. This would completely eliminate the "disposable" nature of the claimed substrate and rewrites the claim language to make all elements disposable.

As *Jensen* explains, the heat re-flow process consists of "melting the tinning metal, to connect the two circuits." Ex. 1011, ¶[0046]; Ex. 2013, ¶[0100]. Simply put, the Petition's position proposes a modification to insert a disposable component even though a POSA would have recognized that such component could not be disposed of without damaging *Jensen's* device. Ex. 2013, ¶¶[0100]-[0103]. This again highlights the Petition's hindsight reconstruction.

iii. A POSA Would Not Have Been Motivated to Redistribute *Jensen*'s Electronics

The Petition's additional modification to redistribute electronics further confirms the Petition's hindsight reconstruction. Petition, 39. After modifying *Jensen* to create a disposable substrate, the Petition argues that a POSA would have been motivated to redistribute "valuable components" on top substrate 49 rather than the disposable substrate. Petition, 39. This alleged "problem" was not an issue before the Petition modified *Jensen* to make the circuit 50 disposable (and notably, in the pre-modified version, all valuable components were already part of the reusable layer). Ex. 2013, ¶¶[0105]-[0107]. The Petition cannot modify *Jensen* to include a disposable substrate, create an issue from this modification (*i.e.*, having to "avoid[] the cost of disposing of valuable electronic circuitry"), and then use this issue to **further modify** *Jensen* selectively back to the form Petitioner deviated from. Petition, 39; Ex. 2013, ¶[0108].

Besides costs-savings, the Petition also fails to establish a motivation to combine based on "hygiene and waterproofing." Petition, 39; Ex. 2013, ¶[0109]. First, the Petition's argument that a disposable circuit improves safety and promotes "hygiene" suffers from the same issues as covered in Section VI.B.i.a.ii. Ex. 2013, ¶[0110]; Petition, 31-32, 39. Namely, *Jensen* uses a heat re-flow process to connect the two circuits. Ex. 1011, ¶[0046]; Ex. 2013, ¶[0110]. To conclude (as the Petition

does) that a POSA would have simply made the circuit 50 disposable ignores the actual structure of *Jensen*. Ex. 2013, ¶[0110]; see Section VI.B.i.a.ii.

Second, the Petition provides no explanation of how redistributing the electronics would improve *Jensen*'s waterproofing. Petition, 39 (“As noted above, this redistribution of components would improve...waterproofing properties of *Jensen*'s device.”) (citing Ex. 1009 ¶¶1499-500). Neither does Dr. Heikenfeld. Ex. 2013, ¶[0111]. Like the Petition, Dr. Heikenfeld fails to provide a basis for this, rather he cross-references an entire section—related to a different patent—on combining *Jensen* and *Matsumura*. Ex. 1009, ¶1500 (citing Section XVIII.C.1); Ex. 2013, ¶[0111]. There, Dr. Heikenfeld argues that a POSA would modify *Jensen* to allegedly achieve a waterproof structure. Ex. 1009, ¶947; Ex. 2013, ¶[0112]. Dr. Heikenfeld fails to even mention redistributing the electronics, let alone explain how redistributing the electronics would improve *Jensen*'s waterproofing as the Petition contends. Ex. 1009, ¶947; Ex. 2013, ¶[0112]. Thus, the Petition fails to establish that “hygiene and waterproofing” would have motivated a POSA to redistribute electronics based on *Jensen* alone. Ex. 2013, ¶[0113].

