UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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iRhythm, Inc.

Petitioner,

v.

Welch Allyn, Inc.

Patent Owner

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

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

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

U.S. Patent No. 10,159,422

EXPERT DECLARATION OF JASON HEIKENFELD

I, Dr. Jason Heikenfeld, hereby declare and state as follows:

I. INTRODUCTION

1. I am submitting this declaration in connection with iRhythm Technologies, Inc.'s ("Petitioner") Petitions for Inter Parties Review of claims 1–8, 10–15, 29, 31–35, 37–39, and 43–45 of U.S. Patent No. 8,214,007 (the "'007 patent") (Ex. 1001); claims 1–8 and 11–14 of U.S. Patent No. 8,965,492 (the "'492 patent") (Ex. 1003); claims 1–8, 11, 12, and 15–20 of U.S. Patent No. 9,155,484 (the "'484 patent") (Ex. 1005); and claims 1–7, 9–12, and 14–20 of U.S. Patent No. 10,159,422 (the "'422 patent") (Ex. 1007) (the '007 patent, '492 patent, '484 patent, and '422 patent; collectively, "the Challenged Patents" and the identified claims of the Challenged Patents collectively, "the Challenged Claims"), before the Patent Trial and Appeal Board of the United States Patent Office (the "Board"). I have been asked by Petitioner to provide information and opinions regarding the level of skill of a person of ordinary skill in the art ("POSA") for the inventions claimed in the Challenged Patents, the general knowledge of such a person at the time of the filing of the applications for the Challenged Patents, the status of the documents relied upon by the Petition, the scope and content of the documents described by the Petition, technical information relating to the Challenged Patents, and whether the claimed inventions in the Challenged Patents would have been obvious to a POSA in view of the grounds asserted by the Petitioner.

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II. QUALIFICATIONS

2. Information concerning my professional background, including my education, experience, and publications, are set forth below. Additional information is provided in my current curriculum vitae, attached as Exhibit 1010.

3. I received a Bachelor of Science (B.S.) in electrical engineering from the University of Cincinnati in 1998 and a Doctor of Philosophy (Ph.D.) in electrical engineering in 2001, also from the University of Cincinnati.

4. I currently hold the titles of Professor of Electrical Engineering, Professor of Biomedical Engineering, and Director of the Novel Devices Laboratory at the University of Cincinnati. In this capacity, I have taught courses including Semiconductor Devices, Optics for Engineers, Biomedical Engineering Seminar, and other electrical and computer engineering courses.

5. In these capacities, I oversee a range of clinical, research and teaching activities in the field of rapid prototyping, electronic materials, microfluidics, electrofluidics, biosensors, electronic displays, flexible electronics, and optics. I have also published widely on topics related to sweat and to interstitial fluid monitoring in the human body and have developed models for both the technology behind wearable biosensing devices and the physiology that provides signals to wearable biosensing devices. I have both academic and industry experience in flexible and wearable electronics and in biosensors, where I have been a leading

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academic authority world-wide. In my most recent research, I am focused on biosensors for cardiovascular diseases such as heart failure.

6. In addition, I have extensive published research relating to the design, operation, and performance of medical devices used in the monitoring of physiological signals, analytes, and/or biofluids. Specifically, my publication record includes titles such as *Adhesive RFID Sensor Patch for Monitoring of Sweat Electrolytes*, 62 IEEE Trans. Biomed. Eng. 1457 (2015); *Wearable Sensors: Modalities, Challenges, and Prospects*, 18 Lab on a Chip 217 (2018); *Accessing Analytes in Biofluids for Peripheral Biochemical Monitoring*, 37 Nature Biotech. 407 (2019); and *Continuous Molecular Monitoring of Human Dermal Interstitial Fluid with Microneedle-Enabled Electrochemical Aptamer Sensors*, 23 Lab on a Chip 3289 (2023).

7. I have worked on numerous projects involving wearable medical devices that monitor various analytes and physiological signals. Nearly all of my wearable medical device work has involved flexible electronics that place electrodes onto the body, including dry electrodes, gel electrodes, iontophoresis electrodes, working and counter and reference electrodes, ion-selective electrodes, and enzymatic electrodes, and heart-rate measurement electrodes. These devices also require electrode leads or traces and electronics and data processing and communication modules. These projects include, but are not limited to, extensive

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research and professional publications on topics including various strategies for detecting glucose and ethanol levels in blood-correlated sweat, monitoring phenylalanine, cortisol, and drugs in biofluids such as interstitial fluid, and using adhesive sensor patches for monitoring sweat electrolytes. I have also co-authored a book-length treatment of fluid dynamics and engineering principles behind "lab-on-a-chip" devices. The book is entitled ELECTROWETTING (2019) and is a comprehensive introduction to the theoretical and practical aspects of fluid manipulation technologies, written to inform academic and industry interests alike.

8. Beyond this, I have been an invited presenter at innumerable academic and professional conferences around the world, where I have given talks with titles such as: "Eccrine Sweat Biomonitoring: Addressing Fundamental Challenges that Advance the Frontiers of Biosensing," ApplySci's Wearable Tech + Digital Health + NeuroTech Conference in Palo Alto, CA, February 26–27, 2018;; and "A Leap Beyond the Wearable's of Today: Non-Invasive Biomarker Sensing Through Sweat" at Point-of-Care Conference, San Diego, CA, USA, 2015. Each of these relates to wearable devices that monitor analytes and other physiological signals.

9. I am also the co-founder of Kilele Health Inc., a company devoted to advancing molecular monitoring devices beyond glucose and diabetes to new applications in cardiovascular diseases such as heart failure. In this role, I regularly interface with cardiologists treating patients with heart disorders. I am also a co-

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founder of HydroLabs Inc., a private company creating technologies and systems for the measurement and analysis of bodily hydration.

10. In addition, I was a co-founder and Member of the Board and Chair of Scientific Advisory Board for Eccrine Systems, a biotechnology company that was developing advanced sweat sensors for personalized medicine. Prior to its intellectual property being acquired by Epicore Biosystems, Eccrine was developing a wearable, "skin-like" microfluidic patch that could capture eccrine sweat and then assay that sweat for various biochemical markers.

11. In addition, during the period of 2000 through 2003, I was actively practicing the development of printed circuit board technologies applied to electronic displays, performing the fabrication myself and in communication with leading industry experts such as Pete Zeigler of Dupont Microcircuit Materials and Charles Price of CW Price Screen Printing equipment. At that time, I was aware of the materials and methods utilized for circuit creation using carbon, silver, copper, insulators, markings, and other printed circuit board materials.

12. I have also been the recipient of numerous awards and honors for my research and teaching. In 2023, I was elected to Fellow Status at both the American Institute for Medical and Biological Engineering and Institute of Electrical and Electronics Engineers. These represent the highest levels of professional recognition for biomedical engineers and also for electrical engineers in their respective fields.

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In 2019, I received the CEAS Research Award, which is the highest career research award bestowed by the University of Cincinnati's College of Engineering. In 2018, I received the Ohio Faculty Council Technology Commercialization Award, which is given to only one faculty statewide per year. In 2015, I was given the Ernst and Young Edge Award for the Ohio Valley region and in 2014, I was elected to the rank of Fellow at the National Academy of Inventors.

13. I have been listed as an inventor on over one hundred patents and patent publications in the past ten years, mostly directed to detecting and measuring physiological signals, body analytes, or biofluids.

III. DOCUMENTS AND MATERIAL REVIEWED

14. I have reviewed the Challenged Patents and their prosecution histories (Exs. 1001–1008, respectively). In addition, I have also reviewed the Petitions and both current and historical industry documentation related to electrophysiology and cardiac monitoring and related to flexible wearable electronics and on-body electrode materials, including all exhibits filed herewith. In preparation of this declaration, I relied on my knowledge of electrical and biomedical engineering, my professional experience, and the exhibits filed herewith.

15. My work on this case is being billed at a rate of $500 per hour, with reimbursement for actual expenses. My compensation is not contingent upon the outcome of these *inter partes* reviews.

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IV. ELECTROCARDIOGRAPHIC MONITORING AND DEFIBRILLATION TECHNOLOGIES

16. Below I describe the state of electrocardiographic body-worn sensor devices as of November 1, 2006, which is the filing date of the '007 patent and the priority date claimed by the '492, '484, and '422 patents. I also summarize the development of technologies underlying the features and methods recited in the Challenged Claims as of November 1, 2006.

A. Electrocardiograms (ECGs or EKGs) Are a Long-Known, Well-Understood Medical Technique

17. Physicians have analyzed their patients' heart rhythms for centuries—even before they had a way to reliably track and interpret the meaning of that rhythm. Ex. 1020 (Jan Adamec & Richard Adamec, *ECG Holter, Guide to Electrocardiographic Interpretation* (2008)) at vii. Electrocardiograms (ECGs or EKGs) were captured for the first time in the late 1880s using a mercury capillary electrometer. Ex. 1021 (Gautham Kalahasty et al., *A Brief History of Remote Cardiac Monitoring*, 5 Cardiac Electrophysiology Clinics 275 (2013)) at 275–76. After making a number of improvements to the early ECGs, Dr. Willem Einthoven won a Nobel Prize in Medicine in 1924 for his development of the first practical ECG monitor. *Id.* at 276.

18. From that point on, physicians have used ECGs to evaluate and monitor patients' heart health. *See, e.g.*, Ex. 1020; Ex. 1022 (Edward K. Chung, *Ambulatory*

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Electrocardiography Holter Monitor Electrocardiography (1979)) at 3–12; Ex. 1023 (U.S. Patent Publication No. 2006/0224072 ("Shennib") (filed March 31, 2005)) at [0005]–[0006].

19. ECGs work by measuring the electrical activity which controls the heartbeat. *See, e.g.*, Ex. 1024 (NLM, *In brief: What is an electrocardiogram (ECG)?*, *available at* https://www.ncbi.nlm.nih.gov/books/NBK536878/). These electrical signals originate from the sinoatrial node in the right atrium of the heart before spreading out throughout the heart muscle tissue. *Id.* These small electrical impulses in the tissue causes the atria and then the ventricles to contract. *Id.* In a healthy heart, the rhythm caused by these electrical impulses is known as a normal sinus rhythm. *See, e.g.*, Ex. 1022 at 5. The sinus rhythm of a heart with irregularities differs from that of normal, healthy hearts, meaning that ECGs can be used to identify irregularities in heart rate and heart rhythm as well as other potential health concerns. *Id.* at 3–12.

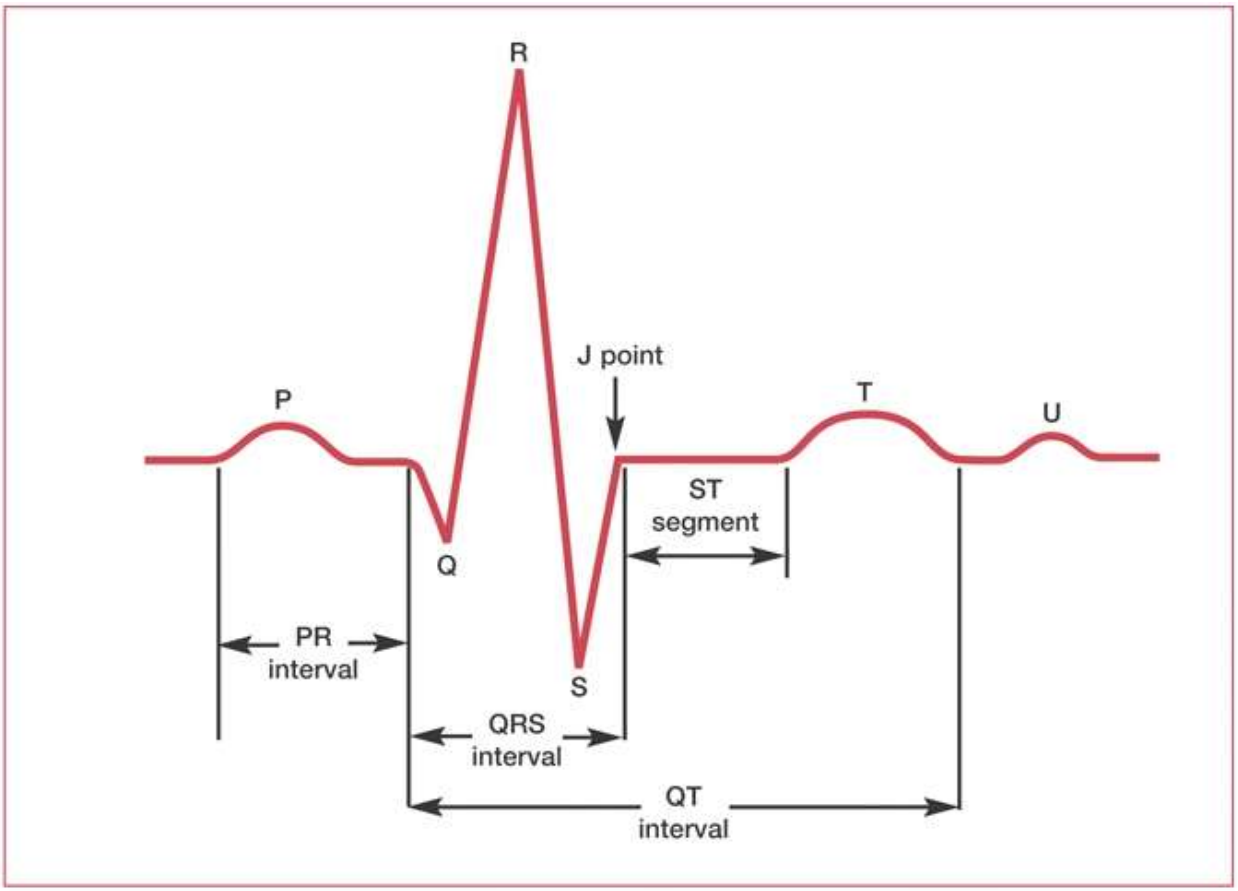
20. The movement of these electrical signals throughout the heart can be measured on the surface of a patient's skin. *Id.* Over a half-century before the invention date, 12-electrode ECG was standardized. Ex. 1025 (Majd AlGhatrif & Joseph Lindsay, *A Brief Review: History to Understand Fundamentals of Electrocardiography*, 2 J. Community Hosp. & Internal Med. Persps. 14383 (2012)). These earlier, "12-lead" ECGs used ten "electrodes" (a type of conductor) to

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measure these electrical signals: six on the patient's chest, two on each of the patient's forearms, and two on each of the patient's calves. Ex. 1024. These electrodes were purposefully positioned on the surface of the patients' skin to provide a three-dimensional view of the heart's electrical activity. The positions of the electrodes correspond to ECG vectors that trace the direction, magnitude, and sense of the electrical activity. *See, e.g.*, Ex. 1026 (Robert P. Grant, *Spatial Vector Electrocardiography*, Circulation Vol. II, 676 (Nov. 1950)) at 677. The vectors detected by the electrodes are transmitted via cables to an ECG machine which converts the signals into an ECG readout. Ex. 1024.

21. A typical ECG readout includes several distinct waves: the P-wave, Q-wave, R-wave, S-wave, and the T-wave. *See, e.g.*, Ex. 1027 (ACLS Medical Training, *The Basics of ECG*, *available at* https://www.aclsmedicaltraining.com/basics-of-ecg/). Physicians can interpret one of more of these waves to derive a patient's heart rate and rhythm. *Id.* The P-wave represents the atrial electrical activity, while the Q, R, S, and T waves all represent ventricular electrical activity. *Id.*

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Ex. 1028 (Euan A. Ashley & Josef Niebauer, *Cardiology Explained* (2004), *available at* https://www.ncbi.nlm.nih.gov/books/NBK2204/).

22. Well before the priority date of the Challenged Patents, physicians used several methods of ECG cardiac monitoring, including screening, short-term monitoring, intermittent monitoring, and long-term monitoring. Ex. 1029 (Am. Coll. Cardiology, Am. Heart Ass'n Task Force on Practice Guidelines, *ACC/AHA Guidelines for Ambulatory Electrocardiography: Executive Summary and Recommendations* 100 Circulation 886 (1999), *available at*

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https://www.ahajournals.org/doi/full/10.1161/01.cir.100.8.886). There are various devices that can be used for each different method of cardiac monitoring. *Id.*

B. The Evolution of Portable Physiological Monitors Decades Prior to the Priority Date

23. The first practical ECG monitor—weighing several hundred pounds—was developed in the 1920s. Ex. 1021 at 276. Recognizing the commercial potential of ECG, the industry quickly sought to reduce and miniaturize these monitors. *Id.* While there were many reasons to reduce the size of stationary ECGs used solely in clinical settings, the commercial and clinical benefits of reducing the size of ECGs became even more salient when long-term, portable ECG recording devices were invented by Dr. Norman Holter in 1949 and released for commercial production in 1962. *Id.*; *see also* Ex. 1022 at 3; Ex. 1020 at xi. These devices became known as "Holter monitors," versions of which are still commonly used today. *Id.* By the early 1960s, the size had decreased enough that Holter monitors were both clinically viable and commercially available. *Id.* One way that this size reduction was achieved was by incorporating transistors, *i.e.*, semiconductor devices that can act as electronic switches and amplifiers that control or alter current or voltage flow, into the Holter monitor. Ex. 1021 at 276. The size of the Holter monitor continued to be reduced throughout the 1960s. By 1969, Holter *mini*monitors (the size of a cigarette package) were being commercially produced. Ex. 1030 (Mike Cadogan, *Norman J. Holter* (2022), *available at* https://litfl.com/norman-j-holter/).

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24. Holter monitors were widely adopted, in part due to clinical reports demonstrating the usefulness of long-term ECG monitoring. Ex. 1031 (Joel Morganroth, *Ambulatory Holter Electrocardiography: Choice of Technologies and Clinical Uses*, Anals. of Internal. Med. (1985)) at 74. By 1979, there were a number of medical uses, referred to as indications, for the use of Holter monitor electrocardiography. These indications included "[d]iagnosis of cardiac arrhythmias," "[e]valuation of symptoms . . . to correlate with actual arrhythmias," "[d]iagnosis of myocardial ischemia," "[e]valuation of anti-arrhythmic drug therapy," and "[e]valuation of artificial pacemaker function." Ex. 1022 at 228, Table 2. By the early 1980s, the incorporation of transistors and other technologies made it possible for the size of portable ECG monitors to continue to shrink while at the same time their functionality improved. Ex. 1031 at 74; Ex. 1032 (Nitish V. Thakor, *From Holter Monitors to Automatic Defibrillators: Developments in Ambulatory Arrhythmia Monitoring*, IEEE Transactions on Biomed. Eng'g, 770 (1984)) at 775–76. Reducing the size and improving the wearability of longer-term ECG monitors, such as the Holter monitor, has been, and continues to be, an industry focus since long-term ECG monitoring was first conceived of decades ago.

C. Wearable ECG Monitors Were Well Known Prior to the Priority Date

25. Prior to November 1, 2006, wearable ECG monitors that allowed for longer monitoring periods were well known in the industry. As the Challenged

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Patents and other prior art references explain, most of these devices comprised, *inter alia*, disposable sensors (*e.g.*, ECG electrodes), electrical traces/wiring, reusable electrical components, portable batteries, wireless communication functionalities, printed circuit boards, and some form of resistor.

26. First, prior to November 1, 2006, wearable devices with disposable sensors—including ECG electrodes—which could be fixed to the patient's body were widely known. *See, e.g.*, Ex. 1001 at 1:20–25 ("Typically . . . [s]ensors, such as, ECG electrodes, are affixed to the patient's body, such as with tape"), 1:34–36 ("typically . . . monitor includes a sensor, which generally makes direct or indirect contact with an individual's chest"), 9:5–11 (noting the "ConMed Cleartrace line of ECG electrodes including the model 1700 Cleartrace electrode manufactured by the ConMed Corp. of Utica, N.Y. or similar type electrodes made by the 3M Corp. of St. Paul, Minn."); Ex. 1003 at 1:40–44, 1:53–55, 9:29–33 (same); Ex. 1005 at 1:44–48, 1:58–59, 9:32–38 (same); Ex. 1007 at 1:58–63, 2:4–7, 9:57–63 (same); Ex. 1023 at [0011] ("The patches (electrodes) employed with these monitors are disposable."), [0007] ("instruments typically use 5 or more ECG electrodes attached to the chest at one end and connected to a portable device at the other end"); WO 2008/005015 A1 ("Shennib PCT") (Ex. 1033) (filed July 5, 2006) at [0009] ("ECG patches (electrodes) used with such prior art ECG monitors are disposable and replaced frequently for extended monitoring"), [0008] ("miniature electronic package

attached to the patient's chest via two to three electrodes"); U.S. Patent No. 6,454,708 ("Ferguson") (Ex. 1034) (issued Sept. 24, 2002) at 4:41–44 ("a portable remote patient telemonitoring system which collects vital signs (health parameter) data from a patient using a disposable sensor device attached to the patient"), 4:62–63 ("first component is an adhesive, cordless, disposable sensor band with electrode patches"). Making the electrodes—which contact the patient's skin—disposable helped ensure that the wearable device is hygienic, as noted below.

27. Second, prior to November 1, 2006, wearable devices including electrical traces or wiring (also known as leads) on flexible substrates that connected the electrodes to the device electronics, were widely known. *See, e.g.*, Ex. 1023 at [0014] (discussing a prior art patch that is a "flexible, nominally flat planer form having integral gel electrodes, a sticky-back rear surface, [and] an internal flex circuit"), [0035] ("The electronic assembly of the patch is formed of a flexible circuit substrate 20 with trace extensions to the electrodes 21, 22, 23"); Ex. 1034 at 8:57–58 ("[t]he signal processing circuitry 12 receives the sensor data from traces 14"), 9:44–48 ("[r]espiration data . . . may also be collected using a printed carbon on flextrate resistance band sensor 19 located on the left hand side of the chest"), 10:35–40 ("[t]he PCB is connected to a flexible substrate which has printed circuit traces 14 providing connections to the electrodes and the connector 13'"). These electrical traces are small, allowing for the device to be miniaturized without needing to use

large or cumbersome individual electrical wires, such as those used in Holter monitors.

28. Third, prior to November 1, 2006, wearable devices including a reusable electronic component used to interpret the signals received by the sensor were widely known. *See, e.g.*, Ex. 1023 at [0011] ("The patches (electrodes) employed with these monitors are disposable. However, the electronic base unit is reusable as it is loaned to patients as part of the diagnostic service provided by the clinic."); Ex. 1034 at 6:12–14 ("the smart card also houses the sensor band's electronics so that the electronics may be reusable from one sensor band to the next"). Reusing some electronic components of the wearable device is more economical and more environmentally sound.

29. Fourth, prior to November 1, 2006, wearable devices including portable batteries and wireless connectivity were widely known. *See, e.g.*, Ex. 1001 at 1:20–27 ("Typically a battery operated monitor can be hung on a belt, shoulder strap, or carried by a patient using some other similar hanging arrangement. . . . After a fixed interval of time, or at a low battery indication, the batteries can be replaced or recharged"), 1:28–32 (discussing the Micropaq wireless patient monitor, manufactured by Welch Allyn, Inc., as "[*o*]*ne* example of a portable patient monitor") (emphasis added); Ex. 1023 at [0010] ("These monitors may have a display to inform the patient if and how many events have been recorded and the

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status of the battery life"), [0022] ("a preformatted report is automatically generated by the patch and transmitted wirelessly to a generic reporting device such as a printer or a wireless network system using infrared or RF signals"); Ex. 1034 at 8:57–62 ("The signal processing circuitry 12 receives the sensor data from traces 14 and a directly connected thermistor (not shown) and is powered by, e.g., an alkaline manganese battery pack (not shown) designed to permit the sensor band 10 to collect vital signs data for approximately 30 hours"), 18:64–65 (noting that "[o]ff the shelf wireless technology options may be used for the wireless transmissions" of the vital signs from the sensor band); U.S. Patent No. 6,238,338 ("DeLuca") (Ex. 1015) (issued May 29, 2001) at 3:20–29 ("[biosignals] are transmitted via wireless communication links 16 to a control station 22"). Wireless transmissions were performed using an antenna, such as a transceiver or transmitter. Ex. 1034 at 4:1-2, 6:49-50, Figs. 4A, 4B; Ex. 1023 at [0046] ("using radio frequency (RF) transmitter…using standard RF protocols such as Bluetooth® and IEEE802®").

30. Fifth, prior to November 1, 2006, *printed* circuit boards were widely known and used in wearable medical devices as described above in this Section. *See, e.g.*, Ex. 1035 (R.S. Khandpur, *Printed Circuit Boards: Design, Fabrication, Assembly, and Testing* (2006)) at 3 (noting that the screen printing technique was used to print "silver paste conductors and graphite resistors . . . onto ceramic substrate" as early as the end of World War II"; noting that "[i]t was [the screen-

printing] technique that ushered in the commercial use of printed circuits"), 4 ("When the completed board provides mechanical support and all necessary electrical connections to the components, it is essentially a Printed Wiring Board or Printed Circuit Board. The term *printed* became popular because the conductive areas are often generated by means of a printed process like screen printing . . . ."), 283 (explaining that "[t]he majority of PCBs produced worldwide are screen printed" because, while "less precise" than other methods, it is "comparatively cheap and simple"), 659 (defining "Printed Circuit" as a "[c]ircuit where the interconnections between components, terminals, subassemblies, etc., are made by conductive strips (traces) that have been printed or etched onto an insulating board"); *see also* Ex. 1036 (AAMI, *Cardiac monitors, heart rate meters, and alarms*, ANSI/AAMI EC13:2002 (2002)) ("EC-13") at 4 (referencing a "printed trace").

31. Sixth, prior to November 1, 2006, wearable devices including resistors, which protected both the patient and the device from unwanted electrical discharge, were widely known. *See, e.g.*, Ex. 1001 at 1:53–57 (noting that medical grade monitors are required to be able to "survive multiple defibrillation cycles of at least 360 joules" and that "[c]onventionally, this requirement has been met by one or more power resistors situated in series with the wire leads of a fixed or portable physiological monitor"); Ex. 1015 at 4:57–64 ("all input stage connections to the ASIC 36 are protected against electrostatic discharge by the circuit formed by the

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current limiting series resistors Rin and Rdrive with their respective diode connected JFETs, D1, D2, D3. This arrangement maintains a low leakage path under normal operating conditions, while providing a current path during over-voltage conditions"); U.S. Patent No. 4,280,507 ("Rosenberg") (Ex. 1018) (issued July 28, 1981) at 1:19–27 (noting that "[m]ost EKG machines are equipped with internal circuits that bypass the front end amplifiers in the presence of a defibrillation pulse, but full protection of the machine requires that voltage limiting means be included in each of the leads from the machine to the electrodes attached to the patient's body").

D. The Use of Disposable Components, Including Disposable Electrodes, Was Well-Established by the Priority Date

32. The use of disposable electrodes or sensors in wearable monitoring devices was common long before the Challenged Patents were filed. *See, e.g.*, Ex. 1037 (P.J.B. Hubner, *Which Disposable Chest Electrode?*, British Med. J., 507 (Aug. 30, 1969)) at 510. Because electrodes are in direct contact with the skin of a patient, re-usable electrodes need to be thoroughly cleaned after each patient to prevent cross contamination of infectious diseases. *Id.*; *see also* Ex. 1038 (V. Trend et al., *Are ECG Welsh cup electrodes effectively cleaned?*, 14 J. Hosp. Infection 325 (1989)) at 331. Even with thorough cleaning, the risk of cross-contamination cannot be eliminated. Ex. 1038. Disposable electrodes, which are disposed after use by a single patient, provide a solution to this hygienic problem.

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33. As ECG technology evolved, disposable electrodes continued to be preferred because of the reduced risk of cross-contamination between patients. For example, U.S. Patent No. 4,763,660 ("Kroll") (Ex. 1013) (issued August 16, 1998) reiterates this benefit:

> The invention further provides an electrode belt device that is disposable, which is an improvement over prior art devices which typically require much maintenance and care. Additionally, its ***disposability is particularly beneficial in a medical setting, wherein the possibility of transfer of communicable diseases from patient to patient is of great concern***.

Id. at 1:66–2:7 (emphasis added).

34. Mechanisms to affix disposable electrodes were also well-known because the electrodes needed to be readily removable and attachable to the other components without damaging either the electrodes themselves or the other components. For example, as acknowledged by the Challenged Patents, the "snap-on" design for disposable electrodes was well-known long before its 2006 filing date. Ex. 1001 at 9:5–11. Both ConMed and 3M Corp. at that time commercially produced a snap-on electrode. *Id.*; *see also* Ex. 1032 at 771, Fig. 1 (titled "Schematic of a disposable ECG electrode"). Thus, by the early 2000s, it was common practice for wearable monitors to use disposable, snap-on electrodes in conjunction with other non-disposable components. *See, e.g.*, U.S. Patent Publication No. 2003/0069510 ("Semler") (Ex. 1039) (filed October 4, 2001) at [0035], [0046], Fig.

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5 (discussing use of snap connectors to attach a monitoring device to 12-lead recorders); Ex. 1040 (*Devices@FDA: Dexcom STS Continuous Monitors*, U.S. Food & Drug Admin. (2005), *available at* https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pma&id=320251) at 30 ("Labeling").

35. Besides the electrodes, other components of pre-2006 wearable devices were also designed to be disposable, to further optimize for factors such as hygiene or cost. Ex. 1013 at 2:4–7 ("Because the belt device and its components are designed for individual patient use, risks that are inherent in multiple patient use devices are minimized."); Ex. 1039 at [0017] (disclosing a monitor that is "meant for limited-term use" and thus is "extremely inexpensive to manufacture" and "may be disposed of, e.g. discarded or recycled, much like a disposable flash camera" after the recorded data is collected from the device), [0035] ("within the spirit and scope of the present invention, some or all of the circuitry including the electrodes, the flex circuit, the memory and/or processor chip and the batteries may be integrated into a thin, laminar configuration"), [0051] (discussing an ECG monitoring device that "minimizes the circuitry required to implement the required functionality in a tiny, thin, planar flexible expanse that—due to its low cost—may be readily disposed of or recycled after use"); Ex. 1023 at [0035], cl. 1 (a disposable patch that includes a "flexible circuit substrate 20 with trace extensions to the electrodes 21, 22, 23, and

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to the battery 35"). The popularity of disposable components increased as the costs of electrical components decreased and recycling programs for those parts became more viable.

E. Industry Standards as of November 1, 2006

36. As acknowledged by the Challenged Patents, prior to November 1, 2006, a number of industry standards relevant to wearable physiological monitoring devices had been promulgated. *See, e.g.*, Ex. 1001 at 4:21–24 (referencing the European Unions' Medical Device Directive and the EC-13 standard for electrocardiographs), 11:39–41 ("The high pass filter causes the input to be AC coupled from a roll off frequency of about 0.05 Hz, as specified by industry ECG standards."), 14:25–30 ("Standard EC13 addresses the ability of an ECG monitor to display and process ECG signals in a satisfactory manner while connected to a patient on whom an electrosurgical device is being used."), 14:30–32 (noting that without the suppression required by EC-13, "the high RF output of an electrosurgical device can render ECG monitoring impossible and or render the monitor unusable."). These standards required that, to achieve compliance, wearable devices contain certain features and/or functionalities. As described by the Challenged Patents, these standards included as requirements, among other things, many of the features that had been well known in the field, such as those described in Sections IV.C–D above.

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37. The Challenged Patents reference the Association for the Advancement of Medical Instrumentation's (AAMI) EC-13 standard, which was published in 2002. EC-13 describes disposable ECG electrodes, affixed to the patient's body, as well known in the art. *See, e.g.*, Ex. 1036 at 60 ("The characteristics of disposable electrodes have been studied extensively by UBTL [(a Division of the University of Utah Research Institute under the sponsorship of the U.S. Food and Drug Administration's then Bureau of Medical Devices)] (Schoenberg, et al., 1979)"); *id* at 48–49 ("This device is attached to the body through ECG electrodes"); *see also id.* at 68 (citing EC-12, a standard concerning "pre-gelled ECG disposable electrodes," and dated 1991). Another relevant standard is AAMI's EC-82 standard, which was published in 1999. Ex. 1041 (AAMI, *Ambulatory Electrocardiographs*, ANSI/AAMI EC38:1998 (1998)) ("EC-38").

38. The EC-13 standard requires protection of both the patient and the device from electrical shock. Ex. 1036 at 55 ("Defibrillator overload protection is necessary for most cardiac monitors" because "***any given monitor might be used on patients potentially requiring defibrillation***.") (emphasis added). In particular, the EC-13 standard specifically requires that wearable devices can survive "multiple defibrillation cycles of at least 360 joules." Ex. 1001 at 1:53–55; Ex. 1036 at 18, Table 4; *see also* Ex. 1041 at 45 (noting the maximum selectable deliverable energy of defibrillators ranges from 250 to 360 joules). The EC-13 standard explains that

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the device should "continue to function after exposure to the short-duration high voltages of a defibrillator discharge" and discusses mechanisms for doing so. Ex. 1036 at 55. This is an important consideration because patients often undergo longer-term ECG monitoring because they are at suspected to have an increased risk of heart conditions which may require defibrillation.

39. Further, the EC-13 standard describes "[e]lectrosurgical interference suppression [ESIS] [t]he ability to display and process ECG signals in a satisfactory manner while connected to a patient on whom an electrosurgical device is being used. Without such suppression, the high RF output of an electrosurgical device renders ECG monitoring impossible." *Id.* at 3. EC-13 also teaches "pacer pulse detector rejection of fast ECG signals" and "[p]acemaker pulse appearance in auxiliary output." *Id.* at 9.

40. In addition, EC-13 explains that "common mode rejection" is the "[a]bility of a differential amplifier to reject common mode voltage." *Id.* at 3, 64, Table 4; *see also* Ex. 1041 at 3. Common mode voltage is any "[u]ndesired voltage of identical amplitude and phase applied to both inputs of a differential amplifier" that would be otherwise detected by the amplifier. Ex. 1036 at 3, 64, Table 4; *see also* Ex. 1042 (David Prutchi & Michael Norris, *Design and Development of Medical Electronic Instrumentation* (2005)) at 3. Common Mode Rejection Ratio (CMRR) is the ability of a differential amplifier to not pass (reject) the portion of

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the signal common to both the positive and negative inputs. Ex. 1036 at 64. Such common mode rejection and other filtering mechanisms can remove or reduce interfering electrical signals typically surrounding the patient during use of the ECG device (such as lighting or other electrical instruments). *Id.* at 3, 64, Table 4; Ex. 1042 at 3.

41. Lastly, "portable and battery-powered ECG monitors" were already so widely known that they were explicitly included in the scope of the EC-13 standard, Ex. 1036 at 1, and the EC-38 standard, *see, e.g.*, Ex. 1041 at 8 Table 2, 42.

42. The EC-13 standard demonstrates that wearable devices—including the components and functions discussed above—were widely known in the industry by 2002.

F. Resistive Protection and Resistive Traces

43. Using electrical resistance for protection of both the device and the patient was also widely known before November 1, 2006. As discussed above, the importance of including such protection in ECG monitors was well-understood because patients who require long-term monitoring are at an increased risk of experiencing a cardiac event, such as a sudden cardiac arrest. *See* Section IV.E., *supra.* It was an industry requirement that ECG monitors were capable of withstanding the surplus electrical discharge associated with defibrillation. *See* Section IV.E., *supra* (discussing the EC-13 standard). This requirement is

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acknowledged by the background sections of the Challenged Patents, which note that "[a]nother problem is related to the ***requirement that a medical grade monitor survive multiple defibrillation cycles*** of at least 360 joules." *See, e.g.*, Ex. 1001 at 1:53-55 (emphasis added). A POSA would understand that 360 Joules is the maximum amount of energy that would be delivered by a defibrillator. *See, e.g.*, Ex. 1036 at 55 ("The American National Standard . . . specifies a maximum selectable deliverable energy [for a defibrillator] in the range of 250 joules (J) to 360 J"). In addition to its use in cardiac monitoring, ECG is also widely used during surgeries that require general anesthesia for patients; these surgeries often use electrosurgical equipment or in some way introduce a risk of defibrillation. The broad field of use for ECG and prior art electrical resistance protection of the device and the patient is not limited to any particular patient population and is, therefore, widely appreciated across medical devices.

44. There were multiple known ways of incorporating electric resistance as protection as of November 1, 2006. While the Challenged Patents note that "[c]onventionally, this requirement has been met by one or more power resistors situated in series with the wire leads of a fixed or portable physiological monitor," this was not the only approach available to a POSA at the time. *See, e.g.*, Ex. 1001 at 1:55–57. One approach was to use leads of "electrically conductive carbon loaded polymer" where the "distributed resistance of each polymer lead" was sufficient to

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provide protection from any excess electrical current. Ex. 1018 at 1:36–45. A POSA would understand that the terms "lead" and "trace" are often used interchangeably because signal traces connect the components on a printed circuit board much like lead wires functioned in the early days of ECG technology. *See* Ex. 1035 at 642 ("Conductor: A single conductive path in conductive pattern. A PCB has at least one layer of conductors. *Synonyms:* path, trace.").

45. This approach is further highlighted in Kroll, which notes that lead strips are comprised of "a flexible conductive ink compound having a conductive filler . . . [p]referably . . . of a preselected conductivity to provide a certain total lead strip resistance so that each strip 34 serves as a current limiter." Ex. 1013 at 5:4–11, Fig. 4. A POSA reading this disclosure would understand that the flexible conductive ink described in Kroll was printed on a flexible circuit board. *See, e.g.*, Ex. 1035 at 255 ("The basic function of the laminate is to provide mechanical support for electronic components and to interconnect them electrically . . . They can be simply described as products obtained by pressing layers of a filler material impregnated with resin under heat and pressure. The resulting thin, insulating material, which is the mixture of filler (reinforcement) and resin on which all conductors and components are mounted, is called *base material* [which] can be either rigid or flexible material."); *see also* Section IV.C, *supra*. Thus, the lead strips in Kroll are electrical traces. *See* Ex. 1035 at 659 (defining a "printed circuit" as one

in which the "interconnections" are "made by conductive strips (traces) that have been printed or etched onto an insulating board").

46. Another approach was to use "a small, flat surface mount resistor soldered to input trace 34 on top of circuit board 28." Ex. 1019 (WO 1987/01024 A1) ("Dunseath") (filed August 21, 1986) at 25:24–26:12. This can be used to "provide adequate protection for some types of integrated circuit amplifiers such as CMOS devices which are sensitive to large input voltages rather than currents." *Id.* at 5:31-6:2.

47. Importantly, resistance in the traces on a body-worn physiological device has a twofold protective effect. It helps protect the patient from shock from the device and it helps to protect the device from the effects of an outside shock. In fact, any approach to limiting current using resistive material to protect the patient from shock would also protect the body-worn device from excess electrical current because the electrical resistance operates to limit the flow of current in *either* direction (flowing from the device toward the patient, or from the patient's skin toward the device). *See, e.g.*, Ex. 1043 (Roger A. Freedman & Hugh D. Young, *University Physics* (15th ed. 2019) at 816–17 (noting that the resistivity of a conductor depends on the properties of the conductor material), 819–20 (noting that current always flows in the direction of decreasing electric potential or voltage). Further, a resistor functions the same regardless of the direction of current flow

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through it: for a given amount of current through a resistor or voltage drop across the resistor the resulting power dissipation, currents, and voltage drops are identical regardless of direction of current flow. *Id.* Therefore, any resistor that simply has the proper range of resistance would protect the body-worn device from excess electrical current (*e.g.*, Ex. 1001 at 7:46-48 ("in a range between about 1 kilo ohm to about 10 kilo ohms," or other ranges depending on the specific electronics used in an ECG device)).

48. Further, consistent with the industry goal of reducing the size of body-worn monitoring devices, a POSA would have prioritized approaches of limiting current that were small and compact. *See, e.g.*, *id.* at 1:57–59 ("The problem [with the conventional approach of using resistors in series] is that the physical volume of conventional power resistors is too large for use in a compact monitor application."). Rosenberg and Kroll have a similar result (*i.e.*, reducing the size of the devices) by incorporating the resistance into the traces or leads or the device, rather than using conventional resistors on the printed circuit board of the device. *See* Ex. 1018 at 1:36–45; Ex. 1013 at 5:4–11.

V. RELEVANT LEGAL STANDARDS

49. I have been asked to provide my opinions as to whether the Challenged Claims of the Challenged Patents would have been obvious to a POSA at the time of the filing date of the Challenged Patents.

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A. Scope of an *Inter Partes* Review

50. I understand that the scope of issues which are to be considered in an *inter partes* review are limited to those grounds disclosed in the Petitions on which it requests the Board institute review.

B. Claim Construction

51. I have been informed and understand that for purposes of this proceeding, the claim terms subject to *inter partes* review are to be "construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by [a POSA] and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b). For purposes of these Petitions, the Challenged Claims are interpreted according to their plain and ordinary meaning.

C. Obviousness

52. It is my understanding that a claim is obvious under 35 U.S.C. § 103 if the claimed subject matter as a whole would have been obvious to a POSA at the time of the alleged invention. I also understand that, in an obviousness analysis, the POSA is presumed to have knowledge of all material prior art.

53. In considering obviousness, I understand that one must determine the scope and content of the prior art. I understand that, in order to be considered as

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prior art to the challenged patent, a prior art reference must be reasonably related to the claimed invention of the challenged patent. A reference is reasonably related if it is in the same field as the claimed invention or is from another field to which a POSA would look to solve a known problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

54. I understand that a patent claim composed of several elements is not proven obvious simply because each of its elements was independently known in the prior art. It is my understanding that, in evaluating obviousness, it is relevant whether there is a reason that would have prompted a POSA to combine the elements or concepts from the prior art in the same way as in the claimed invention. There is no single way to define the line between true inventiveness on one hand (which is patentable) and the application of common sense and ordinary skill to solve a problem on the other hand (which is not patentable). For example, market forces or other design incentives may be what produced a change, rather than true inventiveness.

55. It is my understanding that several rationales may be applied for combining references or modifying a reference to show obviousness of claimed subject matter. These rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known

element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known device (method or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify a prior art reference or to combine prior art teachings to arrive at the claimed invention. Additionally, I understand that the claimed subject matter is obvious if it would have been obvious to a POSA in view of his/her general knowledge, *i.e.*, in light of all knowledge conveyed by the prior art as defined by statute and case law.

VI. PERSON OF ORDINARY SKILL IN THE ART ("POSA")

56. It is my understanding that when interpreting the claims of the patents, I must do so based on the perspective of one of ordinary skill in the art in the same field as the challenged patent at the time of the invention. The earliest claimed priority date for the Challenged Patents is November 1, 2006.

57. It is my opinion that one of ordinary skill in the art in the field of body-worn physiological monitors in 2006 would have had 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.

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Alternatively, a POSA with respect to the technology described by the challenged patent could have had less education with more experience and vice versa.

VII. THE '007 PATENT

58. The '007 patent is titled "Body Worn Physiological Sensor Device Having a Disposable Electrode Module." It was filed November 1, 2006. The stated field of art is "physiological monitor[s]" generally and more specifically "body worn physiological monitor[s]." Ex. 1001 at 1:7–8.

A. Overview of the '007 Patent

59. As discussed above in Section IV, by the November 2006 priority date, the field of body-worn physiological monitoring was well-established.

60. The '007 patent describes a physiological monitor that is worn on the patient's body. According to the '007 patent, the body-worn monitor could be attached to the patient's skin in the same way a BAND-AID® is applied. *Id.* at 5:41–44. Commercially available adhesive, such as a "1.6 mm adhesive foam from Scapa Medical of Bedfordshire, UK" could be used for this purpose, for example. *Id.* at 5:41–46.

61. The body-worn monitor described by the '007 patent consists of two primary components: a "communication-computation module," which is reusable, and a sensor module, which is disposable. *Id.* at Abstract, 4:9–11.

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62. Figure 1B below shows a side view of these two components of the body-worn heart monitor (100): the disposable module (110) in red and the reusable "communication computation module" (102) in blue.

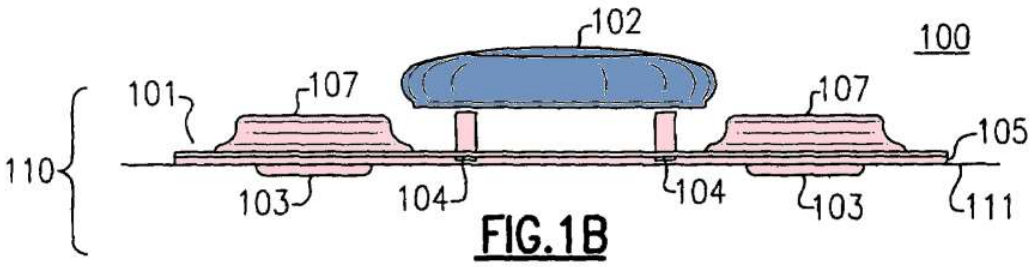


FIG. 1B

Id. at Fig. 1B (annotated).

63. The communication-computation module (102) is "mechanically attach[ed]" to the "top surface of the disposable electrode module" (110) via a retention clip (104), enabling it to receive signals from the disposable module. *Id.* at 2:32–35, 4:58–62. The communication-computation module performs "real-time physiological analysis of the physiological signals" and transmits the result of the physiological analysis "via a radio transmission to a remote radio receiver." *Id.* at Abstract, 2:23–45.

64. Each of the communication-computation module and the disposable electrode module include a number of elements, as shown by Figure 2 below. The reusable communication-computation module (102) includes: a cover (201), a communications and computation printed circuit board assembly (202), and a base (203). *Id.* at 6:28–30. The disposable electrode module (110) includes a "flat planar

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insulating/adhesive member" (105) which has "a plurality of openings that are each sized to receive electrode gels" (103). *Id.* at 5:21–26. Commercially available electrode gels at the time, such as type LT00063 hydrogel supplied by Tyco Healthcare, are suitable for use as the disclosed electrode gels (103). *Id.* at 7:4–7. The insulating member (105) "provides a bottom side cover for the flexible printed circuit layer" (101) and helps to adhere the disposable electrode module to the patient's body. *Id.* at 5:26–28.

65. The '007 patent also describes a variety of commercially available snap-on electrodes. *Id.* at 9:5-14. Specifically, "the ConMed Cleartrace line of ECG electrodes including the model 1700 Cleartrace electrode manufactured by the ConMed Corp. of Utica, N.Y. or similar type electrodes made by the 3M Corp. of St. Paul, Minn." *Id.*

66. The disposable electrode module also includes batteries (204) which are used to power the communication-computation module (102). *Id.* at 5:23–24. The batteries (204) "can be mounted under respective battery flaps" (205) "arranged on opposite sides of the flexible printed circuit layer" (101). *Id.* at 5:57–59. Commercially available battery covers (107), such as the model 2990 from the Keystone Electronics Corp., were used to provide protection for the batteries (204). *Id.* at 5:63–65.

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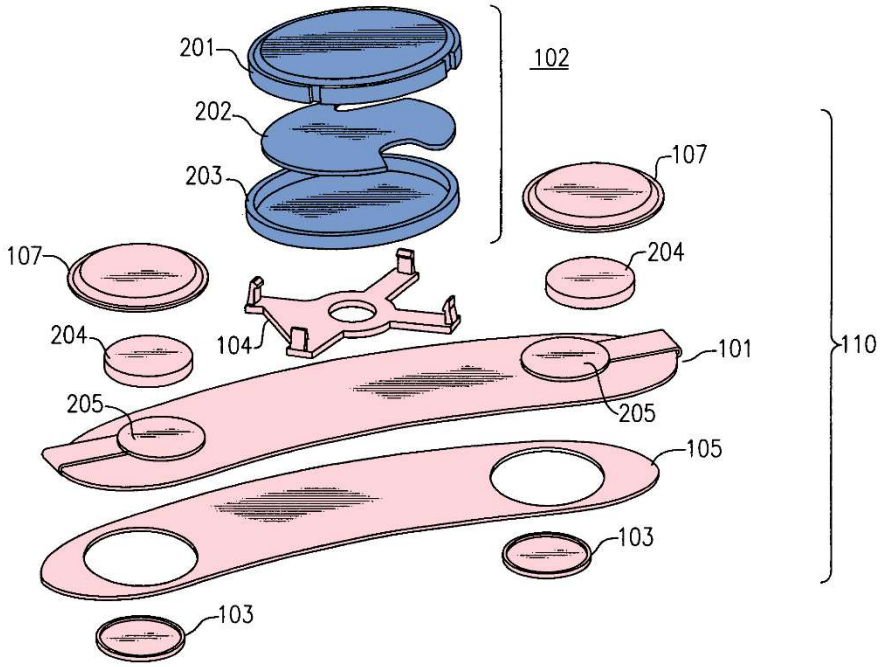


FIG.2

Id. at Fig. 2 (annotated).

67. The flexible circuit board (101) of the disposable ECG module (110) includes a number of additional components. The flexible circuit board (101) is formed on a substrate (406) of commercially available material, *e.g.*, MYLAR®, which is a trademarked type of commonly used polyester film. *See, e.g.*, *id.* at 6:40–41. The flexible circuit board (101) also includes a conductive surface (404) which is "[t]ypically" a "circular or square conductive surface." *Id.* at 6:58–59. The '007 patent refers to the combination of the conductive surface (404) and an electrode gel (103) as an electrode (109). *Id.* at 6:46–57. "Conductive surface 404 can also be viewed as the electrode portion of a half cell and electrode gel 103 can be considered to be the electrolyte portion of a half cell." *Id.* Additionally, the flexible circuit

board (101) includes "resistive traces" (412, 413) used to protect the reusable communication-computation module from "potentially damaging defibrillation energy" in the event that the patient requires defibrillation due to a cardiac event. *Id.* at 7:34–45.

68. The "resistive traces" connect the components which measure physiological signals (*i.e.*, the electrode gels and the conductive surface) to the electrical connection of the communication-computation module. *Id.* at 7:22–33. The "resistive traces" can be made from materials of "determinable electrical resistance" such as resistive metals, carbon, silver ink, powders, or paints. *Id.* at 7:28–33.

B. Summary of the Claims of the '007 Patent

69. Claim 1 of the '007 patent is set forth below with the elements labeled for reference:

Elements Designation	Element
1(pre)	A body worn patient monitoring device comprising:
1(a)	a disposable module including a plurality of electrical connections,
1(b)	said electrical connections adapted to be couplable to a skin surface to measure physiological signals,
1(c)	at least one of said electrical connections comprising a half cell,

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1(d)	the disposable module including a disposable module connector;
1(e)	a power source to power the body worn patient monitoring device;
1(f)	a communication-computation module being removable and reusable,
1(g)	having a communication-computation module connector to receive physiological signals from the disposable module via said disposable module connector, the communication-computation module including:
1(h)	a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals, said analysis determining an occurrence of a predetermined physiological event, and
1(i)	a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event, via a radio transmission to a remote radio receiver,
1(j)	wherein the disposable module is mechanically and electrically coupled directly to the communication-computation module
1(k)	and the body worn patient monitoring device including the disposable module and the communication-computation module is adapted to be directly non-permanently affixed to the skin surface of the patient; and
1(l)	at least one series current-limiting resistor configured to protect the communication-computation module,
1(m)	the at least one series current-limiting resistor being screened on a flexible substrate,
1(n)	the at least one series current-limiting resistor being in the form of resistive traces.

Id. at cl. 1.

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70. Claim 2 of the ’007 patent depends from claim 1 and further requires “the plurality of electrical connections to the body comprise at least one of direct electrical connections to the body and indirect electrical connections to the body.” *Id.* at cl. 2.

71. Claim 3 of the ’007 patent depends on claims 1 and 2 and further requires “wherein the indirect electrical connections to the body comprise capacitive connections to the body.” *Id.* at cl. 3.

72. Claim 4 of the ’007 patent depends from claim 1 and further requires “the body worn patient monitoring device comprises an ECG monitor and at least two of the electrical connections are ECG electrodes.” *Id.* at cl. 4.

73. Claim 5 of the ’007 patent depends from claim 4 and further requires “the ECG electrodes comprise a material screened onto the flexible substrate.” *Id.* at cl. 5.

74. Claim 6 of the ’007 patent depends from claim 5 and further requires “the at least one series current-limiting resistor protects the communication-computation module during a patient defibrillation event.” *Id.* at cl. 6.

75. Claim 7 of the ’007 patent depends from claim 4 and further requires “the mechanical interface from the at least one series current-limiting resistor to the EGG electrode includes a filleted edge.” *Id.* at cl. 7.

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76. Claim 8 of the ’007 patent depends from claim 4 and further requires “the mechanical interface from the at least one series current-limiting resistor to the EGG electrode comprises overlapped layers.” *Id.* at cl. 8.

77. Claim 10 of the ’007 patent depends from claim 1 and further requires “an insulating material overlaying the at least one series current-limiting resistor to prevent arcing.” *Id.* at cl. 10.

78. Claim 11 of the ’007 patent depends from claims 1, 4, and 5 and further requires that “the EGG electrodes are formed substantially in the shape of an annulus.” *Id.* at cl. 11.

79. Claim 12 of the ’007 patent depends from claims 1, 4, 5, and 11 and further requires that “the annulus comprises a conductive link.” *Id.* at cl. 12.

80. Claim 13 of the ’007 patent depends from claim 5 and further requires “the substrate is shaped to allow placement on the patient to monitor at least one of a set of standard ECG vectors while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal.” *Id.* at cl. 13.

81. Claim 14 of the ’007 patent depends from claim 1 and further requires “the power source is a renewable power source internal to the body worn device.” *Id.* at cl. 14.

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82. Claim 15 of the ’007 patent depends from claim 1 and further requires “the power source comprises a rechargeable battery or a one time use battery.” *Id.* at cl. 15.

83. Claim 29 of the ’007 patent depends from claim 1 and further requires “the body worn device includes circuit protection to allow the device to survive multiple defibrillation cycles of at least 360 joules.” *Id.* at cl. 29.

84. Claim 31 of the ’007 patent depends from claim 29 and further requires “a plurality of components of the circuit protection are distributed between the disposable module and the communication-computation module.” *Id.* at cl. 31.

85. Claim 32 of the ’007 patent depends from claim 1 and further requires “a high pass filter with a selectable corner frequency to filter the physiological signals.” *Id.* at cl. 32.

86. Claim 33 of the ’007 patent depends from claims 1 and 32 and further requires “the corner frequency is selected by a switch selectable resistance.” *Id.* at cl. 33.

87. Claim 34 of the ’007 patent depends from claims 1 and 32 and further requires “the corner frequency is selected by one or more switching capacitors switched a rate higher than the corner frequency of a low pass anti-aliasing filter.” *Id.* at cl. 34.

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88. Claim 35 of the ’007 patent depends from claims 1 and 32 and further requires “the high pass filter is implemented in software running on the microprocessor.” *Id.* at cl. 35.

89. Claim 37 of the ’007 patent depends from claim 1 and further requires “the communication-computation module includes circuit components configured to detect failure of contact of one or more of the electrical connections with the skin surface of the patient.” *Id.* at cl. 37.

90. Claim 38 of the ’007 patent depends from claim 1 and further requires “the communication-computation module is protected from external high energy signals by electro-surgical isolation suppression circuits.” *Id.* at cl. 38.

91. Claim 39 of the ’007 patent depends from claim 1 and further requires “an algorithm running on a microprocessor in the body worn device causes the body worn device to enter a low power mode that disables at least one circuit of the body worn device, from the end of a ‘T wave’ at the end of one heart beat to the beginning of a ‘P wave’ at the beginning of the next heart beat, to save power.” *Id.* at cl. 39.

92. Claim 43 of the ’007 patent depends from claim 1 and further requires “the radio circuit communicates an unprocessed physiological signal.” *Id.* at cl. 43.

93. Claim 44 of the ’007 patent depends from claim 1 and further requires “the radio circuit communicates a result of the physiological analysis at a predetermined time.” *Id.* at cl. 44.

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94. Claim 45 of the ’007 patent is set forth below with the elements labeled for reference:

Elements Designation	Element
45(pre)	A body worn patient monitoring device comprising:
45(a)	a disposable module including a plurality of electrical connections,
45(b)	the electrical connections adapted for electrical coupling to a skin surface to receive physiological signals,
45(c)	the disposable module including a disposable module connector;
45(d)	a power source to power the body worn patient monitoring device;
45(e)	a communication-computation module, having a communication-computation module connector to receive the physiological signals from the disposable module via the disposable module connector, the communication-computation module including:
45(f)	a microprocessor to actively monitor a patient and to perform a real-time physiological analysis of the physiological signals, the analysis determining an occurrence of a predetermined ECG event,
45(g)	a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis, at a predetermined time or on an occurrence of a predetermined event, via a radio transmission to a remote radio receiver, and
45(h)	wherein the disposable module has a mechanical and electrical coupling to the communication-computation module,

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

Id. at cl. 45.

VIII. PROSECUTION HISTORY OF THE '007 PATENT

95. I have reviewed the file history of U.S. Patent Application No. 11/591,619 (the "'619 application") from which the '007 patent issued. I provide below a brief (non-exhaustive) summary of its relevant parts.

96. The '619 application was filed on November 1, 2006. Ex. 1002 (U.S. Patent No. 8,214,007 Prosecution History) at 983.

97. Throughout prosecution of the '619 application, the Examiner made repeated rejections of the elected claims based on substantive prior art grounds, resulting in five rejections before the '007 patent issued. *See id.* at 648-55 (December 12, 2008 Office Action); 585–90 (July 20, 2009 Office Action); 294–301 (March 16, 2010 Office Action); 227–34 (September 13, 2010 Office Action); 160–67 (March 2, 2011 Office Action).

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98. In an attempt to overcome the first four of these rejections, the Patent Owner amended the pending claims to recite that the body worn patient monitoring device: performs an "analysis determining an occurrence of a predetermined physiological event," *id.* at 390 (Response to July 20, 2009 Final Office Action); 358 (Supplemental Response to July 20, 2009 Final Office Action), includes a communication-computation module that is "removable and reusable," *id.* at 270 (Amendment and Response to March 16, 2010 Non-Final Office Action), a radio circuit that communicates "upon determination of the predetermined physiological event," *id.*, and "at least one series current-limiting resistor configured to protect the communication-computation module, the at least one series current-limiting resistor being screened in the form of resistive traces on a flexible substrate," *id.* at 204 (Amendment and Response to September 13, 2010 Non-Final Office Action). These amendments were not sufficient to overcome the prior art before the Examiner. *Id.* at 227 (September 13, 2010 Office Action).

99. In the fifth rejection, the Examiner rejected all pending claims under 35 U.S.C. § 103 over U.S. Patent Publication No. 2005/0245839 ("Stivoric") in view of U.S. Patent Publication No. 2007/0270678 ("Fadem"), U.S. Patent Publication No. 2002/0106709 ("Potts"), U.S. Patent Publication No. 2005/0206518 ("Welch") and U.S. Patent No. 6,623,312 ("Merry"). *Id.* at 160 (March 2, 2011 Final Office Action).

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100. In response, Patent Owner further amended claims 1 and 59 to recite "the at least one series current-limiting resistor being in the form of resistive traces." *Id.* at 134, 145 (Amendment and Response to March 2, 2011 Final Office Action). As support for this amendment, Patent Owner stated that the resistive traces in the claimed invention "replace the bulky power resistors needed by prior art monitors." *Id.* at 147–48 (Amendment and Response to March 2, 2011 Final Office Action) .

101. To distinguish from Merry, Patent Owner argued that Merry's resistors are "actually mounted on the printed circuit board" whereas the amended claims recite resistors "in the form of resistive traces." *Id.* at 148.

102. In addition, the Examiner had cited another prior art patent, U.S. Patent No. 6,539,613 ("Ulmer"), to show that it was "well known in the art to form resistors into a substrate via embedding and depositing said resistor into a substrate." *Id.* at 168 (March 2, 2011 Final Office Action). Without identifying any reason for the distinction, Patent Owner argued that the "resistors disclosed in Ulmer are not in the form of resistive traces" as required by the amended claim language. *Id.* at 148 (Amendment and Response to March 2, 2011 Final Office Action). The applicant's argument is not detailed and, in my opinion, does not clearly explain a distinction between the claim and the prior art.

103. However, in view of the claim amendments, the claims were allowed on March 12, 2012. *Id.* at 24–28 (Notice of Allowability). As the reason for

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allowance, the Examiner stated only that "[t]he closest prior art . . . fails to disclose the claimed invention, neither in combination nor alone, since neither reference discloses a body worn patient monitoring device comprising a disposable module including at least one series current-limiting resistor being in the form of resistive traces." *Id.* at 26–27.

104. The '619 application issued as the '007 patent on July 3, 2012. Ex. 1001.

IX. THE '492 PATENT

A. Overview of the '492 Patent

105. The '492 patent is titled "Body Worn Physiological Sensor Device Having a Disposable Electrode Module." It was filed May 2, 2014. The stated field of art is "physiological monitor[s]" generally and more specifically "body worn physiological monitor[s]." Ex. 1003 at 1:27–28. The disclosure of the '492 patent is substantively identical to that of the earlier filed '007 patent.

B. Summary of the Claims of the '492 Patent

106. Claim 1 of the '492 patent is set forth below with the elements labeled for reference:

Elements Designation	Element
1(pre)	A body-worn patient monitoring device comprising:

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1(a)	a flexible printed circuit layer made from an insulating material and defining a substrate;
1(b)	at least one electrode disposed onto a surface of the substrate;
1(c)	at least one connection pad;
1(d)	at least one electrical trace extending between the at least one connection pad and a conductive surface of the [at] least one electrode,
1(e)	the at least one electrical trace being made at least in part from a resistive material; and
1(f)	an insulating layer covering the flexible printed circuit layer.

Id. at cl. 1.

107. Claim 2 of the ’492 patent depends from claim 1 and further requires “the at least one electrical trace includes a filleted portion formed at the electrode.” *Id.* at cl. 2.

108. Claim 3 of the ’492 patent depends from claim 2 and further requires “at least one battery mounted on the flexible circuit layer.” *Id.* at cl. 3.

109. Claim 4 of the ’492 patent depends from claim 3 and further requires “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.” *Id.* at cl. 4.

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110. Claim 5 of the ’492 patent depends from claim 1 and further requires “an ECG monitor having a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals.” *Id.* at cl. 5.

111. Claim 6 of the ’492 patent depends from claim 1 and further requires “the at least one electrode includes an electrode gel and a conductive surface, thereby creating a half cell.” *Id.* at cl. 6.

112. Claim 7 of the ’492 patent is set forth below with the elements labeled for reference:

Elements Designation	Element
7(pre)	A body-worn patient monitoring device comprising:
7(a)	a disposable electrode portion; and
7(b)	a reusable communication module,
7(c)	the disposable electrode portion comprising a flexible printed circuit layer made from an insulating material and defining a substrate,
7(d)	at least two electrodes being disposed onto a surface of the substrate
7(e)	and electrical traces defined between the at least two electrodes and a connection pad,
7(f)	wherein the reusable communication and computation module comprises a housing containing a processor and a wireless communication unit,

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7(g)	and in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip.

Id. at cl. 7.

113. Claim 8 of the ’492 patent depends from claim 7 and further requires “the electrodes are integrated into the flexible printed circuit layer of the disposable portion of the device.” *Id.* at cl. 8.

114. Claim 11 of the ’492 patent depends from claim 7 and further requires “the electrical traces are screened onto the flexible printed circuit layer.” *Id.* at cl. 11.

115. Claim 12 of the ’492 patent depends from claim 11 and further requires “an insulating layer applied onto the electrical traces.” *Id.* at cl. 12.

116. Claim 13 of the ’492 patent depends from claims 7, 11, and 12 and further requires “the insulating layer is screen printed onto the electrical traces of the flexible printed circuit layer.” *Id.* at cl. 13.

117. Claim 14 of the ’492 patent depends from claim 7 and further requires that “each electrode includes an electrode gel and a conductive surface defining a half cell.” *Id.* at cl. 14.

X. PROSECUTION HISTORY OF THE ’492 PATENT

118. I have reviewed the file history of U.S. Patent Application No. 14/268,666 (the “’666 application”) from which the ’492 patent issued.

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119. The ’666 application was filed on May 2, 2014 and ultimately claims priority to the ’619 application. Ex. 1004 (U.S. Patent No. 8,214,007 Prosecution History) at 57, 61. Facing no substantive prior art rejections over any cited references, the Examiner issued a Notice of Allowance on October 14, 2014, stating that “[t]he closest 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.* at 26 (Notice of Allowability).

120. The ’666 application issued as the ’492 patent on February 24, 2015. Ex. 1003.

XI. THE ’484 PATENT

A. Overview of the ’484 Patent

121. The ’484 patent is titled “Body Worn Physiological Sensor Device Having a Disposable Electrode Module.” It was filed January 13, 2015. The stated field of art is “physiological monitor[s]” generally, and more specifically, “body worn physiological monitor[s].” Ex. 1005 at 1:31–31. The disclosure of the ’484 patent is substantively identical to that of the earlier filed ’007 patent.

B. Summary of the Claims of the ’484 Patent

122. Claim 1 of the ’484 patent is set forth below with the elements labeled for reference:

Elements Designation	Element
1(pre)	A body-worn physiological sensor comprising:
1(a)	a computation-communication module including a housing retaining a processor;
1(b)	a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals,
1(c)	said computation-communication module being attached to the flexible circuit layer;
1(d)	an adhesive covering at least a portion of the flexible circuit layer; and
1(e)	a protective covering that protects the adhesive.

Id. at cl. 1.

123. Claim 2 of the ’484 patent depends from claim 1 and further requires that “the flexible circuit layer has traces of determinable electrical resistance.” *Id.* at cl. 2.

124. Claim 3 of the ’484 patent depends from claim 2 and further requires “the traces on the flexible circuit layer are configured to electrically couple the computation-communication module to the flexible circuit layer, thereby forming a disposable module connector.” *Id.* at cl. 3.

125. Claim 4 of the ’484 patent depends from claim 1 and further requires “the traces on the flexible circuit layer are at least partially covered by a non-removable insulating covering.” *Id.* at cl. 4.

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126. Claim 5 of the ’484 patent depends from claim 1 and further requires that “the flexible circuit layer further comprises a plurality of openings sized to receive electrode gels.” *Id.* at cl. 5.

127. Claim 6 of the ’484 patent depends from claim 1 and further requires “a hard-wired communication cable.” *Id.* at cl. 6.

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128. Claim 7 of the ’484 patent is set forth below with the elements labeled for reference:

Elements Designation	Element
7(pre)	A body-worn patient monitoring device comprising:
7(a)	a disposable electrode portion comprising: a flexible printed circuit layer made from an insulating material and defining a substrate,
7(b)	at least two electrodes being disposed onto a surface of the substrate,
7(c)	electrical traces defined between the at least two electrodes, and
7(d)	a connection pad;
7(e)	a reusable communication module comprising: a housing containing a processor, and
7(f)	a wireless communication unit, and
7(g)	in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip; and
7(h)	a hard-wired communication cable.

Id. at cl. 7.

129. Claim 8 of the ’484 patent depends from claim 7 and further requires that “the electrodes are integrated into the flexible circuit layer of the disposable electrode portion.” *Id.* at cl. 8.

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130. Claim 11 of the ’484 patent depends from claim 7 and further requires that “the electrical traces are screened onto the flexible printed circuit layer.” *Id.* at cl. 11. Claim 12 of the ’484 patent depends from claim 11 and further requires “an insulating layer applied onto the electrical traces.” *Id.* at cl. 12.

131. Claim 15 of the ’484 patent is set forth below with the elements labeled for reference:

Elements Designation	Element
15(pre)	A body-worn physiological sensor comprising:
15(a)	a computation-communication module including a housing retaining a processor;
15(b)	a flexible printed circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals,
15(c)	the computation-communication module being attached to the flexible printed circuit layer;
15(d)	an adhesive covering at least a portion of the flexible printed circuit layer; and
15(e)	a protective covering for the flexible printed circuit layer.

Id. at cl. 15.

132. Claim 16 of the ’484 patent depends from claim 15 and further requires that “the protective covering includes at least one opening for electrode gels.” *Id.* at cl. 16. Claim 17 of the ’484 patent depends from claim 15 and further requires that

"the flexible printed circuit layer includes openings sized to receive electrode gels." *Id.* at 17.

133. Claim 18 of the '484 patent depends from claim 15 and further requires that "the protective covering is non removable and made from an insulating material." *Id.* at cl. 18.

134. Claim 19 of the '484 patent depends from claim 15 and further requires that "the computation communication module is releasably attached to the flexible printed circuit layer." *Id.* at cl. 19.

135. Claim 20 of the '484 patent depends from claim 15 and further requires that "the protective covering covers the adhesive." *Id.* at cl. 20.

XII. PROSECUTION HISTORY OF THE '484 PATENT

136. I have reviewed the file history of U.S. Patent Application No. 14/595,815 (the "'815 application") from which the '484 patent issued.

137. The '815 application was filed on January 13, 2015, and ultimately claims priority to the '619 application. Ex. 1006 (U.S. Patent No. 9,155,484 Prosecution History) at 68.

138. The Examiner rejected claims 7–14 based on the judicially created doctrine of non-statutory double patenting given the claims of the previously issued '484 patent. *Id.* at 65 (March 4, 2015 Non-Final Office Action). Patent Owner filed

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a Terminal Disclaimer to overcome this double patenting rejection. *Id.* at 44, 51 (Amendment and Response to March 4, 2015 Non-Final Office Action).

139. In the same office action, the Examiner also rejected claims 1–6 and 15–20 as filed under pre-AIA 35 U.S.C. § 102(b) as anticipated by U.S. Patent Publication No. 2004/0030258 ("Williams"). *Id.* at 63 (March 4, 2015 Non-Final Office Action). In response, the Patent Owner amended claims 1 and 15 to recite that the computation-communication module "include[es] a housing retaining a processor" and is "attached to the flexible circuit layer." *Id.* at 45 (Amendment and Response to March 4, 2015 Non-Final Office Action). While making that change, the Patent Owner stated that "[s]upport for the foregoing amendment is found in the as filed application; see, at a minimum, Fig. 2, as well as paragraphs [0044], [0049]." *Id.* at 49.

140. On June 10, 2015, the Examiner issued a notice of allowance, stating a reason for allowance that was identical to the reason offered for the '492 patent: "[t]he closest prior art (as cited by [the '666 application]) 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.* at 25 (Corrected Notice of Allowability).

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141. The ’815 application issued as the ’484 patent on October 13, 2015. Ex. 1005.

XIII. THE ’422 PATENT

A. Overview of the ’422 Patent

142. The ’422 patent is titled “Body Worn Physiological Sensor Device Having a Disposable Electrode Module.” It was filed January 26, 2018. The stated field of art is “physiological monitor[s]” generally and more specifically “body worn physiological monitor[s].” Ex. 1007 at 1:44–46. The disclosure of the ’422 patent is substantively identical to that of the earlier filed ’007 patent.

B. Summary of the Claims of the ’422 Patent

143. Claim 1 of the ’422 patent is set forth below with the elements labeled for reference:

Elements Designation	Element
1(pre)	A method for manufacturing a body-worn physiological sensor, the method comprising:
1(a)	providing a disposable substrate made from an insulating material, said substrate comprising:
1(b)	a flexible printed circuit board layer made from the insulating material;
1(c)	at least two electrodes disposed on the disposable substrate; and

1(d)	conductive traces defined between the at least two electrodes;
1(e)	providing a computation-communication module, said module comprising:
1(f)	a housing;
1(g)	a processor disposed in the housing; and
1(h)	attaching the computation-communication module to the disposable substrate.

Id. at cl. 1.

144. Claim 2 of the ’422 patent depends from claim 1 and further requires “providing conductive traces in the flexible circuit layer.” *Id.* at cl. 2.

145. Claim 3 of the ’422 patent depends from claim 2 and further requires that “the conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module.” *Id.* at cl. 3.

146. Claim 4 of the ’422 patent depends from claim 1 and further requires “providing a plurality of openings in the flexible printed circuit board layer, the openings being sized for receiving electrode gels.” *Id.* at cl. 4.

147. Claim 5 of the ’422 patent depends from claim 1 and further requires that “the computation-communication module is releasably attached to the disposable substrate.” *Id.* at cl. 5.

148. Claim 6 of the ’422 patent depends from claim 1 and further requires “providing a radio circuit in the computation-communication module.” *Id.* at cl. 6.

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149. Claim 7 of the ’422 patent depends from claim 3 and further requires “at least partially covering the conductive traces with an insulating covering.” *Id.* at cl. 7.

150. Claim 9 of the ’422 patent depends from claim 1 and further requires “integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate.” *Id.* at cl. 9.

151. Claim 10 of the ’422 patent depends from claims 1 and 3 and further requires “screening the conductive traces onto the flexible printed circuit board layer.” *Id.* at cl. 10.

152. Claim 11 of the ’422 patent depends from claim 9 and further requires that “each electrode includes an electrode gel and a conductive surface defining a half cell.” *Id.* at cl. 11.

153. Claim 12 of the ’422 patent depends from claims 1, 9, and 11 and further requires that “the disposable substrate is crescent shaped and in which the body-worn physiological sensor is worn on the chest of a patient.” *Id.* at cl. 12.

154. Claim 14 of the ’422 patent is set forth below with the elements labeled for reference:

Elements Designation	Element
14(pre)	A body-worn physiological sensor made by the process of:

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14(a)	providing a disposable substrate made from an insulating material, said substrate comprising:
14(b)	a flexible printed circuit board layer made from an insulating material;
14(c)	at least two electrodes disposed on the disposable substrate; and
14(d)	conductive traces defined between the at least two electrodes;
14(e)	providing a computation-communication module, said module comprising:
14(f)	a housing;
14(g)	a processor disposed in the housing; and
14(h)	attaching the computation-communication module to the disposable substrate.

Id. at cl. 14.

155. Claim 15 of the ’422 patent depends from claim 14 and further requires “providing the conductive traces in the flexible printed circuit board layer.” *Id.* at cl. 15.

156. Claim 16 of the ’422 patent depends from claim 15 and further requires “configuring the conductive traces in the flexible printed circuit board layer to electrically couple with the attached computation-communication module.” *Id.* at cl. 16.

157. Clam 17 of the ’422 patent depends from claim 14 and further requires that “the computation-communication module is releasably attached to the disposable substrate.” *Id.* at cl. 17.

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158. Claim 18 of the ’422 patent depends from claim 14 and further requires “providing the computation-communication module with a radio circuit.” *Id.* at cl. 18.

159. Claim 19 of the ’422 patent depends from claim 16 and further requires “at least partially covering the conductive traces with an insulating covering.” *Id.* at cl. 19.

160. Claim 20 of the ’422 patent depends from claim 20 and further requires “integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate.” *Id.* at cl. 20.

XIV. PROSECUTION HISTORY OF THE ’422 PATENT

161. I have reviewed the file history of U.S. Patent Application No. 15/880,712 (the “’712 application”) from which the ’422 patent issued.

162. The ’712 application was filed on January 26, 2018 and ultimately claims priority to the ’619 application. Ex. 1008 (U.S. Patent No. 10,159,422 Prosecution History) at 177.

163. In an office action dated June 29, 2018, the Examiner allowed claims 1–13 and rejected claim 14–20 based on the judicially created doctrine of non-statutory double patenting given the claims of previously issued U.S. Patent No. 9,433,366. *Id.* at 137–38 (June 29, 2018 Non-Final Office Action). Patent Owner

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filed a Terminal Disclaimer to overcome the double-patenting rejection of claims 14–20. *Id.* at 123, 125 (Response to June 29, 2018 Non-Final Office Action).

164. On August 24, 2018, the Examiner issued a Notice of Allowance, stating as the reason for allowability was that the closest prior art "fails to disclose, suggest and/or teach the claimed invention since the reference is silent in regards to a monitoring device having a disposable electrode module comprising a flexible circuit layer an insulating member having an opening on opposing sides of the module, each opening sized to receive an electrode gel, in combination with the other claimed elements" *Id.* at 17 (Notice of Allowability).

165. The '712 application issued as the '422 patent on December 25, 2018. Ex. 1007.

XV. SUMMARY OF PRIOR ART

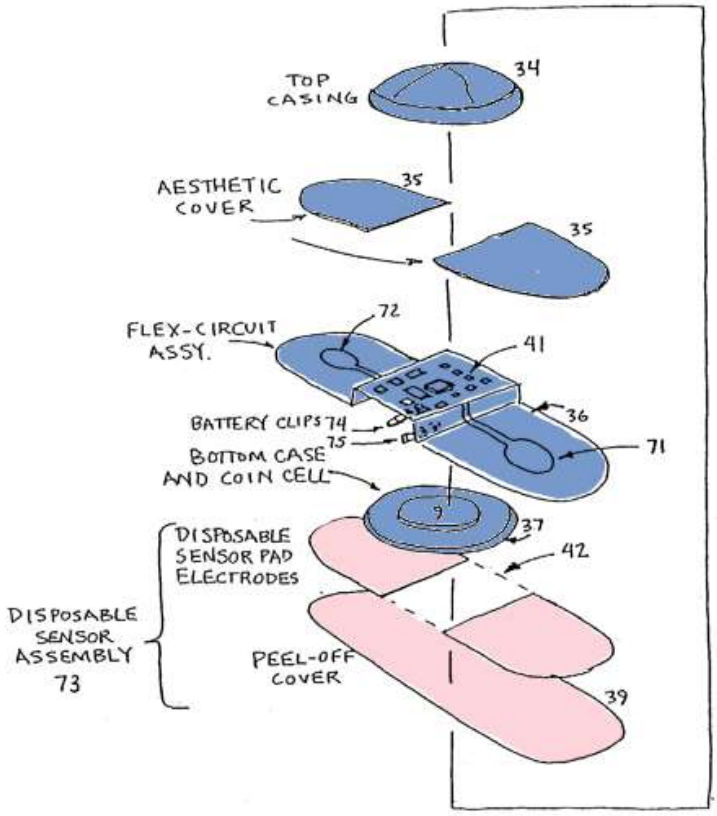
A. Jensen

166. U.S. Patent Publication No. 2003/0149349 to Jensen ("Jensen") (Ex. 1011) (filed December 18, 2002) is a U.S. patent application that published on August 7, 2003, and which claims priority to a December 18, 2001, U.S. provisional patent application. I understand that Jensen is prior art to the Challenged Patents pursuant to 35 U.S.C. § 102(a), (b) and (e).

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167. Like the Challenged Patents, Jensen teaches a body-worn physiological monitor that collects and wirelessly transmits physiological data, such as ECG or heart rate signals. *Id.* at Abstract, [0014], [0029], [0032]–[0033].

168. The body-worn physiological monitor described in Jensen as a "smart patch" includes a "disposable sensor assembly" (73) and a "re-usable (non-disposable) portion" as shown by Figure 5 below. *Id.* at [0042]–[0043].



Id. at Fig. 5 (annotated) (disposable sensor assembly shown in red and the reusable portion shown in blue).

169. The disposable sensor assembly (73) includes: disposable sensor pad electrodes (1 and 2) which can be coated with a conductive adhesive gel, cover tape

(39) used to protect the coated surface of the sensor pads, and connective material (42). *Id.* at [0042].

170. The reusable portion includes a flexible circuit assembly (36), a bottom and top casing (37 and 34, respectively), and two aesthetic covers (35). *Id.* at [0040], [0043].

171. The flexible circuit assembly (36) of the reusable portion contains copper wiring traces that connect the entire circuit (41) to the sensor contacts (71 and 72), as well as to a rechargeable power resource such as a Lithium coin cell (9). *Id.* at [0040]. The Lithium coin cell (9) is attached to the flexible circuit assembly (36) with two small nickel- or gold-plated steel clips (74 and 75). *Id.* at [0043]. Jensen also teaches that the "flexible circuit assembly" (36) includes resistors (24 and 25) and "programmable logic" for "perform[ing] measurement and processing of sensed data." *Id.* at [0014], [0032], [0040], Fig. 2.

172. Jensen also describes a variety of electrical components, such as processors, resistors, and transmitters. For example, Jensen describes that "[t]he resultant signal, at the output of driver 18, may either be input directly to transmitter 7, or may be input into microcontroller 10. Microcontroller 10 runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter 7." *Id.* at [0032]. Microcontroller 10 can be used to process data using one or more signal processing algorithms. One signal processing algorithm

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titled "Beat Reporting" is when a "[m]icrocontroller simply sends transmission that tells of the occurrence of a beat." *Id.* at [0037]. "No data protocol [is] necessary," meaning that this is "[s]imply a transmission to say there was a beat." *Id.* Another signal processing algorithm is titled "Logged Event Reporting" in which the "[m]icrocontroller sends a packet periodically containing a log of all data points since last data transmission." *Id.* Using this algorithm the device can "[s]tore and forward handling yields system efficiencies." *Id.*

173. Jensen also describes that "transmitter 7 may transmit in a variety of modulation and/or keying methods via antenna 8, especially when used in conjunction with microcontroller 10." *Id.* at [0033]. The transmitter may be an "RF transmitter." *Id*.

174. In addition, Jensen teaches that the body-worn monitor may include a piezoelectric respiration sensor (81) with leads (86) that provide the electrical signal output. *Id.* at [0047].

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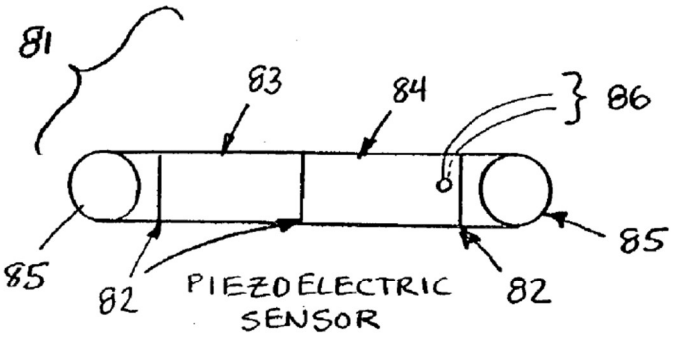


figure 9

Id. at Fig. 9. The sensor (81) is "constructed of insert type rivets or similar fasteners 85 that hold an elastic coupler 83 in tension with a Penwall Corp. Kynar TM piezoelectric strip 84." *Id.* at [0047]. These components of the piezoelectric respiration sensor (81) may be fastened with a suitable adhesive, such as, *e.g.*, epoxy or cyanoacrylate, at glue joints (82). *Id.*

B. Kroll

175. U.S. Patent No. 4,763,660 to Kroll et al. is a United States patent that issued on August 16, 1988. Kroll was filed on March 13, 1987 as a continuation of an application filed December 10, 1985. I understand that Kroll is prior art to the Challenged Patents pursuant to 35 U.S.C. § 102(a), (b), and (e).

176. Kroll discloses a body-worn disposable and flexible electrode assembly like those found in the Challenged Patents, which it described as an "electrode belt" that is used to transfer "electrical signals between predetermined patient body

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locations and the medical therapeutic and diagnostic apparatus." Ex. 1013 at Abstract. The body-worn electrodes described by Kroll may be positioned in a way which would allow for the collection of ECG signals. *Id.* at 10:58–65 (claiming a device in which "contact areas conform with standard pre-cordial positions for 'twelve-lead' electrocardiographic devices"), 14:44–47 (claiming the selection of location of the device so that its positioning "coincide[s] with standard precordial locations for 'twelve-lead' electrocardiographic applications").

177. The body-worn monitor disclosed by Kroll is described as a "flexible and disposable electrode belt" (20), which is shown below in Figure 4:

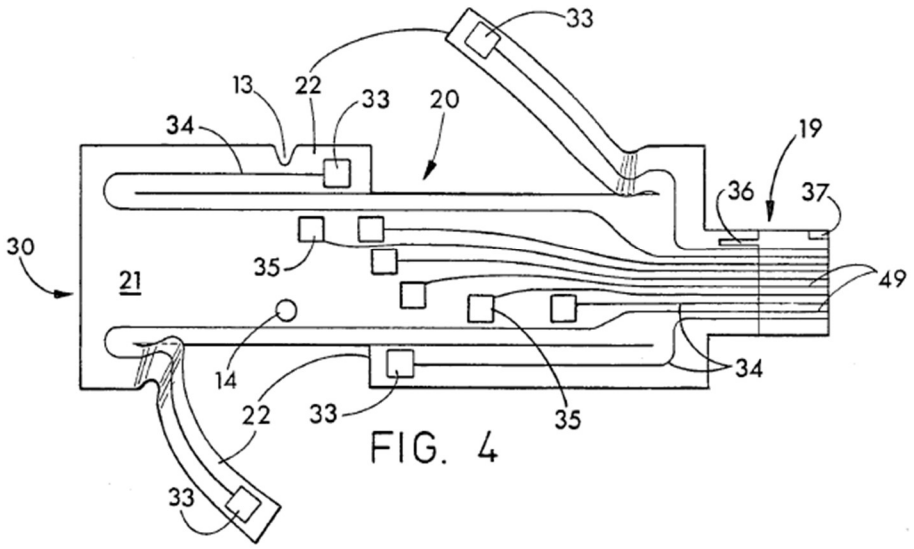


FIG. 4

Id. at Fig. 4. The main body (21) of Kroll's electrode belt has a proximal end (30) and a terminal end (19). *Id.* at 4:48–51. A notch (13) disposed on the top lateral

edges of the device (20) or an aperture (14) are used to properly align the electrode belt on the patient's body. *Id.* at 4:52–58.

178. Both the main body (21) and the adjustable side members (22) of the electrode belt described by Kroll include electrodes (35 and 33, respectively). *Id.* at 4:51–52, 4:67–68. Both the main body electrodes (35) and side member electrodes (33) "transmit and receive electric signals" from the lead strip (34). *Id.* at 5:1–4. Kroll also describes the following:

> The lead strips 34 and electrode portions, discussed below, are 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.

Id. at 5:4-13; *see also id.* at Fig. 4.

179. As shown in Figure 5 below, Kroll teaches that lead strip 34 (current-limiting resistor) extends from and overlaps electrode 35 that includes a matrix 42 composed of a conductive ink compound. *Id.* at 5:17–19, 23–27. "The conductive ink compound used in the matrix lines 42 is ***generally*** the same as that utilized in the lead strips 34," meaning that Kroll discloses that matrix lines 42 and lead strips both can be or cannot be made of the same material. *Id.* at 5:31-33 (emphasis added).

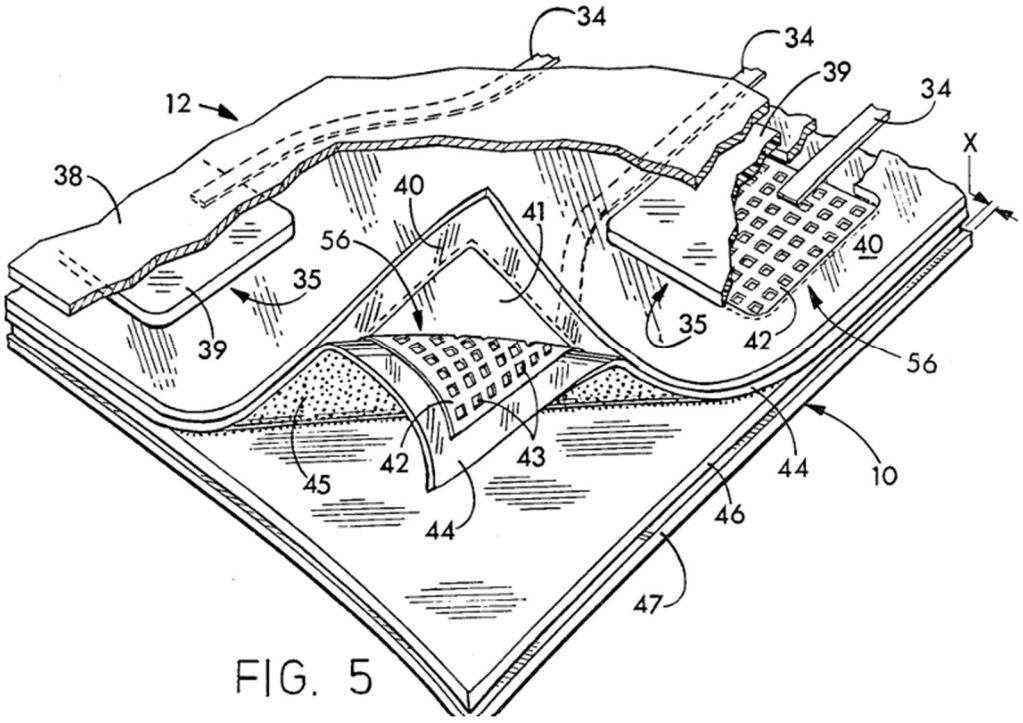


FIG. 5

Id. at Fig. 5. Kroll also teaches that lead strip 34 (current-limiting resistor) is lined with insulation and base support layer 44 and inner patient insulation layer 40. *Id.* at 5:44-50, Fig. 6. Both layers 44 and 40 are made of a polyester laminate which is the same material in the trademarked product Mylar. *Id.*

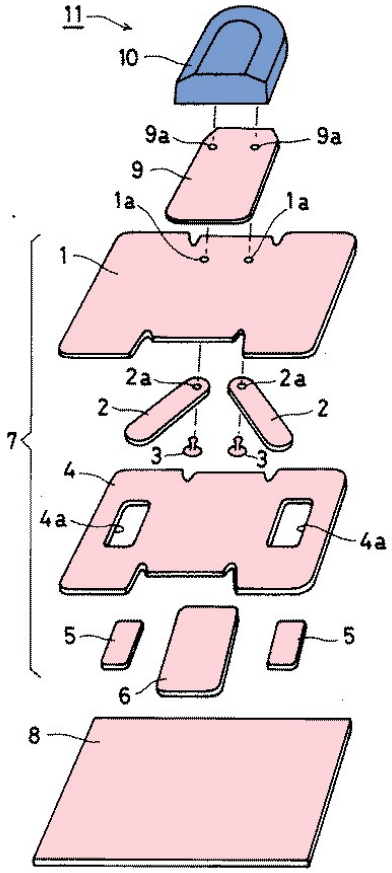
C. Matsumura

180. Japanese Patent Publication No. 2004-121360 to Matsumura ("Matsumura") (Ex. 1012) (filed September 30, 2002) is a Japanese patent application that published on April 22, 2004. I understand that Matsumura is prior art to the Challenged Patents pursuant to 35 U.S.C. § 102(a) and (b).

