

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE

PATENT TRIAL AND APPEAL BOARD

VITAL CONNECT, INC.,

Petitioner

v.

BARDY DIAGNOSTICS, INC.,

Patent Owner

U.S. Patent No. 11,051,743
Original Issue Date: Jul. 6, 2021
Title: ELECTROCARDIOGRAPHY PATCH

Case No. IPR2023-00381

DECLARATION OF DR. JOSEPH AKAR

Declaration

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

By: 

Joseph Akar, Ph.D.

Contents

I.	Professional Background.....	3
II.	Electrocardiographic Patch Technologies.....	7
	A. Electrocardiography (ECG).....	7
	B. ECG Patches and Electrodes.....	8
III.	Relevant Legal Standards	11
IV.	Person of Ordinary Skill in the Art.....	14
V.	The Subject Patent US 11,051,743 ('743 Patent).....	15
	A. Overview.....	15
	i. Field of Art.....	15
	ii. Background – Description of the Prior Art and Admitted Prior Art	16
	iii. Problem statement	18
	iv. Summary of the '743 Patent Disclosure.....	18
	v. The '743 Patent Claim Elements	20
	B. Claimed Components	22
VI.	Prosecution History of the '743 Patent.....	25
VII.	Summary of Prior Art	26
	A. Mazar	26
	B. Oster.....	29
	C. Yang.....	33
VIII.	Motivation to Combine Mazar and Yang	37
IX.	Motivation to Combine Oster and Yang.....	39
X.	Claim Construction	42
	A. “a battery on one of the ends of the backing” (Claim 11)	42
XI.	Overlap Among Independent Claims 1 and 11	45
XII.	Ground I – Claims 1-20 are Anticipated or Rendered Obvious under 35 U.S.C. § 102 or 35 U.S.C. § 103 by Mazar in Combination with Yang.....	47
	A. Independent Claim 1	47
	i. Element [1-PRE]	47
	ii. Element [1-A]	48
	iii. Element [1-B]	52
	iv. Element [1-C]	55
	v. Element [1-D]	57
	B. Independent Claim 11	58
	i. Element [11-E].....	58
	ii. Element [11-F].....	61
	iii. Element [11-G]	62
	C. Claims 2 and 12.....	62
	D. Claims 3 and 13.....	63

E.	Claims 4 and 14.....	64
F.	Claims 5 and 15.....	64
G.	Claims 6 and 16.....	65
H.	Claims 7 and 17.....	66
I.	Claims 8 and 18.....	67
J.	Claims 9 and 19.....	68
K.	Claims 10 and 20.....	69
XIII.	Ground II – Claims 1-20 are Anticipated or Rendered Obvious under 35 U.S.C. § 102 or 35 U.S.C. § 103 by Oster in Combination with Yang	71
A.	Independent Claim 1	71
i.	Element [1-PRE]	71
ii.	Element [1-A]	72
iii.	Element [1-B]	76
iv.	Element [1-C]	79
v.	Element [1-D]	82
B.	Independent Claim 11	83
i.	Element [11-E].....	83
ii.	Element [11-F]	86
iii.	Element [11-G]	87
C.	Claims 2 and 12.....	88
D.	Claims 3 and 13.....	88
E.	Claims 4 and 14.....	89
F.	Claims 5 and 15.....	91
G.	Claims 6 and 16.....	92
H.	Claims 7 and 17.....	92
I.	Claims 8 and 18.....	93
J.	Claims 9 and 19.....	96
K.	Claims 10 and 20.....	98
XIV.	CONCLUSION	100

I, Dr. Joseph Akar, do hereby declare:

1. I am making this Declaration at the request of Vital Connect, Inc. (“VitalConnect”) in connection with a Petition for *Inter Partes Review* (IPR) of U.S. Patent No. 11,051,743 to Jason Felix *et al.*, which I refer to throughout this Declaration as the ’743 patent.

2. I am being compensated for my work in this matter at my standard hourly rate of \$500 for consulting services. My compensation in no way depends on the outcome of this proceeding or the content of my testimony.

3. In preparing this Declaration, I considered the following materials:

- (a) U.S. Patent No. 11,051,743 (Exhibit 1001)
- (b) Prosecution History of U.S. Patent No. 11,051,743 (Exhibit 1007)
- (c) PCT Appl. Publ. No. WO 2010/104952 (“Mazar”) (Exhibit 1003)
- (d) U.S. Patent Appl. Publ. No. 2011/0077497 (“Oster”) (Exhibit 1004)
- (e) U.S. Patent No. 11,116,447 (“Yang”) (Exhibit 1005)
- (f) U.S. Patent No. 5,862,803 (“Besson”) (Exhibit 1008)
- (g) Gary Wolf, “*The Data-Driven Life*,” New York Times Magazine, April 28, 2010 (Exhibit 1009)

- (h) Kashmir Hill, “*Adventures in Self-Surveillance: Fitbit, Tracking My Movement and Sleep,*” Forbes, February 25, 2011 (Exhibit 1010)
- (i) Lori Mehen, “*Open health with the quantified self,*” Opensource.com, August 25, 2011 (Exhibit 1011)
- (j) “*23 Personal Tools to Learn More About Yourself,*” Flowingdata.com, September 18, 2008 (Exhibit 1012)
- (k) PCT Appl. Publ. No. WO 2008/005015 (“Shennib”) (Exhibit 1013)
- (l) U.S. Patent No. 7,206,630 (“Tarler”) (Exhibit 1014)
- (m) U.S. Patent No. 8,611,980 (“Chloe”) (Exhibit 1015)
- (n) M. Puurtinen, *et al.*, *Estimation of ECG Signal of closely separated bipolar electrodes using thorax models*, Proceedings of the 26th Annual International Conference of the IEEE EMBS pp. 801-804, San Francisco, Calif., USA, Sep. 1-5, 2004 (Exhibit 1016)
- (o) Trägårdh E, Engblom H, Pahlm O., *How many ECG leads do we need?* Cardiol Clin. 2006 Aug;24(3):317-30, vii. doi: 10.1016/j.ccl.2006.04.005. PMID: 16939826 (Exhibit 1017)

- (p) May 24, 2022, Letter from Bardy's Counsel in response to VitalConnect letter of May 2, 2022 and May 2, 2022, Letter from VitalConnect's Counsel to Bardy (Exhibit 1018)
- (q) U.S. Patent No. 9,277,864 (Exhibit 1019)

I. Professional Background

4. Information concerning my professional qualifications, experience, and publications, and the matters in which I have served as an expert, are set forth in my current *curriculum vitae*, attached as Exhibit 1006.

5. I hold the titles of Professor of Medicine and Chief of Cardiac Electrophysiology at the Yale University School of Medicine.

6. I am also the Director of the Complex Ablation Program at Yale-New Haven Hospital and the Director of the Cardiac Electrophysiology Laboratories across the Yale-New Haven Health System. In this capacity, I oversee a range of clinical, research and teaching activities in the field of cardiac electrophysiology and arrhythmogenesis. As part of my role at Yale-New Haven Hospital, I prescribe and use mobile ECG monitoring systems, this has included the CardioNet, Zio and Preventice mobile cardiac telemetry units.

7. Having been awarded full scholarships for undergraduate and medical education at the Pennsylvania State University and the University of Pittsburgh

School of Medicine respectively, I went on to complete my internship and residency training in Internal Medicine at the Yale-New Haven Hospital of Yale University.

8. I subsequently completed fellowships in Cardiovascular Disease and Clinical Cardiac Electrophysiology at the University of Virginia (UVA) Health Sciences Center.

9. In addition to my clinical training at UVA, I earned a PhD degree in Molecular Physiology and Biophysics. My doctoral research was focused on the role of structural and electrical remodeling in the pathogenesis of arrhythmias, with a particular emphasis on atrial fibrillation.

10. In 2004, I joined the Loyola University School of Medicine in Chicago as an Assistant Professor of Medicine and faculty member of the cardiac electrophysiology laboratory.

11. I was subsequently recruited to Yale University and Yale-New Haven Hospital in 2009.

12. I am very active clinically as I focus on the treatment of patients with cardiac disease. I specialize in radiofrequency ablation of highly prevalent complex arrhythmias, including ventricular tachycardia and atrial fibrillation.

13. I also specialize in device therapies, such as pacemakers and defibrillators for patients at risk for sudden cardiac death.

14. From an academic standpoint, I study arrhythmias on a basic science, clinical and epidemiological levels. I have particular research interest and clinical expertise in remote monitoring of cardiac devices. My clinical research focuses on catheter and device-based therapies for arrhythmias.

15. I perform large population registry studies on the role of devices in patients who are predisposed to arrhythmias. Specifically, I examine the effect of remote monitoring of cardiac defibrillators on clinical outcomes.

16. I am an active member of the Heart Rhythm Society and a panel member of multiple guideline/consensus statements, including the: Consensus Statement on Device Remote Monitoring, Electrophysiology Laboratory Standards, Atrial Fibrillation Ablation Consensus Statement, and Consensus Statement on Atrial Cardiomyopathy.

17. My basic research focuses on the mechanisms by which electrical and structural abnormalities predispose to arrhythmias and sudden cardiac death. I was the Principal Investigator of a National Institutes of Health sponsored RO 1 grant examining the role of non-invasive imaging of matrix metalloproteinase activity in atrial fibrillation. This was a \$3.7 million grant that was awarded by the National Heart Lung and Blood Institute (NHLBI).

18. I am the author of multiple peer-reviewed articles and an active reviewer of arrhythmia manuscripts in high-profile journals, including *Circulation*,

the *Journal of the American College of Cardiology*, the *Heart Rhythm Journal* and the *Journal of Cardiovascular Electrophysiology*.

19. I am an Associate Editor for *Pacing and Cardiac Electrophysiology Journal (PACE)*. I also serve on the editorial boards of the *Heart Rhythm Journal* and *Arrhythmia and Electrophysiology Review*.

20. Throughout my career, I have worked with ECG monitoring systems, including those used in implantable defibrillators, ambulatory patient heart monitors like Holter and MCT monitors, as well as hospital telemetry. I have experience in how these machines are selected and used by hospital staff and physicians, and the typical problems and solutions associated with ECG monitoring in both in-patient and out-patient settings.

21. I use MCT devices in my clinical practice and I am aware of their various features and utility in the field.

22. As part of my work in cardiac electrophysiology, I am very familiar with some engineering features that are employed in ECG monitoring. Although I have not personally designed ECG monitoring systems from an engineering standpoint, I do understand how they work, and how they affect the data that I review in treating my patients. I consider this understanding to be an important aspect of my practice.

II. Electrocardiographic Patch Technologies

23. Below I describe the state of electrocardiographic patches as of the '743 patent's filing date, and summarize the development of technologies underlying the features and methods recited in claims 1-20 ("Challenged Claims").

A. Electrocardiography (ECG)

24. Electrocardiography (ECG) is a tool used by physicians to monitor cardiac rhythm, diagnose heart problems, and other potential health concerns.

25. ECG measures the electrical activity of the heart. ECG recording uses electrodes attached to specific anatomical positions. Conventionally, a standardized set format 12-lead configuration is used by an ECG reader to record cardiac electrical signals from well-established traditional chest locations. Electrodes at the end of each lead are placed on the skin over the anterior thoracic region of the patient's body to the lower right and to the lower left of the sternum, on the left anterior chest, and on the limbs.

26. An ECG represents electrical activity of the heart based on depolarization and repolarization of the atria and ventricles, which typically show up as distinct waves on the ECG readout—P-wave, Q-wave, R-wave, S-wave, T-wave, and the occasionally observed U-wave.

27. Sensed cardiac electrical activity is represented by PQRSTU waveforms that can be interpreted post-ECG recording to derive heart rate and

physiology. The P-wave represents atrial electrical activity. The QRSTU components represent ventricular electrical activity.

28. ECG cardiac monitoring can be done through several methods including: (1) screening, (2) short-term monitoring, (3) intermittent monitoring, and (4) long-term monitoring.

29. Screenings can be accomplished through consumer wearables with individual spot readings. Short-term monitoring in the hospital setting is typically a Holter Monitor. The Holter Monitor is a wearable and portable version of an ECG that include cables for each electrode placed on the skin and a separate battery-powered ECG recorder

B. ECG Patches and Electrodes

30. To record ECG signals, a minimum of two electrodes are typically used. It is also well-known that different quantities and placement of electrodes on the body can be used to different effect. For example, the interelectrode distance effects the strength and fidelity of detected ECG signals. *See M. Puurtinen, et al., Estimation of ECG Signal of closely separated bipolar electrodes using thorax models*, Proceedings of the 26th Annual International Conference of the IEEE EMBS pp. 801-804, San Francisco, Calif., USA, Sep. 1-5, 2004. And the quantity of leads is a trade-off between sensitivity, specificity, and feasibility. *See Trägårdh E, Engblom H, Pahlm O., How many ECG leads do we need? Cardiol Clin. 2006*

Aug;24(3):317-30, vii. doi: 10.1016/j.ccl.2006.04.005. PMID: 16939826.

Moreover, it is also well-known that different numbers of electrodes can be used for enhanced signal discrimination and localization. Moreover, evaluation of a signal that is simultaneously inscribed on multiple leads is clinically useful in the setting of poor electrode contact with the skin. When noise due to poor electrode contact precludes signal interpretation, having the signal available via other electrodes is invaluable. Given these known differences in the number and placement of electrodes, persons of ordinary skill in the art have long understood that the number of electrodes can be varied to achieve trade-offs between complexity, cost, and functionality. For example, two electrodes could be placed closely together for increased comfort and reduced complexity and cost. Or multiple electrodes could be spaced widely across the body to achieve more robust signal capture. But this naturally would increase costs and complexity.

31. The disadvantages of wired cardiac electrode connectors have also long been known. For example, U.S. Patent No. 5,862,803 (hereinafter “’803 patent”), filed in 1994, states:

Conventional monitoring and diagnostic equipment is structured in such a way that one or several electrode(s) is/are mounted on the patient, which tap the respective signals (predominantly potential and impedance values) and transmit such signals via cables to amplifier units. Normally, separate electrodes are used for each measurement

parameter.

Especially in EKG and EEG examinations, many cables are suspended on the patient, connecting the EKG/EEG-electrodes with the evaluator units, which process and record the signals. ***Such cables obstruct the patient and highly limit his or her freedom of movement***, and, therefore, are only conditionally suitable especially for carrying out examinations at stress (e.g. EKG's at stress). In addition, due to the stiffness of the cables and the lever forces connected therewith, ***the cables become easily detached particularly when the patient moves***. Furthermore, in connection with infants, there is the risk that they may play with the cables and detach the glued-on electrodes.

32. Ex. 1008, at 1:43-59 (emphasis added). In view of these disadvantages, the '803 patent recognizes that even prior to its filing date, patches that wirelessly transmit ECG signals were well known. *See*, Ex. 1008, 2:19-3:34. The '803 patent further recognizes that such patches could sense additional biological characteristics such as temperature, motion, and oxygen. Ex. 1008, 23:14-16. As the '803 patent demonstrates, the field of electrocardiography monitoring was well-established long ago and built upon the understanding of well-known physiological monitoring techniques. In the intervening years between the '803 patent and the filing of the '743 patent, extensive development occurred with a huge variety of wireless patches being developed by mixing and matching various features. In parallel with development of medical oriented patches, consumer electronics products came to

market to track physiological characteristics such as movement, heart rate, sleep cycles, etc. The use of these devices became widespread in the late 2000s under the banner “quantified self” and received widespread media attention. *See, e.g.*, Ex. 1009, Gary Wolf, “*The Data-Driven Life*,” New York Times Magazine, April 28, 2010; Ex. 1010, Kashmir Hill, “*Adventures in Self-Surveillance: Fitbit, Tracking My Movement and Sleep*,” Forbes, February 25, 2011; Ex. 1011, Lori Mehen, “*Open health with the quantified self*,” Opensource.com, August 25, 2011; and Ex. 1012, “*23 Personal Tools to Learn More About Yourself*,” Flowingdata.com, September 18, 2008. The commercial devices demonstrate that in the 2000s, physiology tracking systems had begun using commoditized standard consumer electronics technology such as Bluetooth, off-the-shelf processors, memory, battery technology, etc. And standard consumer electronics/computer design methodologies were well developed for these sorts of devices. Thus, by 2013 this was a crowded art where the concepts employed in the field were well understood, predictable, and routinely mixed and matched as needed to achieve a POSITA’s design goals.

III. Relevant Legal Standards

33. I have been asked to provide my opinions as to whether claims 1-20 (“Challenged Claims”) of the ’743 Patent are anticipated or would have been

obvious to a Person of Ordinary Skill in the Art (or “POSITA” or “one of ordinary skill in the art”) at the time of the filing date of the ’743 patent.¹

34. I am a medical professional by training and profession. The opinions I express in this declaration involve the application of my technical knowledge and experience to the evaluation of certain prior art with respect to the ’743 patent. In addition, I understand that the following legal principles apply.

35. It is my understanding that, in determining whether claims of the ’743 patent are anticipated or obvious in this proceeding, the claim terms are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the relevant art. A person of ordinary skill in the art would read the claim terms in the context of the entire patent specification in which they appear, as well as the prosecution history of the patent.

36. It is my understanding that a claim is anticipated under 35 U.S.C. § 102 if each and every element and limitation of the claim is found, either expressly or inherently, in a single prior art reference. I also understand that a reference must disclose all claimed elements as arranged in the claim, although identical terminology need not be used in the reference and claim elements.

¹ When I use the term person of skill, POSITA or variants thereof herein, I am referring to people of skill at the time of the purported invention of the ’743 patent.

37. It is my understanding that a claim is unpatentable under 35 U.S.C. § 103 if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. I also understand that an obviousness analysis takes into account the scope and content of the prior art, the differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

38. In determining the scope and content of the prior art, it is my understanding that a reference is considered relevant prior art if it falls within the field of the inventor's endeavor. In addition, a reference is prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor's attention in considering his problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

39. To assess the differences between prior art and the claimed subject matter, it is my understanding that 35 U.S.C. § 103 requires the claimed invention to be considered as a whole. This "as a whole" assessment involves showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would

have selected the elements from the prior art and combined them in the claimed manner.

40. It is my further understanding that several rationales may be applied for combining references or modifying a reference to show obviousness of claimed subject matter. These rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known device (method or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify a prior art reference or to combine prior art teachings to arrive at the claimed invention.

41. I understand that during an *inter partes* review, claim terms are interpreted based on the *Philips* claim construction standard.

IV. Person of Ordinary Skill in the Art

42. It is my understanding that when interpreting the claims of the '743 patent I must do so based on the perspective of one of ordinary skill in the art at the relevant priority date. My understanding is that the earliest claimed priority date of the '743 patent is September 25, 2013.

43. It is my opinion that one of ordinary skill in the art in the field of electrocardiographic patches, in 2013, and more generally in the 1998-2013 time period, would have had a bachelor's degree in cardiovascular medicine, electrophysiology, internal medicine, electrical engineering or an equivalent degree, and two to three years of clinical experience in the field of biomedical engineering. Alternatively, a POSITA of the technology described in the '743 patent in 2013, and more generally in the 1998-2013 time period, would have had two or more years of medical work with knowledge of the electronic design and operation of cardiac monitoring technologies.

