

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IRHYTHM, INC.,

Petitioner,

v.

WELCH ALLYN, INC.,

Patent Owner.

CASE: IPR2025-00363

U.S. PATENT NO. 10,159,422

DECLARATION OF DR. BRIAN W. ANTHONY

TABLE OF CONTENTS

I. QUALIFICATIONS AND BACKGROUND	2
II. LEGAL STANDARD	7
A. Claims	7
B. Specification	8
C. Prosecution History	9
D. Burden of Proof	9
E. Anticipation	10
F. Obviousness	11
i. Reasonable Expectation of Success	12
ii. Motivation to Combine	13
iii. Hindsight	15
III. LEVEL OF ORDINARY SKILL IN THE ART	16
IV. SUMMARY OF THE '422 PATENT	17
V. SUMMARY OF THE ART	19
A. Matsumura (Exhibit 1012)	19
B. Jensen (Exhibit 1011)	21
C. Ozguz (Exhibit 1013)	25
VI. SUMMARY OF OPINIONS	28
VII. OPINIONS	30
A. Ground 1: Dr. Heikenfeld Fails to Establish that the Combination of Matsumura and the General Knowledge of a POSITA Renders Obvious Claims 1 to 7, 9 to 11, or 14 to 20	30
i. Ground 1 fails to render obvious claim element 1[b]	30
ii. A POSITA would not have been motivated to replace Matsumura's conductive material and hooks with an insulating material and printed ink traces	34
a. Dr. Heikenfeld does not establish that a POSITA would have been motivated to modify Matsumura in view of the POSITA's "General Knowledge"	34

b. Dr. Heikenfeld ignores the critical role that Matsumura’s rigid conductive material and hooks play in both electrical connectivity and mechanical waterproofing	37
B. Ground 2: Dr. Heikenfeld Fails to Establish that the Combination of Jensen and Matsumura or General Knowledge of a POSITA Renders Obvious Claims 1 to 7, 9, 11, and 14 to 20	39
i. Ground 2 fails to render obvious claim element 1[a].....	40
a. Jensen does not disclose a disposable substrate.....	40
b. Jensen and the general knowledge of a POSITA do not render obvious a disposable substrate	41
c. A POSITA would not have been motivated to make circuit 50 of Jensen a disposable substrate	44
d. A POSITA would not have been motivated to redistribute Jensen’s electronics.....	45
ii. Ground 2 fails to render obvious claim element 1[e].....	48
iii. A POSITA would not have been motivated to modify Jensen in view of the teachings of Matsumura.....	51
a. A POSITA would not have been motivated to modify Jensen to achieve a waterproof structure	52
b. A POSITA would not have been motivated to modify Jensen to achieve a waterproof structure	53
C. Ground 3: Dr. Heikenfeld Fails to Establish that the Combination of Ozguz and Matsumura or General Knowledge of a POSITA Renders Obvious Claims 1 to 3, 5, 6, 9, 11, 12, 14 to 18, and 20.....	54
i. Ground 3 fails to render obvious claim element 1[f]	55
ii. Ground 3 fails to render obvious claim element 1[g]	57
iii. Dr. Heikenfeld’s interpretation of “housing” is improper and erroneous	58
iv. Dr. Heikenfeld’s interpretation of “disposed in the housing” is improper and erroneous.....	61
v. Ozguz is a non-enabling reference insufficient to support Dr. Heikenfeld’s obviousness theories	62
a. A POSA Would Not Have Relied on Ozguz to Reach the Challenged	

Claims.....	62
b. Dr. Heikenfeld’s Reliance on Ozguz’s Infeasible Flexible Battery Technology is Fatal to Ground 3.....	67
c. Dr. Heikenfeld’s reliance on Ozguz’s infeasible thin silicon technology is fatal to Ground 2	69
VIII. RESERVATION OF RIGHTS.....	73

I, Dr. Brian 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 1-7, 9-12, and 14-20 (the “Challenged Claims”) of U.S. Patent No. 10,159,422 (the “’422 Patent”) (Ex. 1007) 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 ’422 Patent (Ex. 1007), its file history (Ex. 1008), the Declaration of Dr. Jason Heikenfeld (Ex. 1009), three prior art references: Jensen (Ex. 1011), Matsumura (Ex. 1012), 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 '422 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 electrical and 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 '422 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 '422 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 '422 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 '422 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 '422 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, patents subject to *inter partes* review, such as this proceeding, are not presumed to be valid, such that a lower burden of proof is used to judge the patentability of challenged claims. Unlike

the district court’s “clear and convincing” burden, here, a “preponderance of the evidence” burden exists.

E. Anticipation

27. I understand that a patent claim is invalid as “anticipated” by a single “prior art” reference if the reference discloses every single element of the claim with sufficient precision and detail to establish that the subject matter of the claim existed in the prior art. In particular, I understand that it is not sufficient to establish that all of the elements are collectively disclosed within the four corners of a particular document. Instead, the operative question is whether a person of ordinary skill would have understood the elements as being arranged as in the claim itself. I also understand that a prior art reference cannot “anticipate” a patent claim unless that reference enables one of ordinary skill in the art to make and use what is disclosed without undue experimentation. Thus, if the reference does not enable one of ordinary skill to make or use each and every claim limitation, then the claim cannot be “anticipated” by the reference.¹

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

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

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

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

F. Obviousness

31. I understand that a patent claim may describe an invention that was new (*i.e.*, not anticipated by any prior art reference), but nevertheless be invalid for “obviousness” if the differences between the patented subject matter and the prior

art are such that the subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the invention was made.²

i. Reasonable Expectation of Success

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

33. I also understand that determining whether or not a claimed invention would have been obvious requires assessing facts related to (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention, (3) the level of ordinary skill in the art, and (4) any objective evidence (“secondary considerations”) of non-obviousness. I understand that this is known as consideration of the “Graham Factors.”

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

ii. Motivation to Combine

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

35. I understand that it will often be necessary for a court to look to interrelated teachings of multiple patents and the background knowledge possessed by a person having ordinary skill in the art in order to determine whether there was

an apparent reason to combine the known elements in the fashion claimed by the patent at issue. I understand that any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed. I understand that when a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. I understand that the combination of familiar elements according to known methods may be obvious when it does no more than yield predictable results.

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

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

38. I also understand that if the prior art “teaches away” from combining known elements in the manner claimed by the invention at issue, discovering a successful way to combine them is less likely to be obvious. In particular, I understand that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was

taken by the applicant, or would understand based on the reference that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. Likewise, I understand that similar subject matter may not be sufficient motivation for a person of skill in the art to combine references if the references have conflicting elements.

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

iii. Hindsight

40. I also understand that one must be cautious and resist the temptation to rely on hindsight reasoning when attempting to combine references to suggest that a claim may be obvious. It is important to analyze validity based on the perspective of one of skilled in the art at the time of the invention, which for this case I have been asked to assume is November 1, 2006, and which I understand is the date Dr. Heikenfeld and the Petition use as the priority date of the '422 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.

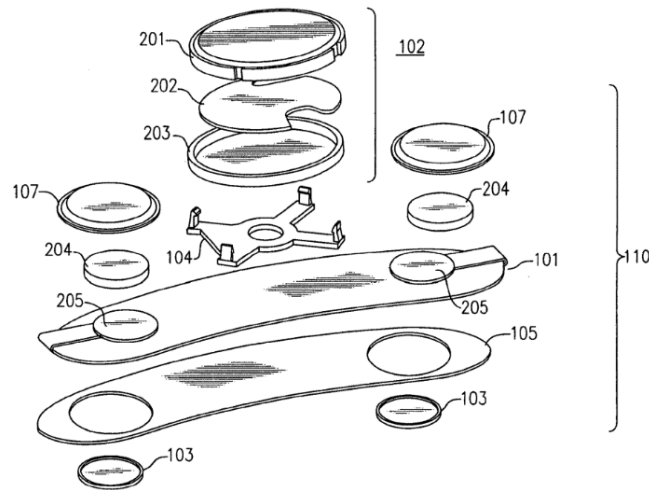
42. My analysis and opinions below are given from the perspective of a POSITA in this technological field in the relevant time frame, unless stated otherwise.

