

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

iRhythm, Inc.

Petitioner,

v.

Welch Allyn, Inc.

Patent Owner.

Case: IPR2025-00363

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

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

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TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104.....	1
A. Standing (37 C.F.R. § 42.104(a)).....	1
B. Identification of Challenge (37 C.F.R. § 42.104(b)).....	1
III. PAYMENT OF FEES	2
IV. OVERVIEW OF CHALLENGES AND RELIEF REQUESTED.....	2
V. SUMMARY OF THE '422 PATENT	3
A. Technical Background.....	3
B. Patent Description	6
C. Priority Date	7
D. Prosecution History	7
E. Level of Ordinary Skill in the Art	8
VI. PRIOR ART OVERVIEW	9
A. Jensen (Ex. 1011)	9
B. Matsumura (Ex. 1012).....	10
C. Ozguz (Ex. 1014)	12
VII. THE CHALLENGED CLAIMS ARE UNPATENTABLE.....	14
A. Ground 1: Claims 1-7, 9-11, and 14-20 are Obvious Over Matsumura in view of the General Knowledge of a Person of Ordinary Skill in the Art.....	14
1. Claim 1	14

TABLE OF CONTENTS

(Continued)

	Page
i. [Pre]: A method for manufacturing a body-worn physiological sensor, the method comprising:	14
ii. [1a.] providing a disposable substrate made from an insulating material, said substrate comprising:	15
iii. [1b.] a flexible printed circuit board layer made from the insulating material;.....	16
iv. [1c.] at least two electrodes disposed on the disposable substrate; and	17
v. [1d.] conductive traces defined between the at least two electrodes;.....	18
vi. [1e.] providing a computation-communication module, said module comprising:.....	19
vii. [1f.] a housing;.....	20
viii. [1g.] a processor disposed in the housing; and.....	20
ix. [1h.] attaching the computation-communication module to the disposable substrate.	21
2. Claim 2.....	22
3. Claim 3.....	23
4. Claim 4.....	23
5. Claim 5.....	24
6. Claim 6.....	25
7. Claim 7.....	25
8. Claim 9.....	26
9. Claim 10.....	26

TABLE OF CONTENTS

(Continued)

	Page
10. Claim 11	27
11. Claim 14	28
i. 14[pre]. A body-worn physiological sensor made by the process of:	28
ii. [14a.] providing a disposable substrate made from an insulating material, said substrate comprising:	28
iii. [14b.] a flexible printed circuit board layer made from an insulating material;	28
iv. [14c.] at least two electrodes disposed on the disposable substrate; and	28
v. [14d.] conductive traces defined between the at least two electrodes;	28
vi. [14e.] providing a computation-communication module, said module comprising:	29
vii. [14f.] a housing;	29
viii. [14g.] a processor disposed in the housing; and	29
ix. [14h.] attaching the computation- communication module to the disposable substrate.	29
12. Claim 15	29
13. Claim 16	29
14. Claim 17	30
15. Claim 18	30
16. Claim 19	30
17. Claim 20	30

TABLE OF CONTENTS

(Continued)

	Page
B. Ground 2: Claims 1-7, 9, 11, 12, and 14-20 are Obvious Over Jensen and the General Knowledge of Person of Ordinary Skill in the Art or Matsumura	30
1. Motivation to Combine	30
2. Claim 1	37
i. [Pre]: A method for manufacturing a body-worn physiological sensor, the method comprising:	37
ii. [1a.] providing a disposable substrate made from an insulating material, said substrate comprising:	37
iii. [1b.] a flexible printed circuit board layer made from the insulating material;.....	41
iv. [1c.] at least two electrodes disposed on the disposable substrate; and	41
v. [1d.] conductive traces defined between the at least two electrodes;.....	42
vi. [1e.] providing a computation-communication module, said module comprising:.....	43
vii. [1f.] a housing;.....	44
viii. [1g.] a processor disposed in the housing; and.....	44
ix. [1h.] attaching the computation-communication module to the disposable substrate.	45
3. Claim 2	46
4. Claim 3	46
5. Claim 4	47
6. Claim 5	48

TABLE OF CONTENTS

(Continued)

	Page
7. Claim 6.....	48
8. Claim 7.....	49
9. Claim 9.....	50
10. Claim 11.....	51
11. Claim 12.....	51
12. Claim 14.....	52
i. 14[pre]. A body-worn physiological sensor made by the process of:	52
ii. [14a.] providing a disposable substrate made from an insulating material, said substrate comprising:	52
iii. [14b.] a flexible printed circuit board layer made from an insulating material;	52
iv. [14c.] at least two electrodes disposed on the disposable substrate; and	52
v. [14d.] conductive traces defined between the at least two electrodes;.....	53
vi. [14e.] providing a computation-communication module, said module comprising:.....	53
vii. [14f.] a housing;.....	53
viii. [14g.] a processor disposed in the housing; and.....	53
ix. [14h.] attaching the computation- communication module to the disposable substrate.	53
13. Claim 15.....	53
14. Claim 16.....	54

TABLE OF CONTENTS

(Continued)

	Page
15. Claim 17.....	54
16. Claim 18.....	54
17. Claim 19.....	54
18. Claim 20.....	54
C. Ground 3: Claims 1-3, 5, 6, 9, 11, 12, 14-18, and 20 are Obvious Over Ozguz in view of the General Knowledge of a Person of Ordinary Skill in the Art	54
1. Claim 1	54
i. [Pre]: A method for manufacturing a body- worn physiological sensor, the method comprising:	54
ii. [1a.] providing a disposable substrate made from an insulating material, said substrate comprising:	55
iii. [1b.] a flexible printed circuit board layer made from the insulating material;.....	56
iv. [1c.] at least two electrodes disposed on the disposable substrate; and	57
v. [1d.] conductive traces defined between the at least two electrodes;.....	58
vi. [1e.] providing a computation-communication module, said module comprising:.....	59
vii. [1f.] a housing;.....	59
viii. [1g.] a processor disposed in the housing; and.....	60
ix. [1h.] attaching the computation-communication module to the disposable substrate.....	61
2. Claim 2	61

TABLE OF CONTENTS **(Continued)**

	Page
3. Claim 3	62
4. Claim 5	62
5. Claim 6	64
6. Claim 9	64
7. Claim 11	65
8. Claim 12	66
9. Claim 14	66
i. 14[pre]. A body-worn physiological sensor made by the process of:	66
ii. [14a.] providing a disposable substrate made from an insulating material, said substrate comprising:	67
iii. [14b.] a flexible printed circuit board layer made from an insulating material;	67
iv. [14c.] at least two electrodes disposed on the disposable substrate; and	67
v. [14d.] conductive traces defined between the at least two electrodes;	67
vi. [14e.] providing a computation-communication module, said module comprising:	67
vii. [14f.] a housing;	68
viii. [14g.] a processor disposed in the housing; and	68
ix. [14h.] attaching the computation- communication module to the disposable substrate.	68
10. Claim 15	68

TABLE OF CONTENTS
(Continued)

	Page
11. Claim 16.....	68
12. Claim 17.....	69
13. Claim 18.....	69
14. Claim 20.....	69
VIII. THE BOARD’S DISCRETION UNDER 35 U.S.C. §§ 314(a) AND 325(d).....	69
IX. CONCLUSION.....	72
X. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8.....	72
A. Real Party in Interest Under 37 C.F.R. § 42.8(b)(1).....	72
B. Related Matters Under 37 C.F.R. § 42.8(b)(2)	72
C. Designation of Counsel Under 37 C.F.R. § 42.8(b)(3).....	72
D. Service Information.....	73

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH</i> , IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020).....	70
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<i>Lyft, Inc. v. RideShare Displays, Inc.</i> , IPR2021-01602, Paper 7 (PTAB Apr. 11, 2022)	71
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STATUTES AND RULES	
35 U.S.C. § 102	9, 10, 12
35 U.S.C. § 311	1
35 U.S.C. § 314(a)	69
35 U.S.C. § 325(d)	69
OTHER AUTHORITIES	
37 C.F.R. Part 42.....	71

TABLE OF AUTHORITIES
(Continued)

	Page(s)
37 C.F.R. § 42.22(a)(1)	2
37 C.F.R. § 42.100	1
37 C.F.R. § 42.104	1, 2
89 Fed. Reg. 28693	71
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LIST OF EXHIBITS

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

¹ The same Declaration of Dr. Jason Heikenfeld, Ph.D. is being submitted with *inter partes review* petitions directed to patents in the same patent family as U.S. Patent No. 10,159,422, but the citations to the declaration in this petition are to the relevant portions of the declaration for the specific grounds and patent challenged.

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

Exhibit No.	Description
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1015	U.S. Patent No. 6,238,338 (“DeLuca”)
1016	C.J. Harland et al., Electric Potential Probes – <i>New Directions in the Remote Sensing of the Human Body</i> , 13 Meas. Sci. Tech. 163 (2002) (“Harland”)
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1036	AAMI, <i>Cardiac monitors, heart rate meters, and alarms</i> , ANSI/AAMI EC13:2002 (2002)
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1040	<i>Devices@FDA: Dexcom STS Continuous Monitors</i> , U.S. Food & Drug Admin. (2005), available at https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pma&id=320251
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1066	Certificate of Translation for Japanese Patent Publication No. JP2004/121360

I. INTRODUCTION

Pursuant to 35 U.S.C. § 311 and 37 C.F.R. § 42.100, iRhythm, Inc. (“Petitioner”) requests *Inter Partes* Review of claims 1–7, 9–12, and 14–20 (the “Challenged Claims”) of U.S. Patent No. 10,159,422 (the “’422 patent”) (Ex. 1007), assigned to Welch Allyn, Inc. The Challenged Claims are obvious over the prior art. Accordingly, the Patent Trial and Appeal Board should institute review of the Challenged Claims.

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

A. Standing (37 C.F.R. § 42.104(a))

Petitioner certifies that the ’422 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR of the Challenged Claims.

B. Identification of Challenge (37 C.F.R. § 42.104(b))

In view of the prior art and evidence presented, the Challenged Claims are unpatentable and should be cancelled. 37 C.F.R. § 42.104(b)(1). Based on the prior art identified below, IPR of the Challenged Claims should be instituted. 37 C.F.R. § 42.104(b)(2).

Proposed Grounds of Unpatentability	
Ground 1	Claims 1-7, 9-11, and 14-20 are obvious under pre-AIA § 103 over Matsumura in view of the General Knowledge of Person of Ordinary Skill in the Art
Ground 2	Claims 1-7, 9, 11, 12, and 14-20 are obvious under pre-AIA § 103 over Jensen and the General Knowledge of Person of Ordinary Skill in the Art or Matsumura

Ground 3	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 Person of Ordinary Skill in the Art or Matsumura
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Sections VII.A-C identify where each element of the Challenged Claims is found in the prior art. 37 C.F.R. § 42.104(b)(4). The exhibit numbers of the evidence relied on to support the challenges are provided above and the relevance of the evidence to the challenges raised are provided in Sections VII.A-C. 37 C.F.R. § 42.104(b)(5). Exhibits 1001-1066 are attached.

III. PAYMENT OF FEES

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

IV. OVERVIEW OF CHALLENGES AND RELIEF REQUESTED

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

Ground 1: Claims 1-7, 9-11, and 14-20 are obvious under pre-AIA § 103 over Matsumura in view of the General Knowledge of Person of Ordinary Skill in the Art.

Ground 2: Claims 1-7, 9, 11, 12, and 14-20 are unpatentable under pre-AIA § 103 over Jensen in view of the General Knowledge of Person of Ordinary Skill in the Art or Matsumura.

Ground 3: 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 Person of Ordinary Skill in the Art or Matsumura.

V. SUMMARY OF THE '422 PATENT

A. Technical Background

Physiological monitoring systems have been used since the early 20th century to measure and report variables associated with human health and performance (*i.e.*, objective signs such as temperature, pulse, respiration, brain wave activity, muscular contractions). Ex. 1009 ¶¶ 17-20. These monitoring systems have been commonly used to remotely monitor patients during their daily activities, outside of a clinical setting. *Id.* ¶ 23. To accommodate their use on a day-to-day basis, these monitoring systems are designed to be both portable and discreet. *Id.* ¶¶ 23-24; Ex. 1007, 1:57–58 (“[p]ortable patient monitors have evolved that allow patients to enjoy at least some mobility”).

Electrocardiograms (ECGs or EKGs) are a type of physiological monitoring used to evaluate and monitor patients’ cardiac health. Ex. 1009 ¶ 17-22; Ex. 1007, 1:44-56. Originating in the 1920s, ECGs measure the electrical signals that result

from the depolarization and repolarization of cardiac muscle during each heartbeat. Ex. 1009 ¶¶ 19. Identified deviations from the normal pattern of voltage changes, known as sinus rhythm, may be used to identify abnormal heart rate and/or rhythm, and may enable a clinician to diagnose a heart condition. *Id.* ¶¶ 19-21. An ECG measures the heart muscles’ polarization/depolarization cycle through the use of electrodes, which are typically disposable and attached to a patient’s skin. Ex. 1009 ¶ 20; Ex. 1007, 1:61-62 (“[s]ensors, such as ECG electrodes, are affixed to the patient’s body, such as with tape”). Those electrodes are connected by electric wiring to “leads,” which in turn connect to electronics capable of processing and displaying the ECG signals. Ex. 1009 ¶ 25-26; Ex. 1007, 1:61-63, 2:28-29.

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

Later-developed wearable monitors for patients improved on the Holter monitor in several key ways. *Id.* ¶¶ 24-31. These wearable monitors were wireless,

smaller, and lightweight. Ex. 1007, 1:65-2:2. These advances in wearable devices were in part attributable to smaller microcontrollers, increased computing power on board the patient-worn device, and improvements in wireless communication technologies. Ex. 1009 ¶¶ 25-31.

Modern wearable monitors also incorporate disposable electrodes and other disposable components. *Id.* ¶ 32. The use of disposable electrodes dates back to the 1960s. *Id.* Relying on disposable electrodes and other components was well-understood to help to reduce the risk of infectious diseases spreading between patients. *Id.* ¶¶ 33 (citing U.S. Patent No. 4,763,660 (“Kroll”) (Ex. 1013), 1:66-2:7 (“disposability is particularly beneficial in a medical setting, wherein the possibility of transfer of communicable diseases from patient to patient is of great concern”)). The ’422 patent acknowledges that disposable, snap-on electrodes were commercially available by November 1, 2006. Ex. 1007, 9:59-64. Other references at the time acknowledge the use of other disposable components, including a “flexible circuit substrate [] trace extensions.” Ex. 1009 ¶ 35 (citing multiple references teaching wearable devices using “flexible circuits”).

Modern wearable devices incorporate both disposable and reusable components, attempting to maximize the benefits of both. Reusable components are generally made of higher quality materials while also being more cost efficient due to their repeated use. *Id.* Disposable components have traditionally been more

expensive due to the need to replace components with each use. But the use of disposable components has become widespread in part because of the reduced costs of modern electrical components and improved recycling programs that lessen the environmental impact of disposing of these components. *Id.*

B. Patent Description

The '422 patent describes a known solution to the known problem outlined above. In particular, the '422 patent is directed to a body-worn heart monitor that includes disposable and reusable components. Ex. 1007, 2:62-3:21. The claimed monitor requires two major structural components: (1) a disposable module (110, shown in red) with electrodes that make physical contact with the patient's skin and "measure[s] physiological signals"; and (2) a "communication-computation module" (102, shown in blue) that "mechanically and electrically" connects to and receives physiological signals from the disposable module. *Id.* Abstract, Fig. 2, 2:62–3:21. The "communication-computation module" performs "real-time physiological analysis" and transmits the analysis to a remote radio receiver. *Id.* Abstract, 3:8-18.

