UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IRHYTHM, INC.,

Petitioner,

v.

WELCH ALLYN, INC.,

Patent Owner.

CASE: IPR2025-00378

U.S. PATENT NO. 8,214,007

DECLARATION OF DR. BRIAN W. ANTHONY

WELCH ALLYN EXHIBIT 2017
iRhythm v. Welch Allyn
IPR2025-00378

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VIII. RESERVATION OF RIGHTS.....70

I, Dr. Brian W. Anthony, declare as follows:

1. I am over eighteen years of age, and I am competent to testify regarding the matters set forth in this declaration if called upon to do so.

2. I have been retained in this matter by K&L Gates LLP on behalf of Patent Owner, Welch Allyn, Inc. ("Welch Allyn").

3. I submit this declaration at the request of K&L Gates as counsel for Patent Owner in this proceeding.

4. I understand that iRhythm, Inc. ("Petitioner") and its expert, Dr. Jason Heikenfeld, have submitted papers in this proceeding arguing that Claims 1 to 8, 10 to 15, 29, 31 to 35, 37 to 39, and 43 to 45 (the "Challenged Claims") of U.S. Patent No. 8,214,007 (the "'007 Patent") (Ex. 1001) are unpatentable under the United States Patent and Trademark Office's *inter partes* review standard of a preponderance of the evidence. I provide certain technical opinions regarding the scope and content of the prior art, including how those skilled in the art as of 2006 would have understood certain references, the industry as a whole, and what factors were driving innovation in this space.

5. In preparing this declaration, I have analyzed the '007 Patent (Ex. 1001), its file history (Ex. 1002), the Declaration of Dr. Jason Heikenfeld (Ex. 1009), and two prior art references: Jensen (Ex. 1011) and Kroll (Ex. 1013). I also considered the other documents or references cited in this declaration. I note that

Dr. Heikenfeld relies on a number of references that are from after the priority date of the '007 Patent, and, to the extent those impacted his opinion, I identify the impact of those opinions in greater detail below.

6. In forming the opinions expressed below, I have considered the documents listed above, the relevant legal standards as provided to me by counsel, and my own knowledge and experience. My opinions are offered from the perspective of a person of ordinary skill, as that term is defined, as of November 1, 2006.

7. I understand Dr. Heikenfeld has already provided his opinions in Exhibit 1009; however, if he is permitted to offer additional opinions, I reserve my right to respond to those should I be asked.

I. QUALIFICATIONS AND BACKGROUND

8. As detailed in my curriculum CV, I am currently a Principal Research Scientist at the Massachusetts Institute of Technology ("MIT") in the Institute for Medical Engineering and Science and Mechanical Engineering. My CV provides additional context regarding my professional background, experience, publications, patents, and other qualifications relevant to providing expert opinions. Here, I highlight experiences specifically pertinent to the technology described in the patent at issue.

9. I earned a Bachelor of Science in Engineering from Carnegie Mellon University in 1994 and a Master's degree in Engineering from MIT in 1998. My master's thesis explored anisotropic waveguides and acoustic non-destructive testing. In 2006, I completed my Ph.D. in Engineering at MIT, where my research emphasized high-performance computation, signal processing, and electro-mechanical system design.

10. Since 1997, I have taught courses in biomedical instrumentation and signal processing, emphasizing electronics design, physiological sensor development (e.g., electrocardiography [ECG] and electromyography [EMG]), and practical electronics implementations. My instruction includes guiding students in designing and constructing microprocessor-controlled for example, ECG monitors, critical medical instruments extensively utilized in clinical settings to monitor cardiac electrical activity. These devices combine analog and digital electronics with advanced signal processing methods, enabling students to amplify minute electrical signals from the body's surface, apply precise filtering to isolate cardiac signals, detect individual heartbeats, measure inter-beat intervals, and visually present summarized trends and statistics. The curriculum also covers electrode design and electrical impedance matching to enhance sensor-tissue compatibility.

11. In 1997, I co-founded Xcitex Inc., a company specializing in data acquisition, video analysis, and signal processing software. I served as Chief

Technology Officer, overseeing product development until 2006. Our products included electronics for interfacing with commercial and research sensors, including those used for machine and human interface applications and diverse electrical consideration for person and sensor safety and protection.

12. Since joining MIT in 2006, I have directed the Master of Engineering in Advanced Manufacturing and Design Program for over a decade. The program encompasses Manufacturing Physics, Manufacturing Systems, Product Design, and Business Fundamentals. Many student projects and research papers under my guidance involve sensor technologies relevant to the '007 Patent, including wearable and non-invasive biosensors.

13. In 2011, I co-founded MIT's Medical Electronic Device Realization Center (MEDRC) and currently serve as co-director. I am also the Director of Medical Technology at the Center for Clinical and Translational Research (CCTR) at MIT's Institute for Medical Engineering & Science and Associate Director at MIT.nano. MEDRC focuses on developing transformative medical technologies through collaboration with clinicians, microelectronics, and medical device industries. Our expertise spans computation, communications, optical, electrical, ultrasound sensing, and consumer electronics. We prioritize device usability, productivity, and enhanced diagnostic capabilities through intelligent signal processing. Our research portfolio includes low-power integrated circuits, big data

analytics, micro-electromechanical systems, bioelectronics, sensors, and microfluidics, with particular emphasis on wearable, non-invasive, minimally invasive biosensors, medical imaging, laboratory instruments, and their data communication to healthcare providers.

14. My research includes developing haptic interfaces, wearable sensors, actuators, and manufacturing processes for flexible electrodes utilized in microfluidic devices and flexible electronics with tailored electrical resistance. This experience directly applies to the technology described in the ’007 Patent.

15. My research further encompasses computational instrumentation, including developing measurement solutions for manufacturing and medical systems. Additionally, my teaching interests involve designing and modeling large-scale systems across diverse decision-making domains and developing optimization algorithms and software tools for system analysis. I teach or have taught courses in Electrical Engineering, Controls, Optics, Communications, Signal Processing, Manufacturing Engineering, Smart Manufacturing, and the Industrial Internet of Things (IoT), all pertinent to the ’007 Patent.

16. I co-founded the Center for Polymer Micro-fabrication at MIT, focusing on polymer-based manufacturing and commercialization of microfluidic devices for chemical, biomedical, and photonic applications. My work in developing polymer-based devices and optical sensors for non-invasive monitoring

of soft, flexible materials during manufacturing is directly relevant to the ’007 Patent technology.

17. I served as MIT Principal Investigator for NextFlex, the Flexible Hybrid Electronics Manufacturing Innovation Institute, a national initiative dedicated to advancing manufacturing ecosystems that integrate traditional integrated circuits (ICs) with printed components. NextFlex enables functionalities such as power management, wireless communication, fluid handling, and bio-sensing in flexible electronics that bend, fold, stretch, and conform to various surfaces.

18. I have authored over 125 publications, earning several best paper and distinguished paper awards. Among these, I co-authored several papers directly related to the ’007 Patent technology, including:

- Hardt, D.E., Anthony, B.W., Tor S.B., “A teaching factory for polymer microfabrication - μFac,” International Journal of Nanomanufacturing, 2010, Vol. 6, No.1/2/3/4, pp. 137–151.
- Anthony, B. W., Namvari, K., “Dimensional variation of polymer substrate electrode production,” Proceedings of SPIE Vol. 8251, 82510G (2012).

- Donoghue, L., Anthony, B. W., "Design for manufacture of a micro-interdigitated electrode for impedance measurement in a biochemical assay," Proceedings of SPIE Vol. 8251, 82510Y (2012).
- Kundu, I., Du, X., & Anthony, B. W., "Imaging platforms for registering and analyzing the skin microrelief structure," SPIE Smart Structures and Materials + Nondestructive Evaluation and Health Monitoring, Denver, Colorado (2018).
- Lee J.H., Traverso G., Ibarra-Zarate D., Boning D.S., Anthony B.W., "Ex Vivo and In Vivo Imaging Study of Ultrasound Capsule Endoscopy," J Med Device, June 2020, 14(2).

II. LEGAL STANDARD

19. Although I am not a lawyer, I have been advised on the relevant legal principles by Welch Allyn's counsel and have used them as a basis for my opinions.

A. Claims

20. I have been informed and understand that terms in the patent claims must be read as they would have been understood by a "person of ordinary skill in the art" ("POSITA") at the time of the claimed invention.

21. I understand that a POSITA is a person to which the claimed subject matter pertains with the capability of understanding the scientific and engineering

principles applicable to the pertinent art. I understand that the following factors may be considered in determining the level of ordinary skill:

- the type of problems encountered in the art;
- prior art solutions to those problems;
- the speed with which innovations are made;
- the sophistication of the technology; and
- the educational level of active workers in the field.

I also understand that not every factor may be present and that one or more factors may predominate others.

22. I understand that the claims within a patent set forth what the inventors have presented as their inventions. I understand that claims can be independent or in dependent form, meaning that they depend from the identified independent claims and add requirements to those claims.

B. Specification

23. I understand that there are other parts of a patent, including the abstract, the figures of a patent, the background of the invention, the summary of the invention, and the detailed description of the invention. I understand that these portions often are collectively referred to as the "specification" of a patent. I understand that technically, the claims are part of the specification, but that referring to the "specification" typically means referring to the written description of the

inventions rather than the claims. I understand that the specification informs the understanding of the claims by, for example, describing the claimed invention and providing preferred examples of the claimed invention.

24. I have also been informed and understand that terms of a claim should be understood in the context of the claim as a whole. I also understand that the specification of the patent is relevant to the meaning of a claim term. I further understand that the claims must be read in light of the specification.

C. Prosecution History

25. I understand that the correspondence back and forth between the representative of the applicant, and the U.S. Patent and Trademark Office, leading up to the issuance of a patent is called the "file history" or "prosecution history." It has been explained to me that, in the process of obtaining a claim of a patent, the inventors and the examiner may make statements explaining their understanding of the scope of their claimed invention. It has also been explained to me that for a statement by the inventors to narrow the scope of a claimed invention, the statement must clearly and unambiguously limit the scope of an invention. I understand this is called "prosecution disclaimer" or "prosecution disavowal." I understand that the claim language, specification, and file history are referred to as "intrinsic evidence" or "the intrinsic record."

D. Burden of Proof

26. I understand that, unlike at the district court, inter partes reviews, such as this proceeding, apply a lower burden of proof to judge the patentability of challenged claims. Unlike the district court's "clear and convincing" burden, here, a "preponderance of the evidence" burden exists.

E. Anticipation

27. I understand that a patent claim is invalid as "anticipated" by a single "prior art" reference if the reference discloses every single element of the claim with sufficient precision and detail to establish that the subject matter of the claim existed in the prior art. In particular, I understand that it is not sufficient to establish that all of the elements are collectively disclosed within the four corners of a particular document. Instead, the operative question is whether a person of ordinary skill would have understood the elements as being arranged as in the claim itself. I also understand that a prior art reference cannot "anticipate" a patent claim unless that reference enables one of ordinary skill in the art to make and use what is disclosed without undue experimentation. Thus, if the reference does not enable one of

ordinary skill to make or use each and every claim limitation, then the claim cannot be "anticipated" by the reference.[1]

28. I understand that a prior art reference can disclose a given claim element actually or inherently.

29. In the case of actual disclosure, I understand that a person of ordinary skill would need to have understood that the disclosure corresponds to the claim element in question. I also understand that such disclosure may be implicit rather than explicit. For example, prior art need not use the same words as the claimed invention. However, I understand that ambiguous references do not anticipate.