43. I satisfied the definition of a POSITA before the filing date of the application leading to the '422 Patent. I now consider myself an expert in the relevant field of technology for the '422 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 '422 PATENT

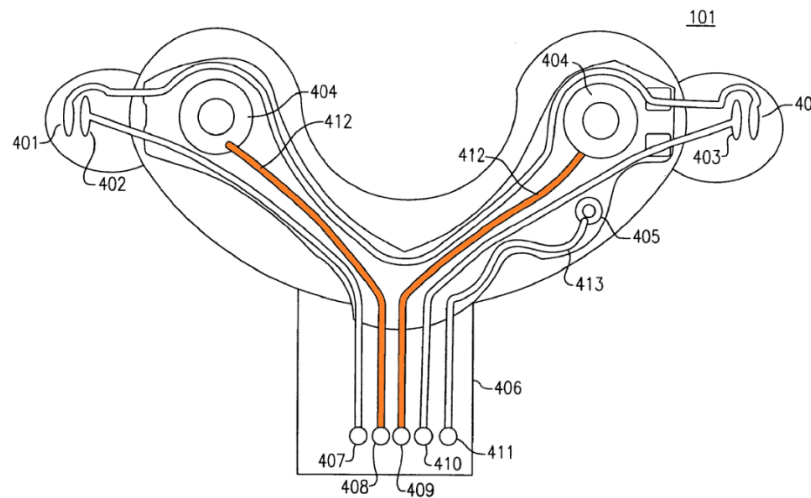
45. The '422 Patent discloses making a body-worn physiological sensor package that adhesively attaches to a patient's skin and measures physiological signals. Ex. 1007, Abstract, cl. 1, Figure 2. The body-worn sensor package includes a computation-communication module 102 and disposable electrode module 110. Ex. 1007, 5:32-47, cl. 1, Figure 2.



Ex. 1007, Figure 2.

46. The disposable electrode module 110 includes a flexible printed circuit layer 101 made from an insulating material. Ex. 1007, cl. 1, 8:4-16. The flexible printed circuit layer transmits electrical signal via traces, which connect a connection pad and an electrode. Ex. 1007, 8:4-17, Figure 4A. The traces 412 (orange), which are preferably printed, “extend[] between conductive surface 404 and connection pads 408 and 409.” Ex. 1007, 8:4-17, Figure 4A. This way, the traces 412, which

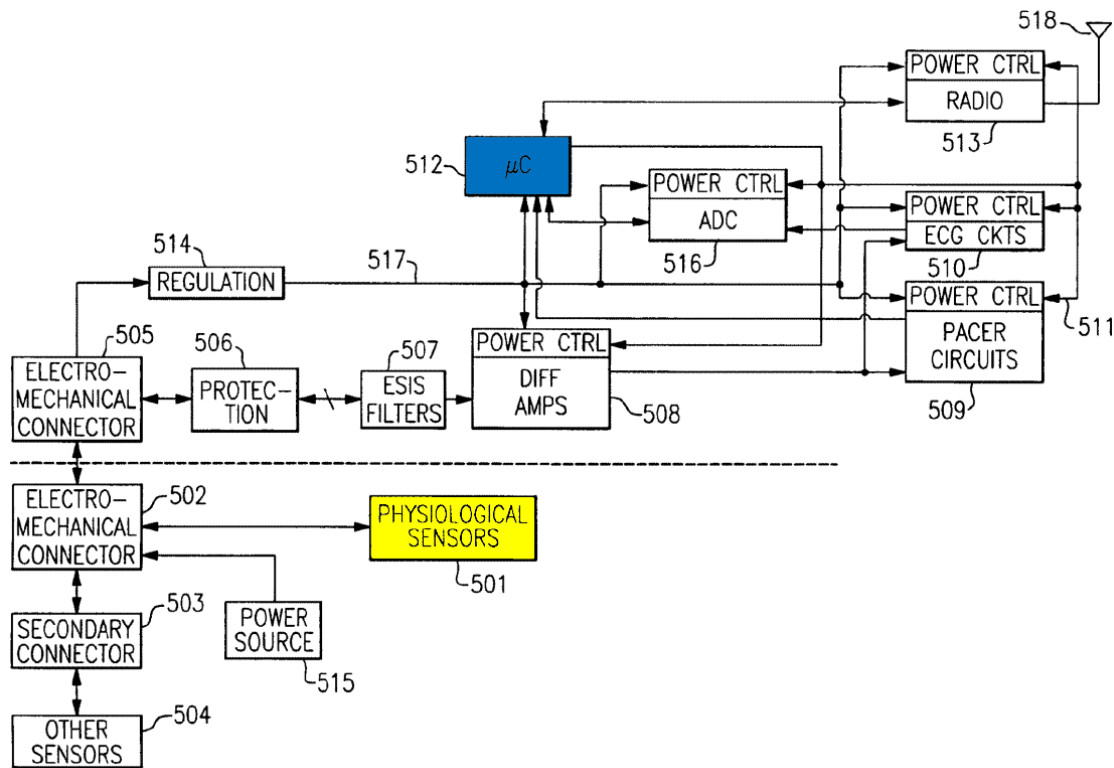
are preferably printed onto electrically couple the signals from electrodes to the computation-communication module. Ex. 1007, 8:4-17.



Ex. 1007, Figure 4A (annotated).

47. Figure 5 also shows the path between each electrode and the computation-communication module. Ex. 1007, 11:62-12:12, Figure 5. In the block diagram of Figure 5, the physiological sensors for capturing an ECG difference potential are indicated in yellow. Ex. 1007, 11:62-12:12, Figure 5. Electrodes are one example of the physiological sensors used for sensing electrical potential produced by the body. Ex. 1007, 11:62-12:12, Figure 5 (indicating the physiological sensors 501 in yellow). Continuing to reference Figure 5, physiological sensors 501 are electrically coupled to electromechanical connector 502, which is further connected to the processor for performing computational analysis on the detected signals. Ex. 1007, 11:62-12:12, Figure 5 (annotated, indicating the microprocessor

512 in blue), Figure 4A. The computation-communication module includes a housing that contains this processor. Ex. 1007, claim 1.



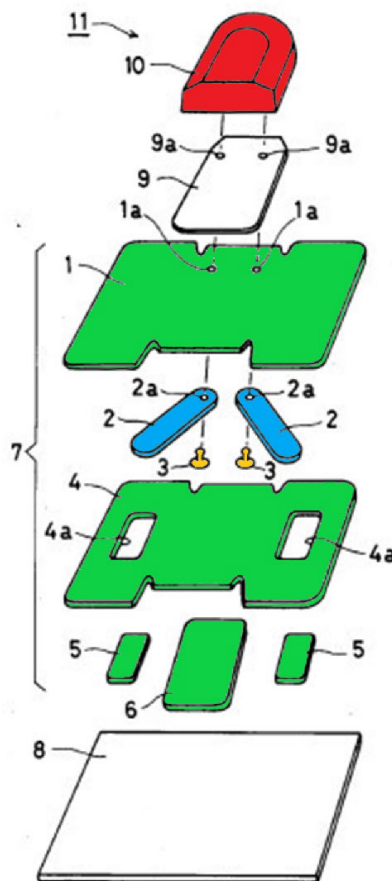
Ex. 1007, Figure 5 (annotated).

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 is a rigid, rod-shaped piece of material that 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].

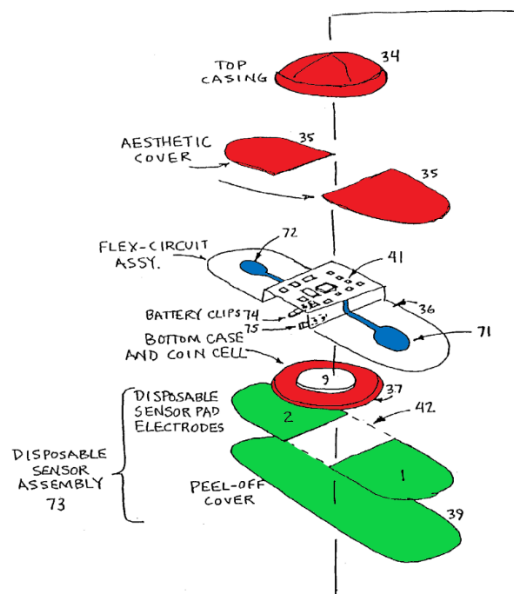
50. Hooks 3 have an electrical role and a mechanical role in preserving the device’s electrical and structural integrity by securely, but releasably, attaching the disposable pad 7 to the signal processor 10, while also transmitting bioelectric potential signals received from the conductive material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

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).

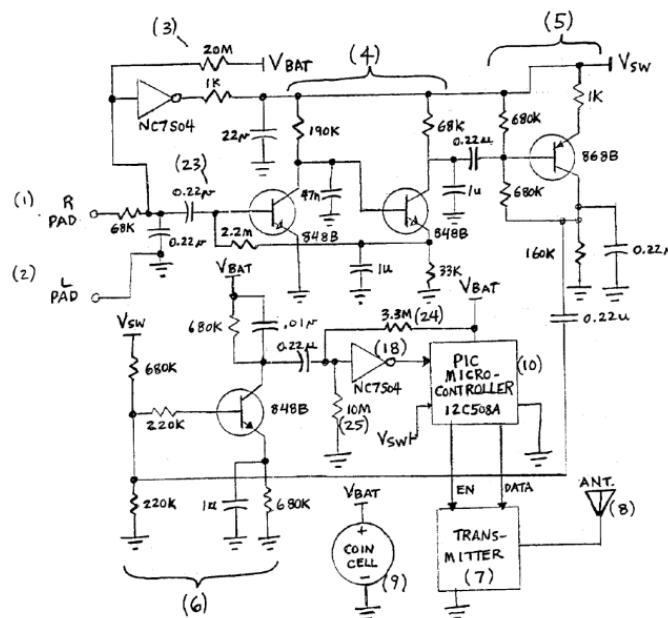


Ex. 1011, Figure 5 (annotated showing disposable portions in green, reusable portions in red).

