

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IRHYTHM, INC.,

Petitioner,

v.

WELCH ALLYN, INC.,

Patent Owner.

CASE: IPR2025-00376

U.S. PATENT NO. 9,155,484

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 1-8, 11-12, and 15-20 (the “Challenged Claims”) of U.S. Patent No. 9,155,484 (the “’484 Patent”) (Ex. 1005) 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 ’484 Patent (Ex. 1005), its file history (Ex. 1006), the Declaration of Dr. Jason Heikenfeld (Ex. 1009), and three prior art references: Matsumura (Ex. 1012), Jensen (Ex. 1011) and Ozguz (Ex. 1014). 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 '484 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 '484 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 '484 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 '484 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 '484 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 '484 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.^{1F2}

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 four “obviousness” theories with Grounds 1 to 4.

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 '484 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.

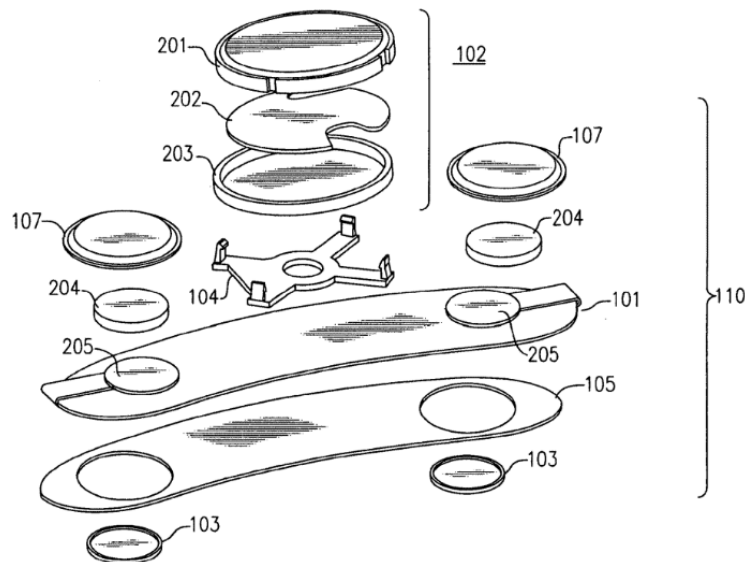
42. My analysis and opinions below are given from the perspective of a POSITA in this technological field in the relevant time frame, unless stated otherwise.

43. I satisfied the definition of a POSITA before the filing date of the application leading to the '484 Patent. I now consider myself an expert in the relevant field of technology for the '484 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 '484 PATENT

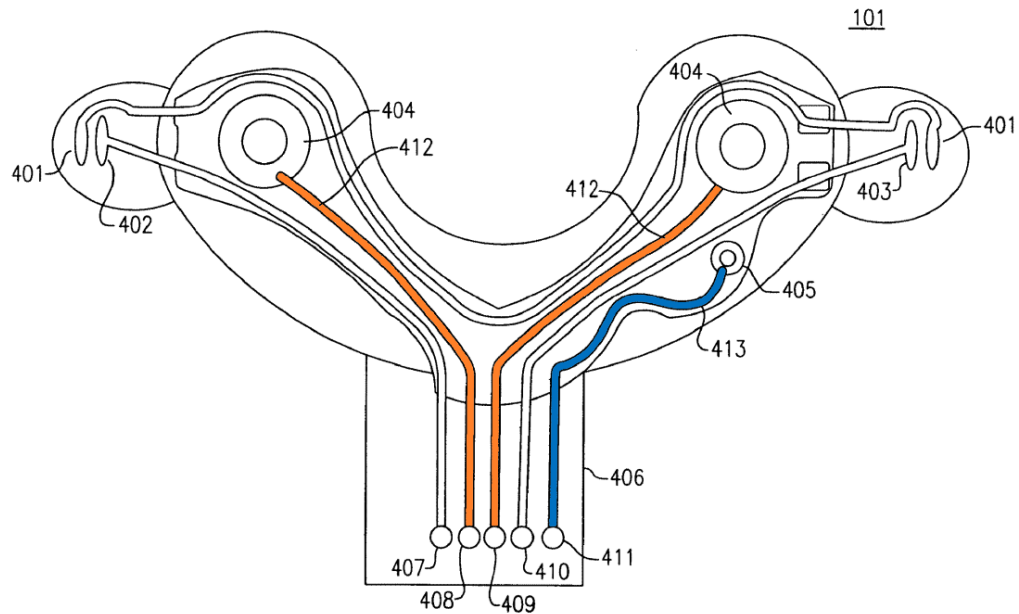
45. The '484 Patent provides a body-worn physiological sensor that adhesively attaches to a patient's skin for measuring physiological signals. Ex. 1005, Abstract, cl. 1. The body-worn patient monitoring device includes computation-communication module 102 releasably attached to disposable electrode module 110. Ex. 1005, cl. 7, 4:59-67, Figure 2. In Figure 2, retention clip 104 secures the computation-communication module to the disposable electrode module. Ex. 1005, cl. 7.



Ex. 1005, Figure 2.

46. The disposable electrode module 110 includes flexible printed circuit layer 101 made from an insulating material. Ex. 1005, 5:15-28, cl. 1. The flexible printed circuit layer transmits electrical signal via traces, which connect a connection pad and an electrode. Ex. 1005, 7:47-58, cls. 1, 7. The traces 412 (orange), which

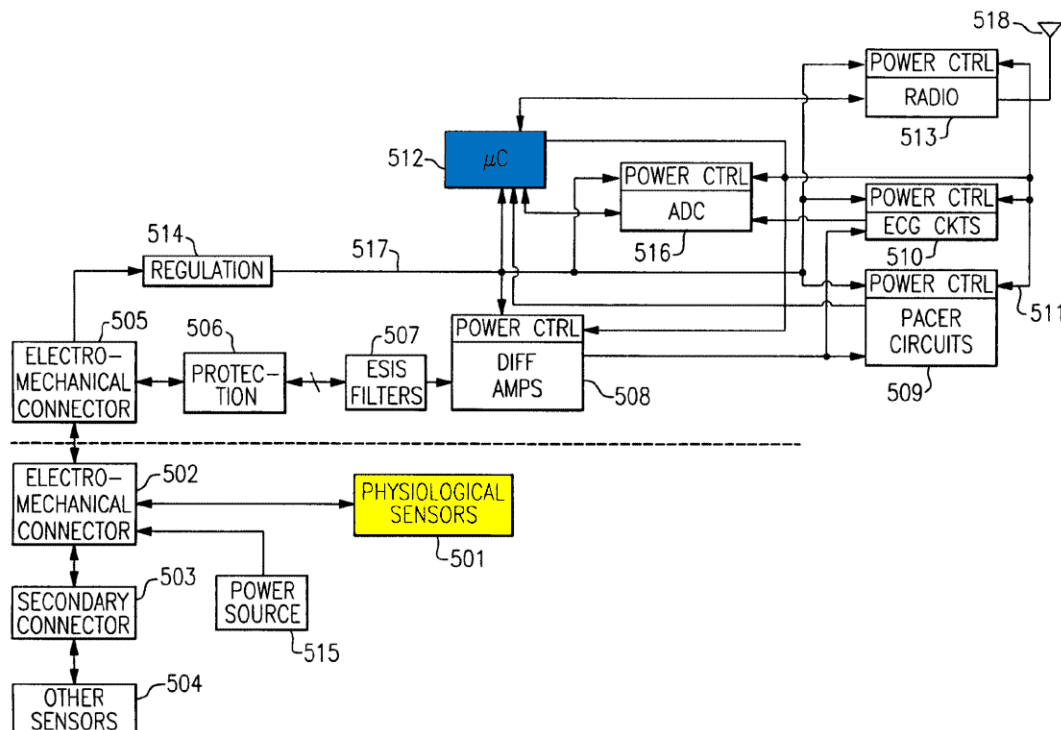
are preferably printed, “extend[] between conductive surface 404 and connection pads 408 and 409.” Ex. 1005, Figure 4A (annotated), 5:36-40 (defining the conductive surface as part of the electrode), 7:53-58. Similarly, the trace 413 (blue), “extend[s] between conductive surface 405 and connection pad 411.” Ex. 1005, 7:47-58, Figure 4A (annotated). The traces are made from a resistive material. Ex. 1005, 7:53-58.



Ex. 1005, Figure 4A (annotated).

47. This pathway from the electrodes to the computation-communication module is also shown in the block diagram of the Figure 5. Ex. 1003, 11:33-50, Figure 5. There, the physiological sensors (*e.g.*, electrodes) for capturing an ECG difference potential are indicated in yellow. Ex. 1005, 11: 33-50, Figure 5 (annotated). The physiological sensors 501 are electrically coupled to an

electromechanical connector 502, which is further connected to the processor for performing computational analysis on the detected signals. Ex. 1005, 11:33-50, Figure 5 (annotated), Figure 4A. The computation-communication module further includes a housing that contains this processor. Ex. 1005, cl. 1.



