Apple Inc. (Petitioner)
v.
Masimo Corporation (Patent Owner)

Petitioner Demonstratives

Case Nos. IPR2020-01520, -01536, -01537, -01538, -01539
U.S. Patent Nos. 10,258,265, 10,588,553, 10,588,554

Before Hon. Amanda Wieker, Robert Kinder, George Hoskins
Administrative Patent Judges

FISH.

Table of Contents

FISH.

Issue 1

Implementing a Cover with a Protruding Convex Surface

Case Nos. IPR2020-01520, -01536, -01537, -01538, -01539
U.S. Patent Nos. 10,258,265, 10,588,553, 10,588,554

FISH.

Multiple Advantages would have Motivated the POSITA

Dr. Kenny's Declaration

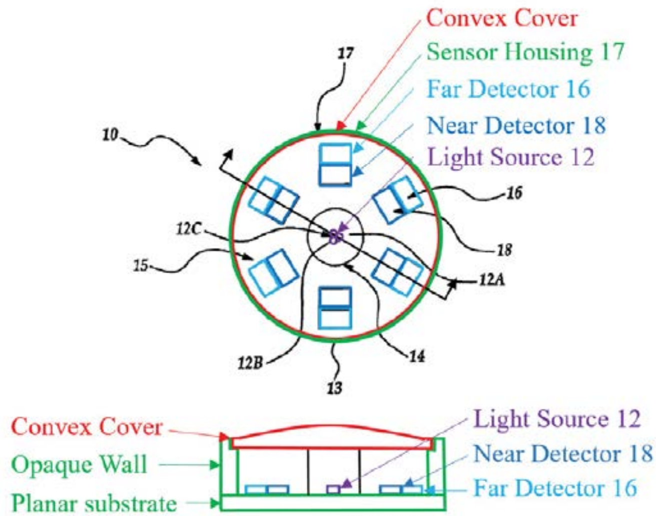
87. Accordingly, Ohsaki would have motivated one of ordinary skill to add a light permeable protruding convex cover to Mendelson '799's sensor, to improve adhesion between the sensor and the user's tissue, to improve detection efficiency, and to provide additional protection to the elements accommodated within sensor housing 17. APPLE-1009, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B.

IPR2020-01536 APPLE-1003, ¶ 87.

88. In more detail, and as shown below in the section view of the Mendelson-Ohsaki sensor, one of ordinary skill would have added a transparent convex cover to sensor 10, the cover being located between tissue of the user and the array of detectors 16 and 18 when worn. APPLE-1012, Abstract, 9:22-10:30, FIG. 8; APPLE-1009, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B; *see also* APPLE-1008, ¶¶14-15, FIG. 1. To obtain the advantages described by Ohsaki, one of ordinary skill would have configured the cover to be sufficiently rigid to conform tissue of the user to at least a portion of the cover's surface when worn. APPLE-1009, ¶[0025]; *see also* APPLE-1009, ¶[0030], FIG. 1(b). And, consistent with Ohsaki's configuration, one of ordinary skill would have configured Mendelson on which detectors 16 and 18 are arranged and, on an opposite side, to the convex cover. APPLE-1012, Abstract, 9:22-10:30, FIG. 7; APPLE-1009, ¶[0017], FIG. 2.

IPR2020-01536 APPLE-1003, ¶ 88.

Mendelson '799



IPR2020-01536 APPLE-1012, FIG. 7 (annotated with additional section view) (APPLE-1003, ¶ 88).

FISH.

