

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**SAMSUNG ELECTRONICS CO., LTD.,
SAMSUNG ELECTRONICS AMERICA, INC.,
FOSSIL GROUP, INC.,
FOSSIL STORES I, INC.,
FOSSIL PARTNERS, L.P.,
OURA HEALTH OY, AND
ONEPLUS TECHNOLOGY (SHENZHEN) CO., LTD.**

Petitioners

v.

OMNI MEDSCI, INC.,

Patent Owner

Patent No. 9,055,868

Case No. IPR2025-01249

PATENT OWNER'S PRELIMINARY RESPONSE

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LISTING OF EXHIBITS

Exhibit No.	Description
2001	Complaint, <i>Omni MedSci, Inc. v. Samsung Electronics Co. Ltd. et al.</i> , 2:24-cv-01070-JRG-RSP (E.D. Tex.) (Dec. 20, 2024)
2002	Samsung, Fossil, and Oura's Invalidity Contentions Cover Document and Charts for the '868 Patent, <i>Omni MedSci, Inc. v. Samsung Electronics Co. Ltd. et al.</i> , 2:24-cv-01070-JRG-RSP (E.D. Tex.) (June 3, 2025)
2003	OnePlus's Invalidity Contentions Cover Document and Charts for the '868 Patent, <i>Omni MedSci, Inc. v. Samsung Electronics Co. Ltd. et al.</i> , 2:24-cv-01070-JRG-RSP (E.D. Tex.) (Sept. 30, 2025)
2004	Omni MedSci's Infringement Contentions Cover Document, <i>Omni MedSci, Inc. v. Samsung Electronics Co. Ltd. et al.</i> , 2:24-cv-01070-JRG-RSP (E.D. Tex.) (Mar. 12, 2025)
2005	Samsung, Fossil, and Oura's Motion to Stay, <i>Omni MedSci, Inc. v. Samsung Electronics Co. Ltd. et al.</i> , 2:24-cv-01070-JRG-RSP (E.D. Tex.) (Aug. 27, 2025)
2006	Order Denying Motion to Stay, <i>Omni MedSci, Inc. v. Samsung Electronics Co. Ltd. et al.</i> , 2:24-cv-01070-JRG-RSP (E.D. Tex.) (Aug. 29, 2025)
2007	Docket Navigator Statistics for District Judge James Rodney Gilstrap
2008	Lex Machina Statistics for District Judge James Rodney Gilstrap
2009	Model Order Focusing Patent Claims and Prior Art to Reduce Costs (E.D. Tex.)

2010	Patent Assignment Record for U.S. Patent Application No. 719,601 (U.S. Patent No. 5,891,022)
2011-2030	Reserved
2031	Declaration of Igor Efimov, Ph.D.
2032	Curriculum vitae of Igor Efimov, Ph.D.
2033	Omni MedSci Inc.'s P.R. 4-2 Disclosure of Preliminary Claim Constructions and Extrinsic Evidence, <i>Omni MedSci, Inc. v. Samsung Electronics Co. Ltd. et al.</i> , 2:24-cv-01070-JRG-RSP (E.D. Tex.) (Oct. 31, 2025)
2034	Samsung Electronics, Co. Ltd., Samsung Electronics America, Inc., Fossil Group, Inc., Fossil Stores I, Inc., and Fossil Partners, L.P., and Oura Health Oy's P.R. 4-2 Disclosure of Preliminary Claim Constructions and Extrinsic Evidence, <i>Omni MedSci, Inc. v. Samsung Electronics Co. Ltd. et al.</i> , 2:24-cv-01070-JRG-RSP (E.D. Tex.) (Oct. 31, 2025)

Omni MedSci, Inc. ("Patent Owner") submits this Preliminary Response under 37 C.F.R. § 42.107 to the Petition for *Inter Partes* Review ("Petition") of U.S. Patent No. 9,055,868 ("the '868 Patent"), filed by Samsung Electronics Co. Ltd., Samsung Electronics America Inc., Fossil Group, Inc., Fossil Stores I, Inc., Fossil Partners, L.P., Oura Health Oy, and OnePlus Technology (Shenzhen) Co., Ltd. ("Petitioners").

I. INTRODUCTION

Patent Owner respectfully requests that the Board deny institution because Petitioners have not shown any challenged claim of the '868 Patent is unpatentable in relation to any ground raised in the Petition.

Petitioners did not meet their burden for Ground 1, which relies on Mault, because Mault primarily describes an invasive microneedle-based glucose monitoring system with only brief and generalized references to optical sensing. Mault's cursory functional mention of light emission and detection does not disclose a "lens system" configured to receive an "input light beam" and communicate it onto a part of the user's body comprising blood as required by independent claim 7. Moreover, Mault's description of a "remote server" and database does not correspond to the claimed host "comprising a digital file for receiving and storing at least a portion of the wireless data" and "control logic ... to generate a status of the user" as required by claim 7.

Petitioners did not meet their burden for Ground 2, which relies on Mault in view of Mitsui, because Mitsui's disclosure of multiple discrete laser sources and detectors does not teach or suggest the claimed spectroscopic diagnostic procedure based on amplitude comparison across multiple associated wavelengths as required by claim 9.

Petitioners did not meet their burden for Grounds 3–4, which rely on Mault and Mitsui in view of Pologe, because the cited references address distinct and unrelated technical problems and operate on incompatible design principles. Mault requires its light sources and photodetectors to be positioned at or near the tissue measurement site, whereas Pologe deliberately relocates all light sources to the main unit to maintain a passive, disposable probe. Since these inventions pursue different objectives—one analytical, the other ergonomic—a person of ordinary skill in the art (“POSITA”) would have had no reason or technical motivation to combine them. Integrating Mault's active optical components into Pologe's passive probe would also undermine each system's intended purpose.

Petitioners did not meet their burden for Grounds 5–8, which rely on Mault, Mitsui, and Pologe in view of Kiani, because Kiani's “probe-off” contact sensor does not provide positional or proximity data as required by the '868 claims. Kiani's contact-based system is inconsistent with the non-contact proximity sensing

architecture of the '868 Patent and substituting it into the claimed design would defeat the patent's safety and operational purpose.

II. OVERVIEW OF THE '868 PATENT

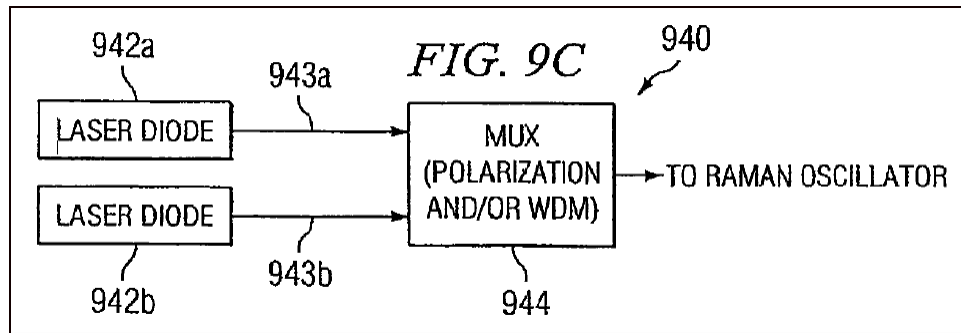
The '868 Patent discloses an integrated medical diagnostic system that combines optical, electronic, and software components to measure physiological parameters of a user. EX2031, ¶48; EX1001, claim 7.

The inventor recognized the need for a noninvasive, networked diagnostic platform capable of providing accurate physiological measurements while supporting responsive user control and remote monitoring. EX1001, 2:34-3:2; EX2031, ¶52. As explained in the specification, in one embodiment, “a diagnostic system includes a light source comprising one or more semiconductor diodes generating an input light beam” and “[a] lens system is configured to receive at least a portion of the input light beam and to communicate at least the portion of the input light beam onto a part of a user's body comprising blood.” EX1001, 2:34-3:2; EX2031, ¶52. The lens system is configured to receive at least the portion of the input beam from the light source and to communicate at least the portion of the input beam by forming an output beam for use in medical diagnostics. EX1001, 2:34-3:2, 3:3-21; EX2031, ¶52. The disclosed diagnostic system incorporates a light source and other optical components for generating an output beam. EX1001, 2:34-3:2, 3:3-21; EX2031, ¶52. In one disclosed embodiment, multiple semiconductor diodes

generate pump beams which are combined and passed through one or more waveguide structures to form an output beam. EX1001, 3:3-21; EX2031, ¶52.

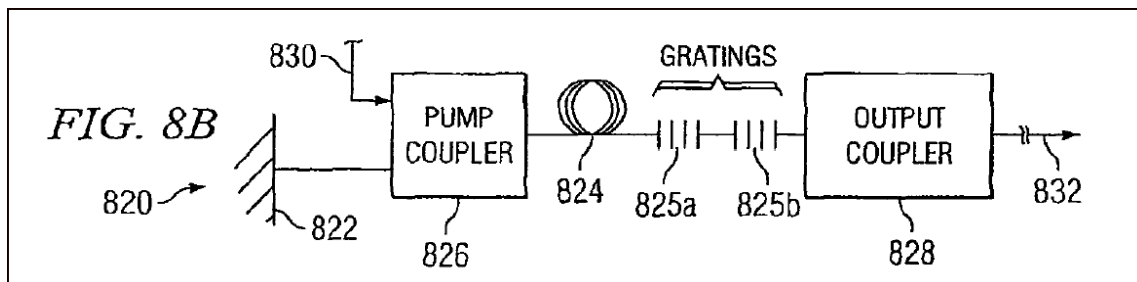
The specification further states that “at least the portion of the output beam is adapted for use in medical diagnostics to measure a property of the patient’s blood, wherein the medical diagnostics comprise a spectroscopic procedure ... based at least in part on a comparison of amplitudes at a plurality of associated wavelengths transmitted or reflected from the patient’s blood.” EX1001, 3:21-28; EX2031, ¶52. Through this configuration, the system generates data representing “physiological information associated with the user” (EX1001, 2:45-48) and “transmits wireless data comprising at least a part of the physiological information” (*id.*, 2:53-55). EX2031, ¶52. This structure enables real-time optical measurement, wireless data transfer, and host-side processing for diagnostic reporting. EX1001, 2:5-3:28; EX2031, ¶52.

