

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

iRhythm, Inc.

Petitioner,

v.

Welch Allyn, Inc.

Patent Owner.

Case: IPR2025-00376

U.S. Patent No. 9,155,484

PETITION FOR *INTER PARTES* REVIEW
UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104

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<i>Apple Inc. v. Fintiv Inc.,</i> IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020)	81, 82
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<i>Lyft, Inc., v. Rideshare Displays, Inc.,</i> IPR2021-01602, Paper 7 (PTAB Apr. 11, 2022)	83
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1001	U.S. Patent No. 8,214,007
1002	File History of U.S. Patent No. 8,214,007
1003	U.S. Patent No. 8,965,492
1004	File History of U.S. Patent No. 8,965,492
1005	U.S. Patent No. 9,155,484
1006	File History of U.S. Patent No. 9,155,484
1007	U.S. Patent No. 10,159,422
1008	File History of U.S. Patent No. 10,159,422
1009	Expert Declaration of Jason Heikenfeld ¹
1010	<i>Curriculum Vitae</i> of Dr. Jason Heikenfeld, Ph.D.
1011	U.S. Patent Publication No. 2003/0149349 (“Jensen”)
1012	Certified English Translation of Japanese Pat. Pub. JP2004/121360 ² (“Matsumura”)
1013	U.S. Patent No. 4,763,660 (“Kroll”)

¹ The same Declaration of Dr. Jason Heikenfeld, Ph.D. is being submitted with *inter partes review* petitions directed to patents in the same patent family as U.S. Patent No. 9,155,484, but the citations to the declaration in this petition are to the relevant portions of the declaration for the specific grounds and patent challenged.

² Exhibit 1065 is the original Japanese language Matsumura reference, and Exhibit 1066 is the declaration attesting to the accuracy of the translation in Exhibit 1012.

Exhibit No.	Description
1014	U.S. Patent Publication No. 2005/0096513 (“Ozguz”)
1015	U.S. Patent No. 6,238,338 (“DeLuca”)
1016	C.J. Harland et al., Electric Potential Probes – <i>New Directions in the Remote Sensing of the Human Body</i> , 13 Meas. Sci. Tech. 163 (2002) (“Harland”)
1017	U.S. Patent No. 6,223,080 (“Thompson”)
1018	U.S. Patent No. 4,280,507
1019	PCT Publication WO 1987/01024 A1
1020	Jan Adamec & Richard Adamec, <i>ECG Holter, Guide to Electrocardiographic Interpretation</i> (2008)
1021	Gautham Kalahasty et al., <i>A Brief History of Remote Cardiac Monitoring</i> , 5 Cardiac Electrophysiology Clinics 275 (2013)
1022	Edward K. Chung, <i>Ambulatory Electrocardiography Holter Monitor Electrocardiography</i> (1979)
1023	U.S. Patent Publication No. 2006/0224072
1024	NLM, <i>In brief: What is an electrocardiogram (ECG)?</i> , available at https://www.ncbi.nlm.nih.gov/books/NBK536878/
1025	Majd AlGhatrif & Joseph Lindsay, <i>A Brief Review: History to Understand Fundamentals of Electrocardiography</i> , 2 J. Community Hosp. & Internal Med. Persps. 14383 (2012)
1026	Robert P. Grant, <i>Spatial Vector Electrocardiography</i> , Circulation Vol. II, 676 (Nov. 1950)
1027	ACLS Medical Training, <i>The Basics of ECG</i> , available at https://www.aclsmedicaltraining.com/basics-of-ecg/
1028	Euan A. Ashley & Josef Niebauer, <i>Cardiology Explained</i> (2004), available at https://www.ncbi.nlm.nih.gov/books/NBK2204/

Exhibit No.	Description
1029	Am. Coll. Cardiology, Am. Heart Ass’n Task Force on Practice Guidelines, <i>ACC/AHA Guidelines for Ambulatory Electrocardiography: Executive Summary and Recommendations</i> 100 Circulation 886 (1999), available at https://www.ahajournals.org/doi/full/10.1161/01.cir.100.8.886
1030	Mike Cadogan, <i>Norman J. Holter</i> (2022), available at https://litfl.com/norman-j-holter/
1031	Joel Morganroth, <i>Ambulatory Holter Electrocardiography: Choice of Technologies and Clinical Uses</i> , <i>Anal. of Internal. Med.</i> (1985)
1032	Nitish V. Thakor, <i>From Holter Monitors to Automatic Defibrillators: Developments in Ambulatory Arrhythmia Monitoring</i> , <i>IEEE Transactions on Biomed. Eng’g</i> , 770 (1984)
1033	PCT Publication WO 2008/005015 A1
1034	U.S. Patent No. 6,454,708
1035	R.S. Khandpur, <i>Printed Circuit Boards: Design, Fabrication, Assembly, and Testing</i> (2006)
1036	AAMI, <i>Cardiac monitors, heart rate meters, and alarms</i> , ANSI/AAMI EC13:2002 (2002)
1037	P.J.B. Hubner, <i>Which Disposable Chest Electrode?</i> , <i>British Med. J.</i> , 507 (Aug. 30, 1969)
1038	V. Trend et al., <i>Are ECG Welsh cup electrodes effectively cleaned?</i> , 14 <i>J. Hosp. Infection</i> 325 (1989)
1039	U.S. Patent Publication No. 2003/0069510
1040	<i>Devices@FDA: Dexcom STS Continuous Monitors</i> , U.S. Food & Drug Admin. (2005), available at https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pma&id=320251
1041	AAMI, <i>Ambulatory Electrocardiographs</i> , ANSI/AAMI EC38:1998 (1998)

Exhibit No.	Description
1042	David Prutchi & Michael Norris, <i>Design and Development of Medical Electronic Instrumentation</i> (2005)
1043	Roger A. Freedman & Hugh D. Young, <i>University Physics</i> (15th ed. 2019)
1044	Bruce R. Bowman & Edward Schuck, <i>Medical Instruments and Devices Used in the Home</i> , CRC Press LLC (2000)
1045	Bert-Uwe Köhler et al., <i>The Principles of Software QRS Detection</i> , IEEE Eng. Med. & Bio. (2002)
1046	Brian Burkhardt, <i>The Future of Electrocardiograph Telemetry Systems</i> , Int'l Telemetry Conference Proceedings (2004)
1047	Patrick J. Nolan, <i>Sterile Medical Device Package Development</i> , Standard Handbook of Biomedical Eng'g & Design (2004)
1048	Lawrence R. Dallett & William E. Donaldson, <i>Plastics and Adhesives: A Guide to Their Physical Properties and Uses</i> , U.S. Dep't of Com. (1956)
1049	N.V. Thakor & J.G Webster, <i>Electrode studies for the long-term ambulatory ECG</i> , Med. & Biol. Eng. & Comput. (1985)
1050	Jiapu Pan & Willis J. Tompkins, <i>A Real-Time QRS Detection Algorithm</i> , BME-22 IEEE Transactions on Biomed. Eng'g 230 (1985)
1051	Roubik Gregorian & William E. Nicholson, Jr., <i>A Switched-Capacitor High-Pass Filter</i> , 27 IEEE Transactions on Circuits and Sys. 226 (1980)
1052	J. Terry Caves et al., <i>Sampled Analog Filtering Using Switched Capacitors as Resistor Equivalents</i> , 12 IEEE Journal of Solid-State Circuits 592 (1977)
1053	Klaus-Peter Hoffmann & Roman Ruff, <i>Flexible dry surface-electrodes for ECG long-term monitoring</i> 5739 (2007)
1054	Tsuyoshi Kato et al., <i>An Application of Capacitive Electrode for Detecting Electrocardiogram of Neonates and Infants</i> , 2006 Int'l Conf. of the IEEE Eng'g Med. & Bio. (2006)
1055	U.S. Patent Publication No. 2003/0055460

Exhibit No.	Description
1056	Tilak Shah, <i>Polyurethane Thin-Film Welding for Medical Device Applications</i> , Med. Device and Diagnostic Indus. (2002)
1057	Creative Materials, <i>Medical Device Specialty Inks and Films</i> , available at http://www.creativematerials.com/lit-erature/medical_device.pdf , archived at Wayback Machine (https://web.archive.org/web/20060508230449/http://www.creative-materials.com/literature/medical_device.pdf) (May 8, 2006)
1058	Aoife Morrin et al., <i>Electrochemical Characterization of Commercial and Home-Made Screen-Printed Carbon Electrodes</i> , 36 Anal. Letters, 2021 (2003)
1059	V.W. Greene, <i>Reuse of Disposable Medical Devices: Historical and Current Aspects</i> , 7 Infection Control & Hosp. Epidemiology 508 (1986)
1060	Robert A. Millikan & E.S. Bishop, <i>Elements of Electricity</i> (1917)
1061	Maeona K. Jacobs, <i>Sources of Measurement Error in Noninvasive Electronic Instrumentation</i> , 13 Nursing Clinics N. Am. 573 (1978)
1062	Michael R. Neuman, <i>Biopotential Electrodes</i> , Medical Instrumentation (3d ed. 1998)
1063	Jaehoon Kim, <i>Implanted Antennas for Medical Wireless Communications: Characterizations, Designs and Performance Evaluations</i> (2005) (Ph. D. dissertation, Univ. Cal. L.A.)
1064	J. Mühlsteff et al., <i>Wearable approach for continuous ECG – and Activity Patient-Monitoring</i> , 1 26th Proc. Int’l Conf. of IEEE Eng’g in Med. & Biol. Soc’y 2184 (2004)
1065	Japanese Patent Publication No. JP2004/121360
1066	Certificate of Translation for Japanese Patent Publication No. JP2004/121360

I. INTRODUCTION

Pursuant to 35 U.S.C. § 311 and 37 C.F.R. § 42.100, iRhythm, Inc. (“Petitioner”) requests *Inter Partes* Review of claims 1-8, 11-12, and 15-20 (the “Challenged Claims”) of U.S. Patent No. 9,155,484 (the “’484 patent”), assigned to Welch Allyn, Inc. The Challenged Claims are obvious over the prior art. Accordingly, the Patent Trial and Appeal Board should institute review of the Challenged Claims.

II. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104

A. Standing (37 C.F.R. § 42.104(a))

Petitioner certifies that the ’484 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR of the Challenged Claims.

B. Identification of Challenge (37 C.F.R. § 42.104(b))

In view of the prior art and evidence presented, the Challenged Claims are unpatentable and should be cancelled. 37 C.F.R. § 42.104(b)(1). Based on the prior art identified below, IPR of the Challenged Claims should be instituted. 37 C.F.R. § 42.104(b)(2).

Proposed Grounds of Unpatentability	
<u>Ground 1</u>	Claims 1-5 and 15-20 are obvious under pre-AIA § 103 over Matsumura and General Knowledge of a Person of Ordinary Skill in the Art
<u>Ground 2</u>	Claims 1-5, 15, 17, 18, and 20 are obvious under pre-AIA § 103 over Jensen and General Knowledge of a Person of Ordinary Skill in the Art

<u>Ground 3</u>	Claims 1-8, 15, 19, and 20 are obvious under pre-AIA § 103 over Ozguz and General Knowledge of a Person of Ordinary Skill in the Art
<u>Ground 4</u>	Claims 6-8, 11, and 12 are obvious under pre-AIA § 103 over Matsumura, Ozguz, and General Knowledge of a Person of Ordinary Skill in the Art

Sections VII.A-D identify where each element of the Challenged Claims is found in the prior art. 37 C.F.R. § 42.104(b)(4). The exhibit numbers of the evidence relied on to support the challenges are provided above and the relevance of the evidence to the challenges raised are provided in Sections VII.A-D. 37 C.F.R. § 42.104(b)(5). Exhibits 1001-1066 are attached.

C. Claim Construction (37 C.F.R. § 42.104(b)(3))

Claims are interpreted with their ordinary and customary meaning as understood from the perspective of a person of ordinary skill in the art (“POSA”). *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

III. PAYMENT OF FEES

The undersigned authorizes the Office to charge the fees specified by 37 C.F.R. § 42.15(a) to Account No. 19-2555. The undersigned further authorizes payment for any additional fees that might be due in connection with this Petition to be charged to the same.

IV. OVERVIEW OF CHALLENGES AND RELIEF REQUESTED

Pursuant to 37 C.F.R. §§ 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner requests cancellation of the Challenged Claims pursuant to the grounds below. Additional support is provided in the Declaration of Jason Heikenfeld, Ph.D. (Ex. 1009).

Ground 1: Claims 1-5 and 15-20 are obvious under pre-AIA § 103 over Matsumura and General Knowledge of a Person of Ordinary Skill in the Art.

Ground 2: Claims 1-5 and 15, 17, 18, and 20 are obvious under pre-AIA § 103 over Jensen and General Knowledge of a Person of Ordinary Skill in the Art.

Ground 3: Claims 1-8, 15, 19, and 20 are obvious under pre-AIA § 103 over Ozguz and General Knowledge of a Person of Ordinary Skill in the Art.

Ground 4: Claims 6-8, 11, and 12 are obvious under pre-AIA § 103 over Matsumura, Ozguz, and General Knowledge of a Person of Ordinary Skill in the Art.

V. SUMMARY OF THE '484 PATENT

A. Technical Background

Physiological monitoring systems have been used since the early 20th century to measure and report variables associated with human health and performance (*i.e.*, objective signs such as temperature, pulse, respiration, brain wave activity, muscular contractions). Ex. 1009 ¶¶17-20. These monitoring systems have been commonly used to remotely monitor patients during their daily activities, outside of a clinical setting. *Id.* ¶23. To accommodate their use on a day-to-day basis, these monitoring

systems are designed to be portable and discreet. *Id.* ¶¶23-24; Ex. 1005, 1:43-44 (“[p]ortable patient monitors have evolved that allow patients to enjoy at least some mobility”).

Electrocardiograms (ECGs or EKGs) are a type of physiological monitoring used to evaluate and monitor patients’ cardiac health. Ex. 1009 ¶¶17-22; Ex. 1005, 1:31-42. Originating in the 1920s, ECGs measure the electrical signals that result from the depolarization and repolarization of cardiac muscle during each heartbeat. Ex. 1009 ¶19. Identified deviations from the normal pattern of voltage changes, known as sinus rhythm, may be used to identify abnormal heart rate and/or rhythm, and may enable a clinician to diagnose a heart condition. *Id.* ¶¶19-21. An ECG measures the heart muscles’ polarization/depolarization cycle through the use of electrodes, which are typically disposable and attached to a patient’s skin. *Id.* ¶ 20; Ex. 1005, 1:46-48 (“[s]ensors, such as ECG electrodes, are affixed to the patient’s body, such as with tape”). Those electrodes are connected by electric wiring to “leads,” which in turn connect to electronics capable of processing and displaying the ECG signals. Ex. 1009 ¶¶25-26; Ex. 1005, 1:46-49, 2:11-13.

In 1949, Dr. Holter introduced long-term ECG recording using the first wearable, ambulatory monitor. Ex. 1009 ¶¶23-24. Following efforts to reduce the size of the monitor, in 1969, commercial production of the Holter “*minimonitor*”—the size of a cigarette package—began. *Id.* Ambulatory “Holter monitoring”

became a mainstay of cardiology practices, especially for the diagnosis and treatment of serious cardiac conditions. *Id.* ¶24. By 1979, the Holter monitors had been recognized for various uses ranging from arrhythmia diagnosis to assessment of pacemakers. *Id.*

Later-developed wearable monitors improved on the Holter monitor in several key ways. *Id.* ¶¶24-31. These wearable monitors were wireless, smaller, and lightweight. Ex. 1005, 1:51-55. These advances in wearable devices were in part attributable to smaller microcontrollers, increased computing power on board the device, and improvements in wireless communication technologies. Ex. 1009 ¶¶25-31.

Modern wearable monitors also incorporate disposable electrodes and other disposable components. *Id.* ¶32. The use of disposable electrodes dates back to the 1960s. *Id.* Relying on disposable electrodes and other components was well-understood to reduce the risk of infectious diseases spreading between patients. *Id.* ¶¶32-33 (citing U.S. Patent No. 4,763,660 (“Kroll”) (Ex. 1013), 1:66-2:7 (“disposability is particularly beneficial in a medical setting, wherein the possibility of transfer of communicable diseases from patient to patient is of great concern”)). The ’484 patent acknowledges that disposable, snap-on electrodes were commercially available by November 1, 2006. Ex. 1005, 9:32-39. Other references at the time acknowledge the use of other disposable components, including a

“flexible circuit substrate with trace extensions.” Ex. 1009 ¶35 (citing U.S. Patent Publication No. 2006/0224072 (“Shennib”) ¶[0035] (a disposable patch that includes a “flexible circuit substrate 20 with trace extensions to electrodes 21, 22, 23”); U.S. Patent Publication No. 2003/0069510 (“Semler”) ¶¶[0035], [0046] (a disposable monitor with “electrodes” and “flex circuit”).

Modern wearable devices incorporate both disposable and reusable components, attempting to maximize the benefits of both. Reusable components are generally made of higher quality materials while also being more cost efficient due to their repeated use. *Id.* Disposable components have traditionally been more expensive due to the need to replace components with each use. But the use of disposable components has become widespread in part because of the reduced costs of modern electrical components and improved recycling programs that lessen the environmental impact. *Id.*

B. Patent Description

The '484 patent describes a known solution to the known problem outlined above. In particular, the '484 patent is directed to a body-worn heart monitor comprising a flexible circuit layer that includes disposable and reusable components. Ex. 1005, 2:46-3:5. The claimed monitor requires two major structural components: (1) a disposable module (110, shown in red) with electrodes that make physical contact with the patient's skin and “measure[s] physiological signals”; and (2) a

reusable “communication-computation module” (102, shown in blue) that “mechanically and electrically” connects to and receives physiological signals from the disposable module. *Id.* The “communication-computation module” performs “real-time physiological analysis” and transmits the analysis to a remote radio receiver. Ex. 1005, Abstract, 2:58-65.

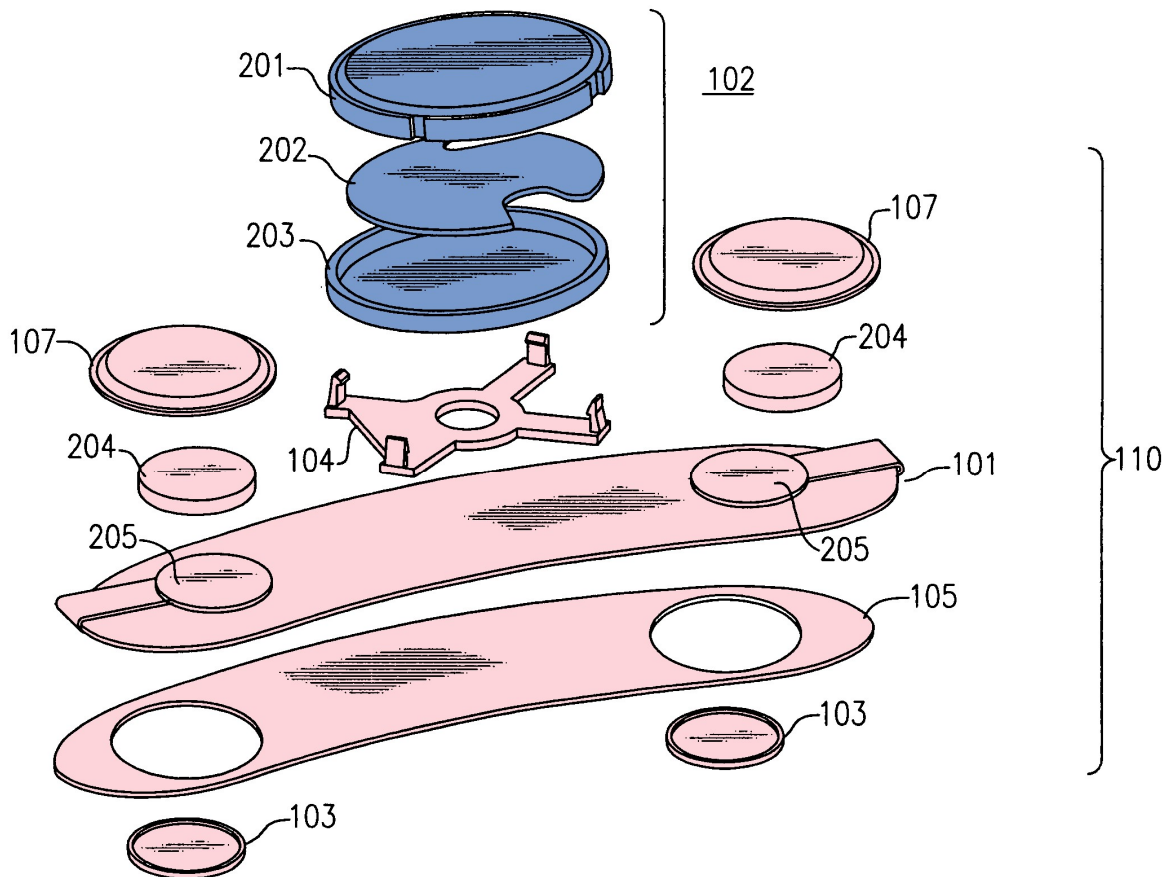


FIG. 2

Id. Fig. 2 (annotated).

C. Priority Date

The application that matured into the '484 patent was filed on January 13, 2015, but claims priority to U.S. Application No. 11/591,619 filed on November 1,

2006. For purposes of this proceeding only, Petitioner contends the priority date is November 1, 2006.

D. Prosecution History

Claims 1-6 and 15-20 were initially rejected under 35 U.S.C. § 102 and allowed after independent claims 1 and 15 were amended to recite that the computation-communication module “includ[es] a housing retaining a processor” and that the computation-communication module is “attached to the flexible circuit layer.” Response to Non-Final Office Action at 2, 4 (May 15, 2015), Ex. 1006, 45, 47. Claims 7-14 were initially rejected for nonstatutory double patenting and were allowed after the filing of a Terminal Disclaimer. *Id.* at 5, Ex. 1006, 48.

