

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

iRhythm, Inc.

Petitioner,

v.

Welch Allyn, Inc.

Patent Owner.

Case: IPR2025-00374

U.S. Patent No. 8,965,492

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

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1001	U.S. Patent No. 8,214,007
1002	File History of U.S. Patent No. 8,214,007
1003	U.S. Patent No. 8,965,492
1004	File History of U.S. Patent No. 8,965,492
1005	U.S. Patent No. 9,155,484
1006	File History of U.S. Patent No. 9,155,484
1007	U.S. Patent No. 10,159,422
1008	File History of U.S. Patent No. 10,159,422
1009	Expert Declaration of Jason Heikenfeld ¹
1010	<i>Curriculum Vitae</i> of Jason Heikenfeld, Ph.D.
1011	U.S. Patent Publication No. 2003/0149349 (“Jensen”)
1012	Certified English Translation of Japanese Pat. Pub. JP2004/121360 ² (“Matsumura”)
1013	U.S. Patent No. 4,763,660 (“Kroll”)

¹ The same Declaration of Dr. Jason Heikenfeld, Ph.D. is being submitted with *inter partes review* petitions directed to patents in the same patent family as U.S. Patent No. 8,965,492, but the citations to the declaration in this petition are to the relevant portions of the declaration for the specific grounds and patent challenged.

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

Exhibit No.	Description
1014	U.S. Patent Publication No. 2005/0096513 (“Ozguz”)
1015	U.S. Patent No. 6,238,338 (“DeLuca”)
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1017	U.S. Patent No. 6,223,080 (“Thompson”)
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1021	Gautham Kalahasty et al., <i>A Brief History of Remote Cardiac Monitoring</i> , 5 Cardiac Electrophysiology Clinics 275 (2013)
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1034	U.S. Patent No. 6,454,708
1035	R.S. Khandpur, <i>Printed Circuit Boards: Design, Fabrication, Assembly, and Testing</i> (2006)
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1038	V. Trend et al., <i>Are ECG Welsh cup electrodes effectively cleaned?</i> , 14 <i>J. Hosp. Infection</i> 325 (1989)
1039	U.S. Patent Publication No. 2003/0069510
1040	<i>Devices@FDA: Dexcom STS Continuous Monitors</i> , U.S. Food & Drug Admin. (2005), available at https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pma&id=320251
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1051	Roubik Gregorian & William E. Nicholson, Jr., <i>A Switched-Capacitor High-Pass Filter</i> , 27 IEEE Transactions on Circuits and Sys. 226 (1980)
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I. INTRODUCTION

Pursuant to 35 U.S.C. § 311 and 37 C.F.R. § 42.100, iRhythm, Inc. (“Petitioner”) requests *Inter Partes* Review of claims 1-8 and 11-14 (the “Challenged Claims”) of U.S. Patent No. 8,965,492 (the “’492 patent”), assigned to Welch Allyn, Inc. The Challenged Claims are obvious over the prior art. Accordingly, the Patent Trial and Appeal Board should institute review of the Challenged Claims.

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

A. Standing (37 C.F.R. § 42.104(a))

Petitioner certifies that the ’492 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 1-3, 5-8, and 11-14 are obvious under pre-AIA § 103 over Matsumura, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art
<u>Ground 2</u>	Claims 1-6 are obvious under pre-AIA § 103 over Jensen, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art

<u>Ground 3</u>	Claims 7, 8, and 11-14 are obvious under pre-AIA § 103 over Jensen, Matsumura, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art
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Sections VII.A-C 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-C. 37 C.F.R. § 42.104(b)(5). Exhibits 1001-1066 are attached.

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

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

III. PAYMENT OF FEES

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

IV. OVERVIEW OF CHALLENGES AND RELIEF REQUESTED

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

Ground 1: Claims 1-3, 5-8, and 11-14 are unpatentable under pre-AIA § 103 over Matsumura, Kroll, and the General Knowledge of Person of Ordinary Skill in the Art.

Ground 2: Claims 1-6 are unpatentable under pre-AIA § 103 over Jensen, Kroll, and the General Knowledge of Person of Ordinary Skill in the Art.

Ground 3: Claims 7, 8, and 11-14 are unpatentable under pre-AIA § 103 over Jensen, Matsumura, Kroll, and the General Knowledge of Person of Ordinary Skill in the Art.

V. SUMMARY OF THE '492 PATENT

A. Technical Background

Physiological monitoring systems have been used since the early 20th century to measure and report variables associated with human health and performance (*i.e.*, objective signs such as temperature, pulse, respiration, brain wave activity, muscular contractions). Ex. 1009 ¶¶ 17-22. These monitoring systems have been commonly used to remotely monitor patients during their daily activities, outside of a clinical setting. *Id.* ¶ 23. To accommodate their day-to-day use, these monitoring systems are designed to be both portable and discreet. *Id.* ¶¶ 23-24; Ex. 1003, 1:39-40 (“[p]ortable patient monitors have evolved that allow patients to enjoy at least some mobility”).

Electrocardiograms (ECGs or EKGs) are a type of physiological monitoring used to evaluate and monitor patients' cardiac health. Ex. 1009 ¶¶ 17-22; Ex. 1003, 1:35-38. Originating in the 1920s, ECGs measure the electrical signals that result from the depolarization and repolarization of cardiac muscle during each heartbeat. Ex. 1009 ¶ 19. Identified deviations from the normal pattern of voltage changes, known as sinus rhythm, may be used to identify abnormal heart rate and/or rhythm, and may enable a clinician to diagnose a heart condition. *Id.* An ECG measures the heart muscles' polarization/depolarization cycle using electrodes, which are typically disposable and attached to a patient's skin. *Id.* ¶ 20; Ex. 1003, 1:42-44 (“[s]ensors, such as ECG electrodes, are affixed to the patient's body, such as with tape”). Those electrodes are connected by electric wiring to “leads,” which in turn connect to electronics capable of processing and displaying the ECG signals. Ex. 1009 ¶¶ 25-26; Ex. 1003, 1:44-45, 2:7-10.

In 1949, Dr. Norman Holter introduced long-term ECG recording using the first wearable, ambulatory monitor. Ex. 1009 ¶¶ 23-24. Following efforts to reduce the size of the monitor, in 1969, commercial production of the Holter “*minimonitor*”—the size of a cigarette package—began. *Id.* Ambulatory “Holter monitoring” became a mainstay of cardiology practices, especially for the diagnosis and treatment of those with serious cardiac conditions. *Id.* ¶ 24. By 1979, the Holter

monitors had been recognized for various uses ranging from arrhythmia diagnosis to assessment of pacemakers. *Id.*

Later-developed wearable monitors for patients improved on the Holter monitor in several key ways. Ex. 1009 ¶¶ 25-32. These wearable monitors were wireless, smaller, and lightweight. Ex. 1003, 1:47–51. These advances in wearable devices were in part attributable to smaller microcontrollers, increased computing power on board the patient-worn device, and improvements in wireless communication technologies. Ex. 1009 ¶¶ 25-32.

Wearable heart monitors are (and have been) designed with their patients—individuals with known or apparent heart conditions that may require future treatment—in mind. Ex. 1009 ¶¶ 25-31. Engineers designing these devices understand that such individuals are at heightened risk for cardiac emergencies and may require treatment for such emergencies, including defibrillation (*i.e.*, the application of a dose of electric current to “reset” the body’s natural pacemaker), while still wearing the device. *Id.* ¶ 43. It was well understood that the voltage increase from defibrillation could potentially damage or destroy the electronics on the wearable heart monitor. *Id.* ¶ 31. This is why regulatory bodies required “that a medical grade monitor survive multiple defibrillation cycles of at least 360 joules.” Ex. 1003, 2:5-7. Multiple standards indicated that such circuit protection would be expected for body-worn ECGs of multiple types. And for such wearable ECGs that

included an arrhythmia alarm feature, the US FDA explicitly required some form of circuit protection that would survive defibrillation. Ex. 1009 ¶ 37.

A common solution in the field was to include “one or more power resistors situated in series with the wire leads of a fixed or portable physiological monitor.” *Id.* 2:8-9. But these resistors are “too large for use in a compact monitor application.” *Id.* 2:11. This problem was well known in the field. Ex. 1009 ¶¶ 43-48.

Multiple solutions existed to solve it, to ensure that the wearable monitor would be standard compliant and withstand multiple defibrillation cycles. *Id.* For example, Dunseath (WO 1987/01024 A1) described “replacing input resistor 12 with a small[er], flat[ter] surface mount resistor soldered to input trace 34 on top of circuit board 28” to improve upon prior art devices. Ex. 1019, 25:24-26:12. Similarly, Rosenberg (U.S. Pat. No. 4,280,507) described making leads of “electrically conductive carbon loaded polymer” where the “distributed resistance of each polymer lead[s] is sufficient to protect [an] EKG machine from defibrillation pulses.” Ex. 1018, 1:36-45. And, as discussed below, Kroll disclosed composing “lead strips” of a “flexible conductive ink compound” with a “preselected conductivity to provide a certain total lead strip resistance so that each lead strip 34 serves as a current limiter to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device.” Ex. 1013, 5:4-13.

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

B. Patent Description

The ’492 patent describes a known solution to the known problem outlined above. In particular, the ’492 patent is directed to a body-worn patient monitoring device that uses “electrical connections [traces]” made of “resistive material.” Ex. 1003, Abstract, cl. 1; Ex. 1009 ¶ 106. The specification explains that the “electrical traces” made of “resistive material” “replace the bulky power resistors needed by prior art monitors,” and are configured to protect the communication-computation module from “multiple defibrillation cycles.” Ex. 1003, cl. 1, 7:56-67.

The body-worn heart monitor includes disposable and reusable components. Ex. 1003, cl. 7. The claimed monitor requires two major structural components: (1) a “disposable electrode portion” (110, shown in red) that makes physical contact with the patient’s skin and “measure[s] physiological signals”; and (2) a “reusable communication and computation module” (102, shown in blue) that is “releasably

attached to the disposable electrode portion.” Ex. 1003, Abstract, Fig. 1B, 2:44-3:3, cl. 7. The “[]computation module” performs “real-time physiological analysis” while the “communication module” transmits the analysis to a remote radio receiver. Ex. 1003, 2:52-66. The “resistive traces” (shown in white in Figure 4A below) are placed on the disposable module between the electrical connections to the “communication and computation module” and the components that measure the “physiological signals.” Ex. 1003, 7:50–55.

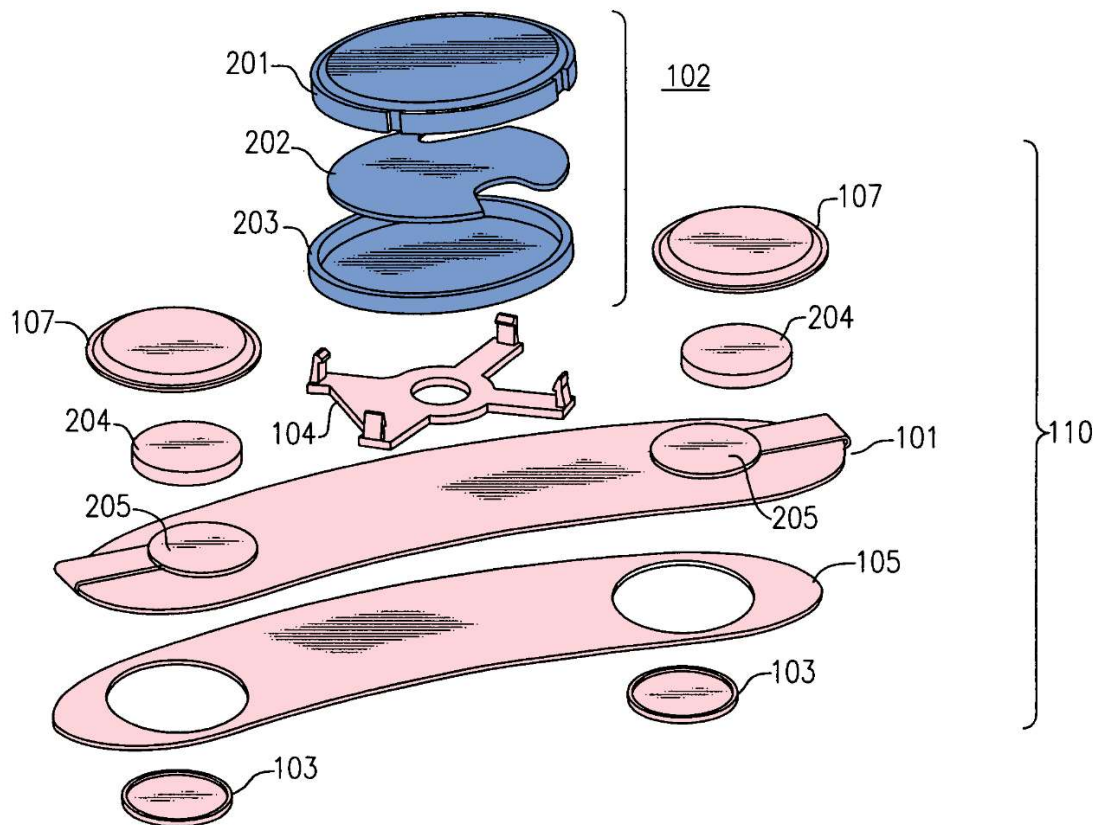


FIG. 2

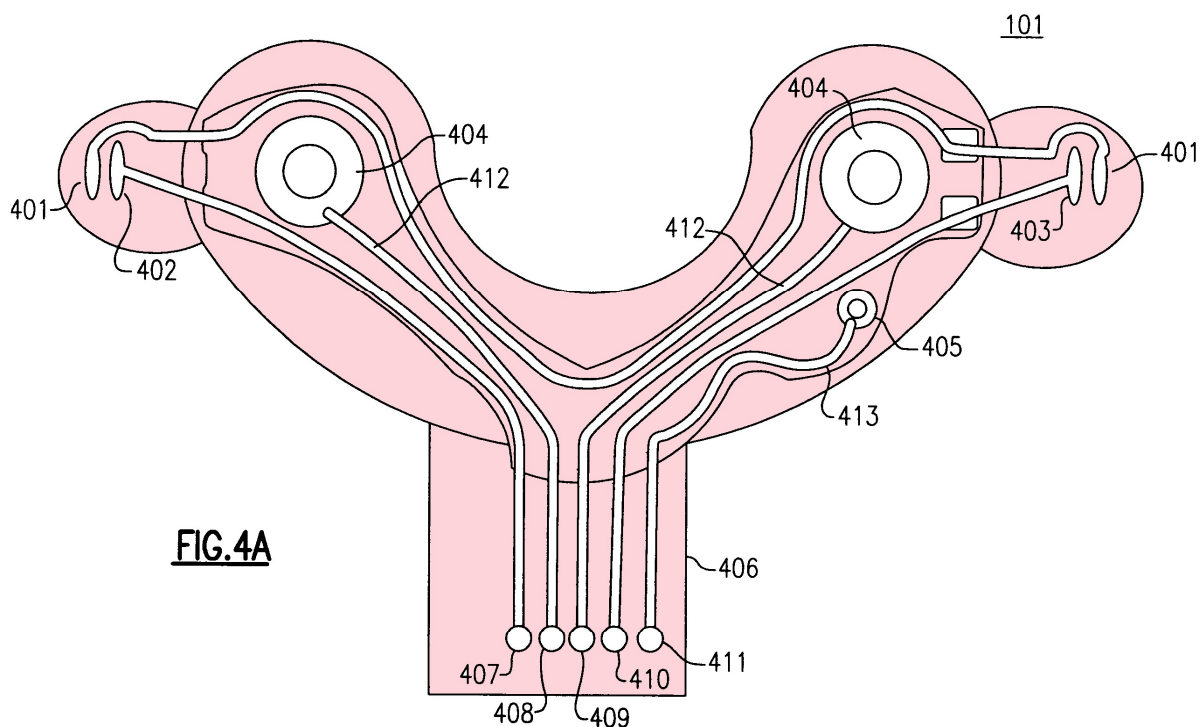


FIG. 4A

Id. Fig. 2, 4A (annotated).

