

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IRHYTHM, INC.,

Petitioner,

v.

WELCH ALLYN, INC.,

Patent Owner.

CASE: IPR2025-00374

U.S. PATENT NO. 8,965,492

DECLARATION OF DR. BRIAN W. ANTHONY

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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 and 11 to 14 (the “Challenged Claims”) of U.S. Patent No. 8,965,492 (the “’492 Patent”) (Ex. 1003) 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 ’492 Patent (Ex. 1003), its file history (Ex. 1004), the Declaration of Dr. Jason Heikenfeld (Ex. 1009), three prior art references: Jensen (Ex. 1011), Matsumura (Ex. 1012), 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 '492 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 '492 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 '492 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 '492 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 '492 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 '492 Patent technology, including:

- Hardt, D.E., Anthony, B.W., Tor S.B., “A teaching factory for polymer microfabrication - μ Fac,” 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.

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

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.

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.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 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.”

² I understand that the Petition and Dr. Heikenfeld are advancing three “obviousness” theories with Grounds 1 to 3.

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 '492 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.

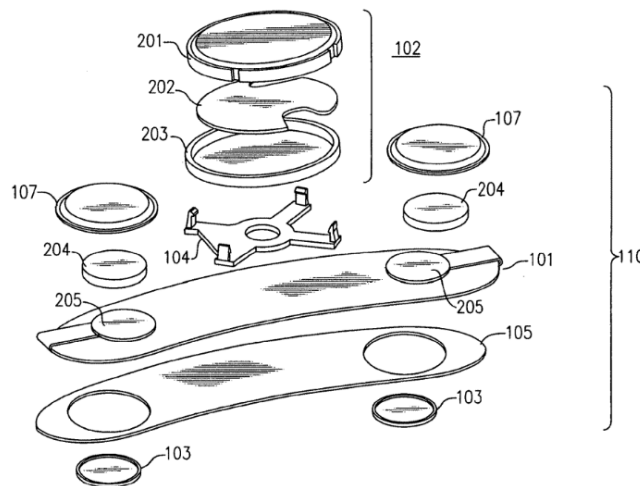
42. My analysis and opinions below are given from the perspective of a POSITA in this technological field in the relevant time frame, unless stated otherwise.

43. I satisfied the definition of a POSITA before the filing date of the application leading to the '492 Patent. I now consider myself an expert in the relevant field of technology for the '492 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 '492 PATENT

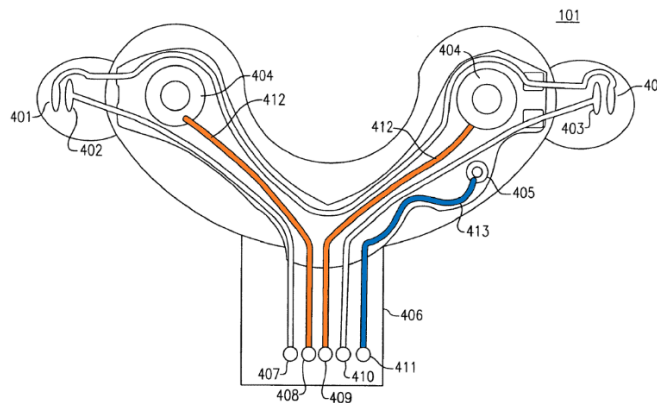
45. The '492 Patent discloses a body-worn patient monitoring device that adhesively attaches to a patient's skin and measures physiological signals. Ex. 1003, Abstract, Claim 1. The body-worn patient monitoring device has two main components: a computation-communication module and a disposable electrode module. Ex. 1003, Claim 7, 4:56-64, Figure 2. The computation-communication module is releasably attached to the disposable electrode module. Ex. 1003, Claim 7, 4:56-64. For example, 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. 1003, Claim 7.



Ex. 1003, Figure 2.

46. Disposable electrode module 110 includes flexible printed circuit layer 101, which is made from an insulating material. Ex. 1003, 5:12-25, Claim 1. The flexible printed circuit layer functions to transmit electrical signal via traces; the

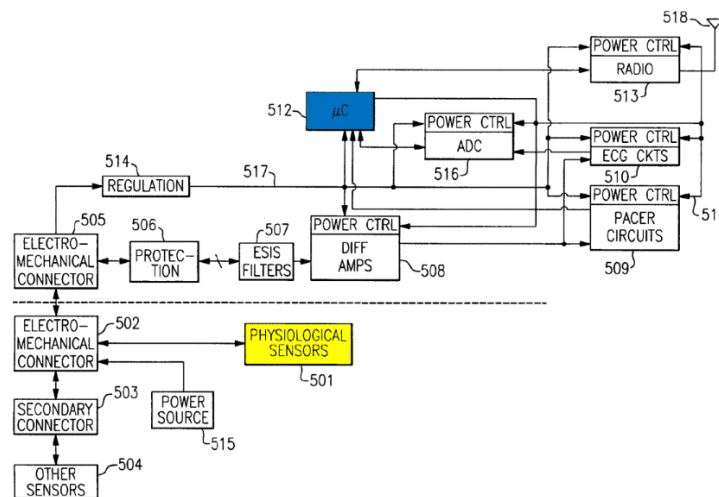
traces connect a connection pad to an electrode. Ex. 1003, 7:44-55, Claims 1, 7. As shown below, the '492 Patent states that traces 412 (indicated in orange), which are preferably printed, “extend[] between conductive surface 404 and connection pads 408 and 409.” Ex. 1003, Figure 4A (annotated), 5:31-37 (defining the conductive surface as part of the electrode), 7:50-55, 11:13-18. Further, the '492 Patent states that trace 413 (indicated in blue), “extend[s] between conductive surface 405 and connection pad 411.” Ex. 1003, Figure 4A (annotated) 7:44-55. The traces are made from a resistive material. Ex. 1003, 7:50-55, Claim 1.



Ex. 1003, Figure 4A (annotated).

47. Figure 5 also shows the path between each electrode and the computation-communication module. Ex. 1003, 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. 1003, 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. 1003, 11:33-43, Figure 5 (annotated), Figure 4A. The computation-communication module also includes a housing that contains this processor. Ex. 1003, Claim 7.



Ex. 1003, Figure 5 (annotated).

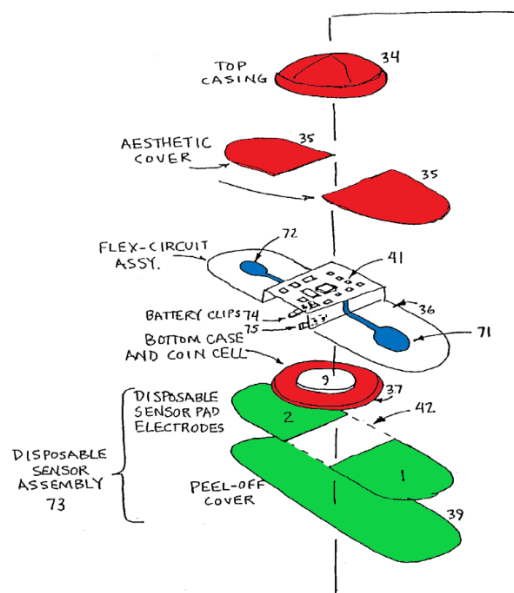
V. SUMMARY OF THE ART

A. Jensen (Exhibit 1011)

48. Jensen discloses an integral patch-type electronic physiological sensor, specifically a “smart bandage” or “smart patch,” designed primarily to monitor physiological signals (*e.g.*, heart rate) without external wires or elastic bands. Jensen’s device integrates electronics and a power supply between insulating layers, utilizing conductive, adhesive gel pads that are applied directly to the skin. Ex. 1011,

Abstract. Jensen also states that the novelty of its sensor “include[s] its physical construction and method of use.” Ex. 1011, ¶ [0030]. Namely, regarding the physical dimensions, Jensen provides “a totally self-contained sensor that is thin, being less than 6 or 7 mm in thickness, [and] low in mass.” Ex. 1011, ¶ [0030].

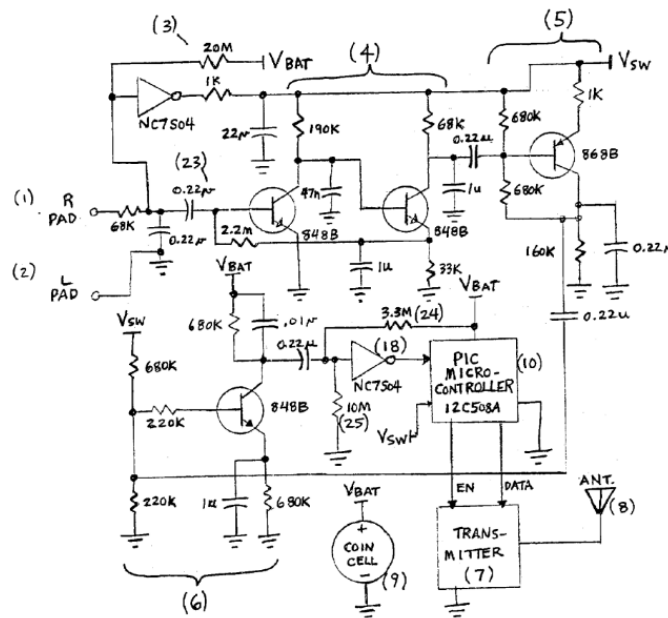
49. As part of Jensen’s integrated design, the sensor includes disposable sensor assembly 73, which includes cover 39, connective material 42, and pads 1 and 2. Ex. 1011, ¶ [0040], Figure 5 (indicating the disposable components in green). Jensen only identifies these three components as disposable components. Jensen also has reusable parts, including bottom case 37, top casing 34, and two aesthetic covers 35. Ex. 1011, ¶ [0040], Figure 5 (indicating the reusable components in red).



Ex. 1011, Figure 5 (annotated showing disposable portions in green, reusable portions in red).