44. I am a person of at least ordinary skill in the art and was so at the time of the purported invention of the '743 patent.

V. The Subject Patent US 11,051,743 ('743 Patent)

45. The '743 patent is titled Electrocardiography Patch. It was filed December 11, 2020, and claims priority to a provisional application, filed September 25, 2013.

A. Overview

i. Field of Art

46. The stated field of art is "electrocardiographic monitoring and in, in particular, ... an electrocardiography patch". Ex. 1001, 1:21-23.

**ii. Background – Description of the Prior Art and
Admitted Prior Art**

47. As described above in Section II, by the September 2013 priority date, the field of electrocardiography monitoring was well-established. It was built upon the understanding of well-known physiological monitoring techniques and the integration of common consumer electronics technology components. It was a crowded art where concepts used in the field were well understood and predictable, with features regularly mixed and matched as needed to achieve a person of ordinary skill's design goals.

48. The '743 patent confirms several of these well understood and predictable features.

49. For example, the '743 patent acknowledges that “[a]n electrocardiogram (“ECG”) measures and records such electrical potentials to visually depict the electrical activity of the heart over time.” Ex. 1001, 1:29-31.

50. The '743 patent assumes a POSITA understands basic biomedical principles. For example, an electrocardiogram (ECG) measures and records electrical signals from the heart to diagnose heart problems and other potential health concerns. *Id.*, 1:29-31, 43-44. An ECG machine includes electrodes placed on the patient's skin to sense cardiac electrical activity. *Id.*, 1:34-42.

51. The '743 patent further explains that a typical ECG is recorded over 12 seconds and, therefore, only provides a partial picture, which could be insufficient to completely diagnose many cardiac disorders. *Id.*, 1:44-59. Diagnostic efficacy can be improved through the use of long-term extended ECG monitoring. *Id.*, 1:44-49, 60-61. For example, the patent describes prior art Holter monitors, which allow for extended monitoring of 24-48 hours or more. *Id.*, 2:36-57. The patent, however, criticizes these devices as cumbersome, expensive, and only able to provide limited recording. *Id.*

52. The '743 patent further describes the prior art “ZIO XT Patch” and the “ZIO Event Card,” which can meet the recognized “gold standard” of a 30-day observation period. *Id.*, 2:58-3:18, 1:65-2:2. The '743 patent explains that the ZIO XT Patch “combines both electronic recordation components, including battery, and physical electrode into a unitary assembly that adheres to the patient’s skin.” *Id.*, 2:67-3:8. The '743 patent lodges general criticisms against the ZIO XT Patch, suggesting its battery capacity is lacking and its electronics are not waterproof. *Id.*, 3:8-15. But improvements of these deficiencies are not claimed in the '743 patent. The '743 patent further recognizes that many prior art consumer devices enable users to record physiological information and that the concept is so well-known that it had been established as the “quantified self” movement. *Id.*, 3:19-35.

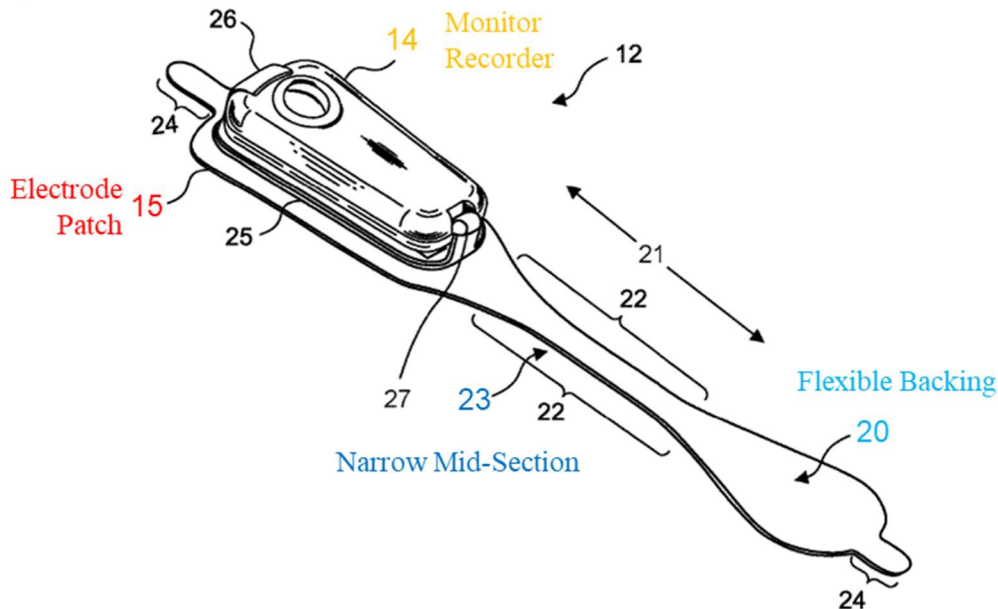
iii. Problem statement

53. In view of the above principles, the '743 patent asserts “a need remains for an extended wear continuously recording ECG monitor practically capable of being worn for a long period of time in both men and women and capable of recording atrial signals reliably.” *Id.*, 3:36-39. As well as a need “to integrate wider-ranging physiological and ‘life tracking’-type data into long-term ECG and physiological data monitoring.” *Id.*, 3:40-42.

iv. Summary of the '743 Patent Disclosure

54. The '743 patent describes an enhanced ECG monitoring patch comprising two primary components: a flexible extended wear electrode patch and a removable reusable monitor recorder. *Id.*, 3:45-49. Fig. 4 (below) shows the extended wear ECG sensor monitor 12 including a monitor recorder 14 and an electrode patch 15. *Id.*, Fig. 4; 5:44-61.

Fig. 4.



55. The wearable monitor comprises a narrow longitudinal mid-section 23 purportedly to benefit the long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. *Id.*, 3:51-56. Instead, the patient is free to place an electrode patch anywhere within the general region of the sternum, which puts the ECG electrodes of the electrode patch 15 in a location better adapted to sensing and recording signals from the heart compared to other placement locations (*e.g.*, the upper left pectoral region, lateral thoracic region, or limb leads). *Id.*, 6:1-15. In other words, it is the placement of the wearable monitor 12 in a location at the sternal midline that benefits long-term extended wear by removing the requirement that

ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. *Id.*, 9:35-42.

56. The electrode patch 15 is constructed using a flexible backing 20 formed as an elongated strip 21 and also includes a removable battery compartment 36 to address battery life issues. *Id.*, 9:55-10:10. And the electrode patch 15 is intended to be disposable such that each time the electrode patch 15 is replaced, a fresh battery is provided for the use of the monitor recorder 14, which enhances ECG monitoring performance quality and duration of use. *Id.*, 13:5-16.

57. To address the insufficient memory issues of prior art systems, the '743 patent describes compressing the monitored data prior to storage in flash memory 62 as long as storage space remains available. *Id.*, 14:31-66. Notably, consistent with the fact that it merely describes routine computer operation, the '743 patent merely states the data is "compressed" with no specificity of how the compression is done. Subsequently, the monitored physiological data is wirelessly offloaded to a remote server for further processing. *Id.*, 15:2-29.

v. The '743 Patent Claim Elements

58. Claim 1 of the '743 patent is set forth below with the elements labeled for reference:

Element Designation	Element
[1-PRE]	An electrocardiography patch, comprising:
[1-A]	a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing;
[1-B]	an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals;
[1-C]	a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes; and
[1-D]	a wireless transceiver to communicate at least a portion of the electrocardiographic signals.

59. Claim 11 of the '743 patent is set forth below with the elements labeled for reference:

Element Designation	Element
[11-PRE]	An electrocardiography patch, comprising:
[11-A]	a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing;
[11-B]	an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals;
[1-C]	a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes;

[11-D]	a wireless transceiver to communicate at least a portion of the electrocardiographic signals;
[11-E]	a battery on one of the ends of the backing;
[11-F]	a processor powered by the battery; and
[11-G]	memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals.

B. Claimed Components

60. The '743 patent specification describes functionality that is standard practice and well known in the art. This includes the basic structure and operation of electrocardiography monitoring patches, and implementations of physical monitoring systems.

61. For example, backings are basically a universal feature of electrocardiography patches as they form the basic patch structure. *See, e.g.*, Ex. 1013 (Shennib), Paras. [0035] (disclosing that its programmable sensor patch 10 comprises a thin substrate 28 made of soft flexible sheath material to provide extremely low profile unobtrusive wear); Ex. 1014 (Tarler), col. 3:31-55 (disclosing its electrode patch for sensing physiological signal “comprising a base having an upper and lower surface”); Ex. 1015 (Chloe), col. 3:45-4:47 (disclosing its EKG patch comprising “a base layer that has a base surface that makes contact with the skin of the patient”). Moreover, patches that narrow in the middle is a common

feature, as they are more flexible and comfortable. *See, e.g.*, Ex. 1013 (Shennib), Para. [0030], Figs. 1, 3; Ex. 1014 (Tarler), Fig. 2; Ex. 1015 (Chloe), Figs. 2A-B.

62. At least two spaced apart electrocardiographic electrodes are a necessary component of an electrocardiograph and appear in all such devices. *See, e.g.*, Ex. 1013 (Shennib), Para. [0037] (disclosing that its programmable sensor patch 10 includes a two-electrode embodiment for sensing the surface ECG); Ex. 1014 (Tarler), col. 3:40-55 (disclosing its electrode patch for sensing physiological signal comprises at least two electrodes); Ex. 1015 (Chloe), col. 3:45-4:47 (disclosing its EKG patch comprising a plurality of electrodes). Similarly, circuit traces from each of the electrodes is also a basic necessity to collect the electrocardiograph signals. *See, e.g.*, Ex. 1013 (Shennib), Para. [0034] (disclosing that its programmable sensor patch 10 includes a flexible circuit substrate 20 with trace extensions to its respective electrodes and to the battery); Ex. 1014 (Tarler), col. 3:40-55 (disclosing its electrode patch comprises at least two electrical pathways connecting to the at least two electrodes to one or more electronic components for receiving the physiological signal); Ex. 1015 (Chloe), col. 5:37-61 (each electrode individually connected to a monitor via lead wires). And implementing these with flexible circuitry was a common approach. *See, e.g.*, Ex. 1013 (Shennib), Paras. [0034]-[0035]; Ex. 1014 (Tarler), col. 6:25-31; Ex. 1015 (Chloe), col. 8:21-22.

63. The further components of a processor, memory, battery and wireless transceiver are common electronics components for wireless patches and other personal electronics devices. *See, e.g.*, Ex. 1013 (Shennib), Paras. [0011], [0033]-[0034] (disclosing that its programmable sensor patch 10 comprises a processor 33, a memory 34, a battery 35, an RF wireless antenna 49 and receiver circuit for achieving wireless communications and to overcome prior art remote monitoring patches that have relatively short term battery life); Ex. 1014 (Tarler), col. 7:27-8:28, 18:1-6.

64. The additional features added by the dependent claims are also completely standard and common additions to these sorts of devices, *e.g.*, accelerometers, temperature sensors, step trackers, hydrocolloid adhesives, communications with computers, rounded edges, etc. *See, e.g.*, Ex. 1008 (Besson), 5:16-22, 11:51-12:64, 23:14-16; Ex. 1013 (Shennib), Paras. [0035] (disclosing that its programmable sensor patch 10 is adhered using a non-conductive adhesive (*i.e.*, Hydrogel)), [0036] (providing the waterproof non-conductive adhesive at the perimeter of the patch to prevent water entry and provide long-term adhesion to the skin); Ex. 1014 (Tarler), col. 11:53-12:32; Ex. 1015 (Chloe), col. 4:20-23 (disclosing its EKG patch comprising a hydrogel).

VI. Prosecution History of the '743 Patent

65. I have reviewed the file history of U.S. Patent Application No. 17/119,945, from which the '743 patent issued.

66. U.S. Patent Application No. 17/119,945, was filed on December 11, 2020, and ultimately claims priority to a September 25, 2013, Provisional Application (No. 61/882,403). Facing no substantive prior art rejections over any cited references, the '743 patent was allowed after a single-office action, which merely rejected the pending claims based on the judicially created non-statutory double patenting based on commonly-owned, parent U.S. Patent No. 10,888,239. Ex. 1007, pp. 175-180 (January 25, 2021, Office Action).

67. Although the Examiner made no use of any other prior art of record, the Examiner noted that compared to the commonly-owned, parent U.S. Patent No. 10,888,239 (the basis of the non-statutory double patenting rejection), the claims were not patentably distinct because “[t]he skilled artisan would recognize narrowing a mid-section between the two ends of a backing obviously reduces weight by eliminating unnecessary material.” Ex. 1007, p. 178 (January 25, 2021, Office Action). Likewise, the Examiner concluded that it was similarly “obvious to provide an accelerometer to measure movement and a hydrocolloid adhesive to attach the device to a patient.” *Id.* The Patent Owner did not rebut these assertions. *Id.*

68. My review of the subject '743 patent is based on the patent as issued.

VII. Summary of Prior Art

A. Mazar

69. WO 2010/104952 to Mazar (hereinafter “Mazar”) is an international PCT application that published on September 16, 2010, which was filed on March 10, 2010, claiming priority to a March 10, 2009, U.S. Provisional Patent Application.

70. Mazar discloses a patient health monitoring device, in the form of a patch, and describes the collection and transmission of data from the device. Ex. 1003, ¶¶ [0006]-[0007], [0051]. Like the '743 patent, Mazar criticizes prior art monitoring devices to be bulky and uncomfortable to use. *Id.*, ¶¶ [0002]-[0005]. Specifically, Mazar recognized that, in order to ensure consistent, comfortable health monitoring of patients, it was well-known to: (1) use a comfortable, adherent patch device; (2) that was capable of wirelessly outputting patient data. *Id.*, ¶¶ [0002]-[0005]. Mazar's patch monitoring device, shown below, provides solutions to these issues.

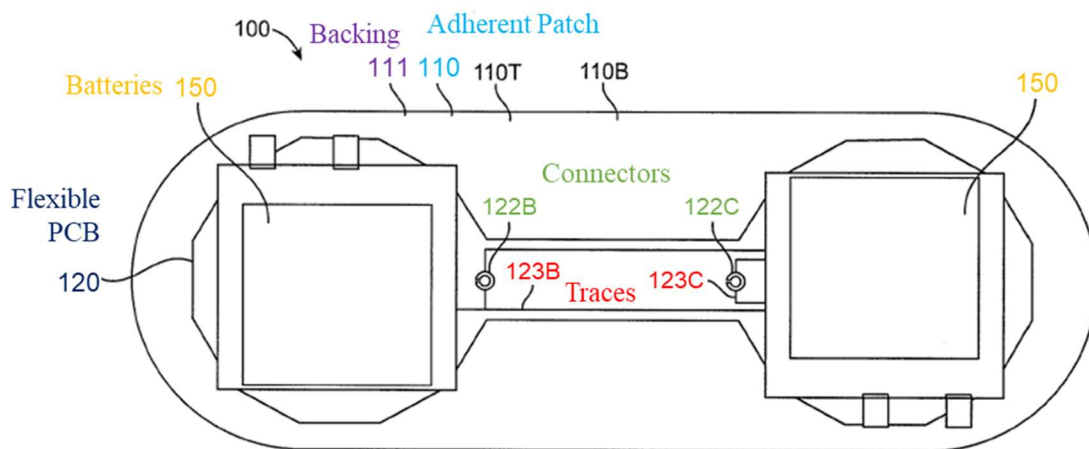
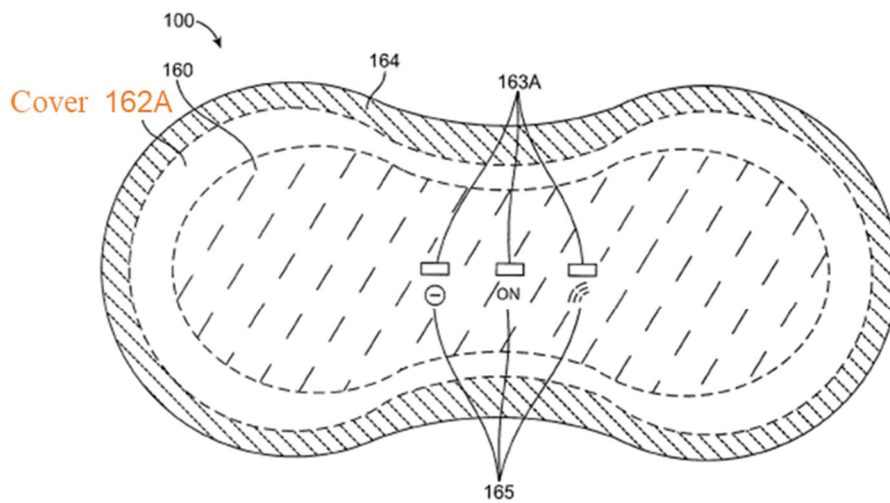
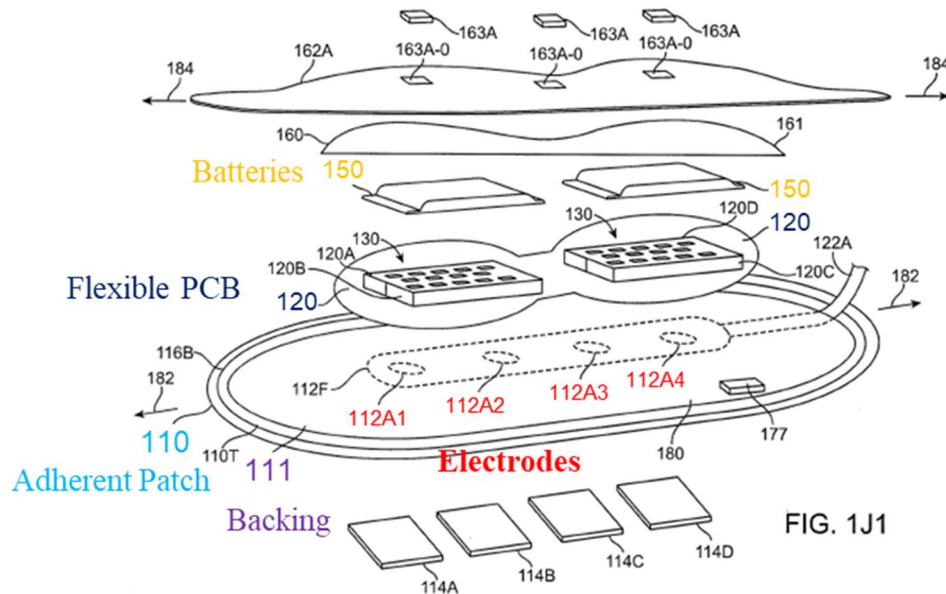


FIG. 1E



(Top View)



71. As shown, the adherent device (100) is a patch used for physiological monitoring, including the measuring the electrocardiogram (ECG) of a patient. *Id.* at ¶¶ [0002], [0098]. The electrodes (112A1, 112A2, 112A3, and 112A4) are affixed to the patch (110) enabling the capture electrocardiographic signals of the patient. *Id.* at ¶ [0098]. Mazar discloses that the patch (110) has a backing (111) that comprises an hourglass shape that is narrower in the middle. *Id.* at ¶¶ [0093], [0127]; see also Fig. 1F1.

