

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

iRhythm, Inc.

Petitioner,

v.

Welch Allyn, Inc.

Patent Owner.

Case: IPR2025-00378

U.S. Patent No. 8,214,007

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

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LIST OF EXHIBITS

Exhibit No.	Description
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. 8,214,007, 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)
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1030	Mike Cadogan, <i>Norman J. Holter</i> (2022), available at https://litfl.com/norman-j-holter/
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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)

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1050	Jiapu Pan & Willis J. Tompkins, <i>A Real-Time QRS Detection Algorithm</i> , BME-22 IEEE Transactions on Biomed. Eng'g 230 (1985)
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1053	Klaus-Peter Hoffmann & Roman Ruff, <i>Flexible dry surface-electrodes for ECG long-term monitoring</i> 5739 (2007)
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1055	U.S. Patent Publication No. 2003/0055460

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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)
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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 1-6, 8, 10-15, 29, 31-35, 37-39, and 43-45 (the “Challenged Claims”) of U.S. Patent No. 8,214,007 (the “’007 patent”), 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 ’007 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, 2, 4-6, 8, 10-15, 29, 31, 37, 38, and 43-45 are obvious under pre-AIA § 103 over Matsumura, Kroll, and General Knowledge of a POSA
<u>Ground 2</u>	Claims 1, 2, 4, 5, 10, 14, 15, and 43-45 are obvious under pre-AIA § 103 over Matsumura, Kroll, and General Knowledge of a

	POSA or Matsumura, Kroll, Ozguz, and General Knowledge of a POSA
<u>Ground 3</u>	Claims 32-35 are obvious under pre-AIA § 103 over Matsumura, Ozguz, Kroll, DeLuca, and General Knowledge of a POSA
<u>Ground 4</u>	Claims 2 and 3 are obvious under pre-AIA § 103 over Matsumura, Ozguz, Kroll, Harland, and General Knowledge of a POSA
<u>Ground 5</u>	Claim 39 is obvious under pre-AIA § 103 over Matsumura, Ozguz, Kroll, Thompson, and General Knowledge of a POSA

Sections VII.A-E 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-E. 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, 2, 4-6, 8, 10-15, 29, 31, 37, 38, and 43-45 are unpatentable under pre-AIA § 103 over Matsumura in view of Kroll and the General Knowledge of a POSA.

Ground 2: Claims 1, 2, 4, 5, 14, 15, and 43-45 are unpatentable under pre-AIA § 103 over Matsumura in view of Ozguz, Kroll, and the General Knowledge of a POSA.

Ground 3: Claims 32-35 are unpatentable under pre-AIA § 103 over Matsumura in view of Ozguz, Kroll, DeLuca, and the General Knowledge of a POSA.

Ground 4: Claims 2 and 3 are unpatentable under pre-AIA § 103 over Matsumura in view of Ozguz, Kroll, Harland, and the General Knowledge of a POSA.

Ground 5: Claim 39 is unpatentable under pre-AIA § 103 over Matsumura in view of Ozguz, Kroll, Thompson, and the General Knowledge of a POSA.

V. SUMMARY OF THE '007 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 daily use, these monitoring systems are designed to be both portable and discreet. *Id.* ¶¶ 23-24; Ex. 1001, 1:20-21 (“[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 cardiac health. Ex. 1009 ¶¶ 17-22; Ex. 1001, 1:15-18. 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 problem heart condition. *Id.* ¶¶ 19-21. An ECG measures the heart muscles’ polarization/depolarization cycle using electrodes, which are typically disposable and attached to a patient’s skin. *Id.* ¶ 20; Ex. 1001, 1:23-26 (“[s]ensors, such as ECG electrodes, are affixed to the patient’s body, such

as with tape”). Those electrodes are electrically connected by “leads,” which in turn connect to electronics capable of processing and displaying the ECG signals. Ex. 1009 ¶¶ 25-26; Ex. 1001, 1:25-26, 1:55-57.

In 1949, Dr. Norman 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 those with 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 for patients improved on the Holter monitor in several key ways. *Id.* ¶¶ 24-31. These wearable monitors were wireless, smaller, and lightweight. Ex. 1001, 1:29-32. These advances in wearable devices were in part attributable to smaller microcontrollers, increased computing power on board the patient-worn device, and improvements in wireless communication technologies. Ex. 1009 ¶¶ 25-31.

Wearable heart monitors are (and have been) designed with their patients—individuals with known or apparent heart conditions that may require future treatment—in mind. *Id.* ¶¶ 43-48. Engineers designing these devices understand

that such individuals are at heightened risk for, and may require treatment of, cardiac emergencies including defibrillation (*i.e.*, the application of a dose of electric current to “reset” the body’s natural pacemaker), while still wearing the device. *Id.* It was well understood that the voltage increase from defibrillation could potentially damage or destroy the electronics on the wearable heart monitor. *Id.* This is why regulatory bodies required “that medical grade monitor survive multiple defibrillation cycles of at least 360 joules.” *Id.* ¶¶ 31-42; Ex. 1001, 1:53-55. Multiple standards indicated that such circuit protection would be expected for body-worn ECGs of multiple types. And for wearable ECGs that included an arrhythmia alarm feature, the US FDA explicitly required some form of circuit protection that would survive defibrillation. Ex. 1009 ¶ 37.

A common solution in the field was to include “one or more power resistors situated in series with the wire leads of a fixed or portable physiological monitor.” Ex. 1001, 1:55-57. But these resistors are “too large for use in a compact monitor application.” *Id.* 1:57-59. This problem was well known in the field. Ex. 1009 ¶¶ 24, 47-48.

Multiple solutions to this problem existed, to ensure that the wearable monitor would be standard compliant and withstand multiple defibrillation cycles. For example, Dunseath (WO 1987/01024) described “replacing input resistor” “with a small[er], flat[ter] surface mount resistor soldered to input trace” “on top of circuit

board.” Ex. 1019, 25:24-26:12. Similarly, Rosenberg (U.S. Pat. No. 4,280,507) described making leads of “electrically conductive carbon loaded polymer” where the “distributed resistance of each polymer lead is sufficient to protect [an] EKG machine from defibrillation pulses.” Ex. 1018, 1:36-45. And, as discussed below, Kroll disclosed composing “lead strips” of a “flexible conductive ink compound” with a “preselected conductivity to provide a certain total lead strip resistance so that each lead strip 34 serves as a current limiter to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device.” Ex. 1013, 5:4-13.

Importantly, resistance in the traces on a body-worn physiological device has a twofold protective effect: It helps to protect the patient from shock from the device and it helps to protect the device from the effects of an outside shock. Ex. 1009 ¶ 47. This is because the electrical resistance operates to limit the flow of current in *either* direction (flowing from the device toward the patient, or from the patient’s skin toward the device). *Id.* Accordingly, including resistive traces on a body-worn ECG device would help manage overflow current flowing from the device toward the patient or from the patient’s body toward the device. *Id.*

B. Patent Description

The ’007 patent describes a known solution to the known problem outlined above. In particular, the ’007 patent is directed to a body-worn heart monitor that

uses “resistive traces” in the form of a “series current limiting resistor” to solve the above-described defibrillation problem. Ex. 1001, Abstract, cl. 1; Ex. 1009 ¶ 69. The specification explains that the “resistive traces” “replace the bulky power resistors needed by prior art monitors,” and are “configured to protect the communication-computation module” from “multiple defibrillation cycles.” Ex. 1001, 7:34-45, 19:44-48, 22:44-48.

The body-worn heart monitor includes disposable and reusable components. *Id.* cl. 1. The claimed monitor requires two major structural components: (1) a disposable module (110, shown in red) that makes 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.* Abstract, Fig. 1B, 2:23-45. The “communication-computation module” performs “real-time physiological analysis” and transmits the analysis to a remote radio receiver. *Id.* Abstract. The “resistive traces” (indicated in white in Figure 4A below) are placed on the disposable module between the electrical connections to the “communication-computation module” and the components that measure the “physiological signals.” *Id.* 7:34-39.

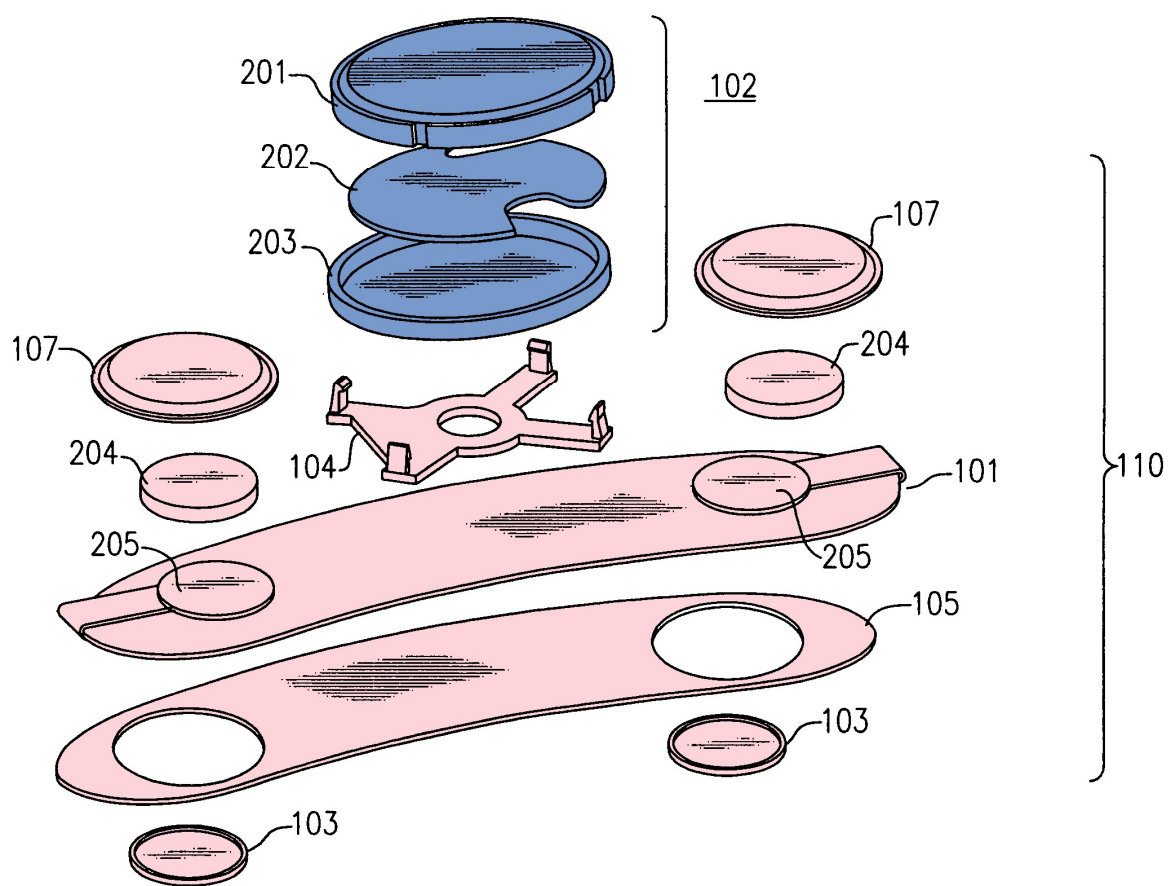


FIG.2

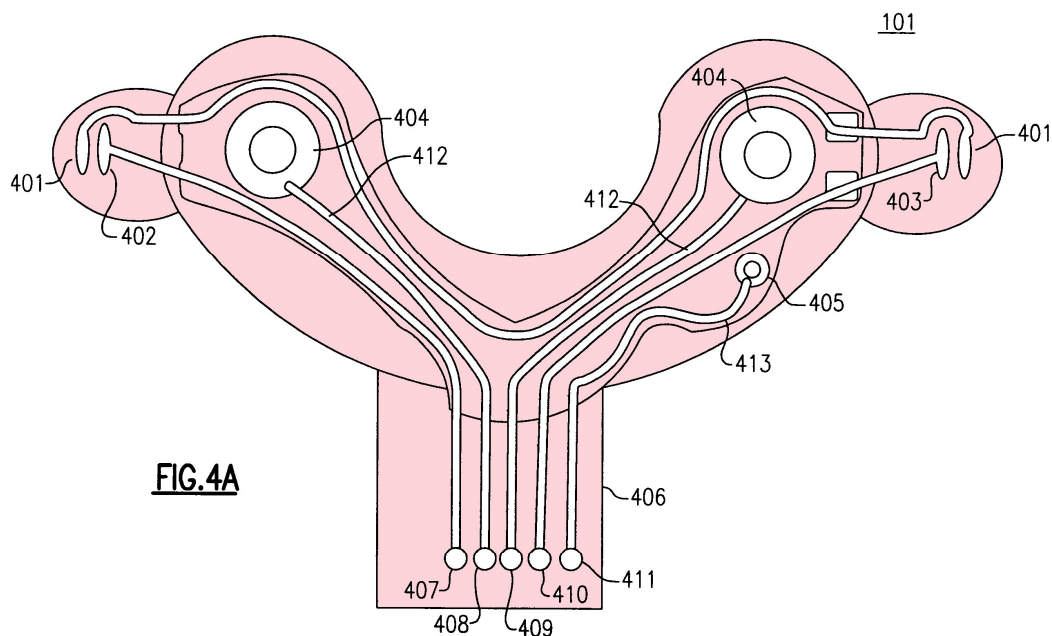


FIG. 4A

Id. Figs. 2, 4a (annotated).

