

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

iRhythm, Inc.

Petitioner,

v.

Welch Allyn, Inc.

Patent Owner.

Case: IPR2025-00377

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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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
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1021	Gautham Kalahasty et al., <i>A Brief History of Remote Cardiac Monitoring</i> , 5 Cardiac Electrophysiology Clinics 275 (2013)
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1034	U.S. Patent No. 6,454,708
1035	R.S. Khandpur, <i>Printed Circuit Boards: Design, Fabrication, Assembly, and Testing</i> (2006)
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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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1066	Certificate of Translation for Japanese Patent Publication No. JP2004/121360

I. INTRODUCTION

Pursuant to 35 U.S.C. § 311 and 37 C.F.R. § 42.100, iRhythm, Inc. (“Petitioner”) requests *Inter Partes* Review of claims 1-8, 10-15, 29, 31-35, 37-39, and 43-45 (the “Challenged Claims”) of U.S. Patent No. 8,214,007 (the “’007 patent”) (Ex. 1001), 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, 4-8, 10-15, 29, 31, 37, 38, and 43-45 are obvious under pre-AIA § 103 over Jensen, Kroll, and General Knowledge of a POSA
<u>Ground 2</u>	Claims 32-35 are obvious under pre-AIA § 103 over Jensen Kroll and General Knowledge of a POSA, and/or Jensen, Kroll, DeLuca, and General Knowledge of a POSA.

<u>Ground 3</u>	Claims 2 and 3 are obvious under pre-AIA § 103 over Jensen, Kroll, Harland and General Knowledge of a POSA
<u>Ground 4</u>	Claim 39 is obvious under pre-AIA § 103 over Jensen, Kroll, Thompson, and General Knowledge of a POSA

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

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

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

III. PAYMENT OF FEES

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

IV. OVERVIEW OF CHALLENGES AND RELIEF REQUESTED

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

Ground 1: Claims 1, 2, 4-8, 10-15, 29, 31, 37, 38, and 43-45 are unpatentable under pre-AIA § 103 over Jensen in view of Kroll and the General Knowledge of a POSA.

Ground 2: Claims 32-35 are unpatentable under pre-AIA § 103 over Jensen in view of Kroll, DeLuca, and the General Knowledge of a POSA.

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

Ground 4: Claim 39 is unpatentable under pre-AIA § 103 over Jensen in view of 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 ¶¶ 17-22. These monitoring systems have been commonly used to remotely monitor patients during their daily activities, outside of a clinical setting. *Id.* ¶ 23-24. To accommodate daily use, these monitoring systems are designed to be both portable and discreet. *Id.*; 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 patients' 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 ¶¶ 17-23. 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 localize a problem in a particular part of the heart. *Id.* An ECG measures the heart muscles' polarization/depolarization cycle using electrodes, which are typically disposable and attached to a patient's skin. *Id.*; 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.* 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.* ¶¶ 23-32. These wearable monitors were wireless, smaller, and lightweight. Ex. 1001, 1:28-32. 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 ¶¶ 25-32.

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.* 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.* ¶¶ 31, 36-42. It was well understood that the voltage increase from defibrillation could potentially damage or destroy the electronics on the wearable heart monitor. *Id.* ¶ 31. This is why regulatory bodies required “that a medical grade monitor survive multiple defibrillation cycles of at least 360 joules.” 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”. *Id.* 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 ¶¶ 43-48.

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 A1) 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[s] 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 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 ¶ 67. 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.” *See id.* 7:28-33.

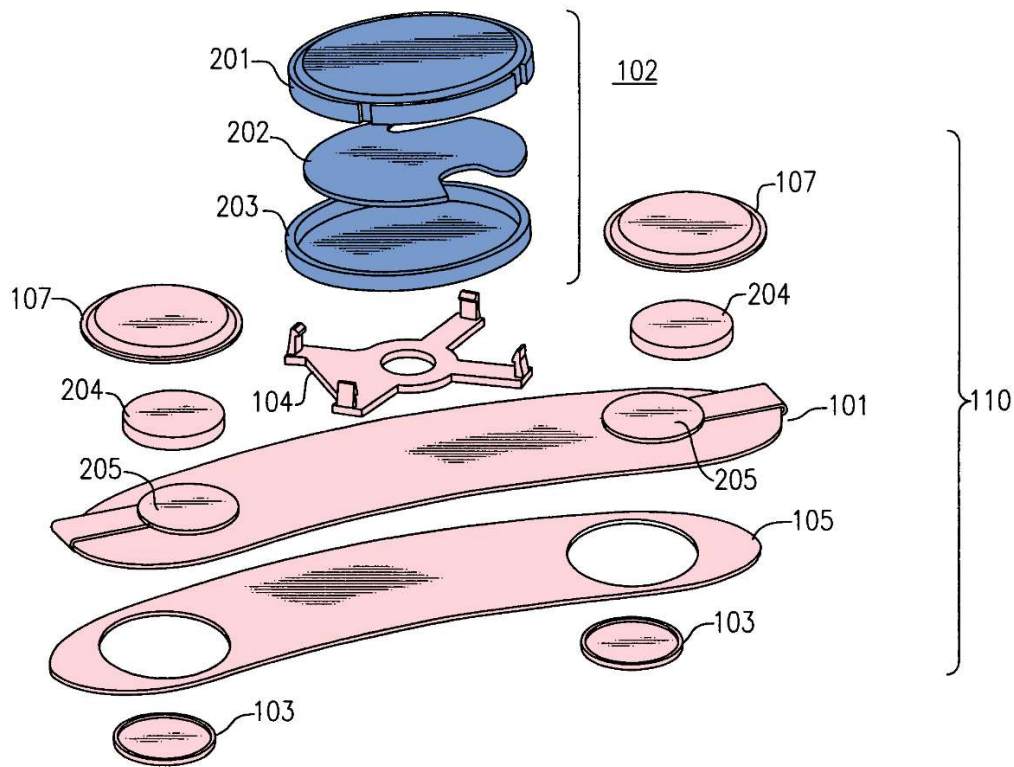
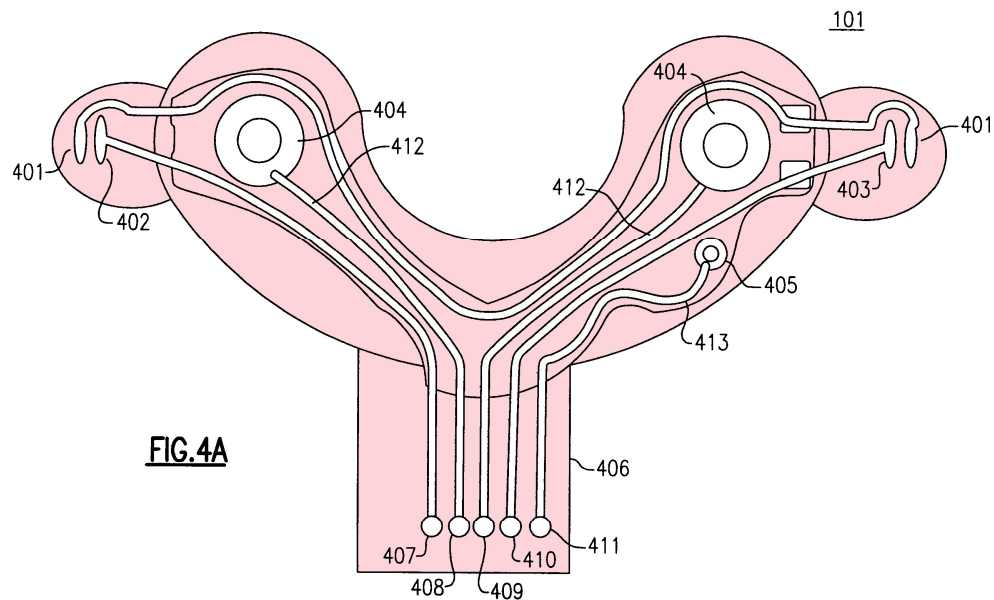


FIG. 2



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 at 3, 14 (Apr. 18, 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 at 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