72. *Mazar* also teaches that electronics components (130) and communications circuitry (132) facilitates wireless communication of physiological data, including an electrocardiogram signal. *Id.* at ¶ [0104]-[0105]. *Mazar* also discloses the use of circuit traces to electrically couple the electrocardiographic electrodes. *Id.* at ¶ [0100]; *see also* Fig. 1D.

73. *Mazar* further teaches that inclusion of a battery, processor, and use of memory for the storing of physiological signals. *Id.* at ¶¶ [0033], [0048], [0094]-[0095], [0104], [0167].

B. Oster

74. US2011/0077497 to Oster (hereinafter “Oster”) is a United States Patent Application Publication that published on March 31, 2011, which was filed on April 29, 2009, claiming priority to a May 1, 2008, U.S. Provisional Patent Application.

75. Oster similarly discloses a biomedical sensor system where multiple sensors on a patch include electrodes for ECG monitoring and diagnostics. Ex. 1004, ¶[0021]. In addition, the biomedical sensor system is disclosed as being employed in telemetry and remote monitoring by transmitting data from the sensor coupled to a subject to a receiver for further data processing. *Id.*, ¶[0022].

76. Figs. 1 and 2 illustrate the biomedical sensor system 100. *Id.*, Figs. 1, 2.

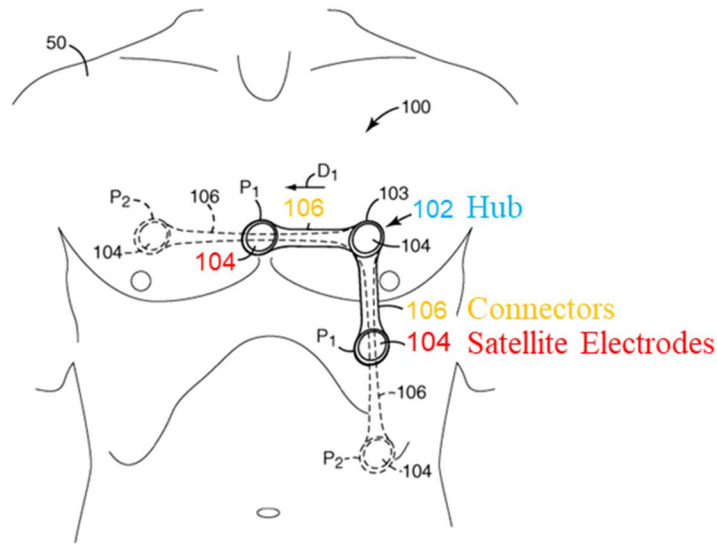


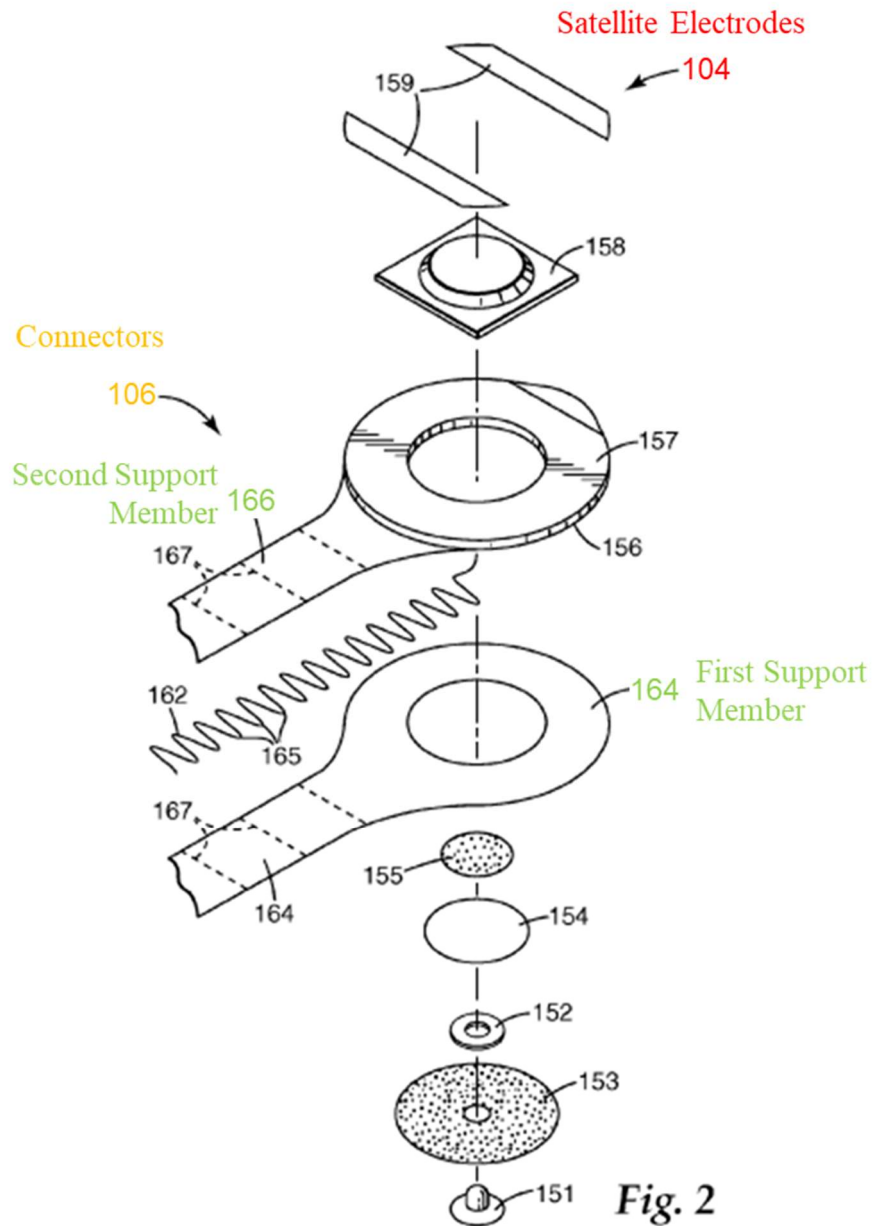
Fig. 1

77. Fig. 1 (shown above) illustrates the biomedical sensor system 100 in a first, unstretched, state, and a second, stretched state, relative to a subject 50. *Id.*, ¶[0030]. Fig. 1 also shows the sensor system 100 including a hub 102, two satellite electrodes 104, and two connectors 106 positioned to couple each satellite electrode 104 to the hub 102. *Id.*, ¶[0031]. The connectors 106 provide a pathway between the electrodes 104 (or other sensors) and the hub 102 for one or more signals that are communicated therebetween. *Id.*

78. The hub 102 provides a single connection site for the biomedical sensor system 100 for downstream computing, signal processing, displaying, or archiving. *Id.*, ¶[0032]. The hub 102 is either hard-wired to downstream equipment or configured to wirelessly communicate with downstream computing, processing,

displaying and/or archiving equipment. *Id.* The hub 102 includes memory 116 to at least temporarily store information relative to the signals received from the electrodes 104 prior to transmitting (*e.g.*, via a wired connection or the wireless transmitter 108) to downstream computers. *Id.*, ¶[0040].

79. With reference to Fig. 2 (shown below), each electrode 104 includes one or more of a surface electrode (*e.g.*, disposable), a suction electrode, a floating metal body-surface electrode, a dry electrode, or a combination thereof. *Id.*, ¶[0043]. *Oster* also confirms that a variety of lead configurations for capturing an ECG are well known in the art (*e.g.*, 3-lead, 5-lead, 12-lead) based on the number of electrodes to be used with the subject. *Id.*, ¶[0029].



80. An adhesive couples the electrodes 104 (and/or the hub 102) to the subject's skin. *Id.*, ¶[0062]. In such embodiments, the adhesive is coupled (*e.g.*, directly or indirectly) to at least a portion of the connector 106, such as one or more

of the support members 164, 166, which in turn functions as the “backing” to the stretch release adhesive. *Id.*, ¶[0062]. As a result, the connector 106 (*e.g.*, one or more of the support members 164, 166) includes one or more stretchable layers that can be stretched to a point that causes debonding of the adhesive. *Id.*, ¶[0062].

81. The biomedical sensor system 100 is size-configurable and conformable to the subject 50, at least partially because of the variable-length connectors 106. *Id.*, ¶[0051]. In other words, the connector 106 is partially formed of a viscoelastic material, such that by applying force to the connector 106 substantially along the length of the connector 106 (*e.g.*, substantially oriented in the first direction D₁), the connector 106 can be elongated. *Id.*, ¶[0051]. By way of example, the connector 106 is illustrated in Fig. 2 as comprising a wire conductor 162 (*e.g.*, a copper wire) positioned between a first support member 164, and a second support member 166 to provide an electrical communication pathway between the hub 102 and the electrode 104. *Id.*, ¶[0057].

C. Yang

82. US 11,116,447 to Yang (hereinafter “*Yang*”) is a U.S. patent filed on March 7, 2016, which issued on September 14, 2021, and claimed priority to a May 24, 2012, U.S. patent application. I also understand that *Yang* is a prior art patent assigned to Petitioner.

83. *Yang* discloses a modular wearable sensor device in a “patch” form that is attached to the user for health monitoring. Ex. 1005, 1:42-52, 2:35-50. Claiming priority over a year before the ’743 priority date, *Yang* also recognized that conventional wireless sensor devices for health monitoring are subject to repeated use and high wear and tear and must be replaced regularly for routine health monitoring. *Id.*, 1:18-31. *Yang*, therefore, proposed a wireless sensor device that comprises a reusable module and a disposable module that each decouple from each other for ease of replacement (of the disposable portion). *Id.*, 2:35-40.

84. Fig. 1 illustrates the modular wearable sensor 100 that looks like a band-aid and adheres to the user’s body. *Id.*, 2:50-57; Fig. 1 (shown below).

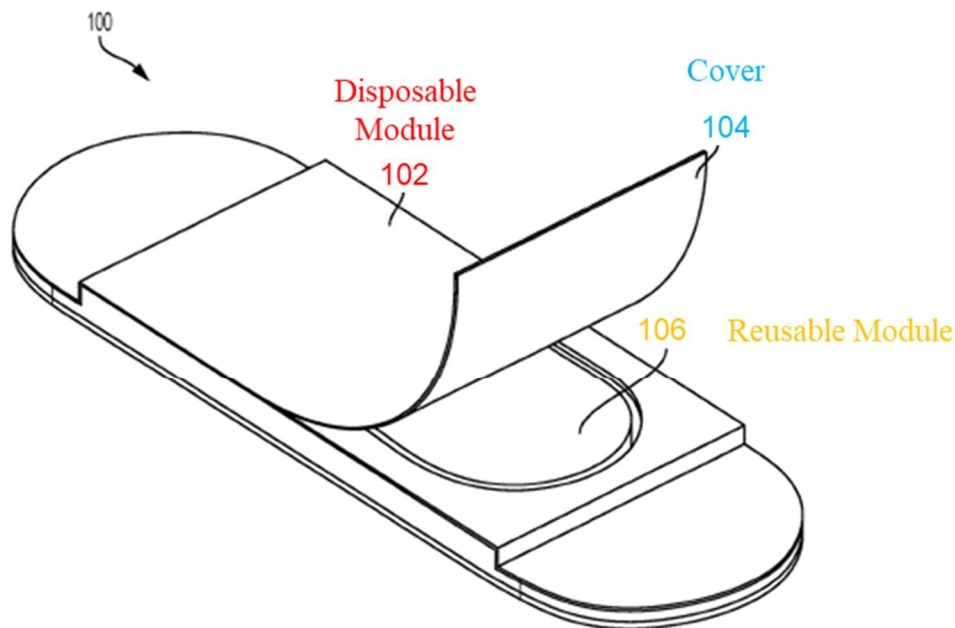


FIG. 1

85. The modular wearable sensor 100 includes a disposable module 102, a flexible cover 104 coupled to the disposable module 102, and a reusable module 106 coupled to the disposable module 102. *Id.*, 2:57-3:2.

86. The disposable module 102 is soft, flexible, and stretchable to provide wear comfort when attached to the body, and can include the cover 104, foam layers, at least one power source (*e.g.*, a coin battery, a button battery, a flexible battery, and an energy harvesting unit), a flexible printed circuit board (PCB) including electrical components such as sensors, electrode contacts to couple electrodes, and adhesive layers. *Id.*, 3:16-28, 41-45.

87. The reusable module 106 houses other reusable electronics including an antenna, a microcontroller, a sensor, and a wireless transceiver. *Id.*, 3:29-39.

88. Fig. 3 illustrates an exploded view of a disposable module 300.

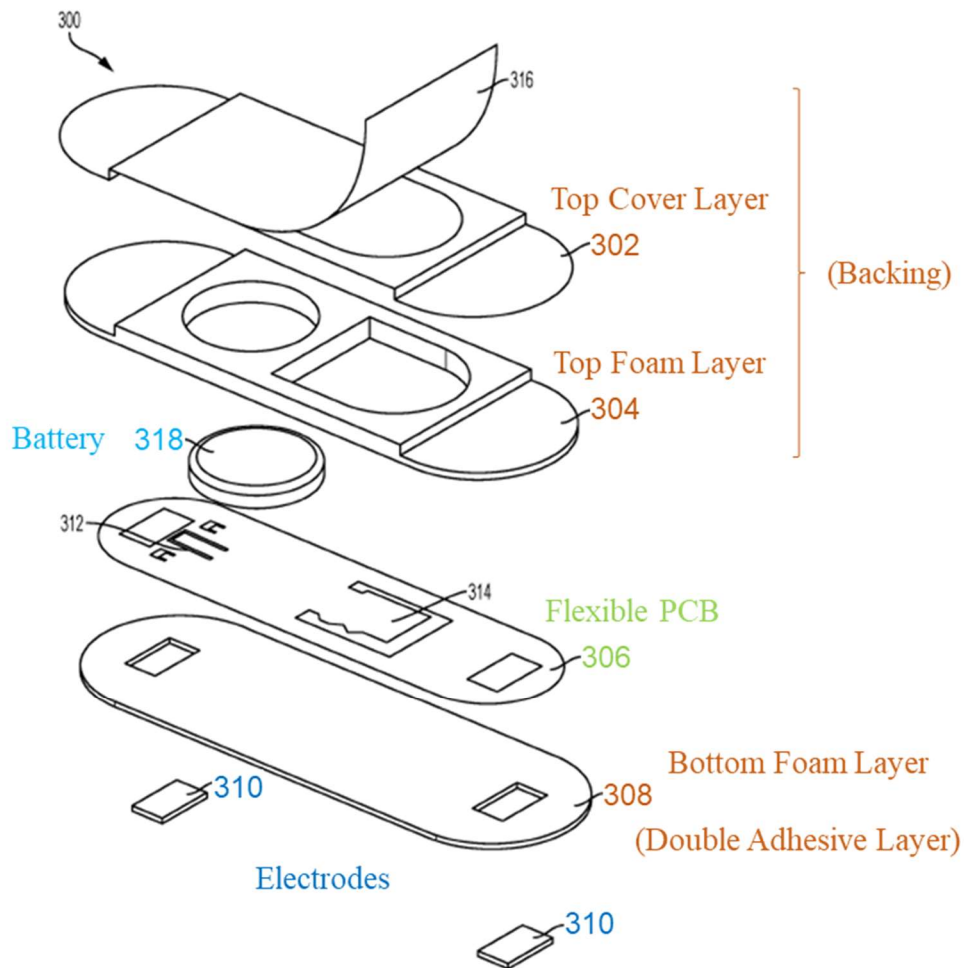


FIG. 3

89. The disposable module 300 includes a top cover layer 302, a top foam layer 304 coupled to the top cover layer 302, a flexible PCB 306 coupled to the top foam layer 304, a bottom foam layer 308 coupled to the flexible PCB 306, and at least two electrodes 310 coupled to the flexible PCB 306. *Id.*, 3:63-4:2. The flexible PCB 306 enables the disposable module 300 to conform and adhere to a user's movements. *Id.*, 3:2-4.

90. The bottom foam layer 310 can be a double-adhesive layer to adhere to the flexible PCB 306 and to a user at the same time. *Id.*, 3:9-11.

VIII. Motivation to Combine Mazar and Yang

91. A POSITA would have found it obvious to combine the systems and methods of *Mazar* and *Yang*.

92. *Mazar* and *Yang* are both patches for solving the same problem of wireless patient monitoring. Due to their similarity, a POSITA would have freely selected among the various features of *Mazar* and *Yang* and combined them to provide whatever mix of features most suited the POSITA's design objectives, such as providing additional cost-effective features of for comfort. In other words, a POSITA would have readily implemented features of one reference in another to use the advantages of that feature, based on a common sense analysis of the pros and cons of the feature.

93. Each of *Mazar* and *Yang* address problems of conventional at-home patient monitoring patches that each references with an eye towards improving, among other things, comfort and/or durability. Ex. 1003 (*Mazar*), ¶ [0007]; Ex. 1005 (*Yang*), 1:18-32. Each reference proceeds to then detail the benefits of its cost-effective adhesive patch, particularly in the context of health monitoring and, even more specifically, for measuring electrocardiography. Ex. 1003 (*Mazar*), ¶ [0026]; Ex. 1005 (*Yang*), 1:22-25.

94. In fact, a POSITA would recognize that *Yang* discloses a simple structure that is more cost-effective and easier to create than the multi-component system of *Mazar*, for example. Therefore, just as the Examiner asserted during prosecution of the '743 patent, a skilled artisan would recognize that minimizing additional components of *Mazar*, such as taught by *Yang*, can reduce weight by eliminating unnecessary material. Additionally, a skilled artisan would recognize that a reduction of the backing's size (*i.e.*, footprint), such as taught by *Mazar's* disclosure of the use of an hourglass shape, is beneficial for the patient's comfort and to reduce patient skin irritation.

95. Furthermore, *Yang* discloses that a POSITA would be aware of the variety of device types that can be used for the reusable module 106, containing the processor and other electronics, and the disposable module 102, which includes, for example, known batteries and/or adhesives. Ex. 1005 (*Yang*), 3:40-45. *Mazar* confirms these components are well-known and, like *Yang*, details the advantages of the particular arrangement of these components. Ex. 1003 (*Mazar*), *e.g.*, ¶ [0125].

96. Given the fact that these references are both directed to solving the same problem in the same application, a POSITA would recognize that the two systems can be used together to create a compatible. Furthermore, combining the basic well-known features at issue here would not present any impediment and could be achieved through routine design process without the need for undue

experimentation. Indeed, the '743 patent and the references simply describe the features to be included without in-depth discussion regarding how to implement them. This limited disclosure demonstrates that these technologies were routine and required minimal information to provide an enabling disclosure. Of course, the flipside of this is the recognition that POSITAs were well versed in this technology and could readily implement features once identified.

97. Additional motivations to combine *Mazar* and *Yang* will be described with respect to the particular limitations discussed below.

IX. Motivation to Combine Oster and Yang

98. A POSITA would have found it obvious to combine the systems and methods of *Oster* and *Yang*.

99. *Oster* and *Yang* are both patches solving problems of wireless patient monitoring. A POSITA would have been aware of a variety of known wireless sensor devices for remote health monitoring, like each of the biomedical sensor systems disclosed in *Oster* and *Yang*. Due to their similarity, a POSITA would have combined the various features of *Oster* and *Yang* to provide the most suitable mix of features to achieve the POSITA's design objectives, such as providing additional cost-effective features to provide a comfortable, adherent patch device, as highlighted separately by each reference. In other words, a POSITA would have

readily implemented features of one reference in another to use the advantages of that feature, based on a common sense analysis of the pros and cons of the feature.