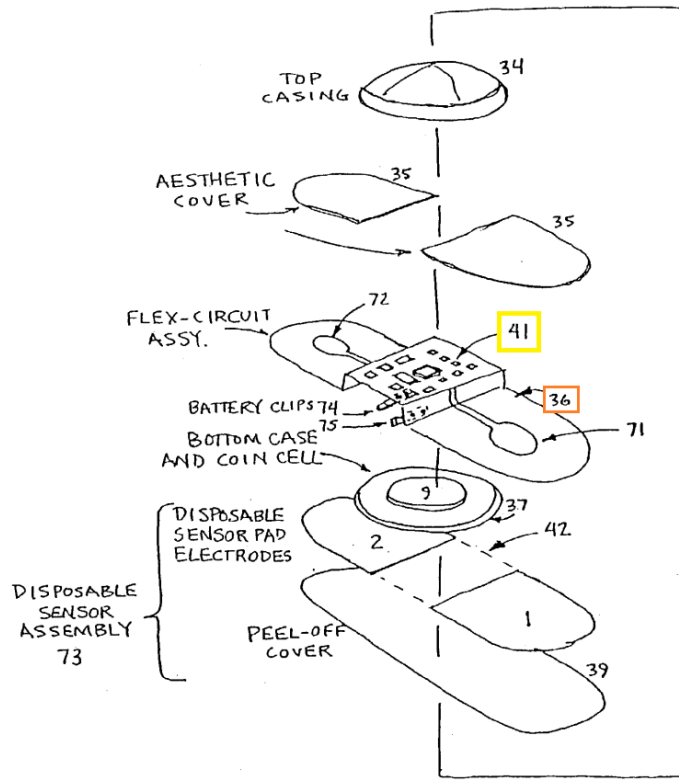
The Petition's alternative theory of modifying *Jensen* in view of *Matsumura* does not address the above issues and similarly fails, for the reasons outlined below in Section VI.B.ii. Petition, 40-41; Ex. 2013, ¶[0114]. Thus, the Petition also fails

to explain how redistributing electronics improves waterproofing. Ex. 2013, ¶¶[0109], [0113].

- b. Ground 2 fails to render obvious the “computation-communication module” of Claim 1[e]

The claimed computation-communication module must be attached to the disposable substrate. The Petition alleges that the disposable substrate is layer 49. However, there is no disclosure in *Jensen* of any computation-communication module attached to layer 49.

*Jensen*’s electronics circuit includes a microcontroller and a transmitter. Ex. 1011, ¶¶[0031]-[0032]; Ex. 2013, ¶[0116]. In Figure 5, electronics circuit 41 (yellow below) connects to the flexible circuit assembly 36 (orange below). Ex. 1011, ¶[0040]; Ex. 2013, ¶[0117].

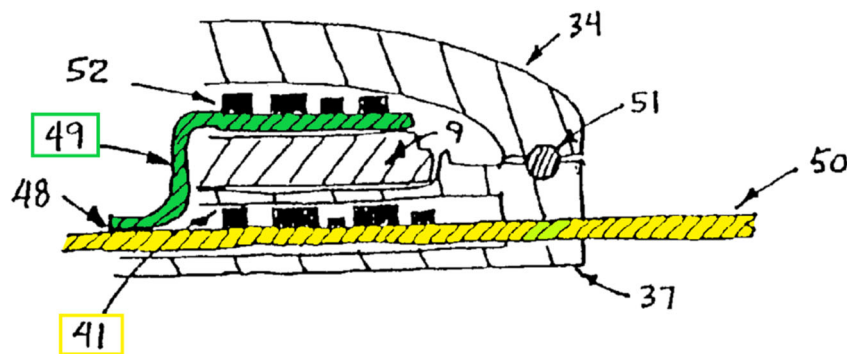


Ex. 1011, Figure 5 (annotated); Ex. 2013, ¶[0117].

*Jensen* also illustrates its electronics circuit 41 in Figure 8, where the electronics circuit 41 is disposed on flexible circuit 50. Ex. 1011, ¶[0046], Figure 8; Ex. 2013, ¶[0118].

*Jensen* provides zero disclosure to support the Petition's argument that the microcontroller or transmitter are located on *substrate 49*. Ex. 2013, ¶[0119]; Petition, 43-44. In reference to the below annotated Figure 8, electronics circuit 41 (which includes the microcontroller and transmitter) is disposed *on circuit 50*. Ex. 2013, ¶[0118]; Ex. 1011, Figure 8 (indicating the circuit 50 in yellow). Contrary to

the Petition's argument, a POSA would *not* have understood that either the microcontroller or the transmitter are "included on non-disposable substrate 49 in the embodiment shown in Figure 8," because they are explicitly indicated as appearing on layer 50. Ex. 2013, ¶[0118]; Ex. 1011, Figure 8 (indicating the circuit 49 in green); Petition, 43-44.



Ex. 1011, Figure 8 (annotated); Ex. 2013, ¶[0118].

This issue is highlighted by the Petition's failure to provide any explanation as to *why* a POSA would have understood the microcontroller and transmitter to be located on substrate 49, especially in view of *Jensen's* clear disclosure that electronics 41 are on layer 50. Ex. 2013, ¶[0118]; Petition, 43-44 (concluding that "[a] POSA would understand that the computation-communication module of *Jensen* would be included on non-disposable substrate 49 in the embodiment shown in Figure 8 of *Jensen*."). The sole citation to Dr. Heikenfeld repeats the same bare conclusion. Ex. 2013, ¶[0119]; *see* Ex. 1009, ¶1522 ("A POSA would understand

that the computation-communication module of Jensen would be included on non-disposable substrate 49 in the embodiment shown in Figure 8 of Jensen.”).