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

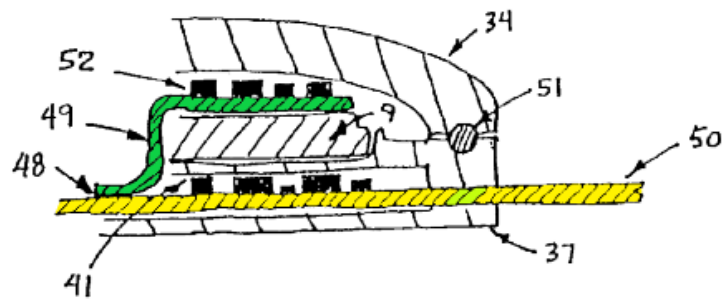
Figure 5. These “traces” connect electronics circuit 41 to sensor contacts 71 and 72, which, in turn, connect to pads 1 and 2 of disposable sensor assembly 73. Ex. 1011, ¶ [0040], Figure 5. This way, the signals captured by sensor pads 71, 72 of disposable sensor assembly 73 are transmitted to electronics 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. Further, these Jensen’s resistors are located the electronics circuit (*see* electronics circuit 41 in Figure 5) as opposed to, for example, the flexible circuit assembly.



Ex. 1011, Figure 2.

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].



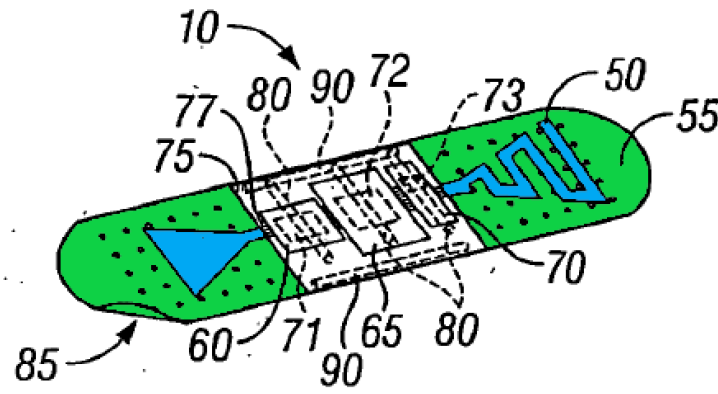
Ex. 1011, Figure 8 (annotated).

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.

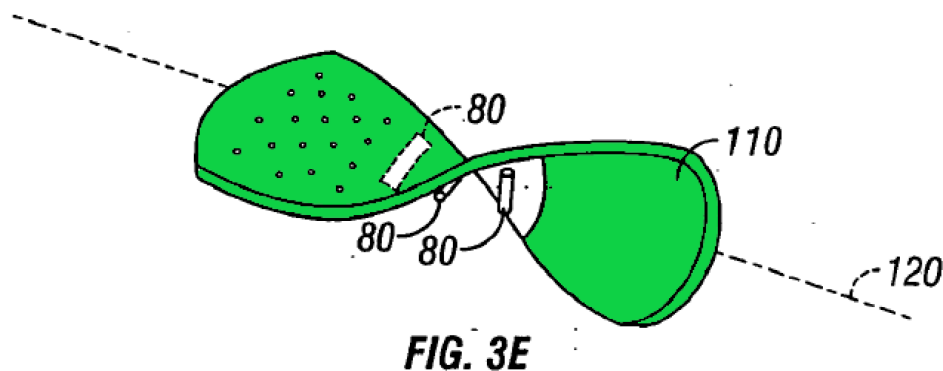
C. Ozguz (Exhibit 1013)

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 or available, or even possible, at the time of its filing. Ex. 1014, ¶ [0003]; *see* Section VII.C.v. 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.



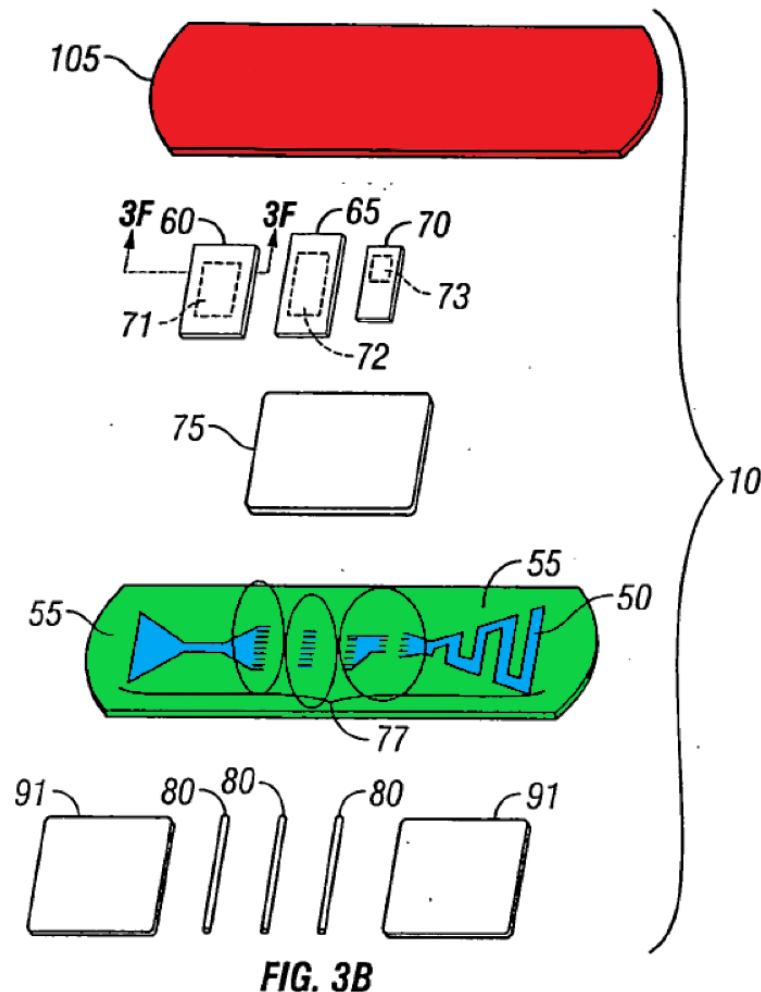
Ex. 1014, Figure 1 (in-part).



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].



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 3 and in them alleges that Claims 1 to 7, 9 to 12, and 14 to 20 of the ’422 Patent are obvious. I disagree with Dr. Heikenfeld.

62. In Ground 1, Dr. Heikenfeld opines that Claims 1 to 7, 9 to 11, and 14 to 20 of the ’422 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 two reasons. First, Ground 1 does not teach or suggest a “a flexible printed circuit board layer.” *See* Section VII.A.i. Second, 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.

63. In Ground 2, Dr. Heikenfeld opines that Claims 1 to 7, 9, 11, 12, and 14 to 20 of the '422 Patent are obvious over the combination of Jensen and the general knowledge of a POSITA or Matsumura. It is my opinion that Ground 2 fails to render the Challenged Claims obvious for the following reasons. First, Ground 2 does not teach or suggest “a disposable substrate made from an insulating material.” *See* Section VII.B.i. Second, Ground 2 does not teach or suggest “a computation-communication module.” *See* Section VII.B.ii. Third, a POSITA would not have been motivated to modify Jensen in view of the general knowledge of a POSITA or the teachings of Matsumura. *See* Section VII.B.iii.

64. In Ground 3, Dr. Heikenfeld opines that Claims 1 to 3, 5, 6, 9, 11, 12, 14-18, and 20 of the '422 Patent are obvious over the combination of Ozguz in view of the general knowledge of a POSITA or Matsumura. It is my opinion that Ground 3 fails to render the Challenged Claims obvious for three reasons. First, Ground 3 does not teach or suggest “a housing.” *See* Section VII.C.i. Second, Ground 3 does not teach or suggest “a processor disposed in the housing.” *See* Section VII.C.ii. Third, a POSITA would have viewed Ozguz as not enabled. *See* Section VII.C.v. As set forth below, all three Grounds fail.

VII. OPINIONS

A. Ground 1: Dr. Heikenfeld Fails to Establish that the Combination of Matsumura and the General Knowledge of a POSITA Renders Obvious Claims 1 to 7, 9 to 11, or 14 to 20

65. Dr. Heikenfeld opines that Claims 1 to 7, 9 to 11, and 14 to 20 of the '422 Patent are obvious over the combination of Matsumura and the “General Knowledge” of a POSITA. I disagree with Dr. Heikenfeld’s opinion.