4

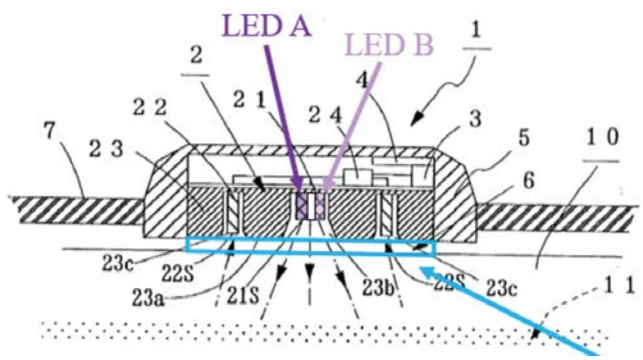
Multiple Advantages would have Motivated the POSITA

Dr. Kenny's Declaration

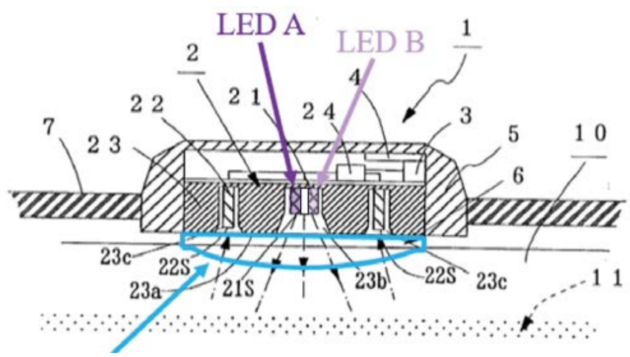
7. As I explained at length in my first declaration, "one of ordinary skill would have found it obvious to modify the [Aizawa] sensor's flat cover…to include a lens/protrusion…similar to Ohsaki's translucent board 8, so as to [1] improve adhesion between the user's wrist and the sensor's surface, [2] improve detection efficiency, [3] and protect the elements within the sensor housing." APPLE-1003, ¶¶84-91 (citing to APPLE-1014, [0025]; APPLE-1006, [0012], [0024]; APPLE-1024, ¶¶[0022]; [0032]-[0033], [0035], FIG. 6). I further explained that a POSITA

IPR2020-01537 APPLE-1047, ¶ 7.

Aizawa



IPR2020-01537 APPLE-1006, FIG. 1(b)
(annotated with flat cover)(APPLE-1003, ¶ 88).



IPR2020-01537 APPLE-1006, FIG. 1(b)
(annotated with protruding cover)(APPLE-1003, ¶ 88).

FISH.

Issue 1A

The Cover's Protruding Convex Surface would Improve Adhesion and Signal Strength

FISH.

A POSITA would have Modified Aizawa's Flat Cover

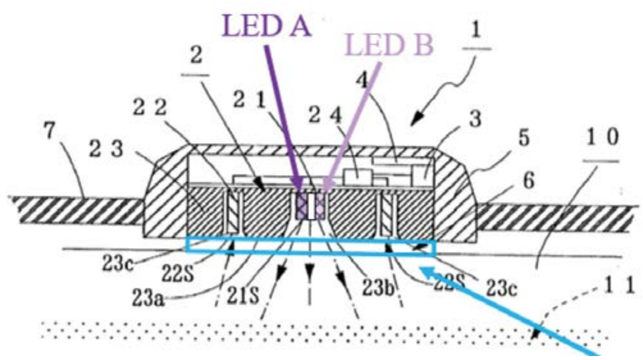
Dr. Kenny's Declarations

2. *Convex surface*

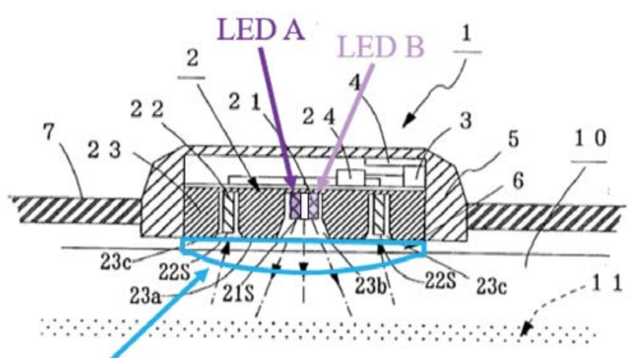
84. Additionally, one of ordinary skill would have combined the teachings of Aizawa-Inokawa with the teachings of Ohsaki such that the cover of Aizawa-Inokawa's wrist-worn sensor would include a convex surface, improving adhesion between a subject's wrist and a surface of the sensor. APPLE-1009, ¶[0025] (the convex surface prevents slippage of the detecting element from its position on the subject's wrist, and the convex nature of the surface suppresses the "variation of the amount of the reflected light" that reaches the detecting element).