The Notice of Allowance notes that the closest examined prior art “fails to disclose a high voltage circuit protection for a body worn monitor comprising the steps of determining a print pattern and thickness of a first and a second material, wherein each material has a resistivity to be printed on said substrate.” Corrected Notice of Allowability at 2 (July 24, 2015), Ex. 1006, 25. The closest approximation of the Notice of Allowance’s requirement that “each material has resistivity to be printed” appears only in dependent claim 2, which requires “traces of determinable electrical resistance.” None of the allowed independent claims includes this requirement. Ex. 1005, cls. 1, 7, 15.

E. Level of Ordinary Skill in the Art

A POSA would have at least a Bachelor's degree in electrical engineering, electrophysiology, biomedical engineering or an equivalent degree, and at least two to three years of experience designing wearable monitors that detect physiological signals with mechanical and/or electrical elements. Ex. 1009 ¶57. Additional experience may substitute for education and vice versa. *Id.*

VI. PRIOR ART OVERVIEW

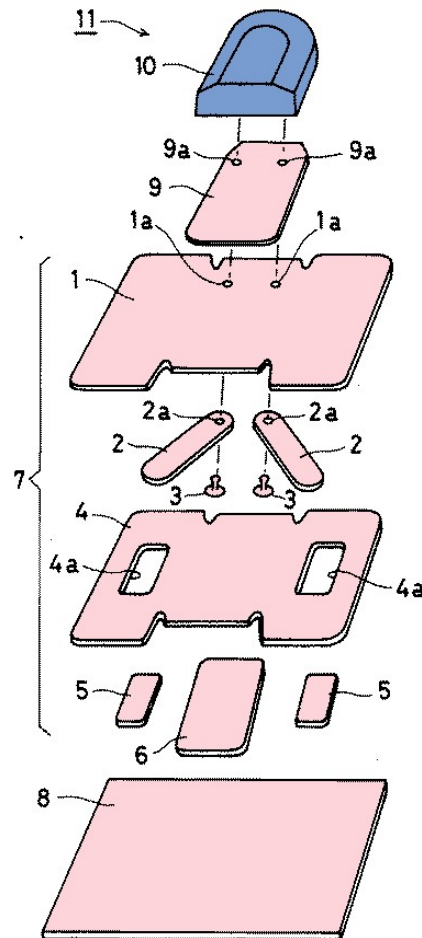
A. Matsumura (Ex. 1012)

Matsumura, published on April 22, 2004 as Japanese Patent Publication 2004-121360, and is prior art under pre-AIA 35 U.S.C. § 102 (a) and (b). Matsumura was neither cited nor considered during prosecution of the '484 patent. Matsumura is directed to “a bioelectric potential detector having a waterproof structure” for detecting ECG signals. Ex. 1012 ¶¶[0001], [0024]. The detector “comprises a disposable bioelectrode pad [in red, below] for detecting bioelectric potentials, and a reusable signal processor [in blue, below] for processing the bioelectric potential signals detected by the bioelectrode pad,” *id.* ¶[0007], Fig. 1.

Matsumura's disposable bioelectrode pad 7 is “composed of a first sheet 1, a conductive material 2, a hook 3, a second sheet 4, a conductive gel 5, a third sheet 6, and double-sided adhesive tape [8].” *Id.* ¶[0016]. “[B]ioelectric potentials detected by the conductive gel 5 are transmitted through the conductive material 2

and the hooks 3” at which point they reach signal processor 10. *Id.* ¶¶[0019], [0025]. A portion of conductive material 2 is in contact with conductive gel 5, while another portion of conductive material 2 electrically connects conductive gel 5 to signal processor 10 via hook 3. *Id.* ¶¶[0019]-[0020], [0024].

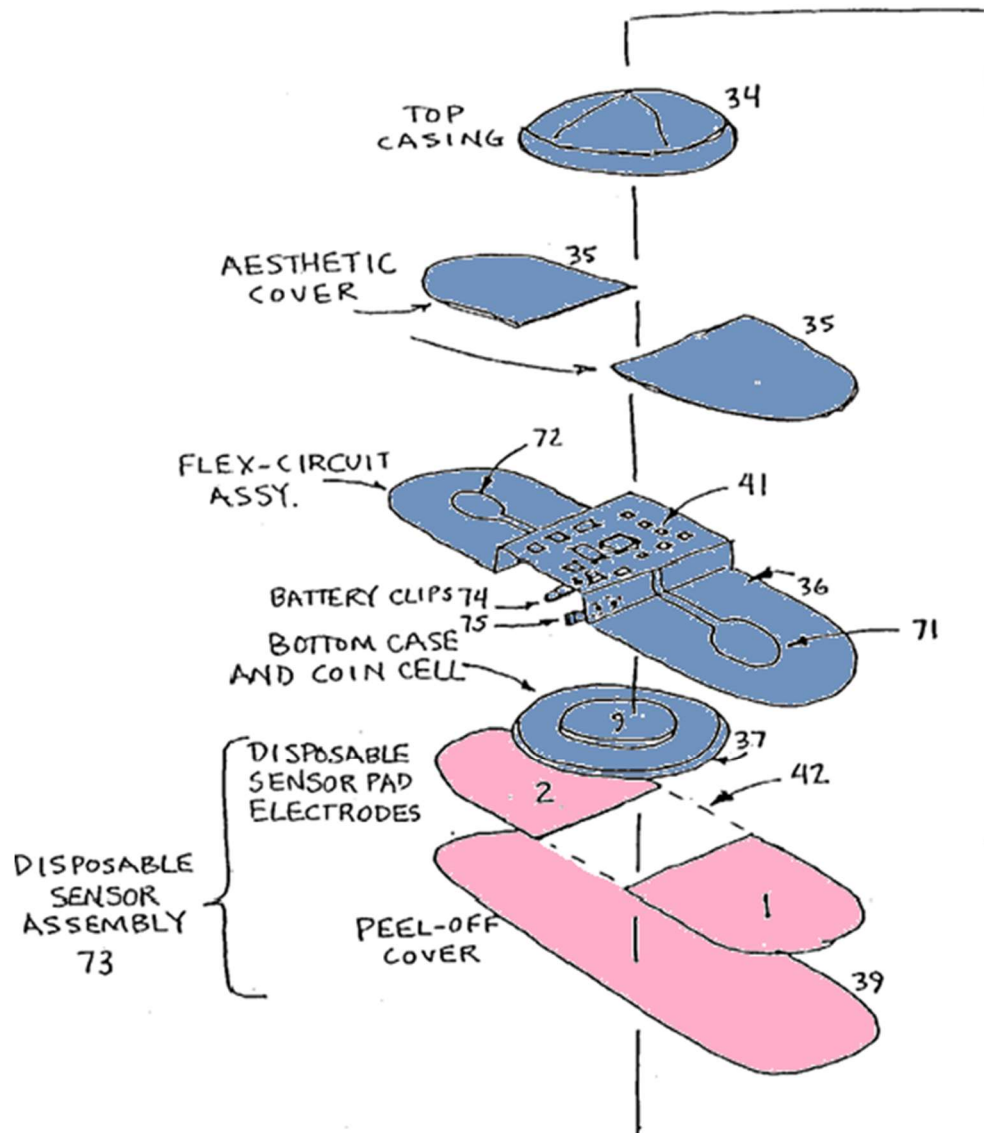
The signal processor “incorporates a processing circuit for filtering and amplifying detected bioelectric potential signals, a memory for storing the processed bioelectric potential signal, a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna.” *Id.*



Id. Fig. 1 (annotated).

B. Jensen (Ex. 1011)

Jensen, published on August 7, 2003 as U.S. Patent Pub. No. 2003/0149349, is prior art under pre-AIA 35 U.S.C. §§ 102 (a), (b), (e). Jensen was cited in Information Disclosure Statements during prosecution but was never substantively examined. Jensen teaches a body worn physiological monitor in the form of a “smart bandage or smart patch” for “physiological monitoring, especially heart rate sensing.” Ex. 1011, Abstract, ¶[0013]. This “smart patch” includes both a “disposable sensor assembly” (shown below in red) that makes direct contact with the skin of the patient and a “re-usable (non-disposable) portion” (shown below in blue). *Id.* ¶¶[0042]-[0043], Fig. 5. Jensen’s monitor includes a flexible circuit assembly with “programmable logic” for “perform[ing] measurement and processing of sensed data.” *Id.* ¶[0014]. The assembly includes “leads 86” that connect the piezoelectric sensors 81 that “sense[] data” with circuit 87 that “process[es]” the “sensed data.” *Id.* ¶[0049]. The monitor will then use a “transmitter” and “antenna” to transmit captured physiological data to “any variety of different receivers.” *Id.* ¶¶[0029], [0032]-[0033].



Id. Fig. 5 (annotated).

C. Ozguz (Ex. 1014)

Ozguz published on May 5, 2005 as U.S. Pat. Pub. No. 2005/0096513 and is prior art under pre-AIA 35 U.S.C. §§ 102(a), (b) and (e). Ozguz was neither cited nor considered during prosecution of the '484 patent. Ozguz teaches a “sensor system comprising a thin flexible ambulatory/self contained bio-sensor module in a form similar to an adhesive bandage [shown in red, below],” Ex. 1014 ¶[0003],

which is “adhered to the skin 15 of a subject body 20 to be monitored,” *id.* ¶[0038]. The bio-sensor module can collect and analyze EKG signals. *Id.* ¶[0017]. Structurally, the bio-sensor module includes an “antenna 50 metallized onto a flexible substrate 55 for transmitting and/or receiving RF signals.” *Id.* ¶[0039], Fig. 2A. “Thin flexible” substrates 60, 65, 70—each with “respective integrated circuits 71, 72, 73—are bonded to the flexible substrate by an anisotropic epoxy layer.” *Id.* Sensor module 20 includes an adhesive pad 91 “formed of double-sided adhesive for application before and removal after each use so that the sensor module can be used repeatedly. The sensor module can be sterilized in an autoclave, for example, between uses.” *Id.* ¶[0049].

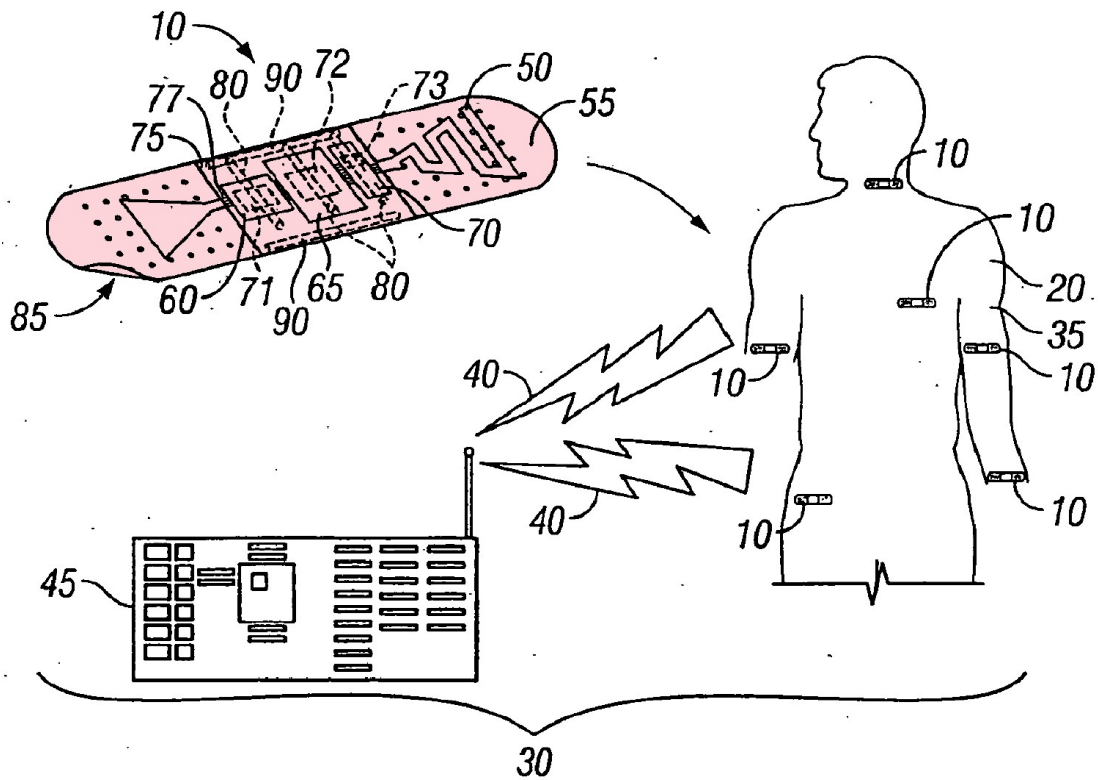


FIG. 2A

Id. Fig. 2A (annotated).

VII. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Ground 1: Claims 1-5 and 15-20 are Obvious Over Matsumura and General Knowledge of a POSA

1. Claim 1

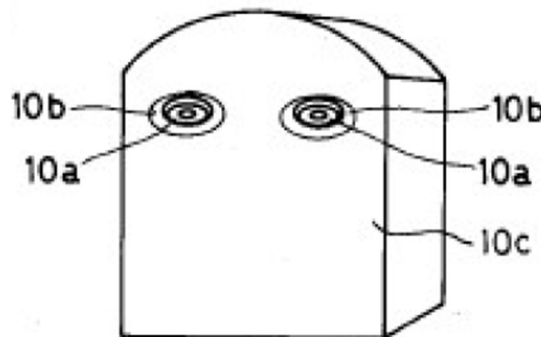
i. [Pre] A body-worn physiological sensor comprising:

Matsumura discloses a body-worn physiological sensor which it refers to as a “bioelectric potential detector.” Ex. 1012, Abstract, ¶¶[0006], [0014]. The detector is worn on the body and can sense physiological signals such as electrocardiogram signals. *Id.* ¶[0024], Figs. 2, 6; Ex. 1009 ¶¶1018-1021.

ii. [1a.] a computation-communication module including a housing retaining a processor;

Matsumura discloses “a computation-communication module.” In particular, Matsumura discloses a “reusable signal processor 10” that is a module. *Id.* ¶[0016]; *see also id.* ¶¶[0008], [0014], [0025], Figs. 1-2. The reusable signal processor incorporates components for computation: a “processing circuit for filtering and amplifying detected bioelectric potential signals” and “a memory for storing the processed bioelectric potential signal.” *Id.* ¶[0025]. The reusable signal processor also incorporates components for communication: “a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna.” *Id.* Accordingly, Matsumura discloses a computation-communication module. Ex. 1009 ¶¶1022-1026.

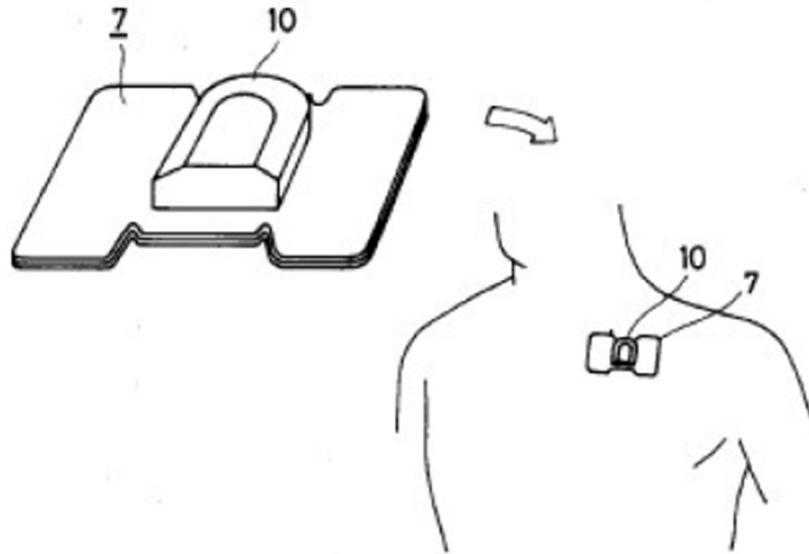
Further, the “reusable signal processor 10” that includes the “processing circuit” and the “loop antenna” is enclosed in housing 10c. *Id.* ¶¶[0025], [0027], [0029]. Retaining “processing circuit” and “loop antenna” in housing 10c ensures that Matsumura’s device is waterproof. *Id.*



Id. Fig. 4(a). Accordingly, Matsumura teaches a computation-communication module including a housing retaining a processor. Ex. 1009 ¶¶1022-1026.

iii. [1b.] a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals,

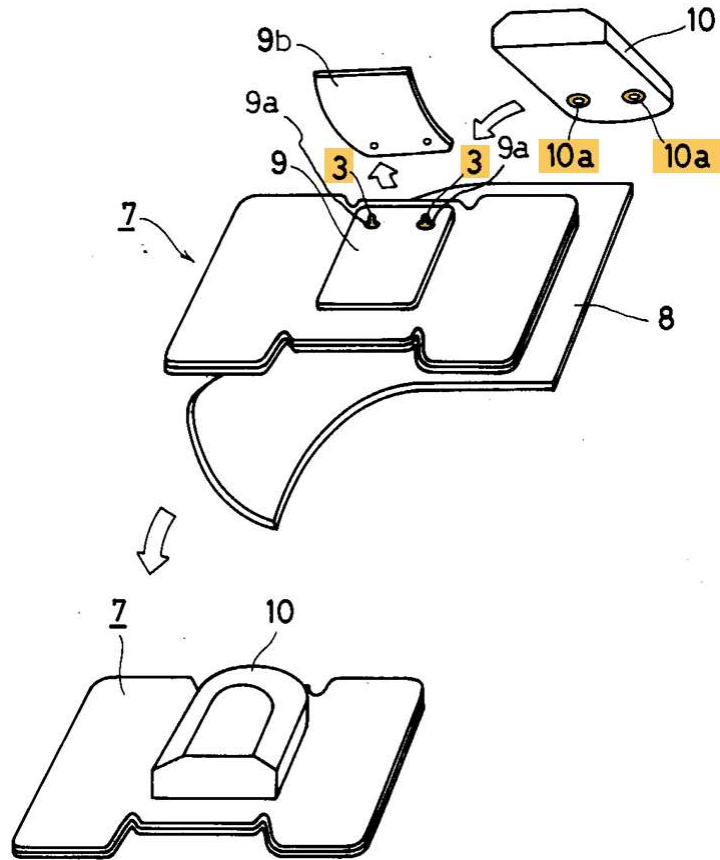
Matsumura discloses a “flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals.” Ex. 1009 ¶¶1027-1031. The “bioelectric potential detector 11” includes a disposable “bioelectrode pad 7” composed of first and second sheets 1, 4, “made of insulating material,” such as, “polyethylene foam, polyurethane foam, or polyurethane sheet” (*id.* ¶¶[0017]-[0018], [0022]), which a POSA would recognize are flexible materials. Ex. 1009 ¶1029. Matsumura’s bioelectrode pad is a flexible circuit layer because it includes conductive material 2, which forms an electrical connection between the computation-communication module and conductive gel 5, which contacts the patient’s skin. The bioelectrode pad 7 is coupled to the skin surface of a subject to measure physiological signals, such as an electrocardiogram, as shown in Figure 2.