100. Each of *Oster* and *Yang* recognizes the importance of comfort and durability for a patch intended for regular use. Ex. 1004 (*Oster*), ¶ [0023]; Ex. 1005 (*Yang*), 1:18-32. Each reference details the goals of creating a cost-effective adhesive patch, particularly in the context of health monitoring and, even more specifically, for measuring electrocardiography. Ex. 1004 (*Oster*), ¶¶ [0023]-[0025]; Ex. 1005 (*Yang*), 1:22-25.

101. In fact, a POSITA would recognize that *Yang* discloses a simple structure with the goal of creating a cost-effective biomedical sensor. Ex. 1005 (*Yang*), 1:22-25. Similarly, *Oster* expressly teaches reducing the waste created in manufacturing and constructions of diagnostic patches to enhance safety and subject comfort. Ex. 1004 (*Oster*), ¶¶ [0023]-[0024]. Therefore, a skilled artisan would recognize that minimizing additional components of a biomedical sensor, such as taught by both references, can enhance safety, comfort, and ease of use.

102. Furthermore, *Yang* discloses that a POSITA would be aware of the variety of device types that can be used for the reusable module 106, containing the processor and other electronics, and the disposable module 102, which includes, for example, known sensors for measuring a variety of health related values including ECG and respiratory rates. Ex. 1005 (*Yang*), 4:9-15. *Oster* confirms these

components are well-known and, like *Yang*, details the variety of lead configurations that can be used, for example, for an ECG, such as the arrangement disclosed in the '743 patent. Ex. 1004 (Oster), *e.g.*, ¶ [0029].

103. Given the fact that these references are both directed to solving the same problem in the same application, a POSITA would recognize that the two systems can be used together to create a compatible. Furthermore, combining the basic well-known features at issue here would not present any impediment and could be achieved through routine design process without the need for undue experimentation. Indeed, the '473 patent and the references simply describe the features to be included without in-depth discussion regarding how to implement them. This limited disclosure demonstrates that these technologies were routine and required minimal information to provide an enabling disclosure. Of course, the flipside of this is the recognition that POSITAs were well versed in this technology and could readily implement features once identified.

104. Additional motivations to combine *Oster* and *Yang* will be described with respect to the particular limitations discussed below.

X. Claim Construction

105. IPR claims are construed “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 42 C.F.R. §42.100(b).

A. “a battery on one of the ends of the backing” (Claim 11)

106. In my view, the term “a battery on one of the ends of the backing” as recited in claim 11 should be construed according to its plain and ordinary meaning.

107. However, I also understand that the parties dispute whether the term is merely directed to locating the battery relative to the overall structure of the patch, as the express language of the claim states, or whether the term must be construed to exclude intervening components between the battery and the backing, as Patent Owner has argued in the context of the parties’ co-pending litigation. *See, e.g.*, Ex. 1018. Specifically, I understand that Patent Owner’s counsel argues that the claims distinguish from the prior art Mazar reference because the Mazar publication describes the batteries (150) as ‘separated from’ the backing (111) and ‘positioned over the flex printed circuit board and electrical components.’” *Id.*

108. Therefore, if the term need be construed, I submit that a POSITA would understand the term to mean “a battery on one end of the backing or the other end of the backing” and that this term does not require the battery to be affixed to the backing with no intervening components.

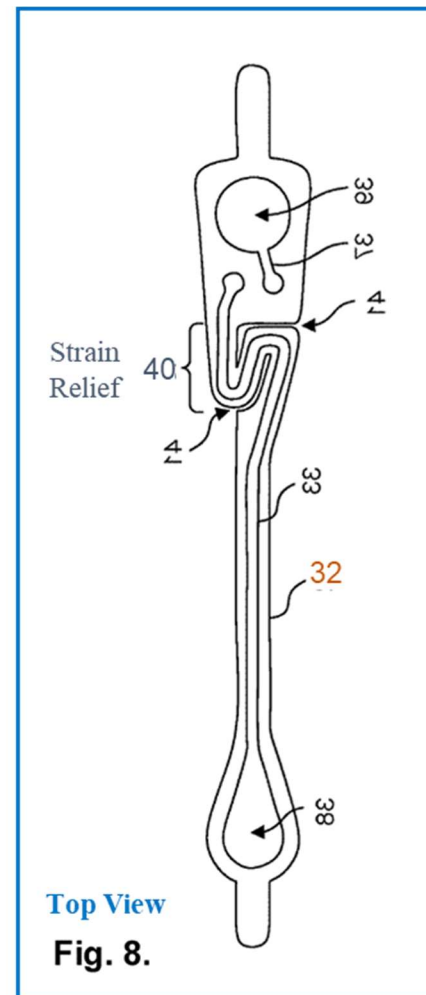
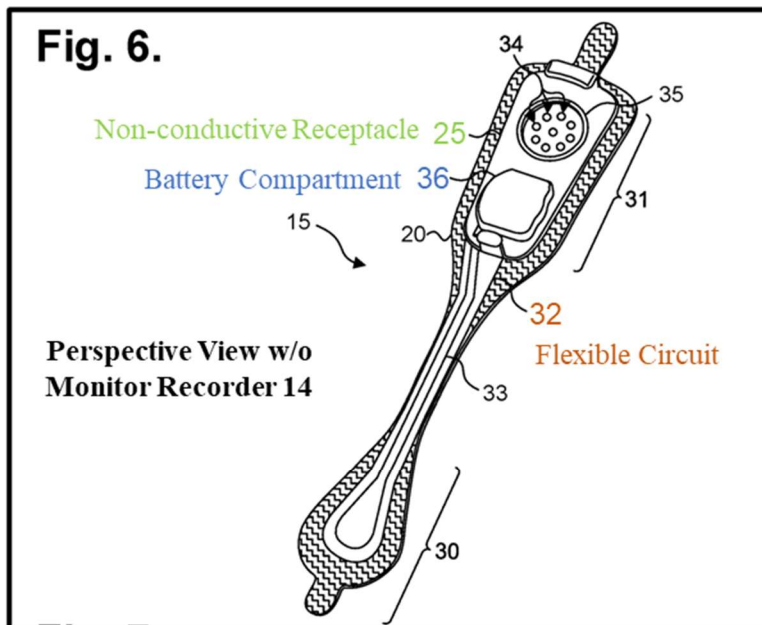
109. Contrary to Patent Owner's arguments, the claim language is plainly directed to the general positioning of the battery on the body of the patch. Specifically, the claim phrase does not say a battery on the backing, it says "a battery on *one of the ends* of the backing." This shows that "on" is governing the positioning of the battery relative to *the ends* of the backing, *i.e.*, the battery is placed on one end or the other. This is consistent with the overall context of the claim in which "the ends" are claimed as "a backing comprising an elongated strip with a midsection connecting two *ends of the backing*." This language orients "the ends" relative to the elongate shape of the patch. And the battery limitation places the battery on one end of the patch or the other, *i.e.*, not in the middle.

110. Patent Owner's assertion that "on" requires direct contact between the backing and the battery is inconsistent with the intrinsic and extrinsic evidence.

111. The plain and ordinary meaning of "on" does not require direct contact for one object to be "on" another. For instance, a coat may be said to be hanging "on" a coat rack even if it is hanging directly "on" a hanger, which is in turn hanging on the rack. Similarly, a book is "on" a table even if it sits on top of a stack of books, rather than directly contacting the surface of the table.

112. Consistent with this plain meaning, the intrinsic record supports Petitioner's construction because it does not disclose a battery in direct contact with a backing. The '743 patent describes its battery compartment 36 as formed on the

bottom surface of the non-conductive receptacle 25. Ex. 1001, 10:5-6, Figs. 6, 8 (each reproduced below). This non-conductive receptacle is mounted to the flexible circuit 32, which is, in turn, mounted on the backing. Ex. 1001, 10:20-29.



113. The '743 patent also confirms that “[a] strain relief 40 is defined in the flexible circuit 32 at a location that is partially underneath the battery compartment 36 when the flexible circuit 32 is affixed to the flexible backing 20.” *Id.*, 10:55-58.

In other words, even the '743 patent describes intervening components between the backing and the battery, specifically, the battery compartment 36 and the flexible circuit 32. Notably, there are no embodiments in the '743 patent where the battery is directly on the backing with no intervening components. Thus, the specification does not support Patent Owner's narrow construction and mandates Petitioner's proposed construction.

114. Accordingly, the claimed relationship of the battery being "on" one of the ends of the backing need not be defined as some integral touching. Petitioner's construction accurately captures this relationship.

XI. Overlap Among Independent Claims 1 and 11

115. There is significant of overlap in the limitations of all challenged independent claims 1 and 11 of the '743 patent.

116. Claim 11 is an independent claim that differs from Claim 1 as shown in the comparison below.

An electrocardiography patch , comprising: a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing; an electrocardiographic electrode on	An electrocardiography monitor , comprising: a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing; an electrocardiographic electrode on
--	--

each end of the backing to capture electrocardiographic signals; a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes; and a wireless transceiver to communicate at least a portion of the electrocardiographic signals.	each end of the backing to capture electrocardiographic signals; a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes; a wireless transceiver to communicate at least a portion of the electrocardiographic signals; <u>a battery on one of the ends of the backing;</u> <u>a processor powered by the battery;</u> <u>and</u> <u>memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals.</u>
--	--

117. Apart from the preamble, Claim 11 contains the same limitations as Claim 1 but adds a few features that were common to remote monitoring patches. In any case, it is my opinion that the preambles are non-limiting and serve only to provide the context for the application of the claimed system. Even if found to be limiting, I discuss below how the prior art teaches even these minor distinctions.

XII. Ground I – Claims 1-20 are Anticipated or Rendered Obvious under 35 U.S.C. § 102 or 35 U.S.C. § 103 by Mazar in Combination with Yang

A. Independent Claim 1

118. In my opinion, claim 1 of the '743 patent is rendered obvious by *Mazar* in combination with *Yang*. In the discussion of claim 1 that follows, I explain the correspondence between the disclosure of *Mazar* and *Yang* for each limitation of claim 1.

119. A POSITA would have found it obvious to predictably combine *Mazar's* adherent patch device with the teachings of *Yang* to achieve the particular design objectives in *Mazar's* system, as explained in Section VIII above.

i. Element [1-PRE]

120. The preamble of claim 1 recites:

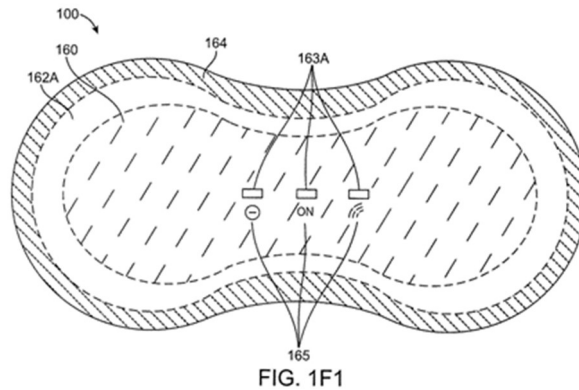
An electrocardiography patch, comprising:

121. *Mazar* discloses an adherent patch device capable of physiological monitoring patients, including measuring the electrocardiogram (ECG), for extended periods. Ex. 1003, ¶¶ [0002], [0098]; see also Fig. 1F1.

“The present invention relates to patient monitoring. Although embodiments make specific reference to monitoring patients with **an adherent patch device**, the system methods and device described herein may be applicable to many applications in which physiological monitoring is used, for example wireless physiological monitoring with devices for extended periods.”
Mazar at ¶ [0002].

“In some embodiments **the patch comprises two electrodes, for example two electrodes to measure the electrocardiogram (ECG) of the patient.**”

Mazar at ¶ [0098].



Mazar, Fig. 1F1.

122. Demonstrating the compatibility of their teachings, Yang also discloses an adherent patch device capable of physiological monitoring patients, including measuring the electrocardiogram (ECG), for extended periods. Ex. 1005, 1:42-52, 2:35-50.

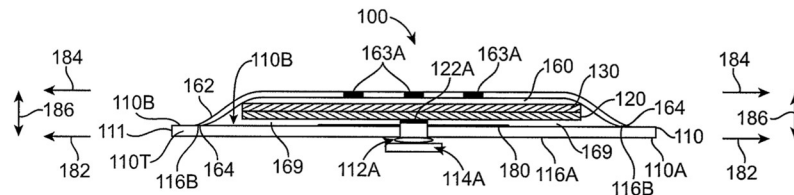
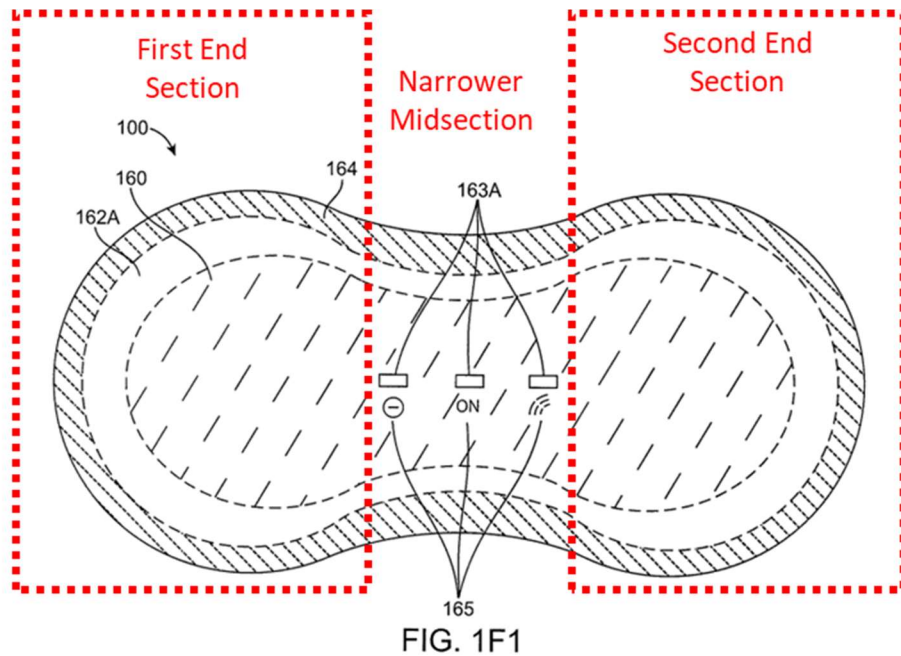
ii. Element [1-A]

123. The 1st limitation of claim 1 recites:

a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the mid-section is narrower than the two ends of the backing.

124. *Mazar* discloses “a backing comprising an elongated strip with a mid-section connecting two ends of the backing.” And *Mazar* further discloses an

elongated patch having a “mid-section [that] is narrower than the two ends of the backing.” Mazar teaches that its adherent device 100 includes an adherent patch 110, which includes a backing material, or backing 111, such as fabric configured to provide properties of patch 110. Ex. 1003, ¶¶ [0098], [0127]. Fig. 1F1 (below), for example, further shows that the adherent patch and its backing comprising an hourglass shape with two ends joined by a narrower midsection. *See, id.* ¶[0093]. Furthermore, while Fig. 1F1 shows a top view, the cross-section of Fig. 1I1 shows that backing 111 extends to the full width of top layer 164. Thus, a POSITA would understand that Mazar discloses an elongated strip with a mid-section that connects and is narrower than two ends of the backing.



125. Moreover, the patent examiner correctly recognized that a narrowed mid-section is obvious because “[t]he skilled artisan would recognize narrowing a mid-section between the two ends of a backing obviously reduces weight by eliminating unnecessary material.” Ex. 1007, ## (January 25, 2021, Office Action). Thus, it would similarly be obvious to a POSITA to use a narrowing in a patch combining the teachings of *Mazar* and *Yang* for that reason. *Mazar* also discloses a backing that is an elongated strip. A POSITA would view an elongated strip design

as a “standard of care” and common sense. Most clinically used monitors have an elongated strip design—even implantable recorders are elongated in shape. This is because in addition to the reduction of weight and the elimination of unnecessary material, reducing excess material will increase patient comfort by reducing the area covered by the patch and allowing patch to twist more easily and therefore conform to the movement of the patient.

126. A POSITA would further understand that Yang discloses a backing comprising an elongated strip with two ends. Ex. 1005, 3:63-4:2, Fig. 3 (reproduced below).

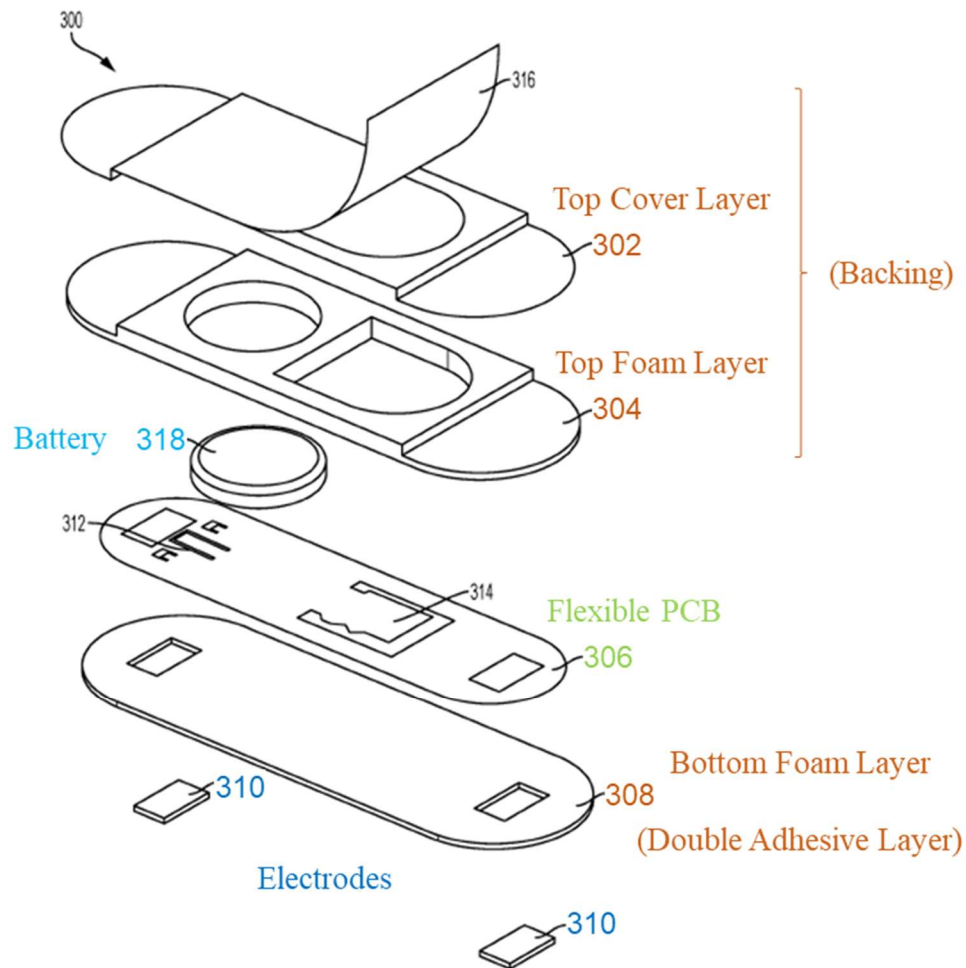


FIG. 3

The fact that both *Mazar* and *Yang* relate to patches shaped as elongated strips further demonstrates their compatibility. *Mazar* further shows patch backings with and without narrowing, further showing the compatibility of the two designs.

iii. Element [1-B]

127. The 2nd limitation of claim 1 recites:

an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals.