These recitations of individual components are immaterial to novelty or non-obviousness because the purportedly inventive aspect of the '007 patent is narrow: As explained below, the Examiner noted that all but the “resistive traces” element were known and disclosed in the prior art. And this finding comports with the Applicant’s own characterization of its invention during prosecution. Put differently, both Examiner and Applicant agreed that, other than the resistive traces, the '007 patent’s claimed elements were conventional and well-known to POSAs in the field of body-worn physiological monitors.

C. Priority Date

The application that matured into the '007 patent was filed on November 1, 2006. For purposes of this proceeding only, Petitioner does not dispute that the priority date is November 1, 2006.

D. Prosecution History

The application that became the '007 patent was allowed after the claims were amended to recite “at least one series current-limiting resistor being in the form of resistive traces.” Response to Final Office Action 3, 14 (Mar. 2, 2011), Ex. 1002, 134, 145. The Examiner found that all other claim elements were disclosed by U.S. Pat. Pub. No. 2005/0245839 (“Stivoric”), U.S. Pat. Pub. No. 2007/0270678 (“Fadem”), U.S. Pat. Pub. No. 2002/0106709 (“Potts”), U.S. Pat. Pub. No. 2005/0206518 (“Welch”), and U.S. Pat. No. 6,623,312 (“Merry”).

The Notice of Allowance explained that the “closest [examined] prior art . . . fails to disclose the claimed invention, neither in combination nor alone, since neither reference discloses a body worn patient monitoring device comprising a disposable module including at least one series current-limiting resistor being in the form of *resistive traces*.” Notice of Allowance, Detailed Action 2-3 (Mar. 12, 2012), Ex. 1002, 21-22 (emphasis added).

However, as shown above and below, the use of resistive traces in body-worn patient monitoring devices was well-known in the art.

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

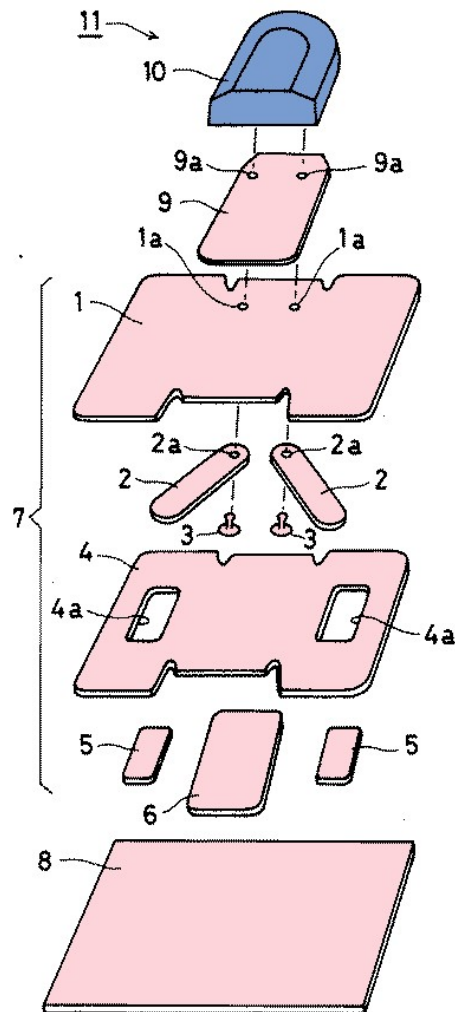
A. Matsumura (Ex. 1012)

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 '007 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 [shown in red, below] for detecting bioelectric potentials, and a reusable signal processor [shown in blue, below] for processing the bioelectric potential signals detected by the bioelectrode pad,” *id.* ¶ [0007], Fig. 1. In particular, 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.” *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], [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. ¶ [0025].



Id. Fig. 1 (annotated).

B. 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 '007 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 metalized 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 55 by an anisotropic epoxy layer.” *Id.*

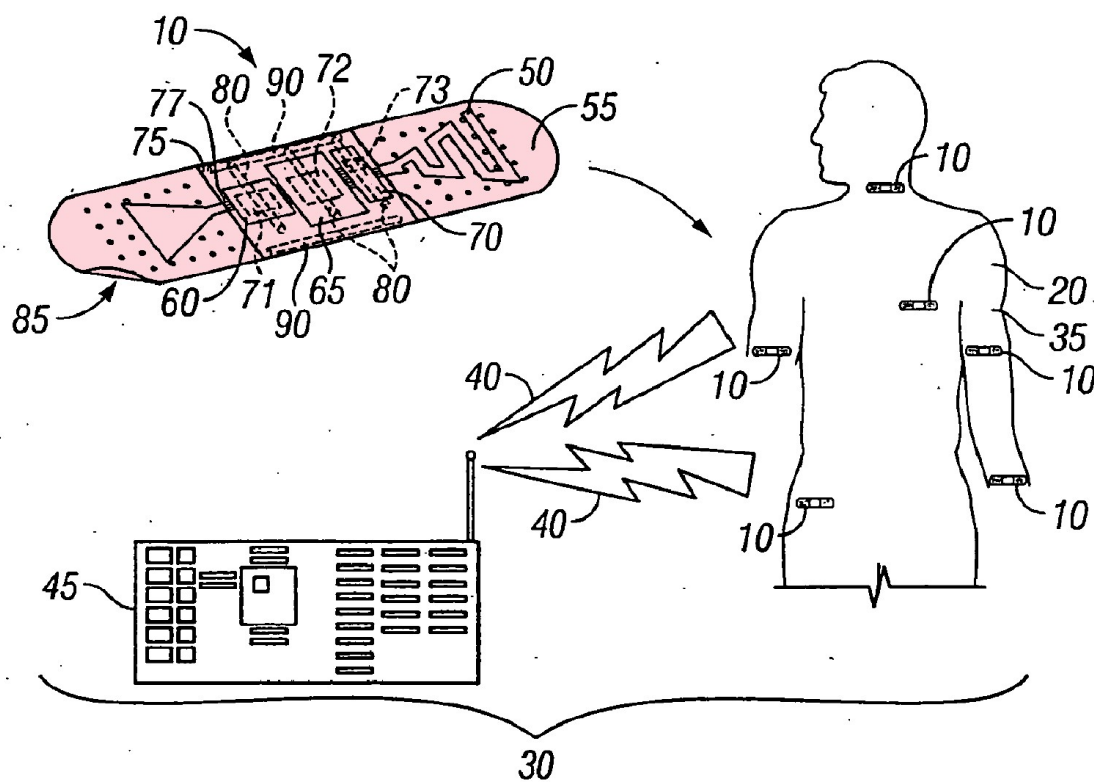


FIG. 2A

Id. Fig. 2A (annotated).

C. Kroll (Ex. 1013)

Kroll issued on August 16, 1988 as U.S. Patent No. 4,763,660. Kroll is prior art under pre-AIA 35 U.S.C. § 102(b). Kroll was neither cited nor considered during prosecution of the '007 patent. Kroll is directed to “a disposable, flexible and layered electrode belt . . . for placement and use on the body of a patient,” and may be configured to “place electrodes at standard EKG limb electrode locations.” Ex. 1013, 1:11-15, 1:59-61; *see also* Ex. 1009 ¶¶ 175-79.

Kroll discloses a “flexible and disposable electrode belt” to be worn by a patient undergoing physiological monitoring. Ex. 1013, Abstract. Kroll teaches using lead strips to transmit electrical signals from electrodes. *Id.* 5:1-4. The lead strips may be made of a “flexible conductive ink compound having a conductive filler having Silver, Aluminum, or compounds thereof, or of a similarly suitable material.” *Id.* 5:4-8. The ink deposits forming the lead strips may be of a “preselected conductivity to provide a certain total lead strip resistance so that each strip 34 serves as a current limiter to protect a patient from shock due to malfunction of the device...or of a complementary medical device.” *Id.* 5:8-13.

D. DeLuca (Ex. 1015)

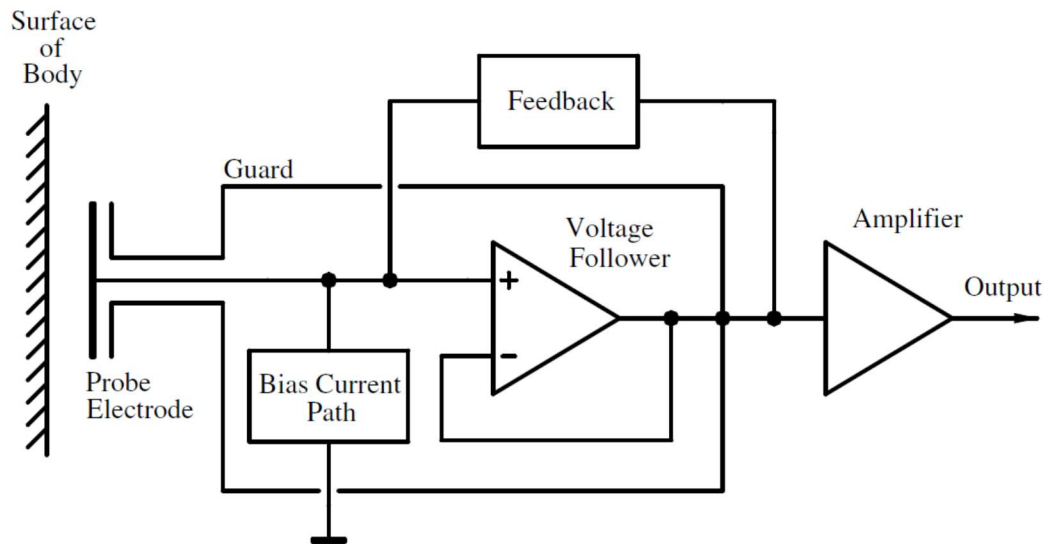
DeLuca issued on May 29, 2001 as U.S. Patent No. 6,238,338. DeLuca is prior art under pre-AIA 35 U.S.C. § 102(b). DeLuca was neither cited nor considered during prosecution of the '007 patent. DeLuca discloses “a biosignal monitoring system including a plurality of sensors for disposition in predetermined positions on the body of a test subject.” Ex. 1015, 1:33-35. DeLuca’s disclosed detector includes “contact surfaces shaped and arranged to detect a particular biosignal generated in the body, a sensor transceiver, a sensor antenna, a voltage supply, and a microprocessor.” *Id.* 1:36-40.

DeLuca discloses that incoming biosignals are subjected to a “signal conditioning stage 56” which “includes a hi-pass filter 56*a*, an amplifier 56*b*, a lo-

pass filter 56c, and an anti-aliasing filter 56d.” *Id.* 5:1-4; *see also id.* Figs. 5, 7. This signal conditioning process takes place on the “microprocessor chip 35 having an Application Specific Integrated Circuit (ASIC) portion 36.” *Id.* 3:36-37, Figs. 5, 7. DeLuca further explains that “[b]ecause of the wide selection range of these [gain and band-pass filters’ cut-off frequency] parameters, the gain and bandwidth of any biosignal can be optimized for a given application.” *Id.* 5:43-48.

E. Harland (Ex. 1016).

Harland was published in the journal *Measurement Science and Technology* in 2002. Harland is therefore prior art under pre-AIA 35 U.S.C. § 102(b). Harland was neither cited nor considered during prosecution of the ’007 patent. Harland reports the development and use of “a new class of sensor—the ultra-high impedance electric potential sensor” as an “alternative” to “traditional contact electrodes (for ECGs and EEGs).” Ex. 1016, 164. Harland’s ultra-high impedance electric potential sensors “allow the remote (non-contact) detection of electric potentials generated by currents flowing in the body.” *Id.* According to Harland, in the “remote, off-body detection” application, these electrodes “form capacitive coupling to the body under measurement.” *Id.*; *see also id.* Fig. 1:



F. Thompson (Ex. 1017)

Thompson issued on April 24, 2001 as U.S. Patent No. 6,223,080. Thompson is prior art under 35 U.S.C. § 102(b). Thompson was neither cited nor considered during prosecution of the '007 patent. Thompson claims “solutions to one or more problems existing in the prior art respecting circuitry design having lower power consumption, particularly with respect to implantable medical devices,” such as pacemakers. Ex. 1017, 3:33-36. Thompson’s invention relates more particularly to “the use of multiple digital signal processors in . . . circuit designs to reduce power consumption.” *Id.* 1:20-23.

In a particular embodiment, Thompson discloses a processor that operates in a “high speed processing mode” “[o]nly during a QRS complex” of the cardiac cycle; “[d]uring the remainder of the cardiac cycle the [waveform] processor [] may be ‘idling along’ at a much lower clock frequency.” *Id.* 18:3-14. Thompson observes

that by idling the processor during some interval of the heartbeat, “the objective of reduced power consumption is realized.” *Id.*

VII. THE CHALLENGED CLAIMS OF THE '007 PATENT ARE UNPATENTABLE OVER THE PRIOR ART

A. Ground 1: Claims 1, 2, 4-6, 8, 10-15, 29, 31, 37, 38, and 43-45 are Obvious Over Matsumura, Kroll, and General Knowledge of a POSA

1. A POSA would have combined Matsumura and Kroll

Matsumura and Kroll teach wearable devices for monitoring physiological signals, including ECG or EKG signals. Ex. 1012 ¶¶ [0024], [0031], Fig. 2; Ex. 1013, 1:11-15, 1:37-45, 1:60. Both references teach that the wearable device is flexible, where such teaching is explicit in Kroll, and Matsumura teaches that its “bioelectrode pad” should be composed of sheets comprising “polyethylene foam, polyurethane foam, or polyurethane sheet,” Ex. 1012 ¶¶ [0017]-[0018], [0022], which a POSA would recognize are “flexible materials.” Ex. 1009 ¶ 465.