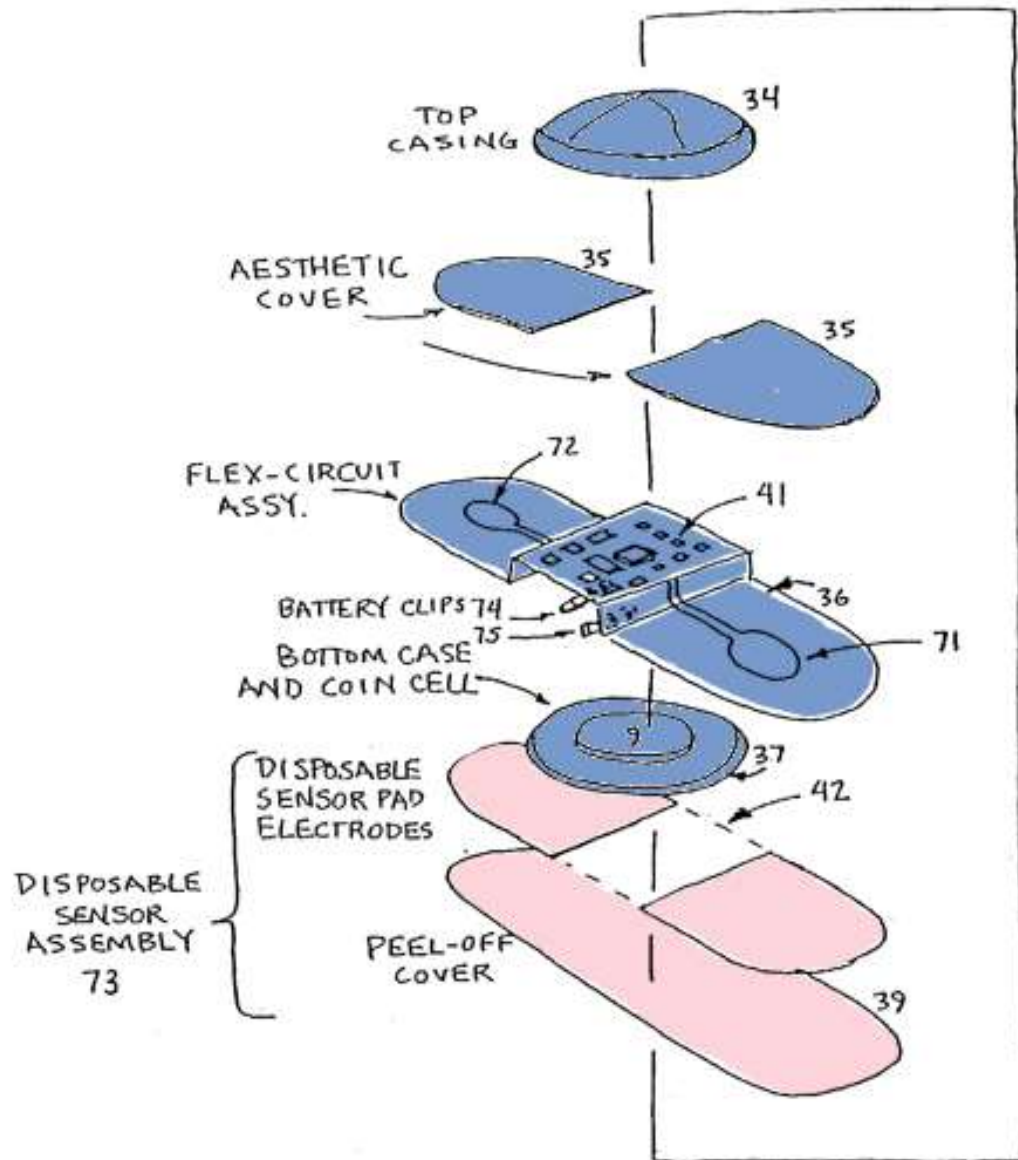
A POSA would have at least a bachelor's degree in electrical engineering, electrophysiology, biomedical engineering, or an equivalent degree, and at least two to three years of experience designing wearable monitors that detect physiological signals with mechanical and/or electrical elements. Ex. 1009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

VI. PRIOR ART OVERVIEW

A. Jensen (Ex. 1011)

Jensen published on August 7, 2003 as U.S. Patent Pub. No. 2003/0149349 and is prior art under pre-AIA 35 U.S.C. §§ 102 (a), (b), (e). Jensen was cited in Information Disclosure Statements during prosecution of the '007 patent but was never substantively examined. Jensen teaches a body worn physiological monitor in the form of a “‘smart bandage’ or ‘smart patch’” for “physiological monitoring, especially heart rate sensing.” Ex. 1011, Abstract; *see also id.* ¶ [0013]. This “smart patch” includes both a “disposable sensor assembly” (shown below in red) that makes direct contact with the skin of the patient and a “re-usable (non-disposable) portion” (shown below in blue). *Id.* ¶¶ [0042]-[0043], Fig. 5. Jensen's monitor includes a flexible circuit assembly with “programmable logic circuitry” for “perform[ing] measurement and processing of sensed data.” *Id.* ¶ [0014]. The monitor will then use a “transmitter” and “antenna” to transmit captured

physiological data to “any variety of different receivers.” *Id.* ¶¶ [0029], [0032]-[0033].



Id. Fig. 5 (annotated).

B. 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.” *Id.* 5:8-13. These resistive lead strips “serve[] as a current limiter to protect a patient from shock due to malfunction of the device . . . or of a complementary medical device.” *Id.*

C. 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

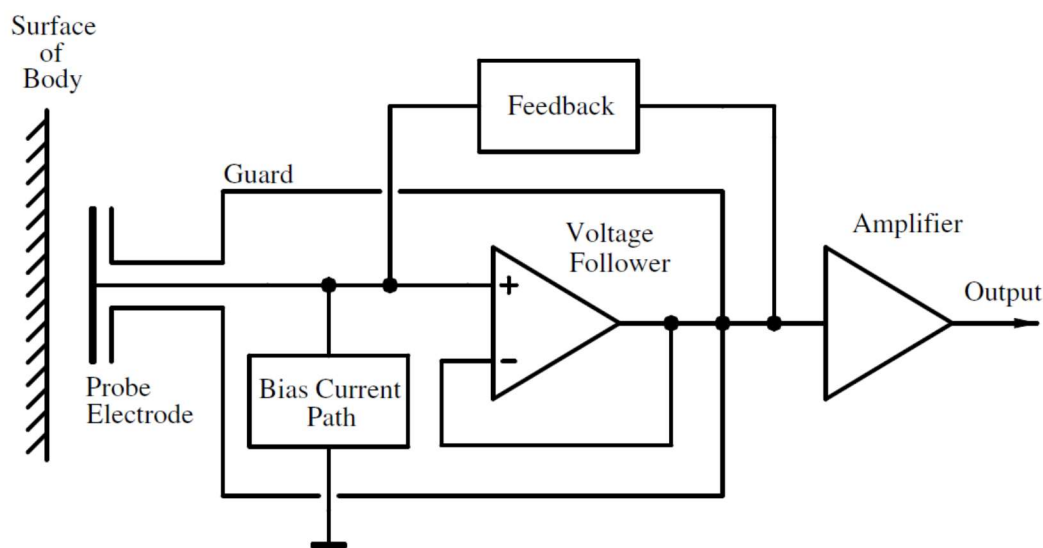
considered during prosecution of the '007 patent. DeLuca discloses “a biosignal monitoring system including a plurality of sensors for disposition in predetermined positions on the body of a test subject.” Ex. 1015, 1:33-35. DeLuca’s disclosed detector includes “contact surfaces shaped and arranged to detect a particular biosignal generated in the body, a sensor transceiver, a sensor antenna, a voltage supply, and a microprocessor.” *Id.* 1:36-39.

DeLuca discloses that incoming biosignals are subjected to a “signal conditioning stage 56” which “includes a hi-pass filter 56a, an amplifier 56b, 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.* 5:46-48.

D. Harland (Ex. 1016)

Harland was published in the journal *Measurement Science and Technology* in 2001. 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 [in the] measurement.” *Id.*; *see also id.* Fig. 1:



E. 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; “during 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.* 18:13-14.

VII. THE CHALLENGED CLAIMS ARE UNPATENTABLE

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

Jensen discloses the essential physical components of the purported invention of the '007 patent. In fact, these components were widely known in the art, and can be found in innumerable references antedating the '007 patent. Jensen does not explicitly disclose the use of resistive inks to manufacture its printed circuit board traces. But, as explained in greater detail below, a POSA would have known that some circuit resistance—to protect the device and the patient—would need to be incorporated into the flexible printed circuit.

Kroll, another prior art reference that discloses a body-worn patient monitoring device, explains that one of the many ways a POSA could implement this resistance was through printing the circuit using a resistive ink. This is *exactly*

what the '007 patent claims as its innovative step. Far from innovative, the '007 patent predictably combines known components, arranged in a known way, to achieve known results. Accordingly, the challenged claims of Ground 1 are obvious over Jensen in combination with Kroll.

1. A POSA would have combined Jensen and Kroll

Jensen and Kroll both teach flexible, wearable devices for monitoring physiological data, including EKG data. Ex. 1011 ¶¶ [0029]-[0030]; Ex. 1013, 1:11-15, 1:37-45.

A POSA would look to incorporate the “resistive trace” of Kroll into the wearable monitor of Jensen for at least two reasons. First, Kroll describes, and teaches a solution to, the known risk of electrical overload: using electrical lead strips of a known resistivity to limit the current transmitted between the worn device and the patient. Ex. 1013, 5:1-17. Kroll specifically discusses this solution in the context of protecting a patient from “shock,” from the worn device or “a complementary medical device.” *Id.* A POSA would have understood that it would be beneficial to limit the current transmitted in either direction (whether towards or away from the patient’s body). *See* Ex. 1009 ¶¶ 209-212. The resistive lead strips would help to (i) protect the patient from shock due to electricity from the device, and (ii) protect the sensitive electronics inside the device from shock due to electricity outside of the device, “such as that caused by a defibrillator.” *Id.*

¶¶ 212-213. Jensen discloses a wearable monitor to which these same considerations apply. Driven by a desire to protect patients from potential shock and ensure the long-term viability of Jensen’s reusable module against potential defibrillation, a POSA would have been motivated to incorporate Kroll’s teaching of resistive “lead strips” to help protect each. *Id.* ¶ 214.