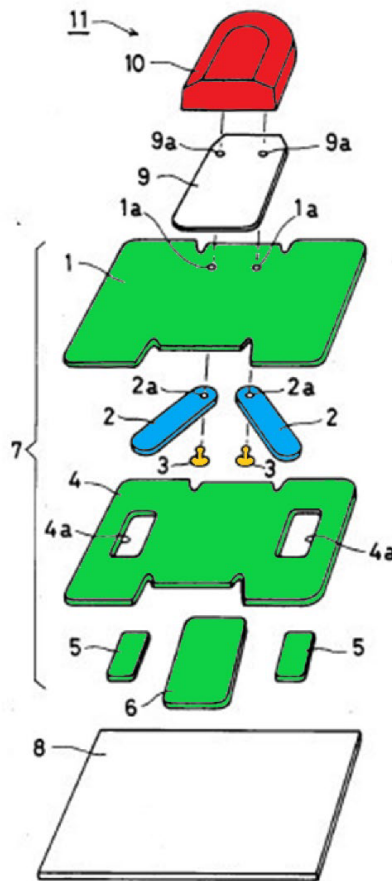
Ex. 1005, Figure 5 (annotated).

V. SUMMARY OF THE ART

A. Matsumura (Exhibit 1012)

48. 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).

49. 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].

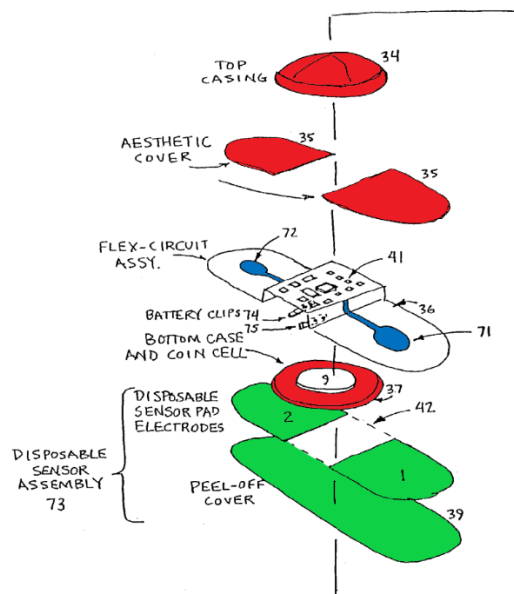
50. Hooks 3 have an electrical and mechanical role in preserving the device’s electrical and structural integrity by securely, but releasably, attaching the disposable pad 7 to the signal processor 10, while also transmitting bioelectric potential signals received from the conductive material 2 to the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

B. Jensen (Exhibit 1011)

51. 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].

52. 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).

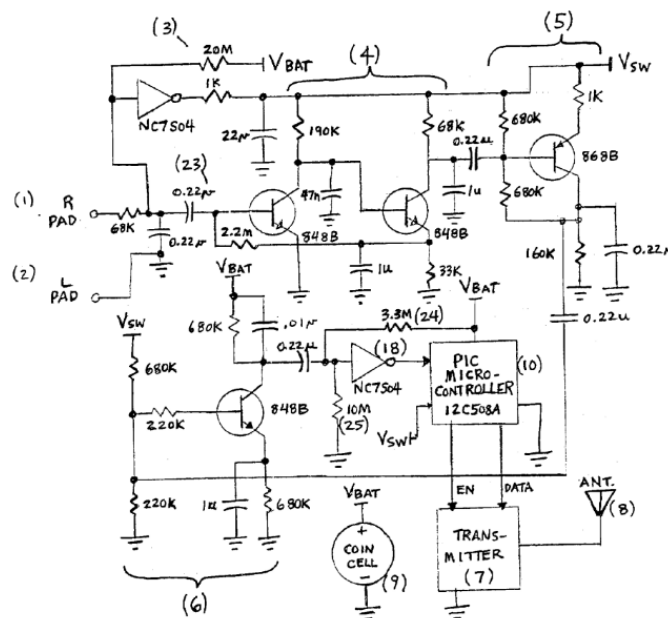


Ex. 1011, Figure 5 (annotated showing disposable portions in green, reusable portions in red).

53. Moreover, Jensen describes an additional, non-disposable flexible circuit assembly 36 having “traces” (annotated in blue above). Ex. 1011, ¶ [0040],

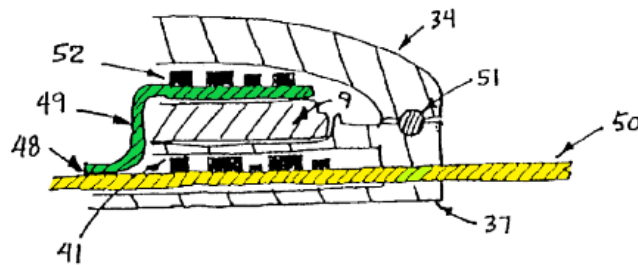
Figure 5. These “traces” connect electronics circuit 41 to sensor contacts 71 and 72, which, in turn, connect to pads 1 and 2 of disposable sensor assembly 73. Ex. 1011, ¶ [0040], Figure 5. This way, the signals captured by sensor pads 71, 72 of disposable sensor assembly 73 are transmitted to electronics circuit 41.

54. 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 selected to accomplish very specific analog processing functions. Further, Jensen’s resistors are located in the electronics circuit (*see* electronics circuit 41 in Figure 5) as opposed to, for example, on the flexible circuit assembly.



Ex. 1011, Figure 2.

55. 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).

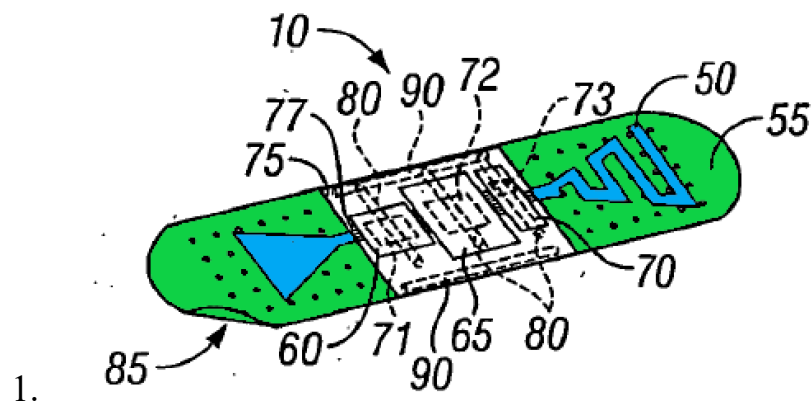
56. To create this connection, “pads of tinned-copper exposed on the bottom side of circuit 49 and the top side of circuit 50” are matched. Ex. 1011, ¶ [0046], Figure 8A. Then, pads 48 “are heat re-flowed together, melting the tinning metal, to connect the two circuits.” Ex. 1011, ¶ [0046], Figure 8,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

C. Ozguz (Exhibit 1014)

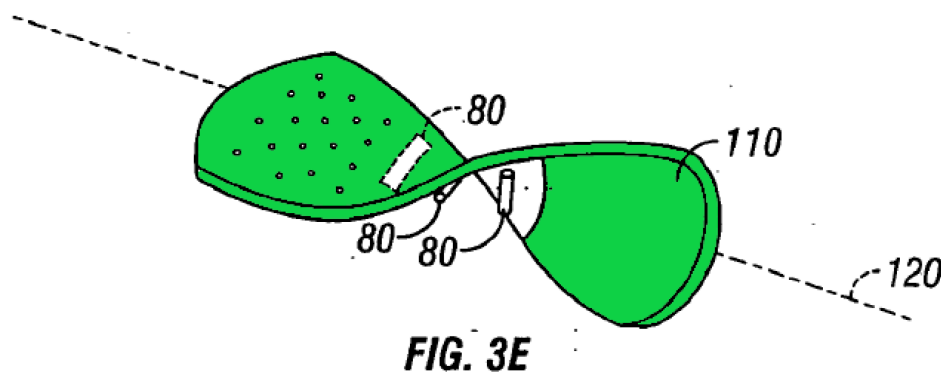
57. Ozguz describes a wearable sensor module for monitoring physiological characteristics, but does so with engineering ideals that are not grounded in the capabilities of the disclosure. Ex. 1014, ¶ [0003]; *infra* Vii.C.iv. Ozguz’s module is described as having a “form similar to an adhesive bandage[,]” both in appearance and application to a patient’s skin. Ex. 1014, ¶ [0003], [0007]. Ozguz’s goal was to “overcome[] the need for [a] stiff substrate material that is normally used to support thin silicon to prevent breaking of the silicon and destruction of any micro-circuitry thereon.” Ex. 1014, ¶ [0019]. The resulting device is described as a module that is approximately 30 to 60 mm in length and 10

to 20 mm in width, approximately the size of a Band-Aid. Ex. 1014, ¶ [0052].

Ozguz's module is shown in Figures 1 and 3E. Ex. 1014, Figures 1, 3E.



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



Ex. 1014, Figure 3E (annotated).

58. Ozguz states that its sensor module is either entirely disposable (*i.e.*, the entire module is discarded without any remains) or entirely reusable after sterilization. Ex. 1014, ¶ [0049] (“The sensor module can be sterilized in an autoclave, for example, between uses. Alternatively, the sensor modules are made

disposable and are discarded after monitoring a particular subject body 20 for purposes of good hygiene.”).