The '868 Patent also provides examples of different optical configurations that can be used to implement the lens system. EX2031, ¶53. For instance, FIG. 9C “is a block diagram illustrating one example embodiment of a pump source 940 capable of being coupled to a Raman wavelength shifter and/or a Raman oscillator. In this example, pump source 940 includes a pump laser 942 and a multiplexer 944 capable of combining a plurality of pump signals into a pump output signal.” EX1001, 22:56-61; EX2031, ¶53.



EX1001, FIG. 9C

Similarly, FIG. 8B (reproduced below) “is a block diagram illustrating one example of a Raman wavelength shifter 820 capable of shifting a shorter pump signal 830 wavelength to a longer output signal wavelength 832.” EX1001, 20:18-21; EX2031, ¶54.



EX1001, FIG. 8B

The disclosed system also includes a software application running on a control system that is capable of generating data representing physiological information based on the user measurement. EX1001, 1:51-55; EX2031, ¶49. In one embodiment, the specification discloses that “[a] software application is capable of generating data based at least in part on the measurement on the user, wherein the data represents at least in part physiological information associated with the user.”

EX1001, 2:34-3:2; EX2031, ¶52. In contrast to earlier medical diagnostic systems with limited integration of optical measurement and user interfaces or remote data processing, the specification describes a “control system [that] may have a touch-screen, proximity sensor, and wireless transceiver to transmit wireless data over a wireless link.” EX1001, 1:58-60; EX2031, ¶49. The control system may also include circuitry for obtaining position information from a location sensor and is capable of receiving voice input signals and manually entered input signal. EX1001, 1:61-63; 2:19-22; EX2031, ¶49.

The control system further enables integration with a host, which comprises a digital file for receiving and storing at least a portion of the wireless data, and control logic at the host that processes the wireless data to generate a status of the user. The specification also describes that a memory storage device on the host allows for recording the status, and an output provides for communicating at least a portion of the status or associated information over a communication link to one or more display output devices. EX1001, 1:63-2:4; EX2031, ¶50.

The specification further acknowledges that at the time of invention, “[i]n conventional medical procedures involving a scope, a medical professional manually manipulates the medical device based on feedback from the medical device. ... conventional systems typically require significant manual dexterity.” EX1001, 9:6-13. Unlike conventional procedures, the systems disclosed in the ‘868 Patent include

a communication device that enables a medical professional to manipulate a medical device using voice commands, auxiliary input commands, and/or automated commands. EX1001, 9:14-17. Allowing a medical professional to use voice commands and/or automated commands can significantly reduce the manual dexterity, and the resulting strain, imposed on the medical professional during a procedure. EX1001, 9:18-21.

Accordingly, the '868 patent advances diagnostic technology by combining optical spectroscopic measurement with user-interactive and wireless communication features, while permitting data to be processed locally or transmitted to a remote host for further storage and analysis. EX2031, ¶51; EX1001, 1:61-63, 2:19-22, 41-45.

III. PROSECUTION HISTORY OF THE '868 PATENT

Petitioners mischaracterize the '868 Patent prosecution history in asserting that “in allowing all claims, the Examiner did not properly examine whether Challenged Claim 7 actually disclosed the purportedly distinguishing feature in independent claim 1.” Petition, 13.

The prosecution record demonstrates that all pending claims, including claims 21-28 and 30-41 (which were later issued as claims 1-20), were allowed without amendment following examination by the Primary Examiner. EX2031, ¶58. The Notice of Allowance includes an Examiner's Statement of Reasons for Allowance,

confirming the conclusion that “the cited prior art does not teach or suggest the whole combination of elements set forth by [then-pending] claims 21–28 and 30–41.” EX1002, 179-83; EX2031, ¶58. In support of this conclusion, the Examiner provided examples of combinations of elements not disclosed or suggested by the prior art, explaining:

For example, there is no teaching or suggestion in the prior art for combining:

a plurality of semiconductor diodes with light beams; a multiplexer capable of combining the plurality of semiconductor diode light beams and generating at least a multiplexed light beam comprising one or more wavelengths; one or more waveguide structures configured to receive at least a portion of the one or more wavelengths and to communicate at least the portion of the one or more wavelengths to an output end of the one or more waveguide structures to form an output beam; and a lens system configured to receive at least a portion of the output beam and to communicate at least the portion of the output beam onto a part of a user's body comprising blood to perform a measurement on a use[r];

Wherein the combination above used with:

a software application capable of generating data based at least in part on the measurement on the user, wherein the data represents at least in part physiological information associated with the user; the software application capable of operating on a control system adapted to receive, store and process at least a portion of the physiological information, the control system having a touch-screen, a proximity sensor, and a wireless transceiver to transmit wireless data over a wireless link, the wireless data comprising at least a part of the physiological information, wherein the control system is further capable of receiving voice input signals and manually entered input signals; and a host comprising: a digital file for receiving and storing at least a portion of the wireless data; control logic at the host to process at least the portion of the

wireless data to generate a status of the user; a memory storage device for recording the status; and an output for communicating at least a portion of the status or associated information over a communication link to one or more display output devices, wherein the one or more display output devices are located remotely from the host.

EX1002, 182-83; EX2031, ¶58.

The Examiner's explanation makes clear that the reasoning quoted above was provided as an *example* illustrating the basis for allowance of some claims. EX1002 at 182-183; EX2031, ¶59. Nothing in the record indicates that the stated examples were the full rationale for allowance of all issued claims—including independent claim 7 and dependent claims 8-11, 13, 14, now challenged. EX2031, ¶59.

Contrary to the assertions from Petitioners and Dr. Anthony, the Examiner fully examined application claim 27 (issued as claim 7) separately from application claim 21 (issued as claim 1). EX2031, ¶60. The file history confirms that the Examiner allowed claims 21-28 and 30-41, reflecting a determination that the combination of elements recited in each of those claims was patentable over the prior art. EX1002, 181; EX2031, ¶60. Nothing in the prosecution history suggests that the Examiner overlooked or failed to consider the specific limitations of application claim 27 or of any other allowed claim when assessing patentability. EX2031, ¶60.

IV. SUMMARY OF PETITIONERS' REFERENCES

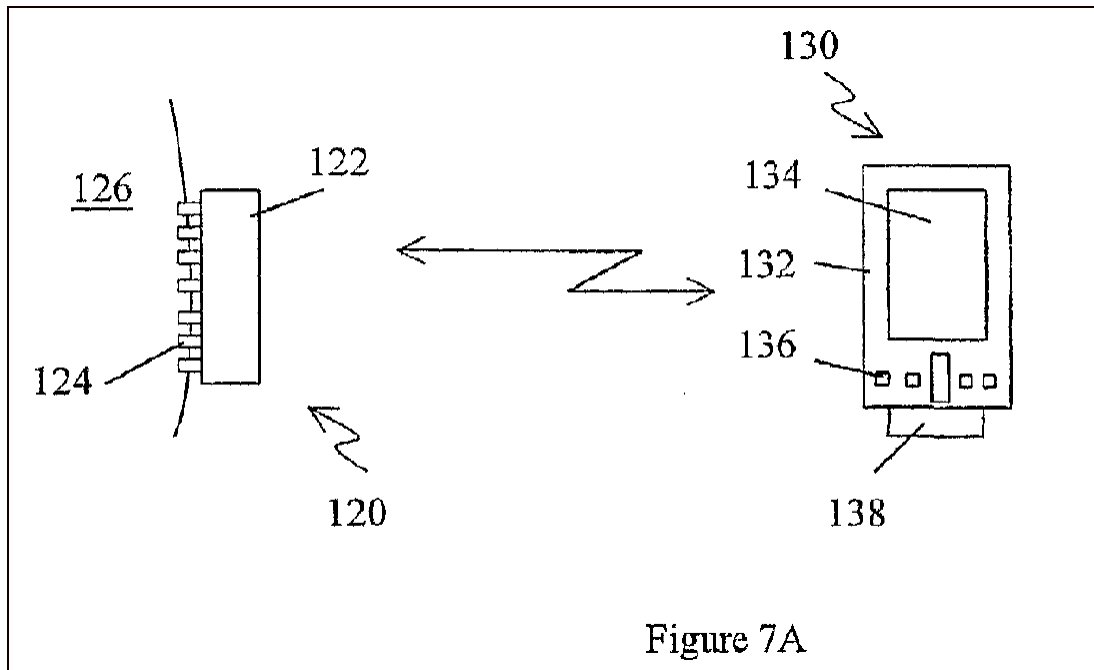
Petitioners' challenge to the '868 Patent rests on a flawed theory of obviousness that improperly reconstructs the invention with hindsight. Their

arguments fail because the cited prior art addresses fundamentally different problems, employs incompatible approaches, and, even if combined, would not yield a coherent or interoperable system resembling the claimed inventions.