181. Like the Challenged Patents, Matsumura discloses a body-worn physiological monitor, which it describes as a "bioelectric potential detector having

a waterproof structure." *Id.* at [0001]. The bioelectric potential detector described by Matsumura "can be used as an electrocardiogram detector that is worn on the subject's chest to detect electrocardiogram signals." *Id.* at [0024].

182. Matsumura's bioelectric potential detector (11) includes two components: "a disposable bioelectrode pad for detecting bioelectric potentials, and a reusable signal processor for processing the bioelectric potential signals detected by the bioelectrode pad." *Id.* at [0007]. Figure 1 below indicates the disposable bioelectrode pad (7) (shown in red) and the reusable signal processor (10) (shown in blue):



Id. at Fig. 1 (annotated). The bioelectrode pad (7) and the signal processor (10) "can be easily attached and detached before and after use." *Id.* at [0016].

183. The disposable bioelectrode pad (7) includes: a first sheet (1), a conductive material (2), a hook (3), a second sheet (4), a conductive gel (5) a third sheet (6), double-sided adhesive tape (9), and a release sheet (8) which is removed before the bioelectric potential detector (11) is attached to the patient's skin. *Id.*

184. The first sheet (1) is made out of an insulating material and has an adhesive applied to the back of the sheet. *Id.* at [0017]. At the center of the first sheet (1) are two holes (1a) through which the protruding portions of the hooks (3) are inserted. *Id.* The second sheet (4) is also made out of an insulating material and has an adhesive applied to the back of the sheet. *Id.* at [0018]. The second sheet (4) has two openings (4a) "into which the conductive gel 5 is inserted." *Id.* An optional third sheet (6) may be used to cover the adhesive surface of the second sheet (4).

185. Two pieces of conductive material (2) and two hooks (3) are arranged between the first sheet (1) and the second sheet (4) "to transmit the bioelectric potentials detected by the conductive gel 5." *Id.* at [0019]. Both ends of the rod-shaped pieces of conductive material (2) have two holes (2a). *Id.* The protruding portions of the hook (3) are inserted into the holes (2a) at one end; the holes at the other end are "for contacting the conductive gel 5." *Id.* This configuration allows

the bioelectric potentials detected by the conductive gel (5) to be transmitted through the two pieces of conductive material (2) and the hooks (3). *Id.*

186. The disposable bioelectrode pad (7) also includes an insulating double-sided adhesive tape (9) which is used to fix the bioelectric pad (7) and the signal processor (1). *Id.* at [0024]. The tape (9) includes a hole (9a) through which the hook (3) can be inserted and a release sheet (9b) that is removed so that the reusable signal processor (10) can be attached to the disposable electrode pad (7). *Id.*

D. Ozguz

187. U.S. Patent Publication No. 2005/0096513 to Ozguz ("Ozguz") (Ex. 1014) (filed December 6, 2004) is a U.S. patent application that published on May 5, 2005. I understand that Ozguz is prior art to the Challenged Patents pursuant to 35 U.S.C. § 102(a) and (b).

188. Like the Challenged Patents, Ozguz teaches a "sensor system comprising a thin flexible ambulatory/self contained bio-sensor module in a form similar to an adhesive bandage for sensing physiologically modulated signals from the body." *Id.* at [0003]. The sensor system disclosed by Ozguz may be used to detect and digitize a number of physiological characteristics, including an EKG. *Id.* at [0044].

189. The sensor system (30) described by Ozguz includes a sensor module (10) shown in red below.

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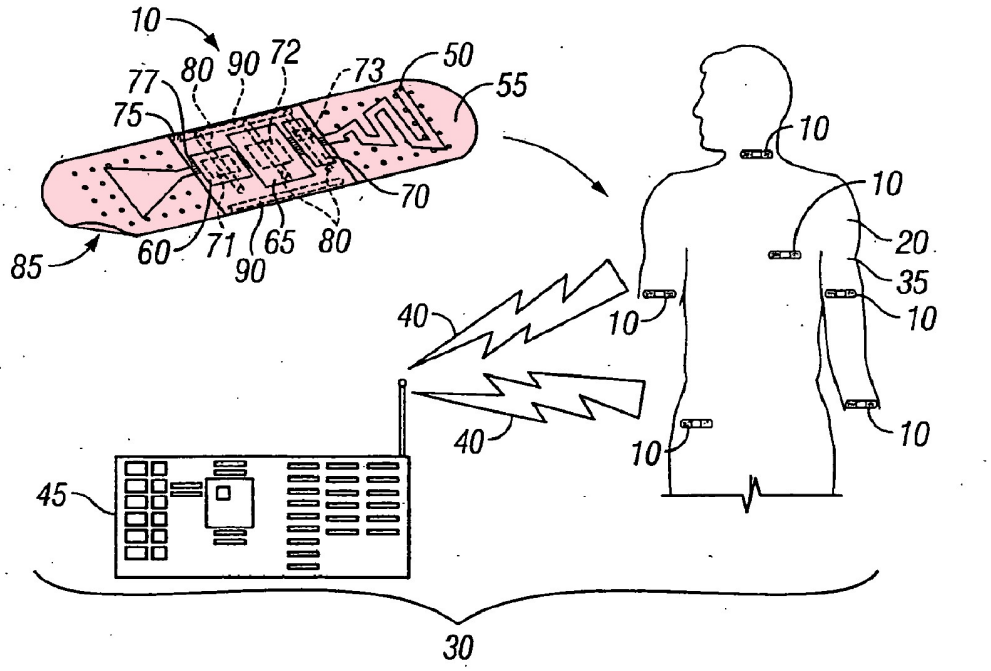


FIG. 2A

Id. at Fig. 2A (annotated). The described system (3) "can incorporate continuous transmission by RF signals 40 to a device 45 having a receiver, data storage, and/or means for analyzing the data." *Id.* at [0039]. To do so, an antenna (50) must be "metalized onto [the] flexible substrate 55 for transmitting and/or receiving RF signals." *Id.*

190. As shown by Figure 3B below, the sensor module (10) of the system (30) includes a flexible substrate (55) and thin flexible silicon substrates (60, 65, 70) which are bonded to the flexible substrate (55) by an anisotropic epoxy layer (75). *Id.* A "flexible, thin battery 105 overlays the silicon substrates 60, 65, 70 and their respective ICs 71, 72, 73." *Id.* at [0048].

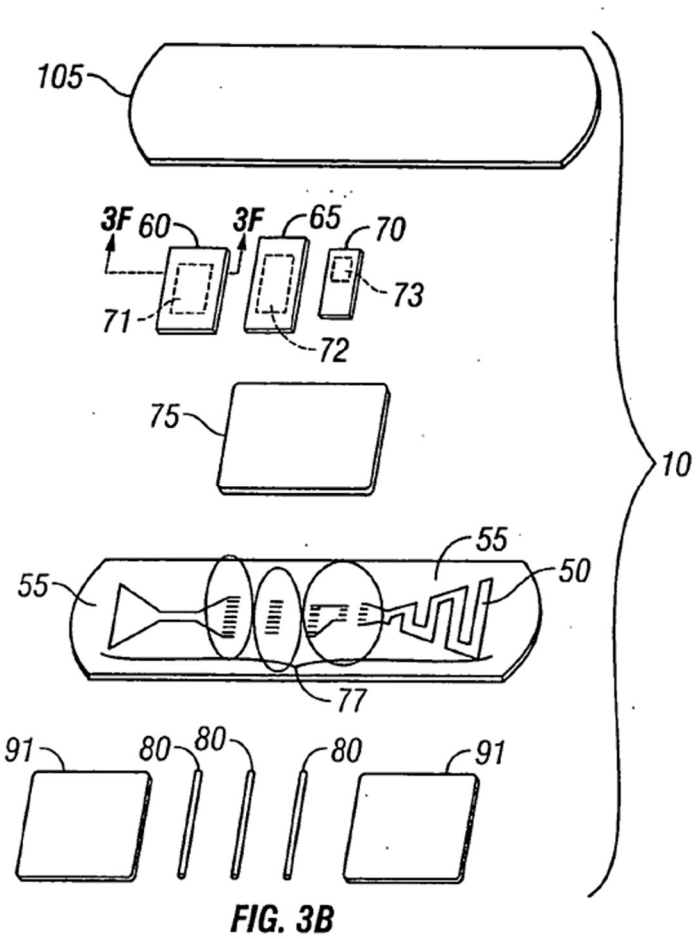


FIG. 3B

Id. at Fig. 3B.

191. Each of the thin flexible silicon substrates (60, 65, 70) include integrated circuits (71, 72, 73). *Id.* at [0039]. "While the silicon substrates 60, 65, 70 are shown separately with separate respective ICs 71, 72, 73, it is to be expressly understood that the ICs 71, 72, 73, can be integrated as one IC on a single silicon substrate." *Id.* at [0042]. The integrated circuits (71, 72, 73) include "a microprocessor 175, a ROM 180 for storing a program to be implemented, a RAM

185 for storing of data, and a transmitter or transceiver 190 for transmitting data by RF signals to a remote receiver." *Id.* at [0058].

192. The metallization (77) is "applied to the flexible substrate 55" and extends both "between the anisotropic layer 75 and the flexible substrate 55" and "to the electrodes 80 disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20." *Id.* at [0039]. The metallization (77) connects the integrated circuits (71, 72, 73) to each other, to the electrodes (80), and to the antenna (50). *Id.* This design "permit[s] flexure about both a longitudinal and a transverse axis, and twisting of the sensor module about a longitudinal axis 120" as shown in annotated Figure 3E below. *Id.* at [0050].

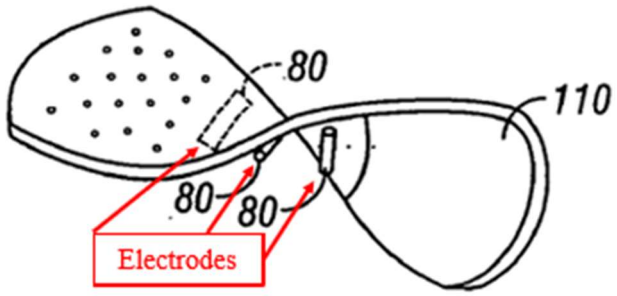


FIG. 3E

Id. at Fig. 3E (annotated).

E. DeLuca

193. U.S. Patent No. 6,238,338 to DeLuca is a U.S. patent that issued on May 29, 2001 and was filed on July 19, 1999. Ex. 1015. I understand that DeLuca is prior art to the Challenged Patents pursuant to 35 U.S.C. § 102 (a), (b) and/or (e).

194. Like the Challenged Patents, DeLuca discloses "a biosignal monitoring system including a plurality of sensors for disposition in predetermined positions on the body of a test subject." *Id.* at 1:33–35. The detector taught by DeLuca includes "contact surfaces shaped and arranged to detect a particular biosignal generated in the body, a sensor transceiver, a sensor antenna, a voltage supply, and a microprocessor." *Id*. at 1:36–40.

195. DeLuca discloses that incoming biosignals are subjected to a "signal conditioning stage 56 which further amplifies and band-pass filters the signal so that it is of suitable voltage range and bandwidth for conversion [by] the A/D converter 57." *Id.* at 4:66–5:2. The signal conditioning process (56) takes place on the "microprocessor chip 35 having an Application Specific Integrated Circuit (ASIC) portion 36," *id.* at 3:36–37, as noted by Figure 5 below.

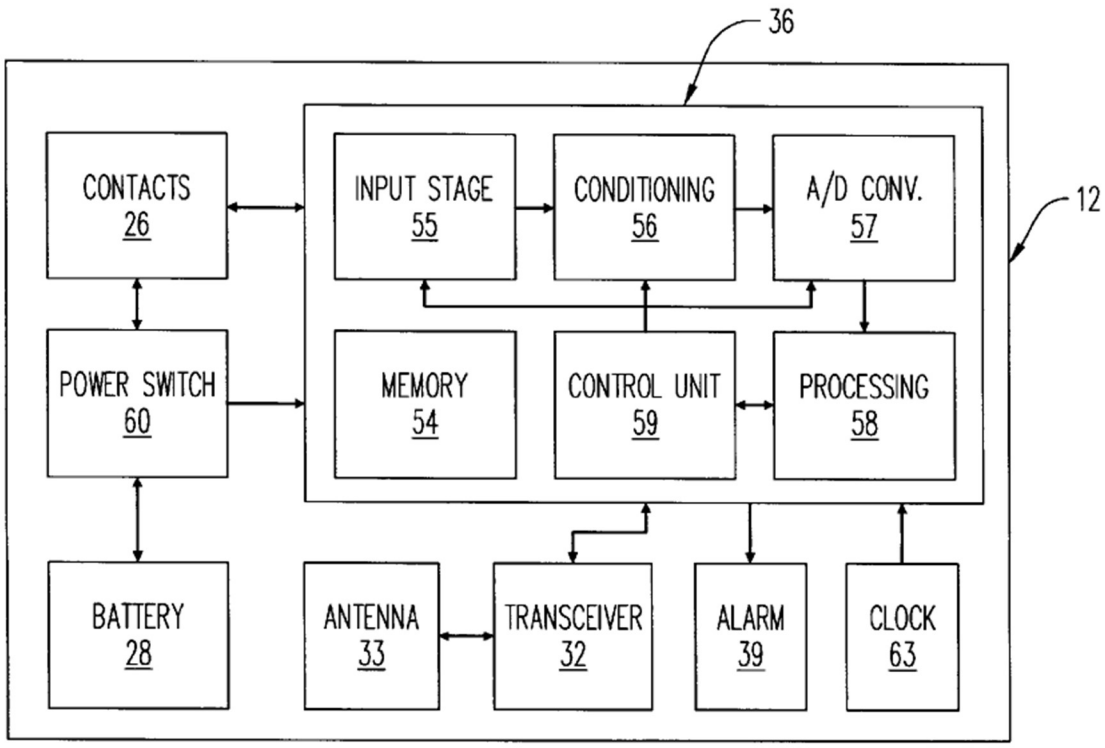


FIG. 5

Id. at Fig. 5.

196. DeLuca teaches that the "signal conditioning stage" "includes a hi-pass filter 56*a*, an amplifier 56*b*, a lo-pass filter 56*c*, and an anti-aliasing filter 56*d*." *Id.* at 5:1–4. "Each of the filter modules 56*a*, 56*c* and 56*d* is a switched-capacitor filter circuit whose cut-off frequency is determined by the clock frequency at which the filter is switched." *Id.* at 5:4–7.

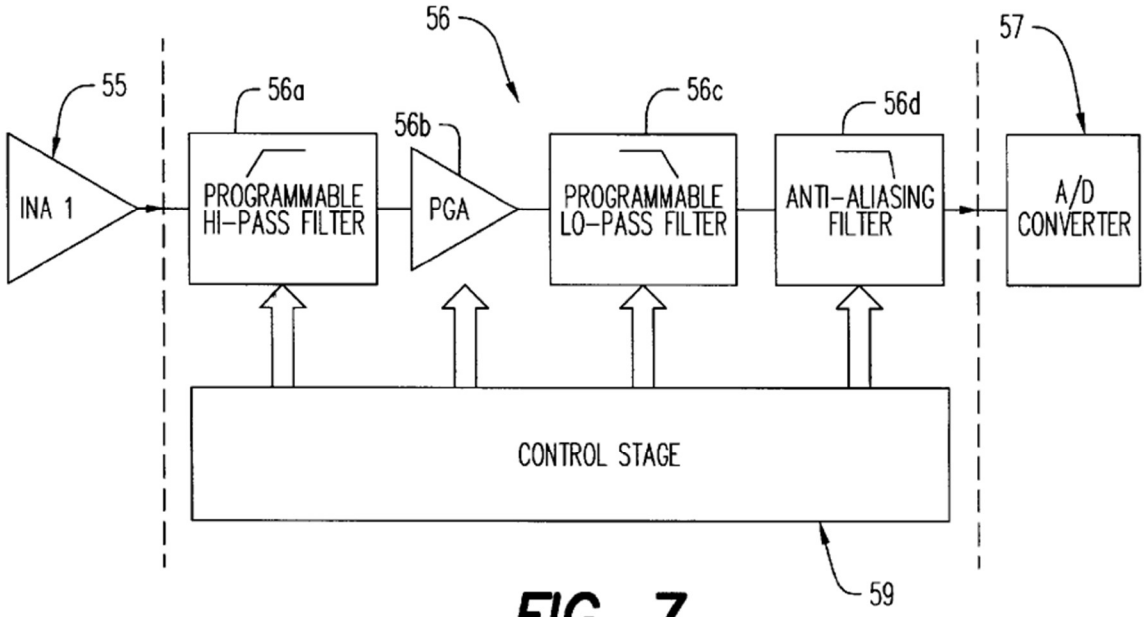


FIG. 7

Id. at Fig. 7. In the signal conditioning stage 56, "[t]he signal output from the input stage 55 is first coupled to the hi-pass filter 56*a* which removes any DC component present in the signal before amplification." *Id.* at 5:9–12.

197. DeLuca specifically teaches that "[t]he gain and band-pass filters cut-off frequency parameters can be externally programmed via the communications link 16 established with the Control Stage section 59 of the ASIC 36. Because of the wide selection range of these [gain and band-pass filters' cut -off frequency] parameters, the gain and bandwidth of any biosignal can be optimized for a given application." *Id*. at 5:43–48.

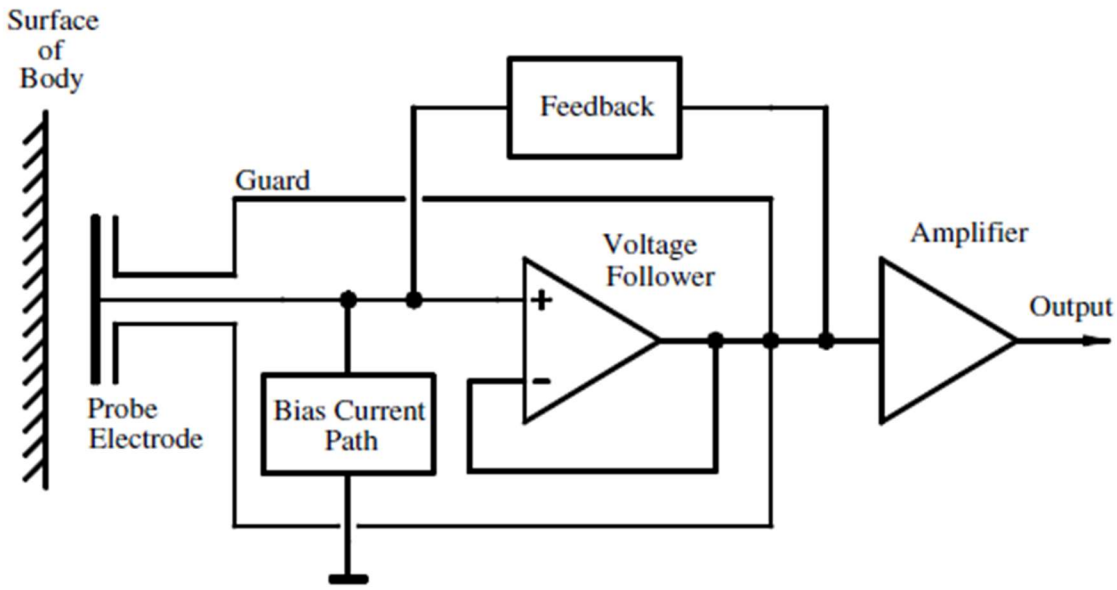
F. Harland

198. The article "Electric potential probes—new directions in the remote sensing of the human body" ("Harland") was published by C.J. Harland, T.D. Clark, and R.J. Prance in the Journal *Measurement Science and Technology* in 2002. Ex. 1016 (C.J. Harland et al., *Electric potential probes—new directions in the remote sensing of the human body,* 13 J. Meas. Sci. Technol. 163, (2002)). I understand that Harland is prior art to the Challenged Patents pursuant to 35 U.S.C. § 102 (b).

199. Harland discusses the development and use of "a new class of sensor—the ultra-high impedance electric potential sensor"—which can be used as an "alternative" to "traditional contact electrodes (for ECGs and EEGs)." *Id.* at 164. Harland's ultra-high impedance electric potential sensors "allow the remote (non-contact) detection of electric potentials generated by currents flowing in the body." *Id*.

200. A "[b]lock diagram of a typical electric potential sensor showing the probe electrode and the feedback, guard and input bias circuits of the electrometer amplifier" is shown below in Figure 1. *Id.* at 165.

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Id. at Fig. 1.

201. The electric potential sensor shown above in Figure 1 is "in the remote off-body mode of operation with no electrical contact to the body." *Id.* at 165. According to Harland, in this "remote, off-body detection" operation, these electrodes "form capacitive coupling to the body under measurement." *Id*. at 164; *see also id.* at Fig. 1.

G. Thompson

202. U.S. Patent No. 6,223,080 to Thompson ("Thompson") (Ex. 1017) (issued April 24, 2001) was filed on October 28, 1998. I understand that Thompson is prior art to the Challenged Patents pursuant to 35 U.S.C. § 102 (a), (b) and/or (e).

203. Thompson discloses "solutions to one or more problems existing in the prior art respecting circuitry design having lower power consumption, particularly

with respect to implantable medical devices," such as pacemakers. *Id.* at 3:33–37. Specifically, Thompson's invention relates to "the use of multiple digital signal processors in [ ] circuit designs to reduce power consumption." *Id*. at 1:20–23.

204. Thompson discloses a processor that operates in a "high speed processing mode" "[o]nly during [the] QRS complex" of the cardiac cycle. *Id.* at 18:3–5. "During the remainder of the cardiac cycle the [waveform] processor" disclosed by Thompson "may be 'idling along' at a much lower clock frequency." *Id.* at 18:5–7. Thompson notes that the idling of the processor during some interval of the heartbeat allows the supply voltage level to be reduced, meaning "the objective of reduced power consumption is realized." *Id*. at 18:13–14.

XVI. THE CHALLENGED CLAIMS OF THE '007 PATENT ARE UNPATENTABLE OVER JENSEN AND THE PRIOR ART

205. In my opinion, claims 1, 2, 4–8, 10–15, 29, 31, 37, 38, and 43–45 of the '007 patent are obvious under pre-AIA § 103 over Jensen, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art.

206. In my opinion, claims 32–35 of the '007 patent are obvious under pre-AIA § 103 over Jensen, Kroll, DeLuca, and General Knowledge of a Person of Ordinary Skill in the Art.

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207. In my opinion, claims 2 and 3 of the '007 patent are obvious under pre-AIA § 103 over Jensen, Kroll, Harland, and General Knowledge of a Person of Ordinary Skill in the Art.

208. In my opinion, claim 39 of the '007 patent is obvious under pre-AIA § 103 over Jensen, Kroll, Thompson, and General Knowledge of a Person of Ordinary Skill in the Art.

A. Jensen Ground 1: Obvious Over Jensen, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art

1. A POSA would have been motivated to combine Jensen and Kroll

209. A POSA would have found it obvious to combine the devices and methods of Jensen with Kroll's teaching of "resistive traces" or "resistive leads."

210. Jensen and Kroll disclose flexible, body-worn devices used to collect and monitor a patient's physiological data, including ECG data. Ex. 1011 at Abstract, [0013]–[0014], [0029]–[0030]; Ex. 1013 at Abstract, 1:11–15, 1:37–45, 1:59–61, 2:41–47.

211. A POSA developing a flexible, body-worn device for monitoring ECG data at this time would have understood the benefits of limiting the current the device could transmit. *See* Section IV.E–F, *supra*. As discussed above, resistive materials which limit the current transmitted would function to limit current in either direction (*i.e.*, either towards or away from the patient's body) and thus would protect both

the patient and the device, depending on the source of the excess electrical current. *See* Section IV.F, *supra*.

212. Kroll describes and teaches a solution to the known risk of electrical overload. Specifically, Kroll teaches incorporating electrical lead strips of a known resistivity to limit the current transmitted between the worn device and the patient, thereby preventing excess current from being transmitted between the device and the patient. Ex. 1013 at 5:1–13. Although Kroll discusses this solution in the context of protecting a patient from electrical "shock" caused by the worn device or a "complementary medical device," a POSA would have understood that it would be advantageous to limit the current transmitted in *either* direction (either toward the body to protect the patient or away from the body to protect the device). *See* Sections IV.E–F, *supra*. Moreover, a POSA would have understood that using a resistive material to limit the current transmitted in one direction (*i.e.*, toward the body, protecting the patient) would also limit the current transmitted in the other direction (*i.e.*, toward the device, protecting the device) depending on the source of the excess current. *Id.* Thus, Kroll's resistive lead strips would protect both the patient and the sensitive electronics inside the device from shock, such as that caused by a defibrillator.

213. Accordingly, a POSA would have understood that the resistive lead strips or traces of Kroll would both (1) protect patients from shock and (2) protect

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the sensitive electronics inside the device from shock caused by a defibrillator. *See, e.g.*, Ex. 1018 at 1:19–27; *see also* Sections IV.C, IV.E, *supra*.

214. These same considerations taught in Kroll apply to Jensen, which also discloses a wearable monitor; that is, a POSA driven by a desire to protect patients from potential shock and to ensure the long-term viability of Jensen's reusable module against potential defibrillation would have been motivated to incorporate Kroll's teaching of resistive "lead strips" into Jensen's device.

215. In addition, a POSA developing a flexible, body-worn device at this time would have sought to reduce the size of the device to increase the commercial and clinical viability of the device. *See* Section IV.B., *supra*. Reducing the size of the wearable devices serves two purposes: reduce the costs of monitors and improve their wearability. *See* Ex. 1044 (Bruce R. Bowman & Edward Schuck, "*Medical Instruments and Devices Used in the Home*," CRC Press LLC (2000)) at 87.2 ("Convenience for the user is also extremely important in encouraging use of a device. Applications that require devices to be portable must certainly be light enough to be carried.").

216. Jensen specifically expressed a desire for its device to be thin. Ex. 1011 at [0030] ("It is intended . . . that the present invention act as a totally self-contained sensor 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, with self-adhesive pads and sensor materials

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on the skin-contact side of the invention."). Modifying Jensen to include Kroll's resistive lead strips formed with ink deposits ink (rather than the larger, conventional resistors on Jensen's circuit assembly) would further Jensen's stated goal of reducing the size of the device.

217. Further, a POSA would have had a reasonable expectation of success in implementing Kroll's resistive leads on Jensen's device without undue experimentation. A POSA would have expected combining Kroll's teaching of resistive traces/leads with Jensen's device (to produce the intended current-limiting effect) to involve only a minimal modification of Jensen's design. Specifically, only a minimal modification to the method and materials used to form electrical traces. It would have been conventional that Jensen would consider printed electronic inks for the amalgam, the insulators, the solder, the solder masking, or for the circuit markings typically found on printed circuits. *See, e.g.*, Ex. 1035 at 3 (noting screen printing had been used to "print[] silver paste conductors and graphite resistors" onto substrates since the end of World War II). Materials such as silver and carbon are typically printed because of cost and/or difficulty in patterning using methods like photolithography. *See id.* at 287 ("The [screen printing] technique is particularly adopted for low cost print and etch plated printed board"). Further, the flexible circuit assembly of Jensen's device would easily be adjusted for the disclosed resistance of Kroll's traces to ensure the traces produce the intended current-limiting

effect. Kroll states that the stated resistance of approximately 1000 ohms "allows for signals transmission throughout the lead strip 34 and also ***provid[es] the above-mentioned current limiter qualities*** as is preferred for this invention." Ex. 1013 at 5:13–17 (emphasis added). This modification would not only produce a functional device, but it would also further Jensen's stated goals. *See* Ex. 1035 at 2 (noting one advantage of using a printed circuit board is that "[t]he size of component assembly is reduced with a corresponding decrease in weight"). Nothing in the art suggests otherwise. Additionally, this change could be easily implemented using the conventionally known and widely used technique of screen-printing. *See* Section IV.C., *supra.*

2. Independent Claim 1

218. In my opinion, claim 1 of the '007 patent is rendered obvious by Jensen in combination with Kroll.

i. Preamble 1[pre]

219. The preamble of claim 1 recites "[a] body worn patient monitoring device comprising."

220. In my opinion, to the extent that the preamble is limiting, Jensen discloses the preamble of claim 1 of the '007 patent.

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221. Jensen discloses a "self-contained, self-attached" device (referred to as a "'smart bandage' or 'smart patch'") capable of measuring physiological signals including ECG or EKG. Ex. 1011 at [0012]–[0013]; *see also id.* at Fig. 5.

> It is the function of the present invention to either a) electrically detect the occurrence of R events in the QRS complex of the EKG signal, and/or b) continuously sample the EKG signal, perform signal processing and calculation upon the data contained within those signals, and provide a transmitted data signal for reception by any variety of different receivers. According to this invention, these components are incorporated into a self-contained assembly that adhesively mounts to the torso of a person or mammal.

Id. at [0029].

222. Demonstrating the compatibility of their teachings, Kroll also discloses "a body-worn patient monitoring device" capable of measuring physiological signals, such as ECG or EKG signals:

> This invention relates to a device and method for receiving and transmitting electrical signals to and from a patient. Particularly, this invention relates to a disposable, flexible and layered electrode belt, also referred to as a "belt", for placement and use on the body of a patient and also for use with medical diagnostic and therapeutic devices.

Ex. 1013 at 1:9–15. Thus, in my opinion, both Jensen and Kroll disclose a body worn patient monitoring device.

ii. Limitation [1a]

223. Limitation [1a] of the '007 patent recites "a disposable module including a plurality of electrical connections."

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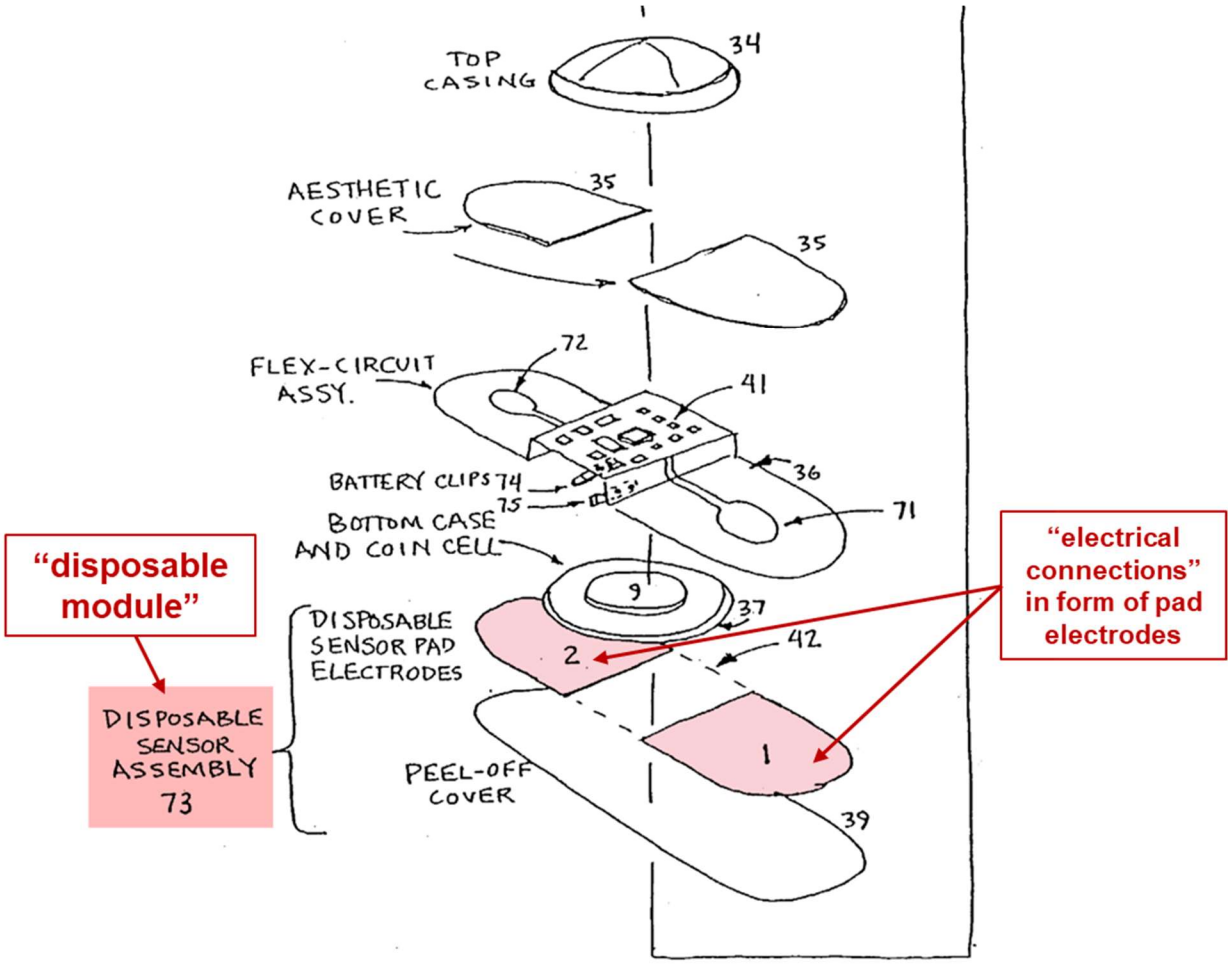
224. In my opinion, Jensen discloses limitation [1a] of the '007 patent.

225. The device disclosed by Jensen includes a disposable module, referred to as the "disposable sensor assembly 73," which includes "disposable sensor pads," labeled 1 and 2, respectively. Ex. 1011 at [0041]–[0042], Fig. 5. Jensen teaches that the "disposable sensor pads," are coated with "a conductive adhesive on the circuit side [*i.e.*, the side contacting flexible circuit assembly 36] and a conductive adhesive-gel that is made using a silver amalgam as found in off-the-shelf EKG sensor pads." *Id.* at [0041]. A silver amalgam, as being taught by Jensen, is a mixture of silver and some other material and, in the case of electrodes used in wearable devices and flexible circuits, is conventionally a screen printed layer of an ink or paste made of silver particles along with a binder material such as acrylic or vinyl that holds the silver particles together and to the substrate on which the amalgam is printed on. Ex. 1035 at 495 ("Composition of Solder Pastes").

226. As shown in Figure 5 below, Jensen teaches that disposable sensor pads 1 and 2 make electrical contact with sensor contacts 71, 72 of flexible circuit assembly 36 through the "conductive adhesive on the circuit side." Ex. 1011 at [0040]–[0041], Fig. 5.

227. Also as shown in Figure 5 below, Jensen teaches that disposable sensor pads 1 and 2 make electrical contact with a patient's skin through the "conductive adhesive-gel" found on the skin side. *Id.* at [0041], Fig. 5.

228. Because of the conductive material coating both sides of the disposable sensor pads, the electricity from the sensor contacts 71, 72 creates an electrical connection with the disposable sensor pads 1, 2 and the patient's skin. *Id.*; *see also id.* at [0042].



Id. at Fig. 5 (annotated).

229. Specifically, electrical connections are formed at each of the disposable sensor pads 1 and 2 so that the skin resistance between the two sensor pads can be measured. This is disclosed by Jensen, which recites:

> [H]eart-rate signals are collected from left and right sensor pads, 1 & 2. The signal from pad 2 is connected to the circuit ground, while the signal from pad 1 provides EKG signal input to a high gain amplifier 4 and acts as a triggering load for power-on detect circuit 3 *once skin resistance* is measured *across the sensors.* Logic driver 29, when enabled, supplies a switched supply voltage to disable and enable the operation of amplifier circuit section 4, filter circuit section 5 and data-slicer circuit section 6. With the use of switched supply voltage driver 29, power from the system power source 9 is conserved *whenever the sensors 1, 2 are* ***not*** *in contact with the user's skin.*

Id. at [0031] (emphases added); *see also id.* at [0036], Figs. 1–3. Thus, Jensen describes a "disposable module," *i.e.*, the disposable sensor assembly 73 that includes "a plurality of electrical connections" in the form of disposable sensor pads 1, 2.

230. A POSA would understand that Jensen's disposable sensor pads form a plurality of electrical connections between the skin surface, at which the electrical potential is detected, and the flexible circuit assembly. Specifically, a POSA would recognize that a disposable electrode pad fundamentally comprises a plurality of electrical connections insofar as it must form an electrical connection with the patient's skin and must form an electrical connection with another component of a monitoring device to allow signal recording/processing. This technique—determining the electrical activity of the heart by measuring skin resistance between electrodes and transferring those signals—is a fundamental principle of ECG. *See* Section IV.A., *supra*. A POSA would recognize Jensen's body worn monitor—which includes disposable sensor pads that form electrical connections with the

patient's skin and with the flexible circuit assembly—as comprising "a plurality of electrical connections." *See* Section IV.A., *supra*. Thus, in my opinion, Jensen discloses "a disposable module including a plurality of electrical connections."

iii. Limitation [1b]

231. Limitation [1b] of the '007 patent recites "said electrical connections adapted to be couplable to a skin surface to measure physiological signals."

232. In my opinion, Jensen discloses limitation [1b] of the '007 patent.

233. As discussed above with respect to Element [1a], Jensen's device includes a plurality of electrical connections made using the disposable sensor pad electrodes 1, 2 which are used to measure the skin resistance between the two sensor pads. Ex. 1011 at [0041]–[0042], Fig. 5; *see also* Section XVI.A.2.ii, *supra.* As discussed above, electrodes must be on the patient's skin to obtain an ECG reading and, therefore, the "electrical connections" of Jensen's device (*i.e.*, sensor pads 1 and 2) are "adapted to be couplable to a skin surface to measure physiological signals." *See* Sections IV.A, XVI.A.2.ii, *supra*.

234. Jensen explicitly teaches that the disclosed device is "applied to the skin much like a bandage, with self-adhesive pads and sensor materials on the skin-contact side of the invention." Ex. 1011 at [0030]. Jensen also notes that a "[heart rate monitoring] chest band only functions when ***good electrical contact is established to the skin***." *Id.* at [0007] (emphasis added); *see also id.* at [0005]. A

POSA reading this disclosure would understand that the Jensen's sensor pads, which are both adhesive and conductive, are couplable to a skin surface to measure physiological signals (such as EKG signals) because they are both electrically and physically coupled to the patient's skin.

235. Thus, in my opinion, Jensen discloses "said electrical connections adapted to be couplable to a skin surface to measure physiological signals."

iv. Limitation [1c]

236. Limitation [1c] of the '007 patent recites "at least one of said electrical connections comprising a half cell."

237. In my opinion, Jensen discloses limitation [1c] of the '007 patent. The '007 patent explains that "[i]n conventional terms of art," the term "half cell" refers to "the combination of electrode and electrolyte," and that the term "electrode" is used interchangeably with "half cell" within the disclosure. Ex. 1001 at 6:48–55. The '007 patent further states that an electrode—*i.e.*, a half cell—typically comprises (1) a conductive surface and (2) an electrode gel. *Id.* at 6:55–57.

238. Jensen discloses a "half cell." As discussed above, Jensen's sensor pads 1, 2 form electrical connections with the patient's skin. Further, the sensor pads 1, 2 are coated with a "***conductive*** adhesive-***gel*** that is made using a [commercially available] silver amalgam as found in off-the-shelf EKG sensor pads, such as those sold by 3M Corporation." Ex. 1011 at [0041] (emphases added); *see, e.g.*, Ex. 1035

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at 495 ("Composition of Solder Pastes"). Thus, in my opinion, Jensen discloses a "half cell" as defined by the '007 patent.

239. Moreover, a POSA would understand from Jensen's disclosure that the sensor pads form electrical connections comprising half cells at the point of contact with the patient's skin. As explained above in Section IV.D., disposable electrodes comprising (1) a conductive surface and (2) an electrode gel were well known in the art. *See* Section IV.D., *supra.* Indeed, these well-known and widely commercially available electrodes often included "conductive adhesive-gel that is made using a silver amalgam." *Cf.* Ex. 1011 at [0041]. A POSA would therefore understand that Jensen's sensor pads form a plurality of electrical connections comprising half cells at the point of contact with the patient's skin, as it is described in the '007 patent. *Cf.* Ex. 1001 at 6:48–57.

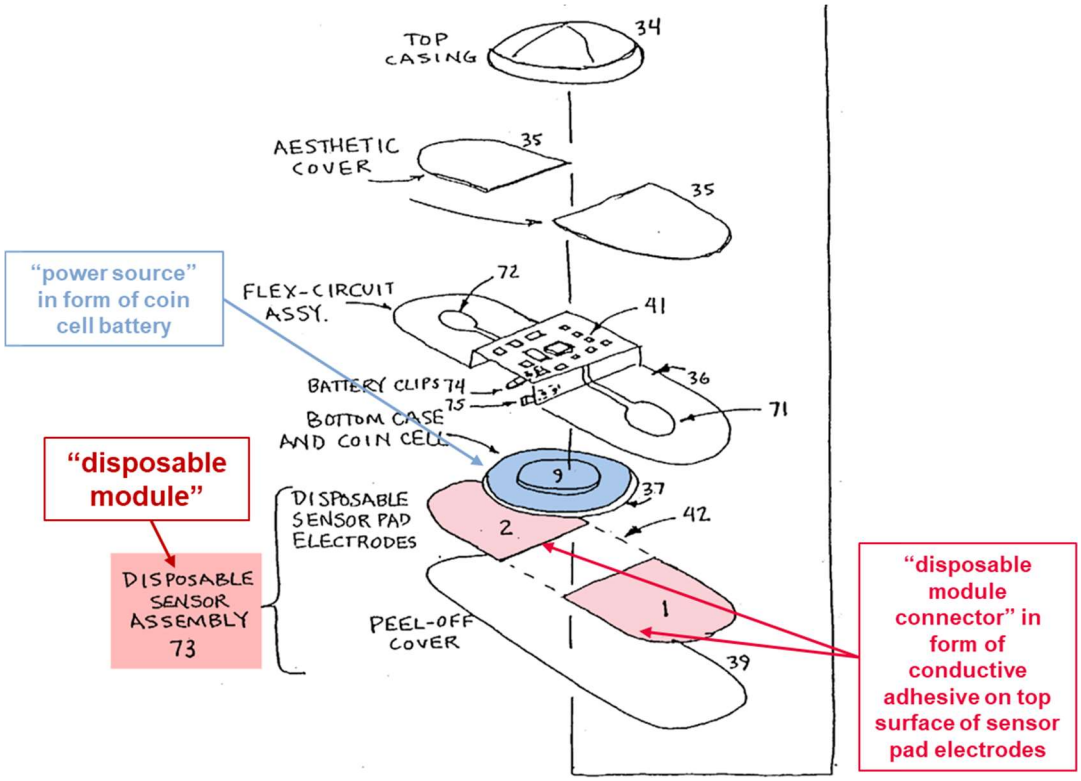
240. Thus, in my opinion, Jensen discloses that "at least one of said electrical connections comprising a half cell."

v. Limitation [1d]

241. Limitation [1d] of the '007 patent recites "the disposable module including a disposable module connector."

242. In my opinion, Jensen discloses limitation [1d] of the '007 patent. Jensen discloses a "disposable module connector" in the form of the conductive

adhesive which coats the circuit side of the disposable sensor pads. Ex. 1011 at [0041].



Id. at Fig. 5 (annotated).

243. Jensen's device is comprised of both a "disposable sensor assembly" and a reusable "flexible circuit assembly." *Id.* at [0040]–[0043]. To assemble the complete device, the reusable flexible circuit assembly "has a location on the bottom side for the disposable sensor assembly 73 to be applied." *Id.* at [0043]. That application is achieved through the "conductive adhesive" on the top surface of sensor pads 1 and 2.

244. A POSA would understand that the conductive adhesive coating on the circuit side of the sensor pads adheres to the location on the bottom side of the reusable flexible circuit assembly in order to connect the disposable sensor pads to the reusable flexible circuit assembly. Thus, in my opinion, Jensen discloses "the disposable module including a disposable module connector."

vi. Limitation [1e]

245. Limitation [1e] of the '007 patent recites "a power source to power the body worn patient monitoring device."

246. In my opinion, Jensen discloses limitation [1e] of the '007 patent. Jensen discloses "a power source to power the body worn patient monitoring device" in the form of a battery. Jensen discloses that the disclosed device "contains all necessary electronic circuitry, including [ ] a battery or other power source." *Id.* at [0014]. Specifically, Jensen discloses that the device's power source could be any of a "lithium coin cell 9" or a "rechargeable type of power source, or a solar cell." *Id.* at [0040]. A POSA would understand any of these contemplated options to be a "power source" to power Jensen's device. Thus, in my opinion, Jensen discloses "a power source to power the body worn patient monitoring device."

vii. Limitation [1f]

247. Limitation [1f] of the '007 patent recites "a communication-computation module being removable and reusable."

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248. In my opinion, Jensen discloses limitation [1f] of the '007 patent. Jensen's device includes a "transmitter" (used for communication) and a "microcontroller" (used for computation). Ex. 1011 at [0032]–[0033]. Jensen teaches that its microcontroller "runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter." *Id.* at [0032]. Jensen also teaches that its transmitter may transmit "encoded data message[s]" "via antenna." *Id.* at [0033].

249. Jensen teaches that the "electronic circuit" of Jensen includes the transmitter and the microcontroller. *Id.* at [0036], Fig. 3. The electronic circuit is part of a "flexible circuit assembly" containing copper wiring to connect the entire circuit to the sensor contacts and the power source. *Id*. at [0040]. Flexible circuit assembly, which includes the electronic circuit containing the communication-computation module, is part of the "re-usable (non-disposable)" portion of Jensen's device. *Id.* at [0043]. Jensen's re-usable portion is separable and removable from the "disposable sensor assembly" portion. *Id.* at [0042]–[0044].

250. The use of transmitters and microcontrollers to process and transmit collected data would have been well known and understood by a POSA at the time of the purported invention. *See, e.g.,* Ex. 1035 at 88 (noting that "[m]icrocontrollers have been available for a long time"); Ex. 1045 (Bert-Uwe Köhler et al., *The Principles of Software QRS Detection*, IEEE Eng. Med. & Bio. (2002)) at 42 (noting

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that "[t]he rapid development of powerful microcomputers promoted the widespread application of software QRS detection algorithms in cardiological devices"). A POSA reading Jensen's disclosures would readily understand that Jensen's description of a "microcontroller" and a "transmitter" as part of a removable and reusable component of the device would constitute a "communication-computation module being removable and reusable" as claimed by the '007 patent. Thus, in my opinion, Jensen discloses "a communication-computation module being removable and reusable." Therefore, in my opinion, Jensen discloses the claimed "communication-computation module being removable and reusable."

viii. Limitation [1g]

251. Limitation [1g] of the '007 patent recites "having a communication-computation module connector to receive physiological signals from the disposable module via said disposable module connector, the communication-computation module including."

252. In my opinion, Jensen discloses limitation [1g] of the '007 patent. As explained above in section XVI.A.2.v, Jensen discloses a "disposable module connector," *viz.* the top surface of disposable sensor pad electrodes 1 and 2 which are coated in a conductive adhesive.

253. Jensen teaches that "[t]he sensor contacts 71, 72 make . . . contact with sensor pads 1 and 2" in order to receive EKG data. Ex. 1011 at [0041]. Jensen also

teaches that those "disposable sensor pad electrodes . . . are coated with a conductive adhesive on the circuit side and a conductive adhesive gel." *Id.* Thus, the sensor contacts 71, 72 are the "computation-communication module connectors" that receive physiological signals from the disposable module via the disposable module connector. The physiological signals are sent to the transmitter and microcontroller. *Id.* at [0032].

254. In my opinion as a POSA at the time of the invention of the '007 patent, Jensen's sensor contacts 71 and 72 constitute a "communication-computation module connector to receive physiological signals [*i.e.*, electrical impulses] from the disposable module connector [*i.e.*, top surface of sensor pads 1 and 2]." Thus, in my opinion, Jensen discloses "having a communication-computation module connector to receive physiological signals from the disposable module via said disposable module connector."

ix. Limitation [1h]

255. Limitation [1h] of the '007 patent recites "a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals, said analysis determining an occurrence of a predetermined physiological event."

256. In my opinion, Jensen discloses limitation [1h] of the '007 patent. As explained above, Jensen's device includes a microcontroller which performs a

"physiological analysis" on collected data: "The device of the present invention contains all necessary electronic circuitry, including sensors, a battery or other power source, and a microcontroller and/or other programmable logic circuitry that perform measurement and processing of sensed data, where said processed data are subsequently stored internally and/or transmitted to other equipment by wireless means." *Id.* at [0014]. When data is input into the microcontroller, Jensen's device "runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter." *Id.* at [0032]. A POSA would understand from the disclosure of the '007 patent that microcontroller could be the same as a microprocessor or could include a microprocessor. *See, e.g.*, Ex. 1001 at 11:48–50 ("A microprocessor, such as microprocessor 512, is defined herein as synonymous and interchangeable with the terms 'microcomputer', 'microcontroller', and 'microprocessor'").

257. Jensen further teaches the processing of a signal and performing a "mean pulse value" calculation to alert a patient "when a predetermined mean pulse value is achieved." Ex. 1011 at [0011]. The physiological analysis may comprise, for example, detecting "the occurrence of R events in the QRS complex of the EKG signal." *Id.* at [0029]. Jensen states that "***[o]nce*** [the] microcontroller [ ] identifies the data as having a heart beat pulse, (a clearly identifiable waveform with a distinctive shape and a high signal amplitude compared to typical ambient noise

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from the sensor), ***then*** the program analyzes the data in a number of optional ways." *Id.* at [0037] (emphases added). Thus, detection of the R-event is the "predetermined physiological event" that precedes a real-time physiological analysis.

258. For example, Jensen's device has the capability to perform "***conventional*** programmatic signal analysis to create and transmit different data records" including, for example, processing the signal and performing a "[r]olling [a]verage [h]eart-rate" calculation to determine "the rolling average of the heart-rate for the last n beats." *Id.* at [0037], Table 1 (emphasis added). Jensen also discloses notifying patients when the microcontroller determines that a predetermined set value for a certain calculation has been achieved. *See id.* at [0011].

259. Thus, in my opinion, Jensen discloses "a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals, said analysis determining an occurrence of a predetermined physiological event," as claimed by the '007 patent.

x. Limitation [1i]

260. Limitation [1i] of the '007 patent recites "a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event, via a radio transmission to a remote radio receiver."

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261. In my opinion, Jensen discloses limitation [1i] of the '007 patent. As discussed above, Jensen's device includes a microcontroller which performs a "physiological analysis" on collected data based on determination of a predetermined physiological event.

262. Jensen further teaches that the microcontroller can "encode a data stream output to the transmitter" which transmits "in a variety of modulation and/or keying methods via antenna." Ex. 1011 at [0032]–[0033]. Jensen further recites "[d]ata modulation methods in an RF transmitter that are easily implemented." *Id.* at [0033]. A POSA would understand that "RF" means radio frequency, such that the transmitter disclosed by Jensen uses a radio circuit to make the transmission. *Id.* at [0033]–[0034]; Ex. 1023 at [0050].

263. Jensen further discloses the transmission of a result of the physiological analysis (which occurs upon the predetermined physiological event, as explained above) via radio circuit. *Id.* at [0031]–[0035]. Jensen teaches that the transmitter may "transmit in a variety of modulation and/or keying methods via antenna 8, especially when used in conjunction with microcontroller 10, whereby the microcontroller 10 may enable and disable the transmitter carrier, and also send encoded data streams." *Id.* at [0033]. Specifically, for example, the transmitter data may be "composed into an encoded data message and output by the program that

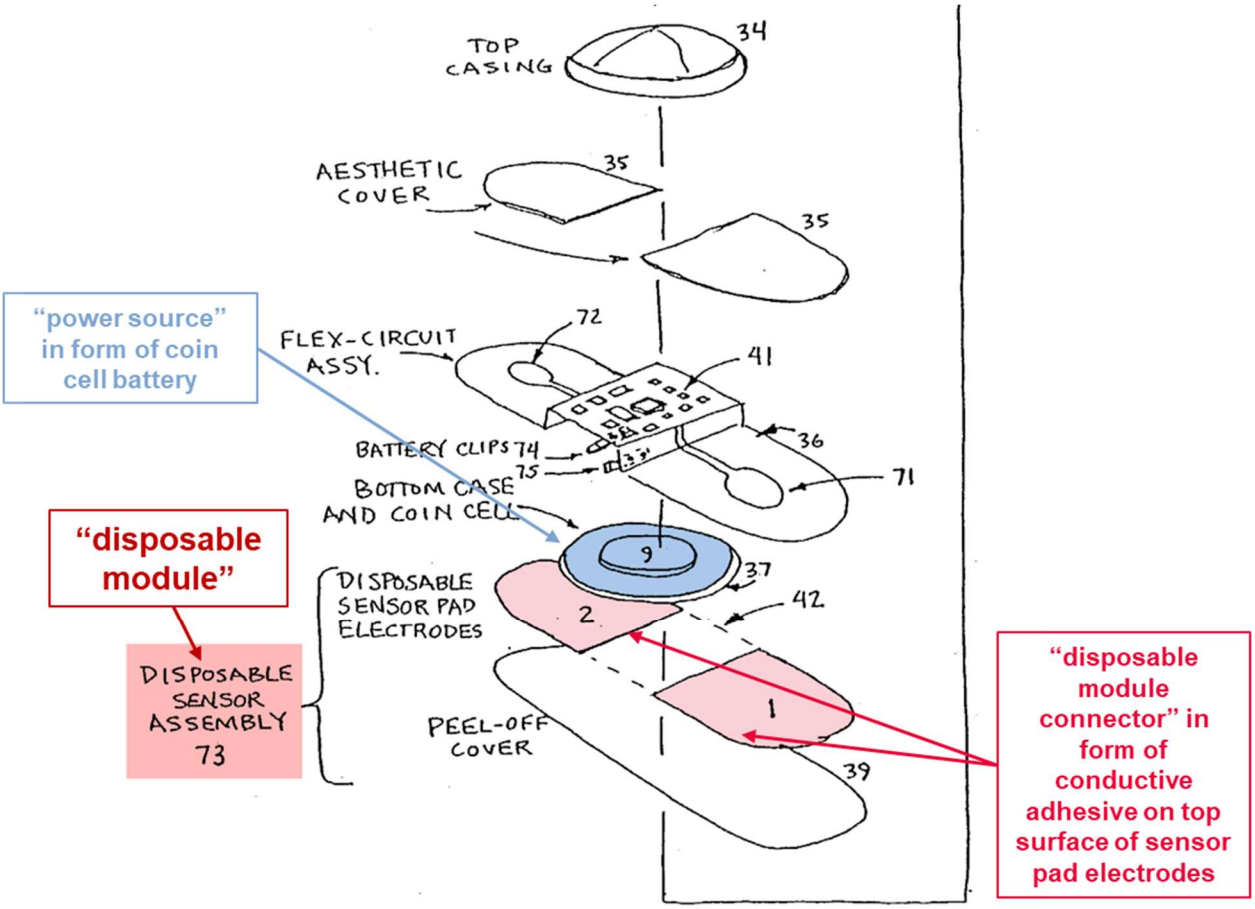
that microcontroller 10 executes." *Id.* In other words, the transmitter may transmit the result of the microcontroller's analysis using a radio frequency. *Id.*

264. Thus, in my opinion, Jensen discloses a "radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event, via a radio transmission to a remote radio receiver."

xi. Limitation [1j]

265. Limitation [1j] of the '007 patent recites "wherein the disposable module is mechanically and electrically coupled directly to the communication-computation module."

266. In my opinion, Jensen discloses limitation [1j] of the '007 patent. As explained above, Jensen teaches a "disposable module connector" in the form of the conductive adhesive which coats the circuit (*i.e.*, top) side of the disposable sensor pads. Ex. 1011 at [0041]; *see also id.* at Fig. 5 (annotated). As further explained above, Jensen teaches a "communication-computation module connector" in the form of sensor contacts 71 and 72, which receive the physiological signals from the disposable module connector. *Id.*



Id. at Fig. 5 (annotated).

267. Jensen's device is comprised of both a "disposable sensor assembly" and a reusable "flexible circuit assembly." *Id.* at [0040]–[0043]. To assemble the complete device, the reusable flexible circuit assembly "has a location on the bottom side for the disposable sensor assembly 73 to be applied." *Id.* at [0043].

268. It is my opinion that a POSA would understand that the conductive adhesive coating on the circuit side of the sensor pads adheres to the location on the bottom side of the reusable flexible circuit. Additionally, a POSA would understand that the function of the conductive adhesive interface with the sensor pads would be

to form a physical (*i.e.*, mechanical) coupling and an electrical (*i.e.*, conductive) coupling between the disposable sensor assembly and the reusable flexible circuit assembly.

269. Thus, in my opinion, Jensen discloses "wherein the disposable module is mechanically and electrically coupled directly to the communication-computation module."

xii. Limitation [1k]

270. Limitation [1k] of the '007 patent recites "and the body worn patient monitoring device including the disposable module and the communication-computation module is adapted to be directly non-permanently affixed to the skin surface of the patient."

271. In my opinion, Jensen discloses limitation [1k] of the '007 patent. As discussed above, Jensen's reusable flexible circuit assembly and disposable sensor assembly are mechanically and electrically coupled. *Supra* Section XVI.A.2.xii.

272. Jensen's disposable module is similarly mechanically and electrically coupled to the patient's skin surface by "a conductive adhesive-gel that is made using a silver amalgam as found in off-the-shelf EKG sensor pads." Ex. 1011 at [0041]. Jensen teaches that, by operation of this conductive adhesive gel, the disposable sensor assembly of the disclosed device is intended to be "applied to the skin much like a bandage, with self-adhesive pads and sensor materials on the skin-contact side

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of the invention." *Id.* at [0030]; *see also id.* at [0031]. In my opinion, a POSA reading Jensen would understand that Jensen discloses "the body worn patient monitoring device including the disposable module and the communication-computation module is adapted to be directly non-permanently affixed to the skin surface of the patient."

273. Jensen further teaches that this element is standard in the art: "Existing art related to the field of this invention require[s] that . . . in the case of standard, clinical EKG hardware, individual sensors be bonded to the skin with adhesive." *Id.* at [0005]. Thus, in my opinion, Jensen discloses that "the body worn patient monitoring device including the disposable module and the communication-computation module is adapted to be directly non-permanently affixed to the skin surface of the patient."

xiii. Limitation [1l]

274. Limitation 1[*l*] of the '007 patent recites "at least one series current-limiting resistor configured to protect the communication-computation module."

275. In my opinion, the combination of Jensen and Kroll, in view of the knowledge of a POSA, renders obvious limitation [1*l*] of the '007 patent. Jensen discloses a communication-computation module and that the flexible circuit assembly of the communication-computation module includes "copper wiring [ ] to

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connect the entire circuit." Ex. 1011 at [0031]–[0033], [0040], [0043]; *supra,* Sections XVI.A.2.vii–ix.

276. Kroll discloses at least one series current-limiting resistor. Kroll's device includes circuits comprising "lead strips" which "transmit and receive electric signals to and from the terminal end [ ] of the belt." Ex. 1013 at 5:1–4. Kroll teaches that these "lead strips" are composed of a preselected "flexible conductive ink compound having a conductive filler having Silver, Aluminum, or compounds thereof, or of a similarly suitable material" where the ink compound is of "a preselected conductivity to provide a certain total lead strip resistance." *Id.* at 5:4–10. Kroll further teaches that the composition of the "lead strips" allows them to serve as "a current limiter to protect a patient from shock due to malfunction of the device [ ] or of a complementary medical device." *Id.* at 5:8–13, 5:31–33.

277. As explained above, it would have been obvious to a POSA to combine Kroll's teaching of resistive traces with the device disclosed by Jensen because Kroll's resistive traces would help to safeguard Jensen's communication-computation module from excess electricity generated in the event of defibrillation. *See* Section XVI.A.1, *supra.* Further, it is my opinion that a POSA would have had a reasonable expectation of success in accomplishing this combination because it would have comprised only a minor design change, requiring only a reconfiguration of the device's amplifier to account for the trace resistance. *Id.*

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278. Furthermore, a POSA seeking to make or use Jensen's device would understand that Kroll's teaching of screen-printed resistive ink to protect the patient would improve the longevity and reduce the size of a body-worn monitoring device. These teachings comport with Jensen's stated desire to create a low form-factor, body worn patient monitoring device. *See* Section XVI.A.1, *supra*. A POSA would immediately understand that Kroll's conductive "lead strips" would function to limit current in both directions and not just toward the patient, thereby protecting both the device and its wearer. *See* Section IV.F., *supra.* Moreover, given the demonstrated industry-wide desire to reduce the size of monitoring devices, Kroll's current-limiting solution, which adds little to no extra size, would be preferred by a POSA when designing a body-worn monitoring device.

279. Thus, it is my opinion that the limitation "at least one series current-limiting resistor configured to protect the communication-computation module" would have been obvious to a POSA in view of the combination of Jensen and Kroll.

xiv. Limitation [1m]

280. Limitation [1m] of the '007 patent recites "the at least one series current-limiting resistor being screened on a flexible substrate."

281. In my opinion, the combination of Jensen and Kroll, in view of the knowledge of a POSA, renders obvious limitation [1m] of the '007 patent. Jensen discloses a communication-computation module that incorporates a "flexible circuit

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assembly." Ex. 1011 at [0040]. The disclosed "flexible circuit assembly" includes "copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72 and, for example, Lithium coin cell 9." *Id.* at [0040]. Thus, Jensen teaches the claimed "flexible substrate," on which traces connect the circuit components.

282. Kroll teaches the use of "lead strips" which "transmit and receive electric signals to and from the terminal end [ ] of the belt." Ex. 1013 at 5:1–4. Kroll teaches that these "lead strips" are composed of a "flexible conductive ink compound having a conductive filler" where the ink compound is of preselected conductivity. *Id.* at 5:4–6, 5:8–9. Kroll teaches that the "conductive filler" of the ink compound contains "Silver, Aluminum, or compounds thereof, or [is composed] of a similarly suitable material." *Id.* at 5:4–8. The "lead strips" are printed on an "insulation and base support layer" which is "preferably comprised of a thin . . . polyester laminate and serves as [ ] a base for the silk screened conductive ink used in the matrix lines 42 and lead strips 34." *Id.* at 5:37–42.

283. Kroll further teaches that the 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.* at 5:8–13, 5:31–33. A "complementary medical device" includes, for example, a defibrillator, which would be used on the patient if necessary due to a cardiac event. Patients undergoing body worn

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physiological monitoring are often at an increased risk of experiencing an acute cardiac episode necessitating defibrillation.

284. In my opinion, it is obvious from Kroll's disclosure that the "lead strips" are created by screening the ink compound onto the device. Screen printing was a preferred method of manufacturing a circuit board at the time. *See, e.g.*, *id.* at 5:23–27, 5:31–33, 5:37–42. Screen printing is preferred because it allows a greater degree of control in printing and thus is cost-effective, which is important when expensive materials such as silver are being used. *See* Ex. 1035 at 296 ("Printing Process. The circuit patterns are screen printed on the substrate by two ways: (1) Manual screen printing process, and (2) Automatic or semi-automatic screen printing process."); *see also* Ex. 1013 at 5:23–42 ("Each electrode 35 has a conductive grid 56 which is comprised of a matrix of approximately 0.050 inch wide lines 42 of conductive ink compound applied to an insulation and base support layer 44 ***preferably by means of a silk screen process.***") (emphasis added); *see also* Ex. 1013 at 5:4–8.

285. Furthermore, a POSA seeking to make or use Jensen's device would understand that Kroll's teaching of screen-printed resistive ink to protect the patient would improve the longevity and reduce the size of a body-worn monitoring device. These teachings comport with Jensen's stated desire to create a low form-factor, body worn patient monitoring device. *See* Section XVI.A.1, *supra.* A POSA would

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immediately understand that Kroll's conductive "lead strips" would function to limit current in *both* directions and not just toward the patient, thereby protecting both the device and its wearer. *See* Section IV.F., *supra.* Moreover, given the demonstrated industry-wide desire to reduce the size of monitoring devices, Kroll's current-limiting solution, which adds little to no extra size, would be preferred by a POSA when designing a body-worn monitoring device.

286. In my opinion, a POSA would have had a reasonable expectation of success in combining Kroll's teaching of resistive traces with Jensen's device because screening the "lead strips" taught by Kroll onto the "flexible circuit assembly" taught by Jensen would be a simple matter of replacing one known component, *i.e.*, the copper traces of Jensen's device, with another, *i.e.*, the conductive ink, which would be routine and predictable for a POSA. *See* Section XVI.A.1, *supra*.

287. Thus, it is my opinion that the limitation "the at least one series current-limiting resistor being screened on a flexible substrate" would have been obvious to a POSA in view of the combination of Jensen and Kroll.

xv. Limitation [1n]

288. Limitation [1n] of the '007 patent recites "the at least one series current-limiting resistor being in the form of resistive traces."

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289. In my opinion, the combination of Jensen and Kroll, in view of the knowledge of a POSA, renders obvious limitation [1n] of the '007 patent. As discussed above with respect to limitation [1m], Kroll teaches the existence of "lead strips" made of "flexible conductive ink compound having a conductive filler having Silver, Aluminum, or compounds thereof, or of a similarly suitable material" in which the "ink deposit is of a preselected conductivity to provide a certain total lead strip resistance" in order for each lead strip to serve as a "current limiter." Ex. 1013 at 5:4–13.

290. A POSA would understand Kroll's disclosure of "lead strips" as referring to a "trace" as recited by the '007 patent. A POSA would understand that the terms "lead strip" and "trace" are often used interchangeably because signal traces connect the components on a printed circuit board much like lead wires functioned in the early days of ECG technology. *See* Ex. 1035 at 642 ("Conductor: A single conductive path in conductive pattern. A PCB has at least one layer of conductors. *Synonyms:* path, trace."); *id.* at 665 ("defining "trace" as "[a] single conductive path in a conductive pattern"). Further, a POSA would have understood the term "*resistive* trace" to simply refer to a lead strip, trace, wire, etc. which has a specific resistance, as taught by Kroll. *See, e.g.*, *Id.* at 665 (defining "trace"); Ex. 1013 at 5:4–21.

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291. As explained above, a POSA seeking to make or use the apparatus taught by Jensen would have looked to the teachings of Kroll to protect the device and its user, and to achieve a slimmer profile. *See* Sections XVI.A.1, XVI.A.2.xiii-xiv, *supra*. In my opinion, a POSA would have had a reasonable expectation of success in combining Kroll's teaching of resistive traces with Jensen's device. *Id.*

292. Thus, it is my opinion that the limitation "at least one series current-limiting resistor being in the form of resistive traces," would have been obvious to a POSA in view of the combination of Jensen and Kroll.

3. Dependent Claim 2

293. Claim 2 of the '007 patent depends directly from claim 1 and additionally requires that "the plurality of electrical connections to the body comprise at least one of direct electrical connections to the body and indirect electrical connections to the body."

294. In my opinion, claim 2 of the '007 patent is rendered obvious by Jensen and Kroll for all the reasons discussed above with respect to claim 1 as well as because Jensen teaches the additional limitation of claim 2. *See* Section XVI.A.2, *supra*.

295. A POSA would understand the term "direct electrical connection" to mean that the conductors make physical contact with the skin, for example through a wet electrode or a dry electrode (and the moisture that naturally exists on the skin).

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See, e.g., Ex. 1018 at 1:19–27; *cf.* Ex. 1019 at 26:13–24 (describing the ground contact as being "a direct connection" to the patient's skin); *see also* Sections IV.C, IV.E., *supra*. Sensor pads 1 and 2 of Jensen are in contact with the patient's skin. Ex. 1011 at [0030]–[0031]. Thus, Jensen's sensor pads form a direct electrical connection with the patient's body.

296. For these reasons, it is my opinion that a POSA would understand that Jensen discloses "the plurality of electrical connections to the body compris[ing] at least one of direct electrical connections to the body and indirect electrical connections to the body" and, therefore, that the combination of Jensen and Kroll renders obvious claim 2 of the '007 patent.

4. Dependent Claim 4

297. Claim 4 of the '007 patent depends from claim 1 and further requires that "the body worn patient monitoring device comprises an ECG monitor and at least two of the electrical connections are ECG electrodes."

298. In my opinion, claim 4 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Jensen teaches the additional limitation of claim 4. *See* Section XVI.A.2, *supra.*

299. A POSA would understand that the terms "ECG" and "EKG" are synonymous and often used interchangeably. *See, e.g.*, Ex. 1046 (Brian Burkhardt,

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The Future of Electrocardiograph Telemetry Systems, Int'l Telemetering Conference Proceedings (2004)).

300. Jensen extensively discusses the usefulness of its disclosed device for EKG monitoring. *See, e.g.*, Ex. 1011 at [0029], [0031]. As one specific example, Jensen teaches a "self-attached device that integrates other sensors together with heart-rate/EKG electronic sensors." *Id.* at [0012]. Jensen also teaches that "at least two of the electrical connections are ECG electrodes." Jensen's device includes "sensor pad electrodes 1 and 2 [which] are coated with a conductive adhesive . . . as found in off-the-shelf EKG sensor pads." *Id.* at [0041]. In other words, a POSA would understand that Jensen's sensor pad electrodes 1 and 2 are two connections which are ECG electrodes, as required by the additional limitation of claim 4.

301. For these reasons, it is my opinion that a POSA would understand that Jensen discloses "the body worn patient monitoring device compris[ing] an ECG monitor and at least two of the electrical connections are ECG electrodes" and, therefore, that the combination of Jensen and Kroll renders obvious claim 4 of the '007 patent.

5. Dependent Claim 5

302. Claim 5 of the '007 patent depends from claims 1 and 4 and additionally requires that "the ECG electrodes comprise a material screened onto the flexible substrate."

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303. In my opinion, claim 5 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claims 1 and 4 as well as because each of Jensen and Kroll teaches the additional limitation of claim 5. *See* Section XVI.A.4, *supra*.

304. Jensen discloses a device comprising a "flexible circuit assembly" which includes "copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72" as well as other components. Ex. 1011 at [0040].

305. Kroll teaches that "each [ECG] electrode 35 has a conductive grid . . . applied to an insulation and base support layer 44 preferably by means of a silk screen process," *i.e.*, a flexible substrate. *See, e.g.*, Ex. 1013 at 5:23–42, Fig. 5. Kroll further explains:

> ***Each electrode 35 has a conductive grid 56 which is comprised of a matrix of approximately 0.050 inch wide lines 42 of conductive ink compound applied to an insulation and base support layer 44 preferably by means of a silk screen process.*** The conductive ink is a silver compound generally used in the electronics industry. . . . The conductive ink compound used in the matrix lines 42 is generally the same as that utilized in the lead strips 34. Apertures 43 in the conductive ink matrix 42 form the grid configuration. The grid configuration itself is provided both for proper electrical function as well as to reduce the amount of ink used while obtaining maximum function. The insulation and base support layer 44 is preferably comprised of a thin approximately 0.001 inch polyester laminate and ***serves as both a base for the silk screened conductive ink used in the matrix lines 42 and lead strips 34***, and as an electrical insulator.

Id. at 5:23–42 (emphases added).

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306. A POSA seeking to make or use the device disclosed in Jensen would have known that electrodes could be attached to the base layer of the "flexible circuit assembly 36" of Jensen's device through screen printing. As discussed above, screen printing was a preferred process for manufacturing circuits in the industry at the time of the purported invention of the '007 patent. *See, e.g.*, Ex. 1035 at 283 (noting that "screen printing is a [ ] cheap and simple method" that is used to produce "[t]he majority of PCBs produced worldwide"); *see also id.* at 3 (noting that screen printing of "printed silver paste conductors and graphite resistors" was "commonly associated with [2006]'s hybrid circuit technology" and "was [the] technique that ushered in the commercial use of printed circuits").

307. For these reasons, it is my opinion that a POSA would understand that Kroll discloses "ECG electrodes compris[ing] a material screened onto the flexible substrate" and, therefore, that the combination of Jensen and Kroll renders obvious claim 5 of the '007 patent.

6. Dependent Claim 6

308. Claim 6 of the '007 patent depends from claims 1, 4, and 5 and additionally requires that the "at least one series current-limiting resistor protects the communication-computation module during a patient defibrillation event."

309. In my opinion, claim 6 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claims

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1, 4, and 5 as well as because Kroll teaches the additional limitation of claim 6. *See* Section XVI.A.5, *supra*.

310. Jensen's device includes a communication-computation module (the "flexible circuit assembly 36"). *See* Section XVI.A.2.vii, *supra*. The disclosed "flexible circuit assembly" includes both a "microcontroller 10" which is "used to perform further analysis" of the collected data (*i.e.*, computation) and a "transmitter 7" used to transmit the collected data (*i.e.*, communication). *Id.*; *see also* Ex. 1011 at [0032].

311. Kroll discloses "lead strips 34," which comprise a conductive ink compound "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 at 5:4–13. In my opinion, a POSA would know that the same ink deposits that protect the patient from shock will also at the same time protect the device from shock. *See, e.g.*, Ex. 1043 at 816–17 (noting that the resistivity of a conductor depends on the properties of the conductor material), 819–20 (noting that current always flows in the direction of decreasing electric potential or voltage); *see also* Ex. 1018 at 1:36–45; Section IV.F., *supra.*

312. As acknowledged by the '007 patent, there were existing medical standards that required "medical grade monitor[s]" to be able to "survive multiple

defibrillation cycles of at least 360 joules." Ex. 1001 at 1:53–55, 10:19–29; *see also* Section IV.E., *supra;* Ex. 1001 at 7:46–48 (the '007 patent disclosing that "the resistances of the protective resistive traces be in a range between about 1 kilo ohm to about 10 kilo ohms"; the stated resistance of Kroll's lead strips fall within this range). In the prior art, this requirement was generally met by including some type of resistor(s) in the wearable device. *See* Section IV.C., *supra.*

313. For these reasons, it is my opinion that a POSA would understand that Kroll discloses that the "at least one series current-limiting resistor protect[ing] the communication-computation module during a patient defibrillation event" and, therefore, that the combination of Jensen and Kroll renders obvious claim 6 of the '007 patent.

7. Dependent Claim 7

314. Claim 7 of the '007 patent depends from claims 1 and 4 and requires that the "mechanical interface from the at least one series current-limiting resistor to the EGG electrode includes a filleted edge."

315. In my opinion, claim 7 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claims 1 and 4 as well as because Jensen teaches the additional limitation of claim 7. *See* Section XVI.A.4, *supra*.

316. The '007 patent explains:

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> According to one solution to the above noted arcing problem, as shown in FIG. 4B, ***a rounded (fillet) section 430 of carbon trace*** can be added at the interface to conductive surface 404. ***A fillet or "tear drop" shape causes the carbon trace to become gradually wider*** as it connects to conductive surface 404 and relieves the electrical potential stress at the interface.

Ex. 1001 at 8:37–43 (emphases added).

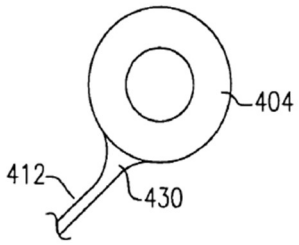


FIG.4B

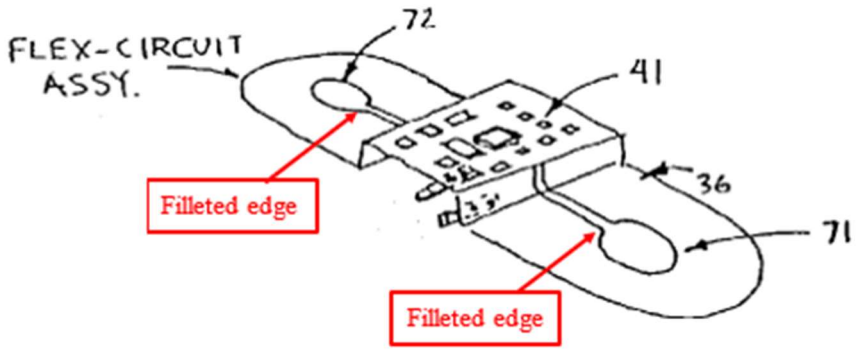
Id. at Fig. 4B.

317. Because the circuitry/traces of a device mechanically connect "the at least one series current-limiting resistor" and "the EGG electrode," the "mechanical interface" is the circuitry/trace of Jensen's device and the "filleted edge" is the "tear drop shape" taught by Jensen. Both of these understandings are in line with the disclosure of the '007 patent.

318. Jensen discloses a device comprising a "flexible circuit assembly" which includes "copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72" as well as other components. Ex. 1011 at [0040], Fig. 5. In my opinion, a POSA would understand that the traces disclosed by Jensen gradually get wider to mechanically connect to the filleted sensor contacts, 71 and 72, because,

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where the end of the trace is connected to the filleted sensor contacts 71, 72, the trace is wider than where the trace is connected to circuit 41. This is illustrated in Figure 5 of Jensen:



Id. at Fig. 5 (annotated). Furthermore, it is my opinion that a POSA would have understood that the traces would eventually get wider to mechanically connect to the filleted sensor contact 71, 72, because this was considered a best practice from the perspective of electrical and mechanical reliability at the time of the invention of the '007 patent. *See, e.g.*, Ex. 1035 at 195 (using the terms "fillet" and "teardrop" synonymously); *id.* at 224–43 (stating that "[t]he general shape of solder pads should be tear-like).

319. In my opinion, in combining the "resistive trace" taught by Kroll with the device disclosed by Jensen, as discussed above, a POSA would use the underlying shape of the trace of Jensen, which includes the claimed "filleted edge." *See* Section XVI.A.1, *supra.*

320. For these reasons, it is my opinion that a POSA would understand that Jensen discloses that the "mechanical interface from the at least one series current-

limiting resistor to the EGG electrode includes a filleted edge" and, therefore, that the combination of Jensen and Kroll renders obvious claim 7 of the '007 patent.

8. Dependent Claim 8

321. Claim 8 of the '007 patent depends from claims 1 and 4 and additionally requires that "the mechanical interface from the at least one series current-limiting resistor to the EGG electrode comprises overlapped layers."

322. In my opinion, claim 8 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claims 1 and 4 as well as because Kroll teaches the additional limitation of claim 8. *See* Section XVI.A.4, *supra.*

323. As discussed previously in Section XVI.A.2.xiii, Kroll discloses "at least one series current-limiting resistor," in the form of lead strips 34.

324. Kroll teaches that "lead strips 34 [shown in green] extend from each electrode 33, 35 [shown in red] to the terminal end 19" and overlap electrode 35 that includes a conductive grid 56 (shown in orange) "comprised of a matrix of approximately 0.050 inch wide lines 42 of conductive ink compound applied to an insulation and base support layer 44 preferably by means of a silk screen process" as shown below by Figure 5. Ex. 1013 at 5:17–21, 5:23–27, Fig. 5. Kroll further teaches that the "conductive ink compound used in the matrix lines 42 is ***generally***

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the same as that utilized in the lead strips 34." *Id.* at 5:23–27, 5:31–33 (emphasis added).

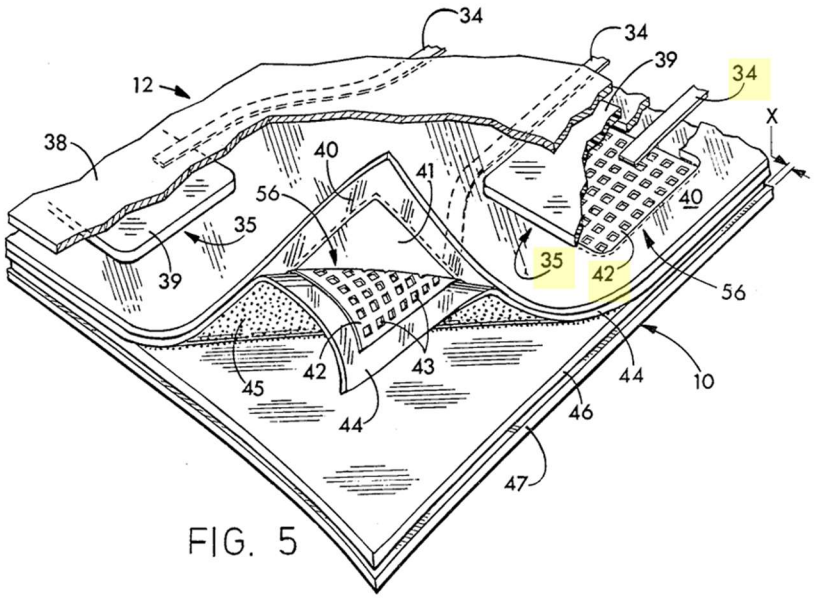


FIG. 5

Id. at Fig. 5 (annotated).

325. A POSA reading Kroll would understand its stated preference for screen-printing. Screen printing of circuits is accomplished by printing overlapping layers of ink, one at a time, to make up the different components. *Cf* Ex. 1035 at 211, Fig. 5.16. Such overlapping layers of ink can be, but do not necessarily need to be, composed of the same compounds. Thus, a POSA would have understood matrix lines 42 and lead strip 34 as overlapping layers that can be made of different materials.

326. For these reasons, it is my opinion that a POSA would understand that Kroll discloses "the mechanical interface from the at least one series current-limiting

resistor to the EGG electrode comprises overlapped layers" and, therefore, that the combination of Jensen and Kroll renders obvious claim 8 of the '007 patent.

9. Dependent Claim 10

327. Claim 10 of the '007 patent depends from claim 1 and additionally requires "an insulating material overlaying the at least one series current-limiting resistor to prevent arcing."

328. In my opinion, claim 10 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Jensen and Kroll teach the additional limitation of claim 10. *See* Section XVI.A.2, *supra.*

329. In addition to teaching the "at least one series current-limiting resistor," *see* Section XVI.A.2.xiii, *supra*, Jensen discloses "aesthetic covers 35 [which] may be constructed from Mylar sheet," Ex. 1011 at [0043]. These aesthetic covers "enclose the entire top side of the flexible circuit assembly 36" which "contains the copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72." Ex. 1011 at [0040], [0043]. Thus, the aesthetic covers 35 are placed on top of the copper wiring traces.

330. In my opinion, a POSA would understand from Jensen's disclosure that the aesthetic covers 35 are an insulating material that overlay the traces to prevent arcing. Jensen discloses that the "aesthetic covers 35 may be constructed from Mylar

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sheet" and "enclose the entire top side of the flexible circuit assembly 36." *Id.* at [0043]. Mylar is a well-known insulating material. *See, e.g.*, Ex. 1047 (Patrick J. Nolan, *Sterile Medical Device Package Development*, Standard Handbook of Biomedical Eng'g & Design (2004)) at 23.10 ("The material most commonly used for flexible packaging applications is oriented polyester (e.g., Mylar™), which is used as a base for properties such as dimensional stability, heat resistance, and strength with an adhesively laminated seal layer such as low-density polyethylene, which provides the film structure with heat scalability.").

331. Additionally, Kroll discloses an "inner patient insulation layer 40" that "serves to insulate the patient's skin from electric current or voltage in the electrode lead strips 34" and an "insulation and base support layer 44" which is bonded to the "inner patient insulation layer 40" via "an adhesive or a lamination process." Ex. 1013 at 5:43–50. Kroll further teaches that both the "inner patient insulation layer 40" and the "insulation and base support layer 44" are comprised of "polyester laminate." *Id.* at 5:37–42, 5:44–47.

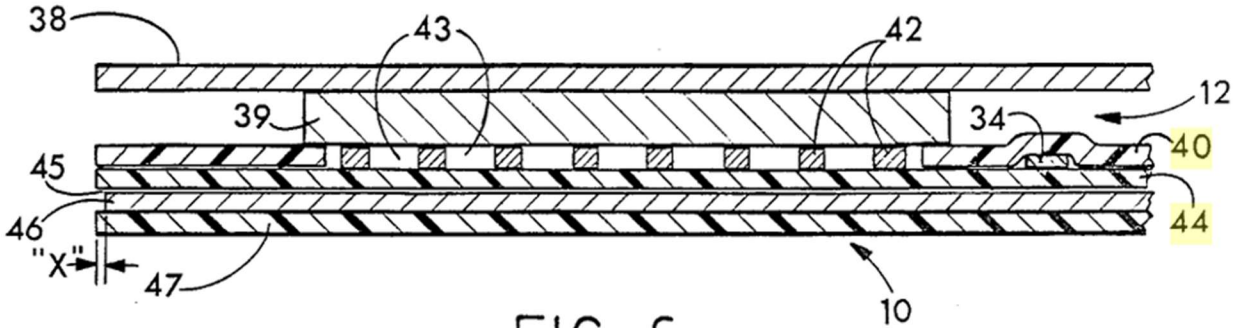


FIG. 6

Id. at Fig. 6 (annotated).

332. As shown above by Figure 6, Kroll's "inner patient insulation layer 40" and "insulation and base support layer 44" both overlay the "lead strip 34." Because Mylar has long been used for electrical insulation, a POSA would understand that polyester laminate has the necessary insulation to prevent the lead strip 34 from jumping a connection (*i.e.*, "arcing"). Ex. 1048 (Lawrence R. Dallett & William E. Donaldson, *Plastics and Adhesives: A Guide to Their Physical Properties and Uses*, U.S. Dep't of Com. (1956)) at 13–14.

333. For these reasons, it is my opinion that a POSA would understand that Jensen and Kroll disclose "an insulating material overlaying the at least one series current-limiting resistor to prevent arcing" and, therefore, that the combination of Jensen and Kroll renders obvious claim 10 of the '007 patent.

10. Dependent Claim 11

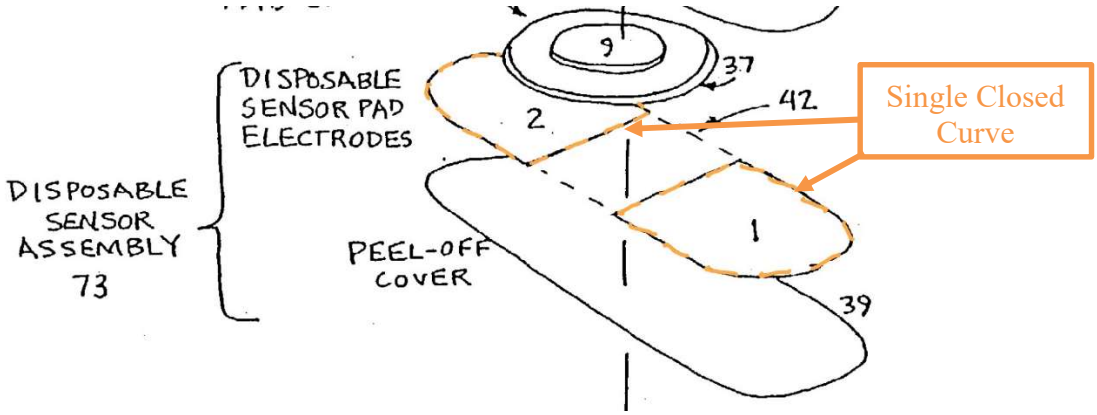
334. Claim 11 of the '007 patent depends from claims 1, 4, and 5 and additionally requires that "the EGG electrodes are formed substantially in the shape of an annulus."

335. In my opinion, claim 11 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claims 1, 4, and 5 as well as because Jensen teaches the additional limitations of claim 11. *See* Sections XVI.A.5, *supra.*

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336. The ’007 patent explicitly defines “annulus,” stating that, “[u]nder this definition, an annulus can include substantially square shapes, substantially rectangular shapes, substantially circular shapes” including “a substantially ‘U’ shaped surface as described by a single closed curve.” Ex. 1001 at 6:64–7:3.

337. As previously discussed, Jensen discloses that “sensor pad electrodes 1 and 2” are at least two ECG electrodes. *See* Section XVI.A.2.ii, *supra.* Sensor pads 1, 2 each define a region between a single closed curve (shown in orange below), as shown below in the annotated version of Figure 5 of Jensen.



Ex. 1011 at Fig. 5 (annotated).

338. For these reasons, it is my opinion that Jensen discloses that “the [ECG] electrodes are formed substantially in the shape of an annulus” and, therefore, that the combination of Jensen and Kroll renders obvious claim 11 of the ’007 patent.

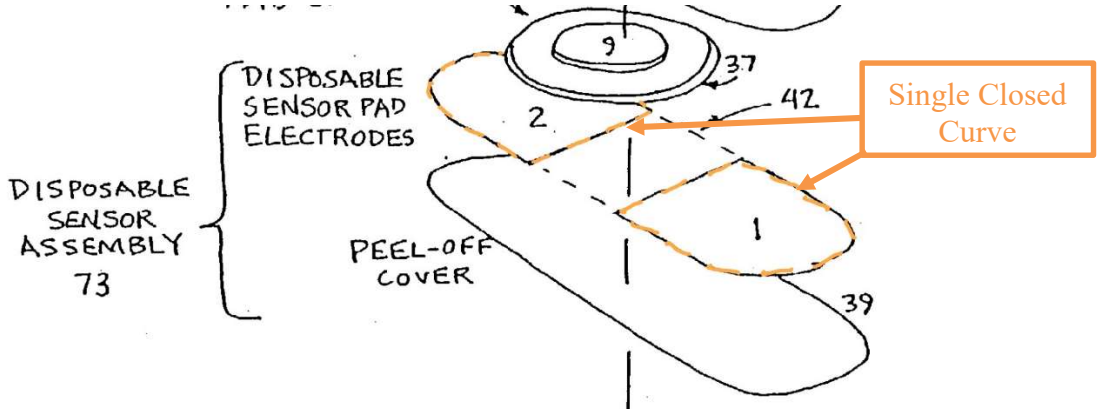
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11. Dependent Claim 12

339. Claim 12 of the '007 patent depends from claims 1, 4, 5, and 11, and additionally requires that "the annulus comprises a conductive link."

340. In my opinion, claim 12 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claims 1, 4, 5, and 11 as well as because Jensen teaches the additional limitation of claim 12. *See* Section XVI.A.10, *supra.*

341. As discussed above, sensor pad electrodes 1 and 2 of Jensen are formed substantially in the shape of an annulus. *See* Section XVI.A.10, *supra.* The disposable sensor pads 1, 2, also form an electrical connection (conductive link) with sensor contacts 71, 72 of the flexible circuit assembly through the conductive adhesive on the circuit side of the annulus. Ex. 1011 at [0041].



