

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

iRhythm Technologies, Inc.

Petitioner,

v.

Welch Allyn, Inc.

Patent Owner.

Case: IPR2025-01081

U.S. Patent No. 8,630,699

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

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LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 8,630,699
1002	File History of U.S. Patent No. 8,630,699
1003	Expert Declaration of Jason Heikenfeld
1004	<i>Curriculum Vitae</i> of Dr. Jason Heikenfeld, Ph.D.
1005	U.S. Patent Publication No. 2003/0149349 (“Jensen”)
1006	Certified English Translation of Japanese Pat. Pub. JP2004/121360 (“Matsumura”) ¹
1007	U.S. Patent No. 4,763,660 (“Kroll”)
1008	Khandpur, Raghbir Singh. <i>Printed Circuit Boards: Design, Fabrication, Assembly and Testing</i> . New York: McGraw Hill, 2006
1009	U.S. Patent No. 6,223,080 (“Thompson”)
1010	Jan Adamec & Richard Adamec, <i>ECG Holter, Guide to Electrocardiographic Interpretation</i> (2008)
1011	Gautham Kalahasty et al., <i>A Brief History of Remote Cardiac Monitoring</i> , 5 Cardiac Electrophysiology Clinics 275 (2013)
1012	Edward K. Chung, <i>Ambulatory Electrocardiography Holter Monitor Electrocardiography</i> (1979)
1013	U.S. Patent Publication No. 2006/0224072 (“Shennib”)

¹ Exhibit 1046 is the original Japanese language Matsumura reference, and Exhibit 1047 is the declaration attesting to the accuracy of the translation in Exhibit 1006. Exhibit 1047 refers to Exhibit 1006 as “403-45924_JP2004121360A_JA into EN,” with JP2004121360A being the publication number of Matsumura.

Exhibit No.	Description
1014	Daniel E. Becker, <i>Fundamentals of Electrocardiography Interpretation</i> , 53 Anesthesia Progress 53, 53 (2006)
1015	Brian Burkhardt, <i>The Future of Electrocardiograph Telemetry Systems</i> , Int'l Telemetering Conference Proceedings (2004)
1016	PCT Publication WO 2008/005015 A1
1017	Majd AlGhatrif & Joseph Lindsay, <i>A Brief Review: History to Understand Fundamentals of Electrocardiography</i> , 2 J. Community Hosp. & Internal Med. Persps. 14383 (2012)
1018	NLM, <i>In brief: What is an electrocardiogram (ECG)?</i> , available at https://www.ncbi.nlm.nih.gov/books/NBK536878/
1019	Michael R. Neuman, <i>Biopotential Electrodes</i> , Medical Instrumentation (3d ed. 1998)
1020	Robert P. Grant, <i>Spatial Vector Electrocardiography</i> , Circulation Vol. II, 676 (Nov. 1950)
1021	ACLS Medical Training, <i>The Basics of ECG</i> , available at https://www.aclsmedicaltraining.com/basics-of-ecg/
1022	Euan A. Ashley & Josef Niebauer, <i>Cardiology Explained</i> (2004), available at https://www.ncbi.nlm.nih.gov/books/NBK2204/
1023	Am. Coll. Cardiology, Am. Heart Ass'n Task Force on Prac. Guidelines, <i>ACC/AHA Guidelines for Ambulatory Electrocardiography: Executive Summary and Recommendations</i> , 100 Circulation 886 (1999), available at https://www.ahajournals.org/doi/full/10.1161/01.cir.100.8.886
1024	Mike Cadogan, <i>Norman J. Holter</i> (2022), available at https://litfl.com/norman-j-holter/
1025	Joel Morganroth, <i>Ambulatory Holter Electrocardiography: Choice of Technologies and Clinical Uses</i> , Annals of Internal Med. (1985)
1026	Nitish V. Thakor, <i>From Holter Monitors to Automatic Defibrillators: Developments in Ambulatory Arrhythmia Monitoring</i> , IEEE Transactions on Biomed. Eng'g, 770 (1984)
1027	U.S. Patent No. 6,454,708 ("Ferguson")

Exhibit No.	Description
1028	David Prutchi & Michael Norris, <i>Design and Development of Medical Electronic Instrumentation</i> (2005)
1029	U.S. Patent Publication No. 2005/0096513
1030	AAMI, <i>Cardiac monitors, heart rate meters, and alarms</i> , ANSI/AAMI EC13:2002 (2002)
1031	U.S. Patent No. 5,169,679 (“Palanisamy”)
1032	U.S. Patent No. 6,229,098 (“Dunn”)
1033	U.S. Patent No. 6,238,338 (“DeLuca”)
1034	U.S. Patent No. 4,280,507 (“Rosenberg”)
1035	U.S. Patent No. 5,093,036 (“Shafe”)
1036	U.S. Patent No. 8,334,464 (“Edwards”)
1037	AAMI, <i>Ambulatory Electrocardiographs</i> , ANSI/AAMI EC38:1998 (1998)
1038	PCT Publication WO 1987/01024 A1 (“Dunseath”)
1039	Roger A. Freedman & Hugh D. Young, <i>University Physics</i> (15th ed. 2019)
1040	Bruce R. Bowman & Edward Schuck, <i>Medical Instruments and Devices Used in the Home</i> , CRC Press LLC (2000)
1041	U.S. Patent Publication No. 2003/0055460 (“Owen”)
1042	Patrick J. Nolan, <i>Sterile Medical Device Package Development</i> , Standard Handbook of Biomedical Eng’g & Design (2004)
1043	Tilak Shah, <i>Polyurethane Thin-Film Welding for Medical Device Applications</i> , Med. Device and Diagnostic Indus. (2002)
1044	J. Mühlsteff et al., <i>Wearable Approach for Continuous ECG –and Activity Patient-Monitoring</i> , 26th Ann. Int’l Conf. of IEEE Eng. Med. & Bio. Society, San Francisco, CA, USA, 2004
1045	Jameco Electronics, <i>8-Pin, 8-Bit CMOS Microcontrollers Data Sheet</i> , https://web.archive.org/web/20031126132956/http://jameco.com/Jameco/Products/ProdDS/200475.pdf (available as of Nov. 26, 2003)

Exhibit No.	Description
1046	Japanese Patent Publication No. JP2004/121360
1047	Certificate of Translation for Japanese Patent Publication No. JP2004/121360
1048	Minute Order, <i>Welch Allyn, Inc. v. iRhythm Techs., Inc.</i> , No. 1:24-cv-00224-MN, (D. Del. Jan. 28, 2025)
1049	Scheduling Order, <i>Welch Allyn, Inc. v. iRhythm Techs., Inc.</i> , No. 1:24-cv-00224-MN, Dkt. No. 25 (D. Del. Jan. 15, 2025)
1050	Declaration of Sylvia D. Hall-Ellis
1051	<i>Curriculum Vitae</i> of Dr. Sylvia D. Hall-Ellis, Ph.D.
1052	Machine-Readable Cataloging record for R.S. Khandpur, <i>Printed Circuit Boards: Design, Fabrication, Assembly and Testing</i>
1053	MARC Display, Library of Congress Authorities
1054	AAMI, <i>Diagnostic electrocardiographic devices</i> , ANSI/AAMI EC11:1991 (1991)

I. INTRODUCTION

Pursuant to 35 U.S.C. § 311 and 37 C.F.R. § 42.100, iRhythm Technologies, Inc. (“Petitioner”) requests *Inter Partes* Review of claims 1-4 and 8 (the “Challenged Claims”) of U.S. Patent No. 8,630,699 (the “’699 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 ’699 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 1-4 are obvious under pre-AIA § 103 over Jensen, Kroll, and General Knowledge of a POSA
<u>Ground 2</u>	Claim 8 is obvious under pre-AIA § 103 over Jensen, Kroll, Thompson, and General Knowledge of a POSA

Proposed Grounds of Unpatentability	
<u>Ground 3</u>	Claims 1, 2, 4 are obvious under pre-AIA § 103 over Matsumura, Kroll, and General Knowledge of a POSA
<u>Ground 4</u>	Claim 3 is obvious under pre-AIA § 103 over Matsumura, Kroll, Khandpur, and of a POSA
<u>Ground 5</u>	Claim 8 is obvious under pre-AIA § 103 over Matsumura, Kroll, Thompson, and General Knowledge of a POSA

Sections VII.A-E identify where each element of the Challenged Claims is found in the prior art. 37 C.F.R. § 42.104(b)(4). The exhibit numbers of the evidence relied on to support the challenges are provided above and the relevance of the evidence to the challenges raised are provided in Sections VII.A-E. 37 C.F.R. § 42.104(b)(5). Exhibits 1001-1054 are attached.

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

Claims are interpreted according to 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. 1003).

Ground 1: Claims 1-4 are unpatentable under pre-AIA § 103 over Jensen in view of Kroll and the General Knowledge of a POSA.

Ground 2: Claim 8 is unpatentable under pre-AIA § 103 over Jensen in view of Kroll, Thompson, and the General Knowledge of a POSA.

Ground 3: Claims 1, 2, and 4 are unpatentable under pre-AIA § 103 over Matsumura in view of Kroll and the General Knowledge of a POSA.

Ground 4: Claim 3 is unpatentable under pre-AIA § 103 over Matsumura in view of Kroll, Khandpur, and the General Knowledge of a POSA.

Ground 5: Claim 8 is unpatentable under pre-AIA § 103 over Matsumura in view of Kroll, Thompson, and the General Knowledge of a POSA.

V. SUMMARY OF THE '699 PATENT

A. Technical Background

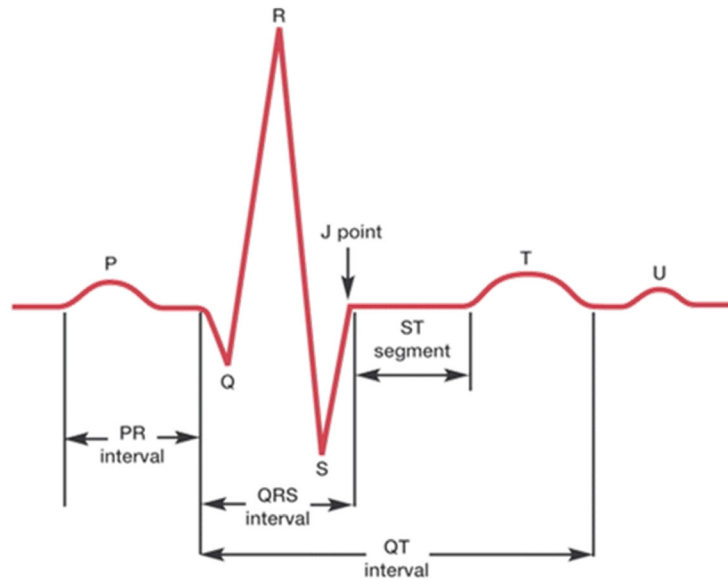
1. Remote Cardiac Monitoring

Since the early 20th century, physiological monitoring systems have been used to measure and report objective signs associated with human health and performance (*e.g.*, temperature, pulse, respiration rate, brain wave activity, muscular

contractions). Ex. 1003 ¶¶ 17-22. Over time, these systems evolved to monitor patients remotely during daily activities, outside of a clinical setting. *Id.* ¶¶ 23-24. To meet the demands of remote monitoring, such systems were designed to be portable and discreet, minimizing interference in the patient’s life. *Id.* ¶ 25.

An electrocardiogram (ECG or EKG)² is a type of physiological monitoring used to evaluate and monitor patients’ cardiac health. Originating in the 1920s, ECGs measure the electrical signals that result from depolarization and repolarization of cardiac muscle during each heartbeat. *Id.* ¶¶ 17-23. The normal pattern of voltage changes is known as “sinus rhythm,” and is represented by a waveform with standard features (shown in the figure below). The most prominent features of that waveform are known respectively as the “P-wave,” the “QRS Complex,” and the “T-wave.”

² The abbreviations “ECG” and “EKG” are used interchangeably by clinicians and scientists. Many clinicians prefer “EKG” (the *k* is based on the Greek word for heart, “*kardia*”) because it is less likely to be confused with “EEG” (the electroencephalogram, for the study of the brain) when spoken aloud in a hospital setting. Ex. 1003 ¶ 120.



Id. ¶¶ 19, 21. Identified deviations from sinus rhythm may be used to identify abnormal heart rate and/or rhythm, and may even enable a physician to localize a problem in a particular part of the heart (*e.g.*, one of the ventricles). *Id.* ¶ 19.

An ECG measures the heart muscles’ cycles of depolarization and repolarization using electrodes, which are typically attached to a patient’s skin using an adhesive. *Id.* ¶ 20; Ex. 1001, 1:31-34 (“[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. 1003 ¶ 27; Ex. 1001, 1:31-34, 1:43-47.