Second, using Kroll’s resistive lead strips addresses the very concerns expressed by Jensen about the physical dimensions of the device. Jensen discloses a device that is “thin, being less than 6 or 7 mm in thickness, low in mass and may be applied to the skin much like a bandage.” Ex. 1011 ¶ [0030]. Jensen’s goal of reducing the size of the device is consistent with other industry efforts at the time to reduce the size of wearable devices. Ex. 1009 ¶ 215 (“reducing the size of the wearable devices serves two purposes: reduce the costs of monitors and improve their wearability”). Using the resistive lead strips of Kroll, formed with ink deposits, instead of the conventional resistors on Jensen’s circuit assembly would further Jensen’s goal. *Id.* ¶ 216. A POSA would know that replacing the conventional resistors of Jensen with resistive lead strips made of an ink compound would reduce the overall size of Jensen’s monitoring device. *Id.*

A POSA would have had a reasonable expectation of success in implementing Kroll’s resistive leads on Jensen’s device without undue experimentation at least because it would involve only a slight modification to the materials used to print

electrical traces. *Id.* ¶ 217. A POSA would know how to combine Kroll’s resistive lead strips with Jensen’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: A POSA would look to well-known screen-printing techniques. *Id.*

2. Claim 1

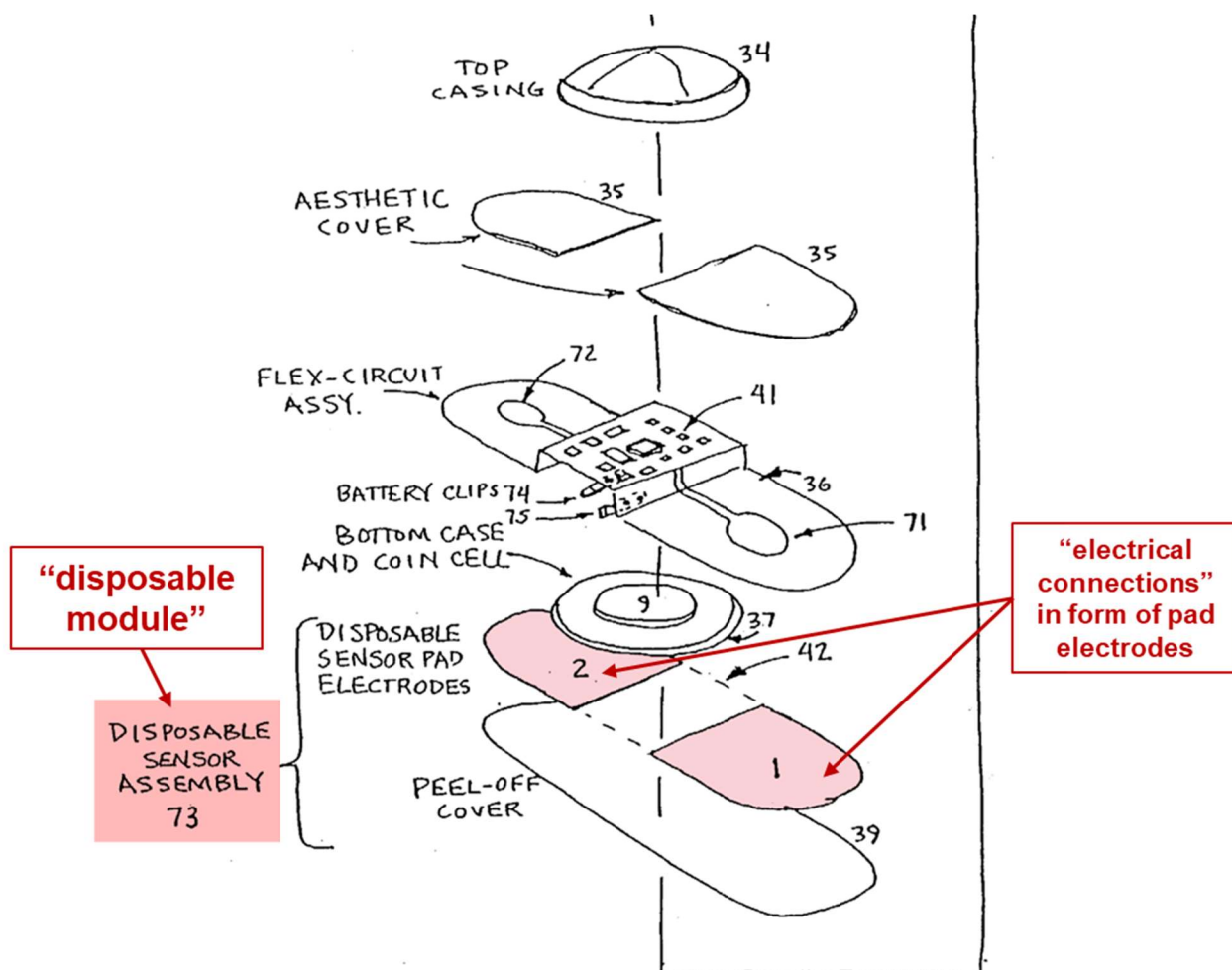
i. [Pre] A body worn patient monitoring device comprising:

Jensen teaches a body worn patient monitoring device. Ex. 1011 ¶¶ [0012], [0029]; Ex. 1009 ¶¶ 220-221. Kroll also discloses a body worn patient monitoring device. Ex. 1013, 1:11-15; Ex. 1009 ¶ 222.

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

Jensen teaches the claimed “disposable module including a plurality of electrical connections.” Jensen discloses a “disposable sensor assembly,” which includes “disposable sensor pads” 1, 2 (shown below in red). Ex. 1011 ¶ [0042]. The disposable sensor pads are coated with a “conductive adhesive on the circuit side and a conductive adhesive-gel that is made using a silver amalgam as found in off-the-shelf EKG sensor pads.” *Id.* ¶ [0041]. A POSA would have understood the “silver amalgam” to be a mixture of silver and other compounds. Ex. 1009 ¶ 225. Through the conductive adhesive on the circuit side, disposable sensor pads form an electrical connection with sensor contacts 71, 72 of the flexible circuit assembly;

through the conductive adhesive-gel on the other side, disposable sensor pads form an electrical connection with the skin of the patient. Ex. 1011 ¶ [0041].



Id. Fig. 5 (annotated).

A POSA would understand that Jensen’s disposable sensor pads form a plurality of electrical connections between the skin surface, at which the electrical potential is detected, and the flexible circuit assembly. Ex. 1009 ¶ 230.

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

Jensen discloses the claimed “electrical connections adapted to be couplable to a skin surface to measure physiological signals.” Jensen’s device “may be applied to the skin much like a bandage, with self-adhesive pads and sensor materials on the skin-contact side of the invention.” Ex. 1011 ¶ [0030]. The disposable sensor pads are adapted with conductive adhesive-gel, making the device couplable to a skin surface. *Id.* ¶ [0041]. A POSA would understand that Jensen’s sensor pads, which are adhesive and conductive, are couplable to a skin surface to measure physiological signals, such as EKG signals. Ex. 1009 ¶¶ 233-235.