128. Mazar expressly teaches that the patch comprises two electrodes to measure the ECG of the patient. Ex. 1003, ¶ [0098]; Fig. 1B. As shown, for example, in Fig. 1B, at least two electrodes (e.g., 112A and 112D) are positioned on each end of the backing of the adherent patch:

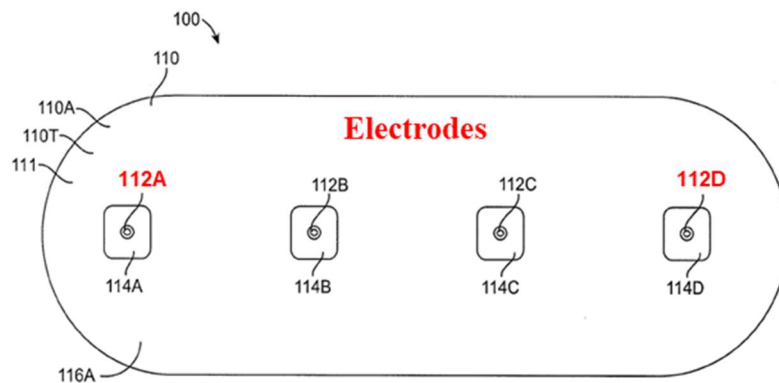


FIG. 1B

129. A POSITA would understand that at least Mazar discloses this element and that it would be obvious to employ electrodes on each end of the backing in its various embodiments.

130. Further, demonstrating the fact that the number of electrodes can be varied to achieve trade-offs between complexity, cost and functionality, Yang discloses an embodiment with just two electrodes 310 positioned only on each end of the backing of the adherent patch (e.g., the top foam layer 304 coupled to the top

cover layer 302 via the flexible PCB 306). Ex. 1005, 3:2-4, 63-4:2, Fig. 3 (reproduced below). Placing two electrodes on opposite ends of the backings optimizes the spread of the electrodes, while minimizing the cost and complexity that would arise from adding more than two electrodes.

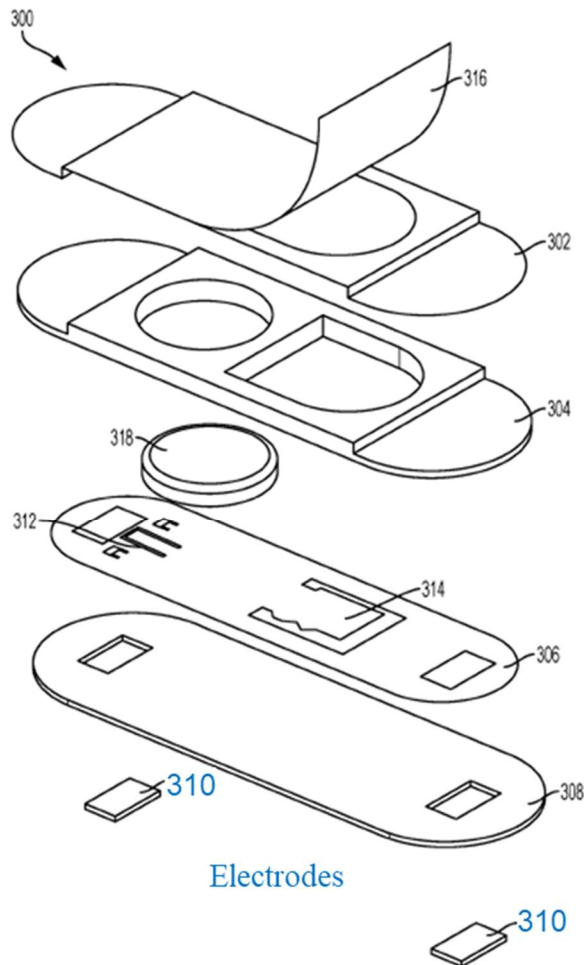


FIG. 3

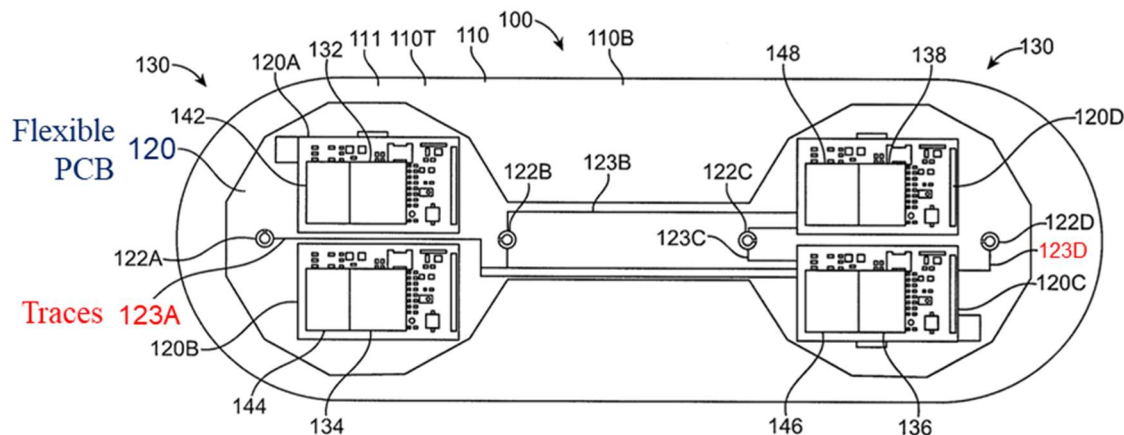
131. A skilled artisan would view an electrocardiographic electrode on each end of the backing as a “standard of care.” Thus, a POSITA would understand that Mazar and Yang, either alone or in combination, discloses this element.

iv. Element [1-C]

132. The 3rd limitation of claim 1 recites:

a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes.

133. As shown below, Mazar expressly teaches a flex printed circuit board 120 includes a pair of traces 123A, 123D to connect to electrodes 112A and 112D, respectively. Ex. 1003, ¶ [0100]; Fig. 1D.



134. It is well understood that a circuit trace is necessary to connect to the electrodes to the processor to record the relevant data. Thus, A POSITA would understand that Mazar discloses this element.

135. Yang similarly teaches a flexible PCB 306 coupled to a top foam layer 304 and a bottom foam layer 308. Ex. 1005, 3:63-4:2, Fig. 3 (reproduced below).

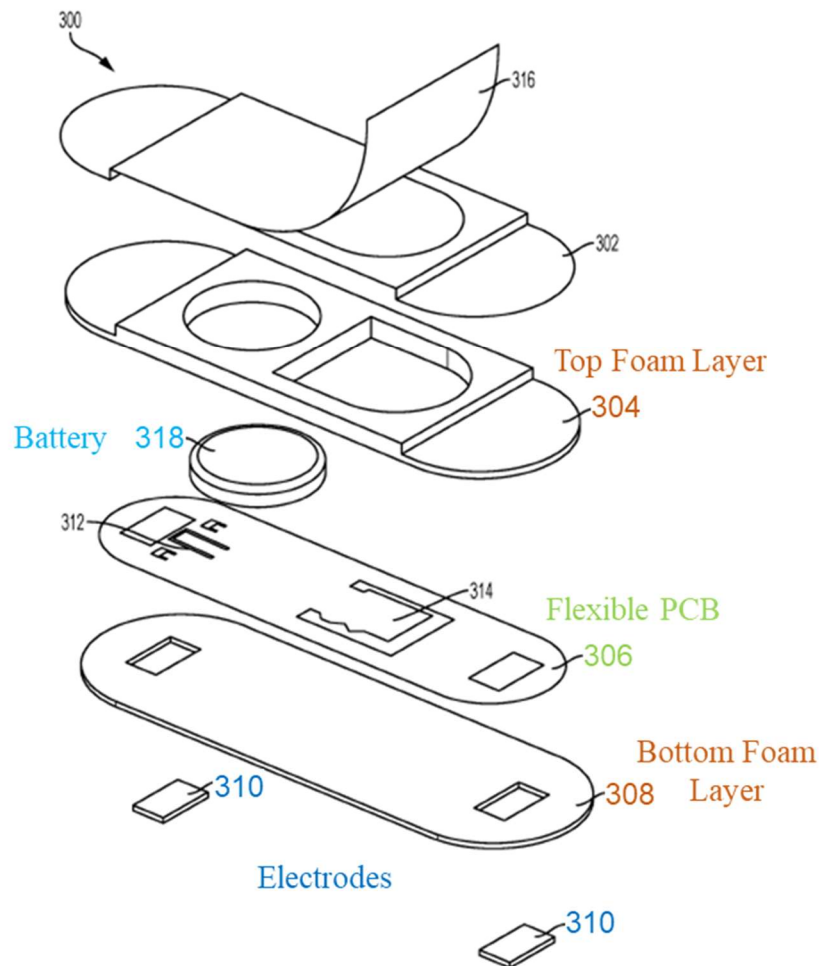


FIG. 3

136. The flexible PCB 306 is coupled to at least two electrodes 310 and enables the disposable module 300 to conform and to adhere to a user's movements. Ex. 1005, 4:2-4. Yang also teaches that the flexible PCB 306 and bottom foam layer 308 each have two openings to allow for the coupling of the at least two electrodes 310 to the flexible PCB 306. Ex. 1005, 4:39-42. A POSITA would readily understand that Yang's teaching to provide an electrical coupling of the electrodes to the PCB would necessarily include a pair of circuit traces, such as taught by Mazar

and since it is well understood that a circuit trace is necessary to connect to the electrodes. All electronic devices, including those used in cardiac electrophysiology such as ablation and recording catheters and pacemakers and defibrillators, have circuit traces. Indeed, a printed circuit board is, by definition, a board with printed traces to connect circuit elements.

137. A POSITA would understand that Mazar and Yang, either alone or in combination, discloses this element.

v. Element [1-D]

138. The 4th limitation of claim 1 recites:

a wireless transceiver to communicate at least a portion of the electrocardiographic signals

139. *Mazar* and *Yang* disclose “a wireless transceiver to communicate at least a portion of the electrocardiographic signals.” *Mazar* teaches that the device 100 can include electronics components 130, such as a wireless communications circuitry 132. Ex. 1003, ¶¶ [0104], [0105]. Specifically, *Mazar* discloses that the “wireless communication circuitry is configured to transmit the hydration signal, the electrocardiogram signal and the inclination signal to the remote center with a single wireless hop, for example from wireless communication circuitry 132 to intermediate device 102.” Ex. 1003, ¶ [0105]. Similarly, *Yang* discloses a wireless sensor. Ex. 1005, 2:48-55. Wireless communication of cardiac electrical signals

existed in implantable devices well before 2013. *See, e.g.*, Ex. 1013 (Shennib), Paras. [0033]-[0034]; Ex. 1014 (Tarler), col. 7:27-8:28, 18:1-6. A POSITA would understand that *Mazar* and *Yang* discloses this element.

B. Independent Claim 11

140. The only material difference between claims 1 and 11 is the further recitation of the following elements required to make such devices function, namely, the battery, the processor, and the memory. These basic elements are disclosed in the prior art shown below. Moreover, although the preamble slightly deviates between claims 1 and 11, a POSITA would understand that the electrocardiographic patch claimed by Claim 1 is an electrocardiographic monitor of Claim 11 and, thus, the different words in the preamble do not materially change the scope of preambles between Claims 1 and 11.

i. Element [11-E]

141. *Mazar* and *Yang* disclose “a battery on one of the ends of the backing.” *Mazar* discloses that the device 100 includes a battery coupled to the electronic components. Ex. 1003, ¶¶ [0031], [0033], [0094]. For example, Fig. 1E shows batteries 150 positioned over the flex printed circuit board and electronic components, which are on the left and right ends of the backing. *Id.*, ¶¶ [0113], [0094], [0064]. Like the '743 patent, these batteries are intended to be removed

and/or replaced when the replaceable patch is replaced. *Id.* A POSITA would understand that *Mazar* discloses this element.

142. Furthermore, while *Mazar* discloses that an air gap “may” be present between the patch 110 and the printed circuit board, a POSITA would understand that teaching to be optional, as the language expressly states. Ex. 1003, ¶¶ [0145]. For example, while the air gap might enhance breathability, the failure to secure the printed circuit board to the backing could result in discomfort as the printed circuit board and backing move separately and stress one another. This movement between the electrode and backing could also cause the metal to introduce wear or tears in the backing. Thus, a POSITA would find it obvious to alternative use the arrangement in *Yang* where the battery 318 is positioned directly on the flexible PCB 306, which is on the backing 308 with no intervening air gap. Ex. 1005, 3:63-4:2, 4:28-38, Fig. 3 (reproduced below).

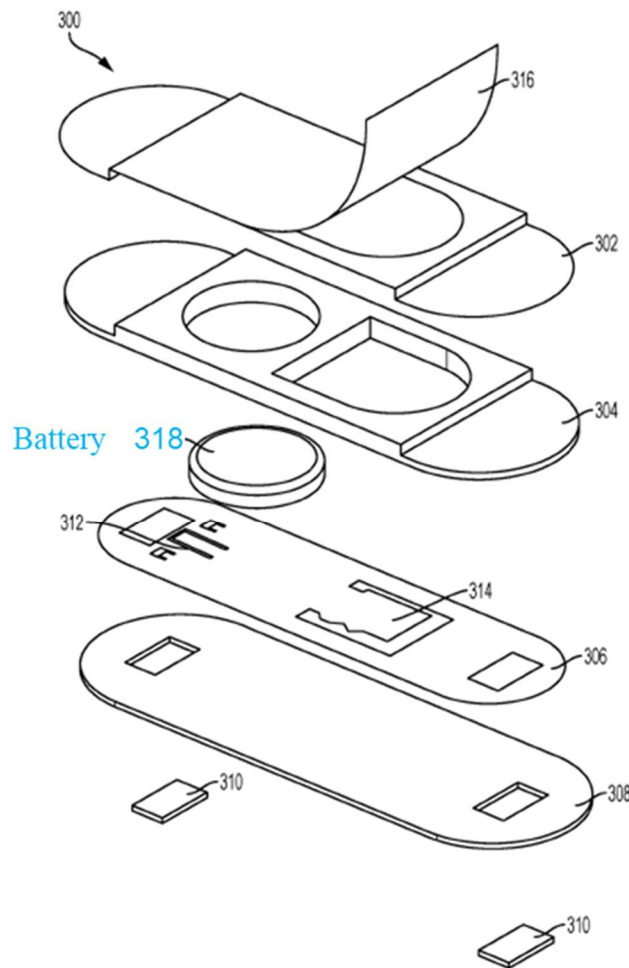


FIG. 3

Furthermore, putting the battery on the ends of the backing, rather than the middle, is a simple design choice that can be readily selected by a POSITA. This placement would be particularly obvious in a patch with a narrowed middle, which would reduce the space available for a battery.

143. Just like the '743 patent, *Yang* teaches that its battery is housed on the replaceable portion of its patch (the disposable module 102 of *Yang* and/or the replaceable extended wear electrode patch of the '743 patent) and on one end of the

backing. Ex. 1005, Fig. 3, 3:63-4:2, 4:28-38. And similar to the '743 patent, *Yang* also teaches that its health monitoring device is cost-efficient because the reusable portion can be separated from the disposable portion (which houses the battery) and fitted with a new replacement disposable portion to extend its lifetime. Ex. 1005, 5:41-53. A POSITA would readily understand that *Yang's* teaching to reuse elements of the patch (such as the electronics) and replace other elements of the patch (such as the battery and the patch body), would improve the cost effectiveness of a disposable portion of a health monitoring device, such as that of *Mazar*, which would include the consumable battery and create a product that is less wasteful.

144. A POSITA would understand that *Mazar* and *Yang*, either alone or in combination, discloses this element.

ii. Element [11-F]

145. *Mazar* and *Yang* disclose “a processor powered by the battery.” *Mazar* teaches that the device 100 includes a processor 262 that is powered by the battery. Ex. 1003, ¶ [0167]. A POSITA would understand that at least *Mazar* discloses this element. *Yang* similarly discloses an electrical component unit 510 for “processing of information collected by the at least two electrodes.” Ex. 1005 4:67-4. A POSITA would understand that the most obvious way to embody this through a processor that is powered by the battery. Thus, a POSITA would understand that the

combination of *Mazar* and *Yang* along with the commonsense knowledge of a POSITA discloses this element.

iii. Element [11-G]

146. *Mazar* discloses “memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals.” *Mazar* teaches that the device 100 includes a memory in communication with a processor for storing the physiological signals. Ex. 1003, ¶¶ [0048], [0095], [0104]. The storage of samples of cardiac electrical signals has long been understood and practiced for decades. *See*, Ex. 1005 5:23-31 (explaining a POSITA would recognize the suitable addition of memory to the disclosed patch). A POSITA would understand that at least *Mazar* discloses this element and that it would be an obvious addition to an electrocardiograph monitor. Moreover, the common typical operation of a processor requires corresponding memory that stores data while it is being input, output, and processed by the processor. Thus, storing data such as cardiac signals in a processor based system is the most obvious thing to do.

C. Claims 2 and 12

147. Claim 2 depends on Claim 1 and further requires that the ECG patch includes “an accelerometer provided on the backing.” Similarly, Claim 12 depends on Claim 11 and further requires that there is “an accelerometer provided on the backing.”

148. In addition to the electrodes, *Mazar* teaches that the device 100 can include electronics components 130, such as an activity sensor and activity circuitry 134. Ex. 1003, ¶¶ [0015], [0107]. Specifically, *Mazar* confirms that the activity sensor and activity circuitry 134 can comprise many known activity sensors and circuitry, such as, an accelerometer, a piezoelectric accelerometer, capacitive accelerometer, or an electromechanical accelerometer. *Id.* Activity sensors, including accelerometers, have long been understood and practiced for decades. *See e.g.*, Ex. 1008, 5:16-22; Ex. 1009 at 6-7, Ex. 1010 at 3, 5. A POSITA would understand that *Mazar* discloses this element and given the popularity of the quantified life movement by the priority date of the '743 it would be obvious to a POSITA to include an accelerometer in this sort of patch.

D. Claims 3 and 13

149. Claim 3 depends on claim 1 and further requires that the ECG patch includes “a physiology sensor provided on the backing to measure body temperature.” Similarly, Claim 13 depends on Claim 11 and further requires “a physiology sensor provided on the backing to measure body temperature.”

150. *Mazar* expressly teaches that the device 100 can include electronics components 130 and a memory for storing physiologic signals. Ex. 1003, ¶¶ [0048], [0095]. Specifically, *Mazar* enumerates several examples that include a temperature sensor. *Id.* Temperature sensors have long been understood and practiced for

decades. *See, e.g.*, Ex. 1008, 5:16-22; Ex. 1009 at 10. A POSITA would understand that at least *Mazar* discloses this element and given the popularity of the quantified life movement by the priority date of the '743 it would be obvious to a POSITA to include a temperature sensor in this sort of patch.