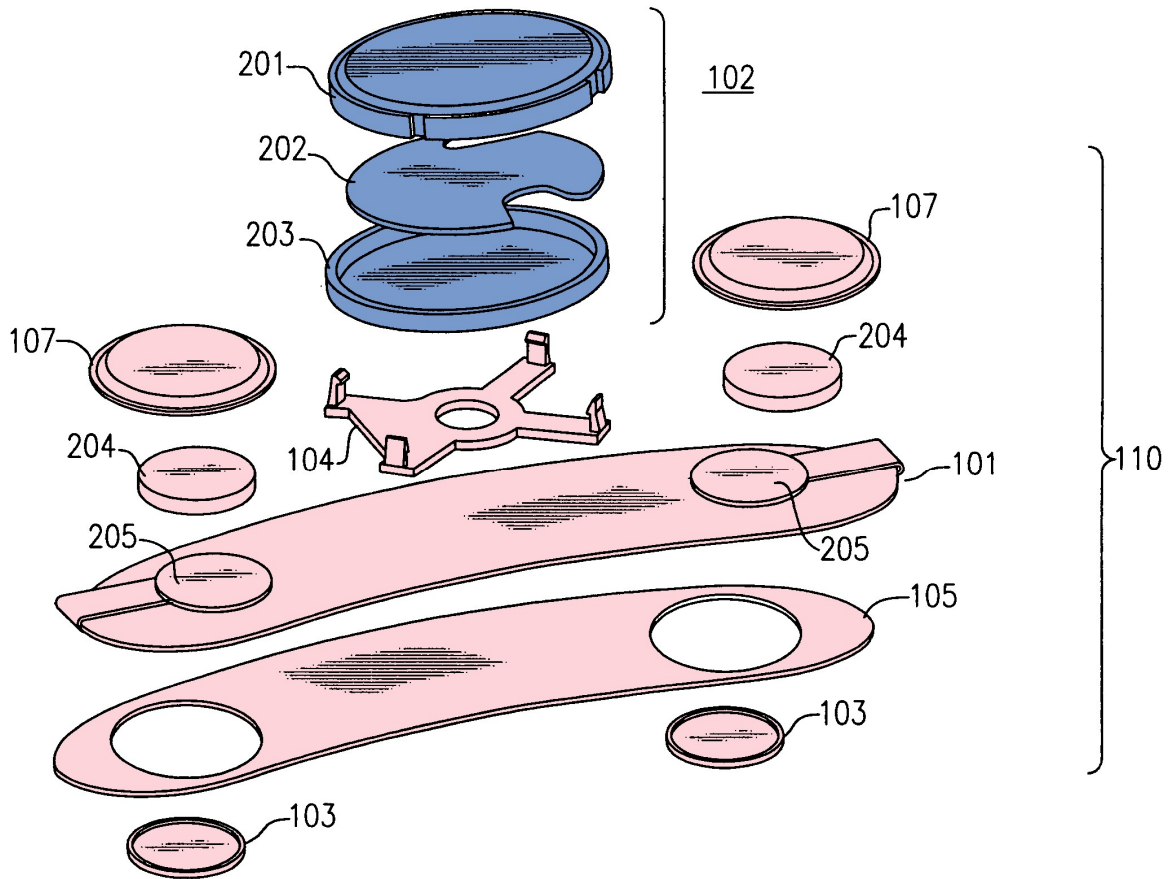


FIG.2

Id. Fig. 2 (annotated).

C. Priority Date

The application that matured into the '422 patent was filed on January 26, 2018, but claims priority to U.S. Appl. No. 11/591,619 filed on November 1, 2006. For purposes of this proceeding only, Petitioner contends the priority date is November 1, 2006.

D. Prosecution History

Claims 1-13 received a first action allowance. Non-Final Office Action at 3 (June 29, 2018) (Ex. 1008, 137). Claims 14-20 were allowed after the filing of a

Terminal Disclaimer to parent patent U.S. Patent No. 9,433,366. Response to Non-Final Office Action at 6 (July 3, 2018) (Ex. 1008, 123). The Notice of Allowance states that the closest examined prior art “fails to disclose . . . a monitoring device having a disposable electrode module comprising a flexible circuit layer an [sic] 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.” Notice of Allowance at 2 (Aug. 24, 2018) (Ex. 1008, 17). The requirement from the Notice of Allowance that the device comprise “an insulating member having an opening on opposing sides of the module, each opening sized to receive an electrode gel,” is absent from the allowed independent claims and found only in dependent claim 4. Accordingly, the only purported improvement of the independent claims identified in the Notice of Allowance over the prior art is that the “monitoring device ha[s] a disposable electrode module comprising a flexible circuit layer.” Ex. 1009 ¶ 164.

E. Level of Ordinary Skill in the Art

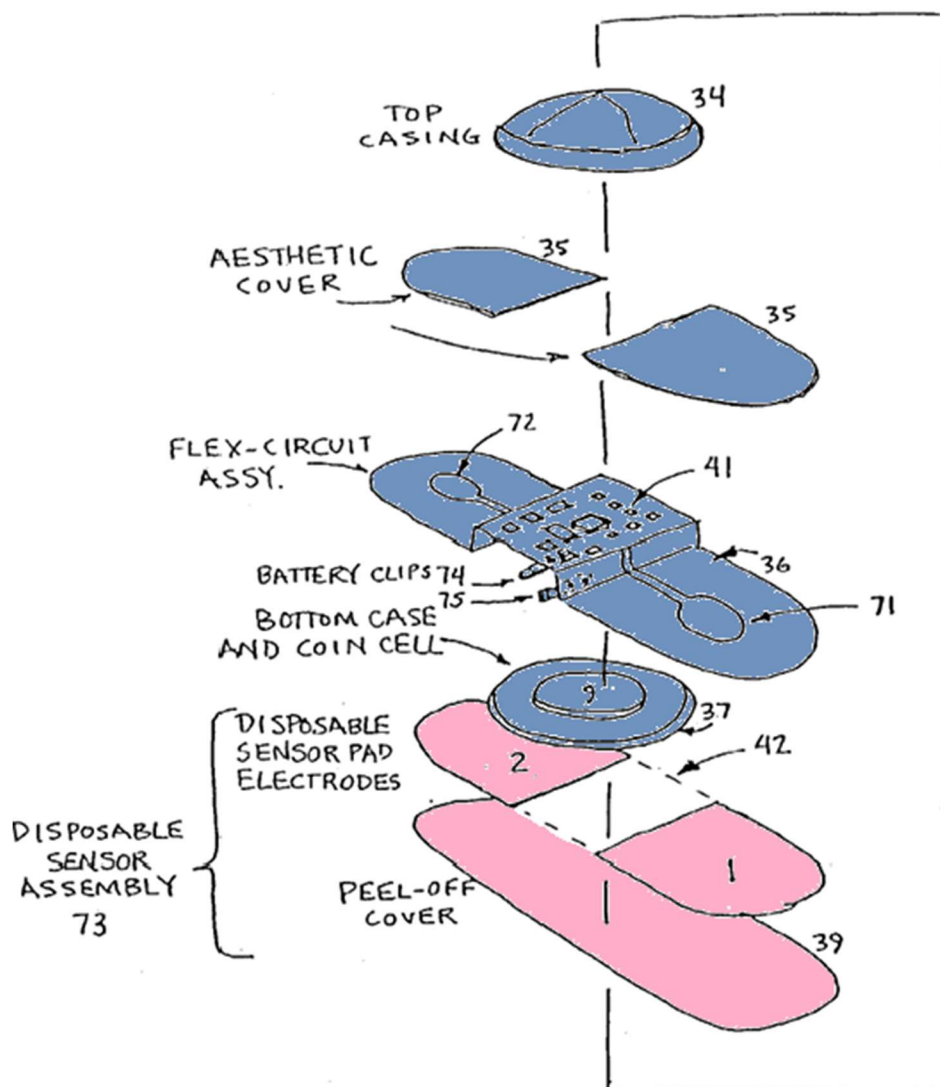
A Person of Ordinary Skill in the Art (“POSA”) would have at least a Bachelor’s degree in electrical engineering, electrophysiology, biomedical engineering or an equivalent degree, and at least two to three years of experience designing wearable monitors that detect physiological signals with mechanical

and/or electrical elements. *Id.* ¶ 57. Additional experience may substitute for education and vice versa. *Id.*

VI. PRIOR ART OVERVIEW

A. Jensen (Ex. 1011)

Jensen, published on August 7, 2003 as U.S. Patent Pub. No. 2003/0149349, is prior art under pre-AIA 35 U.S.C. §§ 102 (a), (b), (e). Jensen was cited in an Information Disclosure Statement during prosecution but was never substantively discussed during prosecution. Jensen teaches a body worn physiological monitor in the form of a “‘smart bandage’ or ‘smart patch’” for “physiological monitoring, especially heart rate sensing.” Ex. 1011, Abstract, ¶ [0013]. This “smart patch” includes both a “disposable sensor assembly” (shown below in red) that makes direct contact with the skin of the patient and a “re-usable (non-disposable) portion” (shown below in blue). *Id.* ¶¶ [0042]-[0043], Fig. 5. Jensen’s monitor includes a flexible circuit assembly with “programmable logic” for “perform[ing] measurement and processing of sensed data.” *Id.* ¶ [0014]. The assembly includes “leads” that connect the piezoelectric sensors that “sense[] data” with a circuit that “process[es]” the “sensed data.” *Id.* ¶ [0049]. The monitor will then use a “transmitter” and “antenna” to transmit captured physiological data to “any variety of different receivers.” *Id.* ¶¶ [0029], [0032]-[0033].

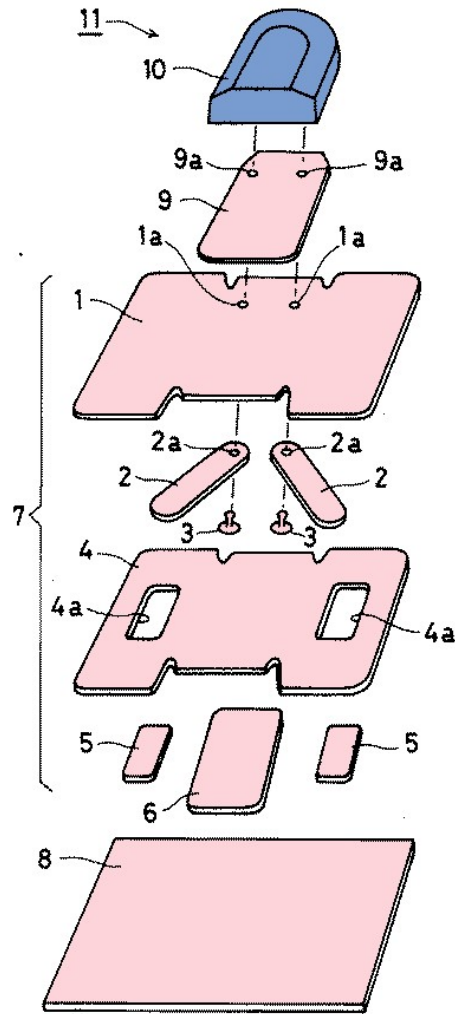


Id. Fig. 5 (annotated).

B. Matsumura (Ex. 1012)

Matsumura published on April 22, 2004 as Japanese Patent Publication 2004-121360, and is prior art under pre-AIA 35 U.S.C. § 102 (a) and (b). Matsumura was neither cited nor considered during prosecution of the '422 patent. Matsumura is directed to “a bioelectric potential detector having a waterproof structure” for detecting ECG signals. Ex. 1012 ¶¶ [0001], [0024]. The detector “comprises a

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



Id. Fig. 1 (annotated).

C. Ozguz (Ex. 1014)

Ozguz published on May 5, 2005 as U.S. Pat. Pub. No. 2005/096513, and is prior art under pre-AIA 35 U.S.C. § 102(a), (b) and (e). Ozguz was neither cited nor considered during prosecution of the '422 patent. Ozguz teaches a “sensor system comprising a thin flexible ambulatory/self contained bio-sensor module in a form

similar to an adhesive bandage [shown in red, below],” Ex. 1014 ¶ [0003], which is “adhered to the skin 15 of a subject body 20 to be monitored,” *id.* ¶ [0038].

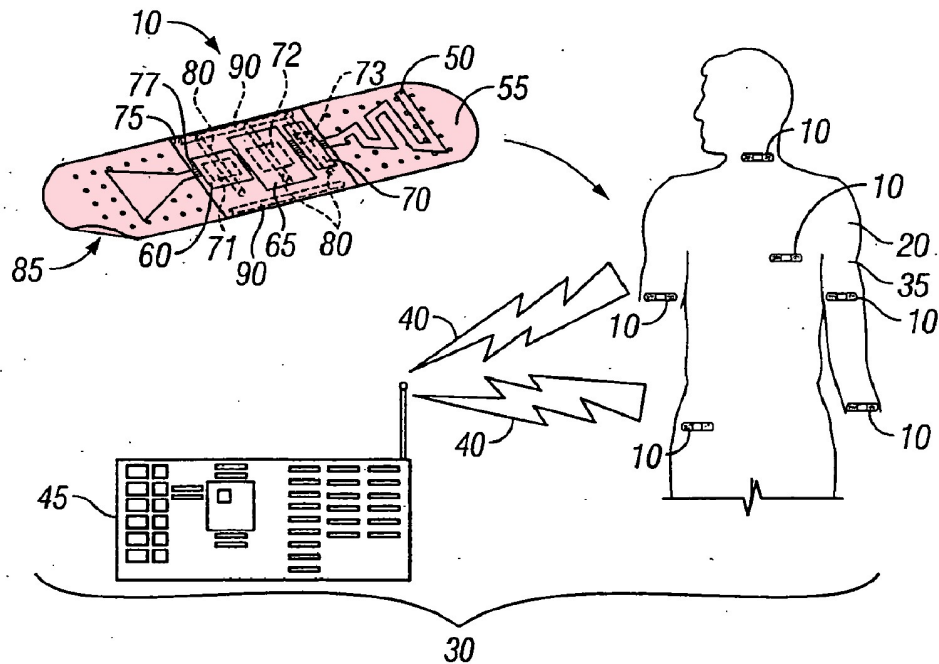


FIG. 2A

Id. Fig. 2A (annotated).

The bio-sensor module can collect and analyze EKG signals (*id.* ¶ [0017]). Structurally, the bio-sensor module includes an “antenna 50 metalized onto a flexible substrate 55 for transmitting and/or receiving RF signals.” *Id.* ¶ [0039], Fig. 2A. Thin flexible substrates 60, 65, 70—each with respective integrated circuits 71, 72, 73—are bonded to the flexible substrate by an anisotropic epoxy layer. *Id.* Sensor module 20 includes an adhesive pad 91 “formed of double-sided adhesive for application before and removal after each use so that the sensor module can be used

repeatedly. The sensor module can be sterilized in an autoclave, for example, between uses.” *Id.* ¶ [0049].