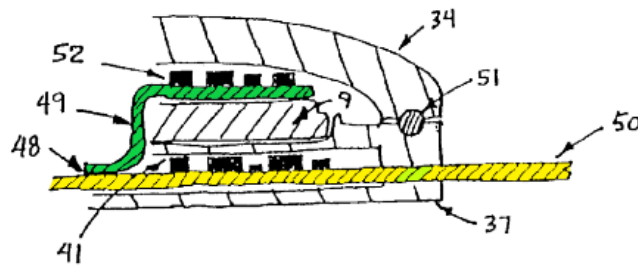
50. Moreover, Jensen describes an additional, non-disposable flexible circuit assembly 36 having “traces” (annotated in blue above). Ex. 1011, ¶ [0040], Figure 5. These “traces” connect electronics circuit 41 to sensor contacts 71 and 72, which, in turn, connect to pads 1 and 2 of disposable sensor assembly 73. Ex. 1011, ¶ [0040], Figure 5. This way, the signals captured by sensor pads 71, 72 of disposable sensor assembly 73 are transmitted to electronics circuit 41.

51. The electronics circuit includes a microcontroller and a transmitter. Ex. 1011, ¶ [0032]. The signals are amplified and filtered internally, with the microcontroller for processing and converting the data to radio-transmittable formats, allowing wireless transmission to external receiving equipment. Ex. 1011, ¶ [0032]. Jensen also explains that the processed signal can either be (1) directly input into the transmitter or (2) input into the microcontroller for further analysis and encoding. Ex. 1011, ¶ [0032]. The electronics circuit also includes various resistors for signal biasing and gain setting. Ex. 1011, ¶¶ [0032], [0036]. Figure 2 of Jensen shows an electronics circuit with resistors 24, 25 for signal biasing. A POSITA would have understood that these resistors are discrete components chosen specifically for their precision, stability, and tuning capability. Further, these Jensen’s resistors are located the electronics circuit (*see* electronics circuit 41 in Figure 5) as opposed to, for example, the flexible circuit assembly.



Ex. 1011, Figure 2.

52. Jensen discloses an alternative structure for its device in Figure 8. Ex. 1011, ¶ [0046], Figure 8. In this embodiment, the device includes flexible printed circuits 49, 50. Ex. 1011, ¶ [0046], Figure 8 (indicating the first circuit 50 in yellow and the second circuit 49 in green). As shown in Figure 8, the electronics circuit 41, which includes the transmitter and microcontroller previously introduced, is disposed on flexible circuit 50 closest to the skin. Ex. 1011, ¶ [0046], Figure 8. The second flexible circuit assembly 49 is connected to first flexible circuit 50 via a set of pads 48. Ex. 1011, ¶ [0046].

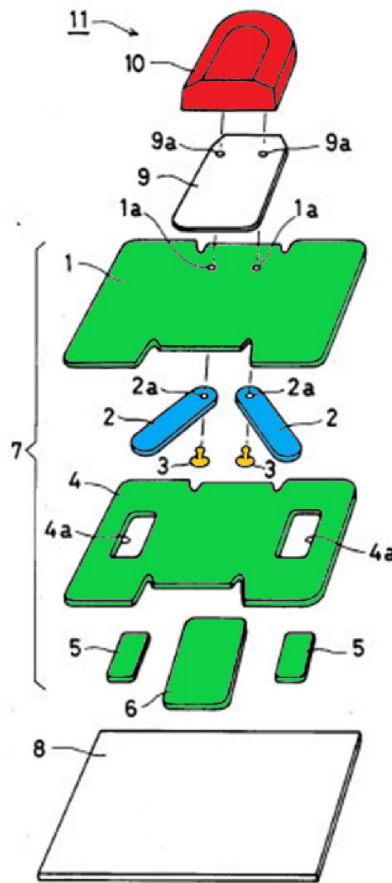


Ex. 1011, Figure 8 (annotated).

53. To create this connection, “pads of tinned-copper exposed on the bottom side of circuit 49 and the top side of circuit 50” are matched. Ex. 1011, ¶ [0046], Figure 8A. Then, pads 48 “are heat re-flowed together, melting the tinning metal, to connect the two circuits.” Ex. 1011, ¶ [0046], Figure 8, 8A.

B. Matsumura (Exhibit 1012)

54. 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).

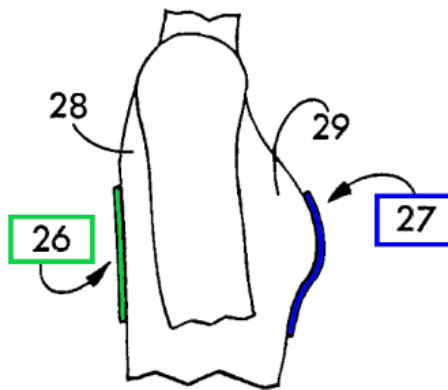
55. Matsumura explains “two pieces of conductive material 2 and two hooks 3 are arranged to transmit the bioelectric potential detected by the conductive gel 5, which is placed in the openings 4a of the second sheet 4.” Ex. 1012, ¶ [0019]. Conductive material 2 is rod-shaped with one end that contacts 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 “the bioelectric potential detected by the conductive gel 5 [to be] transmitted through the conductive material 2 and the hooks 3.” Ex. 1012, ¶ [0019].

56. Hooks 3 have an electrical role and a 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].

C. Kroll (Exhibit 1013)

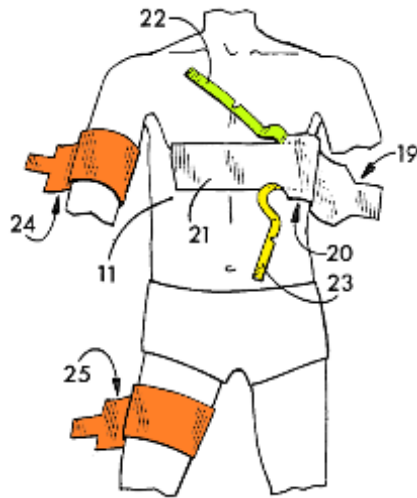
57. Kroll discloses a flexible, disposable electrode belt device intended for use with medical diagnostic and therapeutic equipment. Kroll's electrode belt can "receiv[e] and transmit[] electric current and voltage." Ex. 1013, 2:41-47. The electrode belt comprises a unitary layered belt designed to adhere 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.

58. 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).

59. 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 3 (annotated).

61. 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.

VI. SUMMARY OF OPINIONS

62. I understand that Dr. Heikenfeld advances Grounds 1 to 3 and in them alleges that Claims 1 to 8 and 11 to 14 of the '492 Patent are obvious. I disagree with Dr. Heikenfeld's opinion.

63. In Ground 1, Dr. Heikenfeld opines that Claims 1 to 3, 5 to 8, and 11 to 14 of the '492 Patent are obvious over the combination of Matsumura, Kroll, and the general knowledge of a POSITA. It is my opinion that Ground 1 fails to render the Challenged Claims obvious for two reasons. First, Ground 1 does not teach or suggest a “flexible *printed* circuit layer made from an insulating material,” as required by Claim 1 and 7. *See* Section VII.A.i. Second, a POSITA would not have been motivated to combine Matsumura and Kroll. *See* Section VII.A.ii.

64. In Ground 2, Dr. Heikenfeld opines that Claims 1 to 6 of the '492 Patent are obvious over the combination of Jensen, Kroll, and the general knowledge of a POSITA. It is my opinion that Ground 2 fails to render the Challenged Claims obvious for two reasons. First, Ground 2 does not teach or suggest “at least one electrical trace extending between the at least one connection pad and a conductive surface,” as required by Claim 1. *See* Section VII.B.i. Second, a POSITA would not have been motivated to combine Jensen and Kroll. *See* Section VII.B.ii.

65. In Ground 3, Dr. Heikenfeld opines that Claims 7, 8, and 11 to 14 of the '492 Patent are obvious over the combination of Jensen, Matsumura, Kroll, and the general knowledge of a POSITA. It is my opinion that Ground 3 fails to render the Challenged Claims obvious for four reasons. First, Ground 3 does not teach or suggest “a reusable communication module.” *See* Section VII.C.i. Second, Ground 3 does not teach or suggest a “disposable electrode portion comprising a flexible

printed circuit layer.” *See* Section VII.C.ii. Third, Ground 3 does not teach or suggest an “electrical traces defined between the at least two electrodes and a connection pad.” *See* Section VII.C.iii. Each element is required by Claim 7. Fourth, a POSITA would not have been motivated to combine Jensen and Matsumura. *See* Section VII.C.iv.

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 to 3, 5 to 8, or 11 to 14**

66. Dr. Heikenfeld opines that Claims 1 to 3, 5 to 8, and 11 to 14 of the ’492 Patent are obvious over the combination of Matsumura, Kroll, and the “General Knowledge” of a POSITA. I disagree with Dr. Heikenfeld’s opinion for two reasons.

67. First, Dr. Heikenfeld’s proposed combination fails to render obvious the claims because the combination does not teach or suggest independent Claims 1 or 7. In particular, the proposed combination fails to render obvious claim elements 1[a] and 7[c], which require a “flexible *printed* circuit layer made from an insulating material.” *See* Section VII.A.i. Second, because the proposed combination fails to render obvious a printed circuit layer, the combination fails to render obvious claim element 1[d], which requires “at least one electrical trace extending between the at least one connection pad and a conductive surface of the [at] least one electrode.”

See Section VII.A.i. For the same reasons, Dr. Heikenfeld’s proposed combination fails to render obvious Claims 2 to 3, 5, 6, and 8 to 14.

68. Third, Dr. Heikenfeld fails to establish that a POSITA would have been motivated to combine Matsumura and Kroll. Dr. Heikenfeld’s proposed modification of Matsumura in view of the “General Knowledge” of a POSITA renders Matsumura’s device inoperable for its intended purposes, and a POSITA, therefore, would not have been motivated to make such a combination. Additionally, a POSITA would not have been motivated to combine Matsumura and Kroll to (1) reduce the size of Matsumura’s device, or (2) protect the patient from potential shock during defibrillation.