In 1949, Dr. Norman Holter introduced long-term ECG recording with the first wearable, ambulatory ECG monitor. Ex. 1003 ¶¶ 23-24. Twenty years later (in 1969), following efforts to reduce the size of the device, the Holter “*minimonitor*”—the size of a pack of cigarettes—was introduced. *Id.* Ambulatory monitoring of

patients, known as “Holter monitoring,” became a mainstay of cardiology practices, especially for diagnosis and treatment of those with serious cardiac conditions. *Id.* By 1979, Holter monitors were recognized for various clinical applications, ranging from arrhythmia diagnosis to pacemaker monitoring. *Id.*

Following the introduction of Holter’s “*minimonitor*,” engineers made improvements related to patient experience and data quality. *Id.* ¶¶ 24-25. For example, wearable monitors were made wireless, smaller, and more lightweight. Ex. 1001, 1:36-40, 1:43-47. These advances in wearable monitors were made possible by developments in electronics generally: smaller microcontrollers, increased computing power onboard the patient-worn devices, and improvements in wireless communication techniques. Ex. 1003 ¶ 24.

2. *Constructing Wearable Cardiac Monitors Using Printed Circuit Board Methods*

Along with the advent of better electronic components, the application of printed circuit board (PCB) technology was an essential technological factor in the development of wireless wearable cardiac monitors. Ex. 1003 ¶¶ 30-33. Most basically, printed circuit boards are comprised of a base (referred to as a “substrate”), which provides a mechanical support to all the components that will be mounted to the board, and conductors (referred to as “traces”), which form electrical connections among and between the various components mounted to the board. *Id.* ¶ 30. Given that ECG monitors are essentially electrical circuits connected to the body of a

patient, engineers designing these devices looked to well-known PCB technology to create smaller, self-contained, wearable ECG monitors. *Id.*

For example, it was well known in the field that PCB substrates could be formed from flexible materials, like polyester or polyamide. *Id.* ¶ 31. It was also well known that such so-called “flexible PCBs” were well-suited to body-worn devices because they could adapt to and with the human body in motion (*e.g.*, when a person bends or twists their body). *Id.*

It was also well known in the field that PCB traces—and other components on the board’s surface—could be created using a variety of techniques. *Id.* ¶¶ 32-33. One popular technique for doing so is “screen printing” (“screening” for short), whereby a conductive material (*e.g.*, an ink containing a conductive material such as silver) is extruded through a stencil onto the substrate, forming a predetermined pattern. *Id.* (citing Ex. 1008, 3 (noting that screen printing techniques were used to print “silver paste conductors and graphite resistors . . . onto ceramic substrate” as early as “the end of World War II,” and noting that “[i]t was [the screen-printing] technique that ushered in the commercial use of printed circuits”)). It was well known among PCB designers that varying the composition of the ink, the length of a trace, and the width of a particular trace, would result in traces of varying conductivities/resistivities. *Id.* ¶ 33 (citing Ex. 1031, 1:26-32 (“The resistance *R* of a particular resistor composition is generally tailored by adjusting its aspect ratio,

L/W where L is the length and W is the width of the resistive film. . . . R also increases inversely with the thickness of the film’’)). It was also known in the field that screening techniques could be used to create not only conductive traces, but also screen-printed resistors on the surface of a PCB. *Id.* ¶ 35. For example, it was well-known that resistors could be screened on top of conductive traces by: (1) screening traces using a highly conductive ink, leaving a gap between the traces for a resistor and (2) thereafter, in a second layer, screening a span of highly resistive ink over the “gap,” making contact with both of the traces to form a resistor. *Id.* (citing Ex. 1036, 11:5-7 (“a silver ink is used as a conductive ink to print the interconnections between components”), Fig. 2; Ex. 1035, 5:53-56 (screen printing resistive ink to “connect[] to other electrical components’’)). Similarly, and as described in greater detail below, it was also known that a trace itself could be screened using an ink with a mixture of conductive and resistive elements, thus giving it a known resistivity. *Id.*

These (and other) PCB design features were known in the art and were used in the design and construction of PCBs that were used in wearable cardiac monitors. *Id.* ¶ 26.

3. Defibrillation Protection

Wearable ECG monitors are often prescribed for patients with known or suspected heart conditions that may require future treatment. Ex. 1003 ¶ 36. Thus,

when designing the monitors, engineers are cognizant of the needs of these patients and the risks they face. *Id.* One important consideration relates to emergency cardiac intervention: Engineers designing these devices understand that the patient-users are predisposed to, and may require treatment of, cardiac emergencies. *Id.* They understand that, in some instances, it may be necessary to deliver treatment while the patient is still wearing the monitor. *Id.*

One treatment that may be necessary in a cardiovascular emergency is defibrillation, the application of a dose of electrical current to “reset” the body’s natural pacemaker. *Id.* ¶¶ 34, 36-41. It was well understood in the art that if the device absorbed too much of the electrical energy from the defibrillation shock, the necessary voltage would not reach the patient. *Id.* ¶¶ 36-41. It was also well understood in the art that the voltage increase from defibrillation could damage or destroy the electronics on the wearable heart monitor. *Id.* In view of these risks, regulatory bodies required “that a medical grade monitor survive multiple defibrillation cycles of at least 360 joules.” Ex. 1001, 1:61-63; Ex. 1054 §§ A.3.2.14.2, A.3.2.14.2.1 (“Defibrillator overload protection is necessary for most ECG devices, since in the hospital environment any given ECG device might be used on patients potentially requiring defibrillation. . . . The American National Standard, *Cardiac defibrillator devices*, specifies a maximum selectable deliverable energy in the range of 250 to 360 joules (AAMI, 1989).”). Multiple standards indicated that

such circuit protection would be expected for body-worn ECGs of multiple types. Ex. 1003 ¶¶ 36-41. And, for wearable ECGs, the Association for the Advancement of Medical Instrumentation (AAMI) standard for diagnostic electrocardiographic devices (AAMI-EC11) notes that “[d]efibrillator overload protection is necessary for most ECG devices, since in the hospital environment any given ECG device might be used on patients potentially requiring defibrillation.” Ex. 1054 § A.3.2.14.2. In addition, for ECG devices that include an arrhythmia alarm function, the US FDA explicitly required some form of circuit protection that would survive defibrillation. Ex. 1003 ¶ 38.

A common solution in the field was to include “one or more power resistors situated in series with the wire leads of a fixed or portable physiological monitor.” Ex. 1001, 1:63-65. But such resistors are “too large for use in a compact monitor application.” *Id.* 1:65-67. This problem was well known in the field. Ex. 1003 ¶ 34.

Multiple solutions to this problem existed, ensuring that the wearable monitor would be standard compliant and able to withstand multiple defibrillation cycles. For example, Dunseath (WO 1987/01024 A1) described “replacing [a standard, bulky] input resistor” “with a small[er], flat[ter] surface mount resistor soldered to input trace” “on top of [the] circuit board.” Ex. 1038, 25:24-26:12. Similarly, Rosenberg (U.S. Patent No. 4,280,507) described making leads of “electrically conductive carbon loaded polymer,” where the “distributed resistance of each

polymer lead is sufficient to protect [an] EKG machine from defibrillation pulses.” Ex. 1034, 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. 1007, 5:4-13. A POSA would have understood a “lead strip” to be a strip of conductive material used to connect electronic components and circuit boards. Ex. 1003 ¶ 97 (citing Ex. 1007, 5:4-11).

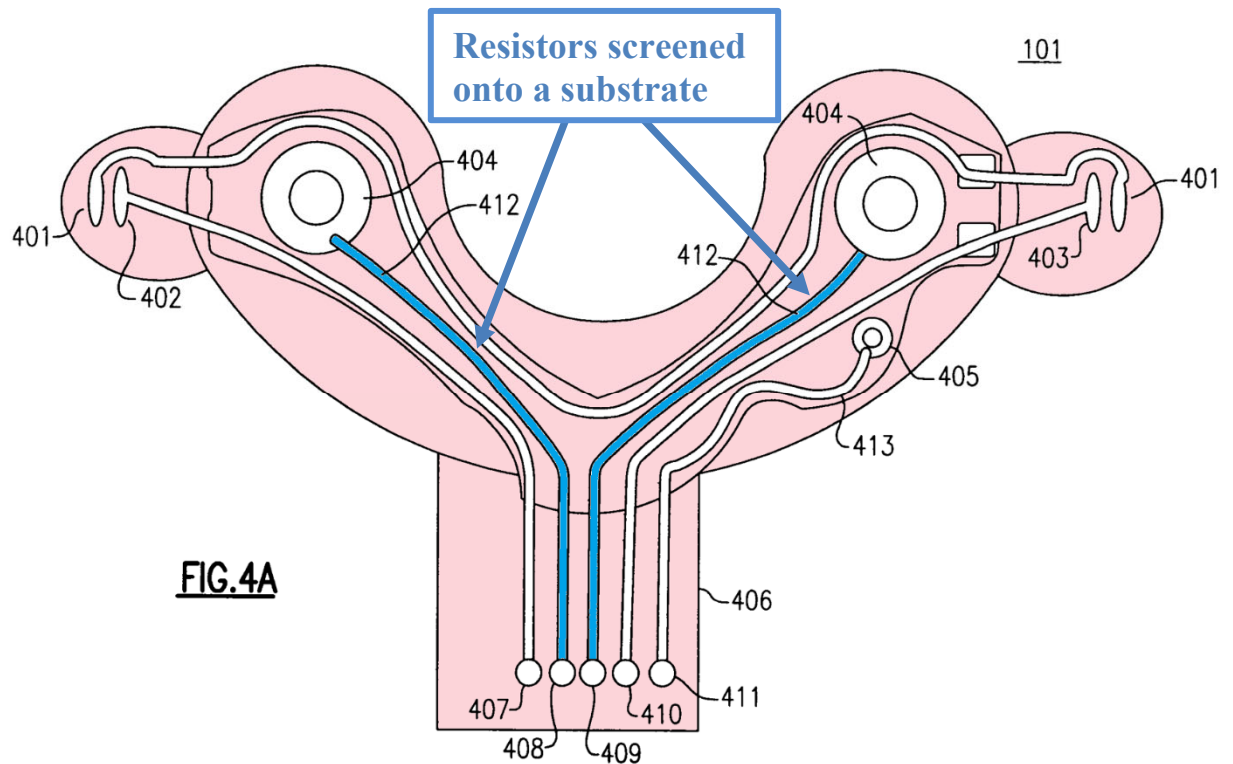
The solution taught by Kroll—resistance in the traces on a body-worn physiological device—has a twofold protective effect: It helps protect the patient from shock from the device *and* it helps to protect the device from the effects of an outside shock. *Id.* ¶ 46. This is because the electrical resistance 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 helps manage overflow current flowing from the device toward the patient (as in a device malfunction) or from the patient’s body toward the device (as in a defibrillation event). *Id.*

B. Patent Description

The ’699 patent describes a known solution to the known problem outlined above. In particular, the ’699 patent is directed to a body-worn heart monitor that

includes a “defibrillation protection resistor” (shown below in blue) that is “screened onto a substrate” (shown below in pink) to solve the above-described defibrillation problem. Ex. 1001, Abstract, cl. 1; Ex. 1003 ¶¶ 58-62. The background section of the ’699 patent explains that there were existing medical standards requiring that “a medical grade monitor survive multiple defibrillation cycles of at least 360 joules.” Ex. 1001, 1:61-63; *see also id.* 10:17-33. A POSA would understand this to mean that the device was required to have a current limiting mechanism to protect the ECG electronics during a defibrillation shock, which is typically 360 Joules. Ex. 1003 ¶ 60. A POSA would also have been aware of well-known ways to protect electronics against shocks, including by using resistors. *Id.*

The specification describes the well-known use of “resistive traces” to “replace the bulky power resistors needed by prior art monitors,” which are configured to protect the communication-computation module from “multiple defibrillation cycles.” Ex. 1001, 7:46-57; *see also* 19:26-30.



Id. Fig. 4A (annotated).

Noting the ideal range of resistances for these traces between 1 and 10 k Ω (*id.* 7:58–8:3), the specification describes the well-known concept that desired resistances are achieved by configuring the resistive traces’ width, thickness (height), and length (*id.* 8:26-30). As in most well-known circuits, “[t]here can be a short overlay distance . . . in which a [conductive] trace overlaps the [resistive] trace to provide a more robust connection between the resistive and conductive portions of the traces.” *Id.* 8:35-40.

C. Priority Date

The application that matured into the ’699 patent was filed on June 5, 2012, as a continuation of U.S. Patent Appl. No. 11/591,619 filed on Nov. 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 '699 patent was allowed after Applicant distinguished U.S. Patent Pub. No. 2003/171,743 ("Tasto"). Response to Office Action, Aug. 16, 2013, 7-10 (Ex. 1002, 40-43). Applicant argued that Tasto teaches an "electrosurgical device that applies high frequency electrical energy to increase the flow of blood to a target tissue so as to improve the condition of a patient" and did not make any reference to an ECG monitor. *Id.*

The Examiner described Tasto as "the closest prior art" and allowed all pending claims on the ground that Tasto does not disclose, suggest, or teach "an ECG monitor that is configured for receiving and processing patient heart signals from a plurality of disposed connections." Notice of Allowability, Sept. 6, 2013, 2 (*Id.* 26).

However, as shown above and below, ECG monitors configured for receiving and processing patient heart signals from a plurality of connections were well-known in the art. So, too, were defibrillation protection resistors.