E. Claims 4 and 14

151. Claim 4 depends on claim 1 and further requires that “each of the ends of the backing is rounded on an outer edge.” Claim 14 depends on claim 11 and further requires “each of the ends of the backing [to be] rounded on an outer edge.”

152. *Mazar* discloses that the device 100 can comprise many shapes, such as a dog bone or an hourglass, which shapes are rounded on the outer edges. Ex. 1003, ¶ [0093]; Fig. 1F1. A POSITA would understand that at least *Mazar* discloses this element. It would be obvious to use rounded edges for comfort of the patient and for aesthetic reasons. For example, the corners of squared off edges have a tendency to peel off since they come to a point.

F. Claims 5 and 15

153. Claim 5 depends on claim 1 and further requires “a physiology and activity sensor provided on the backing to measure one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level.” Claim 15 depends on claim 11 and further requires “a physiology and activity sensor provided on the backing to measure one or more

of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned, and estimated blood glucose level.”

154. Like claims 3 and 13, *Mazar* expressly teaches that the device 100 can include electronics components 130 and a memory for storing physiologic signals. Ex. 1003, ¶¶ [0013], [0014], [0048], [0095]. Specifically, *Mazar* teaches that the plurality of sensors include a heart rate sensor, a blood pressure sensor, a sleep sensor, a temperature sensor, and so on, as claimed. *Id.* Physiology and activity sensors measuring one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level have long been understood and practiced for decades. *See, e.g.*, Ex. 1008, 5:16-22; Ex. 1009, Ex. 1010, Ex. 1011, Ex. 1012. A POSITA would understand that at least *Mazar* discloses this element and given the popularity of the quantified life movement by the priority date of the ’743 it would be obvious to a POSITA to include these sorts of sensors in this sort of patch.

G. Claims 6 and 16

155. Claim 6 depends on claim 1 and further requires that “the electrocardiographic signals are converted to a different format and processed.” Claim 16 depends on claim 11 and further requires “the electrocardiographic signals [to be] converted to a different format and processed.”

156. *Mazar* discloses that the device 100 includes a processor configured to process data received from the sensors and to display information regarding the data. Ex. 1003, ¶¶ [0013], [0104]. Specifically, *Mazar* teaches that at step 435, the signals from the sensors are processed in many known ways, for example, to generate at least one of a derived signal, a time averaged signal, a filtered signal, or so on. *Id.*, ¶¶ [0013], [0104], [0197]. *Mazar* further discloses that at step 445, these processed signals are transmitted to a remote site. *Id.*, ¶¶ [0013], [0104], [0199]. The conversion of electrocardiographic signals to a different format and processed has long been understood and practiced for decades. *See e.g.*, Ex. 1008, 3:17-25; Ex. 1013 (Shennib), Para. [0045]. A POSITA would understand that at least *Mazar* discloses this element.

H. Claims 7 and 17

157. Claim 7 depends on claim 6, which depends on claim 1, and further recites that “the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver.” Claim 17 depends on claim 16, which depends on claim 11, and further requires that “the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver.”

158. As described with reference to Claims 6 and 16, measurement signals, which can include derived and/or processed measurement signals, are transmitted to

a remote site, such as a remote processor 106P, which comprises a client computer or backend server, as claimed. Ex. 1003, ¶¶ [0013], [0104], [0091], [0197], [0199]. The retrieving of the formatted electrocardiographic signals has long been understood and practiced for decades. *See e.g.*, Ex. 1008, 3:17-25. A POSITA would understand that at least *Mazar* discloses this element. Furthermore, by their nature, wireless patches send data to a computer for processing, otherwise the wireless transmission would be lost. As such, this is an obvious feature that is commonly present in wireless patches.

I. Claims 8 and 18

159. Claim 8 depends on claim 1 and further recites that “the electrodes are exposed on a contact surface of the backing.” Claim 18 depends on claim 11 and similarly requires that “the electrodes are exposed on a contact surface of the backing.”

160. *Mazar* discloses that the electrodes can be fabricated in many ways, including being printed on a flexible connector and/or exposed to the gel through apertures of breathable tape such that the gel can be positioned over the electrodes and portions of breathable tape for coupling the electrodes to the skin of the patient. Ex. 1003, ¶¶ [0122], [0133]. A POSITA would understand that at least *Mazar* discloses this element. Moreover, exposing the electrodes on the bottom of the patch is the most obvious way to allow them to make contact with the patient and record

the ECG signals. Thus, this is the epitome of an obvious feature for this sort of device.

J. Claims 9 and 19

161. Claim 9 depends on claim 1 and further requires that the ECG patch includes “a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing.” Claim 19 depends on claim 11 and further requires “a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing.”

162. *Mazar* expressly teaches that an adhesive 116A can be disposed on the underside/contact side of the patch 11. Ex. 1003, ¶ [0128]. And that the adhesive 116A includes a hydrocolloid adhesive, as claimed. *Id.* Furthermore, a POSITA would understand that it is well known for hydrocolloid adhesives to be used in medical applications to avoid skin irritation. Hydrocolloids were one of a few commonly used adhesives for this sort of application. Additionally, a POSITA would understand that it is well known to apply the adhesives to specific parts of contact surface of the backing to ensure adhesion. This would include apply the adhesive to the border of the contact surface of the backing.

163. A POSITA would understand that at least *Mazar* discloses this element. And that it is obvious to use hydrocolloid adhesives to attach electrode patches to a patient’s skin.

K. Claims 10 and 20

164. Claim 10 depends on claim 9, which depends on claim 1, and further recites that “the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface.” Claim 20 depends on claim 19, which depends on claim 11, and further requires that “the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface.”

165. *Mazar* discloses an adhesive 116A, which is at least formed on the ends of the backing on the contact surface as claimed. Ex. 1003, ¶ [0128]. A POSITA would understand that *Mazar* discloses this element.

166. A POSITA would further understand that the placement of the hydrocolloid adhesive is a simple design choice that was already well-known in the prior art. For example, *Yang* shows a bottom foam layer 308 that includes a double adhesive layer positioned directly on one end of the backing of the adherent patch (e.g., the top foam layer 304 coupled to the top cover layer 302 via the flexible PCB 306) to adhere both to the flexible PCB 306 and to a user at the same time. Ex. 1005, 4:9-15, Fig. 3 (reproduced below).

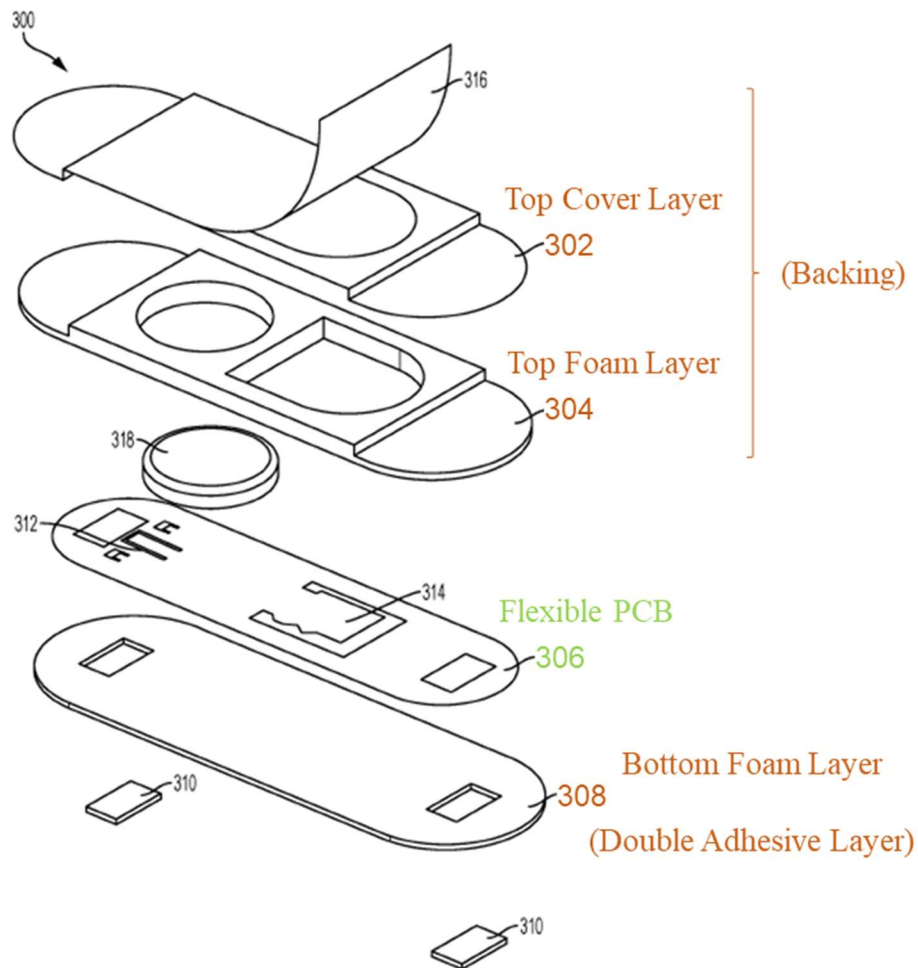


FIG. 3

167. Furthermore, just like the '743 patent, *Yang* teaches that its “patch” looks like a “band-aid” and adheres to the user’s body as such. Ex. 1005, 2:50-55. Skilled artisans have known for decades that even transient exposure to an ECG patch can cause dermatitis and that longer exposure makes it even worse. This supports the obvious design choice of limiting the adhesive usage to the ends of the patch and not the middle. Moreover, placing adhesive on the ends of the backing is the most obvious choice because if the ends are not adhered, it is more likely they

will peel up and cause the adhesive contact to weaken. A POSITA would readily understand that this principle of providing irritation free adhesives for biomedical use only on the ends of the backing, on a contact surface, as claimed, is expressly taught by the “band-aid” analogy taught by *Yang*.

168. A POSITA would understand that *Mazar* and *Yang*, either alone or in combination, discloses this element and that it would be obvious to place adhesive on the ends of the backing.

XIII. Ground II – Claims 1-20 are Anticipated or Rendered Obvious under 35 U.S.C. § 102 or 35 U.S.C. § 103 by Oster in Combination with Yang

A. Independent Claim 1

169. In my opinion, claim 1 of the '743 patent is rendered obvious by *Oster* in combination with *Yang*. In the discussion of claim 1 that follows, I explain the correspondence between the disclosure of *Oster* and *Yang* for each limitation of claim 1.

170. A POSITA would have found it obvious to predictably combine *Oster's* adherent patch device with the teachings of *Yang* to achieve the particular design objectives in *Oster's* system, as explained in Section IX above.

i. Element [1-PRE]

171. The preamble of claim 1 recites:

An electrocardiography patch, comprising:

172. *Oster* and *Yang* disclose “[a]n electrocardiography patch.” *Oster* discloses a biomedical sensor system for use in diagnostic procedures, including monitoring the electrical activity of a subject’s heart, for example, in developing an electrocardiogram (ECG). Ex. 1004, ¶¶ [0021], [0028]; Figs. 1, 2. Similarly, in compatible art, *Yang* also discloses a modular wearable sensor device in a “patch” form that is attached to the user for health monitoring, such as for ECG measurements. Ex. 1005, 1:42-52, 2:35-50.

173. A POSITA would understand that *Oster* and *Yang*, either alone or in combination, discloses this element.

ii. Element [1-A]

174. The 1st limitation of claim 1 recites:

a backing comprising an elongated strip with a mid-section connecting two ends of the backing.

175. *Oster* discloses “a backing comprising an elongated strip with a mid-section connecting two ends of the backing.” And *Oster* further discloses its elongated patch as having a “mid-section [that] is narrower than the two ends of the backing.” Fig. 1 (below), for example, shows that the biomedical sensor system 100 comprises a hub electrode 102, two satellite electrodes 104, and two connectors 106 positioned to couple each satellite electrode 104 to the hub 102. Ex. 1004, ¶¶ [0031], [0034-0035], [0051], [0052], [0062]; Fig. 1.

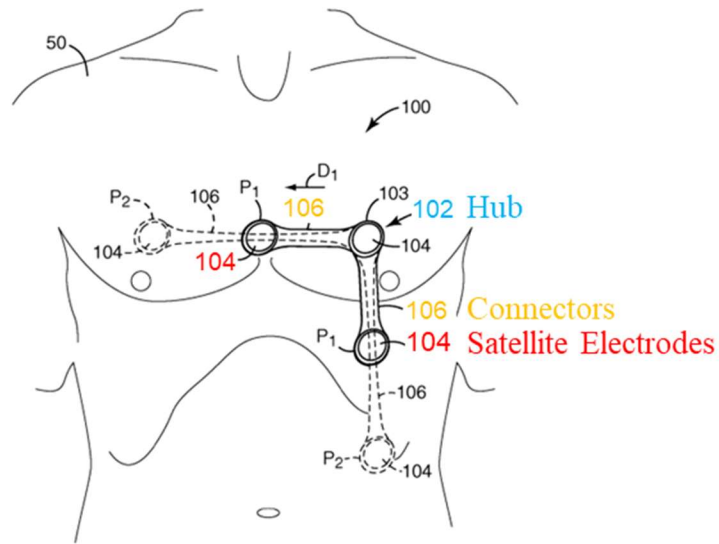
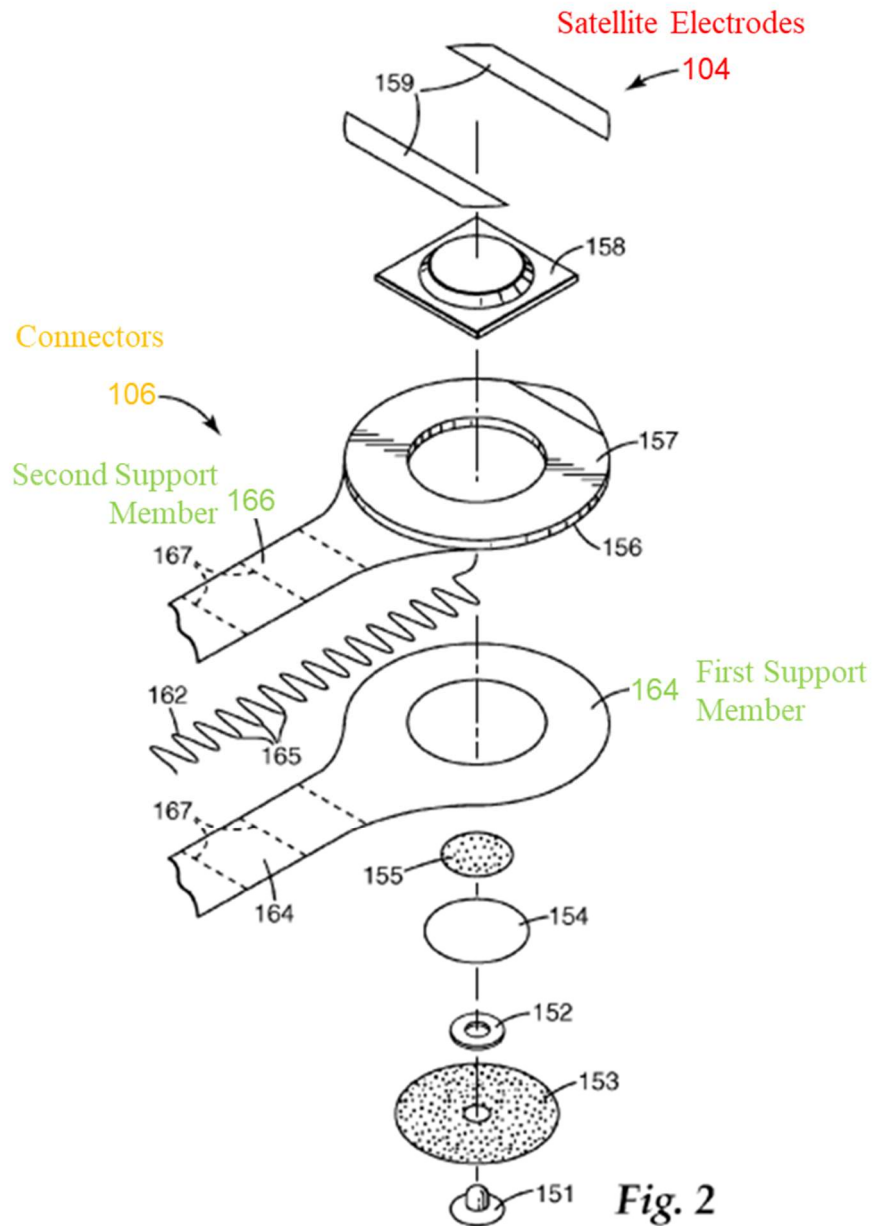


Fig. 1

176. As shown in more detail in Fig. 2, each connector 106 comprises a wire conductor 162 (*e.g.*, a copper wire) positioned between **a first support member 164**, and **a second support member 166** to provide an electrical communication pathway between the hub 102 and the electrode 104. *Id.*, ¶[0057]. One or more of the support members 164, 166, are the “backing” of the connector 106. *Id.*, ¶[0062].



177. As shown in Fig. 1, the ends 104 of the biomedical sensor system 100 are wider than the connector 106, which narrows compared to the ends, as this claim element requires. As shown in Fig. 2, support members 164, 166, disclose a backing comprising an elongated strip with a mid-section connecting two ends of the backing

(where the electrodes 104 and/or hub 102 reside), wherein the mid-section is narrower than the two ends of the backing. In other words, *Oster's* three node embodiment meets this limitation in a variety of ways. Electrodes 104 could be considered to be the ends, which narrow in the connectors to hub electrode 102. *See*, Ex. 1004, ¶ [0035]. Alternately, one could consider just the hub electrode 102 and one satellite electrode 104.

178. Moreover, the patent examiner correctly recognized that a narrowed mid-section is obvious because “[t]he skilled artisan would recognize narrowing a mid-section between the two ends of a backing obviously reduces weight by eliminating unnecessary material.” Ex. 1007, ## (January 25, 2021, Office Action). A POSITA would view an elongated strip design as a “standard of care” and common sense. Most clinically used monitors have an elongated strip design—even implantable recorders are elongated in shape. This is because in addition to the reduction of weight and the elimination of unnecessary material, reducing excess material will increase patient comfort by reducing the area covered by the patch and allowing patch to twist more easily and therefore conform to the movement of the patient. Thus, a POSITA would understand that at least *Oster* expressly discloses this element and that it would be obvious to a POSITA to include this element in a patch.

179. A POSITA would further understand that *Yang* discloses a backing comprising an elongated strip. Ex. 1005, 3:63-4:2, Fig. 3 (reproduced below).