C. Priority Date

The application that matured into the '492 patent was filed on May 2, 2014, and claims priority to November 1, 2006. For purposes of this proceeding only, Petitioner contends the priority date is November 1, 2006.

D. Prosecution History

The application that became the '492 patent received a first action allowance, but the Notice of Allowance does not provide a clear reason for the allowance. Notice of Allowance at 2 (Oct. 14, 2014), Ex. 1004, 26. Specifically, the Notice of Allowance notes that the “closest [examined] prior art fails to disclose a high voltage

circuit protection for a body worn monitor comprising the steps of determining a print pattern and thickness of a first and a second material, wherein each material has a resistivity to be printed on said substrate.” *Id.* Although claim 1 recites “at least one electrical trace being made at least in part from a resistive material,” the other requirements noted in the Examiner’s reasons for allowance do not appear in the claims.

E. Level of Ordinary Skill in the Art

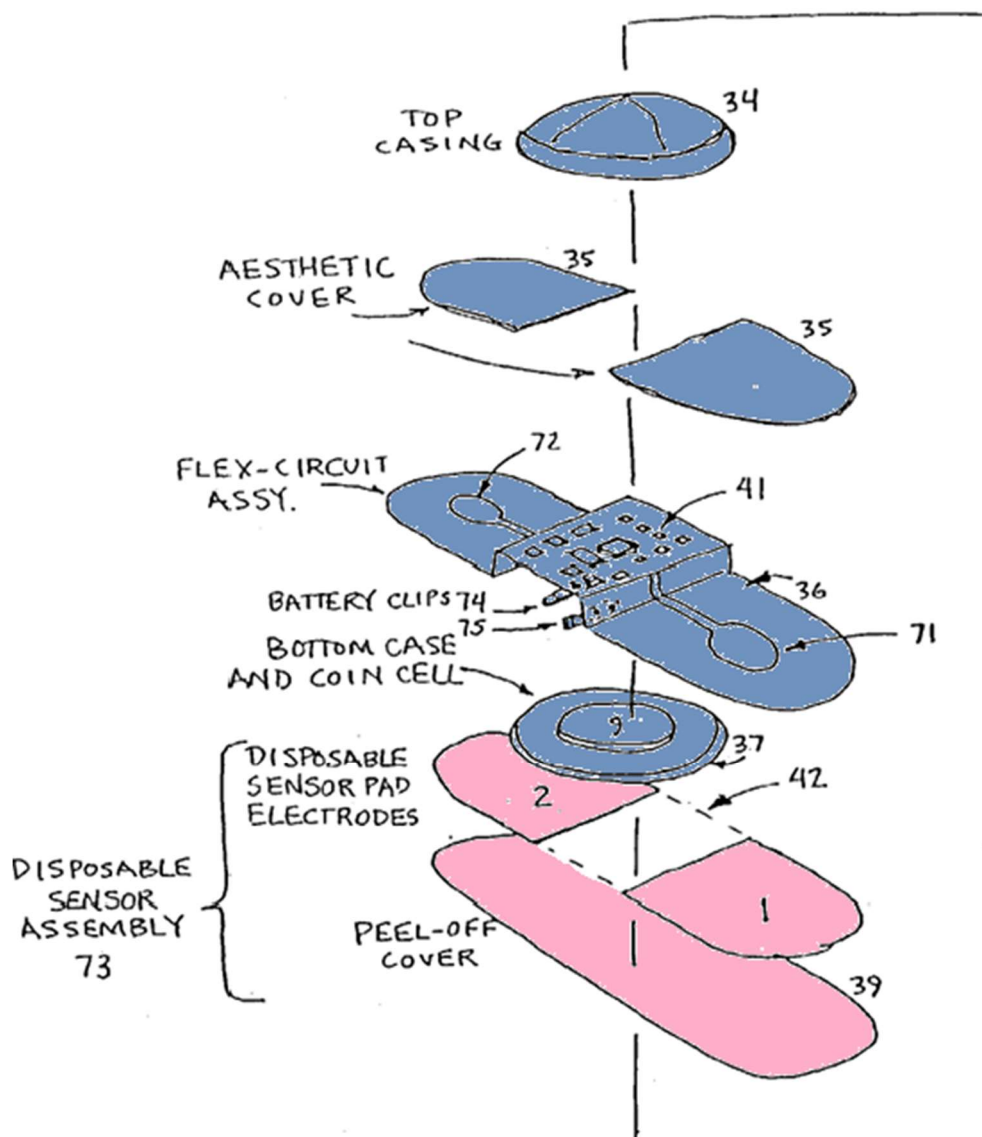
A POSA would have at least a Bachelor’s degree in electrical engineering, electrophysiology, biomedical engineering or an equivalent degree, and at least two to three years of experience designing wearable monitors that detect physiological signals with mechanical and/or electrical elements. Ex. 1009 ¶¶ 56-57. Additional experience may substitute for education and vice versa. *Id.*

VI. PRIOR ART OVERVIEW

A. Jensen (Ex. 1011)

Jensen published on August 7, 2003 as U.S. Patent Pub. No. 2003/0149349 and is prior art under pre-AIA 35 U.S.C. §§ 102 (a), (b), (e). Jensen was cited in an Information Disclosure Statement during prosecution but was never substantively discussed during examination. Jensen teaches a body worn physiological monitor in the form of a “‘smart bandage’ or ‘smart patch’” for “physiological monitoring, especially heart rate sensing.” Ex. 1011, Abstract; *see also id.* ¶ [0013]. This “smart

patch” includes both a “disposable sensor assembly” (shown below in red) that makes direct contact with the skin of the patient and a “re-usable (non-disposable) portion” (shown below in blue). *Id.* ¶¶ [0042]-[0043], Fig. 5. Jensen’s monitor includes a flexible circuit assembly with “programmable logic” for “perform[ing] measurement and processing of sensed data.” *Id.* ¶ [0014]. The assembly includes “leads 86” that connect the piezoelectric sensors 81 that “sense[] data” with circuit 87 that “process[es]” the “sensed data.” *Id.* ¶¶ [0014], [0049]. The monitor will then use a “transmitter” and “antenna” to transmit captured physiological data to “any variety of different receivers.” *Id.* ¶¶ [0029], [0032]-[0033]. The flexible circuit assembly includes resistors 24 and 25 for “signal biasing.” *Id.* ¶ [0032].

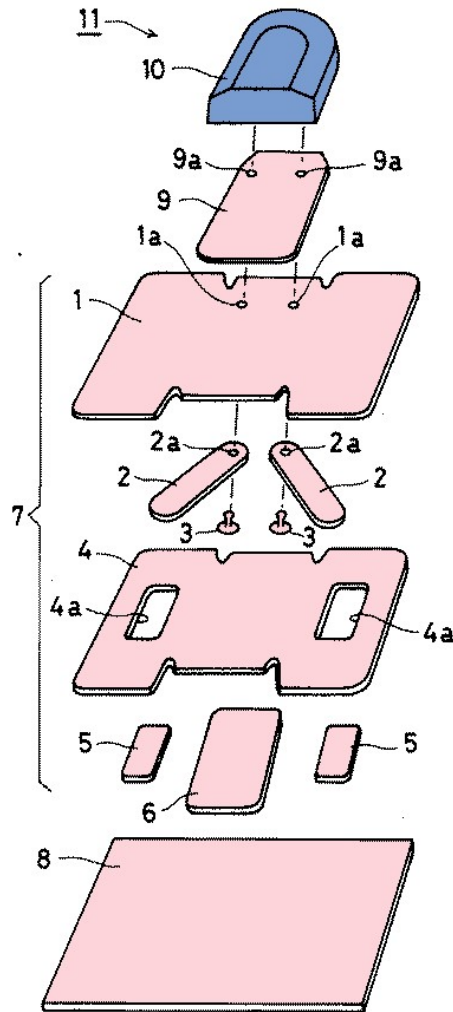


Id. Fig. 5 (annotated).

B. Matsumura (Ex. 1012)

Matsumura published on April 22, 2004 as Japanese Patent Publication 2004-121360, and is prior art under pre-AIA 35 U.S.C. § 102 (a) and (b). Matsumura was neither cited nor considered during prosecution of the '492 patent. Matsumura is directed to “a bioelectric potential detector having a waterproof structure” for detecting ECG signals. Ex. 1012, ¶¶ [0001], [0024]. The detector “comprises a

disposable bioelectrode pad [shown in red, below] for detecting bioelectric potentials, and a reusable signal processor [shown in blue, below] for processing the bioelectric potential signals detected by the bioelectrode pad,” *id.* ¶ [0007], Fig. 1. In particular, Matsumura’s disposable bioelectrode pad 7 is “composed of a first sheet 1, a conductive material 2, a hook 3, a second sheet 4, a conductive gel 5, a third sheet 6, and double-sided adhesive tape 9.” *Id.* ¶ [0016]. “[B]ioelectric potentials detected by the conductive gel 5 are transmitted through the conductive material 2 and the hooks 3” at which point they reach signal processor 10. *Id.* ¶¶ [0019], [0025]. A portion of conductive material 2 forms a “half cell” with conductive gel 5, while another portion of conductive material 2 electrically connects conductive gel 5 to signal processor 10 via hook 3. *Id.* ¶¶ [0019]-[0020], [0024]. The signal processor “incorporates a processing circuit for filtering and amplifying detected bioelectric potential signals, a memory for storing the processed bioelectric potential signal, a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna.” *Id.* ¶ [0025].



Id. Fig. 1 (annotated).

C. Kroll (Ex. 1013)

Kroll issued on August 16, 1988 as U.S. Patent No. 4,763,660. Kroll is prior art under pre-AIA 35 U.S.C. § 102(b). Kroll was neither cited nor considered during prosecution of the '492 patent. Kroll is directed to “a disposable, flexible and layered electrode belt . . . for placement and use on the body of a patient,” and may

be configured to “place electrodes at standard EKG limb electrode locations.” Ex. 1013, 1:11–15, 1:59–61; *see also* Ex. 1009 ¶¶ 222, 343-48.

Kroll discloses a flexible and disposable electrode belt to be worn by a patient undergoing physiological monitoring. Ex. 1013, Abstract. Kroll teaches that electrical signals from electrodes are transmitted using lead strips. *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.*

VII. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Ground 1: Claims 1-3, 5-8, and 11-14 are Obvious Over Matsumura, Kroll, and the General Knowledge of Person of Ordinary Skill in the Art

1. A POSA would have combined Matsumura and Kroll

Matsumura and Kroll teach wearable devices for monitoring physiological signals, including ECG or EKG signals. Ex. 1012 ¶¶ [0024], [0031], Fig. 2; Ex. 1013, 1:11-15, 1:37-45. Kroll teaches that the wearable device is flexible, while Matsumura teaches that its “bioelectrode pad” should be composed of sheets

comprising “polyethylene foam, polyurethane foam, or polyurethane sheet,” Ex. 1012 ¶¶ [0016]-[0018], [0022], which a POSA would recognize as “flexible materials.” Ex. 1009 ¶¶ 772, 465.