66. First, Dr. Heikenfeld’s proposed modification of Matsumura in view of the “General Knowledge” fails to render obvious Claim 1 because it does not teach or suggest claim element 1[b], which requires “a flexible printed circuit board layer.” Ex. 1007, Claim 1; *see* Section VII.A.i. For the same reason, Dr. Heikenfeld’s proposed combination fails to render obvious Claim 14.

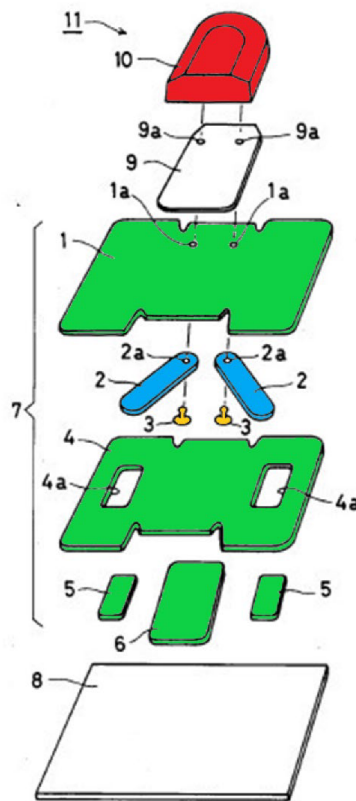
67. Second, Dr. Heikenfeld fails to establish that a POSITA would have been motivated to modify Matsumura in view of the “General Knowledge” in the manner proposed by Dr. Heikenfeld. A POSITA would not have been motivated to replace Matsumura’s pieces of rigid conductive material 2 with a single sheet of insulating material with printed traces. *See* Section VII.A.ii.

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

68. Claim element 1[b] requires “a flexible printed circuit board.” Ex. 1007, Claim 1. Dr. Heikenfeld opines that Matsumura renders obvious this element. Ex. 1009, ¶ 1385. However, to come to this conclusion, Dr. Heikenfeld relies on the

knowledge of a POSITA to opine that a POSITA would have known to use well-known techniques to replace Matsumura's two pieces of conductive material 2 "with a single, flexible sheet of insulating material that contained printed-ink conductive traces on its surface." Ex. 1009, ¶ 1387. I disagree with Dr. Heikenfeld's opinion.

69. Matsumura does not disclose a printed circuit board, and I understand that Dr. Heikenfeld does not argue otherwise. 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]. Importantly, conductive material 2 is a rigid, rod-shaped piece of conductive material, and hooks 3 are protruding stud-like hooks that extend vertically through conductive material 2. Ex. 1012, ¶ [0019]. These components are shown in Figure 1. Ex. 1012, Figure 1.



Ex. 1012, Figure 1 (annotated).

70. None of these components are a flexible printed circuit board, and Matsumura does not identify any other components that are disposable. *See generally* Ex. 1012.

71. Moreover, a POSITA would have understood that conductive material 2, which is rigid and rod-shaped, and hooks 3 are necessarily not printed, and therefore are not part of a flexible printed circuit board. In fact, a POSITA would have understood that replacing Matsumura's conductive material 2 with a sheet of insulating material and printed ink traces would fundamentally alter the function of Matsumura's device. For example, Dr. Heikenfeld's proposed modification would

remove the rigid, three-dimensional conductive rods (conductive material 2), which are necessary for the hooks to clamp onto, thereby preventing the transmission of bioelectric signals detected by conductive gel 5 through the conductive material, through the hooks, and to the signal processor.

72. In other words, Dr. Heikenfeld's proposed modification of Matsumura to add a sheet of insulating material with printed ink traces eliminates the hooks, which are required for transmitting the detected bioelectric signals to the signal processor. Dr. Heikenfeld does not acknowledge the electrical and mechanical functioning of the hooks, and does not address the importance of the hooks for this claim element, which is detrimental to Dr. Heikenfeld's analysis.

73. Dr. Heikenfeld provides self-created clip art to illustrate his proposed "Modification of Conductive Material." Ex. 1009, ¶ 1393. First, I disagree that a POSITA would have modified the conductive material as proposed by Dr. Heikenfeld. Second, a POSITA would not have inserted this "Modified Conductive Material" in the middle of the Matsumura's device.

74. There is no disclosure in Matsumura that suggests making this modification, and it is my opinion that Dr. Heikenfeld's opinion is based solely on a reconstruction of Matsumura's device while using the claims of the '422 Patent as a roadmap.

75. Not only does Matsumura not teach or suggest Dr. Heikenfeld's proposed modification, but Matsumura includes express teachings that Matsumura's electronics are not printed that Dr. Heikenfeld ignores. For example, Matsumura explains that "two pieces of conductive material 2 and two hooks 3 are arranged to transmit the bioelectric potential detected by the conductive gel 5." Ex. 1012, ¶ [0019]. Further, Matsumura is clear that "[t]he bioelectric pad 7 and the signal processor 10 are detachable with hooks." Ex. 1012, ¶ [0016]. Accordingly, the three-dimensional, rigid structure of both conductive material 2 and hook 3 are necessary for the electrical and mechanical connections. Thus, it is my opinion that a POSITA would not have been motivated to replace these components with printed circuitry.

76. As discussed above, Dr. Heikenfeld relies extensively on the "general knowledge" of a POSITA for his obviousness theories. For the additional reasons discussed in Section VII.A.ii, I disagree with Dr. Heikenfeld.

- ii. A POSITA would not have been motivated to replace Matsumura's conductive material and hooks with an insulating material and printed ink traces
 - a. Dr. Heikenfeld does not establish that a POSITA would have been motivated to modify Matsumura in view of the POSITA's "General Knowledge"

77. Dr. Heikenfeld opines that Matsumura as modified by a POSITA's "General Knowledge" would have been obvious to a POSITA for two reasons. Ex.

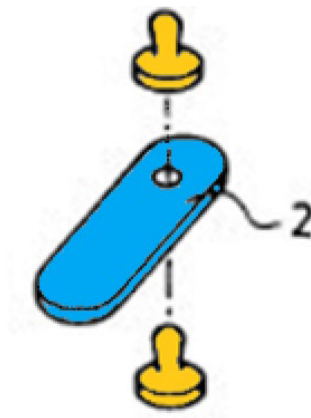
1009, ¶ 1387-1388. Specifically, Dr. Heikenfeld alleges that “a POSA reading Matsumura would have been motivated to replace the two pieces of insulating material coated with conductive Ag/AgCl with a single, flexible sheet of insulating material that contained printed-ink conductive traces.” Ex. 1009, ¶ 1388. According to Dr. Heikenfeld, a POSITA would have been motivated to make this modification “to reduce the manufacturing costs associated with manufacturing the parts.” Ex. 1009, ¶ 1388. Moreover, Dr. Heikenfeld opines that the proposed modification of “Matsumura’s conductive material would comprise a flexible printed circuit, which combined with second sheet 4, would form a flexible printed circuit layer made from the insulating material.” Ex. 1009, ¶ 1389. I disagree with Dr. Heikenfeld’s conclusions.

78. First, Dr. Heikenfeld appears to ignore that Matsumura’s rigid, three-dimensional conductive material 2 is essential to the operation of Matsumura’s waterproof design. 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.”).

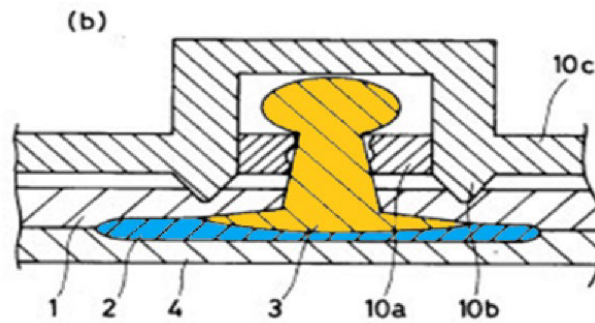
79. In particular, Matsumura’s signal processor and housing are located separate and apart from the rest of Matsumura’s bioelectric pad. Ex. 1012, ¶ [0016], Figures 1-2. Matsumura’s device is waterproofed, in part, because there is a vertical

conductive protrusion that allows for the mechanical connection and electrical flow of signals from the bio-pad upwards to the processor. Ex. 1012, ¶ [0024], [0027], Figures 4-5.

80. As shown in Figures 4 and 5 below, to provide this waterproof design, the rigid nature of conductive material 2 provides a stable support for hook 3. Ex. 1012, ¶ [0019], Figures 4-5. Specifically, “the protruding portions of the hook 3” extend upwards “from the back side of the conductive material 2,” clamping both sides of conductive material 2. Ex. 1012, ¶ [0021], Figures 4(b), 8. Together these components provide the electrical and mechanical connection necessary for carrying the detected bioelectric signals to the signal processor, as well as for waterproofing Matsumura’s device. Ex. 1012, ¶ [0019]. These components 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).