30. In the case of alleged "inherent" anticipation, I understand that the claim element in question must necessarily be present when practicing the described technology even though the prior art reference itself contains no express description of the element in question. In particular, I understand that "possibilities or probabilities" are not sufficient to establish inherency. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. Instead, the essence of inherency is that one of ordinary skill in the art would recognize that a reference unavoidably teaches the property in question.

[1] I understand that the Petition and Dr. Heikenfeld are not advancing any anticipation-based theories of unpatentability.

F. Obviousness

31. I understand that a patent claim may describe an invention that was new (*i.e.*, not anticipated by any prior art reference), but nevertheless be invalid for "obviousness" if the differences between the patented subject matter and the prior art are such that the subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the invention was made.1F[2]

i. Reasonable Expectation of Success

32. I understand that an invention is not rendered obvious simply on the basis of two or more different disclosures that collectively disclose all of the claimed elements. In other words, an invention is not obvious just because all of the elements that comprise the invention may have been known in the prior art. Instead, a person of ordinary skill in the art must have had a reasonable expectation of success in pursuing the possibility that turns out to succeed and is claimed. In particular, I understand that knowledge of a goal does not itself render achievement of that goal obvious.

33. I also understand that determining whether or not a claimed invention would have been obvious requires assessing facts related to (1) the scope and content

[2] I understand that the Petition and Dr. Heikenfeld are advancing four "obviousness" theories with Grounds 1 to 4.

of the prior art, (2) the differences between the prior art and the claimed invention, (3) the level of ordinary skill in the art, and (4) any objective evidence ("secondary considerations") of non-obviousness. I understand that this is known as consideration of the "Graham Factors."

ii. Motivation to Combine

34. I further understand that an invention is not obvious just by demonstrating that each of its elements was, independently, known in the prior art. To prove that an invention is obvious, I understand that it can be important to point to a reason or reasons, such as a teaching, suggestion, or motivation, that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does; however, I further understand that a teaching, suggestion, or motivation need not be explicitly set forth in a reference itself. I understand that this is because inventions in most (if not all) instances rely upon building blocks already known, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known; therefore, it can be important to point to such a reason or reasons. I understand that in identifying such a reason, the analysis need not require precise teachings in the prior art directed to the specific subject matter of the challenged claim. However, I further understand there must be some reason articulated that supports why a POSITA (defined below) would have

made the proposed modification, and that the reason must be rooted in the prior art time.

35. I understand that it will often be necessary for a court to look to interrelated teachings of multiple patents and the background knowledge possessed by a person having ordinary skill in the art in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. I understand that any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed. I understand that when a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. I understand that the combination of familiar elements according to known methods may be obvious when it does no more than yield predictable results.

36. I also understand that a claim is not invalid as obvious if it is more than the predictable use of prior art elements according to their established functions.

37. Further, I understand that while predictability is a touchstone of obviousness, the concept of a "predictable result" under the law refers not only to the expectation that prior art elements are capable of being combined, but also that the combination would have arrived at the challenged claims.

38. I also understand that if the prior art "teaches away" from combining known elements in the manner claimed by the invention at issue, discovering a successful way to combine them is less likely to be obvious. In particular, I understand that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant, or would understand based on the reference that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. Likewise, I understand that similar subject matter may not be sufficient motivation for a person of skill in the art to combine references if the references have conflicting elements.

39. Further, I understand that even if a reference does not necessarily "teach away," the reference's statements regarding preferences are relevant to a finding regarding whether a person of ordinary skill would have had reason to combine that reference with another reference.

iii. Hindsight

40. I also understand that one must be cautious and resist the temptation to rely on hindsight reasoning when attempting to combine references to suggest that a claim may be obvious. It is important to analyze validity based on the perspective of one of skilled in the art at the time of the invention, which for this case I have

been asked to assume is November 1, 2006, and which I understand is the date Dr. Heikenfeld and the Petition use as the priority date of the '007 Patent. I understand that objective indicia (or "secondary considerations") of non-obviousness or obviousness may be particularly probative and helpful in avoiding hindsight. I am not analyzing any secondary considerations as part of this declaration.

III. LEVEL OF ORDINARY SKILL IN THE ART

41. I understand that Dr. Heikenfeld opines that a POSITA in the field of body worn physiological monitors in 2006 would have had at least a bachelor's degree in electrical engineering, electrophysiology, biomedical engineering, or an equivalent degree, and at least two to three years of experience designing wearable monitors that detect physiological signals with mechanical and/or electrical elements. I understand that Dr. Heikenfeld has further opined that a person with less education but more professional experience, and vice versa, may qualify as a POSITA. At this point in time, I do not dispute Dr. Heikenfeld's opinion.

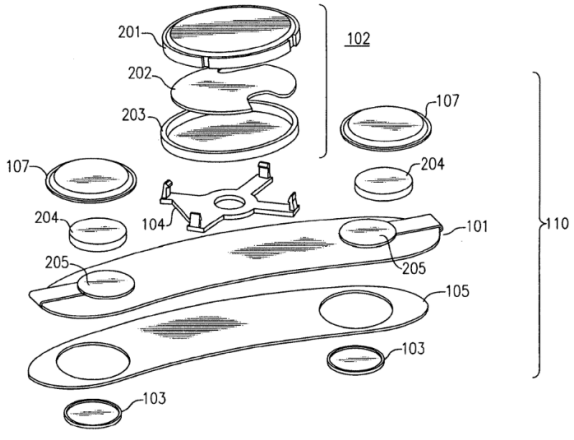
42. My analysis and opinions below are given from the perspective of a POSITA in this technological field in the relevant time frame, unless stated otherwise.

43. I satisfied the definition of a POSITA before the filing date of the application leading to the '007 Patent. I now consider myself an expert in the relevant field of technology for the '007 Patent.

44. In forming my opinions for this declaration, I have used the perspective of one of ordinary skill in the art as defined above. My opinions, however, would not be affected if a POSITA is defined as someone who has slightly more or slightly less experience than described above.

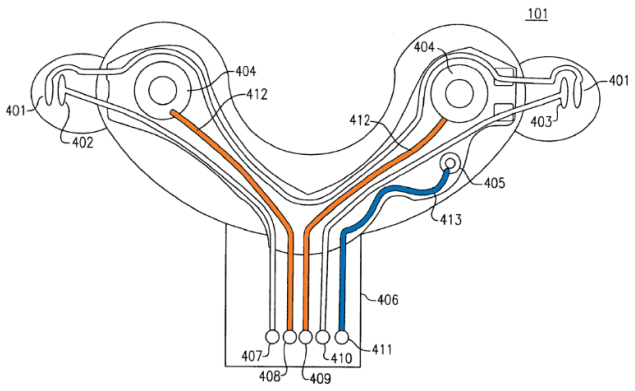
IV. SUMMARY OF THE '007 PATENT

45. The '007 Patent discloses a body-worn patient monitoring device that adhesively attaches to a patient's skin and measures physiological signals. Ex. 1001, Abstract, Claim 1. The body-worn patient monitoring device has two main components: a computation-communication module and a disposable electrode module. Ex. 1001, Claim 1, 4:58-5:4, Figure 2. The computation-communication module is attached to the disposable electrode module. Ex. 1001, Claim 1. In Figure 2, the body-worn patient monitoring device includes retention clip 104 that secures computation-communication module 102 to disposable electrode module 110.



Ex. 1001, Figure 2.

46. Disposable electrode module 110 includes flexible printed circuit layer 101, which is made from an insulating material. Ex. 1001, 4:58-5:4, Claim 1. The flexible printed circuit layer functions to transmit electrical signal via traces; the traces connect a connection pad to an electrode. Ex. 1001, 7:22-33. As shown below, the '007 Patent states that traces 412 (indicated in orange), which are preferably printed, "extend[] between conductive surface 404 and connection pads 408 and 409." Ex. 1001, Figure 4A (annotated), 5:12-16 (defining the conductive surface as part of the electrode). Further, the '007 Patent states that trace 413 (indicated in blue), "extend[s] between conductive surface 405 and connection pad 411." Ex. 1001, Figure 4A, 7:44-55. The traces are made from a resistive material. Ex. 1001, 7:50-55, Claim 1.

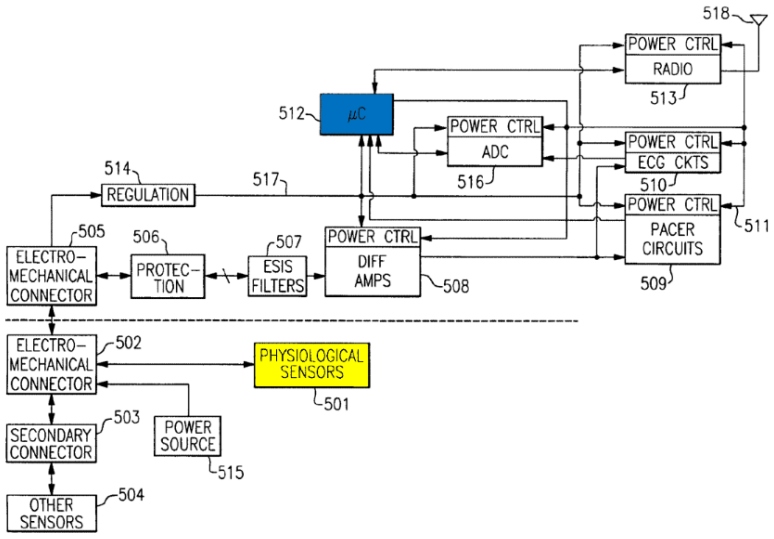


Ex. 1001, Figure 4A (annotated).

47. Based on the resistance of the traces and design of the device, the traces are "protect the communication-computation module" from defibrillation pulses. Ex. 1001, 7:50-55, Cl. 1. The '007 Patent states that the resistance is in the range of

"about 1 kilo ohm to about 10 kilo ohms." Ex. 1001, 7:46-48. The '007 Patent also explains the importance of such a determined range. Ex. 1001, 7:46-58. Below 1 kilo ohm, defibrillation pulses may change the resistance while a resistance of above 10 kilo ohms impairs the signal to noise ratio and thus impairs sensing of the signals. *Id.* In other words, the '007 Patent balances the needs of protection versus sensing.

48. Figure 5 also shows the path between each electrode and the computation-communication module. Ex. 1001, 11:29-46, Figure 5. In the block diagram of Figure 5, the physiological sensors for capturing an ECG difference potential are indicated in yellow. Ex. 1001, 11:29-46, Figure 5 (annotated). Electrodes are one example of the physiological sensors used for sensing electrical potential produced by the body. Continuing to reference Figure 5, physiological sensors 501 are electrically coupled to electromechanical connector 502, which is further connected to the processor for performing computational analysis on the detected signals. Ex. 1001, 11:33-43, Figure 5 (annotated), Figure 4A. The computation-communication module also includes a housing that contains this processor. Ex. 1001, Claim 7.