Finally, the Petition contradicts its own position regarding the location of *Jensen*’s microcontroller. When analyzing a different claim element, the Petition states that “[a]s part of *electronics circuitry 41*, Jensen discloses ‘a microcontroller and/or other programmable logic circuitry that perform measurement and processing of sensed data.’” Petition, 44; Ex. 2013, ¶[0120]. Electronics circuitry 41 is located on the circuit 50. Ex. 2013, ¶[0120]; Ex. 1011 ¶[0046], Figure 8. But as covered above, the Petition also contends that the microcontroller “would be circuitry 52, located on the non-disposable substrate 49.” Petition, 45. Without explaining *why* a POSA would have understood the electronics to be “included on non-disposable substrate 49,” this argument fails, and Dr. Heikenfeld’s testimony should be given no weight. Ex. 2013, ¶¶[0119]-[0120]; Petition, 43-44. The Petition fails to render obvious claim element 1[e].

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

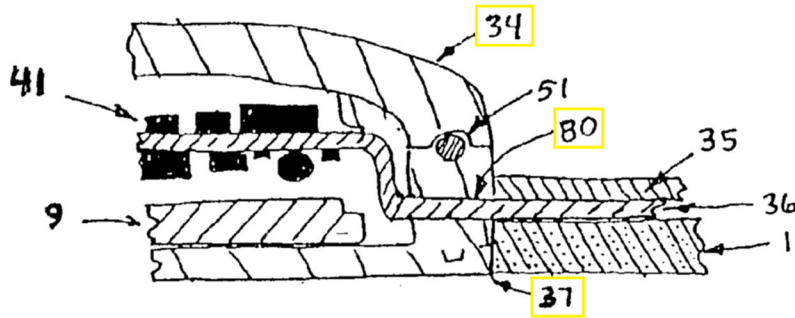
The Petition fails to establish that a POSA would have been motivated to modify *Jensen* based on either a desire to achieve a waterproof structure or the risk of ineffective cleaning. Ex. 2013, ¶[0123]; Petition, 30-36. First, waterproofing is not a sufficient motivation to combine because *Jensen*’s electronics are already

sealed from the surrounding environment. Ex. 1011, ¶[0045]; Ex. 2013, ¶¶[0123]-[0124]; *see* Section VI.B.ii.a. Second, a POSA would not have been motivated to modify *Jensen*'s teachings based on "ineffective cleaning" because the proposed modification to *Jensen* would not actually provide any advantages in the cleaning process over what is already present. Ex. 2013, ¶¶[0123]-[0124]; *see* Section VI.B.ii.b. 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, a POSA would not have been motivated to combine *Jensen* and *Matsumura*, and Ground 2 fails.

a. A POSA Would Not Have Been Motivated to Modify  
*Jensen* to Achieve a Waterproof Structure

A POSA would not have been motivated to modify *Jensen*'s design to achieve a waterproof structure because *Jensen*'s already seals its electronics from the surrounding environment. Ex. 1011, ¶[0045]; Ex. 2013, ¶[0124]; Petition, 34. As shown in Figure 7, *Jensen* provides a top case 34 that mounts to a bottom case 37, which includes a slot cut-out 80 for the passage of flexible circuit assembly 36. Ex. 1011, ¶[0045]; Ex. 2013, ¶[0125].



Ex. 1011, Figure 7 (annotated); Ex. 2013, ¶[0125].

Once assembled, a sealant is applied to the slot 80 “to *seal the electronics* 41 from the surrounding environment.” Ex. 1011, ¶[0045]; Ex. 2013, ¶[0125]. Also, the “top and bottom case halves 34, 37 have an o-ring seal 51 at their mating surfaces.” Ex. 1011, ¶[0045]; Ex. 2013, ¶[0125]. Based on this disclosure, a POSA would not have been motivated to look to other references to modify *Jensen*, let alone redesign *Jensen* as the Petition suggests. Ex. 2013, ¶[0125].