VII. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Ground 1: Claims 1-7, 9-11, and 14-20 are Obvious Over Matsumura in view of the General Knowledge of a Person of Ordinary Skill in the Art

1. Claim 1

i. *[Pre]: A method for manufacturing a body-worn physiological sensor, the method comprising:*

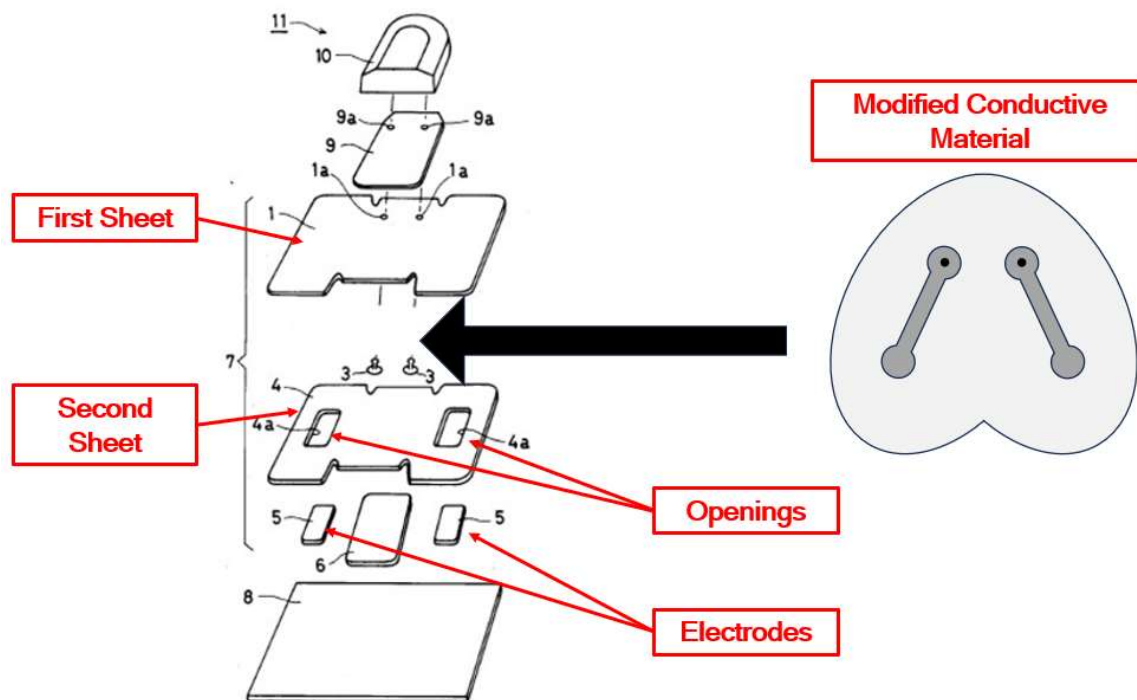
Matsumura discloses a body-worn physiological sensor which it refers to as a “bioelectric potential detector...for detecting bioelectric potentials.” Ex. 1012, Abstract, ¶¶ [0006], [0014]. Matsumura also teaches a method for assembling the disclosed components of the bioelectric potential detector. *Id.* ¶ [0016], Figs. 1, 2 (showing exploded and assembled views of the detector). A POSA would have used well-known methods to manufacture Matsumura’s bioelectric potential detector according to the components, materials, and assembly taught by Matsumura. Ex. 1009 ¶¶ 1376-78; *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1354 (Fed. Cir. 2016); *see also Kamstrup AS v. Axioma Metering UAB*, 43 F.4th 1374, 1382–83 (Fed. Cir. 2022) (claim element “describing a manufacturing method” was not entitled to patentable weight because the use of a different method would not result in a product that was structurally or functionally different from the prior art product).

ii. [1a.] providing a disposable substrate made from an insulating material, said substrate comprising:

Matsumura discloses “providing a disposable substrate made from an insulating material.” Specifically, Matsumura teaches that “bioelectric potential detector 11 is composed of a disposable bioelectrode pad 7.” Ex. 1012 ¶ [0016]. A POSA would recognize that the “bioelectrode pad” defines a substrate as Matsumura explains: “[t]he bioelectrode pad 7 is composed of a first sheet 1, a conductive material 2, a hook 3, a second sheet 4, a conductive gel 5, a third sheet 6, and double-sided adhesive tape 9.” *Id.* ¶¶ [0016]-[0018]; Ex. 1009 ¶¶ 1381-82. The first sheet 1 and second sheet 4 are “made of an insulating material that does not allow moisture to penetrate, for example, polyethylene foam, polyurethane foam, or polyurethane sheet.” Ex. 1012 ¶ [0017]. 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 conductive material 2 with another sheet of insulating material with printed conductive traces (*i.e.*, lines of conductive ink). Ex. 1009 ¶¶ 1386-1389. This modification would result in three sheets of insulating material bonded together, forming the claimed disposable substrate made from an insulating material. Accordingly, Matsumura discloses providing a disposable substrate made from an insulating material.

iii. [1b.] a flexible printed circuit board layer made from the insulating material;

Matsumura renders obvious a “flexible printed circuit board layer made from the insulating material.” Matsumura discloses bioelectrode pad 7, which includes “two pieces of conductive material 2,” which “can be carbon sheet or a PET sheet [which are insulating material] coated with conductive Ag/AgCl.” Ex. 1012 ¶¶ [0019]-[0020], Fig. 1. It would have been obvious to a POSA to use well-known techniques to replace the two, separate flexible pieces of insulating material coated with conductive Ag/AgCl with a single, flexible sheet of insulating material with printed-ink conductive traces on its surface. Ex. 1009 ¶¶ 1387-88. The proposed modification is depicted below.



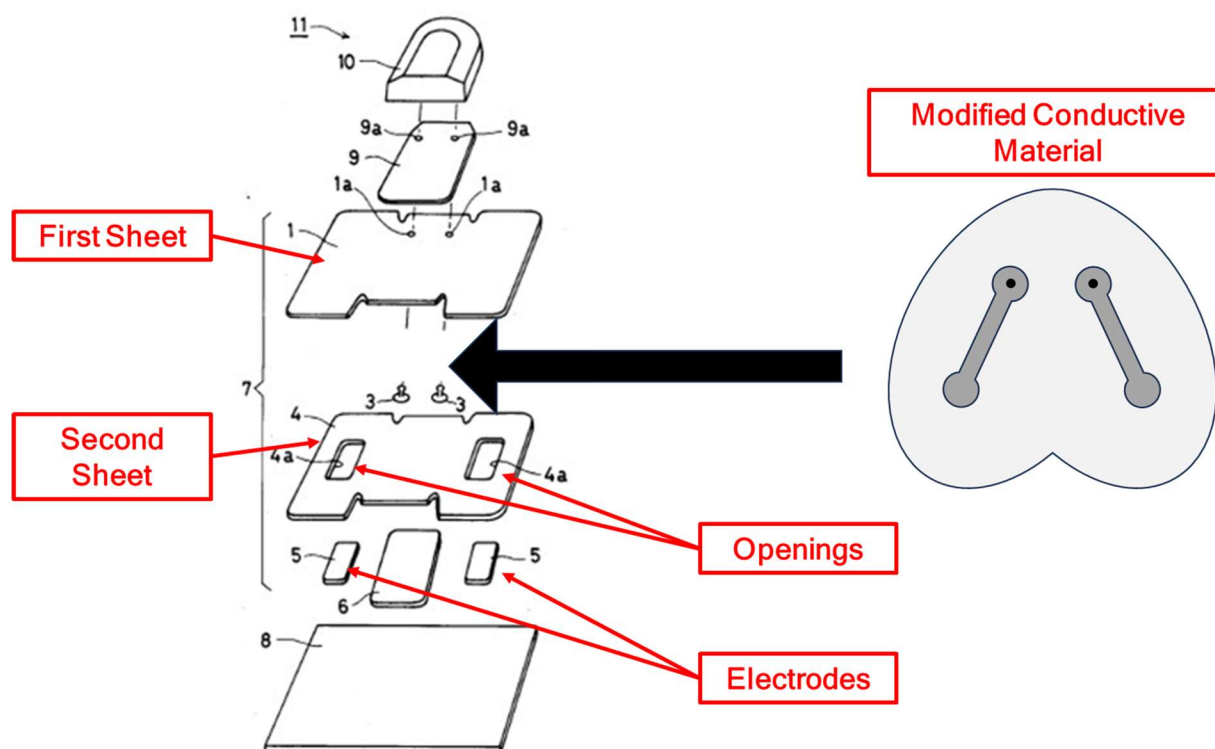
Ex. 1012, Fig. 1 (annotated).

A POSA would have done so because this modification would make manufacturing and assembly easier. Ex. 1009 ¶¶ 1387-1389. The original method suggested by Matsumura would require cutting two, separate pieces of insulating material and coating each one fully with conductive ink (which potentially requires more conductive ink). The modification would require cutting only one piece of insulating material and printing traces on it. *Id.* ¶ 1387.

A POSA would recognize that, so modified, 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 ¶¶ [0017]-[0018]; Ex. 1009 ¶¶ 1386-90.

iv. [1c.] at least two electrodes disposed on the disposable substrate; and

Matsumura discloses “at least two electrodes disposed on the disposable substrate.” As shown in Figure 1 below, Matsumura discloses “conductive gel[s] 5” (electrodes) used to detect bioelectrical potentials. These “conductive gel[s]” are disposed in two openings 4a on second sheet 4, and make contact with a portion of conductive material 2. Ex. 1012 ¶¶ [0018]-[0019]. A POSA would therefore understand that conductive gels 5 are disposed on the disposable substrate (*i.e.*, the disposable bioelectrode pad, modified as described above). *Id.*; *supra* § VII.A.1.iii; Ex. 1009 ¶¶ 1393-95.

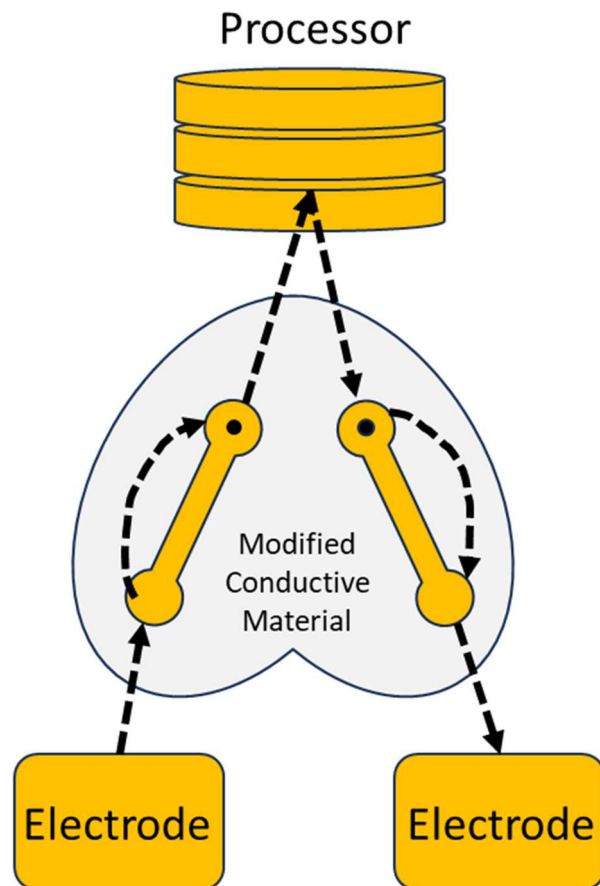


Ex. 1012, Fig. 1 (annotated).

v. *[1d.]* **conductive traces defined between the at least two electrodes;**

Matsumura renders this limitation obvious in view of the knowledge of a POSA. As explained above, a POSA would have been motivated to combine conductive material 2 onto a single, printed sheet. *See supra*, § VII.A.1.iii. Subject to the modification suggested above, traces run “between the at least two electrodes” (conductive gels 5) 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 electrical trace; and, finally, from the other electrical trace to the other electrode. Ex. 1009 ¶ 1398. At the other

end, the traces contact hooks 3. *Id.*; Ex. 1012 ¶¶ [0019], [0024], Fig. 1. The following, simplified schematic illustrates this relationship.



Ex. 1009 ¶ 1398. Therefore, as modified, Matsumura would include conductive traces defined between the at least two electrodes.

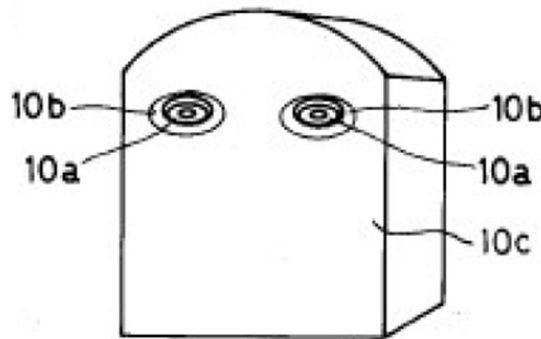
vi. [1e.] providing a computation-communication module, said module comprising:

Matsumura discloses “a computation-communication module.” Matsumura discloses a “reusable signal processor” (10) which is a module that is “detachable with hooks.” Ex. 1012 ¶ [0016]; *see also id.* ¶¶ [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.* ¶ [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. Ex. 1009 ¶¶ 1401-1405.

vii. [1f.] a housing;

Matsumura discloses a housing for the computation-communication module. Matsumura discloses that “reusable signal processor 10” is enclosed in housing 10c, as shown below in Figure 4(a), which can be “easily attached and detached” to bioelectrode pad 7. Ex. 1012 ¶¶ [0016], [0025], [0027], [0029]; Ex. 1009 ¶¶ 1406-1409.



Ex. 1012, Fig. 4(a).

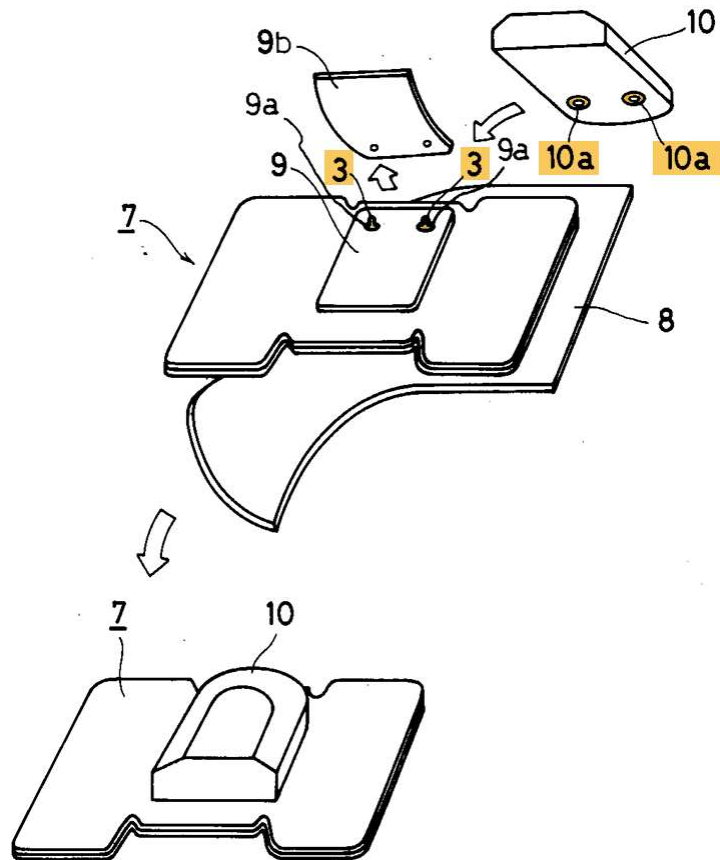
viii. [1g.] a processor disposed in the housing; and

Matsumura discloses a processor disposed in the housing of the computation-communication module. In particular, Matsumura discloses that “signal processor

10” (computation-communication module) “incorporates a processing circuit for filtering and amplifying detected bioelectric potential signals.” *Id.* ¶ [0025]. The processing circuit (processor) is disposed within housing 10c to ensure that Matsumura’s device is waterproof. *Id.* ¶¶ [0025], [0027], [0029]. Accordingly, Matsumura teaches “a processor disposed in the housing.” Ex. 1009 ¶¶ 1411-1413.

ix. [1h.] attaching the computation-communication module to the disposable substrate.