A POSA would look to incorporate the “resistive trace” of Kroll into Matsumura’s bioelectric potential detector. *Id.* ¶ 467. Matsumura teaches a “bioelectric potential detector 11,” which “can be used as an electrocardiogram detector that is worn on the subject’s chest to detect electrocardiogram signals,” Ex. 1012 ¶ [0024], and which “determines whether the detected electrocardiogram of the subject (patient) is abnormal, such as an arrhythmia or an abnormal heart rate,” *id.* ¶ [0037]. Matsumura specifically notes that the system “wirelessly transmits the

bioelectric potential detected . . . to inform medical staff or family members of the bioelectric potential information, so that they can quickly **treat and cope with a sudden change in condition....**” *Id.* ¶ [0041] (emphasis added). To help protect patients from potential shock, ensure the long-term viability of Matsumura’s reusable module against potential defibrillation, and reduce the size of Matsumura’s device, a POSA would have been motivated to incorporate Kroll’s teaching of resistive “lead strips” to protect the circuitry in Matsumura. Ex. 1009 ¶¶ 467-470.

A POSA combining these teachings of Matsumura and Kroll would have had a reasonable expectation of success in doing so because it would involve using well known screen-printing techniques for printed circuit board manufacture. *Id.* ¶ 471. A POSA would know how to achieve this combination with minimal design impact. *Id.* Nothing in the art suggests that the proposed combination would not work. *Id.*

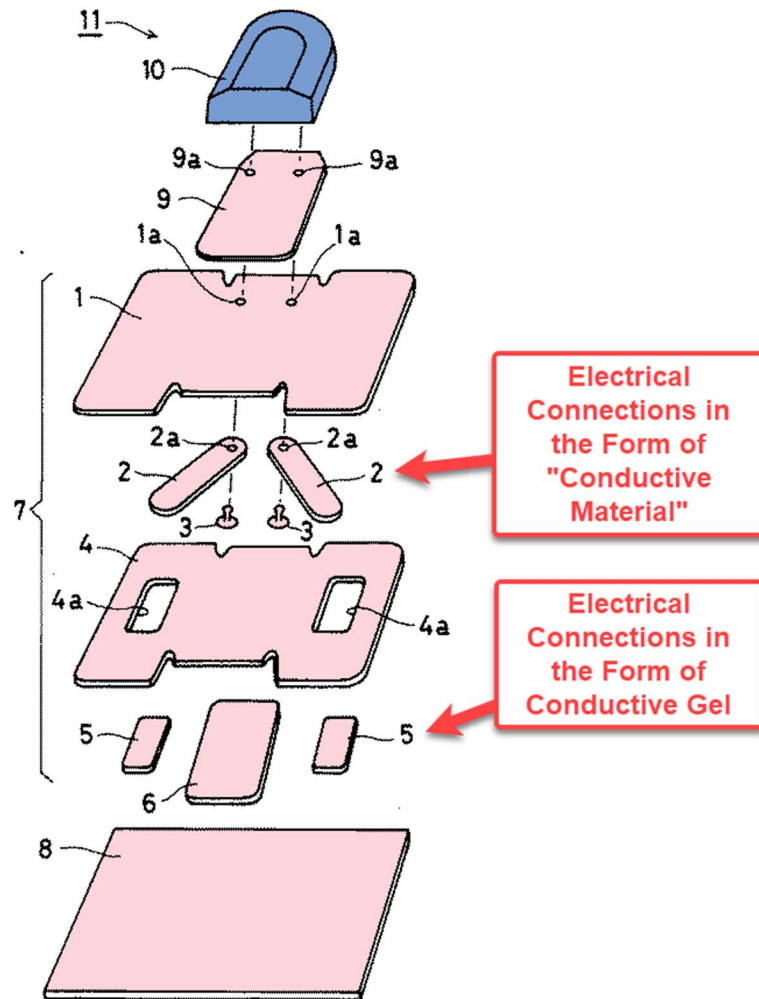
2. Claim 1

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

Matsumura discloses a body-worn patient monitoring device which it refers to as a “bioelectric potential detector.” Ex. 1012, Abstract, [0006], [0014]. Kroll also discloses a body worn patient monitoring device. Ex. 1013, 1:11-15; Ex. 1009 ¶¶ 474-475.

ii. [1a] a disposable module including a plurality of electrical connections,

Matsumura discloses limitation [1a]. The “bioelectric potential detector” of Matsumura comprises a “disposable bioelectrode pad” that includes a plurality of electrical connections. Ex. 1012 ¶¶ [0007]-[0008], [0014], [0016], Figs. 1-2. “[T]wo pieces of ‘conductive material 2’” form electrical connections—through the interface between holes (2a) and hooks (3)—to the signal processor, as shown in the below figure. *Id.* ¶ [0019]. Another two pieces of “conductive gel 5,” shown in the below figure, detect bioelectric potentials and form electrical connections with the patient’s skin. *Id.*; Ex. 1009 ¶¶ 477-478.



Ex. 1012, Fig. 1 (annotated).

iii. [1b] said electrical connections adapted to be couplable to a skin surface to measure physiological signals,

Matsumura discloses limitation [1b]. Among its plurality of electrical connections, Matsumura discloses “conductive gel 5” which transmits “bioelectric potentials detected” at the skin surface and “conductive material 2” that transmit this detected bioelectric potential to the signal processor. *Id.* ¶¶ [0018]-[0019].

The “conductive gel 5” is inserted through “two openings 4a on the left and right sides” of the second sheet. *Id.* ¶ [0018]. An “adhesive, such as acrylic adhesive

for example, is applied to the back surface of the second sheet 4.” *Id.* “When attaching the bioelectric potential detector to a patient . . . the release tape 8 is peeled off from the bioelectric pad 7 and the detector is attached to the subject.” *Id.* ¶ [0024]. Peeling off release tape 8 exposes the bottom of bioelectric pad 7, which is second sheet 4, and allows the adhesive layer to adhere the bioelectric pad to skin. *See also id.* ¶ [0022] (describing option to make the second sheet 4 “less adhesive to the living body” by covering the center with optional third sheet 6). Because the conductive gel 5 is embedded in second sheet 4, conductive gel 5 is “couplable to a skin surface” to measure physiological signals. Ex. 1009 ¶¶ 479-482. A POSA would understand this allows the conductive gel 5 to detect “bioelectric potentials” for transmission “through the conductive material 2 and the hooks 3.” *Id.*; Ex. 1012 ¶ [0019].

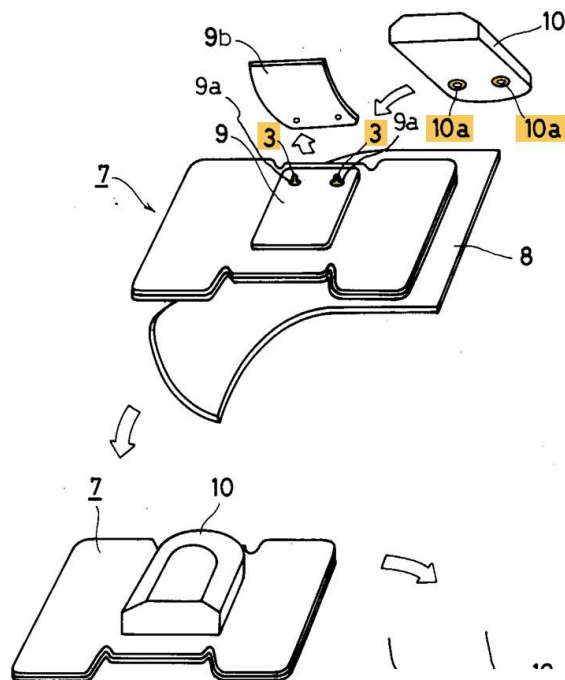
iv. [1c] at least one of said electrical connections comprising a half cell,

Matsumura discloses limitation [1c]. Matsumura teaches that “conductive gel” may be produced from components such as an “acrylic hydrophilic polymer, glycerin, and water.” Ex. 1012 ¶ [0018]. The conductive gel contacts “conductive material 2,” which may be “coated with conductive Ag/AgCl.” *Id.* ¶¶ [0019]-[0020]. A POSA would understand that conductive gels comprising an acrylic hydrophilic polymer, glycerin, and water, and contacting a silver/silver-chloride conductive surface comprise a “half cell,” a term that the ’007 patent describes as a combination

of an “electrode gel” and a “conductive surface.” Ex. 1009 ¶¶ 483-486. Accordingly, a POSA would know that Matsumura’s conductive gels form electrical connections comprising half cells at the point of contact with the patient’s skin. *Id.*

v. [1d] the disposable module including a disposable module connector;

Matsumura discloses limitation [1d]. Matsumura’s disposable bioelectrode pad includes “two hooks 3” that connect to “hook engagement portion 10a on the bottom surface of the signal processor” (shown in the below image), thus forming a mechanical and electrical connection between Matsumura’s disposable module (*i.e.*, disposable bioelectrode pad 7) and Matsumura’s communication-computation module (*i.e.*, signal processor 10). Ex. 1012 ¶¶ [0019], [0024], Fig. 2; Ex. 1009 ¶¶ 488-489.



Ex. 1012, Fig. 2 (annotated).

vi. [1e] a power source to power the body worn patient monitoring device;

The teachings of Matsumura, as understood by a POSA, render this limitation obvious. Matsumura discloses a monitor that transmits the “processed bioelectric potential signal . . . wirelessly.” *E.g., id.* ¶ [0025]. As Matsumura explains, prior art wireless monitors included “a power source.” *Id.* ¶ [0004] (prior art device comprising “conduction portion (equivalent to an electrode element), a power source, a potential difference detection portion, and a wireless transmitting/receiving portion”). A POSA would have understood Matsumura’s device to include an onboard power source to allow for wireless transmissions. Ex. 1009 ¶ 492. The device would otherwise be inoperable. *Id.* It would, therefore, be obvious to a POSA to interpret Matsumura’s disclosure as implicitly requiring “a power source to power the body worn patient monitoring device.” *Id.* ¶¶ 490-493.

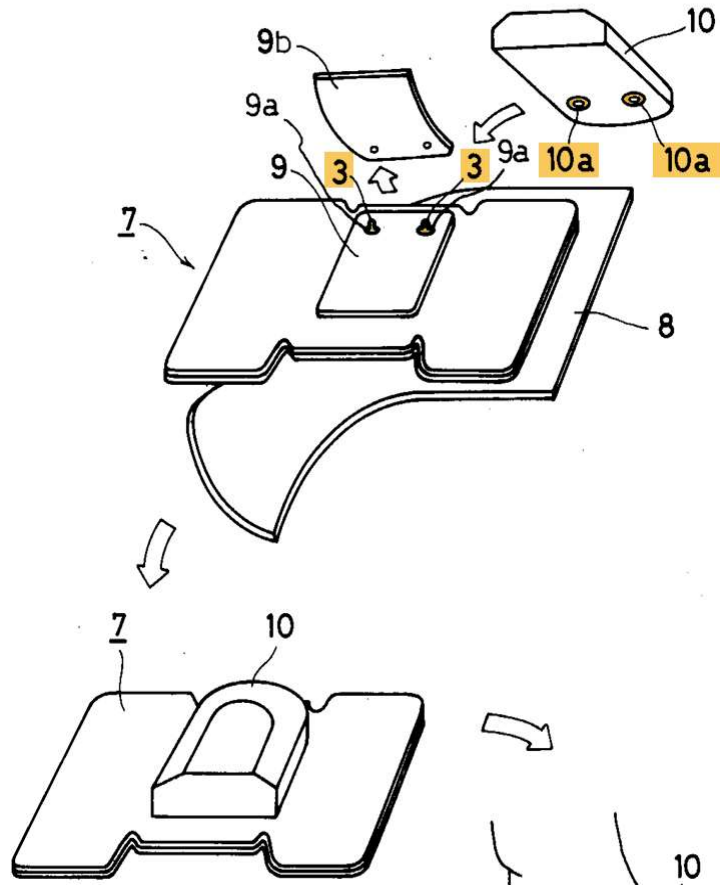
vii. [1f] a communication-computation module being removable and reusable,

Matsumura discloses limitation [1f]. Matsumura discloses a “reusable signal processor” which is “detachable with hooks.” Ex. 1012 ¶ [0016]; *see also id.* ¶¶ [0008], [0014], [0025], Figs. 1-2. The reusable signal processor incorporates components for communication: “a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna.” *Id.* ¶ [0025]. The reusable signal processor also 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.* Thus, Matsumura discloses a removable, reusable, “communication-computation module.” Ex. 1009 ¶¶ 495-496.

viii. [1g] having a communication-computation module connector to receive physiological signals from the disposable module via said disposable module connector, the communication-computation module including:

Matsumura discloses limitation [1g]. As explained with reference to Limitation [1d], *supra*, Matsumura discloses “hooks 3”, which connect to “hook engagement portion 10a on the bottom surface of the signal processor” (shown in the below figure), thus forming a mechanical and electrical connection between Matsumura’s disposable module (*i.e.*, disposable bioelectrode pad 7) and Matsumura’s communication-computation module (*i.e.*, signal processor 10). Ex. 1012 ¶ [0024]; *see also id.* ¶¶ [0008], [0014]. As Matsumura explains, “the bioelectric potentials detected by the conductive gel 5 are transmitted through the conductive material 2 and the hooks 3.” *Id.* ¶ [0019]. Matsumura’s “hook engagement portions” therefore disclose a communication-computation module connector that receive physiological signals from the disposable module connector. Ex. 1009 ¶¶ 498-499.