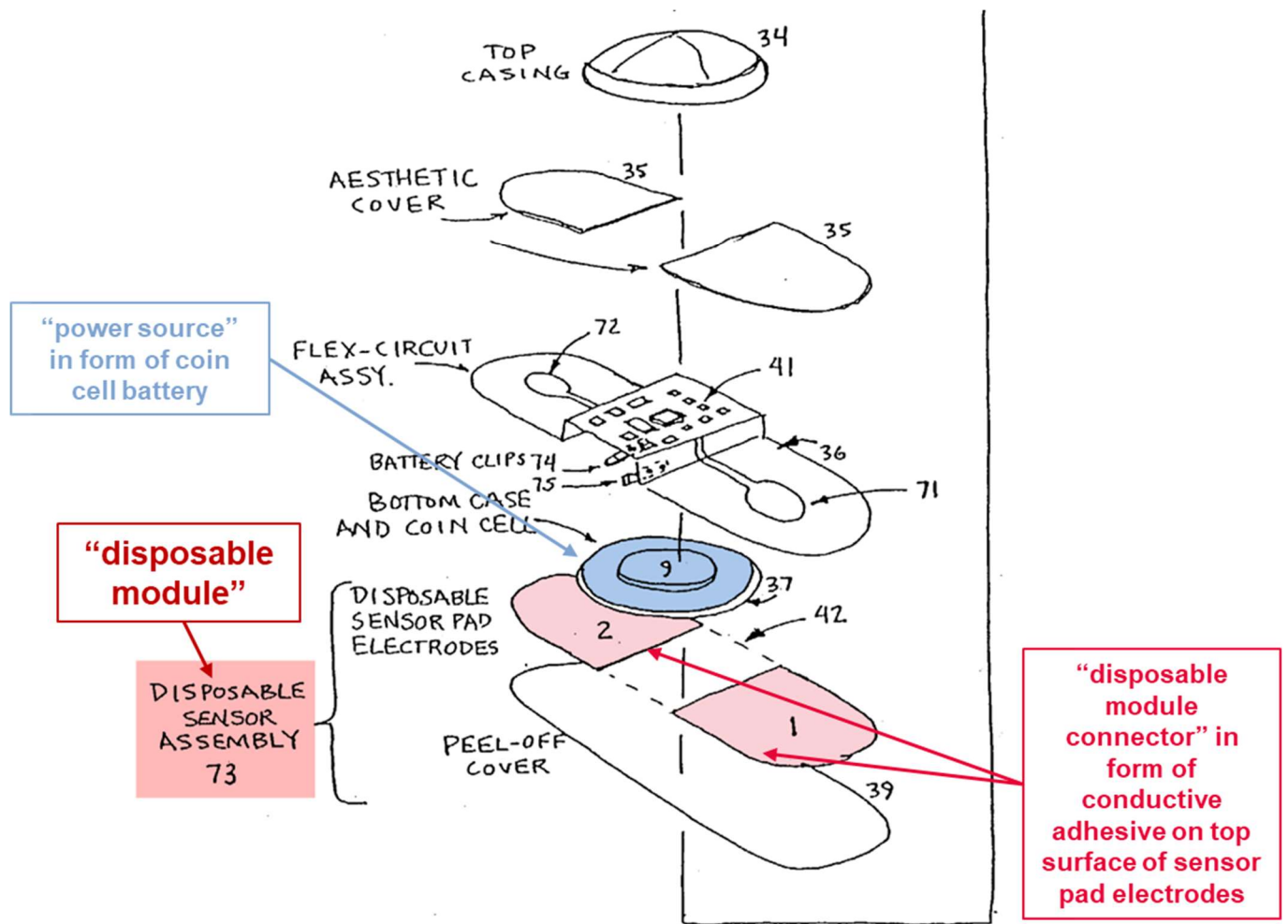
iv. [1c] at least one of said electrical connections comprising a half cell,

Jensen discloses “at least one of said electrical connections comprising a half cell.” On the side that contacts the patient’s skin, Jensen’s disposable sensor pads are coated with “conductive adhesive-gel that is made using a silver amalgam as found in off-the-shelf EKG sensor pads, [such] as those sold by 3M corporation.” Ex. 1011 ¶ [0041]. A POSA would understand that EKG sensor pads coated with a silver amalgam (usually silver-silver chloride) and a conductive gel containing an electrolyte comprise a “half cell,” a term that the ’007 patent describes as a combination of an “electrode gel” and a “conductive surface.” Ex. 1009 ¶¶ 236-40; Ex. 1001, 6:48-52. Accordingly, a POSA would know that Jensen’s sensor pads

form a plurality of electrical connections comprising half cells at the point of contact with the patient's skin. Ex. 1009 ¶¶ 238-40.

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

Jensen discloses “the disposable module including a disposable module connector.” Jensen teaches disposable sensor pads include “conductive adhesive on the circuit side.” Ex. 1011 ¶ [0041]. The disclosed conductive adhesive acts as the claimed “disposable module connector,” connecting—both physically and electrically—the disposable module to the reusable communication-computation module (*i.e.*, Jensen’s “flexible circuit assembly”). *See id.* Fig. 5; Ex. 1009 ¶ 244.



Ex. 1011, Fig. 5 (annotated).

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

Jensen discloses “a power source to power the body worn patient monitoring device.” Jensen teaches that the patient monitoring device may include a “lithium coin cell,” which is a power source to power the body worn patient monitoring device. *Id.* ¶ [0040]. Jensen further teaches that, in the alternative, the patient monitoring device may include “a rechargeable type of power source, or a solar cell,”

which also satisfies limitation 1e. *Id.* Thus, Jensen discloses this limitation. Ex. 1009 ¶ 246.

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

Jensen discloses “a communication, computation module being removable and reusable.” Jensen teaches a “transmitter” for communication and a “microcontroller” for computation. Ex. 1011 ¶ [0032]. Jensen’s microcontroller “runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter.” *Id.* Jensen’s transmitter may transmit encoded data messages via “antenna.” *Id.* ¶ [0033].

Both the transmitter and microcontroller are part of the “electronic circuit” of Jensen’s body-worn physiological sensor. *Id.* ¶ [0036], Fig. 3. That electronic circuit is part of a “flexible circuit assembly” containing copper wiring to connect the entire circuit to the sensor contacts and the power source. *Id.* ¶ [0040]. Jensen further discloses that the electronic circuit containing the communication-computation module is a “re-usable” component, which is separable and removable from the “disposable sensor assembly.” *Id.* ¶¶ [0042]-[0043]. Thus, Jensen discloses this limitation. Ex. 1009 ¶¶ 248-250.

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:

Jensen discloses “a communication-computation module connector to receive physiological signals from the disposable module via said disposable module connector.”

Jensen discloses that “sensor contacts . . . make contact with sensor pads” to receive EKG data; “the disposable sensor pad electrodes . . . are coated with a conductive adhesive on the circuit side and a conductive adhesive-gel.” Ex. 1011 ¶ [0041]. Sensor contacts 71, 72 therefore receive physiological signals and are connected to the disposable module (by the conductive adhesive on the sensor pads). Jensen’s sensor contacts 71, 72 are therefore the “computation-communication module connectors” that receive physiological signals from the disposable module via said disposable module connector. The sensed physiological signals are then sent to the “transmitter” and “microcontroller” of Jensen. *Id.* ¶ [0032]. Thus, Jensen discloses this limitation. Ex. 1009 ¶¶ 252-254.

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

Jensen discloses a communication-computation module including “a microprocessor to actively monitor the patient and to perform a real-time

physiological analysis of the occurrence of a predetermined physiological event.” Jensen’s device includes a “microcontroller,” which “runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter.” Ex. 1011 ¶ [0032]. A POSA would understand a “microcontroller” to either be or include a microprocessor. Ex. 1009 ¶ 256.

Jensen also teaches “processing” a signal and performing a “mean pulse value” calculation to alert a patient “when a predetermined mean pulse value is achieved.” Ex. 1011 ¶ [0011]. As an example, Jensen specifies that one of the functions performed by the “smart patch” is to “electrically detect the occurrence of R events in the QRS complex of the EKG signal.” *Id.* ¶ [0029]. A POSA would understand that the R event is the predetermined physiological event that precedes a real-time physiological analysis: “Once the microcontroller . . . identifies the data as having a heart beat pulse, (a clearly identifiable waveform with a distinctive shape and a high signal amplitude compared to typical ambient noise from the sensor), then the program analyzes the data in a number of optional ways.” *Id.* ¶ [0037]; *see also* Ex. 1009 ¶ 257. Accordingly, Jensen discloses a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the occurrence of a predetermined physiological event. *Id.* ¶¶ 256-259.

- 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,*

Jensen discloses a communication-computation module including “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.”

Jensen teaches that a microcontroller “converts the heart-rate data information into one of multiple data output formats, which are sent by radio data transmission to any variety of outside receiving equipment.” Ex. 1011, Abstract. Jensen further describes “[d]ata modulation methods in an RF [*i.e.*, radio frequency] transmitter that are easily implemented.” *Id.* ¶ [0033]. The transmitter may transmit “an encoded data message and output by the program” executed by the microcontroller. *Id.* The transmitted output includes the results of physiological analysis on the occurrence of the predetermined physiological event. *Id.* ¶¶ [0031]-[0035]; Ex. 1009 ¶¶ 263-64.

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

Jensen discloses “wherein the disposable module is mechanically and electrically coupled directly to the communication-computation module.” Jensen’s

disposable sensor pad electrodes, which are the disposable module, *see* §VII.A.2.ii, are coupled to the flexible circuit assembly, which is Jensen’s communication-computation module, by “conductive adhesive,” which forms both an electrical connection and a physical connection between the two respective components. Ex. 1011 ¶ [0041]; Ex. 1009 ¶¶ 266-269.

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

Jensen discloses “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.”

Jensen’s communication-computation module is mechanically and electrically coupled to Jensen’s disposable module. *Supra*, § VII.A.2.xi. Jensen’s disposable module is similarly mechanically and electrically coupled to the patient’s skin surface by “a conductive adhesive gel that is made using a silver amalgam as found in off-the-shelf EKG sensor pads.” Ex. 1011 ¶ [0041]; Ex. 1009 ¶ 272.

Jensen discloses that the invention is “a totally self-contained sensor that is thin . . . low in mass and may be applied to the skin much like [the] bandage, with self-adhesive pads and sensor materials on the skin-contact side of the invention.”

Ex. 1011 ¶ [0030]. Thus, Jensen’s device is “adapted to be directly non-permanently affixed to the skin surface of the patent.” Ex. 1009 ¶ 273.