IPR2020-01537 APPLE-1003, ¶ 84;
see also APPLE-1047, ¶ 7.

Aizawa



IPR2020-01537 APPLE-1006, FIG. 1(b)
(annotated with flat cover)(APPLE-1003, ¶ 88).



IPR2020-01537 APPLE-1006, FIG. 1(b)
(annotated with protruding cover)(APPLE-1003, ¶ 88).

FISH.

Ohsaki Teaches that a Protruding Convex Surface Prevents Slippage and Improves Signal Strength

Dr. Kenny's First Declaration

2. *Convex surface*

84. Additionally, one of ordinary skill would have combined the teachings of Aizawa-Inokawa with the teachings of Ohsaki such that the cover of Aizawa-Inokawa's wrist-worn sensor would include a convex surface, improving adhesion between a subject's wrist and a surface of the sensor. APPLE-1009, ¶[0025] (the convex surface prevents slippage of the detecting element from its position on the subject's wrist, and the convex nature of the surface suppresses the "variation of the amount of the reflected light" that reaches the detecting element).

85. In more detail, Ohsaki describes a "detecting element" that includes "a package 5, a light emitting element 6 (e.g., LED), a light receiving element 7 (e.g., emitting element 6 and light receiving element 7 are arranged. *Id.*. As shown in Ohsaki's FIG. 2, translucent board 8 is arranged such that, when the sensor is worn "on the user's wrist …| the convex surface of the translucent board … is in intimate contact with the surface of the user's skin"; this contact between the convex surface and the user's skin is said to prevent slippage, which increases the strength of the signals obtainable by Ohsaki's sensor. APPLE-1009, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B.

IPR2020-01537 APPLE-1003, ¶¶ 84-85.

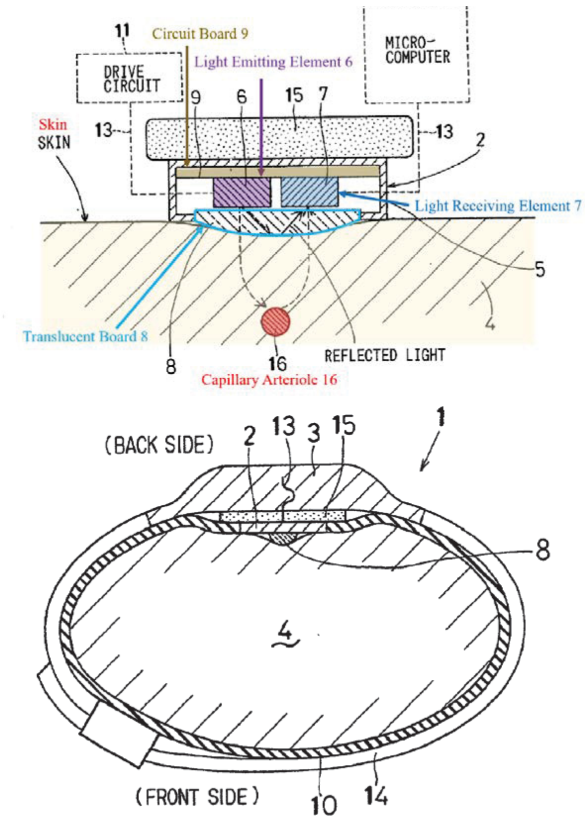
FISH.