E. Level of Ordinary Skill in the Art

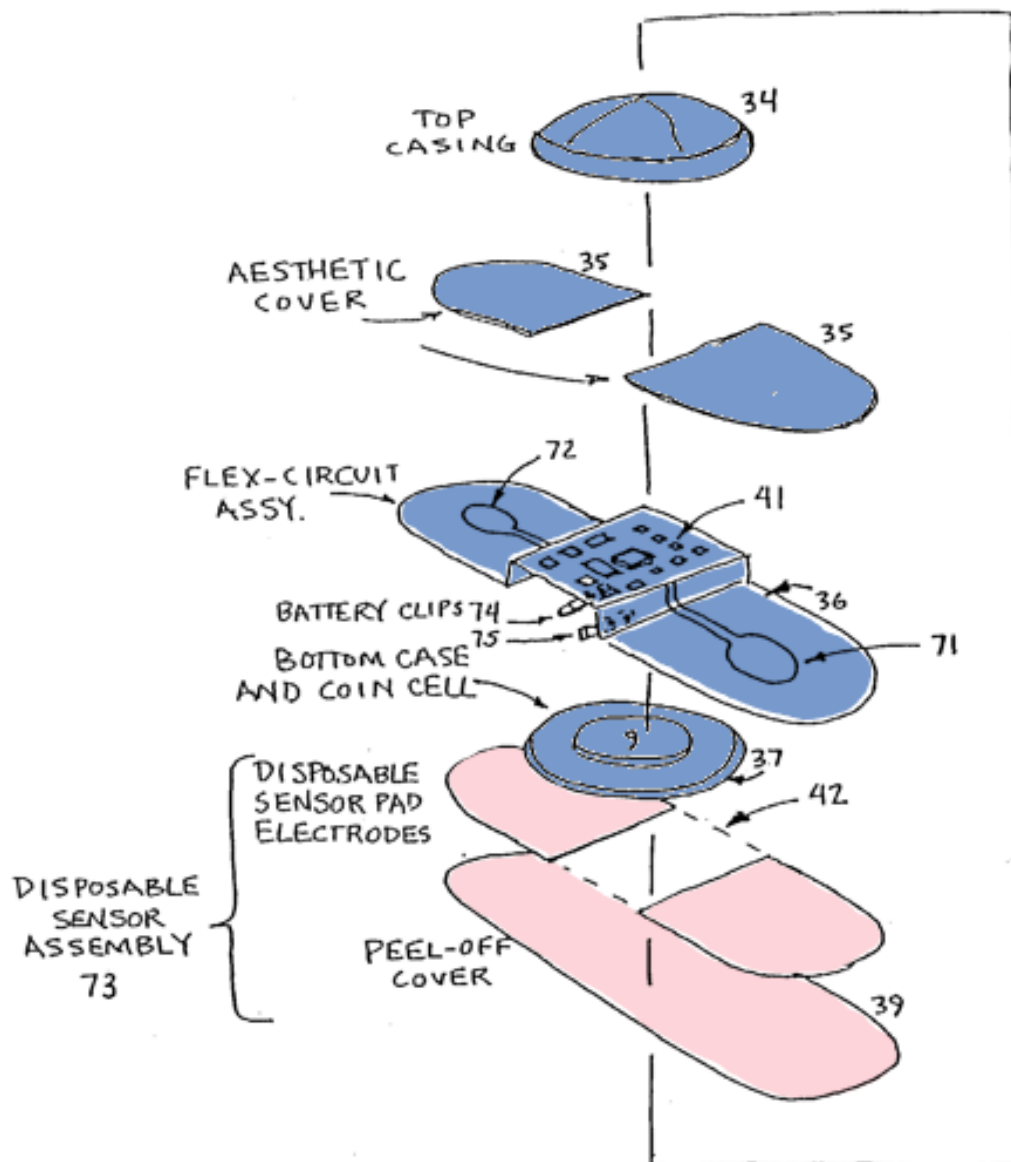
A POSA would have at least a bachelor's degree in electrical engineering, electrophysiology, biomedical engineering, or an equivalent degree, and at least two

to three years of experience designing wearable monitors that detect physiological signals with mechanical and/or electrical elements. Ex. 1003 ¶ 56. Additional experience may substitute for education and vice versa. *Id.*

VI. PRIOR ART OVERVIEW

A. Jensen (Ex. 1005)

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 '699 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. 1005, 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].

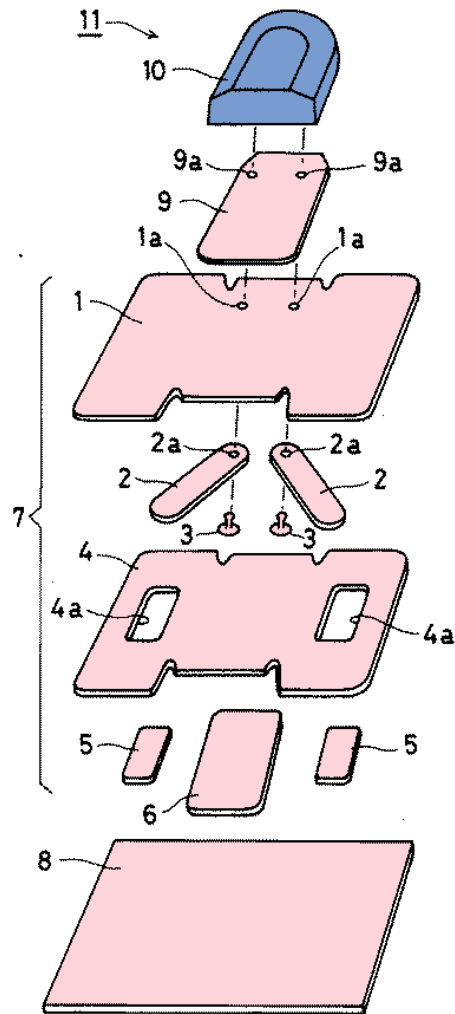


Id. Fig. 5 (annotated).

B. Matsumura (Ex. 1006)

Matsumura published on April 22, 2004 as Japanese Patent Publication 2004-121360, and is prior art under pre-AIA 35 U.S.C. §§ 102 (a), (b). Matsumura was neither cited nor considered during prosecution of the '699 patent. Matsumura

is directed to “a bioelectric potential detector having a waterproof structure” for detecting ECG signals. Ex. 1006 ¶¶ [0001], [0024]. The detector “comprises a disposable bioelectrode pad [shown in red, below] for detecting bioelectric potentials, and a reusable signal processor [shown in blue, below] for processing the bioelectric potential signals detected by the bioelectrode pad.” *Id.* ¶ [0007], Fig. 1. In particular, Matsumura’s disposable bioelectrode pad 7 is “composed of a first sheet 1, a conductive material 2, a hook 3, a second sheet 4, a conductive gel 5, a third sheet 6, and double-sided adhesive tape.” *Id.* ¶ [0016]. “[B]ioelectric potentials detected by the conductive gel 5 are transmitted through the conductive material 2 and the hooks 3” at which point they reach signal processor 10. *Id.* ¶¶ [0019], [0024]. The signal processor “incorporates a processing circuit for filtering and amplifying detected bioelectric potential signals, a memory for storing the processed bioelectric potential signal, a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna.” *Id.* ¶ [0025].



Id. Fig. 1 (annotated).

C. Kroll (Ex. 1007)

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 '699 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. 1007, 1:11-15, 1:59-61; *see also* Ex. 1003 ¶¶ 93-97.

Kroll discloses a “flexible and disposable electrode belt” to be worn by a patient undergoing physiological monitoring. Ex. 1007, 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.*

D. Khandpur (Ex. 1008)

Khandpur is a textbook, entitled “Printed Circuit Boards: Design, Fabrication, Assembly and Testing,” that published on October 12, 2005. Khandpur is prior art under 35 U.S.C. § 102(a). Khandpur was neither cited nor considered during prosecution of the ’699 patent. It describes aspects of printed circuits, including recommended fabrication processes. Ex. 1008, 421.

Khandpur explains that around the solder pads where conductive areas of components and traces are attached, there is generally a “transition from flexible to

rigid material” which is “highly prone to conductor breakage.” *Id.* 442, 642 (a component is “[a]ny of the basic parts used in building electronic equipment”), 656 (a pad is a “portion of the conductive area of which components, terminals, traces, etc., are mechanically attached”). To decrease the chances of breakage in this transition zone, the “general shape of solder pads should be tear-like.” *Id.* 442-43.

E. Thompson (Ex. 1009)

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 ’699 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. 1009, 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 [the] QRS complex” of the cardiac cycle; “[d]uring the remainder of the cardiac cycle the [waveform] processor may be ‘idling along’ at a much lower clock frequency.” *Id.* 18:3-7. 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 1-4 Are Obvious Over Jensen, Kroll, and General Knowledge of a POSA

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. 1005 ¶¶ [0029]-[0030]; Ex. 1007, 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. 1007, 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. 1003 ¶¶ 108-11. 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.* ¶¶ 111-12. Jensen discloses a wearable monitor to which these same considerations apply. Driven by a desire to protect patients from potential shock,

ensure the long-term viability of Jensen's reusable module against potential defibrillation, and comply with industry standards requiring this very protection, a POSA would have been motivated to incorporate Kroll's teaching of resistive "lead strips." *Id.* ¶ 113.

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 1005 ¶ [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 1003 ¶ 114 ("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.* ¶ 115. 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 (*i.e.*, the addition of a resistive ink). *Id.* ¶ 116. 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

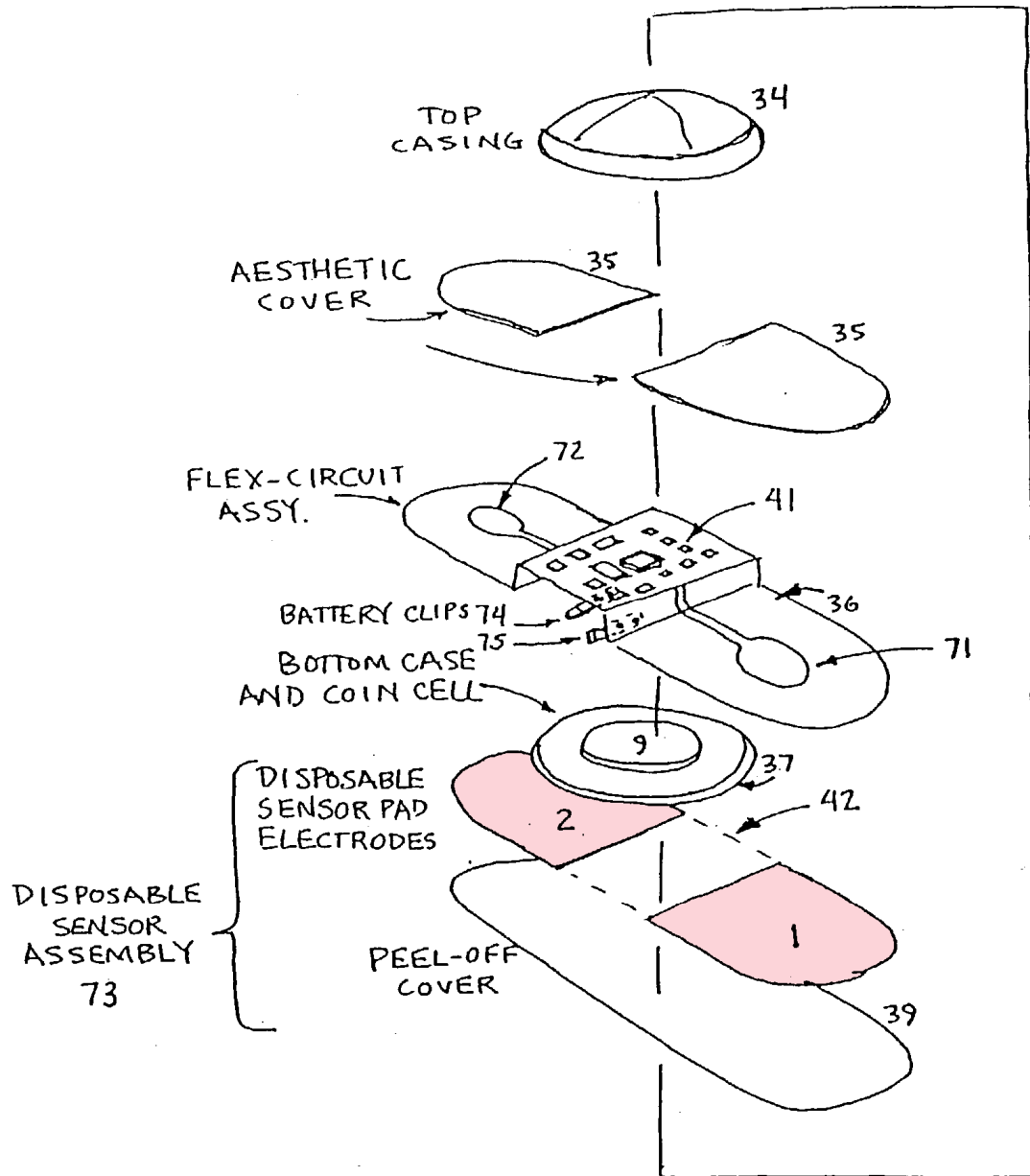
i. 1[Pre] An ECG monitor comprising:

Jensen discloses an ECG monitor. Ex. 1005 ¶¶ [0012], [0029]; Ex. 1003 ¶ 120. Kroll discloses an ECG electrode belt for use in EKG monitoring. Ex. 1007, 1:9-15, 1:59-61; Ex 1003 ¶ 120. A POSA would understand that the acronym ECG and EKG are used interchangeably to refer to an electrocardiogram. Ex. 1003 ¶ 120.

ii. [1a] a plurality of electrical connections including at least one electrode,

Jensen discloses “a plurality of electrical connections including at least one electrode.” Jensen discloses a “disposable sensor assembly,” which includes “sensor pad electrodes” 1, 2 (shown below in red), also referred to as “sensor pads.” Ex. 1005 ¶¶ [0041]-[0042]. The disposable sensor electrodes 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. 1003 ¶ 124. 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. 1005 ¶ [0041].