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

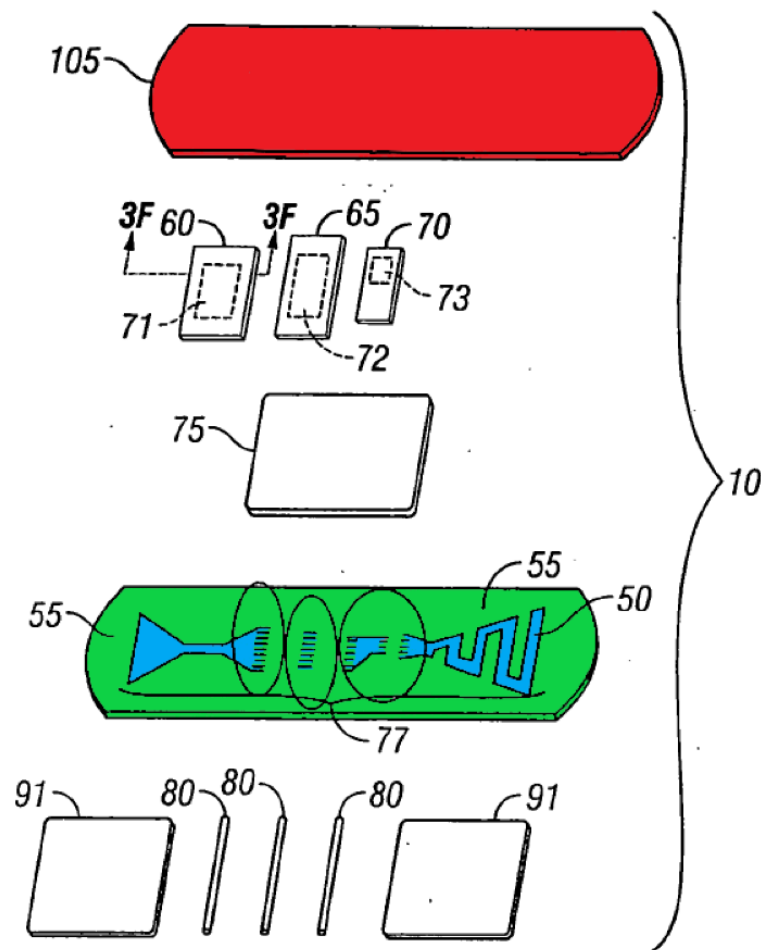


FIG. 3B

Ex. 1014, Figure 3B (annotated).

60. Additionally, Ozguz explains that metallization 77 connects electrodes 80 to the ICs, and the metallization is generally “integral with and forms part of the layer of the flexible substrate.” Ex. 1014, ¶ [0047]-[0048]. A POSITA, reading the express disclosure of Ozguz, would have understood that Ozguz’s module is a single unit, and none of the components are intended to be detached from the module except for adhesive pads 91. Ex. 1014, ¶ [0049]. Otherwise, the “sensor modules are made disposable and are discarded after monitoring a particular subject body 20.” Ex. 1014, ¶ [0049].

VI. SUMMARY OF OPINIONS

61. I understand that Dr. Heikenfeld advances Grounds 1 to 4 and in them alleges that Claims 1 to 8, 11, 12, and 15 to 20 of the ’484 Patent are obvious. I disagree with Dr. Heikenfeld.

62. In Ground 1, Dr. Heikenfeld opines that Claims 1 to 5 and 15 to 20 of the ’484 Patent are obvious over the combination of Matsumura in view of the general knowledge of a POSITA. It is my opinion that Ground 1 fails to render the Challenged Claims obvious for three reasons. First, Ground 1 does not teach or suggest the claimed “traces.” *See* Section VII.A.i-ii. Second, Ground 1 does not teach or suggest a “a flexible printed circuit board layer.” *See* Section VII.A.ii. Third, a POSITA would not have been motivated to modify Matsumura in view of

the general knowledge of a POSITA as proposed by Dr. Heikenfeld. *See* Section VII.A.ii.b.

63. In Ground 2, Dr. Heikenfeld opines that Claims 1 to 5, 15, 17, 18, and 20 of the '484 Patent are obvious over the combination of Jensen and the general knowledge of a POSITA. It is my opinion that Ground 2 fails to render the Challenged Claims obvious for four reasons. First, Ground 2 does not teach or suggest a “computation-communication module being attached to the flexible circuit layer.” *See* Section VII.B.i. Second, Ground 2 does not teach or suggest “an adhesive covering at least a portion of the flexible circuit layer.” *See* Section VII.B.ii. Third, Ground 2 does not teach or suggest “traces of determinable electrical resistance.” *See* Section VII.B.iii. Fourth, Ground 2 does not teach or suggest “a flexible printed circuit layer.” *See* Section VII.B.iv.

64. In Ground 3, Dr. Heikenfeld opines that Claims 1 to 8, 15, 19, and 20 of the '484 Patent are obvious over the combination of Ozguz in view of the general knowledge of a POSITA. It is my opinion that Ground 3 fails to render the Challenged Claims obvious for the following reasons. First, Ground 3 does not teach or suggest a “housing” or a housing “retaining” or “containing” a processor. *See* Section VII.C.i-iii. Second, a POSITA would not have been motivated to modify Ozguz in view of the general knowlegde of a POSITA to reach the challenged claims because a POSITA would have viewed Ozguz as not enabled. *See* Section VII.C.iv.

In Ground 4, Dr. Heikenfeld opines that Claims 6 to 8, 11, and 12 of the '484 Patent are obvious over Matsumura, Ozguz, and the general knowledge of a POSITA. It is my opinion that Ground 4 fails to render the Challenged Claims obvious for the reasons discussed with respect to Grounds 1 to 3.

65. As set forth below, all four Grounds fail.

VII. OPINIONS

A. Ground 1: Dr. Heikenfeld Fails to Establish that the Combination of Matsumura and General Knowledge of a POSITA Renders Obvious Claims 1 to 5 and 15 to 20

66. Dr. Heikenfeld opines that Claims 1 to 5 and 15 to 20 are obvious over Matsumura and the general knowledge of a POSITA. Ex. 1009, ¶ 1013. I disagree with Dr. Heikenfeld's opinion for three reasons.

67. First, because independent Claim 1 was statutorily disclaimed, my analysis focuses on dependent Claim 2, which Dr. Heikenfeld's combination fails to render obvious because it does not teach or suggest Claim 2, which requires "traces." Ex. 1005, Claim 2. Second, Dr. Heikenfeld's combination fails to render obvious Claim 15 because it does not teach or suggest claim element 15[b], which requires "a flexible printed circuit layer." Ex. 1005, Claim 15. Third, a POSITA would not have been motivated to modify Matsumura with the general knowledge as proposed by Dr. Heikenfeld.

i. Matsumura fails to render obvious Claim 2

68. Claim 2 requires “the flexible circuit layer has traces of determinable electrical resistance.” Ex. 1005, Claim 2. Dr. Heikenfeld opines that Matsumura’s “hook 3 and a first portion of conductive material 2” render obvious the trace. Ex. 1009, ¶ 1048. I disagree with Dr. Heikenfeld’s opinion.

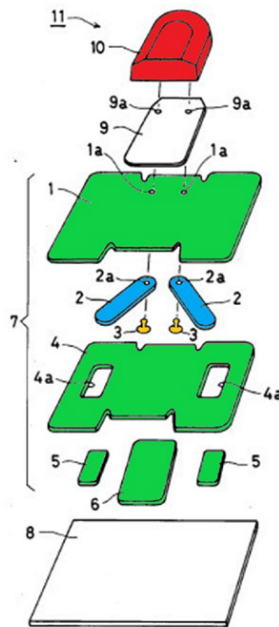
69. Dr. Heikenfeld states “a POSA would have understood hook 3 and a first portion of conductive material to be a ‘trace’ *because they are conductors on a printed circuit board.*” Ex. 1009 ¶ 1048. However, Dr. Heikenfeld has not established that Matsumura’s conductive material 2 and hooks 3 are on a printed circuit board, and Dr. Heikenfeld’s opinion fails for that reason alone. Additionally, Dr. Heikenfeld’s fails because he appears to equate all conductive elements to be traces and baselessly concludes that the hook of Matsumura is printed (without any explanation in support of this incorrect interpretation). Moreover, the cited portion of the Heikenfeld Declaration assumes, without explanation, that Matsumura discloses a printed circuit board, printed hooks, and equates hooks with conductive traces. Matsumura itself does none of those, nor would a POSITA interpret Matsumura in such a way.

70. Dr. Heikenfeld’s assertion that any conductive material is a trace, independent of a printed circuit board context, is misplaced because Dr. Heikenfeld’s opinion necessarily relies on the existence of a printed circuit board.

See Ex. 1009, ¶ 1048 (“[A] POSA would have understood hook 3 and a first portion of conductive material to be a “trace” *because they are conductors on a printed circuit board.*”) (emphasis added).

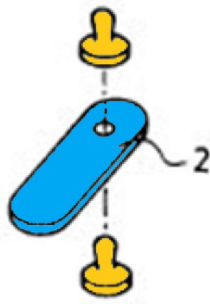
71. Matsumura does not disclose a printed circuit board. The exhibit that Dr. Heikenfeld relies on, Ex. 1035, actually supports a finding that Matsumura’s hook 3 and a first portion of conductive material 2 cannot be a trace based on the definition the exhibit provides: “Traces: The metallic conductive strips that provide connections between components, terminals, etc., on *printed circuits.*” Ex. 1035, 664 (emphasis added).

72. Matsumura discloses stud-like protruding hooks 3 and rigid, three-dimensional rod-shaped conductive material 2. Ex. 1012, ¶¶ [0019], [0021]; Figures 1, 8. While Matsumura’s protruding hook 3 and rod-shaped conductive material 2 may function like a conductor to transmit bioelectric signals, hooks 3 and conductive material 2 are not part of a printed circuitry and are physically incapable of being “printed” given the multiple layers through which they must extend. Ex. 1012, ¶ [0019]; Figure 1.