Matsumura discloses “attaching the computation-communication module to the disposable substrate.” Matsumura teaches that reusable signal processor 10, which includes housing 10c enclosing a processing circuit, is attached to disposable bioelectrode pad 7, which includes the disposable printed circuit board, using hooks 3. Ex. 1012 ¶¶ [0016], [0027], [0029]. Specifically, Matsumura’s disposable bioelectrode pad includes “two hooks 3” that connect to “hook engagement portion 10a on the bottom surface of the signal processor,” as shown in the below image. *Id.* ¶¶ [0019], [0024].



Id. Fig. 2 (annotated); Ex. 1009 ¶¶ 1415-1417.

2. **Claim 2**

In addition to teaching the limitations of claim 1, Matsumura renders obvious “providing conductive traces in the flexible circuit layer,” as recited in claim 2. As explained 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. *Supra* § VII.A.1.iii; Ex. 1009 ¶¶ 1419-1420. As modified, Matsumura would include “conductive traces in the flexible printed circuit layer.”

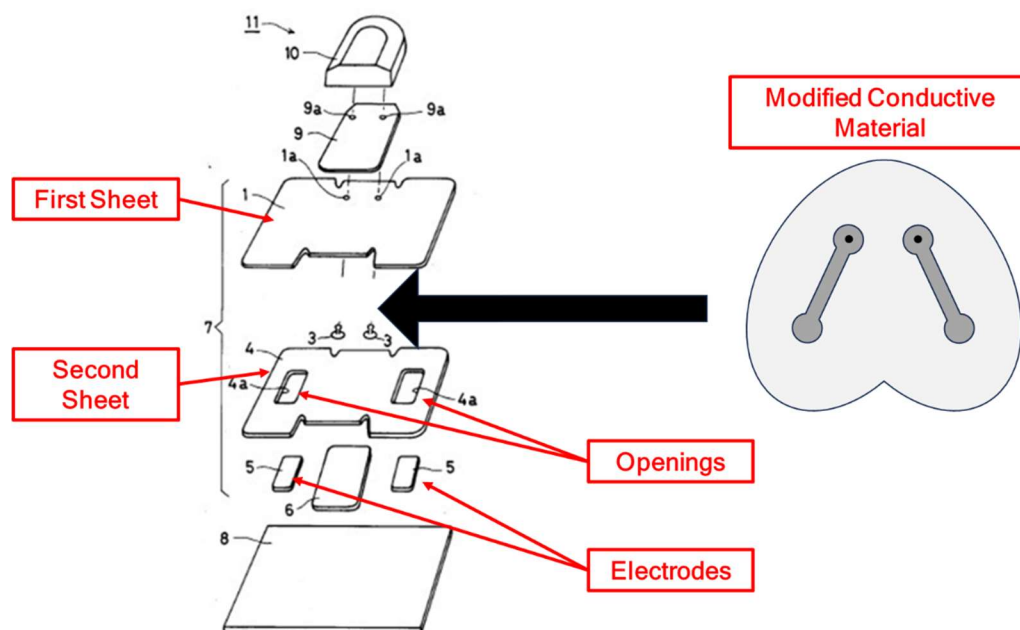
3. *Claim 3*

In addition to teaching the limitations of claims 1 and 2, Matsumura renders obvious “conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module,” as recited in claim 3. As noted above, a POSA would have been motivated to modify Matsumura’s conductive material 2 to comprise a single, flexible, insulating substrate with printed-ink conductive traces. *Supra* § VII.A.1.iii; Ex. 1009 ¶ 1422. As modified, Matsumura’s printed ink traces form a connection to transmit signals through hooks 3 to the computation-communication module. *Supra* § VII.A.1.v; Ex. 1009 ¶¶ 1423-24. Hooks 3 are disposed on the surface of the flexible printed circuit board layer, as modified. Ex. 1012, Fig. 1. As modified, Matsumura’s flexible printed circuit traces are therefore electrically couple[d] with the attached computation-communication module. *Id.* ¶¶ [0016], [0019], [0024], Fig. 2; Ex. 1009 ¶¶ 1421-1424.

4. *Claim 4*

In addition to teaching the limitations of claim 1, Matsumura teaches “providing a plurality of openings in the flexible printed circuit board layer, the openings being sized for receiving electrode gels,” as recited in claim 4. As described above, a POSA would have been motivated to modify conductive material 2 to form a flexible printed circuit. *Supra* § VII.A.1.iii; Ex. 1009 ¶ 1426. So

modified, Matsumura’s flexible printed circuit layer would include flexible printed circuit (substitute for conductive material 2) and second sheet 4, which is also an insulating, protective covering. *Id.* Matsumura discloses that “second sheet 4” “is provided with two openings 4a on the left and right sides into which the conductive gel 5 is inserted.” Ex. 1012 ¶ [0018]. As shown in Figure 1, openings 4a are sized to receive conductive gels 5.



Id. Fig. 1 (annotated); Ex. 1009 ¶¶ 1425-1428.

5. Claim 5

In addition to teaching the limitations of claim 1, Matsumura teaches that “the computation-communication module is releasably attached to the disposable substrate,” as recited in claim 5. As explained above, Matsumura discloses that “[t]he bioelectrode pad 7 [including the flexible printed circuit board layer] and the signal processor 10 are detachable with hooks . . . the reusable signal processor and

the disposable bioelectrode can be easily attached and detached before and after use.” Ex. 1012 ¶ [0016]. Accordingly, Matsumura discloses that signal processor 10 (computation-communication module) is releasably attached to disposable bioelectrode 7 (disposable substrate). Ex. 1009 ¶¶ 1429-1432.

6. Claim 6

In addition to teaching the limitations of claim 1, Matsumura teaches “providing a radio circuit in the computation-communication module,” as recited in claim 6. As noted above, Matsumura discloses that “signal processor 10” (computation-communication module) includes “a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna.” Ex. 1012 ¶ [0025]. A POSA would know 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. 1009 ¶¶ 1435-1437.

7. Claim 7

In addition to teaching every limitation of claims 1 and 3, Matsumura discloses “at least partially covering the conductive traces with an insulating covering,” as recited in claim 7. As noted above, a POSA would have modified Matsumura’s conductive material 2 to comprise a single sheet of flexible, insulating material with printed-ink traces. *Supra* § VII.A.1.iii. A POSA would have understood that this modified conductive material circuit board would be situated

between first sheet 1 and second sheet 4. Ex. 1009 ¶ 1440. Matsumura teaches that both first and second sheets are “made of insulating material that does not allow moisture to penetrate.” Ex. 1012 ¶¶ [0017]-[0018]. Accordingly, Matsumura discloses “at least partially covering the conductive traces with an insulating covering.” Ex. 1009 ¶ 1441.

8. Claim 9

In addition to teaching the limitations of claim 1, Matsumura discloses “integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate,” as recited in claim 9. Matsumura discloses that “disposable bioelectrode pad 7” integrates “conductive gel[s] 5” (electrodes) used to detect bioelectrical potentials. These “conductive gel[s]” are integrated by being disposed in two openings 4a in second sheet 4 of bioelectrode pad 7. Ex. 1012 ¶¶ [0018]-[0019]. 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). Ex. 1009 ¶¶ 1444-1445. Accordingly, Matsumura discloses integrating “conductive gel[s] 5” (electrodes) into the flexible printed circuit board layer. *Id.*

9. Claim 10

In addition to teaching the limitations of claims 1 and 3, Matsumura renders obvious “screening the conductive traces onto the flexible printed circuit board

layer,” as recited in claim 7. As described above, a POSA would have been motivated to modify conductive material 2 to form a flexible printed circuit. *Supra* § VII.A.1.iii. A POSA would have understood that screening was a common way in the industry to attach conductive traces made of Silver/Silver Chloride, as disclosed in Matsumura, to a flexible printed circuit board. Ex. 1009 ¶¶ 1448-1449. Accordingly, Matsumura and a POSA’s knowledge render obvious screening the conductive traces onto the flexible printed circuit board layer.

10. Claim 11

In addition to teaching the limitations of claims 1 and 9, Matsumura teaches that “each electrode includes an electrode gel and a conductive surface defining a half cell,” as recited in claim 11. Matsumura teaches that “conductive gel 5” may be produced from components such as an “acrylic hydrophilic polymer, glycerin, and water.” Ex. 1012 ¶ [0018]. The conductive gel contacts a second portion of “conductive material 2,” which may be “coated with conductive Ag/AgCl.” *Id.* ¶¶ [0019]-[0020]. A POSA would understand that conductive gels comprising an acrylic hydrophilic polymer, glycerin, and water, and contacting a silver/silver-chloride conductive surface comprise a “half-cell,” a term that the ’422 patent describes as a combination of an “electrode gel” and a “conductive surface.” Ex. 1009 ¶¶ 1453-1454. Accordingly, a POSA would know that Matsumura teaches this element. *Id.*

11. Claim 14

- i. 14[pre]. A body-worn physiological sensor made by the process of:**

As described with respect to Claim 1, Matsumura discloses a body-worn physiological sensor. *Supra* § VII.A.1.i; *Purdue Pharma*, 811 F.3d at 1354; *see also Kamstrup*, 43 F.4th at 1382-83; Ex. 1009 ¶ 1456.

- ii. [14a.] providing a disposable substrate made from an insulating material, said substrate comprising:**

As described above, Matsumura discloses this element. *Supra* § VII.A.1.ii; Ex. 1009 ¶¶ 1457-1458.

- iii. [14b.] a flexible printed circuit board layer made from an insulating material;**

As described above, Matsumura and a POSA's general knowledge render this element obvious. *Supra* § VII.A.1.iii; Ex. 1009 ¶¶ 1459-1460.

- iv. [14c.] at least two electrodes disposed on the disposable substrate; and**

As described above, Matsumura and a POSA's general knowledge render this element obvious. *Supra* § VII.A.1.iv; Ex. 1009 ¶¶ 1461-1462.

- v. [14d.] conductive traces defined between the at least two electrodes;**

As described above, Matsumura and a POSA's general knowledge render this element obvious. *Supra* § VII.A.1.v; Ex. 1009 ¶¶ 1463-1464.

vi. [14e.] providing a computation-communication module, said module comprising:

As described above, Matsumura discloses this element. *Supra* § VII.A.1.vi;

Ex. 1009 ¶¶ 1465-1466.

vii. [14f.] a housing;

As described above, Matsumura discloses this element. *Supra* § VII.A.1.vii;

Ex. 1009 ¶¶ 1467-1468.

viii. [14g.] a processor disposed in the housing; and

As described above, Matsumura discloses this element. *Supra* § VII.A.1.viii;

Ex. 1009 ¶¶ 1469-1470.

ix. [14h.] attaching the computation-communication module to the disposable substrate.

As described above, Matsumura discloses this element. *Supra* § VII.A.1.ix;

Ex. 1009 ¶¶ 1471-1472.

12. Claim 15

As described above, Matsumura discloses the dependent limitation of this claim. *Supra* § VII.A.2 (claim 2); Ex. 1009 ¶¶ 1473-1475.

13. Claim 16

As described above, Matsumura discloses the dependent limitation of this claim. *Supra* § VII.A.3 (claim 3); Ex. 1009 ¶¶ 1476-1477.

14. Claim 17

As described above, Matsumura discloses the dependent limitation of this claim. *Supra* § VII.A.5 (claim 5); Ex. 1009 ¶¶ 1478-1480.

15. Claim 18

As described above, Matsumura discloses the dependent limitation of this claim. *Supra* § VII.A.6 (claim 6); Ex. 1009 ¶¶ 1481-1483.

16. Claim 19

As described above, Matsumura discloses the dependent limitation of this claim. *Supra* § VII.A.7 (claim 7); Ex. 1009 ¶¶ 1484-1486.

17. Claim 20

As described above, Matsumura discloses the dependent limitation of this claim. *Supra* § VII.A.8 (claim 9); Ex. 1009 ¶¶ 1487-1489.

B. Ground 2: Claims 1-7, 9, 11, 12, and 14-20 are Obvious Over Jensen and the General Knowledge of Person of Ordinary Skill in the Art or Matsumura

A POSA would have understood Jensen to disclose or teach all the elements of claims 17, 9, 11, 12, and 14-20. Alternatively, a POSA would look to combine Jensen and Matsumura to teach all the elements of these claims.

1. Motivation to Combine

Jensen and Matsumura both teach wearable devices for monitoring physiological signals, including ECG or EKG signals. Ex. 1011 ¶¶ [0029]-[0030]; Ex. 1012 ¶¶ [0024], [0031], Fig. 2.

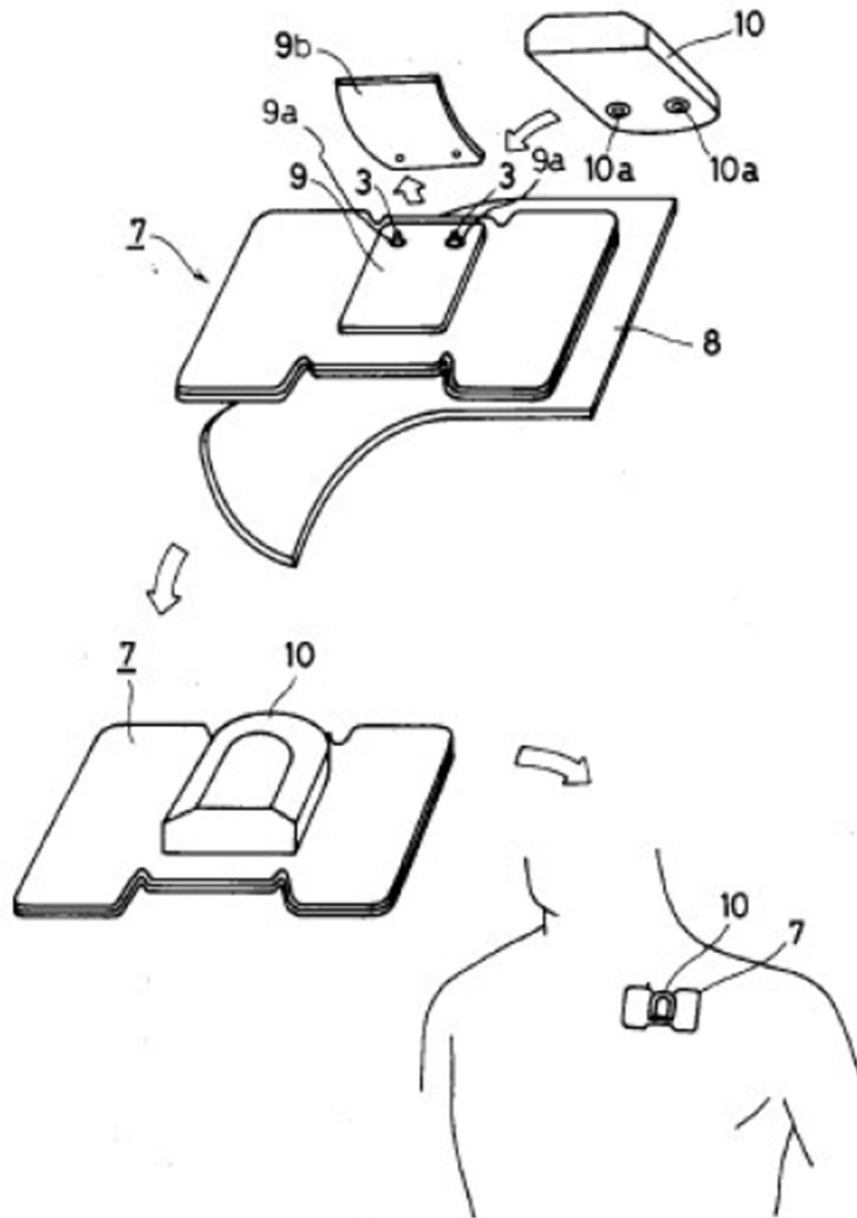
Maintaining hygiene and reducing cross-contamination is important for medical devices that directly contact a patient—even more so for wearable ones in constant patient contact. Ex. 1009 ¶¶ 1490, 937-939 (citing V. Trend et al., *Are ECG Welsh cup electrodes effectively cleaned?*, 14 J. Hosp. Infection 325 (1989) (“Trend”) at 331); Ex. 1013, 2:1-4 (“disposability is particularly beneficial in a medical setting, wherein the possibility of transfer of communicable diseases from patient to patient is of great concern”). Disposing an entire medical device addresses this issue, but cost concerns limit the practicality of doing so. Ex. 1009 ¶¶ 1490, 937. For this reason, certain prior art medical devices have both disposable and reusable parts. *Id.*