Id. at Fig. 5 (annotated).

342. For these reasons, it is my opinion that Jensen discloses that "the annulus comprises a conductive link" and, therefore, that the combination of Jensen and Kroll renders obvious claim 12 of the '007 patent.

12. Dependent Claim 13

343. Claim 13 of the '007 patent depends from claims 1 and 5 and additionally requires that "the substrate is shaped to allow placement on the patient to monitor at least one of a set of standard ECG vectors while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal."

344. In my opinion, claim 13 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claims 1 and 5 as well as because Kroll teaches the additional limitation of claim 13. *See* Sections XVI.A.5, *supra.*

345. Kroll teaches "a plurality of predetermined contact areas for receiving and transmitting electrical signals," and that these "predetermined contact areas" may be "arranged having one at each corner of the body structure and six centrally placed in the body structure to form a generally curvilinear pattern whereby said contact areas conform ***with standard precordial positions for 'twelve-lead' electrocardiographic devices***." Ex. 1013 at cls. 1, 13 (emphasis added). In my opinion, a POSA would have understood that placement at "standard

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EKG . . . electrode locations" as disclosed by Kroll would measure standard EKG vectors. *See* Section IV.A., *supra*.

346. In my opinion, a POSA would have known to place the wearable monitor of Jensen in one of these standard locations, which were widely known in the field, to minimize motion and muscle artifact in the corresponding ECG vector signals. Use of specific electrode placements to reduce the motion and muscle artifacts that interfered with EKG recording was well-known in the art. *See, e.g.*, Ex. 1049 (N.V. Thakor & J.G Webster, *Electrode studies for the long-term ambulatory ECG*, Med. & Biol. Eng. & Comput. (1985)) at 116 (noting that "the motion artefact can be reduced and larger QRS amplitude can be obtained by selective placement of electrodes"), 120; *see also* Ex. 1031 at 74 (referring to the "conventional Holter recorder [which] samples ECG data comparable to data ***recorded by leads V1 and V5 of the standard 12-lead ECG***") (emphasis added).

347. In light of Kroll's teaching of "standard precordial positions," it is my opinion that a POSA would have known to place the wearable monitor of Jensen in one of these standard locations that were well-known in the field to minimize "motion and muscle artifact in the corresponding ECG vector signals" and thus optimize the quality of the EKG recordings. In fact, Jensen even alludes to such standard placement locations. Ex. 1011 at [0007] (noting one problem with prior art devices is that "very vigorous activity" would cause the wearable device to "slip

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down from the ***optimum pick-up location***" resulting in "erratic EKG readings") (emphasis added).

348. For these reasons, it is my opinion that a POSA would understand that Kroll discloses that "the substrate is shaped to allow placement on the patient to monitor at least one of a set of standard ECG vectors while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal" and, therefore, that the combination of Jensen and Kroll renders obvious claim 13 of the '007 patent.

13. Dependent Claim 14

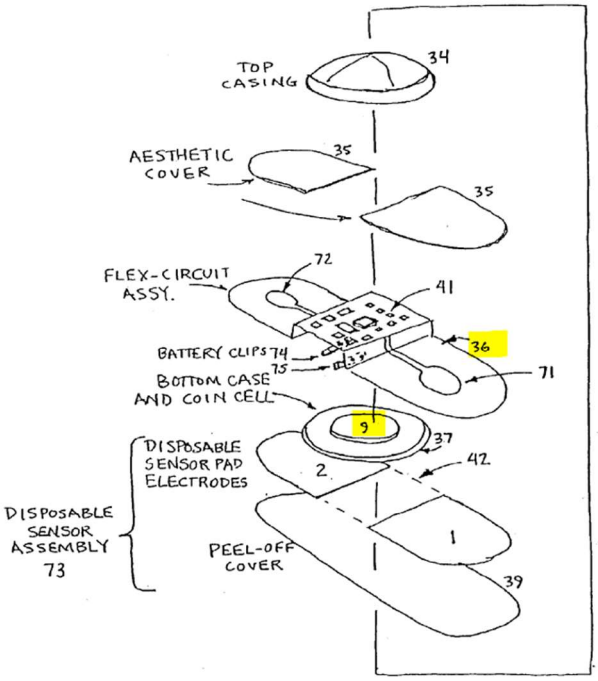
349. Claim 14 of the '007 patent depends from claim 1 and additionally requires that "the power source is a renewable power source internal to the body worn device."

350. In my opinion, claim 14 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Jensen teaches the additional limitation of claim 14. *See* Section XVI.A.2, *supra.*

351. Jensen teaches that the "flexible circuit assembly" is connected to a "rechargeable type of power source," or a "solar cell." Ex. 1011 at [0040]. In my opinion, a POSA would have understood that a "rechargeable type of power source" is the same as a "renewable power source." Jensen also teaches that this power source is "internal to the body worn device" disclosed by Jensen, as it would replace

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the Lithium coin cell battery (9) which is located internally in Jensen's device as shown by annotated Figure 5 below.



Id. at Fig. 5 (annotated); *see also id.* at [0040].

352. For these reasons, it is my opinion that a POSA would understand that Jensen discloses that "the power source is a renewable power source internal to the body worn device" and, therefore, that the combination of Jensen and Kroll renders obvious claim 14 of the '007 patent.

14. Dependent Claim 15

353. Claim 15 of the '007 patent depends from claim 1 and additionally requires that "the power source comprises a rechargeable battery or a one time use battery."

354. In my opinion, claim 15 of the ’007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Jensen teaches the additional limitation of claim 15. *See* Section XVI.A.2, *supra.*

355. Jensen, for example, teaches that the “flexible circuit assembly” is connected to a “Lithium coin cell 9,” which is also known as a “coin battery.” Ex. 1011 at [0040]. In my opinion, a POSA would have understood that the “Lithium coin cell” battery disclosed by Jensen is a “one-time use battery.” *See* Ex. 1042 at 386 (“Power for the circuit is obtained from a single nonrechargeable 3-V lithium battery”).

356. As disclosed above, Jensen also teaches that the “flexible circuit assembly” may be connected to a “rechargeable type of power source,” or a “solar cell.” *Id.* at [0040]. Thus, Jensen discloses that the power source comprises “a rechargeable battery,” as required by claim 15.

357. For these reasons, it is my opinion that a POSA would understand that Jensen discloses that “the power source comprises a rechargeable battery or a one time use battery” and, therefore, that the combination of Jensen and Kroll renders obvious claim 15 of the ’007 patent.

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15. Dependent Claim 29

358. Claim 29 of the ’007 patent depends from claim 1 and additionally requires that “the body worn device includes circuit protection to allow the device to survive multiple defibrillation cycles of at least 360 joules.”

359. In my opinion, claim 29 of the ’007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Kroll teaches the additional limitation of claim 29. *See* Section XVI.A.2, *supra.*

360. Kroll discloses “lead strips 34” composed of a conductive ink compound 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 at 5:4–13. The composition of the conductive filler used results in a lead strip resistance of approximately 1,000 ohms, which “allows for signals transmission” and provides “current limiter qualities.” *Id.* at 5:4–17. In my opinion, a POSA would understand that the same current-limiting component (*i.e.,* the ink deposits) that protects the patient from shock would also function to help protect the device from shock at the same time. *See, e.g.*, Ex. 1043 at 816–17 (noting that the resistivity of a conductor depends on the properties of the conductor material), 819–

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20 (noting that current always flows in the direction of decreasing electric potential or voltage); *see also* Ex. 1018 at 1:36–45; Section IV.F., *supra.*

361. As acknowledged by the '007 patent, there were existing medical standards that required "medical grade monitor[s]" to be able to "survive multiple defibrillation cycles of at least 360 joules." Ex. 1001 at 1:53–55, 10:19–29; *see also* Section IV.E., *supra;* Ex. 1001 at 7:46–48 (the '007 patent disclosing that "the resistances of the protective resistive traces be in a range between about 1 kilo ohm to about 10 kilo ohms"; the stated resistance of Kroll's lead strips fall within this range).

362. For these reasons, it is my opinion that a POSA would understand that Kroll discloses "the body worn device includes circuit protection to allow the device to survive multiple defibrillation cycles of at least 360 joules" and, therefore, that the combination of Jensen and Kroll renders obvious claim 29 of the '007 patent.

16. Dependent Claim 31

363. Claim 31 of the '007 patent depends from claims 1 and 29 and additionally requires that "a plurality of components of the circuit protection are distributed between the disposable module and the communication-computation module."

364. In my opinion, claim 31 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to

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claims 1 and 29 as well as because Kroll teaches the additional limitation of claim 31. *See* Section XVI.A.15, *supra.*

365. As discussed above, Kroll discloses "at least one series current-limiting resistor", *viz.* the "lead strips" are intended to "serve[] as a current limiter to *protect a patient from shock due to malfunction of the device*." Ex. 1013 at 5:8–12 (emphasis added); *see* Sections XVI.A.2.xiii–xv, *supra*. In my opinion, a POSA would understand from Kroll's disclosure that the same current-limiting component (*i.e.,* the ink deposits) that protect the patient from shock would also function to protect the device from shock at the same time. *See, e.g.*, Ex. 1043 at 816–17 (noting that the resistivity of a conductor depends on the properties of the conductor material), 819–20 (noting that current always flows in the direction of decreasing electric potential or voltage); *see also* Ex. 1018 at 1:36–45; Section IV.F., *supra.*

366. In order for the "current-limiting resistor" taught by Kroll to provide circuit and patient protection, the "lead strips" must be placed or distributed between the electrodes on the disposable module (which is fixed to the patient's body) and the communication module (which houses the sensitive electronics). A POSA would understand that during defibrillation, current could move through the patient's skin, through the lead strips/traces and into the communication-computation module. A POSA would similarly understand that, in the case of device malfunction, for example, electrical current would travel in the opposite direction: from the

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communication-computation module, through the disposable module to the patient's skin.

367. As previously discussed, a POSA at the time of the invention of the '007 patent would have been motivated to protect the electronics of the device at least to ensure the necessary monitoring can be completed. For example, it was well known in the art that excess electrical current had the potential to ruin the electronic components. *See, e.g.*, Ex. 1035 at 37 (noting that thermistors can be used as "excess current limiters" as protection "against over-heating"). A POSA would also have been motivated to ensure the electronics of the device were protected to allow for the reuse of the electronic components of the monitor. *See, e.g.*, *id.* at 625 ("Electronic components can be re-used after disassembly for economic and ecological reasons. However, the cost of disassembling, testing and selling the reusable electronic components has to be seen in relation to the cost of a new product."). A POSA would understand that distributing the series current-limiting resistors between the electrodes on the disposable module (in contact with the patient) and the communication-computation module (housing the electronics) would be a way to achieve such protection.

368. For these reasons, it is my opinion that a POSA would understand that the combination of Jensen and Kroll discloses "a plurality of components of the circuit protection are distributed between the disposable module and the

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communication-computation module" and, therefore, that the combination of Jensen and Kroll renders obvious claim 31 of the '007 patent.

17. Dependent Claim 37

369. Claim 37 of the '007 patent depends from claim 1 and further requires that "the communication-computation module includes circuit components configured to detect failure of contact of one or more of the electrical connections with the skin surface of the patient."

370. In my opinion, claim 37 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Jensen teaches the additional limitation of claim 37. *See* Section XVI.A.2, *supra.*

371. Jensen discloses a "[l]ogic driver 29," which "supplies a switched supply voltage to disable and enable the operation of" various processing modules. Ex. 1011 at [0031]. Jensen further teaches that "[w]ith the use of switched supply voltage driver 29, power from the system power source 9 is conserved whenever the sensors 1, 2 are not in contact with the user's skin," meaning that Jensen's device is able to detect the failure of contact of the sensors 1, 2. *Id.*

372. For these reasons, it is my opinion that Jensen discloses that "the communication-computation module includes circuit components configured to detect failure of contact of one or more of the electrical connections with the skin

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surface of the patient" and, therefore, that the combination of Jensen and Kroll renders obvious claim 37 of the '007 patent.

18. Dependent Claim 38

373. Claim 38 of the '007 patent depends from claim 1 and additionally requires that "the communication-computation module is protected from external high energy signals by electro-surgical isolation suppression circuits."

374. In my opinion, claim 38 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Kroll teaches the additional limitation of claim 38. *See* Section XVI.A.2, *supra.*

375. Kroll discloses "lead strips 34" comprised of a conductive ink compound 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 at 5:4–13. In my opinion, a POSA would understand that circuits containing the same current-limiting component (*i.e.,* the ink deposits) that protects the patient from shock would also help to protect the device from interference from an electrosurgical unit, thus forming "electrosurgical isolation suppression circuits. *See generally*, Ex. 1036; *see also* Ex. 1043 at 816–17 (noting that the resistivity of a conductor depends on the properties of the conductor material), 819–20 (noting that

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current always flows in the direction of decreasing electric potential or voltage); *see also* Ex. 1018 at 1:36–45; Section IV.F., *supra.*

376. As acknowledged by the '007 patent, there were existing medical standards that required "medical grade monitor[s]" to be able to "survive multiple defibrillation cycles of at least 360 joules." Ex. 1001 at 1:53–55, 10:19–29; *see* Ex. 1036 at 18, Table 4, 55 (imposing requirement that wearable device be able to survive "multiple defibrillation cycles of at least 360 joules" and noting that such protection was especially important for cardiac monitors); Ex. 1001 at 14:25–30 (the challenged '007 patent acknowledging that techniques to protect devices from electrosurgical interference were well known in the art stating "AAMI standard EC13 on Electrosurgical Interference Suppression (ESIS). Standard EC13 addresses the ability of an ECG monitor to display and process ECG signals in a satisfactory manner while connected to a patient on whom an electrosurgical device is being used"); *see also* Sections IV.C, IV.E–F, *supra*.

377. For these reasons, it is my opinion that a POSA would understand that Kroll discloses "the communication-computation module is protected from external high energy signals by electro-surgical isolation suppression circuits" and, therefore, that the combination of Jensen and Kroll renders obvious claim 38 of the '007 patent.

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19. Dependent Claim 43

378. Claim 43 of the '007 patent depends from claim 1 and additionally requires that "the radio circuit communicates an unprocessed physiological signal."

379. In my opinion, claim 43 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Jensen teaches the additional limitation of claim 43. *See* Section XVI.A.2, *supra.*

380. Jensen discloses a "radio data transmission" and a "microcontroller," which is responsible for making that transmission. Ex. 1011 at Abstract, [0037], Table 1. Jensen further teaches that signals detected by sensors 1, 2 are "input directly to transmitter 7, or may be input into microcontroller 10." *Id.* at [0032]. In my opinion, it would be obvious to a POSA that unprocessed data must be communicated in addition to processed data, at least because the doctor and the patient may want to see the raw data, especially in the case that a cardiac event occurs. *Cf.* Ex. 1034 at cl. 7 (disclosing an interface which "permits the user to select at least one of unprocessed health parameter data and summary data for display to the user of the remote monitoring system").

381. For these reasons, it is my opinion that a POSA would understand that Jensen discloses "the radio circuit communicates an unprocessed physiological

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signal" and, therefore, that the combination of Jensen and Kroll renders obvious claim 43 of the '007 patent.

20. Dependent Claim 44

382. Claim 44 of the '007 patent depends from claim 1 and additionally requires that "the radio circuit communicates a result of the physiological analysis at a predetermined time."

383. In my opinion, claim 44 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Jensen teaches the additional limitation of claim 44. *See* Section XVI.A.2, *supra.*

384. Jensen teaches that the information collected by the body worn device is "sent by radio data transmission to any variety of outside receiving equipment"; Jensen's "microcontroller" is responsible for making that transmission. Ex. 1011 at Abstract, [0037], Table 1. Jensen further teaches a method of signal processing referred to as "Logged Event Reporting" in which the "[m]icrocontroller sends a packet periodically containing a log of all data points since last transmission." *Id.* at [0037], Table 1. In my opinion, a POSA would understand that a periodic transmission is transmitted on a predetermined periodicity (*i.e.*, "at a predetermined time").

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385. For these reasons, it is my opinion that a POSA would understand that Jensen discloses "the radio circuit communicates a result of the physiological analysis at a predetermined time" and, therefore, that the combination of Jensen and Kroll renders obvious claim 44 of the '007 patent.

21. Independent Claim 45

386. In my opinion, claim 45 of the '007 patent is rendered obvious by Jensen in combination with Kroll.

i. Limitation 45[pre]

387. Limitation 45[pre] of the '007 patent recites "a body worn patient monitoring device comprising."

388. As discussed above with respect to claim 1, it is my opinion that Jensen discloses the claimed "body worn monitoring device." *See* Section XVI.A.2.i, *supra*.

ii. Limitation [45a]

389. Limitation [45a] of the '007 patent recites "a disposable module including a plurality of electrical connections."

390. As discussed above with respect to claim 1, it is my opinion that Jensen discloses "a disposable module including a plurality of electrical connections." *See* Section XVI.A.2.ii, *supra.*

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iii. Limitation [45b]

391. Limitation [45b] of the ’007 patent recites “the electrical connections adapted for electrical coupling to a skin surface to receive physiological signals.”

392. As discussed above with respect to claim 1, it is my opinion that Jensen discloses “the electrical connections adapted for electrical coupling to a skin surface to receive physiological signals.” *See* Section XVI.A.2.iii, *supra.*

iv. Limitation [45c]

393. Limitation [45c] of the ’007 patent recites “the disposable module including a disposable module connector.”

394. As discussed above with respect to claim 1, it is my opinion that Jensen discloses “the disposable module including a disposable module connector.” *See* Section XVI.A.2.v, *supra.*

v. Limitation [45d]

395. Limitation [45d] of the ’007 patent recites “a power source to power the body worn patient monitoring device.”

396. As discussed above with respect to claim 1, it is my opinion that Jensen discloses “a power source to power the body worn patient monitoring device.” *See* Section XVI.A.2.vi, *supra.*

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vi. Limitation [45e]

397. Limitation [45e] of the ’007 patent recites “a communication-computation module, having a communication-computation module connector to receive the physiological signals from the disposable module via the disposable module connector, the communication-computation module including.”

398. As discussed above with respect to claim 1, it is my opinion that Jensen discloses “a communication-computation module, having a communication-computation module connector to receive the physiological signals from the disposable module via the disposable module connector, the communication-computation module.” *See* Sections XVI.A.2.vii–viii, *supra.*

vii. Limitation [45f]

399. Limitation [45f] of the ’007 patent recites “a microprocessor to actively monitor a patient and to perform a real-time physiological analysis of the physiological signals, the analysis determining an occurrence of a predetermined ECG event.”

400. It is my opinion that Jensen teaches limitation [45f] of the ’007 patent. Jensen’s device includes a microcontroller which performs a “physiological analysis” on collected data: “[t]he device of the present invention contains all necessary electronic circuitry, including sensors, a battery or other power source, and a microcontroller and/or other programmable logic circuitry that perform

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measurement and processing of sensed data, where said processed data are subsequently stored internally and/or transmitted to other equipment by wireless means." Ex. 1011 at [0014]. If the microcontroller of Jensen's device receives data input, it "runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter." *Id.* at [0032].

401. It is my opinion that a POSA would understand that, by disclosing a microcontroller that processes data, Jensen also discloses a microprocessor. For example, Jensen teaches a microprocessor that is intended to "electrically detect the occurrence of R events in the QRS complex of the EKG signal." *Id.* at [0029]; *see also* Ex. 1001 at 11:48–50 ("A microprocessor, such as microprocessor 512, is defined herein as synonymous and interchangeable with the terms 'microcomputer', 'microcontroller', and 'microprocessor'."). Jensen further explains that "[o]nce microcontroller 10 identifies the data as having a heart beat pulse, (a clearly identifiable waveform with a distinctive shape and a high signal amplitude compared to typical ambient noise from the sensor), then the program analyzes the data in a number of optional ways. . . . The microcontroller has the capability of performing conventional programmatic signal analysis to create and transmit different data records." Ex. 1011 at [0037].

402. Thus, it is my opinion that that Jensen discloses "a microprocessor to actively monitor a patient and to perform a real-time physiological analysis of the

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physiological signals, the analysis determining an occurrence of a predetermined ECG event."

viii. Limitation [45g]

403. Limitation [45g] of the '007 patent recites "a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis, at a predetermined time or on an occurrence of a predetermined event, via a radio transmission to a remote radio receiver."

404. Jensen teaches "[a] microcontroller . . . [that] converts the heart-rate data information into one of multiple data output formats, which are sent by radio data transmission to any variety of outside receiving equipment." *Id.* at Abstract. Jensen discloses that:

> Transmitter 7 may transmit in a variety of modulation and/or keying methods via antenna 8, especially when used in conjunction with microcontroller 10, whereby the microcontroller 10 may enable and disable the transmitter carrier, and also send encoded data streams. Data modulation methods in an RF transmitter that are easily implemented include the well understood methods of On-Off Keying (OOK), phase or frequency shift keying.

Id. at [0033]. Jensen further discloses a method of signal processing referred to as "Logged Event Reporting" in which the "[m]icrocontroller sends a packet periodically containing a log of all data points since last transmission." *Id.* at [0037], Table 1. It is my opinion that a POSA would understand that physiological analysis would need to be performed by the microcontroller to obtain the "log of all data

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points" prior to transmission under this method. Additionally, a POSA would understand that sending these results "periodically" would occur at "predetermined times" as determined by the algorithm. *See id.*

405. Therefore, it is my opinion that the combination of Jensen and Kroll discloses "a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis, at a predetermined time or on an occurrence of a predetermined event, via a radio transmission to a remote radio receiver" and thus renders limitation [45g] obvious.

ix. Limitation [45h]

406. Limitation [45h] of the '007 patent recites "wherein the disposable module has a mechanical and electrical coupling to the communication-computation module."

407. As discussed with respect to claim 1, it is my opinion that Jensen discloses that "the disposable module has a mechanical and electrical coupling to the communication-computation module." *See* Section XVI.A.2.xi, *supra.*

x. Limitation [45i]

408. Limitation [45i] of the '007 patent recites "forming the body worn patient monitoring device as a single unit that is adapted to be directly and non-permanently affixed to the skin surface of the patient."

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409. As discussed with respect to claim 1, it is my opinion that Jensen discloses "forming the body worn patient monitoring device as a single unit that is adapted to be directly and non-permanently affixed to the skin surface of the patient." *See* Section XVI.A.2.xii, *supra.*

xi. Limitation [45j]

410. Limitation [45j] of the '007 patent recites "at least one series current-limiting resistor configured to protect the communication-computation module."

411. As discussed with respect to claim 1, it is my opinion that the combination of Jensen and Kroll discloses "at least one series current-limiting resistor configured to protect the communication-computation module" and, therefore, renders limitation [45j] obvious. *See* Section XVI.A.2.xiii, *supra.*

xii. Limitation [45k]

412. Limitation [45k] of the '007 patent recites "the at least one series current-limiting resistor being screened on a flexible substrate."

413. As discussed with respect to claim 1, it is my opinion that the combination of Jensen and Kroll discloses "the at least one series current-limiting resistor being screened on a flexible substrate" and, therefore, renders limitation [45k] obvious. *See* Section XVI.A.2.xiv, *supra.*

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xiii. Limitation [45l]

414. Limitation [45*l*] of the ’007 patent recites “the at least one series current-limiting resistor being in the form of resistive traces.”

415. As discussed with respect to claim 1, it is my opinion that the combination of Jensen and Kroll discloses “the at least one series current-limiting resistor being in the form of resistive traces” and, therefore, renders limitation [45*l*] obvious. *See* Section XIV.A.2.xv, *supra.*

B. Jensen Ground 2: Obvious Over Jensen, Kroll, DeLuca, and General Knowledge of a Person of Ordinary Skill in the Art

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

416. For all the reasons discussed above in Section XVI.A.1, a POSA would have been motivated to combine the devices and methods of Jensen with Kroll’s teaching of “resistive traces” or “resistive leads” and would have had a reasonable expectation of success in doing so. Additionally, a POSA would have also looked to incorporate DeLuca’s signal conditioning filters into the microcontroller of the device. Signal filtering was a well-known step in the Pan-Tompkins QRS detection algorithm, which was widely known and used for electronically detecting heartbeat signals from EKG data well before the date of the invention of the ’007 patents. *See* Ex. 1050 (Jiapu Pan & Willis J. Tompkins, *A Real-Time QRS Detection Algorithm*, BME-22 IEEE Transactions on Biomed. Eng’g 230 (1985)). Jensen teaches that a bandpass filter is used as a part of the signal conditioning on its device. Ex. 1011

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at [0036]. A POSA seeking to make Jensen's device, which can "perform signal processing and calculation upon data contained within [EKG] signals" onboard, would have sought to implement a signal-filtering algorithm (like the Pan-Tompkins algorithm) to reliably detect patient heartbeats. *See, e.g.*, Ex. 1045 at 42–54; *see also* Ex. 1050 at 230. Thus, in order to implement a signal filtering algorithm, a POSA would have looked to DeLuca, which describes in great detail an implementation of that algorithm's bandpass filters.

417. Further, a POSA would have had a reasonable expectation of success in implementing DeLuca's signal conditioning filters on Jensen's device without undue experimentation. In order to do so, a POSA would only need to modify Jensen's existing switchable, tunable, bandpass filter to result in the specific bandpass filtering configuration taught by DeLuca, which would result in minimal overall design impact. In my opinion, a POSA would know how to make this modification and nothing in the art suggests that this modification would not work or could not be implemented using well-known manufacturing techniques at the time.

2. Dependent Claim 32

418. Claim 32 of the '007 patent depends from claim 1 and additionally requires "a high pass filter with a selectable corner frequency to filter the physiological signals."

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419. In my opinion, claim 32 of the '007 patent is rendered obvious by Jensen in combination with Kroll and/or Jensen, Kroll, and DeLuca for all the reasons discussed above with respect to claim 1 as well as because each of Jensen and DeLuca teaches the additional limitation of claim 32. *See* Section XVI.A.2, *supra.*

420. As previously discussed, a POSA would have looked to combine DeLuca's specific "signal conditioning" filters with Jensen's device, which discloses a tunable, switchable bandpass filter. *See* Section XVI.B.1, *supra*; Ex. 1011 at [0032], [0036]–[0037], [0049].

421. Jensen discloses that "[s]ignals from the sensors 1& 2 are amplified by the amplifier circuit section 4. The amplified signal is then bandpass filtered by filter circuit section 5." Ex. 1011 at [0032]. Jensen's circuit section 5 "is set to operate at a particular gain value by the gain setting resistors 21, and then fed into switched capacitor filter 11." *Id.* at [0036]. A POSA would understand that "switched capacitor filter" is a "high pass filter with a selectable corner frequency to filter the physiological signals," and that Jensen therefore discloses the dependent limitation of claim 32. *See* Ex. 1051 (Roubik Gregorian & William E. Nicholson, Jr., *A Switched-Capacitor High-Pass Filter*, 27 IEEE Transactions on Circuits and Sys. 226 (1980)) at 229.

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

423. As discussed above, it is my opinion that a POSA would have recognized that DeLuca's band-pass filtering disclosures are consistent with the Pan-Tompkins QRS detection algorithm.

424. For these reasons, it is my opinion that it would have been obvious to combine DeLuca's teaching of a high-pass filter with a selectable corner frequency with Jensen's disclosure of bandpass filtering, meaning that the combination of Jensen, Kroll, and DeLuca renders obvious claim 32 of the '007 patent.

3. Dependent Claim 33

425. Claim 33 of the '007 patent depends from claims 1 and 32 and additionally requires that "the corner frequency is selected by a switch selectable resistance."

426. In my opinion, claim 33 of the '007 patent is rendered obvious by Jensen in combination with Kroll and/or Jensen, Kroll, and DeLuca for all the

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reasons discussed above with respect to claims 1 and 32 as well as because each of Jensen and DeLuca teaches the additional limitation of claim 33. *See* Section XVI.B.2, *supra.*

427. Jensen discloses that "[f]requency divider 15 outputs filter control signals that modify the bandpass characteristics of [the switched capacitor] filter 11." Ex. 1011 at [0036]. DeLuca teaches that "the signal conditioning stage 56 includes a hi-pass filter 56a" and that "[e]ach of the filter modules 56*a*, 56*c* and 56d is a switched-capacitor filter circuit whose cut-off frequency [*i.e.*, corner frequency] is determined by the clock frequency at which the filter is switched." Ex. 1015 at 5:2–7.

428. In my opinion, a POSA would understand that a switched-capacitor filter circuit, such as that taught by Jensen and by DeLuca, and a switched circuit including physical resistors are interchangeable methods for filtering. Ex. 1052 (J. Terry Caves et al., *Sampled Analog Filtering Using Switched Capacitors as Resistor Equivalents,* 12 IEEE Journal of Solid-State Circuits 592 (1977)) at 599. A POSA would therefore recognize that Jensen teaches the dependent limitation of claim 33.

429. Additionally, or alternatively, for these reasons, it is my opinion that it would have been obvious to combine DeLuca's teaching of a high-pass filter with a switch-selectable corner frequency with Jensen's disclosure of bandpass filtering,

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meaning that the combination of Jensen, Kroll, and DeLuca renders obvious claim 33 of the ’007 patent.

4. Dependent Claim 34

430. Claim 34 of the ’007 patent depends from claims 1 and 32 and further requires that “the corner frequency is selected by one or more switching capacitors switched a rate higher than the corner frequency of a low pass anti-aliasing filter.”

431. In my opinion, claim 34 of the ’007 patent is rendered obvious by Jensen in combination with Kroll and/or Jensen, Kroll, and DeLuca for all the reasons discussed above with respect to claims 1 and 32 as well as because each of Jensen and DeLuca teaches the additional limitation of claim 34. *See* Section XVI.B.2, *supra.*

432. Jensen explicitly discloses a “switched capacitor filter 11” as an element of its “filter circuit section 5.” Ex. 1011 at [0036]. The output of switched capacitor filter 11 has “bandpass cutoff frequencies of typically 1.5 Hz at the low-end and 17 Hz at the high-end.” *Id.* at [0037]. DeLuca teaches that “the signal conditioning stage 56 includes a hi-pass filter 56*a*” and that “[e]ach of the filter modules 56*a*, 56*c* and 56*d* is a switched-capacitor filter circuit whose cut-off frequency [*i.e.*, corner frequency] is determined by the clock frequency at which the filter is switched.” Ex. 1015 at 5:2–7. DeLuca further discloses that “[t]he signal

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output from the input stage 55 is first coupled to the hi-pass filter 56*a* which removes any DC component present in the signal before amplification." *Id.* at 5:9–12.

433. In my opinion, a POSA would recognize that the corner-frequency of the high-pass filter disclosed by either Jensen or DeLuca would be selected by one or more switching capacitors switched at a rate higher than the corner frequency of the low-pass filter. Ex. 1042 at 76 ("Commercial switched-capacitor ICs based on the same principle offer complete or nearly complete high-order filters in small, inexpensive packages. By switching the capacitor at around 100 times the corner frequency, these filters can attain a good approximation of theoretical performance.").

434. A POSA would therefore recognize that Jensen teaches the dependent limitation of claim 34. Additionally, or alternatively, for these reasons, as well as the reasons discussed above with respect to claim 32, it is my opinion that it would have been obvious to combine DeLuca's teaching of a high-pass filter with a selectable corner frequency selected by one or more switching capacitors switched at a rate higher than that of a low-pass anti-aliasing filter with Jensen's disclosure of bandpass filtering, meaning that the combination of Jensen, Kroll, and DeLuca renders obvious claim 34 of the '007 patent.

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5. Dependent Claim 35

435. Claim 35 of the ’007 patent depends from claims 1 and 32 and further require that “the high pass filter is implemented in software running on the microprocessor.”

436. In my opinion, claim 35 of the ’007 patent is rendered obvious by Jensen in combination with Kroll and DeLuca for all the reasons discussed above with respect to claims 1 and 32 as well as because DeLuca teaches the additional limitation of claim 35. *See* Section XVI.B.2, *supra.*

437. DeLuca teaches that the “operating parameters” of a “signal conditioning stage 56 can be externally programmed via the communications link 16 established with the control stage section 59 of the ASIC 36.” Ex. 1015 at 5:35–42.

438. In my opinion, a POSA would have understood that DeLuca’s ASIC could have also implemented the signal processing steps using software. At the time of the invention of the ’007 patent, heartbeat detection algorithms that included the use of one or more digital filters on a microprocessor were well known in the art. Ex. 1045 at 42–43 (noting publication of a number of algorithms based on digital filters). For example, implementing digital filters in software was a feature of the Pan-Tompkins QRS Detection Algorithm, which was well-known. *Id.* Therefore,

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in my opinion, a POSA would have understood that the high-pass filter of DeLuca could easily be implemented using software, rather than using physical circuits.

439. For these reasons, as well as the reasons discussed above with respect to claim 32, it is my opinion that it would have been obvious to combine DeLuca's teaching of a high-pass filter with a selectable corner frequency implemented in software running on the microprocessor with Jensen's disclosure of bandpass filtering, meaning that the combination of Jensen, Kroll, and DeLuca renders obvious claim 35 of the '007 patent.

C. Jensen Ground 3: Obvious Over Jensen, Kroll, Harland, and General Knowledge of a Person of Ordinary Skill in the Art

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

440. For the same reasons as discussed above, a POSA would have been motivated to combine Kroll's teaching of resistive traces with Jensen's device. *See* Section XVI.A.1, *supra.* Furthermore, for the same reasons as discussed above, a POSA would have had a reasonable expectation of success in combining Kroll's teaching of resistive traces with Jensen's device. *Id.* A POSA would have also looked to incorporate Harland's teaching of a capacitive sensor probe into Jensen's device in order to reduce the skin irritation that a patient may experience. "[G]el substances and the adhesives [used] to fix the electrodes on the body can provoke dermal irritation and even allergies." Ex. 1053 (Klaus-Peter Hoffmann & Roman Ruff, *Flexible dry surface-electrodes for ECG long-term monitoring* 5739 (2007)).

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Concerns over dermal tolerability of electrodes would be more prevalent in devices that are intended to be worn for an extended period of time, such as the device disclosed in Jensen. *Id.*

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

442. In my opinion, a POSA would have had a reasonable expectation of success in implementing Harland's capacitive electrode on Jensen's device without undue experimentation. The primary design change would be to modify the analog front end amplifiers, resistors, and/or capacitors to optimize for the difference in electrical impedances between the electrode and the body for a capacitive coupling like Harland as opposed to a direct coupling. All of the electronic components and methods necessary for a POSA to be successful in making this modification would

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have been commercially available at the time of the invention of the '007 patent. *See* Ex. 1016 at 165 (noting that the "development of the electronics required for these sensors has been discussed in detail in previous publications"). There is nothing in the art to suggest that this modification would not work, and this modification would not be difficult to implement using well-known manufacturing techniques at the time of the invention.

2. Dependent Claim 2

443. Claim 2 of the '007 patent depends directly from claim 1 and additionally requires that "the plurality of electrical connections to the body comprise at least one of direct electrical connections to the body and indirect electrical connections to the body."

444. As discussed previously, it is my opinion that Jensen discloses claim 2 of the '007 patent. Additionally or alternatively, it is further my opinion that claim 2 of the '007 patent is rendered obvious by Jensen in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Harland teaches the additional limitation of claim 2. *See* Section XVI.A.2, *supra*.

445. A POSA would understand that an "indirect electrical connection" to the body is one in which the conductor(s) do not make actual contact with the skin. *See, e.g.*, Ex. 1054 (Tsuyoshi Kato et al., *An Application of Capacitive Electrode for Detecting Electrocardiogram of Neonates and Infants*, 2006 Int'l Conf. of the IEEE

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Eng'g Med. & Bio. (2006)) at 919. The '007 patent explains that one example of an "indirect" electrical connection with the patient's body is "by capacitive coupling." Ex. 1001 at 4:13–19.

446. Harland discloses ultra-high impedance electric potential sensors that "allow the remote (non-contact) detection of electric potentials generated by currents flowing in the body." Ex. 1016 at 164. In the "remote, off-body detection" application, these electrodes "form capacitive [*i.e.*, indirect] coupling to the body under measurement." *Id.* As explained above, it would have been obvious to a POSA to modify Jensen to include at least one such capacitive electrode. *See* Section XVI.C.1, *supra*. As modified, the device of Jensen would therefore include at least one indirect connection to the body. And, as explained above, the electrical connection between the patient's skin and the sensor contacts of Jensen's device are an example of an "direct electrical connection." Ex. 1011 at [0041]; *see* Section XVI.3, *supra*.

447. For these reasons, it is my opinion that a POSA would understand that Harland discloses "the plurality of electrical connections to the body compris[ing] at least one of direct electrical connections to the body and indirect electrical connections to the body" and, therefore, that the combination of Jensen, Kroll, and Harland renders obvious claim 2 of the '007 patent.

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3. Dependent Claim 3

448. Claim 3 of the ’007 patent depends from claims 1 and 2 and additionally requires that “the indirect electrical connections to the body comprise capacitive connections to the body.”

449. In my opinion, claim 3 of the ’007 patent is rendered obvious by Jensen in combination with Kroll and Harland for all the reasons discussed above with respect to claims 1 and 2 as well as because Harland teaches the additional limitation of claim 3. *See* Section XVI.C.2, *supra.*

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

451. For these reasons, it is my opinion that it would have been obvious to a POSA to modify the device taught by Jensen to so that “the indirect electrical connections to the body comprise capacitive connections to the body” and, therefore, that the combination of Jensen, Kroll, and Harland renders obvious claim 3 of the ’007 patent.

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D. Jensen Ground 4: Obvious Over Jensen, Kroll, Thompson, and General Knowledge of a Person of Ordinary Skill in the Art

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

452. For the same reasons as discussed above, a POSA would have been motivated to combine Kroll's teaching of resistive traces with Jensen's device. *See* Section XVI.A.1, *supra.* Furthermore, for the same reasons as discussed above, a POSA would have had a reasonable expectation of success in combining Kroll's teaching of resistive traces with Jensen's device. *See id.*

453. In my opinion, a POSA would have also looked to incorporate Thompson's teaching of a periodic low power mode based on the electrical signals of a heartbeat with Jensen's device. The utility of a battery-powered, wearable device is limited by its battery-life and the size and composition of the battery is limited by the dimensional requirements of a body-worn physiological monitor. Therefore, in my opinion, a POSA would seek to optimize power consumption as a means of prolonging the battery life of the device and extending the period for which the device can collect data.

454. Jensen presents one of the possible solutions for optimizing power consumption of the device by limiting the depletion of the battery: using a "switched supply voltage driver 29" so that "power from the system power source 9 is conserved whenever the sensors 1, 2 are not in contact with the user's skin." Ex. 1011 at [0031]. In addition to Jensen's solution, however, there were many other

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techniques for optimizing battery life of which a POSA would have been aware, including the use of a periodic low power mode. *See, e.g.*, U.S. Patent Publication No. 2003/0055460 ("Owen") (Ex. 1055) (filed May 31, 2002) at [0019] ("By having the processor operate in a low-power consumption mode, the invention reduces the amount of power consumed by the defibrillator. As a result, a power supply will last longer in the defibrillator of the present invention than in its conventional counterparts.").

455. In my opinion, a POSA would by default always consider, and where feasible adapt, additional power conservation solutions that would conserve power while the device was operational. Such solutions would allow battery usage to be even more efficient, thereby allowing for a reduction in the overall size of the batteries—and thus the size of the devices—as desired by the industry. *See* Section IV.B., *supra.*

456. Thompson discloses an approach to power conservation by limiting processing time to certain portions of the heartbeat waveform. In one embodiment, Thompson discloses that "[o]nly during a QRS complex, for example, does waveform analysis processor 520 operate in a high speed processing mode at a relatively high frequency. During the remainder of the cardiac cycle [*i.e.*, during the TP interval] the DSP processor 520 may be 'idling along' at a much lower clock frequency. . . . In addition to the lower clock speed utilized for different portions of

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the cardiac cycle, one skilled in the art will recognize that in accordance with the other aspects of the present invention, as the speed is reduced, the supply voltage level (V_{DD}) may also be reduced accordingly. Thus, the objective of reduced power consumption is realized." Ex. 1017 at 18:3–14.

457. In my opinion, a POSA would have had a reasonable expectation of success in implementing Thompson's low power mode on Jensen's device without undue experimentation. It would only require reprogramming of onboard firmware and/or software to do so. Therefore, it is my opinion that a POSA would know how to combine Thompson's low power mode with Jensen's design with little to no design impact. Further, there is nothing in the art to suggest that this modification would not work.

2. Dependent Claim 39

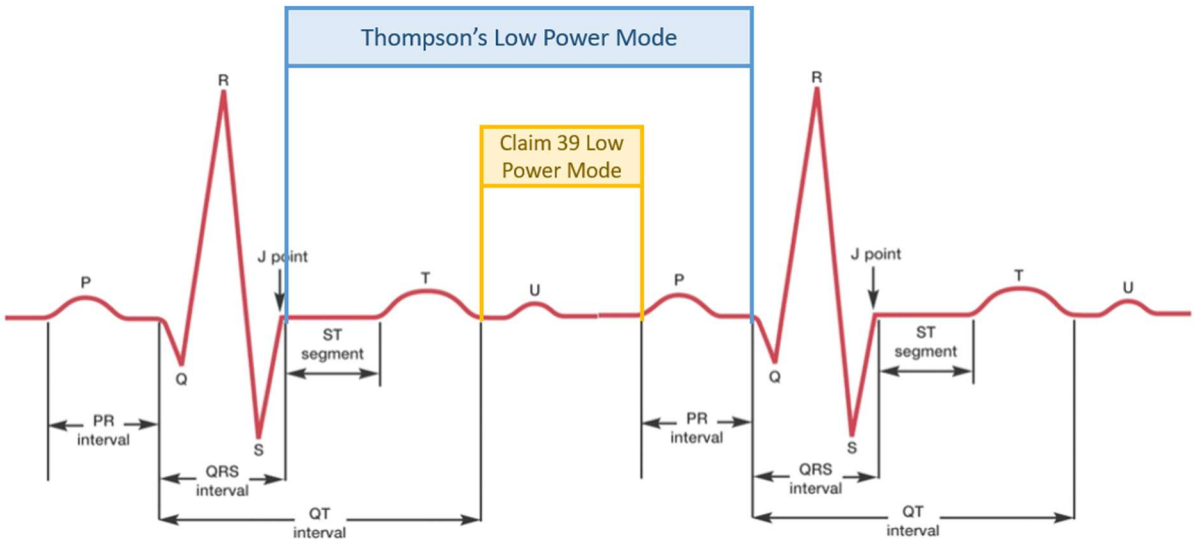
458. Claim 39 of the '007 patent depends from claim 1 and additionally requires that "an algorithm running on a microprocessor in the body worn device causes the body worn device to enter a low power mode that disables at least one circuit of the body worn device, from the end of a 'T wave' at the end of one heart beat to the beginning of a 'P wave' at the beginning of the next heart beat, to save power."

459. In my opinion, claim 39 of the '007 patent is rendered obvious by Jensen in combination with Kroll and Thompson for all the reasons discussed above

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with respect to claim 1 as well as because Thompson teaches the additional limitation of claim 39. *See* Section XVI.A.2, *supra.*

460. The device disclosed by Thompson conserves power by operating in a low power mode from the end of one S-wave of the patient's heartbeat until the commencement of the next Q-wave, meaning Thompson's device operates in a high-power mode only during the QRS interval. Ex. 1017 at 18:3–14. In my opinion, a POSA would understand that Thompson's low power mode is active for a period that includes the period "from the end of a 'T wave' at the end of one heartbeat to the beginning of a 'P wave' at the beginning of the next heartbeat," as shown by the annotated figure below.



461. Furthermore, for the reasons discussed above in Section XVI.C.1, it is my opinion that a POSA would also recognize that this low power mode could be implemented on Jensen's microprocessor. *Id*.

462. For these reasons, it is my opinion that it would have been obvious to a POSA to modify the device taught by Jensen to include "an algorithm running on a microprocessor in the body worn devices causes the body worn device to enter a low power mode that disables at least one circuit of the body worn device, from the end of a 'T wave' at the end of one heart beat to the beginning of a 'P wave' at the beginning of the next heart beat, to save power" and, therefore, that the combination of Jensen, Kroll, and Thompson renders obvious claim 39 of the '007 patent.

XVII. THE CHALLENGED CLAIMS OF THE '007 PATENT ARE UNPANTEABLE OVER MATSUMURA AND THE PRIOR ART

A. Matsumura Ground 1: Obvious Over Matsumura, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art

463. Additionally and alternatively, it is my opinion that claims 1, 2, 4–6, -8, 10-15, 29, 31 37, 38, and 43–45. of the '007 patent are obvious under pre-AIA § 103 over Matsumura, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art.

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1. A POSA would have been motivated to combine Matsumura and Kroll

464. In my opinion, a POSA would have found it obvious to combine the devices and methods of Matsumura and Kroll.

465. Matsumura and Kroll both disclose body-worn devices used to collect and monitor a patient's physiological data, including specifically EKG data. Ex. 1012 at [0024], [0031], Fig. 2; Ex. 1013 at Abstract, 1:11–15, 1:37–45, 1:60. Kroll explicitly teaches that its disclosed device is "flexible." Ex. 1013 at 4:27–30 (describing the "***flexible*** and disposable electrode belt 10 [ ] used to receive and transmit an electric current or voltage from and to the body of a patient") (emphasis added). In my opinion, a POSA would understand that Matsumura's "bioelectrode pad" is flexible. Matsumura teaches that its "bioelectrode pad" is preferably composed of sheets made from "polyethylene foam, polyurethane foam, or polyurethane sheet," which are all materials that a POSA would recognize as "flexible." Ex. 1012 at [0017]. Indeed, the use of flexible polyethylene and polyurethane to create flexible, wearable medical devices was well known in the art at the time of the purported invention. *See, e.g.*, Ex. 1047 at 23.11; Ex. 1056 (Tilak Shah, *Polyurethane Thin-Film Welding for Medical Device Applications*, Med. Device and Diagnostic Indus. (2002)) at 2.

466. Matsumura teaches a "bioelectric potential detector," which is "worn on the subject's chest to detect electrocardiogram signals," Ex. 1012 at [0024], and

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which "determines whether the detected electrocardiogram of the subject (patient) is abnormal, such as an arrhythmia or an abnormal heart rate," *id.* at [0037]. Specifically, Matsumura's device "wirelessly transmits the bioelectric potential detected . . . to inform medical staff or family members of the bioelectric potential information, so that they can quickly treat and cope with a sudden change in condition." *Id.* at [0041].

467. In my opinion, a POSA developing a flexible, body-worn device for monitoring ECG data at this time—such as the device disclosed in Matsumura—would have sought to incorporate the "resistive trace" of Kroll for at least two reasons.

468. First, a POSA would recognize that Kroll's teaching of a solution to electrical overload would be beneficial for Matsumura's device. Specifically, Kroll discloses 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 discusses the use of the lead strips in the context of protecting a patient from "shock," from the worn device or "a complementary medical device." *Id.* In my opinion, 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. 1035 at 644 ("**Current-carrying capacity:** The maximum current which can be carried continuously, under specified conditions, by a conductor without

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causing degradation of electrical or mechanical properties of the printed circuit board."). Kroll's 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.

469. Matsumura's device is a wearable monitor to which these same considerations apply. Thus, in my opinion, a POSA would have been motivated to incorporate Kroll's teaching of resistive "lead strips" with the body-worn monitoring device disclosed by Matsumura in order to protect the patient from potential shock and to ensure the long-term viability of the device by protecting the circuitry of the body-worn device against a possible defibrillation.

470. Second, consistent with industry efforts at the time, a POSA would seek to reduce the size of Matsumura's device to the extent possible. *See* Section III.C., *supra; see also* Ex. 1044 at 87.2 ("Convenience for the user is also extremely important in encouraging use of a device. Applications that require devices to be portable must certainly be light enough to be carried."). A POSA would understand that using the resistive lead strips, as taught by Kroll, would provide the means to reduce the physical size of the reusable portions of Matsumura's wearable device, which Matsumura also seeks to waterproof. Ex. 1012 at [0006]. In my opinion, a POSA would know that using the resistive lead strips made of an ink compound as

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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. *See* Ex. 1035 at 1–2 (noting that "us[e] [of] printed circuit boards" allows for "[t]he size of component assembly [to be] reduced with a corresponding decrease in weight," among other benefits).

471. Further, it is my opinion that a POSA would have had a reasonable expectation of success in combining the teachings of Matsumura and Kroll because doing so would involve using the screen-printing technique which was well-known for printed circuit board manufacture. *See* Section IV.C, *supra.* At the time of invention of the Challenged Patents, printing ink—such as disclosed by Kroll—onto a circuit board was well-known. *See* Ex. 1035 at 296 ("Printing Process. The circuit patterns are screen printed on the substrate by two ways: (1) Manual screen printing process, and (2) Automatic or semi-automatic screen printing process."); *see also* Section IV.C, *supra*. Nothing in the art suggests that this modification would not work, as screen printing was a standard way to manufacture many types of printed circuit boards. *Id.* Further, this modification would not be difficult to implement using well-known manufacturing techniques because, as discussed above, screen-printing of printed circuit boards was well-known.

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2. Independent Claim 1

472. In my opinion, claim 1 of the ’007 patent is rendered obvious by Matsumura in combination with Kroll.

i. Preamble 1[pre]

473. The preamble of claim 1 recites “[a] body worn patient monitoring device comprising.”

474. In my opinion, to the extent that the preamble is limiting, Matsumura discloses the preamble of claim 1 of the ’007 patent. Matsumura discloses a body worn patient monitoring device that it refers to as a “bioelectric potential detector” which “can be used as an electrocardiogram detector that is worn on the subject’s chest to detect electrocardiogram signals.” *See, e.g.*, Ex. 1012 at Abstract, [0024]. Kroll also discloses a body-worn patient monitoring device. *See, e.g.*, Ex. 1013 at 1:11–15 (describing invention as “a disposable, flexible and layered electrode belt . . . for placement and use on the body of a patient and also for use with medical diagnostic and therapeutic devices”).

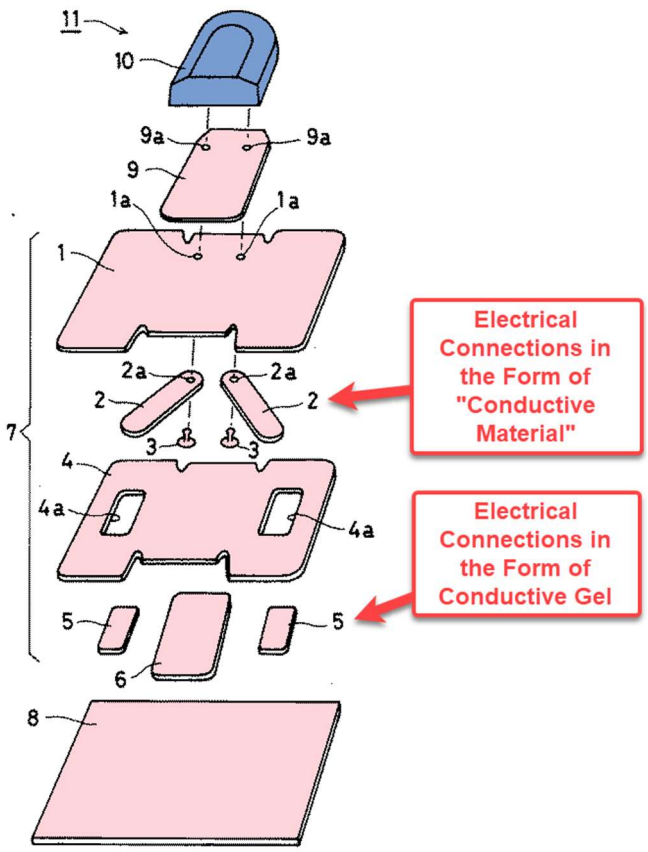
475. Thus, in my opinion, Matsumura and Kroll disclose “[a] body worn patient monitoring device.”

ii. Limitation [1a]

476. Limitation [1a] of the ’007 patent recites “a disposable module including a plurality of electrical connections.”

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477. In my opinion, Matsumura discloses limitation [1a] of the '007 patent. Matsumura's body-worn device (*i.e.*, "bioelectric potential detector") includes a "***disposable*** bioelectrode pad" which uses "conductive gel 5" to detect bioelectric potentials and form electrical connections with the patient's skin. Ex. 1012 at [0016] (emphasis added); *see also id.* at [0007]–[0008], [0014], [0019], Figs. 1–2. As shown by annotated Figure 1 below, Matsumura discloses two pieces of "conductive material 2" which form electrical connections to the signal processor through the interface between holes 2a and hooks 3. *Id.* at [0019]. Matsumura also discloses two pieces of "conductive gel 5" which form electrical connections with the patient's skin and detect bioelectric potentials. *Id.*



Id. at Fig. 1 (annotated).

478. Thus, in my opinion, Matsumura and Kroll render obvious "a disposable module including a plurality of electrical connections."

iii. Limitation [1b]

479. Limitation [1b] of the '007 patent recites "said electrical connections adapted to be couplable to a skin surface to measure physiological signals."

480. In my opinion, Matsumura discloses limitation [1b] of the '007 patent. As discussed above, Matsumura discloses "conductive gel[s] 5" which detect and transmit bioelectric potentials detected at the patient's skin surface and "conductive

material 2" which transmits the detected bioelectric potential to the signal processor 10." *See* Section XVII.A.2.ii, *supra*; Ex. 1012 at [0018]–[0019].

481. Matsumura teaches that its "bioelectric potential detector" is couplable to the patient's skin to measure physiological signals and teaches a protocol for doing so. Ex. 1012 at [0024]. The "conductive gel 5" is inserted through "two openings 4a on the left and right sides" of second sheet. *Id.* at [0018]. Then, an "adhesive, such as acrylic adhesive for example, is applied to the back surface of the second sheet 4." *Id.* In order to attach the bioelectric potential detector to a patient, "the release tape 8 is peeled off from the bioelectrode pad 7 and the detector is attached to the subject." *Id.* at [0024]. Peeling off the release tape 8 exposes second sheet 4 (*i.e.*, the bottom of bioelectric pad 7), which allows the adhesive layer to adhere the bioelectric pad to the patient's skin. *See also id.* at [0022] (describing making second sheet 4 "less adhesive to the living body" by covering center with optional third sheet 6).

482. In my opinion, a POSA would understand that "conductive gel" enables Matsumura's device to detect "bioelectric potentials," which are then transmitted "through the conductive material 2 and the hooks 3." *Id.* at [0019]. In my opinion, a POSA would understand that the conductive gel 5 can detect "bioelectric potentials" for transmission "through the conductive material 2 and the hooks 3" because the conductive gel 5 is embedded in second sheet 4. Thus, in my opinion,

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Matsumura discloses that "said electrical connections [are] adapted to be couplable to a skin surface to measure physiological signals."

iv. Limitation [1c]

483. Limitation [1c] of the '007 patent recites "at least one of said electrical connections comprising a half cell."

484. In my opinion, Matsumura discloses limitation [1c] of the '007 patent.

485. Matsumura discloses that "conductive gel 5" may be produced from components such as an "acrylic hydrophilic polymer, glycerin, and water." *Id.* at [0018]. Matsumura further discloses that the conductive gel 5 contacts "conductive material 2" which may be "coated with conductive Ag/AgCl." *Id.* at [0019]–[0020]. In my opinion, a POSA would understand that conductive gels comprising an acrylic hydrophilic polymer, glycerin, and water, and contacting a silver/silver-chloride conductive surface comprise a "half cell." Ex. 1001 at 6:48–57 (explaining that the term "electrode" is used interchangeably with "half cell" within the disclosure and that an electrode—*i.e.*, a half cell—typically comprises (1) a conductive surface and (2) an electrode gel).

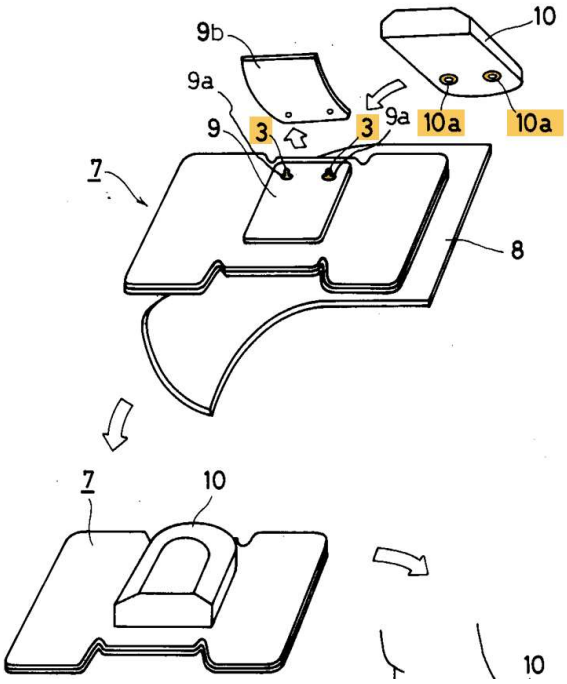
486. Thus, in my opinion, Matsumura discloses "at least one of said electrical connections comprising a half cell."

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v. Limitation [1d]

487. Limitation [1d] of the ’007 patent recites “the disposable module including a disposable module connector.”

488. In my opinion, Matsumura discloses limitation [1d] of the ’007 patent. As shown by annotated Figure 2 below, Matsumura’s disposable bioelectrode pad 7—the claimed “disposable module”—incorporates two “hooks 3” that connect to “hook engagement portion[s] 10a on the bottom surface of the signal processor 10.” Ex. 1012 at [0019], [0024].



Id. at Fig. 2 (annotated).

489. Thus, in my opinion, Matsumura discloses “the disposable module including a disposable module connector.”

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vi. Limitation [1e]

490. Limitation [1e] of the ’007 patent recites “a power source to power the body worn patient monitoring device.”

491. In my opinion, the teachings of Matsumura as understood by a POSA would render obvious limitation [1e] of the ’007 patent.

492. As previously discussed, the use of onboard power sources in wearable monitoring devices was well-known at the time of the invention of the Challenged Patents. *See* Section IV.C.*, supra.* This is also noted by Matsumura which explains that prior art wireless monitors included “a power source.” Ex. 1012 at [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”). In my opinion, a POSA would have understood Matsumura’s device to include an onboard power source because, without one, the device would otherwise be unable to make the wireless transmissions discussed. For example, Matsumura teaches that its device wirelessly transmits bioelectric potential signals from the signal processor to another device. *See, e.g.*, *id.* at Abstract, [0011], [0025] (monitor transmits “processed bioelectric potential signal . . . wirelessly”). Absent a power source integrated into the device, such wireless transmission would not be possible.

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493. Thus, in my opinion, Matsumura in view of a POSA discloses "a power source to power the body worn patient monitoring device."

vii. Limitation [1f]

494. Limitation [1f] of the '007 patent recites "a communication-computation module being removable and reusable."

495. In my opinion, Matsumura discloses limitation [1f] of the '007 patent. Matsumura teaches a "reusable signal processor 10." *Id.* at [0016]; *see also id.* at [0008], [0014], [0025], Figs. 1–2. Matsumura teaches that its "reusable signal processor 10" is "detachable" (*i.e.*, removable) from the disposable bioelectrode pad 7" with "hooks 3." *Id.* Matsumura teaches that its reusable signal processor incorporates components for communication: "a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna" and components for communication: "a processing circuit for filtering and amplifying detected bioelectric potential signals" and "a memory for storing the processed bioelectric potential signal." *Id.* at [0025].

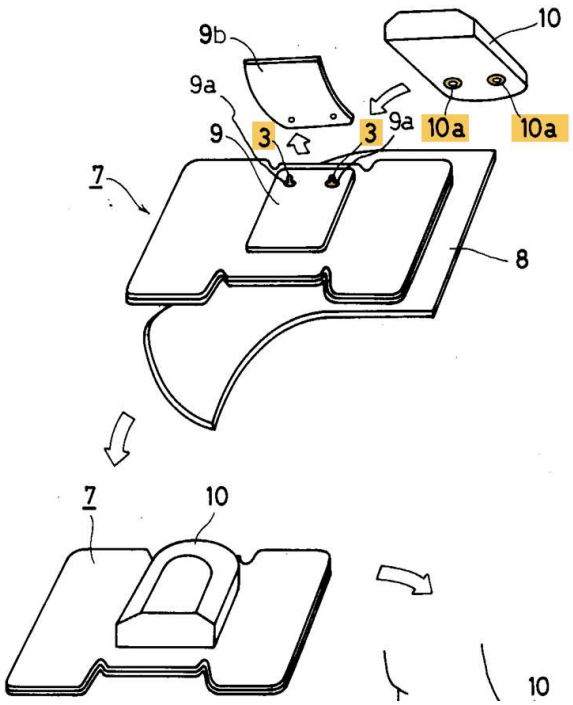
496. Thus, in my opinion, Matsumura discloses "a communication-computation module being removable and reusable."

viii. Limitation [1g]

497. Limitation [1g] of the '007 patent recites "having a communication-computation module connector to receive physiological signals from the disposable

module via said disposable module connector, the communication-computation module including."

498. In my opinion, Matsumura discloses limitation [1g] of the '007 patent. As discussed above, in Section XVII.A.2.v, Matsumura discloses that "hooks 3" (on the disposable bioelectrode pad 7) connect to "hook engagement portion 10a on the bottom surface of the signal processor 10" thus forming a mechanical and electrical connection between the disposable bioelectrode pad 7 and the signal processor 10. Ex. 1012 at [0024]; *see also id.* at [0008], [0014], Fig. 2 (shown below). Matsumura teaches that "the bioelectric potentials detected by the conductive gel 5 are transmitted through the conductive material 2 ***and the hooks 3.***" *Id.* at [0019] (emphasis added).



Id. at Fig. 2 (annotated).

499. Thus, in my opinion, Matsumura discloses "having a communication-computation module connector to receive physiological signals from the disposable module via said disposable module connector, the communication-computation module."

ix. Limitation [1h]

500. Limitation [1h] of the '007 patent recites "a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals, said analysis determining an occurrence of a predetermined physiological event."

501. In my opinion, Matsumura discloses limitation [1h] of the '007 patent. Matsumura teaches a "signal processor 10" which "incorporates ***a processing circuit*** for filtering and amplifying detected bioelectric potential signals." *Id.* at [0025] (emphasis added). Additionally, Matsumura teaches that the signal processor is used to monitor the patient's detected ECG signals and "determine[s] 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.* at [0032], [0037].

502. Thus, in my opinion, Matsumura specifically teaches a communication-computation module capable of actively monitoring the patient and performing a

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real-time physiological analysis of the occurrence of a predetermined physiological (*i.e.*, cardiac) event.

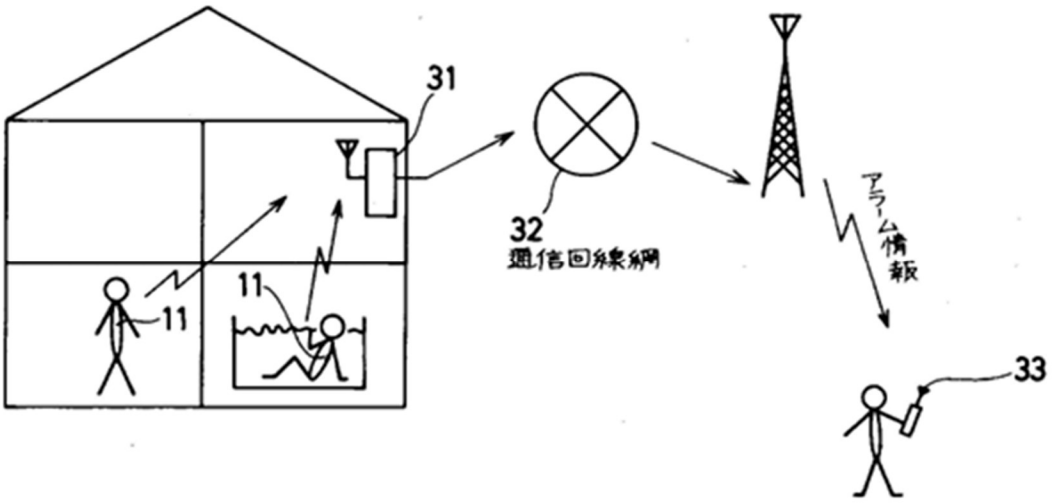
x. Limitation [1i]

503. Limitation [1i] of the '007 patent recites "a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event, via a radio transmission to a remote radio receiver."

504. In my opinion, Matsumura discloses limitation [1i] of the '007 patent. Matsumura teaches a communication-computation module ("signal processor 10") that incorporates "a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly," as well as a "loop antenna." *Id.* at [0025]. Matsumura discloses that the signal processor is used to monitor the patient's detected ECG signals and determines whether a predetermined physiological event, such as "an arrhythmia or an abnormal heart rate," occurs and, if so, "alarm information is sent to the portable terminal 33." *Id.* at [0037]; *see also* Section VI.B.2.ix., *supra.*

505. Matsumura further teaches that the "electrocardiogram signals received by the receiver 31 are transmitted via a communication line 32 to a portable terminal 33 carried by family members or medical staff" as shown by Figure 7 below. Ex. 1012 at [0036].

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Id. at Fig. 7.

506. Thus, in my opinion, Matsumura discloses "a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event [*e.g.*, arrhythmia, abnormal heart rate], via a radio transmission to a remote radio receiver."

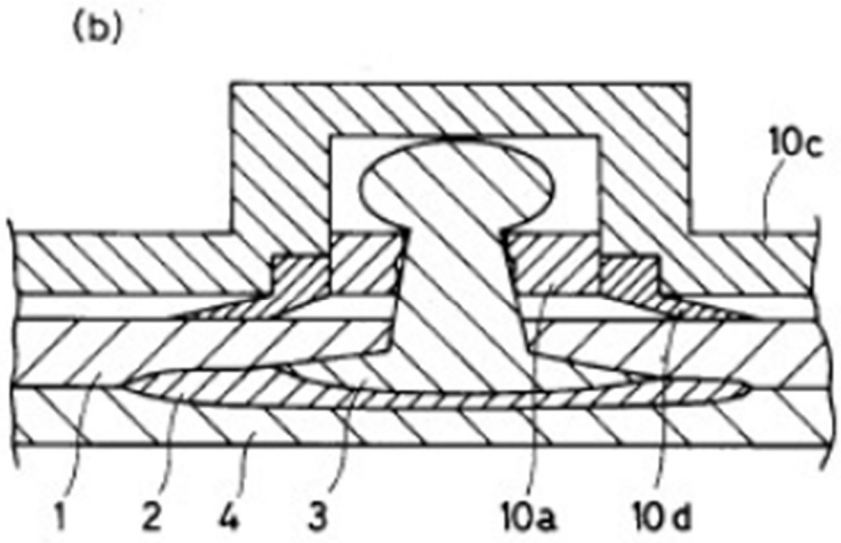
xi. Limitation [1j]

507. Limitation [1j] of the '007 patent recites "wherein the disposable module is mechanically and electrically coupled directly to the communication-computation module."

508. In my opinion, Matsumura discloses limitation [1j] of the '007 patent. Matsumura's bioelectrode pad ("disposable module") is coupled (both physically and electrically) to the disclosed signal processor ("communication-computation module") by the engagement of "hooks 3" that are "inserted into a hook engagement

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portion 10a on the bottom surface of the signal processor 10" as shown in Figure 5(b) below. *Id.* at [0024].



Id. at Fig. 5(b). Matsumura further discloses that this coupling is reinforced by "adhesive tape 9," which ensures that the components remain in contact throughout use. *Id.* at [0024], Fig. 5(b). The "hooks 3" directly contact the "reusable signal processor 10" because they are inserted through "holes 9a" in the "adhesive tape 9." *Id.* at [0016], [0023]–[0024]; *see also id.* at Fig. 2. Thus, in my opinion, Matsumura discloses that "the disposable module is mechanically and electrically coupled directly to the communication-computation module."

xii. Limitation [1k]

509. Limitation [1k] of the '007 patent recites "and the body worn patient monitoring device including the disposable module and the communication-

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computation module is adapted to be directly non-permanently affixed to the skin surface of the patient."

510. In my opinion, Matsumura discloses limitation [1k] of the '007 patent. Matsumura describes a method for attaching the disclosed bioelectric potential detector (which includes the bioelectrode pad and the reusable signal processor) to the patient so that it "can be used as an electrocardiogram detector that is worn on the subject's chest to detect electrocardiogram signals." *Id.* at [0024], Fig. 2. Specifically, Matsumura teaches:

> When attaching the bioelectric potential detector to a patient, the release sheet 9b is peeled off from the adhesive tape 9, the protruding portion of the hooks 3 protruding from the adhesive tape 9 is inserted into a hook engagement portion 10a on the bottom surface of the signal processor 10, the release tape 8 is peeled off from the bioelectrode pad 7 and the detector is attached to the subject. The bioelectric detector 11 can be used as an electrocardiogram detector that is worn on the subject' chest to detect electrocardiogram signals.

Id. at [0024]. Matsumura further discloses that an optional "third sheet 6" may be used to "make[] it easier to use the bioelectrode pad 7 in terms of **attaching it to and detaching it from** the biometric surface [*i.e.*, the skin] by making the center of the back surface of the second sheet 4 less adhesive to the living body," meaning the pad may be attached and detached from the patient's body. *Id.* at [0022] (emphasis added). Thus, in my opinion, Matsumura discloses that "the body worn patient monitoring device including the disposable module and the communication-

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computation module is adapted to be directly non-permanently affixed to the skin surface of the patient."

xiii. Limitation [1l]

511. Limitation [1*l*] of the '007 patent recites "at least one series current-limiting resistor configured to protect the communication-computation module."

512. In my opinion, the combination of Matsumura and Kroll discloses limitation [1*l*] of the '007 patent.

513. As discussed above in Section XVII.A.1, a POSA would have looked to combine Kroll's "resistive traces" with Matsumura's "bioelectric potential detector."

514. Kroll teaches at least one series current-limiting resistor. Kroll's device includes circuits comprising "lead strips" which "transmit and receive electric signals to and from the terminal end [ ] of the belt." Ex. 1013 at 5:1–4. Kroll's "lead strips" are composed of a preselected "flexible conductive ink compound having a conductive filler having Silver, Aluminum, or compounds thereof, or of a similarly suitable material" and "[p]referably the ink deposit is of a preselected conductivity to provide a certain total lead strip resistance so that each strip [ ] serves as a current limiter to protect a patient from shock due to malfunction of the device [ ] or of a complementary medical device." *Id.* at 5:4–13.

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515. As explained above, it is my opinion that a POSA would have known that the "resistive trace" of Kroll on a flexible, wearable medium would help safeguard Matsumura's signal processor/communication-computation module in the event of a patient being defibrillated. *See* Section XVII.A.1, *supra.* As the '007 patent acknowledges, there were existing medical standards that required "medical grade monitor[s]" to be able to "survive multiple defibrillation cycles of at least 360 joules." Ex. 1001 at 1:53–55, 10:19–29. In my opinion, a POSA would understand the EC-13 standard to require resistors that protect the communication-computation module during a defibrillation shock, which is typically 360 Joules. *See* Section IV.E., *supra.*

516. Thus, in my opinion, the combination of Matsumura and Kroll discloses "at least one series current-limiting resistor configured to protect the communication-computation module."

xiv. Limitation [1m]

517. Limitation [1m] of the '007 patent recites "the at least one series current-limiting resistor being screened on a flexible substrate."

518. In my opinion, the combination of Matsumura and Kroll discloses limitation [1m] of the '007 patent. Matsumura discloses a disposable bioelectrode pad composed of materials such as "polyethylene foam, polyurethane foam, or polyurethane sheet." Ex. 1012 at [0017]–[0018], [0022]. In my opinion, a POSA

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would recognize polyethylene foam, polyurethane foam, or polyurethane sheet as "flexible" materials. *See, e.g.*, Ex. 1047 at 23.11; Ex. 1056 at 2.

519. In my opinion, it would have been obvious to a POSA that Matsumura's flexible substrate includes electrical connections, *i.e.*, traces. And Kroll teaches the use of resistive traces or "lead strips" that are comprised of a "conductive ink compound" applied to a base layer "by means of a silk screen process." Ex. 1013 at 5:23–27, 5:37–42. As discussed above, a POSA would have understood "silk screen process" to refer to screen printing. Ex. 1035 at 661 (noting that "[s]creen [p]rinting" is "[a]lso called silk screening"). A POSA would have understood that this change would simply require the substitution of well-known component, *i.e.*, Silver/Silver Chloride, for another, *i.e.*, Carbon ink. Further, the carbon ink used in Kroll would have been readily available to a POSA from the same sources as the Silver/Silver Chloride previously used. Ex. 1057 (Creative Materials, *Medical Device Specialty Inks and Films*, *available at* http://www.creativematerials.com/literature/medical_device.pdf, *archived at Wayback Machine* (https://web.archive.org/web/20060508230449/http://www.creativematerials.com/literature/medical_device.pdf) (May 8, 2006)); *see also* Ex. 1058 (Aoife Morrin et al., *Electrochemical Characterization of Commercial and Home-Made Screen-Printed Carbon Electrodes*, 36 Anal. Letters, 2021 (2003)) at 2023–24.

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520. Thus, it is my opinion that it would have been obvious to a POSA to combine Matsumura's teaching of a communication-computation module on a flexible printed medium with Kroll's teaching of resistive traces screened on a flexible, wearable medium, and, therefore, the limitation "the at least one series current-limiting resistor being screened on a flexible substrate" would have been obvious in view of the combination of Matsumura and Kroll.

xv. Limitation [1n]

521. Limitation [1n] of the '007 patent recites "the at least one series current-limiting resistor being in the form of resistive traces."

522. In my opinion, the combination of Matsumura and Kroll discloses limitation [1n] of the '007 patent.

523. Kroll discloses circuits composed of "flexible conductive ink compound having a conductive filler, having Silver, Aluminum, or compounds thereof, or of a similarly suitable material" and further that the ink deposit is "[p]referably . . . 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 device." Ex. 1013 at 5:4–13.

524. A POSA would understand Kroll's disclosure of "lead strips" as referring to a "trace" as recited by the '007 patent. A POSA would understand that

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the terms "lead" and "trace" are often used interchangeably. Ex. 1035 at 642 ("Conductor: A single conductive path in conductive pattern. A PCB has at least one layer of conductors. *Synonyms:* path, trace."). Further, a POSA would have understood the term "*resistive* trace" to simply refer to a lead, trace, wire, etc. which has a specific resistance. *See, e.g.*, Ex. 1013 at 5:4–21.

525. Thus, in my opinion, it would have been obvious to a POSA to combine Matsumura's teaching of a communication-computation module on a flexible printed medium with Kroll's teaching of resistive traces on a flexible printed medium, thus disclosing the limitation "the at least one series current-limiting resistor being in the form of resistive traces."

3. Dependent Claim 2

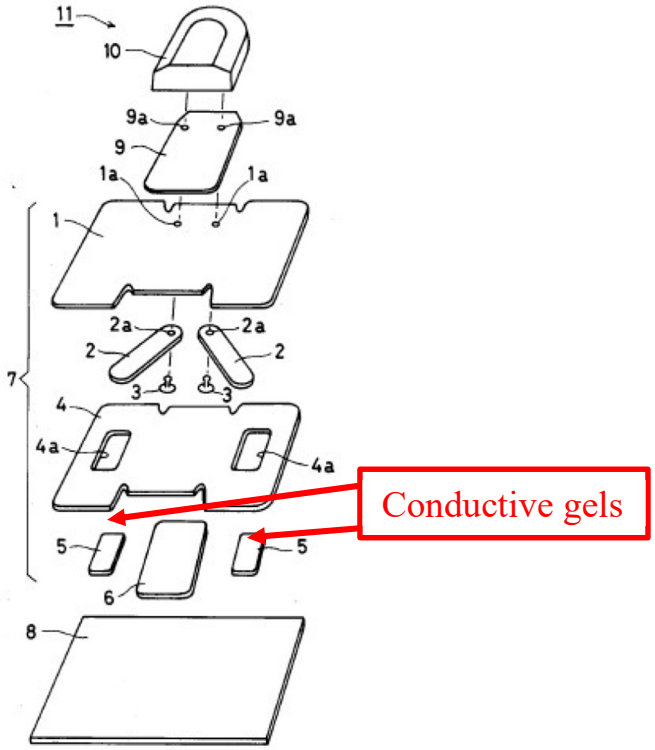
526. Claim 2 of the '007 patent depends from claim 1 and additionally requires that "the plurality of electrical connections to the body comprise at least one of direct electrical connections to the body and indirect electrical connections to the body."

527. In my opinion, claim 2 of the '007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Matsumura teaches the additional limitation of claim 2. *See* Section XVII.A.2, *supra.*

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528. Matsumura teaches that, after release tape 8 is removed, bioelectrode pad 7 of Matsumura is placed on the patient's skin. Ex. 1012 at [0007]–[0008], [0014], [0016], Figs. 1-2. Accordingly, Matsumura discloses "direct electrical connections to the body."

529. Similarly, in Kroll's device, the conductive gel pads form a direct electrical connection with the patient's skin. Ex. 1013 at 5:53–55.



Ex. 1012, Fig. 1 (annotated). Accordingly, Kroll also discloses "direct electrical connections to the body."

530. For these reasons, it is my opinion that a POSA would understand that Matsumura discloses "the plurality of electrical connections to the body compris[ing] at least one of direct electrical connections to the body and indirect

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electrical connections to the body" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 2 of the '007 patent.

4. Dependent Claim 4

531. Claim 4 of the '007 patent depends from claim 1 and further requires that "the body worn patient monitoring device comprises an ECG monitor and at least two of the electrical connections are ECG electrodes."

532. In my opinion, claim 4 of the '007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Matsumura teaches the additional limitation of claim 4. *See* Section XVII.A.2, *supra.*

533. Matsumura discloses a bioelectric potential detector 11 that "can be used as an **electrocardiogram detector** that is worn on the subject's chest to detect electrocardiogram signals" using conductive gels 5. Ex. 1012 at [0024] (emphasis added); *see also id.* at [0018]. Matsumura also teaches that "at least two of the electrical connections are ECG electrodes." Matsumura discloses two "conductive gels 5," which comprise two ECG electrodes. *See* Section XVII.A.2.iv, *supra*.

534. For these reasons, it is my opinion that Matsumura discloses "the body worn patient monitoring device comprises an ECG monitor and at least two of the electrical connections are ECG electrodes" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 4 of the '007 patent.

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5. Dependent Claim 5

535. Claim 5 of the ’007 patent depends from claims 1 and 4 and additionally requires that “the ECG electrodes comprise a material screened onto the flexible substrate.”

536. In my opinion, claim 5 of the ’007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claims 1 and 4 as well as because Matsumura teaches the additional limitation of claim 5. *See* Sections XVII.A.4, *supra.*

537. Matsumura discloses that its disclosed “bioelectrode pad” is preferably composed of sheets made out of “polyethylene foam, polyurethane foam, or polyurethane sheet,” which are all materials that a POSA would recognize as “flexible.” Ex. 1012 at [0017]–[0018]; Section XVII.A.2.xiv, *supra*; Ex. 1047 at 23.11; Ex. 1056 at 2.

538. Kroll teaches a means of attaching ECG electrodes onto a flexible substrate. Specifically, Kroll teaches that “[e]ach electrode 35 has a conductive grid . . . applied to an insulation and base support layer 44 preferably by means of a silk screen process.” Ex. 1013 at 5:23–27. In my opinion, A POSA would have known to use the “silk screen process” taught by Kroll to attach “electrodes 35” to Matsumura’s “bioelectrode pad.” As discussed above, screen printing was a preferred process for manufacturing circuits in the industry at the time of the

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invention of the '007 patent. *See* Ex. 1035 at 283 (noting that "screen printing is a [ ] cheap and simple method" that is used to produce "[t]he majority of PCBs produced worldwide").

539. For these reasons, it is my opinion that the combination of Matsumura and Kroll discloses "the ECG electrodes comprise a material screened onto the flexible substrate" and, therefore, renders obvious claim 5 of the '007 patent.

6. Dependent Claim 6

540. Claim 6 of the '007 patent depends from claims 1, 4, and 5 and additionally requires that the "at least one series current-limiting resistor protects the communication-computation module during a patient defibrillation event."

541. In my opinion, claim 6 of the '007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claims 1, 4, and 5 as well as because the combination of Matsumura and Kroll teaches the additional limitation of claim 6. *See* Section XVII.A.5, *supra*.

542. Matsumura discloses a communication-computation module: the reusable signal processor includes a "processing circuit" of the bioelectrical potential signal and a "circuit for modulating . . . and transmitting" the bioelectrical potential signal). Ex. 1012 at [0025].

543. Kroll discloses using ink deposits to form "lead strips 34" which "provide a certain total lead strip resistance so that each strip 34 serves as a current

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limiter to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device." Ex. 1013 at 5:8–13.

544. In my opinion, a POSA would understand that these same ink deposits that protect the patient from shock would also—at the same time—protect the monitoring device during a defibrillation event. *See, e.g.*, Ex. 1043 at 816–17 (noting that the resistivity of a conductor depends on the properties of the conductor material), 819–20 (noting that current always flows in the direction of decreasing electric potential or voltage); *see also* Ex. 1018 at 1:36–45; Section IV.F., *supra*. As discussed above, it was well-known long before 2007 that body-worn devices must be capable of protecting both the patient and the wearable device from unwanted electrical discharge, such as from a defibrillation of the patient or from surplus electrical discharges from the device. *See* Sections IV.C, IV.E–F., *supra*.

545. Further, as the '007 patent acknowledges, there were existing medical standards that required "medical grade monitor[s]" to be able to "survive multiple defibrillation cycles of at least 360 joules." Ex. 1001 at 1:53–55, 10:19–29. A POSA would understand this to require resistors that protect the communication-computation module during a defibrillation shock, which is typically 360 Joules. *See* Section IV.F, *supra.*

546. For these reasons, it is my opinion that the combination of Matsumura and Kroll renders obvious claim 6 of the '007 patent.

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7. Dependent Claim 8

547. Claim 8 of the ’007 patent depends from claims 1 and 4 and additionally requires that “the mechanical interface from the at least one series current-limiting resistor to the EGG electrode comprises overlapped layers.”

548. In my opinion, claim 8 of the ’007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claims 1 and 4 as well as because the combination of Matsumura and Kroll teaches the additional limitation of claim 8. *See* Section XVII.A.2.4, *supra.*

549. As discussed above in Section XVII.A.2.xiii, Kroll discloses “at least one series current-limiting resistor,” in the form of lead strips 34.

550. Kroll further teaches that “lead strips 34” (shown in green) “extend from each electrode 33, 35 [shown in red] to the terminal end 19” and overlap electrode 35 that includes a conductive grid 56 (shown in orange) “comprised of a matrix of approximately 0.050 inch wide lines 42 of conductive ink compound applied to an insulation and base support layer 44 preferably by means of a silk screen process” as shown below by Figure 5. Ex. 1013 at 5:17–21, 5:23–27, Fig. 5. Kroll further teaches that the “conductive ink compound used in the matrix lines 42 is generally the same as that utilized in the lead strips 34.” *Id.* at 5:23–27, 5:31–33.

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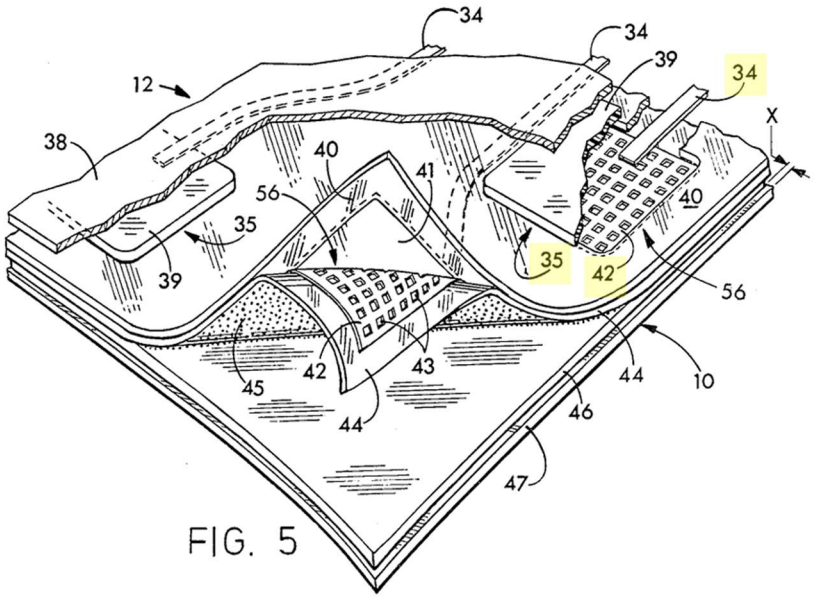


FIG. 5

Id. at Fig. 5 (annotated).

551. It is my opinion that a POSA at the time of the invention of the '007 patent would understand that the lead strips 34 and the matrix lines 42 were both screen-printed, as it was the standard technique for manufacturing circuit boards in the industry at the time. *See* Ex. 1035 at 283 (noting that "screen printing is a [ ] cheap and simple method" that is used to produce "[t]he majority of PCBs produced worldwide"). Screen printing of circuits is accomplished by printing overlapping layers of ink, one at a time, to make up the different components. *Cf. id.* at 211, Fig. 5.16. Such overlapping layers of ink can be, but do not necessarily need to be, composed of the same compounds. Thus, a POSA would have understood matrix lines 42 and lead strip 34 as overlapping layers that can be made of either the same or different materials.

552. For these reasons, it is my opinion that Kroll discloses "the mechanical interface from the at least one series current-limiting resistor to the EGG electrode comprises overlapped layers" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 8 of the '007 patent.

8. Dependent Claim 10

553. Claim 10 of the '007 patent depends from claim 1 and additionally requires "an insulating material overlaying the at least one series current-limiting resistor to prevent arcing."

554. In my opinion, claim 10 of the '007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Kroll teaches the additional limitation of claim 10. *See* Section XVII.A.2, *supra.*

555. In addition to teaching the "at least one series current-limiting resistor," *see* Section XVII.A.2.xiii *supra*, Kroll discloses that lead strip 34 (current-limiting resistor) is lined with insulation and base support layer 44 and inner patient insulation layer 40. Ex. 1013 at 5:43–50. Kroll further discloses that both the "inner patient insulation layer 40" and the "insulation and base support layer 44" are comprised of "polyester laminate." *Id.* at 5:37–42, 5:44–47.

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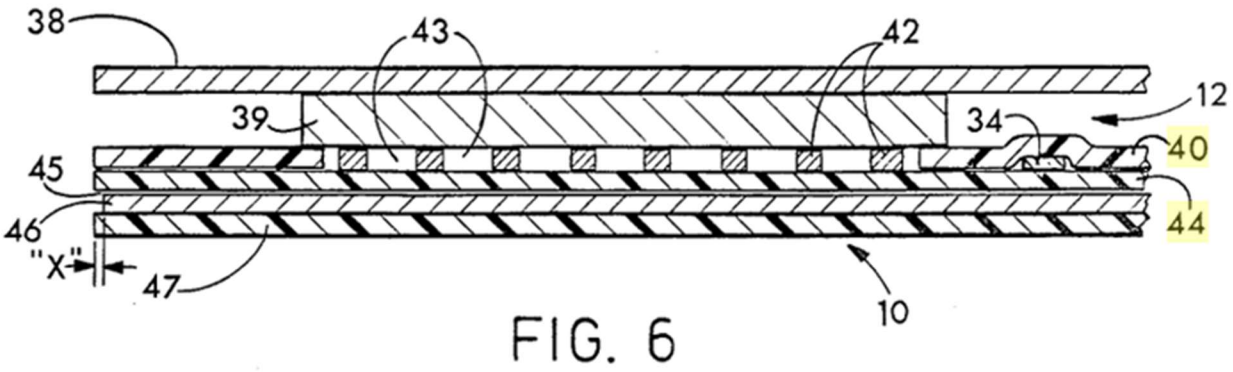


FIG. 6

Id. at Fig. 6 (annotated).

556. As shown above by Figure 6, Kroll's "inner patient insulation layer 40" and "insulation and base support layer 44" both overlay the "lead strip 34." Because Mylar has long been used for electrical insulation, a POSA would understand that polyester laminate has the necessary resistance to prevent the electric current coursing through lead strip 34 from jumping a connection (*i.e.*, "arcing"). Ex. 1048 at 13–14.

557. For these reasons, it is my opinion that a POSA would understand that Kroll discloses "an insulating material overlaying the at least one series current-limiting resistor to prevent arcing" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 10 of the '007 patent.

9. Dependent Claim 11

558. Claim 11 of the '007 patent depends from claims 1, 4, and 5 and further requires that "the EGG electrodes are formed substantially in the shape of an annulus."

559. In my opinion, claim 11 of the ’007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claims 1, 4, and 5 as well as because Matsumura teaches the additional limitation of claim 11. *See* Section XVII.A.5, *supra.*

560. The’007 patent explicitly defines the term “annulus” and notes that “[u]nder this definition, an annulus can include . . . substantially rectangular shapes with rounded corners.” Ex. 1001 at 6:23–63, 6:64-7:1. As previously discussed, the two conductive gels 5 of Matsumura are ECG electrodes. Ex. 1012 at [0019]; *see also* Section XVII.A.4, *supra*. The conductive gels 5 disclosed by Matsumura are substantially rectangular shapes with rounded corners, as shown below in Figure 1 of Matsumura.



Ex. 1012 at Fig. 1 (annotated).

561. For these reasons, it is my opinion that a POSA would understand that Matsumura discloses “the EGG electrodes are formed substantially in the shape of an annulus” and, therefore, that the combination of Matsumura and Kroll renders obvious claim 11 of the ’007 patent.

10. Dependent Claim 12

562. Claim 12 of the ’007 patent depends from claims 1, 4, 5, and 11 and further requires that “the annulus comprises a conductive link.”