A POSA would look to incorporate the “resistive material” of Kroll into the wearable monitor of Matsumura for at least two reasons. First, Kroll teaches a solution to electrical overload: using electrical lead strips of a known resistivity to limit the current transmitted between the worn device and the patient. Ex. 1013 at 5:1-13. Kroll specifically discusses this solution in the context of protecting a patient from “shock”, from the worn device or “a complementary medical device.” *Id.* A POSA would have understood that it would be beneficial to limit the current transmitted in either direction (whether towards or away from the patient’s body). *See* Ex. 1009 ¶¶ 772, 468-69. 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. *See id.* Matsumura discloses a wearable monitor to which these same considerations apply. Driven by a desire to protect patients from potential shock and ensure the long-term viability of Matsumura’s reusable module against potential defibrillation, a POSA would have been motivated to incorporate Kroll’s teaching of resistive “lead strips” to achieve each. *Id.*

Second, using Kroll's resistive lead strips would allow reduction of the physical size of the reusable portions of Matsumura's wearable device. This would not only reduce the size of the device Matsumura seeks to waterproof (Ex. 1012 ¶ [0006]), but also be consistent with other industry efforts at the time to reduce the size of wearable devices. Ex. 1009 ¶¶ 772, 470. Using the resistive lead strips of Kroll, formed with ink deposits, would further these goals. *Id.* A POSA would know that using the resistive lead strips made of an ink compound as taught in Kroll would reduce the overall size of Matsumura's monitoring device by not having to rely on any conventional resistors in its signal processor. *Id.*

A POSA would have had a reasonable expectation of success in implementing Kroll's resistive leads on Matsumura's device, without undue experimentation, at least because it would involve only a slight modification to the materials used to print electrical traces. *Id.* ¶¶ 772, 471. Indeed, deploying Kroll's resistive lead strips on Matsumura's device would have minimal impact, and amount to a minor design change requiring no more than a slight modification to Matsumura's configuration. *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 because screen printing was a well-known manufacturing method at the time of the invention. *Id.*

2. *Claim 1*

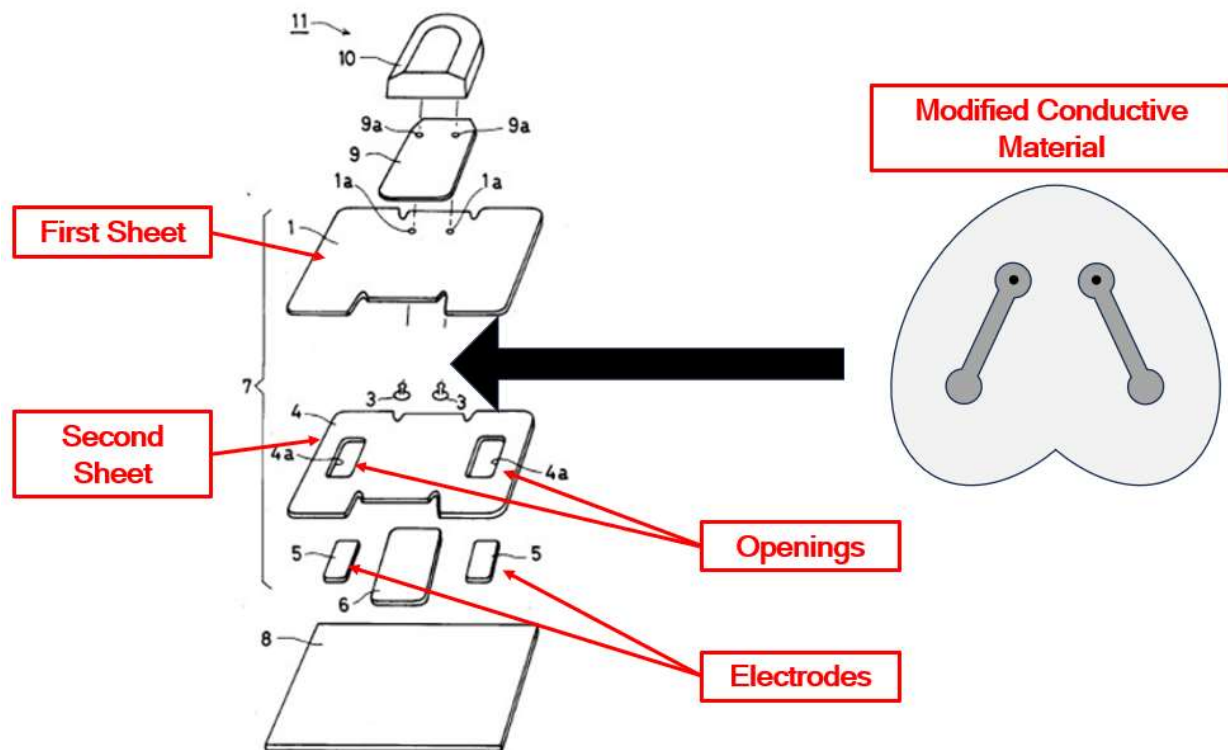
i. [Pre]: A body-worn patient monitoring device comprising:

Matsumura discloses a body-worn patient monitoring device which it refers to as a “bioelectric potential detector.” Ex. 1012, Abstract, ¶¶ [0006], [0014]; Ex. 1009 ¶¶ 775-76. Kroll also discloses a body worn patient monitoring device. Ex. 1013, 1:11-15; Ex. 1009 ¶¶ 777-78.

ii. [1a.] a flexible printed circuit layer made from an insulating material and defining a substrate;

Matsumura renders obvious a “flexible printed circuit layer made from an insulating material and defining a substrate.” Matsumura discloses a flexible circuit layer configured to be coupled to a skin surface of a patient (bioelectrode pad 7), which includes “two pieces of conductive material 2,” which “can be carbon sheet or a PET sheet [which are insulating material] coated with conductive Ag/AgCl.” Ex. 1012 ¶¶ [0019]-[0020], Fig. 1. A POSA would modify this conductive material to form a flexible printed circuit layer made from an insulating material and defining a substrate, as a circuit layer must be formed on insulating material. Ex. 1009 ¶ 781.

Specifically, it would have been obvious to a POSA to use well-known techniques to replace the two pieces of insulating material coated with conductive Ag/AgCl with a single, flexible sheet of insulating material that contains printed-ink conductive traces. *Id.* ¶¶ 782-783. The proposed modification is depicted below:



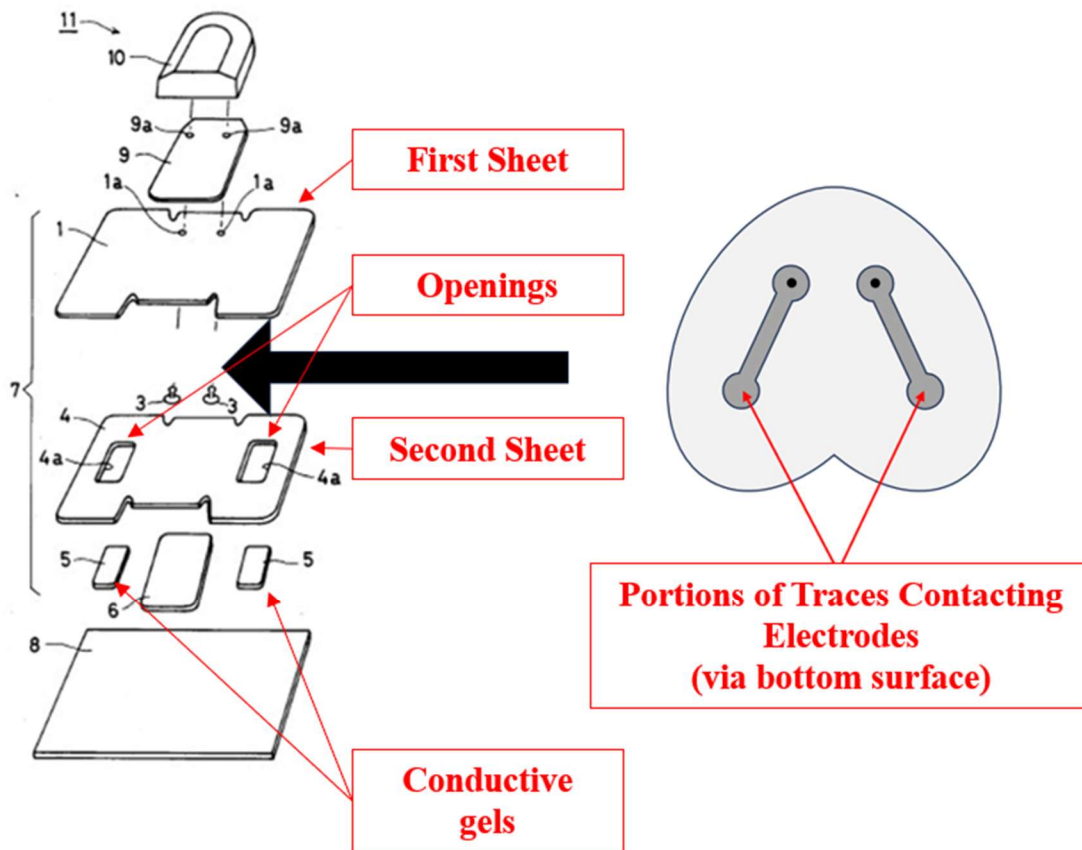
Ex. 1012, Fig. 1 (annotated).

A POSA would have done so because this would require cutting only one piece of insulating material and printing traces on it, whereas the original method suggested by Matsumura would require cutting two pieces of insulating material and coating them. *Id.* A POSA would recognize that, as modified, this sheet with printed traces replacing Matsumura's conductive material 2 would comprise a flexible printed circuit layer made from an insulating material and defining a substrate.

Ex. 1012 ¶¶ [0017]-[0018]; Ex. 1009 ¶ 784.

iii. [1b.] at least one electrode disposed onto a surface of the substrate;

Matsumura renders obvious the claimed “at least one electrode disposed onto a surface of the substrate.” As shown in Figure 1 below, Matsumura discloses “conductive gel[s] 5” (electrodes) used to detect bioelectrical potentials. Ex. 1012 ¶ [0019]. These “conductive gel[s]” are disposed in two openings 4a in second sheet 4, and, subject to the modification explained with reference to limitation [1a], would make contact with the printed sheet of conductive material. Ex. 1012 ¶¶ [0018]-[0019]. A POSA would therefore understand that, subject to the modification, conductive gels 5 are disposed on a surface of the substrate (*i.e.*, the insulating sheet with printed traces replacing conductive material 2). *Id.*; *supra* VII.A.2.ii; Ex. 1009 ¶¶ 785-88.



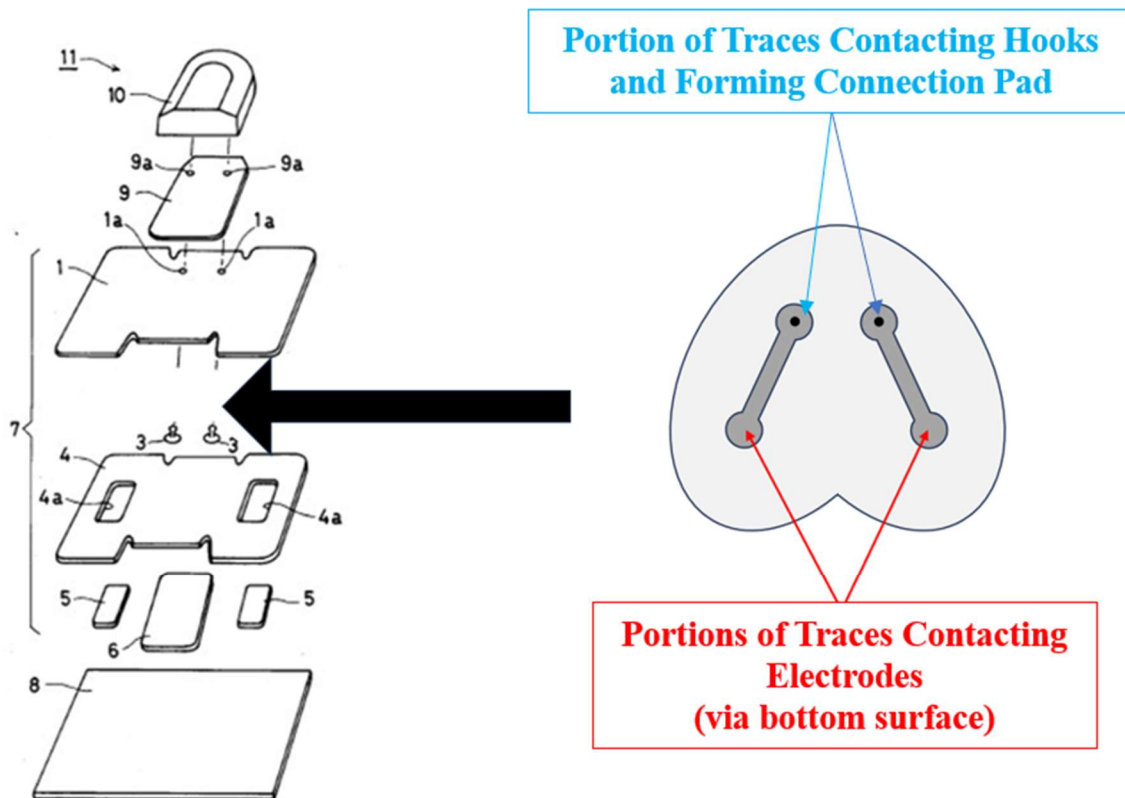
Ex. 1012, Fig. 1 (annotated).

iv. [1c.] at least one connection pad;

Matsumura renders this limitation obvious in view of the knowledge of a POSA. As previously explained, a POSA would have implemented Matsumura’s conductive material 2 by printing traces on a single sheet of insulating material. *Supra* § VII.A.2.ii; Ex. 1009 ¶¶ 779-84.

A POSA would understand that the location where Matsumura’s hooks contact the traces of the flexible printed circuit layer (inserted between the first and second sheets) constitutes a “connection pad” because it forms an electrical

connection between the signal processor 10 and traces leading to the electrodes 5. Ex. 1003, 7:44-55; Ex. 1009 ¶¶ 789-793. Thus, Matsumura renders obvious at least one connection pad.



Ex. 1012, Fig. 1 (annotated).

- v. *[1d.] at least one electrical trace extending between the at least one connection pad and a conductive surface of the least one electrode,*

Matsumura renders this limitation obvious in view of the knowledge of a POSA. As explained above, a POSA would have been motivated to combine conductive material 2 onto a single, printed sheet, forming a flexible printed circuit

layer. *See supra* § VII.A.2.ii. As modified, printed traces would contact conductive gel 5 (the electrodes) at one end. Ex. 1009 ¶ 796. At the other end, as described above, the traces would contact the hooks 3 at the connection pad. *See supra* § VII.A.2.iv; Ex. 1009 ¶ 796. A POSA would therefore understand that, as modified, Matsumura includes “at least one electrical trace extending between the connection pad and a conductive surface of the electrode.” Ex. 1009 ¶ 797.

vi. [1e.] the at least one electrical trace being made at least in part from a resistive material; and

Matsumura and Kroll render this limitation obvious in view of the knowledge of a POSA.

Matsumura discloses a flexible, “disposable bioelectrode pad 7” that includes “conductive material 2” (traces). Ex. 1012 ¶ [0016]. As explained above, it would have been obvious to a POSA to replace conductive material 2 with a single sheet of insulating material that contained printed (ink) electrical traces. *See supra* § VII.A.2.ii.

Kroll teaches traces that are made of resistive material. Specifically, Kroll teaches circuits composed of a “flexible conductive ink compound having a conductive filler having Silver, Aluminum, or compounds thereof, or of a similarly suitable material. Preferably, the ink deposit is of a preselected conductivity to provide a certain total lead strip resistance so that each strip 34 serves as a current limiter to protect a patient from shock due to malfunction of the device 20 or of a

complementary medical device.” Ex. 1013, 5:4-13. Kroll therefore teaches printed ink lead strips, which a POSA would have understood as traces made at least in part of resistive material. *Id.*; Ex. 1009 ¶¶ 798-803.

As explained in Section VII.A.1, *supra*, a POSA would have known that the “resistive trace” of Kroll would help to ensure the viability of Matsumura’s flexible circuit assembly in the event of a patient being defibrillated. It therefore would have been obvious to a POSA to combine Kroll’s teaching of resistive traces with the modified version of Matsumura to meet this limitation.

vii. [1f.] an insulating layer covering the flexible printed circuit layer.