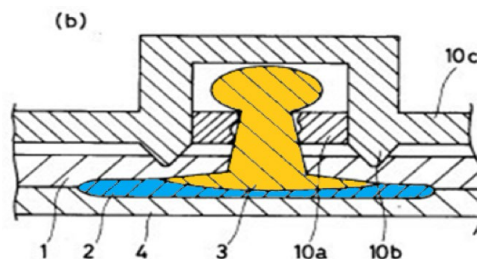


Ex. 1012, Figure 1 (annotated). These hooks and conductive material are not traces. And a POSITA would not have understood Matsumura as disclosing “traces” as commonly understood in the art.

73. 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.

74. Dr. Heikenfeld does not identify any disclosure in Matsumura that suggests Matsumura teaches or discloses the claimed traces. Matsumura's hooks 3 and conductive material 2 are arranged to transmit signals, which are detected by conductive gel 5, to signal processor 10, but the tightly compressed physical orientation of these three separate components (conductive gel 5, conductive material 2, and hooks 3) preclude the existence of "traces." Ex. 1012, ¶¶ [0019], [0021]. Thus, Dr. Heikenfeld fails to render Claim 2 obvious.

ii. Matsumura fails to render obvious Claim 15

75. Claim elements 15[b]-15[e] require “a flexible printed circuit layer.” Ex. 1005, Claim 15. Dr. Heikenfeld’s proposed modification of Matsumura in view of the general knowledge fails to render obvious Claim 15 because (1) Dr. Heikenfeld admits that Matsumura does not teach or suggest the claimed flexible printed circuit layer and does not establish that a POSITA would have made his proposed modification, and (2) Dr. Heikenfeld ignores Matsumura’s disclosure that conflicts with his proposed modification.

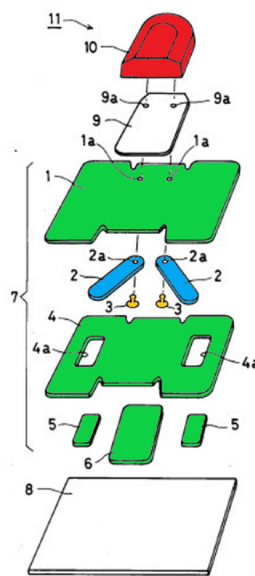
- a. Dr. Heikenfeld fails to establish that Matsumura and the general knowledge render obvious the claimed traces

76. Dr. Heikenfeld opines that modifying Matsumura’s “two pieces of conductive material 2” to be formed as a “flexible ‘printed circuit’ layer” renders Claim 15 obvious. Ex. 1009, ¶ 1069. I disagree with Dr. Heikenfeld’s opinion.

77. Dr. Heikenfeld proposes to “replace the two pieces of insulating material coated with conductive Ag/AgCl with a single, flexible sheet of insulating material containing printed-ink conductive traces.” Ex. 1009, ¶ 1070. Accordingly, Dr. Heikenfeld appears to admit that Matsumura does not disclose a flexible printed circuit layer. Ex. 1009, ¶ 1068-1070.

78. Indeed, Matsumura does not disclose a flexible printed circuit layer. Matsumura discloses a “bioelectric pad” composed of (1) a first sheet, (2) a

conductive material, (3) a hook, (4) a second sheet, (5) a conductive gel, (6) a third sheet, and (7) double-sided adhesive tape. Ex. 1012, ¶ [0016]. Matsumura further discloses that the conductive material is rod-shaped and that the hooks (orange) are studs that protrude through the back side of conductive material 2 (blue). Ex. 1012, ¶ [0019]; Figure 1.



Ex. 1012, Figure 1 (annotated).

79. A POSITA would not have understood Matsumura's conductive material 2 or hooks 3 to be printed. Instead, a POSITA would have known that replacing the conductive rods and hooks with insulating material and printed conductive traces, respectively, would aggravate the purpose of Matsumura. Specifically, replacing the rigid rod-shaped conductive material with a sheet of insulating material with printed traces would prevent the hooks from being able to

clamp down on the rigid structure of conductive material 2. Without that upward force (*i.e.*, the bottom portion of hook 3 pressing upward on the underside of conductive material 2), Matsumura's device loses the waterproof connection. In that case, conductive material 2 and hooks 3 would no longer be compressed securely between first sheet 1 and second sheet 4—which are intentionally made of insulating materials to prevent moisture ingress—allowing fluid to create a break in the electrical connection, compromising the waterproofing of Matsumura's device. Ex. 2012, ¶¶ [0017]-[0019], [0021].

80. Despite the essential electrical and mechanical function of conductive material 2 and hooks 3, Dr. Heikenfeld concludes that POSITA would have modified Matsumura to replace the rigid, rod-shaped conductive material with a sheet of insulating material with printed conductive traces, thereby eliminating the electrical function of the hooks (*i.e.*, receiving bioelectric signals from conductive material 2 and carrying the signals to the signal processor). A POSITA would not have made such a modification because the hooks are required to carry the bioelectric signals to the processor.

81. Dr. Heikenfeld provides clip art to illustrate his proposed modifications. *See, e.g.*, Ex. 1009, ¶ 1070. I do not agree that a POSITA would have made the modifications shown in the clip art. There is no disclosure in Matsumura that teaches or suggests replacing conductive material 2 and inserting

the unitary sheet of insulating material in the middle of the device shown in Figure 1.

- b. Dr. Heikenfeld ignores Matsumura's disclosure that conflicts with his opinions

82. Dr. Heikenfeld fails to acknowledge that conductive material 2 and hooks 3 have an essential dual electrical and mechanical role in Matsumura's device. Overall, Dr. Heikenfeld ignores Matsumura's affirmative teachings that are at odds with the '484 Patent.

83. Matsumura's disclosure is explicit: "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]. Further, Matsumura is clear that "[t]he bioelectric pad 7 and the signal processor 10 are detachable with hooks." Ex. 1012, ¶ [0016]. Matsumura discloses that first sheet 1 and second sheet 4 are "made of an insulating material that does not allow moisture to penetrate." Ex. 1012, ¶ [0017]-[0018]. Matsumura further discloses that "two pieces of conductive material 2 and two hooks 3" are located "[b]etween the first sheet 1 and the second sheet 4," and that "[t]he two hooks 3 are arranged so that the protruding portions of the hook 3 can be inserted through the holes 2a and 1a from the backside of the conductive material 2." Ex. 1012, ¶ [0019]. This three-dimensional layering is essential to waterproofing Matsumura's device:

[T]he circular protrusion 10b contacts and sinks into the first sheet 1 of the bioelectrode pad 7 so as to cover the periphery of the engagement portion of the protruding portion of hook 3 and the hook engagement portion 10a, so that the engagement portion between the protruding portion of the hook 3 and the hook engagement portion 10a is waterproofed.

Ex. 1012, ¶ [0029] (referring to Figure 4(b)), Figure 4. Therefore, the three-dimensional structures of both conductive material 2 and hook 3 are necessary for the electrical and mechanical connections, and a POSITA would not have been motivated to replace them with printed traces.

84. Matsumura's conductive material 2 is a rigid "rod-shaped" piece of material through which the "protruding" hook 3 vertically protrudes through. Ex. 1012, ¶ [0019]. Despite Matsumura's express teachings, Dr. Heikenfeld concludes that it would have been obvious to a POSITA to replace Matsumura's rod-shaped conductive material 2 "with a single, flexible sheet of insulating material that contains printed-ink conductive traces." Ex. 1009, ¶ 1070. According to Dr. Heikenfeld, this modification "would be a routine design choice." Ex. 1009, ¶ 1071. I disagree.

85. Matsumura disclosure is clear that its bioelectrode pad comprises "a conductive material 2," a conductive "hook 3," and "a conductive gel 5." Ex. 1012, ¶ [0016]. These conductive materials are essential to the operation of Matsumura's waterproof design. *See, e.g.*, Ex. 1012, ¶ [0006] ("In order to enable hospitalized or

home-bound patients/subjects to measure electrocardiograms while showering or bathing, a waterproof bioelectric potential detector is first required. [And] [t]he present invention was made in order to achieve these objectives.”). In this regard, Matsumura’s processor and housing are located separate and apart from the bioelectric pad. Ex. 1012, ¶ [0016], Figures 1-2. To accomplish the waterproof design, there must be a vertical conductive protrusion that allows for the electrical flow of signals from the bio-pad upwards to the processor. Ex. 1012, ¶ [0024], [0027], Figures 4-5. It is clear from Figures 4 and 5 that to provide this waterproof design, the rigid nature of conductive rods 2 provides a stable support for hook 3. Ex. 1012, ¶ [0019], Figures 4-5.

86. Specifically, “the protruding portions of the hook 3” extend upwards “from the back side of the conductive material 2,” clamping both sides of conductive rod 2. Ex. 1012, ¶ [0021], Figures 4(b) (annotated), 8 (annotated). The electrical and mechanical function of these components was not by accident but rather provides the dual electrical and mechanical connection essential to Matsumura’s device. Ex. 1012, ¶ [0019].

87. Therefore, a POSITA would not have modified Matsumura to remove these components since replacing Matsumura’s conductive material and hooks with a sheet of insulating material and printed electrical traces destroys the electrical and

mechanical function of Matsumura necessary for the device to function as intended.