A. Mault (EX1004) (Grounds 1-8)

Mault is entitled “Closed Loop Glycemic Index System” and describes “blood glucose management systems that allow a person to view projected future levels of blood glucose, so as to assist the person to keep blood glucose levels within a predetermined range, such as a medically advisable healthy range.” EX1004, ¶[0013]; EX2031, ¶66. Mault illustrates an invasive method involving “a blood glucose sensor housing 60 having a plurality of microneedles 62 projecting from a surface 64 of the housing 60” as shown in Figures 3-7A. EX1004, ¶[0082]; EX2031, ¶66.

As illustrated below, “FIG. 7A shows a blood glucose analysis module [120] having a microneedle array placed against the skin of a person and in wireless communication with a PDA [130].” EX1004, ¶[0091]; EX2031, ¶66.



EX1004, FIG. 7A

Mault provides only limited discussion of noninvasive optical measurement techniques. EX2031, ¶67. For instance, Mault briefly states that “[t]he blood glucose sensor may be a device clipped on to the earlobe of the person, using at least one semiconductor laser or light emitting diode to emit wavelengths in the near-IR. These wavelengths are transmitted through or reflected by blood-containing tissue, and then detected by a near-IR detector.” EX1004, ¶[0020]; EX2031, ¶67. In another instance, Mault mentions that “using a non-invasive spectroscopic technique, the PDA/module combination may be placed against part of the body to obtain a blood glucose reading.” EX1004, ¶[0073]; EX2031, ¶67.

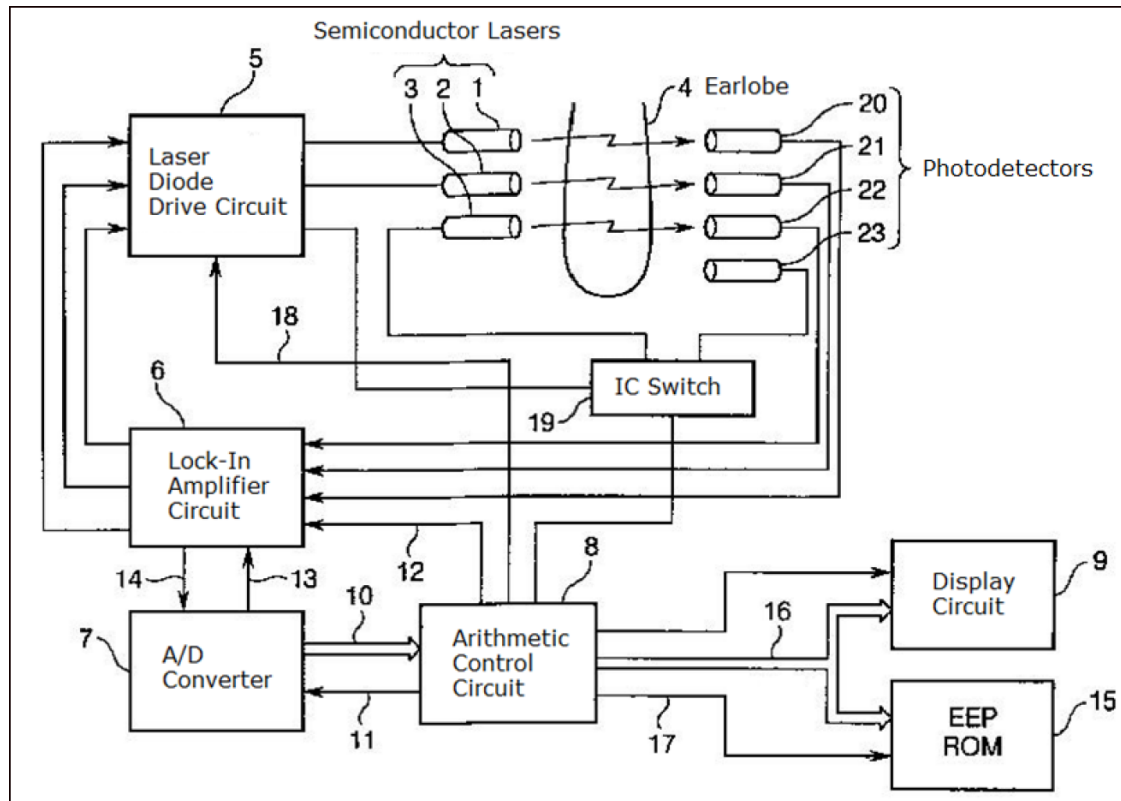
Mault also describes “[a] remote computer system 22 may be a remote server, physician’s computer, home computer, or other computer system accessible over the

communications network 20. The PDA can access the communications network ... Data can be transferred to the remote system over the communications network 20.” EX1004, ¶[0077]. In addition, the “remote server system 56 ... can be used to store a database of physiological parameters, activity, and diet relating to the person, for medical, nutritional, or computer expert system analysis.” EX1004, ¶[0079]; EX2031, ¶68.

B. Mitsui (EX1005) (Grounds 2-8)

Mitsui, which is a translation of a Japanese patent publication entitled “Glucose Sensor,” describes “a glucose sensor comprising: a light emitting means for irradiating light having wavelength λ_1 in the glucose absorption wavelength band, light having wavelength λ_2 outside of the glucose absorption wavelength band, and light having wavelength λ_3 in the infrared wavelength band for measuring volume of blood flow at the light irradiation site.” EX1005, p4, [Claim 1]; EX2031, ¶69. Mitsui describes “a calculating means for calculating the blood glucose concentration at the light irradiation site from the temperature-corrected amount of glucose and the volume of blood flow.” EX1005, ¶[0007]; EX2031, ¶69.

As illustrated in Figure 1 (reproduced below), Mitsui shows a configuration including three semiconductor lasers (having respective wavelengths of 1.55 μm , 1.33 μm , and 0.83 μm) emitting through an earlobe, with corresponding respective photodetectors receiving transmitted light. EX1005, ¶[0009]; EX2031, ¶69.



EX1005, Fig. 1

C. Pologe (EX1006) (Grounds 3-8)

Pologe is entitled “Apparatus for Performing Multiwavelength Photoplethysmography” and relates in general to systems for performing photoplethysmographic measurements and is particularly apt for use in pulse oximetry systems. EX1006, 1:6-8; EX2031, ¶70.

Pologe describes that “signals from multiple light emitters are combined into a single multiplexed light signal in a test unit before being delivered to a physically separated probe head attached to a test subject.” EX1006, Abstract; EX2031, ¶70. Pologe explains that “[l]ight pulses are then delivered from the main test unit 12 to

the probe 14 via a single optical transmission line in the probe cable 16. The light pulses are then directed into the finger 36, travel through the finger 36, and emerge on the other side of the finger 36 where they are received by a light pick up device 38. The received light pulses may then be delivered back to the main test unit 12, via probe cable 16, where they are processed to determine the level of one or more blood analytes in the person's arterial blood." EX1006, 4:38-47; EX2031, ¶70.

D. Kiani (EX1007) (Grounds 5-8)

Kiani is entitled "Pulse Oximeter Probe-Off Detection System") and describes "improvements that can be incorporated into a pulse oximeter probe to detect when a probe has become dislodged from a patient and/or to prevent a probe-off condition." EX1007, Abstract; EX2031, ¶71. Kiani explains that "[i]n the present configuration, the probe-off detector module 138 of the pulse oximeter 140 can verify that the optical probe 202 is properly secured simultaneously with checking the resistance of the coding resistor 132. An open circuit indicates that the probe has become dislodged, whereas a valid resistance of a coding resistor 132 indicates a proper attachment of the probe 202. If the probe has become dislodged, the pulse oximeter 140 can sound an alarm, display a warning message, or both." EX1007, 5:27-36; EX2031, ¶71.

V. LEVEL OF SKILL IN THE ART

Petitioners propose the following definition for a POSITA in relation to the '868 Patent:

On or before the claimed priority date of 9/3/2002, a person of ordinary skill in the art ("POSITA") would have had a good working knowledge of optical sensing techniques and their applications, and some familiarity with optical system design and signal processing techniques. That knowledge would have been gained via an undergraduate education in engineering (electrical, mechanical, biomedical or optical) or a related field of study, along with relevant experience in studying or developing physiological monitoring devices (e.g., non-invasive optical biosensors) in industry or academia. Additional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education.

Petition, 17. For purposes of this Preliminary Response, Patent Owner adopts Petitioners' proposed level of skill in the art. EX2031, ¶¶62-63.

VI. CLAIM CONSTRUCTION

Petitioners propose a potential construction of one term/phrase in the '868 Patent but otherwise contend that all terms/phrases in the challenged claims do not require construction and should be afforded their plain and ordinary meanings. Petition, 17-18. Patent Owner agrees that claim construction is not necessary at this time for the Board to find that Petitioners did not meet their burden for institution.

See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co., 868 F.3d 1013, 1017 (Fed. Cir. 2017). Patent Owner reserves the right to seek constructions of these terms in litigation or if institution is granted, and to further respond to any constructions that the Petitioners propose.

A. The Petition Does Not Comply with the Board's Claim Construction Rules

The Board's rules require that the petition sets forth "[h]ow the challenged claim is to be construed." 37 C.F.R. § 42.104(b)(3). "[W]hen a petitioner takes alternative positions before the Board and a district court, that petitioner should, at a minimum, explain why alternative position are warranted." *Revvo Techs., Inc. v. Cerebrum Sensor Techs., Inc.*, IPR2025-00632, Paper 20 at 3-4 (PTAB Nov. 3, 2025) (precedential). This rule "ensure[s] that the Board correctly construes claim terms and to minimize inconsistency in claim construction between forums." *Id.* at 4. In this case, Petitioners' claim construction positions in the Petition and the Parallel Litigation are inconsistent in at least two material respects, which warrants denial of the Petition.