Ex. 1012, Fig. 2 (annotated).

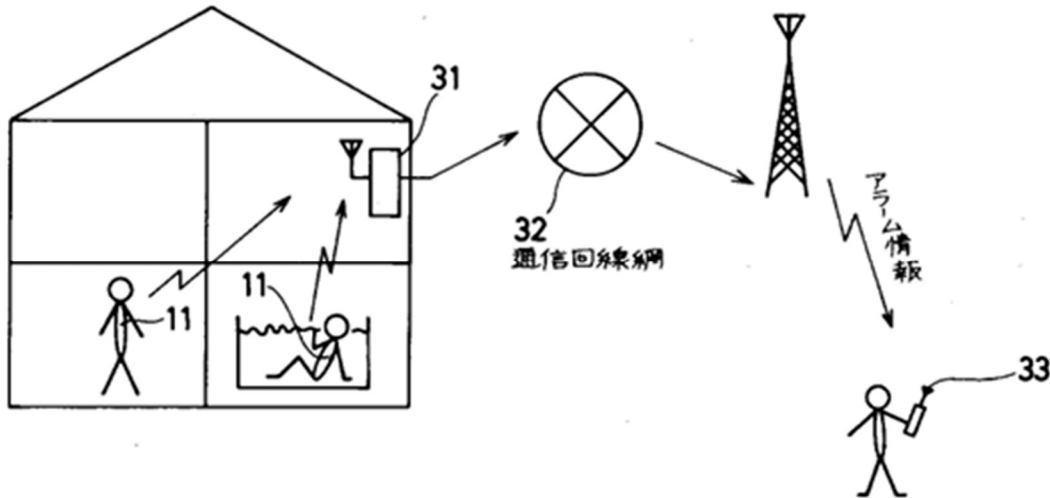
- ix. [1h] a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the occurrence of a predetermined physiological event; and**

Matsumura discloses a signal processor “for filtering and amplifying detected bioelectric potential signals.” *Id.* ¶ [0025]. Matsumura further discloses that its signal processor may “determine[] whether or not the detected electrocardiogram of the subject (patient) is in an abnormal state, such as an arrhythmia or an abnormal heart rate.” *Id.* ¶ [0032]; *see also id.* ¶ [0037]. Thus, Matsumura specifically teaches a communication-computation module capable of actively monitoring the patient

and performing a real-time physiological analysis of the occurrence of a predetermined physiological (*e.g.*, cardiac) event. Ex. 1009 ¶¶ 501-502.

- x. ***[1i] a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event, via a radio transmission to a remote radio receiver,***

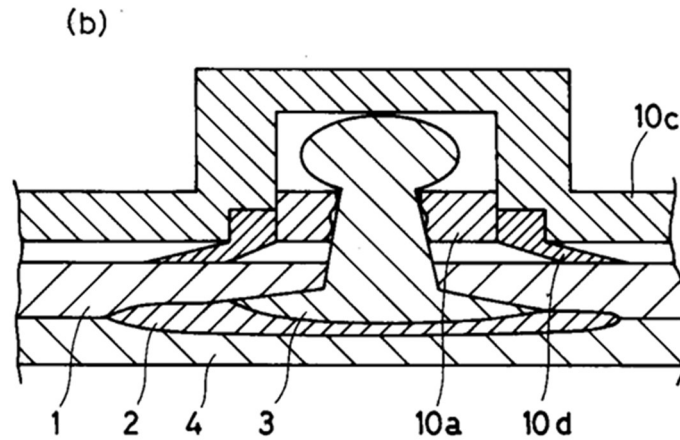
Matsumura discloses a communication-computation module (signal processor) that includes a “circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna.” Ex. 1012 ¶ [0025]. Matsumura further discloses that if an arrhythmia or abnormal heart rate is detected, “alarm information is sent to the portable terminal 33.” *Id.* ¶ [0037]. As shown in Figure 7 below, the “electrocardiogram signals received by the receiver 31 are transmitted via a communication line 32 to a portable terminal 33 carried by family members or medical staff.” *Id.* ¶ [0036]. Matsumura therefore teaches a communication-computation module with a circuit to wirelessly communicate (*e.g.*, using radio), upon determination of the predetermined physiological event (*e.g.*, arrhythmia, abnormal heart rate), a result of the physiological analysis on the occurrence of the predetermined physiological event to a remote receiver in the portable terminal 33. *Id.*; Ex. 1009 ¶¶ 504-506.



Ex. 1012, Fig. 7.

- xi. [1j] wherein the disposable module is mechanically and electrically coupled directly to the communication-computation module,*

Matsumura discloses limitation [1j]. As shown at least in Figure 5(b), Matsumura's disposable module (*i.e.*, the bioelectrode pad) is mechanically and electrically coupled directly to the communication-computation module (*i.e.*, the signal processor) by the engagement of the “hooks 3” on the bioelectrode pad, which engage with “hook engagement portion 10a on the bottom surface of the signal processor 10.” *Id.* ¶ [0024], Fig. 2. This coupling is reinforced by “adhesive tape 9” that ensures that the components remain in contact throughout use. *Id.* “Adhesive tape 9” includes holes 9a through which “hooks 3” are inserted to directly contact reusable “signal processor 10.” *Id.* ¶ [0024]. Thus, Matsumura discloses this limitation. Ex. 1009 ¶ 508.



Ex. 1012, Fig. 5(b).

- xii. [1k] and the body worn patient monitoring device including the disposable module and the communication-computation module is adapted to be directly non-permanently affixed to the skin surface of the patient; and*

Matsumura discloses that limitation [1k]. Matsumura discloses a method for “attaching the bioelectric potential detector to a patient” so that it “can be used as an electrocardiogram detector that is worn on the subject’s chest to detect electrocardiogram signals.” *Id.* ¶ [0024], Fig. 2. Matsumura further teaches that a third sheet may be provided “to make it easier to use the bioelectrode pad 7 in terms of attaching it to and detaching it from the biometric surface [*i.e.*, the skin] by making the center of the back surface of the second sheet 4 less adhesive to the living body.” *Id.* ¶ [0022]. Because the pad may be attached and detached, Matsumura device is adapted to be “directly non-permanently affixed to the skin surface of the patient.” Ex. 1009 ¶ 510.

xiii. [11] at least one series current-limiting resistor configured to protect the communication-computation module,

The combination of Matsumura and Kroll renders this limitation obvious. As noted above, a POSA would have looked to combine the “resistive traces” of Kroll with the bioelectric potential detector of Matsumura. *See supra* § VII.A.1.

Kroll discloses at least one series current-limiting resistor. In particular, Kroll teaches circuits composed of a “flexible conductive ink compound having a conductive filler having Silver, Aluminum, or compounds thereof, or of a similarly suitable material. Preferably, the ink deposit is of a preselected conductivity to provide a certain total lead strip resistance so that each strip [] serves as a current limiter to protect a patient from shock due to malfunction of the device [] or of a complementary medical device.” Ex. 1013, 5:4-13.

As explained in Section VII.A.1, *supra*, a POSA would have known that the “resistive trace” of Kroll on a flexible, wearable medium would ensure the viability of Matsumura’s communication-computation module on a flexible printed medium in the event of a patient being defibrillated. The background section of the ’007 patent also acknowledges that there were existing medical standards requiring that “a medical grade monitor survive multiple defibrillation cycles of at least 360 joules.” Ex. 1001, 1:53-55, 10:19-29. A POSA would understand this to mean that the device was required to have resistors that protect the communication-

computation module during a defibrillation shock, which is typically 360 Joules. Ex. 1009 ¶¶ 511-516. It would have been obvious to a POSA to use the resistive traces taught by Kroll in Matsumura’s device, which would meet limitation 11. *Id.*

***xiv. [1m] the at least one series current-limiting resistor
being screened onto a flexible substrate,***

The combination of Matsumura and Kroll renders this limitation obvious. As noted above, a POSA would have looked to combine the “resistive traces” of Kroll with the bioelectric potential detector of Matsumura. *See supra* § VII.A.1. Matsumura teaches that its “bioelectrode pad” should be composed of sheets comprising “polyethylene foam, polyurethane foam, or polyurethane sheet,” Ex. 1012 ¶¶ [0017]-[0018], [0022], which a POSA would recognize are “flexible materials.” Ex. 1009 ¶ 518. It would have been obvious to a POSA that Matsumura’s flexible substrate includes electrical connections (*i.e.*, traces). *Id.* ¶ 519. And Kroll discloses that the “conductive ink compound” that comprises its resistive trace is applied to a base layer “by means of a silk screen process.” Ex. 1013, 5:23-27, 37-42. It therefore would have been obvious to a POSA to combine Matsumura’s teaching of a communication-computation module on a flexible printed medium with Kroll’s teaching of resistive traces screened on a flexible, wearable medium, which would meet this limitation. Ex. 1009 ¶¶ 517-520.

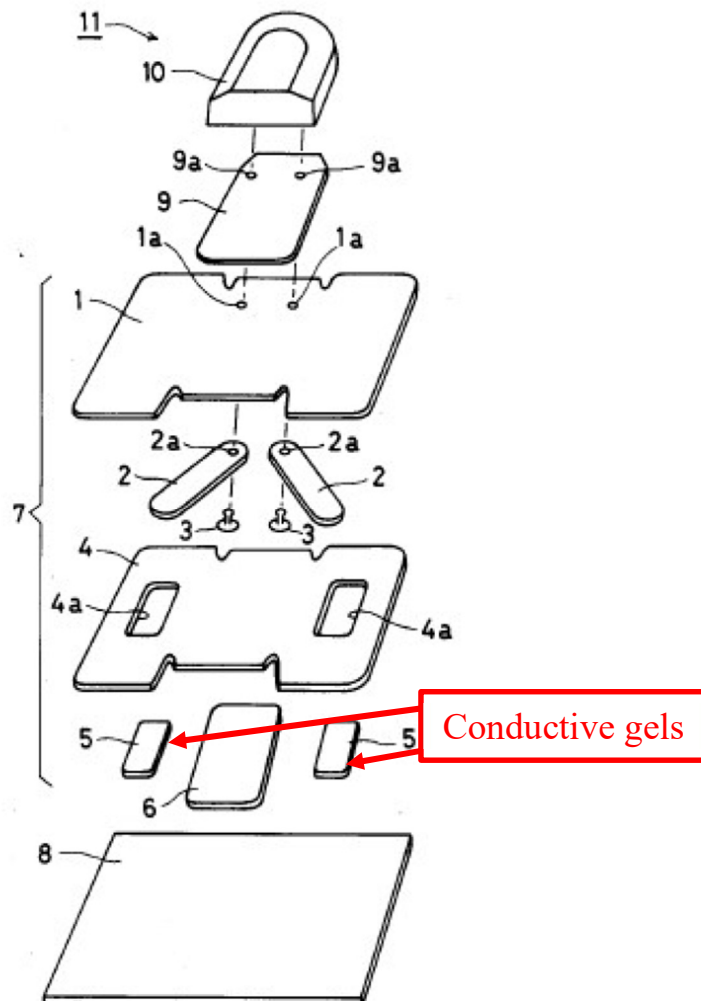
**xv. [1n] the at least one series current-limiting resistor
being in the form of resistive traces.**

The combination of Matsumura and Kroll renders this limitation obvious. Specifically, Kroll teaches circuits composed of a “flexible conductive ink compound having a conductive filler having Silver, Aluminum, or compounds thereof, or of a similarly suitable material. Preferably, the ink deposit is of a preselected conductivity to provide a certain total lead strip *resistance* so that each strip 34 serves as a current limiter to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device.” Ex. 1013, 5:4-13 (emphasis added). Kroll therefore teaches printed ink leads, which a POSA would have understood as traces, having a specific resistance, *i.e.*, “resistive traces.” *Id.*; Ex. 1009 ¶¶ 523-525. It therefore would have been obvious to a POSA to combine Matsumura’s teaching of a communication-computation module on a flexible printed medium with Kroll’s teaching of resistive traces on flexible printed mediums, which would meet this limitation. Ex. 1009 ¶ 525.