Matsumura discloses “an insulating layer covering the flexible printed circuit layer.” As disclosed, a POSA would have modified Matsumura’s conductive material 2 to comprise printed ink traces on a single flexible sheet. *See supra* § VII.A.2.ii. Matsumura discloses a second sheet 4 “provided with two openings . . . into which the conductive gel 5 [*i.e.*, electrodes] is inserted” and that is “made of insulating material that does not allow moisture to penetrate.” Ex. 1012 ¶ [0018]. Second sheet 4 therefore comprises an insulating layer covering the flexible printed circuit layer.

Additionally, or alternatively, Matsumura discloses that first sheet 1 that covers bioelectrode pad 7 “should be made of an insulating material that does not

allow moisture to penetrate, for example, polyethylene foam, polyurethane foam, or polyurethane sheet is preferred.” *Id.* ¶ [0017].

The combination of Matsumura and Kroll discloses an insulating layer (second sheet 4 and/or first sheet 1) that covers a flexible printed circuit layer (the modified, printed sheet of conductive material 2), as modified by the teachings of Kroll). *See also* Ex. 1009 ¶¶ 804-806.

3. *Claim 2*

As explained above, Matsumura and Kroll render claim 1 obvious. It would have been obvious to a POSA that “at least one electrical trace includes a filleted portion formed at the electrode.” As explained above, it would have been obvious to modify Matsumura’s conductive material to comprise printed ink traces on a flexible, insulating substrate. *Supra* § VII.A.2.ii. A POSA would know that, when printing ink traces on a flexible circuit board, it is desirable that contacts—such as the contact between Matsumura’s conductive material 2 and electrode 5, or between Matsumura’s conductive material 2 and hook 3—should be “tear-like” or “filleted” to ensure a good conductive connection. Ex. 1009 ¶ 810. Thus, the dependent limitation of claim 2 would have been obvious in view of a POSA’s general knowledge. *Id.* ¶¶ 807-811.

4. *Claim 3*

Matsumura, Kroll, and a POSA's general knowledge render claim 3 obvious. It would have been obvious to a POSA to include "at least one battery mounted on the flexible circuit layer."

Matsumura discloses a monitor that transmits the "processed bioelectric potential signal . . . wirelessly." *E.g.*, Ex. 1012 ¶ [0025]. As Matsumura explains, prior art wireless monitors included "a power source." *Id.* ¶ [0004] (prior art device comprising "conduction portion (equivalent to an electrode element), a power source, a potential difference detection portion, and a wireless transmitting/receiving portion"). A POSA would have understood Matsumura's device to include an onboard power source to allow for wireless transmissions. Ex. 1009 ¶ 814. The device would otherwise be inoperable. *Id.* It would, therefore, be obvious to a POSA to interpret Matsumura's disclosure as implicitly requiring a battery. *Id.* A POSA would know that such batteries could be rechargeable or disposable. *Id.* And in the case of a disposable battery, it would be obvious to incorporate that element into the (disposable) flexible circuit layer. *Id.* Thus, the dependent limitation of claim 3 is obvious in view of a POSA's general knowledge. *Id.* ¶¶ 812-15.

5. *Claim 5*

In addition to teaching the limitations of claim 1, Matsumura and Kroll teach "an ECG monitor having a programmed microprocessor and a plurality of electrical

connections to measure patient heartbeat signals,” as recited in claim 5. Matsumura and Kroll teach wearable devices for monitoring physiological signals, including ECG or EKG signals that measure a patient’s heartbeat. Ex. 1012 ¶¶ [0024], [0031], Fig. 2; Ex. 1013, 1:11–15, 1:37–45. Specifically, Matsumura discloses “bioelectric potentials detected by the conductive gel[s] 5,” and that the “bioelectrical potentials” can be “electrocardiogram signals” detected while the detector is “worn on the subject’s chest.” Ex. 1012 ¶¶ [0019], [0024].

Matsumura also teaches a wearable device with a programmed microprocessor. Specifically, Matsumura discloses that signal processor 11, which a POSA would recognize as a microprocessor, can “determine[] whether or not the detected electrocardiogram of the subject (patient) is in an abnormal state, such as an arrhythmia or an abnormal heart rate.” *Id.* ¶ [0032]; *see also id.* ¶ [0037]; Ex. 1009 ¶¶ 816-21.

Matsumura and Kroll teach an ECG monitor with a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals. *Id.*

6. Claim 6

In addition to teaching the limitations of claim 1, Matsumura and Kroll teach that “the at least one electrode includes an electrode gel and a conductive surface, thereby creating a half cell,” as recited in claim 6. Matsumura teaches that

“conductive gel 5” may be produced from components such as an “acrylic hydrophilic polymer, glycerin, and water.” Ex. 1012 ¶¶ [0018]-[0019]. The conductive gel 5 contacts a portion of “conductive material 2,” which may be “coated with conductive Ag/AgCl.” *Id.* ¶¶ [0019]-[0020]. A POSA would understand that conductive gel 5 (electrode gel) comprising an acrylic hydrophilic polymer, glycerin, and water, and contacting a portion of conductive material 2 (conductive surface), whose surface is made of silver/silver chloride, comprises a “half cell.” Ex. 1009 ¶ 824. Accordingly, a POSA would know that Matsumura’s conductive gel 5 and/or a portion of conductive material 2 (modified in the manner described above) form electrical connections comprising half cells at the point of contact with the patient’s skin. *Id.* ¶¶ 824-25.

7. Claim 7

i. 7[pre]. A body-worn patient monitoring device comprising:

As described with respect to Claim 1, Matsumura and Kroll disclose a body worn patient monitoring device. *See Supra* § Claim VII.A.2.i.

ii. [7a.] a disposable electrode portion; and

Matsumura discloses “a disposable electrode portion.” As noted above, § VII.A.2.ii-iii, Matsumura discloses “a disposable bioelectrode pad 7” that includes “conductive gel 5” (electrode portion). Ex. 1012 ¶¶ [0016], [0019].

iii. [7b.] a reusable communication module,

Matsumura discloses a “reusable communication module.” Matsumura discloses a “reusable signal processor for processing and wirelessly transmitting the bioelectric potential signals detected by the bioelectrode pad.” *Id.* ¶ [0013]; *see also id.* ¶¶ [0008], [0014], [0016], [0025], Figs. 1-2. The reusable signal processor incorporates components for communication: “a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna.” *Id.* ¶ [0025]. Accordingly, the combination of Matsumura and Kroll discloses “a reusable communication module.” Ex. 1009 ¶¶ 833-837.

iv. [7c.] the disposable electrode portion comprising a flexible printed circuit layer made from an insulating material and defining a substrate,

As described with respect to Claim 1, Matsumura renders this limitation obvious in view of the knowledge of a POSA. Matsumura discloses “a flexible printed circuit layer made from an insulating material and defining a substrate.” *Supra* § VII.A.2.ii. Matsumura discloses “a disposable bioelectrode pad” composed of sheets “made of insulating material,” such as, “polyethylene foam, polyurethane foam, or polyurethane sheet” (Ex. 1012 ¶¶ [0016]-[0018], [0022]), which a POSA would recognize are flexible materials. Ex. 1009 ¶¶ 839-41. As noted previously, *supra* § VII.A.2.ii, a POSA would have used well-known techniques to replace the two separate pieces of conductive material 2 of Matsumura with a single, flexible

sheet comprising insulating material containing printed-ink traces (*i.e.*, a printed circuit board), and situated that printed sheet between Matsumura's first sheet and second sheet. Ex. 1009 ¶¶ 838-41. A POSA would recognize that this, a flexible printed circuit layer made from an insulating material and defining a substrate, would be part of Matsumura's disposable electrode portion. *Id.* ¶ 840; Ex. 1012 ¶¶ [0016]-[0018].

v. [7d.] at least two electrodes being disposed onto a surface of the substrate and

As described with respect to Claim 1, Matsumura discloses two electrodes being disposed on a surface of the substrate. *Supra* § VII.A.2.iii; Ex. 1009 ¶¶ 842-843.

vi. [7e.] electrical traces defined between the at least two electrodes and a connection pad,

As described with respect to Claim 1, Matsumura and Kroll teach electrical traces defined between the at least two electrodes and a connection pad. *Supra* § VII.A.2.v; Ex. 1009 ¶¶ 844-845.

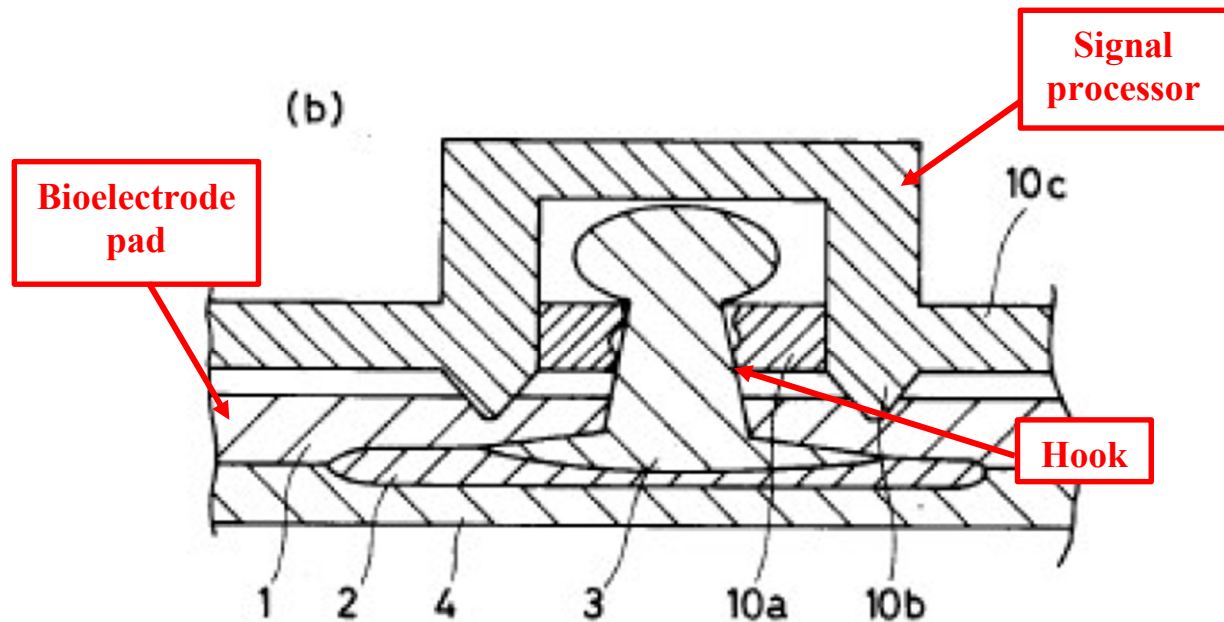
vii. [7f.] wherein the reusable communication and computation module comprises a housing containing a processor and a wireless communication unit, and

Matsumura teaches that the “reusable communication and computation module comprises a housing containing a processor and a wireless communication unit.” Specifically, Matsumura discloses a “reusable signal processor” which is “detachable with hooks.” Ex. 1012 ¶ [0016]; *see also id.* ¶¶ [0008], [0014], [0025],

Figs. 1–2. The reusable signal processor incorporates components for communication: “a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna.” *Id.* ¶ [0025]. The reusable signal processor also incorporates components for computation: a “processing circuit for filtering and amplifying detected bioelectric potential signals” and “a memory for storing the processed bioelectric potential signal.” *Id.* These components are all contained within the closed, waterproof housing of signal processor 10. *Id.* Accordingly, Matsumura and Kroll teach a “reusable communication and computation module comprises a housing containing a processor and a wireless communication unit.” Ex. 1009 ¶¶ 846-849.

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

Matsumura teaches that the “the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip.” In particular, Matsumura discloses a “reusable signal processor” with a wireless transmitter and a “disposable bioelectrode pad 7” with “conductive gel 5” (electrode portion). Ex. 1012 ¶ [0016]; *see also id.* ¶¶ [0008], [0014], [0025], Figs. 1–2. “The bioelectrode pad 7 and the signal processor 10 are detachable with hooks.” *Id.* ¶ [0016]. This is shown in Figure 4(b) of Matsumura, shown below.



Ex. 1012, Fig. 4(b) (annotated). A POSA would understand that “hook 3” of Matsumura renders obvious use of a latch clip. Ex. 1009 ¶¶ 850-54. Accordingly, the combination of Matsumura and Kroll teaches that the signal processor with a wireless transmitter is detachable to disposable bioelectrode pad with conductive gel via hooks 3, which a POSA would understand to a type of latching clip.

8. Claim 8

In addition to teaching the limitations of claim 7, Matsumura and Kroll teach that “the electrodes are integrated into the flexible printed circuit layer of the disposable portion of the device,” as recited in claim 8. Matsumura discloses that conductive gels 5 (electrodes) are integrated into disposable bioelectrode pad 7 (disposable portion) of bioelectric potential detector 11. Ex. 1012 ¶ [0016]. A POSA would understand that the electrodes are bonded together with the other components of the disposable bioelectrode pad 7, including, subject to the

modification described above, the sheet containing printed traces (replacing the conductive material 2) with which the electrodes make contact. Ex. 1009 ¶ 857; Ex. 1012 ¶ [0019]. Accordingly, the combination of Matsumura and Kroll renders obvious that “the electrodes are integrated into the flexible printed circuit layer of the disposable portion of the device.” Ex. 1009 ¶¶ 855-858.

9. Claim 11

In addition to teaching the limitations of claim 7, Matsumura and Kroll teach that “the electrical traces are screened onto the flexible printed circuit layer.” As noted above in Section VII(A)(2)(ii), it would have been obvious to a POSA to modify Matsumura’s conductive material 2 to comprise printed ink traces on a single sheet of flexible, insulating material. A POSA would understand printing ink onto an insulating material to be a form of screening, meaning that incorporating printed ink traces on the flexible printed circuit layer of Matsumura would yield electrical traces that are screened. Ex. 1009 ¶ 861. Accordingly, it would have been obvious to a POSA to screen electrical traces onto the flexible printed circuit layer of Matsumura. *Id.* ¶¶ 859-862.

10. Claim 12

In addition to teaching the limitations of claims 7 and 11, Matsumura and Kroll teach “an insulating layer applied onto the electrical traces.” As noted above in Section VII.A.2.ii., v, the combination of Matsumura and Kroll teach “electrical

traces.” Matsumura teaches that second sheet 4 and first sheet 1 are both made of insulating material. Ex. 1012 ¶¶ [0017]-[0019], Fig. 1. As modified, second sheet 4 and first sheet 1 would be applied onto a portion of the sheet of conductive material 2 that forms part of Matsumura’s “electrical traces.” Ex. 1009 ¶ 865. Accordingly, Matsumura and Kroll teach an insulating layer applied onto the electrical traces. *Id.* ¶¶ 863-66.