Id. Fig. 5 (annotated).

A POSA would understand that Jensen's disposable sensor pads are "a plurality of electrical connections including at least one electrode." Ex. 1003 ¶ 126.

iii. [1b] the electrical connections being couplable to a skin surface to measure patient heartbeat signals;

Jensen discloses "the electrical connections being couplable to a skin surface to measure patient heartbeat 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. 1005 ¶ [0030]. The disposable sensor pad electrodes are coated with conductive adhesive-gel, making the device couplable to a skin surface. *Id.* ¶ [0041]. Once applied to the patient's skin, "heart-rate signals are collected from left and right sensor [electrodes], 1 & 2." *Id.* ¶ [0031]; *see also id.* ¶ [0032] ("signals from the sensors 1 & 2" reach microcontroller 10 for processing and "further analysis"). A POSA would understand that Jensen's sensor pads, which are adhered to a patient's skin and are conductive, are couplable to a skin surface to measure patient heartbeat signals. Ex. 1003 ¶¶ 127-30.

iv. [1c] a power source;

Jensen discloses "a power source." Jensen's device includes a "Lithium coin cell" or, alternatively, "a rechargeable type of power source, or a solar cell." Ex. 1005 ¶ [0040], Fig 5; *id.* ¶ [0014] ("device of the present invention contains all necessary electronic circuitry, including . . . a battery or other power source").

- v. ***[1d] at least one current-limiting defibrillation protection resistor, said at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate;***

Limitation 1d 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 (*i.e.*, current-limiting defibrillation protection) traces of Kroll with the ECG monitoring device of Jensen. *Supra* § VII.A.1.

Jensen discloses a body-worn ECG monitor. Ex. 1005 ¶¶ [0012], [0029]. As the background section of the '699 patent acknowledges, existing medical standards required that “a medical grade monitor survive multiple defibrillation cycles of at least 360 joules.” Ex. 1001, 1:61-63; *see also id.* 10:17-33. Jensen, which discloses a medical monitoring device, would therefore be expected to meet these same standards. Ex. 1003 ¶ 138. A POSA would therefore seek to include at least one series current-limiting defibrillation protection resistor. *Id.*

As explained above, Kroll teaches a current-limiting defibrillation protection resistor in the form “of a flexible conductive ink compound . . . 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. 1007, 5:4-13 (emphasis added). Kroll further teaches that the conductive ink forming the resistive lead strips is “silk **screened**” onto a substrate (*i.e.*, “insulation and base support layer”). *Id.*

5:37-42 (emphasis added). Thus, a POSA would understand that Kroll teaches a current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate. Ex. 1003 ¶¶ 140-42.

A POSA would have looked to incorporate Kroll's resistive traces into Jensen. In particular, Jensen discloses an ECG monitor comprising a substrate in the form of "flexible circuit assembly 36." Ex. 1005 ¶¶ [0031]-[0033], [0040], [0043], Fig. 5. This substrate contains "copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72 and, for example, Lithium coin cell 9." *Id.* ¶ [0040]. A POSA would therefore understand that Jensen discloses a substrate containing traces. Ex. 1003 ¶¶ 138-39. To incorporate Kroll's teaching of a current-limiting defibrillation protection resistor in the form of resistive traces with Jensen's teaching of an ECG monitor that includes defibrillation protection resistors, a POSA would have replaced the copper wiring traces disclosed by Jensen, instead screening Kroll's resistive ink traces onto the flexible circuit disclosed by Jensen. *Id.* ¶¶ 140-43. Screening Kroll's resistive ink traces on the substrate of Jensen would yield "at least one current-limiting defibrillation protection resistor, said at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate." *Id.* ¶¶ 135-45.

vi. [1e] an ECG electronics module,

Jensen discloses “an ECG electronics module.” Jensen discloses ECG electronics such as a “transmitter” for communication and a “microcontroller” for computation. Ex. 1005 ¶ [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]. A POSA would understand that the acronym ECG and EKG are used interchangeably to refer to an electrocardiogram. Ex. 1003 ¶ 148. A POSA would therefore understand that Jensen discloses “an ECG electronics module.” *Id.* ¶¶ 146-49.

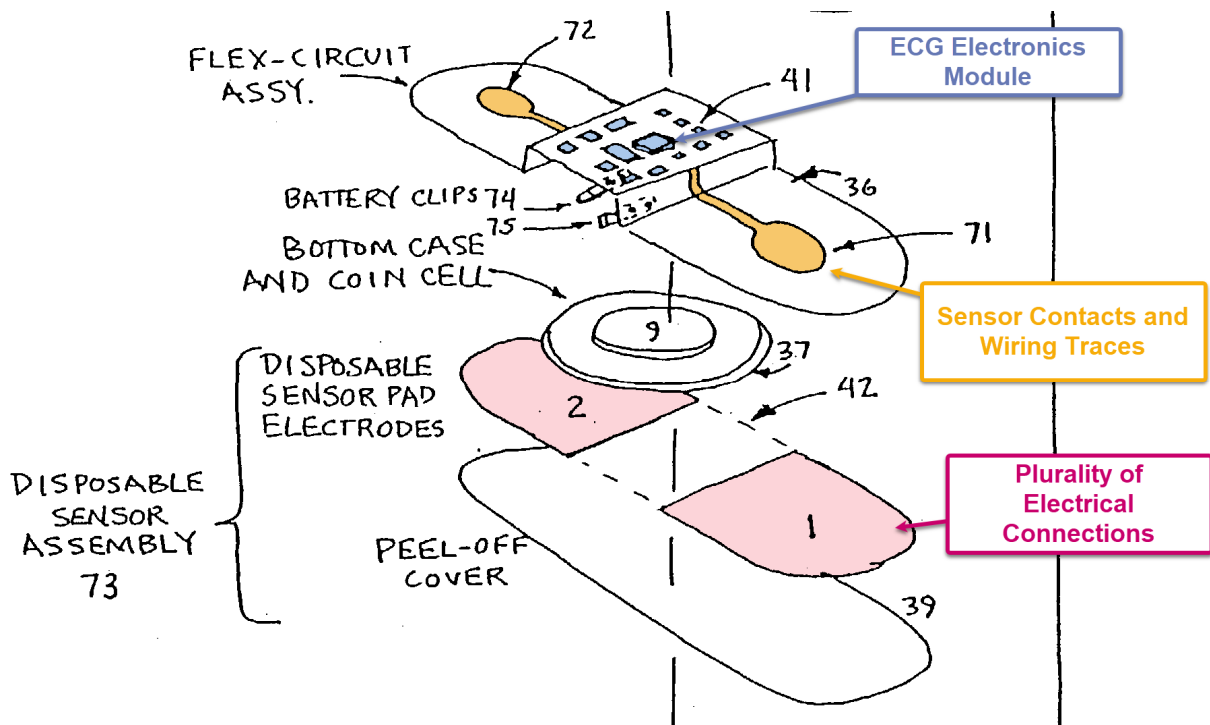
vii. [1f] the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections,

Jensen discloses element 1f. As explained above for element [1e], Jensen discloses an ECG electronics module that includes a “transmitter” for communication and a “microcontroller” for computation. Ex. 1005 ¶ [0032]. 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 71, 72” and the power source. *Id.* ¶ [0040].

As explained above, *see* Section VII.A.2.ii, Jensen’s plurality of electrical connections includes at least one electrode in the form of “sensor pad electrodes” (or “disposable sensor pads”) 1, 2. Ex. 1005 ¶ [0041].

Heartbeat signals are transmitted from the patient’s skin to the conductive adhesive gel on the skin side of sensor pads 1, 2; then through the conductive adhesive on the circuit side of sensor pads 1, 2 to the sensor contacts 71, 72; then through the wiring traces to the “electronics circuit” (*i.e.*, the claimed ECG electronics module). *Id.* ¶¶ [0039]-[0040], Fig. 5; Ex. 1003 ¶¶ 150-55. Therefore, Jensen’s ECG electronics module receives patient heartbeat signals from the plurality of electrical connections.

Jensen’s ECG electronics module further processes the heartbeat signals before transmission. Ex. 1005 ¶¶ [0032]-[0033], [0036]-[0038]. Specifically, Jensen discloses that the signal from the heart-rate sensor is subject to amplification, bandpass filtering, signal extraction, and signal biasing. *Id.*



Id. Fig. 5 (annotated).

A POSA would therefore understand that Jensen discloses “the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections.”

viii. [1g] wherein the at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module.

Limitation 1g is obvious in view of Jensen, Kroll, and a POSA’s general knowledge. As noted above, a POSA would have looked to combine the resistive (*i.e.*, current-limiting defibrillation protection) traces of Kroll with the ECG monitoring device of Jensen. *Supra* § VII.A.1.

Jensen discloses “copper wiring traces” to connect the “entire circuit 41,” including the ECG electronics module, “to the sensor contacts 71, 72,” which make contact with the plurality of electrical connections. Ex. 1005 ¶ [0040], Fig. 5; *supra* § VII.A.2.vii; Ex. 1003 ¶¶ 156-60. Jensen’s “copper wiring traces” are therefore disposed between at least one of the plurality of electrical connections and the ECG electronics module. *Id.*

As explained above, Section VII.A.2.v, it would have been obvious to a POSA to incorporate Kroll’s teaching of screened current-limiting defibrillation protection traces onto the flexible circuit assembly 36 of Jensen. A POSA would understand that Kroll’s resistive traces would be placed over, or alternatively in place of, the copper wiring traces disclosed by Jensen. Ex. 1003 ¶ 160. Thus, the modified traces would be disposed between at least one of the plurality of electrical connections (*i.e.*, the ECG electrode) and the ECG electronics module. *Id.*

A POSA would recognize that the objective of including a defibrillation protection resistor to a wearable ECG device would be to protect the electronics in the device from the potentially destructive flow of current associated with defibrillation. *Id.* ¶ 161. To realize this objective, a POSA would understand that the defibrillation protection resistor *must* be placed between where the device would be exposed to defibrillation (*i.e.*, the ECG electrode that contacts the patient’s skin) and the ECG electronics module that the resistor is intended to protect. *Id.*

Accordingly, a POSA would understand that the combination of Jensen and Kroll discloses “the at least one current-limiting defibrillation protection resistor [being] electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module.” *Id.* ¶¶ 156-62.

3. *Claim 2*

In addition to teaching the limitations of claim 1, the combination of Jensen, Kroll, and a POSA’s general knowledge discloses “wherein the at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.” As explained above, *see* Sections VII.A.1 and VII.A.2.v., a POSA would have been motivated to combine the ECG monitor of Jensen with Kroll’s teaching of current-limiting defibrillation protection resistors screened onto a substrate.

Both Jensen and Kroll disclose flexible substrates. Jensen’s “copper wiring traces”—which a POSA would have modified with the resistive, printed-ink traces disclosed by Kroll—are disposed on “**flexible** circuit assembly 36.” Ex. 1005 ¶ [0040] (emphasis added). Similarly, Kroll discloses a “**flexible** and disposable electrode belt” onto which the ink for the resistive lead strips is “silk screened.” *E.g.*, Ex. 1007, 4:22-24, 4:36-37, 4:48-51, 5:37-42.

A POSA would understand that the combination of Jensen and Kroll, as modified in the manner set forth in claim 1, *supra* Section VII.A.2.v, would meet the dependent limitation of claim 2. Ex. 1003 ¶¶ 163-68.

4. Claim 3

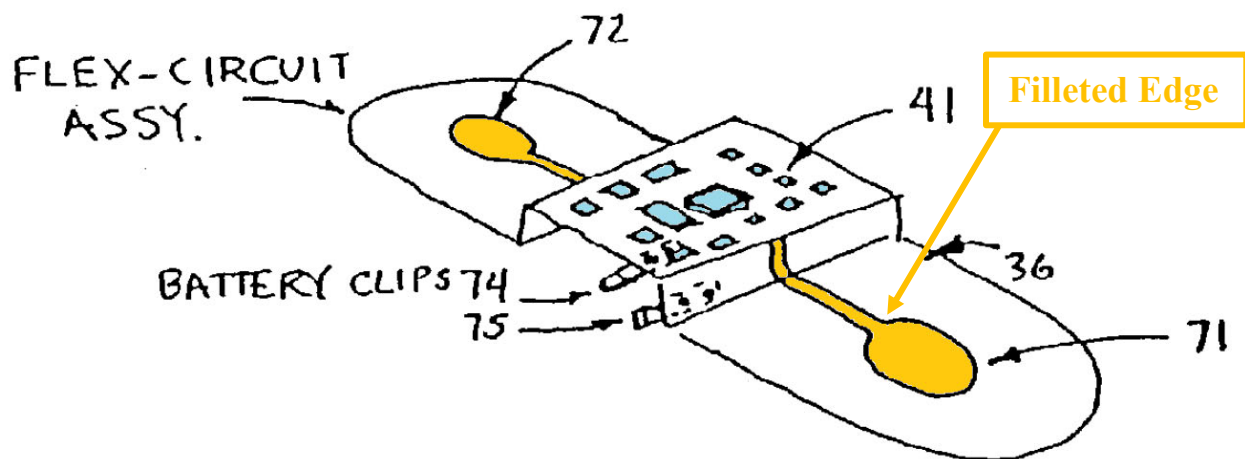
In addition to teaching the limitations of claim 1, the combination of Jensen, Kroll, and a POSA's general knowledge discloses "a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a filleted edge."