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

Limitation 11 is obvious in view of Jensen, Kroll, and the knowledge of a POSA. As noted above, a POSA would have looked to combine the “resistive traces” of Kroll with the monitoring device of Jensen. *Supra* § VII.A.1.

Jensen discloses a communication-computation module comprising “a flexible circuit assembly.” *See supra* § VII.A.2.vii; Ex. 1011 ¶¶ [0031]-[0033], [0040], [0043]. Jensen’s flexible circuit assembly includes “copper wiring [] to connect the entire circuit.” Ex. 1011 ¶ [0040].

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 would help safeguard Jensen’s communication-

computation module in the event of a patient being defibrillated because the resistive traces help reduce excess electrical current flowing in either direction (either towards the computation-communication module or towards the patient). It therefore would have been obvious to a POSA to combine Jensen's teaching of a communication-computation module on a flexible printed medium with Kroll's teaching of resistive traces on a flexible, wearable medium, which would meet limitation 1/. Ex. 1009 ¶¶ 274-279.

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

Limitation 1m is obvious in view of Jensen, Kroll, and the knowledge of a POSA. As noted above, a POSA would have looked to combine the "resistive traces" of Kroll with the monitoring device of Jensen. *See supra* § VII.A.1.

Jensen discloses a communication-computation module comprising a "flexible circuit assembly" containing an electrical circuit. Ex. 1011 ¶ [0040]. Jensen thus teaches the claimed "flexible substrate" on which copper wiring traces connect the circuit components. *Id.* Kroll teaches the use of printed ink comprised of a material with a given resistance. Ex. 1013, 5:8-12. A POSA would understand printing ink onto a circuit board to be a form of screening, meaning that incorporating Kroll's ink traces on the flexible substrate of Jensen would yield "at least one series current-limiting resistor being screened on a flexible substrate." Ex. 1009 ¶¶ 280-287.

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

Limitation 1n is obvious in view of Jensen, Kroll, and the knowledge of a POSA.

Kroll further 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. 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 ¶¶ 288-292.

3. Claim 2

In addition to teaching the limitations of claim 1, Jensen discloses “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,” as recited in claim 2.

A POSA would understand that a “direct” electrical connection to the body is one in which the conductor makes physical contact with the skin, for example through a wet electrode or a dry electrode (plus the moisture that naturally exists on the skin). Ex. 1009 ¶ 295, *see generally, id.* ¶¶ 293-296. Sensor pads 1 and 2 of

Jensen are in contact with the patient's skin (Ex. 1011 ¶¶ [0030]-[0031]), and thus form a "direct electrical connection" to the body. Ex. 1009 ¶ 295; *see generally, id.* ¶¶ 293-296. Thus, Jensen meets this limitation.

4. Claim 4

In addition to teaching the limitations of claim 1, Jensen and Kroll "wherein the body worn patient monitoring device comprises an ECG monitor and at least two of the electrical connections are ECG electrodes," as recited by claim 4. Jensen teaches a "self-attached device that integrates other sensors together with heart-rate/EKG electronic sensors." Ex. 1011 ¶ [0012]; *see also id.* ¶ [0031] (noting "[s]ignals from [] sensors 1, 2"). A POSA would know that EKG is synonymous with ECG. Ex. 1009 ¶ 299. Jensen also teaches that "sensor pad electrodes 1 and 2 are coated with a conductive adhesive . . . as found in off-the-shelf EKG sensor pads." Ex. 1011 ¶ [0041]. "Sensor pad electrodes 1 and 2" are at least two ECG electrodes. *Id.* The combination of Jensen and Kroll therefore discloses both "an ECG monitor" and "at least two of the electrical connections are ECG electrodes." Ex. 1009 ¶¶ 297-301.

5. Claim 5

In addition to teaching all of the limitations of claims 1 and 4, Jensen and Kroll teach that "the ECG electrodes comprise a material screened onto the flexible substrate," as recited in claim 5. Jensen teaches a "flexible circuit assembly 36" and

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, 5:23-29; *see also* Ex. 1011 ¶ [0014]. A POSA would have known to use the “silk screen process” of Kroll to attach “electrodes 35” to a base layer of “flexible circuit assembly 36” of Jensen. Ex. 1009 ¶¶ 305-306. The combination of Jensen and Kroll therefore discloses “a material screened onto the flexible substrate.” *Id.* ¶ 307.

6. Claim 6

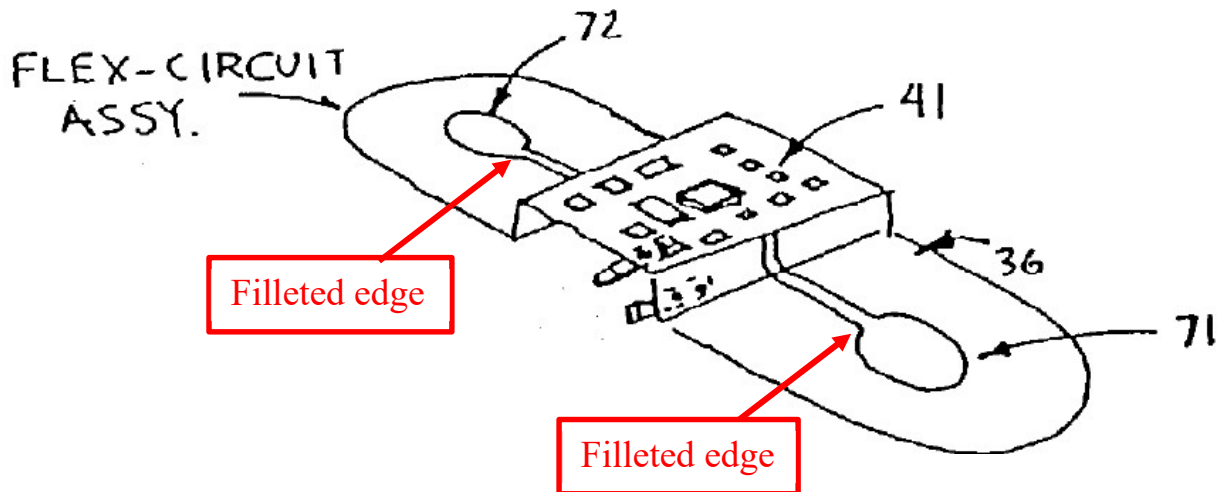
In addition to teaching the limitations of claims 1, 4, and 5, Jensen and Kroll teach the “at least one series current-limiting resistor protects the communication-computation module during a patient defibrillation event,” as recited in claim 6. Jensen teaches a “communication-computation module”—a “transmitter” for communication and a “microcontroller,” for computation. Ex. 1011 ¶ [0032]. 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 at 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 because the resistive traces help reduce excess electrical current flowing in either direction (either towards the computation-communication module or towards the patient). Ex. 1009 ¶ 311; *see also id.* ¶¶ 308-313. 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; *id.* 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 ¶ 312. Accordingly, the combination of Jensen and Kroll teaches that “at least one series current-limiting resistor protects the communication-computation module during a patient defibrillation event.”

7. Claim 7

In addition to teaching the limitations of claims 1 and 4, Jensen and Kroll teach that “the mechanical interface from the at least one series current-limiting resistor to the EGG electrode includes a filleted edge,” as recited in claim 7. As explained in the '007 patent, “[a] fillet or ‘tear drop’ shape causes the carbon trace to become gradually wider as it connect[ed] to [the] conductive surface.” Ex. 1001, 8:40-42. Jensen teaches “copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72” that are shaped as fillets. Ex. 1011 ¶ [0040], Fig. 5. A POSA would understand that the traces would gradually get wider to mechanically connect to the filleted sensor contacts 71, 72. Ex. 1009 ¶ 318; *see also id.* ¶¶ 314-320. This is shown in Figure 5 of Jensen (excerpted below) where the end of the trace

connected to the fillet shaped sensor contact 71, 72 is wider than that connected to circuit 41.



Ex. 1011, Fig. 5 (annotated). As explained above, when incorporating the “resistive trace” of Kroll, a POSA would follow the underlying shape of the electric trace of Jensen, which includes a “filleted edge.” Accordingly, the combination of Kroll and Jensen discloses that “the mechanical interface from the at least one series current-limiting resistor to the ECG electrode includes a filleted edge.”