69. Because a POSITA would not have been motivated to combine Matsumura and Kroll, a POSITA would likewise not have been motivated to combine Matsumura, Kroll, and the “General Knowledge” of a POSITA.

i. Matsumura fails to render obvious claim elements 1[a], 1[d], and 7[c]

70. Claim elements 1[a] and 7[c] require “a flexible printed circuit layer made from an insulating material and defining a substrate.” Ex. 1012, cls. 1, 7. Claim element 1[d] requires “at least one electrical trace extending between the at least one connection pad and a conductive surface of the least one electrode.” Ex. 1012, Cl. 1. Dr. Heikenfeld opines that with respect to claim element 1[a], “a POSA

would modified [sic] the conductive material disclosed by Matsumura to form a flexible printed circuit layer made from an insulating material and defining a substrate.” Ex. 1009, ¶ 782. With respect to claim element 7[c], Dr. Heikenfeld opines “a POSA would have used the same manufacturing technique and the well-known technique of screen printing in order to replace Matsumura’s two separate pieces of conductive material 2 with a single flexible sheet comprising insulating material containing printed-ink traces (i.e., a printed circuit board).” Ex. 1009, ¶ 840. Finally, with respect to claim element 1[d], Dr. Heikenfeld alleges that a POSITA would understand that the modification of Matsumura to have printed circuitry that “contact[s] the hooks 3” renders claim element 1[d] obvious. I disagree with Dr. Heikenfeld’s opinions.

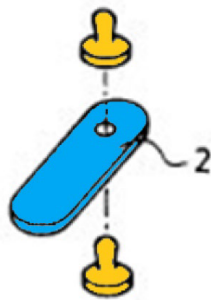
71. A POSITA would not have recognized that Matsumura would be modified to replace Matsumura’s rigid, three-dimensional, conductive material with a flexible printed circuit layer. First, Matsumura does not disclose a flexible *printed* circuit layer having an electrode disposed on the surface, and therefore no electrical trace extends between a connection pad and a conductive surface of an electrode, and Dr. Heikenfeld’s declaration does not contend otherwise. Second, Matsumura’s disclosure debunks Dr. Heikenfeld’s proposed modification and instead supports the conclusion that Matsumura’s electronics are not, and cannot be, printed.

72. From the start, Dr. Heikenfeld’s analysis relies on what “a POSA would recognize.” Ex. 1009, ¶¶ 781, 840. In particular, Dr. Heikenfeld identifies Matsumura’s bioelectric pad, which contains certain components made from polyethylene foam, polyurethane foam, or polyurethane sheet, which “a POSA would recognize polyethylene and polyurethane as flexible materials.” Ex. 1009, ¶¶ 781, 840. Then, Dr. Heikenfeld “opin[es] that a POSA would have known that a circuit layer *must* be formed on an insulating material.” Ex. 1009, ¶ 781. I disagree with Dr. Heikenfeld’s opinion to the extent he is opining that a POSITA’s knowledge that a circuit layer must be formed on insulating material somehow supports the argument that any circuit layer, whether printed or non-printed, is therefore interchangeable.

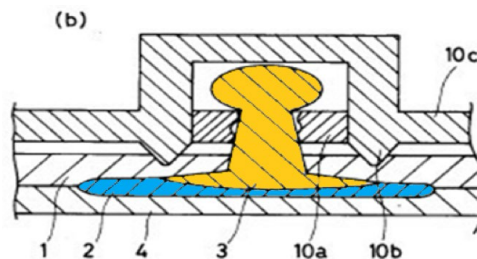
73. Dr. Heikenfeld never identifies any disclosure in Matsumura to support the contention that Matsumura discloses a flexible printed circuit layer made from an insulating material and defining a substrate. As a result, none of the opinions expressed by Dr. Heikenfeld contend that Matsumura itself actually discloses the claimed printed circuit layer. Indeed, Matsumura includes no such disclosure.

74. Rather, Matsumura’s bioelectric pad is composed of first sheet 1, conductive material 2, hook 3, second sheet 4, conductive gel 5, third sheet 6, and double-sided adhesive tape 9. Ex. 1012, ¶ [0016]. Importantly, conductive material 2 is a piece of rigid “rod-shaped” material, and hook 3 is a “protruding” stud. Ex.

1012, ¶ [0019]. Further, Matsumura disclosure is clear that conductive material 2 must be separate “pieces” of rigid, three-dimensional material. Ex. 1012, ¶ [0019]. This structure is necessary because “the protruding portions of the hook 3” extend upwards “from the back side of the conductive material 2,” to “clamp[] the conductive material 2 from both sides.” Ex. 1012, ¶¶ [0019], [0021]. These structures are shown in Figures 4(b) and 8. Ex. 1012, Figures 4(b), 8.



Ex. 1012, Figure 8 (annotated).



Ex. 1012, Figure 4(b) (annotated). The arrangement of these components is not an optional embodiment of Matsumura, but rather provides the electrical and mechanical connection essential to Matsumura’s device.

75. Based on Matsumura’s express disclosure of rigid, three-dimensional conductive material and hooks, a POSITA would have understood that neither the

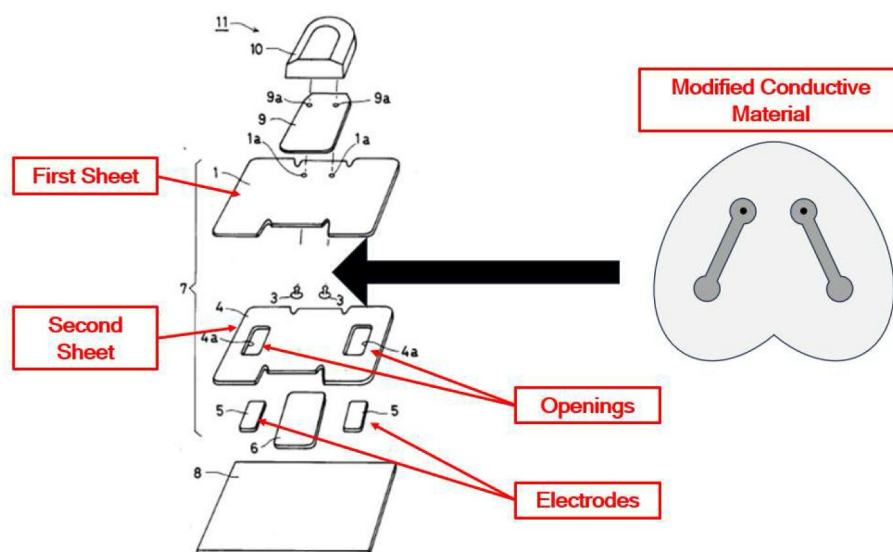
conductive material nor the protruding hooks are *printed*. Because Dr. Heikenfeld's combination fails, a POSITA also would not have understood Matsumura's conductive material 2 and hooks 3 to be "extending between" any connection pad and electrode. Thus, Matsumura does not disclose a flexible printed circuit layer, and does not disclose electrical traces extending between a connection pad and an electrode.

76. Nor would a POSITA have been motivated to replace both pieces of Matsumura's *conductive* material 2 "with a single, flexible sheet of *insulating* material that contained printed-ink, conductive traces," contrary to Dr. Heikenfeld's opinion. Ex. 1009, ¶ 783 (emphasis added). Dr. Heikenfeld's assertion that screen printing silver and/or silver chloride electrodes, connectors, or traces was "well-known" is of no matter because Matsumura does not disclose, teach, or suggest printed circuitry. Ex. 1009, ¶ 783. Therefore, I disagree with Dr. Heikenfeld's opinion that a POSITA would have considered using screen printing techniques to replace Matsumura's conductive material 2 with printed electronics because the protruding, three-dimensional and rigid mechanical structural nature of conductive material 2 and hooks 3 are essential for Matsumura's device to function, and are essential for waterproofing Matsumura's device.

77. In particular, without conductive material 2 and hooks 3, a patient's bioelectric signals detected by Matsumura's device could not be transmitted from

conductive gel 5, through conductive material 2, and through hooks 3 to reach the signal processor. Ex. 1012, ¶ [0019].

78. Dr. Heikenfeld also relies on self-created clip-art to depict “modified conductive material,” which he places within Figure 1 of Matsumura in a manner that suggests conductive material 2 could be replaced with a flexible printed circuit layer formed from insulating material.



See 1009, ¶ 783 (annotations in original). There is no disclosure in Matsumura that supports Dr. Heikenfeld’s proposed modification.

79. Instead, this alteration is speculative and unsupported by the actual disclosure of Matsumura, and it misrepresents what a POSITA would reasonably understand or implement the reference. Dr. Heikenfeld’s alteration is merely the application of hindsight, improperly using the ’492 Patent’s claims as a roadmap.

Moreover, this clip-art—like Dr. Heikenfeld’s analysis in its entirety—fails to acknowledge the necessary dual electrical functionality and mechanical functionality of rod-shaped conductive material 2 and hooks 3, including a protruding and mechanical connection. That being: (1) “the bioelectric potential detected by the conductive gel 5 are transmitted through the conductive material 2 and the hooks 3” to Matsumura’s signal processor, and (2) the layers of Matsumura’s bio-pad are tightly compressed due to the hooks’ vertical traversal through the multiple layers of Matsumura’s bio-pad, resulting in a waterproof device. Ex. 1012, ¶¶ [0016]-[0019], [0027].

80. Matsumura’s disclosure refutes any argument that Matsumura’s conductive material 2 could be replaced with a sheet of insulating material with printed traces. Matsumura’s disclosure also refutes any argument that Matsumura’s conductive material 2 or hooks 3 “extend between” any connection pad and electrode. Dr. Heikenfeld ignores Matsumura’s express teachings regarding the electrical function and mechanical function of conductive material 2, which is fatal to Dr. Heikenfeld’s analysis.

81. For example, Matsumura discloses that “the protruding portions of the hook 3” extend upwards “from the back side of the conductive material 2,” clamping both sides of conductive material 2. Ex. 1012, ¶ [0021]. Matsumura also discloses that “two pieces of conductive material 2 and two hooks 3 are arranged to transmit

the bioelectric potential detected by the conductive gel 5.” Ex. 1012, ¶ [0019]. And, to hold Matsumura’s device together, Matsumura teaches that “[t]he bioelectric pad 7 and the signal processor 10 are detachable with hooks.” Ex. 1012, ¶ [0016]. This three-dimensional mechanically connected structure of conductive material 2 and hooks 3 is necessary for Matsumura’s device. Therefore, I disagree with Dr. Heikenfeld’s opinion that “[i]t would have been obvious to replace the two pieces of insulating material coated with conductive Ag/AgCl with a single, flexible sheet of insulating material that contained printed-ink, conductive traces[.]” Ex. 1009, ¶ 783.