Moreover, the Petition is not saved by its unsupported conclusion that *Jensen*’s design is “susceptible to seepage.” Ex. 2013, ¶[0126]; Petition, 34 (citing Ex. 1009, ¶943). Neither *Jensen* nor *Matsumura* provide any disclosure that suggest *Jensen*’s structure is not sufficiently sealed. Ex. 2013, ¶[0126]; *see generally*, Ex. 1011; Ex. 1012. As a common theme, the Petition instead relies on the general understanding of a POSA to fill gaps—without pointing to *any* disclosure, anywhere. Petition, 52 (concluding a “POSA would have understood [*Jensen*] to be susceptible to seepage.”). In Dr. Heikenfeld’s declaration, he too concludes, without

support, that a POSA would have known that *Jensen* was prone to seepage. Ex. 2013, ¶[0127]; see Ex. 1009, ¶943. But Dr. Heikenfeld confirms that *Jensen* already addresses the problem through sealant. *Id.* This already solved problem fails to provide a motivation to combine *Jensen* and *Matsumura*. Thus, contrary to the Petition, a POSA would not have been motivated to modify *Jensen* to achieve a “waterproof” structure. Petition, 34.

b. A POSA Would Not Have Been Motivated to Modify  
*Jensen* Due to “Ineffective Cleaning”

“[I]neffective cleaning” also fails to suggest a reason to modify *Jensen* to include a disposable layer in view of *Matsumura*. Ex. 2013, ¶[0129]. In Figure 5, for example, disposable sensor pad electrodes 1, 2 couple to the flexible circuit assembly, which includes electronics circuit 41. Ex. 1011, ¶¶[0041]-[0042], Figure 5; Ex. 2013, ¶[0129]. The Petition contends that a POSA would modify *Jensen* to include a disposable layer that (1) connects the electrodes to the electronics while (2) separating the reuseable portion from the skin. Petition, 33-34. The Petition does nothing but state *a result* without articulating any reason, to reconstruct the Challenged Claims. The Petition also fails because its motivation is based on the false premise that its modifications would lead to disposable parts for minimizing the risk of ineffective cleaning. Ex. 2013, ¶[0130]; Petition, 31-32. For the reasons detailed in Section VI.B.i.a.ii, the Petition’s modifications would not lead to any

disposable components (as the circuits are heat re-flowed together), and thus there would be no advantages to the cleaning process. Ex. 2013, ¶[0130].

**C. Ground 3 Fails to Render Obvious the Challenged Claims**

*Ozguz*, alone or in combination with the “general knowledge” of a POSA or *Matsumura* does not render obvious the claimed processor disposed in the housing. The Petition fails to provide any rational basis for modifying *Ozguz* in view of the so-called “general knowledge” and similarly fails to provide any reasonable support for combining *Ozguz* and *Matsumura*. These shortcomings arise primarily from the Petition’s reliance on a reference that is nothing more than an aspirational disclosure that is itself not enabled: *Ozguz*. Ex. 2013, ¶¶[0135]-[0152]. As a result, this Ground fails to render obvious Claims 1 and 14.

**i. The Non-Obviousness Combination of *Ozguz* and the General Knowledge of a POSA Fails to Render Obvious Claim 1**

*Ozguz* in view of the general knowledge of a POSA fails to render obvious Claim 1. Ex. 2013, ¶¶[0132]-[0133]. Specifically, *Ozguz* does not disclose the “housing” much less the “processor *disposed in* the housing” of Claim 1. Ex. 2013, ¶¶[0133]-[0134]. The Petition improperly assumes the flexible battery is somehow analogous to a “housing” without providing any rationale for such an assumption. Ex. 2013, ¶[0136]. The flexible battery disclosed in *Ozguz* is a single flat layer that does not “house” anything, and a POSA would have recognized this. Even worse,

*Ozguz* is an aspirational reference that does not enable the relied upon disclosure. Ex. 2013, ¶[0155]. Notably, neither the flexible battery nor the microns-thick device is adequately enabled, and for that reason alone a POSA would not have been able to arrive at the Challenged Claims using *Ozguz*'s teachings. Ex, 2013, ¶[0172]. The Petition fails to establish that Claim 1 is obvious. Ex. 2013, ¶[0132].

- a. Ground 3 fails to render obvious the housing and the processor disposed in the housing

The Petition fails to render obvious Claim 1 because *Ozguz*'s “flexible, thin battery” is not a housing, and the processor is not “disposed in” the flexible battery. The Petition's own annotation highlights that the flexible battery 105 is not a housing, but a single layer on top. Ex. 2013, ¶[0137] (citing Petition, 59-60).