3. Claim 2

In addition to teaching every limitation of claim 1, Matsumura and Kroll teach that “the plurality of electrical connections to the body comprise at least one of direct electrical connections to the body and indirect electrical connections to the body.” Specifically, after release tape 8 is removed, bioelectrode pad 7 of Matsumura is placed on the patient’s skin. *Id.* ¶¶ 526-528; Ex. 1012 ¶¶ [0007]-[0008], [0014],

[0016]; Figs. 1-2. The conductive gels 5 of the bioelectric pad 7 create direct electrical connections to the body. Ex. 1009 ¶¶ 528-529.



Ex. 1012, Fig. 1 (annotated).

Similarly, Kroll teaches that “[c]onductive gel pads 29 are provided as conductive interfaces between the conductive grids 56 and a patient’s skin” (Ex. 1013, 5:53-55), meaning that conductive grids 56 are in direct electrical connection with the body. Ex. 1009 ¶ 528.

4. Claim 4

In addition to teaching every limitation of claim 1, Matsumura and Kroll teach that “the body worn patient monitoring device comprises an ECG monitor and at least two of the electrical connections are ECG electrodes.” Matsumura teaches a “bioelectric potential detector 11 can be used as an electrocardiogram detector that is worn on the subject's chest to detect electrocardiogram signals” using conductive gels 5. Ex. 1012 ¶¶ [0018], [0024]. Thus, Matsumura discloses this limitation. Ex. 1009 ¶¶ 533-534.

5. Claim 5

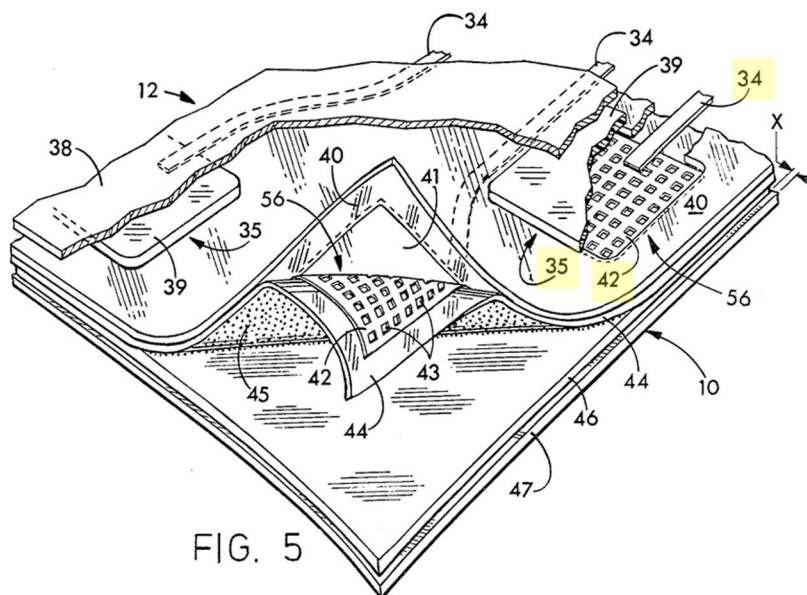
In addition to teaching every limitation of claims 1 and 4, Matsumura and Kroll teach that “the ECG electrodes comprise a material screened onto the flexible substrate,” as recited in claim 5. Matsumura teaches that its “bioelectrode pad” should be composed of sheets comprising “polyethylene foam, polyurethane foam, or polyurethane sheet,” *id.* ¶¶ [0017]-[0018], [0022], which a POSA would recognize are “flexible materials.” Ex. 1009 ¶ 537. Kroll teaches that “each electrode 35 has a conductive grid . . . applied to an insulation and base support layer 44 preferably by means of a silk screen process.” Ex. 1013 at 5:23-29. A POSA would have known to use the “silk screen process” of Kroll to attach “electrodes 35” to “bioelectrode pad” of Matsumura. Ex. 1009 ¶¶ 537-539.

6. *Claim 6*

In addition to teaching every limitation of claims 1, 4, and 5, Matsumura and Kroll teach that the “at least one series current-limiting resistor protects the communication-computation module during a patient defibrillation event.” Matsumura teaches a “communication-computation module”—a circuit for wirelessly transmitting a bioelectric potential signal and for processing, such as “filtering and amplifying,” the bioelectric potential signal. Ex. 1012 ¶ [0025]. Kroll discloses using ink deposits to “provide a certain total lead strip resistance so that each strip 34 serves as a current limiter to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device.” Ex. 1013, 5:8-13. A POSA would understand that the same ink deposits that protect the patient from shock will also at the same time protect the monitoring device from a defibrillation event. Ex. 1009 ¶ 544 (citing Ex. 2018). The background section of the '007 patent also acknowledges that there were existing medical standards that require that “a medical grade monitor survive multiple defibrillation cycles of at least 360 joules.” Ex. 1001, 1:53-55, 10:19-29. A POSA would understand this to mean that the device was required to have resistors that protect the communication-computation module during a monophasic defibrillation shock, which is typically 360 Joules. Ex. 1009 ¶¶ 544-546.

7. **Claim 8**

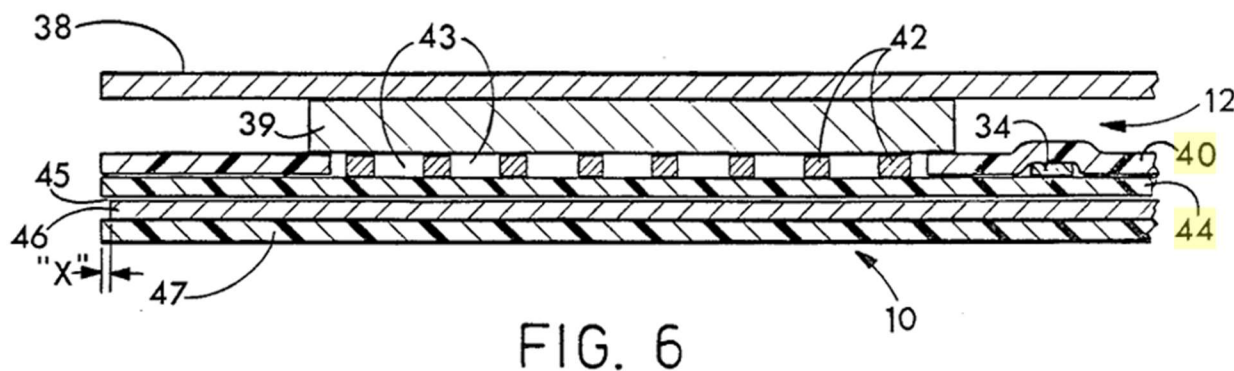
In addition to teaching every limitation of claims 1 and 4, Matsumura and Kroll teach that “the mechanical interface from the at least one series current-limiting resistor to the ECG electrode comprises overlapped layers.” Kroll discloses “at least one series current limiting resistor.” *Supra*, § VII.A.2.xiii. As shown in the annotated figure below, Kroll further teaches that lead strip 34 (current-limiting resistor) extends from and overlaps electrode 35 that includes a matrix 42 composed of a conductive ink compound. Ex. 1013, 5:17-19, 23-27. “The conductive ink compound used in the matrix lines 42 is **generally** the same as that utilized in the lead strips 34.” *Id.* 5:31-33 (emphasis added). A POSA would have understood matrix lines 42 and lead strip 34 as overlapping layers that can be made of either the same or different materials. Ex. 1009 ¶¶ 551-552.



Ex. 1013, Fig. 5 (annotated).

8. Claim 10

In addition to teaching every limitation of claim 1, Matsumura and Kroll teach that “an insulating material overlaying the at least one series current limiting resistor to prevent arcing,” as recited in claim 10. Kroll discloses the claimed “at least one series current limiting resistor.” *Supra*, § VII.A.2.xiii. As shown in the below annotated figure, Kroll teaches that lead strip 34 (current-limiting resistor) is lined with insulation base support layer 44 and inner patient insulation layer 40. Ex. 1013, 5:44-50. Both layers 44 and 40 are made of a polyester laminate, which a POSA would understand to have the necessary resistance to prevent lead strip 34 from arcing. Ex. 1009 ¶¶ 555-557.



Ex. 1013, Fig. 6 (annotated).

9. Claim 11

In addition to teaching every limitation of claims 1, 4, and 5, Matsumura and Kroll teach that “the EGG electrodes are formed substantially in the shape of an annulus.” The specification of the ’007 patent defines the term “annulus” as “the

region between two simple curves.” Ex. 1001, 6:62-63. “Under this definition, an annulus can include...substantially rectangular shapes with rounded corners.” *Id.* 6:64-7:1. As noted above, Section VII.A.2.ii, the two conductive gels 5 of Matsumura are ECG electrodes. Ex. 1012 ¶ [0019]. Conductive gels 5 are substantially rectangular shapes with rounded corners, as shown in Figure 1 of Matsumura, and are therefore formed substantially in the shape of an annulus. Ex. 1009 ¶¶ 560-561.



Ex. 1012. Fig. 1 (annotated).

10. Claim 12

In addition to teaching every limitation of claims 1 4, 5, and 11, Matsumura and Kroll teach that “the annulus comprises a conductive link.” As noted above Section VII.A.9, conductive gels 5 of Matsumura are formed substantially in the shape of an annulus. Conductive gels 5 detect bioelectric potentials and transmit them through a portion of conductive material 2 (conductive link) that contacts the annulus formed by conductive gel 5. Ex. 1012 ¶ [0019]. Thus, Matsumura and Kroll disclose this limitation. Ex. 1009 ¶¶ 564-565.

11. Claim 13

In addition to teaching every limitation of claims 1, 4, and 5, Matsumura and Kroll teach that “the substrate is shaped to allow placement on the patient to monitor at least one of a set of standard ECG vectors while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal.” Matsumura teaches that “bioelectric potential detector 11 can be used as an electrocardiogram detector that is worn on the subject's chest to detect electrocardiogram signals.” Ex. 1012 ¶ [0024]. Kroll describes that the “disposable electrode belt” attached to the patient’s body has a “predetermined contact area[] . . . placed in the body structure to form a generally curvilinear pattern whereby said contact areas conform with standard precordial positions for ‘twelve-lead’ electrocardiographic devices.” Ex. 1013, cl. 13. A POSA would have understood that placement at “standard EKG . . . electrode locations,” as taught by Kroll, would measure standard ECG vectors. Ex. 1009 ¶¶ 569-571. Given the teaching of Kroll, a POSA would have known to place the bioelectrical potential detector 11 of Matsumura in one of these standard locations, and that these standard locations were well known in the field because they were locations where “motion and muscle artifact in the corresponding ECG vector signals” were minimized. *Id.*

12. Claims 14 and 15

In addition to teaching every limitation of claim 1, Matsumura and Kroll teach that “the power source is a renewable power source internal to the body worn device,” as recited in claim 14, and that “the power source comprises a rechargeable battery or a one time use battery,” as recited in claim 15. As shown above, Section VII.A.2.vi, a POSA would have understood Matsumura’s device to include an onboard power source to allow for wireless transmissions. A POSA would have recognized that such a power source could be a renewable power source, including a rechargeable or one time use battery because such devices were commonplace. Ex. 1009 ¶¶ 572-579. Accordingly, Matsumura and Kroll teach both that the power source may be renewable in the form of a battery that a POSA would have understood to be rechargeable or meant for one time use. *Id.*

13. Claim 29

In addition to teaching every limitation of claim 1, Matsumura and Kroll teach that the “body worn device includes circuit protection to allow the device to survive multiple defibrillation cycles of at least 360 joules.” Kroll discloses using ink deposits to “provide a certain total lead strip resistance so that each strip 34 serves as a current limiter to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device.” Ex. 1013, 5:8-13. A POSA would understand that the same ink deposits that protect the patient from shock will also

help protect the monitoring device from a defibrillation event. Ex. 1009 ¶ 588. The background section of the '007 patent also acknowledges that there were existing medical standards requiring that “a medical grade monitor *survive multiple defibrillation cycles of at least 360 joules.*” Ex. 1001, 1:53-55, 10:19-29 (emphasis added).

14. Claim 31

In addition to teaching every limitation of claims 1 and 29, Matsumura and Kroll teach that the “plurality of components of the circuit protection are distributed between the disposable module and the communication-computation module.” Kroll discloses “at least one series current-limiting resistor configured to protect the communication-computation module.” *Supra* § VII.A.2.xiii. A POSA would understand that Kroll’s “current-limiting resistor” helps protect the monitoring device from a defibrillation event. Ex. 1009 ¶ 588. To do so the “current-limiting resistor” that provides the circuit protection could be placed or distributed between the electrodes on the disposable module and the communication-computation module. *Id.*

15. Claim 37

In addition to teaching every limitation of claim 1, Matsumura and Kroll teach that “the communication-computation module includes circuit components configured to detect failure of contact of one or more of the electrical connections

with the skin surface of the patient.” Matsumura discloses a sensor that “alerts medical staff or the like when an abnormality occurs in the bioelectric potential signals detected by the bioelectric potential detector.” Ex. 1012 ¶ [0001]. Matsumura further elaborates that “[i]n the signal processor 10 of the bioelectric potential detector 11 . . . it is determined whether or not the electrocardiogram of the subject (patient) is in an abnormal state, such as an arrhythmia or an abnormal heart rate measured from the electrocardiogram, and if an abnormal state occurs,” an alarm may be triggered. *Id.* ¶ [0032].