81. Accordingly, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to modify Matsumura to replace its non-printed electronics with printed circuitry because such a modification renders Matsumura's device inoperable for its intended purpose of transmitting bioelectric signals through conductive gel 5, conductive material 2, and hooks 3 to signal processor 10.

- b. Dr. Heikenfeld ignores the critical role that Matsumura's rigid conductive material and hooks play in both electrical connectivity and mechanical waterproofing

82. As discussed above in Section VII.A.ii.a, I do not agree with Dr. Heikenfeld's opinion that a POSITA would have modified Matsumura in view of the "General Knowledge" to replace Matsumura's three-dimensional, rigid conductive material with a single sheet of insulating material and printed traces. *See* Section VII.A.ii.a.

83. Instead, a POSITA would have known that replacing Matsumura's conductive material 2 and hooks 3 with printed circuitry (i.e., a single sheet of insulating material and printed ink traces) would destroy the electrical and

mechanical functioning of conductive material 2 and hooks 3. Dr. Heikenfeld does not acknowledge Matsumura's express disclosure that:

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].

84. Based on Matsumura's express disclosure, a POSA would have recognized that replacing the rod-shaped conductive material 2 with a sheet of insulating material with printed traces would prevent hooks 3 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 to prevent moisture ingress from penetrating the device—allowing water to create a break in the electrical connection, compromising the waterproofing of Matsumura's device.

Ex. 2015, ¶ [0017]-[0019], [0021].

85. Thus, replacing the non-printed, three-dimensional, rigid **conductive** electronics of Matsumura's device with flexible sheets of **insulating** material and printed ink traces frustrates Matsumura's goal of providing a waterproof design.

86. Accordingly, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to modify Matsumura to replace its non-printed electronics with printed circuitry because such a modification renders Matsumura's device inoperable for its intended purpose of providing a waterproof device.

B. Ground 2: Dr. Heikenfeld Fails to Establish that the Combination of Jensen and Matsumura or General Knowledge of a POSITA Renders Obvious Claims 1 to 7, 9, 11, and 14 to 20

87. Dr. Heikenfeld opines that Claim 1 to 7, 9, 11, and 14-20 are obvious over the combination of Jensen and the general knowledge of a POSITA or Matsumura. Ex. 1009, ¶ 1372. I disagree with Dr. Heikenfeld's opinion.

88. First, Dr. Heikenfeld's combination fails to render obvious Claim 1 because it does not teach or suggest claim element 1[a], which requires "a disposable substrate made from an insulating material." Ex. 1007, Claim 1; *see* Section VII.B.i. For the same reason, Dr. Heikenfeld's combination fails to render obvious Claim 14.

89. Second, Dr. Heikenfeld's combination fails to render obvious Claim 1 because it does not teach or suggest claim element 1[e], which requires "a computation-communication module." Ex. 1007, Claim 1. Claim 1 further requires the computation-communication module to be attached to the disposable substrate. Ex. 1007, Claim 1; *see* Section VII.B.ii. For the same reason, Dr. Heikenfeld's combination fails to render obvious Claim 14.

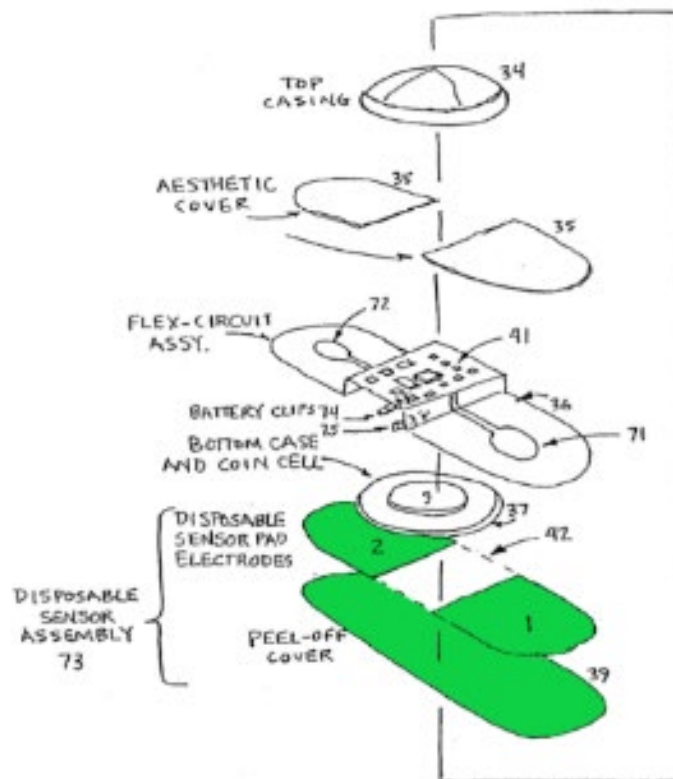
90. Third, Dr. Heikenfeld fails to establish that a POSITA would have been motivated to modify Jensen in view of the teachings of Matsumura. A POSITA would not have been motivated to combine Jensen and Kroll to limit current between the patient and the device or to reduce the size of Jensen's device. *See* Section VII.B.iii.

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

91. Claim element 1[a] requires “a disposable substrate made from an insulating material.” Ex. 1007, Claim 1. Dr. Heikenfeld advances two theories for claim element 1[a]. First, Dr. Heikenfeld opines that Jensen, in view of the knowledge of a POSITA, renders obvious this element. Ex. 1009, ¶ 1497. Second, Dr. Heikenfeld opines that a POSITA would have modified Jensen in view of the teachings of Matsumura. Ex. 1009, ¶ 1502. I disagree with both theories.

a. Jensen does not disclose a disposable substrate

92. Jensen does not disclose a disposable substrate, and I understand that Dr. Heikenfeld does not argue otherwise. Jensen discloses a “disposable sensor assembly,” which includes sensor pad electrodes and a peel-off cover. Ex. 1011, ¶¶ [0041]-[0042]. These components are shown in Figure 5. Ex. 1011, Figure 5.



Ex. 1011, Figure 5 (annotated).

93. None of these components are a disposable substrate, and Jensen does not identify any other components that are disposable substrates. *See generally* Ex. 1011. Thus, Dr. Heikenfeld relies on the knowledge of a POSITA for both of his theories. For the reasons in Section VII.B.i.b, I disagree with Dr. Heikenfeld.

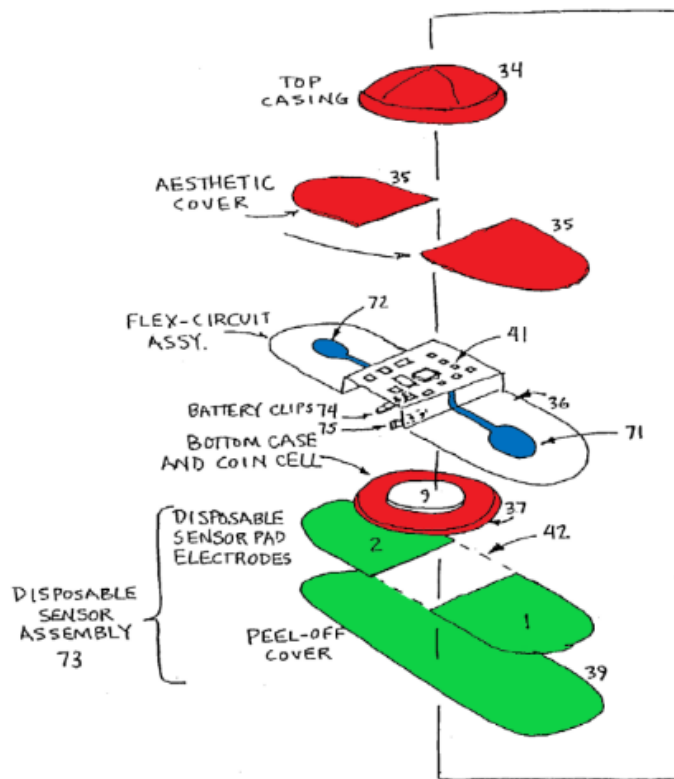
- b. Jensen and the general knowledge of a POSITA do not render obvious a disposable substrate

94. Dr. Heikenfeld opines that Jensen and the knowledge of a POSITA render obvious a disposable substrate because “a POSA would have been motivated to make the circuit closest to the patient’s skin, flexible circuit 50, disposable, while keeping flexible printed circuit 49 non-disposable.” Ex. 1009, ¶ 1499. Dr.

Heikenfeld supports his position by arguing that the disposable substrate “would have ensured that the components of the device most proximal to the patient’s skin (and including the lowest cost materials) were disposable, thereby promoting hygiene generally.” Ex. 1009, ¶ 1499. I disagree with Dr. Heikenfeld.