563. In my opinion, claim 12 of the ’007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claims 1, 4, 5, and 11 as well as because Matsumura teaches the additional limitation of claim 10. *See* Section XVII.A.9, *supra.*

564. As discussed above with respect to claim 11, Matsumura teaches conductive gels 5 that are formed substantially in the shape of an annulus. *See* Section XVII.A.9, *supra.* Matsumura’s conductive gels 5 detect bioelectric potentials and transmit them through a portion of conductive material 2 (*i.e.*, a conductive link) that contacts the annulus formed by conductive gel 5. Ex. 1012 at [0019].

565. For these reasons, it is my opinion that a POSA would understand that Matsumura discloses that “the annulus comprises a conductive link” and, therefore, that the combination of Matsumura and Kroll renders obvious claim 12 of the ’007 patent.

11. Dependent Claim 13

566. Claim 13 of the ’007 patent depends from claims 1 and 5 and additionally requires that “the substrate is shaped to allow placement on the patient

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to monitor at least one of a set of standard ECG vectors while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal."

567. In my opinion, claim 13 of the '007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claims 1 and 5 as well as because the combination of Matsumura and Kroll teach the additional limitation of claim 13. *See* Section XVII.A.5, *supra.*

568. Matsumura teaches that "bioelectric potential detector 11 can be used as an electrocardiogram detector that is worn on the subject's chest to detect electrocardiogram signals." Ex. 1012 at [0024].

569. Kroll teaches that the "disposable electrode belt" attached to the patient's body has "a plurality of predetermined contact areas for receiving and transmitting electrical signals," and that these "predetermined contact areas" may be "arranged having one at each corner of the body structure and six centrally placed in the body structure to form a generally curvilinear pattern whereby said contact areas conform ***with standard precordial positions for 'twelve-lead' electrocardiographic devices***." Ex. 1013 at cls. 1, 13 (emphasis added). In my opinion, a POSA would have understood that placement at "standard EKG . . . electrode locations," as taught by Kroll, would measure standard ECG vectors.

570. Thus, a POSA would have known to place the bioelectrical potential detector 11 of Matsumura in one of the standard locations taught by Kroll. Further,

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a POSA would have understood that the standard locations taught by Kroll were well known in the field because they were locations where motion and muscle artifact in the corresponding ECG vector signals were minimized. Use of specific electrode placements to reduce the motion and muscle artifacts that interfered with EKG recording was well-known in the art. *See, e.g.*, Ex. 1049 at 116 (noting that "the motion artefact can be reduced and larger QRS amplitude can be obtained by selective placement of electrodes"), 120; *see also* Ex. 1031 at 74 (referring to the "conventional Holter recorder [which] samples ECG data comparable to data ***recorded by leads V1 and V5 of the standard 12-lead ECG***") (emphasis added).

571. Thus, in my opinion, a POSA would understand that the combination of Matsumura and Kroll discloses that "the substrate is shaped to allow placement on the patient to monitor at least one of a set of standard ECG vectors while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal" and, therefore, renders claim 13 obvious.

12. Dependent Claim 14

572. Claim 14 of the '007 patent depends from claim 1 and additionally requires that "the power source is a renewable power source internal to the body worn device."

573. In my opinion, claim 14 of the '007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with

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respect to claim 1 as well as because a POSA would understand that "the power source is a renewable power source internal to the body worn device." *See* Section XVII.A.2, *supra*.

574. In my opinion, a POSA have understood that a power source could be a renewable power source. Different types of renewable power sources, such as rechargeable batteries or one-time use batteries, were well known in the rechargeable batteries were well-known and commonly used at the time of the invention of the '007 patent. *Compare* Ex. 1042 at 386 ("Power for the circuit is obtained from a single nonrechargeable 3-V lithium battery"), *with* Ex. 1036 at 7 (specifying that manufacturers of devices that include rechargeable batteries must disclose certain information, *e.g.*, charging time).

575. Thus, in my opinion a POSA would understand that the combination of Matsumura and Kroll renders obvious dependent claim 14.

13. Dependent Claim 15

576. Claim 15 of the '007 patent depends on claim 1 and additionally requires that "the power source comprises a rechargeable battery or a one time use battery."

577. In my opinion, claim 15 of the '007 patent is rendered obvious by Matsumura in combination with Ozguz and Kroll for all the reasons discussed above with respect to claim 1 as well as because a POSA would understand that "the power

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source comprises a rechargeable battery or a one time use battery." *See* Section XVII.A.2, *supra.*

578. In my opinion, a POSA have understood that a power source could be a renewable power source. Different types of renewable power sources, such as rechargeable batteries or one-time use batteries, were well known and commonly used at the time of the invention of the '007 patent. *Compare* Ex. 1042 at 386 ("Power for the circuit is obtained from a single nonrechargeable 3-V lithium battery"), *with* Ex. 1036 at 7 (specifying that manufacturers of devices that include rechargeable batteries must disclose certain information, *e.g.*, charging time).

579. Thus, in my opinion a POSA would understand that the combination of Matsumura and Kroll renders obvious dependent claim 15.

14. Dependent Claim 29

580. Claim 29 of the '007 patent depends from claim 1 and additionally requires that "the body worn device includes circuit protection to allow the device to survive multiple defibrillation cycles of at least 360 joules."

581. In my opinion, claim 29 of the '007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Kroll teaches the additional limitation of claim 29. *See* Section XVII.A.2, *supra.*

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582. Kroll teaches "lead strips 34" which are composed of a conductive ink compound of a "preselected conductivity" in order to "provide a certain total lead strip resistance so that each strip 34 serves as a current limiter to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device." Ex. 1013 at 5:4–13.

583. In my opinion, a POSA would understand that these same ink deposits that protect the patient from shock would also—at the same time—help protect the monitoring device during a defibrillation event. *See, e.g.*, Ex. 1043 at 816–17 (noting that the resistivity of a conductor depends on the properties of the conductor material), 819–20 (noting that current always flows in the direction of decreasing electric potential or voltage); *see also* Ex. 1018 at 1:36–45 (disclosing leads made of "electrically conductive carbon loaded polymer" where the "distributed resistance of each polymer lead is sufficient to protect the EKG machine from defibrillation pulses"); Section IV.F., *supra*. As discussed above, it was well-known long before 2007 that body-worn devices must be capable of protecting both the patient and the wearable device from unwanted electrical discharge, such as from a defibrillation of the patient or from surplus electrical discharges from the device. *See* Sections IV.C, IV.E–F., *supra*.

584. Further, as the '007 patent acknowledges, there were existing medical standards that required "medical grade monitor[s]" to be able to "survive multiple

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defibrillation cycles of at least 360 joules." Ex. 1001 at 1:53–55, 10:19–29. A POSA would understand this to require resistors that protect the communication-computation module during a defibrillation shock, which is typically 360 Joules.

585. For these reasons, it is my opinion that Kroll discloses "the body worn device includes circuit protection to allow the device to survive multiple defibrillation cycles of at least 360 joules" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 29 of the '007 patent.

15. Dependent Claim 31

586. Claim 31 of the '007 patent depends from claims 1 and 29 and additionally requires that "a plurality of components of the circuit protection are distributed between the disposable module and the communication-computation module."

587. In my opinion, claim 31 of the '007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claims 1 and 29 as well as because Kroll teaches the additional limitation of claim 31. *See* Section XVII.A.14, *supra.*

588. As discussed above, Kroll discloses "at least one series current-limiting resistor configured to protect the communication-computation module." *See* Section XVII.A.2.xiii, *supra*. In my opinion, a POSA would understand the Kroll's current-limiting resistor helps protect the monitoring device from a defibrillation

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event. In order for Kroll's lead strips (*i.e.*, the claimed "current-limiting resistor") to provide protection for Matsumura's reusable signal processor (*i.e.*, the claimed "communication-computation module"), the lead strips must be placed or distributed between the electrodes on the disposable module (which is fixed to the patient's body) and the communication module (which houses the sensitive electronics). Notably, if the resistive strips were used as circuit protection with the intention of protecting the patient, the placement of the lead strips could be the same.

589. For these reasons, it is my opinion that the combination of Matsumura and Kroll discloses "a plurality of components of the circuit protection are distributed between the disposable module and the communication-computation module" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 31 of the '007 patent.

16. Dependent Claim 37

590. Claim 37 of the '007 patent depends from claim 1 and additionally requires that "the communication-computation module includes circuit components configured to detect failure of contact of one or more of the electrical connections with the skin surface of the patient."

591. In my opinion, claim 37 of the '007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with

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respect to claim 1 as well as because Matsumura teaches the additional limitation of claim 37. *See* Section XVII.A.2, *supra.*

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

593. In my opinion, a POSA would understand that Matsumura's signal processor would include circuit components that would detect failure of contact of one or more of the electrical connections with the skin surface of the patient. For example, a POSA would understand that if Matsumura's signal processor were capable of detecting arrhythmias, then it would be capable of detecting asystole—the "flat line"—which would occur if all of the electrodes lost contact with the patient's skin. *See* Ex. 1049 at 118–20 (accounting for the "missing data" when electrodes failed to adhere to the patient's skin for the duration of testing).

594. For these reasons, it is my opinion that Matsumura discloses that "the communication-computation module includes circuit components configured to

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detect failure of contact of one or more of the electrical connections with the skin surface of the patient" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 37 of the '007 patent.

17. Dependent Claim 38

595. Claim 38 of the '007 patent depends from claim 1 and additionally requires that "the communication-computation module is protected from external high energy signals by electro-surgical isolation suppression circuits."

596. In my opinion, claim 38 of the '007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Kroll teaches the additional limitation of claim 39. *See* Section XVII.A.2, *supra.*

597. Kroll teaches "lead strips 34" which are composed of a conductive ink compound 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 at 5:4–13.

598. In my opinion, a POSA would understand that circuits containing these same ink deposits that protect the patient from shock would also—at the same time—help protect the monitoring device from interference from an electrosurgical unit, thus forming "electrosurgical isolation suppression circuits." during a

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defibrillation event. *See, e.g.*, Ex. 1043 at 816–17 (noting that the resistivity of a conductor depends on the properties of the conductor material), 819–20 (noting that current always flows in the direction of decreasing electric potential or voltage); *see also* Ex. 1018 at 1:36–45; (disclosing leads made of "electrically conductive carbon loaded polymer" where the "distributed resistance of each polymer lead is sufficient to protect the EKG machine from defibrillation pulses"); Section IV.F., *supra*. As discussed above, it was well-known long before 2007 that body-worn devices must be capable of protecting both the patient and the wearable device from unwanted electrical discharge, such as from a defibrillation of the patient or from surplus electrical discharges from the device. *See* Sections IV.C, IV.E–F., *supra*. Further, as the '007 patent acknowledges, techniques to protect devices from electrosurgical interference were well known in the art: "AAMI standard EC13 on Electrosurgical Interference Suppression (ESIS). Standard EC13 addressed the ability of an ECG monitor to display and process ECG signals in a satisfactory manner while connected to a patient on whom an electroSurgical device is being used." Ex. 1001 at 14:25–30; *see generally*, Ex. 1036.

599. For these reasons, it is my opinion that a POSA would understand that Kroll discloses "the communication-computation module is protected from external high energy signals by electro-surgical isolation suppression circuits" and, therefore,

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that the combination of Matsumura and Kroll renders obvious claim 38 of the '007 patent.

18. Dependent Claim 43

600. Claim 43 of the '007 patent depends from claim 1 and additionally requires that "the radio circuit communicates an unprocessed physiological signal."

601. In my opinion, claim 43 of the '007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Matsumura teaches the additional limitation of claim 43. *See* Section XVII.A.2, *supra.*

602. Matsumura teaches that the detected "bioelectric potential signals are wirelessly transmitted" from detector 10 to a receiver 22a, 23a, 31, that "determines if the bioelectric signals are in an abnormal state." Ex. 1012 at [0013]; *see also* [0031], [0037], Figs. 7–8. In my opinion, a POSA would have understood this to mean that detector 10 merely detects the signal and transmits it to the receiver 22a, 23a, 31 for processing, meaning that the signal remains unprocessed until it is received by receiver 22a, 23a, 31. *See id.* at [0032] (teaching that the detected electrocardiogram data can be processed in either the "signal processor 10 of the bioelectric potential detector 11, the portable monitor 22, ***or*** the central monitor 23" to determine whether or not an abnormal state has been detected) (emphasis added). Further, a POSA would have understood that access to the unprocessed detected

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signals would have been standard at the time, because doctors would want to evaluate the unmanipulated, raw data in the event of an abnormal event or cardiac incident. *Cf.* Ex. 1034 at cls. 6, 76.

603. For these reasons, it is my opinion that a POSA would understand that Matsumura discloses "the radio circuit communicates an unprocessed physiological signal" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 43 of the '007 patent.

19. Dependent Claim 44

604. Claim 44 of the '007 patent depends from claim 1 and additionally requires that "the radio circuit communicates a result of the physiological analysis at a predetermined time."

605. In my opinion, claim 44 of the '007 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Matsumura and Kroll teach the additional limitation of claim 44. *See* Section XVII.A.2, *supra.*

606. Matsumura teaches "a circuit built into the signal processor 10," for "filtering and amplifying detected bioelectric potential signals," and "wirelessly transmit[ing] the bioelectric potential signals using a loop antenna" to a "portable monitor 22 for each subject (patient)." Ex. 1012 at [0003], [0025], [0031]. As Matsumura explains, "signal processor 10" of the "bioelectric potential detecting

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device 11" may determine an abnormality in the electrocardiogram such as arrhythmia or abnormal heart rate, and "[w]hen the state is changed, the alarm information is transmitted." *Id.* at [0037]-[0038]. The transmission "may be performed directly from the signal processor 10." *Id.* at [0039]. Thus, the transmission occurs at a predetermined time based on the change in state of the electrocardiogram.

607. This disclosure is consistent with what a POSA would have known about the design controls for regulatory approval of medical devices, such as bioelectric potential detecting devices. Transmission timing would have been a part of these design controls; continuous or even excessive transmission would have negative effects on critical device features including power consumption, data integrity, and failure modes. A POSA would have understood that predetermined timing for transmission was a fundamental aspect of these devices. Known thresholds upon which timing could have been based included the following: data accumulation into a data packet, periodic or scheduled transmission timing, or a physiological threshold. In addition to Matsumura's explicit disclosure of transmission at a predetermined time based on a physiological threshold, it would also have been obvious to a POSA to consider other thresholds for transmission at predetermined times. For these reasons, it is my opinion that Matsumura discloses that "the radio circuit communicates a result of the physiological analysis at a

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predetermined time" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 44 of the '007 patent.

20. Independent Claim 45

608. In my opinion, claim 45 of the '007 patent is rendered obvious by Matsumura in combination with Kroll.

i. Preamble 45[pre]

609. Limitation 45[pre] of the '007 patent recites "a body worn patient monitoring device comprising." As discussed above with respect to Claim 1, it is my opinion that Matsumura discloses a body worn monitoring device. *See* Section XVII.A.2.i.

ii. Limitation [45a]

610. Limitation [45a] of the '007 patent recites "a disposable module including a plurality of electrical connections." As discussed above with respect to Claim 1, it is my opinion that Matsumura discloses a disposable module including a plurality of electrical connections. *See* Section XVII.A.2.ii, *supra.*

iii. Limitation [45b]

611. Limitation [45b] of the '007 patent recites "the electrical connections adapted for electrical coupling to a skin surface to receive physiological signals." As discussed above with respect to claim 1, it is my opinion that Matsumura

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discloses that "the electrical connections [are] adapted for electrical coupling to a skin surface to receive physiological signals." *See* Section XVII.A.2.iii, *supra.*

iv. Limitation [45c]

612. Limitation [45c] of the '007 patent recites "the disposable module including a disposable module connector." As discussed above with respect to claim 1, it is my opinion that Matsumura discloses a disposable module including a disposable module connector. *See* Section XVII.A.2.v, *supra.*

v. Limitation [45d]

613. Limitation [45d] of the '007 patent recites "a power source to power the body worn patient monitoring device." As discussed above with respect to claim 1, it is my opinion that Matsumura discloses a power source to power the body worn patient monitoring device. *See* Section XVII.A.2.vi, *supra.*

vi. Limitation [45e]

614. Limitation [45e] of the '007 patent recites "a communication-computation module, having a communication-computation module connector to receive the physiological signals from the disposable module via the disposable module connector, the communication-computation module including." As discussed above with respect to claim 1, Matsumura discloses a communication-computation module, having a communication-computation module connector to

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receive the physiological signals from the disposable module via the disposable module connector. *See* Section XVII.A.2.vii–viii, *supra.*

vii. Limitation [45f]

615. Limitation [45f] of the ’007 patent recites “a microprocessor to actively monitor a patient and to perform a real-time physiological analysis of the physiological signals, the analysis determining an occurrence of a predetermined ECG event.”

616. In my opinion, limitation [45f] of the ’007 patent is obvious in view of a POSA’s knowledge.

617. Matsumura discloses using a “signal processor 10” that continuously detects signals to “determine[] whether or not the detected electrocardiogram of the subject (patient) is in an abnormal state, such as an arrhythmia or an abnormal heart rate measured from the electrocardiogram, and if an abnormal state occurs, the portable monitor 22 and the central monitor 23 are set to trigger an alarm.” Ex. 1012 at [0032]; *see also id.* at [0040]. In my opinion, a POSA would interpret the phrase “abnormal state” to mean a predetermined event that is programmed into the signal processor.

618. For these reasons, in my opinion, Matsumura, in view of the knowledge of a POSA, renders obvious “a microprocessor to actively monitor a patient and to

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perform a real-time physiological analysis of the physiological signals, the analysis determining an occurrence of a predetermined ECG event."

viii. Limitation [45g]

619. Limitation [45g] of the '007 patent recites "a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis, at a predetermined time or on an occurrence of a predetermined event, via a radio transmission to a remote radio receiver."

620. As discussed with respect to claim 44 and limitation [45f], it is my opinion that the Matsumura discloses limitation 45[g] of the '007 patent. *See* Sections XVII.A.19, XVII.A.20.viii*, supra.* To the extent that Matsumura does not explicitly disclose communication of an unprocessed physiological signal on the occurrence of a predetermined event, it is my opinion that it would be obvious to a POSA to implement such functionality on Matsumura's device. At the time of the invention of the '007 patent, it was well-known that a monitoring device could perform some various functionality, such as sounding an alarm for the patient, based on the occurrence of a predetermined event. *See, e.g.*, Ex. 1015 at 9:57–10:18 (discussing different types of events that could trigger an alarm or the logging of data). Thus, additionally and alternatively, it is my opinion that Matsumura, in view of the knowledge of a POSA, renders obvious "a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis, at a

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predetermined time or on an occurrence of a predetermined event, via a radio transmission to a remote receiver."

ix. Limitation [45h]

621. Limitation [45h] of the '007 patent recites "wherein the disposable module has a mechanical and electrical coupling to the communication-computation module." As discussed with respect to claim 1, it is my opinion that Matsumura discloses and renders obvious that "the disposable module has a mechanical and electrical coupling to the communication-computation module." *See* Section XVII.A.2.xi, *supra.*

x. Limitation [45i]

622. Limitation [45i] of the '007 patent recites "forming the body worn patient monitoring device as a single unit that is adapted to be directly and non-permanently affixed to the skin surface of the patient." As discussed with respect to claim 1, it is my opinion that Matsumura discloses forming the body worn patient monitoring device as a single unit that is adapted to be directly and non-permanently affixed to the skin surface of the patient. *See* Section XVII.A.2.xii, *supra.*

xi. Limitation [45j]

623. Limitation [45j] of the '007 patent recites "at least one series current-limiting resistor configured to protect the communication-computation module." As discussed with respect to claim 1, it is my opinion that the combination of

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Matsumura and Kroll discloses and renders obvious "at least one series current-limiting resistor configured to protect the communication-computation module." *See* Section XVII.A.2.xiii, *supra.*

xii. Limitation [45k]

624. Limitation [45k] of the '007 patent recites "the at least one series current-limiting resistor being screened on a flexible substrate." As discussed with respect to claim 1, it is my opinion that the combination of Matsumura and Kroll discloses and renders obvious "the at least one series current-limiting resistor being screened on a flexible substrate." *See* Section XVII.A.2.xiv, *supra.*

xiii. Limitation [45l]

625. Limitation [45l] of the '007 patent recites "the at least one series current-limiting resistor being in the form of resistive traces." As discussed with respect to claim 1, it is my opinion that the combination of Matsumura and Kroll discloses and renders obvious "the at least one series current-limiting resistor being in the form of resistive traces." *See* Section XVII.A.2.xv, *supra.*

B. Matsumura Ground 2: Obvious Over Matsumura, Ozguz, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art

626. Additionally and alternatively, it is my opinion that claims 1, 2, 4, 5, 14, 15, and 43–45 of the '007 patent are obvious under pre-AIA § 103 over

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Matsumura, Ozguz, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art.

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

627. For the same reasons as discussed above, a POSA would have been motivated to combine Kroll's teaching of "resistive traces" with Matsumura's device and would have had a reasonable expectation of success in doing so. *See* Section XVII.A.1, *supra*.

628. Like Matsumura, Kroll, and the Challenged Patents, Ozguz teaches a flexible, wearable device for monitoring physiological signals, including ECG or EKG signals. Ex. 1012 at [0024], [0031], Fig. 2; Ex. 1014 at [0003], [0010], [0017], [0046]–[0050], Figs. 1, 2A.

629. Matsumura discloses a "circuit," "signal processor," and "wireless transmitter" used to detect, process, and wirelessly transmit bioelectric signals. Ex. 1012 at [0025]. However, Matsumura does not discuss the specific circuit design or architecture used to perform these functions.

630. To the extent that the proper circuit design or architecture was not within the knowledge of a skilled artisan, an appropriate circuit design is disclosed by Ozguz. Ozguz discloses an architecture and design of "circuitry (71, 72, 73)" which includes a "microprocessor" and "transmitter" that perform the same functions as those same components in Matsumura. Thus, in my opinion, a POSA

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would have looked to the integrated circuits disclosed by Ozguz—which incorporate a "microprocessor 175, a ROM 180 for storing a program to be implemented, a RAM 185 for storing of data, and a transmitter or transceiver"—in order to achieve Matsumura's "signal processor." Ex. 1014 at [0058]; *see also id.* at [0039]. Further, it is my opinion that a POSA would have looked to Ozguz's teaching of a radio circuit to achieve the wireless "signal transmitter" taught by Matsumura. *Id.* at [0039]–[0040], [0042], [0048], [0058], Figs. 3A–3C.

631. In addition to its teaching of the architecture and design of the circuit, Ozguz teaches several advantages that would have motivated a POSA to incorporate its teachings into Matsumura's detector.

632. *First*, Ozguz teaches a "bio-sensor system" which is "unobtrusive," "self-contained," and "permits a subject person to not only be at home or work, but also to remain unencumbered by cords." *Id.* at [0008], [0014]. Ozguz's teaching of "unobtrusive" and "self-contained" circuitry would be helpful in achieving Matsumura's goal of providing a "cable-free and compact" detector. Ex. 1012 at [0006].

633. *Second*, Ozguz teaches that the "small size and wireless aspects of the instant sensor module avoid the noise that normally sullies the signal of past systems." Ex. 1014 at [0009]. Ozguz achieves this result by including a sensor module with "an integral power supply such that the signal remains clean and free

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from noise." *Id.* A POSA would thus be motivated to incorporate the circuit components of Ozguz into Matsumura to avoid noise levels and more "accurately detect electromagnetic" signals. *Id.*

634. *Third*, in addition to wirelessly transmitting detected signals, Ozguz teaches using a hard-wired connection and a non-volatile memory "in case power is lost to the sensor module." *Id.* at [0040]. Matsumura's bioelectrical potential detector 11 includes "a memory for storing the processed bioelectric potential signal." Ex. 1012 at [0025]. A POSA would have looked to modify Matsumura's memory with Ozguz's non-volatile memory to ensure the storage of any detected signals from being lost if the sensor loses power. But doing so may necessitate the storage of a large number of detected signals. To efficiently transmit this large number of stored signals, Ozguz teaches the use of a hard-wired connection through port 86. Ex. 1014 at [0040]. A POSA would have also understood that port 86 could be used to recover the stored signal data of Ozguz, even if power is never restored. Accordingly, a POSA would look to add connection "port 86" taught by Ozguz to Matsumura's bioelectrical potential detector 11. By adding this communication port inside of Matsumura's signal processor 10, a POSA could maintain Matsumura's watertight structure while allowing the option of a hard-wired connection to download stored data "in case power is lost to the sensor module."

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635. Further, it is my opinion that a POSA combining the teachings of Matsumura, Ozguz, and Kroll would have had a reasonable expectation of success in doing so. A POSA would have been able to incorporate Kroll's resistive traces and Ozguz's circuitry design into Matsumura's detector with minimal design impact using methods such as screen-printing, a well-known technique for printed circuit board manufacture. *See* Ex. 1035 at 283 (noting that "screen printing is a [ ] cheap and simple method" that is used to produce "[t]he majority of PCBs produced worldwide"). Nothing in the art suggested that this would not work.

2. Independent Claim 1

636. In my opinion, claim 1 of the '007 patent is rendered obvious by Matsumura in combination with Ozguz and Kroll.

i. Preamble 1[pre]

637. As explained above, it is my opinion that preamble 1[pre] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.i, *supra.*

ii. Limitation [1a]

638. As explained above, it is my opinion that limitation [1a] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.ii, *supra.*

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iii. Limitation [1b]

639. As explained above, it is my opinion that limitation [1b] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.iii, *supra.*

iv. Limitation [1c]

640. As explained above, it is my opinion that limitation [1c] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.iv, *supra.*

v. Limitation [1d]

641. As explained above, it is my opinion that limitation [1d] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.v, *supra.*

vi. Limitation [1e]

642. As explained above, it is my opinion that limitation [1e] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.vi, *supra.*

643. Additionally, and alternatively, it is my opinion that it would have been obvious to a POSA to modify Matsumura with the teachings of Ozguz to include "a power source to power the body worn patient monitoring device."

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644. For the reasons discussed above, a POSA seeking to make or use the invention disclosed by Matsumura would have looked to Ozguz's teachings of specific circuit design and structure and would have been motivated to combine the battery taught by Ozguz with the device taught by Matsumura. *See* Section XVII.B.1, *supra.* Ozguz also discloses a "flexible, thin battery" to power a body worn sensor module. Ex. 1014 at [0048], Figs. 3A–3C. A POSA would have sought to incorporate Ozguz's battery into Matsumura's device for the same reasons as discussed above. *Id.*

645. Thus, it is my opinion that the combination of Matsumura, Ozguz, and Kroll also renders obvious the limitation "a power source to power the body worn patient monitoring device."

vii. Limitation [1f]

646. As explained above, it is my opinion that limitation [1g] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.vii, *supra.*

viii. Limitation [1g]

647. As explained above, it is my opinion that limitation [1f] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.viii, *supra.*

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ix. Limitation [1h]

648. As explained above, it is my opinion that limitation [1h] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.ix, *supra.*

649. Additionally, and alternatively, it is my opinion that it would have been obvious to a POSA to modify Matsumura with the teachings of Ozguz to include "a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals, said analysis determining an occurrence of a predetermined physiological event."

650. Ozguz discloses flexible silicon substrates with respective integrated circuits that include a "microprocessor 175," said microprocessor configured to process data collected by the electrodes. Ex. 1014 at [0058], [0039]. Ozguz further discloses that "it is to be expressly understood that the I[ntegrated] C[ircuit]s 71, 72, 73 can be integrated as one IC on a single silicon substrate." *Id.* at [0042]. As explained above, a POSA would have sought to combine Ozguz's teachings related to circuit design and construction with Matsumura's disclosed monitoring device. *See* Section XVII.B.1, *supra.* Thus, in my opinion, the combination of Matsumura and Ozguz discloses "a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals, said analysis determining an occurrence of a predetermined physiological event."

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x. Limitation [1i]

651. As explained above, it is my opinion that limitation [1i] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.x, *supra.*

652. Additionally, and alternatively, it is my opinion that it would have been obvious to a POSA to modify Matsumura with the teachings of Ozguz to include "a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event, via a radio transmission to a remote radio receiver." As previously discussed, wearable devices which detected and communicated the occurrence of physiological events were standard in the art at the time. *See, e.g.*, Ex. 1041 at 1 (including within the standard's scope all parts of devices necessary to "provide summaries of rhythms, conduction disturbances, and displacements of the ST segment").

653. Ozguz teaches the use of a radio circuit to wirelessly transmit signal from the body-worn device to a remote receiver during monitoring. Ex. 1014 at [0039]–[0040], [0042], [0057]. Ozguz notes that its system "can incorporate continuous transmission by RF [radio frequency] signals 40 to a device 45 having a receiver" and that to achieve this embodiment, the device should include "at least one antenna 50" metallized onto a flexible substrate. *Id.* at [0039]. Ozguz thus

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teaches a "communication-computation module" that continuously transmits information to a remote receiver through a radio circuit. Further, it is my opinion that a POSA would have been motivated to combine incorporate Ozguz's teachings into Matsumura's detector for all the reasons discussed above. *See* Section XVII.B.1, *supra.*

654. For those reasons, as well as the reasons stated above in Section XVII.A.2.x, it is my opinion that the combination of Matsumura, Kroll, and Ozguz renders obvious "a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event, via a radio transmission to a remote radio receiver."

xi. Limitation [1j]

655. As explained above, it is my opinion that limitation [1j] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.xi, *supra.*

xii. Limitation [1k]

656. As explained above, it is my opinion that limitation [1k] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.xii, *supra.*

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xiii. Limitation [1l]

657. As explained above, it is my opinion that limitation [1*l*] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.xiii, *supra.*

xiv. Limitation [1m]

658. As explained above, it is my opinion that limitation [1m] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.xiv, *supra.*

659. Additionally, and alternatively, it is my opinion that it would have been obvious to a POSA to modify Matsumura with the teachings of Ozguz and Kroll to include "at least one series current-limiting resistor being screened onto a flexible substrate."

660. In my opinion, as discussed above, it would have been obvious to a POSA to combine Matsumura's flexible bioelectrode pad with the specific integrated circuits taught by Ozguz. *See* Section XVI.B.1, *supra*; Ex. 1014 at [0039], [0042], [0058]. Further, it would also be obvious to combine the resulting device with Kroll's "lead strips" for the reasons discussed above. *See* Section XVII.A.1.

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661. Thus, in my opinion, the limitation "the at least one series current-limiting resistor being screened on a flexible substrate" would have been obvious to a POSA in view of the combination of Matsumura, Ozguz, and Kroll.

xv. Limitation [1n]

662. As explained above, it is my opinion that limitation [1n] of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.2.xv, *supra.*

663. Additionally and alternatively, in my opinion, the combination of Matsumura, Ozguz, and Kroll discloses limitation [1n] of the '007 patent. As discussed above with respect to limitation [1m], Kroll teaches the existence of "lead strips" made of "flexible conductive ink compound having a conductive filler, having Silver, Aluminum, or compounds thereof, or of a similarly suitable material" in which the "ink deposit is of a preselected conductivity to provide a certain total lead strip resistance" in order for each lead strip to serve as a "current limiter." Ex. 1013 at 5:4–13.

664. A POSA would understand Kroll's disclosure of "lead strips" as referring to a "trace" as recited by the '007 patent. A POSA would understand that the terms "lead" and "trace" are often used interchangeably because signal traces connect the components on a printed circuit board much like lead wires functioned in the early days of ECG technology. *See* Ex. 1035 at 642 ("Conductor: A single

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conductive path in conductive pattern. A PCB has at least one layer of conductors. *Synonyms:* path, trace."). Further, a POSA would have understood the term "*resistive* trace" to simply refer to a lead, trace, wire, etc. which has a specific resistance, as taught by Kroll. *See, e.g.*, Ex. 1013 at 5:4–21.

665. As explained above, a POSA seeking to make or use the device taught by Matsumura would have looked to the teachings of Kroll to protect the device and its user, and to achieve a slimmer profile. *See* Sections XVII.A.1, XVII.A.2.xiii–xv, *supra.* In my opinion, a POSA would have had a reasonable expectation of success in combining Kroll's teaching of resistive traces with Matsumura's device.

666. Thus, in my opinion, the limitation "the at least one series current-limiting resistor being in the form of resistive traces" would have been obvious to a POSA in view of the combination of Matsumura, Ozguz, and Kroll.

3. Dependent Claim 2

667. Claim 2 of the '007 patent depends from claim 1 and additionally requires that "the plurality of electrical connections to the body comprise at least one of direct electrical connections to the body and indirect electrical connections to the body."

668. As explained above, it is my opinion that claim 2 of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.3., *supra.*

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669. Additionally, and alternatively, it is my opinion that claim 2 of the '007 patent is rendered obvious by Matsumura in combination with Kroll and Ozguz. Ozguz discloses "electrodes 80" that are "held secured against" a patient's "skin 15 by. . . adhesive pad 91," meaning that electrodes 80 have a direct electrical connection to the body. Ex. 1014 at [0043], [0045].

670. For these reasons, it is my opinion that a POSA would understand that each of Matsumura, Ozguz, and Kroll discloses "the plurality of electrical connections to the body compris[ing] at least one of direct electrical connections to the body and indirect electrical connections to the body" and, therefore, that the combination of Matsumura, Ozguz, and Kroll renders obvious claim 2 of the '007 patent. *See also* XVII.B.2.

4. Dependent Claim 4

671. Claim 4 of the '007 patent depends from claim 1 and further requires that "the body worn patient monitoring device comprises an ECG monitor and at least two of the electrical connections are ECG electrodes."

672. As explained above, it is my opinion that claim 4 of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.4, *supra.*

673. Additionally, and alternatively, it is my opinion that claim 4 of the '007 patent is rendered obvious by Matsumura in combination with Kroll and Ozguz.

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674. In my opinion, claim 4 of the '007 patent is rendered obvious by Matsumura in combination with Ozguz and Kroll for all the reasons discussed above with respect to claim 1 as well as because Matsumura and Ozguz teach the additional limitation of claim 4. *See* Section XVII.B.2, *supra.*

675. Matsumura specifically teaches the use of its disclosed bioelectric potential detector 11 "as an **electrocardiogram detector** that is worn on the subject's chest to detect electrocardiogram signals" using conductive gels 5. Ex. 1012 at [0024]; *see also id.* at [0018]. Matsumura also teaches that "at least two of the electrical connections are ECG electrodes." Matsumura discloses two "conductive gels 5," which comprise two ECG electrodes. *See* Section XVII.A.2.iv, *supra*.

676. Ozguz extensively discusses the usefulness of its disclosed device for EKG monitoring. *See, e.g.*, Ex. 1014 at [0017], [0044]. A POSA would understand that the terms "ECG" and "EKG" are synonymous and often used interchangeably. *See, e.g.*, Ex. 1046. Ozguz also teaches that "at least two of the electrical connections are ECG electrodes." Ozguz's device includes three "electrodes 80 disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20." Ex. 1014 at [0039].

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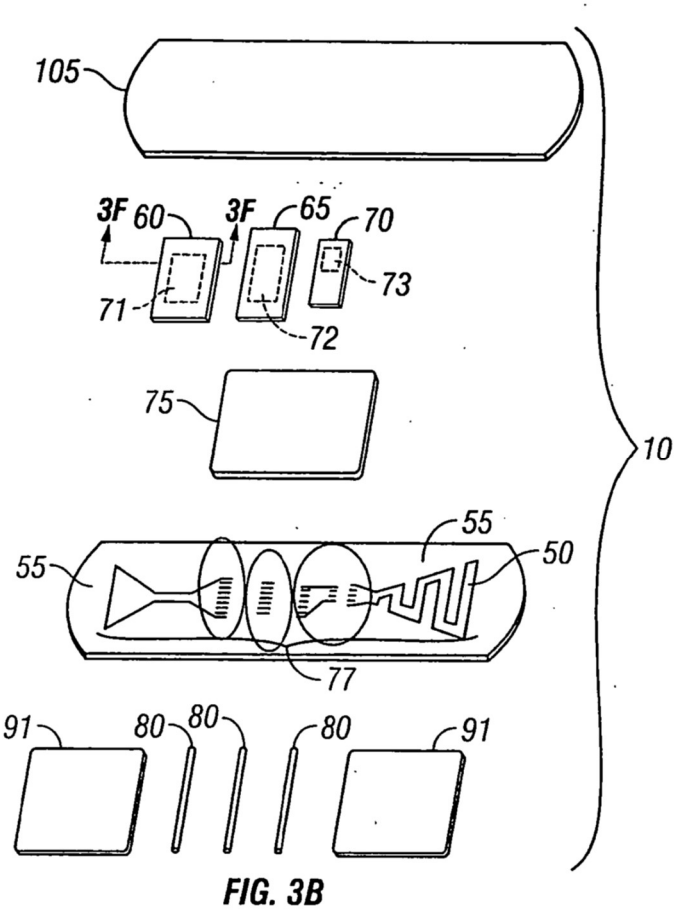


FIG. 3B

Id. at Fig. 3B.

677. For these reasons, it is my opinion that a POSA would understand that each of Matsumura and Ozguz discloses "the body worn patient monitoring device comprises an ECG monitor and at least two of the electrical connections are ECG electrodes" and, therefore, that the combination of Matsumura, Ozguz, and Kroll renders obvious claim 4 of the '007 patent.

5. Dependent Claim 5

678. Claim 5 of the ’007 patent depends from claims 1 and 4 and additionally requires that “the ECG electrodes comprise a material screened onto the flexible substrate.”

679. As explained above, it is my opinion that claim 5 of the ’007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.5, *supra.*

680. Additionally, and alternatively, it is my opinion that claim 5 of the ’007 patent is rendered obvious by Matsumura in combination with Kroll and Ozguz.

681. In my opinion, claim 5 of the ’007 patent is rendered obvious by Matsumura in combination with Ozguz and Kroll for all the reasons discussed above with respect to claims 1 and 4 as well as because Matsumura, Ozguz and Kroll teach the additional limitation of claim 5. *See* Section XVII.B.2., *supra.*

682. Matsumura teaches that its disclosed “bioelectrode pad” is preferably composed of sheets made out of “polyethylene foam, polyurethane foam, or polyurethane sheet,” which are all materials that a POSA would recognize as “flexible.” Ex. 1012 at [0017]; *see also* Section XVII.A.5, *supra*.

683. Ozguz teaches that electrodes 80 are “disposed on an underside 85 of the flexible substrate 55.” Ex. 1014 at [0039].

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684. Kroll teaches a means of attaching ECG electrodes onto a flexible substrate. Specifically, Kroll teaches screening onto "an insulation and base support layer 44", *i.e.*, a flexible substrate. *See, e.g.*, Ex. 1013 at 5:22–42, Fig. 5. Kroll explains that

> ***Each electrode 35 has a conductive grid 56 which is comprised of a matrix of approximately 0.050 inch wide lines 42 of conductive ink compound applied to an insulation and base support layer 44 preferably by means of a silk screen process.*** The conductive ink is a silver compound generally used in the electronics industry. The conductive ink compound used in the matrix lines 42 is generally the same as that utilized in the lead strips 34. Apertures 43 in the conductive ink matrix 42 form the grid configuration. The grid configuration itself is provided both for proper electrical function as well as to reduce the amount of ink used while obtaining maximum function. The insulation and base support layer 44 is preferably comprised of a thin approximately 0.001 inch polyester laminate and ***serves as both a base for the silk screened conductive ink used in the matrix lines 42 and lead strips 34***, and as an electrical insulator.

Id. at 5:23–42 (emphases added).

685. In my opinion, A POSA would have known to use the "silk screen process" of Kroll to attach "electrodes 35" to the "bioelectrode pad" of Matsumura and "flexible substrate 55" of Ozguz. As discussed above, screen printing is one of the preferred processes for manufacturing circuits in the industry. *See* Section IV.C, *supra*. Accordingly, in my opinion, a POSA would have chosen screen printing as the means of affixing ECG electrodes to the rest of the circuit of the device because the most stable ECG electrodes use Silver/Silver Chloride, which is typically screen

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printed. *Id.* And as Kroll's disclosure demonstrates, the use of screen printing specifically to affix ECG electrodes to the circuit of a body-worn patient monitoring device was known in art at the time of the invention. Thus, in my opinion, a POSA would have had a reasonable expectation of success in achieving this combination.

686. For these reasons, it is my opinion that a POSA would understand that each of Matsumura, Ozguz, and Kroll discloses "the ECG electrodes comprise a material screened onto the flexible substrate" and, therefore, that the combination of Matsumura, Ozguz and Kroll renders obvious claim 5 of the '007 patent.

6. Dependent Claim 14

687. Claim 14 of the '007 patent depends from claim 1 and additionally requires that "the power source is a renewable power source internal to the body worn device."

688. As explained above, it is my opinion that claim 14 of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.12, *supra.*

689. Additionally, and alternatively, it is my opinion that claim 14 of the '007 patent is rendered obvious by Matsumura in combination with Kroll and Ozguz.

690. In my opinion, claim 14 of the '007 patent is rendered obvious by Matsumura in combination with Ozguz and Kroll for all the reasons discussed above with respect to claim 1 as well as because Ozguz teaches that "the power source is a

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renewable power source internal to the body worn device." *See* Section XVII.B.2., *supra.*

691. Ozguz teaches that the "sensor module 10" includes a "flexible, thin battery 105" that "overlays the silicon substrates 60, 65, 70 and their respective [integrated circuits] 71, 72, 73." Ex. 1014 at [0048]. In my opinion, a POSA would understand that the battery disclosed by Ozguz would be any type of small battery that was known in the art at the time. Both rechargeable batteries and one-time use batteries were known in the art at the time. *Compare* Ex. 1042 at 386 ("Power for the circuit is obtained from a single nonrechargeable 3-V lithium battery"), *with* Ex. 1036 at 7 (specifying that manufacturers of devices that include rechargeable batteries must disclose certain information, *e.g.*, charging time).

692. Thus, in my opinion a POSA would understand that the combination of Matsumura, Ozguz, and Kroll renders obvious dependent claim 14.

7. Dependent Claim 15

693. Claim 15 of the '007 patent depends on claim 1 and additionally requires that "the power source comprises a rechargeable battery or a one time use battery."

694. As explained above, it is my opinion that claim 15 of the '007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.13, *supra.*

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695. Additionally, and alternatively, it is my opinion that claim 15 of the '007 patent is rendered obvious by Matsumura in combination with Kroll and Ozguz.

696. In my opinion, claim 15 of the '007 patent is rendered obvious by Matsumura in combination with Ozguz and Kroll for all the reasons discussed above with respect to claim 1 as well as because Ozguz teaches that "the power source comprises a rechargeable battery or a one time use battery." *See* Section XVII.B.2., *supra.*

697. Ozguz teaches that the sensor module 10 includes a "flexible, thin battery 105" that "overlays the silicon substrates 60, 65, 70 and their respective [integrated circuits] 71, 72, 73." Ex. 1014 at [0048]. In my opinion, a POSA would understand that the battery disclosed by Ozguz would be any type of small battery that was known in the art at the time. Disposable batteries of appropriate size were known in the art at the time. *Compare* Ex. 1042 at 386 ("Power for the circuit is obtained from a single nonrechargeable 3-V lithium battery"), *with* Ex. 1036 at 7 (specifying that manufacturers of devices that include rechargeable batteries must disclose certain information, *e.g.*, charging time).

698. Thus, in my opinion a POSA would understand that the combination of Matsumura, Ozguz, and Kroll renders obvious dependent claim 15.

8. Dependent Claim 43

699. Claim 43 of the ’007 patent depends from claim 1 and additionally requires that “the radio circuit communicates an unprocessed physiological signal.”

700. As explained above, it is my opinion that claim 43 of the ’007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.18, *supra.*

701. Additionally, and alternatively, it is my opinion that claim 43 of the ’007 patent is rendered obvious by Matsumura in combination with Kroll and Ozguz.

702. Ozguz teaches a sensor module that wirelessly transmits the detected signals using “an integral RF transmitter.” Ex. 1014 at [0006]. In my opinion, a POSA would understand that those signals could be either processed or unprocessed physiological data because a POSA would have understood that access to the unprocessed detected signals would have been standard at the time, because doctors would want to evaluate the unmanipulated, raw data in the event of an abnormal event or cardiac incident. *Cf.* Ex. 1034 at cls. 6, 76; *see also* Section XVII.A.18, *supra*.

703. For these reasons, it is my opinion that a POSA would understand that Ozguz discloses “the radio circuit communicates an unprocessed physiological signal” and, therefore, that the combination of Matsumura, Ozguz, and Kroll renders obvious claim 43 of the ’007 patent.

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9. Dependent Claim 44

704. Claim 44 of the ’007 patent depends from claim 1 and additionally requires that “the radio circuit communicates a result of the physiological analysis at a predetermined time.”

705. As explained above, it is my opinion that claim 44 of the ’007 patent is obvious over Matsumura and Kroll in view of the knowledge of a POSA. *See* Section XVII.A.19, *supra.*

706. Additionally, and alternatively, it is my opinion that claim 44 of the ’007 patent is rendered obvious by Matsumura in combination with Kroll and Ozguz.

707. Ozguz teaches a sensor module where “data is collected through the skin for a predetermined period of time” and then transmitted wirelessly through an “RF transmitter.” Ex. 1014 at [0006], [0017]. In my opinion, a POSA would understand that a transmission following the collection of data for a “predetermined period of time” is a transmission that occurs at a predetermined periodicity (*i.e.*, at a predetermined time).

708. For these reasons, it is my opinion that a POSA would understand that Ozguz discloses that “the radio circuit communicates a result of the physiological analysis at a predetermined time” and, therefore, that the combination of Matsumura, Ozguz, and Kroll renders obvious claim 44 of the ’007 patent.

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10. Dependent Claim 45

709. In my opinion, claim 45 of the ’007 patent is rendered obvious by Matsumura in combination with Kroll and Ozguz.

i. Preamble 45[pre]

710. Limitation 45[pre] of the ’007 patent recites “[a] body worn patient monitoring device comprising.” As explained above, it is my opinion that Matsumura and Kroll in view of a POSA’s knowledge render this preamble obvious. *See* Section XVII.A.20.i, *supra.*

ii. Limitation [45a]

711. Limitation [45a] of the ’007 patent recites “a disposable module including a plurality of electrical connections.” As explained above, it is my opinion that Matsumura and Kroll in view of a POSA’s knowledge render this limitation obvious. *See* Section XVII.A.20.ii, *supra.*

iii. Limitation [45b]

712. Limitation [45b] of the ’007 patent recites “the electrical connections adapted for electrical coupling to a skin surface to receive physiological signals.” As explained above, it is my opinion that Matsumura and Kroll in view of a POSA’s knowledge render this limitation obvious. *See* Section XVII.A.20.iii, *supra.*

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iv. Limitation [45c]

713. Limitation [45c] of the ’007 patent recites “the disposable module including a disposable module connector.” As explained above, it is my opinion that Matsumura and Kroll in view of a POSA’s knowledge render this limitation obvious. *See* Section XVII.A.20.iv, *supra.*

v. Limitation [45d]

714. Limitation [45d] of the ’007 patent recites “a power source to power the body worn patient monitoring device.” As explained above, it is my opinion that Matsumura and Kroll in view of a POSA’s knowledge render this limitation obvious. *See* Section XVII.A.20.v, *supra.*

vi. Limitation [45e]

715. Limitation [45e] of the ’007 patent recites “a communication-computation module, having a communication-computation module connector to receive the physiological signals from the disposable module via the disposable module connector, the communication-computation module including.” As explained above, it is my opinion that Matsumura and Kroll in view of a POSA’s knowledge render this limitation obvious. *See* Section XVII.A.20.vi, *supra.*

vii. Limitation [45f]

716. Limitation [45f] of the ’007 patent recites “a microprocessor to actively monitor a patient and to perform a real-time physiological analysis of the

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physiological signals, the analysis determining an occurrence of a predetermined ECG event." As explained above, it is my opinion that Matsumura and Kroll in view of a POSA's knowledge render this limitation obvious. *See* Section XVII.A.20.vii, *supra.*

717. Additionally, and alternatively, it is my opinion that limitation [45f] of the '007 patent is obvious in view of the combination of Matsumura, Kroll, and Ozguz because Ozguz discloses limitation [45f]. Ozguz teaches a "microprocessor" 175 that processes electrocardiogram signals that are continuously detected. Ex. 1014 at [0042], [0044], [0058]. In my opinion, a POSA would understand Ozguz's disclosures to refer to real-time physiological analysis to determine an occurrence of a predetermined event. *See Id.* at [0040] (discussing the "continuous transmission of [RF] signals 40 to a remote device 45 *during monitoring*") (emphasis added), [0039] (specifying that the remote device 45 includes "a means for analyzing the data"), [0020] (disclosing "software" to be used with the "separate data receiving and/or processing and analysis device"). It would be obvious to a POSA that, as part of its analysis, Ozguz's device would determine the occurrence of a predetermined event. At the time of the invention of the '007 patent, it was well-known that a monitoring device could perform such functionality, such as sounding an alarm for the patient, based on the occurrence of a predetermined event. *See, e.g.*, Ex. 1015 at

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9:57–10:18 (discussing different types of events that could trigger an alarm or the logging of data).

718. For these reasons, it is my opinion, that Ozguz discloses "a microprocessor to actively monitor a patient and to perform a real-time physiological analysis of the physiological signals, the analysis determining an occurrence of a predetermined ECG event."

viii. Limitation [45g]

719. Limitation [45g] of the '007 patent recites "a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis, at a predetermined time or on an occurrence of a predetermined event, via a radio transmission to a remote radio receiver." As explained above, it is my opinion that Matsumura and Kroll in view of a POSA's knowledge render this limitation obvious. *See* Section XVII.A.20.viii, *supra.*

720. Additionally, and alternatively, it is my opinion that limitation [45g] of the '007 patent is obvious in view of the combination of Matsumura, Ozguz, and Kroll for all the reasons set forth with respect to claim 1. *See* Section XVII.B.2.x, *supra.*

ix. Limitation [45h]

721. Limitation [45h] of the '007 patent recites "wherein the disposable module has a mechanical and electrical coupling to the communication-computation

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module." As explained above, it is my opinion that Matsumura and Kroll in view of a POSA's knowledge render this limitation obvious. *See* Section XVII.A.20.ix, *supra.*

x. Limitation [45i]

722. Limitation [45i] of the '007 patent recites "forming the body worn patient monitoring device as a single unit that is adapted to be directly and non-permanently affixed to the skin surface of the patient." As explained above, it is my opinion that Matsumura and Kroll in view of a POSA's knowledge render this limitation obvious. *See* Section XVII.A.20.x, *supra.*

xi. Limitation [45j]

723. Limitation [45j] of the '007 patent recites "at least one series current-limiting resistor configured to protect the communication-computation module." As explained above, it is my opinion that Matsumura and Kroll in view of a POSA's knowledge render this limitation obvious. *See* Section XVII.A.20.xi, *supra*.

xii. Limitation [45k]

724. Limitation [45k] of the '007 patent recites "the at least one series current-limiting resistor being screened on a flexible substrate." As explained above, it is my opinion that Matsumura and Kroll in view of a POSA's knowledge render this limitation obvious. *See* Section XVII.A.20.xii, *supra.*

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xiii. Limitation [45l]

725. Limitation [45l] of the ’007 patent recites “the at least one series current-limiting resistor being in the form of resistive traces.” As explained above, it is my opinion that Matsumura and Kroll in view of a POSA’s knowledge render this limitation obvious. *See* Section XVII.A.20.xiii, *supra.*

C. Matsumura Ground 3: Obvious Over Matsumura, Ozguz, Kroll, DeLuca, and General Knowledge of a Person of Ordinary Skill in the Art

726. Additionally, and alternatively, it is my opinion that claims 32–35 of the ’007 patent are obvious under pre-AIA § 103 over Matsumura, Ozguz, Kroll, DeLuca, and General Knowledge of a Person of Ordinary Skill in the Art.

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

727. As discussed above, it is my opinion that a POSA would have been motivated to combine Ozguz’s disclosures of specific circuits and electronic components and Kroll’s teaching of “resistive traces” with Matsumura’s device and would have had a reasonable expectation of success in doing so. *See* Section XVII.B.1, *supra.*

728. Additionally, in my opinion, a POSA would have also sought to incorporate DeLuca’s teaching of signal conditioning filters into the signal processor of Matsumura’s device. Both DeLuca and Matsumura teach a wearable, flexible

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device for monitoring physiological data, including EKG data. Ex. 1012 at [0024], [0031], Fig. 2; Ex. 1015 at 1:6-9, 1:11-15, 2:1-4, 3:30-39.

729. Matsumura teaches a "circuit," "signal processor," and "wireless transmitter" used to detect, process, and wirelessly transmit bioelectric signals. Ex. 1012 at [0025]. Specifically, Matsumura discloses that its device is capable of detecting anomalous heartbeat signals on the device. *See id.* at [0032] ("In the signal processor 10 of the bioelectric potential detector 11, . . . it is determined whether or not the detected electrocardiogram of the subject (patient) is in an abnormal state"). However, Matsumura does not discuss the particular electronic configurations to be used to perform this task.

730. In my opinion, a POSA would understand that to "determine whether or not the detected electrocardiogram of the subject (patient) is in an abnormal state," the incoming analog signals would need to be processed and would have looked to any number of well-known algorithms to help perform this task. Many well-known algorithms could be used to accomplish this task, such as the "Pan-Tompkins Algorithm." *See generally*, Ex. 1050. In my opinion, a POSA, accordingly, would have looked to deploy the Pan-Tompkins algorithm or a similar signal conditioning algorithm on Matsumura's device and would have looked to Deluca to determine how to perform this signal conditioning step on Matsumura's device because

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DeLuca discloses an implementation of bandpass filters in great detail. *See generally*, Ex. 1015 at 4:65–6:9.

731. Further, it is my opinion that a POSA would have had a reasonable expectation of success in implementing DeLuca's signal conditioning filters on Matsumura's device without undue experimentation. A POSA would know how to combine DeLuca's specific bandpass filtering configuration with Matsumura's device with minimal design impact because it has been known in the art for decades that the switched-capacitor filter circuit and a switched circuit including physical resistors are interchangeable methods for filtering. *See* Ex. 1052 at 592. 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.

2. Dependent Claim 32

732. Claim 32 of the '007 patent depends from claim 1 and additionally requires that "a high pass filter with a selectable corner frequency to filter the physiological signals."

733. In my opinion, claim 32 of the '007 patent is rendered obvious by Matsumura in combination with Ozguz, Kroll, and DeLuca for all the reasons discussed above with respect to claim 1 as well as because DeLuca teaches the additional limitation of claim 32. *See* Section XVII.A.2, *supra.*

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734. In my opinion, a POSA would have looked to incorporate DeLuca's "signal conditioning" filters into Matsumura's device so that Matsumura's device could detect a heartbeat accurately in order to "determine whether or not the detected electrocardiogram of the subject (patient) is in an abnormal state." *See* Section XVII.C.1, *supra*; Ex. 1012 at [0032].

735. Matsumura teaches a "circuit," "signal processor," and "wireless transmitter" used to detect, process, and wirelessly transmit bioelectric signals. Ex. 1012 at [0025]. DeLuca teaches a "signal conditioning stage 56 which further amplifies and band-pass filters the signal so that it is of suitable voltage range and bandwidth for conversion [by] the A/D converter." Ex. 1015 at 4:66–5:2. Specifically, DeLuca teaches that "the signal conditioning stage 56 includes a hi-pass filter 56*a*." *Id.* at 5:2–3. "Each of the filter modules 56*a*, 56*c* and 56*d* is a switched-capacitor filter circuit whose cut-off frequency [*i.e.*, corner frequency] is determined by the clock frequency at which the filter is switched." *Id.* at 5:4–7.

736. In my opinion, as explained above, a POSA would have recognized that DeLuca's band-pass filtering disclosures are consistent with the Pan-Tompkins QRS detection algorithm and it would have been obvious to combine DeLuca's high-pass filter with a selectable corner frequency with Matsumura's signal processing and heartbeat detection functionality. *See* Section XVII.C.1, *supra*.

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737. For these reasons, it is my opinion that DeLuca teaches "a high pass filter with a selectable corner frequency to filter the physiological signals" and, therefore, that the combination of Matsumura, Ozguz, Kroll, and DeLuca renders obvious claim 32 of the '007 patent.

3. Dependent Claim 33

738. Claim 33 of the '007 patent depends from claims 1 and 32 and additionally requires that "the corner frequency is selected by a switch selectable resistance."

739. In my opinion, claim 33 of the '007 patent is rendered obvious by Matsumura in combination with Ozguz, Kroll, and DeLuca for all the reasons discussed above with respect to claims 1 and 32 as well as because DeLuca teaches the additional limitation of claim 33. *See* Sections XVII.C.2, *supra.*

740. DeLuca teaches that "the signal conditioning stage 56 includes a hi-pass filter 56*a*." Ex. 1015 at 5:2-3. "Each of the filter modules 56*a*, 56*c*, and 56*d*, is a switched-capacitor filter circuit whose cut-off frequency [*i.e.*, corner frequency] is determined by the clock frequency at which the filter is switched." *Id.* at 5:4-7. To the extent that the claim requires a switch selectable resistance in a resistor—rather than in a switched capacitor—that configuration would be obvious to a POSA in view of DeLuca's disclosures. In my opinion, a POSA would understand that a switched-capacitor filter circuit and a switched circuit including physical resistors

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are interchangeable methods for filtering; their interchangeability has been known in the art for decades. *See* Ex. 1052.

741. For these reasons, it is my opinion that DeLuca teaches that "the corner frequency is selected by a switch selectable resistance" and, therefore, that the combination of Matsumura, Ozguz, Kroll, and DeLuca renders obvious claim 33 of the '007 patent.

4. Dependent Claim 34

742. Claim 34 of the '007 patent depends from claims 1 and 32 and additionally requires that "the corner frequency is selected by one or more switching capacitors switched a rate higher than the corner frequency of a low pass anti-aliasing filter."

743. DeLuca teaches that "the signal conditioning stage 56 includes a hi-pass filter 56*a*, an amplifier 56*b*, a lo-pass filter 56*c*, and an anti-aliasing filter 56*d*." Ex. 1015 at 5:2–4. "Each of the filter modules 56*a*, 56*c* and 56*d*, is a switched-capacitor filter circuit whose cut-off frequency [*i.e.*, corner frequency] is determined by the clock frequency at which the filter is switched." *Id.* at 5:4-7. "The signal output from the input stage 55 is first coupled to the hi-pass filter 56*a* which removes any DC component present in the signal before amplification." *Id.* at 5:9-12. In my opinion, a POSA would recognize that the corner-frequency of the high-pass filter

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would be selected by one or more switching capacitors switched a rate higher than the corner frequency of the low-pass filter. Ex. 1042 at 76.

744. In my opinion, claim 34 of the ’007 patent is rendered obvious by Matsumura in combination with Ozguz, Kroll, and DeLuca for all the reasons discussed above with respect to claims 1 and 32 as well as because DeLuca teaches the additional limitation of claim 34. *See* Sections XVII.C.2, *supra.*

745. For these reasons, it is my opinion that DeLuca teaches that “the corner frequency is selected by one or more switching capacitors switched a rate higher than the corner frequency of a low pass anti-aliasing filter” and, therefore, that the combination of Matsumura, Ozguz, Kroll, and DeLuca renders obvious claim 34 of the ’007 patent.

5. Dependent Claim 35

746. Claim 35 of the ’007 patent depends from claims 1 and 32 and additionally requires that “the high pass filter is implemented in software running on the microprocessor.”

747. In my opinion, claim 35 of the ’007 patent is rendered obvious by Matsumura in combination with Ozguz, Kroll, and DeLuca for all the reasons discussed above with respect to claims 1 and 32 as well as because DeLuca teaches the additional limitation of claim 35. *See* Section XVII.C.2, *supra.*

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748. DeLuca teaches a "signal conditioning stage," in which the "operating parameters" "can be externally programmed" through the ASIC 36. Ex. 1015 at 5:35-42. In my opinion, a POSA would have understood that DeLuca's ASIC could also have implemented the signal conditioning filters using software because heartbeat detection algorithms using digital filters on a microprocessor were well-known in the art at the time of the invention of the '007 patent. Ex. 1045. For example, the well-known Pan-Tompkins QRS Detection Algorithm implemented digital filters using software. Ex. 1050 at 232. In my opinion, a POSA would have understood that the high-pass filter of DeLuca could easily be implemented using software rather than using physical circuits.

749. For these reasons, it is my opinion that DeLuca teaches that "the high pass filter is implemented in software running on the microprocessor" and, therefore, that the combination of Matsumura, Ozguz, Kroll, and DeLuca renders obvious claim 35 of the '007 patent.

D. Matsumura Ground 4: Obvious Over Matsumura, Ozguz, Kroll, Harland, and General Knowledge of a Person of Ordinary Skill in the Art

750. Additionally, and alternatively, it is my opinion that claims 2 and 3 of the '007 patent are obvious under pre-AIA § 103 over Matsumura, Ozguz, Kroll, Harland, and General Knowledge of a Person of Ordinary Skill in the Art.

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

751. As discussed above, it is my opinion that a POSA would have been motivated to combine Ozguz's disclosures of specific circuits and electronic components and Kroll's teaching of "resistive traces" with Matsumura's device and would have had a reasonable expectation of success in doing so. *See* Section XVII.B.1, *supra.*

752. Additionally, a POSA would have looked to incorporate Harland's teaching of a capacitive sensor probe into Matsumura's device.

753. Matsumura teaches the use of a conductive gel that includes "glycerin, and water." Ex. 1012 at [0018]. In my opinion, a POSA would recognize that "gel substances and the adhesives [used] to fix the electrodes on the body can provoke dermal irritation and even allergies." Ex. 1053 at 5739. This concern is more prevalent for a device such as Matsumura's because it is intended to be worn for an extended period of time. *Id.*; *see also* Ex. 1012 at [0031] (patient wears Matsumura's device "at all times"), [0033].

754. Harland teaches a solution to this problem of dermal tolerability by using "fixed sensor probe electrodes which form capacitive coupling to the body under measurement." Ex. 1016 at 164. Harland's electrodes allow for measurement of ECG signals "without direct electrical contact" and permit recording of "the very highest quality ECG at any point on the body surface, even from the fingertips." *Id.*

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In my opinion, a POSA would recognize the benefit of capacitive electrodes in abating potential dermal irritation because these electrodes do not require the use of potentially skin-irritating gels or adhesives, which was a known problem in long-term ECG monitoring. *See generally*, Ex. 1053 at 5742. Thus, in my opinion, a POSA would have looked to Harland's teaching for specific details in order to implement this technology in Matsumura's device. Ex. 1016 at 164.

755. Further, it is my opinion that a POSA would have had a reasonable expectation of success in implementing Harland's capacitive electrode on Matsumura's device without undue experimentation. All of the electronic components and methods necessary for a POSA to be successful in making this modification would have been commercially available at the time of the invention of the '007 patent. *See* Ex. 1016 at 165 (noting that the "development of the electronics required for these sensors has been discussed in detail in previous publications"). A POSA would know how to combine Harland's capacitive electrode with Matsumura's design with minimal design impact and nothing in the art suggests that this modification would not work. Further, as discussed above, this modification would not be difficult to implement using well-known manufacturing techniques at the time of invention.

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2. Dependent Claims 2 and 3

756. Claim 2 of the ’007 patent depends from claim 1 and additionally requires that “the plurality of electrical connections to the body comprise at least one of direct electrical connections to the body indirect electrical connections to the body.” Claim 3 of the ’007 patent depends from claims 1 and 2 and additionally requires that “the indirect electrical connections to the body comprise capacitive connections to the body.”

757. As explained previously, in my opinion, claim 2 of the ’007 patent is rendered obvious by Matsumura in combination with Kroll and/or Kroll and Ozguz. Section XVII.B.3, *supra*. Matsumura teaches that, after release tape 8 is removed, bioelectrode pad 7 of Matsumura is placed on the patient’s skin, thereby forming a “direct electrical connection.” Ex. 1012 at [0007]-[0008], [0014], [0016], Figs. 1-2. Kroll also discloses that conductive gel pads form a direct electrical connection with the patient’s skin. Ex. 1013 at 5:53-55. Additionally, in my opinion, Matsumura, Kroll, and Ozguz render claim 2 obvious. A POSA would understand that an “indirect electrical connection” to the body is one in which the conductor(s) do not make actual contact with the skin. *E.g.*, Ex. 1054 at 919. The ’007 patent explains that one example of an “indirect” electrical connection with the patient’s body is “by capacitive coupling.” Ex. 1001 at 4:13-19. Harland discloses ultra-high impedance electric potential sensors that “allow the remote (non-contact) detection of electric

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potentials generated by currents flowing in the body." Ex. 1016 at 164. In the "remote, off-body detection" application, these electrodes "form capacitive [*i.e.*, indirect] coupling to the body in the measurement." *Id.* As explained above, it would have been obvious to a POSA to modify Matsumura to include at least one such capacitive electrode. Section XVII.D.1, *supra*. As modified, the device of Matsumura would include at least one indirect connection to the body, thereby meeting the dependent limitation of claim 2.

758. In my opinion, claim 3 of the '007 patent is rendered obvious by Matsumura in combination with Ozguz, Kroll, and Harland for all the reasons discussed above with respect to claims 1 and 2 as well as because Harland teaches the additional limitation of claim 3. *See* Section XVII.B.2, *supra.* Harland discusses the development and use of "a new class of sensor—the ultra-high impedance electric potential sensor" as an "alternative" to "traditional contact electrodes (for ECGs and EEGs)." Ex. 1016 at 164. The ultra-high impedance electric potential sensors disclosed by Harland "allow the remote (non-contact) detection of electric potentials generated by currents flowing in the body." *Id*. In the "remote, off-body detection" application, these electrodes "form capacitive coupling to the body under measurement." *Id*.

759. For these reasons, it is my opinion that Harland teaches that "the plurality of electrical connections to the body comprise at least one of direct

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electrical connections to the body and indirect electrical connections to the body" and, therefore, that the combination of Matsumura, Kroll, Ozguz, and Harland renders obvious claim 2 of the '007 patent. It is further my opinion that Harland teaches "the indirect electrical connections to the body comprise capacitive connections to the body" and, therefore, that the combination of Matsumura, Ozguz, Kroll, and Harland renders obvious claim 3 of the '007 patent.

E. Matsumura Ground 5: Obvious Over Matsumura, Ozguz, Kroll, Thompson, and General Knowledge of a Person of Ordinary Skill in the Art

760. Additionally, and alternatively, it is my opinion that claim 39 of the '007 patent is obvious under pre-AIA § 103 over Matsumura, Ozguz, Kroll, Thompson, and General Knowledge of a Person of Ordinary Skill in the Art.

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

761. As discussed above, it is my opinion that a POSA would have been motivated to combine Ozguz's disclosures of specific circuits and electronic components and Kroll's teaching of "resistive traces" with Matsumura's device and would have had a reasonable expectation of success in doing so. *See* Section XVII.B.1, *supra.*

762. In my opinion, a POSA would have also looked to incorporate Thompson's teaching of a periodic low power mode based on the electrical signals of a heartbeat with Matsumura's device. The utility of a battery-powered, wearable

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device is limited by its battery-life and the size and composition of the battery is limited by the dimensional requirements of a body-worn physiological monitor. Therefore, in my opinion, a POSA would seek to optimize power consumption as a means of prolonging the battery life of the device and extending the period for which the device can collect data.

763. Due to this concern, a POSA would have been aware of techniques for optimizing battery life, including the use of a periodic low power mode. *See, e.g.*, Ex. 1055 at [0019] ("By having the processor operate in a low-power consumption mode, the invention reduces the amount of power consumed by the defibrillator. As a result, a power supply will last longer in the defibrillator of the present invention than in its conventional counterparts."). In my opinion, a POSA would have sought out additional power conservation solutions that would conserve power while the device was operational. Such solutions would allow battery usage to be even more efficient allowing for a reduction in the overall size of the batteries—and thus the size of the devices—as desired by the industry. *See* Section IV.C–D, *supra.*

764. Thompson discloses an approach to power conservation by limiting processing time to certain portions of the heartbeat waveform. In one embodiment, Thompson discloses that "[o]nly during a QRS complex, for example, does waveform analysis processor 520 operate in a high speed processing mode at a relatively high frequency. During the remainder of the cardiac cycle [*i.e.*, during the

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TP interval] the DSP processor 520 may be 'idling along' at a much lower clock frequency. . . . In addition to the lower clock speed utilized for different portions of the cardiac cycle, a POSA would recognize that in accordance with the other aspects of the present invention, as the speed is reduced, the supply voltage level (V_{DD}) may also be reduced accordingly. Thus, the objective of reduced power consumption is realized." Ex. 1017 at 18:3–14.

765. In my opinion, a POSA would have had a reasonable expectation of success in implementing Thompson's low power mode on Matsumura's device without undue experimentation. It would only require reprogramming of onboard software to do so. Therefore, it is my opinion that a POSA would know how to combine Thompson's low power mode with Matsumura's design with little to no design impact. Further, there is nothing in the art to suggest that this modification would not work.

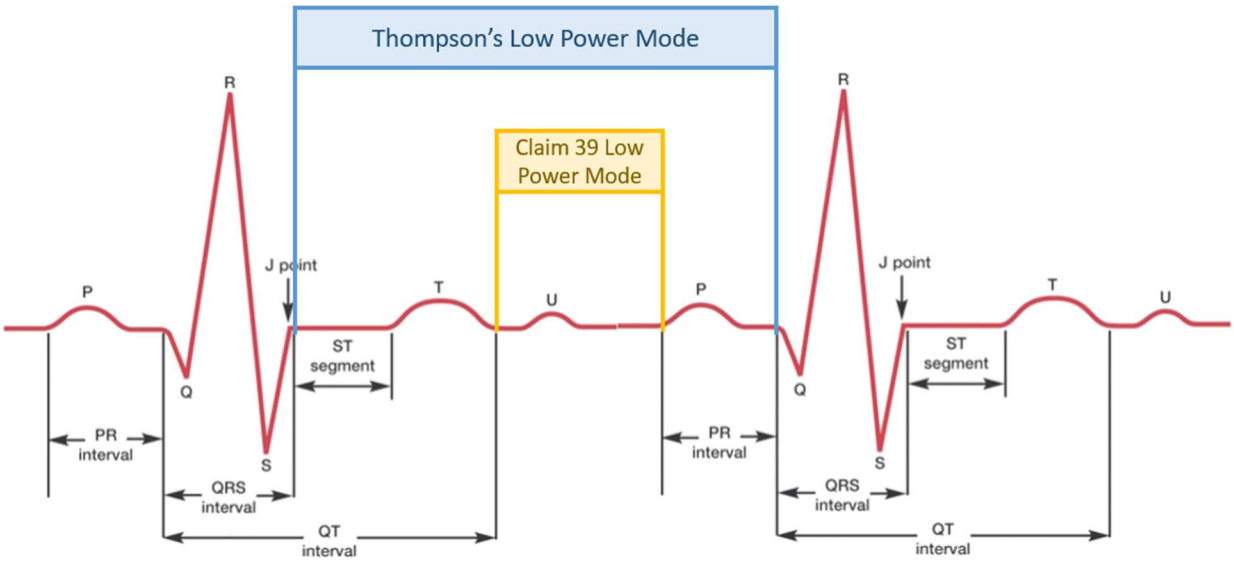
2. Dependent Claim 39

766. Claim 39 of the '007 patent depends from claim 1 and additionally requires "an algorithm running on a microprocessor in the body worn device causes the body worn device to enter a low power mode that disables at least one circuit of the body worn device, from the end of a 'T wave' at the end of one heart beat to the beginning of a 'P wave' at the beginning of the next heart beat, to save power."

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767. In my opinion, claim 39 of the '007 patent is rendered obvious by Matsumura in combination with Ozguz, Kroll, and Thompson for all the reasons discussed above with respect to claim 1 as well as because Thompson teaches the additional limitation of claim 39. *See* Section XVII.B.2, *supra.*

768. The device disclosed by Thompson conserves power by operating in a low power mode from the end of one S-wave of the patient's heartbeat until the commencement of the next Q-wave, meaning Thompson's device operates in a high-power mode only during the QRS interval. Ex. 1017 at 18:3–14. In my opinion, a POSA would understand that Thompson's low power mode is active for a period that includes the period "from the end of a 'T wave' at the end of one heartbeat to the beginning of a 'P wave' at the beginning of the next heartbeat," as shown by the annotated figure below. *Id.*; *see* Section IV.A., *supra*.



769. Furthermore, for the reasons discussed above in Section XVI.C.1, it is my opinion that a POSA would also recognize that this low power mode could be implemented on Matsumura's microprocessor.

770. For these reasons, it is my opinion that Thompson teaches "an algorithm running on a microprocessor in the body worn device causes the body worn device to enter a low power mode that disables at least one circuit of the body worn device, from the end of a 'T wave' at the end of one heart beat to the beginning of a 'P wave' at the beginning of the next heartbeat, to save power" and, therefore, that the combination of Matsumura, Ozguz, Kroll, and Thompson renders obvious claim 39 of the '007 patent.

XVIII. THE CHALLENGED CLAIMS OF THE '492 PATENT ARE UNPATENTABLE

A. Ground 1: Obvious Over Matsumura, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art

771. In my opinion, claims 1–3, 5–8, and 11–14 of the '492 patent are obvious under pre-AIA § 103 over Matsumura, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art.

1. A POSA had motivation to combine Matsumura and Kroll

772. For the reasons set forth above in Section XVII.A.1, with reference to the '007 patent, a POSA would have had motivation to combine the teachings of

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Matsumura and Kroll and would have had a reasonable expectation of success in doing so.

2. Independent Claim 1

773. In my opinion, claim 1 of the '492 patent is rendered obvious by Matsumura in combination with Kroll.

i. Preamble 1[pre]

774. The preamble of claim 1 recites "[a] body-worn patient monitoring device comprising."

775. In my opinion, to the extent the preamble is limiting, Matsumura discloses the preamble of claim 1 of the '492 patent.

776. Matsumura discloses "a waterproof bioelectric potential detector" that is able to "measure [a patient's] electrocardiograms" and alert medical staff or family members "if the condition of the subjects/patients suddenly changes." Ex. 1012 at [0006]. Matsumura further teaches that the disclosed "bioelectric potential detector" includes:

> a disposable bioelectrode pad for detecting bioelectric potentials, and a reusable signal processor for processing the bioelectric potential signals detected by the bioelectrode pad, and determining whether the bioelectric potential signals are in an abnormal state and wirelessly transmitting alarm information notifying at a minimum that the bioelectric potential signals are in an abnormal state if the bioelectric potential signals are in an abnormal state

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Id. at [0014].

777. Kroll also discloses a body worn patient monitoring device. Kroll recites:

> This invention relates to a device and method for receiving and transmitting electrical signals to and from a patient. Particularly, this invention relates to a disposable, flexible, and layered electrode belt, also referred to as a "belt", for placement and use on the body of a patient and also for use with medical diagnostic and therapeutic devices.

Ex. 1013 at 1:9–15.

778. Thus, in my opinion, each of Matsumura and Kroll discloses "[a] body-worn patient monitoring device."

ii. Limitation [1a]

779. Limitation [1a] recites "a flexible printed circuit layer made from an insulating material and defining a substrate."

780. In my opinion, Matsumura discloses limitation [1a] of the '492 patent.

781. Matsumura teaches a "bioelectrode pad" composed of sheets "made of an insulating material . . . for example, polyethylene foam, polyurethane foam, or polyurethane sheet." Ex. 1012 at [0017]; *see also id.* at [0018], [0022]. In my opinion, a POSA would recognize polyethylene and polyurethane as flexible materials. Ex. 1047 at 23.11; Ex. 1056 at 2. Additionally, it is my opinion that a POSA would have known that a circuit layer *must* be formed on an insulating

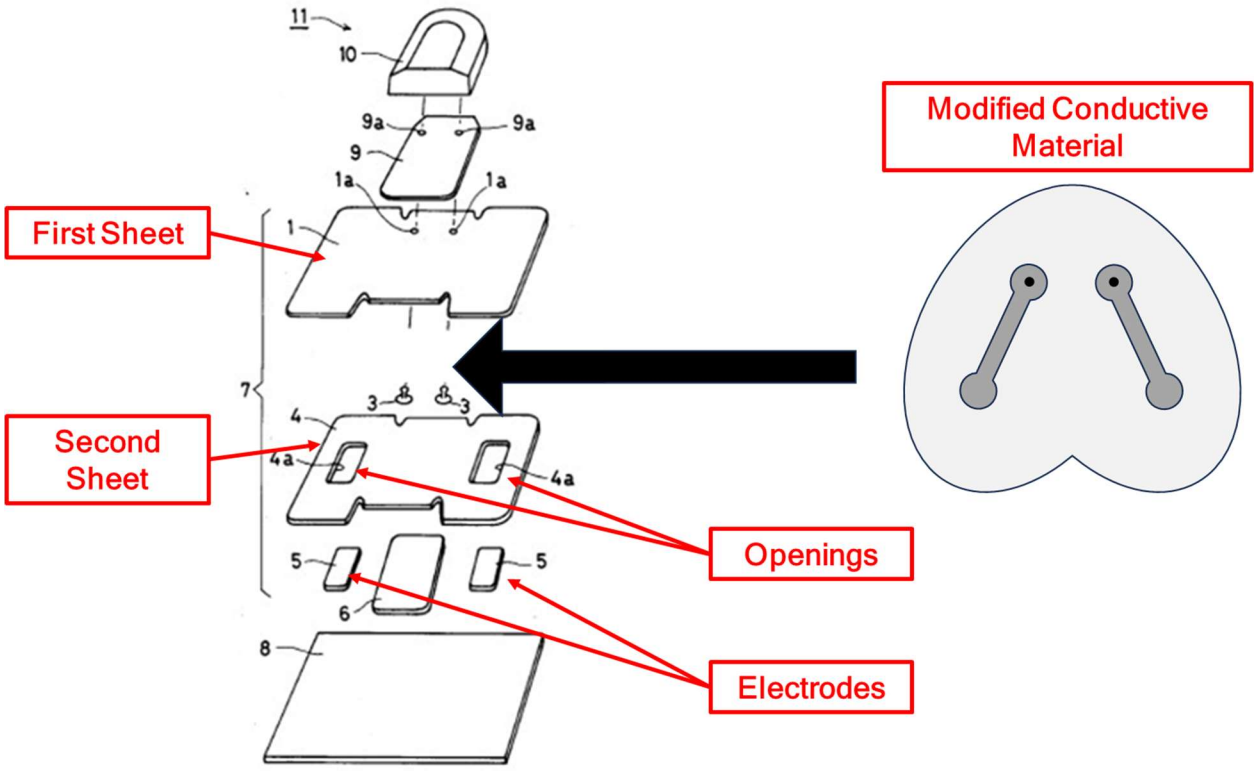
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material. *See e.g.*, Ex. 1035 at 659 (defining "Printed Circuit Board" as "[a]n insulating material onto which an electronic circuit has been printed or etched").

782. Matsumura discloses that its bioelectrode pad includes two pieces of "conductive material 2" which "can be a carbon sheet or a PET sheet coated with ***conductive Ag/AgCl***." Ex. 1012 at [0019]–[0020] (emphasis added). At the time of the invention of the Challenged Patents, it was well-known that silver and/or silver chloride electrodes, connectors, or traces could be created using the screen printing technique. *See* Ex. 1035 at 3 (noting screen printing had been used to "print[] silver paste conductors and graphite resistors" onto substrates since the end of World War II). Thus, a POSA would modified the conductive material disclosed by Matsumura to form a flexible printed circuit layer made from an insulating material and defining a substrate.

783. It would have been obvious to replace the two pieces of insulating material coated with conductive Ag/AgCl with a single, flexible sheet of insulating material that contained printed-ink, conductive traces, as shown below.

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Ex. 1012 at Fig. 1 (annotated). In my opinion, a POSA would have been motivated to make this change to reduce the manufacturing costs associated with manufacturing the parts: it is cheaper to cut out one part (as opposed to two) and it is cheaper to coat a defined area of the insulating material (as opposed to coating the insulating material in its entirety). Further, a POSA would have had a reasonable expectation of success so doing because screen-printing was well-known in the art at the time. *See* Ex. 1035 at 3 (noting screen printing had been used to "print[] silver paste conductors and graphite resistors" onto substrates since the end of World War II).

784. Thus, in my opinion, a POSA would understand that, as modified, this sheet with printed traces replacing Matsumura's conductive material 2 would

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comprise a flexible printed circuit layer made from an insulating material and defining a substrate. Therefore, it is my opinion that Matsumura, in view of the knowledge of a POSA, renders obvious "a flexible printed circuit layer made from an insulating material and defining a substrate."

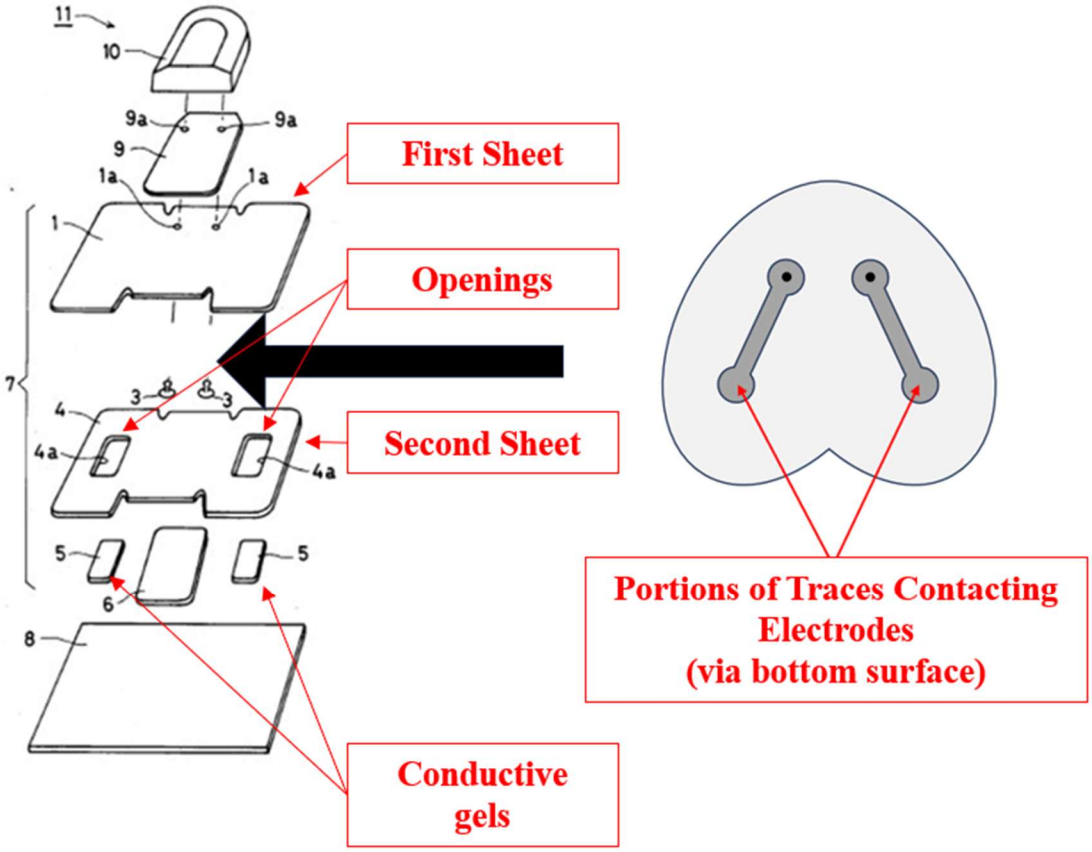
iii. Limitation [1b]

785. Limitation [1b] of the '492 patent recites "at least one electrode disposed onto a surface of the substrate."

786. In my opinion, Matsumura discloses limitation [1b] of the '492 patent.

787. Matsumura discloses "conductive gel[s] 5" (the claimed "electrodes") that are used to detect bioelectrical potentials. Ex. 1012 at [0019]. These "conductive gel[s]" are placed in openings 4a in "second sheet" 4, meaning that, when Matsumura's device was modified as explained above, the conductive gels would make contact with the printed sheet of conductive material. Ex. 1012 ¶¶ [0018]–[0019]. Thus, when modified, the conductive gels 5 are disposed on a surface of the substrate (*i.e.*, the insulating sheet with printed traces replacing conductive material 2)., as shown below by annotated Figure 1. *Id.* at [0018]–[0019].

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Ex. 1012, Fig. 1 (annotated).

788. Thus, in my opinion, Matsumura discloses "at least one electrode disposed onto a surface of the substrate."

iv. Limitation [1c]

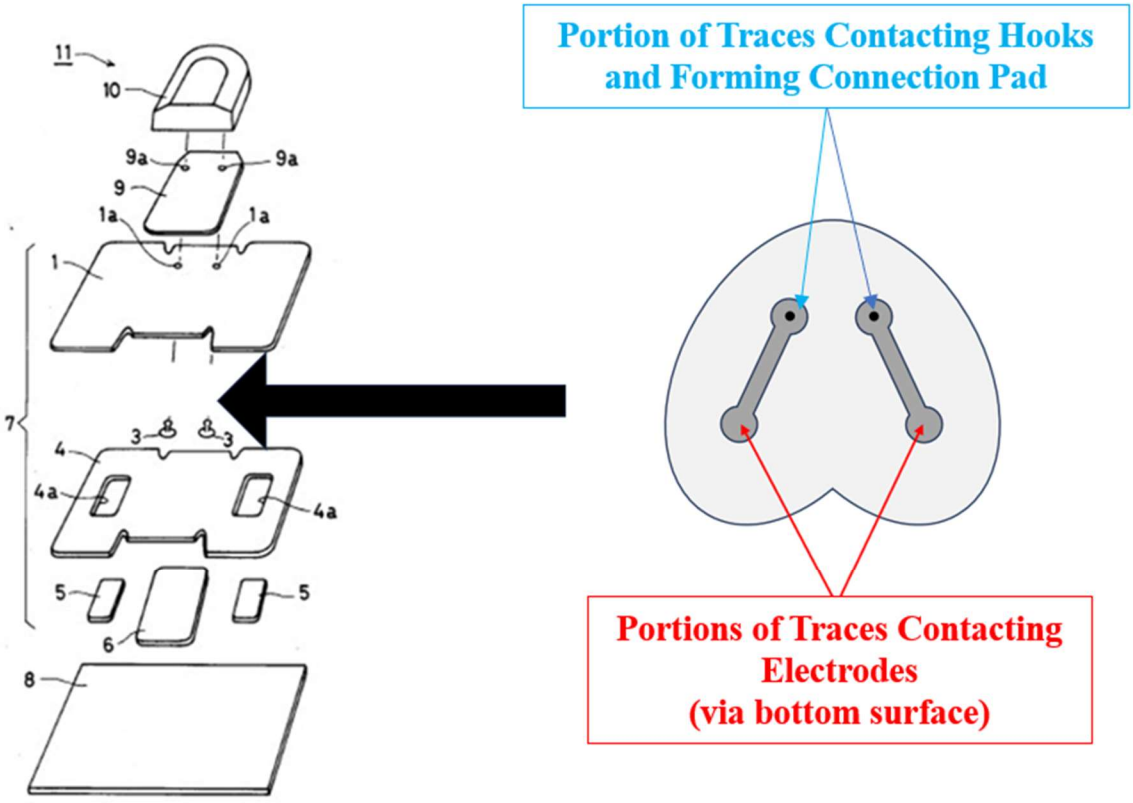
789. Limitation [1c] of the '492 patent recites "at least one connection pad."

790. In my opinion, Matsumura and Kroll, in view of the knowledge of a POSA, render obvious limitation [1c] of the '492 patent.

791. As discussed above, a POSA would have implemented Matsumura's conductive material 2 by printing traces on a single sheet of insulating material. *See* Section XVIII.A.2.ii, *supra.*

792. In my opinion, a POSA would understand that 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 at 7:44-55; *see* Ex. 1035 at 656 (defining "pad" as "[a] portion of the conductive area of which components, terminals, traces, etc., are mechanically attached").

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Ex. 1012, Fig. 1 (annotated).

793. Thus, in my opinion, the combination of Matsumura and Kroll renders obvious "at least one connection pad."

v. Limitation [1d]

794. Limitation [1d] of the '492 patent recites "at least one electrical trace extending between the at least one connection pad and a conductive surface of the at least one electrode."

795. In my opinion, Matsumura, in view of the knowledge of a POSA, renders obvious limitation [1d] of the '492 patent.

796. As discussed above, it is my opinion that a POSA would have been motivated to combine the two pieces of conductive material 2 into a single, printed sheet, forming a flexible circuit layer on which Kroll's lead strips (*i.e.*, the claimed "resistive traces") are printed. *See* Section XVIII.A.2.ii, *supra.* As modified, one end of the printed traces would contact conductive gel 5 (the electrodes) and the other end would contact the hooks 3 at the connection pad. *See* Section XVIII.A.2.iv, *supra*. In my opinion, a POSA would have understood that, as modified, Matsumura includes at least one electrical trace extending between the connection pad and a conductive surface of the electrode.

797. Thus, in my opinion, the combination of Matsumura and Kroll, in view of the knowledge of a POSA, discloses "at least one electrical trace extending between the at least one connection pad and a conductive surface of the [at] least one electrode."

vi. Limitation [1e]

798. Limitation [1e] of the '492 patent recites "the at least one electrical trace being made at least in part from a resistive material."

799. In my opinion, Matsumura and Kroll, in view of the knowledge of a POSA, render obvious limitation [1e] of the '492 patent.

800. Matsumura teaches a flexible, disposable bioelectrode pad 7 that includes conductive material 2 (*i.e.*, traces). Ex. 1012 at [0016]. For the reasons

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discussed above with reference to limitation [1a], it would have been obvious to replace conductive material 2 with a single sheet of insulating material that contained printed (ink) electrical traces. *See* Section XVIII.A.2.ii, *supra.*

801. Kroll teaches resistive traces composed of a "flexible conductive ink compound having a conductive filler having Silver, Aluminum, or compounds thereof, or of a similarly suitable material." Ex. 1013 at 5:4–8. Kroll further teaches that "[p]referably, 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." *Id.* at 5:8–13. As discussed above, it is my opinion that a POSA would have understood the printed ink lead strips taught by Kroll to be referring to traces as described by the '492 patent. *See* Ex. 1035 at 665 ("Traces: The metallic conductive strips that provide connections between components, terminals, etc., on printed circuits.").