As explained with respect to claim 1, a POSA would have been motivated to modify Jensen's ECG monitor with the teaching of Kroll to include a series current-limiting, defibrillation protection resistor in the form of resistive traces, substituting Kroll's resistive ink traces in place of the "copper wiring traces" disclosed by Jensen. *Supra* §§ VII.A.2.i-viii.

Modified accordingly, Jensen's device includes a "mechanical interface" between the series current-limiting resistor and the ECG electrode. Ex. 1003 ¶¶ 169-71. Specifically, Jensen's sensor contacts 71, 72 (part of the resistive traces) form a mechanical interface with sensor pads 1, 2, which as explained above, are the claimed ECG electrodes. Specifically, "sensor contacts 71, 72," which are part of current-limiting, defibrillation protection resistive traces, are electrically and

physically (via an adhesive) attached to “sensor pad electrodes 1 and 2.” Ex. 1005 ¶ [0041]. *See also supra* §§ VII.A.2.ii-iii.

The '699 patent describes a filleted edge as a “‘tear drop’ shape [that] causes the carbon trace to become gradually wider as it [is] connect[ed] to [the] conductive surface.” Ex. 1001, 8:52-55. Jensen teaches “copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72” that are shaped as fillets. Ex. 1005 ¶ [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. 1003 ¶ 172; *see also id.* ¶¶ 167-32. This is shown at least in Figure 5 of Jensen (excerpted below) where the end of the trace connected to the fillet shaped sensor contact 71 is wider than that connected to circuit 41.



Ex. 1005, Fig. 5 (annotated).

Additionally, irrespective of Jensen’s disclosure of a filleted edge, a POSA implementing Kroll’s traces on Jensen’s device would recognize that a “filleted

edge” is the standard or default shape for constructing an electrical connection pad on a printed circuit board. Ex. 1003 ¶¶ 172-73. In constructing a PCB, a POSA would choose this shape wherever possible because it increases the surface area for contact, thereby increasing the reliability/performance of the printed circuit board. *Id.*

Jensen’s “fillet-edged” sensor contacts 71, 72 form a mechanical interface with sensor pads 1, 2. Accordingly, a POSA would understand that Jensen, as modified in the manner set forth above with respect to claim 1, renders obvious the dependent limitation of claim 3. *Id.* ¶¶ 169-75.

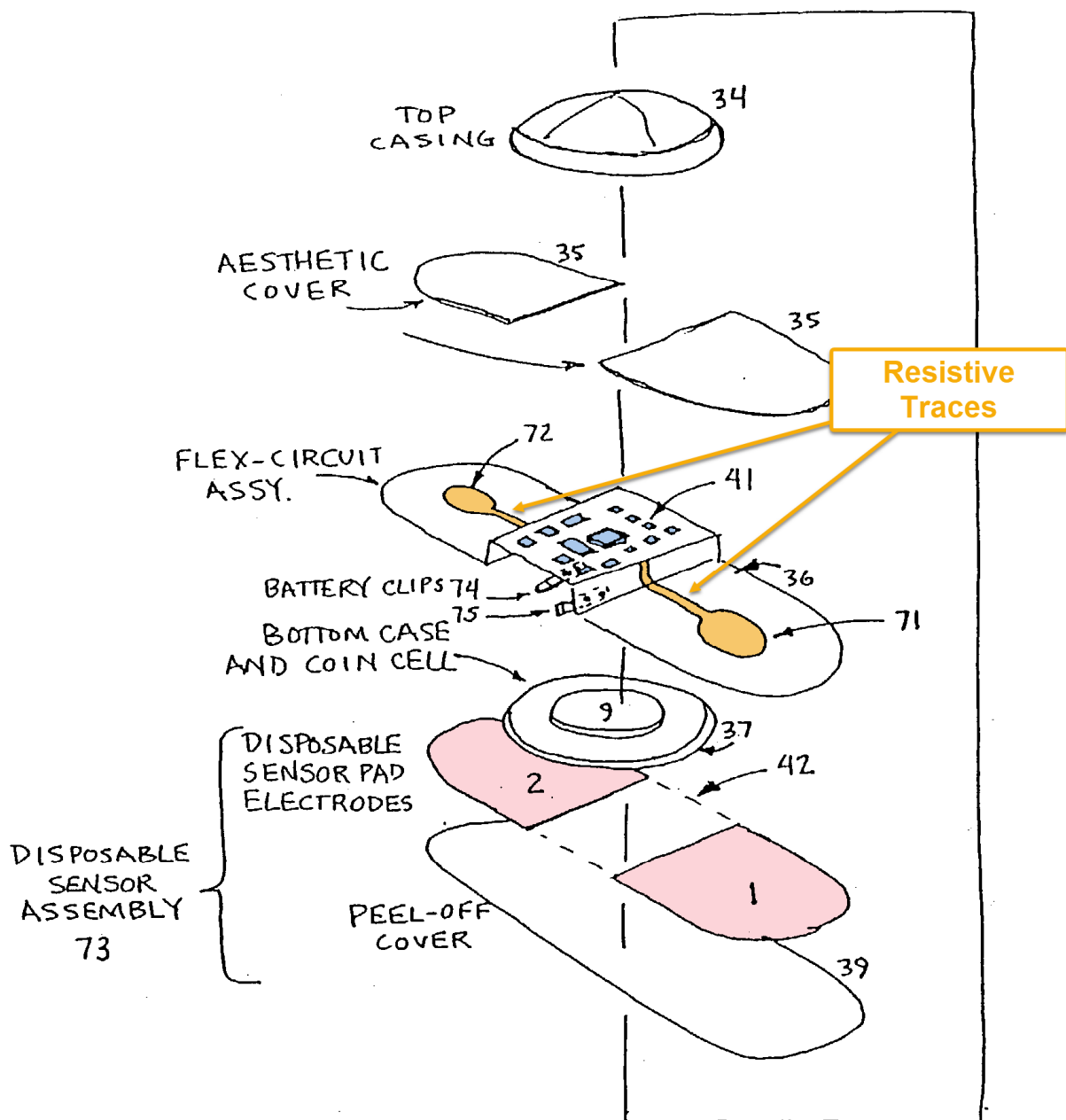
5. Claim 4

In addition to teaching the limitations of claim 1, the combination of Jensen, Kroll, and a POSA’s general knowledge discloses “wherein a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a plurality of overlapped layers.”

As explained with respect to claim 1, a POSA would have been motivated to modify Jensen’s ECG monitor with the teaching of Kroll to include a series current-limiting, defibrillation protection resistor in the form of resistive traces, substituting Kroll’s resistive ink traces in place of the “copper wiring traces” disclosed by Jensen. *Supra* §§ VII.A.2.i-viii.

As modified, Jensen's device includes a "mechanical interface" between the series current-limiting resistor and the ECG electrode. Ex. 1003 ¶¶ 178-79. Specifically, Jensen's sensor contacts 71, 72 (part of the resistive traces that would be screened onto the surface of Jensen's circuit assembly) form a mechanical interface with sensor pads 1, 2, which as explained above, are the claimed ECG electrodes. *See supra* § VII.A.4.

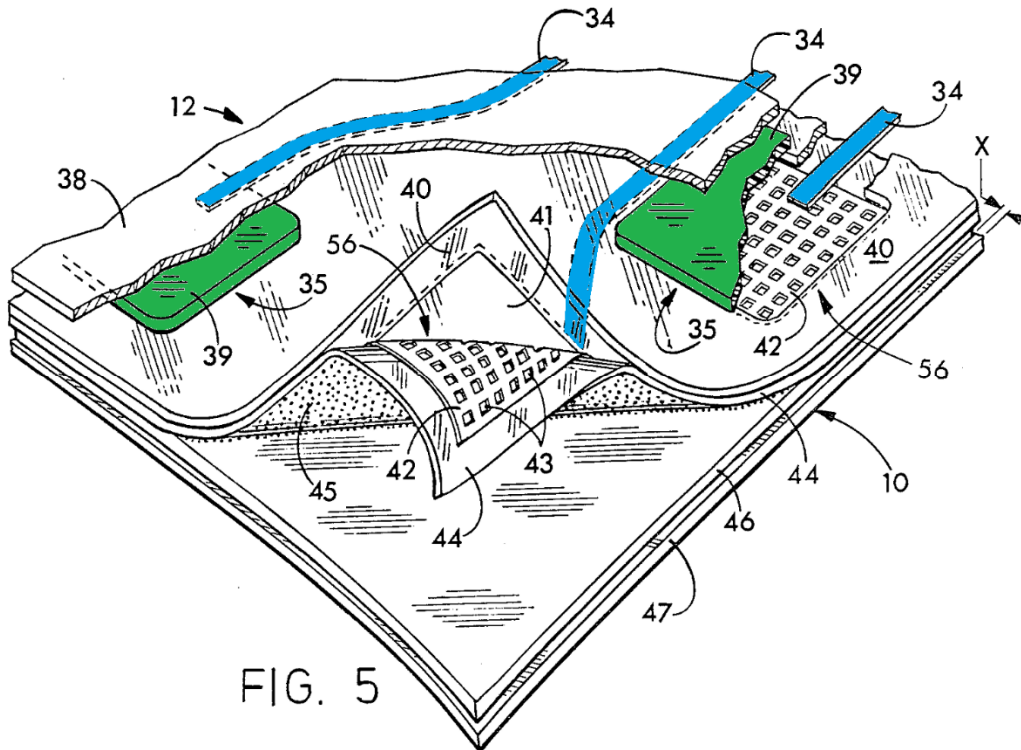
This mechanical interface comprises a "plurality of overlapping layers." As illustrated in Figure 5 below, Jensen discloses electrodes (in the form of sensor pads 1, 2), which form one layer. Jensen's flexible substrate 36, which contains the series current-limiting defibrillation protection resistor (traces), forms another layer. Ex. 1005 ¶¶ [0040]-[0041], Fig. 5. A POSA would understand that for "sensor contacts 71, 72" to "make electrical contact with sensor pads 1 and 2," the two layers are necessarily overlapping. Ex. 1003 ¶ 179.



Ex. 1005, Fig. 5 (annotated).

A POSA would have been motivated to implement Kroll's resistive traces on Jensen's device. *Supra* §§ VII.A.1-2; Ex. 1003 ¶ 180. In doing so, it would have been obvious to a POSA to implement the resistive traces so as to define a

mechanical interface between them and the electrodes, thereby forming a plurality of overlapping layers. Ex. 1003 ¶ 180. Indeed, Kroll itself specifically contemplates such an arrangement: Kroll discloses that the mechanical interface between its current-limiting defibrillation protection resistors (lead strips) and its electrodes comprises a plurality of overlapping layers. *Id.* As shown in Kroll’s Figure 5, Kroll’s lead strips 34 (shown in blue below) are screened onto the flexible substrate, overlapping the electrodes 35 (shown in green below), which are also applied to the substrate using a screening process. Ex. 1007, 5:17-21, 5:37-42, Fig. 5. As explained above, a POSA would implement these resistive lead strips in the same way—overlapping the electrodes—in Jensen’s device. Ex. 1003 ¶ 180.



Accordingly, a POSA would understand that Jensen, as modified in the manner set forth above with respect to claim 1, renders obvious the dependent limitation of claim 4. Ex. 1003 ¶¶ 176-81.

B. Ground 2: Claim 8 is Obvious Over Jensen, Kroll, Thompson, and a POSA's General Knowledge

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. 1003 ¶ 183. 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. 1005 ¶ [0031]; Ex. 1003 ¶ 184.

However, a POSA would have been aware of other techniques for optimizing battery life, including the use of a periodic low power mode. Ex. 1003 ¶ 184. A POSA would have sought other ways to conserve power, even while the device was operational. *Id.* ¶ 185.

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. 1009, 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. 1003 ¶ 187. 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 8

In addition to teaching the limitations of claim 1, *see supra*, Jensen, Kroll, and Thompson render obvious “wherein the ECG electronics module includes a microprocessor to process the heartbeat signals, wherein an algorithm running on the microprocessor causes the ECG monitor to enter a low power mode that disables at least one circuit of the ECG electronics module, 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, in order to reduce said electrical load on the power source.”

Jensen discloses a microprocessor to process heartbeat signals. Jensen discloses a “microcontroller” for computation. Ex. 1005 ¶ [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 microcontroller is capable of “creat[ing] and transmit[ing] different data records” including beat reporting, logged event reporting, beat to beat interval and rolling heart rate average. *Id.* ¶ [0038], Table 1. A POSA would understand that Jensen’s microcontroller is a “a microprocessor to process heartbeat signals.” Ex. 1003 ¶ 190.