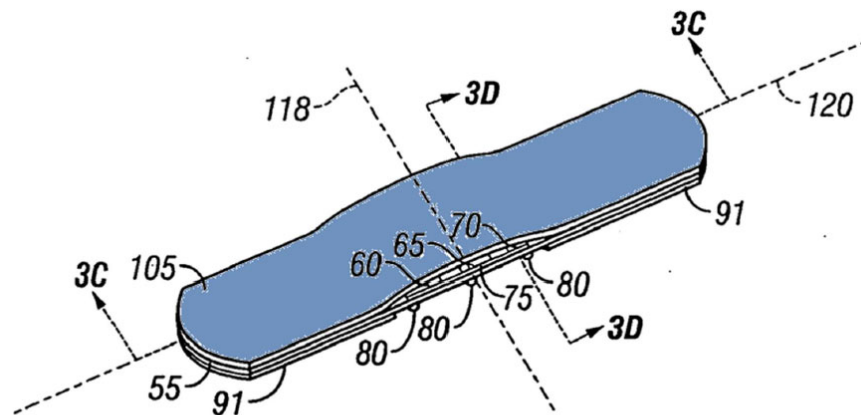


**FIG. 3A**

Petition, 60. Second, *Ozguz* itself characterizes the flexible battery 105 as simply an “overlying battery 105” that “overlays” other components of the device. Ex. 1014

¶¶[0048], [0055]. A POSA would not have understood the term “housing” to mean an overlay. Ex. 2013, ¶¶[0136]-[0138]. *Ozguz* does not disclose any structure that is reasonably considered a housing, and the Petition’s conclusory allegation that the flexible battery is “shaped in a way that houses the computation-communication module” does not pass muster. Ex. 2013, ¶[0138]. The Petition fails to establish that *Ozguz* teaches or suggests the “housing” as recited in Claim 1.

Because *Ozguz* does not disclose a housing, it also does not disclose a processor disposed in the housing as recited by Claim 1. Ex. 2013, ¶¶[0140]-[0141]. Moreover, *Ozguz* teaches that the flexible battery sits atop silicon substrates 60, 65, 70 and their respective ICs 71, 72, 73. Ex. 1014, ¶[0048]. *Ozguz*’s silicon substrates 60, 65, 70 may include circuitry further including a microprocessor. Ex. 1014, ¶[0058]. However, the Petition’s allegation that the flexible battery merely sits atop the silicon substrates is a far leap from the disclosure of *Ozguz*. This does not somehow mean that the silicon substrates are disposed in the flexible battery. Ex. 2013, ¶[0142]. A POSA would have understood that the flexible battery is merely an upper layer to the device and is not critical for housing anything. Ex. 2013, ¶[0142]. The Petitioner fails to establish that *Ozguz* teaches or suggests the housing and the processor disposed in the housing, and therefore this Ground fails to render obvious Claim 1.

- b. Any implicit claim construction by the Petition is improper and should be ignored

Without any explanation or support, the Petition improperly applies an overly broad construction of the terms “housing” and “disposed in the housing.” Petition, 59-60. The Petition’s flawed approach should be ignored for two reasons. First, the Petition did not apply the *Phillips* framework. Petition, 2. Second, even if Petitioner followed the rules and explained its claim construction analysis, the Petition’s constructions for “housing” and “disposed in the housing” are unreasonably broad and do not align with the meaning of those terms in Claim 1.

The Petition hides behind the “ordinary and customary meaning” for all claim terms, leaving the Board to guess the Petition’s position on “housing” and “disposed in the housing.” Petition, 2. In its analysis, the Petition seemingly construes “housing” to mean any type of unenclosed overlay—an interpretation that contradicts the ordinary meaning of “housing,” which a POSA would have understood implies an enclosure rather than a mere layer placed on top. Ex. 2013, ¶¶[0143]-[0145]. The Petition’s own annotation makes clear that the flexible battery is not a “housing” but is instead a thin layer sitting atop the rest of *Ozguz*’s device. Ex. 2013, ¶[0144]; Petition, 60 (annotating Figure. 3A, reproduced below).