82. Further, Dr. Heikenfeld’s interpretation of “extending between” is at odds with the meaning of the term in the ’492 Patent. The disclosure of the ’492 Patent discussed above in Section IV show that the ’492 Patent uses “extending between” as extending directly between two components that are flush to the bio-pad. Ex. 1003, 7:50-55, Figure 4A; *supra* Section IV. The ’492 Patent does not support Dr. Heikenfeld’s interpretation of “extending between” that is a point of contact between *Matsumura*’s protruding hook and the improper trace in Petitioner’s clip art.

83. Accordingly, Dr. Heikenfeld fails to establish that a POSITA would have modified Matsumura’s non-printed conductive material to a flexible printed circuit layer made from an insulating material and defining a substrate of claim elements 1[a] and 7[c]. As a result, Dr. Heikenfeld also fails to establish that a

POSITA would have further modified Matsumura to include an electrical trace extending between a connection pad and a conductive surface of an electrode of claim element 1[d].

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

84. Dr. Heikenfeld opines that a POSITA would have been motivated to combine Matsumura and Kroll. *See* Ex. 1009, ¶ 783. To support this position, Dr. Heikenfeld incorporates by reference Section XVII.A.1 of his declaration, which relates to a different patent (U.S. Patent No. 8,214,007 (the “’007 Patent”)) from a separate proceeding (IPR2025-00378). Despite these differences, I understand that Dr. Heikenfeld is advancing the same position regarding motivation to combine Matsumura and Kroll as it relates to the ’007 Patent and the ’492 Patent in this proceeding.

85. Regarding Dr. Heikenfeld’s opinion here, I understand that he contends that a POSITA would have been motivated to combine Matsumura and Kroll to (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.

86. 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 combine Matsumura and Kroll to reduce the size of Matsumura's device.

87. 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 device and with an entirely different function/use, which would deter a POSITA, from the outset, from looking to Kroll to modify Matsumura's device. Additionally, the proposed combination would make Matsumura's device much larger by requiring large lead strips, and the proposed combination renders Matsumura's device inoperable for its intended purpose; the combination destroys Matsumura's primary goal of waterproofing.

88. 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. 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

89. 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].

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

91. 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.

92. 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.i), and (2) Matsumura in view of Kroll to further modify the printed circuit layer to be made of printed resistive ink. Ex. 1009, ¶ 470, 796.

93. 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, and it does not include 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.

94. Dr. Heikenfeld also opines that a POSITA 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. *See infra* Section VII.A.ii.b.ii. 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 in Matsumura’s signal processor, are functionally and structurally differently than resistive lead strips, and have different purposes depending on the specific device. *See infra* Section VII.A.ii.b.ii.

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

96. 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.

97. 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.

98. 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 POSITA 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 POSITA 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.

99. Thus, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to make Matsumura smaller by adding Kroll's resistive lead strips. To conclude otherwise, Dr. Heikenfeld ignores the teachings of Matsumura and Kroll.

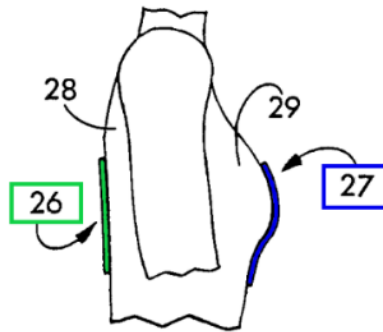
ii. Kroll's device is designed to wrap around the patient's body

100. 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 with a therapeutic function versus a measurement function.

101. Kroll's device wraps around the patient's body to administer therapeutic electrical energy. 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.

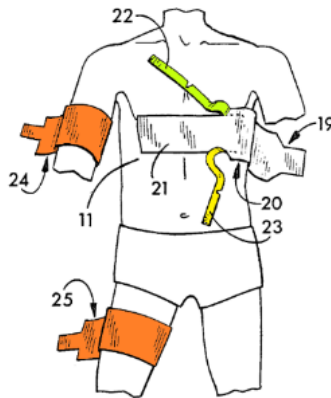
102. For example, the electrode belt is placed on the patient's chest and back. Ex. 1013, 4:44-47, Figure 3 (indicating the chest portion of the belt in blue and the back portion of the belt in green).

103. 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).

104. 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 the 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).

105. 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, Kroll's electrodes can be placed outside of the precordial region. Ex. 1013, 4:37-47.

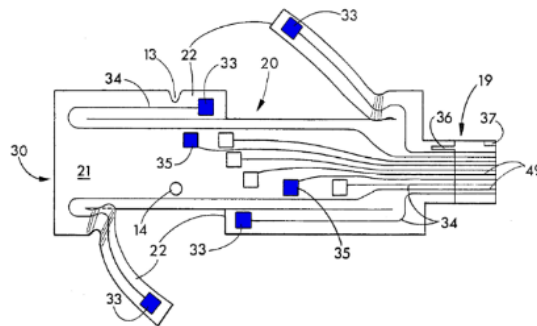
106. Thus, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to make Matsumura smaller by adding resistors with Kroll's traces that are sized and arranged to ensure patient safety to Matsumura. To conclude otherwise, Dr. Heikenfeld ignores the teachings of each reference.

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

107. 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, ¶ 772 (cross-referencing Section XVI.A.1 of his declaration for the motivation to combine argument, which relates to a different patent (the '007 Patent) from a separate proceeding (IPR2025-00377)). 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.

108. 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 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.

109. Kroll provides a disposable electrode belt “for receiving and transmitting electric current and voltage.” Ex. 1013, 2:41-47; *see* Section V.C. 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).

110. Based on the function of Kroll and its disclosure, a POSITA would have understood 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.

111. 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.

112. 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 measures electrical signals from the body.

113. 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.

114. 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.

115. 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.

116. 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.” Without more, 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 and mechanical structure, and a POSITA would not have

been motivated to combine Matsumura, Kroll, and the “General Knowledge” of a POSITA.

- ii. Dr. Heikenfeld fails to address the obstacles in implementing Kroll’s lead strips in Matsumura’s device

117. Kroll’s lead strips are intended for the large, body-area energy delivery applications of Kroll’s electrode belt. In contrast, Matsumura provides a smaller, small signal, compact measurement device. 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.

118. 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 sensing and safety.

119. 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 material selection, resistance value selection, and of controlled layering techniques to ensure trace and device design goal.

120. 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.

121. 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.

122. Fifth, a POSITA would have to managing trace spacing in a miniaturized 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.

123. 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.

124. 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.

125. Thus, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to make Matsumura smaller by adding resistors with Kroll's traces in view of the significant technical obstacles.

B. Ground 2: Dr. Heikenfeld Fails to Establish that the Combination of Jensen, Kroll, and General Knowledge of a POSITA Renders Obvious Claims 1 to 6

126. Dr. Heikenfeld opines that Claim 1 to 6 are obvious over the combination of Jensen, Kroll, and the general knowledge of a POSITA. Ex. 1009, ¶ 875. I disagree with Dr. Heikenfeld's opinion for two reasons.

127. First, Dr. Heikenfeld’s combination fails to render obvious Claim 1 because it does not teach or suggest claim element 1[d], which requires “at least one electrical trace extending between the at least one connection pad and a conductive surface of the [at] least one electrode.” *See* Section VII.B.i. For the same reason, Dr. Heikenfeld’s combination fails to render obvious Claims 2 to 6.

128. Second, Dr. Heikenfeld fails to establish that a POSITA would have been motivated to combine Jensen and Kroll. A POSITA would not have been motivated to combine Jensen and Kroll (1) to limit the current between the patient and the device or (2) to reduce the size of Jensen’s device. *See* Section VII.B.ii.

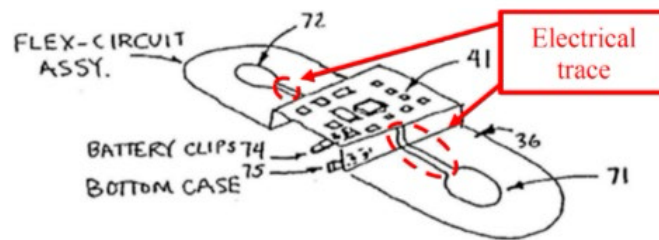
i. Jensen fails to render obvious claim element 1[d]

129. Claim element 1[d] requires “at least one electrical trace extending between the at least one connection pad and a conductive surface of the [at] least one electrode.” Ex. 1003, Claim 1. Dr. Heikenfeld opines that a POSITA would have understood that Jensen’s copper wiring traces disclose claim element 1[d]. *See* Ex. 1009, ¶¶ 896–898. I disagree with Dr. Heikenfeld’s opinion.

130. A POSITA would not have understood that Jensen’s copper wiring traces disclose claim element 1[d] because Jensen’s copper wiring does not “extend[] between the at least one connection pads and a conductive surface of the [at] least one electrode.” Ex. 1003, Claim 1. Dr. Heikenfeld fails to identify any disclosure in Jensen to support his opinion. Further, Jensen’s disclosure supports

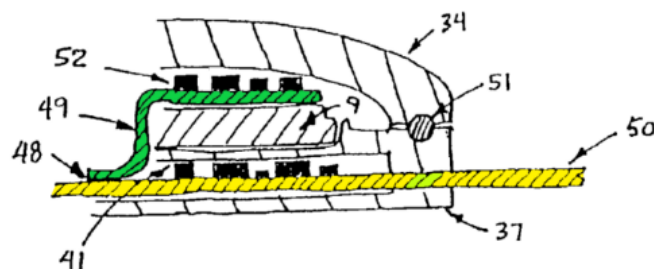
the conclusion that Jensen's copper wiring does not between the connection pad and the conductive surface of the at least one electrode.