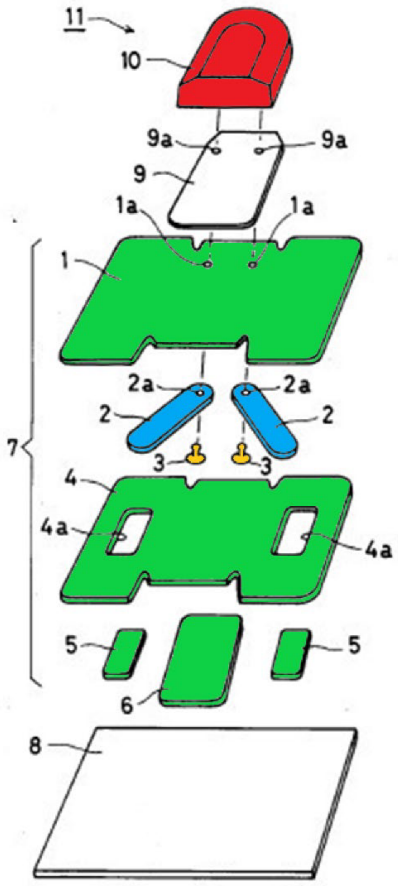


Ex. 1003, Figure 5 (annotated).

V. SUMMARY OF THE ART

A. Matsumura (Exhibit 1012)

49. Matsumura describes a waterproof wearable monitor for detecting bioelectric potential, addressing concerns regarding water submersion of the monitor. Ex. 1012, Abstract. Matsumura provides a bioelectric potential detector 11 comprised of disposable pad 7 (green) and reusable signal processor 10 (red). Ex. 1012, ¶ [0016], Figure 1 (annotated below). Disposable pad 7 further comprises first sheet 1, conductive material 2 (blue), hooks 3 (orange), second sheet 4, conductive gels 5, and double-sided adhesive tape 9. Ex. 1012, ¶ [0016]. Conductive material 2 creates a conductive path between conductive gel 5 and hooks 3, and hooks 3 provide a conductive path upwards through first sheet 1 and double-sided adhesive tape 9 to processor 10. Ex. 1012, ¶ [0019].



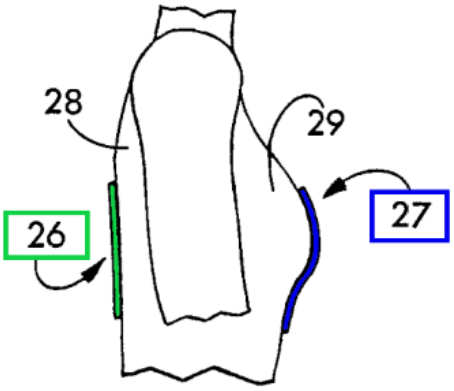
Ex. 1012, Figure 1 (annotated).

50. Matsumura explains "two pieces of conductive material 2 and two hooks 3 are arranged to transmit the bioelectric potential detected by the conductive gel 5, which is placed in the openings 4a of the second sheet 4." Ex. 1012, ¶ [0019]. Conductive material 2 is rod-shaped with one end that contacts conductive gel 5 and the other end that "has two holes 2a through which the protruding portions of hook 3 are inserted." Ex. 1012, ¶ [0019]. This configuration allows "the bioelectric potential detected by the conductive gel 5 [to be] transmitted through the conductive material 2 and the hooks 3." Ex. 1012, ¶ [0019].

51. Hooks 3 have a dual electrical and mechanical role in preserving the device's electrical and structural integrity by securely, but releasably, attaching the disposable pad 7 to the signal processor 10, while also transmitting bioelectric potential signals received from the conductive material 2 to the signal processor for processing. Ex. 1012, ¶¶ [0019], [0021].

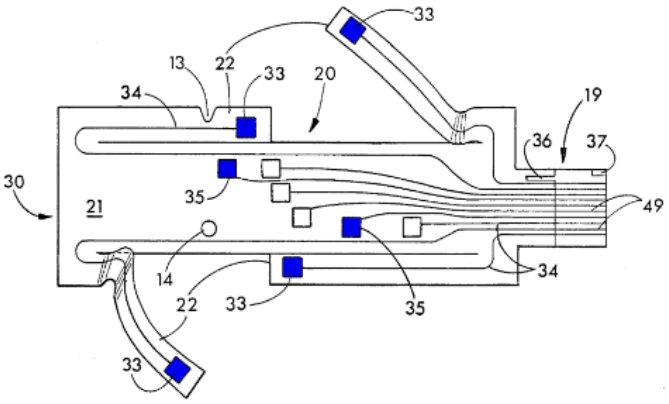
B. Kroll (Exhibit 1013)

52. Kroll discloses a flexible, disposable electrode belt device intended for use with medical diagnostic and therapeutic equipment. Kroll's electrode belt can "receiv[e] and transmit[] electric current and voltage." Ex. 1013, 2:41-47. The electrode belt comprises a unitary layered belt designed to adhere directly to a patient's skin, incorporating multiple electrode-contact areas strategically placed to interface with "specific anatomical locations" of the patient. Ex. 1013, 1:27-36. For example, the electrode belt can be placed on the patient's chest and back concurrently to deliver an electrical current through the chest of the patient. Ex. 1013, 4:44-47, Figure 3 (indicating the chest portion of the disposable electrode belt in blue and the back portion of the belt in green).



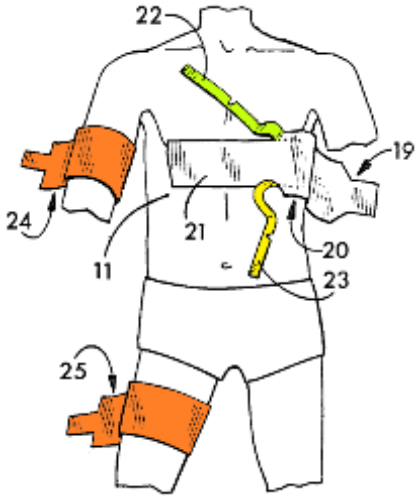
Ex. 1013, Figure 3 (annotated).

53. Figure 4 shows the electrodes (indicated in blue) of Kroll's disposable electrode belt. Ex. 1013, 4:48-68, Figure 4A (annotated). Each electrode "transmit[s] and receive[s] electric signals" over lead strip 34. Ex. 1013, 5:1-4. Because Kroll's device is intended for delivering therapy actively to a patient, Kroll provides various safety features. For example, "to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device," the lead strips may provide a "certain total lead strip resistance," thereby serving as a current limiter. Ex. 1013, 5:4-13. Other than protecting the patient, Kroll does not provide additional functions of its lead strips.



Ex. 1013, Figure 4A (annotated).

54. Moreover, Kroll's electrode belt also includes extendable side members 22 that extend from the electrode belt's main body for placement outside of the precordial region. Ex. 1013, 4:37-47, Figure 4A, Figure 2 (indicating the side members in yellow). The electrode belt may also be placed around the patient's limbs. Ex. 1013, 4:37-47, Figure 2 (indicating the embodiments placed around the limbs in orange). Each embodiment of Kroll is a specific size and structure to provide a desired therapeutic effect to a specific portion of the human body. In turn, Kroll can deliver electrical energy to the desired area, minimizing the chances of injuring the patient.



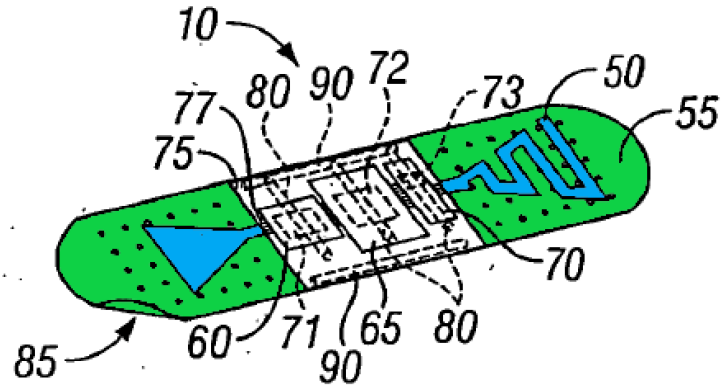
Ex. 1013, Figure 3 (annotated).

55. Kroll's electrode belt also relies on a "shielding layer" to safely administer therapeutic shocks. Ex. 1013, 6:17-24. This shielding layer prevents "interference from the device 10 with other medical diagnostic and therapeutic devices." Ex. 1013, 6:17-24. The electrode belt may include more than one shielding layer "to further shield the device from interference." Ex. 1013, 6:17-24. "[T]o minimize the risk of electrical shorting and patient shock in the event of device 10 failure," the shielding layer is "recessed inwardly at its outer boundaries." Ex. 1013, 7:3-13.

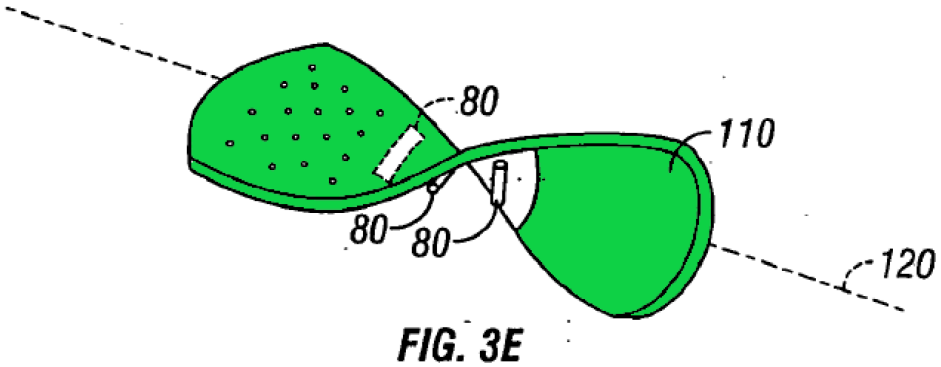
C. Ozguz (Exhibit 1014)

56. Ozguz describes a wearable sensor bandage for monitoring physiological characteristics, but does so with engineering ideals that are not grounded in the capabilities of the disclosure. Ex. 1014, ¶ [0003]; *see* Section VII.B.

Ozguz's module is described as having a "form similar to an adhesive bandage[,]" both in appearance and application to a patient's skin. Ex. 1014, ¶ [0003], [0007]. Ozguz's goal was to "overcome[] the need for [a] stiff substrate material that is normally used to support thin silicon to prevent breaking of the silicon and destruction of any micro-circuitry thereon." Ex. 1014, ¶ [0019]. The resulting device is described as a module that is approximately 30 to 60 mm in length and 10 to 20 mm in width, approximately the size of a Band-Aid. Ex. 1014, ¶ [0052]. Ozguz's module is shown in Figures 1 and 3E. Ex. 1014, Figures 1, 3E.



Ex. 1014, Figure 1 (in-part).



Ex. 1014, Figure 3E (annotated).

57. Ozguz states that its sensor bandage is either entirely disposable (*i.e.*, the entire module is discarded without any remains) or entirely reusable after sterilization. Ex. 1014, ¶ [0049] ("The sensor module can be sterilized in an autoclave, for example, between uses. Alternatively, the sensor bandages are made disposable and are discarded after monitoring a particular subject body 20 for purposes of good hygiene."). It is impossible to imagine any sterilization technique that would allow survivability of all the different materials, components, and connections, for example, because the components all have different properties and tolerances.