A POSA would understand that Matsumura’s signal processor would include circuit components that would detect failure of contact of one or more of the electrical connections with the skin surface of the patient, and therefore that Matsumura discloses the dependent limitation of claim 37. Ex. 1009 ¶ 593. For example, a POSA would understand that if Matsumura’s signal processor could detect arrhythmias, then it would be capable of detecting asystole—the “flat line”—which would occur if all of the electrodes lost contact with the patient’s skin. *Id.*

16. Claim 38

In addition to teaching every limitation of claim 1, Matsumura and Kroll teach that “the communication-computation module is protected from external high energy signals by electro-surgical isolation suppression circuits.” Kroll discloses using ink deposits to “provide a certain total lead strip resistance so that each strip

34 serves as a current limiter to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device.” Ex. 1013, 5:8-13. A POSA would understand that circuits containing these same ink deposits that protect the patient from shock will also help to protect the monitoring device from interference from an electrosurgical unit, thus forming “electrosurgical isolation suppression circuits.” Ex. 1009 ¶ 598 (citing Ex. 1018). The specification of the ’007 also acknowledges that techniques to protect devices from electrosurgical interference were well known in the art: “AAMI standard EC13 on Electrosurgical Interference Suppression (ESIS) . . . addresses the ability of an ECG monitor to display and process ECG signals in a satisfactory manner while connected to a patient on whom an electrosurgical device is being used.” *Id.* (citing Ex. 1001, 14:25-30).

17. Claim 43

In addition to teaching every limitation of claim 1, Matsumura and Kroll teach that “the radio circuit communicates an unprocessed physiological signal.” Matsumura teaches that detected “bioelectric potential signals are wirelessly transmitted” from detector 10 to a receiver 22a, 23a, 31 that “determines if the bioelectric signals are in an abnormal state.” Ex. 1012 ¶¶ [0013], [0031], [0037], Figs. 7-8. A POSA would have understood this to mean that detector 10 merely detects the signal and transmits it to the receiver 22a, 23a, 31 for processing, meaning

that the signal remains unprocessed until it is received by receiver 22a, 23a, 31. Ex. 1009 ¶¶ 602-603.

18. Claim 44

In addition to teaching every limitation of claim 1, Matsumura and Kroll teach that “the radio circuit communicates a result of the physiological analysis at a predetermined time.” Matsumura teaches “a circuit built into the signal processor 10” for “filtering and amplifying detected bioelectric potential signals,” and “wirelessly transmit[ing] the bioelectric potential signals using a loop antenna” to a “portable monitor 22 for each subject (patient).” Ex. 1012 ¶¶ [0003], [0025], [0031]. If “signal processor 10” determines an abnormality in the electrocardiogram—a change in state from a normal heart rate to something like an arrhythmia or abnormal heart rate—it may transmit alarm information. *Id.* ¶¶ [0037]-[0039]. Matsumura thus discloses transmissions occurring at a predetermined time, based on the change in state of the electrocardiogram. Ex. 1009 ¶ 606.

A POSA would have understood that the design controls for medical devices, such as bioelectric potential detecting devices, would have included an evaluation of transmission timing. *Id.* ¶ 607. Continuous or excessive transmission would negatively affect power consumption, data integrity, and failure modes, meaning predetermined timing for transmissions was a known aspect of these devices. *Id.* These predetermined times could have been based on thresholds including data

packet accumulation, periodicity or schedules, or physiological thresholds. *Id.* In addition to Matsumura's explicit disclosure of transmission at a predetermined time based on a physiological threshold, a POSA would have also found it obvious to consider the use of the other kinds of thresholds to perform transmissions at a predetermined time. *Id.* For these reasons, Matsumura teaches the limitation of claim 44.

19. Claim 45

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

As described above, Matsumura and Kroll disclose limitation 45[pre]. *Supra* § VII.A.2.i.

ii. [45a] a disposable module including a plurality of electrical connections,

As described above, Matsumura discloses limitation [45a]. *Supra* § VII.A.2.ii.

iii. [45b] the electrical connections adapted for electrical coupling to a skin surface to receive physiological signals,

As described above, Matsumura discloses limitation [45b]. *Supra* § VII.A.2.iii.

iv. [45c] the disposable module including a disposable module connector;

As described above, Matsumura discloses limitation [45c]. *Supra* § VII.A.2.v.

v. [45d] a power source to power the body worn patient monitoring device;

As described above, Matsumura, in view of a POSA's knowledge, discloses limitation [45d]. *Supra* § VII.A.2.vi.

vi. [45e] a communication-computation module, having a communication-computation module connector to receive physiological signals from the disposable module via the disposable module connector, the communication-computation module including:

As described with respect to Claim 1, Matsumura and Kroll disclose limitation [45e]. *Supra* § VII.A.2.vii-viii.

vii. [45f] a microprocessor to actively monitor a patient and to perform real-time physiological analysis of the physiological signals, the analysis determining an occurrence of a predetermined ECG event,

This limitation is obvious over Matsumura in view of a POSA's knowledge. Matsumura teaches using a "signal processor 10" that continuously detects signals to "determine[] whether or not the detected electrocardiogram of the subject (patient) is in an abnormal state, such as an arrhythmia or an abnormal heart rate measured from the electrocardiogram, and if an abnormal state occurs, the portable monitor 22 and the central monitor 23 are set to trigger an alarm." Ex. 1012 ¶¶ [0032], [0040].

A POSA would have understood the “abnormal state” taught by Matsumura to be a predetermined event that is programmed into the signal processor. Ex. 1009 ¶ 617.

viii. [45g] a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis, at a predetermined time or on an occurrence of a predetermined event, via a radio transmission to a remote radio receiver; and

Matsumura discloses limitation [45g]. *Supra* §§ VII.A.18, VII.A.19.vii.

To the extent that Matsumura does not explicitly disclose communication of an unprocessed physiological signal on the occurrence of a predetermined event, it would be obvious to a POSA to implement such functionality on Matsumura’s device. Ex. 1009 ¶ 620. Performing various other functionalities—for example sounding an alarm for the patient—based on the occurrence of a predetermined event was well-known in the art at the time. *Id.* (citing Ex. 1015). Thus, it would have been obvious to a POSA to include communication of data among those functionalities. *Id.*

ix. [45h] wherein the disposable module has a mechanical and electrical coupling to the communication-computation module,

As described above, Matsumura discloses limitation [45h]. *Supra* § VII.A.2.xi.

- x. [45i] forming the body worn patient monitoring device as a single unit that is adapted to be directly and non-permanently affixed to the skin surface of the patient; and*

As described with respect to Claim 1, Matsumura discloses limitation [45i].

Supra § VII.A.2.xii.

- xi. [45j] at least one series current-limiting resistor configured to protect the communication-computation module,*

As described with respect to Claim 1, this limitation is rendered obvious by the combination of Matsumura and Kroll. *Supra* § VII.A.2.xiii.

- xii. [45k] the at least one series current-limiting resistor being screened on a flexible substrate,*

As described with respect to Claim 1, this limitation is rendered obvious by the combination of Matsumura and Kroll. *Supra* § VII.A.2.xiv.

- xiii. [45l] the at least one series current-limiting resistor being in the form of resistive traces.*

As described with respect to Claim 1, this limitation is rendered obvious by the combination of Matsumura and Kroll. *Supra* § VII.A.2.xv.

B. Ground 2: Claims 1, 2, 4, 5, 14, 15 and 43–45 are Obvious Over Matsumura, Kroll, and General Knowledge of a POSA or Matsumura, Kroll, Ozguz and General Knowledge of a POSA

1. A POSA would have combined Matsumura, Kroll, and Ozguz

For the same reasons set forth above in Section VII.A.1, a POSA would have been motivated to combine—and would have had a reasonable expectation of

success in combining—Kroll’s teaching of “resistive traces” with Matsumura’s device. Ex. 1009 ¶ 627.

Like Matsumura and Kroll, Ozguz also teaches a flexible, wearable device for monitoring physiological signals, including ECG or EKG signals. Ex. 1014 ¶¶ [0003], [0010], [0017], [0046]-[0050], Figs. 1, 2A.

Matsumura discloses a “circuit,” “signal processor,” and wireless transmitter used to detect, process, and wirelessly transmit bioelectric signals. Ex. 1012 ¶ [0025]. But Matsumura does not specify a specific 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 and 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 ¶¶ 629-630.

Specifically, Ozguz details an architecture and design of “circuitry (71, 72, 73)” that includes a “microprocessor” and “transmitter” that perform the same functions as those components perform in Matsumura. A POSA would have therefore looked to the details of Ozguz’s integrated circuits, which 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 ¶ 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 ¶ 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. Ex. 1009 ¶ 631. 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 to achieve one of Matsumura's goals, which is to provide a "cable-free and compact" detector. Ex. 1012 ¶ [0006]; Ex. 1009 ¶ 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. 1012 ¶ [0009]. Ozguz 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 will similarly improve its detector by avoiding noise levels and more "accurately detect[ing] electromagnetic" signals. *Id.*; Ex. 1009 ¶ 633.

A POSA combining these teachings of Matsumura, Ozguz, and Kroll would have had a reasonable expectation of success in doing so because it would involve using well known screen-printing techniques for printed circuit board manufacture.

Ex. 1009 ¶ 635. A POSA would know how to achieve this combination with minimal design impact. *Id.* Nothing in the art suggest that the proposed combination would not work. *Id.*

2. Claim 1

i. Limitations 1[pre]-[1d]

As explained above, limitations 1[pre]-[1d] are obvious over Matsumura and Kroll in view of the knowledge of a POSA. *Supra*, §§ VII.A.2.i-v.

ii. Limitation [1e]

As explained above, limitation [1e] is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *Supra*, § VII.A.2.vi.

Additionally or alternatively, it would have been obvious to a POSA to modify Matsumura with the teachings of Ozguz to include “a power source to power the body worn patient monitoring device.” Ex. 1009 ¶ 643. As explained previously, a POSA, in view of Matsumura’s broad disclosures concerning circuitry, would have looked to Ozguz for teachings concerning the design and structure of these circuits. *See supra* § VII.B.1. Ozguz discloses a “flexible, thin battery” to power a body worn sensor module. Ex. 1014 ¶ [0048], Figs. 3a-3c. Accordingly, and also for the reasons stated above in Section VII.B.1, a POSA would have been motivated to combine Ozguz’s teaching of a battery with Matsumura’s teaching of a disposable module to render limitation [1e] obvious. Ex. 1009 ¶¶ 644-645.

iii. Limitations [1f]-[1g]

As explained above, limitations [1f]-[1g] are obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See supra*, §§ VII.A.2.vii-viii.

iv. Limitation [1h]

As explained above, limitation [1h] is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See supra* § VII.A.2.ix. To the extent the circuit components necessary to achieve active monitoring and real-time physiological analysis is not within the skill of a POSA, Ozguz teaches it and the combination of Matsumura and Ozguz renders this limitation obvious.

Ozguz teaches flexible silicon substrates with respective integrated circuits that incorporate a “microprocessor 175.” Ex. 1014 ¶¶ [0039], [0058]. Accordingly, and also for the reasons stated above in Section VII.B.1, a POSA would have been motivated to combine Ozguz’s teaching of a microprocessor with Matsumura’s device to render limitation [1h] obvious. Ex. 1009 ¶¶ 649-650.

v. Limitation [1i]

As explained above, limitation [1i] is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See supra* § VII.A.2.x. To the extent the circuit components necessary to achieve physiological analysis on the occurrence of the predetermined physiological event is not within the skill of a POSA, Ozguz teaches them and the combination of Matsumura and Ozguz renders this limitation obvious.

Ozguz teaches that a radio circuit is a means to implement wireless communication between a body-worn patient monitoring device and a remote receiver. Ex. 1014 ¶¶ [0039]-[0040], [0042], [0057]. Ozguz explains that its system “can incorporate continuous transmission by RF [radio frequency] signals 40 to a device 45 having a receiver” and that, to achieve this embodiment, the device should include “at least one antenna 50” metallized onto a flexible substrate. *Id.* ¶ [0039]. Ozguz therefore teaches a communication-computation module that continuously transmits information to a remote receiver through a radio circuit. *Id.*; Ex. 1009 ¶ 653. Accordingly, and for the reasons stated above in Section VII.B.1, a POSA would have been motivated to combine Ozguz’s teaching of a radio circuit with Matsumura’s device to render limitation [1i] obvious. Ex. 1009 ¶¶ 653-654.

vi. Limitations [1j]-[1l]

As explained above, limitations [1j]-[1l] are obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See supra*, §§ VII.A.2.xi-xiii.

vii. Limitation [1m]

As explained above, limitation [1m] is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See supra*, § VII.A.2.xiv. To the extent that it would not have been obvious to a POSA that Matsumura’s flexible substrate includes electrical connections (*i.e.*, traces), Ozguz teaches it and the combination of Matsumura, Ozguz, and Kroll renders this limitation obvious.

As explained above, it would have been obvious to incorporate Ozguz's teaching of specific "integrated circuits" into Matsumura's bioelectric potential detector. *Supra* § VII.B.1 (citing Ex. 1014 ¶¶ [0039], [0042], [0058]; Ex. 1009 ¶¶ 658-660. It therefore would have been obvious to a POSA to combine Matsumura's teaching of a communication-computation module with Ozguz's integrated circuits and Kroll's resistive traces, which would meet this limitation. Ex. 1009 ¶¶ 660-661.

viii. Limitation [1n]

As explained above, limitation [1n] is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See supra*, § VII.A.2.xv.