8. *Claim 8*

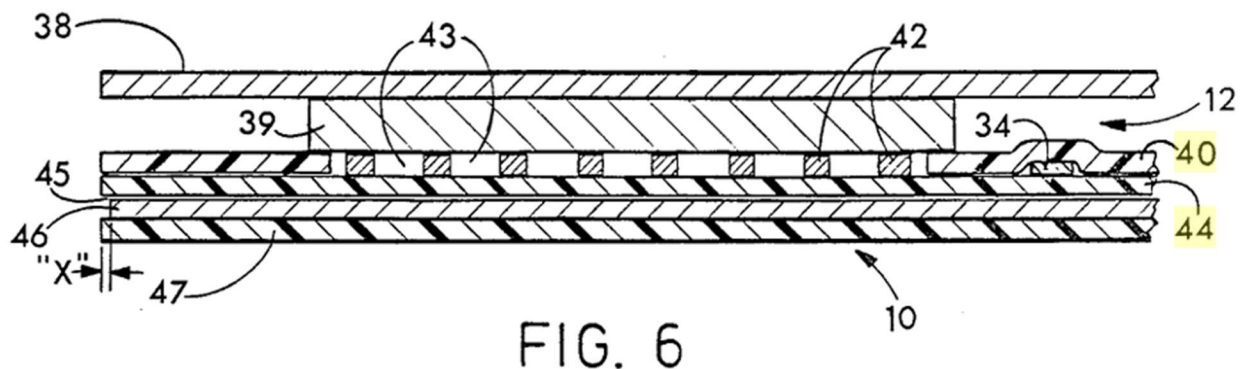
In addition to teaching the limitations of claims 1 and 4, Jensen and Kroll teach that “the mechanical interface from the at least one series current-limiting resistor to the ECG electrode comprises overlapped layers,” as recited in claim 8. Kroll discloses “at least one series current limiting resistor.” *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, 5:17-21, 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 different materials. Ex. 1009 ¶¶ 325-26.

Ex. 1013, Fig. 5 (annotated).

In addition to teaching the limitations of claim 1, Jensen and Kroll teach that “an insulating material overlaying the at least one series current limiting resistor to prevent arcing,” as recited in claim 10. Jensen discloses aesthetic covers 35 made of Mylar sheets that are placed on top of copper wiring traces. Ex. 1011 ¶¶ [0040], [0043]. A POSA would understand aesthetic covers 35 to be an insulating material

that overlay the traces to prevent arcing. Ex. 1009 ¶ 330. In addition, 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 insulating to prevent lead strip 34 from arcing. Ex. 1009 ¶¶ 327-33. Accordingly, Jensen and Kroll teach insulating materials that overlay the current limiting resistor to prevent arcing.

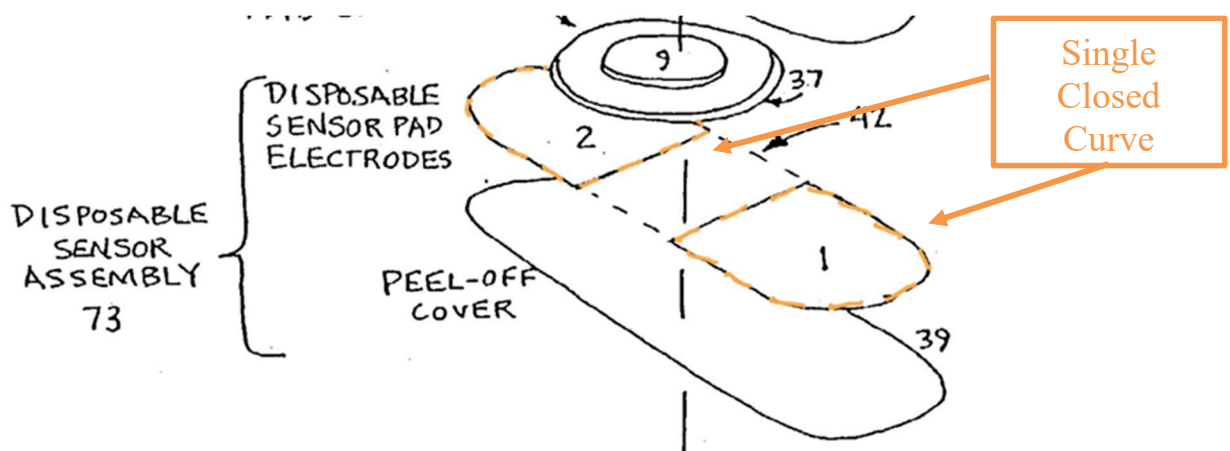


Ex. 1013, Fig. 6 (annotated).

10. Claim 11

In addition to teaching the limitations of claims 1, 4, and 5, Jensen and Kroll teach that “the EGG electrodes are formed substantially in the shape of an annulus,” as recited in claim 11. The ’007 patent explicitly defines “annulus.” Ex. 1001, 6:62-63. “Under this definition, an annulus can include substantially square shapes,

substantially rectangular shapes, substantially circular shapes,” and includes “a substantially ‘U’ shaped surface as described by a single closed curve.” *Id.* 6:64-7:3. As noted above, Section VII.A.2.iv, Jensen discloses that “sensor pad electrodes 1 and 2” are at least two ECG electrodes. Sensor pads 1, 2 each comprise a single closed curve, as shown in Figure 5 of Jensen.



Ex. 1011, Fig. 5 (annotated). Accordingly, Jensen discloses ECG electrodes formed substantially in the shape of an annulus. Ex. 1009 ¶¶ 336-38.

11. Claim 12

In addition to teaching the limitations of claims 1, 4, 5, and 11, Jensen and Kroll teach that “the annulus comprises a conductive link,” as recited in claim 12. As noted above, Section VII.A.10, sensor pad electrodes 1 and 2 of Jensen are formed substantially in the shape of an annulus. Through the conductive adhesive on the circuit side of the annulus, disposable sensor pads 1, 2 also form an electrical connection (conductive link) with sensor contacts 71, 72 of the flexible circuit

assembly. Ex. 1011 ¶ [0041], Fig. 5. Accordingly, Jensen discloses that the annulus comprises a conductive link. Ex. 1009 ¶¶ 341-342.

12. Claim 13

In addition to teaching the limitations of claims 1, 4, and 5, Jensen 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,” as recited in claim 13. 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 at 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 ¶ 345. Given the teaching of Kroll, a POSA would have known to place the wearable monitor of Jensen 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.* ¶¶ 346-48. Jensen reinforces this conclusion through its teaching of an “optim[al] pick-up location,” where moving the device away from that location would result in “erratic EKG readings.” Ex. 1011 ¶ [0007].

13. Claims 14 and 15

In addition to teaching the limitations of claim 1, Jensen 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. Jensen discloses that the flexible circuit assembly 36 of the wearable monitor is connected to “a rechargeable type of power source,” which a POSA would understand to be a renewable power source. *Id.* ¶ [0040]. Jensen also discloses that the flexible circuit assembly 36 is connected to “Lithium coin cell 9,” also known as a coin battery. *Id.* Accordingly, Jensen and Kroll teach both that the power source may be renewable in the form of a rechargeable power source and that a battery may be for one time use in the form of a Lithium coin cell battery. Ex. 1009 ¶¶ 349-357.

14. Claim 29

In addition to teaching the limitations of claim 1, Jensen 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,” as recited in claim 29. 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. A conductive filler composition resulting in a lead strip resistance of approximately 1000 ohms

allows for signals transmission throughout the lead strip 34.” Ex. 1013, 5:8-16. 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 ¶¶ 358-362. 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; *see also id.* 10:19-29 (emphasis added); Ex. 1009 ¶ 361. The ’007 patent also discloses that “[t]he resistances of the protective resistive traces be in a range between about 1 kilo ohm to about 10 kilo ohms” (Ex. 1001, 7:46-48), within which the resistive lead strips of Kroll falls. Accordingly, the combination of Jensen and Kroll teaches circuit protection to allow the device to survive multiple defibrillation cycles of at least 360 Joules. Ex. 1009 ¶ 362.

15. Claim 31

In addition to teaching the limitations of claims 1 and 29, Jensen and Kroll teach that the “plurality of components of the circuit protection are distributed between the disposable module and the communication-computation module,” as recited in claim 31. 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” protects the monitoring device from a defibrillation event. Ex. 1009 ¶¶ 363-368. To

do so the “current-limiting resistor” that provides the circuit protection must be placed or distributed between the electrodes on the disposable module and the communication-computation module. *Id.* Accordingly, the combination of Jensen and Kroll teaches distributing circuit protection between the disposable module and the communication-computation module.

16. Claim 37

In addition to teaching the limitations of claim 1, Jensen 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.” *Id.* ¶¶ 369-372. Jensen teaches the use of a “logic driver 29,” which “supplies a switched supply voltage to disable and enable the operation of” various processing modules. Ex. 1011 ¶ [0031]. Jensen further explains that “[w]ith use of switched supply voltage driver 29, power from the system power source 9 is conserved whenever the sensors 1, 2 are not in contact with the user’s skin.” *Id.* Jensen thus teaches that its 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. Ex. 1009 ¶¶ 370-372.

17. Claim 38

In addition to teaching the limitations of claim 1, Jensen and Kroll teach that “the communication-computation module is protected from external high energy

signals by electro-surgical isolation suppression circuits,” as recited in claim 38. 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 ¶¶ 375-377. 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.” Ex. 1001, 14:25-30.

18. Claim 43

In addition to teaching the limitations of claim 1, Jensen and Kroll teach that “the radio circuit communicates an unprocessed physiological signal,” as recited in claim 43. Jensen discloses that signals detected by sensors 1 and 2 are either “input[ted] directly to transmitter 7, or may be input into microcontroller 10.” Ex. 1011 ¶ [0032]. A POSA would understand that the detected signal being

directed straight to the transmitter means that the radio circuit communicates an unprocessed physiological signal. Ex. 1009 ¶¶ 378-381.