58. Ozguz further describes a sensor bandage including a flexible battery (flexible battery 105). Ex. 1014, ¶ [0046]. Flexible battery 105 is described as laying atop silicon substrates 60, 65, 70 and their respective integrates circuits ("ICs") 71, 72, 73. Ex. 1014, ¶ [0048]. Additionally, as shown in annotated Figure 3B below, flexible battery 105 (red) may lay on top of and/or cover the flexible substrate 55 (green) and the metallization 77 (blue). Ex. 1014, ¶ [0048].

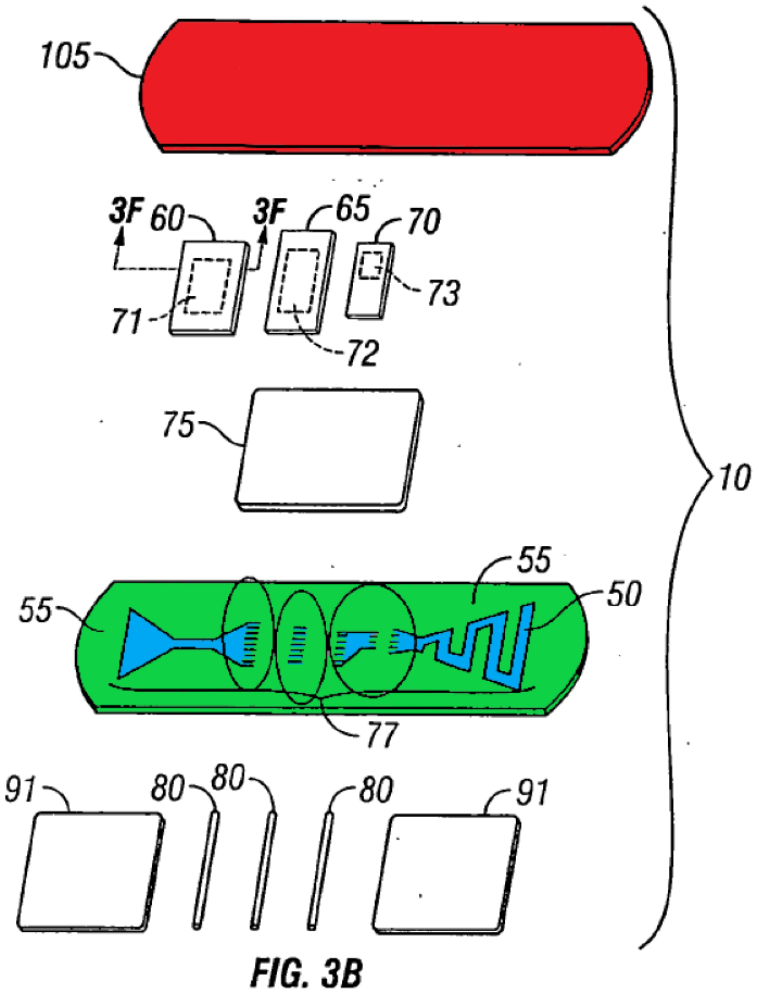


FIG. 3B

Ex. 1014, Figure 3B (annotated).

59. Additionally, Ozguz explains that metallization 77 connects electrodes 80 to the ICs, and the metallization is generally "integral with and forms part of the layer of the flexible substrate." Ex. 1014, ¶¶ [0047]-[0048]. A POSITA, reading the express disclosure of Ozguz, would have understood that Ozguz's module is a single unit, and none of the components are intended to be detached from the module except for adhesive pads 91. Ex. 1014, ¶ [0049]. Otherwise, the "sensor modules

are made disposable and are discarded after monitoring a particular subject body 20." Ex. 1014, ¶ [0049].

VI. SUMMARY OF OPINIONS

60. I understand that Dr. Heikenfeld advances Grounds 1 to 5 and in them alleges that Claims 1-6, 8, 10-15, 29, 31-35, 37-39, and 43-45 of the '007 Patent are obvious. I disagree with Dr. Heikenfeld's opinion.

61. In Ground 1, Dr. Heikenfeld opines that Claims 1, 2, 4 to 6, 8, 10 to 15, 29, 31, 37, 38, and 43 to 45 of the '007 Patent are obvious over the combination of Matsumura, Kroll, and General Knowledge of a POSA. It is my opinion that Ground 1 fails to render the Challenged Claims obvious for three reasons. First, Ground 1 does not teach or suggest "at least one series current-limiting resistor configured to protect the communication-computation module," as required by Claim 1 and 45. *See* Section VII.A.i. Second, Ground 1 does not teach or suggest a "a power source" as required by Claim 1. See Section VII.A.ii. Third, a POSITA would not have been motivated to combine Matsumura and Kroll. *See* Section VII.A.iii-iv. I understand that Dr. Heikenfeld challenges independent Claim 1 and 45 only under Grounds 1 and 45, such that Grounds 2-5 only address dependent claims.

VII. OPINIONS

A. Ground 1: Dr. Heikenfeld Fails to Establish that the Combination of Matsumura, Kroll, and General Knowledge of a POSITA

Renders Obvious Claims 1, 2, 4 to 6, 8, 10 to 15, 29, 31 37, 38, and 43 to 45

62. Dr. Heikenfeld opines that Claims 1, 2, 4 to 6, 8, 10 to 15, 29, 31 37, 38, and 43 to 45 are obvious over the combination of Matsumura, Kroll, and the general knowledge of a POSITA. Ex. 1009, ¶ 463. I disagree with Dr. Heikenfeld's opinion.

63. First, Dr. Heikenfeld's combination fails to render obvious Claim 1 because the combination does not teach or suggest claim element 1[l], which requires "at least one series current-limiting configured to protect the communication-computation module." Ex. 1001, Claim 1; *see* Section VII.A.i. For the same reason, Dr. Heikenfeld's proposed combination fails to render obvious Claim 45.

64. Second, Dr. Heikenfeld's combination fails to render obvious Claim 1 because the combination does not teach or suggest claim element 1[e], which requires "a power source to power the body worn patient monitoring device." Ex. 1001, Claim 1; *see* Section VII.A.ii. For the same reason, Dr. Heikenfeld's proposed combination fails to render obvious Claim 45.

65. Third, Dr. Heikenfeld fails to establish that a POSITA would have been motivated to combine Matsumura and Kroll. A POSITA would not have been motivated to combine Matsumura and Kroll (1) to protect Matsumura's circuitry or

(2) to make Matsumura's device smaller. Ex. 1001, Cl. 1; *see* Section VII.A.iii-iv. For the same reason, Dr. Heikenfeld's combination fails to render obvious Claim 45.

i. Ground 1 fails to render obvious claim element 1[l]

66. Claim element 1[l] requires "at least one series current-limiting resistor configured to protect the communication-computation module." Ex. 1001, Claim 1. Dr. Heikenfeld opines that a POSITA would have understood that the combination of Matsumura and Kroll, in view of the knowledge of a POSITA, renders obvious this element. Ex. 1009, ¶ 511. I disagree with Dr. Heikenfeld's opinion.

67. In support of his opinion that the claimed resistor is obvious, Dr. Heikenfeld relies on Kroll's lead strips, which "provide a certain total lead strip resistance." Ex. 1013, 5:1-10. However, Kroll's lead strips are not "configured to protect the communication-computation module." Ex. 1001, Cl. 1.

68. Instead, Kroll states that its lead strips "serve[] as a current limiter to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device." Ex. 1013, 5:8-13. In other words, Kroll's lead strips protect the patient; there is no disclosure in Kroll (and Dr. Heikenfeld does not identify any) establishing that the lead strips are configured to protect a communication-computation module as required by Claim 1.

69. Furthermore, unlike Kroll, the '007 Patent provides a detailed disclosure regarding how its claimed resistor is configured to protect the

communication-computation module. For example, the '007 Patent states that the "protective resistive traces be in a range between about 1 kilo ohm to about 10 kilo ohms." Ex. 1001, 7:46-48. The '007 Patent also explains the need for this range as it relates to "successive defibrillation pulses" and signal to noise ratio. Ex. 1001, 7:48-58. Aligned with this disclosure, a POSITA would have understood the range of resistance as a critical feature in effectively protecting the communication-computation module. Additionally, the '007 Patent details the structure of the device, the requirements, and various issues in designing and manufacturing its traces as a resistor over several columns of disclosure. *See* Ex. 1001, 7:46-11:6. Again, a POSITA would have understood this disclosure as explaining how to design a resistor to achieve the function of protecting the communication-computation module while also maintaining appropriate noise levels to achieve the function of signal sensing.

70. In view of this disclosure, a POSITA would have understood that the resistor of the '007 Patent was specifically designed for its function of protecting the communication-computation module while also getting a signal from the body with low noise as reflected in the language of Claim 1.

a. Dr. Heikenfeld improperly construes claim element 1[l]

71. Claim element 1[l] requires "at least one series current-limiting resistor configured to protect the communication-computation module." Ex. 1001, Claim 1.

Dr. Heikenfeld appears to argue, at least implicitly, that Kroll's lead strips would render this element obvious because the lead strips "would help safeguard Matsumura's signal processor/communication-computation module in the event of a patient being defibrillated." Ex. 1009, ¶ 515.

72. In my opinion, Dr. Heikenfeld is broadly reading claim element 1[l] as reciting a resistor that is merely "capable of" protecting the communication-computation module, which a POSA would have understood is different than a resistor "configured to" protect the communication-computation module. Further, Dr. Heikenfeld never opines that Kroll's resistors are specifically designed to protect a communication-computation module and function for sensing and instead relies on the disclosure that states Kroll's lead strips "protect a patient from shock." Ex. 1009, ¶ 514 (citing Ex. 1013, 5:8-13, 5:31-33).

73. To the extent that Dr. Heikenfeld is reading claim 1[l] as reciting a resistor that is merely capable, Dr. Heikenfeld's position fails for two reasons. First, Dr. Heikenfeld's reading of claim element 1[l] is overly broad. For the reasons discussed in Section VII.A.i.b, a POSITA would not have understood Claim 1 as reciting mere capability. Rather, in view of the claim language and corresponding disclosure in the specification, a POSITA would have understood that the claimed resistor is specifically designed for its claimed function of protecting the communication-computation module while sensing signals from the body.

Additionally, I note that Dr. Heikenfeld did not identify any disclosure in the '007 Patent or provide any explanation as to why a POSITA would have understood the claim element 1[l] as only requiring a resistor that is capable of protecting the communication-computation module. Second, even if Dr. Heikenfeld's overly broad reading applied, Dr. Heikenfeld does not establish that Kroll's resistors would actually function to protect the communication-computation module. *See* Section VII.A.i.b.

b. Dr. Heikenfeld's combination fails even under his improper interpretation of claim element 1[l]

74. Because neither Matsumura nor Kroll teach or suggest resistors configured to protect the communication-computation module, Dr. Heikenfeld alleges that "a POSA would understand the EC-13 standard to require resistors that protect the communication-computation module during a defibrillation shock." Ex. 1009, ¶ 515. Even if a POSITA would have understood the EC-13 standard to have such a requirement, it is not necessarily true, and Dr. Heikenfeld has not established that the EC-13 standard prescribed or requires any specific circuit elements—such as current-limiting resistors for protecting the device—as a means to accomplish the protection. Moreover, Dr. Heikenfeld does not argue that Kroll's lead strips conform to the EC-13 standard anyway, and his conclusion that any resistor, even Kroll's lead

strips, would serve as a current limiting resistor configured to protect the communication-computation module is misguided and untrue.

ii. Ground 1 fails to render obvious claim element 1[e]

75. Claim element 1[e] requires "a power source to power the body worn patient monitoring device." Ex. 1001, Claim 1. Dr. Heikenfeld opines that a POSITA would have understood Matsumura's teachings as rendering this claim element obvious. Ex. 1009, ¶ 491. I disagree with Dr. Heikenfeld's opinion.