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. 1009, 18:3-14. A POSA would therefore recognize that Thompson's low power mode (which spans the broader period, "from the end of an S-wave to the next Q-wave) includes the narrower 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. 1003 ¶ 188. A POSA would also recognize that this low power mode could be implemented on Jensen's microprocessor. *Id.* ¶ 189. Accordingly, the dependent limitation of claim 8 would be obvious to a POSA in view of the combination of Jensen, Kroll, and Thompson. *Id.* ¶ 193.

C. Ground 3: Claims 1, 2, 4 are Obvious Over Matsumura, Kroll, and the General Knowledge of a POSA

1. A POSA would have combined Matsumura and Kroll

Matsumura and Kroll teach wearable devices for monitoring physiological signals, including ECG or EKG signals. Ex. 1006 ¶¶ [0024], [0031], Fig. 2; Ex. 1007, 1:11-15, 1:37-45, 1:60. Both references teach that the wearable device is flexible, where such teaching is explicit in Kroll, and Matsumura teaches that its "bioelectrode pad" should be composed of sheets comprising "polyethylene foam, polyurethane foam, or polyurethane sheet," which a POSA would recognize are "flexible materials." Ex. 1006 ¶¶ [0017]-[0018], [0022]; Ex. 1003 ¶ 195.

A POSA would look to incorporate the "resistive trace" of Kroll into Matsumura's bioelectric potential detector. Ex. 1003 ¶ 197. Matsumura teaches a

“bioelectric potential detector 11,” which can “be used as an electrocardiogram detector that is worn on the subject’s chest to detect electrocardiogram signals,” Ex. 1006 ¶ [0024], and which “determines whether the detected electrocardiogram of the subject (patient) is abnormal, such as an arrhythmia or an abnormal heart rate,” *id.* ¶ [0037]. Matsumura thus discloses a medical-grade, body worn ECG monitor. Ex. 1003 ¶ 196. As the background section of the ’699 patent acknowledges, at the time of the alleged invention, existing medical standards required that “a medical grade monitor survive multiple defibrillation cycles of at least 360 joules.” Ex. 1001, 1:61-63; *see also id.* 10:17-33. A POSA seeking to practice the invention disclosed by Matsumura would therefore be motivated to include features that would allow the device to survive multiple defibrillation cycles. Ex. 1003 ¶¶ 195-96.

Matsumura specifically notes that the system “wirelessly transmits the bioelectric potential detected . . . to inform medical staff or family members of the bioelectric potential information, so that they can quickly **treat and cope with a sudden change in condition.**” Ex. 1006 ¶ [0041] (emphasis added). A POSA would recognize that one such treatment for a sudden change in condition is defibrillation, which involves the application of high voltage electrical current to the patient’s body. *See supra* § V.A.3; *see also* Ex. 1003 ¶ 200. A POSA would know that, in the event of a defibrillation, Kroll’s resistive strips would help to protect the sensitive electronics contained in Matsumura’s signal processor from the high

voltage. *Id.* A POSA would have known that Kroll’s resistive lead strips would also lead to the additional benefits of helping protect patients from potential shock from the monitor itself and reducing the size of Matsumura’s device. *Id.* Accordingly, a POSA would have been motivated to incorporate Kroll’s teaching of resistive “lead strips” to the circuitry in Matsumura. Ex. 1003 ¶¶ 198-200.

A POSA combining these teachings of Matsumura and Kroll would have had a reasonable expectation of success in doing so because it would involve using well known screen-printing techniques for printed circuit board manufacture. *Id.* ¶ 201. A POSA would know how to achieve this combination with minimal design impact. It was known that screen printing was well-suited to printing circuits on flexible substrates, such as that of Matsumura, and had long been used to do so. *Id.* Indeed, Kroll itself discloses using printing techniques on a flexible substrate. Ex. 1007, 9:36-48 (claim directed to a conduction network printed onto a flexible non-conductive base layer); *see also* Ex. 1029, cl. 26 (“sensor module comprises a flexible thin sheet of silicon comprising circuitry for collecting physiological data, a flexible power source and a flexible substrate”). Nothing in the art suggests that the proposed combination would not work. Ex. 1003 ¶ 201.

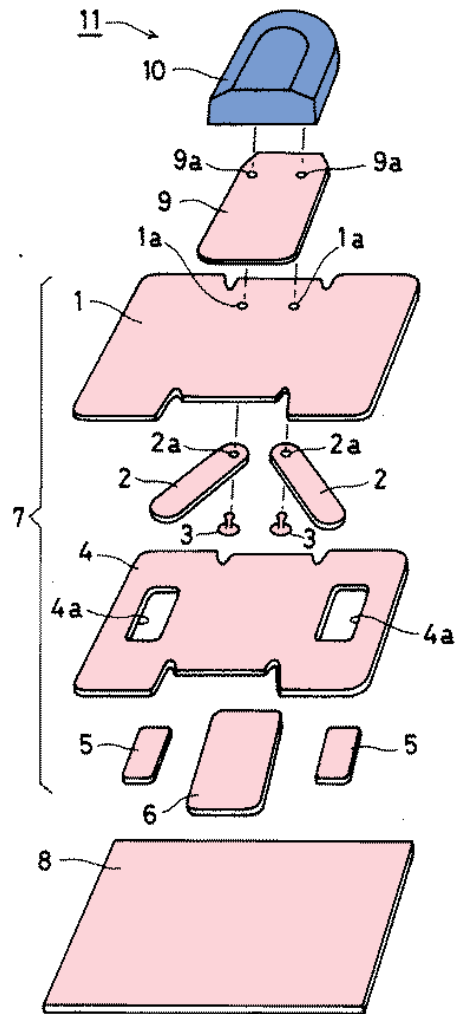
2. *Claim 1*

i. 1[Pre] An ECG monitor comprising:

Matsumura discloses a body-worn patient monitoring device which it refers to as a “bioelectric potential detector.” Ex. 1006, Abstract, ¶¶ [0006], [0014]. Matsumura’s device receives and processes electrocardiogram (ECG) data. *Id.* ¶ [0033]. Kroll discloses an ECG electrode belt for use in ECG monitoring. Ex. 1007, 1:9-15, 1:59-61; Ex. 1003 ¶¶ 203-06.

ii. [1a] a plurality of electrical connections including at least one electrode,

Matsumura discloses “a plurality of electrical connections.” “[T]wo pieces of conductive material 2” form electrical connections—through the interface between holes (2a) and hooks (3)—to the signal processor, as shown in the below figure. Ex. 1006 ¶ [0019]. Another two pieces of “conductive gel 5,” shown in the below figure, detect bioelectric potentials and form electrical connections with the patient’s skin. *Id.*; Ex. 1003 ¶¶ 207-11.



Ex. 1006, Fig. 1 (annotated).

Matsumura teaches that the “conductive gel” may be produced from components such as “acrylic hydrophilic polymer, glycerin, and water.” *Id.* ¶ [0018]. The conductive gel contacts “conductive material 2,” which may be coated with conductive Ag/AgCl.” *Id.* ¶¶ [0019]-[0020]. A POSA would understand that conductive gels comprising an acrylic hydrophilic polymer, glycerin, and water, and contacting a silver/silver-chloride conductive surface comprise an “electrode.”

Ex. 1003 ¶ 210. Accordingly, a POSA would recognize that Matsumura discloses “a plurality of electrical connections including at least one electrode.” *Id.* ¶ 211.

iii. [1b] the electrical connections being couplable to a skin surface to measure patient heartbeat signals;

Matsumura discloses “the electrical connections being couplable to a skin surface to measure patient heartbeat signals.”

Among its plurality of electrical connections, Matsumura discloses “conductive gel 5” which transmits “bioelectric potentials detected” at the skin surface and “conductive material 2” that transmit this detected bioelectric potential to the signal processor. Ex. 1006 ¶¶ [0018]-[0019]. These detected bioelectric potentials are “electrocardiogram[]” signals of a patient (*i.e.*, patient heartbeat signals) wearing Matsumura’s device. *Id.* Abstract.

The “conductive gel 5” is inserted through “two openings 4a on the left and right sides” of the second sheet. *Id.* ¶ [0018]. An “adhesive, such as acrylic adhesive for example, is applied to the back surface of the second sheet 4.” *Id.* “When attaching the bioelectric potential detector to a patient . . . the release tape 8 is peeled off from the bioelectrode pad 7 and the detector is attached to the subject.” *Id.* ¶ [0024]. Peeling off release tape 8 exposes the bottom of bioelectric pad 7, which is second sheet 4, and allows the adhesive layer to adhere the bioelectric pad to skin. *See also id.* ¶ [0022] (describing option to make second sheet 4 “less adhesive to the living body” by covering center with optional third sheet 6). Because

the conductive gel 5 is embedded in second sheet 4, conductive gel 5 is “couplable to a skin surface” to measure physiological signals. Ex. 1003 ¶¶ 212-17. A POSA would understand this allows the conductive gel 5 to detect “bioelectric potentials” for transmission “through the conductive material 2 and the hooks 3.” *Id.*; Ex. 1006 ¶ [0019].

iv. [1c] a power source;

The teachings of Matsumura, as understood by a POSA, render this limitation obvious. Matsumura discloses an ECG monitor that transmits the “processed bioelectric potential signal . . . wirelessly.” *E.g.*, Ex. 1006 ¶ [0025]. Matsumura further explains that wireless ECG monitors include “a power source.” *Id.* ¶ [0004] (prior art device comprising “conduction portion (equivalent to an electrode element), a power source, a potential difference detection portion, and a wireless transmitting/receiving portion”). A POSA would have understood Matsumura’s ECG monitor must include an onboard power source to allow for wireless transmissions. Ex. 1003 ¶ 220. The device would otherwise be inoperable. *Id.* A POSA would therefore understand that Matsumura’s device includes “a power source to power the body worn patient monitoring device.” *Id.* ¶¶ 218-21.

- v. ***[1d] at least one current-limiting defibrillation protection resistor, said at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate; and***

Limitation 1d is obvious in view of Matsumura, Kroll, and a POSA's general knowledge. As noted above, a POSA would have looked to combine the resistive (*i.e.*, current-limiting defibrillation protection) traces of Kroll with the ECG monitoring device of Matsumura. *Supra* § VII.C.1. A POSA would have expected that Matsumura's device would include at least one current-limiting defibrillation protection resistor. Ex. 1003 ¶ 228.

Matsumura discloses a wearable, medical device for monitoring ECG signals of a patient. Ex. 1006 ¶¶ [0024], [0031], Fig. 2. As the '699 patent acknowledges, existing standards required that "a medical grade monitor survive multiple defibrillation cycles of at least 360 joules." Ex. 1001, 1:61-63. Matsumura, which discloses a medical monitoring device, would therefore be expected to meet these same standards. To make a standard-compliant version of the device taught by Matsumura, a POSA would have looked to combine the resistive (*i.e.*, current-limiting defibrillation protection) traces of Kroll with the ECG monitoring device of Matsumura. *See supra* § VII.C.1.

As explained above, Kroll teaches a series current-limiting defibrillation protection resistor in the form "of a flexible conductive ink compound . . . 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. 1007, 5:4-13. Kroll further teaches that the conductive ink forming the resistive lead strips is “**silk screened**” onto a substrate (*i.e.*, “insulation and base support layer”). *Id.* 5:37-42 (emphasis added). Thus, a POSA would understand that Kroll teaches a current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate. Ex. 1003 ¶ 224.

Matsumura discloses a flexible substrate (a “bioelectrode pad”) composed of sheets made of “polyethylene foam, polyurethane foam, or polyurethane sheet.” Ex. 1006 ¶¶ [0017]-[0018], [0022]. This substrate contains, *inter alia*, “two pieces of conductive material 2” and “two hooks 3” that are “arranged to transmit the bioelectric potentials” from the electrodes to the ECG electronics. *Id.* ¶ [0019]. A POSA would thus understand that Matsumura discloses a flexible substrate that incorporates traces. Ex. 1003 ¶ 225.

These traces—the “two pieces of conductive material 2,”—“can be a carbon sheet or a PET sheet [which are insulating material] coated with conductive Ag/AgCl.” Ex. 1006 ¶¶ [0019]-[0020], Fig 1. A POSA would know that this Ag/AgCl would be applied to the insulating material using a screen-printing technique. Ex. 1003 ¶¶ 226-28.

To implement Kroll's printed traces in Matsumura's device, a POSA would have replaced the Ag/AgCl ink disposed on Matsumura's conductive material 2 with Kroll's resistive ink. *Id.* In other words, the POSA would use the same screen-printing method used to manufacture Matsumura's device, just with a different (resistive) type of ink. *Id.*

It therefore would have been obvious to a POSA to combine Matsumura's teaching of conductive silver ink screened on a substrate with Kroll's teaching of resistive traces screened on a substrate to meet this limitation. *Id.* ¶¶ 222-28.

vi. [1e] an ECG electronics module,

Matsumura discloses "an ECG electronics module" and a "reusable signal processor." Ex. 1006 ¶ [0016]; *see also id.* ¶¶ [0008], [0014], [0025], Figs. 1-2. The reusable signal processor also incorporates a "processing circuit for filtering and amplifying detected bioelectric potential signals," "a memory for storing the processed bioelectric potential signal," "a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna." *Id.* ¶ [0025]. A POSA would therefore understand that Matsumura discloses an "ECG electronics module." Ex. 1003 ¶¶ 229-32.

vii. [1f] the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections,

Matsumura discloses “the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections.”