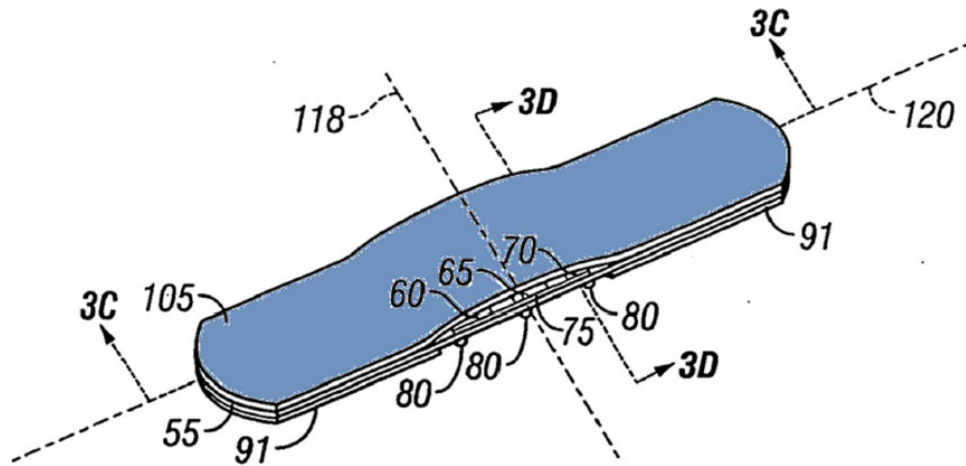


**FIG. 3A**

Ex. 1014, Figure 3A (original annotations by the Petition).

Based on Figure 3A, the Petition alleges that flexible battery 105 “is shaped in a way that houses the computation-communication module.” Petition, 59. Yet, the Petition fails to explain what it means by “shaped in a way” and provides no additional analysis or support that the flexible battery is a housing. Ex. 2013, ¶[0145]. This leaves the Patent Owner and the Board to ask: “Shaped in what way?” Such a conclusory allegation is entirely insufficient to establish that the flexible battery qualifies as a “housing.” Ex. 2013, ¶¶[0146]-[0147].

*Ozguz* itself characterizes flexible battery 105 as an “overlying battery 105” that “overlays” other components of the device. Ex. 1014 ¶¶[0048], [0055]. A POSA would not have understood the term “housing” to mean an overlay. Ex. 2013, ¶[0146]. Rather, a POSA would have known that an overlaying structure does not

imply it is housing anything, particularly in the context of how housings are typically described in the art. Ex. 2013, ¶[0146]. A housing is structured to provide a protective barrier or containment, which is not the role of a flexible battery. Ex. 2013, ¶[0146]. The Petition cites no evidence to establish that a POSA would have thought any different. Petition, 59-60; Ex. 2013, ¶¶[0146]-[0147]. To conclude (as the Petition does) that a POSA would have considered a flexible battery layer to be a housing ignores the actual construction of *Ozguz*. Ex. 2013, ¶[0147]. Thus, the Petition fails to establish the recited housing. Ex. 2013, ¶[0147].

Further, because the Petition applies an improper construction of “housing,” it also improperly construes “disposed in the housing” as recited in Claim 1. However, the Petition also provides an improper construction of “disposed in” separate and apart from its erroneous understanding of “housing.” Ex. 2013, ¶¶[0151]-[0152]. *Ozguz*’s silicon substrates may include circuitry that further includes a microprocessor. Ex. 1014, ¶[0058]. However, the flexible battery merely sits atop of the silicon substrates, and at no point does the microprocessor enter inside any boundary of the flexible battery’s outer walls. Ex. 2013, ¶[0153]. Despite the express teachings of *Ozguz*, the Petition somehow construes the term “disposed in the housing” to mean anything that touches the flexible battery layer. Ex. 2013, ¶[0154]. The Petition’s application of this broad construction is erroneous on the

merits but is made even worse because Petitioner failed to actually construe the term “disposed in the housing.” The Petition’s interpretation of these claim terms are improper and should be ignored.

**ii. Ozguz is Non-enabling for Obviousness**

*Ozguz* discloses speculative and unrealistic features that were not achievable at the time of the invention. Ex. 2013, ¶[0155]. 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. 2013, ¶[0155].