Jensen’s device is one example. The device comprises a disposable sensor assembly, which includes a peel-off cover (39) and disposable sensor pad electrodes (1, 2). Ex. 1011 ¶ [0042], Fig. 5. The rest of Jensen’s device is reusable, including the bottom and top casing, the flexible circuit assembly to which the disposable sensor pad electrodes are attached, and the aesthetic cover. *Id.* A POSA would have known that reuse would require carefully cleaning each of these components for hygiene purposes. Ex. 1009 ¶¶ 1490, 937-939. But “[e]ven with thorough cleaning, the risk of cross-contamination cannot be eliminated.” *Id.* ¶¶ 1490, 939 (citing Trend at 331). To minimize the risk of ineffective cleaning, and thus improve the safety of a medical device, a POSA would have been motivated to look for ways to make

more parts of the device disposable while further isolating the reusable portions to limit contamination. *Id.*

Matsumura provides a way to achieve these goals. Like Jensen, Matsumura discloses a device with both disposable and reusable portions. But Matsumura's design fully insulates the reusable portions from the patient's skin using multiple layers and encloses the reusable portion in a single housing. *Id.* ¶¶ 1490, 940. As Matsumura teaches, "the bioelectrode pad [7] is hygienic because it is disposable" and includes multiple sheets (first sheet 1, second sheet 4, and third sheet 6) that separate the reusable part of the device from a patient, while still maintaining an electrical connection between the patient-facing, disposable electrodes (conductive gels 5) and the reusable component. Ex. 1012 ¶ [0016], Fig. 5. As shown in Figure 2 of Matsumura below, only the disposable bioelectrode pad 7 touches the patient's skin, while reusable signal processor 10 is completely separated from the patient's skin by multiple sheets.

[FIGURE 2]



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

(electronic circuitry 41 and coin cell 9) while separating the reusable portion from the patient's skin. Ex. 1009 ¶¶ 1490, 941-942.

Second, a POSA would have also looked to modify Jensen's design to achieve the waterproof structure of Matsumura. Jensen's design is "sealed on top" using an "o-ring" and several "aesthetic covers" that a POSA would have understood to provide multiple points susceptible to seepage through the top, bottom, and slot which could disrupt the internal electronic circuitry. *Id.* ¶¶ 1490, 943. To attempt to isolate electronic circuit 41, Jensen relies on a "sealant applied to the slot 80, once assembled." Ex. 1011 ¶ [0045]. Jensen therefore acknowledges that even after assembly, the device is not fully sealed. Matsumura teaches an improved waterproofed structure that is completely sealed upon assembly and allows patients to wear the monitor both during and immediately after showering. Ex. 1012 ¶¶ [0027], [0033]. Matsumura explains several advantages of doing so, with which a POSA would have been familiar. Ex. 1009 ¶¶ 1490, 943-44. From a clinical perspective, a continuously wearable monitor that a patient need not remove to shower or bathe is advantageous as it provides uninterrupted monitoring. Ex. 1012 ¶¶ [0001]-[0002]. This permits monitoring during a shower or bath when a patient's "heart may be strained, resulting in tachycardia or arrhythmia." It also permits monitoring "immediately after showering or bathing," when a patient's "body temperature drops suddenly, which puts a strain on the body and may cause sudden

changes in condition, such as dizziness, anemia, or arrhythmia.” *Id.* ¶ [0002]. Incorporating Matsumura’s waterproof structure into Jensen would allow Jensen’s smart patch to be worn continuously, including during or immediately after showering.

To achieve a waterproofed structure, Matsumura teaches i) housing the electronics, such as the microprocessor and wireless transmitter, in an enclosed, reusable casing (signal processor 10), and ii) placing the electrodes (conductive gel 5), sensor contacts (conductive material 2), and traces (hooks 3) in a separate disposable bioelectrode pad 7 that uses an insulating sheet to entirely cover the electrodes and sensor contacts. This insulating sheet contains two small holes through which hooks 3 electrically and mechanically connect the disposable electrodes to the reusable housing containing signal processor 10. *Id.* ¶¶ [0015], [0019], [0022], [0041]-[0043]. A POSA would have sought to modify Jensen in a similar manner to achieve this waterproof structure. Ex. 1009 ¶¶ 1490, 946-947. In particular, a POSA would have enclosed electronic circuit 41 and coin cell 9 of Jensen in a separate housing composed of top case 34 and bottom case 37, while placing the sensor pad electrodes 1, 2, sensor contacts 71, 72, and copper traces in the disposable sensor assembly 73 that could be entirely covered by a single aesthetic cover to ensure waterproofing. *Id.* ¶¶ 1490, 947. This modification would not be

difficult to implement using well-known manufacturing techniques at the time of the invention. *Id.*

A POSA would have had a reasonable expectation of success in modifying Jensen's device based on the disclosures of Matsumura discussed above without undue experimentation. *Id.* ¶¶ 1490, 948. Not only are both devices wearable, self-contained ECG monitors, they both have similar disposable and reusable parts: disposable parts include the electrodes used to detect ECG signals, and reusable parts include a processor and a wireless transmitter. Ex. 1012, Fig. 1; Ex. 1011, Fig. 5. While Jensen discloses an embodiment in which the printed circuit assembly 30 that includes the electronics is separated from disposable sensor pads 31 and 32, it lacks the hygienic and waterproofing benefits taught by Matsumura. Ex. 1011 ¶ [0044], Fig. 6. The modification in view of Matsumura would preserve the electrical traces and sensor contacts 71, 72 on sensor pads 31 and 32 but enclose the remaining reusable portions of the device inside a separate housing. As the processing circuitry within the housing would still be connected to the same electrical traces and sensor contacts, a POSA would have expected the modified device to retain the same monitoring functionality. Ex. 1009 ¶¶ 1490, 949.

2. *Claim 1*

i. [Pre]: A method for manufacturing a body-worn physiological sensor, the method comprising:

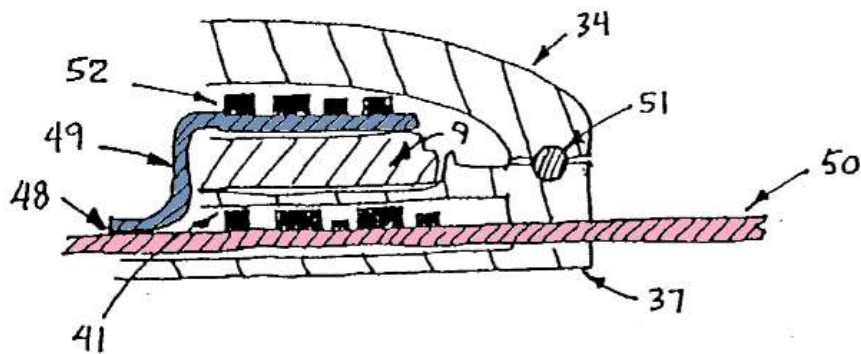
Jensen discloses a body worn “smart patch” “that integrates... heart-rate/EKG electronic sensors.” Ex. 1011 ¶ [0012]; *see also id.* ¶ [0013]; *Purdue Pharma*, 811 F.3d at 1354; *see also Kamstrup*, 43 F.4th at 1382–83 (finding claim element “describing a manufacturing method” not entitled to patentable weight because use of different method would not result in a product that was structurally or functionally different from the prior art product). As Jensen states, “[t]he entire assembly may be designed in such a way that it is easily assembled in a set of progressive operations” including the application of cover materials and pre-assembled electronics “to the inner circuitry and connections.” Ex. 1011 ¶ [0043]. 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. Ex. 1009 ¶¶ 1493-95.

ii. [1a.] providing a disposable substrate made from an insulating material, said substrate comprising:

Jensen and the General Knowledge of a POSA render this limitation obvious. 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. 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 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. Ex. 1009 ¶ 1498.

It would have been obvious for a POSA to configure Jensen's device to include a disposable substrate made from an insulating material. *Id.* ¶ 1499. Specifically, in the embodiment of Figure 8, Jensen depicts a means of "mechanical [inter]connection of inter-related circuits using two flexible printed circuits 49, 50." Ex. 1011 ¶ [0046], Fig. 8. A POSA would recognize that flexible printed circuit 50 would be analogous to Jensen's flexible printed circuit 36. Ex. 1009 ¶ 1498. 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. Ex. 1009 ¶ 1499.



Ex. 1011, Fig. 8 (annotated).

It would have been obvious for a POSA to distribute valuable components on top of flexible circuit assembly 49, rather than on flexible circuit assembly 50. Ex. 1009 ¶¶ 1499-500. This redistribution would allow reuse of the most expensive components (electronic circuitry 52 and/or coin cell 9), while making components that are 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. *Id.* 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. *Id.* 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. *Id.*

Alternatively, a POSA would have looked to modify Jensen in view of the teachings of Matsumura. As noted above, a POSA would have sought to modify Jensen in view of Matsumura to make sensor contacts 71, 72 and flexible circuit assembly 36, 50 part of the disposable sensor assembly 73, while keeping electronics 52 and battery 9 as reusable components. *Id.* ¶¶ 1502-503. Modifying Jensen to place sensor contacts 71, 72 and the connected “copper wiring traces” in the disposable sensor assembly 73 would add an additional layer of protection between the patient’s skin and the reusable components, improving the hygiene of the device in the manner taught by Matsumura. *Id.*; *supra* § VII.B.1. This modification would also help to waterproof Jensen’s design by isolating Jensen’s valuable circuitry and battery in an enclosed housing and allowing the traces and sensor contacts to be fully covered in the manner taught by Matsumura. *Id.*

A POSA would recognize that the “flexible circuit assembly” 36, 50 of Jensen includes a substrate on which “copper wiring traces” are formed. Ex. 1011 ¶ [0040]; Ex. 1009 ¶¶ 1502-503. A POSA would also recognize that the “flexible circuit assembly” is made of insulating material on which the traces, electronics, and sensor contacts 71, 72 are placed, or else the various electrical components on the flexible circuit assembly would short circuit. Ex. 1009 ¶ 1503. Flexible circuit assemblies were commonly made of an insulating material, such as MYLAR®. *Id.* Accordingly,

Jensen alone and/or Jensen and Matsumura teach “a disposable substrate made from an insulating material.”

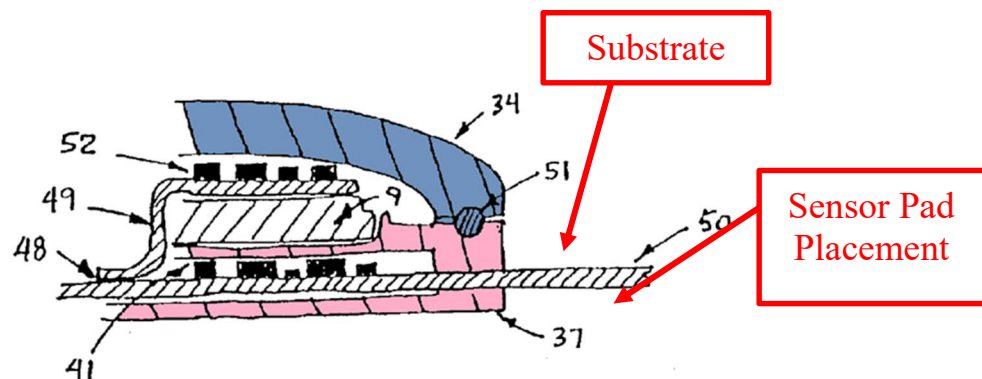
iii. [1b.] a flexible printed circuit board layer made from the insulating material;

As noted above, Jensen teaches “a flexible printed circuit layer made from the insulating material.” Jensen discloses a “flexible circuit assembly” containing an electrical circuit. Ex. 1011 ¶¶ [0040], [0043], Figs. 5, 8. A POSA would recognize that the “flexible circuit assembly” of Jensen defines a substrate on which “copper wiring traces” are formed. *Id.* ¶ [0040]; Ex. 1009 ¶ 1507. A POSA would also recognize that the “flexible circuit assembly” is made of insulating material on which the traces, electronics, and sensor contacts 71, 72 are placed. Ex. 1009 ¶ 1508. Jensen also discloses “a flexible printed” circuit assembly. Ex. 1011 ¶¶ [0044], [0046]. This is consistent with the understanding of a POSA that a well-known way to manufacture a flexible circuit assembly is through printing. Ex. 1009 ¶ 1509. Accordingly, Jensen discloses a flexible printed circuit board layer made from insulating material. *Id.* ¶¶ 1505-1510.

iv. [1c.] at least two electrodes disposed on the disposable substrate; and

Jensen teaches the claimed “at least two electrodes disposed onto a surface of the substrate.” Jensen discloses a “disposable sensor assembly” that includes “sensor contacts 71 and 72.” Ex. 1011 ¶¶ [0041]-[0042]. Jensen’s sensor contacts

71 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 EKG signals. *Id.* The sensor pads 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.

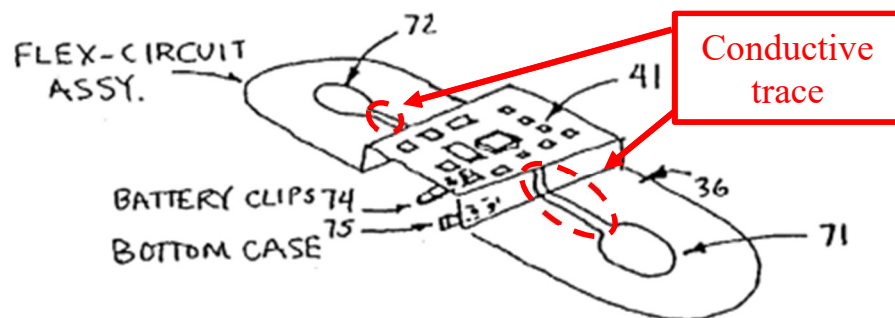


Id. Fig. 8 (annotated); Ex. 1009 ¶¶ 1513-514.

v. ***[Id.] conductive traces defined between the at least two electrodes;***

Jensen teaches a “conductive trace defined between the at least two electrodes.” As shown in Figure 5 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,” which are in electrical contact with the sensor pad electrodes 1, 2 on the bottom of the flex-circuit assembly. Ex. 1011 ¶¶ [0040]-

[0041]. A POSA would understand that the connection 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. Ex. 1009 ¶ 1517.