Matsumura discloses:

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

Ex. 1012, ¶ [0027]. A POSITA would not have been motivated to replace the hooks with a printed conductive trace because the POSITA would have known that the hooks are necessary for waterproofing “the entire bioelectric potential detector.” Ex. 1012, ¶¶ [0027]-[0030]. Rather, a POSITA would have known that Dr. Heikenfeld’s proposed modification frustrates Matsumura’s goal of providing a waterproof device.

88. Accordingly, I disagree with Dr. Heikenfeld. A POSITA would not have understood that Matsumura could be modified to have a flexible printed circuit layer. Thus, Dr. Heikenfeld fails to render Claim 15 obvious.

B. Ground 2: Dr. Heikenfeld Fails to Establish that the Combination of Jensen and the General Knowledge of a POSITA Renders Obvious Claims 1 to 5, 15, 17, 18, or 20

89. Dr. Heikenfeld opines that Claims 1 to 5, 15, 17, 18, and 20 of the ’484 Patent are obvious over Jensen and the general knowledge of a POSITA. Ex. 1009, ¶ 1014. I disagree with Dr. Heikenfeld’s opinion for four reasons.

90. First, as discussed above in Section VII.A.i, it is my understanding the Patent Owner disclaimed independent Claim 1. As a result, my analysis here focuses, in part, on dependent Claim 2, which itself includes each of the limitations of Claim 1 due to its dependency from Claim 1. Dr. Heikenfeld's combination fails to render obvious Claims 2 and 15 because it does not teach or suggest a "computation-communication module being attached to the flexible circuit layer." Ex. 1006, Claim 1; *see* Ex. 1006, Claim 15 (requiring a "computation-communication module being attached to the flexible printed circuit layer"); *see* Section, VII.B.i.

91. Second, Dr. Heikenfeld's combination fails to render obvious Claim 2 because it does not teach or suggest "an adhesive covering at least a portion of the flexible circuit layer." Ex. 1006, Claim 1; *see* Section, VII.B.ii.

92. Third, Dr. Heikenfeld's combination fails to render obvious Claim 2 because it does not teach or suggest "traces of determinable electrical resistance." Ex. 1006, Claim 2; *see* Section, VII.B.iii.

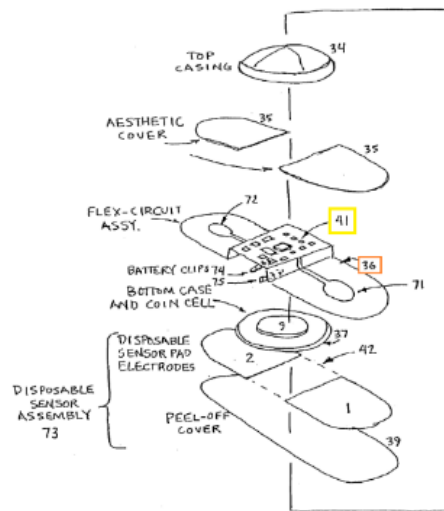
93. Finally, Dr. Heikenfeld's combination fails to render obvious "a flexible printed circuit layer configured to be coupled to a skin surface," as required by Claim 15 of the '484 Patent. Ex. 1006, Claim 15; *see* Section, VII.B.iv.

i. Ground 2 fails to render obvious claim element 1[c]

94. Claim 2 depends from independent Claim 1, and claim element 1[c] requires a “computation-communication module being attached to the flexible circuit layer.” Ex. 1006, Claim 1. Dr. Heikenfeld opines that Jensen’s microcontroller and transmitter are attached to flexible circuit assembly 50 and thus render obvious the computation-communication module. Ex. 1009, ¶ 1125. I disagree with Dr. Heikenfeld’s opinion.

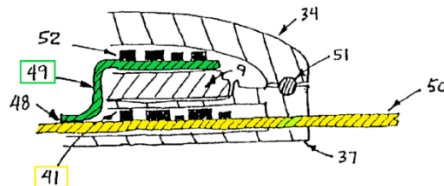
95. Dr. Heikenfeld identifies flexible circuit assembly 50 as the claimed flexible circuit layer. Ex. 1009, ¶ 1125. However, Jensen’s microcontroller and transmitter are not attached to the flexible circuit assembly. Thus, the microcontroller and transmitter cannot be the claimed computation-communication.

96. Jensen’s electronics circuit includes the microcontroller and transmitter. Ex. 1011, ¶¶ [0031]-[0032]. In Figure 5, electronics circuit 41 (yellow below) connects to the flexible circuit assembly 36 (orange below). Ex. 1011 ¶ [0040]. Jensen’s electronics circuit 41 is also shown in Figure 8, where the electronics circuit 41 is disposed on flexible circuit 50. Ex. 1011 ¶ [0046], Figure 8.



Ex. 1011, Figure 5 (annotated).

97. There is no disclosure in Jensen that supports Dr. Heikenfeld's opinion that the microcontroller or transmitter are located on substrate 49. Referring to Figure 8, electronics circuit 41 (which includes the microcontroller and transmitter) is located on circuit 50. Ex. 1011, Figure 8 (indicating the circuit 50 in yellow). A POSITA would not have understood the microcontroller or transmitter to be located on substrate 49 because Jensen states that these components are located on layer 50. Ex. 1011, Figure 8 (indicating the circuit 49 in green).



Ex. 1011, Figure 8 (annotated).

98. Dr. Heikenfeld does not address this disclosure and instead concludes that a “POSA reviewing the embodiment of Jensen’s Figure 8 would understand that the electronics circuit comprising a ‘microcontroller’ and ‘transmitter’ could be located on electronics circuit 52.” Ex. 1009, ¶ 1126. But Dr. Heikenfeld does explain why a POSITA would have understood the alleged computation-communication module to be on electronics circuit 52. Ex. 1009, ¶ 1126.

99. Finally, Dr. Heikenfeld contradicts his position when opining on a different claim element. Specifically, Dr. Heikenfeld states that “Jensen discloses an electronics circuit 41 that includes a ‘microcontroller’ for computation and a ‘transmitter’ for communication.” Ex. 1009, ¶ 1116 (citing Ex. 1011, ¶ [0032]–[0032]). However, Dr. Heikenfeld also contends that the microcontroller and transmitter would be included on electronics circuit 52. Ex. 1009, ¶ 1126.

100. For these reasons, I disagree with Dr. Heikenfeld. A POSITA would not have understood the microcontroller and transmitter to be located on electronics circuit 52. Thus, Jensen does not render obvious the computation-communication module, which must be attached to a flexible circuit assembly.

ii. Ground 2 fails to render obvious claim element 1[d]

101. Claim 2 depends from independent Claim 1, and claim element 1[d] requires “an adhesive covering at least a portion of the flexible circuit layer.” Ex. 1006, Claim 1. Dr. Heikenfeld advances two theories. First, Dr. Heikenfeld opines

that “Jensen discloses an adhesive to attach aesthetic covering 35 to the top surface of the flexible circuit assembly.” Ex. 1009, ¶ 1132. Second, Dr. Heikenfeld opines that the “conductive adhesive covers at least a portion of the flexible circuit layer 36.” Ex. 1009, ¶ 1130. I disagree with Dr. Heikenfeld.

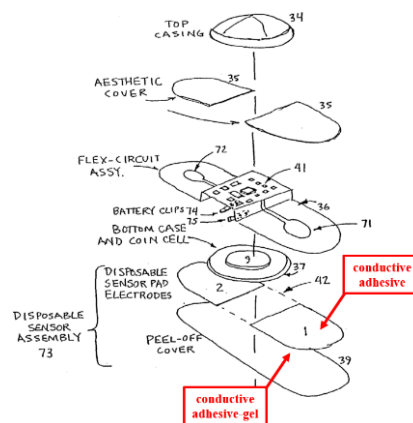
- a. Jensen does not disclose an adhesive to attach the aesthetic covering to the flexible circuit assembly

102. A POSITA would not have understood that Jensen discloses an adhesive to attach the aesthetic covering because Jensen is silent on how the aesthetic covering attaches to the flexible assembly. Ex. 1011, ¶ [0043]. In the only disclosure relevant to aesthetic covering, Jensen states that “two aesthetic covers 35 may be constructed from Mylar sheet, for example, and enclose the entire top side of the flexible circuit assembly 36.” Ex. 1011 ¶ [0043]. Contrary to Dr. Heikenfeld’s opinion, this disclosure does not “disclose[] an adhesive to attach aesthetic covering 35.” Ex. 1009, ¶ 1132. Beyond simply stating that Jensen discloses an adhesive, Dr. Heikenfeld does not provide any explanation for his position.

103. For these reasons, I disagree with Dr. Heikenfeld. Jensen is silent on how the aesthetic covering is attached to the flexible assembly. A POSITA would not have understood Jensen as disclosing an adhesive. Thus, Jensen does not render obvious the “an adhesive covering at least a portion of the flexible circuit layer.”

- b. Jensen does not disclose a protective covering that protects the “conductive adhesive”

104. Jensen does not disclose a protective covering that protects the “conductive adhesive.” *See* Ex. 1009, ¶1136. Jensen’s sensor pads 1, 2 include “a conductive adhesive on the circuit side and a conductive adhesive-gel.” Ex. 1011, ¶ [0041]. This disclosure provides two adhesive layers: (1) the conductive adhesive between sensor pad 1 and flexible circuit assembly 36 and (2) the conductive adhesive-gel between the sensor pad 1 and peel-off cover 39. Ex. 1011, ¶ [0041], Figure 5 (annotated, identifying the adhesives).