802. Further, as explained above, it is my opinion that POSA would have sought to incorporate Kroll's "resistive trace" into Matsumura's device, as modified, in order to help protect Matsumura's device in the event of a patient being defibrillated. *See* Section XVII.A.1, *supra*.

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803. Thus, in my opinion, it would have been obvious to a POSA to combine Matsumura's wearable monitor with Kroll's teaching of resistive traces to meet "the at least one electrical trace being made at least in part from a resistive material."

vii. Limitation [1f]

804. Limitation [1f] of the '492 patent recites "an insulating layer covering the flexible printed circuit layer."

805. In my opinion, Matsumura discloses limitation [1f] of the '492 patent. As discussed above, a POSA would have modified Matsumura's conductive material 2 to comprise printed ink traces on a single flexible sheet. *See* Section XVIII.A.2.ii, *supra.* Matsumura teaches a second sheet 4 that is "made of insulating material that does not allow moisture to penetrate" and which has "two openings . . . into which the conductive gel 5 is inserted." Ex. 1012 at [0018]. Thus, Matsumura's "second sheet 4" therefore comprises an insulating layer covering the flexible printed circuit layer.

806. Additionally, or alternatively, Matsumura teaches 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.* at [0017] (emphasis added). As modified and combined with Kroll, Matsumura's device discloses a second sheet 4 and/or first sheet 1 (the claimed "insulating layer") that covers the modified, printed sheet of

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conductive material 2 (the claimed "flexible printed circuit layer") as modified by the teachings of Kroll. Thus, in my opinion, the combination of Matsumura and Kroll, in view of the knowledge of a POSA, also discloses "an insulating layer covering the flexible printed circuit layer."

3. Dependent Claim 2

807. Claim 2 of the '492 patent depends from claim 1 and additionally requires that "the at least one electrical trace includes a filleted portion formed at the electrode."

808. In my opinion, claim 2 of the '492 patent is rendered obvious by Matsumura and Kroll for all the reasons discussed above with respect to claim 1 as well as because the additional limitation of claim 2 would have been obvious to a POSA. *See* Section XVIII.A.2, *supra.*

809. As discussed above, it would have been obvious to modify Matsumura's conductive material to comprise printed ink traces on a flexible, insulating substrate. *See* Section XVIII.A.2.ii, *supra.*

810. In my opinion, 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. *See* Ex. 1035 at 195 (including, as "[s]tandard pad

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shapes" "Teardrop pads (with fillet radius)" and "Teardrop pads (with straight side fillets)"); *id.* at 442–43 (noting that "[t]he general shape of solder pads should be tear-like").

811. Thus, in my opinion, Matsumura and Kroll, in view of the knowledge of a POSA, render obvious "the at least one electrical trace includes a filleted portion formed at the electrode" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 2 of the '492 patent.

4. Dependent Claim 3

812. Claim 3 of the '492 patent depends from claims 1 and 2 and further requires "at least one battery mounted on the flexible circuit layer."

813. In my opinion, claim 3 of the '492 patent is rendered obvious by Matsumura and Kroll for all the reasons discussed above with respect to claims 1 and 2 as well as because the additional limitation of claim 2 would have been obvious to a POSA. *See* Section XVIII.A.3, *supra.*

814. Matsumura teaches a monitor that transmits the "processed bioelectric potential signal . . . wirelessly." Ex. 1012 at [0025]. As explained by Matsumura, prior art wireless monitors included "a power source." *Id.* at [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"). In my opinion, a POSA would have understood Matsumura's device to

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implicitly require a battery as an onboard power source to allow for wireless transmissions because otherwise the device would be inoperable. *See* Ex. 1003 at 1:39–51 (discussing prior art portable patient monitors with onboard batteries which allow them to be worn for extended periods of time); *see also* Ex. 1035 at 106, Table 3.1 (identifying battery as common electronic component of printed circuit board). It was well known at the time that batteries could be rechargeable or disposable. *See* Ex. 1003 at 1:45–46 (noting that "[a]fter a fixed interval of time, or at a low batter indication, the batteries can be ***replaced or recharged***") (emphasis added). In my opinion, it would be obvious to a POSA that if a disposable battery were to be used, it would be obvious to incorporate the *disposable* battery into the *disposable* flexible circuit layer.

815. Thus, in my opinion, Matsumura and Kroll, in view of the knowledge of a POSA, render obvious "at least one battery mounted on the flexible circuit layer" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 3 of the '492 patent.

5. Dependent Claim 5

816. Claim 5 of the '492 patent depends from claim 1 and additionally requires that the body-worn patient monitoring device "compris[es] an ECG monitor having a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals."

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817. In my opinion, claim 5 of the '492 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Matsumura teaches the additional limitation of claim 5. *See* Section XVIII.A.2, *supra.*

818. Both Matsumura and Kroll teach wearable devices for monitoring physiological signals, including ECG or EKG signals that measure a patient's heartbeat. *See* Ex. 1012 at [0024], [0031]; Ex. 1013 at 1:11–15, 1:37–45.

819. Matsumura, in particular, teaches "bioelectric potentials detected by the conductive gel 5," said bioelectric potentials including "electrocardiogram signals" that are detected while the detector is "worn on the patient's chest." Ex. 1012 at [0019], [0024]. Matsumura's conductive gel 5 forms electrical connections to the patient's body. *See* Section IV.A., *supra.* Therefore, in my opinion, Matsumura discloses "an ECG monitor having . . . a plurality of electrical connections to measure patient heartbeat signals."

820. Additionally, Matsumura discloses a "signal processor 10," which 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." Ex. 1012 at [0032]; *see also id.* at [0037]. In my opinion, a POSA would understand that Matsumura's disclosed "signal processor 10," is a microprocessor that is programmed to identify abnormal heart rates. *See* Ex. 1035 at 82 ("The function of

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the microprocessor is to manipulate data in accordance with the instructions stored in the memory."). Accordingly, in my opinion, a POSA would recognize that Matsumura discloses "an ECG monitor having a programmed microprocessor."

821. For these reasons, it is my opinion the combination of Matsumura and Kroll discloses that the body-worn patient monitoring device "compris[es] an ECG monitor having a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 5 of the '492 patent.

6. Dependent Claim 6

822. Claim 6 of the '492 patent depends from claim 1 and additionally requires "the at least one electrode includes an electrode gel and a conductive surface, thereby creating a half cell."

823. In my opinion, claim 6 of the '492 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claim 1 as well as because Matsumura teaches the additional limitation of claim 6. *See* Section XVIII.A.2, *supra.*

824. Matsumura teaches that "conductive gel 5" may be produced from components such as an "acrylic hydrophilic polymer, glycerin and water." Ex. 1012 at [0018]. Matsumura further explains that conductive gel 5 contacts a portion of "conductive material 2," which may be "coated with conductive Ag/AgCl

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[Silver/Silver Chloride]." *Id.* at [0019]–[0020]. In my opinion, a POSA would understand that conductive gel 5 (*i.e.*, electrode gel), which comprises an acrylic hydrophilic polymer, glycerin and water, and which contacts a portion of conductive material 2 (*i.e.*, conductive surface) whose surface is made of silver/silver chloride comprises a "half cell." *See, e.g.*, Ex. 1003 at 7:3–5 ("In conventional terms of art, the combination of electrode and electrolyte and ECG electrode is typically referred to as a half cell."). Accordingly, in my opinion, a POSA would know that Matsumura's conductive gel 5 and/or a portion of conductive material 2, when modified as explained above, form electrical connections comprising a half cell at the point of contact with the patient's skin.

825. For these reasons, it is my opinion that a POSA would understand that Matsumura discloses "the at least one electrode includes an electrode gel and a conductive surface, thereby creating a half cell" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 6 of the '492 patent.

7. Independent Claim 7

826. In my opinion, claim 7 of the '492 patent is rendered obvious by Matsumura in combination with Kroll.

i. Preamble 7[pre]

827. The preamble of claim 7 recites "[a] body-worn patient monitoring device comprising."

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828. As described with respect to claim 1, to the extent the preamble is limiting, it is my opinion that the combination of Matsumura and Kroll discloses the "body-worn patient monitoring device" of claim 7 of the '492 patent. *See* Section XVIII.A.2.i, *supra*.

ii. Limitation [7a]

829. Limitation [7a] recites "a disposable electrode portion."

830. In my opinion, Matsumura discloses limitation [7a] of the '492 patent.

831. Matsumura teaches "a disposable bioelectrode pad 7" that includes a disposable "conductive gel[s] 5" (the claimed "electrodes") used to detect bioelectrical potentials. Ex. 1012 at [0016], [0019].

832. Thus, in my opinion, Matsumura discloses "a disposable electrode portion."

iii. Limitation [7b]

833. Limitation [7b] recites "a reusable communication module."

834. In my opinion, Matsumura discloses limitation [7b] of the '492 patent.

835. Matsumura teaches a "***reusable signal processor*** for processing and wirelessly transmitting the bioelectric potential signals detected by the bioelectrode pad." *Id.* at [0013] (emphasis added); *see also id.* at [0008], [0014], [0016], [0025], Figs. 1–2. Matsumura specifically teaches that "the signal processor is economical ***because*** it is reusable." *Id.* at [0016] (emphasis added).

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836. Matsumura discloses that the reusable signal processor includes components that allow for communication, stating: "The signal processor 10 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.* at [0025].

837. Thus, in my opinion, Matsumura discloses "a reusable communication module."

iv. Limitation [7c]

838. Limitation [7c] recites "the disposable electrode portion comprising a flexible printed circuit layer made from an insulating material and defining a substrate."

839. In my opinion, the combination of Matsumura and Kroll, in view of the knowledge of a POSA, renders obvious limitation [7c] of the '492 patent.

840. Matsumura teaches a disposable bioelectrode pad 7 (the claimed flexible printed circuit layer) with conductive gel 5 (the claimed electrode). Matsumura discloses that bioelectrode pad 7 is comprised of sheets "made of an insulating material" such as "polyethylene foam, polyurethane foam, or polyurethane sheet." *Id.* at [0017]–[0018], [0022]. As discussed above, it is my opinion that a POSA would have used the same manufacturing technique and the

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well-known technique of screen printing in order to replace Matsumura's two separate pieces of conductive material 2 with a single flexible sheet comprising insulating material containing printed-ink traces (*i.e.*, a printed circuit board). *See* Section XVIII.A.2.ii, *supra*; Ex. 1035 at 659 ("Printed Circuit Board: An insulating material onto which an electronic circuit has been printed or etched."). When modified in that way, it is my opinion that a POSA would recognize that the flexible printed circuit layer made from an insulating material and defining a substrate would be part of Matsumura's disposable electrode portion. Ex. 1012 at [0016]–[0018].

841. Thus, in my opinion, the combination of Matsumura and Kroll discloses "the disposable electrode portion comprising a flexible printed circuit layer made from an insulating material and defining a substrate."

v. Limitation [7d]

842. Limitation [7d] recites "at least two electrodes being disposed onto a surface of the substrate."

843. As discussed above with respect to Claim 1, it is my opinion that Matsumura discloses "at least two electrodes being disposed onto a surface of the substrate." *See* Section XVIII.A.2.iii, *supra*.

vi. Limitation [7e]

844. Limitation [7e] recites "electrical traces defined between the at least two electrodes and a connection pad."

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845. As discussed above with respect to Claim 1, it is my opinion that the combination of Matsumura and Kroll discloses "electrical traces defined between the at least two electrodes and a connection pad." *See* Section XVIII.A.2.v, *supra.*

vii. Limitation [7f]

846. Limitation [7f] recites "wherein the reusable communication and computation module comprises a housing containing a processor and a wireless communication unit."

847. In my opinion, the combination of Matsumura and Kroll discloses limitation [7f] of the '492 patent.

848. Matsumura teaches that its "bioelectric potential detector 11" includes a "reusable signal processor 10" which is "detachable [from the bioelectrode pad 7] with hooks." Ex. 1012 at [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.* at [0025]. Matsumura further teaches that the reusable signal processor includes components which allow for computation, such as a "processing circuit for filtering and amplifying detected bioelectric potential signals" and "a memory for storing the processed bioelectric potential signal." *Id*. All components which comprise the signal processor 10 are contained within the closed, waterproof housing of the signal processor. *Id.*

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849. Thus, in my opinion, the combination of Matsumura and Kroll discloses that "the reusable communication and computation module comprises a housing containing a processor and a wireless communication unit."

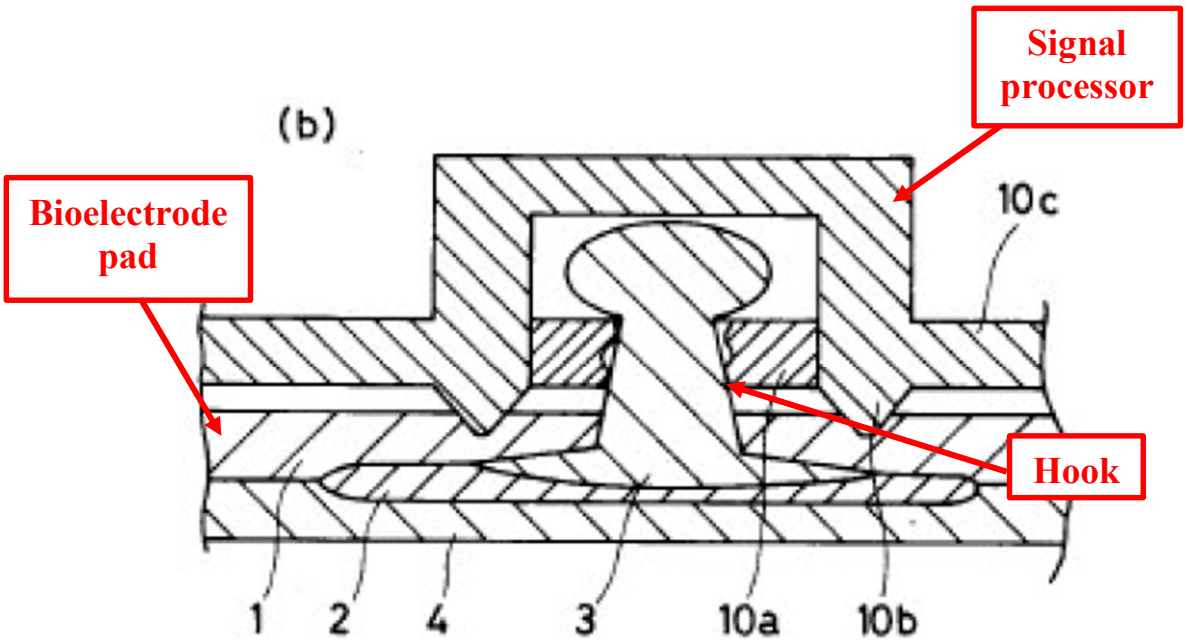
viii. Limitation [7g]

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

851. In my opinion, Matsumura discloses limitation [7g] of the '492 patent.

852. Matsumura teaches a "bioelectric potential detector 11 [that] is composed of a disposable bioelectrode pad 7 and a reusable signal processor 10." *Id.* at [0008], [0014], [0016], [0025], Figs. 1–2. Specifically, Matsumura teaches that the disposable bioelectrode pad includes a "conductive gel 5" (*i.e.*, the claimed "disposable electrode portion"), *see id.* at [0016], [0018]–[0019], and that the reusable signal processor includes a wireless transmitter, *id.* at [0031]–[0032], [0034]. Matsumura further teaches that the "bioelectrode pad 7 and the signal processor 10 are detachable with hooks" as shown by annotated Figure 4(b) below. *Id.* at [0016].

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Id. at Fig. 4(b) (annotated).

853. In my opinion, a POSA would understand that "hook 3" of Matsumura renders obvious use of a latch clip as disclosed by the '492 patent. Both latches and snaps were commonly known and used in the art at the time. *See, e.g.*, Ex. 1003 at 9:27–39; *see also* Section IV.D, *supra*. A POSA would have understood a snap mechanism and a latch mechanism to be interchangeable for the purpose of attaching two components of a medical device such as a body-worn monitor. *See, e.g.*, Ex. 1039 at [0046], Fig. 5 (discussing use of snap connectors to attach a monitoring device to 12-lead recorders); Ex. 1040 at 30 ("Labeling" (providing instructions for use of a body-worn glucose monitoring device which uses a latch to attach the STS Transmitter and the STS Sensor Pod, two components of the device)).

854. Thus, in my opinion, a POSA would understand that the combination of Matsumura and Kroll discloses that "the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip."

8. Dependent Claim 8

855. Claim 8 of the '492 patent depends from claim 7 and additionally requires that "the electrodes are integrated into the flexible printed circuit layer of the disposable portion of the device."

856. In my opinion, claim 8 of the '492 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claim 7 as well as because Matsumura teaches the additional limitation of claim 8. *See* Section XVIII.A.7, *supra.*

857. Matsumura teaches that conductive gels 5 (the claimed electrodes) are integrated into the disposable bioelectrode pad 7 (the claimed disposable portion) of bioelectric potential detector 11. Ex. 1012 at [0016]. Specifically, when modified as discussed above, Matsumura's bioelectrode pad 7 is composed, in part, of the sheet containing printed traces with which the electrodes make contact. *Id.* at [0019]. In my opinion, a POSA would understand that the electrodes are bonded together with the other components of the disposable bioelectrode pad 7, including the sheet of conductive material 2, with which the electrodes make contact. *See* Ex. 1035 at 659 ("Printed Wiring: A conductive pattern within or bonded to the surface of a base

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material intended for point-to-point connection of separate components and not containing printed components.").

858. For these reasons, it is my opinion Matsumura discloses that "the electrodes are integrated into the flexible printed circuit layer of the disposable portion of the device" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 8 of the '492 patent.

9. Dependent Claim 11

859. Claim 11 of the '492 patent depends from claim 7 and additionally requires that "the electrical traces are screened onto the flexible printed circuit layer."

860. In my opinion, claim 11 of the '492 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claim 7 as well as because Kroll teaches the additional limitation of claim 11. *See* Section XVIII.A.7, *supra.*

861. As discussed above, it is my opinion that 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. *See* Section XVIII.A.2.ii, *supra.* Further, it is my opinion that a POSA would understand printing ink onto a circuit board to be a form of screening, meaning that incorporating Kroll's ink traces on the flexible printed circuit layer of Matsumura would yield electrical traces that

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are screened. *See, e.g.*, Ex. 1035 at 296 ("Printing Process. The circuit patterns are screen printed on the substrate by two ways: (1) Manual screen printing process, and (2) Automatic or semi-automatic screen printing process."); *see also* Sections IV.C., XVIII.A.2.ii, *supra*.

862. For these reasons, it is my opinion that a POSA would understand Kroll to disclose that "the electrical traces are screened onto the flexible printed circuit layer" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 11 of the '492 patent.

10. Dependent Claim 12

863. Claim 12 of the '492 patent depends from claims 7 and 11 and additionally requires "an insulating layer applied onto the electrical traces."

864. In my opinion, claim 12 of the '492 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claims 7 and 11 as well as because Matsumura teaches the additional limitation of claim 12. *See* Section XVIII.A.9, *supra.*

865. As discussed above, the combination of Matsumura and Kroll teaches "electrical traces." *See* Section XVIII.A.2.vi, *supra.* Additionally, Matsumura teaches that second sheet 4 and first sheet 1 are both made of "an insulating material" such as "polyethylene foam, polyurethane foam, or polyurethane sheet." Ex. 1012

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at [0017]–[0019], Fig. 1. Matsumura also teaches that second sheet 4 and first sheet 1 are applied onto conductive material 2. *Id*.

866. For these reasons, it is my opinion that Matsumura discloses "an insulating layer applied onto the electrical traces" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 12 of the '492 patent.

11. Dependent Claim 13

867. Claim 13 of the '492 patent depends from claims 7, 11, and 12 and additionally requires that "the insulating layer is screen printed onto the electrical traces of the flexible printed circuit layer."

868. In my opinion, claim 13 of the '492 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claims 7, 11, and 12 as well as because Matsumura teaches the additional limitation of claim 13. *See* Section XVIII.A.10, *supra.*

869. In my opinion, 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" because screen printing was a well-known and common method of manufacturing a printed circuit board. Ex. 1035 at 352 (noting that one of the functions served by a solder mask is "[a]ct[ing] as an insulating barrier between closely placed tracks"). Further, a POSA would have

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understood that insulating layers such as solder mask (*i.e.*, solder resist) were commonly applied using either screen printing or photoprinting. *Id.* at 353.

870. For these reasons, it is my opinion that Matsumura discloses that "the insulating layer is screen printed onto the electrical traces of the flexible printed circuit layer" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 13 of the '492 patent.

12. Dependent Claim 14

871. Claim 14 of the '492 patent depends from claim 7 and additionally requires that "each electrode includes an electrode gel and a conductive surface defining a half cell."

872. In my opinion, claim 14 of the '492 patent is rendered obvious by Matsumura in combination with Kroll for all the reasons discussed above with respect to claim 7 as well as because Matsumura teaches the additional limitation of claim 14. *See* Section XVIII.A.7, *supra.*

873. Matsumura teaches that "conductive gel 5" may be produced from components such as an "acrylic hydrophilic polymer, glycerin and water." Ex. 1012 at [0018]. Matsumura further explains that conductive gel 5 contacts a portion of "conductive material 2," which may be "coated with conductive Ag/AgCl [Silver/Silver Chloride]." *Id.* at [0019]–[0020]. In my opinion, a POSA would understand that conductive gel 5 (*i.e.*, electrode gel), which comprises an acrylic

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hydrophilic polymer, glycerin and water, and which contacts a portion of conductive material 2 (*i.e.*, conductive surface) whose surface is made of silver/silver chloride comprises a "half cell" as claimed by claim 6 of the '492 patent. Accordingly, in my opinion, a POSA would know that Matsumura's conductive gel 5 and/or a portion of conductive material 2 form electrical connections comprising a half cell at the point of contact with the patient's skin.

874. For the same reasons as discussed above in Section XVIII.A.6 with respect to claim 6 of the '492 patent, it is my opinion that a POSA would understand that Matsumura discloses that "each electrode includes an electrode gel and a conductive surface defining a half cell" and, therefore, that the combination of Matsumura and Kroll renders obvious claim 14 of the '492 patent.

B. Ground 2: Obvious Over Jensen, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art

875. Additionally, in my opinion, claims 1–6 are obvious over Jensen and Kroll.

1. A POSA had motivation to combine Jensen and Kroll

876. For the reasons set forth above in Section XVI.A.1, with reference to the '007 patent, a POSA would have had motivation to combine the teachings of Jensen and Kroll and would have had a reasonable expectation of success in doing so.

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2. Independent Claim 1

877. In my opinion, claim 1 of the ’492 patent is rendered obvious by Jensen in combination with Kroll.

i. Limitation 1[pre]

878. The preamble of claim 1 recites “[a] body-worn patient monitoring device comprising.”

879. In my opinion, to the extent that the preamble is limiting, Jensen discloses the preamble of claim 1 of the ’492 patent. Jensen discloses a “self-contained, self-attached” device (referred to as a “‘smart bandage’ or ‘smart patch’”) capable of measuring physiological signals including ECG. Ex. 1011 at [0012], [0013], [0029]; *see also id.* at Fig. 5. Jensen explains that:

> It is the function of the present invention to either a) electrically detect the occurrence of R events in the QRS complex of the EKG signal, and/or b) continuously sample the EKG signal, perform signal processing and calculation upon the data contained within those signals, and provide a transmitted data signal for reception by any variety of different receivers. According to this invention, these components are incorporated into a self-contained assembly that adhesively mounts to the torso of a person or mammal.

Id. at [0029].

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880. Demonstrating the compatibility of their teachings, Kroll also discloses "a body worn patient monitoring device," as recited in the preamble of claim 1 of the '492 patent. Kroll recites:

> This invention relates to a device and method for receiving and transmitting electrical signals to and from a patient. Particularly, this invention relates to a disposable, flexible and layered electrode belt, also referred to as a "belt", for placement and use on the body of a patient and also for use with medical diagnostic and therapeutic devices.

Ex. 1013 at 1:9–15.

881. Thus, in my opinion, both Jensen and Kroll disclose "a body-worn patient monitoring device."

ii. Limitation [1a]

882. Limitation [1a] recites "a flexible printed circuit layer made from an insulating material and defining a substrate."

883. In my opinion, Jensen discloses limitation [1a] of the '492 patent.

884. Jensen discloses a "flexible circuit assembly 36, 50" containing an electrical circuit. Ex. 1011 at [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.* Flexible circuit 50 and flexible circuit 36 are analogous and would contain similar components including sensor contacts 71, 72. In my opinion, a

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POSA reading Jensen would recognize that the "flexible circuit assembly" of Jensen defines a substrate on which traces, electronics, and sensor contacts 71, 72 are placed because if Jensen's "flexible circuit assembly were not made of an insulating material, the electronics 41, 52 on the surface would short circuit. *See* Ex. 1043 at 798 (explaining that while the dielectric breakdown in capacitors can lead to short circuits, this can be prevented by the use of insulating materials with high dielectric strength).

885. In my opinion, a POSA would further understand that Jensen's flexible circuit assembly (the claimed "flexible printed circuit layer") ***must*** be made from an insulating material. If the circuit(s) were printed on a conductive material, then electrical current—rather than traveling through printed traces—would pass diffusely across the entire surface. For this reason, printed circuits boards are defined as "an ***insulating*** material onto which an electronic circuit has been printed or etched." *See e.g.*, Ex. 1035 at 659 (defining "Printed Circuit Board" as "[a]n insulating material onto which an electronic circuit has been printed or etched"). Further, as explained above, it is my opinion that a POSA would have been motivated to combine Kroll's teaching of resistive traces with Jensen's device. *See* Sections XVIII.B.1, XVI.A.1 *supra*.

886. Accordingly, in my opinion, a POSA would understand that Jensen's disclosure of a "flexible circuit assembly," comprises a "flexible printed circuit layer

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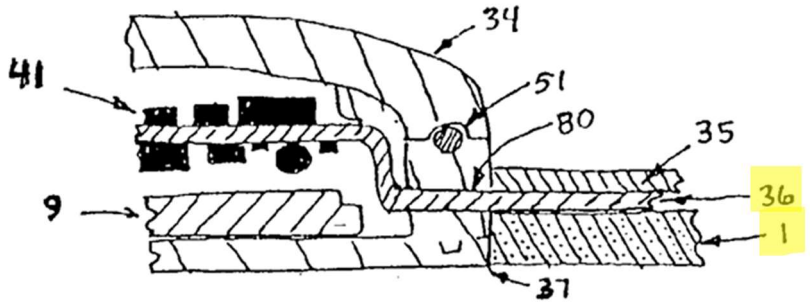
made form an insulating material and defining a substrate," as required by limitation [1a] of the '492 patent.

iii. Limitation [1b]

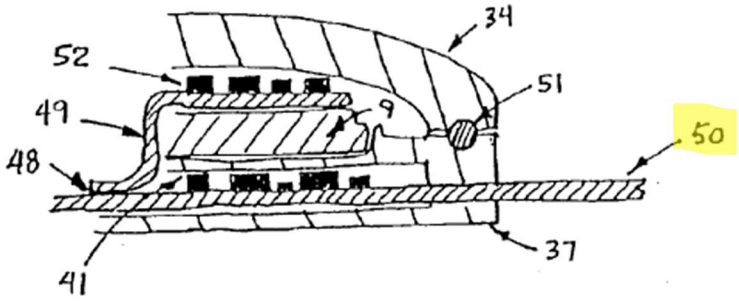
887. Limitation [1b] of the '492 patent recites "at least one electrode disposed onto a surface of the substrate."

888. In my opinion, Jensen discloses limitation [1b] of the '492 patent.

889. Jensen discloses a "disposable sensor assembly," which includes "disposable sensor pad electrodes 1 and 2." Ex. 1011 at [0041]–[0042]. Jensen's sensor pad electrodes 1 and 2 are conductive and couplable to a skin surface to measure physiological signals such as ECG signals. *Id.* at [0041]. As depicted in Figure 7 below, Jensen's sensor pad electrodes 1 and 2 are disposed on the lower surface of flexible circuit assembly 36.



Id. at Fig. 7 (annotations added); *see also id.* at [0045]. Further, a POSA would understand that, while not included in the diagram of Fig. 8, the sensor pad electrodes would also be disposed on the lower surface of flexible circuit assembly 50 in the embodiment of Figure 8 in the same way they are shown in Fig. 7.



Id. at Fig. 8 (annotations added).

890. Accordingly, in my opinion, Jensen discloses limitation [1b] of the '492 patent.

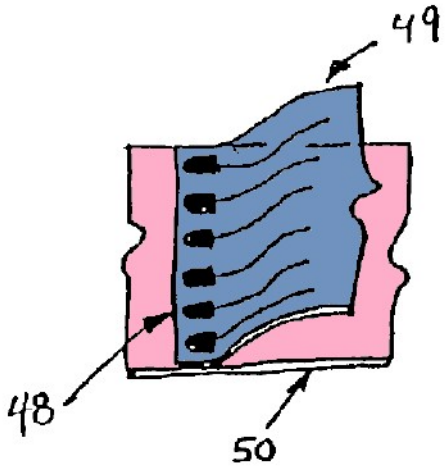
iv. Limitation [1c]

891. Limitation [1c] of the '492 patent recites "at least one connection pad."

892. In my opinion, Jensen discloses limitation [1c] of the '492 patent.

893. Jensen, in the embodiment of Figure 8, discloses two flexible printed circuits 49 and 50 which comprise a substrate for the reusable computation-communication module and a substrate for the disposable module, respectively. *Id.* at [0046], Fig. 8. According to Jensen, the circuits are connected by pads 48, which are "matched on both circuits." *Id.* at [0046], Fig. 8A.

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Id. at Fig. 8A (annotated).

894. In my opinion, 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 at [0044]–[0046]. Jensen also teaches 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.* at [0046]. A POSA would understand that the pads on the disposable, printed circuit board substrate of Jensen, 50, are the claimed connection pads because they form a connection between the power source, *i.e.*, coin cell 9, and the electrical traces that lead to sensor contacts 71, 72. Ex. 1003 at 7:44–55; *see* Ex. 1035 at 656 (defining "pad" as "[a] portion of the conductive area of which components, terminals, traces, etc., are mechanically

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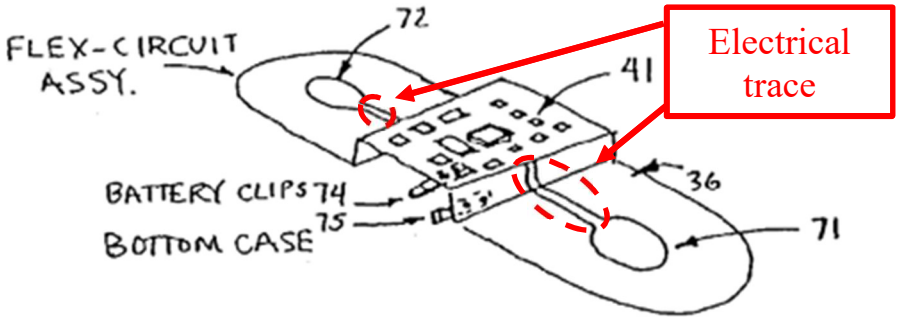
attached"). Therefore, it is my opinion that a POSA would know that Jensen discloses limitation [1c] of the '492 patent.

v. Limitation [1d]

895. Limitation [1d] of the '492 patent recites "at least one electrical trace extending between the at least one connection pad and a conductive surface of the [at] least one electrode."

896. In my opinion, Jensen discloses limitation [1d] of the '492 patent.

897. As depicted in Figure 5 (as annotated below), 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 and 2." Ex. 1011 at [0040]–[0041].



Id. at Fig. 5 (annotated).

898. In my opinion, 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 to connection pad 48. *See Id.,* Figs. 8, 8a (below); *see also* Ex. 1035 at 664

("Surface Mounting: The electrical connection of components to the surface of a conductive pattern").

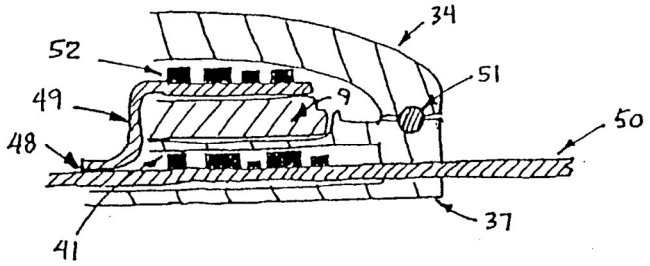


figure 8

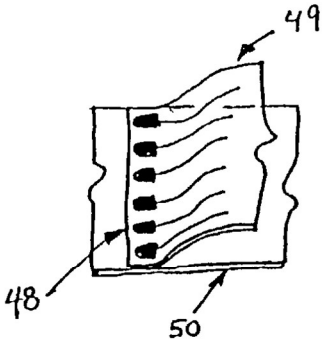


figure 8a

Ex. 1011, Figs. 8, 8a. Specifically, a POSA would understand that, for signals from sensor contacts 71, 72 to reach the electrical circuits located on substrate 49, traces **must** extend between the connection pad and a conductive surface of at least one electrode. Thus, in my opinion, a POSA would understand that Jensen teaches electrical traces between at least one connection pad and a conductive surface of the at least one electrode.

vi. Limitation [1e]

899. Limitation [1e] of the '492 patent recites "the at least one electrical trace being made at least in part from a resistive material."

900. In my opinion, the combination of Jensen and Kroll renders limitation [1e] of the '492 patent obvious in view of the knowledge of a POSA.

901. Jensen discloses a flexible circuit assembly 36, 49, 50, which includes "copper wiring traces to connect the entire circuit." Ex. 1011 at [0040].

902. Kroll teaches that conductive traces on a body-worn patient monitoring device may be made of a resistive material to protect both the patient and the device against shock. Specifically, Kroll discloses 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 at 5:4–13 (emphasis added). Kroll therefore teaches printed ink leads. Moreover, because the printed ink leads are configured to function as a "current limiter," a POSA would understand that Kroll teaches that those printed ink leads are made of a "resistive material." *Id.*

903. As set forth in Sections XVIII.B.1 and XVI.A.1, *supra*, in my opinion, a POSA would have been motivated to combine Kroll's teaching of resistive traces with Jensen's device both to assure the viability of Jensen's flexible circuit assembly in the event of a patient being defibrillated, ***and*** because implementing Kroll's "resistive traces" on Jensen's printed circuit assembly would enable a POSA to remove any resistors on the electronics circuit 41 of Jensen's "smart patch," thereby

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reducing the overall size (and wearability) of the device. Further, and also as recited above, it is my opinion that a POSA would have had a reasonable expectation of success in combining Kroll's resistive traces with Jensen's device.

904. Therefore, it is my opinion that Jensen and Kroll, in view of the knowledge of a POSA, render obvious limitation [1e] of the '492 patent.

vii. Limitation [1f]

905. Limitation [1f] of the '492 patent recites "an insulating layer covering the flexible printed circuit layer."

906. In my opinion, Jensen discloses limitation [1f] of the '492 patent.

907. Jensen discloses "an insulating layer covering the entire flexible printed circuit layer"; Jensen's "smart patch" includes "an electronic circuit . . . sandwiched **between layers of insulating material** and cover plastics." Ex. 1011 at Abstract (emphasis added). More particularly, Jensen discloses that the entire top side of the flexible circuit assembly 36 is "enclose[d]" and "sealed" by "[t]op casing 34 and two aesthetic covers 35" constructed of Mylar®. *Id.* at [0043]. A POSA would recognize that "Mylar" is the trade name for a well-known insulating material. *See, e.g.*, Ex. 1047 at 23.10 ("The material most commonly used for flexible packaging applications is oriented polyester (e.g., Mylar™), which is used as a base for properties such as dimensional stability, heat resistance, and strength with an

adhesively laminated seal layer such as low-density polyethylene, which provides the film structure with heat scalability.").

908. A POSA would understand that, in the 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 at [0043], [0045], Fig. 8;

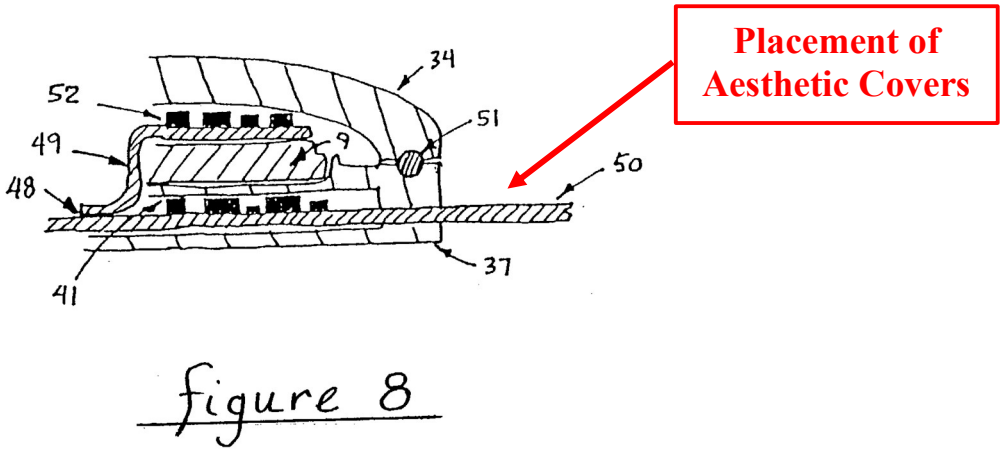


Figure 8

Ex. 1011 at Fig. 8. A POSA would understand aesthetic covers 35 and/or top casing 34 to be insulating covers for flexible circuit 50. 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.

909. Accordingly, in my opinion, Jensen discloses limitation [1f] of the '492 patent.

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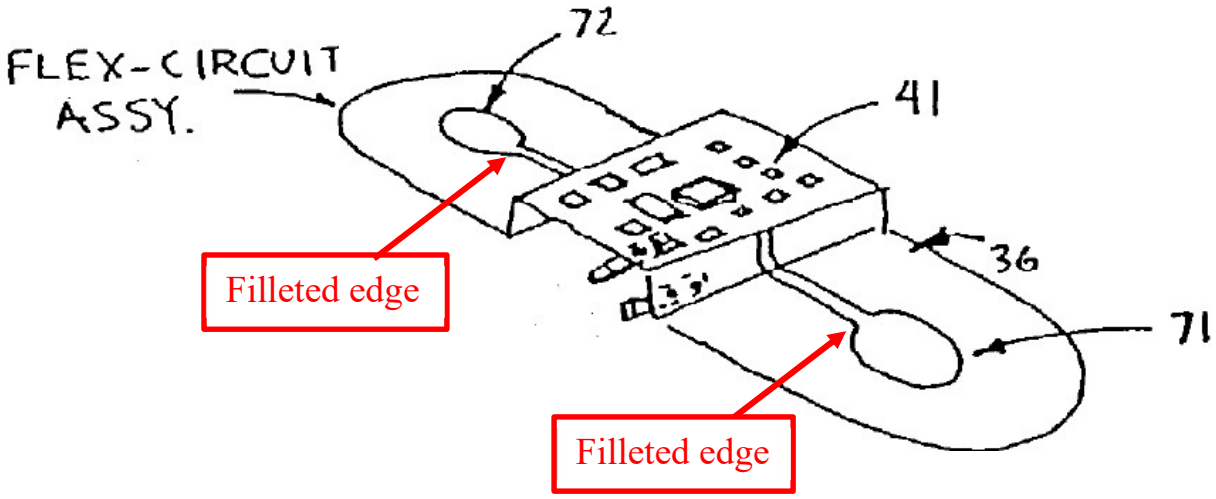
3. Dependent Claim 2

910. Claim 2 of the ’492 patent depends from claim 1 and further requires that “the at least one electrical trace includes a filleted portion formed at the electrode.”

911. In my opinion, a POSA would understand that Jensen discloses the additional limitation of claim 2.

912. The ’492 patent explains that a “fillet or ‘tear drop’ shape causes the carbon trace to become gradually wider as it connects to [the] conductive surface.” Ex. 1003 at 8:62–64.

913. Jensen teaches “copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72” whose edges are shaped as fillets. Ex. 1011 at [0040], Fig. 5. In my opinion, a POSA reviewing Figure 5 of the ’492 patent would recognize that the traces must gradually get wider to mechanically connect to the filleted sensor contacts 71, 72. As shown in the annotated version of Jensen’s Figure 5 below, the end of the trace connected to the fillet shaped sensor contact is wider than that connected to entire circuit 41.



Id. at Fig. 5 (annotated).

914. Further, it is my opinion that, when incorporating the "resistive trace" of Kroll, a POSA would not alter the shape of the electric trace taught by Jensen, which includes a "filleted edge." The benefits of Kroll's resistive traces that would have motivated a POSA to implement them on Jensen's device (*i.e.*, shock protection, no need for inclusion of bulky resistors on surface of circuitry), *see supra* Sections XVIII.B.1, XVI.A.1, would be achieved by simply replacing Jensen's copper traces with the printed ink traces. Additionally, it is my opinion that POSA would have no reason to modify the placement or shape of Jensen's traces, especially because, when printing ink traces on a flexible circuit board, it is desirable that contacts should be "tear-like" or "filleted" to ensure a good conductive connection. *See* Ex. 1035 at 195 (including, as "[s]tandard pad shapes," "Teardrop pads (with fillet radius)" and "Teardrop pads (with straight side fillets)"), 442–43 (noting that "[t]he general shape of solder pads should be tear-like").

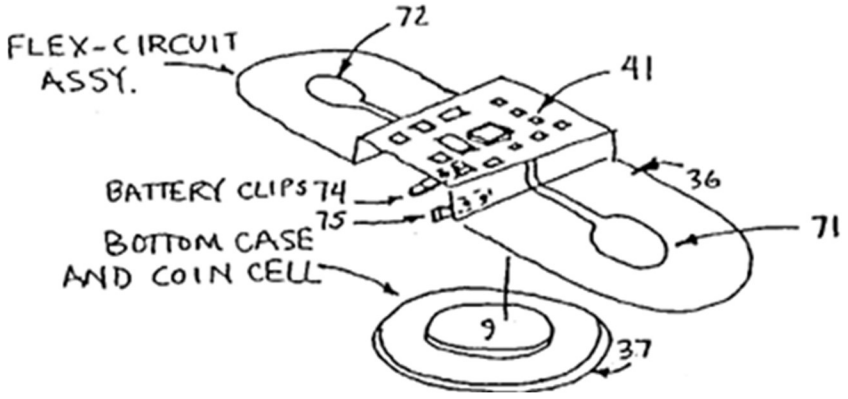
915. Because Jensen discloses the additional limitation of claim 2, and the combination of Jensen and Kroll renders obvious independent claim 1 from which it depends, in my opinion, *see* Section XVIII.B.2, *supra*, claim 2 of the '492 patent is obvious over the combination of Jensen and Kroll.

4. Dependent Claim 3

916. Claim 3 of the '492 patent depends from claims 1 and 2 and additionally requires "at least one battery mounted on the flexible circuit layer."

917. In my opinion, Jensen discloses the dependent limitation of claim 3 of the '492 patent.

918. Jensen describes a "Lithium coin cell 9 [*i.e.*, a battery] attaches to flexible circuit assembly 36 with two small nickel or gold plated steel clips 74, 75." Ex. 1011 at [0043]. The steel clips, 74 and 75, are used to mount the battery to the bottom of the flexible circuit assembly, as shown in the excerpted version of Figure 5 below. The flexible circuit assembly 36 is, in my opinion, the claimed "flexible circuit layer" of the '492 patent. *See* Section XVIII.B.2.ii, *supra*.



Ex. 1011 at Fig. 5.

919. Because Jensen discloses the additional limitation of claim 3 and the combination of Jensen and Kroll renders obvious claims 1 and 2 from which claim 3 depends, *see* Section XVIII.B.3, *supra*, in my opinion, claim 3 of the '492 patent is obvious over the combination of Jensen and Kroll.

5. Dependent Claim 4

920. Claim 4 of the '492 patent depends directly from claim 3 and indirectly from claims 1 and 2. Claim 4 adds the dependent limitation "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."

921. In my opinion, Jensen teaches the dependent limitation of claim 4 of the '492 patent.

922. Jensen discloses "two small nickel or gold plated steel clips 74, 75," which attach "Lithium coin cell 9" to the "flexible circuit assembly 36." Ex. 1011 at [0043]. In my opinion, Jensen's steel clips constitute the claimed retention members; the Lithium coin cell is the claimed battery. *Id.* Steel clips 74 and 75 mechanically attach the Lithium coin cell 9 to the flexible circuit assembly 36. *Id.* The "nickel or gold plated steel clips 74, 75" also electrically connect the Lithium coin cell to the flexible circuit assembly 36, which includes "sensor contacts 71, 72

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[that] ***make electrical contact with*** [***electrode***] ***sensor pads*** 1 and 2." *Id.* at [0041], [0043] (emphasis added).

923. Because Jensen discloses the additional limitation of claim 4, and the combination of Jensen and Kroll renders obvious claims 1, 2, and 3 from which claim 4 depends, *see* Section XVIII.B.4, *supra*, in my opinion, claim 4 of the '492 patent is obvious over the combination of Jensen and Kroll.

6. Dependent Claim 5

924. Claim 5 of the '492 patent depends from claim 1 and additionally requires "an ECG monitor having a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals."

925. In my opinion, Jensen discloses the dependent limitation of claim 5 of the '492 patent.

926. Both Jensen and Kroll teach wearable devices for monitoring physiological signals, including ECG (*i.e.*, EKG) signals that measure a patient's heartbeat. *See* Ex. 1011 at [0029]–[0031]; Ex. 1013 at 1:11–15, 1:37–45. Jensen, in particular, discloses that "heart-rate signals are collected from left and right [electrode] sensor pads, 1 & 2." Ex. 1011 at [0031], [0041]. Thus, in my opinion, Jensen teaches an "ECG monitor having . . . a plurality of electrical connections to measure patient heartbeat signals."

927. Jensen further discloses a wearable device with a programmed microprocessor. In particular, Jensen's device includes a "microcontroller," which "runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter." *Id.* at [0032]; Ex. 1003 at 12:3–5 ("A microprocessor, such as microprocessor 512, is defined herein as synonymous and interchangeable with the terms 'microcomputer', 'microcontroller', and 'microprocessor'."). One such program that may be run on Jensen's microcontroller is one for "detect[ing] the occurrence of R events in the QRS complex of the EKG [*i.e.*, ECG] signal." Ex. 1011 at [0029], [0037]. Thus, in my opinion, Jensen teaches an "ECG monitor having a programmed microprocessor."

928. Because Jensen discloses the additional limitation of claim 5, and the combination of Jensen and Kroll renders obvious independent claim 1 from which claim 5 depends, *see* Section XVIII.B.2, *supra*, in my opinion, claim 5 of the '492 patent is obvious over the combination of Jensen and Kroll.

7. Dependent Claim 6

929. Claim 5 of the '492 patent depends from claim 1 and additionally requires that "the at least one electrode includes an electrode gel and a conductive surface, thereby creating a half cell."

930. In my opinion, Jensen discloses the dependent limitation of claim 6 of the '492 patent.

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931. Jensen teaches that, on the side of the disposable assembly that contacts the patient's skin, electrode sensor pads 1, 2 are coated with a "conductive adhesive-gel that is made using a silver amalgam as found in off-the-shelf EKG sensor pads, such as those sold by 3M Corporation." Ex. 1011 at [0041]. A POSA would understand that EKG sensor pads are a conductive surface and that silver amalgam (which typically is silver/silver-chloride) and a conductive gel (electrode gel) containing an electrolyte comprise a "half cell." *See, e.g.*, Ex. 1003 at 7:3–5 ("In conventional terms of art, the combination of electrode and electrolyte and ECG electrode is typically referred to as a half cell."). Thus, in my opinion, Jensen discloses that "the at least one electrode includes an electrolyte gel and a conductive surface, thereby creating a half cell."

932. Because Jensen discloses the additional limitation of claim 6, and the combination of Jensen and Kroll renders obvious independent claim 1 from which claim 6 depends, *see* Section XVIII.B.2, *supra*, in my opinion, claim 6 of the '492 patent is obvious over the combination of Jensen and Kroll.

C. Ground 3: Obvious Over Jensen, Matsumura, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art

933. Additionally, in my opinion, claims 7, 8, and 11–14 of the '492 patent 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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1. A POSA had motivation to combine Jensen, Matsumura, and Kroll

934. For the reasons set forth above in Sections XVI.A.1 and XVII.A.1, with reference to the '007 patent, a POSA would have had motivation to combine the teachings of Jensen and Matsumura with Kroll, respectively, and would have had a reasonable expectation of success in doing so.

935. In addition, a POSA would have had motivation to combine the teachings of Jensen and Matsumura.

936. Jensen, Matsumura, and Kroll all teach wearable devices for monitoring physiological signals, including, for example, ECG (*i.e.*, EKG) signals. *See* Ex. 1011 at [0029]–[0030]; Ex. 1012 at [0024], [0031]; Ex. 1013 at 1:11–15, 1:37–45.

937. Maintaining hygiene and reducing cross contamination is important for medical devices that directly contact a patient's body. That is even more true for devices that are intended to be worn constantly such that they are in contact with a patient's body for a long period of time. A medical device that is fully disposable addresses this concern. However, a fully disposable medical device is not always feasible as when, for example, the device includes expensive electronic equipment. Indeed, as early as the 1980s—in the midst of the "plastics revolution"—hospitals and healthcare systems began to see the high costs of fully disposable medical devices as a concern. *See, e.g.*, Ex. 1059 (V.W. Greene, *Reuse of Disposable*

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Medical Devices: Historical and Current Aspects, 7 Infection Control & Hosp. Epidemiology 508 (1986)). For this reason (*i.e.*, the need to balance hygienic concerns with issues of cost), certain medical devices are designed to include both disposable and reusable parts.

938. The device taught by Jensen is one example of a device that balances this concern with both disposable and reusable components. Jensen's device comprises a disposable sensor assembly, which includes a peel-off cover and disposable sensor pad electrodes. Ex. 1011 at [0042], Fig. 5. The remainder 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.* at [0043].

939. In my opinion, a POSA would have known that reuse would require carefully cleaning each of these reusable components for hygienic purposes. But, as was known at the time of the purported invention of the '492 patent, "[e]ven with thorough cleaning, a risk of cross-contamination cannot be eliminated." *See, e.g.*, Ex. 1038 at 331. Given this perpetual concern, a POSA would have been motivated to seek out ways to make more parts of the device disposable while also isolating the reusable portions to limit the risk of contamination.

940. Matsumura teaches a specific way to achieve these goals. Like Jensen, Matsumura teaches a device comprising both reusable and disposable parts.

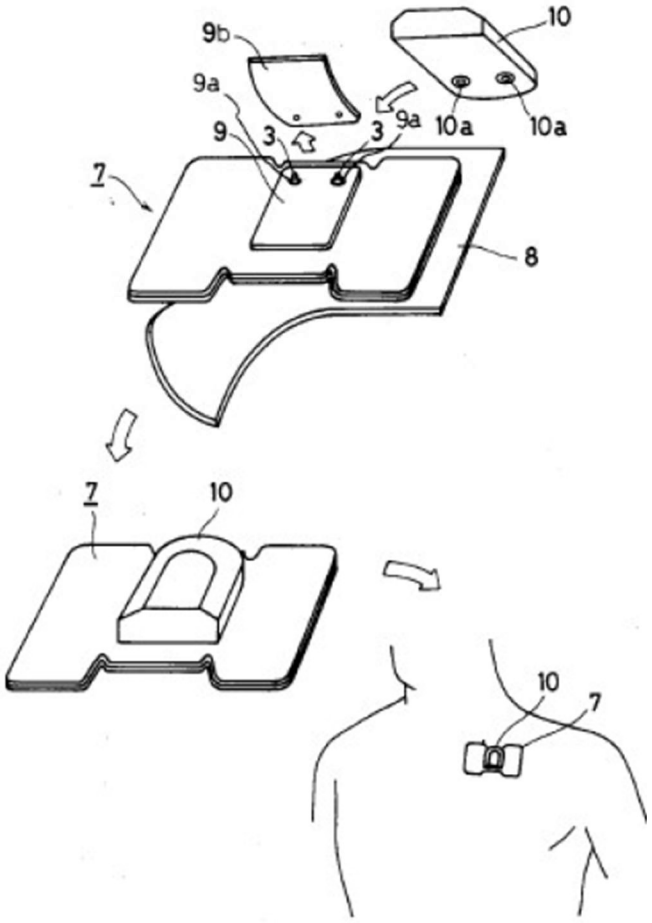
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However, Matsumura's design fully insulates the reusable portions from the patient's skin using multiple layers. Matsumura further encloses the reusable portion within a single housing. As Matsumura explains, "[t]he bioelectrode pad [7] is hygienic because it is disposable" and includes multiple sheets (first sheet 1, second sheet 4, and third sheet 3) that isolate the reusable part of the device from the patient while still maintaining an electrical connection between the disposable electrodes (conductive gels 5), which make contact with the patient's skin, and the reusable component, which does not. Ex. 1012 at [0016], Fig. 5.

941. Figure 2 of Matsumura (reproduced below) shows this isolation: only the disposable bioelectrode pad 7 touches the patient's skin. Reusable signal processor 11 is kept completely separated from the patient's skin by multiple sheets.

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[FIGURE 2]



Id. at Fig. 2.

942. A POSA seeking to use or make the device taught by Jensen would have looked to Matsumura and sought to modify Jensen similarly, to include a disposable layer that electrically connects the electrodes (Jensen's sensor pad electrodes 1, 2) to the circuitry in the reusable component (electronic circuitry 41 and coin cell 9), while still preserving the separation from the patient's skin.

943. A POSA would have also been motivated to modify Jensen with Matsumura's teaching of a waterproof structure. The device taught by Jensen is

"sealed on top" using an "o-ring" and several "aesthetic covers." In my opinion, a POSA would recognize that this sealing technique taught by Jensen is prone to seepage through the top, bottom, and slot in the smart patch through which the flexible circuit assembly extends. Apparently recognizing this risk, Jensen relies on a "sealant [that] is applied to the slot 80, once assembled." Ex. 1011 at [0045]. Jensen therefore acknowledges that, even after assembly, the device is not fully sealed.

944. Matsumura teaches an improved waterproofed structure that is completely sealed upon assembly and permits patients to wear the monitor both during and immediately after showering. Ex. 1012 at [0027], [0033]. Matsumura explains that there are multiple advantages of doing so, each of which, in my opinion, would have been familiar to a POSA.

945. Matsumura explains that from a clinical perspective, a continuously wearable monitor that a patient need not remove to shower or bathe provides the advantage of uninterrupted monitoring. *Id.* at [0002]. This waterproofed design thus permits monitoring during a shower or bath when a patient's "heart may be strained, resulting in tachycardia or arrhythmia." *Id.* 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." *Id.* Thus, incorporating Matsumura's waterproof

structure into Jensen would allow Jensen's smart patch to be worn continuously, including during or immediately after showering, conferring the attendant improvements in the scope of patient monitoring.

946. 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 and traces (conductive material 2), and interface with the reusable module (hooks 3) in a separate, disposable bioelectrode pad 7 that uses an insulating sheet to cover the electrodes and sensor contacts entirely. 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. *See id.* at [0015], [0019], [0027], [0041].

947. In my opinion, a POSA would have sought to modify Jensen similarly, to achieve the waterproof structure taught by Matsumura. In particular, a POSA seeking to make or use the device taught by Jensen, in view of Matsumura's disclosures, 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. Further, in my opinion, this modification would not be

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difficult to implement using well-known manufacturing techniques at the time of the invention.

948. It is also my opinion that a POSA would have had a reasonable expectation of success in modifying Jensen's device as described herein without undue experimentation. Both Jensen and Matsumura teach wearable, self-contained ECG monitors for patient applications. Further, both Jensen and Matsumura have similar disposable and reusable component breakdown: disposable parts include the electrodes used to detect ECG signals, and reusable parts include a processor and a wireless transmitter. *Compare id.* at Fig. 1, *with* Ex. 1011 at Fig. 5.

949. 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 at [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.

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2. Independent Claim 7

950. In my opinion, claim 7 of the ’492 patent is rendered obvious by Jensen in view of Matsumura and Kroll.

i. Limitation 7[pre]

951. The preamble of claim 7 recites “[a] body-worn patient monitoring device comprising.”

952. In my opinion, to the extent the preamble is limiting, each of Jensen, Matsumura, and Kroll discloses the preamble of claim 1 of the ’492 patent.

953. Jensen discloses a body-worn patient monitoring device. *See id.* at [0012], [0014], [0029]. Matsumura also discloses a body-worn patient monitoring device, which it refers to as a “bioelectric potential detector.” *See* Ex. 1012 at Abstract, [0006], [0007], [0014]. Kroll also discloses a body-worn patient monitoring device. *See* Ex. 1013 at 1:11–15.

954. Thus, in my opinion, the combination of Jensen, Matsumura, and Kroll discloses “[a] body-worn patient monitoring device.”

ii. Limitation [7a]

955. Limitation [7a] recites “a disposable electrode portion.”

956. In my opinion, Jensen discloses limitation [7a] of the ’492 patent.

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957. Jensen discloses "[electrode] sensor pads 1 and 2" (the electrode portion). Ex. 1011 at [0041]. Jensen further teaches that the electrode sensor pads 1 and 2 are part of the "disposable sensor assembly 73." *Id* at [0042].

958. Thus, in my opinion, the combination of Jensen, Matsumura, and Kroll discloses "a disposable electrode portion."

iii. Limitation [7b]

959. Limitation [7b] recites "a reusable communication module."

960. In my opinion, Jensen discloses limitation [7b] of the '492 patent.

961. Jensen teaches a "re-usable (non-disposable) portion" of its body-worn patient monitoring device. *Id.* at [0043]. Jensen further discloses a radio frequency transmitter (*i.e.*, a "communication module") that "may transmit in a variety of modulation and/or keying methods via antenna 8." *Id.* at [0032]. In my opinion, a POSA would understand that the transmitter 7 is located on the re-usable (non-disposable) portion of Jensen.

962. Thus, in my opinion, the combination of Jensen, Matsumura, and Kroll discloses "a reusable communication module."

iv. Limitation [7c]

963. Limitation [7c] recites "the disposable electrode portion comprising a flexible printed circuit layer made from an insulating material and defining a substrate."

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964. In my opinion, the combination of Jensen and Matsumura, in view of the knowledge of a POSA, discloses limitation [7c] of the '492 patent.

965. As discussed above with reference to claim 1, Section XVIII.B.2.ii, Jensen teaches a flexible printed circuit layer made from an insulating material and defining a substrate.

966. Moreover, and as set forth in section XVIII.C.1, above, it is my opinion that a POSA would have looked to isolate and waterproof the reusable portions of Jensen (*i.e.*, electronics circuit 41 and battery 9) from the patient's skin, as taught by Matsumura. 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. 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; electronics circuity 41 (including the microcontroller and wireless transmitter) would be kept in Jensen's reusable portion. This is the same configuration that is taught in Matsumura: Matsumura's signal processor 10 (including microprocessor and wireless transmitter) are in the reusable portion while hook 3 (electrical traces), conductive material 2 (sensor contacts) are in the flexible, disposable bioelectrode pad 7. Ex. 1012 at [0015], [0019].

967. In my opinion, a POSA would have understood this modification to Jensen as beneficial in at least two respects. *First*, it would improve the efficiency

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of the cleaning process and the safety of the medical device by making more parts of the device disposable and, simultaneously, further isolating the reusable components to limit contamination risk. *Second*, it would afford Jensen's smart patch a waterproof structure that would allow said smart patch to be worn continuously, including during or immediately after showering.

968. In my opinion, and 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, already known in the art to be disposable. For example, other printed references available at the time of the purported invention of the '492 patent already taught electrical traces and sensor contacts that are part of a disposable assembly. *See, e.g.*, Ex. 1014 at [0048] (disposable bio-sensor module includes "electrodes 80 are located on a lower surface 85 of the flexible substrate 55 and are connected through the flexible substrate 55 to the metallization 77"); Ex. 1023 at [0035] (disposable ECG patch includes "flexible circuit substrate 20 with trace extensions to the electrodes 21, 22, 23").

969. Thus, in my opinion, the combination of Jensen, Matsumura, and Kroll discloses "the disposable electrode portion comprising a flexible printed circuit layer made from an insulating material and defining a substrate."

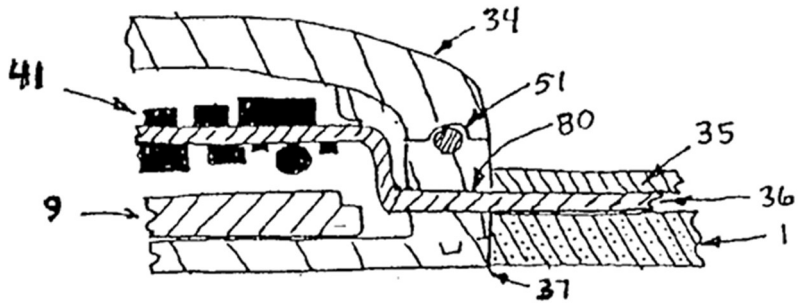
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v. Limitation [7d]

970. Limitation [7d] recites "at least two electrodes being disposed onto a surface of the substrate."

971. In my opinion, Jensen discloses limitation [7d] of the '492 patent.

972. Jensen discloses "[a] disposable sensor assembly," which includes "disposable sensor pad electrodes 1 and 2." Ex. 1011 at [0041]–[0042]. The sensor pad electrodes are disposed on the lower surface of flexible assembly 36, as shown in Figure 7, reproduced below.



Id. at Fig. 7.

973. Thus, in my opinion, the combination of Jensen, Matsumura, and Kroll discloses "at least two electrodes being disposed onto a surface of the substrate."

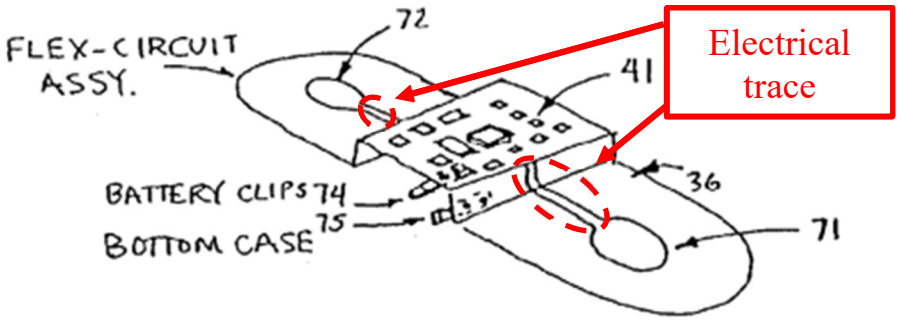
vi. Limitation [7e]

974. Limitation [7e] recites "electrical traces defined between the at least two electrodes and a connection pad."

975. In my opinion, Jensen discloses limitation [7e] of the '492 patent.

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976. Jensen disclose 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. *Id.* at [0040]–[0041]. In my opinion, a POSA reading Jensen's disclosure would understand that the connection that is created by the Jensen's traces extends from the electrode sensor pads 1, 2 to a connection pad 48, as demonstrated in the annotated version of Jensen's Figure 5 below. *Id.* at [0040]. *See also* Section XVIII.B.2.iv–v.



Id. at Fig. 5 (annotated).

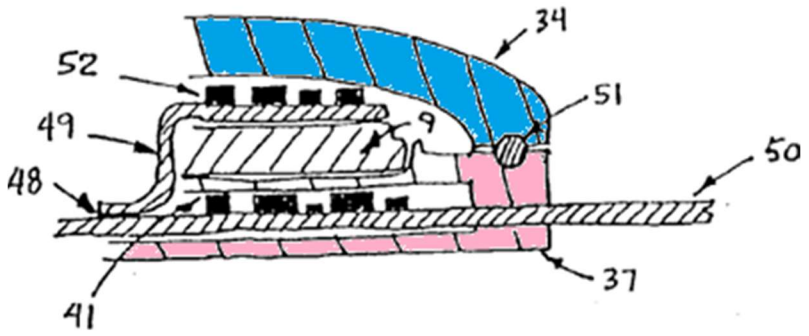
977. Thus, in my opinion, a POSA would understand that the combination of Jensen, Matsumura, and Kroll discloses "electrical traces defined between the at least two electrodes and a connection pad."

vii. Limitation [7f]

978. Limitation [7f] recites "wherein the reusable communication and computation module comprises a housing containing a processor and a wireless communication unit."

979. In my opinion, Jensen discloses limitation [7f] of the '492 patent.

980. Jensen discloses a "transmitter" for communication (*i.e.*, a communication module) and a "microcontroller" for computation (*i.e.*, a computation module). *Id.* at [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.* at [0033]. The transmitter and microcontroller are encased, that is housed, by a top casing 34 and a bottom casing 37. *Id.* at [0043]. The encasing is depicted in the annotated version of Jensen's Figure 8 reproduced below, wherein the top casing 34 is shown in blue and the bottom casing 37 is shown in red.



Id. at Fig. 8 (annotated).

981. Thus, in my opinion, the combination of Jensen, Matsumura, and Kroll discloses that "the reusable communication and computation module comprises a housing containing a processor and a wireless communication unit."

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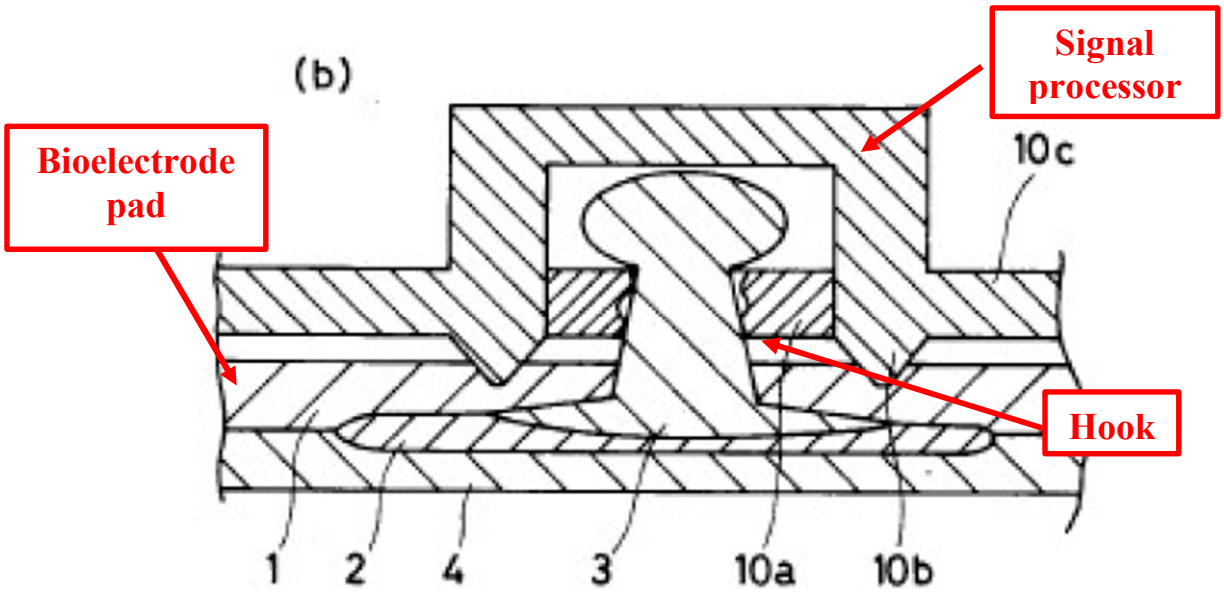
viii. Limitation [7g]

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

983. For the reasons set forth in Sections XVIII.C.2.i–vii, in my opinion, the combination of Jensen and Matsumura discloses limitations 7[pre]–[7f] of the '492 patent.

984. In my opinion, the combination of Jensen and Matsumura also renders obvious limitation [7g] of the '492 patent.

985. As noted above, *see* sections XVIII.C.2.iii–v, Jensen discloses a reusable communication-computation module and a disposable sensor assembly including disposable sensor pad electrodes. Matsumura similarly discloses a "reusable signal processor 10" with a wireless transmitter and a "disposable bioelectrode pad 7" with "conductive gel 5" (electrode portion). Ex. 1012 at [0016]; *see also id.* at [0008], [0014], Figs. 1–2. "The bioelectrode pad 7 and the signal processor 10 are detachable with hooks." *Id.* at [0016]. This is depicted in Figure 4(b) of Matsumura, which is reproduced below.



Id. at Fig. 4(b) (annotated).

986. Both latches and snaps were commonly known and used in the art at the time. *See, e.g.*, Ex. 1003 at 9:27–39; *see also* Section IV.D, *supra*. A POSA would have understood a snap mechanism and a latch mechanism to be interchangeable for the purpose of attaching two components of a medical device such as a body-worn monitor. *See, e.g.*, Ex. 1039 at [0046], Fig. 5 (discussing use of snap connectors to attach a monitoring device to 12-lead recorders); Ex. 1040 at 30 ("Labeling" (providing instructions for use of a body-worn glucose monitoring device which uses a latch to attach the STS Transmitter and the STS Sensor Pod, two components of the device)).

987. Thus, a POSA reading the disclosure of the '492 patent would understand the '492 patent to use the term "latch clip" or "latching clip" interchangeably with the term "snap on." Snap mechanisms were commonly used

in the art to attach two components of a medical device such as a body worn monitor. *See Id*.

988. Therefore, in my opinion, the combination of Jensen, Matsumura, and Kroll renders obvious that "the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip."

989. For all the reasons discussed in this Section as well as in Section XVIII.B.2 above, it is my opinion that the combination of Jensen, Matsumura, and Kroll renders obvious claim 7 of the '492 patent.

3. Dependent Claim 8

990. Claim 8 of the '492 patent depends from claim 7 and additionally requires that "the electrodes are integrated into the flexible printed circuit layer of the disposable portion of the device."

991. In my opinion, claim 8 of the '492 patent is rendered obvious by Jensen in combination with Matsumura and Kroll for all the reasons discussed above with respect to claim 7 as well as because Jensen and Matsumura teach the additional limitation of claim 8. *See* Section XVIII.C.2, *supra.*

992. Jensen discloses "disposable sensor pad electrodes 1 and 2." Ex. 1011 at [0041], Fig. 5. As explained above, *see* Section XVIII.C.1, it would have been obvious to a POSA to modify Jensen in view of Matsumura's teachings so that

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portions of the flexible printed circuit layer would be part of the disposable sensor assembly of Jensen.

993. For these reasons, it is my opinion that a POSA would understand that Jensen and Matsumura together disclose that "the electrodes are integrated into the flexible printed circuit layer of the disposable portion of the device" and, therefore, that the combination of Jensen, Matsumura, and Kroll renders obvious claim 8 of the '492 patent.

4. Dependent Claim 11

994. Claim 11 of the '492 patent depends from claim 7 and additionally requires that "the electrical traces are screened onto the flexible printed circuit layer."

995. In my opinion, claim 11 of the '492 patent is rendered obvious by Jensen in combination with Matsumura and Kroll for all the reasons discussed above with respect to claim 7 as well as because Jensen and Kroll teach the additional limitation of claim 11. *See* Section XVIII.C.2, *supra.*

996. As noted previously herein, *see* Section XVIII.C.2.vi *supra*, 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 at [0040]; *see also id.* at [0041].

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997. Kroll teaches the use of a printed ink comprised of a material with a given resistance. Ex. 1013 at 5:8–12. A POSA would understand that printing ink onto a circuit board would be a form of screening. *See, e.g.*, Ex. 1035 at 296 ("Printing Process. The circuit patterns are screen printed on the substrate by two ways: (1) Manual screen printing process, and (2) Automatic or semi-automatic screen printing process.").

998. Thus, in my opinion, a POSA would understand that Kroll's ink traces on a flexible printed circuit layer of Jensen would yield electrical traces that are screened.

999. For these reasons, it is my opinion that a POSA would understand that the combination of Jensen and Kroll discloses that "the electrical traces are screened onto the flexible printed circuit layer" and, therefore, that the combination of Jensen, Matsumura, and Kroll renders obvious claim 11 of the '492 patent.

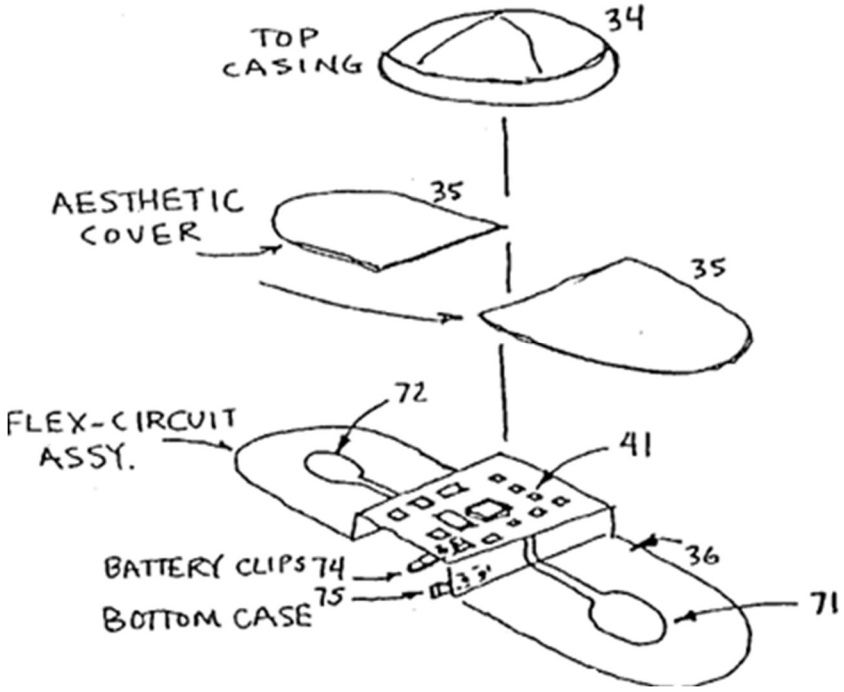
5. Dependent Claim 12

1000. Claim 12 of the '492 patent depends from claims 7 and 11 and additionally requires "an insulating layer applied onto the electrical traces."

1001. In my opinion, claim 12 of the '492 patent is rendered obvious by Jensen, Matsumura, and Kroll for all the reasons discussed above with respect to claims 7 and 11 as well as because Jensen teaches the additional limitation of claim 12. *See* Section XVIII.C.4, *supra.*

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1002. Jensen discloses an insulating layer covering the flexible printed circuit later. Specifically, Jensen discloses that the entire top side of flexible circuit assembly 36 is "enclose[d]" and "sealed" by top casing 34 and aesthetic cover 35, as shown in the excerpt of Jensen's figure 5 below. Ex. 1011 at [0043].



Id. at Fig. 5.

1003. The flexible printed circuit layer of Jensen also discloses electrical traces. *See* Section XVIII.C.2.vi, *supra*. Thus, it is my opinion that a POSA would understand aesthetic covers 35 and/or top casing 34 of Jensen to comprise an insulating layer for the electrical traces of flexible circuit 36.

1004. For these reasons, it is my opinion that a POSA would understand that Jensen discloses "an insulating layer applied onto the electrical traces" and,

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therefore, that the combination of Jensen, Matsumura, and Kroll renders obvious claim 12 of the ’492 patent.

6. Dependent Claim 13

1005. Claim 13 of the ’492 patent depends from claims 7, 11, and 12 and additionally requires that “the insulating layer is screen printed onto the electrical traces of the flexible printed circuit layer.”

1006. In my opinion, claim 13 of the ’492 patent is rendered obvious by Jensen, Matsumura, and Kroll for all the reasons discussed above with respect to claims 7, 11, and 12 as well as because Jensen teaches the additional limitation of claim 13. *See* Section XVIII.C.5, *supra.*

1007. In my opinion, 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” because screen printing an insulating layer was a well-known and common method of manufacturing a printed circuit board. Ex. 1035 at 352 (noting that one of the functions served by a solder mask is “[a]ct[ing] as an insulating barrier between closely placed tracks”). Further, a POSA would have understood that insulating layers such as solder mask (*i.e.*, solder resist) were commonly applied using either screen printing or photoprinting. *Id.* at 353.

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1008. For these reasons, it is my opinion that a POSA would understand that Jensen discloses that "the insulating layer is screen printed onto the electrical traces of the flexible printed circuit layer" and, therefore, that the combination of Jensen, Matsumura, and Kroll renders obvious claim 13 of the '492 patent.

7. Dependent Claim 14

1009. Claim 14 of the '492 patent depends from claim 7 and additionally requires that "each electrode includes an electrode gel and a conductive surface defining a half cell."

1010. In my opinion, claim 14 of the '492 patent is rendered obvious by Jensen, Matsumura, and Kroll for all the reasons discussed above with respect to claim 7 as well as because Jensen teaches the additional limitation of claim 14. *See* Section XVIII.C.2, *supra.*

1011. 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 at [0041]. A POSA would understand that EKG sensor pads (conductive surface) comprising a silver amalgam (usually silver-silver chloride) and a conductive adhesive gel (electrode gel) containing an electrolyte comprise a create "half cell." *See, e.g.*, Ex. 1003 at 7:3–5 ("In conventional terms of art, the

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combination of electrode and electrolyte and ECG electrode is typically referred to as a half cell.").

1012. For these reasons, it is my opinion that a POSA would understand that Jensen discloses that "each electrode includes an electrode gel and a conductive surface defining a half cell" and, therefore, that the combination of Jensen, Matsumura, and Kroll renders obvious claim 14 of the '492 patent.

XIX. THE CHALLENGED CLAIMS OF THE '484 PATENT ARE UNPATENTABLE

1013. In my opinion, claims 1–5 and 15–20 of the '484 patent are obvious under pre-AIA § 103 over Matsumura and general knowledge of a POSA.

1014. Additionally, and alternatively, in my opinion, claims 1–5, 15, 17, 18 and 20 of the '484 patent are obvious under pre-AIA § 103 over Jensen and the general knowledge of a POSA.

1015. Additionally, and alternatively, in my opinion, claims 1–8, 15, 19, and 20 of the '484 patent are obvious under pre-AIA § 103 over Ozguz and the general knowledge of a POSA.

1016. Additionally, and alternatively, claims 6–8, 11, and 12 of the '484 patent are obvious under pre-AIA § 103 over Matsumura in combination with Ozguz and the general knowledge of a POSA.

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A. Ground 1: Obvious Over Matsumura and General Knowledge of a POSA

1. Independent Claim 1

1017. In my opinion, claim 1 of the ’484 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA.

i. Preamble 1[pre]

1018. The preamble of claim 1 recites “a body-worn physiological sensor comprising.”

1019. In my opinion, to the extent the preamble is limiting, Matsumura discloses the preamble of claim 1 of the ’484 patent.

1020. Matsumura discloses a body-worn physiological sensor, which it calls a “bioelectric potential detector.” Ex. 1012 at Abstract, [0006], [0014]. The detector is worn on the body and can sense physiological signals such as electrocardiogram (ECG/EKG) signals. *Id.* at [0024], Figs. 2, 6.

1021. Thus, in my opinion, Matsumura discloses “a body-worn physiological sensor.”

ii. Limitation [1a]

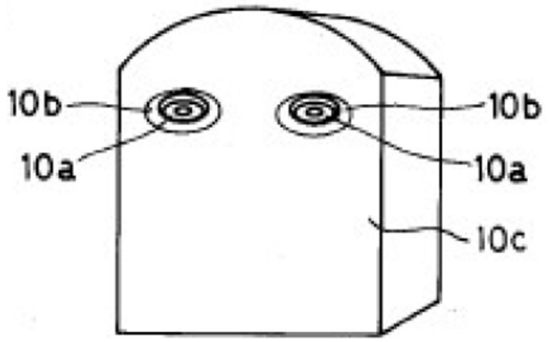
1022. Limitation [1a] recites “a computation-communication module including a housing retaining a processor.”

1023. In my opinion, Matsumura discloses limitation [1a] of the ’484 patent.

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1024. Matsumura discloses a "reusable signal processor 10," which is a module. *Id.* at [0016]; *see also id.* at [0008], [0014], [0025], Figs. 1–2. Matsumura's reusable "signal processor 10" incorporates components for computation: a "processing circuit for filtering and amplifying detected bioelectric potential signals" and "a memory for storing the processed bioelectric potential signal." *Id.* at [0025]. The reusable signal processor also incorporates components for communication: "a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna." *Id.* Accordingly, Matsumura discloses a computation-communication module.

1025. Matsumura's computation-communication module (*i.e.*, "reusable signal processor 10") that includes the "processing circuit" and "loop antenna" is enclosed in housing 10c, as depicted in Figure 4(a) (reproduced below). *Id.* at [0016], [0025], [0027], [0029], Fig. 4(a). Indeed, retaining "processing circuit" and "loop antenna" in housing 10c ensures that Matsumura's device is waterproof. *Id.*



Id. at Fig. 4(a).

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1026. Thus, in my opinion, Matsumura discloses "a computation-communication module including a housing retaining a processor."

iii. Limitation [1b]

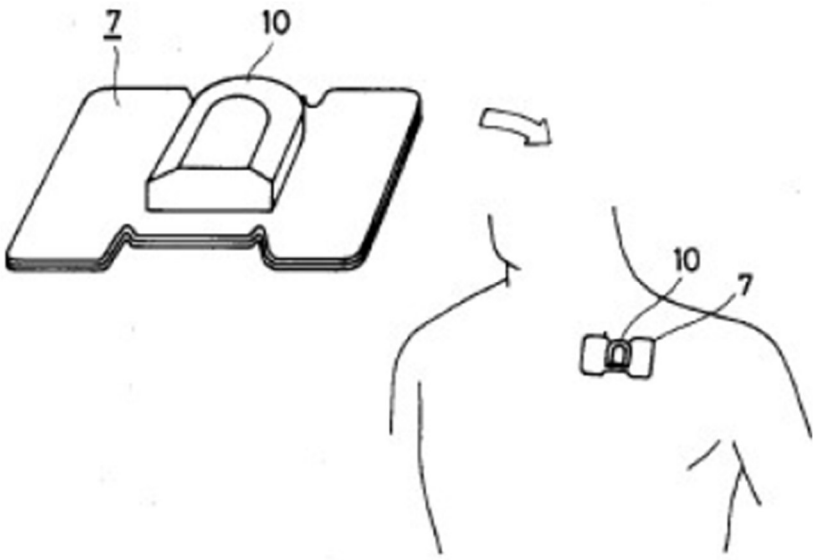
1027. Limitation [1b] recites "a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals."

1028. In my opinion, Matsumura discloses limitation [1b] of the '484 patent.

1029. . The "bioelectric potential detector 11" includes "bioelectrode pad 7" composed of first and second sheets 1, 4, "made of insulating material," such as "polyethylene foam, polyurethane foam, or polyurethane sheet." *Id.* at [0017], [0018], [0024]. In my opinion, a POSA would recognize that each of those materials—polyethylene foam, polyurethane foam, or polyurethane sheet—are flexible polymers. *See, e.g.*, Ex. 1047 at 23.11; Ex. 1056 at 2. Thus, Matsumura's bioelectrode pad is a flexible circuit layer because it includes conductive material 2 which forms an electrical connection between the computation-communication module and conductive gel 5 which contacts the patient's skin.

1030. In order to measure physiological signals such as electrocardiogram, Matsumura's bioelectrode pad 7 is coupled to the skin surface of a subject, as is depicted in Figure 2 (reproduced below).

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Ex. 1012 at Fig. 2. Matsumura also teaches that "[t]he bioelectric potential detector 11 can be used as an electrocardiogram detector that is worn on the subject's chest to detect electrocardiogram signals." *Id.* at [0024]

1031. Thus, in my opinion, a POSA would recognize that Matsumura discloses "a flexible circuit layer configured to be coupled to a skin surface to measure physiological signals."

iv. Limitation [1c]

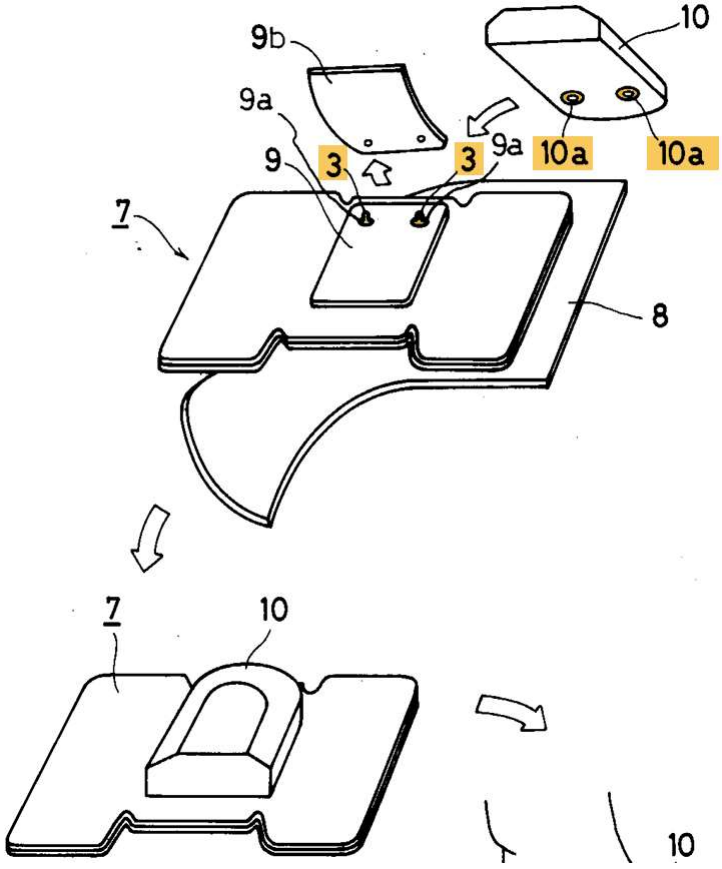
1032. Limitation [1c] recites "said computation-communication module being attached to the flexible circuit layer."

1033. In my opinion, Matsumura discloses limitation [1c] of the '484 patent.

1034. Matsumura discloses that bioelectrode pad 7 (flexible circuit layer) and the signal processor 10 (computation-communication module) are attached with "hooks." *Id.* at [0016]. Specifically, Matsumura's disposable bioelectrode pad

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includes "two hooks 3" that connect to "hook engagement portion 10a on the bottom surface of the signal processor" in order to attach the computation-communication module to the flexible circuit layer, as shown in the annotated version of Matsumura's Figure 2 below. *Id.* at [0019], [0024], Fig. 2.



Id. at Fig. 2 (annotated).

1035. Thus, in my opinion, Matsumura discloses "said computation-communication module being attached to the flexible circuit layer."

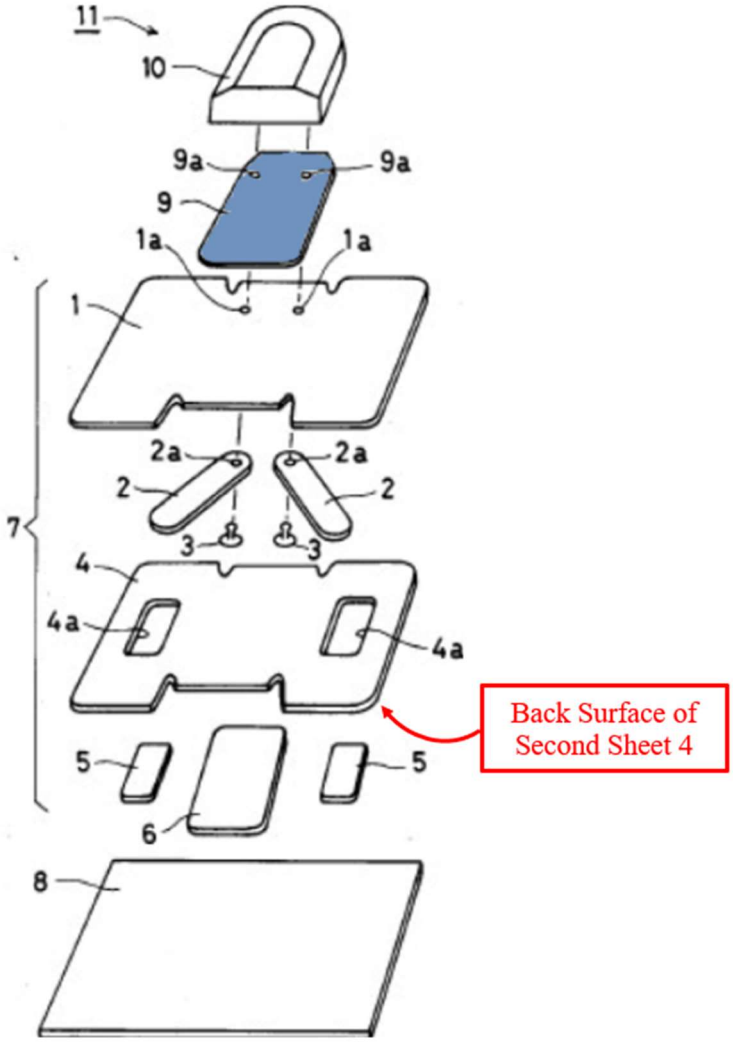
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v. Limitation [1d]

1036. Limitation [1d] recites "an adhesive covering at least a portion of the flexible circuit layer."

1037. In my opinion, Matsumura discloses limitation [1d] of the '484 patent.

1038. Matsumura teaches that "[t]he bioelectrode pad 7 is provided with a double-sided adhesive tape 9 with, for example, acrylic adhesive coated on both sides of the nonwoven fabric at the center of the surface of the first sheet 1." *Id.* at [0023]. As shown below, the adhesive tape (*i.e.*, a first "adhesive covering"; shown in blue) covers at least a portion of first sheet 1 of the bioelectrode pad 7 (*i.e.*, the "flexible circuit layer").



Id. at Fig. 1 (annotated).