Ohsaki Teaches that a Protruding Convex Surface Prevents Slippage

Ohsaki

[0025] The detecting element **2** is arranged on the user's wrist **4** so that the convex surface of the translucent board **8** is in intimate contact with the surface of the user's skin. Thereby it is prevented that the detecting element **2** slips off the detecting position of the user's wrist **4**. If the translucent board **8** has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist **4** as shown in **FIG. 4B**. However, in the case that the translucent board **8** has a convex surface like the present embodiment, the variation of the amount of the reflected light which is emitted from the light emitting element **6** and reaches the light receiving element **7** by being reflected by the surface of the user's skin is suppressed. It is also prevented that noise such as disturbance light from the outside penetrates the translucent board **8**. Therefore the pulse wave can be detected without being affected by the movement of the user's wrist **4** as shown in **FIG. 4A**.

IPR2020-01537 APPLE-1009 ¶ [0025]
(cited at APPLE-1003, ¶ 85).



IPR2020-01537 APPLE-1009, FIGS. 1, 2.

FISH.

Ohsaki Teaches that a Protruding Convex Surface Improves Signal Strength

Ohsaki

[**0025**] The detecting element **2** is arranged on the user's wrist **4** so that the convex surface of the translucent board **8** is in intimate contact with the surface of the user's skin. Thereby it is prevented that the detecting element **2** slips off the detecting position of the user's wrist **4**. If the translucent board **8** has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist **4** as shown in **FIG. 4B**. However, in the case that the translucent board **8** has a convex surface like the present embodiment, the variation of the amount of the reflected light which is emitted from the light emitting element **6** and reaches the light receiving element **7** by being reflected by the surface of the user's skin is suppressed. It is also prevented that noise such as disturbance light from the outside penetrates the translucent board **8**. Therefore the pulse wave can be detected without being affected by the movement of the user's wrist **4** as shown in **FIG. 4A**.

IPR2020-01537 APPLE-1009 ¶ [0025] (cited at APPLE-1003, ¶ 85).

FIG. 4A

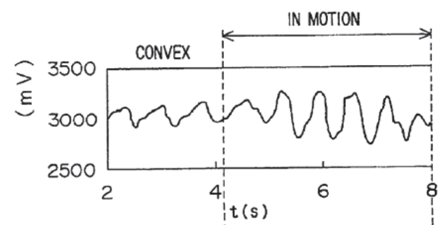
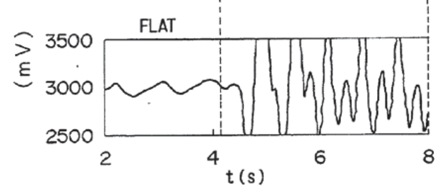
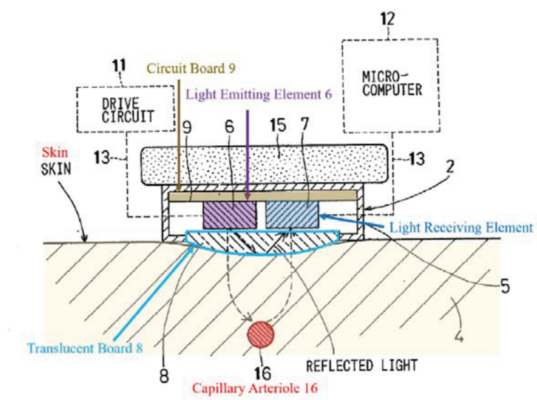


FIG. 4B





IPR2020-01537 APPLE-1009, FIGS. 2, 4A, 4B.

10

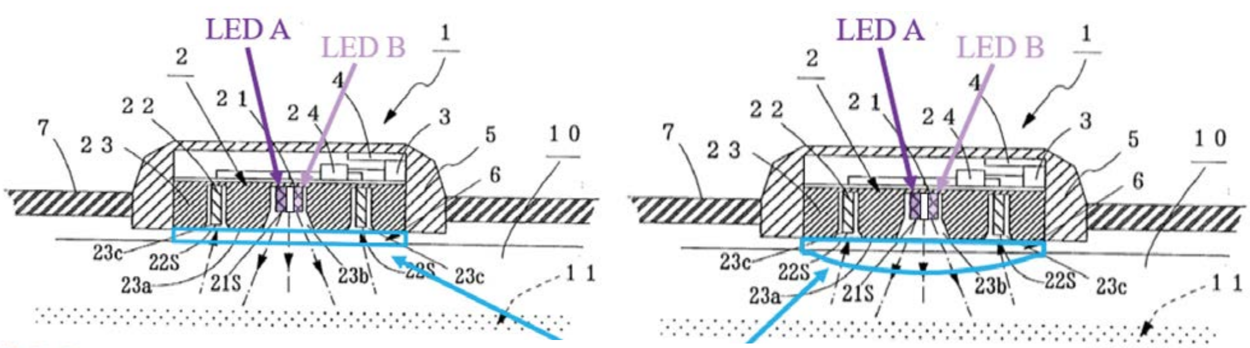
FISH.