131. Dr. Heikenfeld first annotates Figure 5 of Jensen to identify the copper wiring traces. Ex. 1009, ¶ 897. These annotations (shown below) confirm that Jensen's copper wiring does not extend between the connection pad and the conductive surface of the at least one electrode. As shown in Figure 5, which is consistent with Jensen's description of Figure 5, the copper wiring traces is part of flexible circuit assembly 36. Ex. 1011, ¶ [0040]. The copper wiring traces function "to connect the entire circuit 41 to the sensor contacts 71, 72." Ex. 1011, ¶ [0040]. Thus, Jensen's copper wiring traces extend between, for example, sensor contact 71 and electronics circuits 41. Contrary to this disclosure, Dr. Heikenfeld opines that the copper wiring traces extend from sensor contacts 71, 72 to the connection pad 48. As shown in Figure 8, the connection pad 48 functions to connect the internal circuits of Jensen. I disagree with Dr. Heikenfeld's opinion. It is my opinion that the copper wiring traces terminate at the electric circuit 41 because there is no illustration in Figure 5 or description establishing that the copper wiring traces extend from sensor contacts 71, 72 to an internal connection pad 48.



Ex. 1009, Figure 5 (original annotations by the Dr. Heikenfeld).

132. Dr. Heikenfeld also relies on Figure 8 of Jensen. Ex. 1009, ¶ 898. Dr. Heikenfeld’s reliance on the alternative embodiment of Figure 8 does not cure Dr. Heikenfeld’s insufficient position. Like Figure 5, Figure 8 does not illustrate or describe Jensen’s copper wiring traces extending from the sensor pads to the connection pad. Figure 8 includes circuit 49 and circuit 50, which are connected via “a set of pads 48” that are heat re-flowed together. Ex. 1011, ¶ [0046], Figure 8. There is no support, and thus a POSITA would not have understood, that Jensen’s copper wiring traces are in any way connected to the set of pads 48.



Ex. 1011, Figure 8 (annotated).

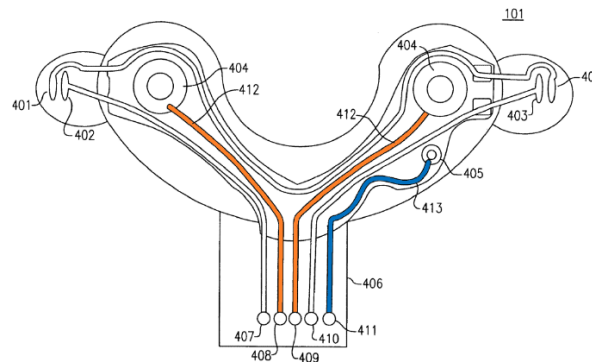
133. Because Jensen does not provide any disclosure that establishes the copper wiring traces extend to connection pad 45, Dr. Heikenfeld assumes that the copper wiring traces “must” extend between the connection pad and a conductive

surface of at least one electrode” for the signals to reach the electrical circuit on substrate 49. Ex. 1009, ¶ 898. I disagree with this position as well.

134. Jensen discloses “the pads 48 at the connection of flexible circuit 49 and 50 are matched on both circuits, with the matched pads of tinned-copper exposed on the bottom side of circuit 49 and the top side of circuit 50.” Ex. 1011, ¶ 46. Here, the circuit 49 and circuit 50 are matched and heat reflowed together. There is no basis to conclude that the copper wiring traces extend to this connection pad and are matched to circuit 49 for this process. Consistent with Jensen’s disclosure, a POSITA would have understood that the copper wiring traces terminate at the electronics circuit 41, and circuit 50 is heat re-flowed together with circuit 49.

135. To the extent that Dr. Heikenfeld is opining that Jensen’s copper wiring traces satisfy claim element 1[d] because they are electrically coupled to sensor pads 71, 72 and connection pad 48, I also disagree with this opinion. A POSITA would have viewed Dr. Heikenfeld’s position as inconsistent with the teachings of the ’492 Patent. For example, the ’492 Patent states that “[t]races 412 extend[] between conductive surface 404 and connection pads 408 and 409.” Ex. 1003, 7:44-55. Traces 412 (indicated in orange) are shown below in Figure 4A. Ex. 1003, 7:44-55, Figure 4A (annotated). In other example, the ’492 Patent states that trace 413 (indicated in blue) “extend[s] between conductive surface 405 and connection pad 411” and trace 413 can connect contact pad 405 to the connection pad 411 “to

provide a direct-connected reference electrode.” Ex. 1003, 7:44-55; Figure 4A (annotated). In view of the disclosure of the ’492 Patent, a POSITA would have understood that claim element 1[d] requires a single, uninterrupted trace from the connection pad to the conductive surface. Accordingly, Jensen’s copper wiring does not satisfy claim element 1[d] because the copper wiring does not extend between the sensor contact 71 and the internal connection pad 48. Rather, the copper wiring terminates at electronics circuit 41 as shown in Figure 5.



Ex. 1003, Figure 4A (annotated).

136. Thus, Dr. Heikenfeld fails to establish that a POSITA would have understood that Jensen’s copper wiring traces disclose claim element 1[d].

ii. A POSITA would not have been motivated to combine Jensen and Kroll

137. Dr. Heikenfeld opines that a POSITA would have been motivated to combine Jensen and Kroll. To support this position, Dr. Heikenfeld cross-references to Section XVI.A.1 of his declaration, which relates to a different patent (the ’007 Patent) from a separate proceeding (IPR2025-00377). Despite this difference, I

understand that Dr. Heikenfeld is advancing the same position regarding motivation to combine Jensen and Kroll as it relates to the '007 Patent and the '492 Patent in this proceeding.

138. Regarding the substance of Dr. Heikenfeld's opinion, I understand that he contends that a POSITA would have been motivated to combine Jensen and Kroll for two reasons: (1) limit current to protect the patient and the device, and (2) a desire to reduce the size of Jensen's device. Ex. 1009, ¶¶ 211, 215. I disagree that a POSITA would have been motivated to combine Jensen and Kroll for either reason.

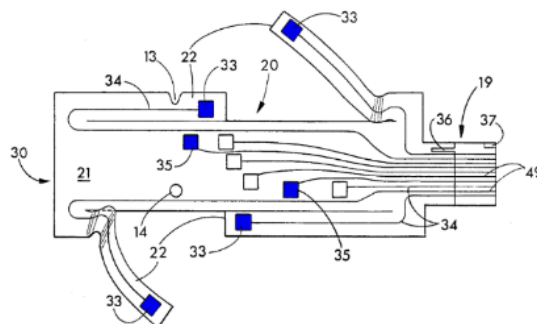
- a. A POSITA would not have been motivated to combine Jensen and Kroll to limit current

139. I understand that Dr. Heikenfeld contends that a POSITA would have been motivated to combine Jensen 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, ¶ 213. 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, ¶ 212. Based on this teaching, Dr. Heikenfeld opines that a POSITA "would have been motivated to incorporate Kroll's teaching of resistive 'lead strips' into Jensen's device." Ex. 1009, ¶ 214. I disagree.

- i. A POSITA would not have been motivated to combine Jensen and Kroll to limit current for protecting the patient

140. A POSITA would not have been motivated to limit the current from Jensen's device to the patient because there is no current being transmitted from Jensen's device to the patient. Dr. Heikenfeld overlooks the differences between Jensen's device and Kroll's device to conclude that a POSITA would have been motivated to combine Jensen and Kroll to limit current from the device to the patient.

141. Kroll provides a disposable electrode belt "for receiving and transmitting electric current and voltage." Ex. 1013, 2:41-47; *see* Section V.C. 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).

142. Based on the function of Kroll and its disclosure, a POSITA would have understood 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 this solution [of using lead strips] in the context of protecting a patient from electrical ‘shock’ caused by the worn device or a ‘complementary medical device.’” Ex. 1009, ¶ 212.

143. 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 Jensen. Jensen’s device simply monitors ECG signals. Namely, Jensen’s device is a patch that “sense[s] the heart-rate voltage differential across [its] sensors.” Ex. 1011, Abstract. These signals are amplified, converted to an output format, and transmitted to receiving equipment. Ex. 1011, Abstract; *see also* Ex. 1011, ¶ [0054] (describing the advantages “for monitoring of heart-rate and other physiological and environmental data”).

144. A POSITA would have understood that the monitoring device of Jensen does not transmit current to the patient, and there is no current going from Jensen’s device to the patient. Jensen 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 Jensen to transmit a

current to the patient. Nor does Jensen include components to transmit current to the patient. At base, Jensen is a device that only monitors ECG signals.

145. A POSITA would have understood that Jensen'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 Jensen'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 the adding Kroll's lead strips into Jensen's device.

146. For these reasons, I disagree with Dr. Heikenfeld, and Dr. Heikenfeld fails to establish a motivation to combine Jensen and Kroll based on "a desire to protect patients from potential shock." Ex. 1009, ¶ 214.

- ii. A POSITA would not have been motivated to combine Jensen and Kroll to limit current for protecting the device's electronics

147. A POSITA would not have been motivated to limit the current to Jensen's device to protect "the sensitive electronics inside the device from shock." Ex. 1009, ¶ 212. First, a POSITA would have understood that Kroll's lead strips are designed "to protect a patient from shock," which aligns with Kroll's disclosure of protecting the patient. Ex. 1013, 5:8-13. Second, a POSITA would have understood that the design of the resistors corresponds to the function for the reasons detailed in Section VII.B.ii.a.ii(b).

(a) A POSITA would have understood that Kroll's lead strips align with Kroll's goal of patient safety

148. Kroll states that its leads strips are designed “to protect a patient from shock.” Ex. 1013, 5:8-13. This clear statement, which Dr. Heikenfeld cites in his declaration, aligns with Kroll’s consistent goal of patient safety. Ex. 1009, ¶ 212.

149. Kroll provides a therapeutic electrode belt “for receiving and transmitting electric current and voltage.” Ex. 1013, 2:41-47. Because Kroll delivers shocks to the patient, Kroll is focused on patient safety, which is reflected in several features of the device. Kroll’s lead strips are one feature that “serve[s] 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. Consistent with this disclosure, a POSITA would have understood that Kroll’s lead strips are one feature that further Kroll’s goal of patient safety while delivering therapeutic shocks.

150. A POSITA would have also recognized Kroll’s goal of patient safety based on its desire to deliver current “to specific anatomical locations” of the patient. Ex. 1013, 1:27-36. This is important because, without delivering the shock to a precise location, the therapeutic effects would not be achieved and delivering a shock to an unintended location may injure the patient.