First, Petitioners acknowledge that "[i]n the Texas Case, Defendants identified certain terms of the '868 Patent as potentially indefinite." Petition, 18 n.3

(citing Ex.1013, 227-228). In the Texas Case, Petitioners contend that the following terms in the '868 Patent are indefinite:

Term	Relevant Claim(s)
"a part of a user's body comprising blood"	7
"physiological information associated with the user"	7
"wireless data"	7
"voice input signals and manually entered input signals"	7
"at least a portion of the status or associated information"	7
"a multiplexer capable of combining the plurality of semiconductor diodes"	8
"generating the input light beam comprising one or more wavelengths"	8
"adapted for use in a diagnostics"	9
"a plurality of associated wavelengths transmitted or reflected from the blood"	9

EX1013, 227-228.

Despite this, Petitioners apply the plain and ordinary meaning for each of these terms in this IPR. Petition, 17-18. Petitioners' only explanation for its inconsistent positions is that "[r]egardless of the outer bounds of these limitations, the prior art discloses the indisputable scope of these limitations." Petition, 18 n.3 (citing EX1003, ¶¶68-69, 91, 98, 109-110, 118, 140-41, 168-69). Dr. Anthony similarly fails to explain the inconsistency and merely repeats the conclusory

assertions from the Petition. EX1003, ¶¶68-69, 91, 98, 109-110, 118, 140-41, 168-69. The Board should deny institution because Petitioners fail to justify their inconsistent positions in this IPR and the district court. *Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00340, Paper 18 at 3-5 (PTAB Nov. 5, 2025) (informative) (denying institution where petitioner argued that claim term was indefinite in district court but adopted patent owner's plain and ordinary meaning construction in its petition).

Second, Petitioners take inconsistent positions on the proper constructions for the term “beam” in claims 7-9 in the Petition and the district court. In the Texas Case, Petitioners have agreed to the following construction for the term “beam” in claims 7-9: “photons or light transmitted to a particular location in space.” EX2033 (Appendix A, 1); EX2034 (Exhibit A, 1). But in the Petition, Petitioners propose plain and ordinary meaning for this term. Petition, 17-18. Petitioners and Dr. Anthony do not apply Petitioners' claim construction from the Texas Case in their analysis of the challenged claims. Petition, 17-18, 23-27; EX1003, ¶¶83-91. Because Petitioners offer no explanation or justification for their inconsistent treatment of the “beam” term in different forums, the Board should deny institution. *Revvo Techs.*, Paper 20 at 3-4.

B. “voice recognition module” (Claim 11)

Petitioners argue that the term “voice recognition module,” which appears in independent claim 11, should be construed according to its plain and ordinary meaning as it would have been understood by a POSITA, but to the extent it is construed as a means-plus-function term, the function should be construed as voice recognition, and the corresponding structure should be construed as “any hardware, software, firmware, or any combination thereof that is capable of converting a voice command signal [] into a control signal.” Petition, 18. Patent Owner agrees that this term should be afforded its plain and ordinary meaning and is not a means-plus-function term for purposes of this Preliminary Response. EX2031, ¶74.

VII. PETITIONERS FAILED TO MEET ITS BURDEN

The Board should deny institution because Petitioners have not met their burden of showing a reasonable likelihood that any claim of the ‘868 Patent is unpatentable for any of the grounds in the Petition.

A. Ground 1: Alleged Obviousness Based on Mault (Claims 7, 10-11, 14)

In Ground 1, Petitioners argue that claims 7, 10-11, and 14 of the ‘868 Patent are obvious over Mault. Petition at 19-46. For the reasons discussed below, Petitioners failed to meet their burden for Ground 1.

Mault discloses a fundamentally different type of glucose management system—a biochemical glucose control algorithm that predicts blood glucose

responses based on user input, dietary data, and insulin delivery parameters. EX1004, ¶¶[0090], [0125], [0130]; EX2031, ¶79. Mault pertains to predictive glucose management, not to the integrated spectroscopic diagnostic system recited in the challenged claims. EX1004, ¶¶[0090], [0125], [0130]; EX2031, ¶79. Nothing in Mault describes, suggests, or implies the claimed system's required hardware, optical functionalities, or integrated architecture necessary for generating, processing, and analyzing light-based diagnostic signals. EX2031, ¶79.

Petitioners' analysis is based entirely on hindsight reconstruction, unsupported expert conclusions, and speculative assertions about what a POSITA might have been able to do, rather than on what Mault teaches or suggests. EX2031, ¶80. A POSITA relying solely on Mault would have had neither motivation to achieve the claimed invention nor a reasonable expectation of success in doing so. EX2031, ¶80; *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361 (Fed. Cir. 2016) (obviousness theories based on a single reference require "reasoned analysis and evidentiary support"); *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (a showing that "one of ordinary skill in the art could combine" but "not that they would have been motivated to do so" does not establish obviousness); *Safe Haven Wildlife Removal and Property Management Experts LLC v. Meridian Wildlife Services LLC*, IPR2023-01341, Paper 12 at 37-38 (PTAB Feb. 22, 2024) (denying institution because the petition failed to articulate why a POSITA

would be motivated to make the proposed combinations as opposed to merely could combine known elements).

1. Petitioners Failed to Meet Their Burden for Independent Claim 7

a. [7.a] and [7.b]: Mault Does Not Disclose or Render Obvious a Semiconductor Diode Light Source and a Lens System for Delivering Light to Tissue

Claim element [7.a] states that “a light source comprising one or more semiconductor diodes generating an input light beam;” and claim element [7.b] states that “a lens system configured to receive at least a portion of the input light beam and to communicate at least the portion of the input light beam onto a part of a user’s body comprising blood, wherein at least the portion of the input light beam is used in a measurement on a user.” EX1001, claim 7. When read together, these limitations require a coordinated optical configuration in which a semiconductor diode generates an input light beam that is subsequently received and directed by a lens system onto the user’s blood-containing tissue. EX2031, ¶82.

Petitioners rely on Mault’s general mention of light emitting diodes (LEDs), asserting that “Mault discloses a light source comprising one or more semiconductor diodes” as required by claim element [7.a]. Petition, 23; EX1003, ¶84. Mault, however, merely states that “[t]he blood glucose sensor may be a device clipped on to the earlobe of the person, using at least one semiconductor laser or light emitting diode to emit wavelengths in the near-IR. These wavelengths are transmitted through

or reflected by blood-containing tissue, and then detected by a near-IR detector.” EX1004, ¶[0020]; EX2031, ¶83. This passage offers only a general reference to possible light sources for glucose sensing and fails to disclose any structure, configuration, or optical operation necessary to meet the requirements of [7.a] and [7.b]. EX2031, ¶83.

The mere mention of “semiconductor diodes” in Mault does not amount to a disclosure of a light source that generates an “input light beam” for subsequent optical manipulation—specifically, for transmission through a downstream lens system as required in element [7.b]. EX2031, ¶84. Mault’s reference to LEDs or lasers provides no teaching of beam formation, collimation, or coupling into any lens system. EX2031, ¶84. Instead, Mault merely describes simple light emission from a diode, not the generation of an input beam configured to be input into a lens system. EX2031, ¶84. Thus, even if Mault’s LEDs emit light, such light does not constitute the “input light beam” recited in claim elements [7.a] or [7.b]. EX2031, ¶84.

Mault also fails to disclose “a lens system configured to receive at least a portion of the input light beam and to communicate at least the portion of the input light beam onto a part of a user’s body comprising blood, wherein at least the portion of the input light beam is used in a measurement on a user” as required by claim [7.b]. EX2031, ¶85. Petitioners’ and Dr. Anthony’s interpretation of Mault ignores that Mault never describes, depicts, or implies any optical system or lensing

configuration for transmitting light to tissue in the manner recited in the challenged claim. EX2031, ¶85.

Petitioners allege that “[t]he ‘at least one light emitting diode’ (LED) in Mault’s blood glucose sensor is part of a lens system.” Petition, 24-25. The cited paragraph [0020] of Mault for this allegation- merely provides that “[t]he blood glucose sensor may be a device clipped on to the earlobe of the person, using at least one semiconductor laser or light emitting diode to emit wavelengths in the near-IR. These wavelengths are transmitted through or reflected by blood-containing tissue, and then detected by a near-IR detector.” EX1004, ¶[0020]; EX2031, ¶88. This description does not suggest any lens or other optical component that provides a lens system that receives at least a portion of an input light beam and communicates at least a portion of the input light beam onto part of a user’s body. EX2031, ¶88. Instead, Mault simply refers to emission and detection in functional terms, without specifying any optical geometry, beam path, or lens system mechanism. EX1004, ¶[0020]; EX2031, ¶88.

By contrast, the ’868 Patent explicitly teaches the presence and structure of a lens system. EX1001, 2:34-3:2, 3:17-28; EX2031, ¶86. The ’868 Patent also describes examples of various optical configurations that may be used in implementing such systems. It provides, for example, embodiments employing multiple laser diodes combined by a multiplexer, and others in which Raman

wavelength shifters and delivery optics, such as tapered ends or lenses, may be used. EX1001, 23:3-25; EX2031, ¶87.