11. Claim 13

In addition to teaching the limitation of claim 12, it would have been obvious to a POSA to modify Matsumura and Kroll such that “the insulating layer is screen printed onto the electrical traces of the flexible printed circuit layer.” *Id.* ¶¶ 867-70. A POSA would recognize that screen printing was a well-known and common method of manufacturing a printed circuit board. *Id.* A POSA would have also recognized that a common means of applying an insulating layer to the printed traces on a circuit board would be to screen said layer on top of the traces. *Id.* For example, solder mask (sometimes called solder resist) was commonly applied using screen printing methods. *Id.* Accordingly, it would have been obvious to a POSA to modify Matsumura and Kroll to screen print the insulating layer onto the electrical traces of the flexible printed circuit layer.

12. Claim 14

In addition to teaching the limitations of claim 7, Matsumura and Kroll disclose that the at least one electrode includes an electrode gel and a conductive surface defining a half cell as discussed above in reference to claim 6. *Supra* § VII.A.6.

B. Ground 2: Claims 1-6 are Obvious Over Jensen, Kroll, and the General Knowledge of Person of Ordinary Skill in the Art

1. A POSA would have combined Jensen and Kroll

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

A POSA would look to incorporate the “resistive trace” of Kroll into the wearable monitor of Jensen for at least two reasons. First, Kroll describes, and teaches a solution to, the known risk of electrical overload (*see supra*): using electrical lead strips of a known resistivity to limit the current transmitted between the worn device and the patient. Ex. 1013, 5:1-13. Kroll specifically discusses this solution in the context of protecting a patient from “shock” from the worn device or “a complementary medical device.” *Id.* A POSA would have understood that it would be beneficial to limit the current transmitted in either direction (whether towards or away from the patient’s body). *See* Ex. 1009 ¶¶ 876, 211. The resistive lead strips would (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. *See id.* ¶¶ 876, 211-14. Jensen discloses a wearable monitor to which these same considerations apply. Driven by a desire to protect patients from potential shock and ensure the long-term viability of Jensen’s reusable module against potential defibrillation, a POSA would have been motivated to incorporate Kroll’s teaching of resistive “lead strips” to achieve each. *Id.*

Second, using Kroll’s resistive lead strips addresses the very concerns expressed by Jensen about the physical dimensions of the device. Jensen discloses a device that is “thin, being less than 6 or 7 mm in thickness, low in mass, and may be applied to the skin much like a bandage.” Ex. 1011 ¶ [0030]. Jensen’s goal of reducing the size of the device is consistent with other industry efforts at the time to reduce the size of wearable devices. Ex. 1009 ¶¶ 876, 215-16. 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.* A POSA would know that removing the conventional resistors of Jensen and instead using the resistive lead strips made of an ink compound as taught by Kroll would reduce the overall size of Jensen’s monitoring device. *Id.*

A POSA would have had a reasonable expectation of success in implementing Kroll’s resistive leads on Jensen’s device without undue experimentation, at least

because it would involve only a slight modification to the materials used to print electrical traces. *Id.* ¶¶ 876, 216-217. Indeed, deploying Kroll’s resistive lead strips on Jensen’s device would have minimal design impact, requiring no more than a slight modification to the amplifier configuration of Jensen’s device. *Id.* Nothing in the art suggests that this modification would not work. *Id.* Nor would this modification be difficult to implement using well-known manufacturing techniques at the time of the invention. *Id.*

2. Claim 1

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

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

ii. [1a.] a flexible printed circuit layer made from an insulating material and defining a substrate;

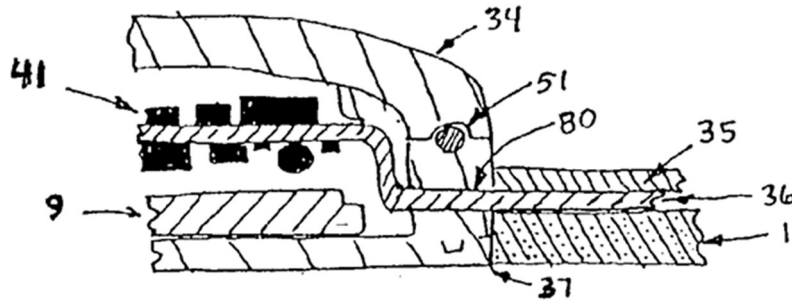
Jensen teaches “a flexible printed circuit layer made from an insulating material and defining a substrate.” Jensen discloses a “flexible circuit assembly” 36, 50, containing an electrical circuit. Ex. 1011 ¶¶ [0040], [0043], [0046], Figs. 5, 8. In the embodiment of Figure 5, the claimed flexible printed circuit layer is flexible circuit assembly 36; in the embodiment of Figure 8, the claimed flexible printed circuit layer is flexible circuit 50. *Id.* A POSA would recognize that flexible circuit 50 and flexible circuit 36 are analogous and would contain similar components,

including sensor contacts 71, 72. Ex. 1009 ¶ 884. A POSA would recognize that the “flexible circuit assembly” of Jensen defines a substrate on which “copper wiring traces” are formed. *Id.* ¶ [0040]; Ex. 1009 ¶¶ 882-86. A POSA would also recognize that the “flexible circuit assembly” is made of insulating material on which the traces, electronics, and sensor contacts 71, 72 are placed; if it were not made of an insulating material, then the electronics 41, 52 on the surface of the flexible printed circuit layer would short circuit. Ex. 1009 ¶¶ 884-86.

As previously explained, a POSA would have been motivated to combine Kroll’s teaching of resistive traces with Jensen’s device. *Supra* § VII.B.1.

iii. [1b.] at least one electrode disposed onto a surface of the substrate;

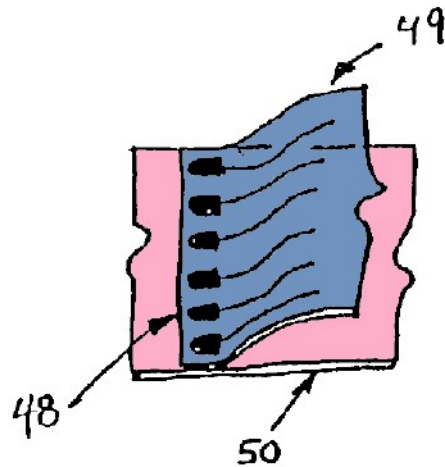
Jensen discloses the claimed “at least one electrode disposed onto a surface of the substrate.” Jensen discloses a “disposable sensor assembly” that includes “disposable sensor pad electrodes 1 and 2.” Ex. 1011 ¶¶ [0041]-[0042]. Jensen’s sensor pad electrodes 1 and 2 are conductive and couplable to a skin surface to measure physiological signals, such as EKG signals. *Id.* ¶ [0041]. The sensor pad electrodes are disposed on the lower surface of flexible circuit assembly 36, as shown in Figure 7 below.



Id. Fig. 7; Ex. 1009 ¶¶ 887-90. A POSA would understand that sensor pad electrodes would also be disposed on the lower surface of flexible circuit assembly 50 in the embodiment of Figure 8. Ex. 1009 ¶ 889.

iv. [1c.] at least one connection pad;

Jensen discloses the “at least one connection pad.” In the embodiment of Figure 8, Jensen discloses two flexible printed circuits 49, 50. A POSA would recognize that the two substrates could be configured to comprise, respectively, one reusable substrate 49, which would house the valuable electronics for the computation-communication module, and one disposable substrate 50, which would be closer to the patient’s skin and would contain sensor contacts and traces. Ex. 1011 ¶¶ [0044]-[0046], Fig. 8. Jensen explains that, in the embodiment of Figure 8, the two flexible circuits 49, 50 are connected by pads 48, which are “matched on both circuits.” *Id.* ¶ [0046].



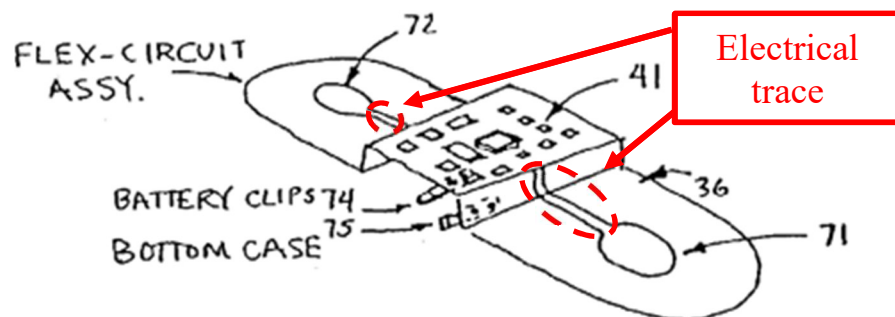
Id. Fig. 8A (annotated).

A POSA would understand that the pads on the disposable, printed circuit board substrate of Jensen, 48, are the claimed connection pads because they form a connection between the power source (coin cell 9) and the electrical traces that lead to sensor contacts 71, 72. Ex. 1009 ¶ 894; Ex. 1003, 7:44-55. Accordingly, a POSA would know that Jensen discloses at least one connection pad. *Id.* ¶¶ 892-94.

- v. ***[Id.] at least one electrical trace extending between the at least one connection pad and a conductive surface of the least one electrode,***

Jensen discloses an “electrical trace extending between the at least one connection pad and a conductive surface of the at least one electrode.” As shown in the below figure, Jensen discloses “a flexible circuit assembly 36 that contains the copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72” of electrode sensor pads 1, 2. Ex. 1011 ¶¶ [0040]-[0041]. A POSA would understand that, in the embodiment of Figure 8, the connection created by Jensen’s traces

extends from the electrode sensor pads 1, 2 (*i.e.*, “the conductive surface of at least one electrode”) to connection pad 48.



Ex. 1009 ¶ 898; Ex. 1011, Fig. 5 (annotated).

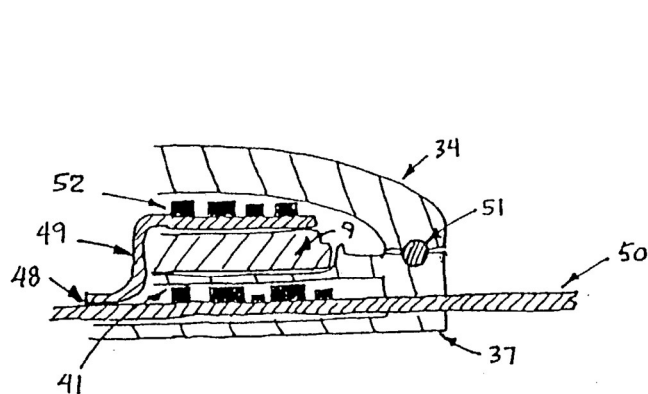


figure 8

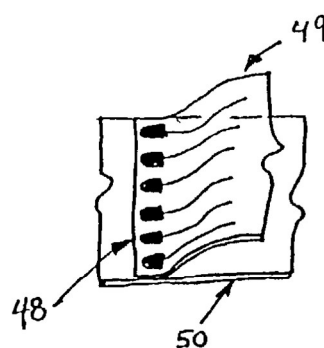


figure 8a

Ex. 1011, Figs. 8, 8a.

Accordingly, a POSA would understand that Jensen teaches electrical traces between at least one connection pad and a conductive surface of at least one electrode. Ex. 1009 ¶¶ 895-98.

vi. [1e] the at least one electrical trace being made at least in part from a resistive material; and

The combination of Jensen and Kroll renders this limitation obvious in view of the knowledge of a POSA.

Jensen discloses a flexible circuit assembly 36, 49, 50 that includes “copper wiring to connect the entire circuit.” Ex. 1011 ¶ [0040].

Kroll teaches traces that may be made of resistive material to protect against shock. Specifically, Kroll teaches circuits composed of a “flexible conductive ink compound having a conductive filler having Silver, Aluminum, or compounds thereof, or of a similarly suitable material. Preferably, the ink deposit is of a preselected conductivity to provide a certain total lead strip resistance so that each strip 34 serves as a current limiter to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device.” Ex. 1013, 5:4–13. Kroll therefore teaches printed ink leads, which a POSA would have understood as traces made at least in part of resistive material. *Id.*; Ex. 1009 ¶¶ 899-904.

As explained in Section VII(B)(1), *supra*, a POSA would have known that the “resistive trace” of Kroll would help to ensure the viability of Jensen’s flexible circuit assembly in the event of a patient being defibrillated. It therefore would have been obvious to a POSA to combine Jensen’s flexible circuit assembly with Kroll’s teaching of resistive traces on a flexible, wearable medium to meet this limitation. In addition, using Kroll’s “resistive traces” would allow a POSA to modify Jensen’s

“smart patch” to remove any resistors on electronics circuit 41, thereby further reducing the size of Jensen’s smart patch.

vii. [1f.] an insulating layer covering the flexible printed circuit layer.

Jensen discloses “an insulating layer covering the flexible printed circuit layer.” The smart patch of Jensen “has an electric circuit . . . sandwiched between layers of insulating material and cover plastics.” Ex. 1011, Abstract. Specifically, Jensen teaches the entire top side of flexible circuit assembly 36 is “enclose[d]” and “sealed” by top casing 34 and aesthetic covers 35 construed of Mylar, which is a common insulating material. *Id.* ¶ [0043]; Ex. 1009 ¶¶ 905-909. A POSA would understand that, in the embodiment of Figure 8, flexible circuit 50 would similarly be entirely covered and enclosed by aesthetic covers 35 and by top case 34 and bottom case 37. Ex. 1011 ¶ [0045], Fig. 8; Ex. 1009 ¶ 908. This is shown in Figure 8 of Jensen.