151. To decrease the likelihood of patient injury by delivering the shock to the correct location, Kroll provides (1) several electrodes, all of which can transmit

and receive electrical signals, and (2) extendable side members 22. Ex. 1013, 4:37-47, 5:1-4. By providing several electrodes that can transmit and receive electrical signals, the device includes a greater number of configurations to administer the shock at a precise location. Moreover, side members extend from the electrode belt's main body for placement outside of the precordial region. Ex. 1013, 4:37-47, Figure 4A. Like Kroll's shielding lead strips, the number, location, and adjustability of the electrodes all further the goal of ensuring patient safety during therapy.

152. A POSITA would have also recognized Kroll's goal of patient safety based on its integrated layers of the belt, which include a "shielding layer" to prevent outside electrical interference, including "interference from the device 10 with other medical diagnostic and therapeutic devices." Ex. 1013, 6:17-24. Kroll also discloses the use of more than one shielding layer "to further shield the device from interference." Ex. 1013, 6:17-24. Kroll's safety considerations are also shown in its design of the shielding layer; "[t]he shielding layer 46 is preferably recessed inwardly at its outer boundaries to minimize the risk of electrical shorting and patient shock in the event of device 10 failure." Ex. 1013, 7:3-13. In view of these features, a POSITA would have understood that Kroll is particularly concerned with protecting the patient. Unlike Kroll, Jensen's device only monitors ECG signals and does not have these same safety concerns.

(b) *Dr. Heikenfeld fails to establish that Kroll's lead strips would protect Jensen's electronics*

153. To the extent that a POSITA would have been motivated to combine Jensen and Kroll, Dr. Heikenfeld fails to establish that Kroll's lead strips would protect Jensen's electronics. Dr. Heikenfeld only supports this position by stating that resistor limit current in both directions. *See* Ex. 1009, ¶ 211.

154. I do not dispute that resistors limit current in both directions. However, I disagree with Dr. Heikenfeld conclusion that follows. Simply because resistors are bi-directional does not mean that any resistor would function to protect Jensen's sensitive electronics. A POSITA would have understood that the design of a resistors corresponds to the function, and Dr. Heikenfeld fails to explain why Kroll's lead strips would function to protect Jensen's electronics circuit.

155. One example taken from Jensen's disclosure demonstrates that Dr. Heikenfeld's blanket conclusion regarding resistors is not correct. Dr. Heikenfeld proposes "[m]odifying Jensen to include Kroll's resistive lead strips formed with ink deposits ink (rather than the larger, conventional resistors on Jensen's circuit assembly)." Ex. 1009, ¶ 216.

156. As Dr. Heikenfeld identifies, Jensen's electronics circuit includes "conventional resistors." These resistors including gain setting resistors, feedback resistors, and resistors for signal biasing. Ex. 1011, ¶¶ [0032], [0036], [0049]. A

POSITA would have understood that replacing Jensen's resistors with Kroll's lead strips does nothing to change the original needed function of Jensen resistors.

157. For example, the gain setting resistor would still be required to have the same nominal resistance, the same tolerance, with the same thermal stability, with the same placement and size on the circuit, and still serve to set the gain of the amplifier or voltage divider to which it was attached. The same is true for the feedback resistors and the signal biasing resistors. Dr. Heikenfeld fails to appreciate that a resistor, given the specifications required by a particular circuit, will be required to meet the same complex set of design requirements regardless of how it was manufactured. Moreover, unlike Dr. Heikenfeld, a POSITA would have understood the fundamental differences between Jensen's resistors and Kroll's lead strips. Based on these differences, a POSITA would not have been motivated to replace Jensen's resistors as discrete components with Kroll's printed lead strips, and indeed it would not be possible to meet the design requirements in Jensen with a printed lead strip.

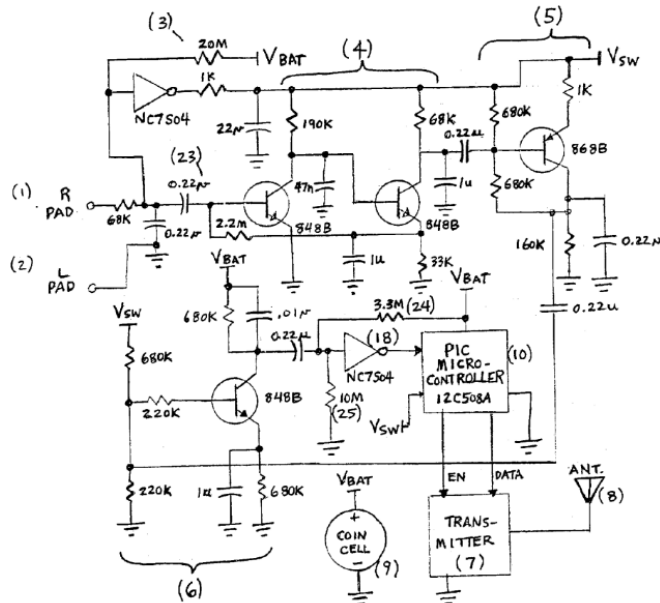
158. The voltage range requirements, resistance value variability tolerances, use variability constraints, geometric constraints, and the necessity for integration with amplifiers and filtering circuits differ substantially for resistors intended for gain-setting, filtering, signal biasing, and feedback applications. These resistors are designed to ensure reliable signal handling (analog processing) performance.

159. Conversely, printed resistive traces designed as current limiters, like Kroll's lead strips, can 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.

160. A proper understanding of resistor design and function shows why Dr. Heikenfeld's logic is flawed. Namely, under Dr. Heikenfeld's logic, Jensen's conventional resistors should protect the electronics because the resistors limit current flow in both directions. I disagree. Just because a resistor limits current flow in both directions does not mean that a resistor would protect the electronics. For the reasons detailed in this Section and VII.B.ii.b.iii, resistors are specifically designed for their respective functions. Dr. Heikenfeld does not consider a single variable of resistor design beyond that resistors are bidirectional. A POSITA would be aware of the complexity of resistor design for varying needs for different contexts.

161. Jensen provides example embodiments of its electronics circuit that includes its resistors. Ex. 1011, ¶ [0036]. In one example, Figure 2 includes resistors 24, 25 for signal biasing. Ex. 1011, ¶ [0032]. In Figure 3, resistors 20, 21 function as gain setting resistors. Ex. 1011, ¶ [0036]. A POSITA would have readily understood that these resistors are specifically designed and located on Jensen's

electronics circuit to achieve their function. Dr. Heikenfeld overlooks all aspects of resistor design to conclude that Kroll's lead strips would protect the electronics.



Ex. 1011, Figure 2.

162. Another example that further demonstrates Dr. Heikenfeld's flawed logic is the gain setting resistors of Jensen. A POSITA would have understood that Jensen's gain setting resistors are constructed with the precision required for low noise signal amplification. Such gain resistors cannot be printed. Moreover, gain setting resistors are often adjustable by including an adjustable resistor. This allows, the resistance to be tuned. Printed resistors, like the lead strips of Kroll, cannot function as gain setting resistors because the resistance cannot be precisely constructed for such low noise amplification. Moreover, printed resistors cannot be tuned. Once printed, the resistance is set. A POSITA would have recognized this

difference in capabilities and would have been motivated against replacing Jensen's gain setting resistors with Kroll's lead strips.

163. For these reasons, I disagree with Dr. Heikenfeld that a POSITA would have understood that Kroll's lead strips would protect Jensen electronics. A POSITA would have understood the complex nature of resistor design for specific applications. Thus, a POSITA would not have been motivated combine Kroll's lead strips with Jensen's device based on a desire to protect the electronics.

- b. A POSITA would not have been motivated to combine Jensen and Kroll to reduce the size of Jensen

164. Dr. Heikenfeld opines that a POSITA would have been motivated to combine Jensen and Kroll "to reduce the size of the device to increase the commercial and clinical viability of the device." Ex. 1009, ¶ 215. I disagree.

165. First, a POSITA would have understood that Jensen already achieves its desired size, and Dr. Heikenfeld does not identify any disclosure that the size of Jensen device is an issue or that Jensen wants to further limit the size. Second, Kroll provides a therapeutic device that wraps around the patient. A POSITA would not have looked to Kroll's larger device to make Jensen's device smaller. Finally, a POSITA would have recognized the significant obstacles in implementing Kroll's lead strips in Jensen. Dr. Heikenfeld does not address a single issue.

i. Jensen already achieves its size goals

166. A POSITA would have recognized that Jensen already achieves this goal; therefore, a POSITA would not have been motivated to replace Jensen's conventional resistors to reduce the size. Jensen states that its device's "novelty include[s] its physical construction." Ex. 1011, ¶ [0030]. This device is "a totally self-contained sensor that is thin, being less than 6 or 7 mm in thickness, [and] low in mass." Ex. 1011, ¶ [0030]. Jensen provides a device that achieves its goal related to physical dimensions while already using several conventional resistors.

167. Dr. Heikenfeld does not identify any disclosure in Jensen to establish that the size is an issue, or that Jensen intends to further limit the size. Again, this is because the disclosure shows that Jensen already achieves its desired physical dimensions. Ex. 1011, ¶ [0030].

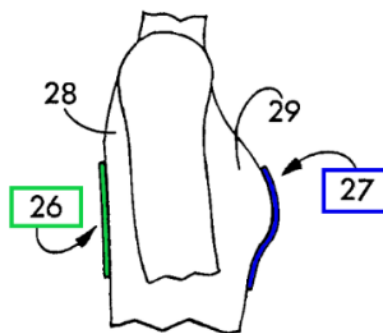
168. Thus, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to replace Jensen's resistors with Kroll's lead strips to further a goal that Jensen already achieves.

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

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

170. 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.

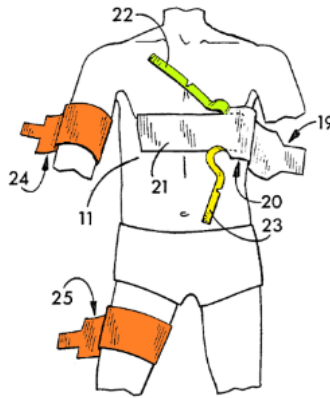
171. For example, the electrode belt is placed on the patient's chest and back. Ex. 1013, 4:44-47, Figure 3 (indicating the chest portion of the belt in blue and the back portion of the belt in green). This placement is required to transmit the current through the chest to the back, allowing Kroll to target specific areas for therapeutic purposes. Ex. 1013, 4:44-47, Figure 3.