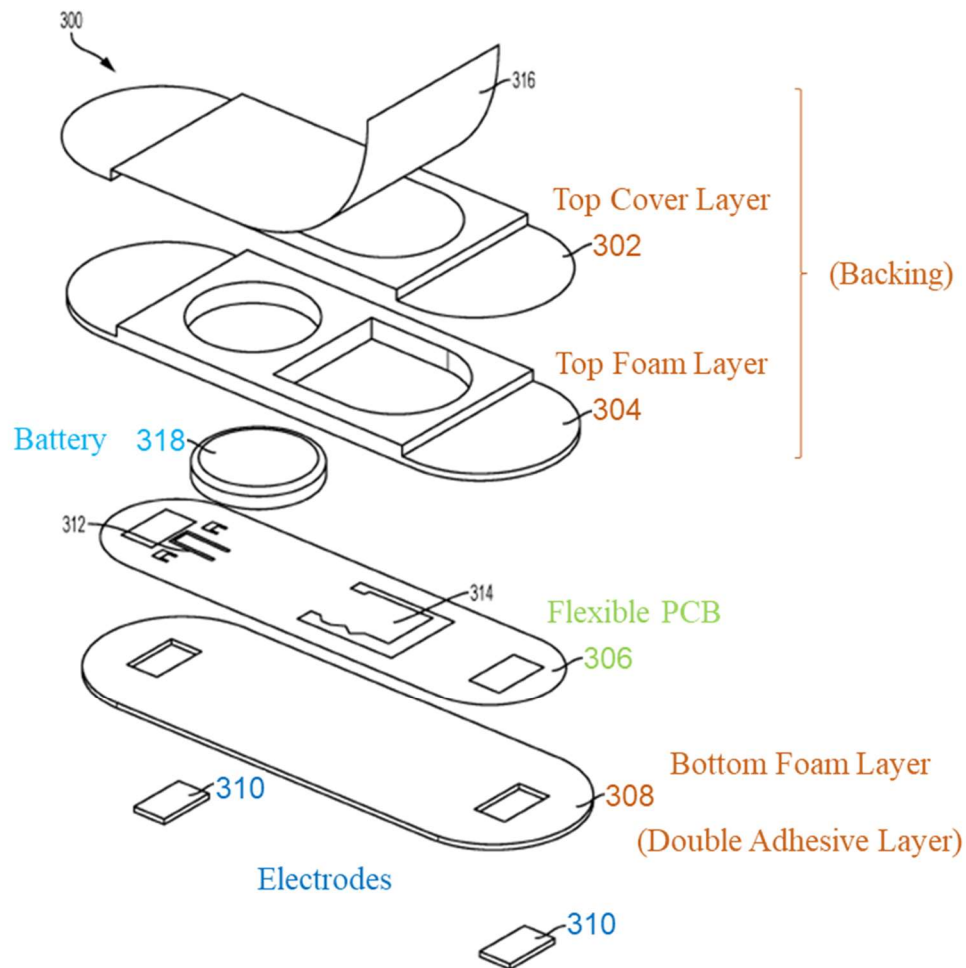


FIG. 3

iii. Element [1-B]

180. The 2nd limitation of claim 1 recites:

an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals.

181. *Oster* discloses “an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals.” As shown in Fig. 1 above, the biomedical sensor system 100 includes a hub electrode 102, **two satellite electrodes 104** on each end of the system 100, and two connectors 106 positioned to couple each satellite electrode 104 to the hub 102. Ex. 1004, ¶¶ [0031], [0035], [0043]; Fig. 1.

182. *Oster* teaches that its biomedical sensor system 100, like the '743 patent, is for monitoring the electrocardiographic signals from the subject's heart, for example, in developing an electrocardiogram (ECG). *Id.*, ¶ [0028]. *Oster* explains that it is well known in the art for an ECG to be captured using a variety of electrode lead configurations, including a variety of 3-lead and 5-lead ECG configurations. *Id.*, ¶ [0029]. A POSITA would also understand that it would have been obvious or well-known to apply the teachings of *Oster* to any other lead configuration, such as the two-electrode configuration of *Yang*, which would reduce cost and aid in simplicity. *Id.*, ¶ [0029]. Moreover, in its 3-lead embodiment as disclosed in the Fig. 1, *Oster's* patch with its triangular shape would effectively have three ends.

183. *Yang* discloses an embodiment with just two electrodes 310 positioned only on each end of the backing of the adherent patch (e.g., the top foam layer 304 coupled to the top cover layer 302 via the flexible PCB 306). Ex. 1005, 3:2-4, 63-4:2, Fig. 3 (reproduced below). Further, demonstrating the fact that the number of

electrodes can be varied to achieve trade-offs between complexity, cost and functionality. Placing two electrodes on opposite ends of the backings optimizes the spread of the electrodes, while minimizing the cost and complexity that would arise from adding more than two electrodes.

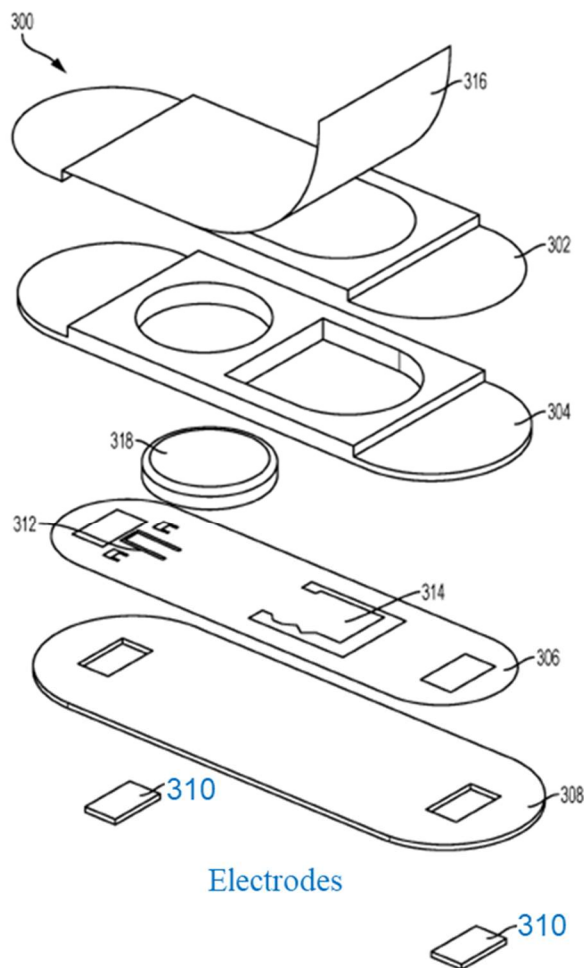


FIG. 3

184. A skilled artisan would view an electrocardiographic electrode on each end of the backing as a “standard of care.” A POSITA would understand that *Oster* discloses this element and that it would be obvious to employ electrodes on each end

of the backing in its various embodiments in view of *Yang*, which presents a simpler two electrode patch.

iv. Element [1-C]

185. The 3rd limitation of claim 1 recites:

a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes.

186. *Oster* discloses “a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes.” As shown in Fig. 1 above, *Oster* teaches that the biomedical sensor system 100 includes a hub 102, two satellite electrodes 104, and **two connectors 106** positioned to couple each satellite electrode 104 to the hub 102. Ex. 1004, ¶¶ [0028], [0031], [0043], [0051], [0052]; Fig. 1. The connectors 106 are adapted to provide a pathway between the electrodes 104 (or other sensors) and the hub 102 for one or more signals that may be communicated between the electrodes 104 and the hub 102. *Id.*

187. The biomedical sensor system 100 is size-configurable and conformable to the subject 50, at least partially because the connector 106 is partially formed of a viscoelastic material, such that by applying force to the connector 106 substantially along the length of the connector 106 (*e.g.*, substantially oriented in the first direction D_1), the connector 106 can be elongated. *Id.*, ¶[0051]. The connector 106 includes a **wire conductor 162** (*e.g.*, a copper wire) positioned between a first

support member 164, and a second support member 166 **to provide an electrical communication pathway between the hub 102 and the electrode 104.** *Id.*, ¶¶ [0028], [0057].

188. It is well understood that a circuit trace is necessary to connect to the electrodes to the processor to record the relevant data. A POSITA would understand that *Oster* discloses this element.

189. The use of flexible PCBs was very common in these applications. And *Yang* similarly teaches a flexible PCB 306 coupled to a top foam layer 304 and a bottom foam layer 308. Ex. 1005, 3:63-4:2, Fig. 3 (reproduced below).

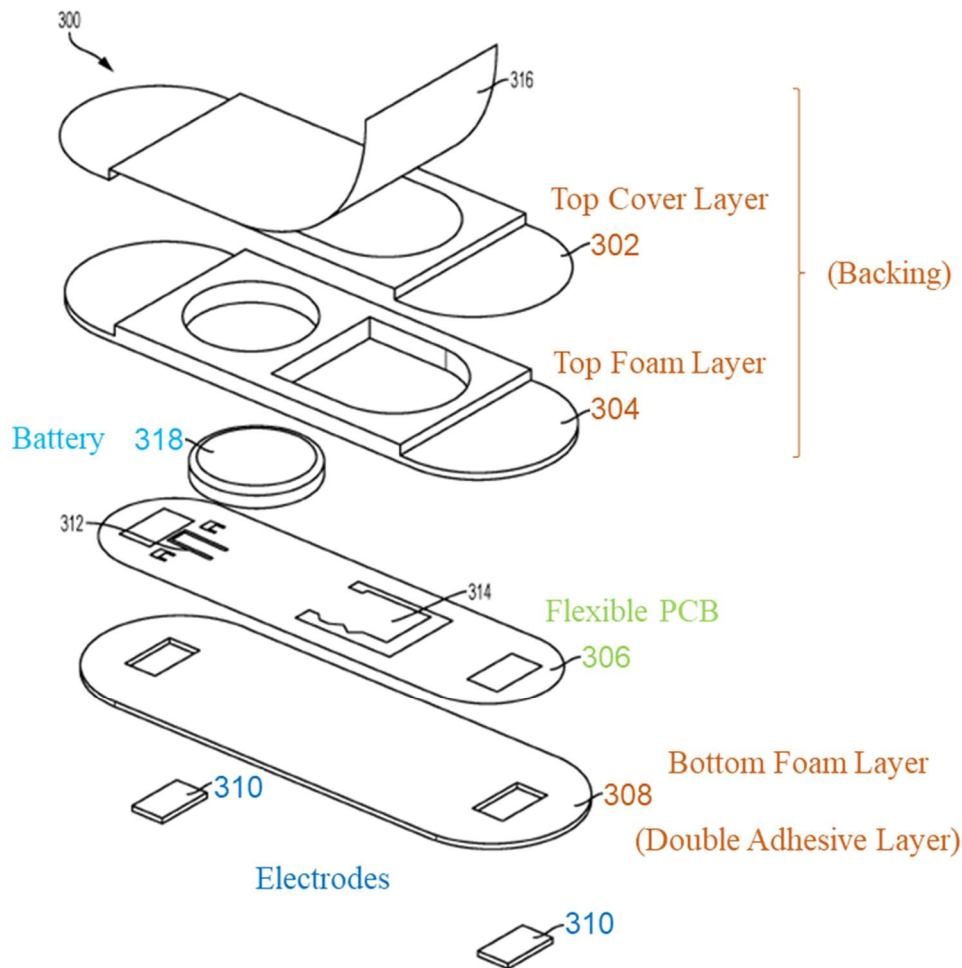


FIG. 3

190. The flexible PCB 306 is coupled to at least two electrodes 310 and enables the disposable module 300 to conform and to adhere to a user's movements. Ex. 1005, 4:2-4. *Yang* also teaches that the flexible PCB 306 and bottom foam layer 308 each have two openings to allow for the coupling of the at least two electrodes 310 to the flexible PCB 306. Ex. 1005, 4:39-42. A POSITA would readily understand that *Yang's* teaching to provide an electrical coupling of the electrodes to the PCB would necessarily include a pair of circuit traces, such as taught by *Oster*

and since it is well understood that a circuit trace is necessary to connect to the electrodes. All electronic devices, including those used in cardiac electrophysiology such as ablation and recording catheters and pacemakers and defibrillators, have circuit traces.

191. A POSITA would understand that *Oster* and *Yang*, either alone or in combination, discloses this element.

v. Element [1-D]

192. The 4th limitation of claim 1 recites:

a wireless transceiver to communicate at least a portion of the electrocardiographic signals

193. *Oster* and *Yang* disclose “a wireless transceiver to communicate at least a portion of the electrocardiographic signals.” *Oster* expressly teaches that the hub 102 can wirelessly communicate with downstream computing. Ex. 1004, ¶¶ [0032], [0035], [0022], [0027]. Specifically, the biomedical sensor 100 includes a **transmitter 108** that receives and transmits wirelessly signals received from the electrodes 104 through a signal processor 112. *Id.*, ¶¶ [0035], [0022], [0027]; Fig. 13. Similarly, *Yang* discloses a wireless sensor. Ex. 1005, 2:48-55. Wireless communication of cardiac electrical signals existed in implantable devices well before 2013.

194. A POSITA would understand that at least *Oster* discloses this element.

B. Independent Claim 11

195. The only material difference between claims 1 and 11 is the further recitation of the following elements required to make such devices function, namely, the battery, the processor, and the memory. These basic elements are disclosed in the prior art shown below. Moreover, although the preamble slightly deviates between claims 1 and 11, a POSITA would understand that the electrocardiographic patch claimed by Claim 1 is an electrocardiographic monitor of Claim 11 and, thus, the different words in the preamble do not materially change the scope of preambles between Claims 1 and 11.

i. Element [11-E]

196. The combination of *Oster* and *Yang* discloses “a battery on one of the ends of the backing.” *Oster* teaches that its wireless biomedical sensor system can create electromagnetic and electrical signals and provide an electrical conduit between its sensors and hubs. Ex. 1004, ¶¶ [0026], [0028], [0032], [0036]. Such a wireless device would include a power source, such as a battery, to function. Indeed, *Oster* discloses that its biomedical sensor system can be applied to telemetric and remote monitoring devices, such as a Holter monitor. *Id.*, ¶ [0022]. A POSITA would understand that a Holter monitor is a small, wearable battery-powered device for cardiac monitoring, which includes a replaceable battery. Moreover, providing

power to run the processor and sensors of the *Oster* patch is the most common way to power a device and as such it would *the* obvious way to do it.

197. Nevertheless, a POSITA would understand that it is obvious to use a battery to power the wireless electronic monitoring systems such as *Oster*. For example, *Yang* also teaches a wireless monitor and expressly discloses a battery 318 positioned directly on one end of the backing of the adherent patch (*e.g.*, the top foam layer 304 coupled to the top cover layer 302 via the flexible PCB 306) to power the electrical component unit 312 of the flexible PCB 306 and the reusable module 106. Ex. 1005, 3:2-4, 63-4:2, 4:28-38, Fig. 3 (reproduced below).

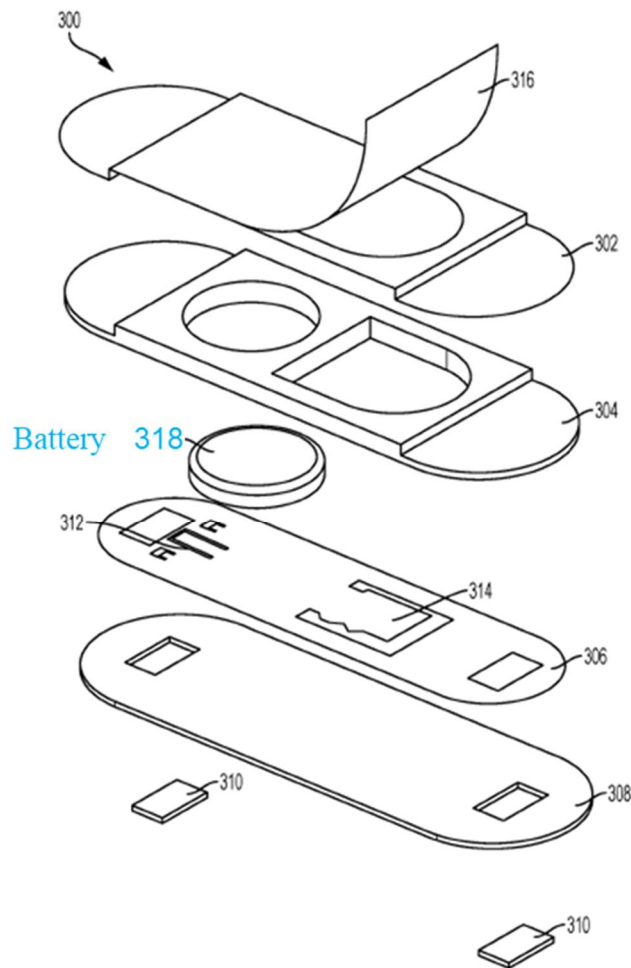


FIG. 3

And common sense dictates that the most obvious placement of the battery in *Oster* would be on one of its ends within one of its nodes, which provide the necessary space.

198. Furthermore, just like the '743 patent, *Yang* teaches that its battery is housed on the replaceable portion of its patch (the disposable module 102 of *Yang* and/or the replaceable extended wear electrode patch of the '743 patent). And similar to the '743 patent, *Yang* also teaches that its health monitoring device is cost-

efficient because the reusable portion can be separated from the disposable portion (which houses the battery) and fitted with a new replacement disposable portion to extend its lifetime. Ex. 1005, 5:41-53. A POSITA would readily understand that *Yang*'s teaching to reuse elements of the patch (such as the electronics) and replace other elements of the patch (such as the battery and the patch body), would improve the cost effectiveness of a disposable portion of a health monitoring device, such as that of *Oster*, which would include the consumable battery and create a product that is less wasteful. Placing a battery as taught by *Yang* into one of the ends of the *Oster* patch would be a simple matter of packing well-understood components, which would be a routine and predictable for a POSITA. Moreover, given the narrow and stretching design of the middle regions 106 of *Oster*, they would not be suitable for a battery or other bulky components.

199. A POSITA would understand that *Oster* and *Yang*, either alone or in combination, discloses this element and renders it obvious.

ii. Element [11-F]

200. The combination of *Oster* and *Yang* discloses “a processor powered by the battery.” *Oster* teaches that the biomedical sensor system 100 can include a processor, such as a controller 114 or a signal processor 112. Ex. 1004, ¶¶ [0035], [0038]. As with the battery element above, a POSITA would understand that the

most obvious way to power the processor of an electrical device like *Oster*'s would be a battery.

201. For example, a POSITA would also know that it is obvious to use a battery to power the patch from prior art like *Yang*, which shows a battery 318 positioned directly on one end of the backing of the adherent patch (*e.g.*, the top foam layer 304 coupled to the top cover layer 302 via the flexible PCB 306) to power the electrical component unit 312 of the flexible PCB 306 and the reusable module 106, which electrical component unit 312 includes a microcontroller (a processor). Ex. 1005, 3:2-4, 29-40, 63-4:2, 4:28-38.

202. A POSITA would understand that *Oster* and *Yang*, either alone or in combination, discloses this element and that it is obvious to power a wearable device—like the claimed patch—with a battery.

iii. Element [11-G]

203. *Oster* discloses “memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals.” *Oster* teaches that the biomedical sensor system 100 can include a memory 116 to at least temporarily store information relative to the signals received from the satellite and/or hub electrodes 104. Ex. 1004, ¶ [0043]; *see also*, Ex. 1005 5:23-31 (explaining a POSITA would recognize the suitable addition of memory to the disclosed patch).

Indeed, the storage of samples cardiac electrical signals has long been understood and practiced for decades.

204. A POSITA would understand that at least *Oster* discloses this element and that it would be an obvious addition to an electrocardiograph monitor.