95. First, a POSITA would have been motivated to make flexible circuit 50 disposable to ensure that the components most proximal to the skin were disposable because Jensen’s layer “most proximal to the patient’s skin” is already disposable. Ex. 1009, ¶ 1499. Dr. Heikenfeld does not address this disclosure.

96. As introduced in Section V.B, Jensen 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). The disposable sensor assembly 73 is the layer most proximal to the skin. Furthermore, Jensen already preserves all metallic conductive components in the reusable portion.



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

97. Because Jensen’s design already provides a disposable layer that contacts the skin, a POSITA would not have been motivated to “ensure[] that the components of the device most proximal to the patient’s skin (and including the lowest cost materials) were disposable” as Dr. Heikenfeld opines. Ex. 1009, ¶ 1499.

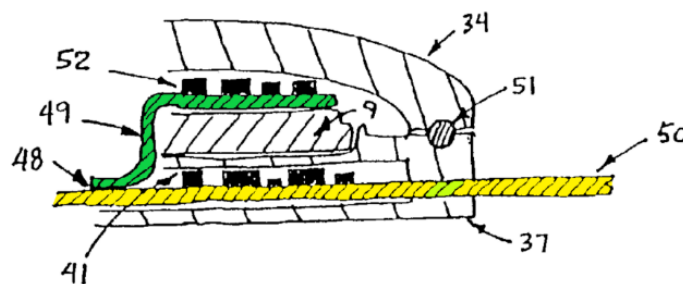
98. Dr. Heikenfeld reference to “promoting hygiene generally” does not save his position. While this motivation could be applied to the entire field of medical devices, Dr. Heikenfeld still does not address Jensen’s disclosure. Jensen skin contacting layer is already disposable. Accordingly, a POSITA would not have

been motivated to make circuit 50 disposable to ensure components closest to the skin are disposable for hygiene purposes, as Dr. Heikenfeld opines.

- c. A POSITA would not have been motivated to make circuit 50 of Jensen a disposable substrate

99. As introduced in Section VII.B.i.b, Dr. Heikenfeld opines that “a POSA would have been motivated to make the circuit closest to the patient’s skin, flexible circuit 50, disposable, while keeping flexible printed circuit 49 non-disposable.” Ex. 1009, ¶ 1499. I disagree with Dr. Heikenfeld.

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



Ex. 1011, Figure 8 (annotated).

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

102. When considering such disclosure, a POSITA would not have been motivated to make circuit 50. Instead, a POSITA would have understood that there are no advantages in making circuit 50 disposable because circuit 50 would still be fixed to reusable circuit 49. Separating circuits 49, 50 would damage (if not destroy) Jensen's device. If Dr. Heikenfeld's proposed modification was made, Jensen would include a "disposable" circuit 50 that could not be detached (and thus not disposable) from the other circuit 49. Thus, a POSITA would have recognized that, contrary to Dr. Heikenfeld's opinion, there would be no advantage in making circuit 50 disposable in Jensen's device.

103. Accordingly, a POSITA would not have been motivated "to make the circuit closest to the patient's skin, flexible circuit 50, disposable, while keeping flexible printed circuit 49 non-disposable." Ex. 1009, ¶ 1499.

d. A POSITA would not have been motivated to redistribute Jensen's electronics

104. Dr. Heikenfeld opines that "a POSA would have been motivated to make the circuit closest to the patient's skin, flexible circuit 50, disposable, while

keeping flexible printed circuit 49 non-disposable.” Ex. 1009, ¶ 1499. For the reasons in Section VII.B.i.c, I disagree with Dr. Heikenfeld.

105. Dr. Heikenfeld also opines that “it would have been obvious for a POSA to distribute valuable components on top of flexible circuit assembly 49,” which would “allow reuse of the most expensive components.” Ex. 1009, ¶ 1500. I disagree with Dr. Heikenfeld further modification of Jensen.

106. First, I note that Dr. Heikenfeld opined that a POSITA would have been motivated to make circuit 50 disposable. Ex. 1009, ¶ 1499. Now, Dr. Heikenfeld opines that a POSITA would take electronics on circuit 50 and redistribute these to circuit 49 to reuse the most expensive components. Ex. 1009, ¶ 1500.

107. However, Dr. Heikenfeld’s own modifications cause the need to redistribute the electronics. In other words, the reuse of “expensive components” was not an issue before Dr. Heikenfeld modified Jensen to make the circuit 50 disposable. Moreover, before such modification, all of Jensen’s valuable components were already part of the reusable layer.

108. For this reason, Dr. Heikenfeld’s methodology is flawed. Dr. Heikenfeld modifies Jensen to create a disposable substrate, creates the issue of disposing expensive components, and then uses this as a motivation to further modify Jensen back to the design that Dr. Heikenfeld deviated from.

109. Besides reuse of the expensive components, Dr. Heikenfeld also opines that a POSITA would have been motivated to redistribute Jensen’s electronics based on “hygiene and waterproofing.” Ex. 1009, ¶ 1500. I disagree; neither hygiene nor waterproofing would motivate a POSITA to redistribute Jensen’s electronics.

110. First, Dr. Heikenfeld motivation that a disposable circuit improves safety and promotes “hygiene” suffers from the same issues as covered in Section VII.B.i.c. Specifically, Jensen uses a heat re-flow process to connect the two circuits. Ex. 1011, ¶ [0046]. Dr. Heikenfeld’s opinion that a POSITA would have modified Jensen to make circuit 50 disposable ignores the structure of Jensen. Section VII.B.i.c.

111. Second, Dr. Heikenfeld does not explain how redistributing the electronics would improve waterproofing. Dr. Heikenfeld cross-references an entire section—related to a different patent—on combining Jensen and Matsumura. Ex. 1009, ¶ 1500 (citing Section XVIII.C.1).

112. In that section, Dr. Heikenfeld opines that a POSITA would modify Jensen to allegedly achieve a waterproof structure. Ex. 1009, ¶ 947. But Dr. Heikenfeld fails to even mention redistribution of the electronics, and Dr. Heikenfeld does not explain how redistributing the electronics would improve Jensen’s waterproofing. Ex. 1009, ¶ 947.

113. Accordingly, Dr. Heikenfeld fails to establish that hygiene or waterproofing would have motivated a POSITA to redistribute electronics based on Jensen alone.

114. Finally, Dr. Heikenfeld's alternative theory that relies on Jensen in view of Matsumura does not address the above issues and similarly fails, for the reasons outlined below in Section VII.B.iii.

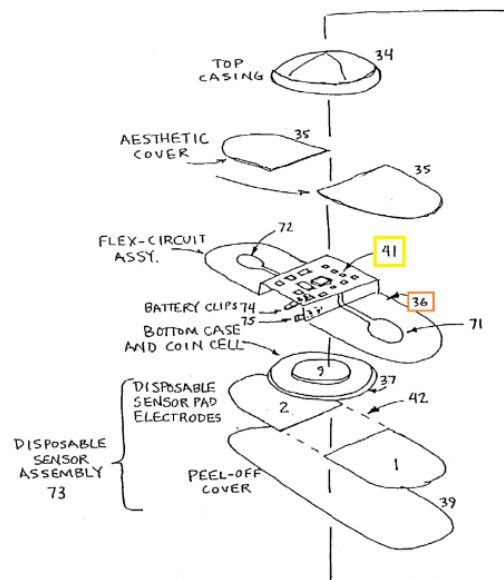
ii. Ground 2 fails to render obvious claim element 1[e]

115. Claims 1 and 14 require a computation-communication module, which is attached to a disposable substate. Ex. 1007, Claim 1, 15. Dr. Heikenfeld opines that Jensen's microcontroller and transmitter render obvious the computation-communication module. Ex. 1009, ¶ 1522. I disagree with Dr. Heikenfeld.

116. Both Claim 1 and 14 require a computation-communication, which must be attached to the disposable substrate. Ex. 1007, Claim 1, 14. Dr. Heikenfeld identifies substrate 50 as the claimed disposable substrate. Ex. 1009, ¶ 1535. However, Jensen's microcontroller and transmitter, which Dr. Heikenfeld identifies as the computation-communication module, are not attached to substrate 50. Therefore, the microcontroller and transmitter cannot be the claimed computation-communication module as Dr. Heikenfeld opines.

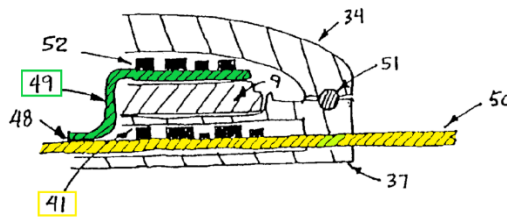
117. Jensen's electronics circuit includes the microcontroller and transmitter. Ex. 1011 ¶¶ [0031]-[0032]. In Figure 5, electronics circuit 41 (yellow

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).

118. 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).