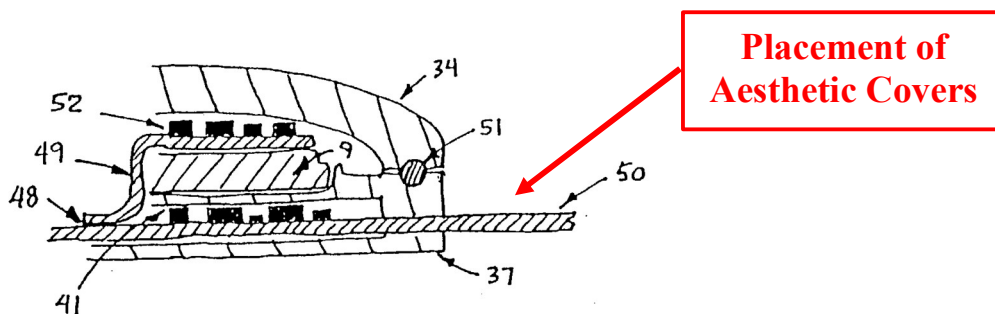


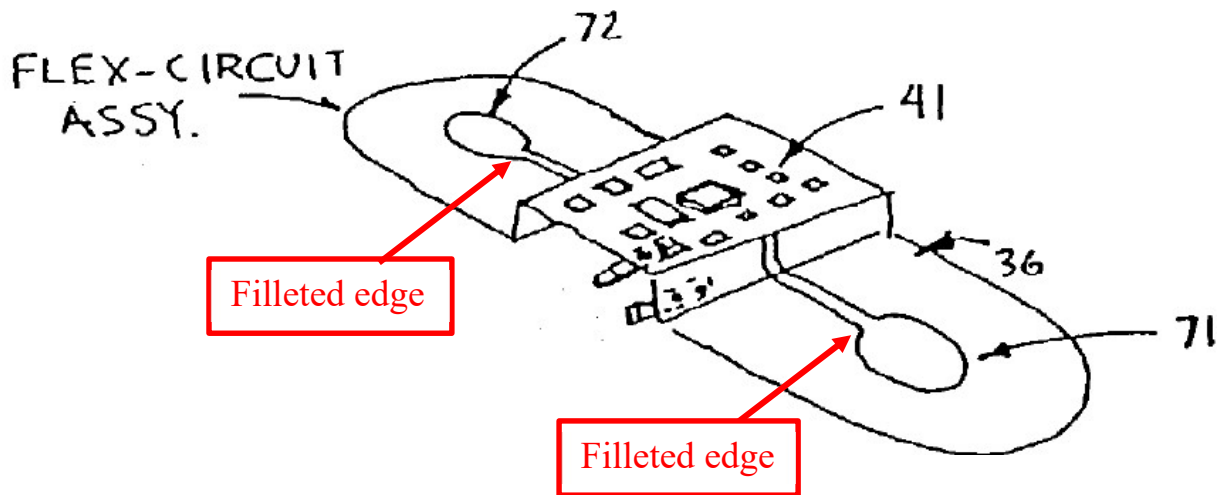
figure 8

Ex. 1011, Fig. 8(annotated); *see also id.* ¶¶ [0043], [0045]. A POSA would understand aesthetic covers 35 and/or top casing 34 to be insulating covers for flexible circuit 50. Ex. 1009 ¶¶ 905-909.

Additionally, or alternatively, Jensen discloses that disposable sensor pads may optionally include “non-conductive connecting material 42” which covers the lower surface of the flexible circuit assembly 36, 50. This connecting material 42 also comprises an insulating cover for the flexible printed circuit layer.

3. Claim 2

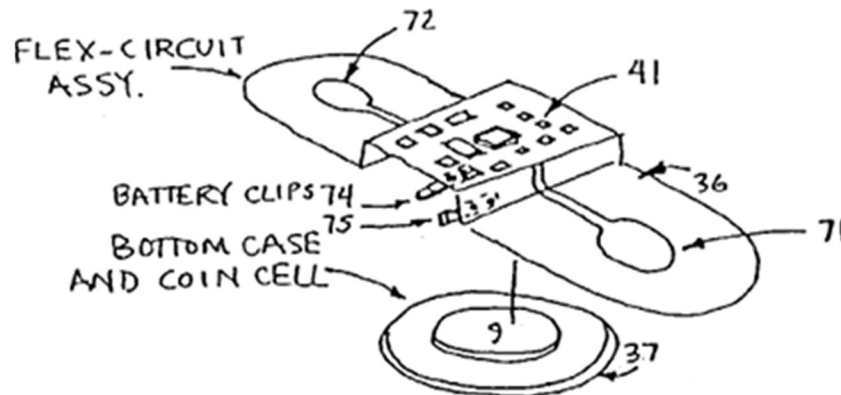
In addition to teaching every limitation of claim 1, the combination of Jensen and Kroll teaches that “the at least one electrical trace includes a filleted portion formed at the electrode,” as recited in claim 2. As explained in the ’492 patent, a “fillet or ‘tear drop’ shape causes the carbon trace to become gradually wider as it connect[ed] to [the] conductive surface.” Ex. 1003, 8:62-65. Jensen teaches “copper wiring traces to connect the entire circuit 41 to sensor contacts 71, 72” whose edges are shaped as fillets. Ex. 1011 ¶ [0040], Fig. 5. A POSA would understand that the traces would gradually get wider to mechanically connect to the filleted sensor contacts 71, 72. Ex. 1009 ¶ 913. This is shown in Figure 5 of Jensen (excerpted below) where the end of the trace connected to the fillet shaped sensor contact 71, 72 is wider than that connected to circuit 41.



Ex. 1011, Fig. 5 (annotated). When incorporating the “resistive trace” of Kroll, a POSA would follow the underlying shape of the electric trace of Jensen, which includes a “filleted edge.” Ex. 1009 ¶ 914. Accordingly, the combination of Jensen and Kroll discloses that “the at least one electrical trace includes a filleted portion formed at the electrode.” *Id.* ¶¶ 910-915.

4. *Claim 3*

In addition to teaching all of the limitations of claims 1 and 2, the combination of Jensen and Kroll teaches “at least one battery mounted on the flexible circuit layer,” as recited in claim 3. *Id.* ¶¶ 917-919. Specifically, Jensen discloses that “[l]ithium coin cell 9 [battery] attaches to flexible circuit assembly 36 with two small nickel or gold plated steel clips 74, 75.” Ex. 1011 ¶ [0043]. Steel clips 74, 75 are used to mount the battery to the bottom of flexible circuit assembly.



Ex. 1011, Fig. 5.

5. *Claim 4*

In addition to teaching all of the limitations of claims 1, 2, and 3, the combination of Jensen and Kroll teaches “a retention member to provide mechanical support for the at least one battery and to enable an electrical connection with the conductive surface of the at least one electrode,” as recited in claim 4. Specifically, Jensen discloses “two small nickel or gold plated steel clips 74, 75” (retention members) that attach “lithium coin cell 9” (battery) to “flexible circuit assembly 36.” *Id.* ¶ [0043]. Steel clips 74, 75 mechanically attach lithium coin cell 9 to flexible circuit assembly 36. *Id.* The “nickel or gold plated steel clips 74, 75” also electrically connect the lithium coin cell 9 to the flexible circuit assembly that contains “[t]he sensor contracts 71, 72 [that] make electrical contact with [electrode] sensor pads 1, 2.” *Id.* ¶¶ [0041], [0043]. The combination of Jensen and Kroll teaches retention members that mechanically support and electrically connect a

battery to the electrode through the flexible printed circuit layer. *See* Ex. 1009 ¶¶ 921-923.

6. Claim 5

In addition to teaching all of the limitations of claim 1, Jensen and Kroll teaches “an ECG monitor having a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals,” as recited in claim 5. Jensen and Kroll teaches wearable devices for monitoring physiological signals, including ECG or EKG signals that measure a patient’s heartbeat. Ex. 1011 ¶¶ [0029]-[0031]; Ex. 1013, 1:11–15, 1:37–45. In particular, Jensen discloses that “heart-rate signals are collected from left and right [electrode] sensor pads 1& 2.” Ex. 1011 ¶ [0031]; *see also id.* ¶ [0041].

Jensen also teaches a wearable device with a programmed microprocessor. Specifically, Jensen’s device includes a “[m]icrocontroller,” which “runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter.” *Id.* ¶ [0032]. One example of a program run on Jensen’s microcontroller is “detect[ing] the occurrence of R events in the QRS complex of the EKG signal.” *Id.* ¶ [0029]; *see also id.* ¶ [0037].

The combination of Jensen and Kroll teaches an ECG monitor with a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals. *See* Ex. 1009 ¶¶ 925-928.

7. *Claim 6*

In addition to teaching all of the limitations of claim 1, Jensen and Kroll teach that “the at least one electrode includes an electrode gel and a conductive surface, thereby creating a half cell,” as recited in claim 6. On the side that contacts the patient’s skin, Jensen’s electrode sensor pads 1, 2 are coated with “conductive adhesive-gel that is made using a silver amalgam as found in off-the-shelf EKG sensor pads, such as those sold by 3M corporation.” *Id.* ¶ [0041]. A POSA would understand that EKG sensor pads (conductive surface) comprising a silver amalgam (usually silver-silver chloride) and a conductive gel (electrode gel) containing an electrolyte comprise a create “half cell.” Ex. 1009 ¶ 931. Accordingly, a POSA would know that Jensen’s sensor pads form electrical connections comprising half cells at the point of contact with the patient’s skin. *Id.* ¶¶ 929-932.

C. Ground 3: Claims 7, 8, and 11-14 are Obvious Over Jensen, Matsumura, Kroll, and the General Knowledge of Person of Ordinary Skill in the Art

Independent claim 7 of the ’492 patent includes most of the same elements as independent claim 1, but further recites a “disposable electrode portion comprising a flexible printed circuit layer” and a “reusable communication and computation module.” Both of these limitations are rendered obvious by Jensen and Matsumura.

1. Motivation to Combine

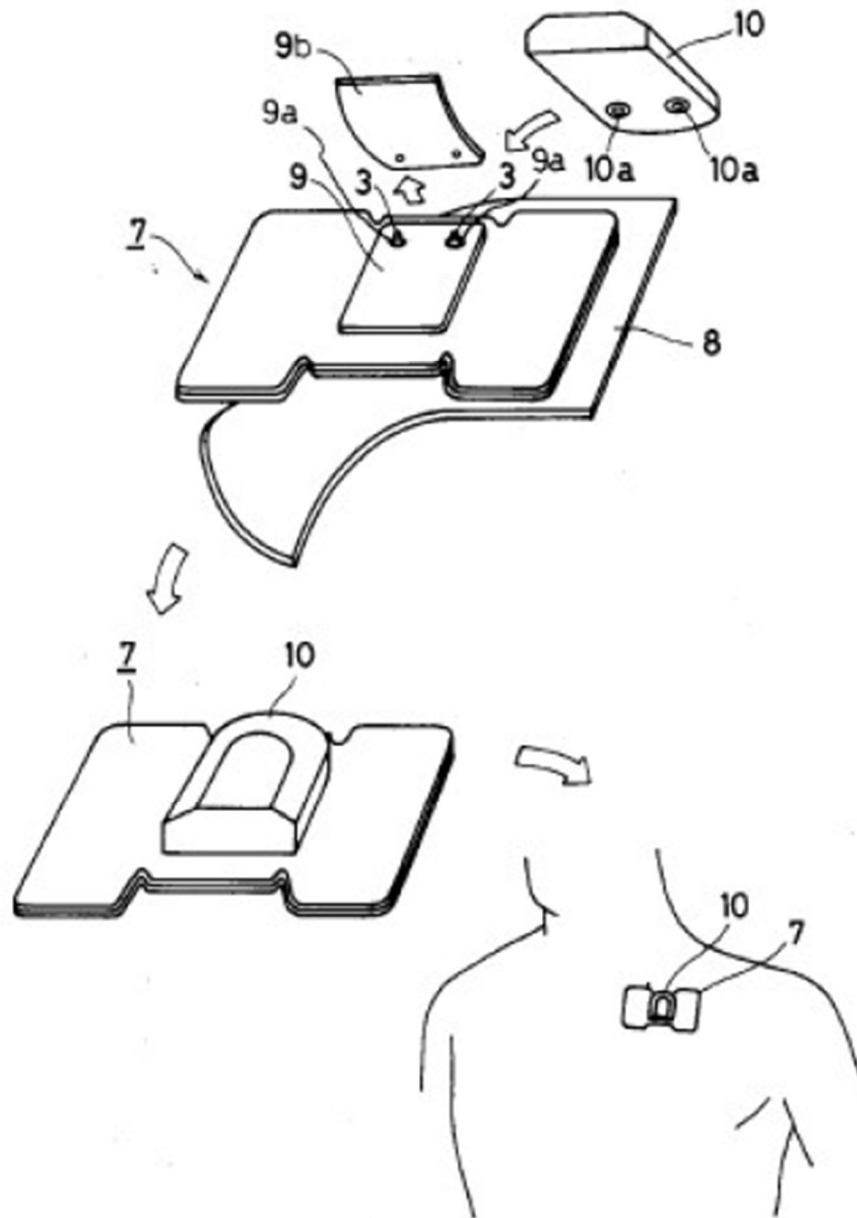
Jensen, Matsumura, and Kroll all teach wearable devices for monitoring physiological signals, including ECG or EKG signals. Ex. 1011 ¶¶ [0029]-[0030]; Ex.1012 ¶¶ [0024], [0031], Fig. 2; Ex. 1013, 1:11–15, 1:37–45.

Maintaining hygiene and reducing cross-contamination is important for medical devices that directly contact a patient—even more so for wearable ones in constant patient contact. Ex. 1009 ¶ 937. Disposing an entire medical device addresses this issue, but cost concerns limit the practicality of doing so. *Id.* For this reason, certain medical devices have both disposable and reusable parts. *Id.*

Jensen’s device is one example. The device comprises a disposable sensor assembly, which includes “a peel-off cover” and disposable sensor pad electrodes. Ex. 1011 ¶ [0042], Fig. 5. The rest of Jensen’s device is reusable, including the bottom and top casing, the flexible circuit assembly to which the disposable sensor pad electrodes are attached, and the aesthetic cover. *Id.* ¶¶ [0042]-[0043]. A POSA would have known that reuse would require carefully cleaning each of these components for hygiene purposes. But even with thorough cleaning, the risk of cross-contamination cannot be eliminated. Ex. 1009 ¶ 939 (quotation omitted). To improve the efficacy of the cleaning process and the safety of a medical device, a POSA would have been motivated to look for ways to make more parts of the device disposable while further isolating the reusable portions to limit contamination. *Id.*

Matsumura provides a way to achieve these goals. Like Jensen, Matsumura discloses a device with both disposable and reusable portions. But Matsumura's design fully insulates the reusable portions from the patient's skin using multiple layers and encloses the reusable portion in a single housing. *Id.* ¶ 940. As Matsumura teaches, "the bioelectrode pad [7] is hygienic because it is disposable" and includes multiple sheets (first sheet 1, second sheet 4, and third sheet 3) that separate the reusable part of the device from a patient, while still maintaining an electrical connection between the patient-facing, disposable electrodes (conductive gels 5) and the reusable component. Ex. 1012 ¶ [0016], Fig. 5. As shown in Figure 2 of Matsumura below, only the disposable bioelectrode pad 7 touches the patient's skin, while reusable signal processor 11 is completely separated from the patient's skin by multiple sheets.