Ex. 1012, Fig. 2 (annotated); *see also id.* ¶[0024] (“[t]he bioelectric potential detector 11 can be used as an electrocardiogram detector that is worn on the subject’s chest to detect electrocardiogram signals”).

iv. [1c.] said computation-communication module being attached to the flexible circuit layer;

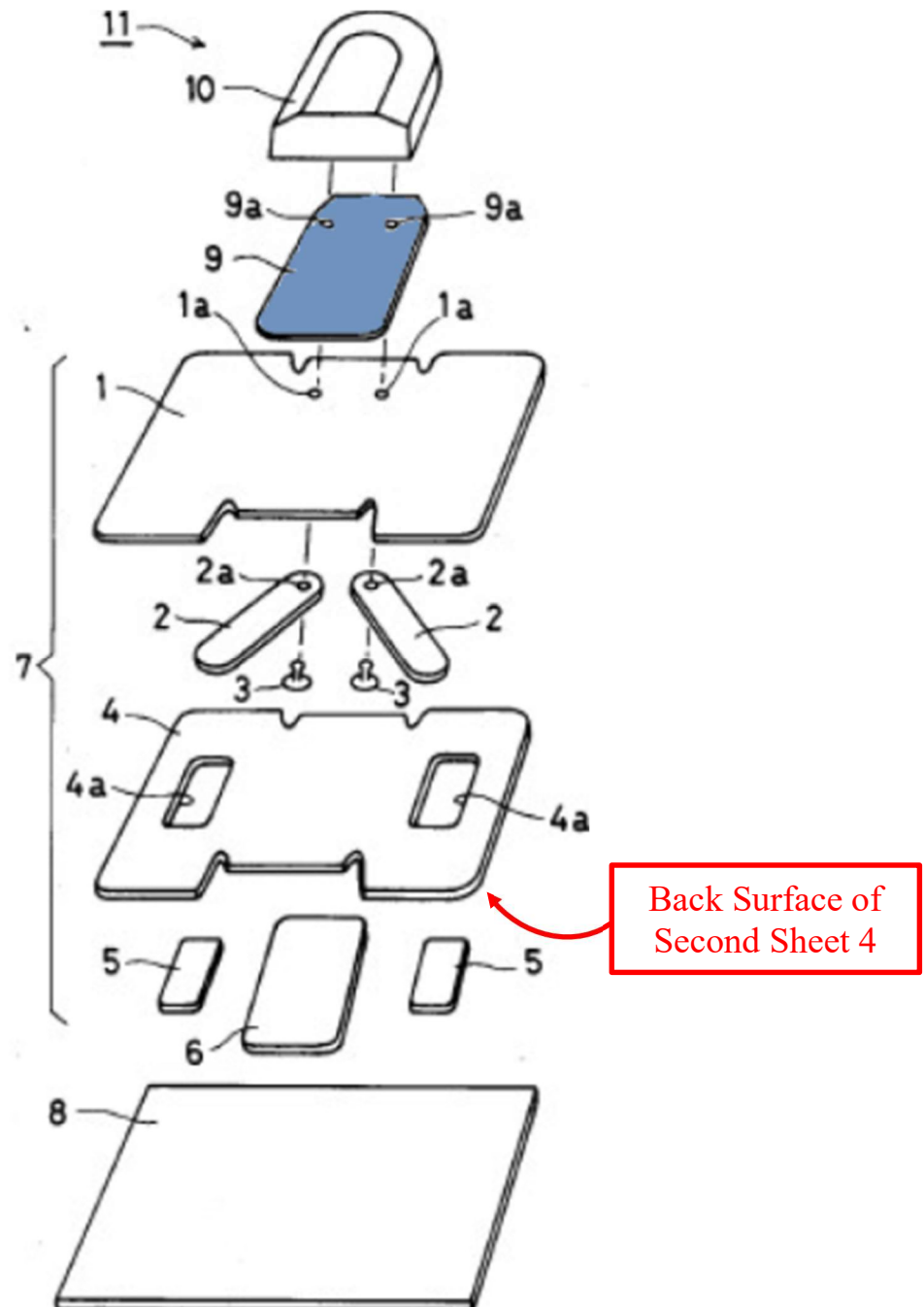
Matsumura discloses a “computation-communication module being attached to the flexible circuit layer.” Ex. 1009 ¶¶1032-1035. Matsumura discloses that the bioelectrode pad 7 (flexible circuit layer) and the signal processor 10 (computation-communication module) are attached with hooks. Ex. 1012, ¶[0016]. In particular, Matsumura’s disposable bioelectrode pad includes “two hooks 3” that connect to “hook engagement portion 10a on the bottom surface of the signal processor,” thereby attaching the computation-communication module to the flexible circuit layer, as shown in the image below. *Id.* ¶¶[0019], [0024], Fig. 2.



Id. Fig. 2 (annotated); Ex. 1009 ¶1034.

- v. *[Id.] an adhesive covering at least a portion of the flexible circuit layer; and*

Matsumura discloses “an adhesive covering at least a portion of the flexible circuit layer.” In particular, Matsumura discloses that “[t]he bioelectrode pad 7 is provided with a double-sided adhesive tape 9 with, for example, acrylic adhesive coated on both sides of the nonwoven fabric at the center of the surface of the first sheet 1.” Ex. 1012 ¶[0023]. Adhesive tape (first adhesive covering), shown in blue below, covers at least a portion of first sheet 1 of bioelectrode pad 7 (flexible circuit layer).

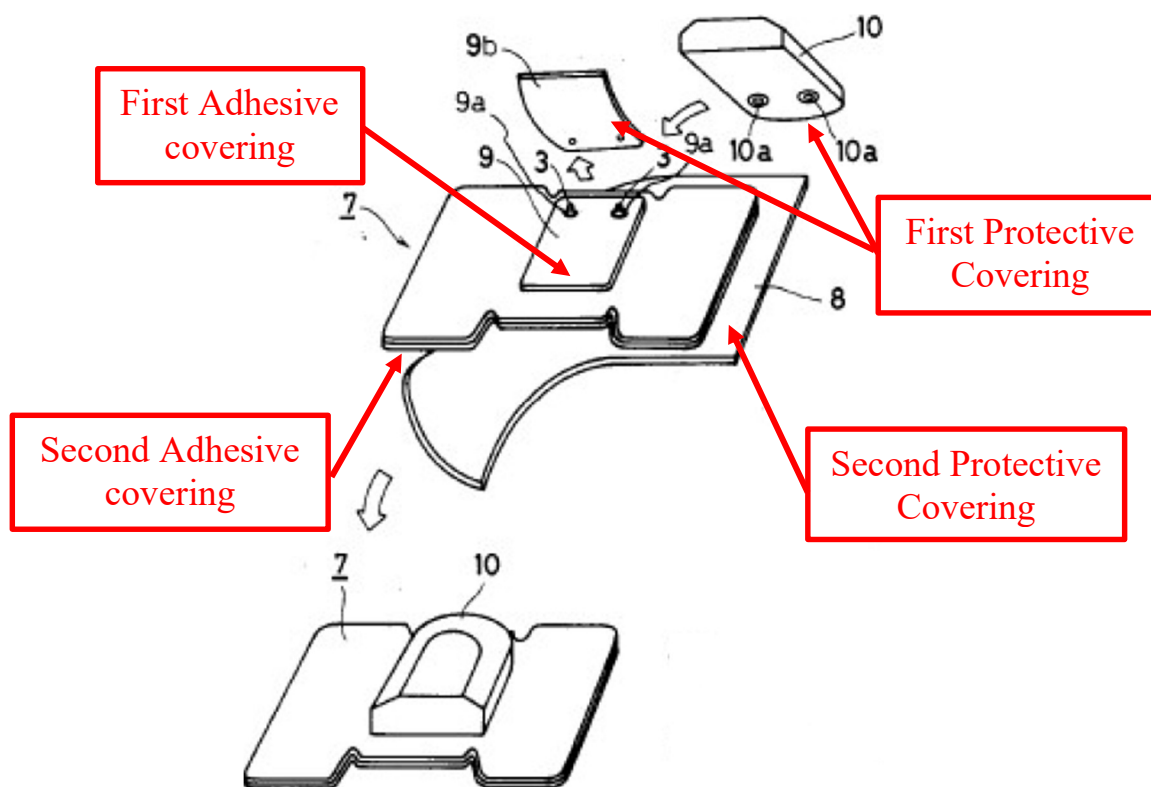


Id. Fig. 1 (annotated); Ex. 1009 ¶1038. In addition to, or alternatively, Matsumura’s bioelectrode pad 7 includes second sheet 4 whose back surface is covered with an “adhesive, such as acrylic adhesive” (*i.e.*, a second adhesive covering). Ex. 1012

¶[0018]. Accordingly, Matsumura discloses multiple “adhesive covering[s]” that cover several “portion[s] of the flexible circuit layer.” Ex. 1009 ¶¶1036-1040.

i. [1e.] a protective covering that protects the adhesive.

Matsumura discloses “a protective covering that protects the adhesive.” Adhesive tape 9 (first adhesive covering) is attached to and covered by the bottom surface of the housing of signal processor 10 (first protective covering). Ex. 1012 ¶[0024]. Additionally, or alternatively, adhesive tape (first adhesive covering) is covered by “release sheet 9b” (first protective covering) that is “peeled off from the adhesive tape 9” prior to signal processor 10 being hooked and attached to bioelectrode pad 7. *Id.*



Id. Fig. 2 (annotated); Ex. 1009 ¶1043.

Additionally, or alternatively, Matsumura includes a “release tape 8 [] attached to the back surface of the bioelectrode pad 7” (flexible circuit layer). Ex. 1012 ¶[0024]. This release tape 8 (second protective covering) covers portions of the adhesive on the back surface of second sheet 4 (second adhesive covering), and “is peeled off from the bioelectrode pad 7” when attaching the detector to the body. *Id.* Accordingly, Matsumura discloses multiple “protective covering[s]” that protect “adhesive covering[s].” Ex. 1009 ¶¶1041-1045.

2. Claim 2

In addition to teaching the limitations of claim 1, Matsumura discloses that “the flexible circuit layer has traces of determinable electrical resistance.” Matsumura discloses a hook 3 that electrically connects a first portion of conductive material 2 to engagement portions 10a of signal processor 10. Ex. 1012 ¶¶[0019], [0024], Fig. 1. A second portion of conductive material 2 directly contacts conductive gels 5 (electrodes) and transmits the detected bioelectrical potential through the first portion of conductive material 2 to signal processor 10. *Id.* ¶[0019], Fig. 1. Accordingly, a POSA would have understood hook 3 and a first portion of conductive material 2 to be a “trace.” Ex. 1009 ¶1048. Conductive material 2 “can be a carbon sheet or a PET sheet coated with conductive Ag/AgCl” and “hook 3 may also be made of a stainless-steel stud, carbon stud, or Ag/AgCl.” Ex. 1012 ¶¶[0020]-[0021]. Thus, a POSA would also have understood that hook 3 and a first portion

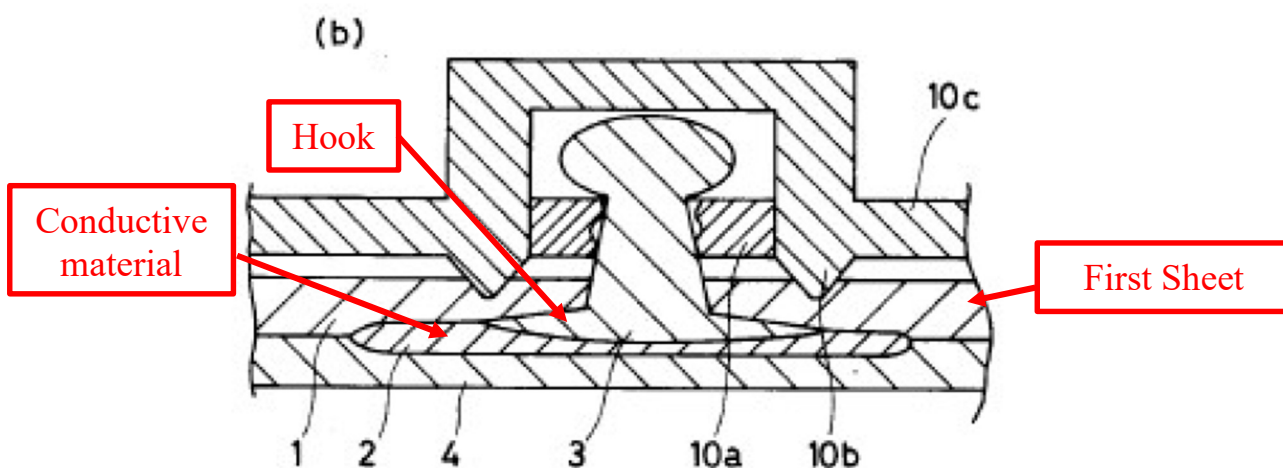
of conductive material 2, and the materials taught by Matsumura, have a determinable electrical resistance. Ex. 1009 at ¶¶1048-1050.

3. *Claim 3*

In addition to teaching the limitations of claims 1 and 2, Matsumura discloses that “the traces on the flexible circuit layer are configured to electrically couple the computation-communication module to the flexible circuit layer, thereby forming a disposable module connector.” As noted above, Matsumura discloses traces on the flexible circuit layer. *Supra* § VII.A.2. Matsumura’s disposable bioelectrode pad 7 (flexible circuit layer) includes “two hooks 3” that electrically couple or connect to “hook engagement portion 10a on the bottom surface of the signal processor” (computation-communication module). Ex. 1012 ¶¶[0019], [0024], Fig. 2. Once received from the electrodes, “the bioelectric potentials detected . . . are transmitted through the conductive material 2 and the hooks 3.” *Id.* ¶[0019]. Accordingly, Matsumura discloses that hook 3 and a first portion of conductive material 2 (*i.e.*, traces) are configured to electrically couple the signal processor 10 (computation-communication module) to bioelectrode pad 7 (flexible circuit layer), thereby forming a disposable module connector (hook 3 located on disposable bioelectrode pad 7). Ex. 1009 ¶¶1051-1054.

4. Claim 4

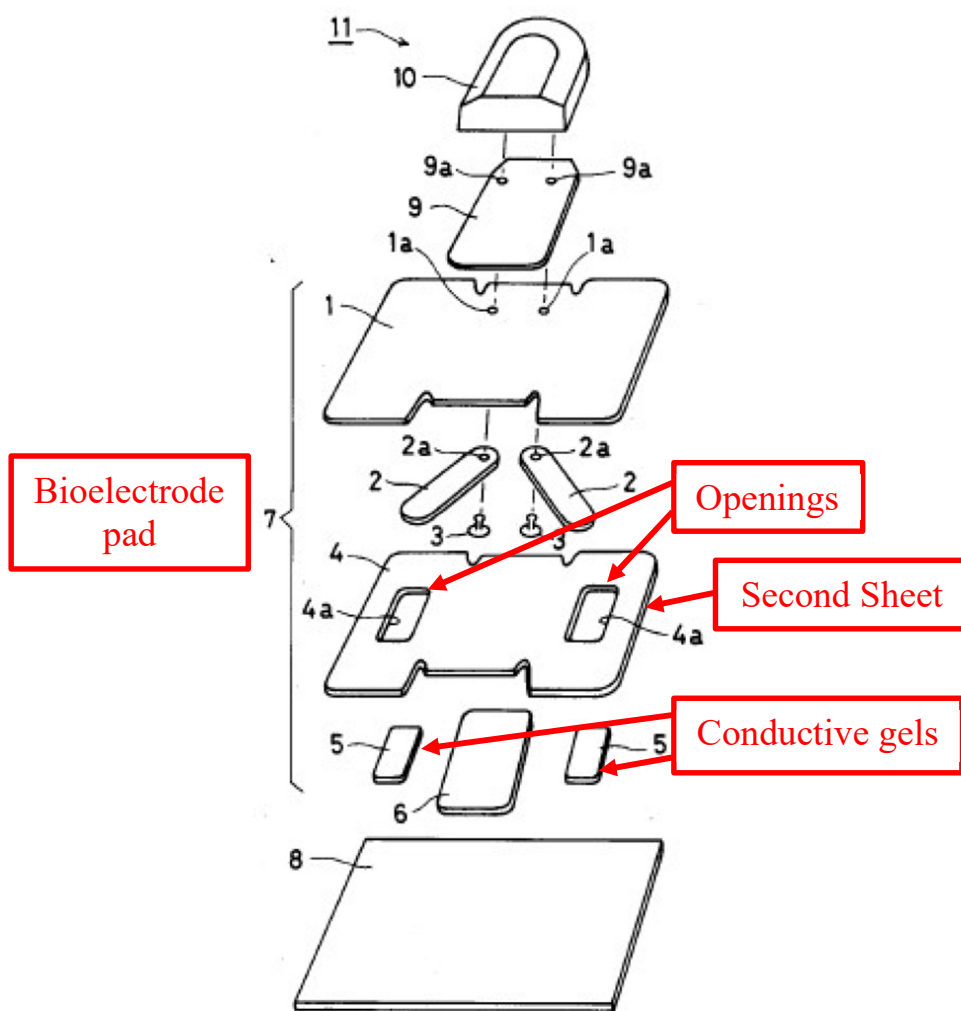
In addition to teaching the limitations of claim 1, Matsumura discloses that “the traces on the flexible circuit layer are at least partially covered by a non-removable insulating covering.” As noted above, Matsumura discloses a first sheet 1 that covers hook 3 and a first portion of conductive material 2. “[F]irst sheet 1 should be made of an insulating material that does not allow moisture to penetrate, for example, polyethylene foam, polyurethane foam, or polyurethane sheet is preferred.” Ex. 1012 ¶[0017]. An example is shown in Figure 5 of Matsumura below, with bottom portion of hook 3 being covered by first sheet 1, and top portion of conductive material 2 being covered by first sheet 1.



Id. Fig. 1 (annotated); Ex. 1009 ¶¶1055-1058. First sheet 1 is non-removable because it is attached to the conductive material 2 by adhesive. Ex. 1012 ¶[0017] (“an adhesive or glue, such as an acrylic adhesive for example, is applied to the back surface of the first sheet 1”).

5. Claim 5

In addition to teaching the limitations of claim 1, Matsumura teaches that “the flexible circuit layer further comprises a plurality of openings sized to receive electrode gels,” as recited in claim 5. Matsumura discloses that “second sheet 4” of bioelectrode pad 7 “is provided with two openings 4a on the left and right sides into which the conductive gel 5 [*i.e.*, electrode gels] is inserted.” Ex. 1012 ¶[0018]. As shown in Figure 1 below, openings 4a are sized to receive electrode gels.



Id. Fig. 1 (annotated); Ex. 1009 ¶¶1059-1062.

6. Claim 15

i. [Pre] A body-worn physiological sensor comprising:

As described above, Matsumura discloses this element. *Supra* § VII.A.1.i;
Ex. 1009 ¶¶1064-1065.

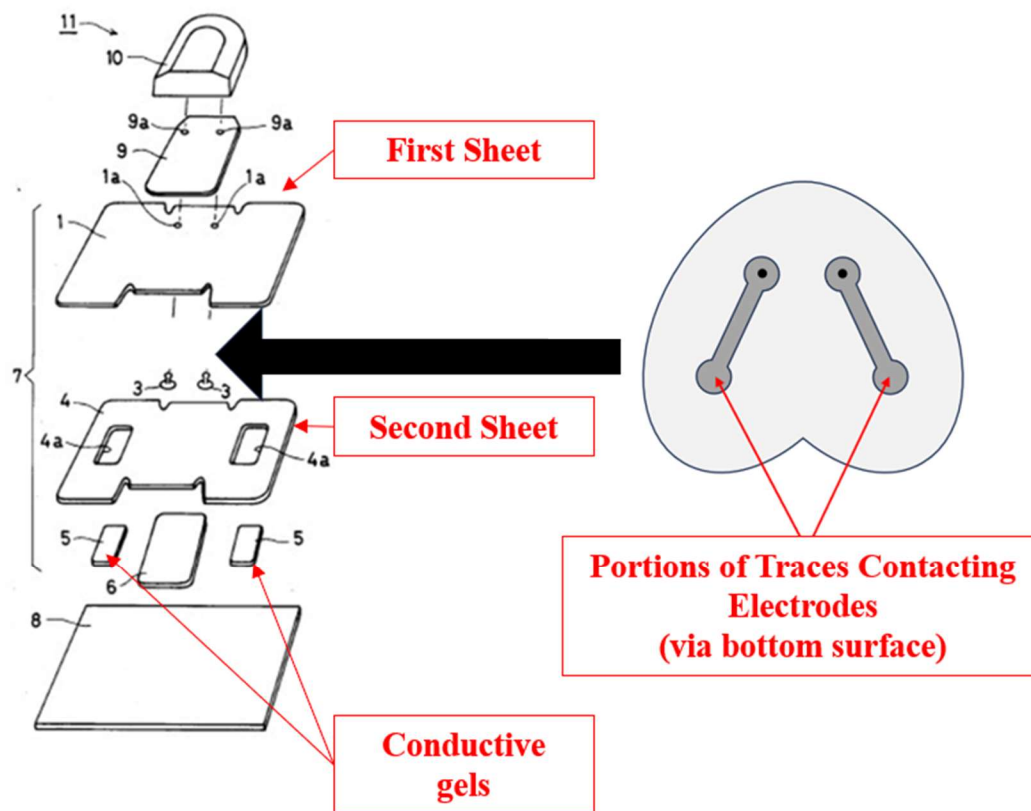
ii. [15a.] a computation-communication module including a housing retaining a processor;

As described above, Matsumura discloses this element. *Supra* § VII.A.1.ii;
Ex. 1009 ¶¶1066-1067.

iii. [15b.] a flexible printed circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals,

As described with respect to Claim 1, Matsumura discloses a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals. *Supra*, § VII.A.1.iii. It would have been obvious to a POSA how to form this layer as a “printed circuit” layer. Ex. 1009 ¶¶1069-1074.

The circuit layer of Matsumura comprises “two pieces of conductive material 2,” which “can be a carbon sheet or a PET sheet [which are insulating material] coated with conductive Ag/AgCl.” Ex. 1012 ¶¶[0019]-[0020], Fig 1. It would have been obvious to a POSA to use well-known techniques to replace the two pieces of insulating material coated with conductive Ag/AgCl with a single, flexible sheet of insulating material that contains printed-ink conductive traces. Ex. 1009 ¶¶1070-1071. The proposed modification is depicted below:



Ex. 1012, Fig. 1 (modified); Ex. 1009 ¶1070.

A POSA would have made this modification because it would make manufacturing and assembly easier. Ex. 1009 ¶1070. The original method suggested by Matsumura would require cutting two, separate pieces of insulating material and coating each one fully with conductive ink (which potentially requires more conductive ink); the modification would require cutting only one piece of insulating material. *Id.* ¶¶1070-1071. A POSA would recognize that, so modified, Matsumura's conductive material would comprise a flexible printed circuit, which

combined with Matsumura's insulating second sheet 4, would form a flexible printed circuit layer. Ex. 1012 ¶¶[0017]-[0018]; Ex. 1009 ¶1072. As a component of disposable bioelectrode pad 7, a POSA would understand that the modified sheet of conductive material is configured to be coupled to a skin surface of a subject to measure physiological signals. Ex. 1009 ¶¶1073-1074; *supra* § VII.A.1.iii.

iv. [15c.] the computation-communication module being attached to the flexible printed circuit layer;

As described above, Matsumura discloses this element. *Supra* § VII.A.1.iv. The computation-communication module (signal processor 10) is attached to the flexible printed circuit layer via hooks 3 and hook engagement portions 10a.