76. Matsumura only recites "power source" one time when describing an entirely different prior art monitor that was "comprised of a conduction portion (equivalent to an electrode element), ***a power source***, a potential difference detection portion, and a wireless transmitting/receiving portion." Ex. 1012, ¶ [0004]. Matsumura describes this prior art monitor's components as "embedded in a sealing material" and "not detachable from the conduction portion, which is equivalent to the electrode element." Ex. 1012, ¶ [0004]. In other words, the prior art monitor does not include a disposable and non-disposable portion, which made the prior art monitor "unhygienic to reuse" and "uneconomical to use it as a disposable device." Ex. 1012, ¶ [0004]. Thus, the recited power source in Matsumura is fundamentally different than the invention disclosed in the remainder of Matsumura, which itself requires the bio-pad to be detachable from the signal processor, and otherwise does not refer to or identify any power source. *See, e.g.*, Ex. 1012, ¶¶ [0012] ("[T]he

bioelectric potential detector is hygienic because the ***bioelectrode pad is disposable***, the ***signal processor is economical because it is reusable***, and the ***reusable signal processor and the disposable bioelectrode can be easily attached and detached*** before and after use and are waterproofed.").

iii. A POSITA would not have been motivated to combine Matsumura and Kroll

77. Dr. Heikenfeld opines that a POSITA would have been motivated to combine Matsumura and Kroll. I understand that he contends that a POSITA would have been motivated to combine Matsumura and Kroll for two reasons: (1) reduce the size of Matsumura's device; (2) protect the patient from potential shock; and (3) to protect the circuitry of the device against possible defibrillation. Ex. 1009, ¶ 469-470. I disagree with Dr. Heikenfeld's motivation to combine opinion in its entirety. I disagree that a POSITA would have been motivated to combine Matsumura and Kroll for either reason.

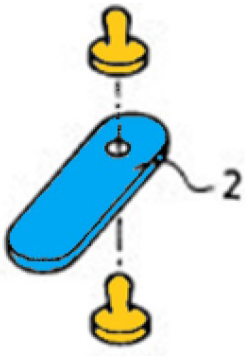
78. First, Dr. Heikenfeld's opinion is not based on any teaching in Matsumura or Kroll. Second, Dr. Heikenfeld fails to set forth any reason ***why*** a POSITA would have combined the references.

a. A POSITA Would Not Have Been Motivated to Modify *Matsumura's* Conductive Rods and Hooks with Screen Printed Resistors

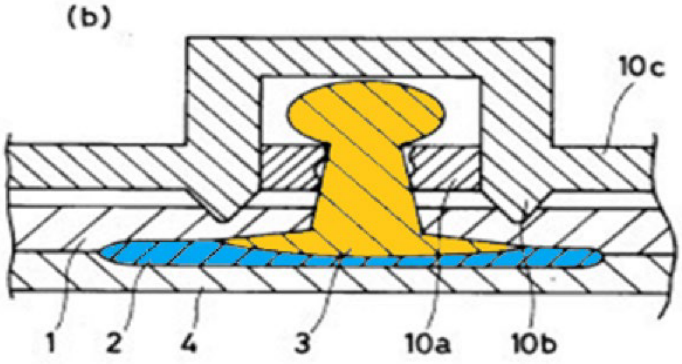
79. Dr. Heikenfeld opines that the combination of Matsumura and Kroll renders obvious claim element 1[m] and 1[n], which require "at least one series current-limiting resistor being screened on a flexible substrate," and "at least one series current-limiting resistor being in the form of resistive traces," respectively. Ex. 1001, Claim 1. I disagree with Dr. Heikenfeld's opinion because a POSITA would not have been motivated to combine use Kroll's lead strips to protect Matsumura's signal processor. This is because the proposed combination would make Matsumura's device much larger, and the proposed combination renders Matsumura's device inoperable for its intended purpose; the combination destroys Matsumura's primary goal of waterproofing.

80. Matsumura discloses that its bioelectrode pad comprises rigid, rod-shaped "conductive material 2," protruding conductive "hook 3," and "conductive gel 5." Ex. 1012, ¶ [0016]. These conductive materials are essential to the operation of Matsumura's waterproof design. *See, e.g.*, Ex. 1012, ¶ [0006] ("In order to enable hospitalized or home-bound patients/subjects to measure electrocardiograms while showering or bathing, a waterproof bioelectric potential detector is first required. [And] [t]he present invention was made in order to achieve these objectives.").

81. In this regard, Matsumura's processor and housing are located separate and apart from the bioelectric pad. Ex. 1012, ¶ [0016], Figures 1-2. To accomplish the waterproof design, there must be a vertical conductive protrusion that allows for the electrical flow of signals from the bio-pad to the processor. Ex. 1012, ¶ [0024], [0027], Figures 4-5. As shown in Figures 4 and 5, to provide this waterproof design, the rigid nature of conductive rods 2 provides a stable support for hook 3 to clamp. Ex. 1012, ¶ [0019], [0021], Figures 4-5. Specifically, "the protruding portions of the hook 3" extend upwards "from the back side of the conductive material 2," clamping both sides of conductive rod 2. Ex. 1012, ¶ [0021], Figures 4(b), 8. These components are intentionally and necessarily positioned this way to provide the dual electrical and mechanical connection essential to Matsumura's device. Ex. 1012, ¶ [0019].



Ex. 1012, Figure 8 (annotated).



Ex. 1012, Figure 4(b) (annotated).

82. Thus, Dr. Heikenfeld ignores Matsumura's express teachings and opines that "it would have been obvious to a POSA that Matsumura's flexible substrate includes electrical connections, i.e., traces." Ex. 1009, ¶ 519. Dr. Heikenfeld's opinion completely bypasses the fact that Matsumura includes solely non-printed circuitry, and moves on to his opinion that "[a] POSA would understand Kroll's disclosure of 'lead strips' as referring to a 'trace' as recited by the '007 patent" and that "the terms 'lead' and 'trace' are often used interchangeably." Ex. 1009, ¶ 524.

83. Dr. Heikenfeld's opinion that the terms "lead" and "trace" are used interchangeably, while also opining that Matsumura's non-printed circuitry are also somehow "traces" significantly undermines Dr. Heikenfeld's opinion. Matsumura's electrical connections are three-dimensional conductive rods and hooks. Ex. 1012, ¶ [0019]. There is no disclosure in Matsumura that suggests replacing its rigid conductive rods (conductive material 2) and hooks or their compatibility with

Kroll's screen printed resistive traces. Nor does Dr. Heikenfeld explain how Matsumura's waterproof goals could be accomplished without the mechanical structural support from the conductive rods, which serve to maintain waterproof electrical and mechanical connections and contacts.

84. Accordingly, I disagree with Dr. Heikenfeld's opinion that "[i]t would have been obvious to a POSA to combine Matsumura's teaching of a communication-computation module on a flexible printed medium with Kroll's teaching of resistive traces screened on a flexible, wearable medium[.]" Ex. 1009, ¶ 520. For the same reasons, I disagree with Dr. Heikenfeld's opinions regarding claim element 1[n].

b. A POSITA would have understood that adding Kroll's printed resistive traces would frustrate Matsumura's goal of a waterproof device

85. Dr. Heikenfeld characterizes Matsumura as having a "flexible substrate [that] includes electrical connections (*i.e.*, traces)." Ex, 1009, ¶ 518. Then, Dr. Heikenfeld alleges that because Kroll discloses "conductive ink compound" that comprises its resistive trace is applied to a base layer "by means of a silk screen process[,]" "[i]t therefore would have been obvious to a POSA to combine Matsumura's teaching of a communication-computation module on a flexible printed medium with Kroll's teaching of resistive traces screened on a flexible,

wearable medium, which would meet this limitation." Ex. 1009, ¶¶ 519-520. I disagree with Dr. Heikenfeld's conclusions.

86. Matsumura's conductive rods 2 and hooks 3 necessarily do not comprise printed traces, but Dr. Heikenfeld apparently assumes otherwise. Dr. Heikenfeld appears to consider Matsumura's circuitry as printed and therefore easy to combine with Kroll's printed electronics. This combination, however, would directly undermine the waterproof functionality central to Matsumura's device because the combination fails to consider the electrical and mechanical function of Matsumura's rigid, rod-shaped conductive material 2 and hooks 3.

87. Matsumura discloses:

> By using the structure described above, the housing of the signal processor 10, the part that transmits bioelectric potential from the bioelectrode pad 7 to the signal processor 10, i.e. engagement portion between the protruding part of the hook 3 and the hook engagement portion 10a is waterproofed, thus the entire bioelectric potential detector 11 is waterproofed.

Ex. 1012, ¶ [0027]. A POSITA would not have been motivated to replace the conductive rods 2, to which the hook "clamps" onto both sides, with printed circuitry. Ex. 1012, ¶ [0021]. This is because the POSITA would have known that the hooks and conductive material 2 provide the necessary electrical and mechanical structural integrity required for waterproofing "the entire bioelectric potential detector." Ex. 1012, ¶¶ [0027]-[0030]. Dr. Heikenfeld is silent with regard to the

device being waterproof and fails to recognize or address the hooks' electrical and mechanical role altogether. For these same reasons, and because Matsumura's device has achieved its desired dimensions, a POSITA would not have been motivated to combine Matsumura and Kroll to protect Matsumura's device, or to reduce Matsumura's size in view of the much larger device disclosed in Kroll.

c. A POSITA would not have been motivated to combine Matsumura and Kroll to reduce the size of Matsumura's device

88. I understand that Dr. Heikenfeld contends that a POSITA would have been motivated to combine Matsumura and Kroll to reduce the size of Matsumura's device. Ex. 1009, ¶ 470. Reducing the size of Matsumura's device is not a sufficient motivation to combine because Matsumura's device has already achieved a sufficiently miniature device, and a POSITA would not have been motivated to further reduce the size. This is particularly true because Kroll's device is much larger than Matsumura's, which would deter a POSITA, from the outset, from looking to Kroll to modify Matsumura's device.

89. First, a POSITA would have understood that Matsumura already achieves its desired size, and Dr. Heikenfeld does not identify any disclosure that the size of Matsumura device is an issue or that Matsumura wants to further limit the size. Second, Kroll provides a therapeutic device that wraps around the patient. Notwithstanding all the other design considerations important to resistor design and

selection, printed traces would create resistors larger than resistors that would be used in Matsumura's signal processor (although Matsumura does not even mention any resistors) and would have the effect of increasing the size of the overall device.