Aizawa's Modified Cover would have Improved Adhesion and Signal Strength

Dr. Kenny's First Declaration

87. As shown below, one of ordinary skill would have found it obvious to modify the sensor's flat cover (left) to include a lens/protrusion (right), similar to Ohsaki's translucent board 8, so as to improve adhesion between the user's wrist and the sensor's surface, improve detection efficiency, and protect the elements within the sensor housing. APPLE-1009, ¶[0025] (explaining that the convex surface of translucent board 8 prevents slippage of a detecting element from its position on the wrist, and suppresses the "variation of the amount of the reflected light" that reaches the detecting element); APPLE-1024, ¶¶[0033], [0035], FIG. 6 (depicting an LED featuring a convex lens).

IPR2020-01537 APPLE-1003, ¶¶ 87-88.



FISH.

IPR2020-01537 APPLE-1006, FIG. 1(b) (annotated)(APPLE-1003, ¶ 88).

11

A POSITA would have Incorporated a Cover with a Protrusion into Mendelson ’799

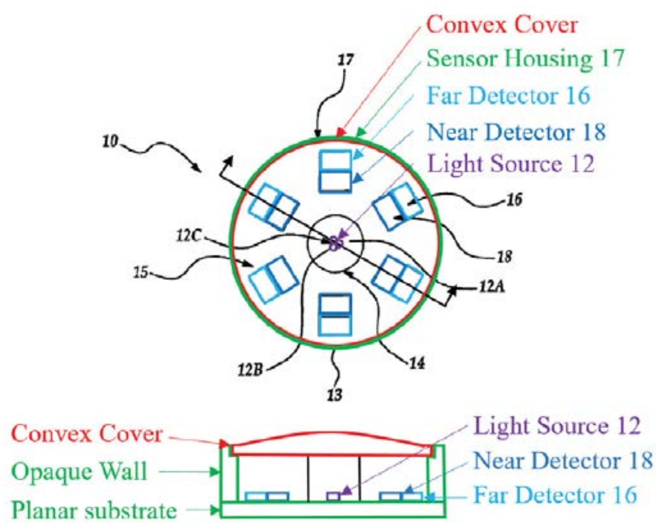
Dr. Kenny’s First Declaration

87. Accordingly, Ohsaki would have motivated one of ordinary skill to add a light permeable protruding convex cover to Mendelson ’799’s sensor, to improve adhesion between the sensor and the user’s tissue, to improve detection efficiency, and to provide additional protection to the elements accommodated within sensor housing 17. APPLE-1009, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B.

88. In more detail, and as shown below in the section view of the Mendelson-Ohsaki sensor, one of ordinary skill would have added a transparent convex cover to sensor 10, the cover being located between tissue of the user and the array of detectors 16 and 18 when worn. APPLE-1012, Abstract, 9:22-10:30, FIG. 8; APPLE-1009, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B; *see also* APPLE-

IPR2020-01536 APPLE-1003, ¶¶ 87-88.

Mendelson ’799



IPR2020-01536 APPLE-1012, FIG. 7
(annotated with additional section view)
(APPLE-1003, ¶ 88).

FISH.

Masimo Fails to Rebut Dr. Kenny's Testimony

Dr. Kenny's Second Declaration

8. Rather than attempting to rebut my testimony on these points, Masimo offers, through its witness Dr. Madisetti, arguments that are factually flawed.