Ex. 1011, Figure 5 (annotated).

105. Dr. Heikenfeld identifies the conductive adhesive between the sensor pad and the flexible circuit assembly at the claimed adhesive. Ex. 1009, ¶ 1136 (“This peel-off cover 39 protects all of the sensor pad component, including the adhesive covering on those sensor pads.”). Dr. Heikenfeld conflates the conductive adhesive-gel on the bottom side of the sensor pads with the conductive adhesive on

the top side of the sensor pads. Peel-off cover 39 does not protect the conductive adhesive between the sensor pad and the flexible circuit assembly.

106. As shown in Figure 5, the peel-off cover does not protect the “conductive adhesive on the circuit side” of the sensor pads because the conductive adhesive is sandwiched between sensor pad 1 and flexible circuit assembly 36. A POSITA would have understood that the peel-off cover only protects the adhesive on the bottom surface of the sensor pads. This position aligns with Jensen’s disclosure, which states that “[t]he pads, when they are first installed, typically come pre-applied to a peel-off cover 39 that protects the conductive surface of sensor pads 1 and 2 until ready for use.” Ex. 1011, ¶ [0042]. Dr. Heikenfeld does not provide any explanation as to how a peel-off cover would protect an adhesive when the adhesive and the peel-off cover are separated by the sensor pads.

107. For these reasons, I disagree with Dr. Heikenfeld. A POSITA would not have understood Jensen as disclosing the adhesive protected by a protective covering. Thus, Jensen does not render obvious the “an adhesive covering at least a portion of the flexible circuit layer.”

iii. Ground 2 fails to render obvious Claim 2

108. Claim 2 requires “traces of determinable electrical resistance.” Ex. 1006, Claim 2. Dr. Heikenfeld opines that “a POSA would have understood that the copper in the wiring trace has a determinable electrical resistance” because “**every**

substance has a determinable electrical resistance.” Ex. 1009, ¶ 1141 (emphasis in original). I disagree with Dr. Heikenfeld’s opinion.

109. First, I do not disagree that resistance is a physical property. However, Dr. Heikenfeld’s reading of Claim 2 is incorrect. A POSITA would have understood that Claim 2 requires traces to be comprised of a resistive material in order to satisfy a desired design function and to therefore have a target “determinable electrical resistance.” This position aligns with the disclosure of the ’484 Patent, which states that “[t]races 412 extending between conductive surface 404 and connection pads 408 and 409 and trace 413 extending between conductive surface 405 and connection pad 411 can be made from resistive materials including resistive metals, carbon, silver ink, powders, paints, or other material of determinable electrical resistance.” Ex. 1006, 7:53-58.

110. Under the correct reading in view of the specification, Jensen does satisfy Claim 2 simply because “copper in the wiring trace” is a material and materials have a resistance. Rather, a POSITA would have understood the opposite. The copper in Jensen’s wiring acts as a conductor, with minimal resistance, to carry an electrical signal sensed from the body. Jensen’s copper wiring are not traces with determinable resistance.

111. Accordingly, I disagree with Dr. Heikenfeld. A POSITA would not have understood Jensen as rendering obvious Claim 2, which requires “flexible circuit layer ha[ving] traces of determinable electrical resistance.”

iv. Ground 2 fails to render obvious “a flexible printed circuit layer” as required by Claim 15

112. Claim 15 requires “a flexible printed circuit layer configured to be coupled to a skin surface.” Ex. 1006, Claim 15. Dr. Heikenfeld opines that a “POSA would understand that Jensen’s flexible circuit layer 36, 50 is fashioned as a flexible printed circuit board.” Ex. 1009, ¶ 1132. I disagree with Dr. Heikenfeld.

113. Jensen’s flexible circuit layer 36, 50 cannot teach the claimed printed circuit layer because flexible circuit 36, 50 are not coupled to the skin surface as required by Claim 15. Rather, a POSITA would have understood that the disposable sensor pads are the layer that attach to the skin surface, not flexible circuit 36, 50. *See* Ex. 1006, Figure 7. This is important because the ’484 Patent requires “a flexible printed circuit layer” to be attached to the skin surface. Moreover, Jensen’s sensors are not printed, so they also cannot satisfy the claimed a flexible printed circuit layer.

114. Accordingly, I disagree with Dr. Heikenfeld. A POSITA would not have understood that Jensen’s flexible circuit layer 36, 50 is a flexible printed circuit board. Thus, Dr. Heikenfeld fails to render Claim 15 obvious.

C. Ground 3: Dr. Heikenfeld Fails to Establish that the Combination of Ozguz and General Knowledge of a POSITA Renders Obvious Claims 1 to 8, 15, 19, and 20

115. Dr. Heikenfeld opines that Claims 1 to 8, 15, 19, and 20 are obvious over Ozguz in view of the “General Knowledge” of a POSITA. Ex. 1009, ¶ 1190. I disagree with Dr. Heikenfeld’s opinion.

116. First, Dr. Heikenfeld’s modification of Ozguz fails to render obvious Claim 1 because it does not teach or suggest claim element 1[a], which requires “a housing retaining a processor.” Ex. 1014, Cl. 1. Ozguz does not disclose any “housing” much less any “housing retaining a processor.” For the same reason, Dr. Heikenfeld’s combination fails to render obvious Claims 7 and 15.

117. Second, Dr. Heikenfeld’s reliance on Ozguz is erroneous because Ozguz is not enabled for the disclosure Dr. Heikenfeld relies upon. Because Ozguz is an aspirational, infeasible reference, a POSITA would not have relied upon its disclosure to reach Claims 1, 7, or 15.

i. Ground 3 fails to render obvious claim element 1[a]

118. Claim element 1[a] requires “a housing retaining a processor.” Ex. 1005, Cl. 1. Dr. Heikenfeld’s only analysis for claim element 1[a] is that the “flexible, thin battery 105” disclosed in Ozguz “overlays the silicon substrates.” Ex. 1009, ¶1199; *see also* Ex. 1009, ¶ 1217 (regarding claim element 1[e], Dr. Heikenfeld asserts that Ozguz’s flexible battery “is shaped in a way that it overlays”

the flexible silicon, adhesive, and substrate). According to Dr. Heikenfeld, this disclosure means that the flexible battery “houses the computation-communication module.” Ex. 1009, ¶ 1199. Dr. Heikenfeld assumes, without explanation, that flexible battery 105 is analogous to a “housing.” Ex. 1009, ¶ 1199-1200. His interpretation of “housing” is improper.

119. As evidenced by Ozguz’s disclosure, the flexible battery is a single flat layer that does not “house” anything. This flat, single-layer flexible battery (pink) is shown in Dr. Heikenfeld’s own annotation of Figure 3A:

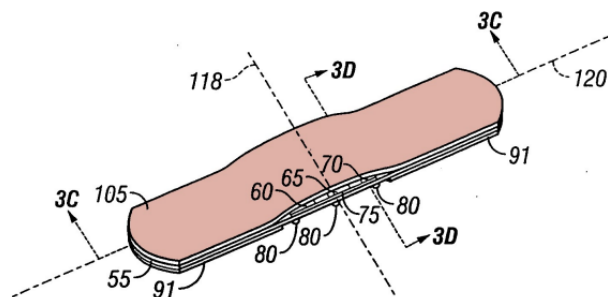


FIG. 3A

Ex. 1009, ¶ 1217 (annotation in original). At best, it is a layer in a sandwich not the roof and walls of a house.

120. Thus, Ozguz does not disclose any structure that is reasonably considered a housing. Accordingly, I disagree with Dr. Heikenfeld’s analysis and opinion.

121. Further, Dr. Heikenfeld alleges that Ozguz’s flexible battery 105 “houses the computation-communication module formed by flexible substrate 55

and components bonded to [the flexible substrate], such as flexible silicon substrates 60, 65, 70, integrated circuits 71, 72, 73, and antenna 50.” Ex. 1009, ¶ 1199. Then, Dr. Heikenfeld alleges that Ozguz discloses a microprocessor “incorporated into the thin silicon substrates 60, 65, 70.” Ex. 1009, ¶ 1199. According to Dr. Heikenfeld, this means that “Ozguz discloses ‘a communication-computation module including a housing retaining a processor.’” Ex. 1009, ¶ 1200. I disagree with Dr. Heikenfeld’s opinions. Ozguz actually discloses that flexible battery 105 sits atop silicon substrates 60, 65, 70 and their respective ICs 71, 72, 73. Ex. 1014, ¶ [0048]. A POSITA would not have understood Ozguz’s flexible battery to be any type of housing for Ozguz’s other components, including a processor. Instead, a POSITA would have understood that the flexible battery is merely an upper layer to the device and is not critical for housing anything.

122. As a result, Ozguz does not render Claim 1 obvious because Ozguz does not disclose a housing, nor anything that could be construed as a housing. And, Ozguz does not disclose a housing “retaining” (Claims 1 and 15) or “containing” (Claim 7) a processor.

ii. Dr. Heikenfeld’s interpretation of “housing” is improper and erroneous

123. Dr. Heikenfeld’s interpretation of “housing” is improper and erroneous because it is an impermissibly broad reading of the claim language that no POSITA would have endorsed.