3. Claim 2

As explained above, claim 2 is obvious over Matsumura and Kroll in view of a POSA's knowledge. *Supra* § VII.A.3. Ozguz also discloses this claim. Ozguz discloses electrodes that are "held secured against" a patient's "skin 15 by [] adhesive pads 91," meaning that electrodes 80 have a direct electrical connection to the body. Ex. 1014 ¶ [0045]; Ex. 1009 ¶ 669.

4. Claim 4

As explained above, claim 4 is obvious over Matsumura and Kroll in view of a POSA's knowledge. *Supra* § VII.A.4. Ozguz also discloses this claim. Ozguz teaches "electrodes 80" to detect "physiological characteristics such as an EKG

(from the heart).” Ex. 1014 ¶¶ [0039], [0044]. A POSA would know that EKG is synonymous with ECG. Ex. 1009 ¶¶ 676-677.

5. Claim 5

As explained above, claim 5 is obvious over Matsumura and Kroll in view of a POSA’s knowledge. *Supra* § VII.A.5. Ozguz also discloses this claim. Ozguz teaches electrodes 80 disposed on “underside 85 of the flexible substrate 55.” Ex. 1014 ¶ [0039]. A POSA would have known to use the “silk screen process” of Kroll to attach “electrodes 35” to “bioelectrode pad” of Matsumura and “flexible substrate 55” of Ozguz. Ex. 1009 ¶¶ 685-686.

6. Claims 14 & 15

As explained above, claims 14 and 15 are obvious over Matsumura and Kroll in view of a POSA’s knowledge. *Supra* § VII.A.12. To the extent that these claims would not have been obvious in view of Matsumura and a POSA’s knowledge, Ozguz teaches their dependent limitations and the combination of Matsumura, Ozguz, and Kroll renders them obvious.

Ozguz’s sensor module includes a “flexible, thin battery 105 [that] overlays the silicon substrates 60, 65, 70 and their respective [integrated circuits] 71, 72, 73.” Ex. 1014 ¶ [0048]. A POSA would understand that “battery 105” may be a renewable power source that is either rechargeable or disposable, meaning that it’s a “one time use battery.” Ex. 1009 ¶¶ 687-698.

7. Claim 43

As explained above, claim 43 is obvious over Matsumura and Kroll in view of a POSA's knowledge. *Supra* § VII.A.17. Ozguz also discloses this limitation, such that the combination of Matsumura, Kroll, and Ozguz renders it obvious. Ozguz teaches a sensor module that wirelessly transmits detected signals using an "RF transmitter." Ex. 1014 ¶ [0006]. A POSA would understand that those signals could be either processed or unprocessed physiological data. Ex. 1009 ¶ 702.

8. Claim 44

As explained above, claim 44 is obvious over Matsumura and Kroll in view of a POSA's knowledge. *Supra* § VII.A.18. Ozguz also discloses this claim. Ozguz teaches a sensor module where "data is collected through the skin for a predetermined period of time" and then transmitted wirelessly through an "RF transmitter." Ex. 1014 ¶¶ [0006], [0017]. A POSA would understand that a transmission following the collection of data for a "predetermined period of time" is a transmission that occurs at a predetermined periodicity. Ex. 1009 ¶ 707.

9. Claim 45

i. Limitations 45[pre]-[45e]

As explained above, limitations 45[pre]-[45e] are obvious over Matsumura and Kroll in view of the knowledge of a POSA. *Supra* §§ VII.A.19.i-vi.

ii. Limitation [45f]

As explained above, limitation [45f] is obvious over Matsumura and Kroll in view of a POSA's knowledge. *Supra* § VII.A.19.vii. Ozguz also discloses this limitation. Ozguz teaches a “microprocessor” 175 that processes electrocardiogram signals that are continuously detected. Ex. 1014 ¶¶ [0042], [0044], [0058]. A POSA would understand Ozguz's disclosures to refer to real-time physiological analysis to determine an occurrence of a predetermined event. Ex. 1009 ¶ 717.

iii. Limitation [45g]

As explained above, Matsumura and Kroll in view of a POSA's knowledge render this limitation obvious. *Supra* § VII.A.19.viii. Additionally, and for the reasons set forth with respect to claim 1, this limitation is obvious in view of the combination of Matsumura, Kroll, and Ozguz. *Supra* § VII.B.2.v.

i. Limitations 45[h]-[45l]

As explained above, limitations 45[h]-[45l] are obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See supra*, §§ VII.A.19.ix-xiii.

C. Ground 3: Claims 32-35 are Obvious Over Matsumura, Ozguz, Kroll, DeLuca, and General Knowledge of a POSA

1. A POSA would have combined Matsumura, Ozguz, Kroll, and DeLuca

For the same reasons set forth above in Section VII.B.1, a POSA would have been motivated to combine—and would have had a reasonable expectation of

success in combining—Ozguz’s disclosures of specific circuits and electronic components and Kroll’s teaching of “resistive traces” with Matsumura’s device.

Additionally, a POSA would have looked to incorporate DeLuca’s teaching of signal conditioning filters into the signal processor of Matsumura’s device. Ex. 1009 ¶ 728. DeLuca, like Matsumura, teaches a wearable, flexible device for monitoring physiological data, including EKG data. Ex. 1015, 1:6-9, 1:11-13, 2:1-4, 3:30-39.

Matsumura discloses a circuit, signal processor, and wireless transmitter used to detect, process and wirelessly transmit bioelectric signals. Ex. 1012 ¶ [0025]. Matsumura further specifies that its device is capable of detecting anomalous heartbeat signals on the device. *Id.* ¶ [0032]. Matsumura does not specify the particular electronic configurations that are required to accomplish this task.

A POSA would understand that to “determine whether or not the electrocardiogram of the subject (patient) is in an abnormal state,” the incoming analog signals would need to be processed. Ex. 1009 ¶ 730. A POSA would have looked to any number of well-known algorithms to help perform this task. *Id.* Such algorithms, including the widely-utilized “Pan-Tompkins Algorithm,” were well known in the art. *See id.* A POSA, accordingly, would have looked to deploy this or a similar signal conditioning algorithm on Matsumura’s device. *Id.* A POSA would have looked to DeLuca to determine how to perform this signal conditioning

step on Matsumura's device because DeLuca discloses an implementation of bandpass filters in great detail. *Id.*

A POSA would have had a reasonable expectation of success in implementing DeLuca's signal conditioning filters on Matsumura's device without undue experimentation, at least because it would involve the implementation of well-known components on a device. *Id.* ¶ 731. A POSA would know how to combine DeLuca's specific bandpass filtering configuration with Matsumura's device with minimal design impact. *Id.* Nothing in the art suggests that this modification would not work. *Id.* Nor would this modification be difficult to implement using well-known manufacturing techniques at the time of the invention. *Id.*

2. Claim 32

In addition to teaching the limitations of claim 1, Matsumura, Ozguz, Kroll, and DeLuca teach "a high pass filter with a selectable corner frequency to filter the physiological signals." As noted above, a POSA would have looked to combine DeLuca's specific "signal conditioning" filters with Matsumura's device to enable Matsumura's device to detect a heartbeat accurately for purposes of "determine[ing] whether the electrocardiogram of the subject (patient) is in an abnormal state." *See supra* § VII.C.1; Ex. 1012 ¶ [0032]; Ex. 1009 ¶¶ 727-731, 733.

Matsumura discloses a circuit, signal processor, and wireless transmitter to detect, process and wirelessly transmit bioelectric signals. Ex. 1012 ¶ [0025].

DeLuca discloses a “signal conditioning stage 56 which further amplifies and band-pass filters the signal so that it is of suitable voltage range and bandwidth for conversion [by] the A/D converter.” Ex. 1015, 4:66-5:2. DeLuca discloses that “the signal-conditioning stage 56 includes a hi-pass filter 56a.” *Id.* 5:2-3. “Each of the filter modules 56a, 56c, and 56d, is a switched-capacitor filter circuit whose cut-off frequency [*i.e.*, corner frequency] is determined by the clock frequency at which the filter is switched.” *Id.* 5:4-7.

As explained above, a POSA would have recognized that DeLuca’s band-pass filtering disclosures are consistent with the Pan-Tompkins QRS detection algorithm. *See supra* § VII.C.1; Ex. 1009 ¶ 736. It therefore would have been obvious to combine DeLuca’s teaching of a high-pass filter with a selectable corner frequency with Matsumura’s disclosure of a signal processing and heartbeat detection, meeting the dependent limitation of claim 32. Ex. 1009 ¶¶ 736-737.

3. Claim 33

In addition to teaching the limitations of claims 32 and 1, Matsumura, Ozguz, Kroll, and DeLuca teach that “the corner frequency is selected by a switch selectable resistance.”

DeLuca discloses that “the signal-conditioning stage 56 includes a hi-pass filter 56a.” Ex. 1015, 5:2-3. “Each of the filter modules 56a, 56c, and 56d, is a switched-capacitor filter circuit whose cut-off frequency [*i.e.*, corner frequency] is

determined by the clock frequency at which the filter is switched.” *Id.* 5:4-7. A POSA would understand that a switched-capacitor filter circuit and a switched circuit including physical resistors are interchangeable methods for filtering. Ex. 1009 ¶ 740. The interchangeability of these circuit designs has been known in the art since at least the 1970s. *Id.*

For the same reasons set forth above, and with respect to claim 32, it would have been obvious to combine DeLuca’s teaching of a high-pass filter with a switch-selectable corner frequency with Matsumura’s disclosure of a signal processing and heartbeat detection, meeting the dependent limitation of claim 33. *Id.* ¶¶ 740-741.

4. Claim 34

In addition to teaching the limitations of claims 32 and 1, Matsumura, Ozguz, Kroll, and DeLuca teach that “the corner frequency is selected by one or more switching capacitors switched at a rate higher than the corner frequency of a low pass anti-aliasing filter.”

DeLuca discloses that “the signal-conditioning stage 56 includes a hi-pass filter 56a, an amplifier 56b, a lo-pass filter 56c, and an anti-aliasing filter 56d. ” Ex. 1015, 5:2-4. “Each of the filter modules 56a, 56c, and 56d, is a switched-capacitor filter circuit whose cut-off frequency [*i.e.*, corner frequency] is determined by the clock frequency at which the filter is switched.” *Id.* 5:4-7. “The signal input from the input stage 55 is first coupled to the hi-pass filter 56a which removes any

DC component present in the signal before amplification.” *Id.* 5:9-12. A POSA would recognize that the corner-frequency of the high-pass filter would be selected by one or more switching capacitors switched at a rate higher than the corner frequency of the low-pass filter. Ex. 1009 ¶ 743.

For the same reasons set forth above, and with respect to claim 32, it would have been obvious to combine DeLuca’s teaching of a high-pass filter with a selectable corner frequency selected by one or more switching capacitors switched at a rate higher than that of a low-pass anti-aliasing filter with Matsumura’s disclosure of signal processing and heartbeat detection, meeting the dependent limitation of claim 34. *Id.* ¶¶ 744-745.

5. Claim 35

In addition to teaching all of the limitations of claims 32 and 1, it would have been obvious to a POSA to modify the combination of Matsumura, Ozguz, Kroll, and DeLuca such that “the high pass filter is implemented in software running on the microprocessor.”

DeLuca discloses a “signal conditioning stage,” wherein the “operating parameters” “can be externally programmed” through the ASIC 36. Ex. 1015, 5:35-42. A POSA would have understood that DeLuca’s ASIC could also have implemented the signal conditioning filters using software. Heartbeat detection algorithms that included the use of one or more digital filters on a microprocessor

were well known in the art. Ex. 1009 ¶ 748 (citing reference from 2002). Implementing such filters in software was a feature of the well-known Pan-Tompkins QRS Detection Algorithm. *Id.*

Thus, a POSA would have understood that the high-pass filter of DeLuca could easily be implemented using software, rather than using physical circuits. *Id.* For the same reasons set forth above, and with respect to claim 32, it would have been obvious to combine DeLuca’s teaching of a high-pass filter with a selectable corner frequency implemented in software running on the microprocessor with Matsumura’s disclosure of signal processing and heartbeat detection, meeting the dependent limitation of claim 35. *Id.* ¶ 749.

D. Ground 4: Claims 2 and 3 are Obvious Over Matsumura, Ozguz, Kroll, Harland, and General Knowledge of a POSA

1. A POSA would have combined Matsumura, Ozguz, Kroll, and Harland

For the same reasons set forth above in Section VII.B.1, a POSA would have been motivated to combine—and would have had a reasonable expectation of success in combining—Ozguz’s disclosures of specific circuits and electronic components and Kroll’s teaching of “resistive traces” with Matsumura’s device.

Additionally, a POSA would have looked to incorporate Harland’s teaching of a capacitive sensor probe into Matsumura’s device. Ex. 1009 ¶ 752. Matsumura discloses the use of a conductive gel that includes “glycerin, and water.”