19. Claim 44

In addition to teaching the limitations of claim 1, Jensen and Kroll teach that “the radio circuit communicates a result of the physiological analysis at a predetermined time,” as recited in claim 44. Jensen discloses a “radio data transmission” and that a “[m]icrocontroller sends a packet periodically containing a log of all data points since last transmission.” Ex. 1011 ¶ [0037], Table 1; *see also id.* Abstract. A POSA would understand that a periodic transmission is transmitted as a predetermined periodicity. Ex. 1009 ¶ 384. Accordingly, Jensen and Kroll disclose the dependent limitation of claim 44.

20. Claim 45

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

As described above, Jensen discloses this element. *Supra* § VII.A.2.i.

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

As described above, Jensen discloses this element. *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, Jensen discloses this element. *Supra* § VII.A.2.iii.

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

As described above, Jensen discloses this element. *Supra* § VII.A.2.v.

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

As described above, Jensen discloses this element. *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 above, Jensen discloses this element. *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,**

Jensen discloses 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. Ex. 1009 ¶¶ 399-402.

Jensen discloses a “microcontroller,” which “runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter.” Ex. 1011 ¶ [0032]. A POSA would understand that Jensen’s microcontroller that processes data includes a microprocessor. Ex. 1009 ¶ 401. One of the functions of the disclosed microprocessor is to “electrically detect the occurrence of R events in the QRS complex of the EKG signal.” Ex. 1011 ¶ [0029].

As Jensen explains, “[o]nce microcontroller 10 identifies the data as having a heart beat pulse, (a clearly identifiable waveform with a distinctive shape and a high signal amplitude compared to typical ambient noise from the sensor), then the program analyzes the data in a number of optional ways. . . . The microcontroller has the capability of performing conventional programmatic signal analysis to create and transmit different data records.” *Id.* ¶ [0037]. Thus, Jensen discloses this element. Ex. 1009 ¶¶ 401-402.

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

Jensen discloses 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.

Jensen discloses that “a microcontroller then converts the heart-rate data information into one of multiple data output formats, which are sent by radio data transmission to any variety of outside receiving equipment.” *Id.* Abstract. Jensen further discloses “transmitter 7,” which “may transmit in a variety of modulation and/or keying methods via antenna 8.” *Id.* ¶ [0033]. Jensen describes “[d]ata modulation methods in an RF [*i.e.*, radio frequency] transmitter that are easily

implemented.” *Id.* Transmitter 7 may transmit “an encoded data message and output by the program that microcontroller 10 executes.” *Id.* The transmitted output includes the results of physiological analysis on the occurrence of the predetermined physiological event. *Supra* § VII.A.20.vii; *see also* Ex. 1011 ¶ [0037], Table 1.

Jensen discloses, in Table 1, both unprocessed physiological signals and results of the physiological analysis which may be transmitted using Jensen’s radio circuit. *See* Ex. 1011 ¶ [0037], Table 1 (disclosing, *e.g.*, “beat reporting” and “rolling average heart rate” reporting). Such reporting may occur on a fixed time or upon occurrence of a predetermined event. *Id.*

Additionally, or alternatively, to the extent that Jensen does not 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 Jensen’s device. Ex. 1009 ¶¶ 403-405. 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.* 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, Jensen discloses this element. *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 above, Jensen discloses this element. *Supra* § VII.A.2.xii.

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

As described above, this element is obvious in view of Jensen 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 above, this element is obvious in view of Jensen 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 above, this element is obvious in view of Jensen and Kroll.

Supra § VII.A.2.xv.

B. Ground 2: Claims 32-35 Are Obvious Over Jensen and Kroll, and/or Jensen, Kroll, DeLuca, and General Knowledge of a POSA

Claims 32-35 of the '007 patent depend from claim 1 and recite limitations related to signal filtering. As demonstrated below, signal filtering was well known in the art at the time of the invention and these challenged claims merely recite those well-known techniques. Jensen discloses signal filtering techniques. And so do

other references, including DeLuca. In view of these disclosures, claims 32–35 are also obvious.

1. A POSA would have combined Jensen, Kroll, and DeLuca

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 Jensen’s device. A POSA seeking to make the Jensen-Kroll combination would have also been motivated to incorporate DeLuca’s signal conditioning filters into the device. DeLuca, like Jensen and Kroll, teaches a flexible, wearable device for monitoring physiological data, including EKG data. Ex. 1015, 1:6-9, 1:11-15, 2:1-4, 3:30-39. DeLuca also discloses techniques that improve the quality of the signal received by the processor.

Jensen itself discloses the use of a bandpass filter as part of the signal conditioning on the device. Ex. 1011 ¶ [0036]. The use of signal filtering was a well-known step, for example in the Pan-Tompkins QRS detection algorithm, a widely known and utilized algorithm for electronically detecting heartbeat signals from EKG data. *See* Ex. 1009 ¶¶ 416-417. A POSA seeking to make a device—which can “perform signal processing and calculation upon the data contained within [EKG] signals” onboard, Ex. 1011 ¶ [0029]—would have sought to implement a signal-filtering algorithm, such as the Pan-Tomkins algorithm, on the device

“to reliably detect patient heartbeats.” Ex. 1009 ¶ 416. And to do so, a POSA would have looked to DeLuca, which describes an implementation of that algorithm’s bandpass filters in great detail. *Id.*

A POSA would have had a reasonable expectation of success in implementing DeLuca’s signal conditioning filters on Jensen’s device, as modified by Kroll, without undue experimentation, at least because it would involve only a modification of Jensen’s existing switchable, tunable, bandpass filter. *Id.* ¶ 417. A POSA would know how to combine DeLuca’s specific bandpass filtering configuration with Jensen’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.* ¶¶ 416-417.

2. Claim 32

In addition to teaching the limitations of claim 1, Jensen and Kroll and/or Jensen, Kroll, and DeLuca teach “a high pass filter with a selectable corner frequency to filter the physiological signals.” Jensen teaches that “signals from the sensors 1 & 2 are amplified by the amplifier circuit section 4. The amplified signal is then bandpass filtered by circuit section 5.” Ex. 1011 ¶ [0032]. Jensen’s circuit section 5 “is set to operate at a particular gain value by the gain setting resistors 21, and then fed into switched capacitor filter 11.” *Id.* ¶ [0036]. A POSA would

understand that “switched capacitor filter” is a “high pass filter with a selectable corner frequency to filter the physiological signals,” and that Jensen therefore discloses the dependent limitation of claim 32. Ex. 1009 ¶ 421.

Additionally, or alternatively, DeLuca discloses the dependent limitation of claim 32. As noted above, a POSA would have looked to combine DeLuca’s specific “signal conditioning” filters with Jensen’s device, which itself already discloses a tunable, switchable bandpass filter. *See supra* § VII.B.1; Ex. 1011 ¶¶ [0032], [0036]-[0037], [0049]. 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, 4:65-5:2. DeLuca discloses that “the signal conditioning stage 56 includes a hi-pass filter 56a.” *Id.* 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.

As explained above, a POSA would have recognized that DeLuca’s band-pass filtering disclosures are consistent with the Pan-Tompkins QRS detection algorithm. *Supra* § VII.B.1. It therefore would have been obvious to combine DeLuca’s teaching of a high-pass filter with a selectable corner frequency with Jensen’s disclosure of bandpass filtering, meeting the dependent limitation of claim 32. Ex. 1009 ¶¶ 418-424.

3. *Claim 33*

In addition to teaching the limitations of claims 32 and 1, Jensen and Kroll, and/or Jensen, Kroll, and DeLuca teach that “the corner frequency is selected by a switch selectable resistance.” Jensen discloses that the “[f]requency divider 15 outputs filter control signals that modify the bandpass characteristics of [the switched capacitor] filter 11.” Ex. 1011 ¶ [0036]. DeLuca discloses that “the signal-conditioning stage 56 includes a hi-pass filter 56a.” 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.

A POSA would understand that a switched-capacitor filter circuit, such as that taught by Jensen and by DeLuca, and a switched circuit including physical resistors are interchangeable methods for filtering. Ex. 1009 ¶ 428. The interchangeability of these circuit designs has been known in the art since at least the 1970s. *Id.* Additionally or alternatively, 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 Jensen’s disclosure of bandpass filtering, meeting the dependent limitation of claim 33. *Id.* ¶¶ 425-429.

4. *Claim 34*

In addition to teaching the limitations of claims 32 and 1, Jensen and Kroll, and/or Jensen, 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. Jensen explicitly discloses a “switched capacitor filter 11” as an element of its “filter circuit section 5.” Ex. 1011 ¶ [0036]. The output of switched capacitor filter 11 has “bandpass cutoff frequencies of typically 1.5 Hz at the low-end and 17 Hz at the high-end.” *Id.* ¶ [0037]. DeLuca discloses that “the signal-conditioning stage 56 includes a hi-pass filter 56*a*, an amplifier 56*b*, a lo-pass filter 56*c*, and an anti-aliasing filter 56*d*.” Ex. 1015, 5:2-4. “Each of the filter modules 56*a*, 56*c*, and 56*d*, 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 output from the input stage 55 is first coupled to the hi-pass filter 56*a* 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 disclosed by either Jensen or DeLuca 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 ¶ 433.