124. Dr. Heikenfeld seemingly interprets “housing” to mean any type of unenclosed overlay—an interpretation that contradicts the ordinary meaning of “housing,” which a POSITA would have understood implies a unitary enclosure rather than a mere layer placed on top. Dr. Heikenfeld’s own annotation of Ozguz’s module illustrates that flexible battery 105 is a simple upper layer, not a unitary enclosure, and therefore not a housing. Ex. 1009, ¶ 1217; *see* Section VII.C.i. Dr. Heikenfeld provides no other support for this interpretation, and a POSITA would not have understood Ozguz’s flexible batter 105 to be a housing. Therefore, Dr. Heikenfeld’s conclusory assertions without any supporting evidence fail.

125. Ozguz itself characterizes flexible battery 105 as “overlying battery 105” that “overlays” other components of the device. Ex. 1014 ¶¶ [0048], [0055]. In the context of the ’484 Patent, a POSITA would have understood “housing” as a structural element that encases or encloses internal components of a device, specifically a computation-communication module which includes a processor. The “housing” is mentioned in conjunction with this module, indicating it serves as a

physical protective casing for the processor and possibly other electronic components associated with the module. Thus, a POSITA would not have understood the term “housing” to mean an overlay. Rather, a POSITA would have known that an overlaying structure does not imply it is housing anything, particularly in the context of how housings are generally understood in the art—as unitary enclosures, typically structured to provide a protective barrier or containment, which is not the role of a flexible battery. Dr. Heikenfeld cites no evidence to establish that a POSITA would have thought any different. *See* Ex. 1009, ¶ 1195-1200.

126. To conclude (as Dr. Heikenfeld does) that a POSITA would have considered a flexible battery layer to be a housing ignores the actual construction of Ozguz. Therefore, I disagree with Dr. Heikenfeld. Accordingly, Dr. Heikenfeld fails to establish that Claim 1 is obvious because Ozguz does not teach or suggest the recited housing. For the same reasons, Dr. Heikenfeld fails to establish that Claims 7 and 15 are obvious.

iii. Dr. Heikenfeld’s interpretation of “a housing retaining a processor” is improper and erroneous

127. Dr. Heikenfeld’s interpretation of “housing retaining a processor” is also improper and erroneous because it is an impermissibly broad reading of the claim language that no POSITA would have endorsed.

128. While Ozguz’s silicon substrates may include circuitry that further includes a microprocessor (Ex. 1014, ¶ [0058]), the flexible battery merely sits on top of the silicon substrates, and at no point does the microprocessor enter inside any boundary of the flexible battery, nor does Dr. Heikenfeld make such an allegation. *See* 1009, ¶¶ 1195-1200, 1214-1218. Despite the express disclosure in Ozguz, Dr. Heikenfeld nonetheless appears to interpret “housing retaining a processor” to mean anything that touches the flexible battery layer. Ex. 1009, ¶ 1195-1200, 1214-1218.

129. In view of the ’484 patent, a POSITA would understand the term “housing retaining a processor” to indicate that certain internal components, specifically electronic or mechanical parts, are placed, enclosed, or situated inside a protective enclosure or casing, which serves to protect these components from external environmental factors, provide structural integrity, and facilitate attachment or connection with other elements of the device.

130. This understanding aligns with the specific context in the ’484 patent, wherein a processor and related electronic components are positioned and enclosed within a housing of a computation-communication module. The housing is specifically described as physically enclosing or containing electronic circuitry, such as the processor and associated components, to form a distinct and protected internal environment separate from other portions of the device, like the flexible substrate and electrodes. Ex. 1005, 6:29-33, 6:40-62.

131. To conclude (as Dr. Heikenfeld does) that a POSITA would have considered a processor “a housing retaining a processor” to mean a processor touching the external wall of a flexible battery ignores the actual construction of Ozguz. Therefore, I disagree with Dr. Heikenfeld.

132. Accordingly, Dr. Heikenfeld fails to establish that Claim 1 is obvious because Ozguz does not teach or suggest the recited housing retaining a processor. For the same reasons, Dr. Heikenfeld fails to establish that Claims 7 and 15 are obvious.

iv. Ozguz is a non-enabling reference insufficient to support Dr. Heikenfeld’s obviousness theories

133. Dr. Heikenfeld relies solely on Ozguz as modified by the “General Knowledge” of a POSITA for his obviousness theories regarding Claims 1 to 8, 15, 19, and 20. Ozguz discloses speculative and unrealistic features that were not achievable at the time of the invention. As a result, a POSITA would not have been motivated to modify Ozguz to reach independent Claims 1, 7, or 15, or any of the dependent claims with a reasonable expectation of success. This is because Ozguz is a non-enabling reference that a POSITA would not have relied on to reach the challenged claims, and a POSITA would have recognized that Ozguz’s disclosed flexible battery and thinned flexible silicon technology was infeasible at the time of Ozguz’s claimed priority date, 2005.

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

134. Ozguz provides a sensor module that uses futuristic flexible batteries as part of the module. At the time of Ozguz's claimed priority date (2005) and at the time of the '484 Patent's priority date (2006), flexible batteries were not viable or commercially available in the form described in Ozguz.

135. Conceptually, flexible batteries may have been proposed or theoretically envisioned, but the technology to implement flexible batteries in a real-world, realistic device was in its infancy, and its commercial availability was far from practical. In other words, a POSITA, relying on the state of the art at the time of the invention, would not have considered it possible to use flexible battery technology as described in Ozguz.

136. Ozguz suggests the use of integrated flexible batteries to power the biomonitor. *See, e.g.*, Ex. 1014, ¶ [0019]. However, at the time of the invention, flexible batteries were not capable of supporting extended use without frequent recharging or replacement. Ozguz oversimplifies the real-world constraints on battery capacity, longevity, and energy efficiency, overlooking the fact that flexible battery technologies at that time were not sufficiently advanced to support the sustained, low-power requirements of continuous physiological monitoring. These flexible batteries lacked the reliability and durability needed to power such a device

over extended periods, and in the context of a patient wearable medical device where patient safety is of the utmost importance, a flexible battery would not have been considered a suitable option. Importantly, the miniature size and layered structure of Ozguz's device would significantly increase the risk of thermal overheating in the flexible battery, making the design impractical for real-world use.

137. Additionally, a POSITA, understanding the technological and economic landscape at the time of the invention, would have recognized that incorporating a flexible battery as described in Ozguz would be inconsistent with the cost-effective solution sought by the inventors of the '484 Patent. Ex. 1005, 2:6-8. Further, even if a theoretical or experimental flexible battery existed at the time of the invention, it would not have been reliable enough for use in a wearable cardiac device. Consequently, a POSITA would not have been able to implement the flexible battery in a functional ambulatory monitor, which significantly undermines the enablement of Ozguz.

138. Moreover, the use of flexible batteries for a patient wearable device, particularly one designed for continuous monitoring, would have faced significant challenges regarding user comfort and practicality. A wearable device would need to offer long-term battery life, ideally without frequent recharging or the discomfort of bulky or frequently replaced batteries. In the context of a medical or patient-monitoring device, the battery's reliability and longevity are critical not only for user

convenience but also for ensuring accurate and consistent monitoring. Flexible batteries of the time were not capable of achieving this, making them impractical for the intended use in wearable devices designed for patient care. Ozguz does not address these technical and practical limitations, which renders the reference non-enabling, as Ozguz's proposed sensor module could not have been practically implemented with the technology available at the time.

139. Finally, Ozguz's discussion of waterproofing and environmental protection is overly simplistic wishful thinking and fails to account for the technical challenges of protecting flexible electronics from moisture and sweat—two critical environmental factors for a wearable monitor. The reference assumes that basic waterproofing techniques, such as standard skin adhesion methods, would suffice to ensure the device's operation under real-world conditions. However, this assumption overlooks the complexity of waterproofing flexible materials, which was not feasible with the available materials and methods at the time. Waterproofing such a device requires the integration of specialized coatings or barriers that can protect sensitive electronic components from moisture without compromising the flexibility or comfort of the device. At the time of the invention, the technology for achieving long-term environmental resistance in flexible electronics was still in its infancy, and there was no reliable method for ensuring the longevity and durability of such devices when exposed to sweat, moisture, or other environmental conditions.

140. Specifically, a critical and overlooked challenge in Ozguz's design is the incompatibility between the (what could have been achieved at the time) minimally flexible battery and the more flexible layers of the device. The incompatibility in the stiffness, i.e. flexibility, of the battery layered against a more flexible structure would create significant waterproofing issues, particularly at the edges where the battery meets the flexible layers. This combination of variable flexible components would lead to poor sealing between layers and at the edges, allowing moisture to seep into the device. The lack of a reliable seal would expose the internal electronics to potential water damage, particularly in environments where sweat, moisture, or even rain could compromise the device's integrity. This issue further highlights the unrealistic nature of Ozguz's proposal, as a practical, wearable device could not afford to risk water damage, especially when used in environments that are prone to moisture exposure.