Ex. 1011, Fig. 5 (annotated). A POSA would understand that the same traces and sensor contacts would be included on disposable substrate 50 in the embodiment of Figure 8. Ex. 1009 ¶ 1518. Accordingly, a POSA would understand that Jensen teaches copper wiring traces (conductive traces) defined between the at least two electrode sensor pads 1, 2. *Id.* ¶ 1519.

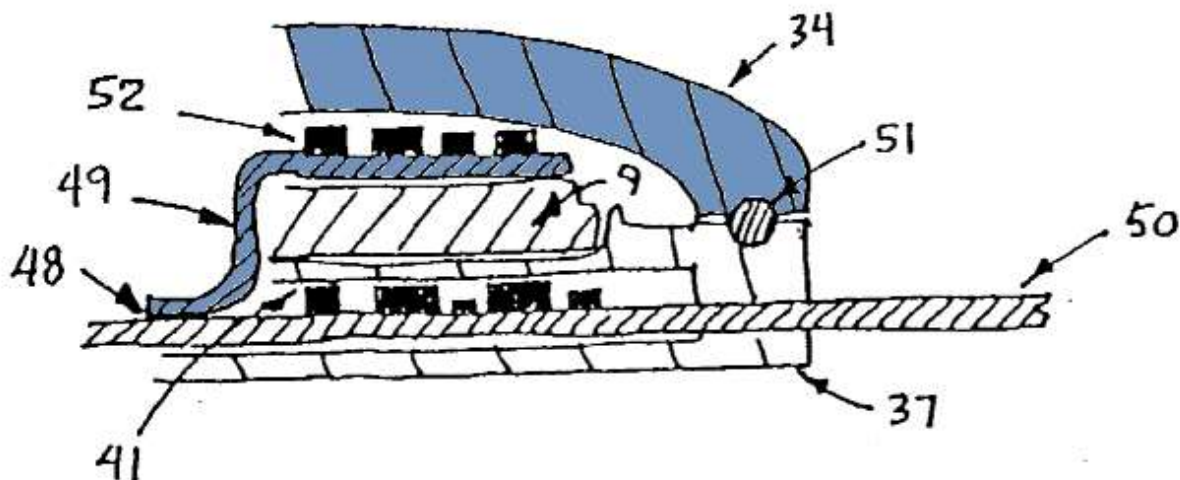
vi. [1e.] providing a computation-communication module, said module comprising:

Jensen discloses “a computation-communication module.” Specifically, Jensen discloses a “microcontroller” for computation and a “transmitter” for communication. Ex. 1011 ¶ [0032]. Jensen’s microcontroller “runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter.” *Id.* Jensen’s transmitter may transmit data via “antenna.” *Id.* ¶ [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. Ex. 1009 ¶ 1522. Accordingly, Jensen discloses a computation-communication module. *Id.* ¶ 1523.

vii. [1f.] a housing;

Jensen discloses a housing. As shown in the below figure, “top case 34” (shown in blue below) mounts onto “bottom case 37” forming a housing that encloses electronics circuit 52. Ex. 1011 ¶¶ [0044]-[0046]; Ex. 1009 ¶¶ 1524-1527.



Ex. 1011, Fig. 8 (annotated).

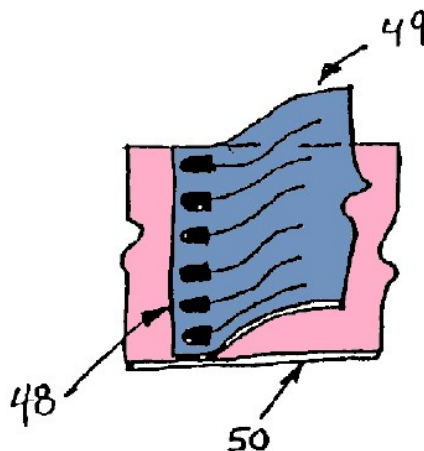
viii. [1g.] a processor disposed in the housing; and

Jensen discloses “a processor disposed in the housing.” As part of electronics circuitry 41, Jensen discloses “a microcontroller and/or other programmable logic circuitry that perform measurement and processing of sensed data.” *Id.* ¶ [0014]. Jensen also discloses 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.* ¶ [0032]. In the embodiment of Figure 8, a POSA would understand that the microcontroller, 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 1009 ¶¶ 1530-1532.

ix. [1h.] attaching the computation-communication module to the disposable substrate.

Jensen discloses “attaching the computation-communication module to the disposable substrate.” Ex. 1009 ¶¶ 1533-1536. Jensen discloses 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.” Ex. 1011 ¶ [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. 1009 ¶ 1535.



Ex. 1011, Fig. 8A (annotated).

3. *Claim 2*

In addition to teaching the limitations of claim 1, Jensen teaches “providing conductive traces in the flexible circuit layer,” as recited in claim 2. Jensen discloses a “flexible circuit assembly that contains copper wiring traces that connect the entire circuit 41 to the sensor contracts.” *Id.* ¶ [0040]. As described above, these same traces would be found in the embodiment of Figure 8. Ex. 1009 ¶¶ 1537-40.

4. *Claim 3*

In addition to teaching the limitations of claims 1 and 2, Jensen teaches that “conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module,” as recited in claim 3. Ex. 1009 ¶¶ 1541-1544. 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 ¶¶ [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.* ¶ [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. Ex. 1009 ¶ 1543. 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. *Id.*

5. *Claim 4*

In addition to teaching all the limitations of claim 1, Jensen and Matsumura teach “providing a plurality of openings in the flexible printed circuit board layer, the openings being sized for receiving electrode gels,” as recited in claim 4. Ex. 1009 ¶¶ 1545-1550. Jensen discloses “disposable sensor pad electrodes 1 and 2” disposed on the lower surface of flexible assembly 36. Ex. 1011 ¶¶ [0041]-[0042], 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. Ex. 1009 ¶ 1547.

As noted above, Matsumura discloses that “second sheet 4 ...is provided with two openings 4a on the left and right sides into which the conductive gel 5 is inserted.” Ex. 1012 ¶ [0018]. It would have been an obvious design choice for 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. Ex. 1009 ¶¶ 1548-1549. Accordingly, Jensen and Matsumura teach a plurality of openings in the flexible printed circuit board layer, the openings being sized for receiving electrode gels.

6. Claim 5

In addition to teaching all of the limitations of claim 1, Jensen renders obvious “the computation-communication module is releasably attached to the disposable substrate,” as recited in claim 5. Ex. 1009 ¶¶ 1551-1554. As noted above, Jensen discloses that the computation-communication module on substrate 49 is attached to the disposable module on substrate 50 at connection 48. *Supra* § VII.C.1.ix; Ex. 1011, Fig. 8. It would have been obvious to a POSA to make the attachment between substrate 49 and substrate 50 a “releasable attachment.” Ex. 1009 ¶ 1553. For example, a POSA would know how to use releasable attachment methods, including adhesives that could be removed with solvents or with heat. *Id.* 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. Accordingly, the dependent limitation of claim 5 is obvious. *Id.* ¶¶ 1553-1554.

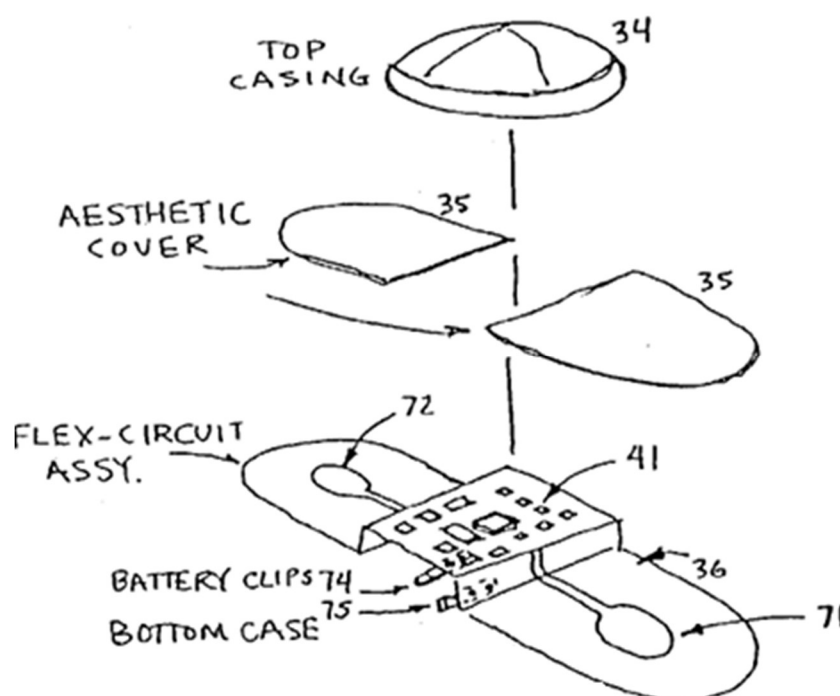
7. Claim 6

In addition to teaching all the limitations of claim 1, Jensen discloses “providing a radio circuit in the computation-communication module,” as recited in claim 6. Ex. 1009 ¶¶ 1555-1558. In particular, Jensen discloses a circuit that includes a radio frequency transmitter 7 (radio circuit) that “may transmit in a variety

of modulation and/or keying methods via antenna 8.” Ex. 1011 ¶ [0032]; *see also id.* ¶¶ [0033], [0039].

8. Claim 7

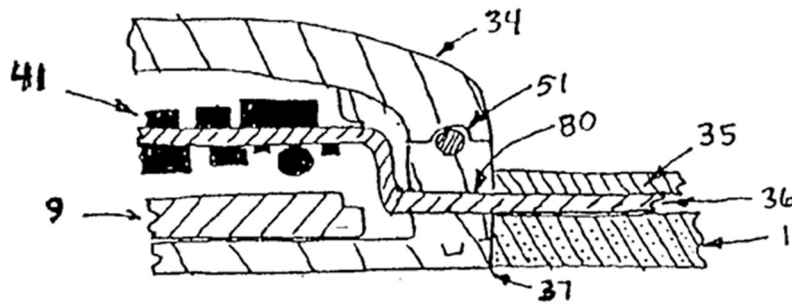
In addition to teaching all the limitations of claims 1 and 3, Jensen discloses “at least partially covering the conductive traces with an insulating cover.” Ex. 1009 ¶¶ 1559-1564. The smart patch of Jensen “has an electric circuit...sandwiched between layers of insulating material and cover plastics.” Ex. 1011, Abstract. Specifically, Jensen teaches the entire top side of flexible circuit assembly 36 that contains the “copper wiring trace” is “enclosed” and “sealed” by top casing 34 and aesthetic covers 35 construed of Mylar, which is a common insulating material. *Id.* ¶¶ [0040], [0043]; Ex. 1009 ¶ 1561. This is shown in Figure 5 of Jensen. Ex. 1011 ¶ [0043].



Id. Fig. 5. 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. Ex. 1009 ¶¶ 1562-1564.

9. *Claim 9*

In addition to teaching the limitations of claim 1, Jensen teaches “integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate,” as recited in claim 9. Ex. 1009 ¶¶ 1565-1569. Jensen discloses a “disposable sensor assembly” that includes “disposable sensor pad electrodes 1 and 2. Ex. 1011 ¶¶ [0041]-[0042]. The sensor pad electrodes 1, 2 are disposed on the lower surface of flexible assembly 36, as shown in Figure 7 below.



Id. Fig. 7. A POSA would have understood that having sensor pad electrodes 1, 2 disposed on flexible-circuit assembly 73 would be a form of integration. Ex. 1009 ¶ 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. *Id.* ¶¶ 1567-1569.

10. Claim 11

In addition to teaching all the limitations of claims 1 and 9, Jensen teaches that “each electrode includes an electrode gel and a conductive surface defining a half cell,” as recited in claim 11. Ex. 1009 ¶¶ 1570-1574. On the side that contacts the patient’s skin, Jensen’s electrode sensor pads 1, 2 are coated with “conductive adhesive-gel that is made using silver amalgam as found in off-the-shelf EKG sensor pads, such as those sold by 3M corporation.” Ex. 1011 ¶ [0041]. A POSA would understand that EKG sensor pads (conductive surface) comprising a silver amalgam (usually silver-silver chloride) and a conductive gel (electrode gel) containing an electrolyte comprise a “half-cell.” Ex. 1009 ¶ 1573. Accordingly, a POSA would know that Jensen’s electrodes define a half cell. *Id.* ¶¶ 1573-1574.

11. Claim 12

In addition to teaching all the limitations of claims 1, 9, and 11, Jensen teaches that “the disposable substrate is crescent shaped and in which the body-worn physiological sensor is worn on the chest of a patient,” as recited in claim 12. Ex. 1009 ¶¶ 1575-1578. Jensen generally explains that EKG electronic-rate sensors are placed on the chest of a patient. Ex. 1011 ¶¶ [0006]-[0007]. Jensen’s “smart patch” is similarly applied to “the skin much like a bandage.” *Id.* ¶ [0030]. Given the placement of Jensen’s “smart patch” on the patient’s chest, it would have been

obvious for POSA to make the disposable sensor assembly crescent shaped to better fit the curvature of the patient's body. Ex. 1009 ¶¶ 1577-78.

12. Claim 14

i. 14[pre]. A body-worn physiological sensor made by the process of:

As described above, Jensen discloses a body-worn physiological sensor. *Supra* § VII.B.2.i; *Purdue Pharma*, 811 F.3d at 1354; *see also Kamstrup*, 43 F.4th at 1382–83; Ex. 1009 ¶¶ 1580-1581.

ii. [14a.] providing a disposable substrate made from an insulating material, said substrate comprising:

As described above, Jensen or, alternatively Jensen in view of the general knowledge of a POSA or Matsumura, discloses this element. *Supra* § VII.B.2.ii; Ex. 1009 ¶¶ 1582-1583.

iii. [14b.] a flexible printed circuit board layer made from an insulating material;

As described above, Jensen discloses this element. *Supra* § VII.B.2.iii; Ex. 1009 ¶¶ 1584-1585.

iv. [14c.] at least two electrodes disposed on the disposable substrate; and

As described above, Jensen discloses this element. *Supra* § VII.B.2.iv; Ex. 1009 ¶¶ 1586-1587.

v. [14d.] conductive traces defined between the at least two electrodes;

As described above, Jensen discloses this element. *Supra* § VII.B.2.v; Ex.

1009 ¶¶ 1588-1589.

vi. [14e.] providing a computation-communication module, said module comprising:

As described above, Jensen discloses this element. *Supra* § VII.B.2.vi; Ex.

1009 ¶¶ 1590-1591.

vii. [14f.] a housing;

As described above, Jensen discloses this element. *Supra* § VII.B.2.vii; Ex.

1009 ¶¶ 1592-1593.

viii. [14g.] a processor disposed in the housing; and

As described above, Jensen discloses this element. *Supra* § VII.B.2.viii; Ex.

1009 ¶¶ 1594-1595.

ix. [14h.] attaching the computation-communication module to the disposable substrate.

As described above, Jensen discloses this element. *Supra* § VII.B.2.ix; Ex.

1009 ¶¶ 1596-1597.

13. Claim 15

As described above, Jensen discloses the dependent limitation of this claim.

Supra § VII.B.3 (claim 2); Ex. 1009 ¶¶ 1598-1600.

14. Claim 16

As described above, Jensen discloses the dependent limitation of this claim.