[FIGURE 2]



Id. Fig. 2. In view of Matsumura's teachings, a POSA would have sought to modify Jensen to similarly include a disposable layer that electrically connects electrodes (disposable sensor pad electrode 1, 2) to the circuitry in the reusable component

(electronic circuitry 41 and coin cell 9) while maintaining separation from the patient's skin. Ex. 1009 ¶¶ 940-942.

A POSA would have also looked to modify Jensen's design to achieve the waterproof structure of Matsumura. Jensen's design is "sealed on top" using an "o-ring" and several "aesthetic covers" that a POSA would have understood to be susceptible to seepage through the top, bottom, and slot in the smart patch through which the flexible circuit assembly extends. *Id.* ¶¶ 943-944. To attempt to isolate electronic circuit 41, in Jensen, a "sealant is applied to the slot 80, once assembled." Ex. 1011 ¶ [0045]. Jensen therefore acknowledges that even after assembly the devices is not fully sealed. Matsumura teaches an improved waterproofed structure that is completely sealed upon assembly and allows patients to wear the monitor both during and immediately after showering. Ex. 1012 ¶¶ [0027], [0033]. Matsumura explains several advantages of doing so, with which a POSA would have been familiar. Ex. 1009 ¶¶ 944-948. From a clinical perspective, a continuously wearable monitor that a patient need not remove to shower or bathe is advantageous as it provides uninterrupted monitoring. Ex. 1012 ¶¶ [0001]-[0002]; Ex. 1009 ¶ 945. This permits monitoring during a shower or bath when a patient's "heart may be strained, resulting in tachycardia or arrhythmia." It also permits monitoring "immediately after showering or bathing," when a patient's "body temperature drops suddenly, which puts a strain on the body and may cause sudden changes in condition, such as

dizziness, anemia, or arrhythmia.” Ex. 1012 ¶ [0002]. Incorporating Matsumura’s waterproof structure into Jensen would allow Jensen’s smart patch to be worn continuously, including during or immediately after showering. Ex. 1009 ¶ 945.

To achieve a waterproofed structure, Matsumura teaches (i) housing the electronics, such as the microprocessor and wireless transmitter, in an enclosed, reusable casing (signal processor 10), and (ii) placing the electrodes (conductive gel 5), sensor contacts (conductive material 2), and traces (hooks 3) in a separate disposable bioelectrode pad 7 that uses an insulating sheet to entirely cover the electrodes and sensor contacts. This insulating sheet contains two small holes through which hooks 3 electrically and mechanically connect the disposable electrodes to the reusable housing containing signal processor 10. Ex. 1012 ¶¶ [0015], [0019], [0022], [0041]-[0043]; Ex. 1009 ¶ 946. A POSA would have sought to modify Jensen in a similar manner to achieve this waterproof structure. Ex. 1009 ¶¶ 945-947. In particular, a POSA would have enclosed electronic circuit 41 and coin cell 9 of Jensen in a separate housing composed of top case 34 and bottom case 37, while placing the sensor pad electrodes 1, 2, sensor contacts 71, 72, and copper traces in the disposable sensor assembly 73 that could be entirely covered by a single aesthetic cover to ensure waterproofing. *Id.* This modification would not be difficult to implement using well-known manufacturing techniques at the time of the invention. *Id.* ¶ 947.

And a POSA would have had a reasonable expectation of success in modifying Jensen's device based on the disclosures of Matsumura discussed above without undue experimentation. *Id.* ¶¶ 948-949. Not only are both wearable, self-contained ECG monitors, they both have similar disposable and reusable parts: disposable parts include the electrodes used to detect ECG signals, and reusable parts include a processor and a wireless transmitter. Ex. 1012, Fig. 1; Ex. 1011, Fig. 5. While Jensen discloses an embodiment in which the printed circuit assembly 30 that includes the electronics is separated from disposable sensor pads 31 and 32, it lacks the hygienic and waterproofing benefits taught by Matsumura. Ex. 1011 ¶ [0044], Fig. 6. The modification in view of Matsumura would preserve the electrical traces and sensor contacts 71, 72 on sensor pads 31 and 32 but enclose the remaining reusable portions of the device inside a separate housing. As the processing circuitry within the housing would still be connected to the same electrical traces and sensor contacts, a POSA would have expected the modified device to retain the same monitoring functionality. Ex. 1009 ¶¶ 948-949.

In addition, as noted above, a POSA would have looked to incorporate the "resistive material" of Kroll into the modified wearable monitor of Jensen and Matsumura to help prevent electrical overload and to reduce the size of Jensen's "smart patch." *Supra* §§ VII(A)(1), VII(B)(1),

2. *Claim 7*

i. 7[pre]. A body-worn patient monitoring device comprising:

Jensen teaches a body worn patient monitoring device. Ex. 1011 ¶¶ [0012], [0029]. Matsumura discloses a body-worn patient monitoring device which it refers to as a “bioelectric potential detector.” Ex. 1012, Abstract, ¶¶ [0006], [0014]. Kroll also discloses a body worn patient monitoring device. Ex. 1013, 1:11–15; *see also* Ex. 1009 ¶¶ 952-954.

ii. [7a.] a disposable electrode portion; and

As noted above, *supra* Section VII.B.iii, Jensen discloses “electrode sensor pads 1, 2” (electrode portion) that are part of the “disposable sensor assembly 73.” Ex. 1011 ¶ [0042]. Accordingly, Jensen teaches a disposable electrode portion. *See* Ex. 1009 ¶¶ 956-958.

iii. [7b.] a reusable communication module,

Jensen teaches a “reusable communication module.” In particular, Jensen discloses a “re-usable (non-disposable) portion.” Ex. 1011 ¶ [0043]. Jensen also discloses a radio frequency transmitter 7 (communication module) that “may transmit in a variety of modulation and/or keying methods via antenna 8.” *Id.* ¶ [0033]. A POSA would understand that transmitter 7 is located on the “re-usable (non-disposable) portion” of Jensen. Ex. 1009 ¶ 961.

Accordingly, the combination of Jensen, Matsumura, and Kroll discloses “a reusable communication module.” *Id.* ¶¶ 959-962.

iv. [7c.] the disposable electrode portion comprising a flexible printed circuit layer made from an insulating material and defining a substrate,

Jensen, Kroll, and Matsumura render this limitation obvious in view of a POSA’s knowledge. As described with respect to claim 1 above, Jensen and Matsumura each render obvious “a flexible printed circuit layer made from an insulating material and defining a substrate.” *Supra* § VII(B)(1)(a).

As outlined in section VII.C.1, a POSA would have looked to isolate and waterproof the reusable portions of Jensen (electronics circuit 41 and battery 9) from the patient’s skin as taught by Matsumura. Ex. 1009 ¶¶ 943-949, 966. To do so, a POSA would have modified Jensen by incorporating portions of flexible circuit assembly 36 into the disposable sensor assembly 73 as taught by Matsumura. *Id.* ¶ 966. Specifically, a POSA would have sought to move the flexible circuit assembly 36, electrical traces, and sensor contacts 71, 72 to the disposable sensor assembly 73, while keeping electronics circuitry 41 (including the microcontroller and wireless transmitter) in Jensen’s reusable portion. *Id.*

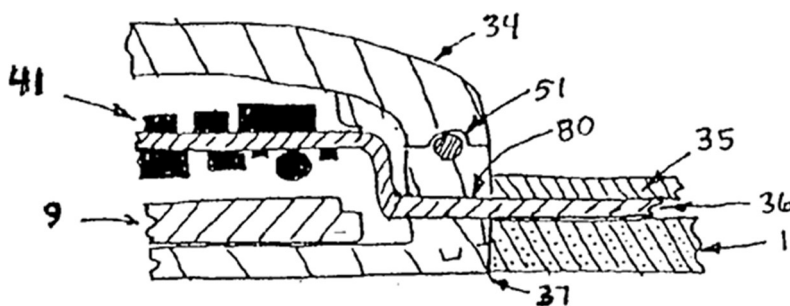
This same configuration is taught in Matsumura, where the signal processor 10 (including the microprocessor and wireless transmitter) is in the reusable portion, while the flexible circuit assembly is in the flexible, disposable bioelectrode pad 7.

Id. ¶ 966 (citing Ex. 1012 ¶¶ [0015], [0019]). A POSA would have understood this modification to Jensen as: (i) improving the efficacy of the cleaning process and the safety of a medical device by making more parts of the device disposable while further isolating the reusable portions to limit contamination and (ii) achieving a waterproof structure that would allow Jensen’s smart patch to be worn continuously, including during or immediately after showering. *Id.* ¶ 967.

As noted above, A POSA would have had a reasonable expectation of success in rearranging Jensen’s components according to Matsumura’s teaching without undue experimentation at least because these were well-known components that were already known to be disposable. *Supra* § VII(C)(1); Ex. 1009 ¶ 968. For example, other references at the time already taught electrical traces and sensor contacts that are part of a disposable assembly. *Id.* (citing Ex. 1014 ¶ [0048] (teaching disposable bio-sensor module includes “electrodes 80 [] located on a lower surface 85 of the flexible substrate 55 and are connected through the flexible substrate 55 to the metallization 77”); U.S. Patent Publication No. 2006/0224072 (“Shennib”) ¶ [0035] (teaching disposable ECG patch includes “a flexible circuit substrate 20 with trace extensions to the electrodes 21, 22, 23”).) Accordingly, this modification would not be difficult to implement using well-known manufacturing techniques at the time of the invention. *Id.* ¶¶ 947-949.

v. *[7d.] at least two electrodes being disposed onto a surface of the substrate and*

Jensen teaches “at least two electrodes being disposed onto a surface of the substrate.” Specifically, Jensen discloses a “disposable sensor assembly” that includes “disposable sensor pad electrodes 1 and 2.” Ex. 1011 ¶ [0042]. The sensor pad electrodes are disposed on the lower surface of flexible assembly 36, as shown in Figure 7 below.

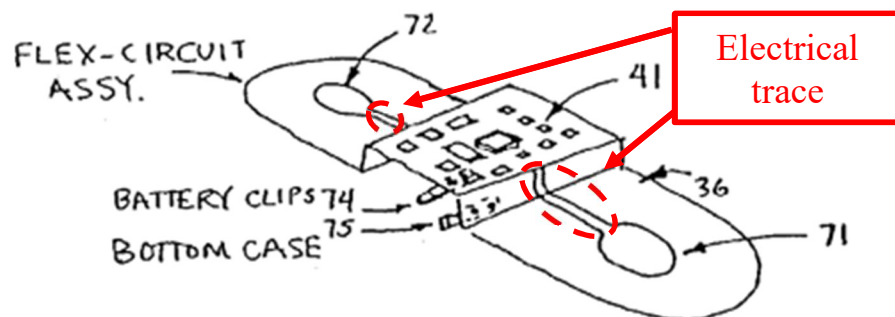


Id. Fig. 7. Accordingly, the combination of Jensen, Matsumura, and Kroll teaches at least two sensor pad electrodes disclosed onto the surface of the flexible assembly. *See* Ex. 1009 ¶¶ 971-973.

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

Jensen teaches “electrical traces defined between the at least two electrodes and a connection pad.” As shown in the below figure, Jensen discloses “a flexible circuit assembly 36 that contains the copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72” of electrode sensor pads 1, 2. Ex. 1011 ¶¶ [0040]-[0041]. A POSA would understand that the connection created by Jensen’s traces

extends from the electrode sensor pads 1, 2, to a connection pad 48. *See supra* §§ VII.B.2.iv-v.



Ex. 1011 ¶ [0040], Fig. 5 (annotated). Accordingly, a POSA would understand that Jensen teaches electrical traces between at least one connection pad and a conductive surface of at least one electrode. Ex. 1009 ¶¶ 974-977.

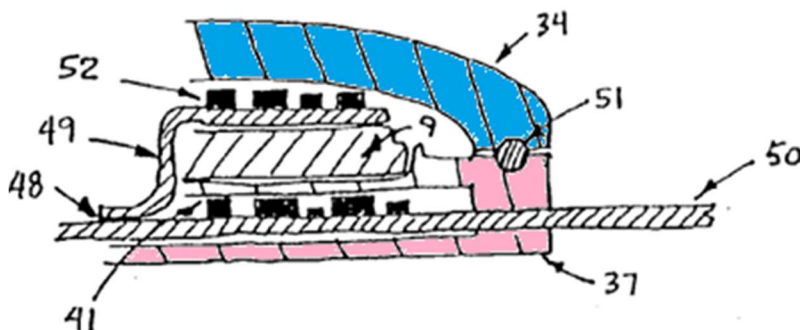
vii. [7f.] wherein the reusable communication and computation module comprises a housing containing a processor and a wireless communication unit, and

Jensen teaches that the “reusable communication and computation module comprises a housing containing a processor and a wireless communication unit.”

Jensen teaches a “transmitter” for communication (communication module) and a “microcontroller” for computation (computation module). Ex. 1011 ¶ [0032]. Jensen’s microcontroller “runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter.” *Id.* Jensen’s transmitter may be an RF transmitter that transmits data wirelessly via an “antenna.” *Id.* ¶ [0033]. The transmitter and microcontroller are encased, meaning housed, by

a top casing 34 (shown below in blue) and a bottom casing 37 (shown below in red).

Id. ¶ [0043]. For example, the encasing is shown below in blue in Figure 8 of Jensen.