Ex. 1013, Figure 3 (annotated).

172. 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 the 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).

173. Dr. Heikenfeld argument that a POSITA would have looked to Kroll's belt device to make Jensen'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.

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

- iii. Dr. Heikenfeld fails to address the obstacles in implementing Kroll's lead strips in Jensen's device

175. Kroll's lead strips are originally intended for the large, body-area applications of Kroll's electrode belt. In contrast, Jensen provides a smaller, compact device, which utilizes conventional discrete resistors. A POSITA would have recognized the substantial technical difficulties that must be overcome to incorporate Kroll's lead strips in Jensen's device. Dr. Heikenfeld does not acknowledge or address any of these technical difficulties.

176. Below, I list non-limiting examples of technical difficulties that a POSITA would have to consider when implementing the resistors of Kroll in Jensen'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.

177. 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 material selection, resistance value selection, and of controlled layering techniques to ensure trace and device design goal.

178. 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.

179. 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 Jensen's device.

180. Fifth, a POSITA would have to managing trace spacing in a miniaturized 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.

181. 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.

182. 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 Jensen, as further evidenced by my declaration and technical analyses provided within the scope of this matter.

183. Thus, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to make Jensen smaller by replacing Jensen's resistors with Kroll's traces in view of the significant technical obstacles.

C. Ground 3: Dr. Heikenfeld Fails to Establish that the Combination of Jensen, Matsumura, Kroll, and General Knowledge of a POSITA Renders Obvious Claims 7, 8, or 11 to 14

184. Dr. Heikenfeld opines that Claim 7, 8, and 11 to 14 are obvious over the combination of Jensen, Matsumura, Kroll, and the general knowledge of a POSITA. Ex. 1009, ¶ 933. I disagree with Dr. Heikenfeld's opinion for four reasons.

185. First, Dr. Heikenfeld’s combination fails to render obvious Claim 7 because it does not teach or suggest claim element 7[b], which requires “a reusable communication module.” Ex. 1003, Claim 7; *see* Section VII.C.i.

186. Second, Dr. Heikenfeld’s combination fails to render obvious Claim 7 because it does not teach or suggest claim element 7[c], which requires a “disposable electrode portion comprising a flexible printed circuit layer.” Ex. 1003, Claim 7; *see* Section VII.C.ii.

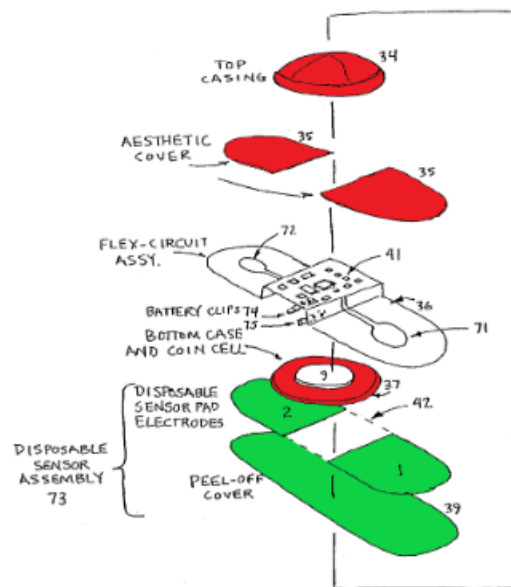
187. Third, Dr. Heikenfeld’s combination fails to render obvious Claim 7 because it does not teach or suggest claim element 7[e], which requires an “electrical traces defined between the at least two electrodes and a connection pad.” Ex. 1003, Claim 7; *see* Section VII.C.iii

188. Four, Dr. Heikenfeld fails to establish that a POSITA would have been motivated to combine Jensen and Matsumura. A POSITA would not have been motivated to combine Jensen and Matsumura (1) to achieve Matsumura’s waterproof structure or (2) “to limit the risk of contamination.” *See* Section VII.C.iv.

i. Jensen fails to render obvious claim element 7[b]

189. Claim element 7[b] requires “a reusable communication module.” Ex. 1003, Claim 7. Dr. Heikenfeld opines that “a POSA would understand that the transmitter 7 is located on the re-usable (non-disposable) portion of Jensen.” Ex. 1009, ¶ 961. I disagree with Dr. Heikenfeld’s opinion.

190. Jensen identifies transmitter 7 as part of its electronics circuit. Ex. 1011, ¶¶ [0032], [0033], [0040]. However, Jensen is silent as to whether its transmitter is reusable. In contrast, Jensen states that its reusable portion is “comprised of bottom case 37, top casing 34 and two aesthetic covers 35.” Ex. 1011, ¶ [0042], Figure 5 (identifying the “re-useable” components of Jensen in red).



Ex. 1011, Figure 5 (annotated).

191. Jensen does not identify the transmitter as one of these reusable components, and nothing in Jensen identifies the transmitter as a reusable component. Ex. 1011, ¶ [0042], Figure 5. Dr. Heikenfeld does not address this lack of evidence but instead selectively cites to Jensen’s “re-usable (non-disposable) portion.” Ex. 1009, ¶ 961 (citing Ex. 1011, ¶ [0043]). But this disclosure is not describing the transmitter that Dr. Heikenfeld identifies.

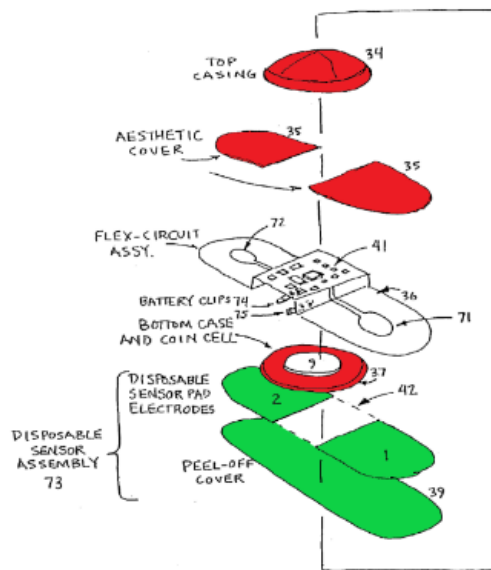
192. Further, I disagree that Dr. Heikenfeld can simply conclude that “a POSA would understand that the transmitter 7 is located on the re-usable (non-disposable) portion of Jensen.” Ex. 1009, ¶ 961. Dr. Heikenfeld provides no reason why a POSITA would have understood this, especially when Jensen identifies reuseable components that do not include the transmitter.

193. Thus, I disagree with Dr. Heikenfeld. A POSITA would not have understood (and Dr. Heikenfeld provides no explanation) that the transmitter is reuseable. Accordingly, Dr. Heikenfeld does not establish that Jensen renders obvious the “reusable communication module” of claim element 7[b].

ii. Jensen fails to render obvious claim element 7[c]

194. Claim element 7[c] requires a “disposable electrode portion comprising a flexible printed circuit layer.” Ex. 1003, Claim 7. Dr. Heikenfeld opines that the combination of Jensen, Matsumura, and the knowledge of a POSITA discloses claim element 7[c]. Ex. 1009, ¶ 964. I disagree with Dr. Heikenfeld’s opinion.

195. Jensen does not disclose a disposable electrode portion having a flexible printed circuit layer. Jensen’s only disposable portion is the “disposable sensor assembly.” Ex. 1011, ¶¶ [0041]-[0042]. The “disposable sensor assembly” includes (1) disposable sensor pad electrodes and (2) a peel-off cover, which are indicated in green components in Figure 5. Ex. 1011, ¶¶ [0041]-[0042], Figure 5.



Ex. 1011, Figure 5 (annotated).

196. The disposable sensor pad electrodes and the peel-off cover are the only two components that Jensen identifies as disposable. Dr. Heikenfeld does not identify (because he cannot) a disposable electrode portion having a printed circuit layer in Jensen's disclosure. Thus, Dr. Heikenfeld proposed major structural changes to Jensen's device to reconstruct Claim 7.

197. A POSITA would not have been motivated to modify Jensen's structure and move (1) the flexible circuit assembly, (2) the electrical traces, and (3) the sensor contacts to the disposable sensor assembly. For the reasons discussed in Section VII.C.iv, a POSITA would not have been motivated to make this combination, and Dr. Heikenfeld fails to render Claim 7[c] obvious in view of Jensen and Matsumura.

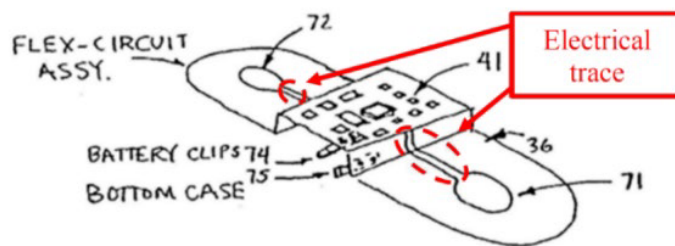
iii. Jensen fails to render obvious claim element 7[e]

198. Claim element 7[e] requires “electrical traces defined between the at least two electrodes and a connection pad.” Ex. 1003, Claim 7. Dr. Heikenfeld opines that a POSITA “would understand that the connection that is created by the Jensen’s traces [that] extend[] from the electrode sensor pads 1, 2 to a connection pad 48.” Ex. 1009, ¶ 976. I disagree with Dr. Heikenfeld’s opinion because Dr. Heikenfeld’s analysis is flawed for the same reasons as discussed in Section VII.B.i.

199. A POSITA would not have understood that Jensen’s copper wiring traces disclose claim element 7[e] because Jensen’s copper wiring is not “defined between the at least two electrodes and a connection pad.” Ex. 1003, Claim 7. Dr. Heikenfeld fails to identify any disclosure in Jensen to support his opinion. Jensen’s disclosure instead supports the conclusion that Jensen’s copper wiring is not defined between the connection pad and the conductive surface.