Supra § VII.B.4 (claim 3); Ex. 1009 ¶¶ 1601-1603.

15. Claim 17

As described above, Jensen discloses the dependent limitation of this claim.

Supra § VII.B.6 (claim 5); Ex. 1009 ¶¶ 1604-1606.

16. Claim 18

As described above, Jensen discloses the dependent limitation of this claim.

Supra § VII.B.7 (claim 6); Ex. 1009 ¶¶ 1607-1609.

17. Claim 19

As described above, Jensen discloses the dependent limitation of this claim.

Supra § VII.B.8 (claim 7); Ex. 1009 ¶¶ 1610-1612.

18. Claim 20

As described above, Jensen discloses the dependent limitation of this claim.

Supra § VII.B.9 (claim 9); Ex. 1009 ¶¶ 1613-1615.

C. Ground 3: Claims 1-3, 5, 6, 9, 11, 12, 14-18, and 20 are Obvious Over Ozguz in view of the General Knowledge of a Person of Ordinary Skill in the Art

1. Claim 1

i. [Pre]: A method for manufacturing a body-worn physiological sensor, the method comprising:

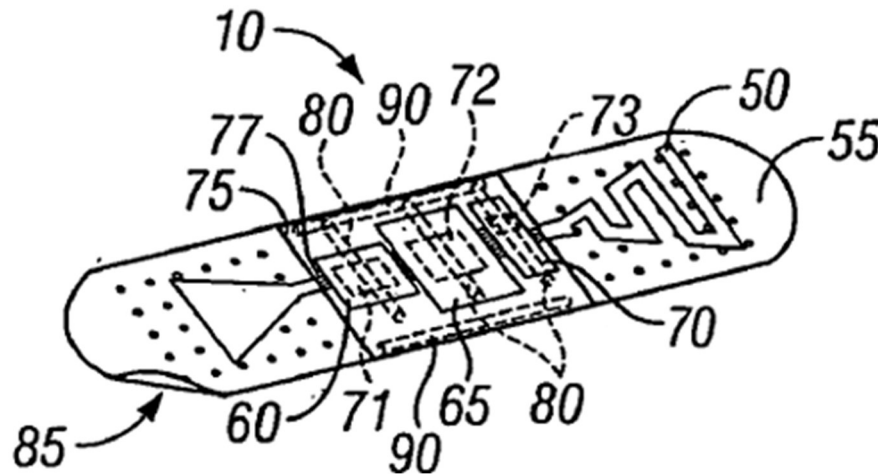
Ozguz discloses “a method for manufacturing a body-worn physiological sensor.” Ex. 1009 ¶¶ 1617-1620. In particular, Ozguz discloses “a sensor system

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, and a method of making such a sensor system and module.” Ex. 1014 ¶ [0003]; *Purdue Pharma*, 811 F.3d at 1354; *see also Kamstrup*, 43 F.4th at 1382–83. 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. Ex. 1009 ¶ 1619.

ii. [1a.] providing a disposable substrate made from an insulating material, said substrate comprising:

Ozguz discloses “providing a disposable substrate made from an insulating material.” Ex. 1009 ¶¶ 1621-1625. In particular, Ozguz discloses that sensor module 10 is “made disposable” and is “discarded after monitoring a particular subject body 20 for purposes of good hygiene.” Ex. 1014 ¶ [0049]. In addition, Ozguz includes a “flexible substrate 55” (shown below) 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.* ¶ [0039]. Circuits 71, 72, and 73 can be integrated into a single circuit. *Id.* ¶ [0042]. 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.* ¶ [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.* ¶ [0049].



Id. Fig. 2A. Accordingly, Ozguz discloses providing a disposable flexible substrate 55 made from an insulating material, such as polyimide that is electrically non-conductive. Ex. 1009 ¶ 1625

iii. [1b.] a flexible printed circuit board layer made from the insulating material;

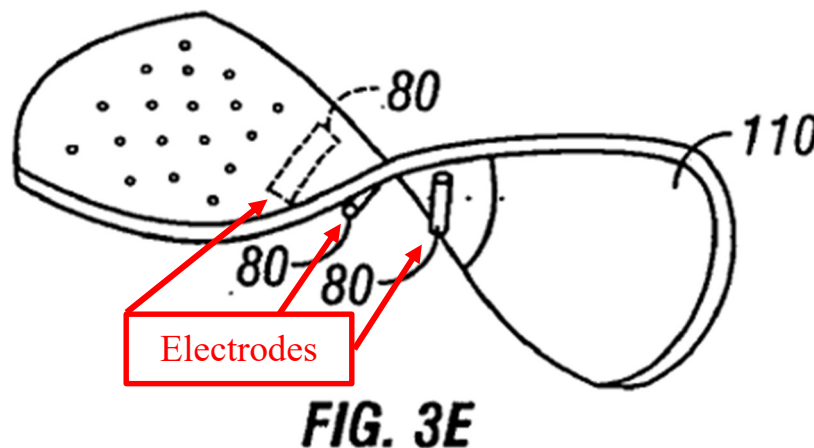
Ozguz discloses “a flexible printed circuit board layer made from an insulating material.” Ex. 1009 ¶¶ 1626-1631. In particular, Ozguz discloses that flexible substrate 55 includes metallization 77 that interconnects integrated circuits 71, 72, 73 and other components to form a circuit board layer. Ex. 1014 ¶ [0039]. A POSA would have understood substrate 55 to be a printed circuit layer on which components or materials are printed, such as metallization 77. Ex. 1009 ¶ 1629.

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 ¶ [0046]. Accordingly, Ozguz discloses flexible substrate 55 that includes metallization 77 and integrated circuits 71, 72, 73 and other components that form a flexible printed circuit board layer made from an insulating material, such as polyimide that is electrically non-conductive. Ex. 1009 ¶ 1631.

iv. [1c.] at least two electrodes disposed on the disposable substrate; and

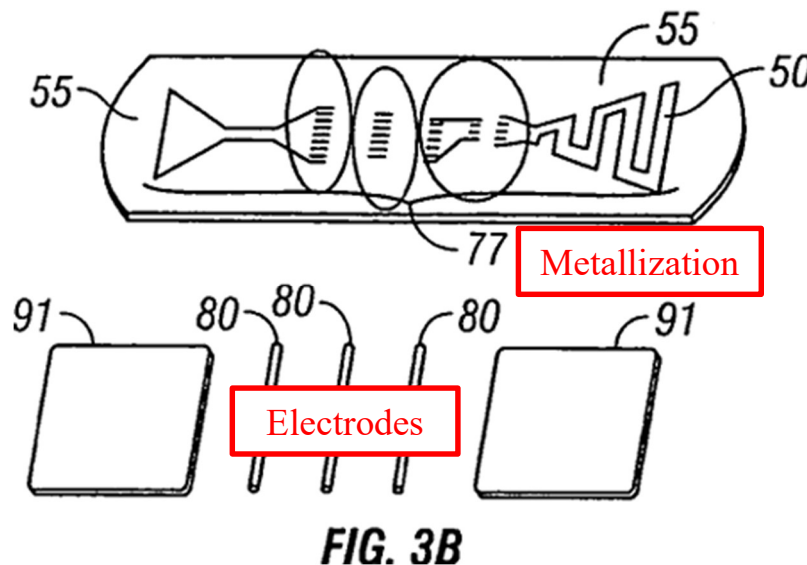
Ozguz discloses “at least two electrodes disposed on the disposable substrate.” Ex. 1009 ¶¶ 1632-1635. In particular, sensor module 10 includes at least two “electrodes 80 disposed on an underside 85 of the flexible substrate 55 for contact with the skin 15 of the subject body 20.” Ex. 1014 ¶ [0039]; Ex. 1009 ¶ 1634. As noted above, flexible substrate 55 is disposable. *Supra* § VII.C.1.ii; Ex. 1014 ¶ [0049].



Ex. 1014, Fig. 3E (annotated). Ozguz also discloses “a pair of electrodes 90” that “extend longitudinally relative to the sensor module 10.” *Id.* ¶ [0043].

v. [1d.] conductive traces defined between the at least two electrodes;

Ozguz discloses “conductive traces defined between the at least two electrodes.” Ex. 1009 ¶¶ 1636-1639. In particular, 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 ¶¶ [0039], [0048]. A POSA would understand metallization 77 to be a form of conductive traces. Ex. 1009 ¶¶ 1638-1639.



Ex. 1014, Fig. 3B (annotated).

vi. [1e.] providing a computation-communication module, said module comprising:

Ozguz discloses “providing a computation-communication module.” Ex. 1009 ¶¶ 1640-1644. 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.” Ex. 1014 ¶ [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.* ¶ [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.* ¶ [0042]. Thin silicon substrates 60, 65, 70 can also include a computation module: “a microprocessor 175” for processing signals and “controlling input, storage, and analysis of the collected data.” *Id.* ¶¶ [0041], [0044], [0058]. Accordingly, Ozguz discloses a computation-communication module. Ex. 1009 ¶¶ 1640-1644.

vii. [1f.] a housing;

Ozguz discloses “a housing” for the computation-communication module. Ex. 1009 ¶¶ 1645-1648. In particular, Ozguz discloses that the “flexible, thin battery 105 overlays the silicon substrates 60, 65, 70 and their respective ICs 71, 72, 73.” Ex. 1014 ¶ [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.*

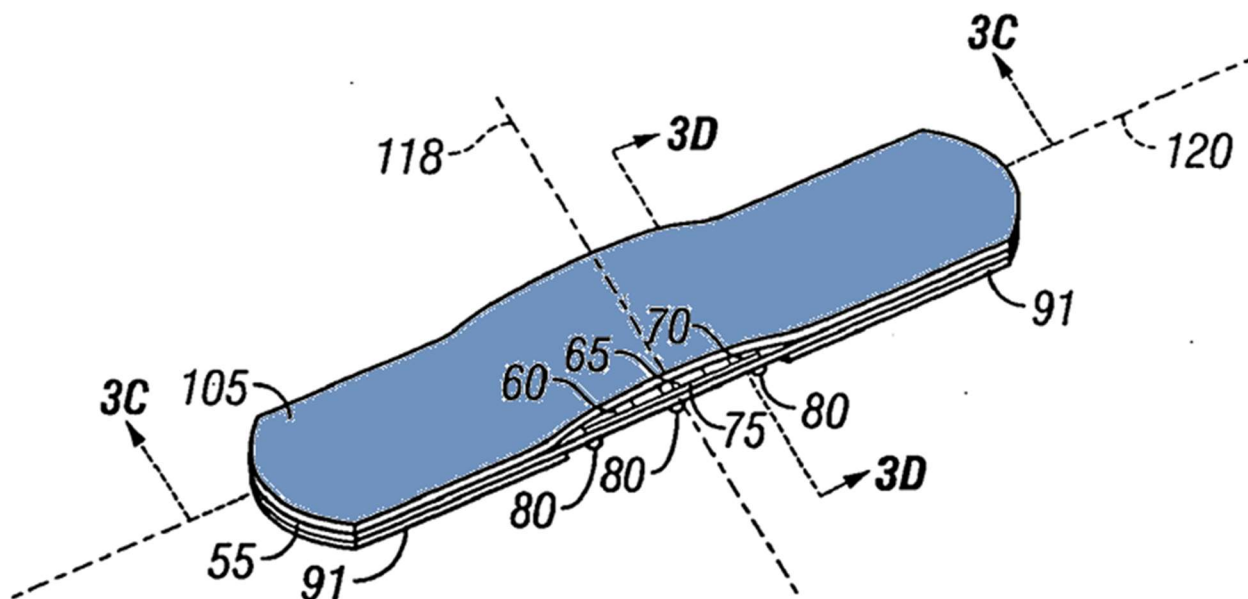


FIG. 3A

Id. Fig. 3A (annotated).

viii. [1g.] a processor disposed in the housing; and

Ozguz discloses “a processor disposed in the housing” of the computation-communication module. Ex. 1009 ¶¶ 1649-1652. In particular, Ozguz discloses a “microprocessor 175” that is “incorporated into thin silicon substrates 60, 65, 70.” Ex. 1014 ¶ [0058]. As noted above, Section VII.C.1.vii, overlay 105 houses “the silicon substrates 60, 65, 70, and their respective ICs 71, 72, 73.” Ex. 1014 ¶ [0048]. Accordingly, Ozguz discloses a processor disposed in the housing. Ex. 1009 ¶ 1652.

ix. [1h.] attaching the computation-communication module to the disposable substrate.

Ozguz discloses “attaching the computation-communication module to the disposable substrate.” Ex. 1009 ¶¶ 1653-1656. As noted above, Section VII.C.1.ii, Ozguz discloses a disposable “flexible substrate 55.” Ex. 1014 ¶¶ [0046], [0049]. Silicon 60, 65, 70, which include both transmitter or transceiver 190 and microprocessor 175, is bonded to the flexible substrate 55. *Id.* ¶¶ [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.* ¶ [0042]. Accordingly, Ozguz discloses attaching the computation-communication module to the disposable substrate. Ex. 1009 ¶ 1655.

2. Claim 2

In addition to teaching all the limitations of claim 1, Ozguz discloses or teaches “providing conductive traces in the flexible circuit layer,” as recited in claim 2. Ex. 1009 ¶¶ 1657-1660. As noted above, 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 ¶ [0039]. A POSA would understand metallization 77 to be a form of conductive traces. Ex. 1009 ¶ 1659. Accordingly, Ozguz discloses or renders obvious providing conductive traces in the flexible circuit layer. *Id.* ¶ 1660.

3. *Claim 3*

In addition to teaching all the limitations of claims 1 and 2, Ozguz teaches that “conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module,” as recited in claim 3. Ex. 1009 ¶¶ 1661-1664. As noted above, Ozguz discloses “metallization 77 . . . applied to flexible substrate 55.” Ex. 1014 ¶ [0039]. “[M]etallization 77 interconnects the ICs 71, 72, 73” on flexible silicon 60, 65, 70 “to each other and to the antenna 50.” *Id.* As noted above, microprocessor 175 and transmitter or transceiver 190 (computation-communication module) are incorporated into flexible silicon 60, 65, 70. *Id.* ¶ [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.* ¶ [0042]. Accordingly, Ozguz discloses conductive traces on the flexible circuit layer to electrically couple with the attached computation-communication module. Ex. 1009 ¶ 1663

4. *Claim 5*

In addition to teaching all the limitations of claim 1, Ozguz and Matsumura teach that “the computation-communication module is releasably attached to the disposable substrate,” as recited in claim 5. Ex. 1009 ¶¶ 1665-1669. Specifically, Ozguz discloses “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. The sensor module can be sterilized in an autoclave, for example, between uses.” Ex. 1014 ¶ [0049]. Ozguz therefore teaches that some components of sensor module 10 are reusable and that those components are releasably attached to other disposable components, such as adhesive pad 91. *Id.*; Ex. 1009 ¶ 1667. A POSA would know that “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; its repeated use would reduce costs and minimize waste. Ex. 1009 ¶ 1667.

Matsumura teaches a way to connect reusable and disposable components of a sensor module. Specifically, as noted above, Matsumura discloses that “[t]he bioelectrode pad 7 and the signal processor 10 are detachable with hooks . . . the reusable signal processor and the disposable bioelectrode can be easily attached and detached before and after use.” Ex. 1012 ¶ [0016]. 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. Ex. 1009 ¶ 1668. Not only are both wearable, self-contained ECG monitors, a POSA would have known that they could have similar disposable and reusable parts: disposable parts include the electrodes used to detect ECG signals, while the reusable parts include the processor and transmitter. *Id.* And Matsumura teaches a common mechanical way

(using hooks) to connect and release disposable and reusable components. *Id.* Accordingly, Ozguz and Matsumura teach a computation-communication module that is releasably attached to the disposable substrate. *Id.* ¶ 1669.