9. Specifically, Masimo contends that "Ohsaki and Aizawa employ different sensor structures (rectangular versus circular) for different measurement locations (back side versus palm side of the wrist), using different sensor surface shapes (convex versus flat) that are tailored to those specific measurement locations" and from this concludes that "[a] POSITA would not have been motivated to combine the references," and would not have "reasonably expected such a combination to be successful." IPR2020-01537 Pap. 24 ("POR"), 1-4. Masimo also contends that "[a]dding another LED complicates Aizawa's sensor and increases power consumption" in addition to "eliminat[ing] the ability to take and display real-time measurements." *Id.*

IPR2020-01536 APPLE-1047, ¶¶ 8-9.

FISH.

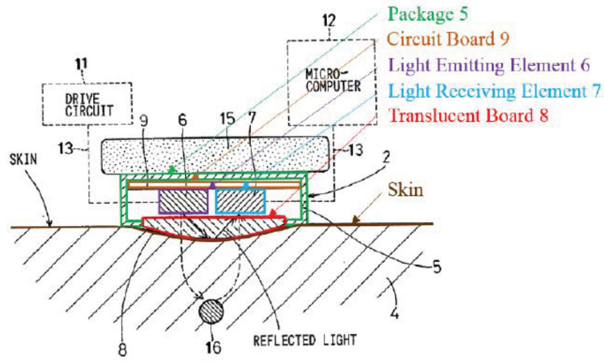
Sensor Structures and Shapes

Dr. Kenny's Second Declaration

10. In my opinion, contrary to Masimo's contentions, Ohsaki nowhere describes its benefits as being limited to a rectangular sensor applied to a particular body location, and a POSITA would not have understood those benefits as being so limited. Instead, and as shown in Ohsaki's FIG. 2 (reproduced below), Ohsaki attributes the prevention of slippage afforded by use of translucent board 8 (and related improvements in signal quality) to the fact that "***the convex surface of the translucent board…is in intimate contact with the surface of the user's skin***"[1] when the sensor is worn. APPLE-1003, ¶148; APPLE-1009, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B (all emphasis added unless otherwise noted).

IPR2020-01537 APPLE-1047 ¶ 10.

Ohsaki



FISH.

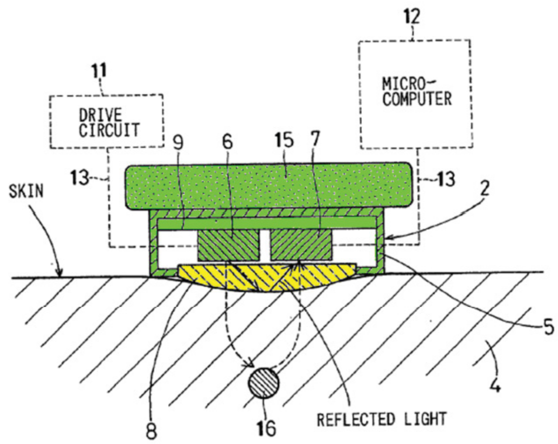
Sensor Structures and Shapes

Dr. Kenny's Second Declaration

17. Masimo argues that it is not the "convex surface" that improves adhesion (*i.e.*, prevents slippage) in Ohsaki, but instead a supposed "longitudinal shape" of "Ohsaki's translucent board [8]." *See* POR, 19-20 (citing APPLE-1009, [0019]). But the portion of Ohsaki cited to support this characterization of the shape of the board does not include any reference to translucent board 8. *See* APPLE-1009, [0019]. Instead, the cited portion of Ohsaki ascribes this "longitudinal" shape to a different component: "detecting element 2." *See id.* ("it is desirable that the ***detecting element 2*** is arranged so that ***its longitudinal direction*** agrees with the longitudinal direction of the user's arm"). Ohsaki never describes the "translucent board 8" as "longitudinal," and nowhere does Ohsaki describe the "translucent board 8" and "detecting element 2" as having the same shape. *See generally* APPLE-1009. In fact, as illustrated in Ohsaki's FIG. 2 (reproduced below), the translucent board 8 (annotated yellow) is not coextensive with the entire tissue-facing side of detecting element 2 (annotated green).