Ex. 1012 ¶ [0018]. A POSA would recognize that gel substances and the adhesives used to fix the electrodes on the body can provoke dermal irritation and even allergies. Ex. 1009 ¶ 753. Concerns over dermal tolerability of electrodes would be especially acute in a device such as Matsumura's because it was intended to be worn for an extended period. *Id.*; *see also* Ex. 1012 ¶¶ [0031] (Matsumura's device worn "at all times"), [0033] (patient "can take a shower or bath" while wearing).

Harland discloses a solution to this problem in the form of "fixed sensor probes which form capacitive coupling to the body under measurement." Ex. 1016, 164. These electrodes allow for measurement of ECG signals "without direct electrical contact" and permit recording of "the very highest quality ECG at any point on the body surface, even from the fingertips." *Id.* A POSA would recognize the benefit of capacitive electrodes in abating potential dermal irritation because these electrodes do not require the use of potentially skin-irritating gels or adhesives. Ex. 1009 ¶ 754. Accordingly, a POSA would have looked to Harland's work for specific details on implementing this technology in Matsumura's device. *Id.*

A POSA would have had a reasonable expectation of success in implementing Harland's capacitive electrode on Matsumura's device without undue experimentation, at least because all necessary components were commercially available and manufacturing techniques known at the time of the '007 patent's

invention. *Id.* ¶ 755. A POSA would know how to combine Harland’s capacitive electrode with Matsumura’s design with minimal design impact. *Id.* Nothing in the art suggests that this modification would not work. *Id.* Nor would this modification be difficult to implement using well-known manufacturing techniques at the time of invention. *Id.*

2. Claim 2

In addition to teaching every limitation of claim 1, the combination of Matsumura, Kroll, Ozguz, and Harland teaches that “the plurality of electrical connections to the body comprise at least one of direct electrical connections to the body and indirect electrical connections to the body.”

As explained above, Matsumura discloses “direct electrical connections to the body.” *Supra* § VII.A.3.

A POSA would understand that an “indirect” electrical connection to the body is one in which the conductor does not make actual contact with the skin, for example through a capacitive coupling. Ex. 1009 ¶ 757. Harland discloses ultra-high impedance electric potential sensors that “allow the remote (non-contact) detection of electric potentials generated by currents flowing in the body.” Ex. 1016, 164. In the “remote, off-body detection” application, these electrodes “form capacitive [*i.e.*, indirect] coupling to the body under measurement.” *Id.* As explained above, it would have been obvious to a POSA to modify Matsumura to include at least one

such capacitive electrode. *Supra* § VII.D.1. As modified, the device of Matsumura would include at least one indirect electrical connection to the body.

3. *Claim 3*

In addition to teaching all of the limitations of claims 1 and 2, *see supra*, Matsumura, Ozguz, Kroll, and Harland teach that “the indirect electrical connections to the body comprise capacitive connections to the body.”

Harland reports the development and use of “a new class of sensor—the ultra-high impedance electric potential sensor” as an “alternative” to “traditional contact electrodes (for ECGs and EEGs).” Ex. 1016, 164. Harland’s ultra-high impedance electric potential sensors “allow the remote (non-contact) detection of electric potentials generated by currents flowing in the body.” *Id.* According to Harland, in the “remote, off-body detection” application, these electrodes “form capacitive coupling to the body under measurement.” *Id.*

As explained above, it would have been obvious to a POSA to modify the device taught by Matsumura, which would meet the dependent limitation of claim 3. *See supra*, § VII.D.1; Ex. 1009 ¶¶ 758-759.

E. Ground 5: Claim 39 is Obvious Over Matsumura, Ozguz, Kroll, Thompson, and General Knowledge of a POSA

1. *A POSA would have combined Matsumura, Ozguz, Kroll, and Thompson*

For the same reasons set forth above in Section VII.B.1, a POSA would have been motivated to combine—and would have had a reasonable expectation of success in combining—Ozguz’s disclosures of specific circuits and electronic components and Kroll’s teaching of “resistive traces” with Matsumura’s device.

Additionally, a POSA would have been motivated to incorporate Thompson’s teaching of a periodic low power mode on Matsumura’s device. A POSA would recognize that the utility of a battery-powered, wearable device is limited by its battery life. Ex. 1009 ¶ 762. Given the dimensional requirements of a body-worn physiological monitor, the size and composition of the battery will necessarily be limited; a POSA would thus seek to optimize power consumption (*i.e.*, battery depletion) as a means of prolonging the battery life of the device and extending the period for which it can collect data. *Id.*

However, a POSA would have been aware of techniques for optimizing battery life, including the use of a periodic low power mode. *Id.* ¶ 763. A POSA would have sought other ways to conserve power, even while the device was operational. *Id.*

Thompson teaches one way to conserve power is to limit processing time to certain portions of the heartbeat waveform. In one embodiment, Thompson discloses that “[o]nly during a QRS complex, for example, does waveform analysis processor 520 operate in a high-speed processing mode at a relatively high frequency. During the remainder of the cardiac cycle [*i.e.*, including the TP interval] the DSP processor 520 may be ‘idling along’ at a much lower clock frequency. . . . In addition to the lower clock speed utilized for different portions of the cardiac cycle, one skilled in the art will recognize that in accordance with the other aspects of the present invention, as the speed is reduced, the supply voltage level (V_{DD}) may also be reduced accordingly. Thus, the objective of reduced power consumption is realized.” Ex. 1017, 18:3-14; *see also* Ex. 1009 ¶ 764.

A POSA would have had a reasonable expectation of success in implementing Thompson’s low power mode on Matsumura’s device without undue experimentation, at least because it would require only reprogramming of onboard software. Ex. 1009 ¶ 765. A POSA would know how to combine Thompson’s low power mode with Matsumura’s design with little to no design impact. *Id.* Nothing in the art suggests that this modification would not work. *Id.*

2. Claim 39

In addition to teaching all of the limitations of claim 1, *see supra*, Matsumura, Ozguz, Kroll, and Thompson teach that “an algorithm running on the microprocessor

in the body worn device causes the body worn device to enter a low power mode that disables at least one circuit of the body worn device, from the end of a ‘T wave’ at the end of one heart beat to the beginning of a ‘P wave’ at the beginning of the next heartbeat, to save power.”

Thompson discloses a device that conserves power by operating in a low power mode from the end of one S-wave of the patient’s heartbeat until the commencement of the next Q-wave. Ex. 1017, 18:3-14. A POSA would therefore recognize that Thompson’s low power mode is active for a period that includes the period “from the end of a ‘T wave’ at the end of one heartbeat to the beginning of a ‘P wave’ at the beginning of the next heartbeat.” Ex. 1009 ¶¶ 768-770. A POSA would also recognize that this low power mode could be implemented on Matsumura’s “signal processor.” *Id.*; Ex. 1012 ¶¶ [0025], [0032]. Accordingly, the dependent limitation of claim 39 would be obvious to a POSA in view of the combination of Matsumura, Kroll, and Thompson. *Id.*

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.*, IPR2020-0019, 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).

Parallel Petitions. Petitioner submits two petitions for *inter partes* review of the '007 patent. Petitioner requests that the Board consider this petition's grounds second. The petitions differ on the basis of primary references in the grounds. This Petition uses as a primary reference art that was not previously presented to the Office; the other cites art that was identified during prosecution. For the reasons set forth in the accompanying petition, the grounds asserted in that petition are novel, and substantially differ from grounds raised during prosecution. Nonetheless, Petitioner offers the grounds in the parallel petition, should the Board disagree with Petitioner's *Becton Dickinson* analysis. Each petition challenges over 20 claims, and the challenged independent claims involve over 16 limitations, including numerous lengthy limitations. Petitioner does not, as of the time of filing, know which claims of the '007 patent will be asserted in the co-pending District Court litigation. For at

least these reasons, there is good cause for the Board to consider and institute trial on the grounds set forth in each petition.

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 '007 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 St Mountain View, CA 94041 T: (650) 988-8500 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 patient monitoring device comprising:
[1a.]	a disposable module including a plurality of electrical connections,
[1b.]	said electrical connections adapted to be couplable to a skin surface to measure physiological signals,
[1c.]	at least one of said electrical connections comprising a half cell,
[1d.]	the disposable module including a disposable module connector;
[1e.]	a power source to power the body worn patient monitoring device;
[1f.]	a communication-computation module being removable and reusable,
[1g]	having a communication-computation module connector to receive physiological signals from the disposable module via said disposable module connector, the communication-computation module including:
[1h.]	a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the occurrence of a predetermined physiological event; and
[1i.]	a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event, via a radio transmission to a remote radio receiver,
[1j.]	wherein the disposable module is mechanically and electrically coupled directly to the communication-computation module,
[1k.]	and the body worn patient monitoring device including the disposable module and the communication-computation module is adapted to be directly non-permanently affixed to the skin surface of the patient; and
[1l.]	at least one series current-limiting resistor configured to protect the communication-computation module,

Claim	Recitation
[1m.]	the at least one series current-limiting resistor being screened onto a flexible substrate,
[1n.]	the at least one series current-limiting resistor being in the form of resistive traces.
2.	The body worn device of claim 1, wherein the plurality of electrical connections to the body comprise at least one of direct electrical connections to the body and indirect electrical connections to the body.
3.	The body worn device of claim 2, wherein the indirect electrical connections to the body comprise capacitive connections to the body.
4.	The body worn device of claim 1, wherein the body worn patient monitoring device comprises an ECG monitor and at least two of the electrical connections are ECG electrodes.
5.	The body worn device of claim 4, wherein the ECG electrodes comprise a material screened onto the flexible substrate.
6.	The body worn device of claim 5, wherein the at least one series current-limiting resistor protects the communication-computation module during a patient defibrillation event.
8.	The body worn device of claim 4, wherein the mechanical interface from the at least one series current-limiting resistor to the EGG electrode comprises overlapped layers.
10.	The body worn device of claim 1, further comprising an insulating material overlaying the at least one series current-limiting resistor to prevent arcing.
11.	The body worn device of claim 5, wherein the EGG electrodes are formed substantially in the shape of an annulus.
12.	The body worn device of claim 11, wherein the annulus comprises a conductive link.
13.	The body worn device of claim 5, wherein the substrate is shaped to allow placement on the patient to monitor at least one of a set of

Claim	Recitation
	standard ECG vectors while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal.
14.	The body worn device of claim 1, wherein the power source is a renewable power source internal to the body worn device.
15.	The body worn device of claim 1, wherein the power source comprises a rechargeable battery or a one time use battery.
29.	The body worn device of claim 1, wherein the body worn device includes circuit protection to allow the device to survive multiple defibrillation cycles of at least 360 joules.
31.	The body worn device of claim 29, wherein a plurality of components of the circuit protection are distributed between the disposable module and the communication-computation module.
32.	The body worn device of claim 1, further comprising a high pass filter with a selectable corner frequency to filter the physiological signals.
33.	The body worn device of claim 32, wherein the corner frequency is selected by a switch selectable resistance.
34.	The body worn device of claim 32, wherein the corner frequency is selected by one or more switching capacitors switched a rate higher than the corner frequency of a low pass anti-aliasing filter.
35.	The body worn device of claim 32, wherein the high pass filter is implemented in software running on the microprocessor.
37.	The body worn device of claim 1, wherein the communication-computation module includes circuit components configured to detect failure of contact of one or more of the electrical connections with the skin surface of the patient.
38.	The body worn device of claim 1, wherein the communication-computation module is protected from external high energy signals by electro-surgical isolation suppression circuits.
39.	The body worn device of claim 1, wherein an algorithm running on a microprocessor in the body worn device causes the body worn

Claim	Recitation
	device to enter a low power mode that disables at least one circuit of the body worn device, from the end of a “T wave” at the end of one heart beat to the beginning of a “P wave” at the beginning of the next heart beat, to save power.
43.	The body worn device of claim 1, wherein the radio circuit communicates an unprocessed physiological signal.
44.	The body worn device of claim 1, wherein the radio circuit communicates a result of the physiological analysis at a predetermined time.
45[pre].	A body worn patient monitoring device comprising:
[45a.]	a disposable module including a plurality of electrical connections,
[45b.]	the electrical connections adapted for electrical coupling to a skin surface to receive physiological signals,
[45c.]	the disposable module including a disposable module connector;
[45d.]	a power source to power the body worn patient monitoring device;
[45e.]	a communication-computation module, having a communication-computation module connector to receive physiological signals from the disposable module via the disposable module connector, the communication-computation module including:
[45f.]	a microprocessor to actively monitor a patient and to perform real-time physiological analysis of the physiological signals, the analysis determining an occurrence of a predetermined ECG event,
[45g.]	a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis, at a predetermined time or on an occurrence of a predetermined event, via a radio transmission to a remote radio receiver; and
[45h.]	wherein the disposable module has a mechanical and electrical coupling to the communication-computation module,

Claim	Recitation
[45i.]	forming the body worn patient monitoring device as a single unit that is adapted to be directly and non-permanently affixed to the skin surface of the patient; and
[45j.]	at least one series current-limiting resistor configured to protect the communication-computation module,
[45k.]	the at least one series current-limiting resistor being screened on a flexible substrate,
[45l.]	the at least one series current-limiting resistor being in the form of resistive traces.

**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 13,741 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 /

Robert E. Counihan

Reg. No. 61,381

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. 8,214,007, 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
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Syracuse, NY 13202

Further, courtesy copies are also being sent via electronic mail to Patent Owner's litigation counsel of record:

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