90. A POSITA would not have looked to Kroll's larger device to make Matsumura's device smaller. Finally, a POSITA would have recognized the significant obstacles in implementing Kroll's lead strips in Matsumura. Dr. Heikenfeld does not address a single one of these issues.

i. Matsumura already achieves its size goals

91. A POSITA would have recognized that Matsumura already achieves this goal; therefore, a POSITA would not have been motivated to add Kroll's resistive strips to Matsumura's device to reduce the size. Matsumura states that the claimed invention "achieves the[] objective" of providing a "cable-free and compact" bioelectric potential detector. Ex. 1012, ¶¶ [0006]-[0007].

92. Dr. Heikenfeld does not identify any disclosure in Matsumura to establish that the size is an issue, or that Matsumura intends to further reduce the size. Again, this is because the disclosure shows that Matsumura already achieves its desired "compact" size. Ex. 1012 ¶ [0006].

93. Thus, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to replace any conventional resistors in Matsumura (to the extent that

resistors are even disclosed by Matsumura, which they are not) with resistors with Kroll's lead strips to further a goal that Matsumura already achieves.

94. Dr. Heikenfeld relies on the combination of Matsumura and Kroll to opine that the references teach claim element 1[d], which recites "at least one electrical trace being made at least in part from a resistive material." Ex. 1012, Claim 1. Dr. Heikenfeld also relies on the combination of Matsumura and Kroll to opine that the references teach claim element 7[e], which recites "electrical traces defined between the at least two electrodes and a connection pad." Ex. 1012, Claim 7. This proposed combination, however, still relies on modifications that are two critical steps removed from Matsumura's disclosed device. Specifically, the proposed combinations include (1) Matsumura in view of the "general knowledge" of a POSITA to obtain a printed circuit layer (*see supra* Section VII.A.iii.a), and (2) Matsumura in view of Kroll to further modify the printed circuit layer to be made of printed resistive ink (*see supra* Section VII.A.iii.b). Ex. 1009, ¶ 470, 796.

95. In my opinion, even if a POSITA would have been motivated to reduce the size of Matsumura's device, a POSITA would not have done so by replacing "***conductive*** material 2" with Kroll's ***resistive*** lead strips. While it is a standard characteristic of all conductive materials to have some resistance, this does not mean that conductors and resistors are interchangeable or functionally equivalent. Matsumura specifically discloses two options of material that may comprise

conductive material 2, neither of which result in a predominantly resistive material. Ex. 1012, ¶ [0020] ("The conductive material 2 can be a carbon sheet or a PET sheet coated with conductive Ag/AgCl."). As a result, the proposed modification based on Kroll's resistive ink strips would contradict Matsumura's explicit teachings.

96. Dr. Heikenfeld also opines that a POSA would know that adding Kroll's resistive strips to replace "conventional resistors in [Matsumura's] signal processor" would reduce the size of Matsumura's device. However, in my opinion, a POSA would have known that one cannot simply replace resistors in a circuit with large resistive lead strips. Dr. Heikenfeld's assertion oversimplifies the design considerations and overlooks the distinct electrical and mechanical characteristics of the respective components. This is true because discrete resistors used in conventional signal processing circuits, such as would be found internal in Matsumura's signal processor, are functionally and structurally differently than resistive lead strips, and have different purposes. *See* Section VII.A.iii.b.

97. For example, although Matsumura does not disclose any resistors, signal processing may include internal resistors, which cannot be created as printed resistive traces.

98. Thus, a POSITA would have understood that removing the resistors out of Matsumura's reusable signal processor and adding the resistive strips to Matsumura's disposable bioelectric pad is not a simple substitution.

99. Resistors used in signal processors, for example, are precision components selected to provide specific and stable resistance values under tightly controlled tolerances. These resistors are typically chosen based on the needs of the signal conditioning or processing circuitry. Their placement and value are determined through careful circuit design and simulation. Further, the voltage range requirements, resistance value variability tolerances, use variability constraints, geometric constraints, and the necessity for integration with amplifiers and filtering circuits differ substantially for resistors intended for gain-setting, filtering, signal biasing, and feedback applications. These resistors are designed to ensure reliable signal handling (processing) performance.

100. In contrast, resistive lead strips typically have a resistance that is distributed and imprecise; the resistance varies depending on the length, geometry, material properties, and even temperature of the lead strip. A POSA would have understood that such resistive lead strips are not suitable substitutes for precision components within a reusable signal processor, where consistent and reliable performance is critical. Printed resistive traces designed as current limiters can also tolerate greater variation and do not require the same level of precision, stability, or integration complexity. Thus, the two categories of resistive components—precision discrete resistors for gain, filtering, and feedback versus printed resistive traces serving as current limiters—are fundamentally different in their electrical,

mechanical, and application requirements. Therefore, I do not agree that a POSA would have been motivated to make this modification, as this purported problem is not even mentioned in Matsumura likely because Matsumura has already achieved its preferred size goals.

101. Thus, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to replace any conventional resistors in Matsumura with resistors with Kroll's lead strips to further a goal that Matsumura already achieves. To conclude otherwise, Dr. Heikenfeld ignores the teachings of Matsumura and Kroll.

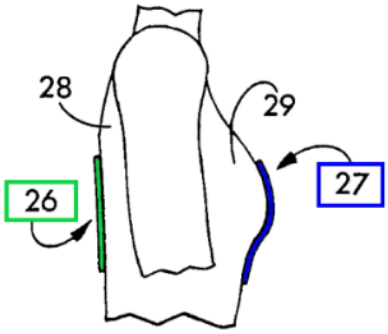
ii. Kroll's device is designed to wrap around the patient's body

102. Even if motivated to make Matsumura's device smaller (which I disagree is the case), a POSITA would not have looked to the much larger device of Kroll.

103. Kroll's device wraps around the patient's body to administer therapeutic shocks. Specifically, Kroll discloses an "electrode belt…for receiving and transmitting electric current or voltage for use on the body of a patient." Ex. 1013, Abstract, Figure 1. The electrical current is transmitted "to specific anatomical locations for therapeutic purposes." Ex. 1013, 1:27-36.

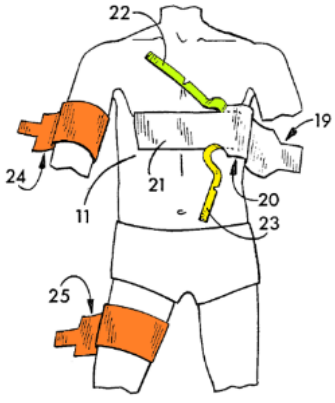
104. For example, the electrode belt is placed on the patient's chest and back. Ex. 1013, 4:44-47, Figure 3 (indicating the chest portion of the best in blue and the

back portion of the belt in green). This placement is required to transmit the current through the chest to the back, allowing Kroll to target specific areas for therapeutic purposes. Ex. 1013, 4:44-47, Figure 3.



Ex. 1013, Figure 3 (annotated).

105. In another example, Kroll's electrode belt has extendable side members that extend from the electrode belt's main body for placement outside of the precordial region. Ex. 1013, 4:37-47, Figure 2 (indicating side members in yellow). Kroll's device may also be placed around the patient's limbs. Ex. 1013, 4:37-47, Figure 2 (indicating the embodiments placed around the limbs in orange).



Ex. 1013, Figure 3 (annotated).

106. Dr. Heikenfeld's argument that a POSITA would have looked to Kroll's belt device to make Matsumura's device smaller ignores the teachings and size of each reference. Kroll's lead strip highlights this issue. Based on Kroll's disclosure, a POSITA would have recognized that Kroll's lead strips, which are placed on the extendable side members, are specifically designed to make the electrode belt larger. Ex. 1013, 4:37-47. With the lead strips on the extendable side members, the Kroll's electrodes can be placed outside of the precordial region. Ex. 1013, 4:37-47.

107. Thus, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to make Matsumura smaller by adding resistors with Kroll's traces to Matsumura. To conclude otherwise, Dr. Heikenfeld ignores the teachings of each reference.

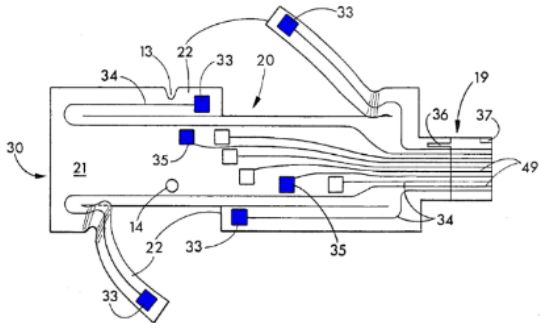
d. A POSITA would not have been motivated to combine Matsumura and Kroll as a solution to electrical overload.

108. I understand that Dr. Heikenfeld contends that a POSITA would have been motivated to combine Matsumura and Kroll to limit current because limiting current would (1) protect patients from shock and (2) protect the sensitive electronics inside the device. Ex. 1009, ¶ 468-469. Specifically, Dr. Heikenfeld states that Kroll uses "lead strips of a known resistivity to limit the current transmitted between the worn device and the patient." Ex. 1009, ¶ 468. Based on this teaching, Dr. Heikenfeld opines that a POSITA "would have been motivated to incorporate

Kroll's teaching of resistive 'lead strips' with the body-worn monitoring device disclosed by Matsumura." Ex. 1009, ¶ 469. I disagree.

109. Dr. Heikenfeld's position does not arise from the teachings of Matsumura or Kroll. In my opinion, a POSITA would not have been motivated to limit the current from Matsumura's device to the patient because there is no current being transmitted from Matsumura's device to the patient. Dr. Heikenfeld overlooks the differences between Matsumura's device and Kroll's device to conclude that a POSITA would have been motivated to combine Matsumura's and Kroll to limit current from the device to the patient.

110. Kroll provides a disposable electrode belt "for receiving and transmitting electric current and voltage." Ex. 1013, 2:41-47. Figure 4 shows an example of the disposable electrode belt, which includes electrodes (indicated in blue). Ex. 1013, 4:48-68, Figure 4A (annotated). Each of the electrode "transmit and receive electric signals" over a lead strip. Ex. 1013, 5:1-4. "[T]o protect a patient from shock due to malfunction of the device 20 or of a complementary medical device," the lead strips may provide a "certain total lead strip resistance," thereby serving as a current limiter. Ex. 1013, 5:4-13.



Ex. 1013, Figure 4A (annotated).

111. Based on the function of Kroll and its disclosure, a POSITA would have understood that that the lead strips protect the patient from shock by limiting the current from the device to the patient. Dr. Heikenfeld acknowledges this disclosure, stating that "Kroll discusses the use of the lead strips in the context of protecting a patient from 'shock,' from the worn device or 'a complementary medical device.'" Ex. 1009, ¶ 468.

112. However, contrary to Dr. Heikenfeld's analysis, the same considerations of protecting the patient by limiting current from the device to the patient do not apply to Matsumura. Matsumura's device simply detects ECG signals. Namely, Matsumura's device is "a bioelectric potential detector that can measure bioelectric potential (electrocardiograms)." Ex. 1012, Abstract. These bioelectric potential signals processed, transmitted to the signal processor, and then wirelessly transmitted to a portable monitor. Ex. 1012, Abstract.

113. A POSITA would have understood that Matsumura's detection device does not transmit current to the patient, and there is no current going from Matsumura's device to the patient. Matsumura does not provide any disclosure on transmitting a current from its device to the patient and Dr. Heikenfeld points to none. Moreover, a POSITA would have understood that there is no reason for Matsumura to transmit a current to the patient. Nor does Matsumura include components to transmit current to the patient. At base, Matsumura is a device that only detects ECG signals.