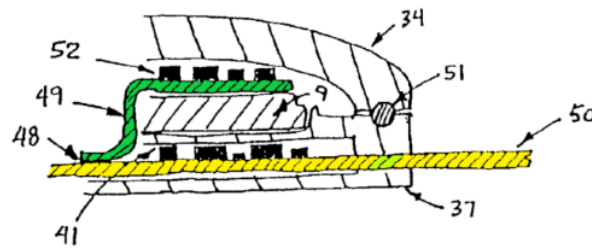
200. Dr. Heikenfeld first annotates Figure 5 of Jensen to identify the copper wiring traces. Ex. 1009, ¶ 976. These annotations (shown below) confirm that Jensen’s copper wiring is not defined between the at least two electrodes and a connection pad. As shown in Figure 5, which is consistent with Jensen’s description of Figure 5, the copper wiring traces is part of flexible circuit assembly 36. Ex. 1011, ¶ [0040]. The copper wiring traces function “to connect the entire circuit 41 to the sensor contacts 71, 72.” Ex. 1011, ¶ [0040]. Thus, Jensen’s copper wiring

traces extend from sensor contact 71 to electronics circuits 41. Contrary to Dr. Heikenfeld's opinion, the copper wiring traces terminate at the electronics circuit; there is no illustration in Figure 5 or corresponding description that establishes that the copper wiring traces are defined between "the at least two electrodes and a connection pad" as required by Claim 7. Ex. 1003, Claim 7.



Ex. 1009, Figure 5 (original annotations by the Dr. Heikenfeld).

201. Dr. Heikenfeld also relies on Figure 8 of Jensen. Ex. 1009, ¶ 898. Dr. Heikenfeld also cites to Section XVIII.B.2.iv–v (Ex. 1009, ¶¶ 891–898), which relies also relies on Figure 8 of Jensen. However, Dr. Heikenfeld's reliance on the alternative embodiment of Figure 8 does not cure Dr. Heikenfeld's insufficient reliance on Figure 5. Like Figure 5, Figure 8 does not illustrate or describe Jensen's copper wiring traces defined between the at least two electrodes and a connection pad. Figure 8 includes circuit 49 and circuit 50, which are connected via "a set of pads 48" that are heat re-flowed together. Ex. 1011, ¶ [0046], Figure 8. There is no support, and thus a POSITA would not have understood, that Jensen's copper wiring traces are in any way connected to the set of pads 48.



Ex. 1011, Figure 8 (annotated).

202. Because Jensen does not provide any disclosure that establishes the copper wiring traces are defined between the at least two electrodes and a connection pad, Dr. Heikenfeld contends that a POSITA “would understand that the connection that is created by the Jensen’s traces extends from the electrode sensor pads 1, 2 to a connection pad 48.” Ex. 1009, ¶ 976. I disagree with Dr. Heikenfeld’s opinion.

203. Jensen discloses “the pads 48 at the connection of flexible circuit 49 and 50 are matched on both circuits, with the matched pads of tinned-copper exposed on the bottom side of circuit 49 and the top side of circuit 50.” Ex. 1011, ¶ [0046]. Here, the circuit 49 and circuit 50 are matched and heat reflowed together. There is no basis to conclude that the copper wiring traces extend to this connection pad and are matched to circuit 49 for this process. Consistent with Jensen’s disclosure, a POSITA would have understood that the copper wiring traces terminate at electronics circuit 41, and circuit 50 is heat re-flowed together with circuit 49.

204. To the extent that Dr. Heikenfeld is opining that Jensen’s copper wiring traces satisfy claim element 7[e] because it is electrically coupled to sensor pads 71,

72 and connection pad 48, I also disagree with this opinion. A POSITA would not have understood Dr. Heikenfeld's position as consistent with the teachings of the '492 Patent. For example, the '492 Patent states that "[t]races 412 extend[] between conductive surface 404 and connection pads 408 and 409." Ex. 1003, 7:44-55. Traces 412 (indicated in orange) are shown below in Figure 4A. Ex. 1003, 7:44-55, Figure 4A (annotated). In other example, the '492 Patent states that trace 413 (indicated in blue) "extend[s] between conductive surface 405 and connection pad 411" and trace 413 can connect contact pad 405 to the connection pad 411 "to provide a direct-connected reference electrode." Ex. 1003, 7:44-55; Figure 4A (annotated). The '492 Patent demonstrate that any components electrically coupled satisfy claim element 7[e] does not fall within the claim language.

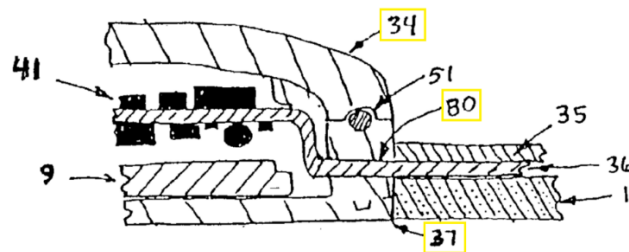
205. Thus, Dr. Heikenfeld fails to establish that a POSITA would have understood that Jensen's copper wiring traces disclose claim element 7[e].

iv. A POSITA would not have been motivated to combine Jensen and Matsumura

206. Dr. Heikenfeld opines that a POSITA would have been motivated to combine Jensen and Matsumura. Ex. 1009, ¶ 935. Dr. Heikenfeld opines that a POSITA would have been motivated to combine Jensen and Matsumura (1) to achieve Matsumura's waterproof structure and (2) "to limit the risk of contamination." Ex. 1009, ¶¶ 939, 943. I disagree with Dr. Heikenfeld's opinion.

- a. A POSITA would not have been motivated to combine Jensen and Matsumura to achieve a waterproof structure

207. A POSITA would not have been motivated to combine Jensen and Matsumura to achieve a waterproof structure because Jensen's electronics are already sealed from the surrounding environment. Ex. 1011, ¶ [0045].



Ex. 1011, Figure 7 (annotated).

208. Jensen provides top case 34 that mounts to bottom case 37, which includes slot cut-out 80 for the passage of flexible circuit assembly 36. Ex. 1011, ¶ [0045]. This structure is shown in Figure 7. Ex. 1011, Figure 7. Once Jensen's device is assembled, a sealant is applied to the slot 80 "to seal the electronics 41 from the surrounding environment." Ex. 1011, ¶ [0045]. Also, the "top and bottom case halves 34, 37 have an o-ring seal 51 at their mating surfaces." Ex. 1011, ¶ [0045]. Reading this disclosure, a POSITA would not have been motivated to look to other references to achieve a waterproof structure as Dr. Heikenfeld opines.

209. Moreover, Dr. Heikenfeld concludes, without support, that a POSITA "would recognize that this sealing technique taught by Jensen is prone to seepage through the top, bottom, and slot in the smart patch through which the flexible circuit

assembly extends.” Ex. 1009, ¶ 943. But Dr. Heikenfeld acknowledges that Jensen applies a sealant to slot 80 once assembled. Ex. 1009, ¶ 943.

210. Thus, Dr. Heikenfeld fails to establish that a POSITA would have been motivated to combine Jensen and Matsumura to achieve a waterproof structure.

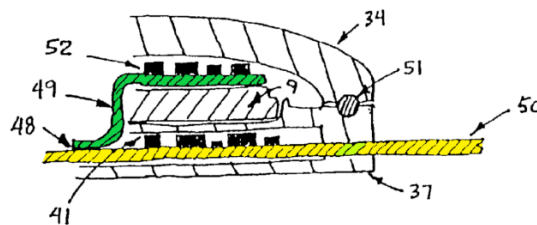
- b. A POSITA would not have been motivated to combine Jensen and Matsumura to limit the risk of contamination

211. A POSITA would not have been motivated to combine Jensen and Matsumura “to limit the risk of contamination.” Ex. 1009, ¶ 939.

212. In Figure 5, Jensen provides disposable sensor pad electrodes 1, 2 coupled to the flexible circuit assembly, which includes electronics circuit 41. Ex. 1011, ¶¶ [0041]-[0042], Figure 5. Dr. Heikenfeld opines that, in view of Matsumura, a POSITA would modify to Jensen “to include a disposable layer that electrically connects the electrodes (Jensen’s sensor pad electrodes 1, 2) to the circuitry in the reusable component (electronic circuitry 41 and coin cell 9).” Ex. 1009, ¶ 942.

213. Dr. Heikenfeld’s proposed modification uses Claim 7 as a roadmap. Moreover, Dr. Heikenfeld opinion is based on the false premise that the modification would lead to disposable parts and thus minimize the risk of ineffective cleaning. Ex. 1009, ¶ 939 (“[A] POSA would have been motivated to seek out ways to make more parts of the device disposable.”).

214. A POSITA would not have been motivated to make this modification because circuit 50 and circuit 49 are “heat re-flowed together.” Ex. 1011, ¶ [0046]. Figure 8 of Jensen shows both circuits. Ex. 1011, ¶ [0046], Figure 8. Jensen states that circuit 49 is connected to circuit 50 via “a set of pads 48.” Ex. 1011, ¶ [0046]. The pads are “heat re-flowed together, melting the tinning metal, to connect the two circuits.” Ex. 1011, ¶ [0046], Figure 8A. A POSITA would have understood that Jensen’s heat re-flow process forms a permanent bond, like a weld.



Ex. 1011, Figure 8 (annotated).

215. Dr. Heikenfeld opines that a POSITA would have been motivated to make circuit 50 disposable but fails to explain how a POSITA would make this change in view of Jensen’s heat re-flow process. Dr. Heikenfeld does not address Jensen’s disclosure regarding its heat re-flow process.

216. When considering such disclosure, a POSITA would not have been motivated to make circuit 50 disposable. Instead, a POSITA would have understood that there are no advantages in making circuit 50 disposable because circuit 50 would still be fixed to reusable circuit 49. Separating circuits 49, 50 would damage (if not

destroy) Jensen's device. If Dr. Heikenfeld's proposed modification was made, Jensen would include a "disposable" circuit 50 that could not be detached (and thus not disposable) from the other circuit 49. Thus, a POSITA would have recognized that, contrary to Dr. Heikenfeld's opinion, there would be no advantage in making circuit 50 disposable in Jensen's device.

217. Thus, Dr. Heikenfeld fails to establish that a POSITA would have been motivated to combine Jensen and Matsumura to limit the risk of contamination.

VIII. RESERVATION OF RIGHTS

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

219. 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