IPR2020-01537 APPLE-1047 ¶ 17.

Ohsaki



IPR2020-01537 APPLE-1009 FIG. 2
(as annotated at APPLE-1047 ¶ 17).

FISH.

Sensor Structures and Shapes

Dr. Kenny's Second Declaration

11. Ohsaki's discussion of these benefits does not mention or suggest that they relate to a shape of the exterior edge of translucent board 8 (whether circular, rectangular, ovoid, or other). Rather, when describing the advantages associated with translucent board 8, Ohsaki contrasts a "convex detecting surface" from a "flat detecting surface," and explains that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist," but that ***if the board "has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed.***" APPLE-1003, ¶149; APPLE-1009, ¶¶[0015], [0025].

IPR2020-01537 APPLE-1047 ¶ 11.

12. From this and related description, a POSITA would have understood that a protruding convex cover would reduce the adverse effects of user movement on signals obtainable by the photodetectors within Aizawa's sensor, which like Ohsaki's light receiving elements, detect light reflected from user tissue. APPLE-1003, ¶[0055]-[0063], [0068]-[0152]; APPLE-1009, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B; *see also* APPLE-1006, ¶¶[0012], [0013], [0023], [0024], [0026], [0030], [0034], FIGS. 1(a), 1(b).

IPR2020-01537 APPLE-1047 ¶ 12.

FISH.

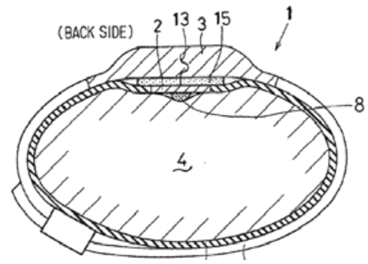
Sensor Structures and Shapes

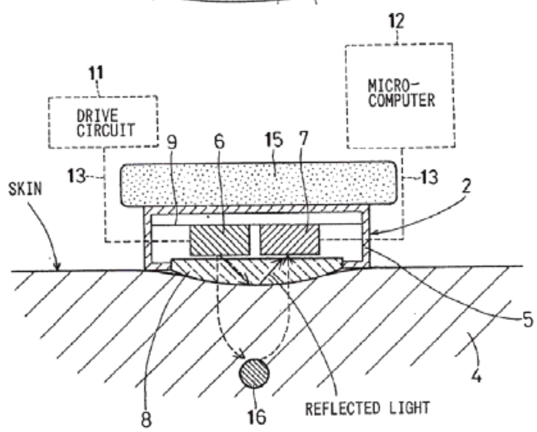
Dr. Kenny's Second Declaration

19. In an attempt to support its claim that the board must have a specific shape, Masimo relies on the assertion that "***Ohsaki illustrates two cross-sectional views*** of its board that confirm it is rectangular." POR, 14 (citing Ex. 2004, [39]-[42]). Masimo identifies these "two cross-sectional views" as FIGS. 1 and 2 of Ohaski, and infers the supposed "rectangular shape" of the translucent board 8 based on FIG. 1 showing the "short" side of the device, and FIG. 2 showing the "long" side of the same device. *See* POR, 14-16. But, according to Ohsaki, FIG. 2 is "a schematic diagram," not a cross-sectional view, and Ohsaki never specifies that FIGS. 1 and 2 are different views of the same device. APPLE-1009, [0013]. In my opinion, nothing in Ohsaki supports Masimo's inference that the "translucent board 8" ***must be*** "rectangular" in shape. *See, e.g.,* APPLE-1009, [0013], [0019], [0025], FIG. 2. Further, even if it is possible for the translucent board 8 to be "rectangular," Ohsaki certainly does not include any disclosure "***requiring***" this or any other particular shape of the board's exterior edge. *See id.*

IPR2020-01537 APPLE-1047 ¶ 19.