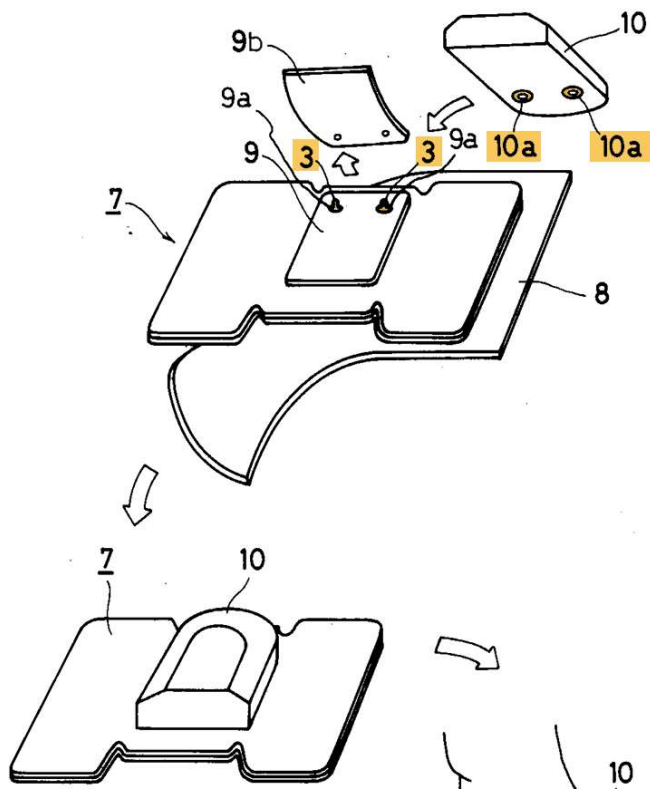


Fig. 2 (annotated); Ex. 1009 ¶¶1075-1076.

v. *[15d.] an adhesive covering at least a portion of the flexible printed circuit layer; and*

As described above, *supra* § VII.A.1.v, Matsumura discloses multiple adhesive coverings that meet this element. A POSA would have modified Matsumura to include the flexible printed circuit described in limitation [15b], *supra* § VII.A.6.iii.

Matsumura discloses “an adhesive covering at least a portion of the flexible printed circuit layer.” As modified, the flexible printed circuit would have been placed between Matsumura’s first sheet 1 and second sheet 4. Ex. 1009 ¶¶1077-80; Ex. 1012, Fig. 1. Matsumura discloses that bottom surface of first sheet 1 is coated with “an adhesive or glue, such as an acrylic adhesive” to ensure bonding between it and conductive material 2. Ex. 1012 ¶¶[0017]-[0018]. The adhesives on the inner surface of first sheet 1 would therefore form “an adhesive covering at least a portion of the flexible printed circuit layer.” Ex. 1009 ¶1080.

Additionally, or alternatively, Matsumura discloses a third sheet 6, which may “cover the center of the back surface of second sheet 4” (*i.e.*, the bottom of the flexible printed circuit layer). Ex. 1012 ¶[0022]. A POSA would understand that third sheet 6 is bonded to the second sheet using an adhesive, the same way the other sheets of the bioelectrode pad are attached to one another. Ex. 1009 ¶1081. This is adhesive is another adhesive covering a portion of the flexible printed circuit layer.

vi. [15e.] a protective covering for the flexible printed circuit layer.

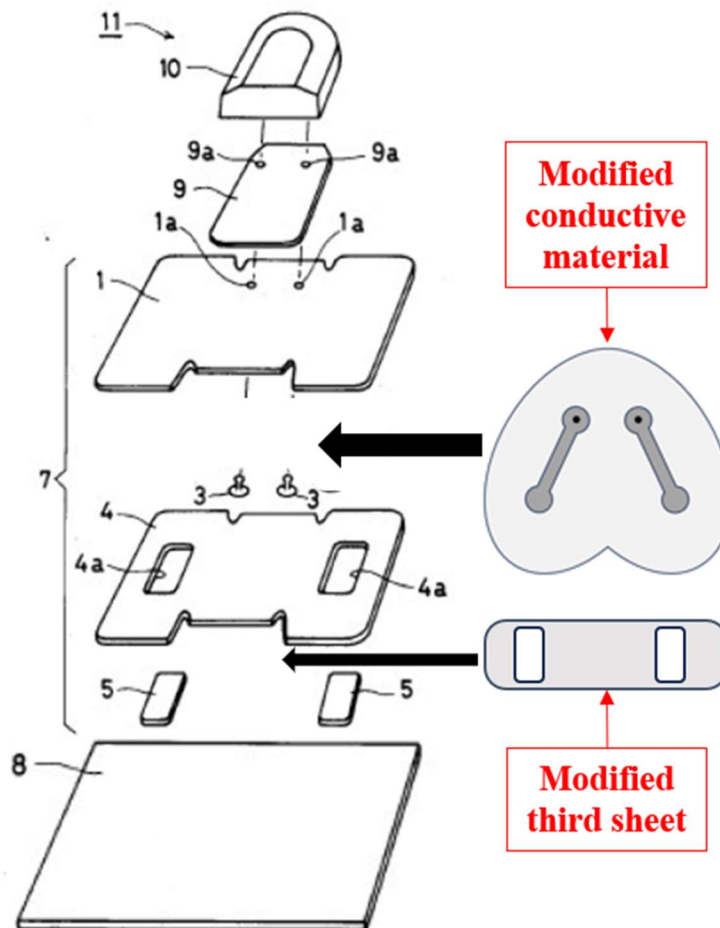
Matsumura discloses a “protective covering for the flexible printed circuit layer.” As explained above, a POSA would have modified Matsumura to include the flexible printed circuit described in limitation [15b], *supra* § VII.A.6.iii.

Matsumura discloses “a protective covering for the flexible printed circuit layer” specific to the modified flexible circuit layer 2. As described above, a POSA would have been motivated to combine Matsumura’s conductive material 2 into a single, printed circuit on a flexible, insulating substrate, situated between first sheet 1 and second sheet 4. Ex. 1009 ¶¶1077-1080, 1085. Matsumura discloses that first sheet is “made of insulating material that does not allow moisture to penetrate.” Ex. 1012 ¶¶[0017]-[0018]. Thus, Matsumura’s first sheet is a “protective covering for the flexible printed circuit layer” and satisfies this limitation. Ex. 1009 ¶1085.

Additionally, or alternatively, Matsumura discloses that “third sheet 6, made, for example of polyethylene or the like, may be provided to cover the center of the back surface of the second sheet 4.” Ex. 1012 ¶[0022]. A POSA would understand that third sheet 6 is therefore a “protective covering for the flexible printed circuit layer” on its bottom surface because it adheres to and partially covers the bottom surface of the modified printed circuit layer. Ex. 1009 ¶1086.

7. *Claim 16*

In addition to teaching the limitations of claim 15, it would have been obvious to a POSA to modify Matsumura so that “the protective covering includes at least one opening for electrode gels.” As described above, Section VII.A.6.vi, Matsumura discloses protective coverings, including third sheet 6.



Id. Fig. 1 (modified). It would have been obvious to a POSA to modify third sheet 6 to extend its width and include openings for electrode gels 5. Ex. 1009 ¶¶1090-1091. This would be a simple modification because third sheet is a cut sheet that is

placed in the device when assembled both as disclosed by Matsumura and when modified as suggested above, so the method of manufacturing would be the same. *Id.* In addition, as modified, third sheet 6 would still serve its stated purpose of making the center of the back surface of the flexible printed circuit layer less adhesive to the body. *Id.*; Ex. 1012 ¶[1022].

8. Claim 17

In addition to teaching the limitations of claim 15, it would have been obvious to a POSA that “the flexible printed circuit layer includes openings sized to receive electrode gels,” as recited in claim 17. Ex. 1009 ¶¶1092-96. As described above, a POSA would have been motivated to modify conductive material 2 to form a flexible printed circuit. *Supra* § VII.A.6.iii. So modified, Matsumura’s flexible printed circuit layer would include flexible printed circuit (substitute for conductive material 2) and second sheet 4. *Id.* Matsumura discloses that “second sheet 4” of bioelectrode pad 7 “is provided with two openings 4a on the left and right sides into which the conductive gel 5 is inserted.” Ex. 1012 ¶[0018]. As shown in Figure 1, openings 4a are sized to receive conductive gels 5. *Id.* Fig. 1; Ex. 1009 ¶¶1092-1096.

9. Claim 18

In addition to teaching the limitations of claim 15, Matsumura teaches that “the protective covering is non removable and made from an insulating material,” as recited in claim 18. As noted above, first sheet 1 (which is made from an insulating

material (*id.* ¶[0017])) and third sheet 6 (made from polyethylene, which a POSA would understand is an insulating material (*id.* ¶[0022]) are “protective coverings”. *Supra* § VII.A.6.vi; Ex. 1009 ¶1099. A POSA would have understood that once assembled, first sheet 1 and third sheet 6 are “non removable” from the rest of bioelectrode pad 7, including because they are glued in place. Ex. 1009 ¶¶1099-1100.

10. Claim 19

In addition to teaching all the limitations of claim 15, Matsumura teaches that “the computation communication module is releasably attached to the flexible printed circuit layer,” as recited in claim 19. Matsumura discloses that “[t]he bioelectrode pad 7 and the signal processor 10 are detachable with hooks, . . . the reusable signal processor and the disposable bioelectrode can be easily attached and detached before and after use.” Ex. 1012 ¶[0016]. Accordingly, Matsumura discloses that signal processor 10 (computation-communication module) is releasably attached to disposable bioelectrode 7. Ex. 1009 ¶¶1101-1104.

11. Claim 20

In addition to teaching all the limitations of claim 15, Matsumura teaches that “the protective covering covers the adhesive,” as recited in claim 20. Matsumura’s first sheet 1 (a “protective covering” on the top surface of the flexible printed circuit layer) and third sheet 6 (a “protective covering” on the bottom surface of the flexible

printed circuit layer) are bonded to the flexible printed circuit by an adhesive. Ex. 1012 ¶¶[0017]-[0018]; Ex. 1009 ¶1107. Accordingly, Matsumura’s protective coverings cover an adhesive. *Id.* ¶¶1107-1108.

B. Ground 2: Claims 1-5, 15, 17, 18, and 20 are Obvious Over Jensen and General Knowledge of a POSA

1. Claim 1

i. [Pre] A body-worn physiological sensor comprising:

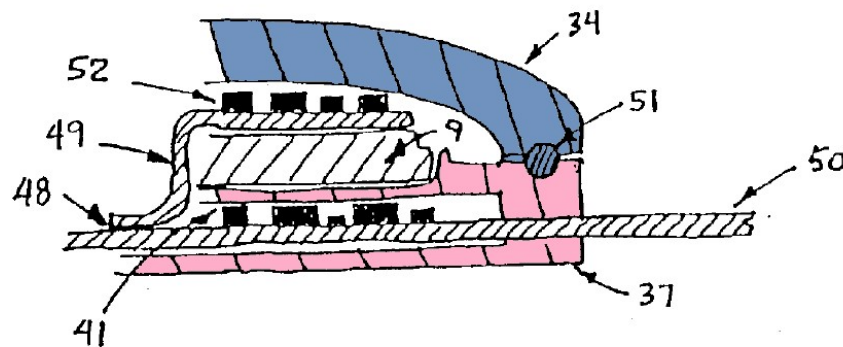
Jensen discloses a body worn “smart patch” “that integrates . . . heart-rate/EKG electronic sensors,” which are physiological sensors. Ex. 1011 ¶[0012]; *see also id.* ¶ [0013]; Ex. 1009 ¶¶1110-1113.

ii. [1a.] a computation-communication module including a housing retaining a processor;

Jensen discloses “a computation-communication module.” Specifically, Jensen discloses an electronics circuit 41 that includes a “microcontroller” for computation and a “transmitter” for communication. Ex. 1011 ¶[0032]. Jensen’s microcontroller “runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter.” *Id.* Jensen’s transmitter may communicate data via an “antenna.” *Id.* ¶[0033]. Accordingly, Jensen discloses a computation-communication module. Ex. 1009 ¶1116. In the embodiment of Figure 8, Jensen discloses multiple electronics circuits 41, 52. Ex. 1011 ¶[0046], Fig. 8. A POSA would understand that the components of electronics circuit 41 (the

computation-communication module) could be located on electronics circuit 52. Ex. 1009 ¶1116.

Jensen discloses that its computation-communication module includes a housing that retains a processor. *Id.* ¶1117. As shown in the figure below, “top case 34 [shown in blue below] mounts onto bottom case 37” forming a housing that encloses electronics circuit 52. Ex. 1011 ¶¶[0044]-[0045]. As part of electronics circuitry, Jensen discloses “a microcontroller and/or other programmable logic circuitry that perform measurement and processing of sensed data.” *Id.* ¶[0014]. Jensen also discloses that the microcontroller can “run[] a conventional program that may perform further analysis and can also encode a data stream output to the transmitter.” *Id.* ¶[0032]. The microcontroller (processor), along with other electronics circuitry 52, is disposed in the housing formed from top case 34 and bottom case 37.



Id. Fig. 8 (annotated); Ex. 1009 ¶¶1114-1118.

- iii. *[1b.] a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals,*

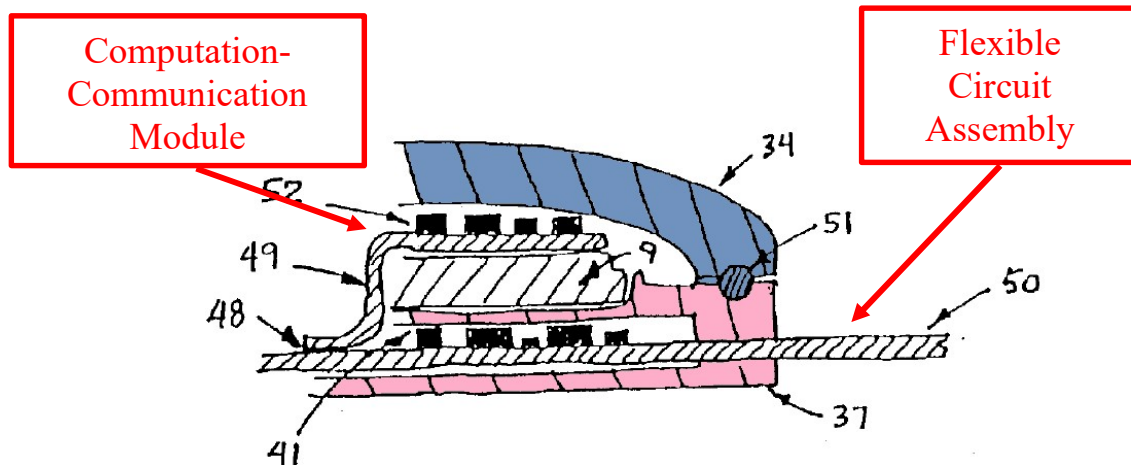
Jensen discloses “a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals.” Jensen’s “smart patch” may be “applied to the skin much like a bandage, with self-adhesive pads and sensor materials on the skin-contact side of the invention.” Ex. 1011 ¶[0030]. The “smart patch” is attached to the skin through sensor pads 1, 2 that collect heart-rate signals. *Id.* ¶¶[0031], [0041]. Sensor pads 1, 2 are electrically connected to sensor contacts 71, 72 located on flexible circuit assembly 36. *Id.* ¶¶[0040]-[0041], [0043], Fig. 5. A POSA would understand that flexible printed circuit 50 in the embodiment of Figure 8 is analogous to flexible circuit assembly 36, and that flexible printed circuit 50 is also attached to the skin through disposable sensor pads 1, 2. Ex. 1009 ¶1121.

A POSA would also recognize that this is the same way that the printed circuit layer 101 of the '492 patent is configured to be coupled to the skin (*i.e.*, by means of an adhesive layer 105 that sits between the patient's skin and the flexible printed circuit layer 101). Ex. 1009 ¶1121; Ex. 1005, Fig. 2.

Accordingly, Jensen discloses a flexible circuit layer that is coupled through disposable sensor pads 1, 2 to a skin surface of a subject to measure heart-rate signals, which are physiological signals. Ex. 1009 ¶¶1121-1122.

iv. [1c.] said computation-communication module being attached to the flexible circuit layer;

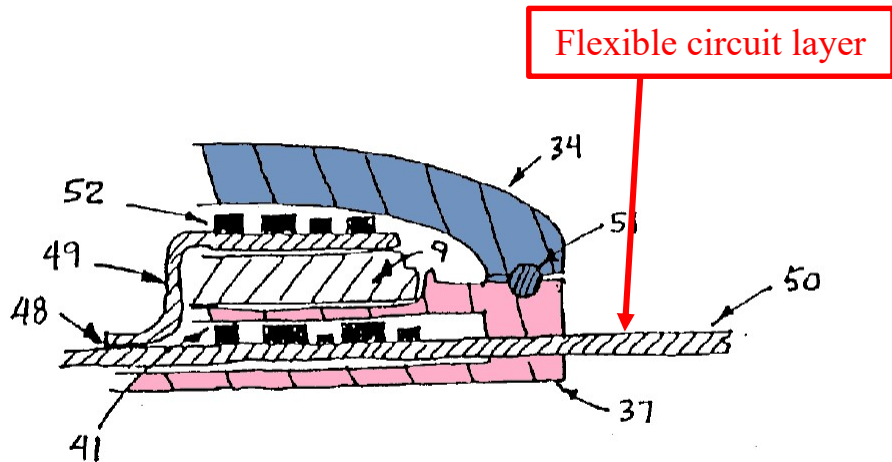
Jensen discloses the “computation-communication module being attached to the flexible circuit layer.” Jensen discloses an electronics circuit 52 that contains a “microcontroller” for computation and a “transmitter” for communication is connected and attached to flexible circuit assembly (36, 50). Ex. 1011 ¶¶[0032]-[0033], [0045]-[0046], Figs. 8, 8A. A POSA reviewing the embodiment of Jensen's Figure 8 would understand that the electronics circuit comprising a “microcontroller” and “transmitter” could be located on electronics circuit 52. *Id.*; Ex. 1009 ¶¶1125-1126. As shown in Figure 8 below, computation-communication module 52 resides on flexible circuit 49, which is attached to flexible circuit layer 50.



Ex. 1011, Fig. 8 (annotated); Ex. 1009 ¶¶1125-1127.

v. *[Id.] an adhesive covering at least a portion of the flexible circuit layer; and*

Jensen discloses “an adhesive covering at least a portion of the flexible circuit layer.” Jensen discloses sensor pads 1, 2 that are coated with an adhesive “on the circuit side” that is adhered to the flexible circuit layer. *Id.* ¶¶[0040]-[0042] (“[T]he disposable sensor pad electrodes 1 and 2 are coated with a conductive adhesive on the circuit side and a conductive adhesive-gel that is made using a silver amalgam as found in off-the-shelf EKG sensor pads, such as those sold by 3M Corporation.”), Fig. 5. This adhesive therefore covers at least a portion of the flexible circuit layer 36. A POSA would understand that, in the embodiment of Figure 8, sensor pad electrodes 1, 2 would be mounted to the bottom surface of flexible circuit layer 50 in the same way. Ex. 1009 ¶¶ 1130-1131. Therefore, Jensen teaches an adhesive covering at least a portion of the flexible circuit layer.



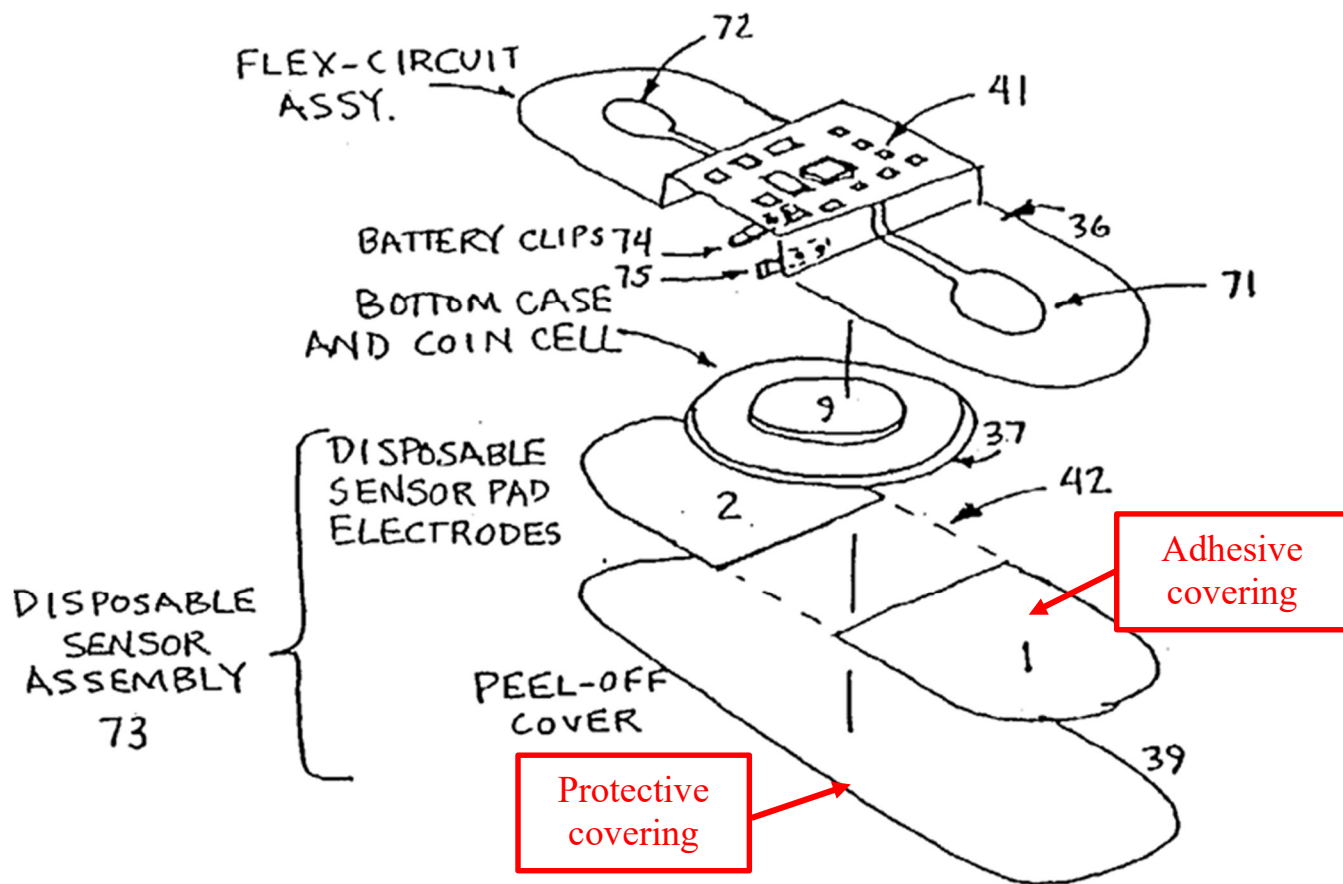
Ex. 1011, Fig. 8 (annotated).