The Petitioner does not propose using any combination of references with *Ozguz* to meet independent Claims 1 or 14. In the absence of such other supporting evidence to enable a skilled artisan to make the claimed invention, a standalone § 103 reference must enable the portions of its disclosure being relied upon. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297 (Fed. Cir. 1985). Here, the portions of *Ozguz* relied on by the Petition are not enabled and *Ozguz*

cannot render obvious the claimed invention. “In the absence of such other supporting evidence to enable a skilled artisan to make the claimed invention, a standalone § 103 reference must enable the portions of its disclosure being relied upon.” *Raytheon Techs. Corp. v. GE*, 993 F.3d 1374, 1377, 1380-1381 (Fed. Cir. 2021) (rejecting, as dispositive, the standalone prior art reference [Knip] asserted in § 103 concerning a “futuristic turbine engine” as not self-enabled). “[I]f an obvious case is based on a non-self-enabled references and no other prior art reference or evidence would have enabled a skilled artisan to make the claimed invention, then the invention cannot be said to have been obvious.” *Id.* at 1376.

a. A POSA Would Not Have Relied on *Ozguz* to Reach the Challenged Claims

*Ozguz* describes the use of futuristic flexible batteries and infeasible thin silicon technology as part of the device. However, at the time of *Ozguz*’s purported priority date (2005) and at the time of the date of the ’422 Patent (2006), flexible batteries were not viable or commercially available in the form described in *Ozguz*. Ex. 2013, ¶[0156]. While the concept of flexible batteries may have been proposed, the technology to implement such a feature in a working device was in its infancy, and its availability was far from practical. Ex. 2013, ¶[0157]. 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 and thin silicon technology as described in *Ozguz*. Ex. 2013, ¶[0157].

*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. 2013, ¶[0158]. The reference oversimplifies the real-world constraints on battery capacity, longevity, and energy efficiency, and overlooks the fact that flexible battery technologies at that time were not advanced enough to support the sustained, low-power requirements of continuous physiological monitoring. Ex. 2013, ¶[0158].

The flexible batteries lacked reliability and durability needed for powering such a device over extended periods, and for 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. 2013, ¶¶[0159]-[0160]. Importantly, the miniature size and layered structure of *Ozguz*'s device would have a significant risk of thermal overheating in the flexible battery, making the design impractical for real-world use, and particularly unsuitable in the context of a patient wearable device. Ex. 2013, ¶[0160].

Further, a POSA would have understood the technological and economic landscape at the time of the invention, and would have recognized that incorporating a flexible battery as described in *Ozguz* would be at odds with the cost-effective solution sought by the inventors of the '422 Patent. Ex. 2013, ¶[0159]; Ex. 1007, 2:21-23. Finally, even if a theoretical or experimental flexible battery existed at the time of the invention, it would not have been reliable for use in a wearable cardiac device. Ex. 2013, ¶[0159]. Consequently, a POSA would not have been able to use a flexible battery in a functional ambulatory monitor, undermining the enablement of *Ozguz*. Ex. 2013, ¶[0159].

Further, using flexible batteries in a patient wearable device, particularly one designed for continuous wear and monitoring, would have posed significant challenges in terms of user comfort and practicality, as such devices require long battery life, preferably without frequent recharging or the discomfort of bulky or frequently replaced batteries. Ex. 2013, ¶[0160]. 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. 2013, ¶[0160]. 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. 2013, ¶[0160]. 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. 2013, ¶¶[0159]-[0160].

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. 2013, ¶[0161]. *Ozguz* assumes that basic waterproofing techniques, such as skin adhesion methods, would suffice to ensure the device's operation under real-world conditions. Ex. 2013, ¶[0161]. This assumption overlooks the complexity of waterproofing flexible materials, which was not feasible with the available materials and methods at the time. Ex. 2013, ¶[0161]. Waterproofing such a device requires integrating specialized coatings or barriers that protect sensitive electronic components from moisture without compromising the flexibility or comfort of the device. Ex. 2013, ¶[0161].

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. 2013, ¶¶[0157], [0161].

Specifically, an overlooked critical challenge in *Ozguz's* design is the incompatibility between a more rigid battery, which in reality would have been only minimally flexible, and the flexible layers of the device. The use of the battery layer inside a flexible structure would create significant waterproofing issues, particularly at the edges of the device where the battery meets the flexible layers. Ex. 2013, ¶[0162]. This combination of rigid and flexible components would lead to poor sealing around the edges, allowing moisture to seep into the device. Ex. 2013, ¶[0162]. The lack of a reliable seal would expose the internal electronics to potential water damage, particularly in environments where sweat, moisture, or even rain could compromise the device's integrity. Ex. 2013, ¶¶[0162]-[ 0163]. This issue further highlights the unrealistic nature of *Ozguz's* disclosure, as a wearable device could not afford to risk water damage, especially when used in environments that are prone to moisture exposure.