Acknowledging the absence of any lens system in Mault, and without citing a single relevant passage from the Mault reference, Petitioners and Dr. Anthony instead attempt to fill this gap by relying on the concept of “lens[ing] encapsulants.” Petition, 24-25; EX1003, ¶¶87-90; EX2031, ¶89. They cite prior IPR final written decisions (EX1016, 36 and EX1028, 23) to argue that LEDs commonly include encapsulating material that can act as a lens. *See* Petition, 24-25; EX1003, ¶88 (“For example, as the Board previously found in its final written decisions in the prior ’533 and ’484 IPRs, “a [person of ordinary skill in the art] would have known that LEDs are often covered by lensing encapsulants, and would have selected such LEDs for wireless sensor 102/312 in order to ‘direct more of the light produced by the LED outward toward the tissue’”); EX2031, ¶89.

Yet Petitioners and Dr. Anthony fail to explain why the Board’s findings in unrelated IPRs, concerning different patents with later priority dates, should be applicable to the ’868 Patent. EX2031, ¶90. The prior Board’s findings stating that “a [person of ordinary skill in the art], knowing a lens is a basic building block of an optical sensor, would have included lenses in Lisogurski’s wireless sensor 102/312” were directed to a different reference than those at issue in this IPR. *See* EX1003, ¶88 (citing EX1016, 36); EX2031, ¶90. They did not address Mault. *Id.* Dr. Anthony

also concedes that “the ’533 and ’484 [Patents] have a later claimed priority date (in 2012) than the earliest claimed priority date of the challenged ’868 patent here (in 2002),” yet he fails to address the ten-year technological gap or provide any rationale for applying those findings retroactively. EX1003, ¶89; EX2031, ¶90.

Petitioners’ reliance on unrelated U.S. Patent Nos. 5,122,943 (EX1035) and 6,661,167 (EX1036) similarly fails to supply the missing disclosure, as Petitioners offer no motivation to combine those references with Mault or demonstrate that the alleged encapsulant structure performs the claimed function. Petition, 24-25; EX1003, ¶89. EX2031, ¶90; *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1366 (Fed. Cir. 2017) (“In determining whether there would have been a motivation to combine prior art references to arrive at the claimed invention, it is insufficient to simply conclude the combination would have been obvious without identifying any reason why a person of skill in the art would have made the combination.”); *see also Safe Haven*, IPR2023-01341, Paper 12 at 37-38.

Even assuming that “lens encapsulants” exist, Petitioners and Dr. Anthony do not establish that such features are “configured to receive at least a portion of the input light beam and to communicate at least the portion of the input light beam onto a part of a user’s body comprising blood,” as expressly required by claim [7.b]. Petition, 24-25; EX1003, ¶¶87-90; EX2031, ¶91. The prior Board findings dealt with different patents and addressed whether LEDs inherently have encapsulants capable

of directing emitted light—not whether such encapsulants constitute a lens system that receives an input light beam formed upstream of the lens system. EX1016, 35-37; EX1028, 23; EX2031, ¶91. The issue of a “lens system” was never at stake in those IPRs, making those findings irrelevant to the '868 patent's distinct claim requirements. EX1016, 35-37; EX1028, 23; EX2031, ¶91.

Moreover, a POSITA would understand that any lens covering or encapsulant typically associated with an LED, if existing, merely aids light emission from that LED and does not constitute a “lens system configured to receive” an already formed input beam as required by claim [7.b] for further optical communication. EX2031, ¶92. In the context of the '868 Patent, the claimed “lens system” is a distinct and downstream optical component that receives, focuses, and directs at least a portion of the input light beam onto the user's tissue. EX2031, ¶92. The LED's integral encapsulant or lens cover is simply part of the diode package itself and serves only to assist emission; it is not a distinct optical system receiving an input beam. EX2031, ¶92. There is nothing in the '868 Patent claims or specification to suggest that the “light source” and the “lens system” can be the same structure. *See CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co.*, 224 F.3d 1308, 1317 (Fed. Cir. 2000) (“In the absence of any evidence to the contrary, we must presume that the use of ... different terms in the claims connotes different meanings.”). Therefore,

even if Mault's LEDs have encapsulating materials, those structures do not meet the claimed "lens system" requirement. EX2031, ¶92.

In conclusion, Petitioners and Dr. Anthony identify no disclosure in Mault that describes or implies a lens system located within the optical path that performs the claimed optical function. EX2031, ¶93. Mault lacks any teaching of a lens structure that receives, focuses, or directs input light beam from a semiconductor source to a user's body. EX2031, ¶93. Consequently, Mault does not disclose, suggest, or render obvious at least the "input light beam" and "lens system" limitations of claim [7.a] and [7.b]. EX2031, ¶93.

b. [7.f]: Mault Fails to Disclose Or Renders Obvious a Host Receiving and Processing Wireless Data

Claim [7.f] requires "a host comprising: a digital file for receiving and storing at least a portion of the wireless data; control logic at the host to process at least the portion of the wireless data to generate a status of the user; a memory storage device for recording the status; and an output for communicating at least a portion of the status or associated information over a communication link to one or more display output devices, wherein the one or more display output devices are located remotely from the host." EX1001, claim 7. Claim 7 also requires that "at least the portion of the input light beam is used in a measurement on a user; ... generating data based at least in part on the measurement on the user, wherein the data represents at least in

part physiological information associated with the user; ... the wireless data comprising at least a part of the physiological information.” EX1001, claim 7.

Mault does not disclose the claimed host “comprising a digital file for receiving and storing at least a portion of the wireless data” and “control logic ... to generate a status of the user.” EX1001, claim 7. Petitioners misinterpret Mault’s system architecture and overextend its disclosure to suggest functionality that does not exist in the reference. Petition, 37-43; EX2031, ¶94. Petitioners rely on Mault’s “remote server system 56” as allegedly corresponding to the claimed “host.” *See* Petition, 37-43; EX1003, ¶112. Their interpretation, however, is misplaced, as Mault’s remote server performs a fundamentally different function. EX2031, ¶95.

In Mault, the remote server stores user supplied information such as diet, activity, and insulin dosage but is not configured to receive or store wirelessly transmitted physiological data based on an optical measurement of the user. EX1004, ¶¶[0077], [0079], [0106]; EX2031, ¶96. Nor does Mault’s remote system include “control logic” capable of generating a “status of the user” as required by the claim. Petitioners’ assertion that Mault’s remote server equates to the claimed “host” is unsupported by the intrinsic disclosure and technically inaccurate. EX1003, ¶¶113-17; EX2031, ¶96.

For instance, Mault discloses only that:

Remote computer system 22 may be a remote server, physicians computer, home computer, or other computer system accessible over the communications network 20. The PDA can access the communications network, such as the Internet, using a wireless connection. Data can be transferred to the remote system over the communications network 20, allowing examination by a dietician, physician, other specialist, or by the person themselves using the PDA or any computer. Feedback, generated by a specialist or computer expert system, may be transmitted to the PDA from the remote computer over the communications network.

EX1004, ¶[0077].

The portable computing device 30 is in linked to a communications network 52, allowing communication a remote computer system 54, which may be located at the person's home, doctor's office, or other remote location. A remote server system 56 is also accessible through the communications network 52, and can be used to store a database of physiological parameters, activity, and diet relating to the person, for medical, nutritional, or computer expert system analysis.

EX1004, ¶[0079].

The electronic device 240 is used as a diet log and to store blood glucose readings. The device provides dietary feedback to the mother based on a measured and modeled (or estimated) glycemic response. The device also collects data from physiological sensors monitoring the health of the baby and/or mother. An audible alert can sound if projected or actual blood glucose levels deviate from a predetermined range.

EX1004, ¶[0106].

None of these sections disclose or suggest that the “remote server system 56” receives wireless physiological data from sensors and processes that data using host-side logic to determine a user’s physiological “status.” EX2031, ¶98. Instead,

Mault's system operates as a database and communication node for logging and reviewing information. EX1004, [0077], [0079], [0106]; EX2031, ¶98.

Mault also fails to disclose “a digital file for receiving and storing at least a portion of the wireless data.” EX2031, ¶99. In particular, Mault does not disclose or suggest that a digital file receives and stores transmitted physiological wireless data based on optical measurement results, as required by claim 7. *Id.* Petitioners improperly equate Mault's mention of a “database” on a “remote server” with a “digital file” recited in the claim. Petition, 37-38.

Because Mault lacks such disclosure, Petitioners attempt to fill this gap with extrinsic reasoning outside the reference, asserting that:

A person of ordinary skill in the art would have known, or at minimum found obvious, that the remote server's database is a digital file ... because databases are stored in files in a server or system's storage. Since system information is stored in files and a database is a structured collection of information, a database would also be stored on the system as one or more files—and at minimum it would have been obvious to do so, as illustrated by e.g., U.S. Patent Nos. 5,544,357 [Ex. 1031] and 4,817,050 [Ex. 1032].

Petition, 38; EX1003, ¶114; EX2031, ¶100. This statement oversimplifies how data storage works and fails to establish that Mault's “database” corresponds to the claimed “digital file” for receiving wireless physiological data generated from an optical measurement. EX2031, ¶101. It also provides no articulated reasoning or motivation to combine Mault with the cited unrelated patents that are not part of

Ground 1. Petition, 38; EX1003, ¶114; EX2031, ¶101; *see Metacraft*, 848 F.3d at 1366 (“In determining whether there would have been a motivation to combine prior art references to arrive at the claimed invention, it is insufficient to simply conclude the combination would have been obvious without identifying any reason why a person of skill in the art would have made the combination”).