Matsumura discloses that “the bioelectric potentials detected by the conductive gel 5 are transmitted through the conductive material 2 and the hooks 3” to the signal processor 10. Ex. 1006 ¶¶ [0019], [0024]. Matsumura further discloses that, “[i]n the signal processor 10,” “it is determined whether or not the detected electrocardiogram of the subject (patient) is in an abnormal state, such as an arrhythmia or an abnormal heart rate measured from the electrocardiogram.” *Id.* ¶ [0032]. Thus, a POSA would understand that Matsumura’s ECG electronics module (signal processor 10) receives and processes patient heartbeat signals from the plurality of electrical connections.” Ex. 1003 ¶¶ 233-36.

viii. [1g] wherein the at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module.

Limitation 1g is obvious in view of Matsumura, Kroll, and a POSA’s general knowledge. As noted above, a POSA would have looked to combine the resistive (*i.e.*, current-limiting defibrillation protection) traces of Kroll with the ECG monitor of Matsumura. *Supra* § VII.C.1.

Matsumura discloses “conductive material 2” and “hooks 3” which interconnect the “conductive gel 5” (the ECG electrodes) and the signal processor 10 (the ECG electronics). Ex. 1006 ¶¶ [0019], [0024] (describing interface between hook and hook engagement portion); *see also supra* § VII.C.2.vii. Matsumura’s “conductive material” is therefore disposed between at least one of the plurality of electrical connections and the ECG electronics module. Ex. 1003 ¶¶ 239-40.

As explained above, Section VII.C.2.v, it would have been obvious to a POSA to incorporate Kroll’s teaching of screened current-limiting defibrillation protection traces into the device taught by Matsumura. A POSA would understand that Kroll’s resistive ink would form an electrical connection between the electrodes contacting the patient’s skin and the ECG electronics module. Ex. 1003 ¶¶ 241-42; *supra* § VII.C.2.v.

A POSA would understand that the objective of including a defibrillation protection resistor to a wearable ECG device would be to protect the electronics in the device from the potentially destructive flow of current associated with defibrillation. Ex. 1003 ¶¶ 241-42. To realize this objective, the defibrillation protection resistor *must* be placed between where the device would be exposed to defibrillation (*i.e.*, the ECG electrode that contacts the patient’s skin) and the ECG electronics module that the resistor is intended to protect. *Id.*

Accordingly, a POSA would understand that the combination of Matsumura and Kroll discloses “the at least one current-limiting defibrillation protection resistor [being] electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module.” *Id.* ¶¶ 237-43.

3. Claim 2

In addition to teaching the limitations of claim 1, the combination of Matsumura, Kroll, and a POSA’s general knowledge renders obvious “wherein the at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.”

Both Matsumura and Kroll disclose flexible substrates. Matsumura’s “conductive material 2” can be a carbon sheet or a “PET sheet.” Ex. 1006 ¶ [0020]. A POSA would understand that carbon or PET sheets are “flexible” substrates. Ex. 1003 ¶ 246. Similarly, Kroll discloses a “flexible and disposable electrode belt” onto which the ink for the resistive lead strips is “silk screened.” *E.g.*, Ex. 1007, 4:22-24, 4:36-37, 4:48-51, 5:37-42.

As explained above, *see* Sections VII.C.1 and VII.C.2.v, a POSA would have been motivated to combine the ECG monitor of Matsumura with Kroll’s teaching of current-limiting defibrillation protection resistors screened onto a substrate. Kroll further teaches that the conductive ink forming the resistive lead strips is “silk

screened” onto a substrate (*i.e.*, “insulation and base support layer”). Ex. 1007, 5:37-42 (emphasis added).

As modified in the manner set forth in claim 1, *supra* Section VII.C.2.v, a POSA would understand that the combination of Matsumura and Kroll would meet the dependent limitation of claim 2. Ex. 1003 ¶¶ 244-49.

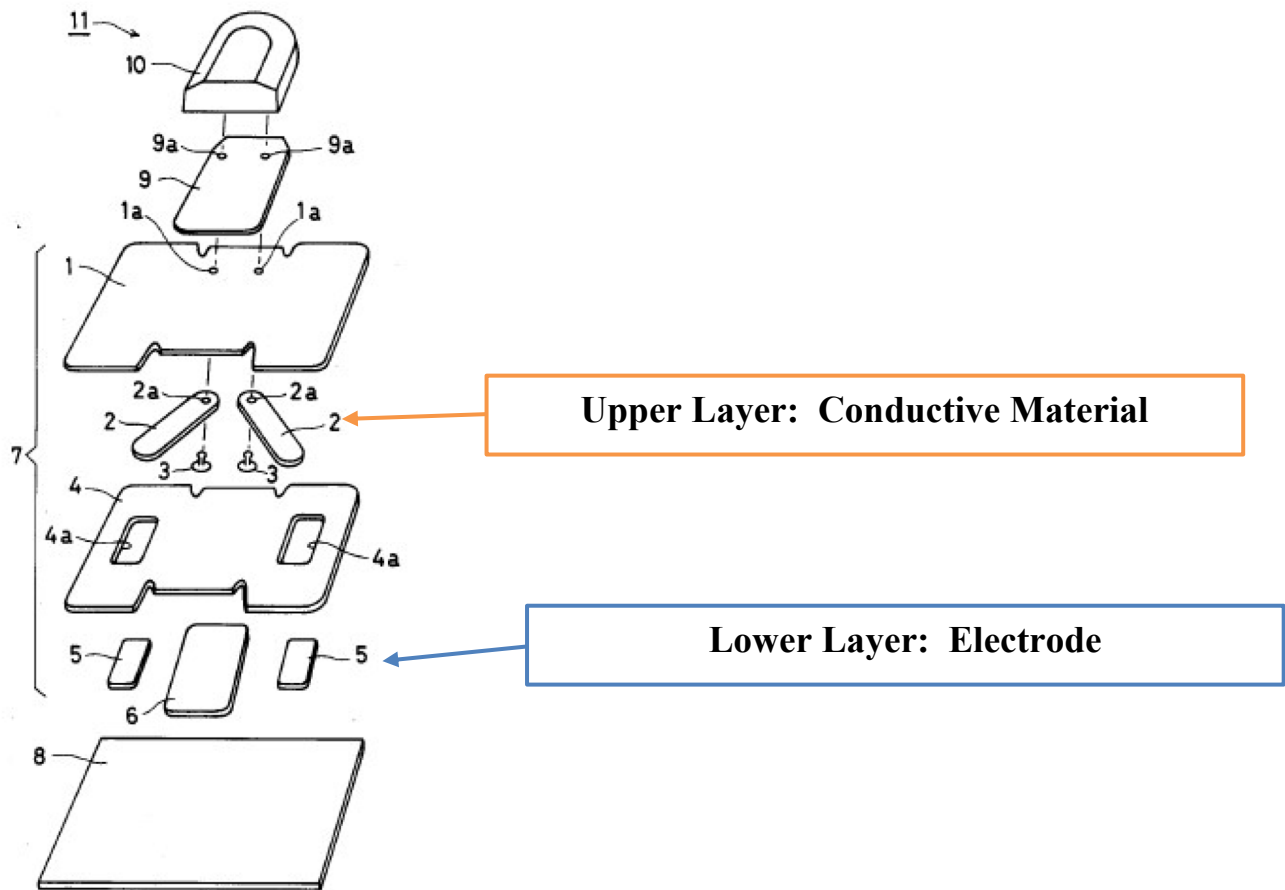
4. Claim 4

In addition to teaching the limitations of claim 1, the combination of Jensen, Matsumura, and a POSA’s general knowledge discloses “wherein a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a plurality of overlapped layers.”

As explained with respect to claim 1, a POSA would have been motivated to modify Matsumura’s ECG monitor with the teaching of Kroll to include a series current-limiting, defibrillation protection resistor in the form of resistive traces. *Supra* §§ VII.C.2.i-viii.

A POSA would recognize that the interface between conductive material 2, as modified, and conductive gel pad 5 (the ECG electrode) is a mechanical interface because the lower surface of the conductive material 2 is electrically and physically connected to the bottom surface of the conductive gel pad. Ex. 1006 ¶ [0019]; Ex. 1003 ¶¶ 250-56.

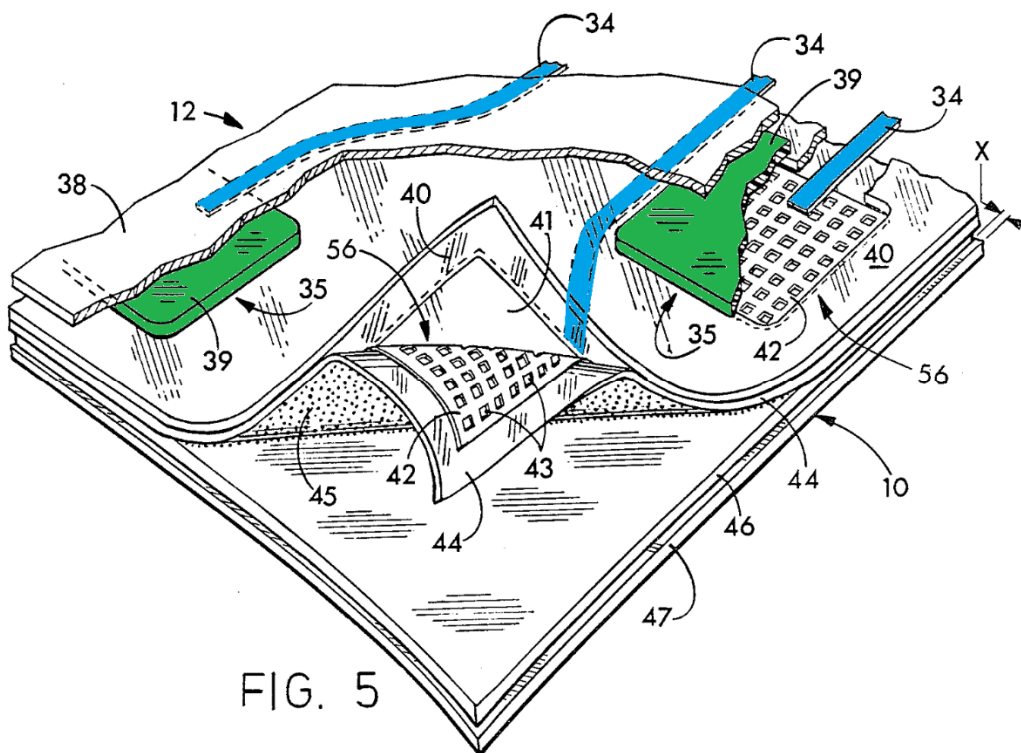
A POSA would further understand that this mechanical interface necessarily includes a plurality of overlapped layers, wherein the conductive material 2 is an upper layer, and the conductive gel electrode 5 is a lower layer. Ex. 1003 ¶¶ 250-56. A POSA would understand that an overlapping layer structure is how the “bioelectric potentials detected by the conductive gel 5 are transmitted through the conductive material 2 and the hooks 3.” *Id.* (quoting Ex. 1006 ¶ [0019]).



Ex. 1006, Fig. 1 (annotated).

A POSA would have been motivated to implement Kroll’s resistive traces on Matsumura’s device. *Supra* §§ VII.C.1-2; Ex. 1003 ¶ 255. In doing so, it would

have been obvious to a POSA to implement the resistive traces so as to define a mechanical interface between them and the electrodes, thereby forming a plurality of overlapping layers. Ex. 1003 ¶ 255. Indeed, Kroll itself specifically contemplates such an arrangement: Kroll discloses that the mechanical interface between its current-limiting defibrillation protection resistors (lead strips) and its electrodes comprises a plurality of overlapping layers. *Id.* As shown in Kroll's Figure 5, Kroll's lead strips 34 are screened onto the flexible substrate, overlapping the electrodes (which are also applied to the substrate using a screening process). Ex. 1007, 5:17-21, 5:37-42, Fig. 5. As explained above, a POSA would implement these resistive lead strips in the same way—overlapping the electrodes—in Jensen's device. Ex. 1003 ¶ 255.



Ex. 1007, Fig. 5 (annotated).

Accordingly, a POSA would understand that Matsumura, Kroll, and a POSA's general knowledge together render obvious the dependent limitation of claim 4.

Ex. 1003 ¶ 256.

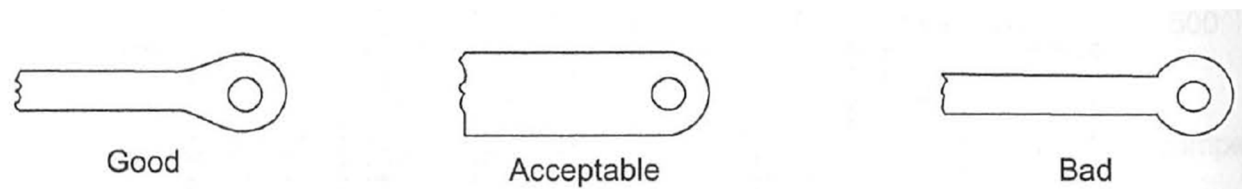
D. Ground 4: Claim 3 is Obvious over Matsumura, Kroll, Khandpur, and the General Knowledge of a POSA.