Additionally, or alternatively, Jensen discloses an adhesive to attach aesthetic covering 35 to the top surface of the flexible circuit assembly. Ex. 1011 ¶ [0043] (“two aesthetic covers 35 may be constructed from Mylar sheet, for example, and enclose the entire top side of the flexible circuit assembly 36”). A POSA would have understood that an aesthetic cover would also be included in the embodiment of Figure 8, and that an adhesive would be used to attach flexible circuit assembly 50 to aesthetic covering 35 in the same way. Ex. 1009 ¶¶ 1132-1133. Accordingly, an adhesive covers at least a portion of flexible circuit assembly (36, 50) on top on which aesthetic covering 35 is placed. *Id.*

vi. [1e.] a protective covering that protects the adhesive.

Jensen discloses “a protective covering that protects the adhesive.” Jensen discloses that sensor pads 1, 2 coated with a conductive adhesive are surrounded by a “protective cover tape 39.” Ex. 1011 ¶ [0041]. Specifically, “[t]he pads, when they

are first installed, typically come pre-applied to a peel-off cover 39 that protects the conductive surface of sensor pads 1 and 2 until ready for use.” *Id.* ¶[0042].



Id. Fig. 5 (annotated). This peel-off cover 39 protects all portions of the sensor pad electrode component, including the adhesive covering on that component. Ex. 1009 ¶ 1136.

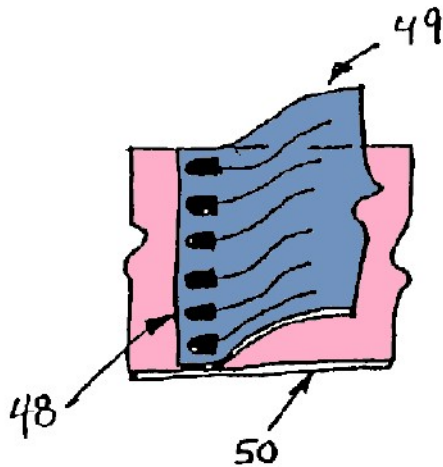
Additionally, or alternatively, aesthetic covering 35 protects the adhesive used to attach the covering to flexible circuit assembly 36, 50. Ex. 1009 ¶¶1137-38; Ex. 1011 ¶ [0035]. Accordingly, Jensen discloses a protective covering that protects an adhesive. Ex. 1009 ¶¶1134-1138.

2. *Claim 2*

In addition to teaching the limitations of claim 1, Jensen discloses that “the flexible circuit layer has traces of determinable electrical resistance.” In particular, Jensen discloses “flexible circuit assembly 36 that contains the copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72.” Ex. 1011 ¶[0040]. A POSA would understand that flexible circuit assembly 50 of the embodiment of Figure 8 would have the same structure. Ex. 1009 ¶¶1140-1142. A POSA would have understood that the copper in the wiring trace has a determinable electrical resistance. *Id.* ¶¶1141-1142. Accordingly, Jensen discloses that the flexible circuit layer has traces of determinable electrical resistance. *Id.* ¶¶1139-1142.

3. *Claim 3*

In addition to teaching the limitations of claims 1 and 2, Jensen discloses that “the traces on the flexible circuit layer are configured to electrically couple the computation-communication module to the flexible circuit layer, thereby forming a disposable module connector.” In one embodiment, Jensen discloses two flexible printed circuits 49, 50, which comprise, respectively, the substrate for the reusable computation-communication module and the substrate for the disposable module. Ex. 1011 ¶¶[0045]-[0046], Fig. 8. Jensen further explains that the circuits are connected (*i.e.*, “electrically coupled”) by pads 48, which are “matched on both circuits.” *Id.* ¶[0046].

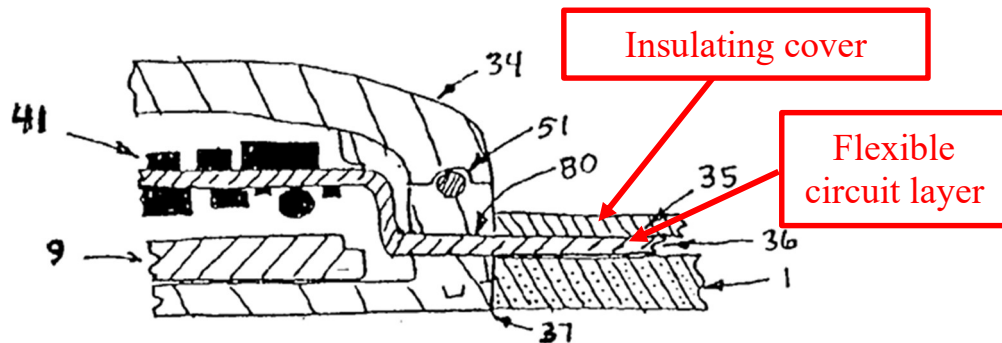


Id. Fig. 8A (annotated).

A POSA would understand that pads on the disposable, printed circuit board substrate of Jensen, 50, are formed by traces that run to sensor contacts. Ex. 1009 ¶¶1143-1147. Therefore, a POSA would understand that traces on the flexible circuit layer of Jensen electrically couple the computer-communication module to the flexible circuit layer and form a disposable module connector. *Id.*

4. ***Claim 4***

In addition to teaching the limitations of claim 1, Jensen discloses that “the traces on the flexible circuit layer are at least partially covered by a non-removable insulating covering.” As noted above, Jensen discloses “flexible circuit assembly 36 that contains the copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72.” Ex. 1011 ¶[0040]. The traces are covered by “two aesthetic covers 35” that are part of the device’s “re-usable (non-disposable) portion.” *Id.* ¶[0043]. This is shown at least in Jensen’s Figure 7, shown below.



Id. Fig. 7 (annotated). A POSA would have understood that aesthetic cover 35 insulates the flexible circuit assembly 36 (or 50) and its traces, and that the aesthetic cover would be utilized in any embodiment of Jensen, including the embodiment of Figure 8. Ex. 1009 ¶¶1151-1153. Therefore, the aesthetic covers 35 are non-removable insulating coverings that at partially cover the traces on the flexible circuit layer. *Id.*

5. Claim 5

In addition to teaching the limitations of claim 1, it would have been obvious to a POSA to modify Jensen such that “the flexible circuit layer further comprises a plurality of openings sized to receive electrode gels.” Commercially available electrode gels were known in the art at the time of the claimed invention. Ex. 1009 ¶1156. A POSA would have recognized that it could integrate these commercially available disposable electrodes into the invention of Jensen by including recesses or openings to accommodate those commercially available electrode gels. *Id.* A POSA would have been motivated to modify Jensen in this manner because reliance on

commercially available electrodes would ease manufacturing and stabilize the electrode gels. *Id.*

6. Claim 15

i. [Pre] A body-worn physiological sensor comprising:

As described above, Jensen discloses this element. *Supra* § VII.B.1.i; Ex. 1009 ¶¶1158-1159.

ii. [15a.] a computation-communication module including a housing retaining a processor;

As described above, Jensen discloses this element. *Supra* § VII.B.1.ii; Ex. 1009 ¶¶1160-1161.

iii. [15b.] a flexible printed circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals,

As described above, Jensen discloses a “flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals.” *Supra* § VII.B.1.iii. A POSA would understand that Jensen’s flexible circuit layer 36, 50 is fashioned as a flexible printed circuit board, and would therefore understand that Jensen discloses a “flexible printed circuit layer.” Ex. 1009 ¶1163.

iv. [15c.] the computation-communication module being attached to the flexible printed circuit layer;

As described above, Jensen discloses this element. *Supra* § VII.B.1.iv; Ex. 1009 ¶¶1164-1165.

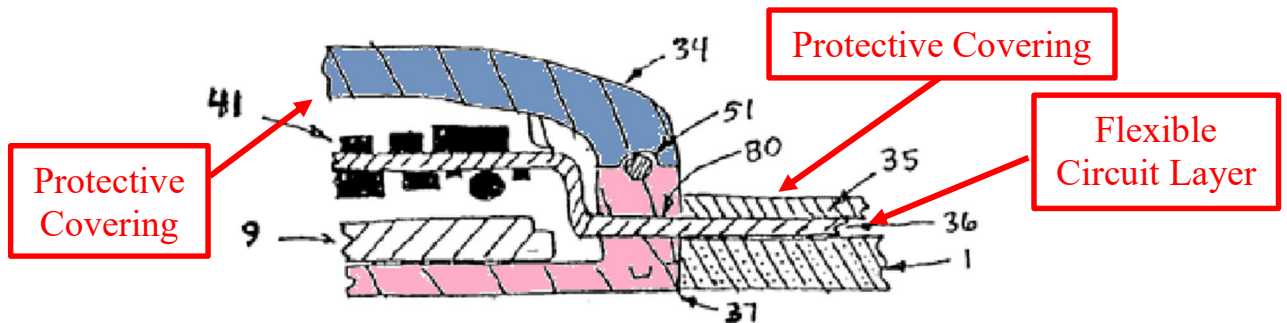
**v. *[15d.] an adhesive covering at least a portion of the
flexible printed circuit layer; and***

As described above, Section VII.B.1.v, Jensen or alternatively, Jensen in view of the general knowledge of a POSA, teach an adhesive covering at least a portion of the flexible circuit layer. Jensen discloses sensor pads 1, 2 that are coated with an adhesive “on the circuit side” that is then adhered to the flexible circuit layer; the adhesive covers at least a portion of the flexible circuit layer 36. Ex. 1011 ¶¶[0040]-[0042] (“[T]he disposable sensor pad electrodes 1 and 2 are coated with a conductive adhesive on the circuit side and a conductive adhesive-gel that is made using a silver amalgam as found in off-the-shelf EKG sensor pads, such as those sold by 3M Corporation.”), Fig. 5; Ex. 1009 ¶1168. A POSA would understand that, in the embodiment of Figure 8, sensor pads 1, 2 would be mounted to the bottom surface of flexible circuit 36, 50 with an adhesive in the same way. Ex. 1009 ¶1168.

Additionally, or alternatively, a POSA would have understood that an adhesive would be used to attach an aesthetic covering 35 to the top surface of flexible circuit assembly 36, 50. Ex. 1009 ¶1169; Ex. 1011 ¶[0043]. Accordingly, an adhesive covers at least a portion of flexible circuit assembly 36, 50 on top of which aesthetic covering 35 is placed. Ex. 1009 ¶1169.

vi. *[15e.] a protective covering for the flexible printed circuit layer.*

Jensen discloses “a protective covering for the flexible printed circuit layer.” Specifically, Jensen discloses that “two aesthetic covers 35 may be constructed from Mylar sheet, for example, and enclose the entire top side of the flexible circuit assembly 36.” Ex. 1011 ¶[0043], Fig. 7. A POSA would understand that such aesthetic covers would be utilized in all the embodiments of Jensen, and that “aesthetic covers 35” of Jensen are a protective covering for the top surface of Jensen’s flexible printed circuit layer 36, 50. Ex. 1009 ¶¶1173-1174.



Ex. 1011, Fig. 7 (annotated).

Additionally, or alternately, Jensen discloses that sensor pads 1, 2 attached to flexible circuit assembly 36, 50 are surrounded by a “protective cover tape 39.” *Id.* ¶[0041]. Specifically, “[t]he pads, when they are first installed, typically come pre-applied to a peel- off cover 39 that protects the conductive surface of sensor pads 1 and 2 until ready for use.” *Id.* ¶[0042]. Accordingly, Jensen discloses a protective covering for the bottom surface of the flexible circuit assembly 36, 50 (flexible printed circuit layer) as well. Ex. 1009 ¶¶1175-1176.

7. Claim 17

In addition to teaching the limitations of claim 15, it would have been obvious to a POSA to modify Jensen such that “the flexible printed circuit layer further comprises a plurality of openings sized to receive electrode gels.” Commercially available electrode gels were known in the art at the time of the claimed invention. Ex. 1009 ¶1179. A POSA would have recognized that it could integrate these commercially available disposable electrodes into the invention of Jensen by including recesses or openings to accommodate those commercially available electrode gels. *Id.* A POSA would have been motivated to modify Jensen in this manner because reliance on commercially available electrodes would ease manufacturing and stabilize the electrode gels. *Id.* ¶1179-1180.

8. Claim 18

In addition to teaching the limitations of claim 15, Jensen discloses “the protective covering is non removable and made from an insulating material.” As disclosed above, Jensen teaches the protective covering for the flexible printed circuit layer, including “two aesthetic covers 35 [which] may be constructed from Mylar sheet.” *See* § VII.B.6.vi; Ex. 1011 ¶[0043]. A POSA would recognize that Mylar is an insulating material and that aesthetic covers 35 are a “protective material.” Ex. 1009 ¶¶1181-1184. A POSA would further understand that Mylar protective covers are not removable from disposable substrate 50 and would be

discarded with disposable substrate 50 (after it was detached from the communication-computation module) after each use for hygienic reasons and because they are attached by adhesive. *Id.* ¶1183. Therefore, Jensen discloses the dependent limitation of claim 18.

9. Claim 20

In addition to teaching the limitations of claim 15, Jensen teaches that “the protective covering covers the adhesive,” as recited in claim 20. Specifically, Jensen discloses a “protective cover tape 39” that surrounds sensor pads 1, 2 coated with a conductive adhesive attached to flexible circuit assembly 36, 50. Ex. 1011 ¶¶[0041]-[0042]. Additionally, or alternatively, aesthetic covering 35 protects the adhesive used to attach the covering to flexible circuit assembly 36, 50. Ex. 1009 ¶¶ 1188-1189; Ex. 1011 ¶¶ [0035], [0043]. Accordingly, Jensen discloses a protective covering that protects an adhesive.

C. Ground 3: Claims 1-8, 15, 19, and 20 are Obvious Over Ozguz and General Knowledge of a POSA

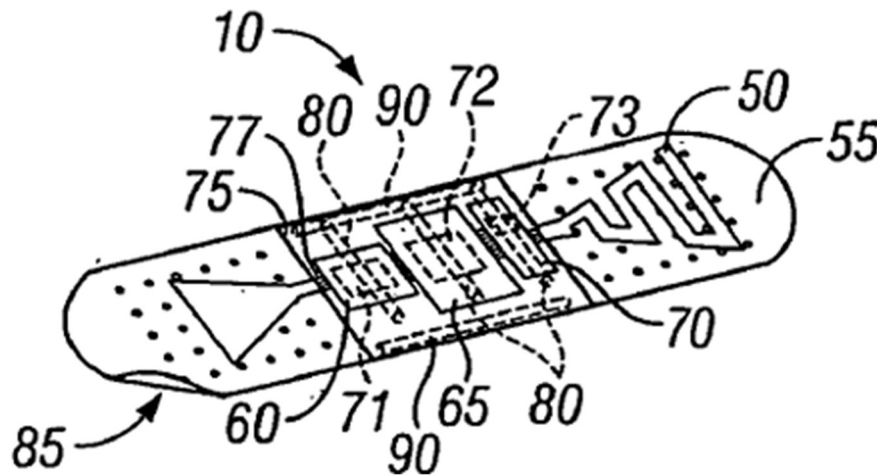
1. Claim 1

i. [Pre] A body-worn physiological sensor comprising:

Ozguz discloses “a body-worn physiological sensor.” In particular, Ozguz discloses “a thin flexible ambulatory/self contained bio-sensor module in a form similar to an adhesive bandage for sensing physiologically modulated signals from the body.” Ex. 1014 ¶[0003]; Ex. 1009 ¶¶1191-1194.

ii. [1a.] a computation-communication module including a housing retaining a processor;

Ozguz discloses “a computation-communication module.” Sensor module 10 includes “flexible silicon substrates 60, 65, 70 having respective integrated circuits 71, 72, 73 [that] are bonded to the flexible substrate 55.” Ex. 1014 ¶[0039]. Thin silicon substrates 60, 65, 70 can include a communication module: “transmitter or transceiver 190 for transmitting data by RF signals to a remote receiver.” *Id.* ¶ [0058]. Thin silicon substrates 60, 65, 70 can also include a computation module: “a microprocessor 175” for processing signals and “controlling input, storage, and analysis of the collected data.” *Id.* ¶¶[0041], [0044], [0058]. Accordingly, Ozguz discloses a computation-communication module.



Id. Fig. 2A; Ex. 1009 ¶ 1198. Ozguz also discloses that the “computation-communication module” includes “a housing retaining a processor.” In particular, Ozguz discloses that the “[f]lexible, thin battery 105 overlays the silicon substrates 60, 65, 70 and their respective ICs 71, 72, 73.” Ex. 1014 ¶[0048]. Circuits 71, 72,

and 73 can be integrated into a single circuit on a single silicon substrate. *Id.* ¶[0042]. Overlay 105 houses the computation-communication module formed by flexible substrate 55 and components bonded to it, such as flexible silicon substrates 60, 65, 70, integrated circuits 71, 72, 73, and antenna 50. *Id.* A “microprocessor 175” can be “incorporated into the thin silicon substrates 60, 65, 70.” *Id.* ¶ [0058]. Accordingly, Ozguz discloses a computation-communication module that includes a housing retaining a processor. Ex. 1009 ¶¶1195-1200.

iii. [1b.] a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals,

Ozguz discloses the claimed “a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals.” Specifically, Ozguz discloses a “flexible substrate 55” that includes metallization 77 that interconnects integrated circuits 71, 72, 73 and other components to form a circuit layer. Ex. 1014 ¶ [0039]. “[E]lectrodes 80” (shown below) are “disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20.” *Id.* These electrodes are used to “detect...physiological characteristics such as an EKG (from the heart).” *Id.* ¶[0044]. Accordingly, Ozguz discloses a flexible circuit layer (flexible substrate 55) configured to be coupled to a skin surface of a subject to measure physiological signals. Ex. 1009 ¶¶1201-1204.

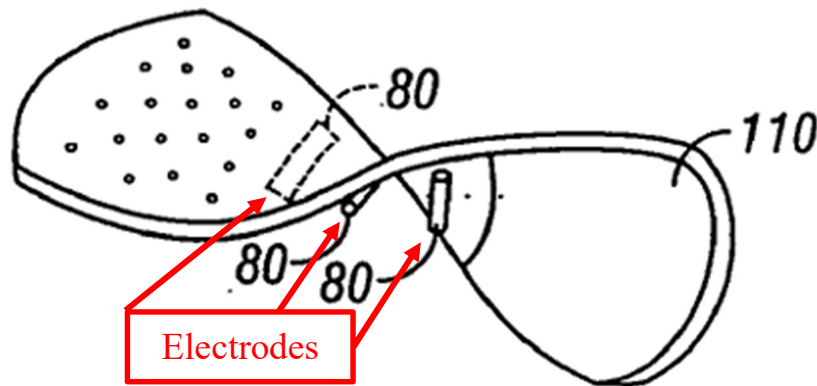


FIG. 3E

Id. Fig. 3E (annotated).

- iv. *[1c.] said computation-communication module being attached to the flexible circuit layer;*

Ozguz disclose a “computation-communication module being attached to the flexible circuit layer.” As noted above, Section VII.C.1.ii, a microprocessor 175 and a transmitter or transceiver 190 forming the computation-communication module are incorporated into “flexible silicon substrates 60, 65, 70 having respective integrated circuits 71, 72, 73.” Ex. 1014 ¶¶[0039], [0058]. The “thin flexible silicon substrates 60, 65, 70 having respective integrated circuits 71, 72, 73 are bonded to the flexible substrate 55 by an anisotropic epoxy layer 75 or the like.” *Id.* ¶[0039]. Ozguz specifically contemplates that these separate “ICs 71, 72, 73 can be integrated as one IC on a single silicon substrate.” *Id.* ¶[0042]. Accordingly, Ozguz discloses that the computation-communication module is attached to the flexible circuit layer. Ex. 1009 ¶¶1205-1208.

- v. *[1d.] an adhesive covering at least a portion of the flexible circuit layer; and*

Ozguz discloses “an adhesive covering at least a portion of the flexible circuit layer.” In particular, Ozguz discloses adhesive pads 91 (adhesive covering) disposed on the underside 85 of flexible substrate 55 (flexible circuit layer). Ex. 1014 ¶[0049].