A POSA would therefore recognize that Jensen teaches the dependent limitation of claim 34. Ex. 1009 ¶ 430-34. Additionally or alternatively, 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 Jensen's disclosure of bandpass filtering, meeting the dependent limitation of claim 34. *Id.*

5. Claim 35

In addition to teaching the limitations of claims 32 and 1, it would have been obvious to a POSA to modify the combination of Jensen, Kroll, and DeLuca such that "the high pass filter is implemented in software running on the microprocessor." *Id.* ¶¶ 435-439. 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 processing steps 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 ¶ 438. 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. 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 Jensen’s disclosure of bandpass filtering, meeting the dependent limitation of claim 35. *Id.* ¶¶ 435-439.

C. Ground 3: Claims 2 and 3 Are Obvious Over Jensen, Kroll, Harland, and General Knowledge of a POSA

Claims 2 and 3 of the ’007 patent refer to “indirect” and “capacitive” connections to the body of a patient undergoing physiological monitoring. As with the other dependent limitations of the ’007 patent, indirect or capacitive connections to the body were well known in the art. Harland, an electrical engineering article, demonstrates just that. For the reasons set forth below, a POSA would have been motivated to combine Harland’s teaching with Jensen and Kroll, rendering claims 2 and 3 obvious.

1. *A POSA would have combined Jensen, Kroll, and Harland*

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 Jensen’s device.

Additionally, a POSA would have looked to incorporate Harland’s teaching of a capacitive sensor probe into Jensen’s device as modified by Kroll. Ex. 1009 ¶¶ 440-442. 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.”

Id. ¶ 440. Concerns over dermal tolerability of electrodes would be especially acute in a device such as Jensen’s because it is intended to be worn for an extended period.

Id.

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 ¶¶ 440-442. Accordingly, a POSA would have looked to Harland’s work for specific details on implementing this technology in Jensen’s device. *Id.*

A POSA would have had a reasonable expectation of success in implementing Harland’s capacitive electrode on Jensen’s device without undue experimentation, at least because it would require only alterations to the circuitry according to the architecture set forth in Harland. *Id.* ¶ 442. A POSA would know how to combine Harland’s capacitive electrode with Jensen’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

As explained above, *supra* § VII.A.3, Jensen discloses claim 2 because Jensen teaches direct electrical connections to the body.

Additionally, or alternatively, the combination of Jensen, Kroll, 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 recited in dependent claim 2.

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 ¶ 445. 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 in the measurement.” *Id.* As explained above, it would have been obvious to a POSA to modify Jensen to include at least one such capacitive electrode. *Supra* § VII.C.1. As modified, the device of Jensen would therefore include at least one indirect electrical connection to the body. Ex. 1009 ¶¶ 443-447.

3. *Claim 3*

In addition to teaching the limitations of claims 1 and 2, *see supra*, Jensen, 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 in the measurement.” *Id.*

As explained above, it would have been obvious to a POSA to modify the device taught by Jensen, which would meet the dependent limitation of claim 3. *Supra* § VII.C.1; Ex. 1009 ¶¶ 448-451.

D. Ground 4: Claim 39 Is Obvious Over Jensen, Kroll, Thompson, and General Knowledge of a POSA

Claim 39 of the ’007 patent recites a low-power mode based on certain physiological indicators. Low-power modes were ubiquitous in portable electronics because they conserve battery power. Jensen discloses a low-power mode. And Thompson discloses another variation on a low-power mode, which is driven by key points in the typical human heartbeat. As explained below, the dependent limitation

of claim 39 was known and obvious in view of the prior art, including Jensen, Kroll and Thompson.

1. A POSA would have combined Jensen, Kroll, and Thompson

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 Jensen’s device.

Additionally, a POSA would have been motivated to incorporate Thompson’s teaching of a periodic low power mode on Jensen’s device. A POSA would recognize that the utility of a battery-powered, wearable device is limited by its battery life. Ex. 1009 ¶ 453. 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.*

Jensen recognizes this concern and suggests one possibility for accomplishing this goal: using a “switched supply voltage driver 29” so that “power from the system power source 9 is conserved whenever the sensors 1,2 are not in contact with the user’s skin.” Ex.1011 ¶ [0031]; Ex. 1009 ¶ 454.

However, a POSA would have been aware of other techniques for optimizing battery life, including the use of a periodic low power mode. Ex. 1009 ¶ 454. A

POSA would have sought other ways to conserve power, even while the device was operational. *Id.* ¶ 455.

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.*, during 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.

A POSA would have had a reasonable expectation of success in implementing Thompson’s low power mode on Jensen’s device without undue experimentation, at least because it would require only reprogramming of onboard software. Ex. 1009 ¶ 457. A POSA would know how to combine Thompson’s low power mode with Jensen’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 the limitations of claim 1, *see supra*, Jensen, 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 heart beat, to save power.”

Thompson discloses a device that operates in a high-power mode only during the QRS interval; Thompson’s device 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. *See* 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 ¶ 460. A POSA would also recognize that this low power mode could be implemented on Jensen’s microprocessor. *Id.* ¶ 461. Accordingly, the dependent limitation of claim 39 would be obvious to a POSA in view of the combination of Jensen, Kroll, and Thompson. *Id.* ¶ 462.

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, which differ on the basis of the primary reference asserted. Each petition challenges over 20 claims, and the challenged independent claims involve over 16 limitations, including numerous lengthy limitations, necessitating two petitions.

Petitioner requests that the Board consider this petition's grounds first. This Petition uses as a primary reference art that was previously presented to the Office combined with secondary references that were not; the other cites art not previously before the office. For the reasons set forth below, the grounds asserted herein 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. Further, 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.

Section 325(d). Jensen qualifies as art previously presented to the Office because it was listed on Information Disclosure Statements supplied by the Applicant. Ex. 1002, 61, 195, 261, 327, 610, 669, 698. *Cf. Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020). None of Kroll, DeLuca, Harland, and Thompson were presented to the Office during examination.

The factors enumerated in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) do not counsel against institution. At minimum, none of the references submitted as part of Ground 2 were considered by the Office and, for that reason alone, Section 325(d) does not warrant denial of institution.

As to Jensen, the Examiner failed to consider how Jensen alone or in combination with any other reference would render obvious the purported invention of the '007 patent. The art cited by the Examiner during prosecution did not disclose, *inter alia*, resistive traces on a body-worn physiological monitor as Kroll does

(Factor A). The Examiner did not substantively address any combination that was similar to Jensen and Kroll during prosecution (Factor B). This is at least because none of the grounds considered by the Examiner discloses a monitor that includes a resistive trace. For example, Merry (U.S. 6,623,312), relied on by the Examiner to disclose the series current-limiting resistors, is a traditional resistor located on a printed circuit board (Merry, 7:35-43, Fig. 3; *see also* Applicant Response to Final OA at 17 (Mar. 2, 2011), Ex. 1002, 148), not the “resistive trace” described in Kroll. In another example, Ulmer (U.S. 6,539,613) cited by the Examiner teaches embedding a conventional resistor into a substrate (Ulmer, Abstract, Figs. 2-8; Applicant Response to Final OA at 17 (Mar. 2, 2011), Ex. 1002, 148), not the “resistive trace” described in Kroll.

In addition, neither Jensen nor a Jensen-based combination formed the basis for rejection during prosecution (Factor C). Instead, Jensen was cited in an Information Disclosure Statement along with 45 other references, none of which was substantively addressed during examination of the application that became the ’007 patent. The Board has repeatedly held that a reference that is merely cited in an IDS does not weigh in favor of a discretionary denial. *See, e.g., Gene Co. Pty Ltd. v. Trs. of Columbia Univ.*, IPR 2024-00313, Paper 13 at 56-57 (PTAB June 24, 2024); *Advanced Energy Indus. v. Reno Techs. Inc.*, IPR2021-01397, Paper 7 at 7 (PTAB Feb. 16, 2022); *Lyft, Inc. v. RideShare Displays, Inc.*, IPR2021-01602, Paper 7 at

15-16 (PTAB Apr. 11, 2022). These decisions are consistent with the USPTO’s notice of proposed rulemaking on this issue, which notes that “[a]n initialed Information Disclosure Statement, without more, does not satisfy” the criteria of 325(d). Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement, 89 Fed. Reg. 28693 (proposed Apr. 19, 2024) (to be codified at 37 C.F.R. pt. 42). The arguments in this Petition related to Jensen, which rely on combinations of prior art that include Kroll, DeLuca, Thompson, and Harland (never before the Office), do not overlap with those made during examination (Factor D). That is because none of the references considered during prosecution discloses the “resistive trace” of Kroll.

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
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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.
7.	The body worn device of claim 4, wherein the mechanical interface from the at least one series current-limiting resistor to the EGG electrode includes a filleted edge.
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.

Claim	Recitation
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 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.

Claim	Recitation
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 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

Claim	Recitation
	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,
[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 13,420 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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