5. Claim 6

In addition to teaching all the limitations of claim 1, Ozguz discloses “providing a radio circuit in the computation-communication module,” as recited in claim 6. Ex. 1009 ¶¶ 1670-1673. As noted above, Ozguz discloses “circuitry 170 that could be incorporated into the thin silicon substrates 60, 65, 70.” Ex. 1014 ¶ [0058]. The “circuitry will include . . . a transmitter or transceiver 190 for transmitting data by [radio frequency] RF signals to a remote receiver.” *Id.* Accordingly, Ozguz discloses providing a radio circuit in the computation-communication module. Ex. 1009 ¶¶ 1640-1644.

6. Claim 9

In addition to teaching the limitations of claim 1, Ozguz discloses “integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate,” as recited in claim 9. Ex. 1009 ¶¶ 1674-1677. In particular, 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 ¶ [0039]. As noted above, flexible substrate 55 is disposable. *Supra* § VII.C.1.ii; Ex. 1014 ¶ [0049]; Ex. 1009 ¶¶ 1676-77

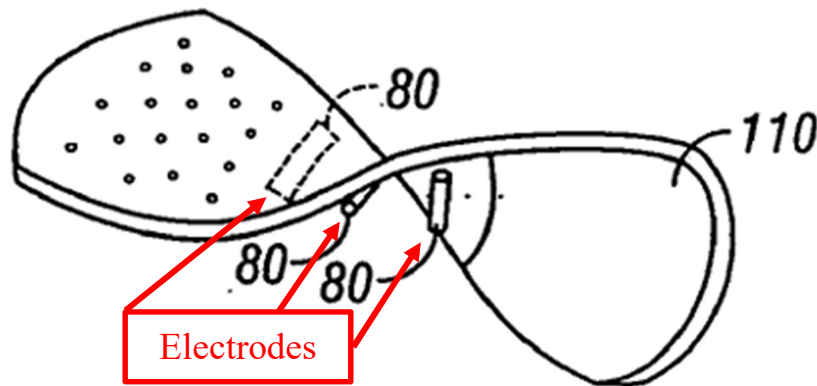


FIG. 3E

Ex. 1014, Fig. 3E (annotated).

7. Claim 11

In addition to teaching the limitations of claims 9 and 1, it would be obvious to a POSA to modify Ozguz to include “an electrode gel and a conductive surface defining a half cell,” as recited in claim 11. Ex. 1009 ¶ 1679. As described above, Section VII.C.6, Ozguz includes integrated electrode sensor contacts on its bottom surface. A POSA 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. Ex. 1009 ¶ 1680. To improve signal accuracy, a POSA would have looked to include commercially available electrode gels, which were well-known in the art, and could be included with a reasonable expectation of success. *Id.* ¶¶ 1680-1681. Integrating such gels into the device would result in an “electrode gel and a conductive surface defining a half cell.” *Id.* ¶¶ 1680-1682.

8. *Claim 12*

In addition to teaching all the limitations of claims 1, 9, and 11, Ozguz teaches that “the disposable substrate is crescent shaped and in which the body-worn physiological sensor is worn on the chest of a patient,” as recited in claim 12. Ex. 1009 ¶¶ 1683-1686. Ozguz describes that sensor module 10 is attached to the patient’s chest. Ex. 1014 ¶ [0038], Fig. 2A. Given the placement of sensor module 10 on the patient’s chest, it would have been obvious for a POSA to make Ozguz’s disposable sensor assembly crescent shaped to better fit the curvature of the patient’s body. Ex. 1009 ¶¶ 1685-1686.

9. *Claim 14*

i. 14[pre]. A body-worn physiological sensor made by the process of:

As described with respect to Claim 1, Ozguz discloses a body-worn physiological sensor. *Supra* § VII.C.1.i; Ex. 1009 ¶¶ 1688-1689; *Purdue Pharma*, 811 F.3d at 1354 (explaining that process limitations which do not impart “structural or functional differences” as compared to the prior art should not be considered as part of the obviousness analysis); *see also Kamstrup*, 43 F.4th at 1382–83 (finding a claim element “describing a manufacturing method” was not entitled to patentable weight because the use of a different method would not result in a product that was structurally or functionally different from the prior art product).

ii. [14a.] providing a disposable substrate made from an insulating material, said substrate comprising:

As described with respect to Claim 1, Ozguz discloses a disposable substrate made from an insulating material. *Supra* § VII.C.1.ii; Ex. 1009 ¶¶ 1690-1691.

iii. [14b.] a flexible printed circuit board layer made from an insulating material;

As described with respect to Claim 1, Ozguz discloses a flexible printed circuit board layer made from an insulating material. *Supra* § VII.C.1.iii; Ex. 1009 ¶¶ 1692-1693.

iv. [14c.] at least two electrodes disposed on the disposable substrate; and

As described with respect to Claim 1, Ozguz discloses at least two electrodes disposed on the disposable substrate. *Supra* § VII.C.1.iv; Ex. 1009 ¶¶ 1694-1695.

v. [14d.] conductive traces defined between the at least two electrodes;

As described with respect to Claim 1, Ozguz discloses conductive traces defined between the at least two electrodes. *Supra* § VII.C.1.v; Ex. 1009 ¶¶ 1696-1697.

vi. [14e.] providing a computation-communication module, said module comprising:

As described with respect to Claim 1, Ozguz discloses a computation-communication module. *Supra* § VII.C.1.vi; Ex. 1009 ¶¶ 1698-1699.

vii. [14f.] a housing;

As described with respect to Claim 1, Ozguz discloses a computation-communication module comprising a housing. *Supra* § VII.C.1.vii; Ex. 1009 ¶¶ 1700-1701.

viii. [14g.] a processor disposed in the housing; and

As described with respect to Claim 1, Ozguz discloses a processor disposed in the housing. *Supra* § VII.C.1.viii; Ex. 1009 ¶¶ 1702-1703.

ix. [14h.] attaching the computation-communication module to the disposable substrate.

As described with respect to Claim 1, Ozguz discloses attaching the computation-communication module to the disposable substrate. *Supra* § VII.C.1.ix; Ex. 1009 ¶¶ 1704-1705.

10. Claim 15

As described with respect to Claim 2, Ozguz discloses providing the conductive traces in the flexible printed circuit board layer. *Supra* § VII.C.2; Ex. 1009 ¶¶ 1706-1708.

11. Claim 16

As described with respect to Claim 3, Ozguz discloses configuring the conductive traces in the flexible printed circuit board layer to electrically couple with the attached computation-communication module. *Supra* § VII.C.3; Ex. 1009 ¶¶ 1709-1711.

12. Claim 17

As described with respect to Claim 5, Ozguz discloses that the computation-communication module is releasably attached to the disposable substrate. *Supra* § VII.C.4; Ex. 1009 ¶¶ 1712-1714.

13. Claim 18

As described with respect to Claim 6, Ozguz in view of a POSA's general knowledge teaches providing the computation-communication module with a radio circuit. *Supra* § VII.C.5; Ex. 1009 ¶¶ 1715-1717.

14. Claim 20

As described with respect to Claim 9, Ozguz discloses integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate. *Supra* § VII.C.6; Ex. 1009 ¶¶ 1718-1720.

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

Section 314(a). Here, none of the factors enumerated in *Apple Inc. v. Fintiv Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) favors discretionary denial of institution. A scheduling order has not been entered nor a trial date set for the co-pending litigation (Factor 2). The proceedings have not progressed beyond the pleadings stage, and neither the parties nor the district court have invested substantial resources in the litigation to date (Factor 3). To date, there is no overlap between the issues raised in the petition and the parallel proceeding (Factor 4). Petitioner is

the sole defendant in the parallel proceeding (Factor 5). The grounds raised herein present a compelling unpatentability challenge that on its own prevents a discretionary denial under *Fintiv* (Factor 6). Katherine K. Vidal, Interim Procedure For Discretionary Denials in AIA Post-Grant Proceedings With Parallel District Court Litigation (June 21, 2022).

Section 325(d). Jensen qualifies as art previously presented to the Office because it was listed on an Information Disclosure Statement (IDS) supplied by the Applicant. '422 patent, IDS at 4 (January 26, 2018) (Ex. 1008, 242). *Cf. Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020). Neither Matsumura nor Ozguz was ever presented to the Office during examination.

The factors enumerated in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) do not counsel against institution. At minimum, none of the references submitted as part of Grounds 1 or 3 were considered by the Office and, for that reason alone, Section 325(d) does not warrant denial of institution.

As to Jensen, the Examiner failed to consider how Jensen alone or in combination with any other reference would render obvious the purported invention of the '422 patent. The art cited by the Examiner during prosecution did not disclose a body-worn physiological monitor like that of Jensen, Matsumura, or Ozguz (Factor

A). The Examiner did not substantively address any combination that was similar to Jensen and Matsumura or Ozguz and Matsumura during prosecution, or any combination similar to Matsumura, Jensen, or Ozguz with the general knowledge of a POSA (Factor B).

In addition, neither Jensen nor a Jensen-based combination formed the basis for rejection during prosecution (Factor C). Instead, Jensen was cited in an IDS along with 125 other references, none of which was substantively addressed during examination of the application that became the '422 patent. The Board has repeatedly held that a reference that is merely cited in an IDS does not weigh in favor of a discretionary denial. *See, e.g., Gene Co. Pty Ltd, v. Trs. of Columbia Univ.*, IPR 2024-00313, Paper 13 at 56–57 (PTAB June 24, 2024); *Advanced Energy Indus. Inc. v. Reno Techs. Inc.*, IPR2021-01397, Paper 7 at 7 (PTAB Feb. 16, 2022); *Lyft, Inc. v. RideShare Displays, Inc.*, IPR2021-01602, Paper 7 at 15-16 (PTAB Apr. 11, 2022). These decisions are consistent with the USPTO's notice of proposed rulemaking on this issue, which notes that “[a]n initialed Information Disclosure Statement, without more, does not satisfy” the criteria of 325(d). Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement, 89 Fed. Reg. 28693 (proposed Apr. 19, 2024) (to be codified at 37 C.F.R. pt. 42). The arguments in this Petition related to Jensen, which

rely on a combination of prior art that includes Matsumura (never before the Office), do not overlap with those made during examination (Factor D).

IX. CONCLUSION

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

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

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

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

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

The '422 patent is presently the subject of a patent infringement lawsuit brought by the assignee, Welch Allyn, Inc., against iRhythm, Inc. and captioned *Welch Allyn, Inc. v. iRhythm, Inc.*, C.A. No. 24-224-MN (D. Del.).

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

Petitioner provides the following designation of counsel:

Lead Counsel	Backup Counsel
Robert E. Counihan (Reg. No. 61,382) Fenwick & West LLP 902 Broadway, Floor 18 New York, NY 10010 T: (212) 430-2600 rcounihan@fenwick.com	Allen W. Wang (Reg. No. 68,456) Fenwick & West LLP 801 California Street Mountain View, CA 94041-1990 T: (650) 335-7288 allen.wang@fenwick.com

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

D. Service Information

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

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

Dated: December 23, 2024

FENWICK & WEST LLP

/Robert E. Counihan /

Robert E. Counihan

Reg. No. 61,381

Attorneys for Petitioner

iRhythm, Inc

CLAIMS APPENDIX

Claim	Recitation
1[pre]	A method for manufacturing a body-worn physiological sensor, the method comprising:
[1a.]	providing a disposable substrate made from an insulating material, said substrate comprising:
[1b.]	a flexible printed circuit board layer made from the insulating material;
[1c.]	at least two electrodes disposed on the disposable substrate; and
[1d.]	conductive traces defined between the at least two electrodes;
[1e.]	providing a computation-communication module, said module comprising:
[1f.]	a housing;
[1g]	a processor disposed in the housing; and
[1h.]	attaching the computation-communication module to the disposable substrate.
[2]	The method of claim 1, further comprising: providing conductive traces in the flexible circuit layer.
[3]	The method of claim 2, in which the conductive traces are configured on the flexible circuit layer to electrically couple with the attached computation-communication module.
[4]	The method of claim 1, further comprising: providing a plurality of openings in the flexible printed circuit board layer, the openings being sized for receiving electrode gels.
[5]	The method of claim 1, in which the computation-communication module is releasably attached to the disposable substrate.
[6]	The method of claim 1, further comprising: providing a radio circuit in the computation-communication module.

Claim	Recitation
[7]	The method of claim 3, further comprising: at least partially covering the conductive traces with an insulating covering.
[9]	The method of claim 1, further comprising: integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate.
[10]	The method of claim 3, further comprising: screening the conductive traces onto the flexible printed circuit board layer.
[11]	The method of claim 9, in which each electrode includes an electrode gel and a conductive surface defining a half cell.
[12]	The method of claim 11, in which the disposable substrate is crescent shaped and in which the body-worn physiological sensor is worn on the chest of a patient.
14[pre].	A body-worn physiological sensor made by the process of:
[14a.]	providing a disposable substrate made from an insulating material, said substrate comprising:
[14b.]	a flexible printed circuit board layer made from an insulating material;
[14c.]	at least two electrodes disposed on the disposable substrate; and
[14d.]	conductive traces defined between the at least two electrodes;
[14e.]	providing a computation-communication module, said module comprising:
[14f.]	a housing;
[14g.]	a processor disposed in the housing; and
[14h.]	attaching the computation-communication module to the disposable substrate.

Claim	Recitation
[15]	The body-worn physiological sensor of claim 14, wherein the process further comprises: providing the conductive traces in the flexible printed circuit board layer.
[16]	The body-worn physiological sensor of claim 15, in which the process further comprises: configuring the conductive traces in the flexible printed circuit board layer to electrically couple with the attached computation-communication module.
[17]	The body-worn physiological sensor of claim 14, in which the computation-communication module is releasably attached to the disposable substrate.
[18]	The body-worn physiological sensor of claim 14, wherein the process further comprises: providing the computation-communication module with a radio circuit.
[19]	The body-worn physiological sensor of claim 16, in which the process further comprises: at least partially covering the conductive traces with an insulating covering.
[20]	The body-worn physiological sensor of claim 14, in which the process further comprises: integrating at least two electrodes into the flexible printed circuit board layer of the disposable substrate.

**CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION**

Under the provisions of 37 C.F.R. § 42.24(d). I certify that this petition complies with the type-volume limits of 37 C.F.R. § 42.24(a)(1)(i) because it contains 12,889 words, according to the word-processing system used to prepare this petition, excluding the parts of this petition that are exempted by 37 C.F.R. § 42.24(a) (including the table of contents, a table of authorities, mandatory notices, a certificate of service or this certificate word count, appendix of exhibits, and claim listings).

Dated: December 23, 2024

FENWICK & WEST LLP

/Robert E. Counihan /

Robert E. Counihan

Reg. No. 61,381

Attorneys for Petitioner

iRhythm, Inc

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

I hereby certify, pursuant to 37 C.F.R. §§ 42.6(e), 42.105, that a complete copy of the above-captioned PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 10,159,422, all associated exhibits, and Petitioner's Power of Attorney were served in their entireties via Federal Express, Priority Delivery, on December 23, 2024, upon Patent Owner by serving the correspondence address of record with the USPTO as follows:

BARCLAY DAMON, LLP
Barclay Damon Tower
125 East Jefferson Street
Syracuse, NY 13202

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

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Dated: December 23, 2024

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