Mault's disclosure of “stor[ing] a database of physiological parameters” (EX1004, ¶[0079]) is different than storing transmitted wireless physiological data based on optical measurements, as claim 7 requires. EX2031, ¶102. Mault's server acts as a passive repository of input information, not a receiver of active wireless measurement data. EX1004, ¶[0079] (“A remote server system 56 is also accessible through the communications network 52, and can be used to store a database of physiological parameters, activity, and diet relating to the person, for medical, nutritional, or computer expert system analysis.”). Likewise, Mault's reference to data does not equate to the claimed transmitted wireless physiological data based on optical measurement. EX1004, ¶[0077] (“Data can be transferred to the remote system.”); EX2031, ¶102.

Mault also fails to disclose “control logic at the host to process ... the wireless data to generate a status [of the user].” EX2031, ¶103. None of Petitioners' citations to Mault identify any host-side control logic, computation, or algorithm for generating a user status based on transmitted measurement data. Petition, 37-43;

EX2031, ¶103. The only relevant disclosure refers to a “PDA ... used to monitor the physiological state of the person” based on “a variety of monitoring methods from other physiological sensors.” EX1004, ¶[0201]. EX2031, ¶103. This description relates to the handheld device's monitoring capability, not any host-side computation or control logic. EX2031, ¶103.

Mault's discussion of a “computer expert system” and “feedback” similarly fail to disclose the required control logic. Petition, 37-43; EX1003, ¶117; EX2031, ¶104. For example, Mault states: “[t]he PDA can access the communications network, such as the Internet, using a wireless connection. Data can be transferred to the remote system over the communications network 20, allowing examination by a dietician, physician, other specialist, or by the person themselves using the PDA or any computer. Feedback, generated by a specialist or computer expert system, may be transmitted to the PDA from the remote computer over the communications network.” EX1004, ¶[0077]; EX2031, ¶104. These generic statements describe communication and user interaction, not algorithmic processing or logical generation of a user “status” at the host. EX1004, ¶[0077]; EX2031, ¶104. Mault's general references to connectivity and display functions also fail to attribute any host-based computation to the transmitted physiological data. *See* Petition, 37-43; EX1003, ¶117; EX2031, ¶105.

Because Mault does not disclose or render obvious any of the host-related limitations—including a digital file for receiving and storing wireless data, control logic for generating a user status, or host-side output of such information—Petitioners fail to meet their burden for Ground 1. EX2031, ¶106.

2. Petitioners Failed to Meet Their Burden for Dependent Claims 10-11 and 14

Dependent claims 10-11 and 14 depend from independent claim 7. Petitioners and Dr. Anthony's discussion of these dependent claims fails to cure the deficiencies identified above with respect to claim 7. *Supra*, §VII.A.1; Petition, 43-46; EX2031, ¶107. Accordingly, Petitioners failed to meet their burden for dependent claims 10-11, and 14 for at least the same reasons as independent claim 7. Petition, 43-46; EX1003, ¶¶119-130; EX2031, ¶107; *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) ("Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious").

B. Ground 2: Alleged Obviousness Based on Mault in view of Mitsui (Claim 9)

In Ground 2, Petitioners assert that dependent claim 9 of the '868 Patent is obvious over Mault in view of Mitsui. Petition, 46-51. For the reasons discussed below, Petitioners failed to meet their burden for Ground 2.

1. Petitioners Failed to Meet its Burden for Claim 9

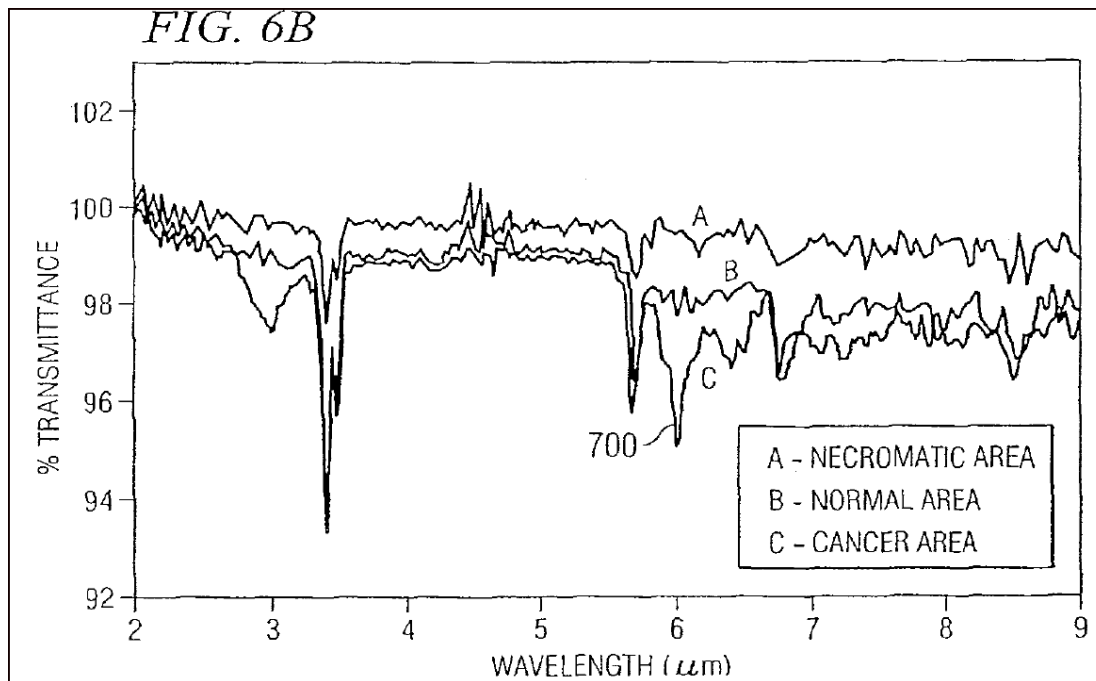
Dependent claim 9 depends from independent claim 7. Petitioners' and Dr. Anthony's analysis of claim 9 does not address the deficiencies discussed above with respect to claim 7. EX2031, ¶109; *supra*, §VII.A.1. Because Mault fails to disclose or render obvious claim 7—including the semiconductor light source, lens system, and host for wireless data processing—the combination of Mault and Mitsui similarly fails to render dependent claim 9 obvious. EX2031, ¶109; *Fine*, 837 F.2d at 1076.

Additionally, claim 9 recites: “wherein at least the portion of the input light beam is adapted for use in a diagnostics to measure a property of the blood, wherein the diagnostics comprise a spectroscopic procedure, wherein the spectroscopic procedure is based at least in part on a comparison of amplitudes at a plurality of associated wavelengths transmitted or reflected from the blood.” EX1001, claim 9. Neither Mault nor Mitsui discloses or suggests the claimed spectroscopic diagnostic procedure based on the comparison of amplitudes at multiple associated wavelengths transmitted or reflected from blood. EX2031, ¶111.

Mitsui does not disclose a spectroscopic diagnostic procedure based on a comparison of amplitudes at a plurality of associated wavelengths transmitted or reflected from blood, as required by claim 9. EX2031, ¶114. Instead, Mitsui describes a system employing three discrete laser sources—each paired with its own

detector—to compute glucose concentration using ratios of individual intensity measurements. EX1005, ¶[0009]; EX2031, ¶114. Mitsui uses multiple discrete photodetectors, each dedicated to a specific laser wavelength. Three semiconductor lasers (at 1.55 μm , 1.33 μm , and 0.83 μm) are used, and each corresponds to a separate photodetector (photodetectors 20, 21, and 22). EX1005, ¶[0009]; EX2031, ¶115. These detectors merely measure light intensity at their respective wavelengths, and the resulting signals are compared to determine glucose concentration and blood flow characteristics. EX1005, ¶[0009]; EX2031, ¶115. This method constitutes a simple multi-point intensity comparison, not a spectroscopic analysis that resolves and compares amplitudes across a continuous or finely sampled range of wavelengths. EX2031, ¶115.

By contrast, the spectroscopic diagnostic system described in the '868 Patent operates in a fundamentally different manner. EX2031, ¶116. The '868 Patent utilizes broadband or multiwavelength light dispersed through a grating or prism that is detected by a single spectrometer or detector array capable of recording an entire spectrum simultaneously, as shown in FIG. 6B (reproduced below). EX2031, ¶116.



EX1001, FIG. 6B

Unlike Mitsui's discrete setup with separate detectors for each wavelength, the '868 Patent's system disperses the "input light beam" into its component wavelengths and measures the amplitude across hundreds of spectral channels at once. EX1001, 19:31-22:7, FIGS. 8A-8D; EX2031, ¶117. This enables comparison of spectral amplitudes over a broad wavelength range to detect subtle biochemical and structural variations in blood. EX1001, 18:24-41; EX2031, ¶117. The claimed spectroscopic procedure—based on amplitude comparisons at a plurality of associated wavelengths—is not disclosed or suggested by Mitsui's limited, discrete-wavelength system or by Mault's generalized glucose control algorithm. EX2031, ¶117.

In summary, Mault and Mitsui, either alone or in combination, do not teach or render obvious the spectroscopic diagnostic system required by claim 9. EX2031, ¶118. Their respective disclosures are technologically distinct from the claimed method, and the combination proposed by Petitioners and Dr. Anthony fails to show these references satisfy the limitations of claim 9. EX2031, ¶118.

C. Grounds 3-4: Alleged Obviousness Based on Grounds 1-2 in view of Pologe (Claims 7-11, 14)

In Grounds 3-4, Petitioners assert that claims 7-11 and 14 of the '868 Patent are obvious over Grounds 1-2 in view of Pologe. Petition, 51-61. For the reasons discussed below, Petitioners failed to meet their burden for Ground 3-4.