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

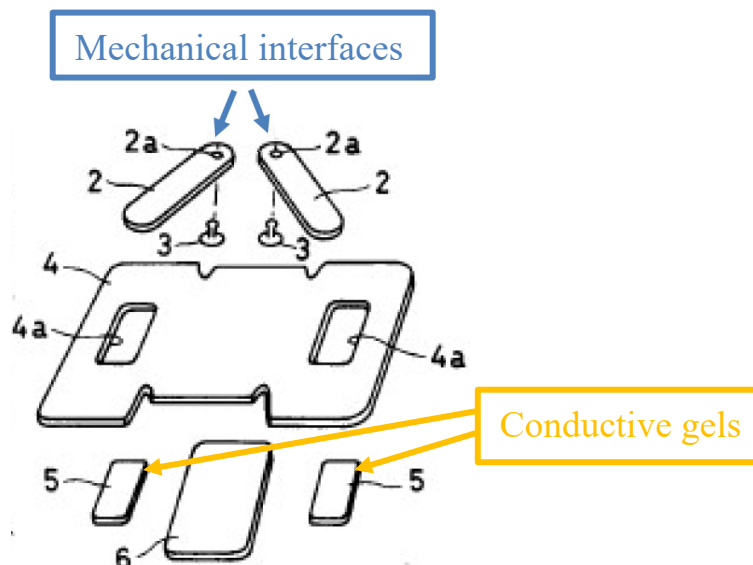
For the same reasons set forth above in Section VII.C.1, a POSA would have been motivated to combine—and would have had a reasonable expectation of success in combining—Kroll's teaching of “resistive traces” with Matsumura's device.

Additionally, a POSA would have been motivated to incorporate Khandpur's teachings of a “tear-like” or “filleted” edge to the interface between the more rigid conductive material 2, on which the “resistive traces” of Kroll are printed, and the flexible “conductive gel” 5 of Matsumura. Ex. 1008, 442-43. The terms “tear-like” and “fillet” are used synonymously to refer to the shape of components or layers on the PCB. *Id.* 195. As noted in Khandpur, due to the transition between flexible and rigid materials, the zone is “highly prone to conductive breakage.” *Id.* 442-43. To solve this issue, Khandpur teaches having a “tear-like” or “filleted” transition

between the flexible and rigid materials. *Id.* Khandpur identifies the “filleted” edge as “good,” while identifying other shapes as “acceptable” or “bad.” *Id.*



Id. Fig. 12.10. As shown below, the shape of Matsumura’s mechanical interface connecting conductive material 2 to conductive gel 5 is “acceptable.” And a POSA would have sought to improve that shape from “acceptable” to “good” as taught by Khandpur.



Ex. 1006, Fig. 2 (annotated).

A POSA would have had a reasonable expectation of success in implementing Khandpur’s transition to Matsumura’s device with Kroll’s “resistive traces” without undue experimentation. Ex. 1003 ¶ 259. This combination would have been a

simple design change that would alter the “acceptable,” straight edge design of Matsumura’s interface to the “good,” “filleted” edge design of Khandpur. *Id.* Nothing in the art suggests that this modification would not work. *Id.*

2. Claim 3

In addition to teaching the limitations of claim 1, the combination of Matsumura, Kroll, Khandpur, and a POSA’s general knowledge renders obvious “a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a filleted edge.”

As explained with respect to claim 1, a POSA would have been motivated to modify Matsumura’s ECG monitor with the teaching of Kroll to include a series current-limiting, defibrillation protection resistor in the form of resistive traces. *Supra* §§ VII.C.1, VII.C.2.i-viii .

A POSA would recognize that the interface between conductive material 2, as modified, and conductive gel pad 5 (the ECG electrode) is a mechanical interface because the lower surface of the conductive material 2 is physically connected to the top surface of the conductive gel pad. Ex. 1006 ¶ [0019]; Ex. 1003 ¶¶ 260-64. It would have been obvious to a POSA to shape printed traces on conductive material to have a “filleted edge,” as taught by Khandpur. Ex. 1003 ¶ 263. Specifically, a POSA would have done so to improve the interface between the more rigid conductive material 2 and flexible conductive gel 5. *Id.* ¶ 262 (Ex. 1008, 195 (using

the terms “fillet” and “teardrop” synonymously); *id.* 442-43 (stating that “[t]he general shape of solder pads should be tear-like” to prevent conductive breakage)). A POSA would have recognized that this “filleted” shape not only prevents conductor breakage, as taught in Khandpur, but also increases the reliability and performance of the printed circuit board. *Id.* This “filleted” shape also lowers the cost of manufacturing by reducing the amount of materials needed to be used. *Id.* ¶ 263.

Accordingly, the combination of Matsumura, Kroll, Khandpur, and a POSA’s knowledge renders obvious the dependent limitation of claim 3.

E. Ground 5: Claim 8 is Obvious over Matsumura, Kroll, Thompson, and the General Knowledge of a POSA.

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

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

Additionally, a POSA would have been motivated to incorporate Thompson’s teaching of a periodic low power mode on Matsumura’s device. A POSA would recognize that the utility of a battery-powered, wearable device is limited by its battery life. Ex. 1003 ¶ 265. Given the dimensional requirements of a body-worn

physiological monitor, the size and composition of the battery will necessarily be limited; a POSA would thus seek to optimize power consumption (*i.e.*, battery depletion) as a means of prolonging the battery life of the device and extending the period for which it can collect data. *Id.*

However, a POSA would have been aware of techniques for optimizing battery life, including the use of a periodic low power mode. *Id.* ¶ 266. A POSA would have sought other ways to conserve power, even while the device was operational. *Id.*

Thompson teaches one way to conserve power is to limit processing time to certain portions of the heartbeat waveform. In one embodiment, Thompson discloses that “[o]nly during a QRS complex, for example, does waveform analysis processor 520 operate in a high speed processing mode at a relatively high frequency. During the remainder of the cardiac cycle [*i.e.*, including the TP interval] the DSP processor 520 may be ‘idling along’ at a much lower clock frequency. . . . In addition to the lower clock speed utilized for different portions of the cardiac cycle, one skilled in the art will recognize that in accordance with the other aspects of the present invention, as the speed is reduced, the supply voltage level (V_{DD}) may also be reduced accordingly. Thus, the objective of reduced power consumption is realized.” Ex. 1009, 18:3-14; *see also* Ex. 1003 ¶ 267.

A POSA would have had a reasonable expectation of success in implementing Thompson's low power mode on Matsumura's device without undue experimentation, at least because it would require only reprogramming of onboard software. Ex. 1003 ¶ 268. A POSA would know how to combine Thompson's low power mode with Matsumura's design with little to no design impact. *Id.* Nothing in the art suggests that this modification would not work. *Id.*

2. Claim 8

In addition to teaching the limitations of claim 1, *see supra*, Matsumura, Kroll, and Thompson render obvious “wherein the ECG electronics module includes a microprocessor to process the heartbeat signals, wherein an algorithm running on the microprocessor causes the ECG monitor to enter a low power mode that disables at least one circuit of the ECG electronics module, 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, in order to reduce said electrical load on the power source.”

Thompson discloses a device that conserves power by operating in a low power mode from the end of one S-wave of the patient's heartbeat until the commencement of the next Q-wave. Ex. 1009, 18:3-14. A POSA would therefore recognize that Thompson's low power mode (which spans the broader period, from the end of an S-wave to the next Q-wave) includes the narrower 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. 1003 ¶¶ 269-73. A POSA would also recognize that this low power mode could be implemented on Matsumura’s “signal processor.” *Id.*; Ex. 1006 ¶¶ [0025], [0032]. Accordingly, the dependent limitation of claim 8 would be obvious to a POSA in view of the combination of Matsumura, Kroll, and Thompson. Ex. 1003 ¶ 273.

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. Although litigation between Petitioner and Patent Owner has been pending since February 20, 2024, no substantive progress was made until the Court ruled on a motion to dismiss on January 28, 2025. *See* Ex. 1048. Further, the ’699 patent was added to the litigation in a Second Amended Complaint, which was filed on February 14, 2025; this Petition was filed as soon as practicable thereafter (Factor 3).

According to the present scheduling order, a trial is not scheduled until March 22, 2027 (Factor 2). *See* Ex. 1049. The parties have only recently begun the exchange of technical documents, and neither the parties nor the district court have invested substantial resources in the litigation to date. 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).

Additional relevant considerations militate against a discretionary denial (Factor 6). *See also* Coke Morgan Stewart, Interim Processes for PTAB Workload Management (Mar. 26, 2025). Neither the PTAB nor any other forum has already adjudicated the validity or patentability of the challenged patent claims. The grounds herein present a strong unpatentability challenge, unlike any grounds raised during examination. The prosecution history and reason for allowance suggest that the only art substantively analyzed by the Examiner's was from a different field of invention. *See supra* § V.D. Finally, the challenged claims are broad and threaten to stifle innovation in a field of technology directly relevant to the public health.

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.

Despite Jensen being previously presented to the Office, the factors enumerated in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) do not counsel against institution. At minimum, none of the references submitted as part of Grounds 3 and 4 were

considered by the Office and, for that reason alone, Section 325(d) does not warrant denial of institution.

As to Jensen, the Examiner failed to consider how Jensen alone or in combination with any other reference would render obvious the purported invention of the '699 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). Indeed, the only art that appears to have been substantively considered by the Examiner was subsequently deemed to read on a different technology altogether. *See supra* § V.D.

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 122 other references, none of which was substantively addressed during examination of the application that became the '699 patent. The Board has repeatedly held that a reference that is merely cited in an IDS does not weigh in favor of a discretionary denial. *See, e.g., Gene Co. Pty Ltd. v. Trs. of Columbia Univ.*, IPR 2024-00313, Paper 13 at 56-57 (PTAB June 24, 2024); *Advanced Energy Indus. Inc. v. Reno Techs. Inc.*, IPR2021-01397, Paper 7 at 7 (PTAB Feb. 16, 2022); *Lyft, Inc. v. RideShare Displays, Inc.*, IPR2021-01602, Paper 7 at 15-16 (PTAB Apr. 11, 2022). These decisions are consistent with the

USPTO’s notice of proposed rulemaking on this issue, which notes that “[a]n initialed Information Disclosure Statement, without more, does not satisfy” the criteria of 325(d). Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement, 89 Fed. Reg. 28693 (proposed Apr. 19, 2024) (to be codified at 37 C.F.R. pt. 42). The arguments in this Petition related to Jensen, which rely on combinations of prior art that include Kroll and Thompson (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 Technologies, Inc. is the real party in interest for the Petitioner.

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

The ’699 patent is presently the subject of a patent infringement lawsuit brought by the assignee, Welch Allyn, Inc., against iRhythm, Inc. and captioned *Welch Allyn, Inc. v. iRhythm, Inc.*, C.A. No. 24-224-MN (D. Del.).

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

Petitioner provides the following designation of counsel:

Lead Counsel	Backup Counsel
Robert E. Counihan (Reg. No. 61,382) Fenwick & West LLP 902 Broadway, Floor 18 New York, NY 10010 Telephone: (212) 430-2600 rcounihan@fenwick.com	Allen W. Wang (Reg. No. 68,456) Fenwick & West LLP 801 California St Mountain View, CA 94041 Telephone: (650) 988-8500 allen.wang@fenwick.com

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

D. Service Information

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

Dated: June 3, 2025

FENWICK & WEST LLP

/Robert E. Counihan/
Robert E. Counihan
Reg. No. 61,381
Attorneys for Petitioner
iRhythm Technologies, Inc.

CLAIMS APPENDIX

Claim	Recitation
1[pre]	An ECG monitor comprising:
[1a.]	a plurality of electrical connections including at least one electrode,
[1b.]	the electrical connections being couplable to a skin surface to measure patient heartbeat signals;
[1c.]	a power source;
[1d.]	at least one current-limiting defibrillation protection resistor, said at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate; and
[1e.]	an ECG electronics module,
[1f.]	the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections,
[1g.]	wherein the at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module.
2.	The ECG monitor of claim 1, wherein the at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.
3.	The ECG monitor of claim 1, wherein a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a filleted edge.
4.	The ECG monitor of claim 1, wherein a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a plurality of overlapped layers.
8.	The ECG monitor of claim 1, wherein the ECG electronics module includes a microprocessor to process the heartbeat signals, wherein an algorithm running on the microprocessor causes the ECG monitor to enter a low power mode that disables at least one circuit of the ECG electronics module, 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, in order to reduce said electrical load on the power source.

**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 12,946 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: June 3, 2025

FENWICK & WEST LLP

/Robert E. Counihan/

Robert E. Counihan

Reg. No. 61,381

Attorneys for Petitioner

iRhythm Technologies, 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. 8,630,699, all associated exhibits, and Petitioner's Power of Attorney were served in their entireties via Federal Express, Priority Delivery, on June 3, 2025, upon Patent Owner by serving the correspondence address of record with the USPTO as follows:

BARCLAY DAMON, LLP
Barclay Damon Tower
125 East Jefferson Street
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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Dated: June 3, 2025

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