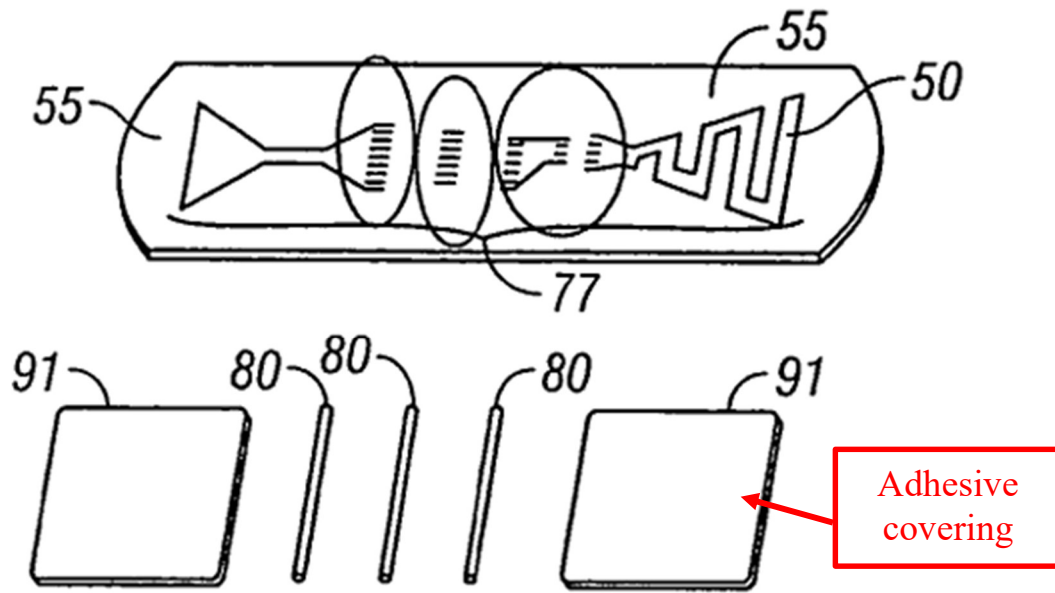
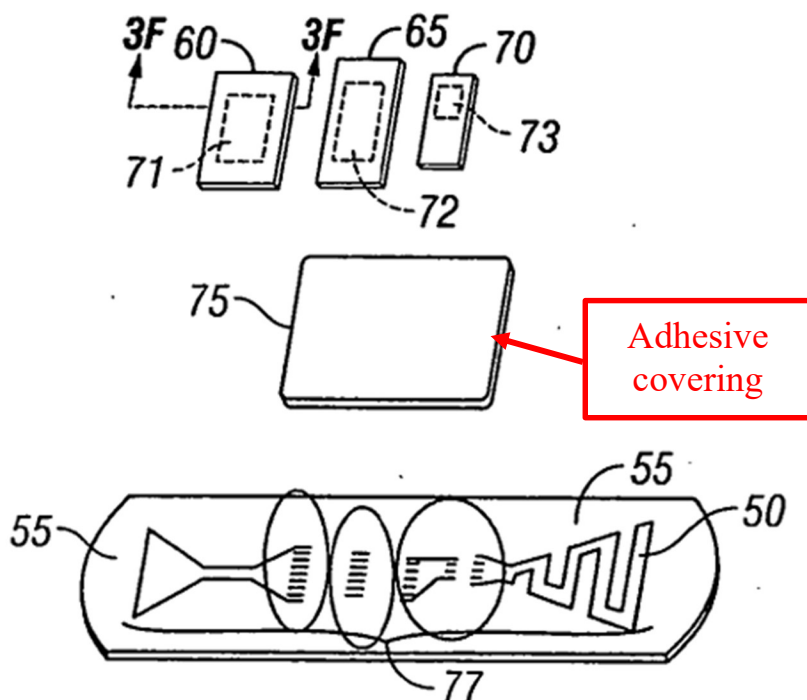


FIG. 3B

Id. Fig. 3B (annotated). Additionally, or alternatively, Ozguz discloses an “anisotropic epoxy 75” that covers at least part of flexible substrate 55. *Id.* ¶[0046]. This is shown below in Figure 3B.



Id. Fig. 3B (annotated). The anisotropic epoxy 75 is an adhesive that bonds silicon 60, 65, 70 with flexible substrate 55. *Id.* ¶ [0046]. Accordingly, Ozguz discloses an adhesive covering at least a portion of the flexible circuit layer. Ex. 1009 ¶¶1209-1213.

vi. [1e.] a protective covering that protects the adhesive.

Ozguz discloses “a protective covering that protects the adhesive.” In particular, “protective cover 115” (shown in red below) covers “adhesive pads 91” (shown in blue below). Ex. 2014 ¶[0049].

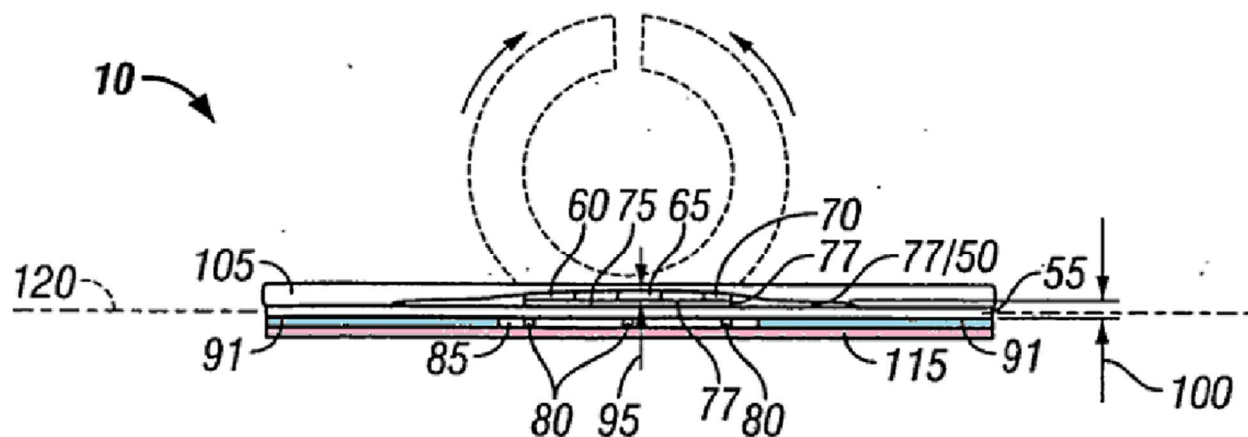


FIG. 3C

Id. Fig. 3C (annotated).

Additionally, or alternatively, Ozguz discloses an overlying battery 105 (protective covering) that is shaped in a way that overlays silicon 60, 65, 70 and anisotropic epoxy 75 (adhesive). *Id.* Fig. 3A. Accordingly, Ozguz discloses a protective covering that protects the adhesive. Ex. 1009 ¶¶1214-1218.

2. Claim 2

In addition to teaching the limitations of claim 1, Ozguz discloses that “the flexible circuit layer has traces of determinable electrical resistance.” In particular, Ozguz discloses that “metallization 77 further extends through the flexible substrate 55 and connects the ICs 71, 72, 73 to the electrodes 80 disposed on an underside 85 of the flexible substrate 55.” Ex. 2014 ¶[0039]. A POSA would understand metallization 77 to be traces. Ex. 1009 ¶1221. A POSA would also understand that

metallization 77, like all metals, has a determinable electrical resistance. *Id.* ¶¶1222-1223.

3. *Claim 3*

In addition to teaching the limitations of claims 1 and 2, Ozguz discloses that “the traces on the flexible circuit layer are configured to electrically couple the computation-communication module to the flexible circuit layer, thereby forming a disposable module connector.” As noted above, Ozguz discloses a “computation-communication module being attached to the flexible circuit layer.” *Supra* § VII.C.1.iv. Ozguz also discloses that “metallization 77” is “applied to the flexible substrate 55” and “interconnects the ICs 71, 72, 73” on flexible silicon 60, 65, 70 “to each other and to the antenna 50.” Ex. 1014 ¶[0039]. Accordingly, Ozguz discloses conductive traces on the flexible circuit layer to electrically couple with the attached computation-communication module. Ex. 1009 ¶1226.

A POSA would also understand metallization 77 to form “a disposable module connector.” Specifically, Ozguz discloses that some portions of sensor module 10 are “remov[ed] after each use,” while other portions are “used repeatedly.” Ex. 2014 ¶[0049]. A POSA would know that “flexible silicon 60, 65, 70” with incorporated “microprocessor 175” and “transmitter or transceiver 190” (computation-communication module), would be a portion of sensor module that can be used repeatedly to reduce costs and minimize waste. Ex. 1009 ¶1227. On

the other hand, flexible substrate 55, whose underside 85 is in contact with a patient's skin, would be a portion of sensor module that a POSA would dispose to prevent any infections from spreading as a result of repeated use. *Id.* Metallization 77 connecting flexible substrate 55 to microprocessor 175 and transmitter or transceiver 190 (the computation-communication module) would therefore be a disposable module connector. *Id.* ¶¶1227-1228.

4. Claim 4

In addition to teaching the limitations of claim 1, Ozguz discloses that “the traces on the flexible circuit layer are at least partially covered by a non-removable insulating covering.” Ozguz discloses a flexible power source 105, which covers the entire flexible circuit layer (including metallization 77). Ex. 1014 ¶[0048]. This is shown below in Ozguz's Figure 3A.

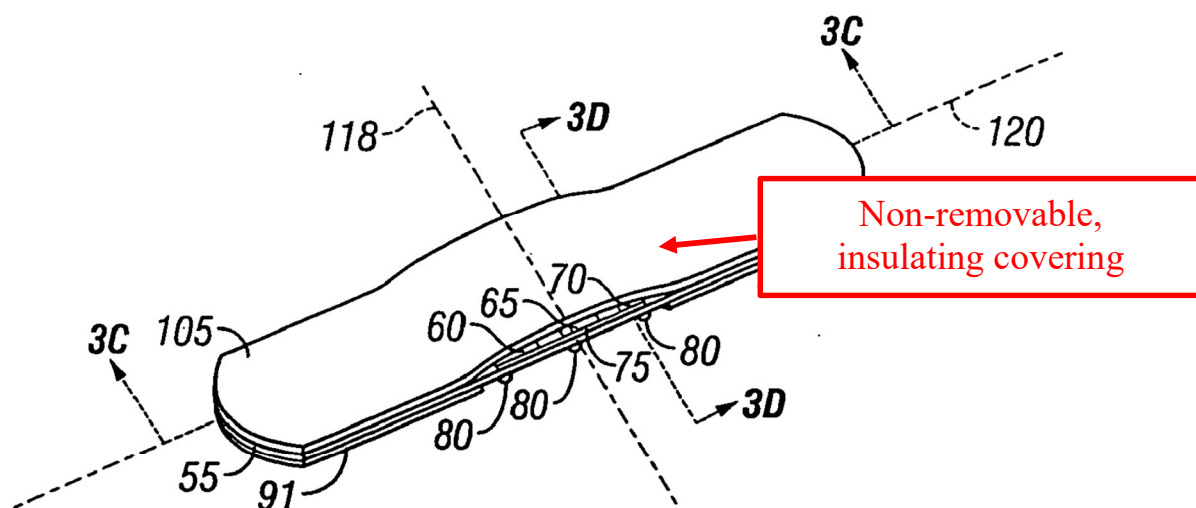


FIG. 3A

Id. Fig. 3A (annotated). A POSA would understand that the flexible, thin battery 105 is not removable, and must be insulating to prevent shorts due to unintended contact with other components. Ex. 1009 ¶¶1229-1233.

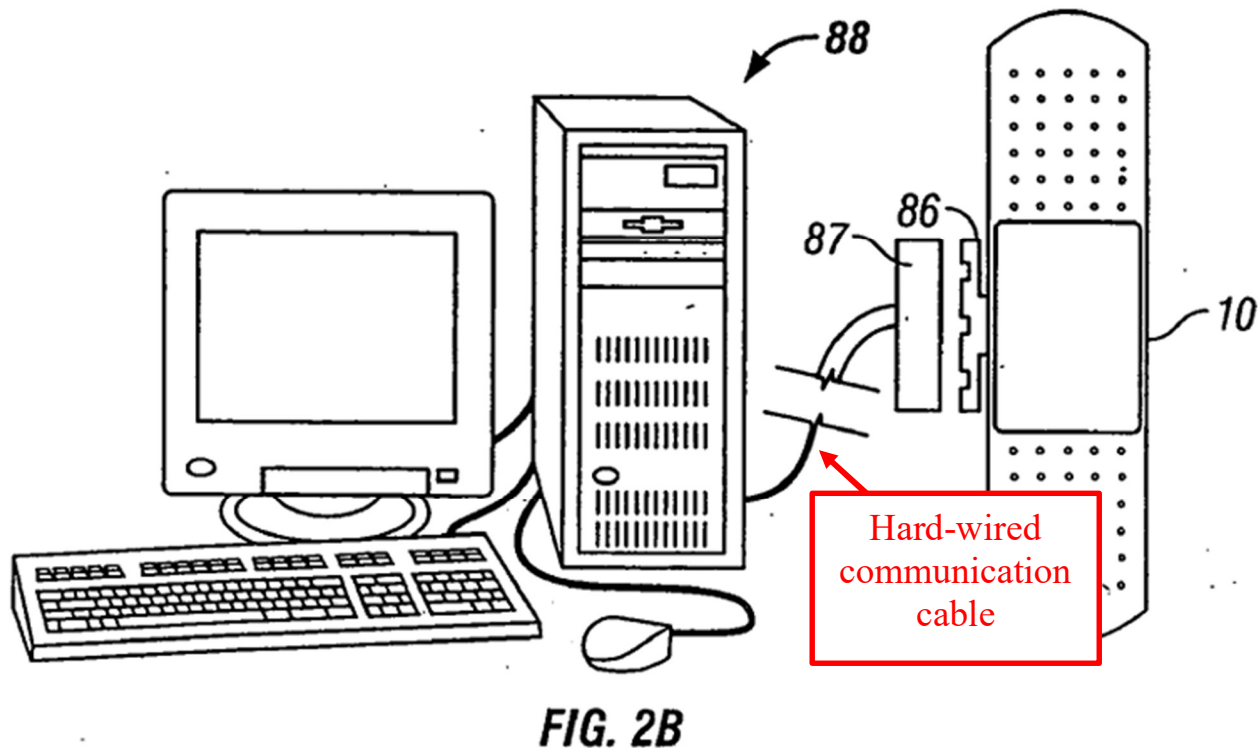
5. *Claim 5*

In addition to teaching the limitations of claim 1, it would have been obvious to a POSA to modify the flexible circuit layer to “further comprise[] a plurality of openings sized to receive electrode gels.” Ozguz discloses a sensor module 10 that includes “electrodes 80 disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20.” Ex. 1014 ¶[0039]. It would have been obvious to a POSA to modify Ozguz’s flexible substrate 55 to form openings

in the bottom of the flexible substrate to receive electrode gels. Ex. 1009 ¶¶1234-37. This modification would comprise a simple design change from Ozguz’s disclosed construction (in which the electrodes are integrated into flexible substrate 55). *Id.* A POSA would have been motivated to make this change to make Ozguz’s device compatible with a variety of commercial, pre-gelled, adhesive, disposable electrodes. *Id.*

6. Claim 6

In addition to teaching the limitations of claim 1, Ozguz discloses “a hard-wired communication cable,” as recited in claim 6. Ozguz discloses that sensor module 10 can include a “port 86.” Ex. 1014 ¶ [0040]. Port 86 connects to “a mating connection 87” of a wire that “physically connect[s] the sensor module 10” to a computer 88. *Id.* This is shown in Ozguz’s Figure 2B.



Id. Fig. 2B (annotated). Accordingly, Ozguz discloses a hard-wired communication cable. Ex. 1009 ¶¶1238-1241.

7. Claim 7

i. [Pre] A body-worn patient monitoring device comprising:

Ozguz discloses “a sensor system comprising a thin flexible ambulatory/self contained bio-sensor module in a form similar to an adhesive bandage for sensing physiologically modulated signals from the body.” Ex. 2014 ¶[0003]. Figure 2A of Ozguz shows sensor module 10 (shown in red) being worn on the body of a patient. *Id.* ¶¶[0038]-[0039].

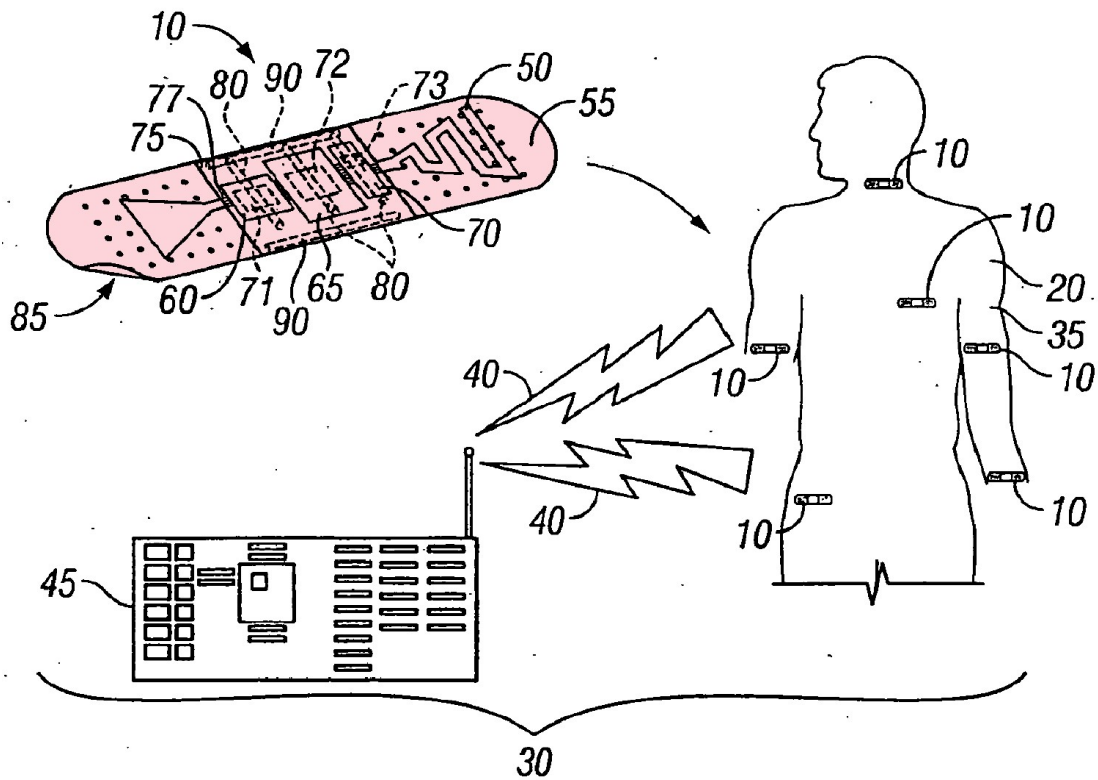


FIG. 2A

Id. Fig. 2A (annotated); Ex. 1009 ¶¶1242-1245.

ii. [7a.] a disposable electrode portion comprising:

Ozguz discloses “a disposable electrode portion.” Specifically, Ozguz discloses a flexible substrate 55 with electrodes 80. Ex. 2014 ¶[0039]. As noted above, Section VII.C.3, Ozguz discloses that some portions of sensor module 10 are “remov[ed] after each use,” while other portions are “used repeatedly.” *Id.* ¶[0049]. A POSA would know that flexible substrate 55, whose underside 85 is in contact with a patient’s skin, would be a portion of the sensor module that a POSA would dispose of for hygienic reasons. Ex. 1009 ¶¶1246-1249. Accordingly, Ozguz discloses a disposable electrode portion. *Id.*

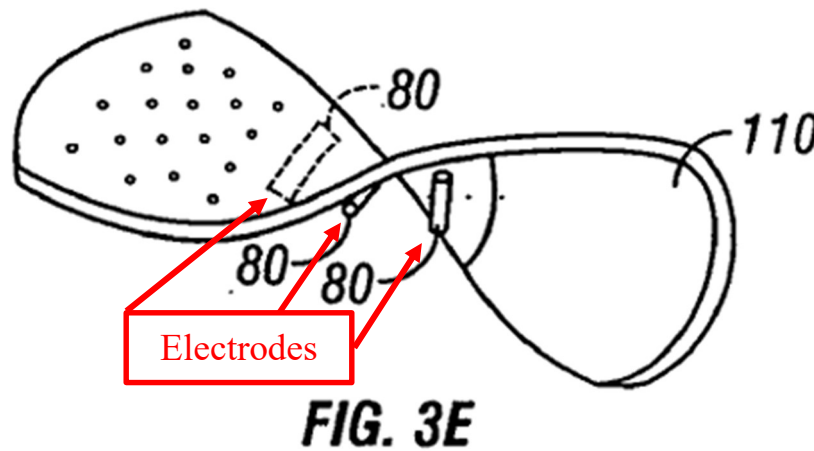
iii. [7b.] a flexible printed circuit layer made from an insulating material and defining a substrate,

Ozguz discloses “a flexible printed circuit board layer made from an insulating material.” Specifically, Ozguz discloses that flexible substrate 55 includes metallization 77 that interconnects integrated circuits 71, 72, 73 and other components to form a circuit board layer. Ex. 1014 ¶[0039]. Flexible substrate 55 is made of an insulating material, “preferably in the form of a polyimide, and is electrically non-conductive and flexible. However other flexible non-conducting substrates can be substituted.” *Id.* ¶[0046]. A POSA would have recognized that Ozguz’s flexible substrate 55 comprises a flexible printed circuit board, and therefore is a flexible printed circuit layer. Ex. 1009 ¶1253. Accordingly, Ozguz discloses flexible substrate 55 (flexible printed circuit board) made from an insulating material, such as polyimide, that is electrically non-conductive, and defining a substrate. *Id.* ¶¶1251-1254.

iv. [7c.] at least two electrodes being disposed onto a surface of the substrate,

Ozguz discloses “at least two electrodes disposed onto a surface of the substrate.” In particular, sensor module 10 includes “electrodes 80 disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20.” Ex. 1014 ¶[0039]. Accordingly, Ozguz discloses at least two electrodes

80 disposed on the bottom surface 85 of flexible substrate 55. Ex. 1009 ¶¶1255-1258.