119. Dr. Heikenfeld does not address this disclosure and instead concludes that a “POSA would understand that the computation-communication module of Jensen would be included on non-disposable substrate 49.” Ex. 1009, ¶ 1522. But Dr. Heikenfeld does explain why a POSITA would have understood the alleged computation-communication module to be on substrate 49.

120. Finally, Dr. Heikenfeld contradicts his position when opining on a different claim element. Specifically, Dr. Heikenfeld states that “[a]s part of electronics circuitry 41, Jensen discloses ‘a microcontroller and/or other programmable logic circuitry that perform measurement and processing of sensed data.’” Ex. 1009, ¶ 1531 (citing Ex. 1011, [0014]). As introduced in paragraph 115, Dr. Heikenfeld also contends that the microcontroller and transmitter would be included on non-disposable substrate 49. Ex. 1009, ¶ 1522.

121. For these reasons, I disagree with Dr. Heikenfeld. A POSITA would not have understood the microcontroller and transmitter to be located on substrate

49. Thus, Jensen does not render obvious the computation-communication module, which must be attached to a disposable substrate.

iii. A POSITA would not have been motivated to modify Jensen in view of the teachings of Matsumura

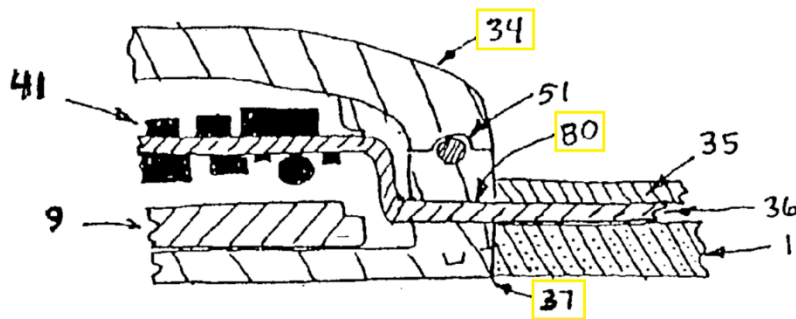
122. Dr. Heikenfeld opines that a POSITA would have been motivated to modify Jensen in view of the teachings of Matsumura. To support this position, Dr. Heikenfeld cross-references to Section XVIII.C.1 of his declaration, which relates to a different patent (the '492 Patent) from a separate proceeding (IPR2025-00374). Despite this difference, I understand that Dr. Heikenfeld is advancing the same position regarding motivation to modify Jensen as it relates to the '492 Patent and the '422 Patent in this proceeding.

123. Dr. Heikenfeld opines that a POSITA would have been motivated to modify Jensen in view of the teachings of Matsumura for two reasons. First, Dr. Heikenfeld opines that “a POSA would have been motivated to seek out ways to make more parts of the device disposable” to minimize the risk of cross-contamination. Ex. 1009, ¶ 939. Second, Dr. Heikenfeld opines that a “POSA would have also been motivated to modify Jensen with Matsumura’s teaching of a waterproof structure.” Ex. 1009, ¶ 943. I disagree with these opinions. A POSITA would not have been motivated to modify Jensen based on either a desire to achieve a waterproof structure or the risk of ineffective cleaning.

- a. A POSITA would not have been motivated to modify Jensen to achieve a waterproof structure

124. Contrary to Dr. Heikenfeld opinion, a POSITA would not have been motivated to modify Jensen to achieve a waterproof structure because Jensen's already seals its electronics from the surrounding environment. Ex. 1011, ¶ [0045].

125. In Figure 7, Jensen's device includes a top case 34 that mounts to a bottom case 37, which includes a slot cut-out 80 for the passage of flexible circuit assembly 36. Ex. 1011, ¶ [0045]. Once Jensen's device is assembled, a sealant is applied to the slot 80 "to seal the electronics 41 from the surrounding environment." Ex. 1011, ¶ [0045]. Moreover, "top and bottom case halves 34, 37 have an o-ring seal 51 at their mating surfaces." Ex. 1011, ¶ [0045]. Based on this disclosure, a POSITA would not have been motivated to look Matsumura to modify Jensen.



Ex. 1011, Figure 7 (annotated).

126. Dr. Heikenfeld also concludes that "Jensen is prone to seepage through the top, bottom, and slot in the smart patch through which the flexible circuit assembly extends." Ex. 1009, ¶ 943. However, the teachings of Jensen or

Matsumura do not provide any disclosure to suggest that Jensen is not sufficiently sealed. *See generally*, Ex. 1011; Ex. 1012. And Dr. Heikenfeld does not cite anything in Jensen or provide any additional explanation.

127. Further, in the same paragraph that Dr. Heikenfeld concludes that Jensen is “prone to seepage,” Dr. Heikenfeld acknowledges that “Jensen relies on a ‘sealant [that] is applied to the slot 80, once assembled.’” Ex. 1009, ¶ 943. Thus, Dr. Heikenfeld recognizes that, even if Jensen was prone to seepage, Jensen provides a sealant to slot 80 and thereby solves any alleged problem.

128. Accordingly, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to modify Jensen to achieve a waterproof structure because Jensen’s already seals its electronics from the surrounding environment.

- b. A POSITA would not have been motivated to modify Jensen to achieve a waterproof structure

129. A POSITA would not have been motivated to modify Jensen to include a disposable layer in view of Matsumura based on the “risk of cross-contamination.” Ex. 1009, ¶ 939. In Figure 5, Jensen’s disposable sensor pad electrodes 1, 2 are coupled to the flexible circuit assembly, which includes electronics circuit 41. Ex. 1011, ¶¶ [0041]-[0042], Figure 5. Based solely on the “risk of cross-contamination,” Dr. Heikenfeld opines that, in view of Matsumura’s teachings, a POSITA would

redesign Jensen to include a disposable layer that (1) connects the electrodes to the electronics while (2) separating the reuseable portion from the skin. Ex. 1009, ¶ 942.

130. Dr. Heikenfeld's conclusion is based on the false premise that the modification of Jensen would provide disposable parts and thus minimize the risk of cross-contamination. For the reasons detailed in Section VII.B.i.c, Dr. Heikenfeld's modifications would not lead to any disposable components because Jensen circuits are heat re-flowed together, and breaking this would require significant re-design and experimentation. Thus, a POSITA would not recognize any advantages to the cleaning process in Dr. Heikenfeld's proposed modification.

131. Accordingly, I disagree with Dr. Heikenfeld. A POSITA would not have been motivated to modify Jensen to minimize the risk of cross-contamination because Dr. Heikenfeld's modification would not lead to disposable components.

C. Ground 3: Dr. Heikenfeld Fails to Establish that the Combination of Ozguz and Matsumura or General Knowledge of a POSITA Renders Obvious Claims 1 to 3, 5, 6, 9, 11, 12, 14 to 18, and 20

132. Dr. Heikenfeld opines that Claims 1 to 3, 5, 6, 9, 11, 12, 14 to 18, and 20 are obvious over Ozguz in view of the "General Knowledge" of a POSITA. Ex. 1009, ¶ 1616. I disagree with Dr. Heikenfeld's opinion.

133. First, Dr. Heikenfeld's modification of Ozguz fails to render obvious Claim 1 because it does not teach or suggest claim element 1[f], which requires "a

housing.” Ex. 1014, Claim 1; *see* Section VII.C.i. For the same reason, Dr. Heikenfeld’s combination fails to render obvious Claim 14.

134. Second, Dr. Heikenfeld’s proposed modification of Ozguz in view of the “General Knowledge” fails to render obvious Claim 1 because it does not teach or suggest claim element 1[g], which requires “a processor disposed in the housing.” Ex. 1014, Claim 1; *see* Section VII.C.ii. For the same reason, Dr. Heikenfeld’s combination fails to render obvious Claim 14.

135. Third, 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 or 14. *See* Section VII.C.v.

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

136. Claim element 1[f] requires “a housing.” Ex. 1007, Claim 1. Dr. Heikenfeld’s only analysis for claim element 1[f] is that the “flexible, thin battery 105” disclosed in Ozguz “is shaped in a way that houses” other components, and therefore “Ozguz discloses ‘a housing.’” Ex. 1009, ¶¶ 1647-1648. As a preliminary matter, Dr. Heikenfeld’s assertion that flexible battery 105 is “shaped in a way” similar to a housing is vague and unsupported by the remainder of his declaration and unsupported by Ozguz’s disclosure. Dr. Heikenfeld assumes, without

explanation, that flexible battery 105 is analogous to a “housing.” Ex. 1009, ¶ 1645-1648. I disagree with Dr. Heikenfeld’s opinion.