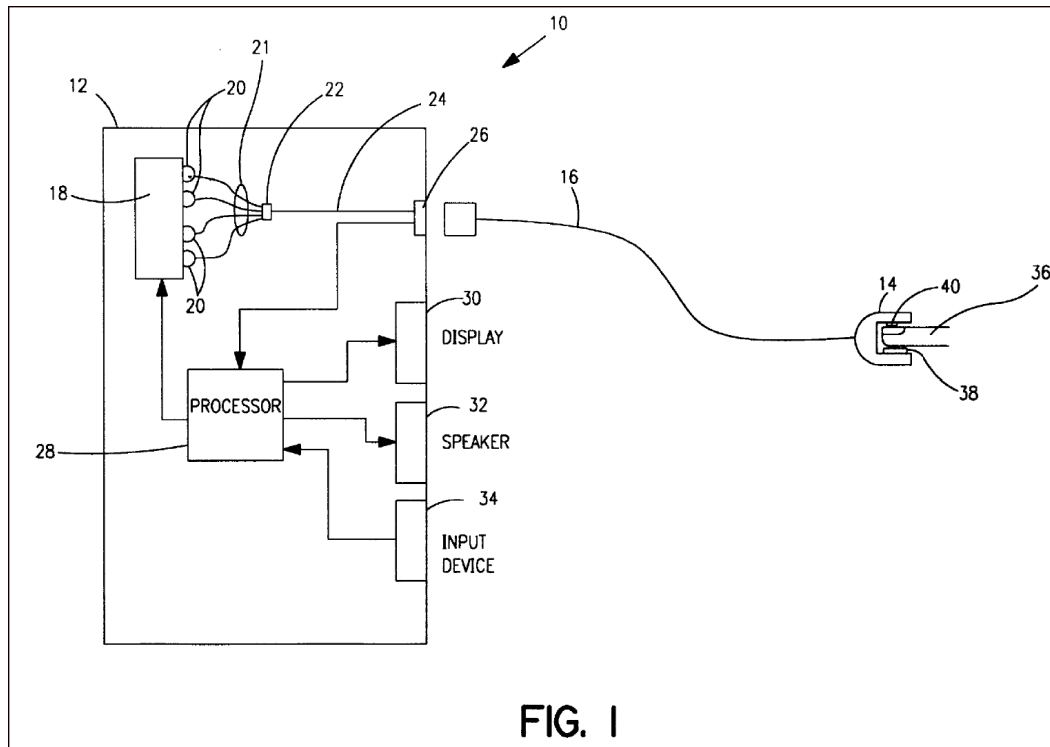
1. A POSITA Would Not Have Combined Mault with Pologe

Petitioners failed to show that a POSITA would have been motivated to combine Maut with Pologe. Petition, 52-56. Pologe and Mault address distinct technical problems in unrelated contexts. EX2031, ¶122.

Pologe's photoplethysmographic (PPG) device operates at one or two fixed wavelengths to measure blood oxygen level or volume changes. EX1006, 1:6-8, 19-29; EX2031, ¶120. Compared with claimed invention in the '868 Patent, PPG, as described in Pologe, is a fundamentally different technique that detects time-varying signal fluctuations caused by cardiac pulsation. EX1006, 5:60-6:3 ("TDM [time division multiplexing] can be implemented by appropriately timing the pulsing of the individual light sources in the plurality of light sources 20."); EX2031, ¶120.

Because PPG systems are designed to measure temporal variations in light intensity, they cannot produce the physiological or biochemical data obtained through glucose detection or spectroscopic techniques such as those discussed in Mault, even when a wavelength-division multiplexing (WDM) coupler is used. EX2031, ¶120.

Pologe discloses that light pulses are sent from a main test unit through a single optical transmission line within a probe cable to a probe placed at a distance. The detected light pulses are then transmitted back through the probe cable to the main test unit, which processes the returned signals to determine concentrations of one or more blood analytes (e.g., in arterial blood). EX1006, 4:38-47; EX2031, ¶121. As illustrated in FIG. 1 of Pologe (reproduced below), Pologe describes that “[l]ight pulses are then delivered from the main test unit 12 to the probe 14 via a single optical transmission line in the probe cable 16.” EX1006, 4:38-40; EX2031, ¶121. “The light pulses are then directed into the finger 36, travel through the finger 36, and emerge on the other side of the finger 36, where they are received by a light pick up device 38.” EX1006, 4:41-44; EX2031, ¶121. “The received light pulses may then be delivered back to the main test unit 12, via probe cable 16, where they are processed to determine the level of one or more blood analytes in the person’s arterial blood.” EX1006, 4:44-47; EX2031, ¶121.



EX1006, FIG. 1

Pologe “relates in general to systems for performing photoplethysmographic measurements and is particularly apt for use in pulse oximetry systems.” Pologe 1:6-8; EX2031, ¶123. Pologe explains that “[o]ne type of photoplethysmographic [(PPG)] process, known as pulse oximetry, is used to measure the oxygen saturation level of a person’s arterial blood.” EX1006, 1:19-21; EX2031, ¶123. “In a pulse oximetry system, pulses of light having different spectral contents and center wavelengths are directed into the tissue under test, such as a finger or an earlobe.” EX1006, 1:22-29; EX2031, ¶123.

Pologe’s objective is to enhance the physical configuration of photoplethysmographic devices employing wavelength-division multiplexing

(WDM) to deliver light from multiple narrowband emitters - “relatively narrow band light pulses having different center wavelengths” (EX1006, 1:11-17) - through a single light guide. EX1006, 2:7-16; EX2031, ¶124. Pologe seeks to reduce the number of signal carriers, minimize probe heating, and make the probe small, lightweight, and inexpensive so that it can be disposable. EX1006, 2:16-44; EX2031, ¶124. To accomplish this, Pologe positions the light sources in the main test unit and transmits a combined multiplexed light signal to a passive probe via a single fiber optic cable. EX1006, 2:41-44 (“because the light sources are included in the main test unit, rather than the probe, the probe may be relatively lightweight, is not prone to heating, and is relatively inexpensive to produce, allowing it to be disposable.”); EX2031, ¶124. This configuration addresses mechanical and ergonomic drawbacks—specifically simplifying cabling and minimizing probe complexity—without changing the physiological measurement method or analyte being detected. EX2031, ¶124.

By contrast, Mault briefly describes that the “blood glucose sensor may be a device clipped on to the earlobe of the person, using at least one semiconductor laser or light emitting diode to emit wavelengths in the near-IR.... two wavelengths may be chosen, one absorbed and one not absorbed by blood glucose, the absorption ratio then being used to compute the blood glucose level of the person.” EX1004, ¶[0020]; EX2031, ¶125. Mault further states at a high level that “Infrared and Raman

spectroscopy can also be used for noninvasive analysis of blood glucose levels. A module may be placed against the skin to detect the IR signature of glucose of fluid beneath the skin, or a spectroscopic mechanism can be included into the analysis module described above so as to detect levels of glucose within the interstitial fluid extracted from the skin.” EX1004, ¶[0089]; EX2031, ¶125.

Mault's problem is biochemical rather than mechanical: it seeks to detect and analyze subtle absorption differences to determine glucose concentration. EX1004, [0089]; EX2031, ¶126. “The structure and purpose of Mault's device are fundamentally different from Pologe's.” EX2031, ¶126. Mault requires the light sources and photodetectors located at or near the tissue measurement site to perform differential analysis (EX1004, ¶¶[0020], [0089]), whereas Pologe intentionally relocates all light sources to the main unit to maintain a passive and disposable probe (EX1006, 2:16-44). EX2031, ¶126. Because these two references pursue entirely different goals—one analytical, the other ergonomic—a POSITA would have had no reason or technical motivation to combine their teachings. EX2031, ¶126. Such a combination would not further either invention's purpose and would instead constitute hindsight reconstruction. EX2031, ¶126. The Federal Circuit has held that improper hindsight is evident where, as here, Petitioners fail “to demonstrate ... that the problem was known in the art or that [the petitioner's] formulation of the problem was derived directly from the prior art, rather than from the challenged claims.”

Purdue Pharma L.P. v. Depomed, Inc., 643 F. App'x 960, 966 (Fed. Cir. 2016); *see also Grain Processing Corp. v. Am. Maize-Prods. Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988) (“Care must be taken to avoid hindsight reconstruction by using ‘the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit’”) (quoting *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983)).

Moreover, combining Pologe and Mault would fundamentally alter the operating principles of both systems, rendering the resulting device inoperable for its intended purposes. EX2031, ¶127; *Application of Ratti*, 270 F.2d 810, 813 (CCPA 1959) (no motivation to combine because combination “would require a substantial reconstruction and redesign of the elements shown in [the prior art reference] as well as a change in the basic principles under which [that reference’s] construction was designed to operate”); *see also Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (finding it would not be obvious “to substitute the recessed barbs of [the primary reference] with the protuberances of [the secondary reference], since TriVascular’s proposed substitution would destroy the basic objective of the [invention]”).