Id. Fig. 3E (annotated).

- v. *[7d.] electrical traces defined between the at least two electrodes, and a connection pad;*

Ozguz teaches “electrical traces defined between the at least two electrodes and a connection pad.” In particular, Ozguz discloses that “metallization 77 further extends through the flexible substrate 55 and connects the ICs 71, 72, 73 to the electrodes 80 disposed on an underside 85 of the flexible substrate 55.” Ex. 2014 ¶[0039]. A POSA would understand metallization 77 to be electrical traces. Ex. 1009 ¶¶1259-1262.

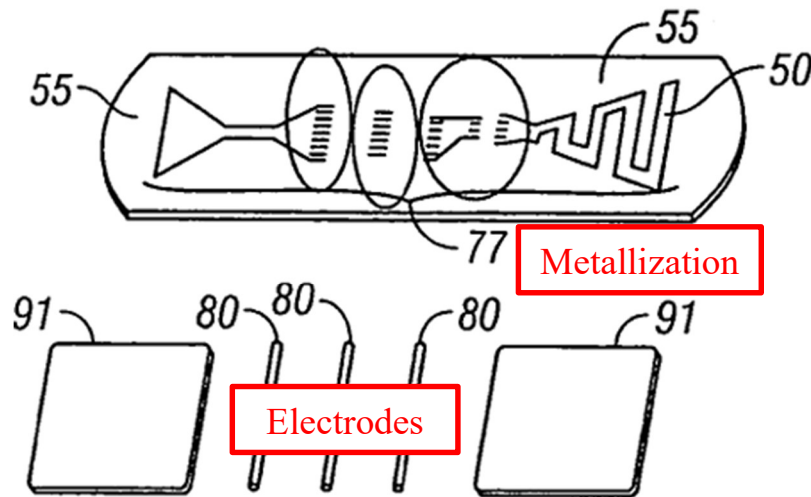


FIG. 3B

Ex. 1014, Fig. 3B (annotated). Ozguz also discloses “a pair of electrodes 90” that “extend longitudinally relative to the sensor module 10.” *Id.* ¶[0043].

Ozguz also teaches “a connection pad.” Specifically, the electrodes 80 located on lower surface 85 of flexible substrate 55 and metallization 77 on the upper surface of flexible substrate 55 are electrically connected through flexible substrate 55. *Id.* ¶[0048]. A POSA would understand that a portion of metallization further connects the electrodes to the overlying silicon circuit of Ozguz, thereby forming a connection pad. Ex. 1009 ¶1263. Accordingly, Ozguz teaches electrical traces defined between the at least two electrodes and a connection pad.

vi. [7e.] a reusable communication module comprising:

Ozguz discloses “a reusable communication module.” As noted above, Section VII.C.1.ii, Ozguz discloses a communication module: “flexible silicon 60, 65, 70 having respective ICs 71, 72, 73” with “transmitter or transceiver 190 for transmitting data by RF signals to a remote receiver” (communication module) and

“microprocessor 175.” Ex. 1014 ¶¶[0039], [0058]. Ozguz discloses that some portions of sensor module 10 are “remov[ed] after each use,” while other portions are “used repeatedly.” *Id.* ¶[0049]. A POSA would know that “flexible silicon 60, 65, 70 having respective ICs 71, 72, 73” with “transmitter or transceiver 190” (communication module) and “microprocessor 175” would be a portion of sensor module 10 that would be used repeatedly to reduce costs and minimize waste. *Id.* ¶¶[0039], [0058]; Ex. 1009 ¶¶1265-1269. This portion can be “sterilized in an autoclave” for repeated use. Ex. 1014 ¶[0049]. Accordingly, Ozguz discloses a reusable communication module. Ex. 1009 ¶¶1265-1269.

vii. [7f.] a housing containing a processor, and

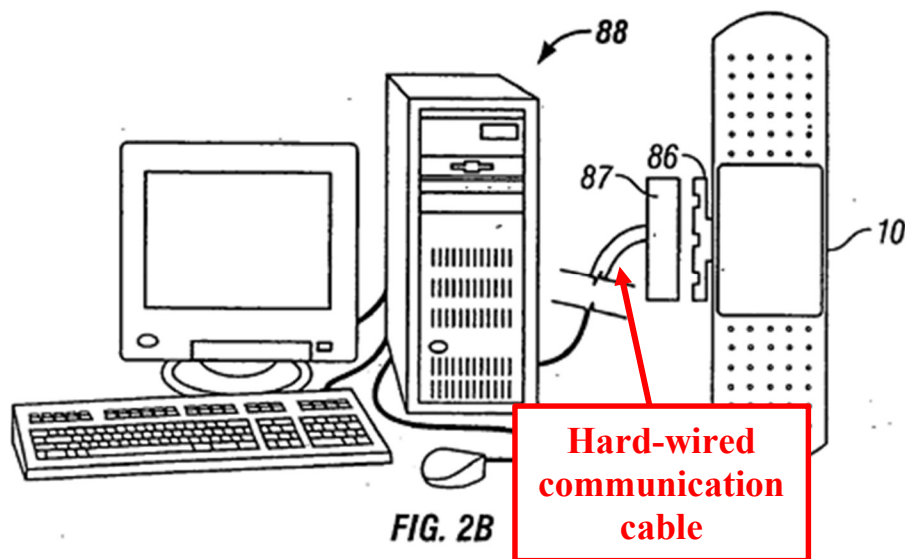
Ozguz discloses “a housing containing a processor” in the communication module. In particular, Ozguz discloses “microprocessor 175” that is “incorporated into the thin silicon substrates 60, 65, 70.” Ex. 2014 ¶[0058]. Sensor module 10 includes a “flexible, thin battery 105” that “overlays the silicon substrates 60, 65, 70 and their respective ICs 71, 72, 73.” *Id.* ¶[0048]. On the other side, silicon substrates 60, 65, 70 are disposed on flexible substrate 55. *Id.* ¶[0039]. Microprocessor 175 of the communication module is therefore housed between overlay 105 and flexible substrate 55. *Id.*; Ex. 1009 ¶1272. Accordingly, Ozguz discloses a processor disposed in the housing. Ex. 1009 ¶¶1270-1273.

viii. [7g.] a wireless communication unit, and in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip; and

Ozguz discloses “a wireless communication unit, and in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip.” Specifically, Ozguz discloses that sensor module 10 functions as a wireless data collection device. Ex. 2014, Abstract. To that end, silicon substrates 60, 65, 70 located on flexible substrate 55 incorporates “transmitter or transceiver 190 for transmitting data by RF signals to a remote receiver.” *Id.* ¶[0058]. As noted above, Ozguz discloses a “disposable electrode portion” and a “reusable communication module.” *Supra* §§ VII.C.7.ii, VII.C.7.vi. A POSA would have understood that, for the “reusable communication module” to be reusable, it must be releasably attached to the “disposable electrode portion.” Ex. 1009 ¶ 1277. Ozguz teaches attaching via an adhesive, but latching is one of a finite number of options for mechanically attaching “disposable electrode portion” and “reusable communication module.” *Id.* Accordingly, Ozguz and the general knowledge of a POSA renders obvious a wireless communication unit, and in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip. *Id.* ¶¶1274-1280.

ix. [7h.] a hard-wired communication cable.

Ozguz discloses “a hard-wired communication cable.” As shown in Figure 2B, Ozguz teaches “a port 86 on the sensor module 10 and a mating connection 87 connected to a PC 88 for physically connecting the sensor module 10 to the PC 88 or other processor for downloading, analyzing, and archiving collected data.” Ex. 1014 ¶[0040].

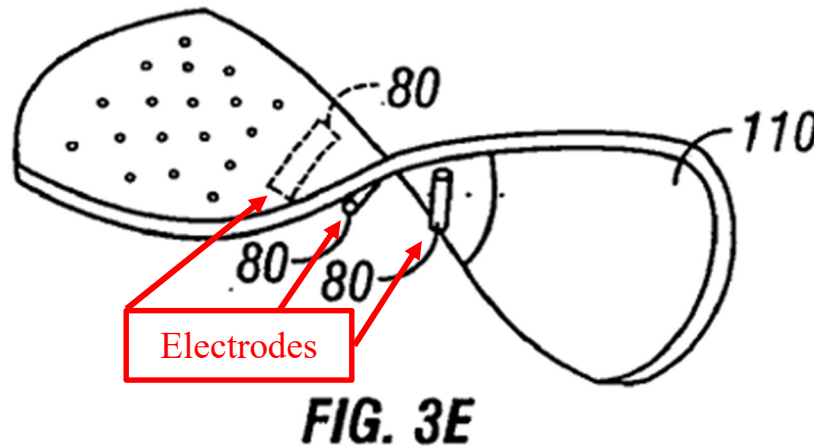


Id. Fig. 2B (annotated). This hard-wired connection, along with a non-volatile memory, can be used “in case power is lost to the sensor module.” *Id.* ¶ [0040]; Ex. 1009 ¶¶1281-1285.

8. Claim 8

In addition to teaching all the limitations of claim 7, Ozguz teaches that “the electrodes are integrated into the flexible circuit layer of the disposable electrode

portion,” as recited in claim 8. Sensor module 10 includes “electrodes 80 disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20.” Ex. 2014 ¶[0039]. Accordingly, Ozguz discloses at least two electrodes 80 integrated into flexible substrate 55.



Id. Fig. 3E (annotated); Ex. 1009 ¶¶1286-1289.

9. Claim 15

i. [Pre] A body-worn physiological sensor comprising:

As described above, Ozguz discloses this element. *Supra* § VII.C.1.i; Ex. 1009 ¶¶1291-1292.

ii. [15a.] a computation-communication module including a housing retaining a processor;

As described above, Ozguz discloses this element. *Supra* § VII.C.1.ii; Ex. 1009 ¶¶1293-1294.

iii. [15b.] a flexible printed circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals,

As described with respect to Claim 1, Ozguz discloses a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals. *Supra* § VII.C.1.iii. A POSA would have understood that a known way to construct substrate 55 would be through printing. Ex. 1009 ¶¶1295-1296.

iv. [15c.] the computation-communication module being attached to the flexible printed circuit layer;

As described above, Ozguz discloses this limitation. *Supra* § VII.C.1.iv; Ex. 1009 ¶¶1297-1298.

v. [15d.] an adhesive covering at least a portion of the flexible printed circuit layer; and

As described above, Ozguz discloses this limitation. *Supra* § VII.C.1.v; Ex. 1009 ¶¶1299-1300.

vi. [15e.] a protective covering for the flexible printed circuit layer.

As described with respect to Claim 1, Ozguz discloses a protective covering. *Supra* § VII.C.1.vi. Specifically, Ozguz discloses that “protective cover 115” (shown in red below) covers the “underside 85” of the “flexible substrate” (shown in blue below). Ex. 1014 ¶[0049].

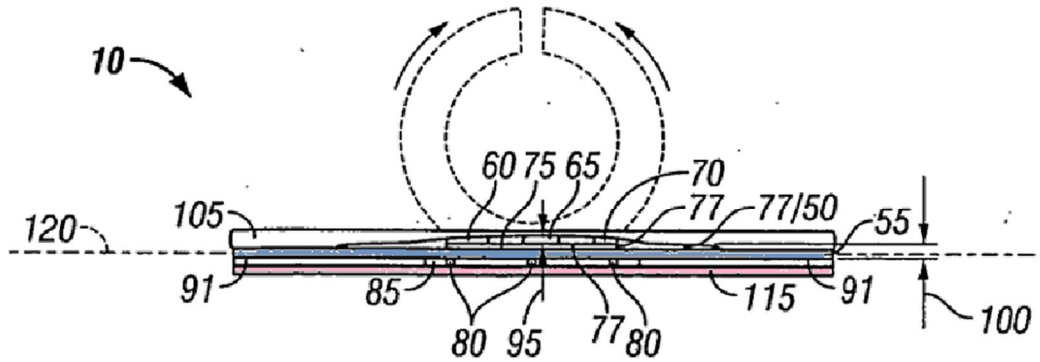


FIG. 3C

Id. Fig. 3C (annotated).

In addition to, and alternatively, Ozguz discloses an overlying battery 105 (protective covering) that is shaped in a way that overlays flexible substrate 55. *Id.* Fig. 3A. Accordingly, Ozguz discloses a protective covering for the flexible printed circuit layer. Ex. 1009 ¶¶1301-1306.

10. Claim 19

In addition to teaching all the limitations of claim 15, Ozguz teaches that “the computation communication module is releasably attached to the flexible printed circuit layer,” as recited in claim 19. Specifically, Ozguz discloses that some portions of sensor module 10 are “remov[ed] after each use,” while other portions are “used repeatedly.” Ex. 1014 ¶[0049]. A POSA would know that “flexible silicon 60, 65, 70” with incorporated “microprocessor 175” and “transmitter or transceiver 190” (computation-communication module), would be a portion of sensor module that can be used repeatedly to reduce costs and minimize waste. Ex. 1009 ¶1309. On the other hand, flexible substrate 55, whose underside 85 is in contact with a

patient's skin, would be a portion of sensor module that a POSA would dispose of to prevent any infections from spreading as a result of repeated use. *Id.* Ozguz therefore discloses that the disposable flexible printed circuit layer is releasably attached to the portions of Ozguz that would be reused, such as “microprocessor 175” and “transmitter or transceiver 190” (computation-communication module). *Id.* ¶¶1307-1310.

11. Claim 20

In addition to teaching all of the limitations of claim 15, Ozguz teaches that “the protective covering covers the adhesive,” as recited in claim 20. This is described with respect to claim 1. *Supra* § VII.C.1.vi; Ex. 1009 ¶¶1311-1312.

D. Ground 4: Claims 6-8, 11, and 12 are Obvious Over Matsumura and Ozguz and General Knowledge of a POSA

While independent claim 7 of the '484 patent recites many of the same limitations as independent claims 1 and 15, claim 7 recites “a hard-wired communication cable.” The same limitation is included in claim 6. To the extent that inclusion of a “hard-wired communication cable” is not obvious as a back-up to wireless communication (Ex. 1009 ¶¶1238-41), it is rendered obvious by the combination of Matsumura and Ozguz.

1. A POSA would have combined Matsumura and Ozguz

Matsumura and Ozguz both teach flexible wearable devices for monitoring physiological signals, including ECG or EKG signals. Ex. 1012 ¶¶[0024], [0031],

Fig. 2; Ex. 1014 ¶¶[0003], [0010], [0046]-[0050], Figs. 1, 2A. Ozguz teaches that the wearable device is flexible, while Matsumura teaches that its “bioelectrode pad” should be made of sheets comprising “polyethylene foam, polyurethane foam, or polyurethane sheet,” Ex. 1012 ¶¶[0017]-[0018], [0022], which a POSA would recognize as “flexible materials.” Ex. 1009 ¶1028.

A POSA would look to incorporate the specific design and structure of circuits and electronic components taught by Ozguz into the detector of Matsumura. Ex. 1009 ¶¶1313, 629-30. Matsumura discloses a “circuit,” “signal processor,” and “signal transmitter” used to detect, process, and wirelessly transmit bioelectric signals. Ex. 1012 ¶[0025]. But Matsumura does not specify a circuit design or architecture to perform these functions. *See generally, id.* To the extent such circuit design or architecture is not within the knowledge of a POSA, Ozguz discloses such a design. Ex. 1009 ¶¶1313, 630.

Specifically, Ozguz details an architecture and design of “circuitry (71, 72, 73)” that includes a “microprocessor” and “transmitter” used to perform the same functions described in Matsumura. A POSA would have therefore looked to Ozguz’s integrated circuits that incorporate a “microprocessor 175, a ROM 180 for storing a program to be implemented, a RAM 185 for storing of data, and a transmitter or transceiver” to achieve Matsumura’s “signal processor.” Ex. 1014 ¶¶ [0039], [0058]; Ex. 1009 ¶¶1313, 630. A POSA would have also looked to

Ozguz’s teaching of a radio circuit to achieve the wireless “signal transmitter” of Matsumura. Ex. 1014 ¶¶[0039]-[0040], [0042], [0048], [0057], Figs. 3A-3C; Ex. 1009 ¶¶1313, 630.

Besides looking to Ozguz for the architecture and design of the circuit, Ozguz provides several advantages that would have led a POSA to incorporate its teachings into Matsumura’s detector. First, Ozguz teaches an “unobtrusive,” “self-contained” design that “is void of the monitor wires and other encumbrances” making it “as convenient as wearing an adhesive bandage.” Ex. 1014 ¶¶[0008], [0038]. Using this “unobtrusive,” “self-contained” circuitry design would help satisfy one of Matsumura’s goals, which is to provide a “cable-free and compact” detector. Ex. 1012 ¶[0006]; Ex. 1009 ¶¶1313, 632. Second, Ozguz teaches that “[t]he small size and wireless aspects of the instant sensor module avoid the noise that normally sullies the signal of past systems.” Ex. 1014 ¶[0009]. It achieves this by having a sensor module with “an integral power supply such that the signal remains clean and free from noise.” *Id.* Incorporating the circuit components of Ozguz into Matsumura would similarly improve its detector by avoiding noise levels and more “accurately detect[ing] electromagnetic” signals. *Id.*; Ex. 1009 ¶¶1313, 633.

Third, in addition to wirelessly transmitting detected signals, Ozguz teaches using a hard-wired connection and a non-volatile memory “in case power is lost to the sensor module.” Ex. 1014 ¶[0040]. Matsumura’s bioelectrical potential detector

11 includes “a memory for storing the processed bioelectric potential signal.” Ex. 1012 ¶[0025]. A POSA would have looked to modify Matsumura’s memory with Ozguz’s non-volatile memory to ensure that any stored, detected signals are not lost if the sensor loses power. Ex. 1009 ¶¶1313, 634. But doing so may necessitate the storage of a large number of detected signals. *Id.* To efficiently transmit this large number of stored signals, Ozguz teaches the use of a hard-wired connection through port 86. Ex. 1014 ¶[0040]; Ex. 1009 ¶¶1313, 634. A POSA would have also understood that port 86 could be used to recover the stored signal data of Ozguz, even if power is never restored. *Id.* Accordingly, a POSA would look to add connection “port 86,” as taught by Ozguz, to Matsumura’s bioelectrical potential detector 11. *Id.* This modification would allow the option of a hard-wired connection to download stored data “in case power is lost to the sensor module.” *Id.*

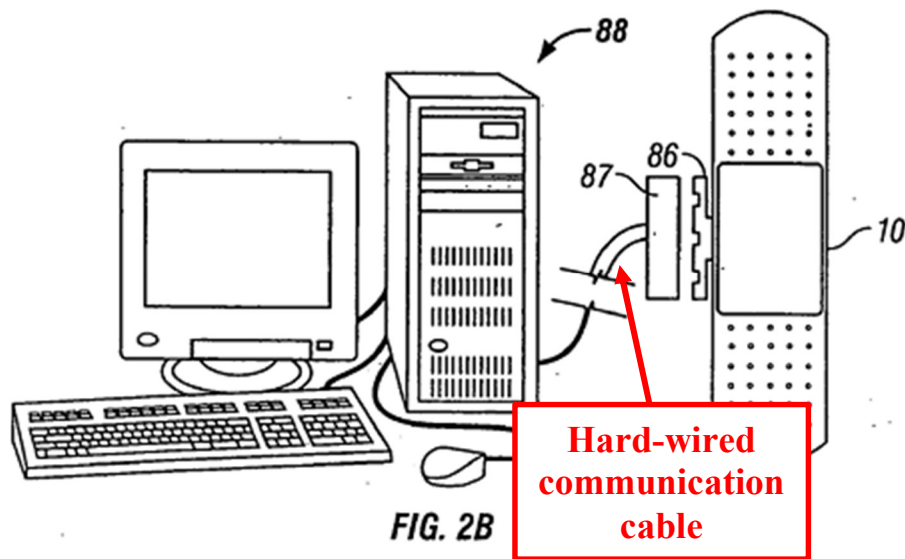
A POSA combining the teachings of Matsumura and Ozguz would have had a reasonable expectation of success in doing so; nothing in the art suggests this would not work. Ex. 1009 ¶¶1313, 635.

2. Claim 6

Matsumura discloses every limitation of claim 1. *Supra* § VII.A.1. The combination of Matsumura and Ozguz discloses “a hard-wired communication cable,” required by dependent claim 6.

In the first instance, it would have been obvious to a POSA to modify Matsumura's device to include a hard-wired communication cable. *See* Ex. 1009 ¶¶1314-1316.

Ozguz discloses “a sensor module 10 adhered to the skin 15 of a subject body 20” that can wirelessly transmit detected signals to a remote receiver device. Ex. 1014 ¶¶[0038]-[0039]. As shown in Figure 2B, Ozguz also teaches “a port 86 on the sensor module 10 and a mating connection 87 connected to a PC 88 for physically connecting the sensor module 10 to the PC 88 or other processor for downloading, analyzing, and archiving collected data.” *Id.* ¶[0040].