137. Further, 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 is shown in Dr. Heikenfeld’s own annotation.

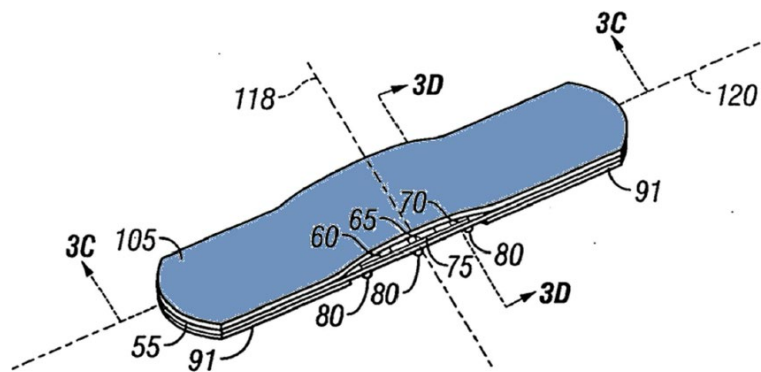


FIG. 3A

Ex. 1009, ¶ 1647 (annotation in original). At best, it is a layer in a sandwich not the roof and walls of a house.

138. Thus, Ozguz does not disclose any structure that a POSITA would have reasonably considered a housing, and Dr. Heikenfeld’s conclusory allegation that the flexible battery is “shaped in a way that houses the computation-communication module” is implausible. Accordingly, I disagree with Dr. Heikenfeld’s analysis and opinion.

139. 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.

ii. Ground 3 fails to render obvious claim element 1[g]

140. Claim element 1[g] requires “a processor disposed in the housing.” Ex. 1007, Claim 1. Because Dr. Heikenfeld interprets “housing” improperly, Dr. Heikenfeld’s conclusions regarding claim element 1[g] are erroneous. Dr. Heikenfeld alleges that Ozguz discloses a microprocessor 175 “incorporated into the thin silicon substrates 60, 65, 70.” Ex. 1009, ¶ 1651. Then, Dr. Heikenfeld alleges that flexible battery 105 “houses ‘the silicon substrates 60, 65, 70 and their respective ICs 71, 72, 73.’” Ex. 1009, ¶ 1651. According to Dr. Heikenfeld, this means that “Ozguz discloses ‘a processor disposed in the housing.’” Ex. 1009, ¶ 1652. I disagree with Dr. Heikenfeld’s opinion.

141. First, as discussed above in Section VII.C.i, Ozguz does not disclose a “housing.” *See* Section VII.C.i; *see generally* Ex. 1014. Therefore, Ozguz cannot, and does not, disclose a processor disposed in a housing.

142. Second, 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.

iii. Dr. Heikenfeld's interpretation of "housing" is improper and erroneous

143. 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.

144. Dr. Heikenfeld seemingly interprets "housing" to mean any type of unenclosed overlay—an interpretation that contradicts the ordinary meaning of "housing," which a POSA 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.

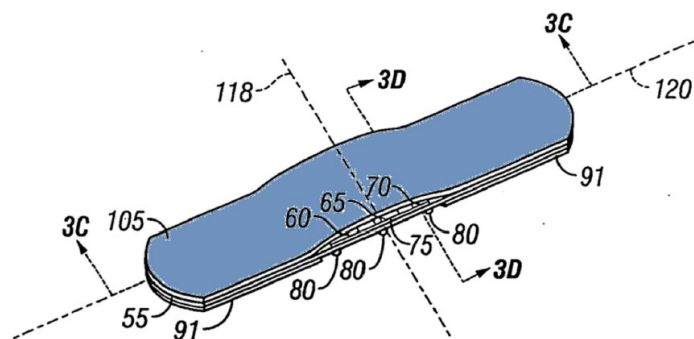


FIG. 3A

Ex. 1009, ¶ 1647.

145. Moreover, Dr. Heikenfeld's only support for this interpretation is that flexible battery 105 is "shaped in a way that houses" other components. Ex. 1009, ¶ 1647. A POSITA would not have understood Ozguz's flexible battery 105 to be a

housing, and Dr. Heikenfeld's arguments are merely conclusory assertions without any supporting evidence.

146. Ozguz itself characterizes flexible battery 105 as an “overlying battery 105” that “overlays” other components of the device. Ex. 1014 ¶¶ [0048], [0055]. In the context of the '422 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 POSA would have thought any different. *See* Ex. 1009, ¶¶ 1640-1652.

147. 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 Claim 14 is obvious.

148. In view of the '422 patent, a POSITA would understand the term “disposed in a housing” 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.

149. This understanding aligns with the specific context in the '422 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.

150. Thus, the phrase “disposed in a housing,” from the perspective of a POSITA, clearly signifies components being fully or substantially enclosed within a structural casing or enclosure, and not merely being adjacent to or externally attached to it.

iv. Dr. Heikenfeld's interpretation of "disposed in the housing" is improper and erroneous

151. Dr. Heikenfeld's interpretation of "disposed in the housing" is also improper and erroneous because it is an impermissibly broad reading of the claim language that no POSITA would have endorsed.

152. First, as discussed above in Section VII.C.iii, Dr. Heikenfeld improperly interprets "housing"; therefore, Dr. Heikenfeld also improperly interprets the term "housing" in claim element 1[g].

153. Additionally, Dr. Heikenfeld improperly interprets "disposed in the housing." 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. Despite the express disclosure in Ozguz, Dr. Heikenfeld nonetheless appears to interpret "disposed in the housing" to mean anything that touches the flexible battery layer. Ex. 1009, ¶ 1649-1652.

154. To conclude (as Dr. Heikenfeld does) that a POSITA would have considered a processor "disposed in the housing" to mean a processor touching the external wall of a flexible battery 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

processor disposed in the housing. For the same reasons, Dr. Heikenfeld fails to establish that Claim 14 is obvious.

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

155. Dr. Heikenfeld only relies on Ozguz for his obviousness theories regarding independent Claims 1 and 14. Ex. 1009, ¶¶ 1616-1656, 1688-1705. 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 or 14 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 technology was infeasible at the time of Ozguz's claimed priority date, 2005.

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

156. Ozguz provides a sensor bandage 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 '422 Patent's priority date (2006), flexible batteries were not viable or available in the form described in Ozguz.

157. Conceptually, flexible batteries may have been proposed or theoretically envisioned, but the technology to implement flexible batteries in a real-

world, realistic device was in its infancy, and its availability was far from practical. 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.

158. Ozguz suggests the use of integrated flexible batteries to power the bandage 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.

159. Additionally, a POSA, 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 '422 Patent. Ex. 1007, 2:21-23. Further, even if a theoretical or experimental flexible battery existed at the time of the invention, it would not have been reliable enough for use in a wearable cardiac device in bandage form. Consequently, a POSA would not have been able to implement the flexible battery in a functional ambulatory monitor, which significantly undermines the enablement of Ozguz.

160. Moreover, the use of flexible batteries for a patient wearable device, particularly one designed for continuous monitoring in a bandage form factor, would have faced significant challenges regarding user comfort and practicality. A wearable device would need to offer long-term battery life, significant flexibility, and tolerance to rough use, 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.

161. 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, which are 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.

162. 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 stiffness, i.e., flexibility, of the battery inside 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 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.

163. 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 Infeasible Flexible Battery Technology is Fatal to Ground 3

164. As discussed above in Sections VII.C.i-ii, Dr. Heikenfeld relies on Ozguz’s “flexible battery 105” for at least two of the claim elements in independent Claim 1. Ex. 1009, ¶¶ 1645-1652. This flexible battery technology, however, was infeasible at the time of Ozguz’s purported priority date (2005), infeasible at the time of the priority date of the ’422 Patent (2006), and still infeasible up to at least 2015 for at least four reasons.

165. 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.

166. 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 ($\sim 1 \text{ mWh/cm}^2$). Hence, by 2005, flexible battery technologies simply could not offer sufficient power density and durability required by the *Ozguz* device specification.

167. 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.

168. 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

169. Dr. Heikenfeld relies on *Ozguz*'s thinned silicon substrates for at least five of the claim elements in independent Claim 1. Ex. 1009, ¶¶ 1624 (Claim

element 1[a]), 1642-1643 (claim element 1[e]), 1647 (claim element 1[f]), 1651 (claim element 1[g]), 1655 (claim element 1[h]).

170. 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, ¶ 1655. 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 'attaching the computation-communication module to the disposable substrate'" does not necessarily follow. Ex. 1014, ¶ [0042]; Ex. 1009, ¶ 1655. 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 '422 Patent (2006). And, such thinned silicon devices certainly could not have physically supported the needs of the computation-communication module.

171. 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.

172. 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.

173. 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.

174. 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.

175. 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.

176. Accordingly, in 2005, flexible thinned silicon technologies lacked the mechanical robustness, manufacturing maturity, integrated system-level capability, and commercial feasibility required to create a wearable, flexible, physiological

monitoring device as described in Ozguz. The subsequent recognition of these inadequacies by the U.S. government via FOA-RQKM-2015-0014—ten years later—strongly underscores the depth and persistence of these technical and manufacturing challenges. Consequently, such a wearable, flexible device was not realizable by a POSITA in 2005.

VIII. RESERVATION OF RIGHTS

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

178. 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