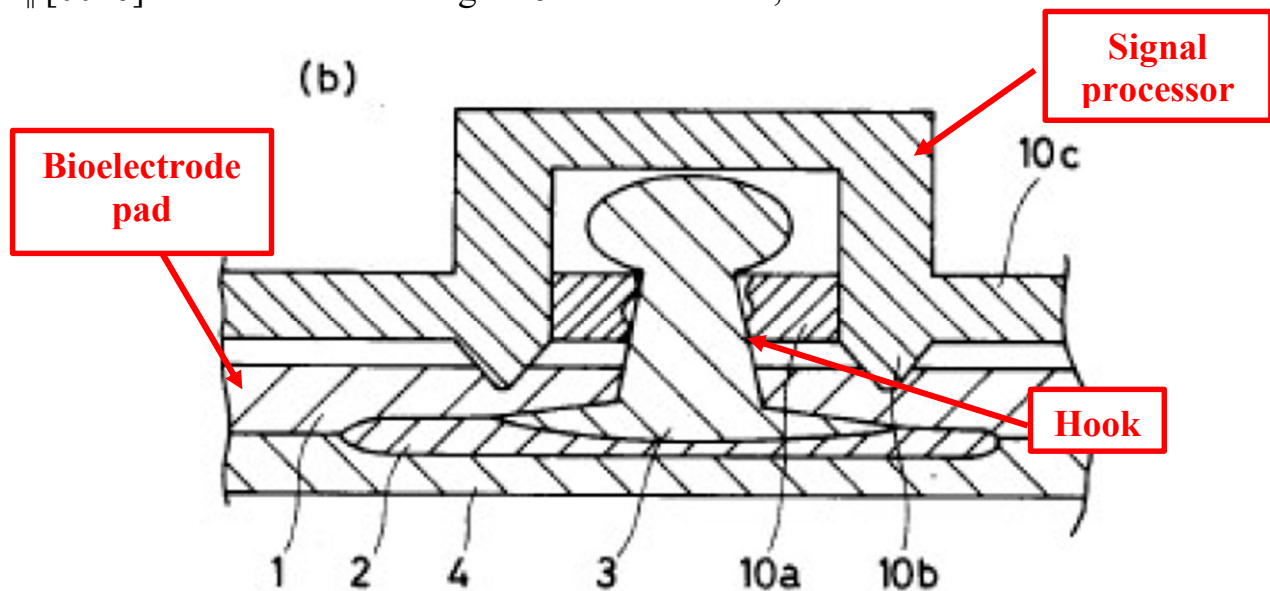
Id. Fig. 8 (annotated). Accordingly, the combination of Jensen, Matsumura, and Kroll teaches a reusable communication and computation module that comprises a housing containing a processor and a wireless communication unit. *See* Ex. 1009 ¶¶ 979-981.

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

The combination of Jensen and Matsumura teaches that the “the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip.” As noted above, Jensen discloses a reusable communication module and a disposable sensor assembly including disposable sensor pad electrodes. *Supra* §§ VII(C)(2)(iii)-(v).

Matsumura also discloses a “reusable signal processor” with a wireless transmitter and a “disposable bioelectrode pad” with “conductive gel 5” (electrode portion). Ex. 1012 ¶ [0016]; *see also id.* ¶¶ [0008], [0014], [0025], Figs. 1-2. “The

bioelectrode pad 7 and the signal processor 10 are detachable with hooks.” *Id.* ¶ [0016]. This is shown in Figure 5 of Matsumura, shown below.



Id. Fig. 5 (annotated). A POSA would understand that “hook 3” of Matsumura renders obvious use of a latch clip because the two just well-known methods of attaching items. Ex. 1009 ¶¶ 982-989. And a POSA would have known that the design of “hook 3” can be used to attach the reusable portions with the disposable portions of Jensen’s design as modified by the teachings of Matsumura. *Id.* Accordingly, the combination of Jensen, Matsumura, and Kroll teaches that “the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip.”

3. Claim 8

In addition to teaching all of the limitations of claim 7, Jensen, Matsumura, and Kroll teach that “the electrodes are integrated into the flexible printed circuit

layer of the disposable portion of the device,” as recited in claim 8. Jensen discloses disposable sensor pad electrodes 1, 2. Ex. 1011 ¶ [0041], Fig. 5. In addition, as explained above in Section VII(C)(2)(iv), it would have been obvious to a POSA to modify Jensen in view of Matsumura’s teachings so that portions of the flexible printed circuit layer would be part of disposable sensor assembly 73 of Jensen. Accordingly, the combination of Jensen, Matsumura, and Kroll renders obvious that the electrodes are integrated into the flexible printed circuit layer of the disposable portion of the device. Ex. 1009 ¶¶ 990-993.

4. Claim 11

In addition to teaching all of the limitations of claim 7, Jensen, Matsumura, and Kroll teach that “the electrical traces are screened onto the flexible printed circuit layer.” As noted above in § VII(B)(2)(ii), Jensen discloses “a flexible circuit assembly 36 that contains the copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72.” Ex. 1011 ¶¶ [0040]-[0041]. Kroll teaches the use of printed ink comprised of a material with a given resistance. Ex. 1013, 5:8-12. A POSA would understand printing ink onto a circuit board to be a form of screening (Ex. 1009 ¶ 997), meaning that incorporating Kroll’s ink traces on the flexible printed circuit layer of Jensen would yield electrical traces that are screened. Accordingly, it would have been obvious to a POSA to screen the electrical traces of Kroll into the flexible circuit of Jensen. *Id.* ¶¶ 994-999.

5. Claim 12

In addition to teaching all of the limitations of claims 7 and 11, Jensen, Matsumura, and Kroll disclose “an insulating layer applied to the electrical traces,” as recited in claim 12. As discussed above in Section VII(B)(2)(vii), Jensen discloses an insulating layer covering the flexible printed circuit layer. In particular, Jensen teaches that the entire top side of flexible circuit assembly 36 is “enclosed” and “sealed” by top casing 34 and aesthetic covers 35, as shown in the below figure. Ex. 1011 ¶ [0043]. The flexible printed circuit layer of Jensen also discloses electrical traces. *See* §§ VII(B)(2)(v), VII(C)(2)(e). Accordingly, a POSA would understand aesthetic covers 35 and/or top casing 34 of Jensen to be an insulating layer for the electrical traces of flexible circuit 36. Ex. 1009 ¶¶ 1000-1004. The combination of Jensen, Matsumura, and Kroll therefore discloses “an insulating layer applied to the electrical traces.”

6. Claim 13

In addition to teaching the limitation of claim 12, it would have been obvious to a POSA to modify Matsumura and Kroll such that “the insulating layer is screen printed onto the electrical traces of the flexible printed circuit layer.” *Id.* ¶¶ 1005-1008. A POSA would recognize that screen printing was a well-known and common method of manufacturing a printed circuit board. *Id.* A POSA would have also recognized that a common means of applying an insulating layer to the printed traces

on a circuit board would be to screen an insulating layer on top of the traces. *Id.* Solder mask (sometimes called solder resist) was commonly applied using either screen printing or photoprinting methods. *Id.* Accordingly, it would have been obvious to a POSA to modify Jensen, Matsumura and Kroll to screen print the insulating layer onto the electrical traces of the flexible printed circuit layer.

7. Claim 14

In addition to teaching all of the limitations of claim 1, the combination of Jensen, Matsumura, and Kroll teaches that “the at least one electrode includes an electrode gel and a conductive surface, thereby creating a half cell,” as recited in claim 6. On the side that contacts the patient’s skin, Jensen’s electrode sensor pads 1, 2 are coated with “conductive adhesive-gel that is made using silver amalgam as found in off-the-shelf EKG sensor pads, such as those sold by 3M corporation.” Ex. 1011 ¶ [0041]. A POSA would understand that EKG sensor pads (conductive surface) comprising a silver amalgam (usually silver-silver chloride) and a conductive gel (electrode gel) containing an electrolyte comprise a create “half cell.” Ex. 1009 ¶¶ 1009-1012. Accordingly, a POSA would know that Jensen’s sensor pads form electrical connections comprising half cells at the point of contact with the patient’s skin.

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

Section 314(a). Here, none of the factors enumerated in *Apple Inc. v. Fintiv Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) favors discretionary denial of institution. A scheduling order has not been entered nor a trial date set for the co-pending litigation (Factor 2). The proceedings have not progressed beyond the pleadings stage, and neither the parties nor the district court have invested substantial resources in the litigation to date (Factor 3). To date, there is no overlap between the issues raised in the petition and the parallel proceeding (Factor 4). Petitioner is the sole defendant in the parallel proceeding (Factor 5). The grounds raised herein present a compelling unpatentability challenge that on its own prevents an unpatentability challenge under *Fintiv* (Factor 6). Katherine K. Vidal, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (June 21, 2022).

Section 325(d). Jensen qualifies as art previously presented to the Office because it was listed on Information Disclosure Statements supplied by the Applicant. Ex. 1004, 31, 155. *Cf. Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020). Neither Kroll nor Matsumura were ever presented to the Office during examination.

The factors enumerated in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) do not counsel against

institution. At minimum, none of the references submitted as part of Ground 2 were considered by the Office and, for that reason alone, Section 325(d) does not warrant denial of institution.

As to Jensen, the Examiner failed to consider how Jensen alone or in combination with any other reference would render obvious the purported invention of the '492 patent. The art cited by the Examiner during prosecution did not disclose, *inter alia*, resistive traces on a body-worn physiological monitor as Kroll does (Factor A). The Examiner did not substantively address any combination that was similar to Jensen and Kroll during prosecution (Factor B). This is at least because none of the grounds considered by the Examiner discloses a monitor that includes a resistive trace. For example, Merry (U.S. 6,623,312) (“Merry”) relied on by the Examiner to disclose the series current-limiting resistors is a traditional resistor located on a printed circuit board (Merry, 7:35-43, Fig. 3; *see also* Applicant Response to Final OA at 17 (Mar. 2, 2011), Ex. 1002, 148), not the “resistive trace” described in Kroll. In another example, Ulmer (U.S. 6,539,613) (“Ulmer”) cited by the Examiner teaches embedding a conventional resistor into a substrate (Ulmer, Abstract, Figs. 2-8; Applicant Response to Final OA at 17 (Mar. 2, 2011), Ex. 1002, 148), not the “resistive trace” described in Kroll.

In addition, neither Jensen nor a Jensen-based combination formed the basis for rejection during prosecution (Factor C). Instead, Jensen was cited in an

Information Disclosure Statement along with 45 other references, none of which were substantively addressed during examination of the application that became the '492 patent. The Board has repeatedly held that a reference that is merely cited in an IDS does not weigh in favor of a discretionary denial. *See, e.g., Gene Co. Pty Ltd. v. Trs. of Columbia Univ.*, IPR 2024-00313, Paper 13 at 56–57 (PTAB June 24, 2024); *Advanced Energy Indus. v. Reno Techs. Inc.*, IPR2021-01397, Paper 7 at 7 (PTAB Feb. 16, 2022); *Lyft, Inc. v. RideShare Displays, Inc.*, IPR2021-01602, Paper 7 at 15–16 (PTAB Apr. 11, 2022). These decisions are consistent with the USPTO's notice of proposed rulemaking on this issue, which notes that “[a]n initialed Information Disclosure Statement, without more, does not satisfy” the criteria of 325(d). Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement, 89 Fed. Reg. 28693 (proposed Apr. 19, 2024) (to be codified at 37 C.F.R. pt. 42).

Finally, the arguments in this Petition related to Jensen, which rely on a combination of prior art that includes Kroll (never before the Office), do not overlap with those made during examination (Factor D). That is because none of the references considered during prosecution discloses the “resistive trace” of Kroll.

IX. CONCLUSION

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

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

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

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

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

The '492 patent is presently the subject of a patent infringement lawsuit brought by the assignee, Welch Allyn, Inc., against iRhythm, Inc. and captioned *Welch Allyn, Inc. v. iRhythm, Inc.*, C.A. No. 24-224-MN (D. Del.).

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

Petitioner provides the following designation of counsel:

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

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

D. Service Information

Please address all correspondence and serve to the address listed above.

Petitioner consents to electronic service directed to iRhythm-WelchAllyn_IPR@fenwick.com.

Dated: December 23, 2024

FENWICK & WEST LLP

/Robert E. Counihan /

Robert E. Counihan

Reg. No. 61,381

Attorneys for Petitioner

iRhythm, Inc

CLAIMS APPENDIX

Claim	Recitation
1[pre]	A body-worn patient monitoring device comprising:
[1a.]	a flexible printed circuit layer made from an insulating material and defining a substrate;
[1b.]	at least one electrode disposed onto a surface of the substrate;
[1c.]	at least one connection pad;
[1d.]	at least one electrical trace extending between the at least one connection pad and a conductive surface of the least one electrode,
[1e.]	the at least one electrical trace being made at least in part from a resistive material; and
[1f.]	an insulating layer covering the flexible printed circuit layer.
2	The body-worn patient monitoring device of claim 1, wherein the at least one electrical trace includes a filleted portion formed at the electrode.
3	The body-worn patient monitoring device of claim 2, including at least one battery mounted on the flexible circuit layer.
4	The body-worn patient monitoring device of claim 3, including a retention member to provide mechanical support for the at least one battery and to enable an electrical connection with the conductive surface of the at least one electrode.
5	The body worn patient monitoring device of claim 1, further comprising an ECG monitor having a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals.
6	The body-worn patient monitoring device of claim 1, wherein the at least one electrode includes an electrode gel and a conductive surface, thereby creating a half cell.
7[pre]	A body-worn patient monitoring device comprising:

[7a.]	a disposable electrode portion; and
[7b.]	a reusable communication module,
[7c.]	the disposable electrode portion comprising a flexible printed circuit layer made from an insulating material and defining a substrate,
[7d.]	at least two electrodes being disposed onto a surface of the substrate and
[7e.]	electrical traces defined between the at least two electrodes and a connection pad,
[7f.]	wherein the reusable communication and computation module comprises a housing containing a processor and a wireless communication unit, and
[7g.]	in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip.
8	The body-worn patient monitoring device of claim 7, wherein the electrodes are integrated into the flexible printed circuit layer of the disposable portion of the device.
11	The body-worn patient monitoring device of claim 7, wherein the electrical traces are screened onto the flexible printed circuit layer.
12	The body-worn patient monitoring device of claim 11, including an insulating layer applied onto the electrical traces.
13	The body-worn patient monitoring device of claim 12, wherein the insulating layer is screen printed onto the electrical traces of the flexible printed circuit layer.
14	The body-worn patient monitoring device of claim 7, wherein each electrode includes an electrode gel and a conductive surface defining a half cell.

**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 12,861 words, according to the word-processing system used to prepare this petition, excluding the parts of this petition that are exempted by 37 C.F.R. § 42.24(a) (including the table of contents, a table of authorities, mandatory notices, a certificate of service or this certificate word count, appendix of exhibits, and claim listings).

Dated: December 23, 2024

FENWICK & WEST LLP

/Robert E. Counihan /

Robert E. Counihan

Reg. No. 61,381

Attorneys for Petitioner

iRhythm, Inc

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

I hereby certify, pursuant to 37 C.F.R. §§ 42.6(e), 42.105, that a complete copy of the above-captioned PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,965,492, all associated exhibits, and Petitioner's Power of Attorney were served in their entireties via Federal Express, Priority Delivery, on December 23, 2024, upon Patent Owner by serving the correspondence address of record with the USPTO as follows:

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Service copies are also being sent via electronic aml to litigation counsel of record:

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