114. A POSITA would have understood that Matsumura's device simply monitors the patient without transmitting a current to the patient. Thus, a POSITA would not have been motivated to limit current from Matsumura's device to the patient because there is no current to limit. For the same reason, a POSITA would not have seen any benefit from adding Kroll's lead strips into Matsumura's device.

115. For these reasons, I disagree with Dr. Heikenfeld, and Dr. Heikenfeld fails to establish a motivation to combine Matsumura and Kroll based on "a desire to protect patients from potential shock." Ex. 1009, ¶ 768.

i. Dr. Heikenfeld fails to establish that Kroll's lead strips would protect Matsumura's electronics.

116. To the extent a POSITA would have been motivated to combine Matsumura and Kroll, Dr. Heikenfeld fails to establish that Kroll's lead strips would

protect Matsumura's electronics. Dr. Heikenfeld's provides no argument or supporting evidence that Kroll's resistive lead strips protect Matsumura's electronics.

117. Dr. Heikenfeld only concludes that "Kroll's resistive lead strips would help to … (ii) protect the sensitive electronics inside the device from shock due to electricity outside of the device, such as that caused by a defibrillator." Ex. 1009, ¶ 468. Dr. Heikenfeld's opinion is baseless and fails. Regardless, a POSITA would not have been motivated to combine any aspect of Kroll, including Kroll's resistive lead strips, with Matsumura to achieve the claimed invention, as doing so requires modifying Matsumura in view of the "General Knowledge" of a POSITA, and further in view of Kroll. This proposed combination undermines Matsumura's device's core functionality, size, and mechanical structure, and a POSITA would not have been motivated to combine Matsumura, Kroll, and the "General Knowledge" of a POSITA.

iv. Dr. Heikenfeld fails to address the obstacles in implementing Kroll's lead strips in Matsumura's device

118. Kroll's lead strips are originally intended for the large, body-area applications of Kroll's electrode belt. In contrast, Matsumura provides a smaller, compact device. Moreover, Matsumura does not even disclose or describe resistors, and any resistors that would be present in Matsumura's device would be internal

resistors (*i.e.*, located in the signal processor) and would have very specific size tolerance and other constraints. A POSITA would have recognized the substantial technical difficulties that must be overcome to incorporate Kroll's lead strips in Matsumura's device. Dr. Heikenfeld does not acknowledge or address any of these technical difficulties.

119. Below, I list non-limiting examples of technical difficulties that a POSITA would have to consider when implementing the resistors of Kroll in Matsumura's device. First, a POSITA would have to select appropriate resistive materials for the conductive trace while also considering the specific resistivity, geometry, and reliability requirements to achieve reliable signal transmission and safety.

120. Second, a POSITA would be required to decide the layered, or overlapping, structure while using multiple materials to precisely achieve the target resistance and overall trace length for sensing and voltage discharge and for minimizing change post high voltage event. This complex issue underscores the necessity of controlled layering techniques to ensure trace and device design goal.

121. Third, a POSITA would need to balance the size and resistance of the trace, particularly managing the interplay between minimizing noise, safely discharging power during high-voltage events, and compensating for variations in trace resistance following multiple high-voltage occurrences, which requires an

understanding of detailed aspects related to transient response, resistance change and variability, and safety margins.

122. Fourth, a POSITA would have to design contact pad shapes that effectively reduce arcing risks, an engineering consideration emphasized as crucial within the context of miniature electrode structures, such as Matsumura's device.

123. Fifth, a POSITA would have to manage trace spacing in a miniatured device to minimize arcing potential, for example, a spacing at 3mm/kV. This would also require developing innovative coating methods involving insulating dielectric coatings to reduce spacing requirements significantly (down to 0.01mm/kV), an approach that would fall far beyond POSITA's capabilities without substantial experimentation with the complexities regarding trace properties and dielectric properties and manufacturing variability.

124. Sixth, a POSITA would have recognized the necessity and complexity of physically validating the design through functional simulations and experimental verification, underscoring the extensive and unpredictable experimentation required, an aspect reinforced by the detailed iterative testing procedures described.

125. In sum, the ability to address these multifaceted considerations would have been beyond the routine knowledge and skills possessed by a POSITA and would require expertise spanning across multiple disciplines. Dr. Heikenfeld does not address a single technical issue with his combination, which a POSITA would

have recognized. Moreover, a POSITA would not be able to use Kroll's disclosure. Kroll provides only sparse and insufficient guidance regarding these complex and interrelated challenges, underscoring that substantial research and extensive, non-routine experimentation would have been required to achieve the integration proposed by Matsumura, as further evidenced by my declaration and technical analyses provided within the scope of this matter.

126. Thus, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to combine Matsumura and Kroll in view of the significant technical obstacles.

B. Ground 2: Dr. Heikenfeld Fails to Establish that the Combination of Matsumura, Kroll, and General Knowledge of a POSITA or Matsumura, Kroll, Ozguz, and General Knowledge of a POSITA Renders Obvious Claims 1, 2, 4, 5, 14, 15, and 43 to 45

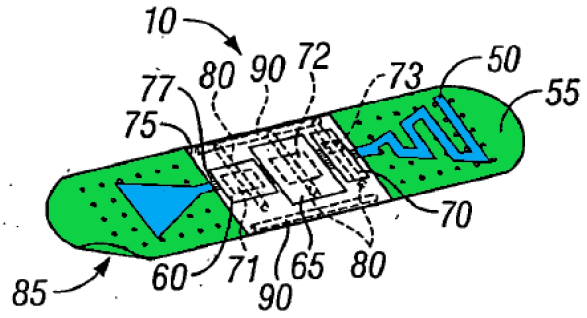
127. As a preliminary matter, Dr. Heikenfeld's opinions set forth in Ground 2 fail for the same reasons discussed above in Section VII.A, for Ground 1.

128. Further, Dr. Heikenfeld opines that a POSITA would have been motivated to combine Matsumura with either Kroll or Ozguz because "[a] POSA would have been able to incorporate Kroll's resistive traces and Ozguz's circuitry design into Matsumura's detector with minimal design impact using methods such as screen-printing, a well-known technique for printed circuit board manufacture" Ex. 1009, ¶ 635. I disagree with Dr. Heikenfeld's opinion.

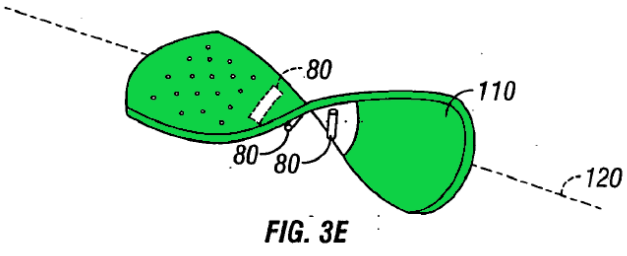
i. A POSITA would not have been motivated to combine Matsumura, Kroll, and Ozguz

129. In contrast with Dr. Heikenfeld's opinion, Ozguz's disclosure specifically teaches away from using printed circuit board materials. Ozguz states: "Use of rigid circuitry is due to the rigid nature of conventional microcircuit materials such as silicon and printed circuit board materials. The result is that the circuitry is inflexible, if not bulky, and is ***unsuitable for comfortably adhering and conforming to a localized portion of a human body***." Ex. 1014, ¶ [0004].

130. This teaching is supported by the rest of Ozguz's disclosure. For example, Ozguz is entirely focused on a thin, flexible monitor as thin as a bandage:



Ex. 1014, Figure 1 (in-part).



Ex. 1014, Figure 3E (annotated).

131. Dr. Heikenfeld admits that "Matsumura does not discuss the specific circuit design or architecture used to perform" detecting, processing, and transmitting bioelectric signals. Ex. 1009, ¶ 629. Then, Dr. Heikenfeld alleges that "[t]o the extent that the proper circuit design or architecture was not within the knowledge of a skilled artisan, an appropriate circuit design is disclosed by Ozguz." Ex. 1009, ¶ 630. I disagree with Dr. Heikenfeld's conclusions.

132. There are several reasons why a POSITA would not have looked to Ozguz "to incorporate the specific design and structure of circuits and electronic components taught by Ozguz." Ex. 1009, ¶ 630.

133. First, Ozguz includes printed electronic traces, and as discussed above in Section V.C, a POSITA would unequivocally not have been motivated to replace Matsumura's rigid, three-dimensional conductive rods and protruding hooks with printed circuity. *See supra* Section VII.A.iii.

134. Second, when considered in combination with Matsumura and Kroll, Ozguz provides no motivation for a POSITA to combine these references in a way that would lead to the claimed invention. Ozguz's concepts, as discussed further below, are speculative and futuristic, lacking the practical enablement required for a POSITA to build upon them in a meaningful way. The combination of Matsumura's rigid conductive rods and hooks with Ozguz's speculative flexible technology on its bandage is not suggested by any of the cited references. A POSITA would not have

been motivated to replace Matsumura's rigid, waterproof components with speculative, non-enabled flexible electronics as proposed by Ozguz.

135. Third, integrating Kroll's resistive traces with the teachings of Ozguz would not be a logical step for a POSA, as Ozguz's reference does not provide practical details on integrating such large technologies in a bandage monitor device. The challenges associated with flexible power systems, wireless communication, and environmental protection make any combination with Matsumura and Kroll unworkable. Thus, the combination of these references—Matsumura, Kroll, and Ozguz—lacks the motivation necessary to support an obviousness rejection.

a. A POSITA Would Not Have Relied on Ozguz to Reach the Challenged Claims

136. Ozguz provides a sensor bandage that uses futuristic flexible batteries as part of the bandage. At the time of Ozguz's claimed priority date (2005) and at the time of the '422 Patent's priority date (2006), flexible batteries were not viable or commercially available in the form described or required in Ozguz. Flexible battery technology was even more unrealistic given the required ability to bend and stretch in Ozguz's sensor bandage.

137. Conceptually, flexible batteries may have been proposed or theoretically envisioned, but the technology to implement flexible batteries in a real-world, realistic device was in its infancy, and its availability was far from practical

and not within the skills of a POSITA. In other words, a POSITA, relying on the state of the art at the time of the invention, would not have considered it possible to use flexible battery technology as described in Ozguz.

138. Ozguz suggests the use of integrated flexible batteries to power the biomonitor. *See, e.g.*, Ex. 1014, ¶ [0019]. However, at the time of the invention, flexible batteries were not capable of supporting extended use without frequent recharging or replacement. Ozguz oversimplifies the real-world constraints on battery capacity, longevity, and energy efficiency, overlooking the fact that flexible battery technologies at that time were not sufficiently advanced to support the sustained, low-power requirements of continuous physiological monitoring. These flexible batteries lacked the reliability and durability needed to power such a device over extended periods, and in the context of a patient wearable medical device where patient safety is of the upmost importance, a flexible battery would not have been considered a suitable option. Importantly, the miniature size and layered structure of Ozguz's device would significantly increase the risk of thermal overheating in the flexible battery, making the design impractical for real-world use.