1039. Additionally, or alternatively, Matsumura's bioelectrode pad 7 also includes second sheet 4, whose back surface is covered with an "adhesive, such as acrylic adhesive" (*i.e.*, a second "adhesive covering"). *Id.* at [0018]. This second "adhesive covering" therefore also covers "portion[s] of the flexible circuit layer."

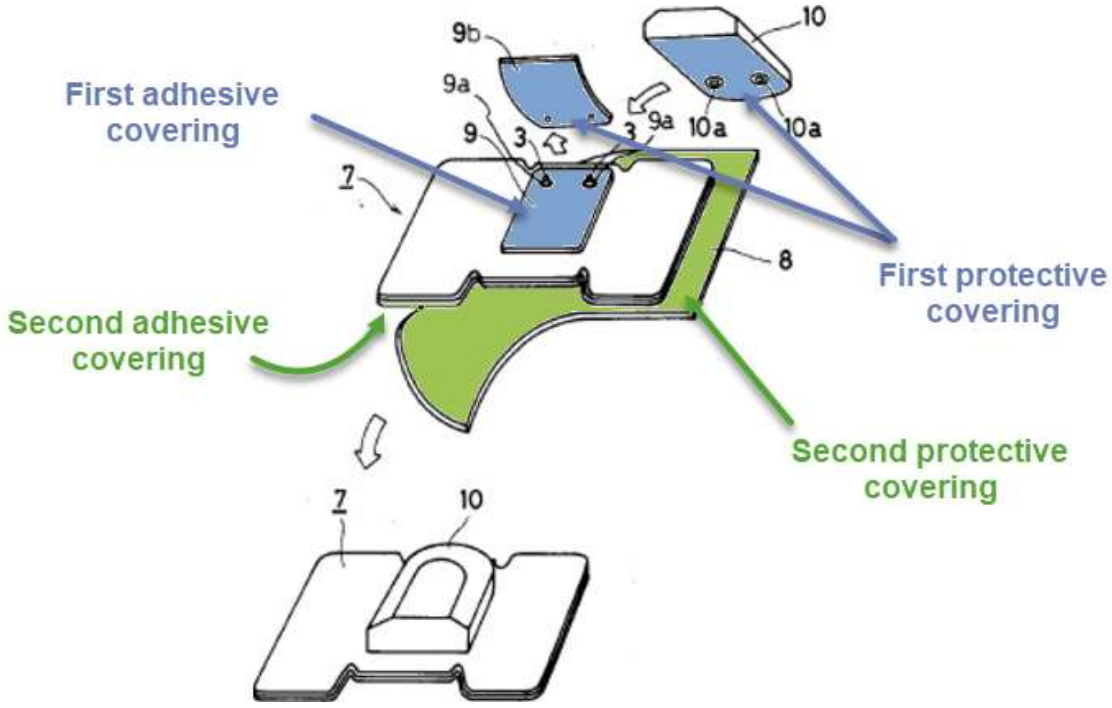
1040. Thus, in my opinion, Matsumura discloses "an adhesive covering at least a portion of the flexible circuit layer."

vi. Limitation [1e]

1041. Limitation [1e] recites "a protective covering that protects the adhesive."

1042. In my opinion, Matsumura discloses limitation [1e] of the '484 patent.

1043. Matsumura discloses that adhesive tape 9 (first "adhesive covering"; *see* Section XIX.A.1.v, *supra*) is attached to and covered by bottom surface of the housing of signal processor 10 (first "protective covering"). Ex. 1012 at [0024]. Additionally, or alternatively, adhesive tape (first "adhesive covering") is covered by "release sheet 9b" (first "protective covering") that is "peeled off from the adhesive tape 9" prior to signal processor 10 being hooked and attached to bioelectrode pad 7. *Id.*



Id. at Fig. 2 (annotated with blue to show "[f]irst "protective covering[s] and "[f]irst adhesive covering").

1044. Additionally, and alternatively, and as illustrated in green in the preceding image, Matsumura also discloses a "release tape 8 . . . attached to the back surface of the bioelectrode pad 7 [the "flexible circuit layer"]." *Id.* at [0024]. This release tape 8 is a second "protective covering" that covers portions of the adhesive on the back surface of the second sheet 4 (second "adhesive covering") and is "peeled off from the bioelectrode pad 7" when attaching the bioelectric potential detector to the body. *Id.*; *see also id.* at Fig. 2 (annotated version *supra*, preceding paragraph).

1045. Thus, in my opinion, Matsumura discloses "a protective covering that protects the adhesive."

2. Dependent Claim 2

1046. Claim 2 of the '484 patent depends from claim 1 and additionally requires that "the flexible circuit layer has traces of determinable electrical resistance."

1047. In my opinion, claim 2 of the '484 patent is obvious over Matsumura in view of a POSA's general knowledge for all the reasons discussed above with respect to claim 1 as well as because a POSA would understand Matsumura to disclose the additional limitation of claim 2. *See* Section XIX.A.1, *supra*.

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1048. Matsumura discloses that a "hook 3" electrically connects a first portion of "conductive material 2" to "engagement portion[s] 10a" of signal processor 10. Ex. 1012 at [0019], [0024]; *see also id.* at Fig. 1. A second portion of "conductive material 2" directly contacts "conductive gel[s] 5" (electrodes) and transmits the detected bioelectrical potential through the first portion of "conductive material 2" to signal processor 10. *Id.* at [0019], Fig. 1. Accordingly, in my opinion, a POSA would have understood hook 3 and a first portion of conductive material to be a "trace" because they are conductors on a printed circuit board. *Cf.* Ex. 1035 at 129 (using "trace" and "conductor" interchangeably).

1049. Matsumura further teaches that "conductive material 2" "can be a carbon sheet or a PET sheet coated with conductive Ag/AgCl"; "hook 3 may also be made of a stainless-steel stud, carbon stud, or Ag/AgCl." Ex. 1012 at [0020]–[0021]. Accordingly, a POSA would have understood that hook 3 and a first portion of conductive material 2, and the materials taught by Matsumura, have a determinable electrical resistance. Indeed, **every** substance has a determinable electrical resistance—it is a physical property. *See, e.g.*, Ex. 1060 (Robert A. Millikan & E.S. Bishop, *Elements of Electricity* (1917)) at 53 ("Electrical Resistance. . . . [E]very particular substance has its own characteristic power of transmitting electrical currents").

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1050. For these reasons, it is my opinion that a POSA would understand that Matsumura discloses that "the flexible circuit layer has traces of determinable electrical resistance" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 2 of the '484 patent.

3. Dependent Claim 3

1051. Claim 3 of the '484 patent depends from claims 1 and 2 and additionally requires that "the traces on the flexible circuit layer are configured to electrically couple the computation-communication module to the flexible circuit layer, thereby forming a disposable module connector."

1052. In my opinion, claim 3 of the '484 patent is rendered obvious by Matsumura in view of the knowledge of a POSA for all the reasons discussed above with respect to claims 1 and 2 as well as because Matsumura discloses the additional limitation of claim 3. *See* Section XIX.A.2, *supra*.

1053. As noted above, *supra* Section XIX.A.1.iv, Matsumura discloses traces on the flexible circuit layer. Matsumura's disposable bioelectrode pad 7 (*i.e.*, the "flexible circuit layer") includes "two hooks 3" that electrically couple or connect to "hook engagement portion 10a on the bottom surface of the signal processor" (*i.e.*, the "communication-computation module). Ex. 1012 at [0019], [0024], Fig. 2. Once received from the electrodes, "the bioelectric potentials detected . . . are transmitted through the conductive material 2 and the hooks 3." *Id.* at [0019].

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Accordingly, Matsumura discloses that hook 3 and a first portion of conductive material 2 (traces) are configured to electrically couple the signal processor 10 (computation-communication module) to bioelectrode pad 7 (flexible circuit layer), thereby forming a disposable module connector (hook 3 located on disposable bioelectrode pad 7).

1054. For these reasons, it is my opinion that Matsumura discloses that "the traces on the flexible circuit later are configured to electrically couple the computation-communication module to the flexible circuit layer, thereby forming a disposable module connector" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 3 of the '484 patent.

4. Dependent Claim 4

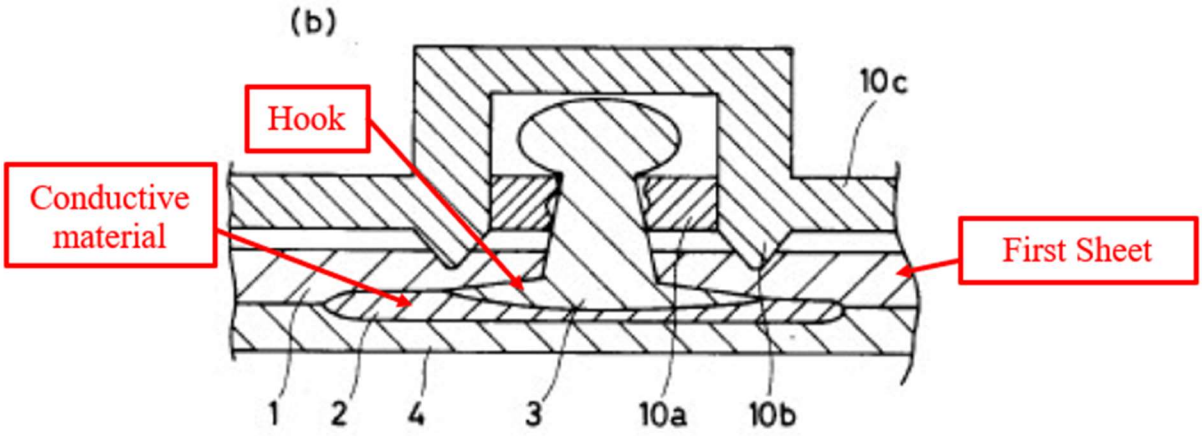
1055. Claim 4 of the '484 patent depends from claim 1 and additionally requires that "the traces on the flexible circuit layer are at least partially covered by a non-removable insulating covering."

1056. In my opinion claim 4 of the '484 patent is rendered obvious by Matsumura in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because Matsumura discloses the additional limitation of claim 4. *See* Section XIX.A.1, *supra*.

1057. Matsumura discloses a first sheet 1 that covers hook 3 and a first portion conductive material 2. Ex. 1012 at [0019]. "[F]irst sheet 1 should be made of an

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insulating material that does not allow moisture to penetrate, for example, polyethylene foam, polyurethane foam, or polyurethane sheet is preferred." *Id* at [0017]. An example of this is shown in Figure 4(b) of Matsumura (reproduced below) with bottom portion of hook 3 being covered by first sheet 1, and top portion of conductive material 2 being is covered by first sheet 1.



Id. at Fig. 4(b) (annotated).

1058. For these reasons, it is my opinion that Matsumura discloses that "the traces on the flexible circuit layer are at least partially covered by a non-removable insulating covering" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 4 of the '484 patent.

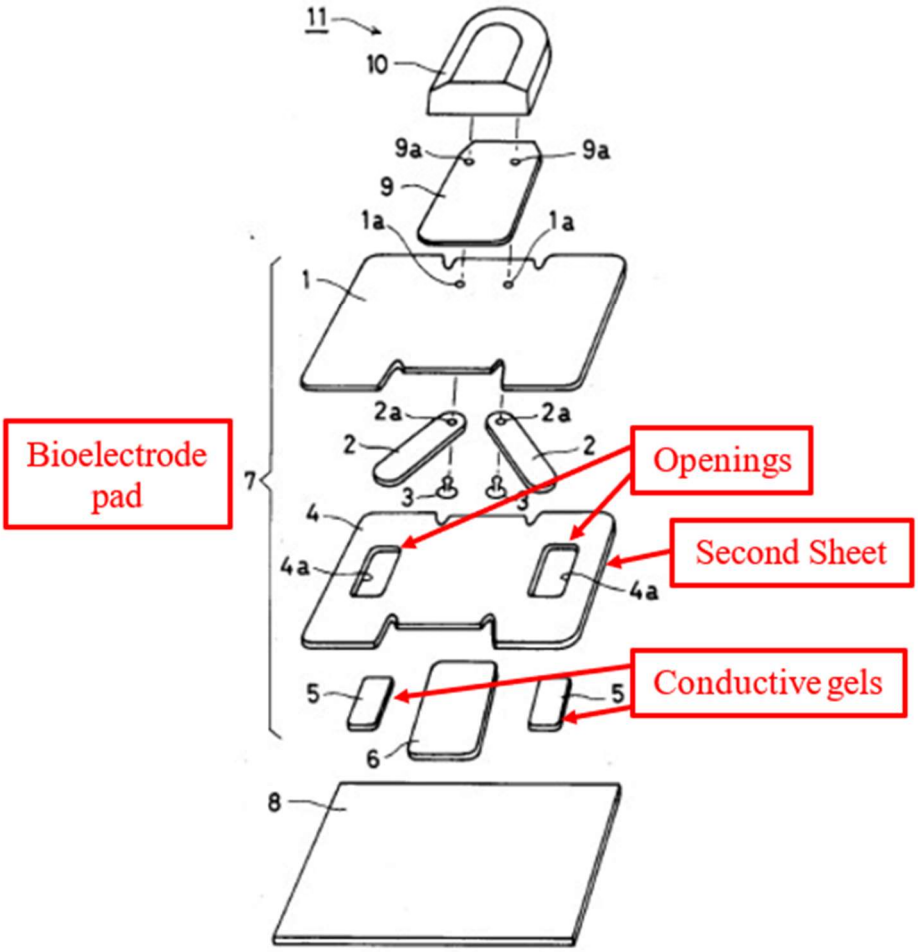
5. Dependent Claim 5

1059. Claim 5 of the '484 patent depends from claim 1 and additionally requires that "the flexible circuit layer further comprises a plurality of openings sized to receive electrode gels."

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1060. In my opinion claim 5 of the '484 patent is rendered obvious by Matsumura in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because Matsumura discloses the additional limitation of claim 5. *See* Section XIX.A.1, *supra*.

1061. Matsumura discloses that "second sheet 4" of bioelectrode pad 7 "is provided with two openings 4a on the left and right sides into which the conductive [*i.e.*, electrode] gel 5 is inserted." Ex. 1012 at [0018]. As shown in Figure 1 (reproduced below), openings 4a are sized to receive conductive gels 5.



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Id. at Fig. 1 (annotated).

1062. For these reasons, it is my opinion that a POSA would understand that Matsumura discloses that "the flexible circuit layer further comprises a plurality of openings sized to receive electrode gels" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 5 of the '484 patent.

6. Independent Claim 15

1063. In my opinion, claim 15 of the '484 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA.

i. Preamble 15[pre]

1064. The preamble of claim 15 recites "a body-worn physiological sensor."

1065. As described with respect to claim 1, to the extent that the preamble is limiting, it is my opinion that Matsumura discloses "a body-worn physiological sensor." *See* Section XIX.A.1.i, *supra*.

ii. Limitation [15a]

1066. Limitation [15a] recites "a computation-communication module including a housing retaining a processor."

1067. As explained with respect to claim 1, it is my opinion that Matsumura discloses "a computation-communication module including a housing retaining a processor." *See* Section XIX.A.1.ii, *supra*.

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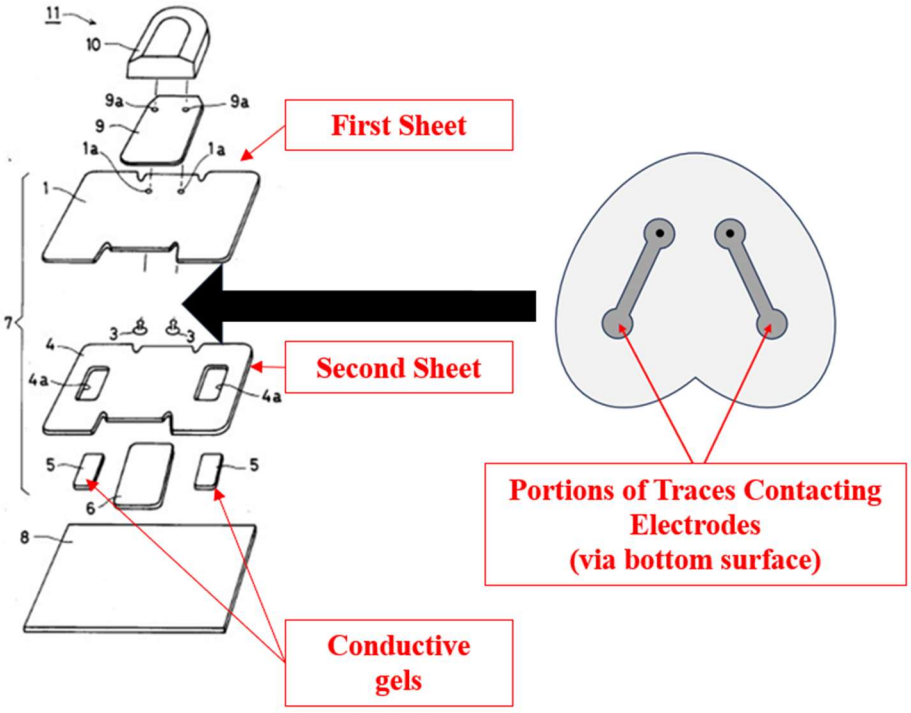
iii. Limitation [15b]

1068. Limitation [15b] recites "a flexible printed circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals."

1069. As described with respect to Claim 1, in my opinion, Matsumura discloses a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals. *See* Section XIX.A.1.iii, *supra*. The circuit layer of Matsumura comprises "two pieces of conductive material 2," which "can be a carbon sheet or a PET sheet [which are insulating materials] coated with conductive Ag/AgCl." Ex. 1012 at [0019]–[0020], Fig. 1. It would have been obvious to a POSA how to form this flexible circuit layer as a flexible "printed circuit" layer.

1070. Specifically, in my opinion, 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 containing printed-ink conductive traces as shown below.

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Id. at Fig. 1 (modified). A POSA would have been motivated to do so because this modification would simplify the manufacture and assembly of the wearable device. The method disclosed by Matsumura would require cutting two separate pieces of insulating material and coating each of those two pieces in their entirety, requiring a significant amount of expensive conductive ink to do so. The proposed modification, however, would require cutting only one piece of insulating material and would require coating only specific portions of the insulating material with the conductive ink, as shown above, thereby reducing the cost of manufacturing. .

1071. In my opinion this would be a routine design choice that would improve, at minimum, efficiency of manufacture and assembly. Matsumura already

discloses silver/silver chloride (Ag/AgCl) conductive material, which a POSA would understand could easily be printed on the single piece of flexible, insulating material. *Id.* at [0020]–[0021]; *see also, e.g.*, Ex. 1035 at 296 ("Printing Process. The circuit patterns are screen printed on the substrate by two ways: (1) Manual screen printing process, and (2) Automatic or semi-automatic screen printing process."). Thus, in my opinion, this modification would have been well within the skill of a POSA.

1072. A POSA would recognize that, so modified, Matsumura's conductive material would comprise a flexible printed circuit, which, combined with Matsumura's insulating second sheet 4, would form a flexible printed circuit layer. Ex. 1012 at [0017]–[0018].

1073. Moreover, in my opinion, a POSA would recognize that, as modified, the sheet of conductive material situated between first sheet 1 and second sheet 4 is a component of disposable bioelectrode pad. Accordingly, a POSA would understand that the modified sheet of conductive materials is configured to be coupled to a skin surface of a subject to measure physiological signals. *E.g.*, *id.* at [0024] (describing attaching bioelectrode pad to skin).

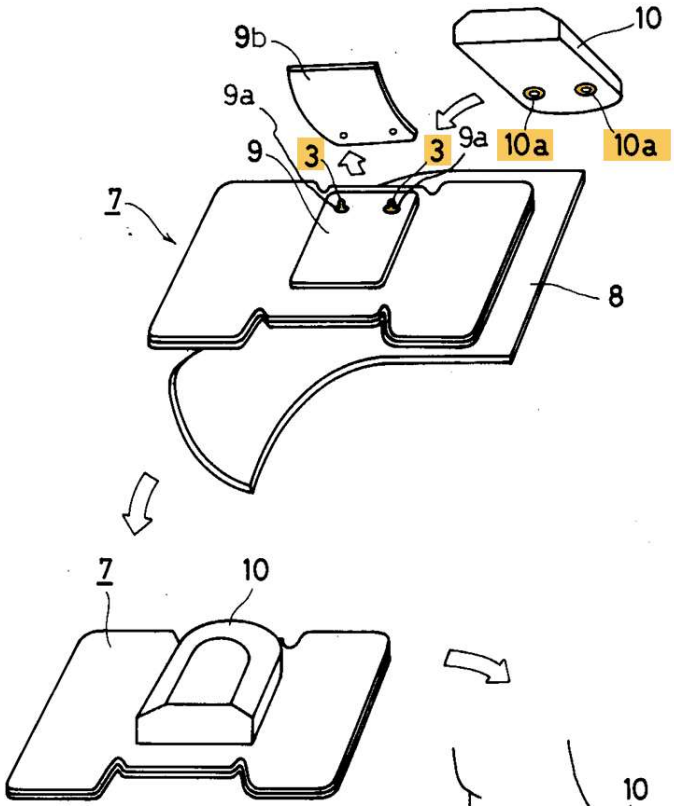
1074. Thus, in my opinion, Matsumura discloses "a flexible printed circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals."

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iv. Limitation [15c]

1075. Limitation [15c] recites "the computation-communication module being attached to the flexible printed circuit layer."

1076. As explained with respect to claim 1, it is my opinion that Matsumura discloses "the computation-communication module being attached to the flexible printed circuit layer." *See* Section XIX.A.1.iv, *supra*. The computation-communication module (signal processor 10) is attached to the flexible printed circuit layer via hooks 3 and engagement portions 10a. *See* Ex. 1012 at [0019], [0024].



Id., Fig. 2 (annotated).

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v. Limitation [15d]

1077. Limitation [15d] recites "an adhesive covering at least a portion of the flexible printed circuit layer."

1078. In my opinion, Matsumura discloses limitation [15d] of the '484 patent.

1079. As described above, *supra* Section XIX.A.1.v, Matsumura discloses multiple adhesive coverings that meet this element, even if the flexible printed circuit is modified as described in limitation [15b], *supra* Section XIX.A.6.iii. Alternatively, and additionally, Matsumura discloses "an adhesive covering at least a portion of the flexible printed circuit layer" specific to the modified printed circuit layer 2.

1080. As explained with respect to limitation [15b], a POSA would have been motivated to combine Matsumura's conductive material 2 into a single, printed circuit layer on a flexible, insulating substrate. *See* Section XIX.A.6.iii, *supra*. As modified, the flexible printed circuit would be placed between Matsumura's first sheet 1 and second sheet 4. *Id.* Matsumura discloses that bottom surface of first sheet 1 is coated with "an adhesive or glue, such as an acrylic adhesive" to ensure bonding between it and conductive material 2. Ex. 1012 at [0017]; *see also id.* at [0018] (same). The adhesives on the inner surfaces of first sheet 1 would therefore form "an adhesive covering at least a portion of the flexible printed circuit layer."

1081. Additionally, or alternatively Matsumura discloses a third sheet 6 which may "cover the center of the back surface of the second sheet 4," Ex. 1012 ¶ [0022], which is the bottom of the flexible printed circuit layer. In my opinion, a POSA would understand that the third sheet 6 is bonded to the second sheet using an adhesive because an adhesive "is applied to the back surface of the second sheet 4" and the third sheet 6 would be in contact with the back surface of the second sheet. Ex. 1012 at [0018]. The other sheets of the bioelectrode pad are similarly attached to one another using adhesive. Ex. 1012 at [0017].

1082. Thus, in my opinion, Matsumura discloses "an adhesive covering at least a portion of the flexible printed circuit layer."

vi. Limitation [15e]

1083. Limitation [15e] recites "a protective covering for the flexible printed circuit layer."

1084. In my opinion, Matsumura discloses limitation [15e] of the '484 patent.

1085. As explained with respect to limitation [15b], a POSA would have been motivated to combine Matsumura's conductive material 2 into a single, printed circuit layer on a flexible, insulating substrate. *See* Section XIX.A.6.iii, *supra*. As modified, the flexible printed circuit would have been placed between Matsumura's first sheet 1 and second sheet 4. *Id.* Matsumura discloses that first sheet 1 is "made of [ ] insulating material that does not allow moisture to penetrate." Ex. 1012

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at [0017]; *see also id.* at [0018] (same). Therefore, the first sheet 1 would function as a "protective covering" for the flexible circuit layer 2 as modified.

1086. Additionally, or alternatively, Matsumura discloses that "third sheet 6, made, for example of polyethylene or the like, may be provided to cover the center of the back surface of the second sheet 4." Ex. 1012 [0022]. In my opinion, a POSA would understand that third sheet 6 is a protective cover because it adheres to and partially covers the bottom surface of the modified printed circuit layer 2.

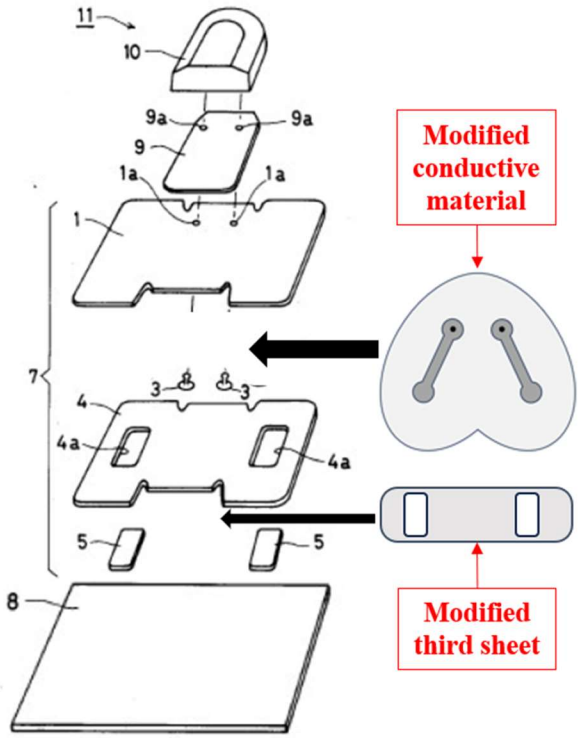
1087. Thus, in my opinion, Matsumura discloses "a protective covering for the flexible printed circuit layer."

7. Dependent Claim 16

1088. Claim 16 depends from claim 15 and further requires that "the protective covering includes at least one opening for electrode gels."

1089. In my opinion, claim 16 of the '484 patent is rendered obvious by Matsumura in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 15 as well as because Matsumura discloses the additional limitation of claim 16. *See* Section XIX.A.6, *supra*.

1090. As described above with respect to limitation [15e], Matsumura discloses "protective coverings," including third sheet 6. In my opinion, it would have been obvious to a POSA to modify third sheet 6 to extend its width and include openings for electrode gels 5, as shown below.



Id. at Fig. 1 (modified). This would be a simple change because third sheet 6 is a cut sheet that is placed in the device when assembled both as disclosed by Matsumura and when modified as suggested above. The method of manufacturing would not change simply by extending the width of third sheet and including openings for electrode gels. Further, as modified, third sheet 6 would still serve its stated purpose of making the center of the back surface of the flexible printed circuit layer less adhesive to the body. Ex. 1012 at [0022].

1091. For this reason, it is my opinion that Matsumura teaches "the protective covering includes at least one opening for electrode gels" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 16 of the '484 patent.

8. Dependent Claim 17

1092. Claim 17 depends from claim 15 and further requires that "the flexible printed circuit layer includes openings sized to receive electrode gels."

1093. In my opinion, claim 17 of the '484 patent is rendered obvious by Matsumura in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 15 as well as because Matsumura discloses the additional limitation of claim 17. *See* Section XIX.A.6, *supra*.

1094. As explained with respect to limitation [15b], a POSA would have been motivated to combine Matsumura's conductive material 2 into a single, printed circuit layer on a flexible, insulating substrate; this flexible printed circuit would be inserted between first sheet 1 and second sheet 4. *See* Section XIX.A.6.iii, *supra*.

1095. As modified, the flexible printed circuit layer would include flexible printed circuit (substitute for conductive material 2) and second sheet. *Id.* Matsumura discloses that "second sheet 4" of bioelectrode pad 7 "is provided with two openings 4a on the left and right sides into which the conductive gel 5 is inserted." Ex. 1012 at [0018]. As shown in Figure 1, openings 4a are sized to receive conductive gels 5. *Id.* at Fig. 1.

1096. For these reasons, it is my opinion that a POSA would understand that Matsumura discloses "the flexible printed circuit layer includes openings sized to

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receive electrode gels" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 17 of the '484 patent.

9. Dependent Claim 18

1097. Claim 18 depends from claim 15 and further requires that "the protective covering is non removable and made from an insulating material."

1098. In my opinion claim 18 of the '484 patent is rendered obvious by Matsumura in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 15 as well as because a POSA would understand that Matsumura discloses the additional limitation of claim 18. *See* Section XIX.A.6, *supra*.

1099. As noted above, Matsumura's first sheet 1 (made from an insulating material) is a protective covering. Ex. 1012 at [0017]. Additionally, as noted above, third sheet 6 (made from polyethylene, which is an insulating material) is a protective covering. *Id.* at [0022]; Ex. 1047 at 23.10 ("The material most commonly used for flexible packaging applications is oriented polyester (e.g., Mylar™), which is used as a base for properties such as dimensional stability, heat resistance, and strength with an adhesively laminated seal layer such as low-density polyethylene, which provides the film structure with heat scalability"). In my opinion, a POSA would have understood that, once assembled, first sheet 1 and third sheet 6 are "non removable" from the rest of the bioelectrode pad 7. Specifically, a POSA would

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have understood that for first sheet 1, which made of "polyethylene foam, polyurethane foam, or polyurethane sheet," to "not allow moisture to penetrate," it would need to be bonded to the remainder of bioelectrode pad 7, Ex. 1012 at [0018], and that third sheet 6 would be bonded to the bottom surface of the modified flexible printed circuit layer 2 via adhesive, *id.* at [0018], [0022].

1100. For these reasons, it is my opinion that Matsumura discloses that "the protective covering is non removable and made from an insulating material" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 18 of the '484 patent.

10. Dependent Claim 19

1101. Claim 19 depends from claim 15 and additionally requires that "the computation communication module is releasably attached to the flexible printed circuit layer."

1102. In my opinion claim 19 of the '484 patent is rendered obvious by Matsumura in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 15 as well as because Matsumura discloses the additional limitation of claim 19. *See* Section XIX.A.6, *supra*.

1103. Matsumura discloses that "[t]he bioelectrode pad 7 and the signal processor 10 are detachable with hooks. . . . [T]he reusable signal processor and the disposable bioelectrode can be easily attached and detached before and after use."

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Ex. 1012 at [0016]. Accordingly, Matsumura discloses that signal processor 10 (computation-communication module) is releasably attached to disposable bioelectrode 7.

1104. Thus, it is my opinion that Matsumura discloses that "the computation communication module is releasably attached to the flexible printed circuit layer" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 19 of the '484 patent.

11. Dependent Claim 20

1105. Claim 20 depends from claim 15 and additionally requires that "the protective covering covers the adhesive."

1106. In my opinion claim 20 of the '484 patent is rendered obvious by Matsumura in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 15 as well as because Matsumura discloses the additional limitation of claim 20. *See* Section XIX.A.11, *supra*.

1107. As modified, Matsumura's first sheet 1 (on the top surface) and third sheet 6 (on the bottom surface) are bonded to the flexible printed circuit by an adhesive. Section XIX.A.6.iii, *supra*; Ex. 1012 at [0017]–[0018], [0022]. Accordingly, each of Matsumura's protective coverings (first sheet 1 and third sheet 6) covers an adhesive.

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1108. For these reasons, it is my opinion that a POSA would understand that Matsumura discloses that "the protective covering covers the adhesive" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders claim 20 obvious.

B. Ground 2: Obvious Over Jensen and General Knowledge of a POSA

1. Independent Claim 1

1109. In my opinion, claim 1 of the '484 patent is rendered obvious by Jensen in view of the general knowledge of a POSA.

i. Preamble 1[pre]

1110. The preamble of claim 1 recites "a body-worn physiological sensor comprising."

1111. In my opinion, to the extent the preamble is limiting, Jensen discloses the preamble of claim 1 of the '484 patent.

1112. Jensen discloses a body worn "smart patch" "that integrates . . . heart-rate/EKG electronic sensors," which are physiological sensors. Ex. 1011 at [0012]; *see also id.* at [0013].

1113. Thus, in my opinion, Jensen discloses "a body-worn physiological sensor."

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ii. Limitation [1a]

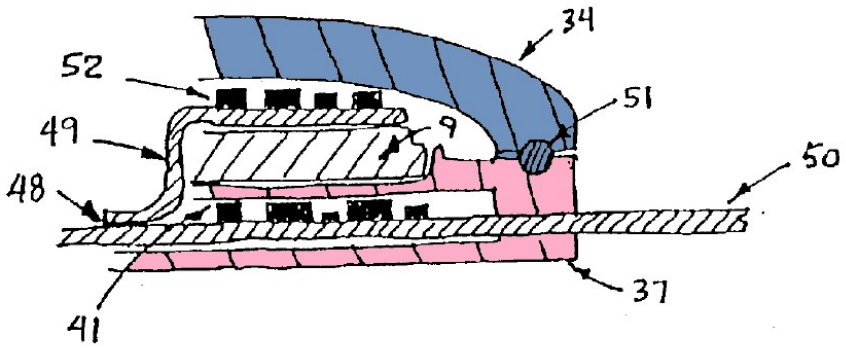
1114. Limitation [1a] recites "a computation-communication module including a housing retaining a processor."

1115. In my opinion, Jensen discloses limitation [1a] of the '484 patent.

1116. Jensen discloses an electronics circuit 41 that includes a "microcontroller" for computation and a "transmitter" for communication. *Id.* at [0032]–[0033]. Jensen's microcontroller "runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter." *Id.* at [0032]. Jensen's transmitter may communicate data via an "antenna." *Id.* at [0033]. Accordingly, Jensen discloses a computation-communication module. In the embodiment of Figure 8, Jensen discloses multiple electronics circuits 41, 52. *Id.* at [0046], Fig. 8. A POSA would understand that the components of electronics circuit 41 (computation-communication module) could be located on electronics circuit 52.

1117. Jensen further explains that the "computation-communication module" includes a housing that retains a processor. As shown in the annotated version of Jensen's Figure 7 below, "[t]op case 34 [shown in blue below] mounts onto bottom case 37 [shown in pink below]" forming a housing that encloses electronics circuit 52. *Id.* at [0045]. As part of electronics circuitry, Jensen discloses "a microcontroller and/or other programmable logic circuitry that perform

measurement and processing of sensed data." *Id.* at [0014]. Jensen also teaches that the microcontroller can "run[] a conventional program that may perform further analysis and can also encode a data stream output to the transmitter." *Id.* at [0032]. The microcontroller (processor), along with other electronics circuitry 52, is disposed in the housing formed from top case 34 (shown below in blue) and bottom case 37 (shown below in red). Ex. 1005 at 12:7–9 ("A microprocessor, such as microprocessor 512, is defined herein as synonymous and interchangeable with the terms 'microcomputer', 'microcontroller', and 'microprocessor').



Ex. 1011 at Fig. 8 (annotated).

1118. Thus, in my opinion, Jensen discloses "a computation-communication module including a housing retaining a processor."

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iii. Limitation [1b]

1119. Limitation [1b] recites "a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals."

1120. In my opinion, Jensen discloses limitation [1b] of the '484 patent.

1121. The "smart patch" disclosed by Jensen may be "applied to the skin much like a bandage, with self-adhesive pads and sensor materials on the skin-contact side of the invention." *Id.* at [0030]. The "smart patch" is attached to the skin through sensor pads 1, 2 that collect heart-rate signals. *Id.* at [0031], [0041]. Sensor pads 1, 2 are electrically connected to sensor contacts 71, 72 located on flexible circuit assembly 36. *Id.* at [0040]–[0041], [0043], Fig. 5. In my opinion, a POSA would understand that flexible printed circuit 50 in the embodiment of Figure 8 is analogous to flexible circuit assembly 36, and that flexible printed circuit 50 is also attached to the skin through disposable sensor pads 1, 2. *Id.* at Fig. 8. In my opinion, a POSA would recognize that the printed circuit layer 101 of the '492 patent is also configured to be coupled to the skin by means of an adhesive layer 105 that sits between the patient's skin and the flexible printed circuit layer 101. *See* Ex. 1005, Fig. 2. Accordingly, Jensen discloses a flexible circuit layer that is coupled through disposable sensor pads 1, 2 to a skin surface of a subject to measure heart-rate signals, which are physiological signals.

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1122. Thus, in my opinion, Jensen discloses "a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals.

iv. Limitation [1c]

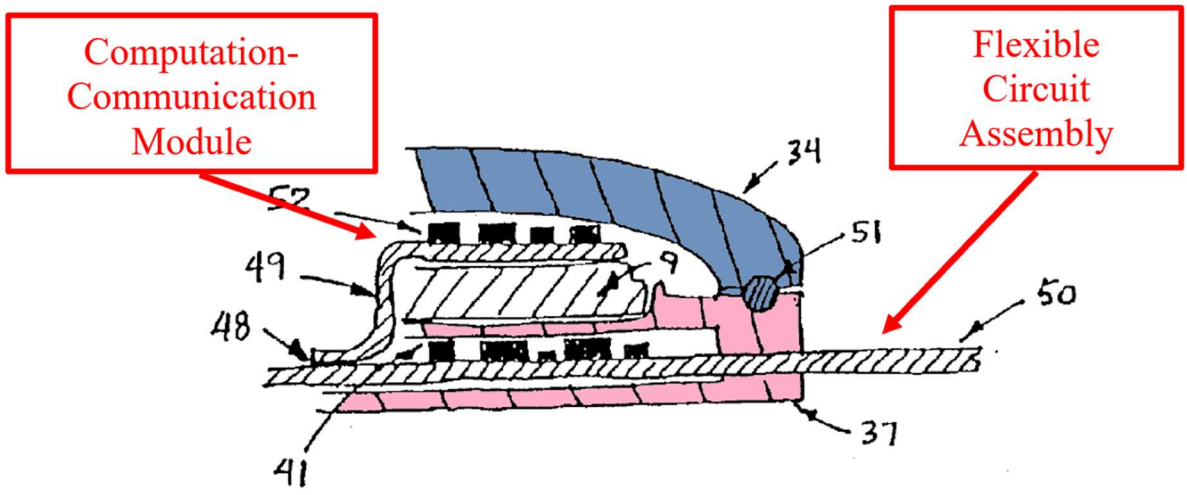
1123. Limitation [1c] recites "said computation-communication module being attached to the flexible circuit layer."

1124. In my opinion, Jensen discloses limitation [1c] of the '484 patent.

1125. Jensen discloses that its computation-communication module (*i.e.*, electronics circuit 41 that contains a "microcontroller" for computation and a "transmitter" for communication) is connected and attached to flexible circuit assembly 50. *Id.* at [0032]–[0033], [0045]–[0046], Figs. 8, 8A.

1126. A POSA reviewing the embodiment of Jensen's Figure 8 would understand that the electronics circuit comprising a "microcontroller" and "transmitter" could be located on electronics circuit 52. *Id.* As shown in Figure 8 below, computation-communication module 52 resides on flexible circuit 49, which is attached to flexible circuit layer 50.

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Id. at Fig. 8 (annotated).

1127. Thus, in my opinion, Jensen discloses "said computation-communication module being attached to the flexible circuit layer."

v. Limitation [1d]

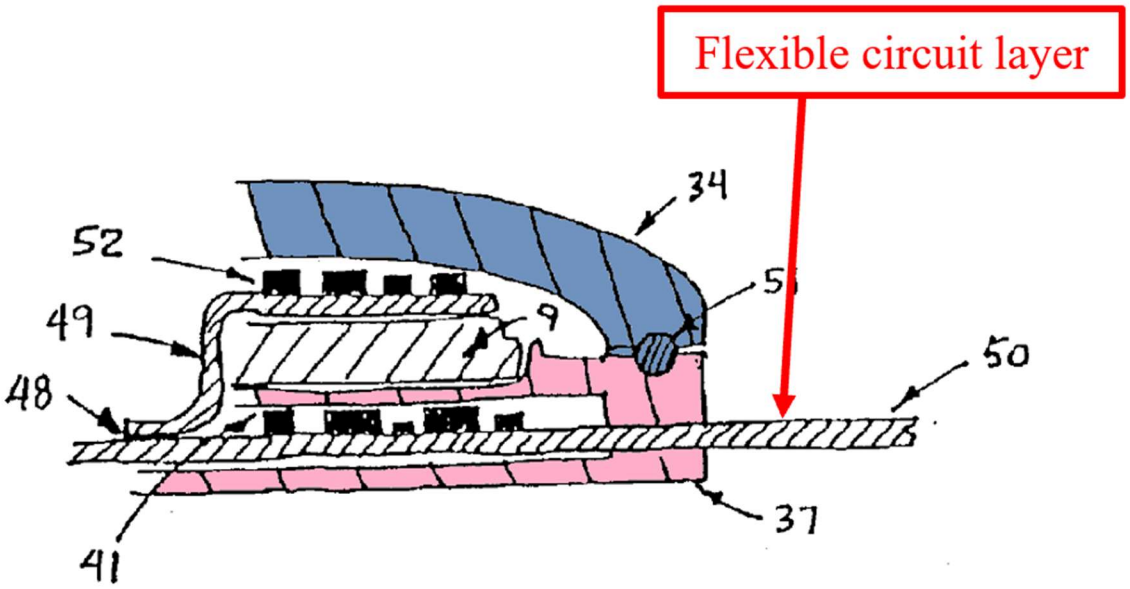
1128. Limitation [1d] recites "an adhesive covering at least a portion of the flexible circuit layer."

1129. In my opinion, Jensen discloses limitation [1d] of the '484 patent.

1130. Jensen discloses sensor pads 1, 2 that are coated with an adhesive "on the circuit side" that is adhered to the flexible layer. Ex. 1011 ¶¶ [0040]–[0042]. "[T]he disposable sensor pad electrodes 1 and 2 are coated with a conductive adhesive on the circuit side and a conductive adhesive-gel that is made using a silver amalgam as found in off-the-shelf EKG sensor pads, such as those sold by 3M

Corporation." *Id.* at [0041]. The conductive adhesive covers at least a portion of the flexible circuit layer 36. *Id.* Fig. 5.

1131. A POSA would understand that, in the embodiment of Figure 8, sensor pad electrodes 1, 2 would be mounted to the bottom surface of flexible circuit layer 50 in the same way.



Id. at Fig. 8 (annotated).

1132. Additionally or alternatively, Jensen discloses an adhesive to attach aesthetic covering 35 to the top surface of the flexible circuit assembly, noting that "two aesthetic covers 35 may be constructed from Mylar sheet" and "enclose the entire top side of the flexible circuit assembly 36." Ex. 1011 at [0043]. In my opinion, a POSA would have understood that an aesthetic cover would also be included in the embodiment of Figure 8, and that an adhesive would be used to attach

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flexible circuit assembly 50 to aesthetic covering 35. *Id.* at [0032]–[0033]. Accordingly, the adhesive covers at least a portion of flexible circuit assembly (36, 50) on top on which aesthetic covering 35 is placed.

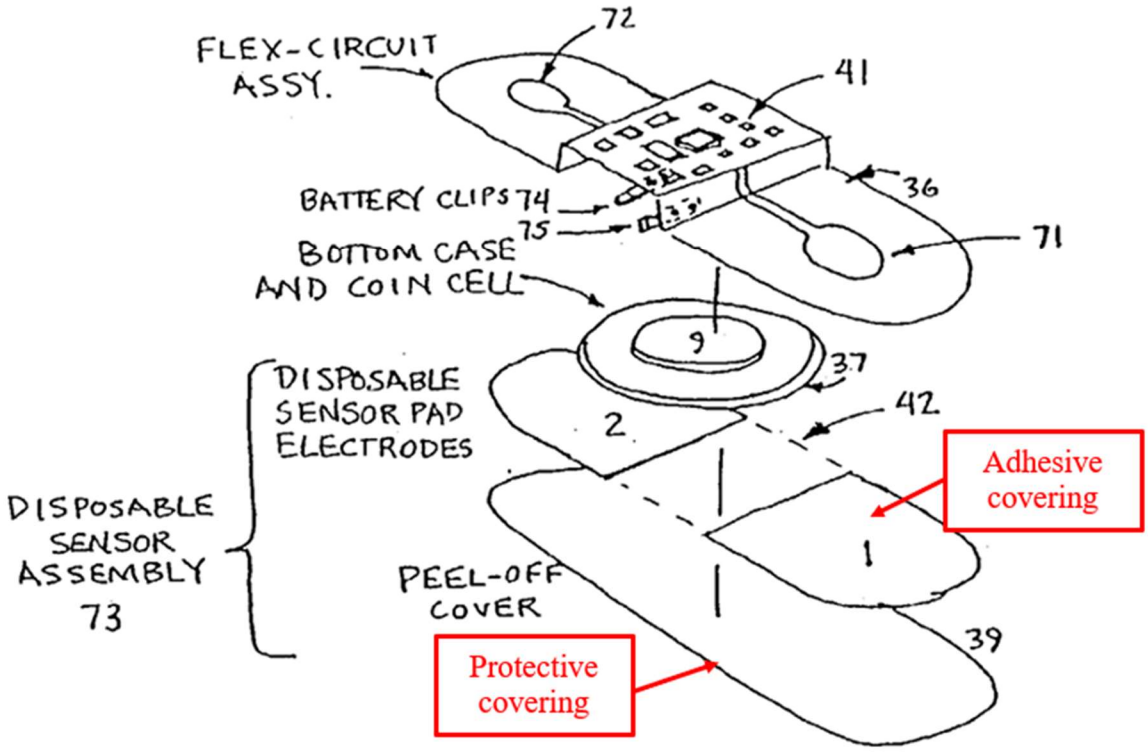
1133. Thus, in my opinion, Jensen discloses "an adhesive covering at least a portion of the flexible circuit layer."

vi. Limitation [1e]

1134. Limitation [1e] recites "a protective covering that protects the adhesive."

1135. In my opinion, Jensen discloses limitation [1e] of the '484 patent.

1136. Jensen discloses that the sensor pads 1, 2 coated with a conductive adhesive and are surrounded by a "protective cover tape 39." *Id.* at [0041]. As shown in Jensen's Figure 5 reproduced below, "[t]he pads, when they are first installed, typically come pre-applied to a peel- off cover 39 that protects the conductive surface of sensor pads 1 and 2 until ready for use." *Id.* at [0042].



Id. at Fig. 5 (annotated). This peel-off cover 39 protects all of the sensor pad component, including the adhesive covering on those sensor pads.

1137. Additionally, or alternatively, aesthetic covering 35 protects the adhesive used to attach the covering to flexible circuit assembly 36, 50. As explained with reference to limitation [1d], *supra*, a POSA would understand that aesthetic covering 35 must be affixed to flexible circuit assembly by an adhesive. Thus, the aesthetic covering itself would become a "protective covering" relative to the adhesive.

1138. Thus, in my opinion, Jensen discloses "a protective covering that protects the adhesive."

2. Dependent Claim 2

1139. Claim 2 depends from claim 1 and further requires that "the flexible circuit layer has traces of determinable electrical resistance."

1140. In my opinion, claim 2 of the '484 patent is obvious over Jensen in view of a POSA's general knowledge for all the reasons discussed above with respect to claim 1 as well as because a POSA would understand Jensen to disclose the additional limitation of claim 2. *See* Section XIX.B.1, *supra*.

1141. Jensen discloses "flexible circuit assembly 36 that contains the copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72." Ex. 1011 at [0040]. A POSA would understand that flexible circuit assembly 50 of the embodiment of Figure 8 would have the same structure. A POSA would have understood that the copper in the wiring trace has a determinable electrical resistance. Indeed, **every** substance has a determinable electrical resistance—it is a physical property. *See, e.g.*, Ex. 1060 at 53 ("Electrical Resistance. . . . [E]very particular substance has its own characteristic power of transmitting electrical currents").

1142. For these reasons, it is my opinion that a POSA would understand that Jensen discloses that "the flexible circuit layer has traces of determinable electrical resistance" and, therefore, that Jensen, in view of the general knowledge of a POSA, renders obvious claim 2 of the '484 patent.

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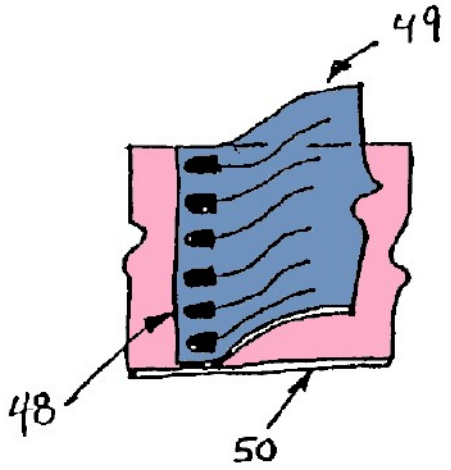
3. Dependent Claim 3

1143. Claim 3 of the ’484 patent depends from claims 1 and 2 and additionally requires that “the traces on the flexible circuit layer are configured to electrically couple the computation-communication module to the flexible circuit layer, thereby forming a disposable module connector.”

1144. In my opinion claim 3 of the ’484 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claims 1 and 2 as well as because Jensen discloses the additional limitation of claim 3. *See* Section XIX.B.2, *supra*.

1145. In one embodiment, Jensen discloses two flexible printed circuits 49, 50, which a POSA would understand could comprise, respectively, the substrate for the reusable computation-communication module and the substrate for the disposable module. Ex. 1011 at [0045]–[0046], Fig. 8. Jensen further explains that the circuits are connected (*i.e.*, “electrically coupled”) by pads 48, which are “matched on both circuits.” *Id.* at [0046].

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Id. at Fig. 8A (annotated).

1146. A POSA would understand that pads on the disposable, printed circuit board substrate of Jensen, 50, are formed by traces that run to sensor contacts because printed circuit board substrate of the embodiment of Figure 8A is analogous to the flexible circuit layer 36 of the embodiment of Figure 5.

1147. It is my opinion that Jensen discloses that "the traces on the flexible circuit later are configured to electrically couple the computation-communication module to the flexible circuit layer, thereby forming a disposable module connector" and, therefore, that Jensen, in view of the general knowledge of a POSA, renders obvious claim 3 of the '484 patent.

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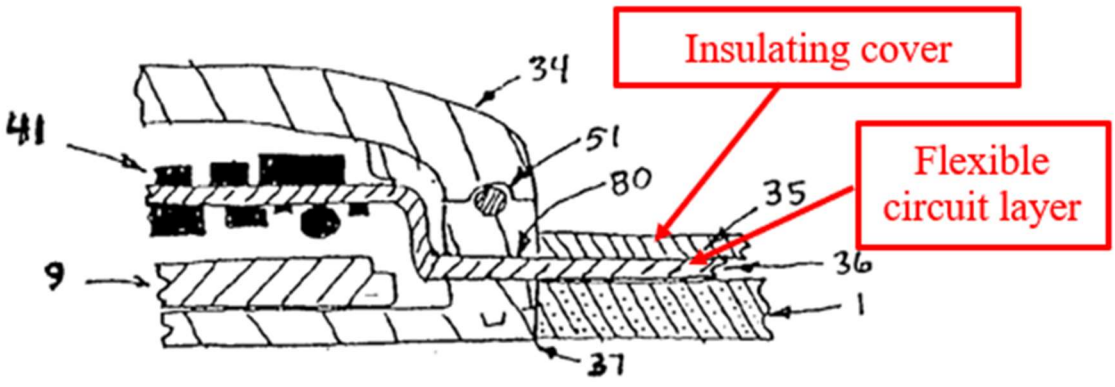
4. Dependent Claim 4

1148. Claim 4 of the '484 patent depends from claim 1 and additionally requires that "the traces on the flexible circuit layer are at least partially covered by a non-removable insulating covering."

1149. In my opinion claim 4 of the '484 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because Jensen discloses the additional limitation of claim 4. *See* Section XIX.B.1, *supra*.

1150. As noted above, Jensen discloses "flexible circuit assembly 36 that contains the copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72." Ex. 1011 at [0040].

1151. The traces are covered by "two aesthetic covers 35" that are part of the device's "re-usable (non-disposable) portion." *Id.* at [0043]. This is shown at least in Figure 7 of Jensen.



Id. at Fig. 7 (annotated).

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1152. A POSA would have understood that aesthetic cover 35 insulates the flexible circuit assembly 36 (or 50) and its traces, and that the aesthetic cover would be utilized in any embodiment of Jensen, including the embodiment of Figure 8.

1153. It is therefore my opinion that Jensen discloses that "the traces on the flexible circuit layer are at least partially covered by a non-removable insulating covering" and, therefore, that Jensen, in view of the general knowledge of a POSA, renders obvious claim 4 of the '484 patent.

5. Dependent Claim 5

1154. Claim 5 of the '484 patent depends from claim 1 and further requires that "the flexible circuit layer further comprises a plurality of openings sized to receive electrode gels."

1155. In my opinion claim 5 of the '484 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because the additional limitation of claim 5 would have been obvious to a POSA. *See* Section XIX.B.1, *supra*.

1156. In my opinion it would have been obvious to a POSA to modify Jensen such that "the flexible circuit layer further comprises a plurality of openings sized to receive electrode gels." Commercially available electrode gels were known in the art at the time of the claimed invention. *See, e.g.*, Ex. 1011 at [0041] (describing "off-the-shelf EKG sensor pads, such as those sold by 3M Corporation"). A POSA

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would have recognized that it could integrate these commercially available, disposable electrodes into the invention of Jensen by including recesses or openings to accommodate those commercially available electrode gels. A POSA would have been motivated to modify Jensen in this manner for at least two reasons. First, relying on commercially available electrodes (rather than creating a novel electrode 'from scratch') would ease manufacturing and assembly. Second, providing a recess would help to prevent movement of the electrode gels, which was known in the art (*e.g.*, by recessing gels in a cup geometry). Ex. 1061 (Maeona K. Jacobs, *Sources of Measurement Error in Noninvasive Electronic Instrumentation*, 13 Nursing Clinics N. Am. 573 (1978)) at 578–79 ("If a portion of the electrode loses contact with the skin, current flow across it is altered because, in effect, the size of the interface changes. Current flow may be altered further if movement allows the conductive medium to dry"); *see also* Ex. 1062 (Michael R. Neuman, *Biopotential Electrodes*, Medical Instrumentation (3d ed. 1998)) at 203–04.

6. Independent Claim 15

1157. In my opinion, claim 15 of the '484 patent is rendered obvious by Jensen in view of the general knowledge of a POSA.

i. Preamble 15[pre]

1158. The preamble of claim 15 recites "a body-worn physiological sensor."

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1159. As described with respect to claim 1, to the extent that the preamble is limiting, it is my opinion that Jensen discloses "a body-worn physiological sensor." *See* Section XIX.B.1.i, *supra*.

ii. Limitation [15a]

1160. Limitation [15a] recites "a computation-communication module including a housing retaining a processor."

1161. As explained with respect to claim 1, it is my opinion that Jensen discloses "a computation-communication module including a housing retaining a processor." *See* Section XIX.B.1.ii, *supra*.

iii. Limitation [15b]

1162. Limitation [15b] recites "a flexible printed circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals."

1163. As explained with respect to Claim 1, it is my opinion that Jensen discloses "a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals." *See* Section XIX.B.1.iii, *supra*. A POSA would understand that Jensen's flexible circuit layer 36, 50 is fashioned as a flexible printed circuit board, and would therefore understand that Jensen discloses a flexible printed circuit layer. *Cf.* Ex. 1035 at 4–5 (defining printed circuit board as comprising base of insulating material and conductors).

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iv. Limitation [15c]

1164. Limitation [15c] recites "the computation-communication module being attached to the flexible printed circuit layer."

1165. As explained with respect to claim 1, it is my opinion that Jensen discloses "the computation-communication module being attached to the flexible printed circuit layer." *See* Section XIX.B.1.iv, *supra*.

v. Limitation [15d]

1166. Limitation [15d] recites "an adhesive covering at least a portion of the flexible printed circuit layer."

1167. In my opinion, Jensen discloses limitation [15d] of the '484 patent.

1168. Jensen discloses sensor pads 1, 2, that are coated with an adhesive "on the circuit side" that is then adhered to the flexible circuit layer. Ex. 1011 at [0040]–[0042]. The adhesive covers at least a portion of the flexible circuit layer. *Id.*; *see also id.* at Fig. 5. "[T]he disposable sensor pad electrodes 1 and 2 are coated with a conductive adhesive on the circuit side and a conductive adhesive-gel that is made using a silver amalgam as found in off-the-shelf EKG sensor pads, such as those sold by 3M Corporation." *Id.* at [0041]. In my opinion, a POSA would understand that, in the embodiment of Figure 8, the sensor pad electrodes 1, 2 would be mounted to the bottom surface of flexible circuit 36, 50 with an adhesive in the same way.

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1169. Additionally, or alternatively, a POSA would have understood that an adhesive would be used to attach an aesthetic covering 35 to the top surface of the flexible circuit assembly 36. *See* Section XIX.B.1.v, *supra*; Ex. 1011 at [0043], [0045]. Accordingly, in my opinion, a POSA would also understand that the adhesive covers at least a portion of the flexible circuit assembly 36, 50 (*i.e.*, the portion on top of which aesthetic covering is placed).

1170. Thus, in my opinion, Jensen discloses "an adhesive covering at least a portion of the flexible printed circuit layer."

vi. Limitation [15e]

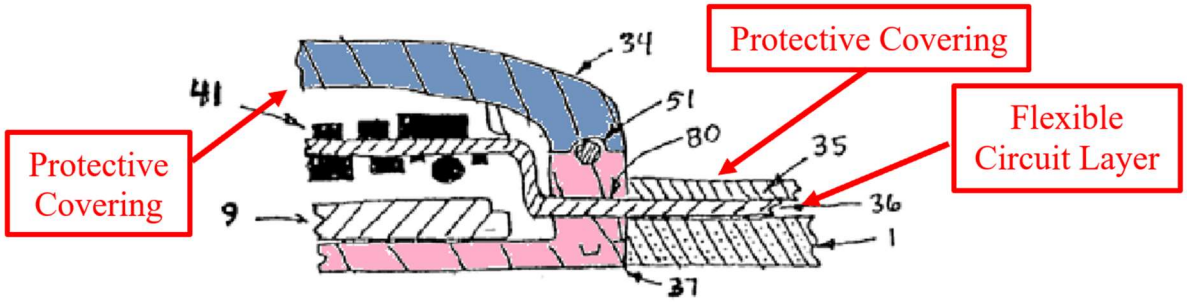
1171. Limitation [15e] recites "a protective covering for the flexible printed circuit layer."

1172. In my opinion, Jensen discloses limitation [15e] of the '484 patent.

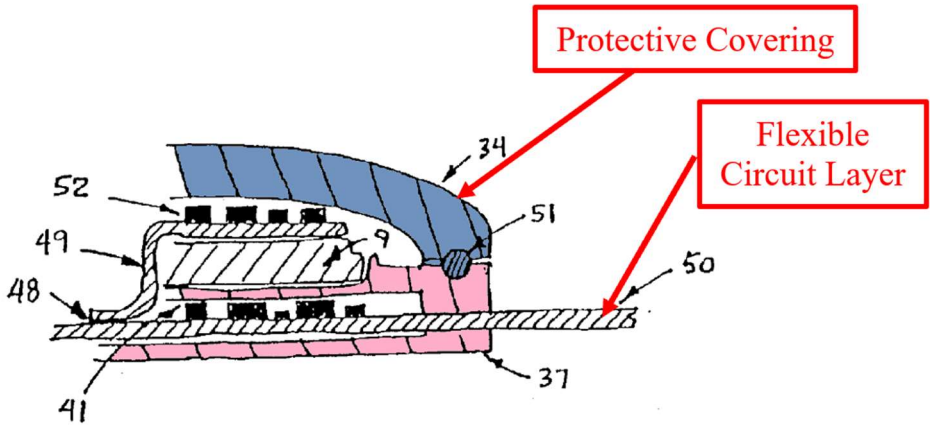
1173. Jensen discloses that "two aesthetic covers 35 may be constructed from Mylar sheet, for example, and enclose the entire top side of the flexible circuit assembly 36." Ex. 1011 at [0043], Fig. 7.

1174. In my opinion, a POSA would understand that such aesthetic covers would be utilized in all of the embodiments of Jensen, and that "aesthetic covers 35" of Jensen are a "protective covering" for the top surface of Jensen's flexible printed circuit layer 36, 50. A POSA would recognize that Mylar—or a similar material—would isolate the flexible circuit assembly from the elements and would insulate the

device electrically because Mylar is a well-known insulating material. *See* Ex. 1047 at 23.10 ("The material most commonly used for flexible packaging applications is oriented polyester (e.g., Mylar™), which is used as a base for properties such as dimensional stability, heat resistance, and strength with an adhesively laminated seal layer such as low-density polyethylene, which provides the film structure with heat scalability").



Id. at Fig. 7 (annotated).



Id. at Fig. 8 (annotated).

1175. Additionally, or alternatively, Jensen discloses that sensor pads 1, 2 attached to a flexible circuit assembly 36, 50 are surrounded by a "protective cover

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tape 39." *Id.* at [0041]. "The pads, when then they are first installed, typically come pre-applied to a peel-off cover 39 that protects the conductive surface of sensor pads 1 and 2 until ready for use." *Id.* at [0042]. The protective cover tape 39 protects the bottom surface of the flexible circuit assembly 36, 50 (the flexible printed circuit layer). For wearable medical devices, all surfaces that are placed over skin for prolonged periods of time should be kept clean and hygienic, and therefore protective tape 39 would protect any exposed surfaces facing the skin such as sensor pads 1 and 2, bottom case 37, and flexible circuit assembly 36, 50.

1176. Thus, it is my opinion that Jensen discloses "a protective covering for the flexible printed circuit layer."

7. Dependent Claim 17

1177. Claim 17 depends from claim 15 and additionally requires that "the flexible printed circuit layer includes openings sized to receive electrode gels."

1178. In my opinion, claim 17 of the '484 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 15 as well as because the additional limitation of claim 17 would have been obvious to a POSA. *See* Section XIX.B.6, *supra*.

1179. Commercially available electrode gels were known in the art at the time of the claimed invention. *E.g.*, Ex. 1011 at [0041] (describing "off-the-shelf EKG sensor pads, such as those sold by 3M Corporation"). A POSA would have

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recognized that it could integrate these commercially available disposable electrodes into the invention of Jensen by including recesses or openings to accommodate those commercially available electrode gels. A POSA would have been motivated to modify Jensen in this manner for at least two reasons. First, relying on commercially available electrodes (rather than creating a novel electrode 'from scratch') would ease manufacturing and assembly. Second, providing a recess would help to prevent movement of the electrode gels, which was known in the art (*e.g.*, by recessing gels in a cup geometry). Ex. 1061 at 578–79 ("If a portion of the electrode loses contact with the skin, current flow across it is altered because, in effect, the size of the interface changes. Current flow may be altered further if movement allows the conductive medium to dry"); *see also* Ex. 1062 at 203–04.

1180. For these reasons, it is my opinion that Jensen discloses that "the flexible printed circuit layer includes openings sized to receive electrode gels" and, therefore, that Jensen, in view of the general knowledge of a POSA, renders obvious claim 20 of the '484 patent.

8. Dependent Claim 18

1181. Claim 18 depends from claim 15 and additionally requires that "the protective covering is non-removable and made from an insulating material."

1182. In my opinion, claim 18 of the '484 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with

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respect to claim 15 as well as because the additional limitation of claim 18 would have been obvious to a POSA. *See* Section XIX.B.6, *supra*.

1183. As disclosed above, Jensen teaches discloses protective covering for the flexible printed circuit layer, including "two aesthetic covers 35 [which] may be constructed from Mylar sheet." *See* Section XIX.B.6.vi, *supra*; Ex. 1011 at [0043]. In my opinion, a POSA would recognize that Mylar is an insulating material, *see* Ex. 1047 at 23.10 ("The material most commonly used for flexible packaging applications is oriented polyester (e.g., Mylar™), which is used as a base for properties such as dimensional stability, heat resistance, and strength with an adhesively laminated seal layer such as low-density polyethylene, which provides the film structure with heat scalability"), and that aesthetic covers 35 are therefore a "protective material." A POSA would further understand that Mylar protective covers were not removable from disposable substrate 50, and would be discarded with the disposable substrate 50 after each use (and after it was detached from the communication-computation module) for hygienic reasons.

1184. For these reasons, it is my opinion that Jensen discloses that "the protective covering is non-removable and made from an insulating material" and, therefore, that Jensen, in view of the general knowledge of a POSA, renders obvious claim 18 of the '484 patent.

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9. Dependent Claim 20

1185. Claim 20 depends from claim 15 and additionally requires that "the protective covering covers the adhesive."

1186. In my opinion, claim 20 of the '484 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 15 as well as because Jensen discloses the additional limitation of claim 20. *See* Section XIX.B.6, *supra*.

1187. Jensen discloses a "protective cover tape 39" that surrounds sensor pads 1, 2 coated with a conductive adhesive attached to flexible circuit assembly 36, 50. Ex. 1011 at [0041]; *see also id.* at [0042]. This cover tape therefore "covers the adhesive."

1188. Additionally, or alternatively, aesthetic covering 35 protects the adhesive used to attach the covering to flexible circuit assembly 36, 50. *See* Section XIX.B.1.iv, *supra*; Ex. 1011 at [0043], [0045]. Thus, aesthetic covering 35 also "covers the adhesive."

1189. For these reasons, it is my opinion that Jensen discloses that "the protective covering covers the adhesive" and, therefore, that Jensen, in view of the general knowledge of a POSA, renders obvious claim 20 of the '484 patent.

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C. Ground 3: Obvious Over Ozguz and General Knowledge of a POSA

1. Independent Claim 1

1190. In my opinion, claim 1 of the ’484 patent is rendered obvious by Ozguz in view of the general knowledge of a POSA.

i. Preamble 1[pre]

1191. The preamble of claim 1 recites “a body-worn physiological sensor comprising.”

1192. In my opinion, to the extent the preamble is limiting, Ozguz discloses the preamble of claim 1 of the ’484 patent.

1193. Ozguz discloses “a thin flexible ambulatory/self contained bio-sensor module in a form similar to an adhesive bandage for sensing physiologically modulated signals from the body.” Ex. 1014 at [0003].

1194. Thus, in my opinion, Ozguz discloses “a body-worn physiological sensor.”

ii. Limitation [1a]

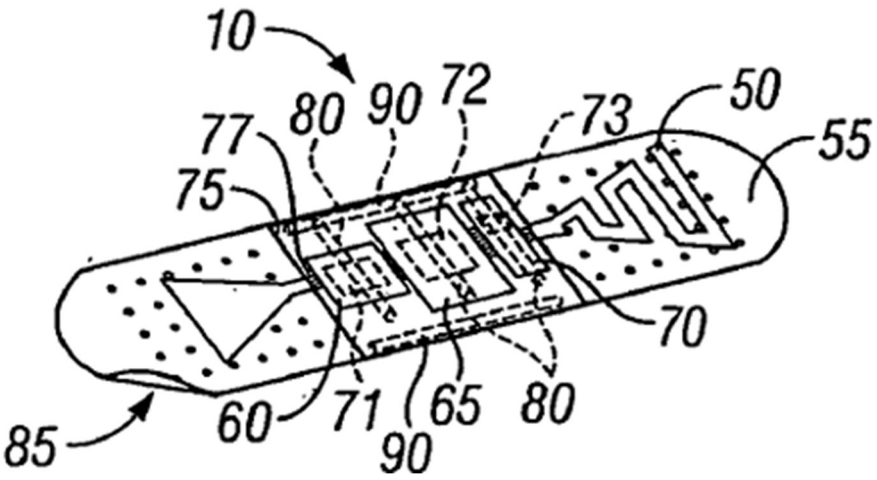
1195. Limitation [1a] recites “a computation-communication module including a housing retaining a processor.”

1196. In my opinion, Ozguz discloses limitation [1a] of the ’484 patent.

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1197. Ozguz's sensor module 10 includes "flexible silicon substrates 60, 65, 70 having respective integrated circuits 71, 72, 73 [which] are bonded to the flexible substrate 55." *Id.* at [0039]. Thin silicon substrates 60, 65, 70 can include a communication module: "transmitter or transceiver 190 for transmitting data by RF signals to a remote receiver." *Id.* at [0058]. Ozguz states that "it is to be expressly understood that the ICs 71, 72, 73, can be integrated as one IC on a single silicon substrate." *Id.* at [0042].

1198. Ozguz's thin silicon substrates 60, 65, 70 may also include a computation module: "a microprocessor 175" for processing signals and "controlling input, storage, and analysis of the collected data." *Id.* at [0041], [0044], [0058]. Accordingly, Ozguz discloses a communication-computation module.



Id. at Fig. 2A.

1199. Ozguz also discloses that the "computation-communication module" includes "a housing retaining a processor." In particular, Ozguz discloses that the

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"flexible, thin battery 105 overlays the silicon substrates 60, 65, 70 and their respective ICs 71, 72, 73." *Id.* at [0048]. Circuits 71, 72, and 73 can be integrated into a single circuit on a single silicon substrate. *Id.* at [0039], [0042]. Overlay 105 houses the computation-communication module formed by flexible substrate 55 and components bonded to it, such as flexible silicon substrates 60, 65, 70, integrated circuits 71, 72, 73, and antenna 50. *Id.* A "microprocessor 175" can be "incorporated into thin silicon substrates 60, 65, 70." *Id.* at [0058].

1200. Thus, in my opinion, Ozguz discloses "a communication-computation module including a housing retaining a processor."

iii. Limitation [1b]

1201. Limitation [1b] recites "a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals."

1202. In my opinion, Ozguz discloses limitation [1b] of the '484 patent.

1203. Ozguz discloses that "flexible substrate 55" includes metallization 77 that interconnects integrated circuits 71, 72, 73 and other components to form a circuit layer. *Id.* at [0039]. "[E]lectrodes 80" (shown below) are "disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20." *Id.* These electrodes are used to "detect . . . physiological characteristics such as an EKG (from the heart)." *Id.* at [0044]. Accordingly, Ozguz discloses a

flexible circuit layer (flexible substrate 55) configured to be coupled to a skin surface of a subject to measure physiological signals (such as EKG).

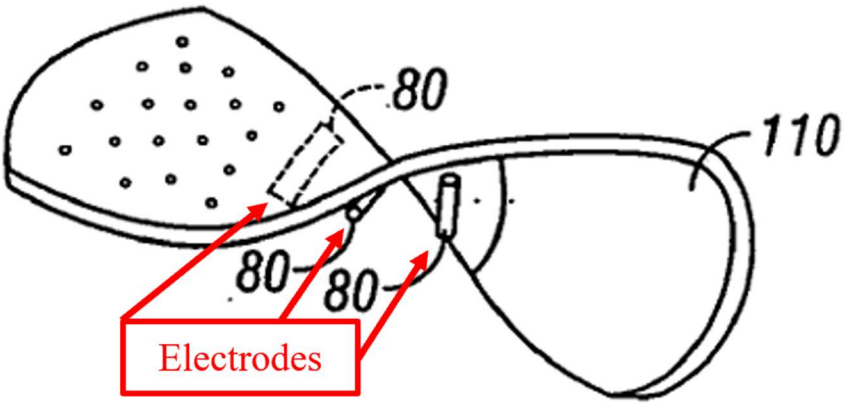


FIG. 3E

Id. at Fig. 3E (annotated).

1204. Thus, in my opinion, Ozguz discloses "a flexible circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals.

iv. Limitation [1c]

1205. Limitation [1c] recites "said computation-communication module being attached to the flexible circuit layer."

1206. In my opinion, Ozguz discloses limitation [1c] of the '484 patent.

1207. As noted previously, a microprocessor 175 and a transmitter or transceiver 190 forming the computation-communication module are incorporated into "flexible silicon substrates 60, 65, 70 having respective integrated circuits 71, 72, 73." *See* Section XIX.C.1.ii, *supra*; *see also* Ex. 1014 at [0039], [0058]. The

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"thin flexible silicon substrates 60, 65, 70 having respective integrated circuits 71, 72, 73 are bonded to the flexible substrate 55 by an anisotropic epoxy layer 75 or the like." Ex. 1014 at [0039]. Ozguz specifically contemplates that these separate "ICs 71, 72, 73 can be integrated as one IC on a single silicon substrate." *Id.* at [0042].

1208. Therefore, in my opinion, Ozguz discloses "said computation-communication module being attached to a flexible circuit layer."

v. Limitation [1d]

1209. Limitation [1d] recites "an adhesive covering at least a portion of the flexible circuit layer."

1210. In my opinion, Ozguz discloses limitation [1d] of the '484 patent.

1211. Ozguz discloses "[a]dhesive pads 91 [*i.e.*, the claimed "adhesive covering"] are also disposed on the underside 85 of flexible substrate [55]" (*i.e.*, the claimed "flexible circuit layer"). *Id.* at [0049].

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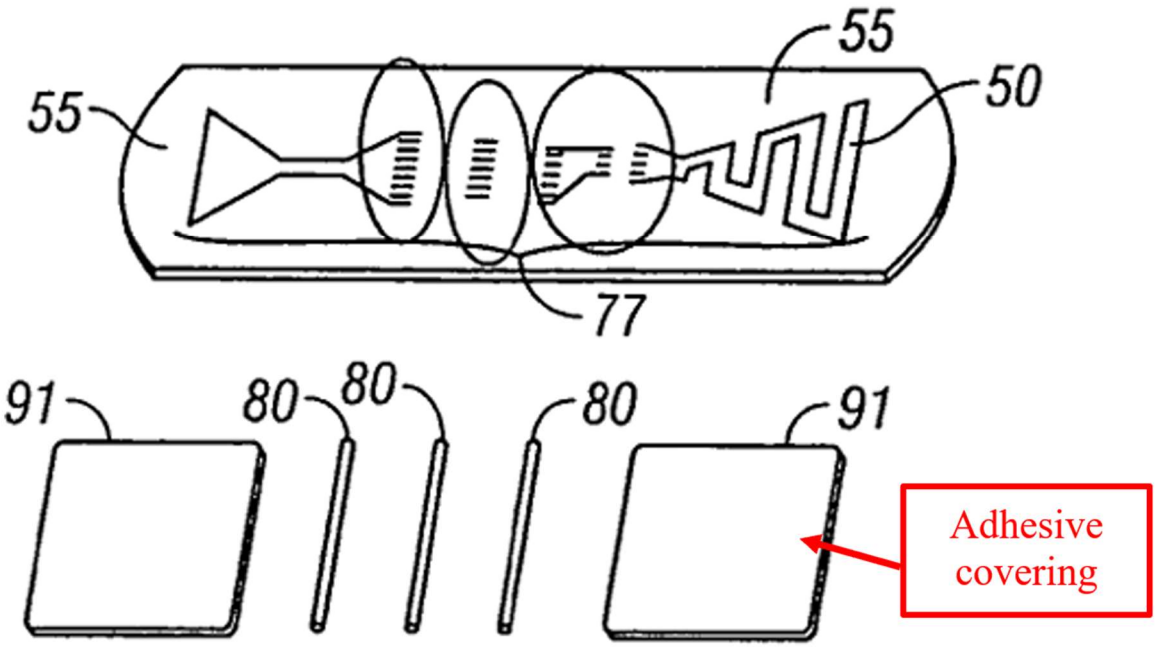
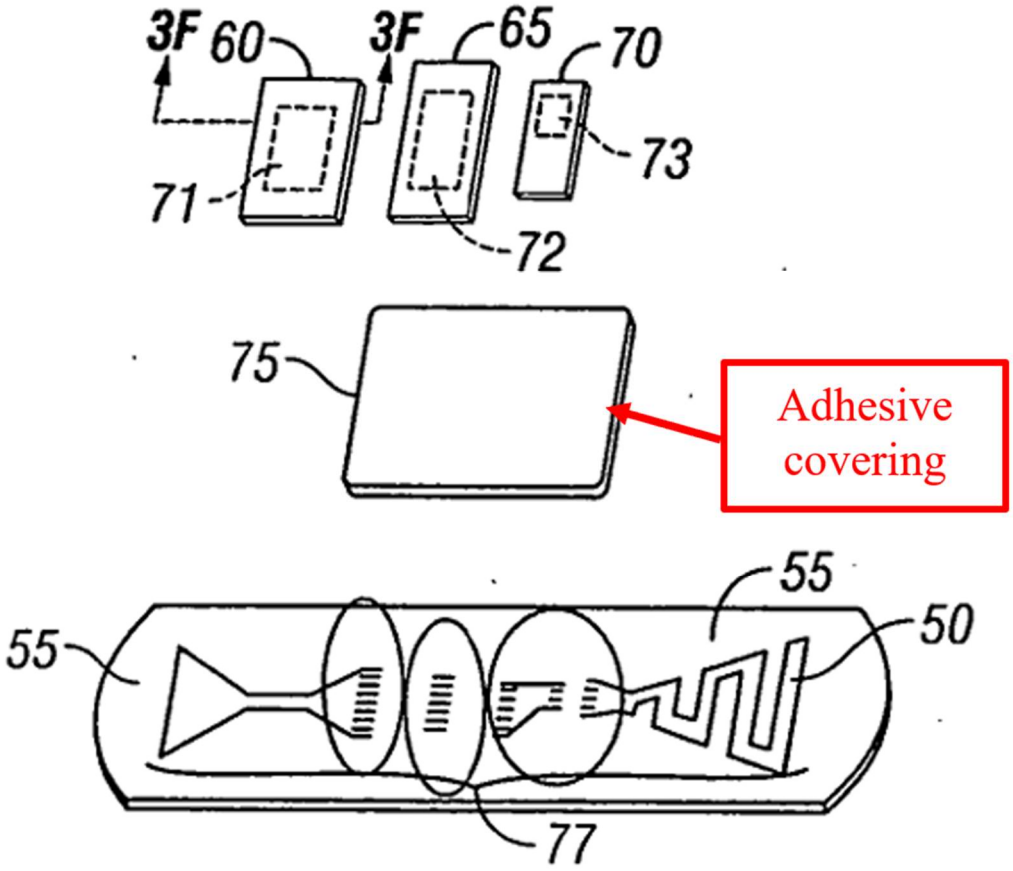


FIG. 3B

Id. at Fig. 3B (annotated).

1212. Additionally, or alternatively, Ozguz discloses an "anisotropic epoxy 75," (*i.e.*, the claimed "adhesive layer") which covers at least part of flexible substrate 55 (*i.e.*, the claimed "flexible circuit layer). *Id.* at [0046]; *see also id.* at Fig. 3B (reproduced below). The anisotropic epoxy is an adhesive that bonds silicon 60, 65, 70 with flexible substrate 55. *Id.*

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Id. at Fig. 3B (annotated).

1213. Thus, in my opinion, Ozguz discloses "an adhesive covering at least a portion of the flexible circuit layer."

vi. Limitation [1e]

1214. Limitation [1e] recites "a protective covering that protects the adhesive."

1215. In my opinion, Ozguz discloses limitation [1e] of the '484 patent.

1216. Ozguz discloses a "protective cover 115" (shown in red below), which covers "adhesive pads 91" (shown in blue below). *See id.* at [0049].

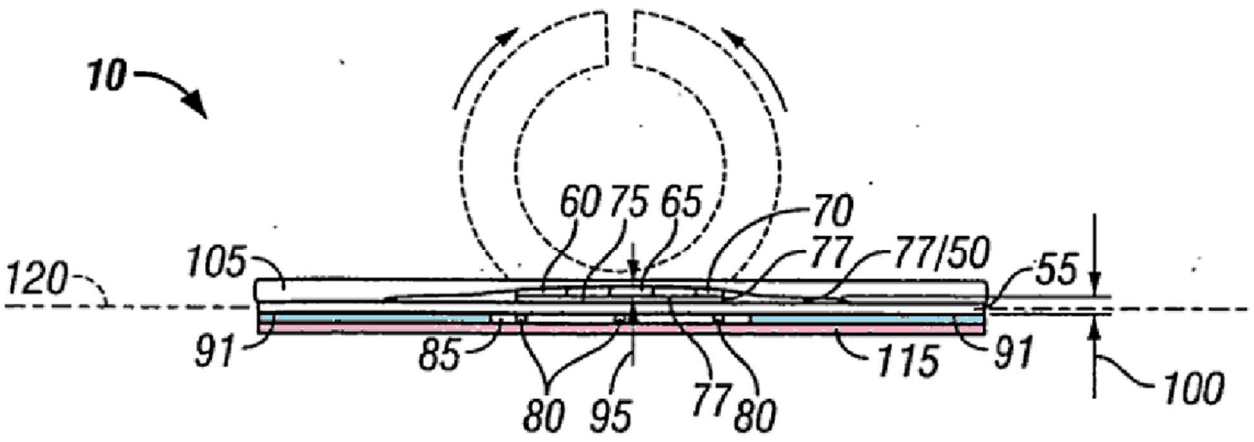


FIG. 3C

Id. at Fig. 3C (annotated).

1217. Additionally, or alternatively, Ozguz discloses an overlying battery 105 (protective covering; shown in red below) that is shaped in a way that it overlays silicon 60, 65, 70 and anisotropic epoxy 75 (adhesive) as well as flexible substrate 55. *Id.* at [0048].

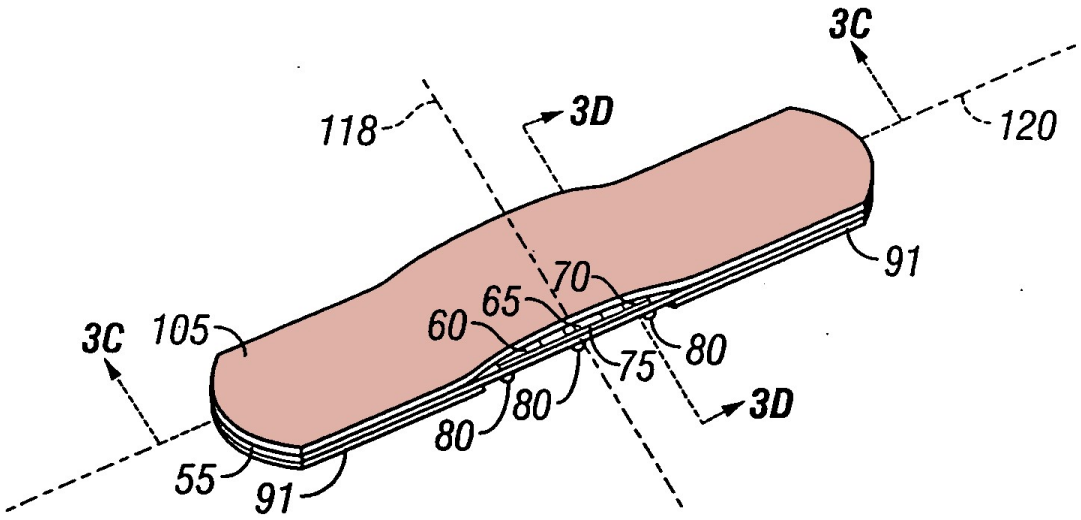


FIG. 3A

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Id. at Fig. 3A (annotated).

1218. Thus, in my opinion, Ozguz discloses "a protective covering that protects the adhesive."

2. Dependent Claim 2

1219. Claim 2 of the '484 patent depends from claim 1 and additionally requires that "the flexible circuit layer has traces of determinable electrical resistance."

1220. In my opinion, claim 2 of the '484 patent is obvious over Ozguz in view of a POSA's general knowledge for all the reasons discussed above with respect to claim 1 as well as because a POSA would understand Ozguz to disclose the additional limitation of claim 2. *See* Section XIX.C.1, *supra*.

1221. Ozguz discloses that "metallization 77 further extends through the flexible substrate 55 and connects the [integrated circuits] ICs 71, 72, 73 to the electrodes 80 disposed on an underside 85 of the flexible substrate 55." Ex. 1014 at [0039]. In my opinion, a POSA would understand metallization 77 to be traces. *See, e.g.*, Ex. 1035 at 129 (using "trace" and "conductor" interchangeably).

1222. Further, in my opinion, a POSA would have understood that metallization—which is a metal—must have a determinable electrical resistance. Indeed, *every* substance has a determinable electrical resistance—it is a physical

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property. *See, e.g.*, Ex. 1060 at 53 ("Electrical Resistance. . . . [E]very particular substance has its own characteristic power of transmitting electrical currents").

1223. For these reasons, it is my opinion that a POSA would understand that Ozguz discloses that "the flexible circuit layer has traces of determinable electrical resistance" and, therefore, that Ozguz, in view of the general knowledge of a POSA, renders obvious claim 2 of the '484 patent.

3. Dependent Claim 3

1224. Claim 3 of the '484 patent depends from claims 1 and 2 and additionally requires that "the traces on the flexible circuit layer are configured to electrically couple the computation-communication module to the flexible circuit layer, thereby forming a disposable module connector."

1225. In my opinion claim 3 of the '484 patent is rendered obvious by Ozguz in view of the knowledge of a POSA for all the reasons discussed above with respect to claims 1 and 2 as well as because Ozguz discloses the additional limitation of claim 3. *See* Section XIX.C.2, *supra*.

1226. As noted previously, Ozguz discloses "a computation-communication module being attached to the flexible circuit layer." *See* Section XIX.C.1.iv, *supra*. Ozguz further discloses that "metallization 77" is "applied to flexible substrate 55" and "interconnects the ICs 71, 72, 73" on flexible silicon 60, 65, 70 "to each other and to the antenna 50." Ex. 1014 at [0039]. Accordingly, Ozguz discloses

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conductive traces on the flexible circuit layer to electrically couple with the attached computation-communication module.

1227. In my opinion, a POSA would understand metallization 77 to form the claimed "disposable module connector." Ozguz discloses that some portions of sensor module 10 are "remov[ed] after each use," while other portions are "used repeatedly." *Id.* at [0049]. In my opinion, a POSA would know that "thin flexible silicon 60, 65, 70," with incorporated "microprocessor 175" and "transmitter [or transceiver] 190" (computation-communication module), would be a portion of sensor module that can be used repeatedly to reduce costs and minimize waste. *Id.* at [0046], [0049], [0058]. On the other hand, flexible substrate 55, whose underside 85 is in contact with a patient's skin, would be a portion of sensor module that a POSA would dispose of to prevent any infections from spreading because of repeated use. In view of these considerations, metallization 77—connecting flexible substrate 55 (a disposable portion) to microprocessor 175 and transmitter or transceiver 190 (the computation-communication module)—would therefore be a disposable module connector.

1228. For these reasons, it is my opinion that Ozguz discloses that "the traces on the flexible circuit later are configured to electrically couple the computation-communication module to the flexible circuit layer, thereby forming a disposable

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module connector" and, therefore, that Ozguz, in view of the general knowledge of a POSA, renders obvious claim 3 of the '484 patent.

4. Dependent Claim 4

1229. Claim 4 of the '484 patent depends from claim 1 and additionally requires that "the traces on the flexible circuit layer are at least partially covered by a non-removable insulating covering."

1230. In my opinion claim 4 of the '484 patent is rendered obvious by Ozguz in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because Ozguz discloses the additional limitation of claim 4. *See* Section XIX.C.1, *supra*.

1231. Ozguz discloses a flexible power source 105, which covers the entire flexible circuit layer (including metallization 77). Ex. 1014 at [0048]. This is shown below in Figure 3A of Ozguz.

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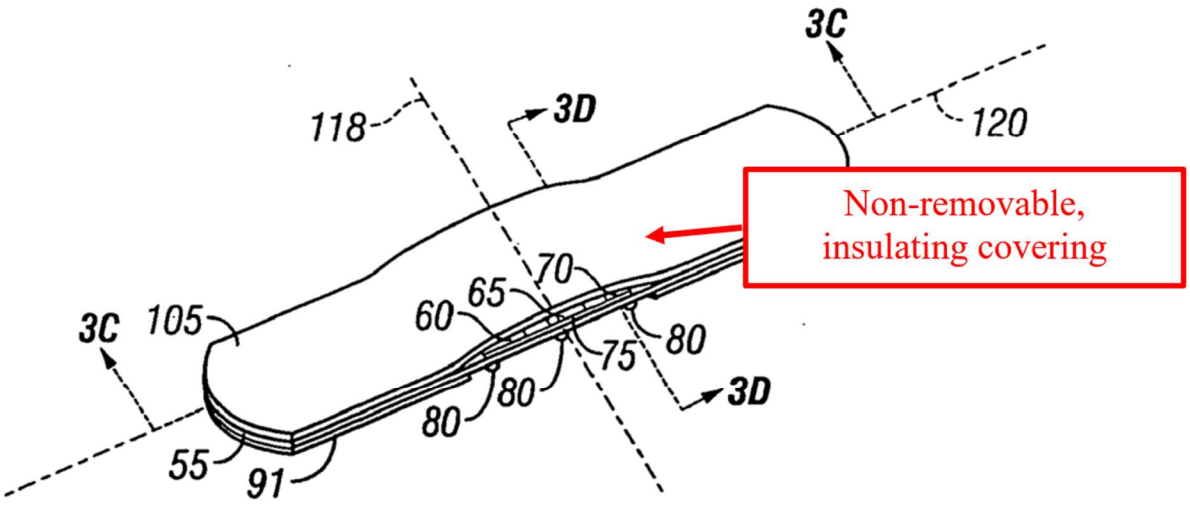


FIG. 3A

Id. at Fig. 3A (annotated).

1232. A POSA would understand that the "flexible, thin battery 105" is not removable and must be insulating to prevent shorts due to unintended contact with other components. *Id.* at [0048].

1233. For these reasons, it is my opinion that Ozguz discloses that "the traces on the flexible circuit layer are at least partially covered by a non-removable insulating covering" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 4 of the '484 patent.

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5. Dependent Claim 5

1234. Claim 5 depends from claim 1 and additionally requires that "the flexible circuit layer further comprises a plurality of openings sized to receive electrodes."

1235. In my opinion claim 5 of the '484 patent is rendered obvious by Ozguz in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because claim 5 would have been obvious to a POSA. *See* Section XIX.C.1, *supra*.