The lack of consideration for long-term environmental resistance and the durability of flexible materials significantly diminishes the relevance of *Ozguz* as prior art, as its teachings do not provide enabling disclosure for a viable wearable monitor that could withstand the rigors of real-world use. Ex. 2013, ¶[0163]. 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 alone or with other prior art unrealistic and impractical. Ex. 2013, ¶[0163]. Accordingly, a POSA would not have been motivated to look at *Ozguz*'s teachings to create a functional wearable monitor.

b. The Petition's Reliance on *Ozguz*'s Infeasible Flexible Battery Technology is Fatal to Ground 3

The Petition relies on *Ozguz*'s "flexible battery 105" for at least two of the claim elements in independent Claim 1. Petition, 59, 60. However, this 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. 2013, ¶[0164].

**First**, in 2005 there was limited mechanical flexibility of commercially available batteries. Ex. 2013, ¶[0165]. 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 *Ozguz*, particularly the repeated bending and twisting needed for a wearable "adhesive bandage" form factor. Ex. 2013, ¶[0165]. 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. 2013, ¶[0165]. 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 wearable applications. Ex. 2013, ¶[0165].

**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. 2013, ¶[0166]. 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. 2013, ¶[0166]. 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. 2013, ¶[0166]. Rechargeable technologies like NEC's Organic Radical Battery (ORB), while flexible and seemingly promising, were only experimental prototypes with very limited energy density ( $\sim 1$  mWh/cm<sup>2</sup>). Ex. 2013, ¶[0166]. By 2005, flexible battery technologies simply could not offer sufficient power density and durability required by the *Ozguz* device specification. Ex. 2013, ¶[0166].

**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. 2013, ¶[0167]. As of 2005, flexible battery manufacturing was either experimental or limited to niche applications. Ex. 2013, ¶[0167]. Mass-scale production processes (e.g., roll-to-roll printing) of thin-film batteries were only in pilot stages, with limited reliability and inconsistent quality. Ex. 2013, ¶[0167]. The flexible, thin-film silicon-based integrated circuit described in *Ozguz* (which itself is not enabled as discussed below in Section VI.C.ii.c), highlights a degree of integration and complexity requiring robust, reliable power delivery. Ex. 2013, ¶[0167]. 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. 2013, ¶[0167].

*Fourth*, integrating the flexible battery into *Ozguz*'s device would have presented additional significant challenges. Ex. 2013, ¶[0168]. *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. 2013, ¶[0168]. 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. 2013, ¶[0168]. The delicate thin-silicon layers and sensitive integrated circuitry required extremely uniform and mechanically stable battery technology. Ex. 2013, ¶[0168]. The available battery solutions could not satisfy this stringent mechanical integration requirement (without compromise in structural integrity, operational lifetime, or safety). Ex. 2013, ¶[0168].

c. The Petition's Reliance on *Ozguz*'s Infeasible Thin Silicon Technology is Fatal to Ground 3

Dr. Heikenfeld relies on *Ozguz*'s thinned silicon substrates for at least five of the claim elements in independent Claim 1. Ex. 1009, ¶¶1624 (claim element 1[a]), 1642-1643 (claim element 1[e]), 1647 (claim element 1[f]), 1651 (claim element 1[g]), 1655 (claim element 1[h]). However, this thin silicon technology was infeasible in 2005 (*Ozguz*'s purported priority date), 2006 (the '422 Patent's priority date), and still infeasible up to at least 2015. Ex. 2013, ¶¶[0169]-[0170].

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). This prevented the technology from achieving consistency, reliability, and high throughput manufacturing necessary for practical use. Ex. 2013, ¶¶[0171]-[0172].

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. 2013, ¶[0172]. 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. 2013, ¶¶[0171]-[0172]; 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. 2013, ¶¶[0173]-[0174]. However, even the research-based developments of flexible thinned silicon devices suffered from difficulties with power and wireless communication interoperability. Ex. 2013, ¶[0175]. The U.S. government, in 2015, recognized these inadequacies, which underscores the depth and persistence of these technical and manufacturing challenges. Ex. 2013, ¶¶[0175]-[0176]. Thus, the wearable, flexible device as described by *Ozguz* was not realizable by a POSA in 2005.

**iii. The Non-Obvious Combination of *Ozguz* and the General Knowledge of the POSA Fails to Render Obvious Claim 14**

As described above with respect to Claim 1, the Petition fails to render obvious Claim 14.

**VII. CONCLUSION**

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

Dated: May 12, 2025

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

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**CERTIFICATE OF SERVICE**

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