139. Additionally, a POSITA, understanding the technological and economic landscape at the time of the invention, would have recognized that incorporating a flexible battery as described in Ozguz would be inconsistent with the cost-effective solution sought by the inventors of the '007 Patent. Ex. 1001, 2:21-

23. Further, even if a theoretical or experimental flexible battery existed at the time of the invention, it would not have been reliable enough for use in a wearable cardiac device. Consequently, a POSITA would not have been able to implement the flexible battery in a functional ambulatory monitor, which significantly undermines the enablement of Ozguz.

140. Moreover, the use of flexible batteries for a patient wearable device, particularly one designed for continuous monitoring, would have faced significant challenges regarding user comfort and practicality. A wearable device would need to offer long-term battery life, ideally without frequent recharging or the discomfort of bulky or frequently replaced batteries. In the context of a medical or patient-monitoring device, the battery's reliability and longevity are critical not only for user convenience but also for ensuring accurate and consistent monitoring. Flexible batteries of the time were not capable of achieving this, making them impractical for the intended use in wearable devices designed for patient care. Ozguz does not address these technical and practical limitations, which renders the reference non-enabling, as Ozguz's proposed sensor bandage could not have been practically implemented with the technology available at the time.

141. Finally, Ozguz's discussion of waterproofing and environmental protection is overly simplistic wishful thinking and fails to account for the technical challenges of protecting flexible electronics from moisture and sweat—two critical

environmental factors for a wearable monitor, especially while resisting the bending and stretching that would be inherent to a bandage. The reference assumes that basic waterproofing techniques, such as standard skin adhesion methods, would suffice to ensure the device's operation under real-world conditions. However, this assumption overlooks the complexity of waterproofing flexible materials, which was not feasible with the available materials and methods at the time. Waterproofing such a device requires the integration of specialized coatings or barriers that can protect sensitive electronic components from moisture without compromising the flexibility or comfort of the device. At the time of the invention, the technology for achieving long-term environmental resistance in flexible electronics was still in its infancy, and there was no reliable method for ensuring the longevity and durability of such devices when exposed to sweat, moisture, or other environmental conditions.

142. Specifically, a critical and overlooked challenge in Ozguz's design is the incompatibility between the flexibility of the flexible battery and the flexibility of the thin silicon layers of the device. The incompatibly flexible components would create significant waterproofing issues, particularly at the edges where the battery meets the layers. This combination of incompatible components would lead to poor sealing around the edges, allowing moisture to seep into the device. The lack of a reliable seal would expose the internal electronics to potential water damage, particularly in environments where sweat, moisture, or even rain could compromise

the device's integrity. This issue further highlights the unrealistic nature of Ozguz's proposal, as a practical, wearable device could not afford to risk water damage, especially when used in environments that are prone to moisture exposure.

143. Given these challenges, the proposed device in Ozguz would have been highly susceptible to failure upon exposure to moisture or sweat, undermining its viability as a continuous-use wearable monitor. The failure to address these concerns in Ozguz's reference renders the device impractical and speculative. Therefore, a POSITA at the time would not have been motivated to combine Ozguz's teachings with the intention of creating a functional, reliable, sterilizable, wearable monitor. The lack of consideration for long-term environmental resistance and the durability and sterilizability of flexible materials significantly diminishes the relevance of Ozguz as prior art, as its teachings do not provide an enabling disclosure for creating a viable wearable monitor that could withstand the rigors of real-world use. A POSITA would have recognized that these barriers could not be overcome with the materials and technologies available at the time, making the combination of Ozguz's teachings with other prior art unrealistic and impractical.

b. Dr. Heikenfeld's reliance on Ozguz's infeasible flexible battery technology is fatal to Ground 2

144. As discussed above, Dr. Heikenfeld's analysis does not render obvious "a power source" as recited by Claims 1 and 45. *See* Section VII.A.i.a. In Ground

2, Dr. Heikenfeld relies on Ozguz's "flexible battery 105" for the claimed power source. Ex. 1009, ¶¶ 642-645. This flexible battery technology, however, was infeasible at the time of Ozguz's purported priority date (2005), infeasible at the time of the priority date of the '422 Patent (2006), and still infeasible up to at least 2015 for at least four reasons.

145. First, in 2005 there was limited mechanical flexibility of commercially available batteries. While several battery technologies—such as lithium polymer (Li-poly), thin-film batteries, and printed primary cells—were theoretically flexible by 2005, none could achieve the mechanical flexibility described in the Ozguz patent, particularly the repeated bending and twisting needed for a wearable "adhesive bandage" form factor. Specifically, commercially available Li-poly pouch cells could slightly bend to conform to curved surfaces, but were neither repeatedly flexible nor stretchable without risking internal short circuits or physical damage. Similarly, thin-film lithium-ion cells developed by Oak Ridge National Laboratory (ORNL) demonstrated limited bending capabilities and were typically fabricated on rigid substrates, severely constraining their real-world flexibility and practical use in dynamic, wearable applications.

146. Second, as of 2005 there were significant energy density and power delivery constraints that would have precluded using a flexible battery in Ozguz's device. Printed thin-film zinc-based batteries, like those from Power Paper Ltd. and

Enfucell, were indeed thin and highly flexible but had severely limited energy storage (tens of milliamp-hours at best). Such batteries were adequate only for low-power, short-duration tasks (like RFID tags or greeting cards), insufficient for continuous physiological monitoring devices that require sustained power delivery for data collection, digitization, and wireless data transmission. Rechargeable technologies like NEC's Organic Radical Battery (ORB), while flexible and seemingly promising, were only experimental prototypes with very limited energy density (~1 mWh/cm^2). Hence, by 2005, flexible battery technologies simply could not offer sufficient power density and durability required by the Ozguz device specification.

147. Third, incorporating flexible battery technology into Ozguz's device would not have been feasible from a manufacturing standpoint, nor would it have provided reliable performance in such a device. As of 2005, flexible battery manufacturing was either experimental or limited to niche applications. Mass-scale production processes (roll-to-roll printing) of thin-film batteries remained in pilot stages, with limited reliability and inconsistent quality. The flexible, thin-film silicon-based integrated circuit described in Ozguz specifically highlights a degree of integration and complexity requiring robust, reliable power delivery. None of the battery technologies available prior to or in 2005 were manufactured with the

reliability, consistency, and volume required to power such an integrated wearable monitoring device.

148. Fourth, integrating the flexible battery into Ozguz's device would have presented significant challenges. Ozguz explicitly describes integrating a thin, flexible battery layer with equally flexible silicon circuitry and substrates. Ex. 1014, ¶ [0048]. Further, Ozguz emphasizes significant mechanical flexibility—such as twisting about the longitudinal axis (Ex. 1014, Figure 3E) and bending along multiple axes (Ex. 1014, Figs. 3C, 3D). Achieving this degree of flexibility with battery technologies available by 2005 was not only impractical but posed significant risks for battery failure, leakage, or structural breakdown. The delicate thin-silicon layers and sensitive integrated circuitry required extremely uniform and mechanically stable battery technology. The available battery solutions could not satisfy this stringent mechanical integration requirement (without compromise in structural integrity, operational lifetime, or safety).

c. Dr. Heikenfeld's reliance on Ozguz's infeasible thin silicon technology is fatal to Ground 2

149. Dr. Heikenfeld identifies Ozguz's "flexible silicon substrates with integrated circuits that include a 'microprocessor 175,'" Ex. 1009, ¶ 650. Then, Dr. Heikenfeld points to Ozguz's disclosure that "it is to be expressly understood that the I[ntegrated] C[ircuit]s 71, 72, 73 can be integrated as one IC on a single silicon

substrate." Ex.1009, ¶ 650. Based on this disclosure, Dr. Heikenfeld opines that "Ozguz's thin silicon substrates 60, 65, 70 may also include a computation module: 'a microprocessor 175' for processing signals and 'controlling input, storage, and analysis of the collected data,'" for claim elements 1[a] and 1[c]. I disagree with Dr. Heikenfeld's opinion because thinned silicon devices, such as that described by Ozguz, were infeasible at the time of Ozguz's claimed priority (2005), and at the time of the invention disclosed in the '007 Patent (2006), and even more infeasible as a thin flexible silicon would not, and could not, support a microprocessor.

150. First, flexible thinned silicon did not have reliable mechanical flexibility. This flexible thinned silicon, while theoretically bendable, was still fundamentally brittle in 2005. Ozguz itself acknowledges challenges around the mechanical fragility of thin silicon, highlighting efforts to carefully position silicon circuits at a neutral, or "zero stress plane" to mitigate breakage risks. Ex. 1014, ¶ [0055]. However, in practical terms, the integration complexity, especially for layered structures (such as battery, silicon circuits, substrate, adhesive), drastically increased the likelihood of mechanical failures from repeated bending or stress concentrations.

151. Second, in 2005 there was limited manufacturing capability and yield. Specifically, flexible thinned silicon was confined largely to experimental laboratory demonstrations. Ozguz describes methods like "grinding" thin silicon wafers to 10-

50 microns. Ex. 1014, ¶ [0054], cls. 34-37. Such processes, while achievable in lab-scale prototypes, suffered from low yield, high fragility, and inadequate scalability for commercial or even robust prototype-level production. Achieving consistency, reliability, and high throughput manufacturing necessary for commercialization was beyond available methods at the time.

152. Third, flexible thinned silicon was difficult to integrate into real-world applications. For example, Ozguz's envisioned wearable sensor (as depicted in Figures 2a, 3a, and 3b) required complex integration: flexible silicon circuitry, flexible battery, electrodes, wireless transmission capability, and adhesives into a thin, bendable form factor. As of 2005, the available integration and packaging techniques lacked maturity to reliably assemble these components. Even the patent disclosure describes this integration conceptually without providing actual demonstrated examples or results of functional integrated devices tested under real-world conditions, underscoring the speculative and aspirational nature of the technology at the time.

153. Fourth, in 2005 there were no commercially available flexible integrated circuits or components. No research devices could have supported the requirements as articulated in Ozguz, and no off-the-shelf flexible integrated circuits or thin silicon chips were commercially available in 2005. Industry standards and supply chains for flexible electronic components simply did not exist. All

demonstrations were strictly research-based, bespoke, and not robust enough for reliable or repeatable use, particularly for wearable physiological monitoring that demands reliability, stability, and user safety.

154. Fifth, in 2005 there were difficulties with power and wireless communication interoperability and flexible thinned silicon devices. Ozguz highlights the inclusion of RF communication capabilities integrated into the flexible system (*see* Figures 2a, 9). However, integrating reliable, low-power wireless communication into thin flexible silicon circuits was not feasible at the time, due to power consumption issues, battery integration complexities, and limited antenna efficiency in flexible formats. Such limitations severely constrained device functionality and practicality.

155. Accordingly, in 2005, flexible thinned silicon technologies lacked the mechanical robustness, manufacturing maturity, integrated system-level capability, and commercial feasibility required to create a wearable, flexible, physiological monitoring device as described in Ozguz. The subsequent recognition of these inadequacies by the U.S. government via FOA-RQKM-2015-0014—ten years later—strongly underscores the depth and persistence of these technical and manufacturing challenges. Consequently, such a wearable, flexible device was not realizable by a POSITA in 2005.

VIII. RESERVATION OF RIGHTS

156. I reserve the right to amend or supplement this declaration as this case proceeds and any additional information comes to light.

157. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true. I also declare 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 18 U.S.C. §1001. I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: May 11, 2025

Dr. Brian W. Anthony