Incorporating Mault’s glucose-sensing architecture into Pologe’s passive probe would defeat the very benefits that Pologe explicitly teaches. EX2031, ¶127. As Pologe emphasizes, “the light sources are included in the main test unit, rather

than the probe, [so] the probe may be relatively lightweight, is not prone to heating, and is relatively inexpensive to produce, allowing it to be disposable.” EX1006, 2:41-44; EX2031, ¶127. In contrast, Mault’s approach requires emitters and detectors positioned at the earlobe or skin interface. EX1004, ¶¶[0020], [0089]; EX2031, ¶127. Integrating such components into Pologe’s probe would reintroduce heat, weight, and cost—the precise drawbacks Pologe was designed to avoid. EX2031, ¶127. Consequently, the proposed combination would undermine each reference’s core functionality and render the resulting system inoperable for either pulse oximetry or spectroscopic glucose detection. *Id.*; *Arctic Cat Inc. v. Polaris Indus., Inc.*, 795 F. App’x 827, 833 (Fed. Cir. 2019) (“[t]he Board must weigh the benefits and drawbacks of the modification against each other, to determine whether there would be a motivation to combine”); *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (“the prior art as a whole must ‘suggest the desirability’ of the combination”).

For at least these reasons, a POSITA would not have been motivated to combine Pologe and Mault and would have had no reasonable expectation of success in doing so. EX2031, ¶128. The references address unrelated technical challenges, rely on incompatible optical architectures, and embody conflicting design objectives. *Id.* Any such combination would negate the core objectives of both

inventions and result in a system that is nonfunctional for either application. *Id.* Accordingly, Petitioners failed to meet their burden.

2. Petitioners Failed to Meet Their Burden for Independent Claim 7

Pologe does not remedy or otherwise cure the deficiencies identified above regarding claim 7 in view of Mault. As previously discussed, Mault fails to at least disclose claim element [7.b]. EX2031, ¶129; *supra*, §VII.A.1.

Petitioners assert that “Pologe discloses a “lens system” (e.g., “lenses” within “WDM coupler”) configured to receive at least a portion of the input light beam (e.g., “light pulses” from “light sources, such as light emitting diodes”).” Petition, 57; EX1003, ¶154. For the same reasons discussed above, a POSITA would not have been motivated to apply Pologe’s teaching of wavelength division multiplexing (WDM) couplers configuration to Mault’s “blood glucose sensor.” EX2031, ¶130; *supra*, §VII.C.2.

3. Petitioners Failed to Meet Their Burden for Dependent Claims 8-11 and 14

Dependent claims 8-11 and 14 depend from independent claim 7. Petitioners’ discussion of these dependent claims does not address the deficiencies identified above with respect to claim 7. Petition, 59-61. Thus, Petitioners failed to meet their burdens for dependent claims 8-11, 14 for at least the same reasons as independent claim 7. EX2031, ¶131; *supra*, §VII.A.1, VII.C.1, VII.C.2.

D. Grounds 5-8: Alleged Obviousness Based on Grounds 1-4 in view of Kiani (Claims 7-11, 13-14)

In Grounds 5-8, Petitioners argue that claims 7-11 and 13-14 of the '868 Patent are obvious over Grounds 1-4 in view of Kiani. Petition, 61-68. For the reasons discussed below, Petitioners failed to meet their burden for Grounds 5-8. EX2031, ¶132.

As explained in detail below, Kiani does not remedy the deficiencies found in Mault, Mitsui, or Pologe. In particular, Kiani fails to disclose or suggest the claimed “circuitry for obtaining position information from a location sensor” or “control system ... further coupled to a proximity sensor,” as recited in at least independent claim 7 and dependent claim 13. EX2031, ¶133.

1. Petitioners Failed to Meet Their Burden for Independent Claim 7

a. Limitation [7.e] (“circuitry for obtaining position information from a location sensor”)

Contrary to Petitioners' suggestion, Kiani's “contact sensor” does not meet the claim 7's “control system,” which includes “circuitry for obtaining position information from a location sensor.” Petition, 61-68; EX1003, ¶¶170-87; EX2031, ¶134. Kiani is directed to a fundamentally different sensing mechanism that does not provide positional or proximity data as required by claim 7. EX1007, 5:27-36; 6:53-62; EX2031, ¶134.

Consistent with the requirements of claim 7, the '868 Patent describes sensors configured to generate positional or proximity information rather than mere binary contact data: “[i]n one embodiment, sensors 442 are capable of generating and transmitting data associated with insertable portion’s 420 proximity to tissue of the patient.” EX1001, 13:37-40; EX2031, ¶135. A POSITA would understand that the claimed sensors are designed to measure spatial relationships or distances, enabling the system to detect how close the insertable portion is to the tissue. EX2031, ¶135.

By contrast, Kiani describes only a “probe-off” detection circuit that determines whether a pulse oximeter sensor is attached to the patient’s skin. FIG. 6 of Kiani illustrates a method used by a pulse oximeter to detect when its probe has been dislodged or removed. The system checks for electrical continuity between skin contacts, and if none is detected, it triggers an alarm to alert that the probe requires attention. EX1007, 6:53-62; EX2031, ¶136.

Kiani describes only a binary contact check, not the acquisition of “position information.” EX2031, ¶137. Kiani merely detects whether the probe maintains contact with the skin; it does not calculate spatial coordinates, measure proximity, or determine the distance between the sensor and tissue. EX1007, 5:27-36; 6:53-62; EX2031, ¶137. Consequently, Kiani does determine the location of the device on the body or its relative position to a reference point. EX2031, ¶137. Simply detecting

the presence or absence of contact does not satisfy the claim requirement of “circuitry for obtaining position information.” EX2031, ¶137.

Furthermore, Kiani's contact-based detection conflicts with the '868 Patent's safety objectives. EX2031, ¶138. The '868 Patent warns that:

Injury may occur when a medical professional accidentally or mistakenly causes insertable portion 420 to contact tissue associated with the patient, which can cause bruising or damage to the tissue. Sensors 442 can comprise any device capable of providing data and/or a signal to a medical professional. Sensors 442 may be capable of generating and transmitting, for example, positioning information associated with insertable portion 420, physiological information associated with the patient, control signals, a signal indicating the presence or absence of blood, or any other data. In one particular embodiment, sensors 442 are capable of generating and transmitting data associated with insertable portion's 420 proximity to tissue of the patient.

EX1001, 13:27-40.

The '868 Patent's system is explicitly designed to avoid physical contact with tissue by monitoring proximity, while Kiani's probe requires physical contact to function. EX1007, 5:27-36; 6:53-62; EX2031, ¶139. Thus, incorporating Kiani's contact detection sensor into the claimed architecture would defeat the '868 Patent's functional and safety purpose, rendering the resulting system non-operational for its intended use. EX2031, ¶139. Thus, Kiani teaches away from Petitioners' proposal to use the contact sensor of Kiani as a location or proximity sensor. *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1360 (Fed. Cir. 2017) (prior

art teaches away when a POSITA “would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant”) (quoting *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1305 (Fed. Cir. 2015)).

Kiani's sensor is operational only when it makes contact with the patient's skin (Kiani, 6:53-62), whereas the '868 Patent requires sensors capable of detecting positional or proximity information to prevent unwanted contact ('868 Patent at 13:27-40). EX2031, ¶140. In addition, combining Kiani with the cited references does not cure the deficiencies introduced by Kiani and would not yield an operative system as disclosed and intended by the '868 Patent. EX2031, ¶140. Kiani therefore fails to disclose or suggest the circuitry for obtaining position information from a location sensor as required by claim 7. EX2031, ¶140.

2. Petitioners Failed to Meet Their Burden for Dependent Claims 8-11 and 13-14

a. Claim 13 (“wherein the control system is further coupled to a proximity sensor”)

Dependent claim 13 depends from independent claim 7 and therefore incorporates all of its limitations. Petitioners and Dr. Anthony's discussion of this dependent claim fails to cure the deficiencies identified above with respect to Claim 7. Petition, 67-68; EX2031, ¶141. Accordingly, Petitioners failed to meet their

burden for dependent claim 13 for at least the same reasons as independent claim 7. Petition, 67-68; EX2031, ¶141.

Petitioners' reliance on Kiani's "contact sensor" likewise does not disclose the claimed "control system" that is "further coupled to a proximity sensor" as required by claim 13. Petition, 67-68; EX2031, ¶141. "The Kiani reference does not disclose any proximity-based sensing function or circuitry for non-contact positional detection." EX2031, ¶141. Its "probe-off" feature merely detects the presence or absence of electrical continuity between contacts, which is not the claimed proximity sensing. EX1007, 5:27-36; 6:53-62. EX2031, ¶141.

For the same reasons discussed above regarding the "location sensor" of claim 7, Kiani—alone or in combination with Mault, Mitsui, or Pologe—does not teach or suggest the claimed proximity sensor. EX2031, ¶142. Moreover, any such combination would produce an inoperative system inconsistent with the '868 Patent's non-contact, proximity-based architecture. EX2031, ¶142. Kiani's contact-dependent system is directly contrary to the '868 Patent's focus on maintaining safe, non-contact operation. EX2031, ¶142.

VIII. CONCLUSION

For at least the foregoing reasons, the Petition should be denied as to each of the requested grounds. For brevity, Patent Owner may not have addressed all characterizations of the applied references and the challenged claims and reserves

the right to do so should institution be granted. The absence of a response by Patent Owner to any of the positions presented in the Petition or the associated expert declaration is not a concession to those positions. The fact that Patent Owner's Preliminary Response has focused on particular arguments is not a concession that there are no other arguments for patentability of the challenged claims.

Respectfully submitted,

Dated: November 7, 2025

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CERTIFICATION OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the foregoing Patent Owner's Preliminary Response is produced using a 14-point Times New Roman font and contains approximately 10,556 words, which is less than the 14,000 total words permitted by the U.S. Patent Trial and Appeal Board rules. Counsel relies on the word count of the computer program used to prepare the response on November 7, 2025.

Dated: November 7, 2025

By: /s/ Jennifer Hayes

Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Patent Owner's Preliminary Response** was served on November 7, 2025, by email:

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