C. Claims 2 and 12

205. Claim 2 depends on claim 1 and further requires that the ECG patch includes “an accelerometer provided on the backing.” Similarly, Claim 12 depends on Claim 11 and further requires that there is “an accelerometer provided on the backing.” Activity sensors, including accelerometers, have long been understood and practiced for decades. *See e.g.*, Ex. 1008, 5:16-22; Ex. 1009 at 6-7, Ex. 1010 at 3, 5. A POSITA would understand that *Oster* discloses this element and given the popularity of the quantified life movement by the priority date of the '743 it would be obvious to a POSITA to include an accelerometer in this sort of patch. *Oster* expressly describes that in addition to sensing electrodes, its sensors can include an accelerometer. Ex. 1004, ¶ [0026].

206. A POSITA would understand that at least *Oster* discloses this element.

D. Claims 3 and 13

207. Claim 3 depends on claim 1 and further requires that the ECG patch includes “a physiology sensor provided on the backing to measure body

temperature.” Claim 13 depends on claim 11 and further requires “a physiology sensor provided on the backing to measure body temperature.”

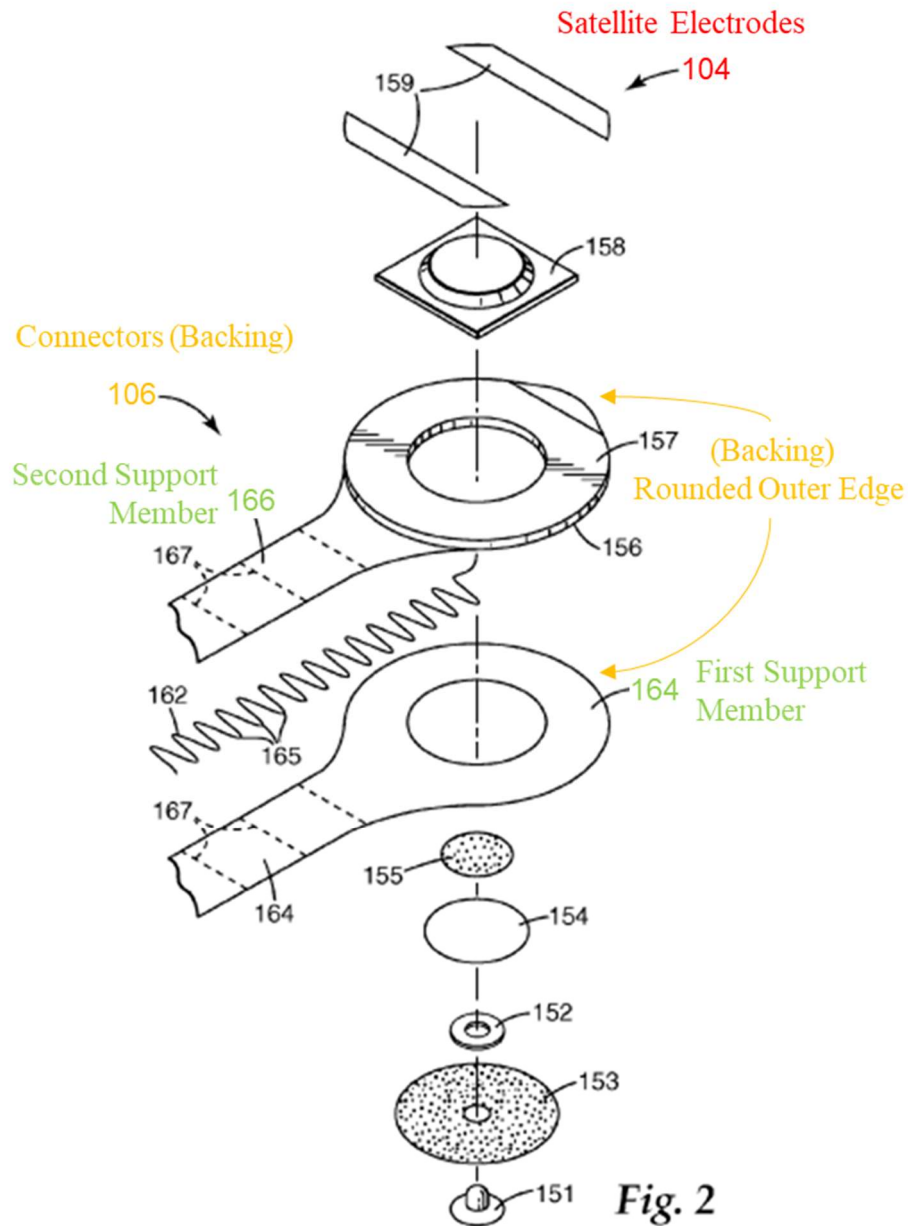
208. Like the accelerometer of claims 2 and 12, *Oster* expressly describes that its sensors can include a thermocouple and/or sensors for sensing one or more of blood oxygen saturation, glucose, body temperature, blood pressure, and combinations thereof for creating one or more signals based on one or more physiological characteristics. Ex. 1004, ¶¶ [0024], [0026]. Temperature sensors have long been understood and practiced for decades. *See e.g.*, Ex. 1008, 5:16-22; Ex. 1009 at 10.

209. A POSITA would understand that at least *Oster* discloses this element and given the popularity of the quantified life movement by the priority date of the ’743 patent, it would be obvious to a POSITA to include a temperature sensor in this sort of patch.

E. Claims 4 and 14

210. Claim 4 depends on claim 1 and further requires that “each of the ends of the backing is rounded on an outer edge.” Claim 14 depends on claim 11 and further requires “each of the ends of the backing [to be] rounded on an outer edge.”

211. As shown in Fig. 2, the connector 106 (which includes the support members 164, 166 as the backing) terminates at the electrodes 104, which is shown to be rounded on an outer edge.



212. A POSITA would understand that at least *Oster* discloses this element. It would have been obvious to use rounded edges for comfort of the patient and for aesthetic reasons. For example, the corners of squared off edges have a tendency to peel off since they come to a point.

F. Claims 5 and 15

213. Claim 5 depends on claim 1 and further requires “a physiology and activity sensor provided on the backing to measure one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level.” Claim 15 depends on claim 11 and further requires “a physiology and activity sensor provided on the backing to measure one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned, and estimated blood glucose level.”

214. Like claims 3 and 13, *Oster* states that its sensors include a thermocouple and/or sensors for sensing one or more of blood oxygen saturation, glucose, body temperature, blood pressure, and combinations thereof for creating one or more signals based on one or more physiological characteristics. Ex. 1004, ¶¶ [0021], [0024], [0026]. Physiology and activity sensors measuring one or more of heart rate, temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level have long been understood and practiced for decades. *See, e.g.*, Ex. 1008, 5:16-22; Ex. 1009, Ex. 1010, Ex. 1011, Ex. 1012.

215. A POSITA would understand that at least *Oster* discloses this element and given the popularity of the quantified life movement by the priority date of the '743 patent, it would be obvious to a POSITA to include these sorts of sensors in this sort of patch.

G. Claims 6 and 16

216. Claim 6 depends on claim 1 and further requires that “the electrocardiographic signals are converted to a different format and processed.” Claim 16 depends on claim 11 and further requires “the electrocardiographic signals [to be] converted to a different format and processed.”

217. *Oster* teaches that the transmitter 108 is adapted to translate signals from the electrodes 104 into a signal that can be transmitted (*e.g.*, one or more of an electromagnetic signal, an acoustic signal, and combinations thereof), and wirelessly transmit information relative to the signal(s) from the electrodes 104 to a receiver 110. Ex. 1004, ¶¶ [0035], [0024], [0025], [0026]. The conversion of electrocardiographic signals to a different format and processed has long been understood and practiced for decades. *See e.g.*, Ex. 1008, 3:17-25; Ex. 1013 (Shennib), Para. [0045].

218. A POSITA would understand that at least *Oster* discloses this element.

H. Claims 7 and 17

219. Claim 7 depends on claim 6, which depends on claim 1, and further recites that “the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver.” Claim 17 depends on claim 16, which depends on claim 11, and further requires that “the

formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver.”

220. As described with reference to Claims 6 and 16, the transmitter 108 translates signals from the electrodes 104 and wirelessly transmits this information to a receiver 110. *Oster* teaches that the receiver 110 can include or be a portion of a downstream computer, which comprises a client computer as claimed. Ex. 1004, ¶¶ [0035], [0024], [0025], [0026]. The retrieving and conversion of the formatted electrocardiographic signals has long been understood and practiced for decades. *See e.g.*, Ex. 1008, 3:17-25.

221. A POSITA would understand that at least *Oster* discloses this element. Furthermore, by their nature, wireless patches send data to a computer for processing, otherwise the wireless transmission would be lost. As such, this is an obvious feature that is commonly present in wireless patches.

I. Claims 8 and 18

222. Claim 8 depends on claim 1 and further recites that “the electrodes are exposed on a contact surface of the backing.” Claim 18 depends on claim 11 and further requires that “the electrodes are exposed on a contact surface of the backing.”

223. Fig. 2 shows an exploded view of the electrode 104, which shows that the electrodes are on a contact surface of the backing of the connector 106. Ex. 1004, ¶¶ [0048], [0047], [0076]. Additionally, *Oster* discloses an embodiment where the

adhesive of the electrodes 104 can be directly coated onto a backing (e.g., a support member 164, 166 of the connector 106) or it can be formed as a separate layer and laminated to the backing. *Id.* The effect of contact on tracing quality has been known for decades from an engineering and clinical perspective. Skilled artisans understand the importance of electrode contact with the patient in the use of ECGs, for example, when body hair is shaved/remove to ensure electrode contact. Nevertheless, a POSITA would also understand that the electrodes are necessarily exposed to a contact surface of the surface it is attached to conduct electrical signals.

224. A POSITA would understand that *Oster* discloses this element.

225. A POSITA would further understand that the placement of the electrodes/sensors on a contact surface of a backing was already well-known in the prior art and necessary for electronic components to function. For example, *Yang* teaches a flexible PCB 306 coupled to at least two electrodes 310. Ex. 1005, 3:63-4:4, Fig. 3 (reproduced below).

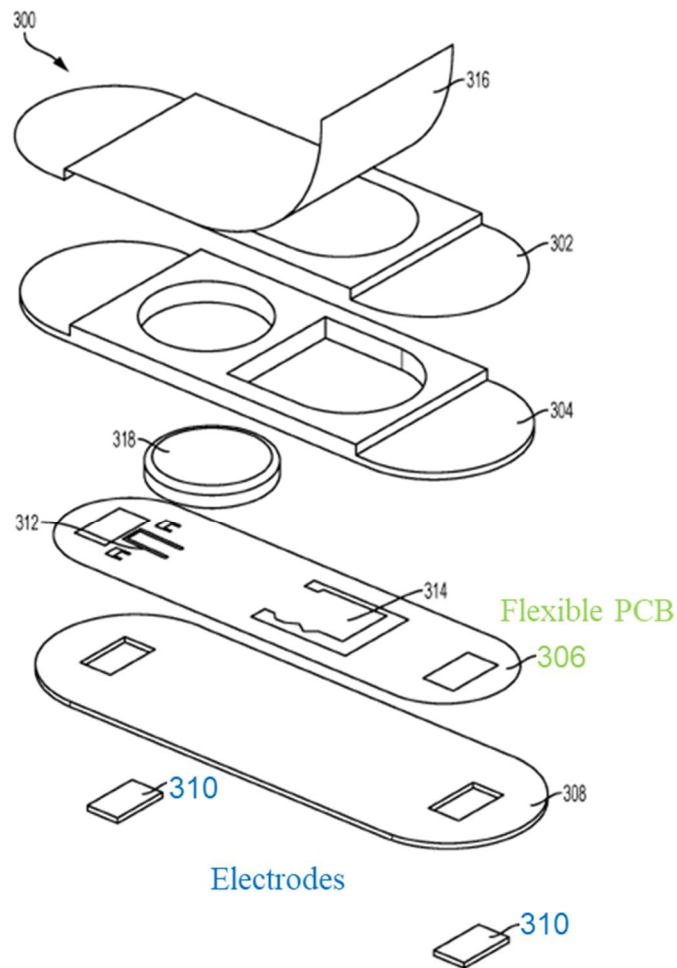


FIG. 3

226. *Yang* teaches that the flexible PCB 306 and bottom foam layer 308 each have two openings to allow for the coupling of the at least two electrodes 310 to the flexible PCB 306. Ex. 1005, 4:39-42. A POSITA would readily understand that *Yang's* teaching of providing cutouts for its electrodes would necessarily include a placement of the electrodes on a contact surface of the backing (which includes the support members 164, 166 (not shown in Fig. 3) as the backing) to adhere to the patient. Moreover, exposing the electrodes on the bottom of the patch is the most

obvious way to allow them to make contact with the patient and record the ECG signals. Thus, this is the epitome of an obvious feature for this sort of device. A POSITA would therefore be motivated to combine the teaching of *Oster* and *Yang* to include this in a wireless electrocardiograph patch.

J. Claims 9 and 19

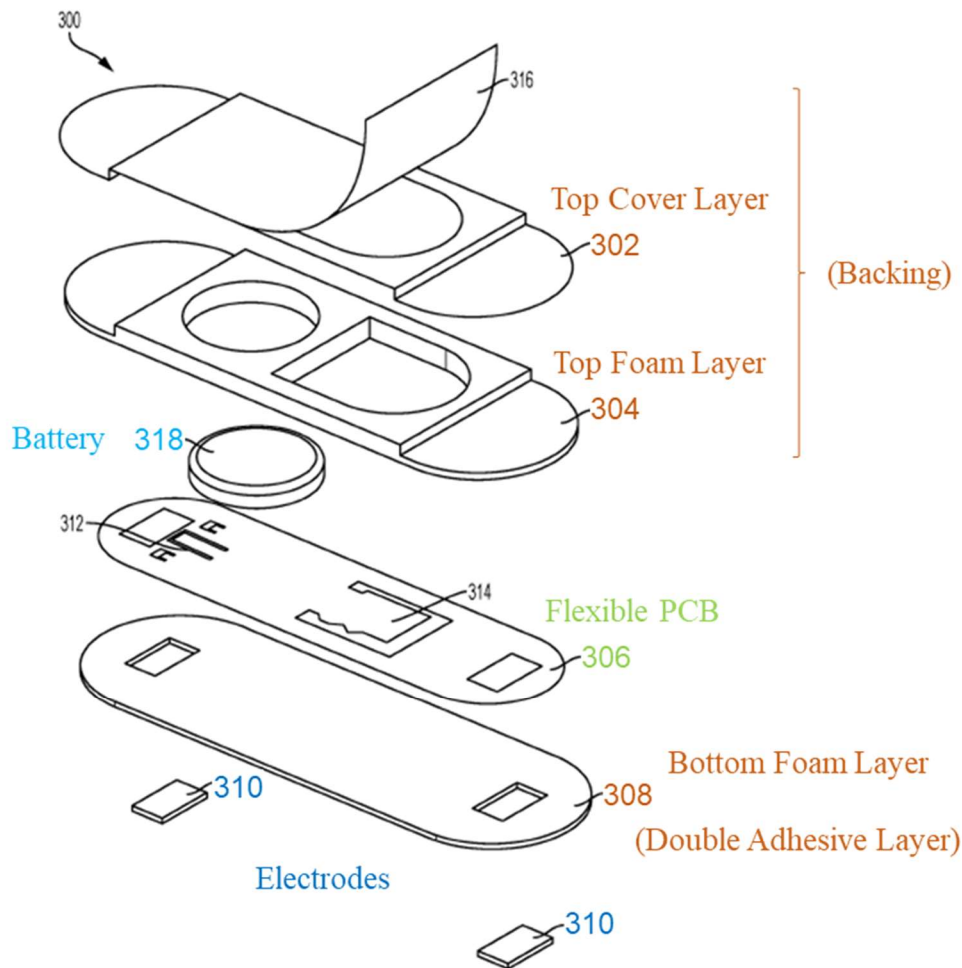
227. Claim 9 depends on claim 1 and further requires that the ECG patch includes “a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing.” Claim 19 depends on claim 11 and further requires “a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing.”

228. *Oster* discloses stretch release adhesives for at least a portion of a contact surface of the connector 106 to couple the electrodes 105 (and/or the hub 102) to the subject. Ex. 1004, Para. [0062]. Additionally, *Oster* discloses that the electrodes 104 can include pregelled electrodes, wet gel electrodes, and combinations thereof. *Id.*, ¶ [0043]. And *Oster* expressly teaches that these electrodes can include an adhesive, such as an adhesive hydrogel, a bicontinuous hydrogel pressure sensitive adhesive, and so on. *Id.* In fact, a POSITA would understand that in the context of applying adhesives to a subject’s skin, it is obvious to use a non-irritating adhesive, such as a hydrocolloid adhesive. As before, hydrocolloids were one of a few commonly used adhesives for this sort of application. A POSITA would understand that *Oster* discloses this element. And

that it is obvious to use hydrocolloid adhesives to attach electrode patches to a patient's skin.

229. Additionally, a POSITA would understand that the placement of the hydrocolloid adhesive is a simple design choice that was already well-known in the prior art. For example, the POSITA would understand that it is well known to apply the adhesives to specific parts of contact surface of the backing to ensure adhesion, such as taught by *Yang*.

230. For example, *Yang* shows a bottom foam layer 308 that includes a double adhesive layer positioned directly on one end of the backing of the adherent patch (*e.g.*, the top foam layer 304 coupled to the top cover layer 302 via the flexible PCB 306) to adhere both to the flexible PCB 306 and to a user at the same time. Ex. 1005, 4:9-15, Fig. 3 (reproduced below).



231. A POSITA would understand that *Oster* and *Yang*, either alone or in combination, renders this element obvious.

K. Claims 10 and 20

232. Claim 10 depends on claim 9, which depends on claim 1, and further recites that “the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface.” Claim 20 depends on claim 19, which depends on claim 11, and

further requires that “the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface.”

233. Figs. 1 and 2 of *Oster* illustrate that the electrodes 104 and corresponding skin adhesives are provided on the ends of the backing, which is on the contact surface. Furthermore, a POSITA would understand that in the context of applying adhesives to a subject’s skin, it is obvious to use a non-irritating adhesive, such as a hydrocolloid adhesive, minimally as needed to secure the device. In applying biomedical devices, the concept to apply adhesives on the ends of the device has been well-known, for example, as illustrated by a Band-aid®. *Id.*

234. A POSITA would understand that at least *Oster* discloses this element.

235. Nevertheless, a POSITA would readily understand that it is well known to apply the adhesives to specific parts of contact surface of the backing to ensure adhesion, such as taught by *Yang*. This would include applying the adhesive to the border of the contact surface of the backing.

236. Just like the ’743 patent, *Yang* teaches that its “patch” looks like a “band-aid” and adheres to the user’s body as such. Ex. 1005, 2:50-55. A POSITA would readily understand that this principle of providing irritation free adhesives for biomedical use only on the ends of the backing, on a contact surface, as claimed, is expressly taught by the “band-aid” analogy taught by *Yang*.

237. A POSITA would understand that *Oster* and *Yang*, either alone or in combination, discloses this element. And a POSITA would be motivated by the teachings of *Oster* and *Yang* to include this element in a wireless electrocardiographic patch.

XIV. CONCLUSION

238. I am therefore of the opinion that claims 1-20 of the '743 patent would be obvious to a person of ordinary skill in the art given the prior art references discussed above.