1236. Ozguz discloses a sensor module 10 that includes "electrodes 80 disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20." Ex. 1014 at [0039]. In my opinion, it would have been obvious to a POSA to modify Ozguz's "flexible substrate 55" to form openings in the bottom of the flexible substrate to receive electrode gels. This modification would comprise a simple design change from Ozguz's disclosed construction (in which the electrodes are integrated into "flexible substrate 55"). *Id.*

1237. A POSA would have been motivated to make this change to make Ozguz's device compatible with a variety of commercial, pre-gelled, adhesive, disposable electrodes, such as those manufactured by 3M and well-known in the field, or else to mechanically stabilize a non-commercial gel in Ozguz's device. *See, e.g.*, Ex. 1011 at [0041] (referring to well-known, off-the-shelf electrodes

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manufactured "by 3M Corporation"). Relying on commercially available electrodes (rather than creating a novel electrode 'from scratch') would ease manufacturing and assembly. Further, providing a recess would help to prevent movement of the electrode gels, which was known in the art (*e.g.*, by recessing gels in a cup geometry). Ex. 1061 at 578–79 ("If a portion of the electrode loses contact with the skin, current flow across it is altered because, in effect, the size of the interface changes. Current flow may be altered further if movement allows the conductive medium to dry"); *see also* Ex. 1062 at 203–04.

6. Dependent Claim 6

1238. Dependent claim 6 depends from claim 1 and additionally requires "a hard-wired communication cable."

1239. In my opinion claim 6 of the '484 patent is rendered obvious by Ozguz in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because Ozguz discloses the additional limitation of claim 5.

1240. Ozguz discloses that sensor module 10 can include a "port 86." Ex. 1014 at [0040]. Port 86 connects to "a mating connection 87" of a wire that "physically connect[s] the sensor module 10 to the [computer] 88." *Id.* This is shown in Figure 2B of Ozguz.

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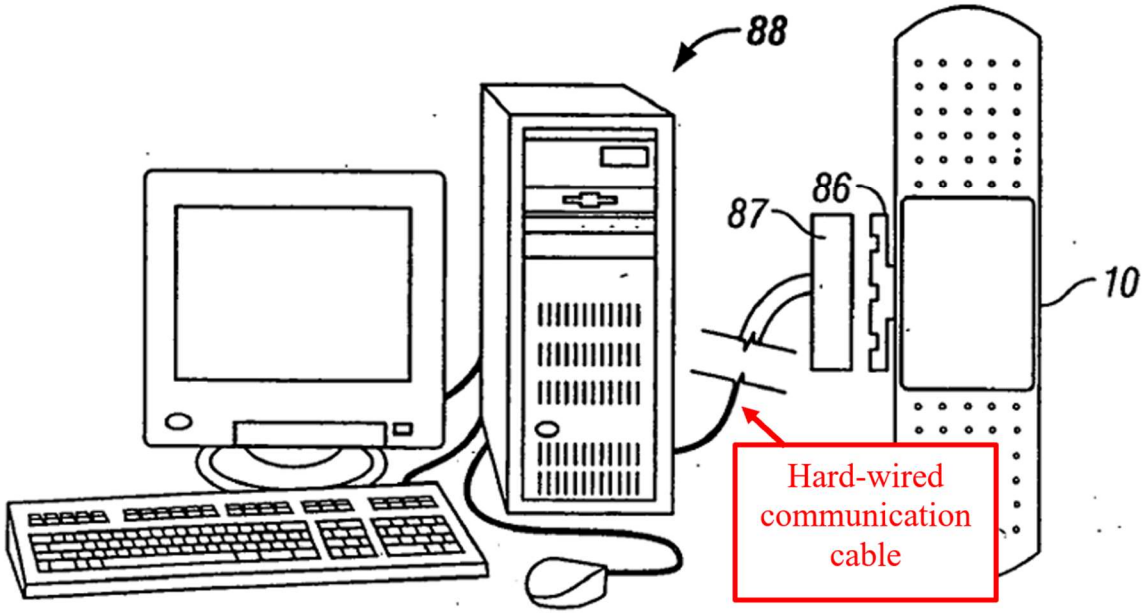


FIG. 2B

Id. at Fig. 2B (annotated).

1241. For these reasons, it is my opinion that Ozguz discloses a "hard-wired communication cable" and, therefore, that Ozguz, in view of the general knowledge of a POSA, renders obvious claim 6 of the '484 patent.

7. Independent Claim 7

i. Preamble 7[pre]

1242. The preamble of claim 7 recites "a body-worn patient monitoring device."

1243. In my opinion, to the extent that the preamble is limiting, Ozguz discloses the preamble of claim 1 of the '484 patent.

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1244. Ozguz discloses "a sensor system comprising a thin flexible ambulatory/self contained bio-sensor module in a form similar to an adhesive bandage for sensing physiologically modulated signals from the body." *Id.* at [0003]. Figure 2A of Ozguz shows sensor module 10 (shown in red) being worn on the body of a patient. *Id.* at [0038]–[0039].

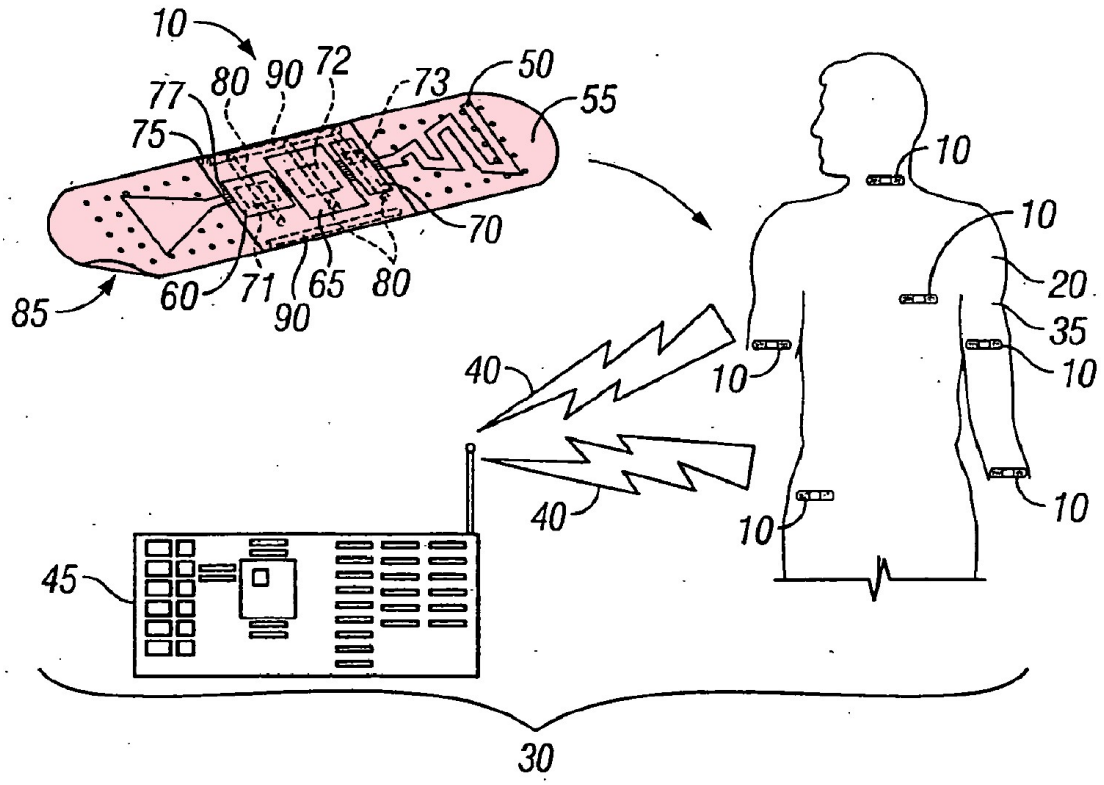


FIG. 2A

Id. at Fig. 2A (annotated).

1245. Thus, in my opinion, Ozguz discloses "a body-worn patient monitoring device."

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ii. Limitation [7a]

1246. Limitation [7a] of the '484 patent recites "a disposable electrode portion comprising."

1247. In my opinion, Ozguz discloses limitation [7a] of the '484 patent.

1248. As noted above, Ozguz discloses that some portions of sensor module 10 are "remov[ed] after each use," while other portions are "used repeatedly." *See* Section XIX.C.3, *supra* (citing Ex. 1014 at [0049]). A POSA would understand that "flexible substrate 55", whose underside is in direct contact with the patient's skin, would be a portion of the sensor module that a POSA would discard/dispose of for hygienic reasons. *Id.* Accordingly, the flexible substrate 55 is a "disposable electrode portion."

1249. Thus, in my opinion, Ozguz discloses "a disposable electrode portion."

iii. Limitation [7b]

1250. Limitation [7b] recites "a flexible printed circuit layer made from an insulating material and defining a substrate."

1251. In my opinion, Ozguz discloses limitation [7b] of the '484 patent.

1252. Ozguz discloses that "flexible substrate 55" includes "metallization 77" that interconnects "integrated circuits 71, 72, 73" and other components to form a circuit board layer. Ex. 1014 at [0039].

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1253. Ozguz further discloses that flexible substrate 55 is made of an insulating material, "preferably in the form of a polyimide, and is electrically non-conductive and flexible. However other flexible non-conducting substrates can be substituted." *Id.* at [0046]. A POSA would have recognized that Ozguz's flexible substrate 55 comprises a flexible printed circuit board and, therefore, comprises a flexible printed circuit layer. *Cf.* Ex. 1035 at 4–5 (defining printed circuit board's essential components as base of insulating material and conductors).

1254. Thus, in my opinion, Ozguz discloses "a flexible printed circuit layer made from an insulating material and defining a substrate."

iv. Limitation [7c]

1255. Limitation [7c] recites "at least two electrodes being disposed onto a surface of the substrate."

1256. In my opinion, Ozguz discloses limitation [7c] of the '484 patent.

1257. Ozguz teaches that sensor module 10 includes "electrodes 80 disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20." Ex. 1014 at [0039].

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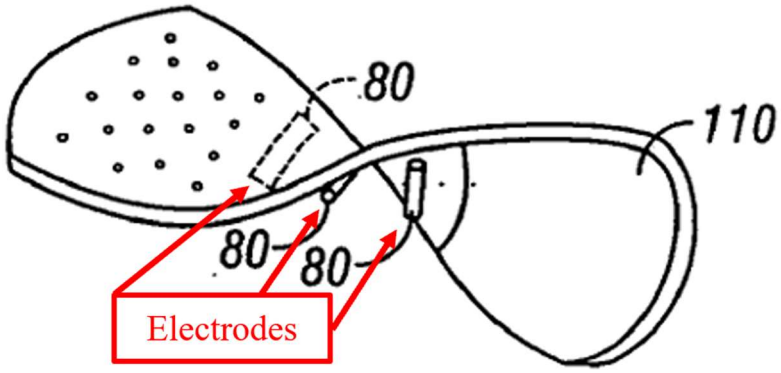


FIG. 3E

Id. at Fig. 3E (annotated).

1258. Thus, in my opinion, Ozguz discloses "at least two electrodes being disposed on to a surface of the substrate."

v. Limitation [7d]

1259. Limitation [7d] recites "electrical traces defined between the at least two electrodes, and a connection pad."

1260. In my opinion, Ozguz discloses limitation [7d] of the '484 patent.

1261. Ozguz discloses that "metallization 77 further extends through the flexible substrate 55 and connects the [integrated circuits] ICs 71, 72, 73 to the electrodes 80 disposed on an underside 85 of the flexible substrate 55. . . ." *Id.* at [0039]. In my opinion, a POSA would understand metallization 77 to be electrical traces. *See* Section XIX.C.2, *supra*. *See, e.g.*, Ex. 1035 at 129 (using "trace" and "conductor" interchangeably).

1262. Ozguz further discloses "a pair of electrodes 90" that "extend longitudinally relative to the sensor module 10" and which contact the metallization. Ex. 1014 at [0043].

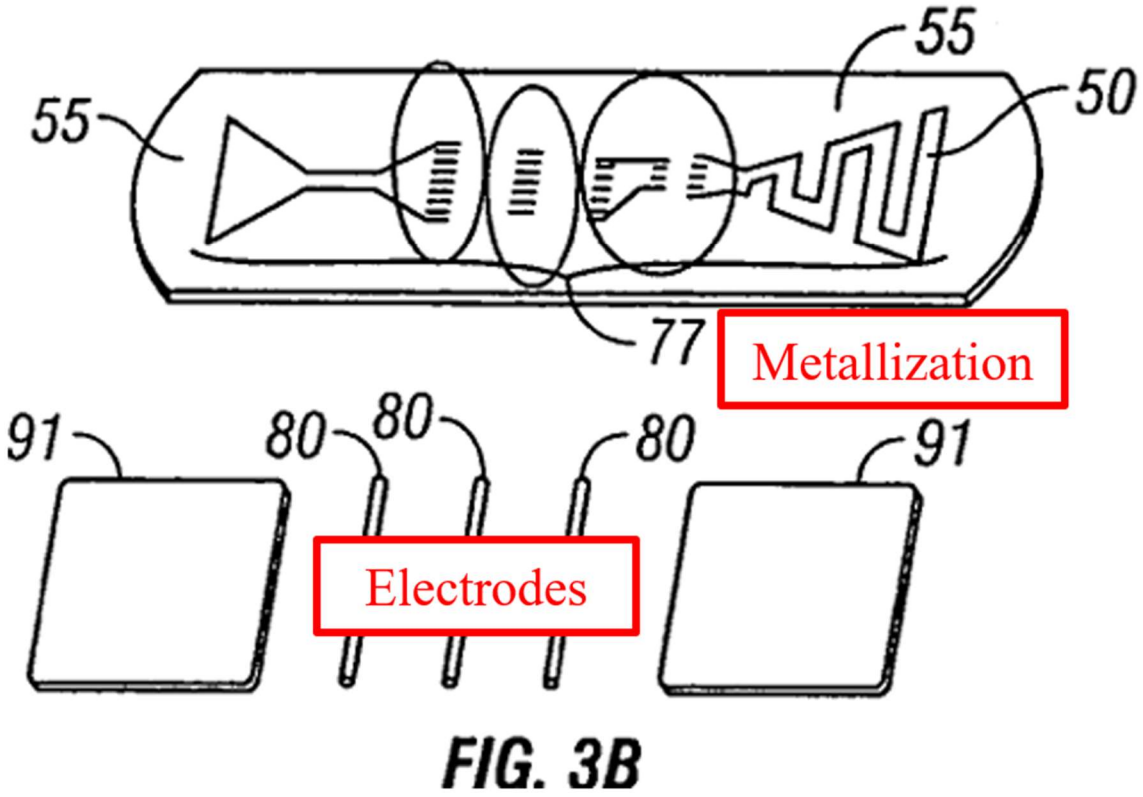


FIG. 3B

Id. at Fig. 3B (annotated).

1263. Ozguz also teaches "a connection pad." Specifically, the electrodes 80 "located on a lower surface 85 of flexible substrate 55" and "metallization 77" on the upper surface of flexible substrate 55 are electrically connected through "flexible substrate 55." *Id.* at [0048]. A POSA would understand that the portion of metallization that connects the electrodes to the overlying silicon circuit of Ozguz is a connection pad. *Id.*; *see also* Ex. 1035 at 656 (defining "pad" as "[a] portion of

the conductive area of which components, terminals, traces, etc., are mechanically attached").

1264. Thus, in my opinion, Ozguz discloses "electrical traces defined between the at least two electrodes, and a connection pad."

vi. Limitation [7e]

1265. Limitation [7e] recites "a reusable communication module, comprising."

1266. In my opinion, a POSA would recognize that Ozguz discloses limitation [7e] of the '484 patent.

1267. As noted above, Ozguz discloses a communication module: "flexible silicon 60, 65, 70 having respective integrated circuits 71, 72, 73" with "transmitter or transceiver 190 for transmitting data by RF signals to a remote receiver" (communication module) and "microprocessor 175." *See* Section XIX.C.1.ii, *supra*; Ex. 1014 at [0046], [0058]; *see also* Ex. 1014 at [0039].

1268. A POSA would know that "flexible silicon 60, 65, 70 having respective integrated circuits 71, 72, 73" with "transmitter or transceiver 190" (communication module) and "microprocessor 175" would be a portion of sensor module 10 that would be used repeatedly to reduce costs and minimize waste. *See* Section XIX.C.3, *supra*. This portion can be "sterilized in an autoclave" for repeated use, as contemplated by Ozguz. Ex. 1014 at [0049].

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1269. Accordingly, in my opinion, a POSA would recognize that Ozguz discloses "a reusable communication module."

vii. Limitation [7f]

1270. Limitation [7f] recites "a housing containing a processor."

1271. In my opinion, Ozguz discloses limitation [7f] of the '484 patent.

1272. Ozguz discloses "microprocessor 175" that is "incorporated into thin silicon substrates 60, 65, 70." *Id.* at [0058]. Sensor module 10 includes a "flexible, thin battery 105" that "overlays the silicon substrates 60, 65, 70 and their respective ICs 71, 72, 73." *Id.* at [0048]. On the other side, "silicon substrates 60, 65, 70" are disposed on "flexible substrate 55." *Id.* at [0039]. Microprocessor 175 of the communication module is therefore housed between overlay 105 and "flexible substrate 55." *Id.* Accordingly, Ozguz's processor is contained in a housing formed by the flexible battery 105 and flexible substrate 55.

1273. Thus, in my opinion, Ozguz discloses "a housing containing a processor."

viii. Limitation [7g]

1274. Limitation [7g] recites "a wireless communication unit, and in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip."

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1275. In my opinion, a POSA would recognize that Ozguz discloses limitation [7g] of the '484 patent.

1276. Ozguz discloses that sensor module 10 functions as a wireless data collection device. *Id.* at Abstract. To that end, "silicon substrates 60, 65, 70" located on flexible substrate 55 incorporate "transmitter or transceiver 190 for transmitting data by RF signals to a remote receiver." *Id.* at [0058].

1277. As noted above, Ozguz discloses a "disposable electrode portion" and a "reusable communication module." *See* Sections XIX.C.7.ii, XIX.C.7.vi, *supra*. In my opinion, a POSA would have understood that the disposable electrode portion and reusable communication module must be releasably attached to one another so that the disposable portion may be discarded and the reusable component may be "sterilized in an autoclave" for repeated use, as contemplated by Ozguz. Ex. 1014 at [0049]. A POSA would have further recognized that latching is one of a finite number of options for mechanically attaching "disposable electrode portion" and "reusable communication module" together.

1278. Both latches and snaps were commonly known and used in the art at the time. *See, e.g.*, Ex. 1005 at 9:32–44; *see also* Section IV.D, *supra.*

1279. In my opinion, a POSA would have understood a snap mechanism and a latch mechanism to be interchangeable for the purpose of attaching two components of a medical device such as a body-worn monitor. *See, e.g.*, Ex. 1039

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at [0046] (discussing use of snap connectors to attach a monitoring device to 12-lead recorders), Fig. 5; Ex. 1040 at 30 ("Labeling").

1280. Thus, in my opinion, Ozguz and the general knowledge of a POSA render obvious "a wireless communication unit, and in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip."

ix. Limitation [7h]

1281. Limitation [7h] recites "a hard-wired communication cable."

1282. In my opinion, Ozguz discloses limitation [7h] of the '484 patent.

1283. As shown in Figure 2B, Ozguz teaches "a port 86 on the sensor module 10 and a mating connection 87 connected to a PC 88 for physically connecting the sensor module 10 to the PC 88 or other processor for downloading, analyzing, and archiving collected data." Ex. 1014 at [0040].

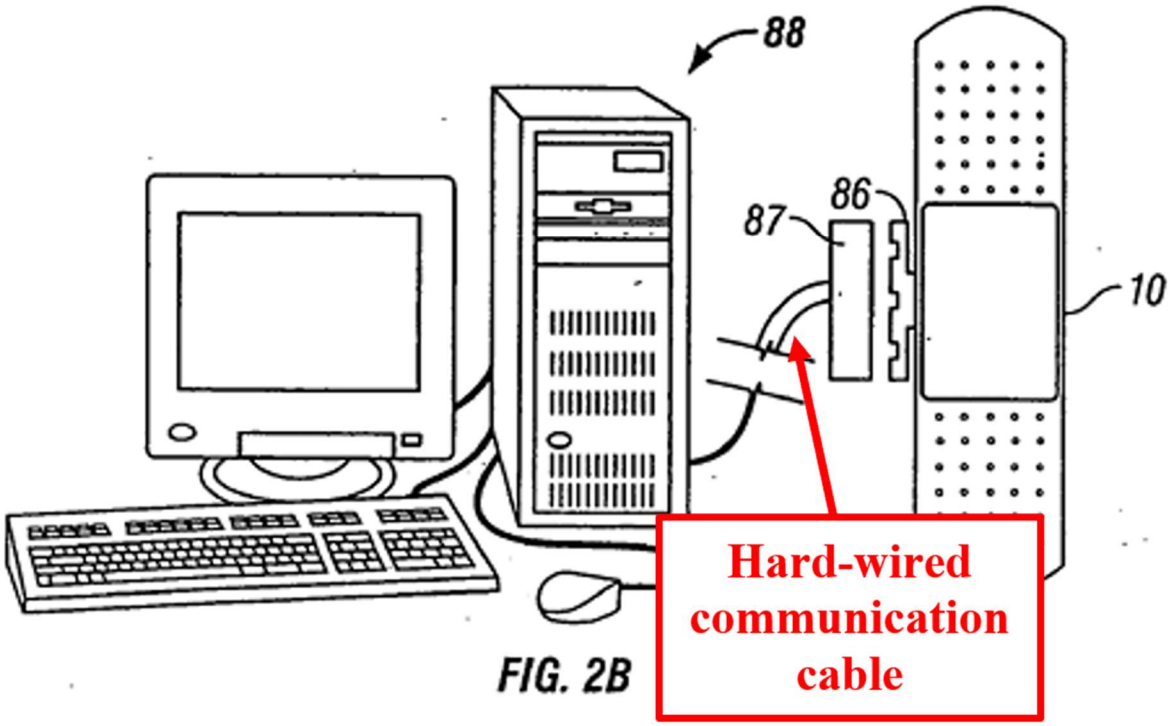


FIG. 2B

Id. at Fig. 2B (annotated).

1284. This hard-wired connection, along with a non-volatile memory in Ozguz's device, can be used "in case power is lost to the sensor module." *Id.* at [0040].

1285. Thus, in my opinion, Ozguz discloses "a hard-wired communication cable."

8. Dependent Claim 8

1286. Dependent claim 8 depends from claim 7 and additionally requires that "the electrodes are integrated into the flexible circuit layer of the disposable electrode portion."

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1287. In my opinion, claim 8 of the '484 patent is rendered obvious by Ozguz in view of the general knowledge of a POSA for all the reasons discussed above with respect to claim 7 as well as because Ozguz teaches the additional limitation of claim 8. *See* Section XIX.C.7, *supra*.

1288. Ozguz discloses "sensor module 10" which includes "electrodes 80 disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20." Ex. 1014 at [0039].

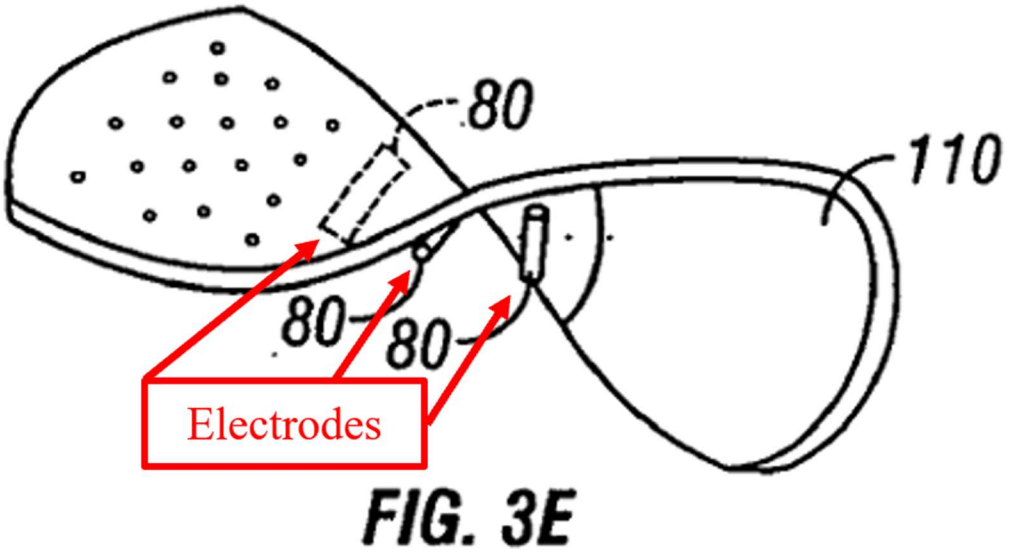


FIG. 3E

Id. at Fig. 3E (annotated).

1289. Thus, it is my opinion that Ozguz discloses that "the electrodes are integrated into the flexible circuit layer of the disposable electrode portion" and, therefore, that the combination of Ozguz and the general knowledge of a POSA renders obvious claim 8 of the '484 patent.

9. Independent Claim 15

1290. In my opinion, claim 15 of the ’484 patent is rendered obvious by Ozguz in view of the general knowledge of a POSA.

i. Preamble 15[pre]

1291. The preamble of claim 15 recites “a body-worn physiological sensor.”

1292. As described with respect to claim 1, to the extent that the preamble is limiting, it is my opinion that Ozguz discloses “a body-worn physiological sensor.” *See* Section XIX.C.1.i, *supra*.

ii. Limitation [15a]

1293. Limitation [15a] recites “a computation-communication module including a housing retaining a processor.”

1294. As explained with respect to claim 1, it is my opinion that Ozguz discloses “a computation-communication module including a housing retaining a processor.” *See* Section XIX.C.1.ii, *supra*.

iii. Limitation [15b]

1295. Limitation [15b] recites “a flexible printed circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals.”

1296. As explained with respect to Claim 1, it is my opinion that Ozguz discloses “a flexible printed circuit layer configured to be coupled to a skin surface

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of a subject to measure physiological signals." *See* Sections XIX.C.1.iii, XIX.C.7.ii, *supra*.

iv. Limitation [15c]

1297. Limitation [15c] recites "the computation-communication module being attached to the flexible printed circuit layer."

1298. As explained with respect to claim 1, it is my opinion that Ozguz discloses "the computation-communication module being attached to the flexible printed circuit layer." *See* Section XIX.C.1.iv, *supra*.

v. Limitation [15d]

1299. Limitation [15d] recites "an adhesive covering at least a portion of the flexible printed circuit layer."

1300. As explained above with respect to claim 1, it is my opinion that Ozguz discloses "an adhesive covering at least a portion of the flexible printed circuit layer." *See* Section XIX.C.1.v, *supra*.

vi. Limitation [15e]

1301. Limitation [15e] recites "a protective covering for the flexible printed circuit layer."

1302. In my opinion, Ozguz discloses limitation [15e] of the '484 patent.

1303. As described previously above, Ozguz discloses a "protective covering." *See* Section XIX.C.1.vi, *supra*.

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1304. Ozguz discloses that "protective cover 115" (shown in red below) covers the "underside 85" of "flexible substrate 55" (shown in blue below). Ex. 1014 at [0039], [0048]–[0049].

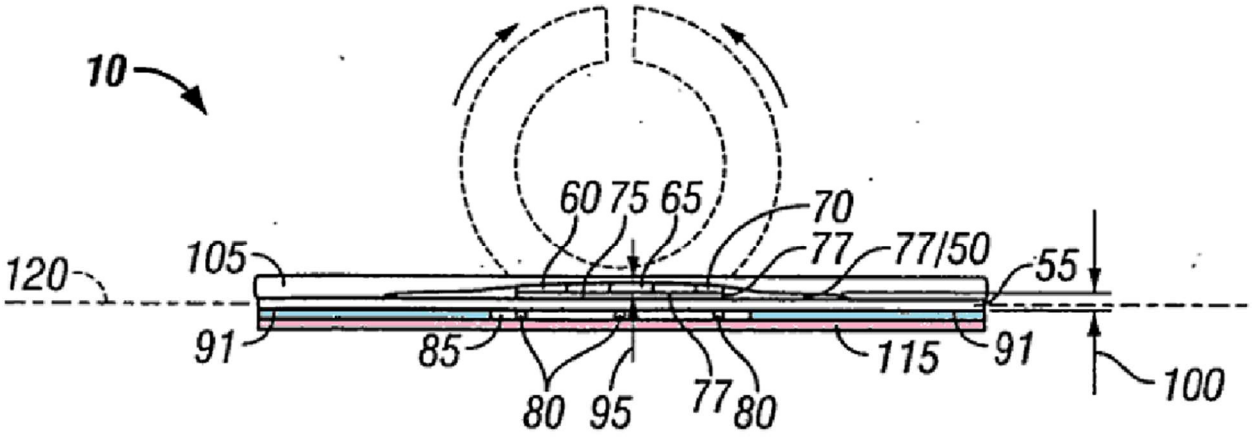


FIG. 3C

Id. at Fig. 3C (annotated).

1305. Additionally, or alternatively, Ozguz discloses an overlying battery 105 (protective covering) that is shaped in a way that overlays silicon 60, 65, 70 and anisotropic epoxy 75 (adhesive) as well as flexible substrate 55. *Id.* at [0048].

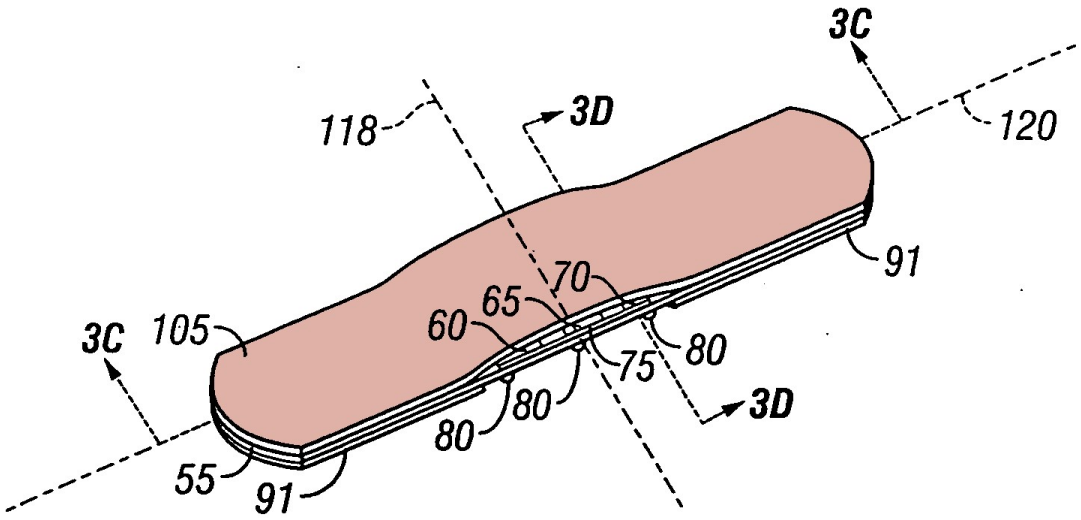


FIG. 3A

Id. at Fig. 3A (annotated).

1306. Thus, in my opinion, Ozguz discloses "a protective covering for the flexible printed circuit layer."

10. Dependent Claim 19

1307. Claim 19 depends from claim 15 and additionally requires that "the computation communication module is releasably attached to the flexible printed circuit layer."

1308. In my opinion, claim 19 of the '484 patent is rendered obvious by Ozguz in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 15 as well as because a POSA would understand Ozguz as disclosing the additional limitation of claim 19. *See* Section XIX.C.9, *supra*.

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1309. Ozguz discloses that some portions of sensor module 10 are "remov[ed] after each use," while other portions are "used repeatedly." Ex. 1014 at [0049]. A POSA would know that "flexible silicon 60, 65, 70" with incorporate "microprocessor 175" and "transmitter or transceiver 190" (computation-communication module), would be a portion of sensor module that can be used repeatedly to reduce costs and minimize waste. On the other hand, flexible substrate 55, whose underside 85 is in contact with a patient's skin, would be a portion of sensor module that a POSA would seek to discard/dispose of to prevent any infections from spreading as a result of repeated use. Ozguz therefore discloses that the disposable flexible printed circuit layer is releasably attached from the portions of Ozguz that would be reused, such as "microprocessor 175" and "transmitter or transceiver 190" (computation-communication module).

1310. For these reasons, it is my opinion that a POSA would understand that Ozguz discloses that "the computation communication module is releasably attached to the flexible printed circuit layer" and, therefore, that Ozguz, in view of the general knowledge of a POSA, renders obvious claim 19 of the '484 patent.

11. Dependent Claim 20

1311. Claim 20 depends from claim 15 and additionally requires that "the protective covering covers the adhesive."

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1312. In my opinion, in addition to teaching all of the limitations of claim 15, Ozguz teaches that "the protective covering covers the adhesive" for the reasons set forth above with respect to claim 1. *See* Section XIX.C.1.vi, *supra*.

D. Ground 4: Obvious Over Matsumura, Ozguz, and General Knowledge of a Person of Ordinary Skill in the Art

1. A POSA Would Have Been Motivated to Combine Matsumura and Ozguz

1313. For the reasons set forth above in Section XVII.B.1, with reference to the '007 patent, a POSA would have had motivation to combine the teachings of Matsumura and Ozguz.

2. Dependent Claim 6

1314. Claim 6 depends from claim 1 and additionally requires "a hard-wired communication cable."

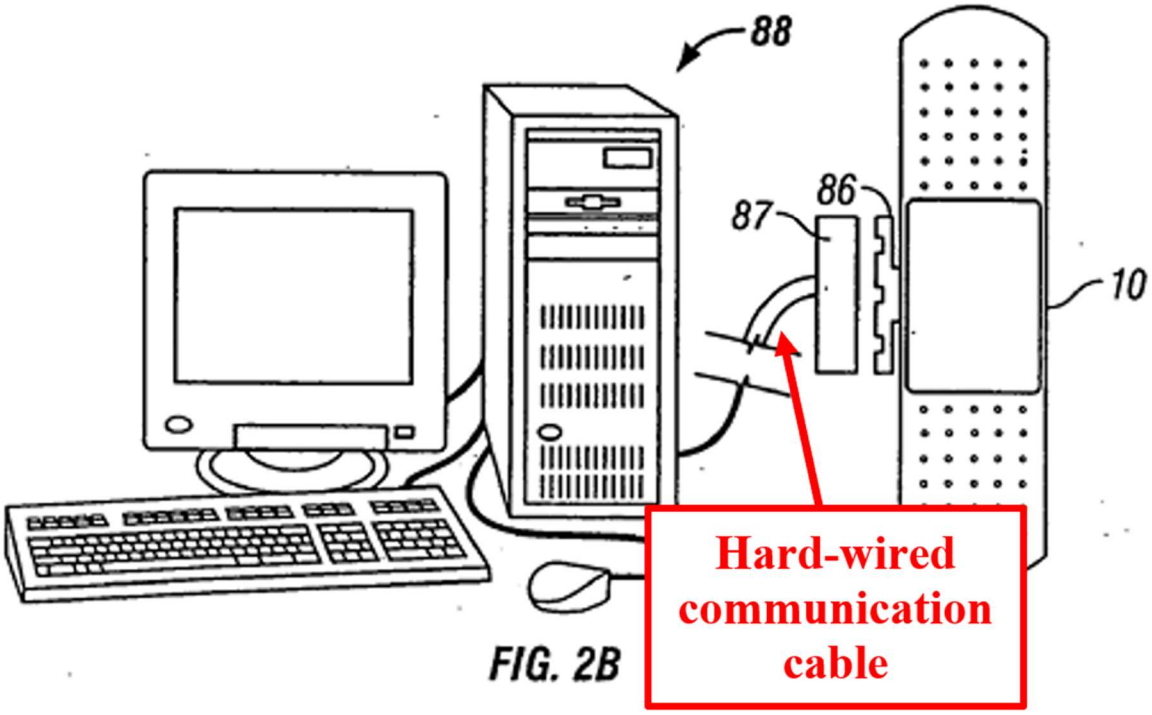
1315. In my opinion, in addition to teaching all of the limitations of claim 1, the combination of Matsumura and Ozguz renders obvious "a hard-wired communication cable." *See* Section XIX.A.1, *supra*.

1316. In the first instance, a POSA seeking to make or use Matsumura's invention would have recognized that a device capable only of wireless communication would present downsides. *Cf.* Ex. 1012 at [0025], [0036]. Specifically, a POSA would recognize a number of likely situations would limit the ability of the device to transfer important patient health information wirelessly,

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including, for example: the wireless communication module could break, the battery could die, firmware installation could be required during manufacturing before wireless communication would be possible, or wireless communication networks could be subject to interference or interruption. Accordingly, in my opinion, it would have been obvious to a POSA to include a hard-wired communication cable as a backup to the wireless communication module in Matsumura.

1317. To the extent that it would not have been obvious to include a hard-wired communication cable as a backup to wireless communications, Ozguz discloses "a sensor module 10 adhered to the skin 15 of a subject body 20" that can wirelessly transmit detected signals to a remote receiver device. Ex. 1014 at [0038]–[0039]. As shown in Figure 2B, Ozguz also teaches "a port 86 on the sensor module 10 and a mating connection 87 connected to a PC 88 for physically connecting the sensor module 10 to the PC 88 or other processor for downloading, analyzing, and archiving collected data." *Id.* at [0040].



Id. at Fig. 2B (annotated).

1318. As noted above, *see* Section XVII.B.1, *supra*, this hard-wired connection can be used to efficiently transmit a large quantity of detected signals stored in non-volatile memory "in case power is lost to the sensor module." Ex. 1014 at [0040]. The hard-wired connection can also be used to recover data in case power is never restored to the sensor module. In my opinion, a POSA would have looked to add "port 86" of Ozguz to the bioelectric potential detector 11 taught by Matsumura to be connected to "mating connection 87."

1319. Thus, it is my opinion that Matsumura and Ozguz together disclose that "a hard-wired communication cable" and, therefore, that the combination of Matsumura and Ozguz renders obvious claim 6 of the '484 patent.

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3. Independent Claim 7

1320. In my opinion, claim 7 of the ’484 patent is rendered obvious the combination of Matsumura and Ozguz.

i. Preamble 7[pre]

1321. The preamble of claim 7 recites “a body-worn patient monitoring device.”

1322. In my opinion, to the extent that the preamble is limiting, Matsumura and Ozguz disclose the preamble of claim 1 of the ’484 patent.

1323. Matsumura discloses a body-worn patient monitoring device which it refers to as a “bioelectric potential detector.” Ex. 1012 at Abstract, [0006], [0014].

1324. Ozguz also discloses a body-worn patient monitoring device. Ex. 1014 at [0003], [0010].

1325. Thus, in my opinion, each of Matsumura and Ozguz discloses “a body-worn patient monitoring device.”

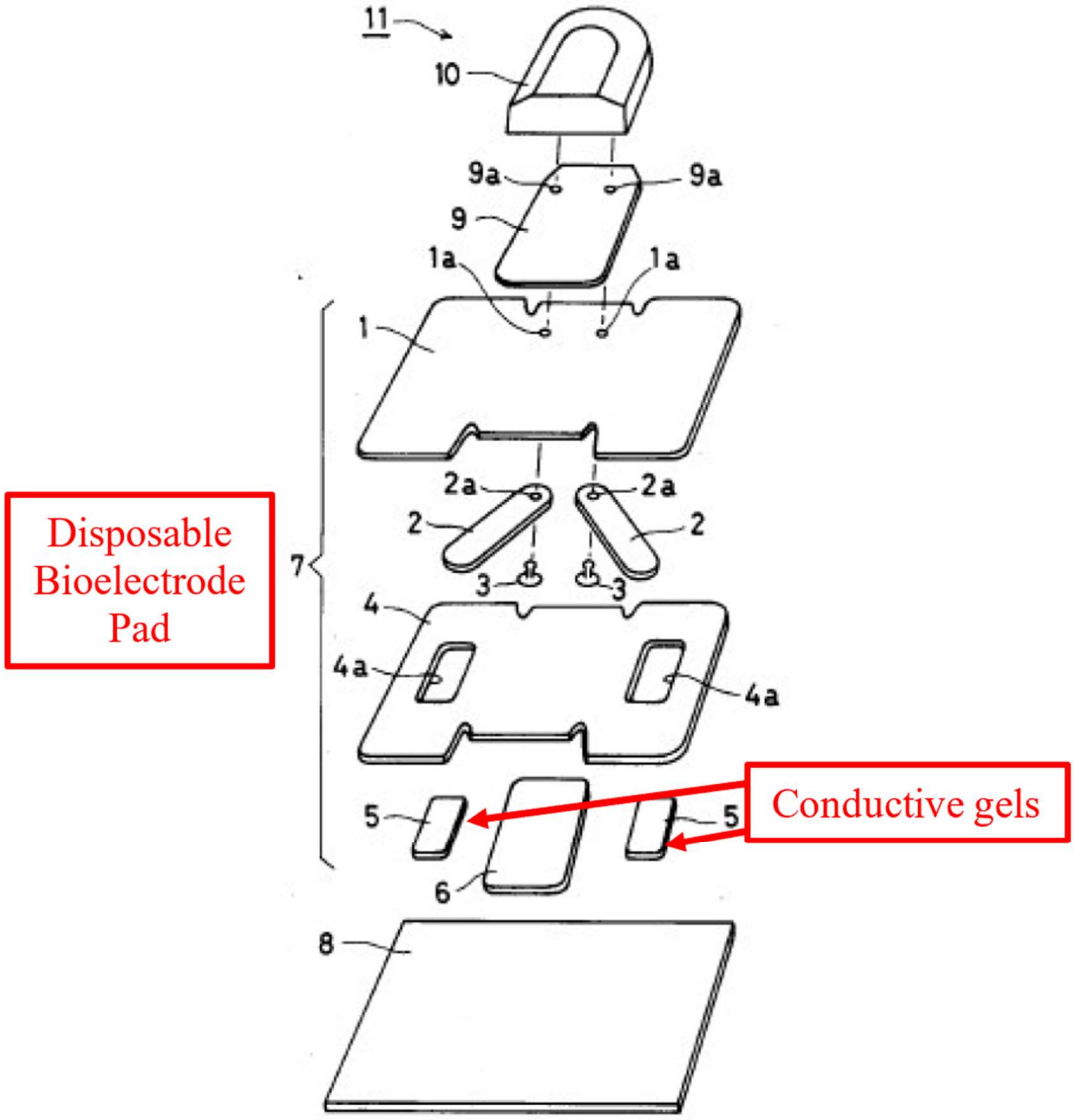
ii. Limitation [7a]

1326. Limitation [7a] of the ’484 patent recites “a disposable electrode portion comprising.”

1327. In my opinion, Matsumura discloses limitation [7a] of the ’484 patent.

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1328. As shown in Matsumura's Figure 1, reproduced below, Matsumura discloses that "disposable bioelectrode pad 7" includes "conductive gel 5" (electrode portion) used to detect bioelectrical potentials. Ex. 1012 at Abstract, [0016], [0018].



Id. at Fig. 1 (annotated).

1329. Thus, in my opinion, Matsumura discloses "a disposable electrode portion."

iii. Limitation [7b]

1330. Limitation [7b] recites "a flexible printed circuit layer made from an insulating material and defining a substrate."

1331. In my opinion, a POSA would recognize that Matsumura renders obvious limitation [7b] of the '484 patent.

1332. It would have been obvious to a POSA to modify Matsumura's conductive material 2 to comprise a flexible printed circuit layer configured to be coupled to a skin surface of a subject to measure physiological signals. *See* Section XIX.A.6.iii, *supra*. The circuit layer of Matsumura comprises "two pieces of conductive material 2," which "can be a carbon sheet or a PET sheet [which are insulating material] coated with conductive Ag/AgCl." Ex. 1012 at [0019]–[0020], Fig 1. A POSA would recognize that, as modified, Matsumura's conductive material would comprise a flexible printed circuit made from an insulating material and which, if combined with second sheet 4, would form a flexible printed circuit layer and define a substrate. *Id.* at [0017]–[0018].

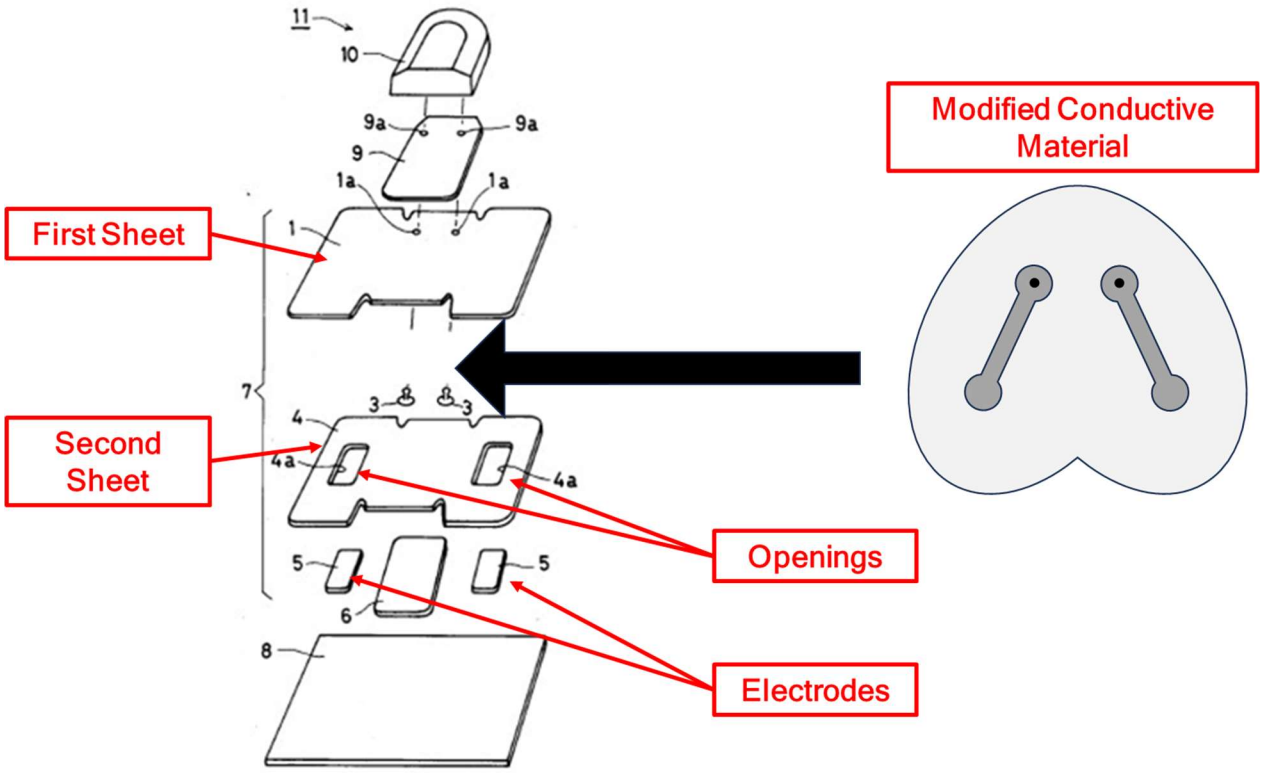
1333. Thus, in my opinion, a POSA would recognize Matsumura renders obvious "a flexible printed circuit layer made from an insulating material and defining a substrate."

iv. Limitation [7c]

1334. Limitation [7c] recites "at least two electrodes being disposed onto a surface of the substrate."

1335. In my opinion, Matsumura discloses limitation [7c] of the '484 patent.

1336. Matsumura discloses "disposable bioelectrode pad 7" that includes "conductive gel[s] 5" (electrodes) used to detect bioelectrical potentials. These "conductive gel[s]" are disposed in two openings 4a in second sheet 4. *Id.* at [0018]–[0019]. A POSA would recognize that the electrodes are bonded together with the other components of the disposable bioelectrode pad, including the sheet of conductive material 2 with which the electrodes make contact. *Id.* at [0019]. Conductive gels 5 (electrodes) are therefore disposed on a surface of "disposable bioelectrode pad 7" (disposable substrate) of Matsumura. *Id.* at [0018]–[0019].



Id. at Fig. 1 (annotated).

1337. Thus, in my opinion, Matsumura discloses "at least two electrodes being disposed on to a surface of the substrate."

v. Limitation [7d]

1338. Limitation [7d] recites "electrical traces defined between the at least two electrodes, and a connection pad."

1339. In my opinion, Matsumura renders obvious limitation [7d] of the '484 patent.

1340. As explained above, a POSA would have been motivated to combine conductive material 2 onto a single, printed sheet, thereby forming a flexible printed

circuit. *See* Section XIX.D.3.iii, *supra*. As modified, traces run "between the at least two electrodes" (*i.e.,* the conductive gels 5). Specifically, there is an electrical connection from one electrode to the printed trace it contacts; from the printed trace to the hook at its end; from the hook to the signal processor; from the signal processor to the other hook; from the other hook down the length of the other electrical trace; and from the other electrical trace to the other electrode.

1341. A POSA would understand that where Matsumura's hooks contact the traces of the flexible printed circuit layer constitutes a connection pad because it forms an electrical connection between the signal processor 10 and the traces leading to the electrodes 5. *See* 1012 at [0019]; Ex. 1035 at 656 (defining "pad" as "[a] portion of the conductive area of which components, terminals, traces, etc., are mechanically attached").

1342. Thus, in my opinion, Matsumura discloses "electrical traces defined between the at least two electrodes and a connection pad."

vi. Limitation [7e]

1343. Limitation [7e] recites "a reusable communication module comprising."

1344. In my opinion, Matsumura discloses limitation [7e] of the '484 patent.

1345. Matsumura discloses a "reusable signal processor" which is a module that is "detachable with hooks" from disposable bioelectrode portion 7. Ex. 1012 at

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[0016]; *see also id.* at [0008], [0014], [0025], Figs. 1–2. The reusable signal processor incorporates components for computation: a "processing circuit for filtering and amplifying detected bioelectric potential signals" and "a memory for storing the processed bioelectric potential signal." *Id.* at [0025]. The reusable signal processor also incorporates components for communication: "a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna." *Id.*

1346. Thus, in my opinion, Matsumura discloses "a reusable communication module."

vii. Limitation [7f]

1347. Limitation [7f] recites "a housing containing a processor."

1348. In my opinion, Matsumura discloses limitation [7f] of the '484 patent.

1349. Matsumura discloses that reusable "signal processor 10" is enclosed in housing 10c which can be "easily attached and detached" to bioelectrode pad 7. *Id.* at [0025], [0027], [0029], [0041]. "[S]ignal processor 10 incorporates a processing circuit for filtering and amplifying detected bioelectric potential signals." *Id.* at [0025]. The processing circuit is disposed within housing 10c to ensure signal processor 10 is waterproof. *Id.* at [0025], [0027], [0029].

1350. Thus, in my opinion, Matsumura discloses "a housing containing a processor."

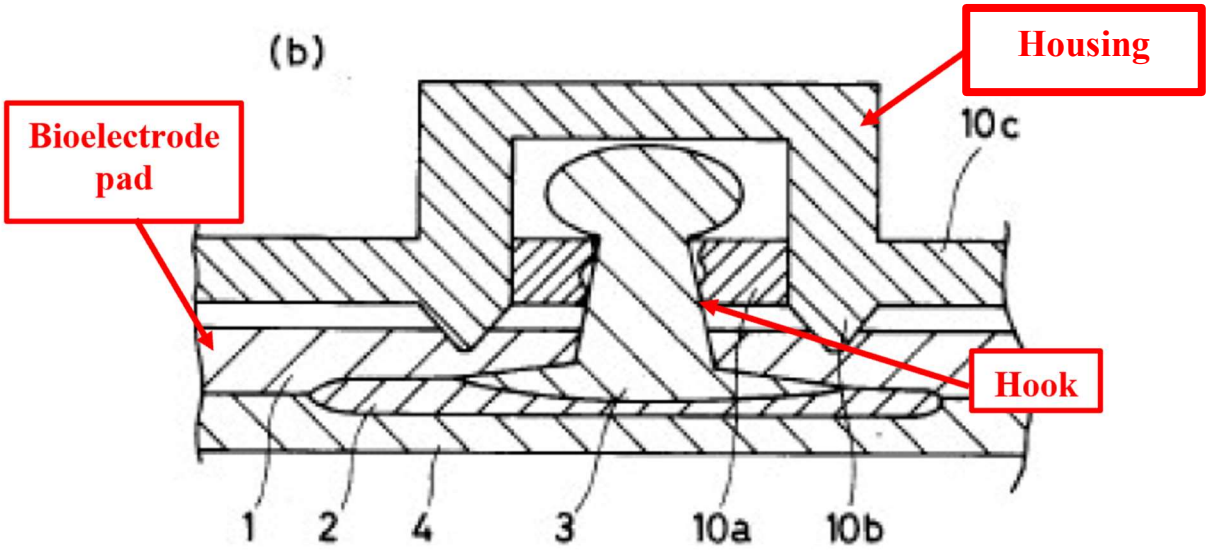
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viii. Limitation [7g]

1351. Limitation [7g] recites "a wireless communication unit, and in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip."

1352. In my opinion, a POSA would understand that Matsumura discloses limitation [7g] of the '484 patent.

1353. Matsumura discloses that "reusable signal processor 10" is "easily attached and detached" with hook 3 (releasably attached) to disposable bioelectrode pad 7 that includes conductive gels 5 (disposable electrode portion). *Id.* at [0016]; *see also id.* at [0008], [0014], [0025], Figs. 1–2. The reusable signal processor incorporates components for wireless communication: "a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna" (wireless communication unit). *Id.* at [0025]. This is illustrated in Matsumura's Figure 4(b), reproduced below.



Id. at Fig. 4(b) (annotated).

1354. It is also my opinion that the "hook 3" of Matsumura would render obvious the use of a latch clip, for the reasons set forth with respect to limitation [7g] of the '492 patent. *See* Section XVIII.A.7.viii, *supra*; *see also* Ex. 1039 at [0046], Fig. 5 (discussing use of snap connectors to attach a monitoring device to 12-lead recorders); Ex. 1040 at 30 ("Labeling").

1355. Thus, in my opinion, Matsumura and the general knowledge of a POSA render obvious "a wireless communication unit, and in which the reusable communication module is releasably attached to the disposable electrode portion by at least one latching clip."

ix. Limitation [7h]

1356. Limitation [7h] recites "a hard-wired communication cable."

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1357. For the reasons set forth above with respect to dependent claim 6, in my opinion, Matsumura in view of Ozguz renders obvious limitation [7h] of the '484 patent. *See* Section XIX.D.2, *supra*.

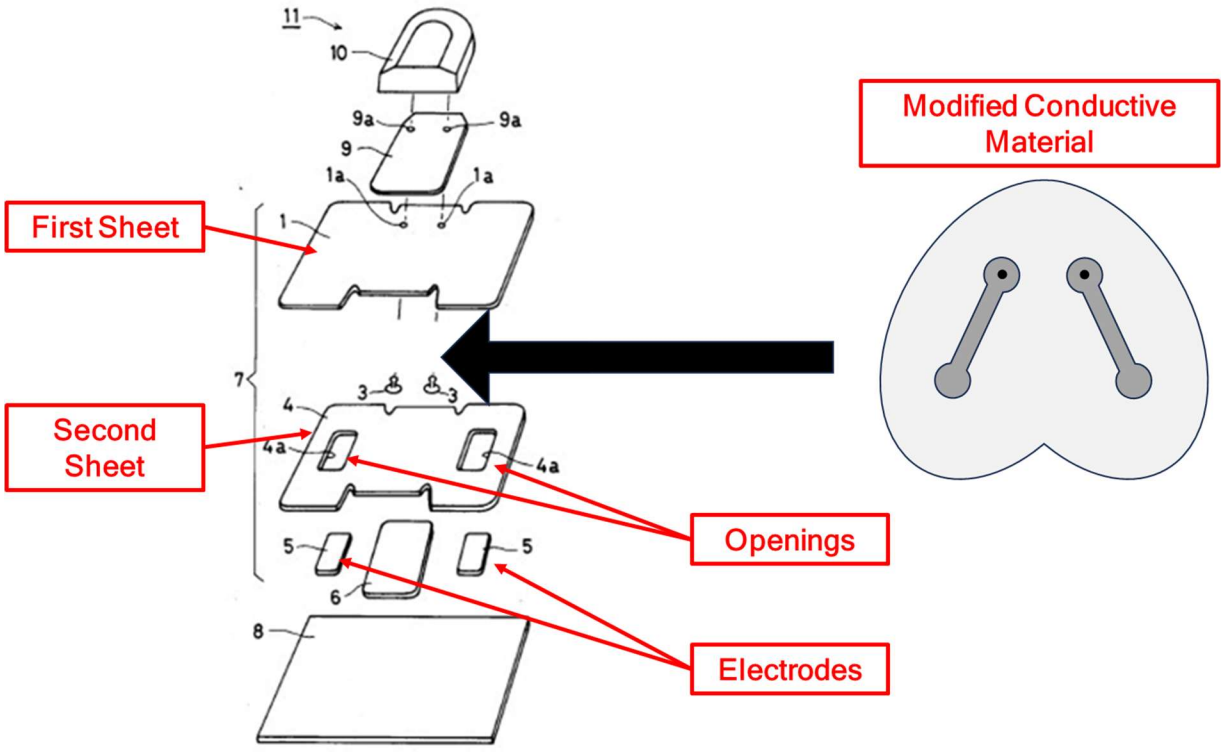
4. Dependent Claim 8

1358. Dependent claim 8 depends from claim 7 and additionally requires that "the electrodes are integrated into the flexible circuit layer of the disposable electrode portion."

1359. In my opinion, claim 8 of the '484 patent is rendered obvious by Matsumura in view of Ozguz for all the reasons discussed above with respect to claim 7 as well as because Matsumura teaches the additional limitation of claim 8. *See* Section XIX.D.3, *supra*.

1360. Matsumura discloses that "second sheet 4" of bioelectrode pad 7 "is provided with two openings 4a on the left and right sides into which the conductive gel 5 is inserted." Ex. 1012 at [0018]. As shown in Figure 1, annotated and reproduced below, openings 4a are sized to receive conductive gels 5, which are integrated into the bioelectrode pad when assembled. *Id.* at Fig. 1. A POSA would understand that the electrodes are bonded together with the other components of the disposable bioelectrode pad 7, including the sheet of conductive material with which the electrodes make contact. *Id.* at [0019].

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Id. at Fig. 1 (annotated).

1361. Thus, it is my opinion that Matsumura discloses that "the electrodes are integrated into the flexible circuit layer of the disposable electrode portion" and, therefore, that the combination of Matsumura and Ozguz renders obvious claim 8 of the '484 patent.

5. Dependent Claim 11

1362. Dependent claim 11 depends from claim 7 and additionally requires that "the electrical traces are screened onto the flexible printed circuit layer."

1363. In my opinion, claim 11 of the '484 patent is rendered obvious by Matsumura in view of Ozguz for all the reasons discussed above with respect to

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claim 7 as well as because Matsumura teaches the additional limitation of claim 11. *See* Section XIX.D.3, *supra*.

1364. As noted above, Matsumura discloses "electrical traces" in the form of portions of conductive material 2 made of Silver/Silver Chloride. Ex. 1012 at [0019]–[0021]. A POSA would understand printing ink onto a circuit board to be a form of screening. In the industry, screening the standard way to attach electrical traces made of Silver/Silver Chloride, such as those as disclosed in Matsumura, to a flexible printed circuit board. *See* Ex. 1035 at 4 (identifying screen printing as one of the printing processes by which "conductive areas are usually generated" in the art).

1365. Printing Ag/AgCl ink traces on the flexible printed circuit layer of Matsumura, per the modification suggested above, would yield electrical traces that are screened.

1366. Thus, it is my opinion that Matsumura discloses that "the electrical traces are screened onto the flexible printed circuit layer" and, therefore, that the combination of Matsumura and Ozguz renders obvious claim 11 of the '484 patent.

6. Dependent Claim 12

1367. Dependent claim 12 depends from claims 11 and 7 and additionally requires "an insulating layer applied onto the electrical traces."

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1368. In my opinion, claim 12 of the ’484 patent is rendered obvious by Matsumura in view of Ozguz for all the reasons discussed above with respect to claims 11 and 7 as well as because Matsumura teaches the additional limitation of claim 12. *See* Section XIX.D.5, *supra*.

1369. As explained above, a POSA would modify Matsumura’s conductive material 2 to form a single sheet of printed-ink traces between first sheet 1 and second sheet 4. *See* Section XIX.D.3.iii, *supra*. Matsumura teaches that first sheet 1 and second sheet 4 are both “made of an insulating material.” Ex. 1012 at [0017]–[0018].

1370. Thus, it is my opinion that Matsumura discloses “an insulating layer applied onto the traces” and, therefore, that the combination of Matsumura and Ozguz renders obvious claim 12 of the ’484 patent.

XX. THE CHALLENGED CLAIMS OF THE ’422 PATENT ARE UNPATENTABLE

1371. In my opinion, claims 1–7, 9–11, and 14–20 of the ’422 patent are obvious under pre-AIA § 103 over Matsumura in view of the knowledge of a POSA.

1372. Additionally and alternatively, in my opinion, claims 1–7, 9, 11, 12, and 14–20 of the ’422 patent are obvious under pre-AIA § 103 over Jensen in view of the general knowledge of a POSA or Matsumura.

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1373. Additionally and alternatively, in my opinion, claims 1–3, 5, 6, 9, 11, 12, 14–18, and 20 are obvious under pre-AIA § 103 over Ozguz in view of the general knowledge of a POSA.

A. Ground 1: Obvious Over Matsumura in View of the General Knowledge of a POSA

1. Independent Claim 1

1374. In my opinion, claim 1 of the ’422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA.

i. Preamble 1[pre]

1375. The preamble of claim 1 of the ’422 patent recites “[a] method for manufacturing a body-worn physiological sensor, the method comprising.”

1376. In my opinion, to the extent the preamble is limiting, Matsumura discloses the preamble of claim 1 of the ’422 patent.

1377. Matsumura teaches a “bioelectric potential detector . . . for detecting bioelectric potentials.” Ex. 1012 at Abstract, [0007], [0014]. Matsumura further teaches the components needed to assemble the disclosed bioelectric potential detector. *Id.* at [0016], Figs. 1–2 (showing exploded and assembled views of the detector). In my opinion, a POSA would have understood that well-known methods could be used to manufacture Matsumura’s bioelectric potential detector according to the components, materials, and assembly disclosed by Matsumura.

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1378. Thus, in my opinion, Matsumura discloses "[a] method for manufacturing a body-worn physiological sensor."

ii. Limitation [1a]

1379. Limitation [1a] recites "providing a disposable substrate made from an insulating material, said substrate comprising."

1380. In my opinion, Matsumura discloses limitation [1a] of the '422 patent.

1381. Matsumura discloses a "bioelectric potential detector 11" that is composed of, in part, a "disposable bioelectrode pad 7." *Id.* at [0016]. In my opinion, a POSA would recognize that the "bioelectrode pad" defines a substrate. A POSA would have understood the term "substrate" to mean a material that provides some type of support.

1382. Matsumura teaches that the bioelectrode pad (the claimed substrate) "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.* at [0016]. Matsumura further teaches that the first sheet 1 and the second sheet 4 (the claimed insulating material) "should be made of [an] ***insulating material*** that does not allow moisture to penetrate" such as "polyethylene foam, polyurethane foam, or polyurethane sheet." *Id.* at [0017]–[0018] (emphasis added). As discussed in greater detail below, with reference to limitation [1b], a POSA would have been motivated to modify Matsumura's disposable bioelectrode pad 7, to replace

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conductive material 2 with another sheet of insulating material with printed conductive traces (*i.e.*, lines of conductive ink). This modification would result in *three* sheets of insulating material bonded together, forming the claimed disposable substrate made from an insulating material.

1383. Thus, in my opinion, Matsumura discloses "providing a disposable substrate made from an insulating material, said substrate comprising."

iii. Limitation [1b]

1384. Limitation [1b] recites "a flexible printed circuit board layer made from the insulating material."

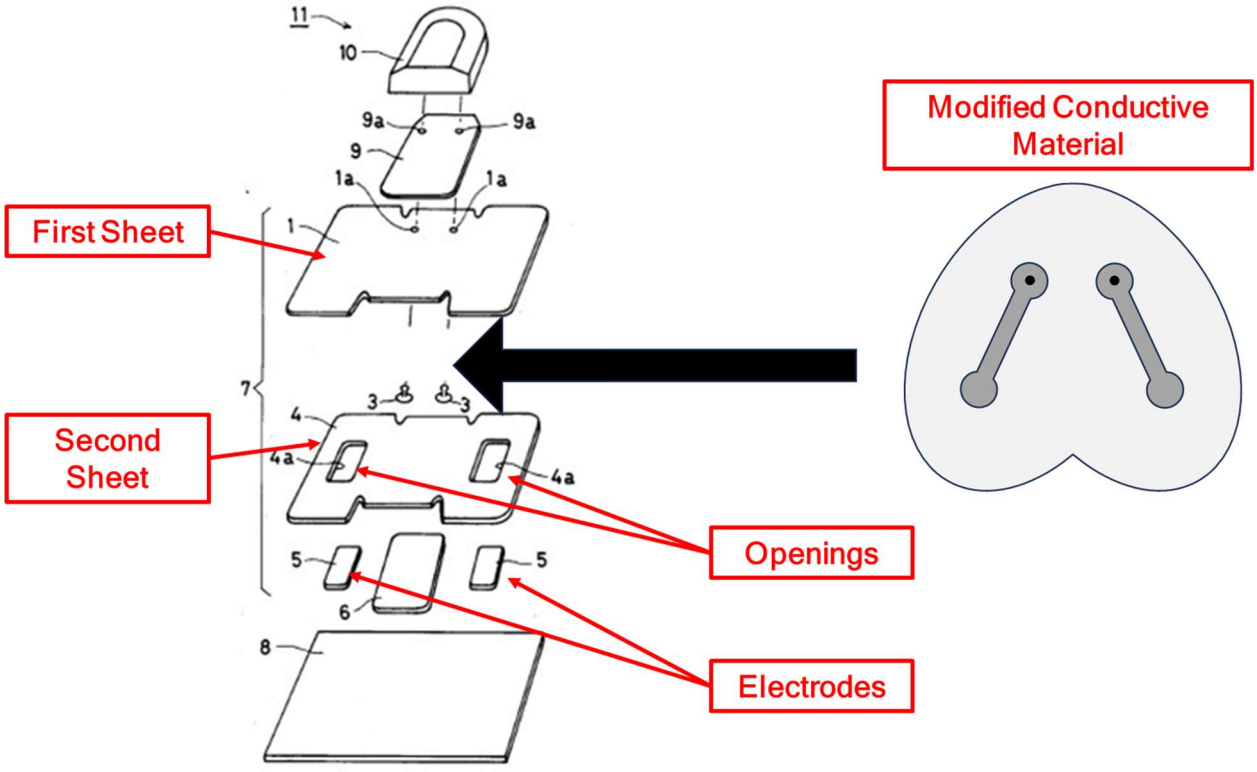
1385. In my opinion, Matsumura renders obvious limitation [1b] of the '422 patent.

1386. Matsumura teaches a "bioelectrode pad" which is a flexible circuit layer configured to be coupled to a skin surface of a patient. *Id.* at [0019]–[0020]. Matsumura's flexible circuit layer includes "two pieces of conductive material 2," which "can be a carbon sheet or a PET sheet coated with conductive Ag/AgCl." *Id.* PET is both an "insulating material," *id.* at [0019]–[0020], and a "flexible material," Ex. 1047 at 23.10; Ex. 1056 at 2.

1387. In my opinion, 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

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contained printed-ink conductive traces on its surface. *See generally*, Section XIX.A.6.iii, *supra*. The proposed modification is depicted in the following figure:

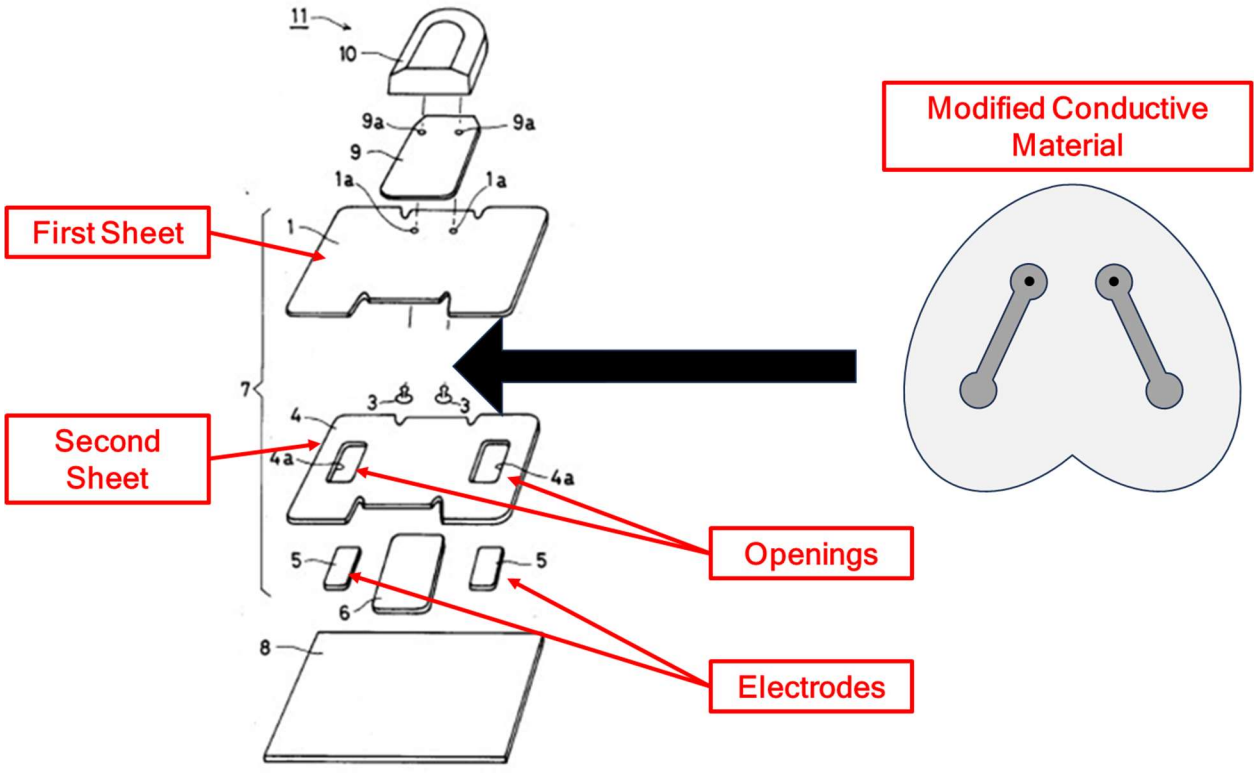


Ex. 1012 at Fig. 1 (annotated). *First*, at the time of the invention of the Challenged Patents, it was well-known that silver and/or silver paste could be applied using the screen-printing technique. *See* Ex. 1035 at 3 (noting that screen printing had been used to "print[] silver paste conductors and graphite resistors" onto substrates since the end of World War II). Using screen printing to apply the Ag/AgCl would require significantly less material than would be needed to coat the sheet with AgCl, thus significantly reducing manufacturing costs. *Compare id.* at 363 ("Methods of Applying Conformal Coatings"), *with id.* at 287–92 ("Screen Printing"). Thus, a

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POSA would have understood that the Ag/AgCl coating taught by Matsumura would have been screen printed onto the conductive material 2 to form traces and would have had a reasonable expectation of success in doing so using the well-known method of screen printing.

1388. *Second*, a POSA reading Matsumura would have been motivated to replace the two pieces of insulating material coated with conductive Ag/AgCl with a single, flexible sheet of insulating material that contained printed-ink conductive traces, as shown below, in order to reduce the manufacturing costs associated with manufacturing the parts.



Ex. 1012 at Fig. 1 (annotated). A POSA would have had a reasonable expectation

of success so doing because the exact same manufacturing technique could be used to create the one conductive piece as was used to create the two conductive pieces.

1389. In my opinion, when modified as explained above, Matsumura's conductive material would comprise a flexible printed circuit, which combined with second sheet 4, would form a flexible printed circuit layer made from the insulating material. Ex. 1012 at [0017]–[0018].

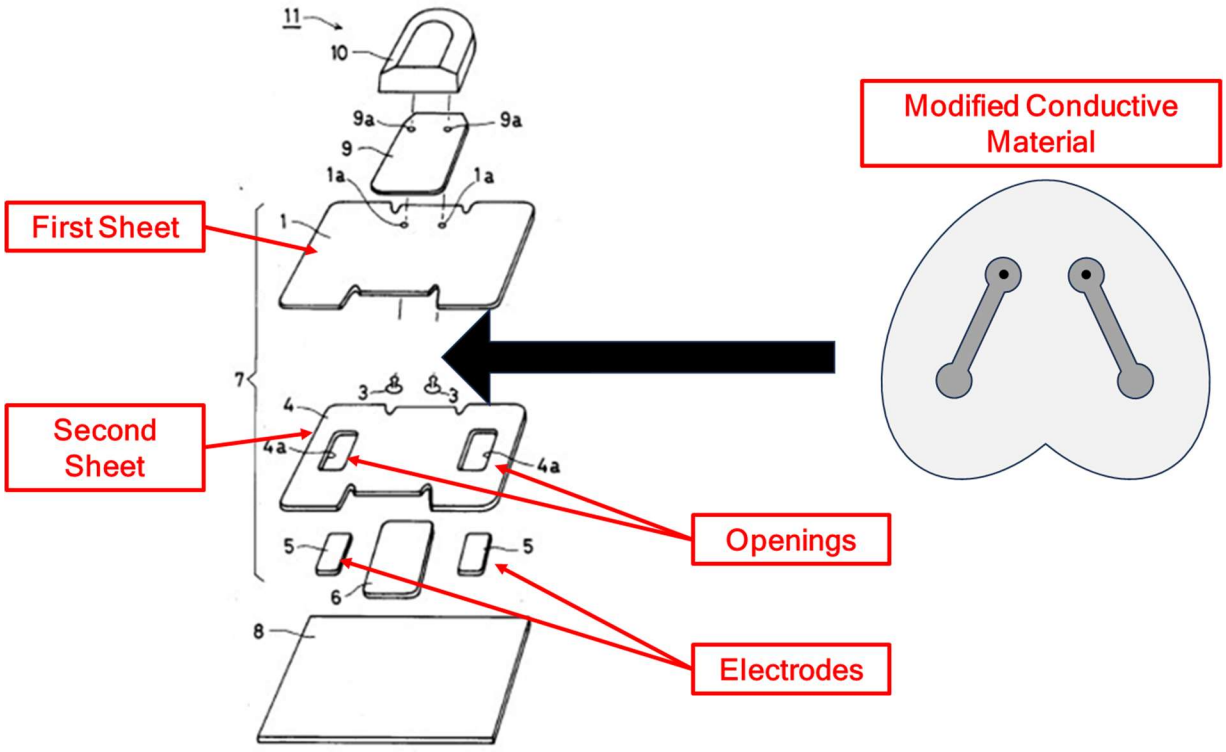
1390. Thus, in my opinion, Matsumura discloses "a flexible printed circuit board layer made from the insulating material."

iv. Limitation [1c]

1391. Limitation [1c] recites "at least two electrodes disposed on the disposable substrate."

1392. In my opinion, Matsumura renders obvious limitation [1c] of the '422 patent.

1393. Matsumura discloses "conductive gel[s] 5" (the claimed "electrodes") that are used to detect bioelectrical potentials. *Id.* at [0019]. These "conductive gel[s]" are placed in openings 4a on the "second sheet" 4 and make contact with a portion of the conductive material 2 (modified as described above and depicted below), meaning the conductive gels are disposed on a surface of the first sheet or second sheet, as shown below by annotated Figure 1. *Id.* at [0018]–[0019].



Id. at Fig. 1 (annotated).

1394. Therefore, in my opinion, a POSA would understand that conductive gels 5 are disposed on the disposable substrate, which is the disposable bioelectrode pad 7, modified by a POSA as discussed above. *See* Section XX.A.1.iii, *supra.*

1395. Thus, in my opinion, Matsumura renders obvious "at least two electrodes disposed on the disposable substrate."

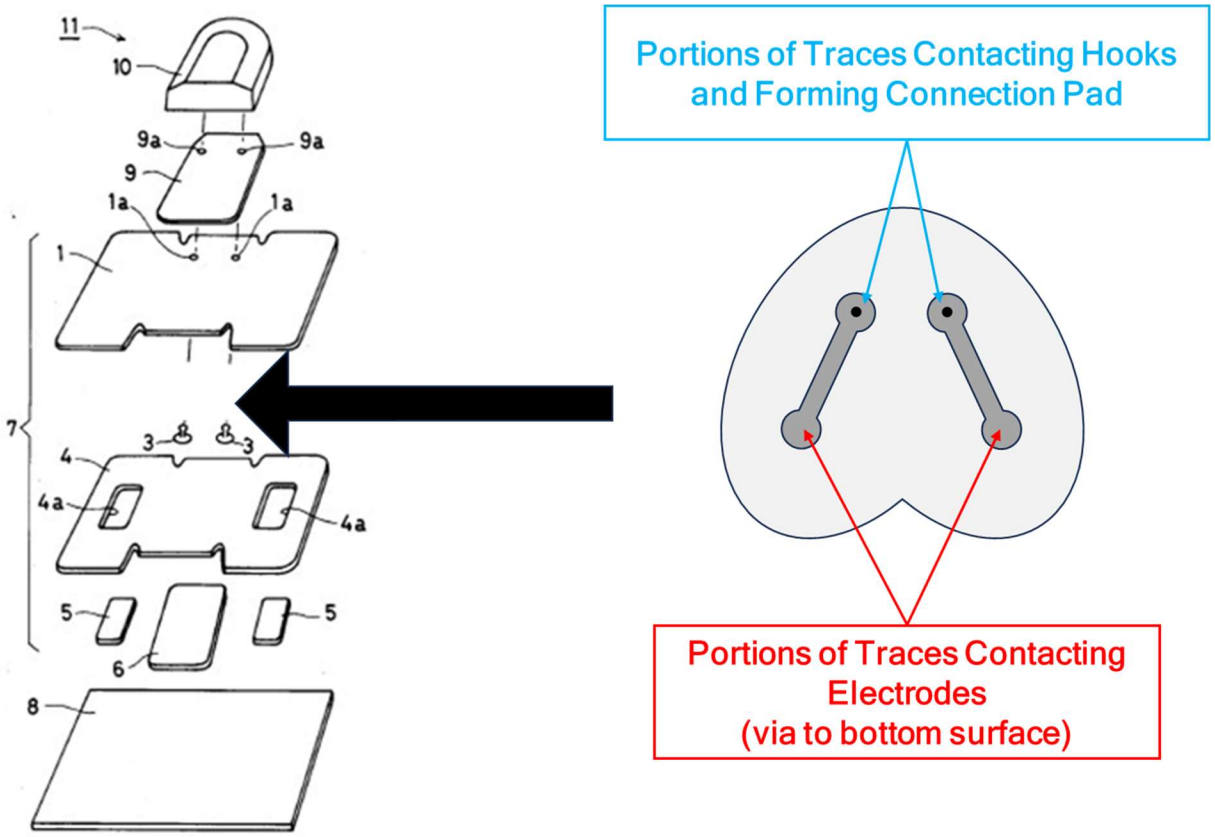
v. Limitation [1d]

1396. Limitation [1d] recites "conductive traces defined between the at least two electrodes."

1397. In my opinion, Matsumura renders limitation [1d] of the '422 patent obvious in view of the general knowledge of a POSA.

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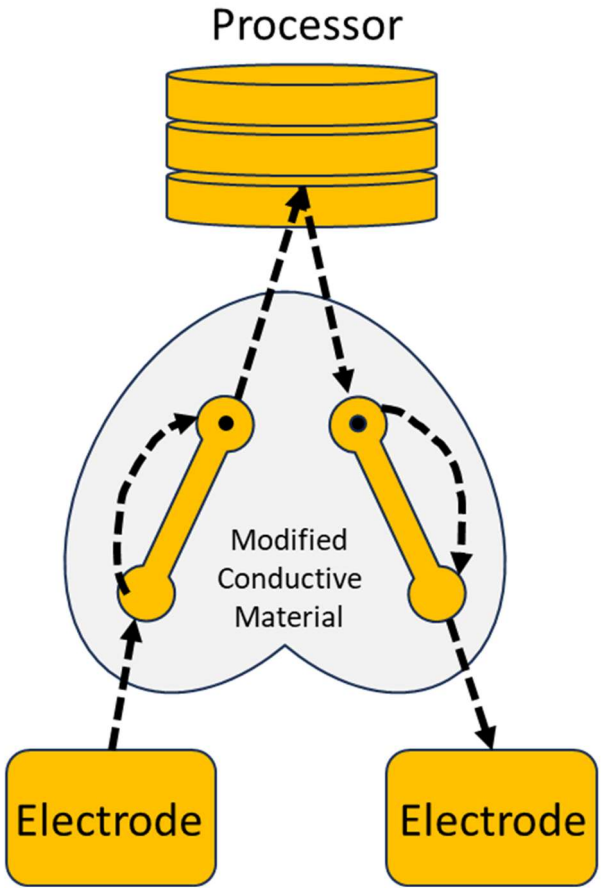
1398. In my opinion, a POSA would have been motivated to combine conductive material 2 onto a single, printed sheet, forming a flexible printed circuit layer. *See* Section XX.A.1.iii, *supra*. In this modified device, the printed traces would contact conductive gel 5, *i.e.*, the electrodes, at one end. At the other end, the printed traces would contact hooks 3. Ex. 1012 at [0019], [0024], Fig. 1.



Id. at Fig. 1 (annotated). The traces therefore run "between the at least two electrodes" (conductive gels) in the following manner: there is an electrical connection from one electrode to the printed trace it contacts; from the printed trace to the hook at its end; from the hook to the signal processor; from the signal processor to the other hook; from the other hook down the length of the other

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electrical trace; and, finally, from the other electrical trace to the other electrode. The following, simplified schematic illustrates this relationship:



1399. Thus, in my opinion, Matsumura, in view of the general knowledge of a POSA, renders obvious "conductive traces defined between the at least two electrodes."

vi. Limitation [1e]

1400. Limitation [1e] recites "providing a computation-communication module, said module comprising."

1401. In my opinion, Matsumura discloses limitation [1e] of the '422 patent.

1402. Matsumura teaches a "reusable signal processor for processing and wirelessly transmitting the bioelectric potential signals detected by the bioelectrode pad." *Id.* at [0013]; *see also id.* at [0008], [0014], [0016], [0025], Figs. 1–2.

1403. Matsumura discloses that the reusable signal processor includes components that allow for communication, stating: "The signal processor 10 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.* at [0025]

1404. Notably, Matsumura teaches that the reusable signal processor (the claimed computation-communication module) includes both components used for computation (*i.e.*, the processing circuit and memory) and components used for communication (*i.e.*, the modulating/transmitting circuit and the loop antenna). *Id.*

1405. Thus, in my opinion, Matsumura discloses "providing a computation-communication module."

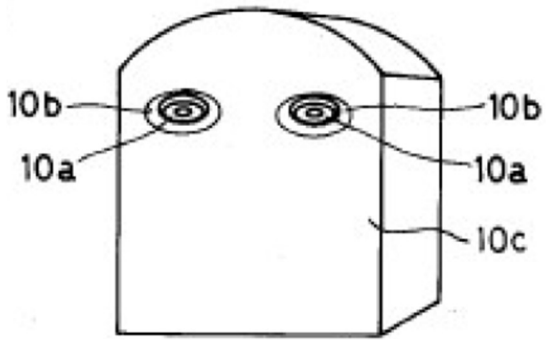
vii. Limitation [1f]

1406. Limitation [1f] recites "a housing."

1407. In my opinion, Matsumura discloses limitation [1f] of the '422 patent.

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1408. Matsumura teaches that "reusable signal processor 10" is enclosed in a housing 10c which can be "easily attached and detached" to bioelectrode pad 7. *Id.* at [0016], [0025], [0027], [0029].



Id. at Fig. 4(a).

1409. Thus, in my opinion, Matsumura discloses "a housing."

viii. Limitation [1g]

1410. Limitation [1g] recites "a processor disposed in the housing."

1411. In my opinion, Matsumura discloses limitation [1g] of the '422 patent.

1412. Matsumura teaches that signal processor 10 (the claimed computation-communication module) "incorporates a processing circuit for filtering and amplifying detected bioelectric potential signals." *Id.* at [0025]. That processing circuit (the claimed processor) is disposed within the housing 10c of the signal processor 10. *Id.* at [0025], [0027]. This ensures that "the entire bioelectric potential detector 11 is waterproofed." *Id.* at [0027]; *see also id.* at [0029].

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1413. Thus, in my opinion, Matsumura discloses "a processor disposed in the housing."

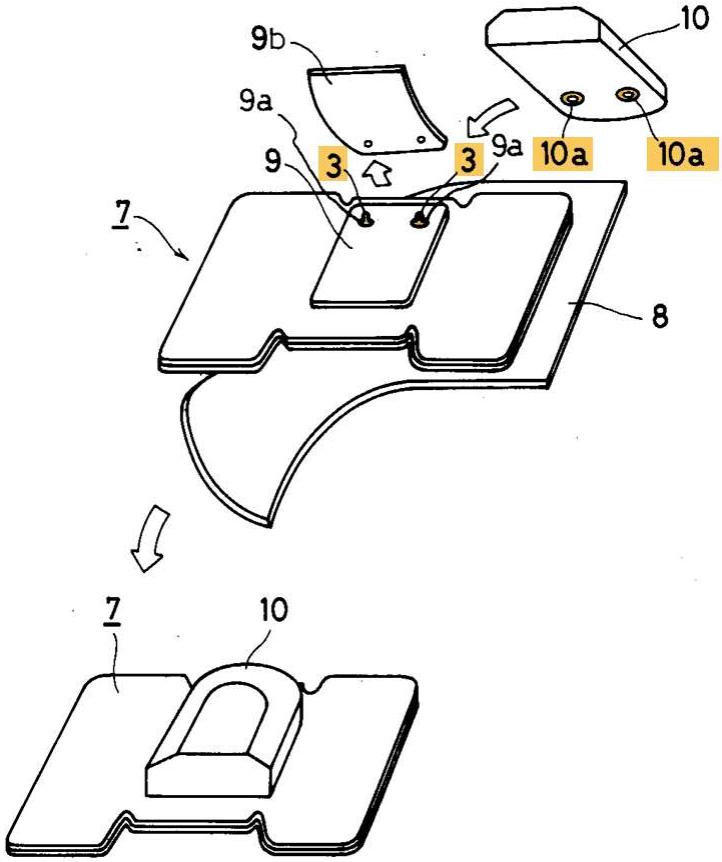
ix. Limitation [1h]

1414. Limitation [1h] recites "attaching the computation-communication module to the disposable substrate."

1415. In my opinion, Matsumura discloses limitation [1h] of the '422 patent.

1416. Matsumura teaches that reusable signal processor 10 includes housing 10c which encloses a processing circuit. *Id.* at [0025], [0027], [0029]. Matsumura further teaches that the reusable signal processor (the claimed computation-communication module) is attached to disposable bioelectrode pad 7, which includes the disposable printed circuit board (*i.e.*, the claimed disposable substrate) using hooks 3. *Id.* at [0016], [0027], [0029]. Specifically, as shown below, Matsumura discloses that the disposable bioelectrode pad includes "two hooks 3" that connect to "hook engagement portion 10a on the bottom surface of the signal processor." *Id.* at [0019], [0024], Fig. 2.

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Id. at Fig. 2 (annotated).

1417. Thus, in my opinion, Matsumura discloses "attaching the computation-communication module to the disposable substrate."

2. Dependent Claim 2

1418. Claim 2 of the '422 patent depends from claim 1 and additionally requires "providing conductive traces in the flexible circuit layer."

1419. In my opinion, claim 2 of the '422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed

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above with respect to claim 1 as well as because Matsumura teaches the additional limitation of claim 2. *See* Section XX.A.1, *supra.*

1420. In my opinion, as discussed above, a POSA would have been motivated to modify the conductive material 2 of Matsumura to comprise a single, flexible, insulating substrate with printed-ink conductive traces. *See* Section XX.A.1.iii, *supra.* In my opinion, so modified, Matsumura would "provid[e] conductive traces in the flexible circuit layer." *Id.*; *see also* Ex. 1035 at 642 ("Conductor: A single conductive path in conductive pattern. A PCB has at least one layer of conductors. *Synonyms:* path, trace."). Therefore, Matsumura, in view of the general knowledge of a POSA, renders obvious claim 2 of the '422 patent.

3. Dependent Claim 3

1421. Claim 3 of the '422 patent depends from claims 1 and 2 and additionally requires that "the conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module."

1422. In my opinion, claim 3 of the '422 patent is rendered obvious by Matsumura for all the reasons discussed above with respect to claims 1 and 2 as well as because Matsumura teaches the additional limitation of claim 3. *See* Sections XX.A.2, *supra.*

1423. As discussed above, it is my opinion that a POSA would have been motivated to modify Matsumura's conductive material 2 to comprise a single,

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flexible, insulating substrate with printed ink conductive traces. *See* Section XX.A.1.iii, *supra*. So modified, hooks 3 are disposed on the surface of the flexible printed circuit board layer. Ex. 1012 at Fig. 1. Matsumura's printed ink traces form a connection pad and transmit signals through these hooks 3 to the computation-communication module, therefore creating an electrical connection. *Id.* at [0019]–[0020]; *see also* Ex. 1035 at 656 (defining "pad" as "[a] portion of the conductive area of which components, terminals, traces, etc., are mechanically attached").

1424. For these reasons, it is my opinion Matsumura discloses that "the conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 3 of the '422 patent.