Id. Fig. 2B (annotated). As noted above, Section VII.D.1, this hard-wired connection can be used to efficiently transmit a large quantity of detected signals stored in non-volatile memory “in case power is lost to the sensor module.” *Id.*

¶[0040]; Ex. 1009 ¶1318. The hard-wired connection can also be used to recover data in case power is never restored to the sensor module. *Id.* Accordingly, a POSA would have looked to add “port 86” of Ozguz to bioelectrical potential detector 11 of Matsumura to be connected to “mating connection 87.” *Id.*

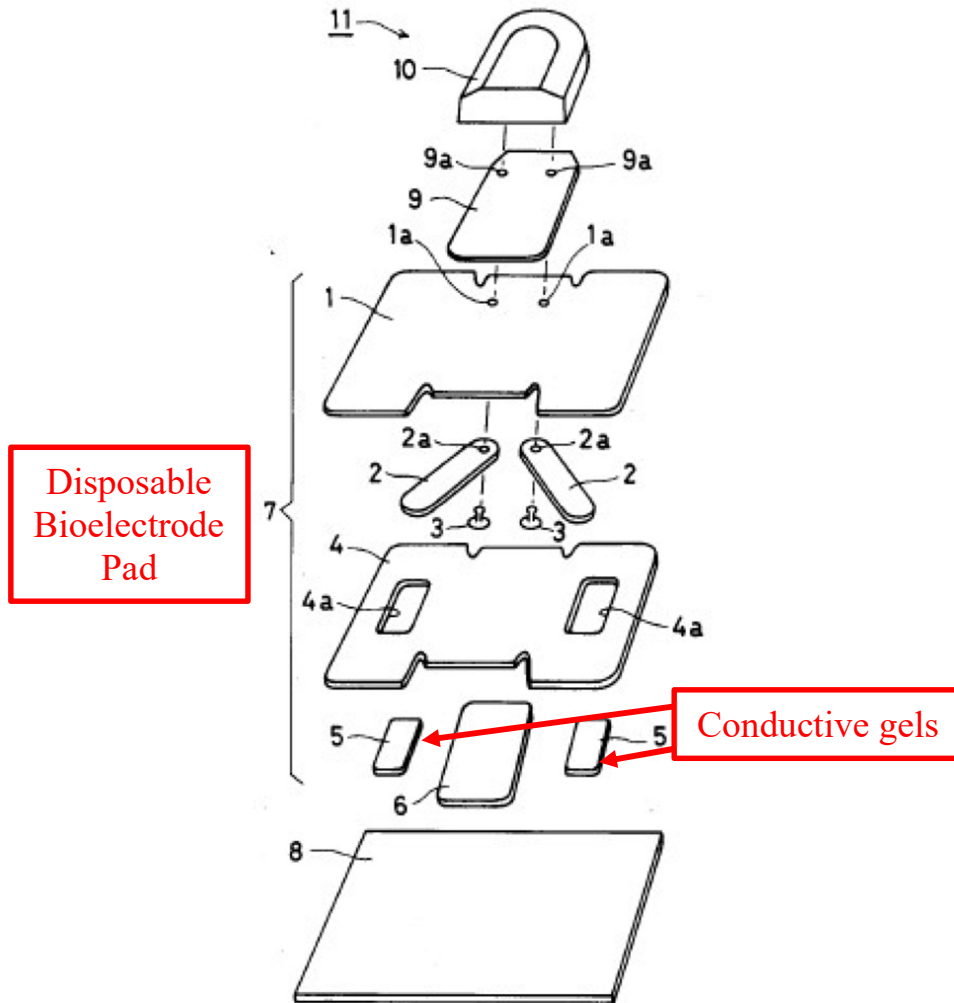
3. *Claim 7*

i. [Pre] A body-worn patient monitoring device comprising:

As described above, each of Matsumura and Ozguz disclose this element. *Supra* §§ VII.A.1.i, VII.C.7.i; Ex. 1009 ¶¶1321-1325.

ii. [7a.] a disposable electrode portion comprising:

Matsumura discloses “a disposable electrode portion.” Ex. 1009 ¶¶1326-1329. As shown in Figure 1 below, Matsumura discloses that “disposable bioelectrode pad 7” includes “conductive gel 5” (electrode portion) used to detect bioelectrical potentials. Ex. 1012, Abstract, ¶¶[0016], [0018].



Id. Fig. 1 (annotated).

iii. [7b.] a flexible printed circuit layer made from an insulating material and defining a substrate,

Matsumura renders this limitation obvious in view of a POSA's knowledge. It would have been obvious to a POSA to modify Matsumura's conductive material 2 to comprise a flexible printed circuit configured to be coupled to a skin surface of a subject to measure physiological signals. *Supra* § VII.A.6.iii; Ex. 1009 ¶1332. The original circuit of Matsumura comprises "two pieces of conductive material 2," which "can be a carbon sheet or a PET sheet [which are insulating materials] coated

with conductive Ag/AgCl.” Ex. 1012 ¶¶[0019]-[0020], Fig 1. A POSA would recognize that, so modified, Matsumura’s conductive material would comprise a flexible printed circuit made from an insulating material; combined with second sheet 4, it would form a flexible printed circuit layer and define a substrate. *Id.* ¶¶ [0017]-[0018]; Ex. 1009 ¶¶1331-1333.

iv. [7c.] at least two electrodes being disposed onto a surface of the substrate,

Matsumura discloses “at least two electrodes being disposed onto a surface of the substrate.” In particular, Matsumura discloses “disposable bioelectrode pad 7” that includes “conductive gel[s] 5” (electrodes) used to detect bioelectrical potentials. These “conductive gel[s]” are disposed in two openings 4a in second sheet 4. Ex. 1012 ¶¶[0018]-[0019]. A POSA would understand that the electrodes are bonded together with the other components of the disposable bioelectrode pad 7, including the sheet of conductive material 2 with which the electrodes make contact. Ex. 1009 ¶¶1334-1337; Ex. 1012 ¶[0019].

v. [7d.] electrical traces defined between the at least two electrodes, and a connection pad;

Matsumura renders obvious “electrical traces defined between the at least two electrodes, and a connection pad.” As explained above, a POSA would have been motivated to combine conductive material 2 onto a single, printed sheet, forming a flexible printed circuit. *See supra* § VII.A.6.iii; Ex. 1009 ¶1340. Subject to that

modification, traces run “between the at least two electrodes” (conductive gels 5) in the following manner: there is an electrical connection from one electrode to the printed trace it contacts; from the printed trace to the hook at its end; from the hook to the signal processor; from the signal processor to the other hook; from the other hook down the length of the other electrical trace; and, finally, from the other electrical trace to the other electrode.. Ex. 1009 ¶1340.

A POSA would further understand that where Matsumura’s hooks contact the traces of the flexible printed circuit layer constitutes a connection pad because it forms an electrical connection between the signal processor 10 and the traces leading to the electrodes 5. *Id.* ¶1341.

A POSA would therefore understand that, as modified, Matsumura includes at least one electrical trace extending between the connection pad and a conductive surface of the electrode. *Id.* ¶¶1338-1342.

vi. [7e.] a reusable communication module comprising:

Matsumura discloses “a computation-communication module.” Matsumura discloses a “reusable signal processor” which is a module that is “detachable with hooks” from disposable bioelectrode portion 7. Ex. 1012 ¶[0016]; *see also id.* ¶¶[0008], [0014], [0025], Figs. 1-2. The reusable signal processor incorporates components for computation: a “processing circuit for filtering and amplifying detected bioelectric potential signals” and “a memory for storing the processed

bioelectric potential signal.” *Id.* at [0025]. The reusable signal processor also incorporates components for communication: “a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna.” *Id.* Accordingly, Matsumura discloses a computation-communication module. Ex. 1009 ¶¶1343-1346.

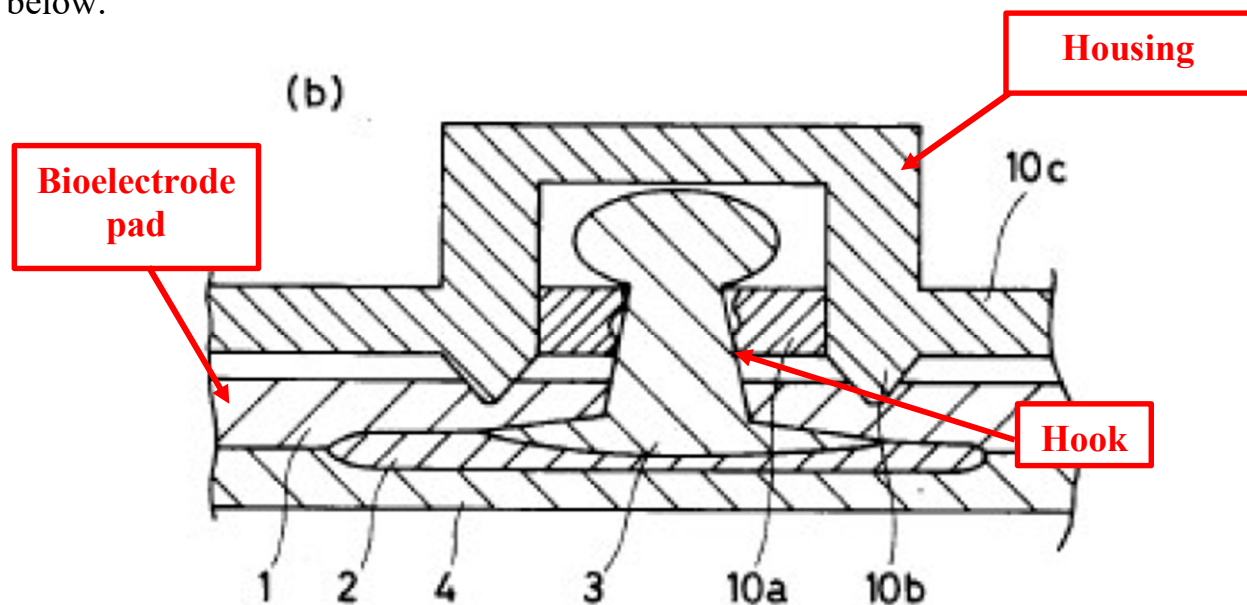
vii. [7f.] a housing containing a processor, and

Matsumura discloses “a housing containing a processor.” Matsumura discloses that “reusable signal processor 10” is enclosed in housing 10c, which can be “easily attached and detached” to bioelectrode pad 7. Ex. 1012 ¶¶[0016], [0025], [0027], [0029]. “[S]ignal processor 10 incorporates a processing circuit for filtering and amplifying detected bioelectric potential signals.” *Id.* ¶[0025]. The processing circuit is disposed within housing 10c to ensure signal processor 10 is waterproof. *Id.* ¶¶[0025], [0027], [0029]. Accordingly, Matsumura teaches “a housing containing a processor.” Ex. 1009 ¶¶1347-1350.

viii. [7g.] a wireless communication unit, and in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip; and

Matsumura discloses “a wireless communication unit, and in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip.” Specifically, Matsumura discloses that “reusable signal processor 10” is “easily attached and detached” with hook 3

(releasably attached) to disposable bioelectrode pad 7 that includes conductive gels 5 (disposable electrode portion). Ex. 2012 ¶¶[0016]; *see also id.* ¶¶[0008], [0014], [0016], [0025], Figs. 1-2. The reusable signal processor incorporates components for wireless communication: “a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna” (wireless communication unit). *Id.* ¶[0025]. This is shown in Figure 4(b) of Matsumura below.



Id. Fig. 4(b) (annotated). A POSA would understand that “hook 3” of Matsumura renders obvious use of a latch clip. Ex. 1009 ¶¶1352-55.

ix. [7h.] a hard-wired communication cable.

As explained above, the combination of Matsumura and Ozguz teaches “a hard-wired communication cable.” *Supra* § VII.D.2; Ex. 1009 ¶¶1356-1357.

4. Claim 8

In addition to teaching the limitations of claim 7, Matsumura teaches that “the electrodes are integrated into the flexible circuit layer of the disposable electrode portion,” as recited in claim 8. Matsumura discloses that “second sheet 4” of bioelectrode pad 7 “is provided with two openings 4a on the left and right sides into which the conductive gel 5 is inserted.” Ex. 1012 ¶[0018]. A POSA would understand that the electrodes are bonded together with the other components of the disposable bioelectrode pad 7, including the sheet with printed traces (substitute for conductive material 2) with which the electrodes make contact. Ex. 1009 ¶1360; Ex. 1012 ¶[0019]. Accordingly, Matsumura renders obvious that the electrodes are integrated into the flexible printed circuit layer of the disposable portion of the device. Ex. 1009 ¶¶1358-1361.

5. Claim 11

In addition to teaching the limitations of claim 7, Matsumura teaches “the electrical traces are screened onto the flexible printed circuit layer,” as recited in claim 11. As noted above, Matsumura discloses “electrical traces” in the form of portions of conductive material 2 made of silver/silver chloride. Ex. 1012 ¶¶[0019]-[0021]. A POSA would modify this conductive material to comprise a flexible sheet with printed circuits. *Supra* § VII.A.6.iii. A POSA would further understand printing ink onto a circuit board to be a form of screening. Ex. 1009 ¶1364. Printing

Ag/AgCl ink traces on the modified flexible printed circuit of Matsumura would yield electrical traces that are screened. *Id.* ¶1365. Accordingly, it would have been obvious to a POSA to screen the electrical traces onto the flexible circuit of Matsumura. *Id.* ¶¶1362-1366.

6. Claim 12

In addition to disclosing the limitations of claims 11 and 7, Matsumura teaches “an insulating layer applied onto the electrical traces,” as recited in claim 12. As explained above, a POSA would modify Matsumura’s conductive material to form as single sheet of printed-ink traces between first sheet 1 and second sheet 4. *See* § VII.A.6.iii. Matsumura teaches that first sheet 1 is “made of an insulating material,” and covers the sheet of printed-ink traces. Ex. 1012 ¶¶[0017]-[0018]. Matsumura therefore discloses the dependent limitation of claim 12. Ex. 1009 ¶¶1367-1370.

VIII. THE BOARD’S DISCRETION UNDER 35 U.S.C. §§ 314(A) AND 325(D)

Section 314(a). Here, none of the factors enumerated in *Apple Inc. v. Fintiv Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) favors discretionary denial of institution. A scheduling order has not been entered nor a trial date set for the co-pending litigation (Factor 2). The proceedings have not progressed beyond the pleadings stage, and neither the parties nor the district court have invested substantial resources in the litigation to date (Factor 3). To date, there is no overlap between

the issues raised in the petition and the parallel proceeding (Factor 4). Petitioner is the sole defendant in the parallel proceeding (Factor 5). The grounds raised herein present a compelling unpatentability challenge that on its own prevents a discretionary denial under *Fintiv* (Factor 6). Katherine K. Vidal, Interim Procedure For Discretionary Denials in AIA Post-Grant Proceedings With Parallel District Court Litigation (June 21, 2022).

Section 325(d). Jensen qualifies as art previously presented to the Office because it was listed on Information Disclosure Statements supplied by the Applicant. Ex. 1006, 77, 155. *Cf. Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020). Matsumura and Ozguz were never presented to the Office during examination.

The factors enumerated in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) do not counsel against institution. At minimum, none of the references submitted as part of Grounds 1, 3 or 4 were considered by the Office and, for that reason alone, Section 325(d) does not warrant denial of institution.

As to Jensen, the Examiner failed to consider how Jensen would render the purported invention of the '484 patent obvious or anticipated. The Examiner did not substantively address Jensen or any similar reference during prosecution (Factor B). This is at least because none of the grounds considered by the Examiner discloses a

monitor that includes a resistive trace. For example, Williams *et al.* (U.S. Patent Pub. No. 2004/0030258 A1) did not disclose a computation-communication module and a separate flexible circuit layer.

In addition, Jensen did not form the basis for rejection during prosecution (Factor C). Instead, Jensen was cited in an Information Disclosure Statement along with 120 other references, none of which was substantively addressed during examination of the application that became the '484 patent. The Board has repeatedly held that a reference that is merely cited in an IDS does not weigh in favor of a discretionary denial. *See, e.g., Gene Co. Pty Ltd. v. Trs. of Columbia Univ.*, IPR 2024-00313, Paper 13 at 56-57 (PTAB June 24, 2024); *Advanced Energy Indus. Inc., v. Reno Techs. Inc.*, IPR2021-01397, Paper 7 at 7 (PTAB Feb. 16, 2022); *Lyft, Inc., v. Rideshare Displays, Inc.*, IPR2021-01602, Paper 7 at 15-16 (PTAB Apr. 11, 2022). These decisions are consistent with the USPTO's notice of proposed rulemaking on this issue, which notes that "[a]n initialed Information Disclosure Statement, without more, does not satisfy" the criteria of 325(d). Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement, 89 Fed. Reg. 28693 (proposed Apr. 19, 2024) (to be codified at 37 C.F.R. pt. 42). The arguments in this Petition, which rely on art not previously before the office (Grounds 1, 3, and 4) and/or combine Jensen with the

general knowledge of a POSA (Ground 2), do not overlap with those made during examination (Factor D). That is because none of the references considered during prosecution discloses a computation-communication module and a separate flexible circuit layer.

IX. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests cancellation of the Challenged Claims.

X. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

A. Real Party in Interest Under 37 C.F.R. § 42.8(b)(1)

iRhythm, Inc. is the real party in interest for the Petitioner.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

The '484 patent is presently the subject of a patent infringement lawsuit brought by the assignee, Welch Allyn, Inc., against iRhythm, Inc. and captioned *Welch Allyn, Inc. v. iRhythm, Inc.*, C.A. No. 24-224-MN (D. Del.).

C. Designation of Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel:

Lead Counsel	Backup Counsel
Robert E. Counihan (Reg. No. 61,382) Fenwick & West LLP 902 Broadway, Floor 18 New York, NY 10010 T: (212) 430-2600 rcounihan@fenwick.com	Allen W. Wang (Reg. No. 68,456) Fenwick & West LLP 801 California Street Mountain View, CA 94041-1990 T: (650) 335-7288 allen.wang@fenwick.com

Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney is being submitted with this Petition.

D. Service Information

Please address all correspondence and serve to the address listed above. Petitioner consents to electronic service directed to iRhythm-WelchAllyn_IPR@fenwick.com.

Dated: December 23, 2024

FENWICK & WEST LLP

/Robert E. Counihan /

Robert E. Counihan

Reg. No. 61,381

Attorneys for Petitioner

iRhythm, Inc

CLAIMS APPENDIX

Claim	Recitation
1[pre]	A body-worn physiological sensor comprising:
[1a.]	a computation-communication module including a housing retaining a processor;
[1b.]	a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals,
[1c.]	said computation-communication module being attached to the flexible circuit layer;
[1d.]	an adhesive covering at least a portion of the flexible circuit layer; and
[1e.]	a protective covering that protects the adhesive.
[2]	The sensor of claim 1, in which the flexible circuit layer has traces of determinable electrical resistance.
[3]	The sensor of claim 2, in which the traces on the flexible circuit layer are configured to electrically couple the computation-communication module to the flexible circuit layer, thereby forming a disposable module connector.
[4]	The sensor of claim 1, in which the traces on the flexible circuit layer are at least partially covered by a non-removable insulating covering.
[5]	The sensor of claim 1, wherein the flexible circuit layer further comprises a plurality of openings sized to receive electrode gels.
[6]	The sensor of claim 1, further comprising a hard-wired communication cable.
7[pre]	A body-worn patient monitoring device comprising:
[7a.]	a disposable electrode portion comprising:
[7b.]	a flexible printed circuit layer made from an insulating material and defining a substrate,

Claim	Recitation
[7c.]	at least two electrodes being disposed onto a surface of the substrate,
[7d.]	electrical traces defined between the at least two electrodes, and a connection pad;
[7e.]	a reusable communication module comprising:
[7f.]	a housing containing a processor, and
[7g.]	a wireless communication unit, and in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip; and
[7h.]	a hard-wired communication cable.
[8]	The body-worn patient monitoring device of claim 7, wherein the electrodes are integrated into the flexible circuit layer of the disposable electrode portion.
[11]	The body-worn patient monitoring device of claim 7, wherein the electrical traces are screened onto the flexible printed circuit layer.
[12]	The body-worn patient monitoring device of claim 11, including an insulating layer applied onto the electrical traces.
15[pre]	A body-worn physiological sensor comprising:
[15a.]	a computation-communication module including a housing retaining a processor;
[15b.]	a flexible printed circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals,
[15c.]	the computation-communication module being attached to the flexible printed circuit layer;
[15d.]	an adhesive covering at least a portion of the flexible printed circuit layer;
[15e.]	and a protective covering for the flexible printed circuit layer.

Claim	Recitation
[16]	The body-worn physiological sensor of claim 15, in which the protective covering includes at least one opening for electrode gels.
[17]	The body-worn physiological sensor of claim 15, wherein the flexible printed circuit layer includes openings sized to receive electrode gels.
[18]	The body-worn physiological sensor of claim 15, wherein the protective covering is non removable and made from an insulating material.
[19]	The body-worn physiological sensor of claim 15, wherein the computation communication module is releasably attached to the flexible printed circuit layer.
[20]	The body-worn physiological sensor of claim 15, wherein the protective covering covers the adhesive.

**CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION**

Under the provisions of 37 C.F.R. § 42.24(d). I certify that this petition complies with the type-volume limits of 37 C.F.R. § 42.24(a)(1)(i) because it contains 13,990 words, according to the word-processing system used to prepare this petition, excluding the parts of this petition that are exempted by 37 C.F.R. § 42.24(a) (including the table of contents, a table of authorities, mandatory notices, a certificate of service or this certificate word count, appendix of exhibits, and claim listings).

Dated: December 23, 2024

FENWICK & WEST LLP

/Robert E. Counihan /

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Attorneys for Petitioner

iRhythm, Inc

**CERTIFICATE OF SERVICE ON PATENT OWNER
UNDER 37 C.F.R. § 42.105**

I hereby certify, pursuant to 37 C.F.R. §§ 42.6(e), 42.105, that a complete copy of the above-captioned PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,155,484, all associated exhibits, and Petitioner's Power of Attorney were served in their entireties via Federal Express, Priority Delivery, on December 23, 2024, upon Patent Owner by serving the correspondence address of record with the USPTO as follows:

BARCLAY DAMON, LLP
Barclay Damon Tower
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Further, courtesy copies are also being sent via electronic mail to Patent Owner's litigation counsel of record:

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