141. Given these challenges, the proposed device in Ozguz would have been highly susceptible to failure upon exposure to moisture or sweat, undermining its viability as a continuous-use wearable monitor. The failure to address these concerns in Ozguz's reference renders the device impractical and speculative. Therefore, a POSITA at the time would not have been motivated to combine Ozguz's teachings with the intention of creating a functional, reliable wearable monitor. The lack of consideration for long-term environmental resistance and the durability of

flexible materials significantly diminishes the relevance of Ozguz as prior art, as its teachings do not provide an enabling disclosure for creating a viable wearable monitor that could withstand the rigors of real-world use. A POSITA would have recognized that these barriers could not be overcome with the materials and technologies available at the time, making the combination of Ozguz's teachings with other prior art unrealistic and impractical.

b. Dr. Heikenfeld's reliance on Ozguz's flexible battery technology is fatal to Ground 3

142. Dr. Heikenfeld relies on Ozguz's "flexible battery 105" for at least two of the claim elements in independent Claim 1. Ex. 1009, ¶¶ 1199, 1217. This flexible battery technology, however, was infeasible at the time of Ozguz's purported priority date (2005), infeasible at the time of the priority date of the '484 Patent (2006), and still infeasible up to at least 2015 for at least four reasons.

143. First, in 2005 there was limited mechanical flexibility of commercially available batteries. While several battery technologies—such as lithium polymer (Li-poly), thin-film batteries, and printed primary cells—were theoretically flexible by 2005, none could achieve the mechanical flexibility described in the Ozguz patent, particularly the repeated bending and twisting needed for a wearable "adhesive bandage" form factor. Specifically, commercially available Li-poly pouch cells could slightly bend to conform to curved surfaces, but were neither

repeatedly flexible nor stretchable without risking internal short circuits or physical damage. Similarly, thin-film lithium-ion cells developed by Oak Ridge National Laboratory (ORNL) demonstrated limited bending capabilities and were typically fabricated on rigid substrates, severely constraining their real-world flexibility and practical use in dynamic, wearable applications.

144. Second, as of 2005 there were significant energy density and power delivery constraints that would have precluded using a flexible battery in Ozguz's device. Printed thin-film zinc-based batteries, like those from Power Paper Ltd. and Enfucell, were indeed thin and highly flexible but had severely limited energy storage (tens of milliamp-hours at best). Such batteries were adequate only for low-power, short-duration tasks (like RFID tags or greeting cards), insufficient for continuous physiological monitoring devices that require sustained power delivery for data collection, digitization, and wireless data transmission. Rechargeable technologies like NEC's Organic Radical Battery (ORB), while flexible and seemingly promising, were only experimental prototypes with very limited energy density (~ 1 mWh/cm²). Hence, by 2005, flexible battery technologies simply could not offer sufficient power density and durability required by the *Ozguz* device specification.

145. Third, incorporating flexible battery technology into Ozguz's device would not have been feasible from a manufacturing standpoint, nor would it have

provided reliable performance in such a device. As of 2005, flexible battery manufacturing was either experimental or limited to niche applications. Mass-scale production processes (roll-to-roll printing) of thin-film batteries remained in pilot stages, with limited reliability and inconsistent quality. The flexible, thin-film silicon-based integrated circuit described in Ozguz specifically highlights a degree of integration and complexity requiring robust, reliable power delivery. None of the battery technologies available prior to or in 2005 were manufactured with the reliability, consistency, and volume required to power such an integrated wearable monitoring device.

146. Fourth, integrating the flexible battery into *Ozguz's* device would have presented significant challenges. Ozguz explicitly describes integrating a thin, flexible battery layer with equally flexible silicon circuitry and substrates. Ex. 1014, ¶ [0048]. Further, *Ozguz* emphasizes significant mechanical flexibility—such as twisting about the longitudinal axis (Ex. 1014, Figure 3E) and bending along multiple axes (Ex. 1014, Figs. 3C, 3D). Achieving this degree of flexibility with battery technologies available by 2005 was not only impractical but posed significant risks for battery failure, leakage, or structural breakdown. The delicate thin-silicon layers and sensitive integrated circuitry required extremely uniform and mechanically stable battery technology. The available battery solutions could not

satisfy this stringent mechanical integration requirement (without compromise in structural integrity, operational lifetime, or safety).

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

147. Dr. Heikenfeld relies on Ozguz's thinned silicon substrates for at least four of the claim elements in independent Claim 1. Ex. 1009, ¶¶ 1197 (Claim element 1[a]), 1207 (claim element 1[c]), 1212 (claim element 1[d]), 1217 (claim element 1[e]).

148. In one notable example, Dr. Heikenfeld identifies Ozguz's thin silicon substrates as including a "includ[ing] a 'transmitter or transceiver 190 for transmitting data by RF signals to a remote receiver' (*i.e.*, a communication module)." Ex. 1009, ¶ 1197. While Ozguz discloses that "it is to be expressly understood that the ICs 71, 72, 73, can be integrated as one IC on a single silicon substrate," Dr. Heikenfeld's conclusion that "Ozguz discloses 'said computation-communication module being attached to the disposable substrate'" does not necessarily follow. Ex. 1014, ¶ [0042]; Ex.1009, ¶ 1197, 1207-1208. In other words, I disagree with Dr. Heikenfeld's opinion because thinned silicon devices, such as that described by Ozguz, were infeasible at the time of Ozguz's claimed priority (2005), and at the time of the priority date of the '484 Patent (2006).

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

150. Second, in 2005 there was limited manufacturing capability and yield. Specifically, flexible thinned silicon was confined largely to experimental laboratory demonstrations. Ozguz describes methods like “grinding” thin silicon wafers to 10-50 microns. Ex. 1014, ¶ [0054], cls. 34-37. Such processes, while achievable in lab-scale prototypes, suffered from low yield, high fragility, and inadequate scalability for commercial or even robust prototype-level production. Achieving consistency, reliability, and high throughput manufacturing necessary for commercialization was beyond available methods at the time.

151. Third, flexible thinned silicon was difficult to integrate into real-world applications. For example, Ozguz’s envisioned wearable sensor (as depicted in Figures 2a, 3a, and 3b) required complex integration: flexible silicon circuitry,

flexible battery, electrodes, wireless transmission capability, and adhesives into a thin, bendable form factor. As of 2005, the available integration and packaging techniques lacked maturity to reliably assemble these components. Even the patent disclosure describes this integration conceptually without providing actual demonstrated examples or results of functional integrated devices tested under real-world conditions, underscoring the speculative and aspirational nature of the technology at the time.

152. Fourth, in 2005 there were no commercially available flexible integrated circuits or components. No off-the-shelf flexible integrated circuits or thin silicon chips were commercially available as a standardized product in 2005. Industry standards and supply chains for flexible electronic components simply did not exist. All demonstrations were strictly research-based, bespoke, and not robust enough for reliable or repeatable use, particularly for wearable physiological monitoring that demands reliability, stability, and user safety.

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

efficiency in flexible formats. Such limitations severely constrained device functionality and practicality.

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

D. Ground 4: Dr. Heikenfeld Fails to Establish that the Combination of Matsumura, Ozguz, and General Knowledge of a POSITA Renders Obvious Claims 6 to 8, 11, and 12

155. Dr. Heikenfeld opines that Claims 6 to 8, 11, and 12 of the '484 Patent are obvious over Matsumura, Ozguz, and the general knowledge of a POSITA. Ex. 1009, ¶¶ 1313-1370. I disagree with Dr. Heikenfeld's opinion.

156. For the reasons discussed above in Section VII.A, Dr. Heikenfeld fails to establish that Matsumura and the general knowledge of a POSITA render obvious the Challenged Claims. *See* Section VII.A. Moreover, Dr. Heikenfeld does not allege or establish that Ozguz cures any of the deficiencies in Matsumura with

respect to Claims 1 or 15, nor does Dr. Heikenfeld establish that a POSITA would have combined Matsumura and Ozguz. A POSITA would not have done so.

157. Specifically, Dr. Heikenfeld admits that Matsumura does not disclose “the specific circuit design or architecture to perform” functions including using a wireless transmitted to detect, process, and wirelessly transmit bioelectric signals. Ex. 1009, ¶ 1313 (citing Ex. 1009, ¶ 629, which is Dr. Heikenfeld’s analysis of the motivation to combine Matsumura, Ozguz, and Kroll for a separate IPR petition regarding a different patent, the ’007 Patent). Then Dr. Heikenfeld opines that a POSITA would have been motivated to combine the teachings of Matsumura and Ozguz. Ex. 1009, ¶ 1313. I disagree with Dr. Heikenfeld’s opinion.

158. There are several reasons why a POSITA would not have looked to Ozguz “to incorporate the specific design and structure of circuits and electronic components taught by Ozguz.” Ex. 1009, ¶ 633.

159. Ozguz includes printed electronic traces, and as discussed above in Section VII.A, a POSITA would not have been motivated to replace Matsumura’s conductive rods and hooks with printed circuitry. *See supra* Section VII.A. Further, Ozguz, when considered in combination with Matsumura, provides no motivation for a POSITA to combine these references in a way that would lead to the claimed invention. Ozguz’s concepts, as discussed above in Section VII.C.iv, are speculative and futuristic, lacking the practical enablement required for a POSITA to build upon

them in a meaningful way. The combination of Matsumura's rigid conductive rods and hooks with Ozguz's speculative flexible technology and speculative flexible thinned silicon technology is not suggested by any of the cited references. Thus, a POSITA would not have been motivated to replace Matsumura's rigid, waterproof components with speculative, non-enabling flexible electronics as proposed by Ozguz. *See supra* Section VII.C.iv.

160. Accordingly, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to combine Matsumura and Ozguz, and a POSITA would not have understood either reference to teach the Challenged Claims. Thus, Dr. Heikenfeld fails to render Claims 6 to 8, 11, and 12 obvious.

VIII. RESERVATION OF RIGHTS

161. 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