4. Dependent Claim 4

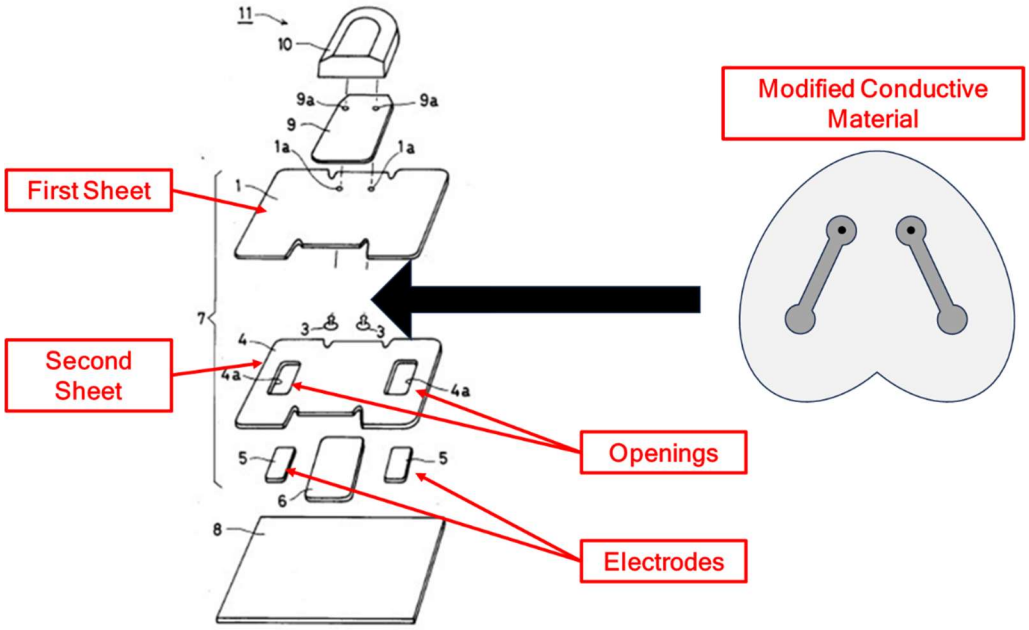
1425. Claim 4 of the '422 patent depends from claim 1 and additionally requires "providing a plurality of openings in the flexible printed circuit board layer, the openings being sized for receiving electrode gels."

1426. In my opinion, claim 4 of the '422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed

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above with respect to claim 1 as well as because Matsumura teaches the additional limitation of claim 4. *See* Section XX.A.1, *supra.*

1427. In my opinion, a POSA would have been motivated to modify the conductive material 2 to form a flexible printed circuit layer as described above. *See* Section XX.A.1.iii, *supra.* Matsumura's flexible printed circuit layer, as modified, would include flexible printed circuit—*i.e.*, the substitute for conductive material 2—and second sheet 4. *Id.* Second sheet 4 is also an insulating, protective covering. *Id.* Matsumura teaches that the bioelectrode pad 7 is comprised, in part, of a second sheet 4. Ex. 1012 at [0016]. Matsumura further teaches that "second sheet 4 . . . is provided with two openings 4a on the left and right sides into which the conductive gel 5 is inserted." *Id.* at [0018]. Annotated Figure 1 of Matsumura, shown below, shows that these openings 4a in second sheet 4 are sized to receive conductive gels 5 (the claimed electrode gels).



Id. at Fig. 1. (annotated).

1428. For these reasons, it is my opinion that Matsumura discloses "providing a plurality of openings in the flexible printed circuit board layer, the openings being sized for receiving electrode gels" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 4 of the '422 patent.

5. Dependent Claim 5

1429. Claim 5 of the '422 patent depends from claim 1 and additionally requires that "the computation-communication module is releasably attached to the disposable substrate."

1430. In my opinion, claim 5 of the '422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed

above with respect to claim 1 as well as because Matsumura teaches the additional limitation of claim 5. *See* Section XX.A.1, *supra.*

1431. Matsumura teaches that "[t]he bioelectrode pad 7," which includes the flexible printed circuit board layer, and "the signal processor 10 are detachable with hooks" and thus "the reusable signal processor and the disposable bioelectrode can be easily attached and detached before and after use." Ex. 1012 at [0016]. Thus, the signal processor 10 (the claimed computation-communication module) is releasably attached to the disposable bioelectrode pad 7 (the claimed disposable substrate).

1432. For these reasons, it is my opinion that Matsumura discloses that "the computation-communication module is releasably attached to the disposable substrate" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 5 of the '422 patent.

6. Dependent Claim 6

1433. Claim 6 of the '422 patent depends from claim 1 and additionally requires "providing a radio circuit in the computation-communication module."

1434. In my opinion, claim 6 of the '422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because Matsumura teaches the additional limitation of claim 6. *See* Section XX.A.1, *supra.*

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1435. Matsumura teaches signal processor 10 (the claimed computation-communication module) that includes "a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna." Ex. 1012 at [0025].

1436. In my opinion, a POSA would understand that a loop antenna is a type of radio antenna, meaning that a circuit that is used to transmit wirelessly using a loop antenna would be a radio circuit. Ex. 1063 (Jaehoon Kim, *Implanted Antennas for Medical Wireless Communications: Characterizations, Designs and Performance Evaluations* (2005) (Ph. D. dissertation, Univ. Cal. L.A.).

1437. For these reasons, it is my opinion that a POSA would understand that Matsumura discloses "providing a radio circuit in the computation-communication module" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 6 of the '422 patent.

7. Dependent Claim 7

1438. Claim 7 of the '422 patent depends from claims 1, 2, and 3 and additionally requires "at least partially covering the conductive traces with an insulating covering."

1439. In my opinion, claim 7 of the '422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed

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above with respect to claims 1, 2, and 3 as well as because Matsumura teaches the additional limitation of claim 7. *See* Sections XX.A.1–3, *supra.*

1440. In my opinion, as discussed above, a POSA would have modified Matsumura's conductive material 2 to comprise a single sheet of flexible, insulating material with printed-ink traces. *See* Section XX.A.1.ii, *supra.* In my opinion, a POSA would have understood that this modified conductive material circuit board would be situated between first sheet 1 and second sheet 4. Matsumura further discloses that both the first sheet and second sheet are "made of insulating material that does not allow moisture to penetrate," *i.e.*, a "covering." Ex. 1012 at [0017]–[0018].

1441. For these reasons, it is my opinion that Matsumura discloses "at least partially covering the conductive traces with an insulating covering" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 7 of the '422 patent.

8. Dependent Claim 9

1442. Claim 9 of the '422 patent depends from claim 1 and additionally requires "integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate."

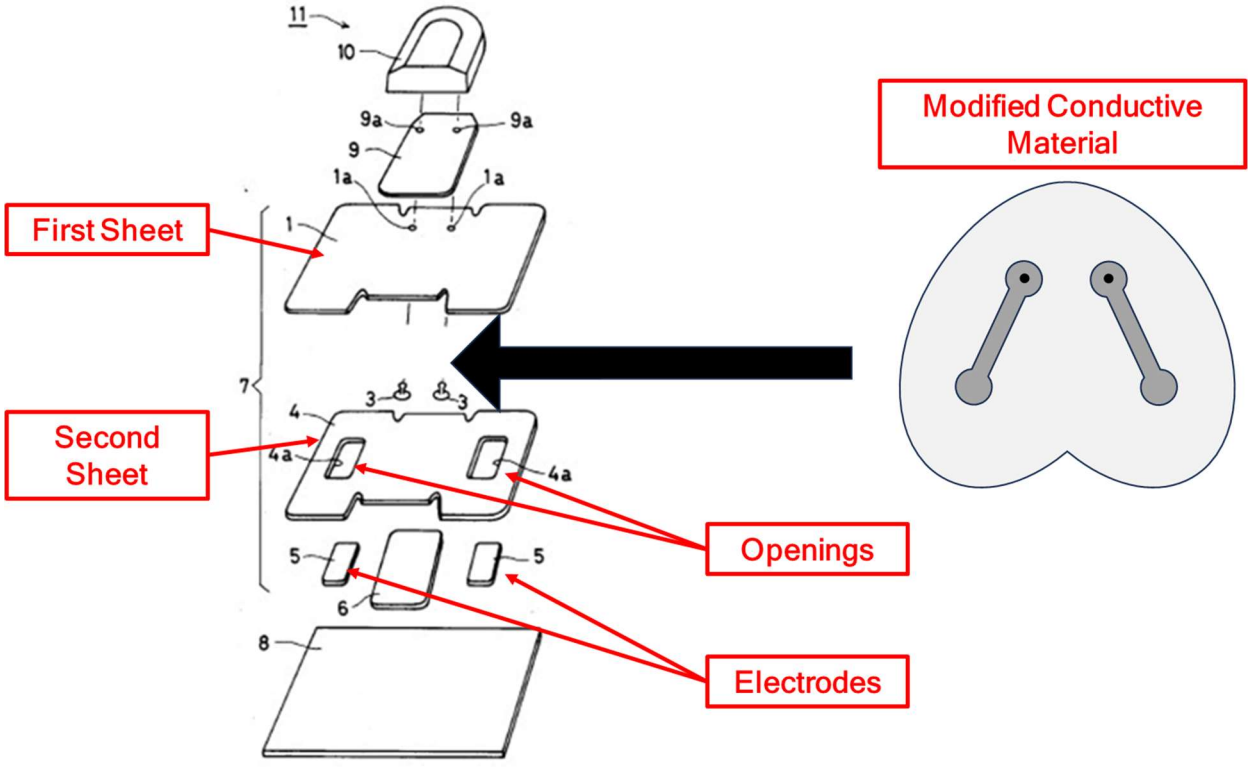
1443. In my opinion, claim 9 of the '422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed

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above with respect to claim 1 as well as because Matsumura teaches the additional limitation of claim 9. *See* Section XX.A.1, *supra.*

1444. Matsumura teaches that disposable bioelectrode pad 7—which includes the flexible printed circuit board layer—includes, in part, conductive gels 5. Ex. 1012 at [0016]. Conductive gels 5 are used to detect bioelectric potentials. *Id.* at [0019]. Matsumura discloses that the conductive gels (the claimed electrodes) are disposed in two openings 4a between first sheet 1 and second sheet 4 of bioelectrode pad 7 (the claimed flexible printed circuit board layer). *Id.* at [0018]–[0019]. In my opinion, a POSA would understand that the conductive gels 5 (electrodes) are bonded to the other components of the flexible circuit board layer (*e.g.*, modified conductive material 2). *See, e.g.*, Ex. 1035 at 421 ("The individual layers [of a multi-layer PCB board] are arranged and bonded by placing them in a pressing tool to prevent misalignment of the layers."). Thus, the conductive gels 5 are integrated into the flexible printed circuit board layer as shown below by Figure 1.

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Ex. 1012 at Fig. 1. (annotated).

1445. For these reasons, it is my opinion that Matsumura discloses that "integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 9 of the '422 patent.

9. Dependent Claim 10

1446. Claim 10 of the '422 patent depends from claims 1, 2, and 3 and additionally requires "screening the conductive traces onto the flexible printed circuit board layer."

1447. In my opinion, claim 10 of the '422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed

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above with respect to claims 1, 2, and 3 as well as because Matsumura renders obvious the additional limitation of claim 10. *See* Sections XX.A.1–3, *supra.*

1448. In my opinion, as discussed above, a POSA would have been motivated to modify conductive material 2 to form a flexible printed circuit. *See* Section XX.A.1.iii, *supra.* In the industry at the time of the invention of the '422 patent, screening was the standard way to attach electrical traces made of Silver/Silver Chloride, such as those as disclosed in Matsumura, to a flexible printed circuit board. *See, e.g.*, Ex. 1035 at 283 (noting that "screen printing is a [ ] cheap and simple method" that is used to produce "[t]he majority of PCBs produced worldwide"), 3 (noting that the screen printing of "printed silver paste conductors and graphite resistors" was "commonly associated with [2006]'s hybrid circuit technology" and "was [the] technique that ushered in the commercial use of printed circuits").

1449. For these reasons, it is my opinion that a POSA would understand that Matsumura discloses that "screening the conductive traces onto the flexible printed circuit board layer" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 10 of the '422 patent.

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10. Dependent Claim 11

1450. Claim 11 of the ’422 patent depends from claims 1 and 9 and additionally requires that “each electrode includes an electrode gel and a conductive surface defining a half cell.”

1451. In my opinion, claim 11 of the ’422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed above with respect to claims 1 and 9 as well as because Matsumura teaches the additional limitation of claim 11. *See* Section XX.A.8, *supra.*

1452. Matsumura discloses that “conductive gel 5 is produced from components such as an acrylic hydrophilic polymer, glycerin, and water.” Ex. 1012 at [0018]. Matsumura further discloses that the conductive gel contacts a second portion of “conductive material 2,” which can be “coated with conductive Ag/AgCl.” *Id.* at [0019]–[0020].

1453. In my opinion, a POSA would understand that conductive gels comprising an acrylic hydrophilic polymer, glycerin, and water, and contacting a silver/silver-chloride conductive surface comprise a “half cell.” *See, e.g.*, Ex. 1007 at 7:28–38 (explaining that the term “electrode” is used interchangeably with “half cell” within the disclosure and that an electrode—*i.e.*, a half cell—typically comprises (1) a conductive surface and (2) an electrode gel).

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1454. For these reasons, it is my opinion that a POSA would understand that Matsumura discloses that "each electrode includes an electrode gel and a conductive surface defining a half cell" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 11 of the '422 patent.

11. Independent Claim 14

1455. In my opinion, claim 14 of the '422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA.

i. Preamble 14[pre]

1456. The preamble of claim 14 recites "[a] body-worn physiological sensor made by the process of." As described with respect to claim 1, to the extent the preamble is limiting, it is my opinion that Matsumura renders obvious the "body-worn physiological sensor" made by the process claimed by the '422 patent. *See* Section XX.A.1.i, supra.

ii. Limitation [14a]

1457. Limitation [1a] recites "providing a disposable substrate made from an insulating material, said substrate comprising."

1458. As described with respect to claim 1, it is my opinion that Matsumura discloses "providing a disposable substrate made from an insulating material." *See* Section XX.A.1.ii, *supra.*

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iii. Limitation [14b]

1459. Limitation [14b] recites "a flexible printed circuit board layer made from an insulating material."

1460. As described with respect to claim 1, it is my opinion that Matsumura, in view of the general knowledge of a POSA, renders obvious "a flexible printed circuit board layer made from an insulating material." *See* Section XX.A.1.iii, *supra.*

iv. Limitation [14c]

1461. Limitation [14c] recites "at least two electrodes disposed on the disposable substrate."

1462. As described with respect to claim 1, it is my opinion that Matsumura, in view of the general knowledge of a POSA, renders obvious "at least two electrodes disposed on the disposable substrate." *See* Section XX.A.1.iv, *supra.*

v. Limitation [14d]

1463. Limitation [14d] recites "conductive traces defined between the at least two electrodes."

1464. As described with respect to claim 1, it is my opinion that Matsumura and a POSA's general knowledge render obvious "conductive traces defined between the at least two electrodes." *See* Section XX.A.1.v, *supra.*

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vi. Limitation [14e]

1465. Limitation [14e] recites "providing a computation-communication module, said module comprising."

1466. As described with respect to claim 1, it is my opinion that Matsumura discloses the claimed "computation-communication module." *See* Section XX.A.1.vi, *supra.*

vii. Limitation [14f]

1467. Limitation [14f] recites "a housing."

1468. As described with respect to claim 1, it is my opinion that Matsumura discloses "a housing." *See* Section XX.A.1.vii*, supra.*

viii. Limitation [14g]

1469. Limitation [14g] recites "a processor disposed in the housing."

1470. As described with respect to claim 1, it is my opinion that Matsumura discloses "a processor disposed in the housing." *See* Section XX.A.1.viii, *supra.*

ix. Limitation [14h]

1471. Limitation [14h] recites "attaching the computation-communication module to the disposable substrate."

1472. As described with respect to claim 1, it is my opinion that Matsumura discloses "attaching the computation-communication module to the disposable substrate." *See* Section XX.A.1.ix, *supra.*

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12. Dependent Claim 15

1473. Claim 15 of the ’422 patent depends from claim 14 and additionally requires “providing the conductive traces in the flexible printed circuit board layer.”

1474. In my opinion, claim 15 of the ’422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed above with respect to claim 14 as well as because Matsumura teaches the additional limitation of claim 15. *See* Section XX.A.11, *supra.*

1475. As described above with respect to claim 2, it is my opinion that Matsumura discloses “providing the conductive traces in the flexible printed circuit board layer” and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 15 of the ’422 patent. *See* Section XX.A.2, *supra.*

13. Dependent Claim 16

1476. Claim 16 of the ’422 patent depends from claims 14 and 15 and additionally requires that “configuring the conductive traces in the flexible printed circuit board layer to electrically couple with the attached computation-communication module.”

1477. As described above with respect to claim 3, it is my opinion that that Matsumura discloses “configuring the conductive traces in the flexible printed circuit board layer to electrically couple with the attached computation-communication module” and, therefore, that Matsumura, in view of the general

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knowledge of a POSA, renders obvious claim 16 of the '422 patent. *See* Section XX.A.3, *supra.*

14. Dependent Claim 17

1478. Claim 17 of the '422 patent depends from claim 14 and additionally requires that "the computation-communication module is releasably attached to the disposable substrate."

1479. In my opinion, claim 17 of the '422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed above with respect to claim 14 as well as because Matsumura teaches the additional limitation of claim 17. *See* Section XX.A.11, *supra.*

1480. As described above with respect to claim 5, it is my opinion that Matsumura discloses that "the computation-communication module is releasably attached to the disposable substrate" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 17 of the '422 patent. *See* Section XX.A.5, *supra.*

15. Dependent Claim 18

1481. Claim 18 of the '422 patent depends from claim 14 and additionally requires "providing the computation-communication module with a radio circuit."

1482. In my opinion, claim 18 of the '422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed

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above with respect to claim 14 as well as because Matsumura, in view of the general knowledge of a POSA, teaches the additional limitation of claim 18. *See* Section XX.A.11, *supra.*

1483. As described above with respect to claim 6, it is my opinion that Matsumura discloses "providing the computation-communication module with a radio circuit" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 18 of the '422 patent. *See* Section XX.A.6, *supra.*

16. Dependent Claim 19

1484. Claim 19 of the '422 patent depends from claims 14, 15, and 16 and additionally requires "at least partially covering the conductive traces with an insulating covering."

1485. In my opinion, claim 19 of the '422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed above with respect to claims 14, 15, and 16 as well as because Matsumura teaches the additional limitation of claim 19. *See* Section XX.A.13, *supra.*

1486. As described above with respect to claim 7, it is my opinion that Matsumura discloses "at least partially covering the conductive traces with an insulating covering" and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 19 of the '422 patent. *See* Section XX.A.7, *supra*.

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17. Dependent Claim 20

1487. Claim 20 of the ’422 patent depends from claim 14 and additionally requires “integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate.”

1488. In my opinion, claim 20 of the ’422 patent is rendered obvious by Matsumura in view of the general knowledge of a POSA for all the reasons discussed above with respect to claim 14 as well as because Matsumura teaches the additional limitation of claim 20. *See* Section XX.A.11, *supra.*

1489. As described above with respect to claim 9, it is my opinion that Matsumura discloses “integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate” and, therefore, that Matsumura, in view of the general knowledge of a POSA, renders obvious claim 20 of the ’422 patent. *See* Section XX.A.8, *supra.*

B. Ground 2: Obvious Over Jensen and the General Knowledge of Person of Ordinary Skill in the Art or Matsumura

1. A POSA had motivation to combine Jensen and Matsumura

1490. For the reasons set forth above in Section XVIII.C.1, with reference to the ’492 patent, a POSA would have had motivation to combine the teachings of Jensen and Matsumura and would have had a reasonable expectation of success in doing so.

2. Independent Claim 1

1491. In my opinion, claim 1 of the ’422 patent is rendered obvious by Jensen in view of the general knowledge of a POSA and/or Matsumura.

i. Preamble 1[pre]

1492. The preamble of claim 1 of the ’422 patent recites “[a] method for manufacturing a body-worn physiological sensor, the method comprising.”

1493. In my opinion, to the extent the preamble is limiting, Jensen, in view of the general knowledge of a POSA, discloses the preamble of claim 1 of the ’422 patent.

1494. Jensen teaches a body worn “smart patch” “that integrates . . . heart-rate/EKG electronic sensors to measure respiration, temperature, and/or other physiological or environmental parameters.” Ex. 1011 at [0012]; *see also id.* at [0013], [0051]. Jensen discloses that:

> The entire assembly may be designed in such a way that it is easily assembled in a set of progressive operations whereby reels or rolls of die-cut cover materials, along with the pre-assembled electronics, are applied by machine operation to the inner circuitry and connections, yielding a final product that may be more easily mass-produced than if handling and hand operations were required.

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Id. at [0043]. It is my opinion that a POSA would have used well-known methods to manufacture Jensen's "smart patch" based on Jensen's disclosure of components, materials, and assembly techniques.

1495. Thus, in my opinion, a POSA would understand that Jensen discloses "[a] method for manufacturing a body-worn physiological sensor."

ii. Limitation [1a]

1496. Limitation [1a] recites "providing a disposable substrate made from an insulating material, said substrate comprising."

1497. In my opinion, Jensen, in view of the general knowledge of a POSA, renders obvious limitation [1a] of the '422 patent.

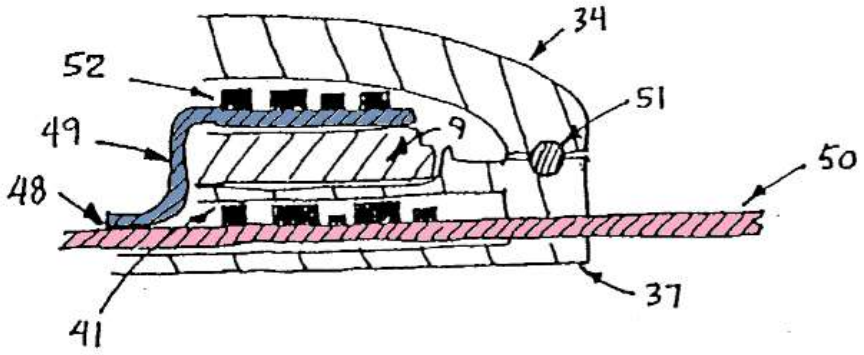
1498. Jensen discloses multiple embodiments, including the embodiment of Figure 5 and the embodiment of Figure 8. Ex. 1011, Figs. 5, 8. The embodiment of Jensen's Figure 5 includes a "disposable sensor assembly 73," and a separate flexible circuit assembly 36 (which incorporates sensor contacts 71 and 72 and processing circuit 41). *Id.* ¶¶ [0040]-[0042], Fig. 5. Figure 8 shows an alternative embodiment that comprises two flexible circuits 49, 50 instead of one. *Id.* ¶ [0046], Fig. 8.

In my opinion, a POSA would understand that the embodiment of Figure 8 is simply a variation on the embodiment of Figure 5, and in particular, that the features of flexible circuit assembly 36 (*e.g.*, sensor contacts 71, 72, and the copper wiring

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traces connecting them to the entire circuit) would be included on Figure 8's flexible substrate 50 because flexible substrate 50 is the closest to the patient.

1499. Further, it is my opinion that it would have been obvious for a POSA to configure Jensen's device to include a disposable substrate made from an insulating material. Specifically, in the embodiment of Jensen's Figure 8, Jensen teaches a means of "mechanical connection of inter-related circuits using two flexible printed circuits 49, 50." *Id.* at [0046], Fig. 8 (annotated, depicted below). A POSA would recognize that flexible printed circuit 50 would be analogous to Jensen's flexible printed circuit 36. However, given two flexible circuits, a POSA would have been motivated to make the circuit closest to the patient's skin, flexible circuit 50, disposable, while keeping flexible printed circuit 49 non-disposable. This configuration would have ensured that the components of the device most proximal to the patient's skin (and including the lowest cost materials) were disposable, thereby promoting hygiene generally.



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Id. at Fig. 8 (annotated).

1500. In my opinion, it would have been obvious for a POSA to distribute valuable components on top of flexible circuit assembly 49 (in circuit 52) instead of being kept below or within it, to allow for the components closest to the skin to be disposable. This redistribution would allow reuse of the most expensive components (electronic circuitry 52 and/or coin cell 9), while making components closest to the surface of the skin (sensor contacts 71, 72 and copper traces, which would be located on flexible printed circuit layer 50) disposable. As noted above, this redistribution of components would improve both the hygiene and waterproofing properties of Jensen's device, while avoiding the cost of disposing of valuable electronic circuitry 52 or coin cell 9. *See* Section XVIII.C.1, *supra*. Given that modern wearable devices commonly used a combination of disposable and reusable components, including the use of disposable flexible printed circuit boards, a POSA would have been able to modify the layout of Jensen's device with a reasonable expectation of success. Ex. 1012 at [0007]; *see* Section XVIII.C.1, *supra*; *see also* Section IV.C–D, *supra.*

1501. Thus, in my opinion, Jensen, in view of the general knowledge of a POSA, renders obvious "providing a disposable substrate made from an insulating material, said substrate comprising."

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1502. Additionally, or alternatively, it is my opinion that a POSA would have looked to modify Jensen in view of the teachings of Matsumura. For the same reasons as discussed above, a POSA would have been motivated to modify Jensen in view of Matsumura to make sensor contacts 71, 72 and flexible circuit assembly 36 part of the disposable sensor assembly 73, which would add an additional layer of protection and separation between the patient's skin and the reusable components, such as electronics 41 and battery 9. As discussed earlier in this section, this modification would be beneficial to improve the hygiene of the Jensen's device as well as help to waterproof Jensen's design by isolating Jensen's circuitry and battery in an enclosed housing and allowing the traces and sensor contacts to be fully covered, as taught by Matsumura.

1503. In my opinion, a POSA would recognize that the "flexible circuit assembly" of Jensen 36, 50 includes a substrate on which "copper wiring traces" are formed as well as that the "flexible circuit assembly" is made of insulating material on which the traces, electronics, and sensor contacts 71, 72 are placed, or else the various electrical components on the flexible circuit assembly would short circuit. Flexible circuit assemblies were commonly made of an insulating material, such as Mylar. *See* Ex. 1007 at 8:49–55, 9:35–38, 11:48–50; Ex. 1011 at [0043].

1504. Thus, in my opinion, Jensen alone and/or the combination of Jensen and Matsumura teaches "a disposable substrate made from an insulating material."

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iii. Limitation [1b]

1505. Limitation [1b] recites "a flexible printed circuit board layer made from the insulating material."

1506. In my opinion, Jensen discloses limitation [1b] of the '422 patent.

1507. Jensen teaches a "flexible circuit assembly" 36, 50 containing an electrical circuit 41. Ex. 1011 at [0040], [0043], Figs. 5, 8. In my opinion, a POSA would recognize that the "flexible circuit assembly" of Jensen defines a substrate (*i.e.*, "a substrate that supports one or more electrical connections to a patient's body"), Ex. 1003 at Abstract, on which "copper wiring traces" are formed, *see* Ex. 1011 at [0040]. In my opinion, a POSA would recognize that the "flexible circuit assembly" is made of insulating material on which the traces, electronics, and sensor contacts 71, 72 are placed. Ex. 1035 at 4–5.

1508. It is further my opinion that a POSA would understand that Jensen's flexible circuit assembly (the claimed "flexible printed circuit layer") ***must*** be made from an insulating material. If the circuit(s) were printed on a conductive material, then electrical current—rather than traveling through printed traces—would pass diffusely across the entire surface. For this reason, printed circuits boards definitionally include a base comprised of "insulating material." *See, e.g.*, *id.*

1509. Jensen also discloses "a flexible printed" circuit assembly. Ex. 1011 at [0044], [0046]. In my opinion, a POSA would understand that screen printing is

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one of the preferred methods of manufacturing a circuit board. *See* Ex. 1035 at 296 ("Printing Process. The circuit patterns are screen printed on the substrate by two ways: (1) Manual screen printing process, and (2) Automatic or semi-automatic screen printing process."); *see also* Ex. 1013 at 5:23–42 ("Each electrode 35 has a conductive grid 56 which is comprised of a matrix of approximately 0.050 inch wide lines 42 of conductive ink compound applied to an insulation and base support layer 44 ***preferably by means of a silk screen process.***") (emphasis added); *see also* Ex. 1013 at 5:4–8. Screen printing is preferred because it allows a greater degree of control in printing and thus is cost-effective, which is important when expensive materials such as silver are being used. *Id.*; *see also* Section IV.C., *supra.*

1510. Thus, in my opinion, Jensen discloses "a flexible printed circuit board layer made from the insulating material."

iv. Limitation [1c]

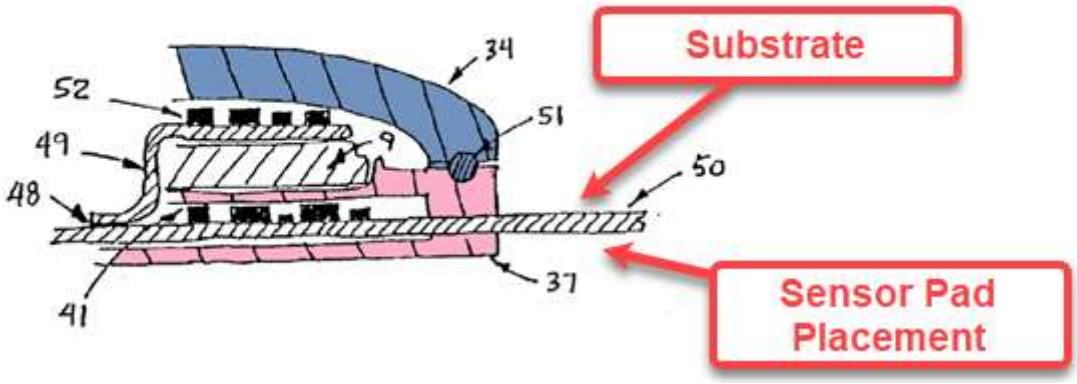
1511. Limitation [1c] recites "at least two electrodes disposed on the disposable substrate."

1512. In my opinion, Jensen discloses limitation [1c] of the '422 patent.

1513. Jensen discloses a "disposable sensor assembly," which includes "sensor contacts 71 and 72." Ex. 1011 at [0041]–[0042]. Jensen's sensor pad contacts 72 and 72 are electrodes; they are conductive and couplable to a skin surface via sensor pads 1 and 2 to measure physiological signals such as ECG signals. *Id.*

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at [0041]. The sensor pad electrodes are disposed on the lower surface of flexible assembly 36, as shown in Figure 7. A POSA would recognize that the sensor contacts 71, 72 would be disposed on the surface of disposable substrate 50 of the embodiment of Figure 8; and that sensor pads 1,2 would also be disposed on the lower surface of disposable substrate 50 (analogous to substrate 36), as shown below.



Id. at Fig. 8 (annotated).

1514. Thus, in my opinion, Jensen discloses "at least two electrodes disposed on the disposable substrate."

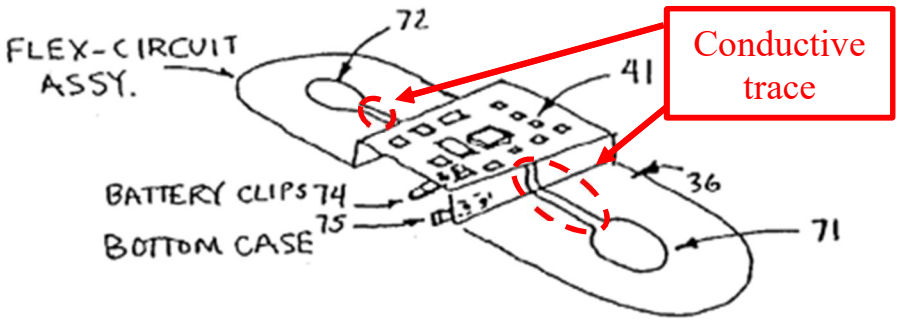
v. Limitation [1d]

1515. Limitation [1d] recites "conductive traces defined between the at least two electrodes."

1516. In my opinion, Jensen discloses limitation [1d] of the '422 patent.

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1517. 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. *Id.* at [0040]–[0041]. In my opinion, a POSA reading Jensen's disclosure would understand that the connection that is created by the "copper wiring traces" extends from the electrode sensor pads 1, 2 to a processing circuit as demonstrated in the annotated version of Jensen's Figure 5 below.



Id. at Fig. 5 (annotated).

1518. Further, in my opinion, a POSA would understand that the same traces and sensor contacts would be included on disposable substrate 50 in the embodiment of Jensen's Figure 8.

1519. Thus, in my opinion, Jensen discloses "conductive traces defined between the at least two electrodes."

vi. Limitation [1e]

1520. Limitation [1e] recites "providing a computation-communication module, said module comprising."

1521. In my opinion, Jensen discloses limitation [1e] of the '422 patent.

1522. Jensen discloses a "microcontroller" for computation and a "transmitter" for communication. *Id.* at [0032]. Jensen's microcontroller "runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter." *Id.* Jensen's transmitter may communicate data via an "antenna." *Id.* at [0033]. A POSA would understand that the computation-communication module of Jensen would be included on non-disposable substrate 49 in the embodiment shown in Figure 8 of Jensen.

1523. Thus, in my opinion, Jensen discloses "providing a computation-communication module."

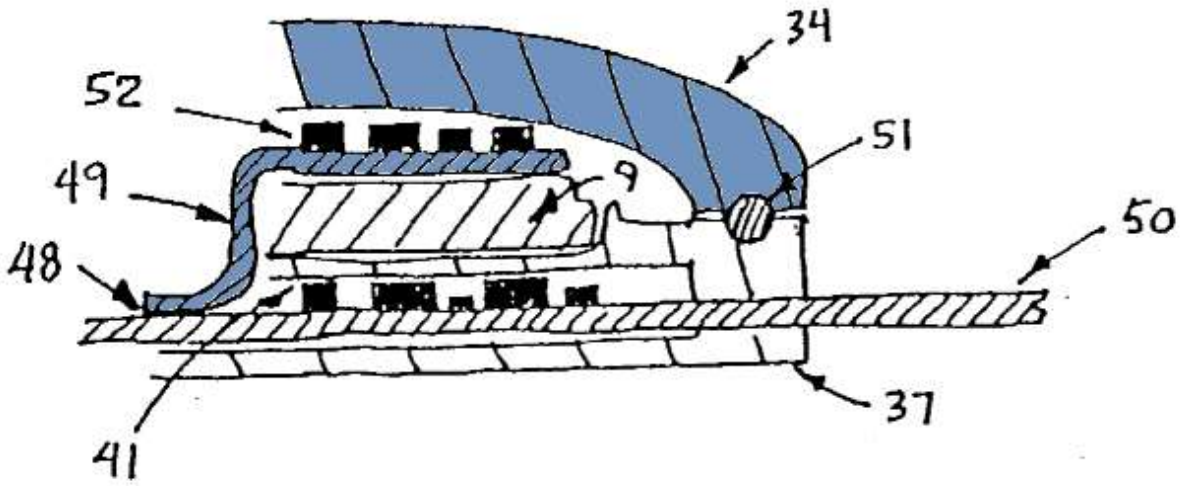
vii. Limitation [1f]

1524. Limitation [1f] recites "a housing."

1525. In my opinion, Jensen discloses limitation [1f] of the '422 patent.

1526. As shown in the annotated version of Jensen's Figure 8 below, "top case 34" (shown in blue) mounts onto "bottom case 37", forming a housing that encloses electronics circuit 52. *Id.* at [0044]–[0046].

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Id. at Fig. 8 (annotated).

1527. Thus, in my opinion, Jensen discloses "a housing."

viii. Limitation [1g]

1528. Limitation [1g] recites "a processor disposed in the housing."

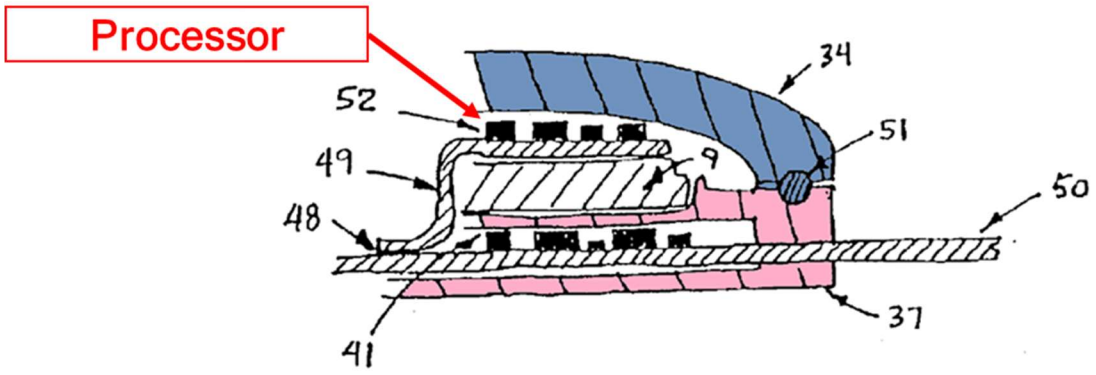
1529. In my opinion, Jensen discloses limitation [1g] of the '422 patent.

1530. As explained above, Jensen discloses a housing. *See* Section XX.B.2.vii, *supra*.

1531. As part of electronics circuitry 41, Jensen discloses "a microcontroller and/or other programmable logic circuitry that perform measurement and processing of sensed data." Ex. 1011 at [0014]. Jensen also teaches that the microcontroller can "run[] a conventional program that may perform further analysis and can also encode a data stream output to the transmitter." *Id.* at [0032]. In the embodiment of Figure 8 shown below, a POSA would understand that the microcontroller

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(processor), along with other electronics circuitry, would be circuitry 52, located on the non-disposable substrate 49, and would be disposed in the housing formed from top case 34 and bottom case 37. Ex. 1007 at 12:37–39 ("A microprocessor, such as microprocessor 512, is defined herein as synonymous and interchangeable with the terms 'microcomputer', 'microcontroller', and 'microprocessor'").



Ex. 1011 at Fig. 8 (annotated).

1532. Thus, in my opinion, Jensen discloses "a processor disposed in the housing."

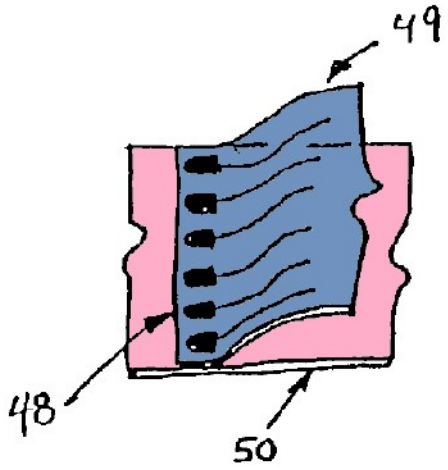
ix. Limitation [1h]

1533. Limitation [1h] recites "attaching the computation-communication module to the disposable substrate."

1534. In my opinion, Jensen discloses limitation [1h] of the '422 patent.

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1535. Jensen teaches that computation-communication module, which includes 49, and disposable substrate 50 are "heat re-flowed together, melting the tinning metal, to connect the two circuits." *Id.* at [0046], Fig. 8A. Similarly, a POSA would have been familiar with a "variety of possibilities for providing terminations," many of which would have formed a releasable attachment between two substrates. Ex. 1035 at 449, 451.



Ex. 1011 at Fig. 8A (annotated).

1536. Thus, in my opinion, Jensen discloses "attaching the computation-communication module to the disposable substrate."

3. Dependent Claim 2

1537. Claim 2 of the '422 patent depends from claim 1 and additionally requires "providing conductive traces in the flexible circuit layer."

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1538. In my opinion, claim 2 of the '422 patent is rendered obvious by Jensen in view of the general knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because Jensen teaches the additional limitation of claim 2. *See* Section XX.B.2, *supra.*

1539. Jensen teaches a "flexible circuit assembly 36 that contains the copper wiring traces that connect the entire circuit 41 to the sensor contracts." Ex. 1011 at [0040]. As described above, these traces would be found in the embodiment of Figure 8. *See* Section XX.B.2.v.

1540. For these reasons, it is my opinion that Jensen discloses "providing conductive traces in the flexible circuit layer" and, therefore, that Jensen, in view of the general knowledge of a POSA, renders obvious claim 2 of the '422 patent.

4. Dependent Claim 3

1541. Claim 3 of the '422 patent depends from claims 1 and 2 and additionally requires that "the conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module."

1542. In my opinion, claim 3 of the '422 patent is rendered obvious by Jensen in view of the general knowledge of a POSA for all the reasons discussed above with respect to claims 1 and 2 as well as because Jensen teaches the additional limitation of claim 3. *See* Section XX.B.3, *supra.*

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1543. In one embodiment, Jensen discloses two flexible printed circuits 49, 50, which comprise, respectively, the substrate for the reusable computation-communication module and the substrate for the disposable module. Ex. 1011 at [0045]–[0046], Fig. 8. Jensen further explains that the circuits are connected (*i.e.*, "electrically coupled") by pads 48, which are "matched on both circuits." *Id.* at [0046], Fig. 8A. A POSA would understand that the pads on the disposable, printed circuit board substrate of Jensen, 50, are connected to sensor contacts 71, 72 through printed traces. A POSA would similarly understand that the pads on the reusable substrate of Jensen 49 are connected ("electrically coupled") to computation-communication module 52 through printed traces. This arrangement would be necessary to transmit detected biosignals from the sensor contacts to the communication-computation module.

1544. For these reasons, it is my opinion Jensen discloses that "the conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module" and, therefore, that Jensen, in view of the general knowledge of a POSA, renders obvious claim 3 of the '422 patent.

5. Dependent Claim 4

1545. Claim 4 of the '422 patent depends from claim 1 and additionally requires "providing a plurality of openings in the flexible printed circuit board layer, the openings being sized for receiving electrode gels."

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1546. In my opinion, claim 4 of the '422 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because Jensen teaches the additional limitation of claim 4. *See* Section XX.B.2, *supra.*

1547. Jensen teaches that "disposable sensor pad electrodes 1 and 2" are disposed on the lower surface of flexible assembly 36. Ex. 1011 at [0041], Fig. 7. As described above, A POSA would understand that flexible substrate 50 is analogous to flexible substrate 36, and includes the same disposable sensor pad electrodes. XX.B.2.ii.

1548. Matsumura teaches a "second sheet 4 . . . [that] is provided with two openings 4a on the left and right sides into which the conductive gel 5 is inserted." Ex. 1012 at [0018]. In my opinion, it would have been obvious to a POSA to incorporate the openings of Matsumura into Jensen's flexible assembly 36, 50 and for electrodes sensor pad electrodes 1 and 2 to connect to the flexible assembly 36, 50 through the plurality of openings.

1549. Commercially available electrode gels were known in the art at the time of the claimed invention. *See, e.g.*, Ex. 1011 at [0041] (describing "off-the-shelf EKG sensor pads, such as those sold by 3M Corporation"). A POSA would have recognized that it could integrate these commercially available disposable electrodes into the invention of Jensen by including recesses or openings to accommodate those

commercially available electrode gels. A POSA would have been motivated to modify Jensen in this manner for at least two reasons. First, relying on commercially available electrodes (rather than creating a novel "from scratch") would ease manufacturing and assembly. Second, providing a recess would help to structurally stabilize the electrode gels, which was known in the art (*e.g.*, by recessing gels in a cup geometry). Ex. 1061 at 578–79 ("If a portion of the electrode loses contact with the skin, current flow across it is altered because, in effect, the size of the interface changes. Current flow may be altered further if movement allows the conductive medium to dry"); *see also* Ex. 1062 at 203–04.

1550. For these reasons, it is my opinion Jensen discloses "providing a plurality of openings in the flexible printed circuit board layer, the openings being sized for receiving electrode gels" and, therefore, Jensen, in view of the knowledge of a POSA, renders obvious claim 4 of the '422 patent.

6. Dependent Claim 5

1551. Claim 5 of the '422 patent depends from claim 1 and additionally requires that "the computation-communication module is releasably attached to the disposable substrate."

1552. In my opinion, claim 5 of the '422 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect

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to claim 1 as well as because Jensen teaches the additional limitation of claim 5. *See* Section XX.B.2, *supra.*

1553. As previously discussed, Jensen discloses that the computation-communication module on substrate 49 is attached to the disposable module on substrate 50 at connection 48. *See* Section XX.B.2.ix, *supra*. It would have been obvious to a POSA to make the attachment between substrate 49 and substrate 50 a "releasable attachment," for example by using adhesives that could be removed with solvents or heat. Similarly, a POSA would have been familiar with a "variety of possibilities for providing terminations," many of which would have formed a releasable attachment between two substrates, including the detachable hooks of Matsumura. Ex. 1035 at 449, 451.

1554. For these reasons, it is my opinion Jensen discloses that "the computation-communication module is releasably attached to the disposable substrate" and, therefore, Jensen, in view of the knowledge of a POSA, renders obvious claim 5 of the '422 patent.

7. Dependent Claim 6

1555. Claim 6 of the '422 patent depends from claim 1 and additionally requires "providing a radio circuit in the computation-communication module."

1556. In my opinion, claim 6 of the '422 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect

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to claim 1 as well as because Jensen teaches the additional limitation of claim 6. *See* Section XX.B.2, *supra.*

1557. Jensen teaches a circuit that includes a radio frequency transmitter 7 (the claimed radio circuit) that "may transmit in a variety of modulation and/or keying methods via antenna 8." Ex. 1011 at [0033]; *see also id.* at [0039].

1558. For these reasons, it is my opinion that Jensen discloses "providing a radio circuit in the computation-communication module" and, therefore, that Jensen, in view of the knowledge of a POSA, renders obvious claim 6 of the '422 patent.

8. Dependent Claim 7

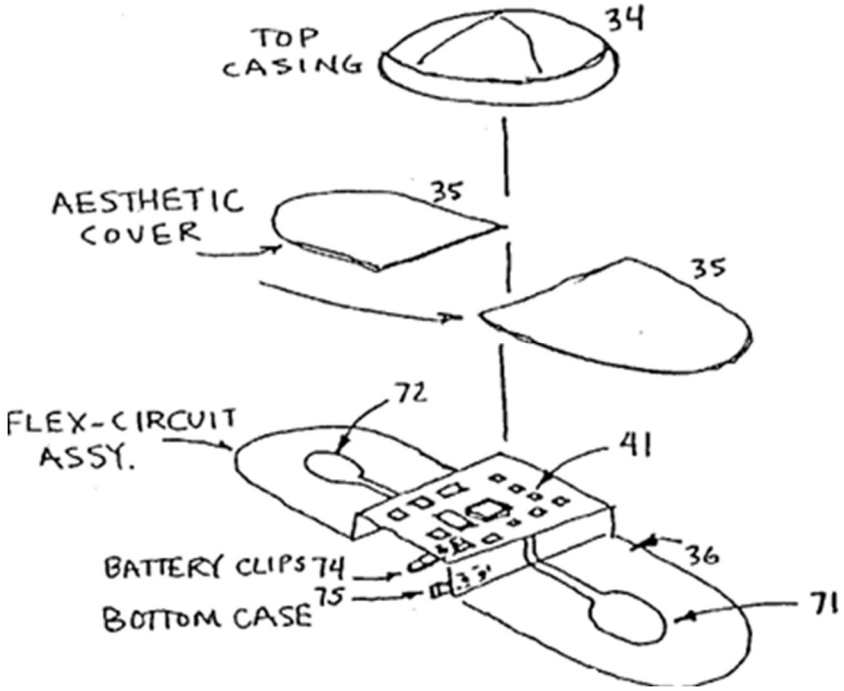
1559. Claim 7 of the '422 patent depends from claims 1, 2, and 3 and additionally requires "at least partially covering the conductive traces with an insulating covering."

1560. In my opinion, claim 7 of the '422 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claims 1, 2, and 3 as well as because Jensen teaches the additional limitation of claim 7. *See* Sections XX.B.4, *supra.*

1561. Jensen discloses a "smart patch" that "has an electronic circuit . . . sandwiched between layers of insulating material and cover plastics." Ex. 1011 at Abstract. Jensen specifically teaches the entire top side of "flexible circuit assembly 36 that contains the copper wiring traces" is "enclose[d]" and "sealed" by top casing

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34 and aesthetic covers 35 which "may be constructed from Mylar sheet," a common insulating material. *Id.* at [0040], [0043]. Figure 5 of Jensen, shown below, demonstrates this arrangement. *Id.* at [0043].



Id. at Fig. 5 (annotated).

1562. A POSA would have understood that aesthetic cover 35 insulates the flexible circuit assembly 36 and its traces, and that the aesthetic cover would be utilized in any embodiment of Jensen, including the embodiment of Figure 8.

1563. In my opinion, a POSA would understand aesthetic covers 35 and/or top casing 34 to be insulating covers for flexible circuit 36 containing the "copper wiring trace."

1564. For these reasons, it is my opinion that a POSA would understand that Jensen discloses "at least partially covering the conductive traces with an insulating

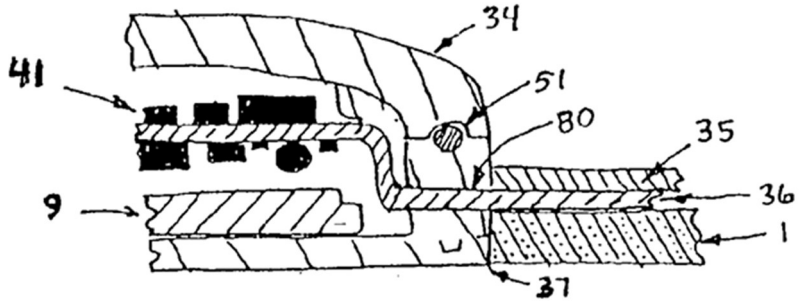
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covering" and, therefore, that Jensen, in view of the knowledge of a POSA, renders obvious claim 7 of the '422 patent.

9. Dependent Claim 9

1565. Claim 9 of the '422 patent depends from claim 1 and additionally requires "integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate."

1566. In my opinion, claim 9 of the '422 patent is rendered obvious by Jensen in combination with Matsumura for all the reasons discussed above with respect to claim 1 as well as because Jensen teaches the additional limitation of claim 9. *See* Section XX.B.2, *supra.* Jensen discloses a "disposable sensor assembly" that includes "disposable sensor pad electrodes 1 and 2." Ex. 1011 at [0041]–[0042]. As shown in Figure 7 below, Jensen further discloses that the sensor pad electrodes 1, 2 are disposed on the lower surface of flexible assembly 36.



Id. at Fig. 7.

1567. A POSA would understand that the same sensor pad electrodes would be integrated into flexible substrate 50 of the embodiment of Figure 8 of Jensen.

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1568. In my opinion, a POSA would have understood that having sensor pad electrodes 1, 2 disposed of on flexible-circuit assembly 73 would be a form of integration.

1569. For these reasons, it is my opinion that Jensen discloses that "integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate" and, therefore, that Jensen renders obvious claim 9 of the '422 patent.

10. Dependent Claim 11

1570. Claim 11 of the '422 patent depends from claims 1 and 9 and additionally requires that "each electrode includes an electrode gel and a conductive surface defining a half cell."

1571. In my opinion, claim 11 of the '422 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claims 1 and 9 as well as because Jensen teaches the additional limitation of claim 11. *See* Sections XX.B.9, *supra.*

1572. Jensen discloses that 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" on the side of the sensor pad that contacts the patient's skin. Ex. 1011 at [0041]. The '422 patent

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describes the term "half cell" comprising (1) a conductive surface and (2) an electrode gel. Ex. 1007 at 5:55–57.

1573. In my opinion, 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 "half cell." Thus, it is my opinion that a POSA would know that Jensen's electrodes define a half cell as defined by the '422 patent.

1574. For these reasons, it is my opinion that a POSA would understand that Jensen discloses that "each electrode includes an electrode gel and a conductive surface defining a half cell" and, therefore, that the Jensen, in view of the knowledge of a POSA, renders obvious claim 11 of the '422 patent.

11. Dependent Claim 12

1575. Claim 12 of the '422 patent depends from claims 1, 9, and 11 and additionally requires that "the disposable substrate is crescent shaped and in which the body-worn physiological sensor is worn on the chest of a patient."

1576. In my opinion, claim 12 of the '422 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claims 1, 9, and 11 as well as because Jensen teaches the additional limitation of claim 12. *See* Sections XX.B.10, *supra.*

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1577. Jensen explains that EKG electronic-rate sensors are generally placed on the chest of a patient. Ex. 1011 at [0006]–[0007]. Jensen teaches that its "smart patch" is similarly applied to "the skin much like a bandage." *Id.* at [0030]. In my opinion, given Jensen's disclosure of the placement of the "smart patch" on the patient's chest, it would have been obvious for a POSA to make the disposable sensor assembly crescent shaped in order to better fit the curvature of the patient's body.

1578. For these reasons, it is my opinion that a POSA would understand that Jensen renders obvious that "the disposable substrate is crescent shaped and in which the body-worn physiological sensor is worn on the chest of a patient" and, therefore, that Jensen, in view of the knowledge of a POSA, renders obvious claim 12 of the '422 patent.

12. Independent Claim 14

1579. In my opinion, claim 14 of the '422 patent is rendered obvious by Jensen in view of the general knowledge of a POSA and/or Matsumura.

i. Preamble 14[pre]

1580. The preamble of claim 14 recites "[a] body-worn physiological sensor made by the process of."

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1581. As described above with respect to claim 1, it is my opinion that, to the extent the preamble is limiting, Jensen discloses a "body-worn physiological sensor" made by the process claimed by the '422 patent. *See* Section XX.B.2.i, *supra.*

ii. Limitation [14a]

1582. Limitation [14a] recites "providing a disposable substrate made from an insulating material, said substrate comprising."

1583. In my opinion, as described above with respect to claim 1, Jensen discloses "providing a disposable substrate made from an insulating material." *See* Section XX.B.2.ii*, supra.*

iii. Limitation [14b]

1584. Limitation [14b] recites "a flexible printed circuit board layer made from an insulating material."

1585. In my opinion, as described above with respect to claim 1, Jensen discloses "a flexible printed circuit board layer made from an insulating material." *See* Section XX.B.2.iii*, supra.*

iv. Limitation [14c]

1586. Limitation [14c] recites "at least two electrodes disposed on the disposable substrate."

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1587. In my opinion, as described above with respect to claim 1, Jensen discloses "at least two electrodes disposed on the disposable substrate." *See* Section XX.B.2.iv, *supra.*

v. Limitation [14d]

1588. Limitation [14d] recites "conductive traces defined between the at least two electrodes."

1589. In my opinion, a described above with respect to claim 1, Jensen discloses "conductive traces defined between the at least two electrodes." *See* Section XX.B.2.v*, supra.*

vi. Limitation [14e]

1590. Limitation [14e] recites "providing a computation-communication module, said module comprising."

1591. In my opinion, as described above with respect to claim 1, Jensen discloses the claimed "computation-communication module." *See* Section XX.B.2.vi, *supra.*

vii. Limitation [14f]

1592. Limitation [14f] recites "a housing."

1593. In my opinion, as described above with respect to claim 1, Jensen discloses "a housing." *See* Section XX.B.2.vii, *supra.*

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viii. Limitation [14g]

1594. Limitation [14g] recites "a processor disposed in the housing."

1595. In my opinion, as described above with respect to claim 1, Jensen discloses "a processor disposed in the housing." *See* Section XX.B.2.viii*, supra.*

ix. Limitation [14h]

1596. Limitation [14h] recites "attaching the computation-communication module to the disposable substrate."

1597. In my opinion, as described above with respect to claim 1, Jensen discloses "attaching the computation-communication module to the disposable substrate." *See* Section XX.B.2.ix, *supra.*

13. Dependent Claim 15

1598. Claim 15 of the '422 patent depends from claim 14 and additionally requires "providing the conductive traces in the flexible printed circuit board layer."

1599. In my opinion, claim 15 of the '422 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 14 as well as because Jensen teaches the additional limitation of claim 15. *See* Section XX.B.12, *supra.*

1600. As described with respect to claim 2, it is my opinion that Jensen discloses "providing the conductive traces in the flexible printed circuit board layer"

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and, therefore, that Jensen renders obvious claim 15 of the '422 patent. *See* Section XX.B.3, *supra.*

14. Dependent Claim 16

1601. Claim 16 of the '422 patent depends from claims 14 and 15 and additionally requires that "configuring the conductive traces in the flexible printed circuit board layer to electrically couple with the attached computation-communication module."

1602. In my opinion, claim 16 of the '422 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claims 14 and 15 as well as because Jensen teaches the additional limitation of claim 16. *See* Section XX.B.13 *supra.*

1603. As described with respect to claim 3, it is my opinion that Jensen discloses "configuring the conductive traces in the flexible printed circuit board layer to electrically couple with the attached computation-communication module" and, therefore, that Jensen renders obvious claim 16 of the '422 patent. *See* Section XX.B.14*, supra.*

15. Dependent Claim 17

1604. Claim 17 of the '422 patent depends from claim 14 and additionally requires that "the computation-communication module is releasably attached to the disposable substrate."

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1605. In my opinion, claim 17 of the ’422 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 14 as well as because Jensen teaches the additional limitation of claim 17. *See* Section XX.B.12 *supra.*

1606. As described with respect to claim 5, it is my opinion that a POSA would understand that Jensen discloses “the computation-communication module is releasably attached to the disposable substrate” and, therefore, that Jensen renders obvious claim 17 of the ’422 patent. *See* Section XX.B.6*, supra.*

16. Dependent Claim 18

1607. Claim 18 of the ’422 patent depends from claim 14 and additionally requires “providing the computation-communication module with a radio circuit.”

1608. In my opinion, claim 18 of the ’422 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 14 as well as because Jensen teaches the additional limitation of claim 18. *See* Section XX.B.12, *supra.*

1609. As described with respect to claim 6, it is my opinion that Jensen discloses “providing the computation-communication module with a radio circuit” and, therefore, that Jensen renders obvious claim 18 of the ’422 patent. *See* Section XX.B.7*, supra.*

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17. Dependent Claim 19

1610. Claim 19 of the ’422 patent depends from claims 14, 15, and 16 and additionally requires “at least partially covering the conductive traces with an insulating covering.”

1611. In my opinion, claim 19 of the ’422 patent is rendered obvious by Jensen in view of the knowledge of a POSA for all the reasons discussed above with respect to claims 14, 15, and 16 as well as because Jensen teaches the additional limitation of claim 19. *See* Section XX.B.14, *supra.*

1612. As described above with respect to claim 7, it is my opinion that a POSA would understand that Jensen discloses “at least partially covering the conductive traces with an insulating covering” and, therefore, that Jensen renders obvious claim 19 of the ’422 patent. *See* Section XX.B.8, *supra.*

18. Dependent Claim 20

1613. Claim 20 of the ’422 patent depends from claim 14 and additionally requires “integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate.”

1614. In my opinion, claim 20 of the ’422 patent is rendered obvious by Jensen in combination with Matsumura for all the reasons discussed above with respect to claim 14 as well as because Jensen teaches the additional limitation of claim 20. *See* Section XX.B.12, *supra.*

1615. As described above with respect to claim 9, it is my opinion that Jensen discloses "integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate." *See* Section XX.B.9, *supra.*

C. Ground 3: Obvious Over Ozguz in view of the General Knowledge of a Person of Ordinary Skill in the Art

1. Independent Claim 1

1616. In my opinion, claim 1 of the '422 patent is rendered obvious by Ozguz in view of the general knowledge of a POSA.

i. Preamble 1[pre]

1617. The preamble of claim 1 of the '422 patent recites "[a] method for manufacturing a body-worn physiological sensor, the method comprising."

1618. In my opinion, to the extent the preamble is limiting, Ozguz discloses the preamble of claim 1 of the '422 patent.

1619. Ozguz teaches "a sensor system comprising a thin flexible ambulatory/self contained bio-sensor module in a form similar to an adhesive bandage for sensing physiologically modulated signals from the body, and a method of making such a sensor system and module." Ex. 1014 at [0003]. In my opinion, a POSA would have used well-known methods to manufacture Ozguz's "bio-sensor" based on Ozguz's disclosure of components, materials, and assembly techniques.

1620. Thus, in my opinion, Ozguz discloses "[a] method for manufacturing a body-worn physiological sensor."

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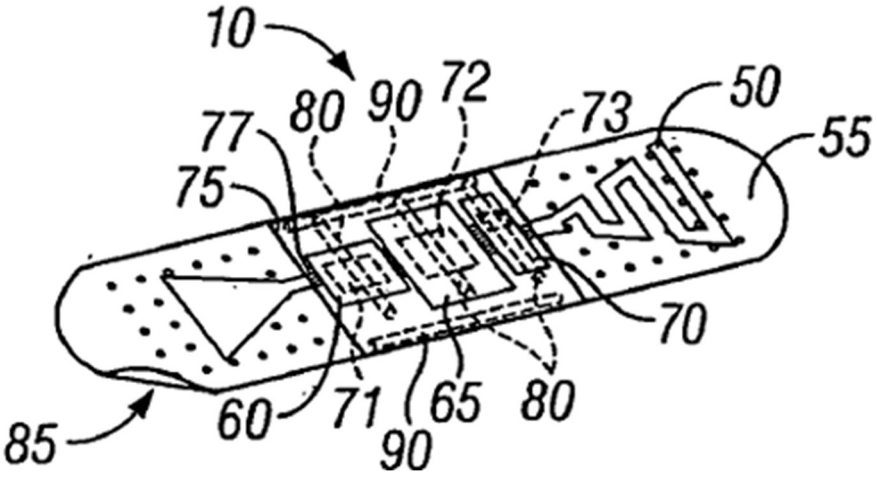
ii. Limitation [1a]

1621. Limitation [1a] recites "providing a disposable substrate made from an insulating material, said substrate comprising."

1622. In my opinion, Ozguz discloses limitation [1a] of the '422 patent.

1623. Ozguz discloses that sensor module 10 is "made disposable and [is] discarded after monitoring a particular subject body 20 for purposes of good hygiene." *Id.* at [0049].

1624. As shown by Figure 2A below, Ozguz includes a "flexible substrate 55" on which at least one antenna 50 is metalized and to which "thin flexible silicon substrates 60, 65, 70 having respective integrated circuits 71, 72, 73 are bonded." *Id.* at [0039]. Circuits 71, 72, and 73 can be integrated into a single circuit. *Id.* at [0042].



Id. at Fig. 2A. Ozguz discloses that flexible substrate 55 is made of an insulating material, "preferably in the form of a polyimide, and is electrically non-conductive

and flexible. However other flexible non-conducting substrates can be substituted." *Id.* at [0046]. "Furthermore, the adhesive pads 91 can be formed of double-sided adhesive for application before and removal after each use so that the sensor module can be used repeatedly." *Id.* at [0049].

1625. Thus, in my opinion, Ozguz discloses "providing a disposable substrate made from an insulating material, said substrate comprising."

iii. Limitation [1b]

1626. Limitation [1b] recites "a flexible printed circuit board layer made from the insulating material."

1627. In my opinion, Ozguz discloses limitation [1b] of the '422 patent.

1628. Ozguz discloses that flexible substrate 55 includes metallization 77 that interconnects integrated circuits 71, 72, 73 and other components to form a circuit board layer. *Id.* at [0039].

1629. In my opinion, a POSA would have understood substrate 55 to be a printed circuit layer on which components or materials are printed, such as metallization 77, because screen printing was a preferred method of manufacturing a circuit board at the time of the invention of the '422 patent. *See* Ex. 1035 at 296 ("Printing Process. The circuit patterns are screen printed on the substrate by two ways: (1) Manual screen printing process, and (2) Automatic or semi-automatic screen printing process."); *see also* Ex. 1013 at 5:23–42 ("Each electrode 35 has a

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conductive grid 56 which is comprised of a matrix of approximately 0.050 inch wide lines 42 of conductive ink compound applied to an insulation and base support layer 44 ***preferably by means of a silk screen process.***") (emphasis added); *see also* Ex. 1013 at 5:4–8. Screen printing was and is preferred because it allows a greater degree of control in printing and thus is cost-effective, which is important when expensive materials such as silver are being used. *Id.*; *see also* Section IV.C., *supra*.

1630. Ozguz further discloses that flexible substrate 55 is made of an insulating material, "preferably in the form of a polyimide, and is electrically non-conductive and flexible. However other flexible non-conducting substrates can be substituted." Ex. 1014 at [0046].

1631. Thus, in my opinion, Ozguz discloses "a flexible printed circuit board layer made from the insulating material."

iv. Limitation [1c]

1632. Limitation [1c] recites "at least two electrodes disposed on the disposable substrate."

1633. In my opinion, Ozguz discloses limitation [1c] of the '422 patent.

1634. As demonstrated by annotated Figure 3E below, Ozguz discloses that sensor module 10 includes *at least* "electrodes 80 disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20." *Id.* at [0039].

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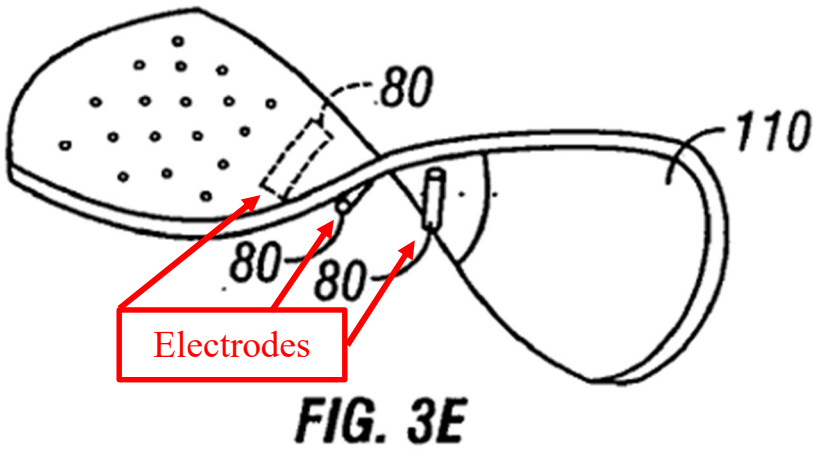


FIG. 3E

Id. at Fig. 3E (annotated). As discussed above, Ozguz discloses that flexible substrate 55 is disposable. *Id.* at [0049]; *see also* Section XIX.C.1.ii., *supra.* Ozguz further discloses "a pair of electrodes 90" that "extend longitudinally relative to the sensor module 10." Ex. 1014 at [0043], Fig. 2.

1635. Thus, in my opinion, Ozguz discloses "at least two electrodes disposed on the disposable substrate."

v. Limitation [1d]

1636. Limitation [1d] recites "conductive traces defined between the at least two electrodes."

1637. In my opinion, Ozguz discloses limitation [1d] of the '422 patent.

1638. Ozguz discloses that "metallization 77 further extends through the flexible substrate 55 and connects the [integrated circuits] ICs 71, 72, 73 to the electrodes 80 disposed on an underside 85 of the flexible substrate 55." *Id.* at [0039]; *see also id.* at [0048]. A POSA would understand metallization 77 is conductive

traces because the metallization is a conductive material that connects components of the flexible circuit.

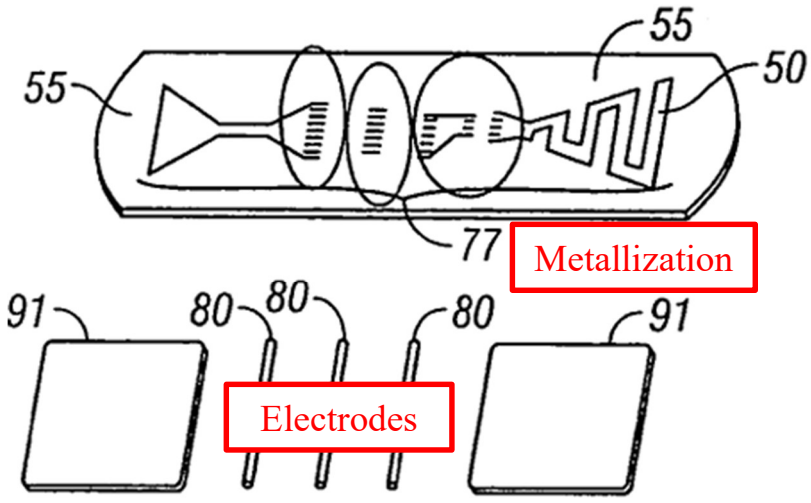


FIG. 3B

Id. at Fig. 3B (annotated).

1639. Thus, in my opinion, Ozguz discloses "conductive traces defined between the at least two electrodes."

vi. Limitation [1e]

1640. Limitation [1e] recites "providing a computation-communication module, said module comprising."

1641. In my opinion, Ozguz discloses limitation [1e] of the '422 patent.

1642. Ozguz discloses that sensor module 10 includes "flexible silicon substrates 60, 65, 70 having respective integrated circuits 71, 72, 73 [that] are bonded to the flexible substrate 55." *Id.* at [0039]. These thin silicon substrates 60, 65, 70 can include a "transmitter or transceiver 190 for transmitting data by RF signals to a

remote receiver" (*i.e.*, a communication module). *Id.* at [0058]. Ozguz discloses that "it is to be expressly understood that the ICs 71, 72, 73, can be integrated as one IC on a single silicon substrate." *Id.* at [0042].

1643. Ozguz also discloses that thin silicon substrates 60, 65, 70 can also include "a microprocessor 175" for processing signals and "controlling input, storage, and analysis of the collected data" (*i.e.*, a computation module). *Id.* at [0041], [0044], [0058].

1644. Thus, in my opinion, Ozguz discloses "providing a computation-communication module."

vii. Limitation [1f]

1645. Limitation [1f] recites "a housing."

1646. In my opinion, Ozguz discloses limitation [1f] of the '422 patent.

1647. Ozguz discloses a "flexible, thin battery 105 overlays the silicon substrates 60, 65, 70 and their respective [integrated circuits] ICs 71, 72, 73." *Id.* at [0048]. The battery overlay 105 (shown in blue below) is shaped in a way that houses the computation-communication module formed by flexible substrate 55 and components bonded to it, such as flexible silicon substrates 60, 65, 70, integrated circuits 71, 72, 73, and antenna 50. *Id.*

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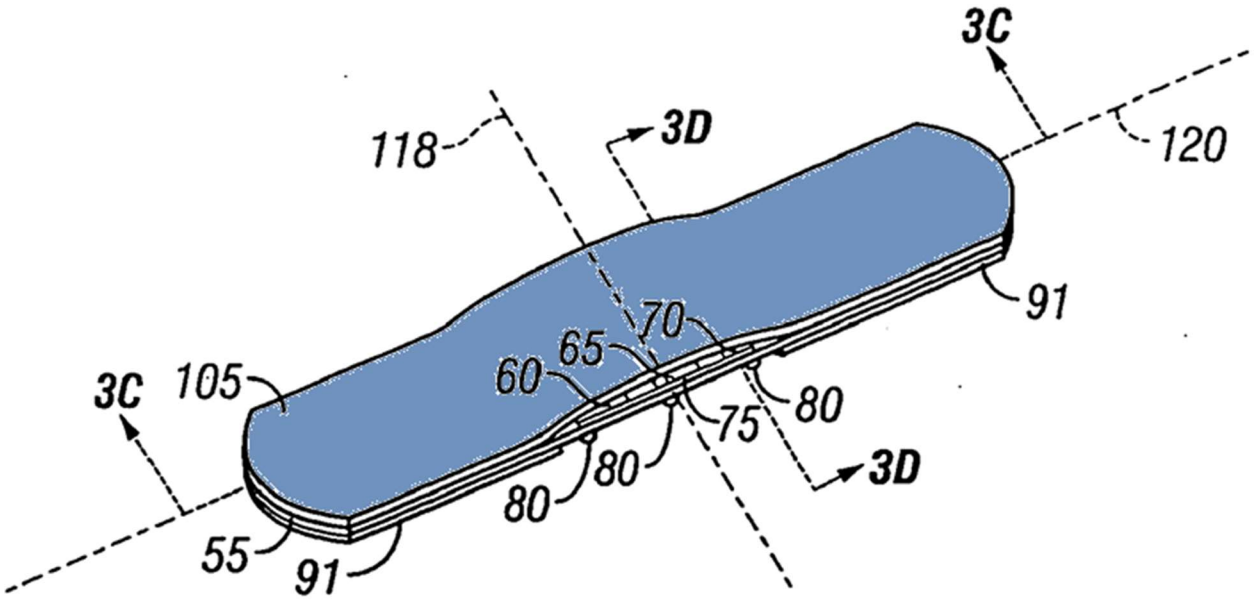


FIG. 3A

Id. at Fig. 3A (annotated).

1648. Thus, in my opinion, Ozguz discloses "a housing."

viii. Limitation [1g]

1649. Limitation [1g] recites "a processor disposed in the housing."

1650. In my opinion, Ozguz discloses limitation [1g] of the '422 patent.

1651. Ozguz discloses a "microprocessor 175" that is "incorporated into the thin silicon substrates 60, 65, 70." *Id.* at [0058]. As noted above, battery overlay 105 houses "the silicon substrates 60, 65, 70 and their respective ICs 71, 72, 73." *Id.* at [0048]; *see also* Section XX.C.1.vii, *supra.*

1652. Thus, in my opinion, Ozguz discloses "a processor disposed in the housing."

ix. Limitation [1h]

1653. Limitation [1h] recites "attaching the computation-communication module to the disposable substrate."

1654. In my opinion, Ozguz discloses limitation [1h] of the '422 patent.

1655. As noted above, Ozguz discloses a disposable "flexible substrate 55." Ex. 1014 at [0046], [0048]; *see also* Sections XX.C.1.ii, XX.C.1.iii*, supra.* Silicon 60, 65, 70, which include both transmitter or transceiver 190 (for communication) and microprocessor 175 (for computation), are bonded to the flexible substrate 55. Ex. 1014 at [0046], [0058]. Ozguz discloses that "it is to be expressly understood that the ICs 71, 72, 73, can be integrated as one IC on a single silicon substrate." *Id.* at [0042].

1656. Thus, in my opinion, Ozguz discloses "attaching the computation-communication module to the disposable substrate."

2. Dependent Claim 2

1657. Claim 2 of the '422 patent depends from claim 1 and additionally requires "providing conductive traces in the flexible circuit layer."

1658. In my opinion, claim 2 of the '422 patent is disclosed or rendered obvious by Ozguz for all the reasons discussed above with respect to claim 1 as well as because Ozguz discloses or teaches the additional limitation of claim 2. *See* Section XX.C.1, *supra.*

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1659. Ozguz discloses that "metallization 77 further extends through the flexible substrate 55 and connects the [integrated circuits] ICs 71, 72, 73 to the electrodes 80 disposed on an underside 85 of the flexible substrate 55." Ex. 1014 at [0039]. A POSA would understand metallization 77 is conductive traces because the metallization is a conductive material that connects components of the flexible circuit.

1660. For these reasons, it is my opinion that a POSA would understand that Ozguz discloses or renders obvious "providing conductive traces in the flexible circuit layer."

3. Dependent Claim 3

1661. Claim 3 of the '422 patent depends from claims 1 and 2 and additionally requires that "the conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module."

1662. In my opinion, claim 3 of the '422 patent is rendered obvious by Ozguz for all the reasons discussed above with respect to claims 1 and 2 as well as because Ozguz discloses the additional limitation of claim 3. *See* Section XX.C.2, *supra.*

1663. Ozguz discloses that "metallization 77 is applied to the flexible substrate 55" and "interconnects the ICs 71, 72, 73" on flexible silicon 60, 65, 70 "to each other and to the antenna 50." Ex. 1014 at [0039]. As discussed above, Ozguz teaches that microprocessor 175 and transmitter or transceiver 190

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(computation-communication module) are incorporated into flexible silicon layers 60, 65, 70. *Id.* at [0058]; *see also* Section XX.C.1.vi, *supra.* Ozguz discloses that "it is to be expressly understood that the ICs 71, 72, 73, can be integrated as one IC on a single silicon substrate." Ex. 1014 at [0042].

1664. For these reasons, it is my opinion that Ozguz discloses that "the conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module."

4. Dependent Claim 5

1665. Claim 5 of the '422 patent depends from claim 1 and additionally requires that "the computation-communication module is releasably attached to the disposable substrate."

1666. In my opinion, claim 5 of the '422 patent is rendered obvious for all the reasons discussed above with respect to claim 1 as well as because the combination of Ozguz and Matsumura teach the additional limitation of claim 5. *See* Section XX.C.1, *supra.*

1667. Ozguz discloses that "the adhesive pads 91 can be formed of double-sided adhesive ***for application before and removal after each use*** so that the sensor module can be used repeatedly" and notes that "[t]he sensor module can be sterilized in an autoclave . . . ***between uses***." Ex. 1014 at [0049] (emphases added). Thus, Ozguz teaches that some components of sensor module 10 are reusable and that those

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components are releasably attached to other disposable components, such as adhesive pad 91. *Id*. In my opinion, a POSA would know that "flexible silicon 60, 65, 70" with incorporated "microprocessor 175" and "transmitter or transceiver 190" (the claimed computation-communication module), would be a portion of sensor module that can be used repeatedly to reduce costs and minimize waste.

1668. Matsumura teaches a way to connect reusable and disposable components of a sensor module. Matsumura discloses that "[t]he bioelectrode pad 7 and the signal processor 10 are detachable with hooks" and "the reusable signal processor and the disposable bioelectrode can be easily attached and detached before and after use." Ex. 1012 at [0016]. In my opinion, a POSA would have had a reasonable expectation of success in modifying Ozguz's sensor module based on this disclosure of Matsumura without undue experimentation, and would have been motivated to do so. *See* Section XIX.D.1, *supra*. Both Ozguz and Matsumura disclose wearable, self-contained ECG monitors. *See* Ex. 1014 at [0003]; Ex. 1012 at Abstract, [0006], [0014]. Additionally, it is my opinion that a POSA would have recognized that Ozguz and Matsumura could have similar disposable and reusable parts; the disposable parts for both include the electrodes used to detect ECG signals and the reusable parts for both include the processor and transmitter. *See* Sections XX.A.1.ii, XX.A.1.vi; XX.C.1.ii, XX.C.1.vi, *supra.* Further, Matsumura teaches using hooks to connect and release the disposable and reusable components

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which is a common mechanical approach taken in the art. Ex. 1012 at [0024], [0027].

1669. For these reasons, it is my opinion the combination of Ozguz and Matsumura renders obvious "the computation-communication module is releasably attached to the disposable substrate."

5. Dependent Claim 6

1670. Claim 6 of the '422 patent depends from claim 1 and additionally requires "providing a radio circuit in the computation-communication module."

1671. In my opinion, claim 6 of the '422 patent is rendered obvious by Ozguz for all the reasons discussed above with respect to claim 1 as well as because Ozguz teaches the additional limitation of claim 6. *See* Section XX.C.1, *supra.*

1672. As previously discussed, Ozguz discloses "circuitry 170 that could be incorporated into the thin silicon substrates 60, 65, 70" which "will include . . . a transmitter or transceiver 190 for transmitting data by [radio frequency] RF signals to a remote receiver." Ex. 1014 at [0058].

1673. For these reasons, it is my opinion that Ozguz discloses "providing a radio circuit in the computation-communication module."

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6. Dependent Claim 9

1674. Claim 9 of the '422 patent depends from claim 1 and additionally requires "integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate."

1675. In my opinion, claim 9 of the '422 patent is rendered obvious by Ozguz for all the reasons discussed above with respect to claim 1 as well as because Ozguz teaches the additional limitation of claim 9. *See* Section XX.C.1, *supra.*

1676. Ozguz discloses that sensor module 10 includes three "electrodes 80 disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20." Ex. 1014 at [0039]. As previously discussed, flexible substrate 55 is disposable. *Id.* at [0049]; *see also* Section XX.C.1.ii, *supra*.

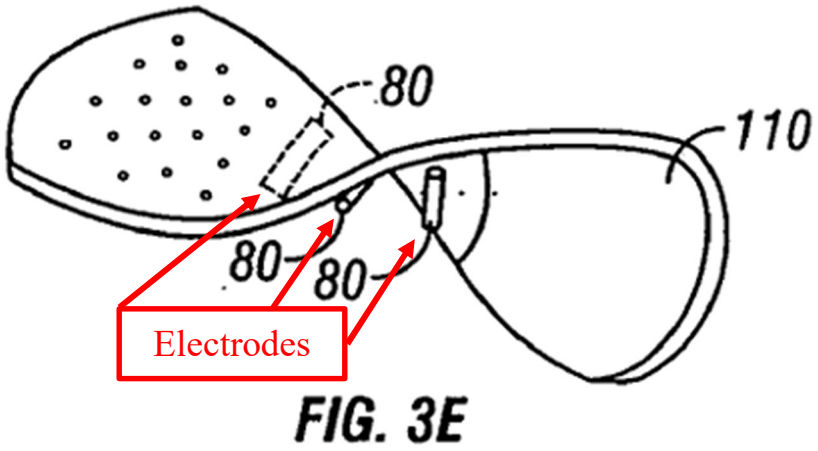


FIG. 3E

Ex. 1014 at Fig. 3E (annotated).

1677. For these reasons, it is my opinion Ozguz discloses "integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate."

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7. Dependent Claim 11

1678. Claim 11 of the ’422 patent depends from claims 1 and 9 and additionally requires “an electrode gel and a conductive surface defining a half cell.”

1679. In my opinion, claim 11 of the ’422 patent is rendered obvious by Ozguz and the general knowledge of a POSA for all the reasons discussed above with respect to claims 1 and 9 as well as because the additional limitation of claim 11 would be obvious to a POSA. *See* Sections XX.C.1, XX.C.6, *supra*.

1680. As described above *supra* Section XX.C.6, Ozguz includes integrated electrode sensor contacts on its bottom surface. A POSA would recognize that Ozguz’s device uses “dry electrodes.” Dry electrodes, which do not use electrode gel or paste, are notoriously susceptible to motion artifacts, which limit the performance of systems that use them. *See, e.g.*, Ex. 1064 (J. Mühlsteff et al., *Wearable approach for continuous ECG – and Activity Patient-Monitoring*, 1 26th Proc. Int’l Conf. of IEEE Eng’g in Med. & Biol. Soc’y 2184 (2004)) at 2187. A POSA therefore would have been motivated to modify Ozguz’s bottom surface to include an electrode gel and a conductive surface defining a half cell as a means of improving the quality of the ECG signal.

1681. Commercially available electrode gels were known in the art at the time of the claimed invention. *See, e.g.*, Ex. 1011 at [0041] (describing “off-the-shelf EKG sensor pads, such as those sold by 3M Corporation”). A POSA would have

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recognized that it could integrate these commercially available disposable electrodes into the invention of Ozguz with a reasonable expectation of success. Integrating such gels into the device would result in an "electrode gel and a conductive surface defining a half cell."

1682. For these reasons, it is my opinion that Ozguz and a POSA's general knowledge render obvious "an electrode gel and a conductive surface defining a half cell."

8. Dependent Claim 12

1683. Claim 12 of the '422 patent depends from claims 1, 9, and 11 and additionally requires that "the disposable substrate is crescent shaped and in which the body-worn physiological sensor is worn on the chest of a patient."

1684. In my opinion, claim 12 of the '422 patent is rendered obvious by Ozguz for all the reasons discussed above with respect to claims 1, 9, and 11 as well as because Ozguz teaches the additional limitation of claim 12. *See* Section XX.C.7, *supra.*

1685. Ozguz discloses that sensor module 10 is attached to the patient's chest. Ex. 1014 at [0038], Fig. 2A. In my opinion, given the placement of sensor module 10 on the patient's chest, it would have been obvious for a person of skill in the art to make Ozguz's disposable sensor assembly crescent shaped to better fit the curvature of the patient's body.

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1686. For these reasons, it is my opinion that Ozguz renders obvious that "the disposable substrate is crescent shaped and in which the body-worn physiological sensor is worn on the chest of a patient."

9. Independent Claim 14

1687. In my opinion, claim 14 of the '422 patent is rendered obvious by Ozguz in view of the general knowledge of a POSA.

i. Preamble 14[pre]

1688. The preamble of claim 14 recites "[a] body-worn physiological sensor made by the process of."

1689. As described above with respect to claim 1, it is my opinion that, to the extent the preamble is limiting, Ozguz discloses a "body-worn physiological sensor" made by the process claimed by the '422 patent. *See* Section XX.C.1.i, *supra.*

ii. Limitation [14a]

1690. Limitation [1a] recites "providing a disposable substrate made from an insulating material, said substrate comprising."

1691. In my opinion, as described above with respect to claim 1, Ozguz discloses "providing a disposable substrate made from an insulating material." *See* Section XX.C.1.ii*, supra.*

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iii. Limitation [14b]

1692. Limitation [14b] recites "a flexible printed circuit board layer made from an insulating material."

1693. In my opinion, as described above with respect to claim 1, Ozguz discloses "a flexible printed circuit board layer made from an insulating material." *See* Section XX.C.1.iii*, supra.*

iv. Limitation [14c]

1694. Limitation [14c] recites "at least two electrodes disposed on the disposable substrate."

1695. In my opinion, as described above with respect to claim 1, Ozguz discloses "at least two electrodes disposed on the disposable substrate." *See* Section XX.C.1.iv, *supra.*

v. Limitation [14d]

1696. Limitation [14d] recites "conductive traces defined between the at least two electrodes."

1697. In my opinion, a described above with respect to claim 1, Ozguz discloses "conductive traces defined between the at least two electrodes." *See* Section XX.C.1.v*, supra.*

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vi. Limitation [14e]

1698. Limitation [14e] recites "providing a computation-communication module, said module comprising."

1699. In my opinion, as described above with respect to claim 1, Ozguz discloses the claimed "computation-communication module." *See* Section XX.C.1.vi, *supra.*

vii. Limitation [14f]

1700. Limitation [14f] recites "a housing."

1701. In my opinion, as described above with respect to claim 1, Ozguz discloses "a housing." *See* Section XX.C.1.vii, *supra.*

viii. Limitation [14g]

1702. Limitation [14g] recites "a processor disposed in the housing."

1703. In my opinion, as described above with respect to claim 1, Ozguz discloses "a processor disposed in the housing." *See* Section XX.C.1.viii*, supra.*

ix. Limitation [14h]

1704. Limitation [14h] recites "attaching the computation-communication module to the disposable substrate."

1705. In my opinion, as described above with respect to claim 1, Ozguz discloses "attaching the computation-communication module to the disposable substrate." *See* Section XX.C.1.ix, *supra.*

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10. Dependent Claim 15

1706. Claim 15 of the ’422 patent depends from claim 1 and additionally requires “providing the conductive traces in the flexible printed circuit board layer.”

1707. In my opinion, claim 15 of the ’422 patent is rendered obvious by Ozguz for all the reasons discussed above with respect to claim 14 as well as because Ozguz discloses or renders obvious the additional limitation of claim 15. *See* Section XX.C.9, *supra.*

1708. As described with respect to Claim 2, it is my opinion that Ozguz discloses or renders obvious “providing the conductive traces in the flexible printed circuit board layer.” *See* Section XX.C.2, *supra.*

11. Dependent Claim 16

1709. Claim 16 of the ’422 patent depends from claims 14 and 15 and additionally requires that “configuring the conductive traces in the flexible printed circuit board layer to electrically couple with the attached computation-communication module.”

1710. In my opinion, claim 16 of the ’422 patent is rendered obvious by Ozguz for all the reasons discussed above with respect to claims 14 and 15 as well as because Ozguz discloses the additional limitation of claim 16. *See* Section XX.C. 10, *supra.*

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1711. As described above with respect to Claim 3, it is my opinion that Ozguz discloses "configuring the conductive traces in the flexible printed circuit board layer to electrically couple with the attached computation-communication module." *See* Section XX.C.3*, supra.*

12. Dependent Claim 17

1712. Claim 17 of the '422 patent depends from claim 14 and additionally requires that "the computation-communication module is releasably attached to the disposable substrate."

1713. In my opinion, claim 17 of the '422 patent is rendered obvious by Ozguz in combination with Matsumura for all the reasons discussed above with respect to claim 14 as well as because the combination of Ozguz and Matsumura teaches the additional limitation of claim 17. *See* Section XX.C.9, *supra.*

1714. As described above with respect to claim 5, it is my opinion that the combination of Ozguz and Matsumura teaches that "the computation-communication module is releasably attached to the disposable substrate." *See* Section XX.C.4*, supra.*

13. Dependent Claim 18

1715. Claim 18 of the '422 patent depends from claim 14 and additionally requires "providing the computation-communication module with a radio circuit."

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1716. In my opinion, claim 18 of the ’422 patent is rendered obvious by Ozguz for all the reasons discussed above with respect to claim 14 as well as because Ozguz discloses the additional limitation of claim 18. *See* Section XX.C.9, *supra.*

1717. As described above with respect to claim 6, it is my opinion that Ozguz discloses “providing the computation-communication module with a radio circuit.” *See* Section XX.C.5*, supra.*

14. Dependent Claim 20

1718. Claim 20 of the ’422 patent depends from claim 14 and additionally requires “integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate.”

1719. In my opinion, claim 20 of the ’422 patent is rendered obvious by Ozguz for all the reasons discussed above with respect to claim 14 as well as because Ozguz teaches the additional limitation of claim 20. *See* Section XX.C.9, *supra.*

1720. As described above with respect to claim 9, it is my opinion that Ozguz discloses “integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate.” *See* Section XX.C.6, *supra.*

XXI. CONCLUSION

1721. For all of the reasons I discussed above, it is my opinion that claims 1–8, 10–15, 29, 31–35, 37–39, and 43–45 of the ’007 patent; claims 1–8 and 11–14 of

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the ’492 patent; claims 1–8, 11, 12, and 15–20 of the ’484 patent; and 1–7, 9–12, and 14–20 of the ’422 patent are unpatentable.

1722. I reserve the right to change, amend, and/or supplement my opinions as necessary in response to new information and evidence made available to me, additional scientific analysis that leads me to conclude that supplementation is necessary, new issues that may arise, and any additional discovery, arguments, evidence, or testimony presented in this matter.

1723. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner raises and to consider new information as it becomes available to me.

1724. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the full knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code.

Dated: December 20, 2024

Jason Heikenfeld

Jason Heikenfeld