Ohsaki





IPR2020-01537 APPLE-1009 FIGS. 1, 2.

FISH.

Masimo Improperly Relies on Bodily Incorporation

Petitioner's Reply

[2] Notably, Ohsaki nowhere depicts or describes its cover as rectangular. APPLE-1047, ¶14; APPLE-1009, [0001]-[0030]; FIGS. 1, 2, 3A, 3B, 4A, 4B. Even if Ohsaki's cover were understood to be rectangular, "[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference…." *Allied Erecting v. Genesis Attachments*, 825 F.3d 1373, 1381 (Fed. Cir. 2016).

IPR2020-01537 Pap. 27 (Petitioner's Reply), 11.

In addition, as discussed above, even if Ohsaki's translucent board 8 were somehow understood to be rectangular, obviousness does not require "bodily incorporation" of features from one reference into another, and a POSITA, being "a person of ordinary creativity, not an automaton," would have been fully capable of modifying Aizawa to feature a light permeable protruding convex cover to obtain the benefits attributed to such a cover by Ohsaki. *Facebook*, 953 F.3d at 1333; *KSR*, 550 U.S. at 418; APPLE-1047, ¶21.

IPR2020-01537 Pap. 27 (Petitioner's Reply), 16.

FISH.

Measurement Locations

Patent Owner's Response

Ohsaki's translucent board 8." Pet. 27. As discussed below, however, Ohsaki indicates that its sensor's convex board ***only*** improves adhesion when used on the ***back*** (i.e., watch) side of the wrist. In contrast, Aizawa ***requires*** its sensor be positioned on the palm side of the wrist, where it measures light reflected from an artery not accessible on the wrist's back side. A POSITA seeking to improve adhesion of Aizawa's sensor would not incorporate a feature that only improves adhesion at a different and unsuitable measurement location. Ex. 2004 ¶66.

IPR2020-01537 Pap. 24 (POR), 27-28.

Dr. Kenny's Second Declaration

10. In my opinion, contrary to Masimo's contentions, Ohsaki nowhere describes its benefits as being limited to a rectangular sensor applied to a particular body location, and a POSITA would not have understood those benefits as being so limited. Instead, and as shown in Ohsaki's FIG. 2 (reproduced below), Ohsaki attributes the prevention of slippage afforded by use of translucent board 8 (and related improvements in signal quality) to the fact that "***the convex surface of the translucent board…is in intimate contact with the surface of the user's skin***"[1] when the sensor is worn. APPLE-1003, ¶148; APPLE-1009, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B (all emphasis added unless otherwise noted).

IPR2020-01537 APPLE-1047, ¶ 10.

FISH.

Measurement Locations

Dr. Kenny's Second Declaration

unsuitable measurement location." POR, 27-28. But Ohsaki does not describe that its sensor can ***only*** be used at a backside of the wrist. Instead, at most, Ohsaki describes such an arrangement with respect to a preferred embodiment. APPLE-1009, [0019] ("it is desirable that the detecting element 2 is arranged so that its longitudinal direction agrees with the longitudinal direction of the user's arm").

23. Indeed, Ohsaki's claim language reinforces that Ohsaki's description would not have been understood as so limited. For example, although Ohsaki's independent claim 1 states that "the detecting element is constructed to be worn on a back side of a user's wrist ***or a user's forearm***." *See also* APPLE-1009, Claim 2. However, Ohsaki's independent claims 3, 4 and 5 each state that "the detecting element is constructed to be worn on a user's wrist or a user's forearm," ***without even mentioning a backside*** of the wrist or forearm. Dependent claims 6, 7 and 8 are also not limited to the backside of the wrist. *See also* APPLE-1009, Claims 4-8. A POSITA would have understood this claim language to directly contradict Masimo's assertion that "[t]o achieve any of Ohsaki's benefits, its sensor must be used at a specific measurement location: the backhand side of the wrist." POR,

IPR2020-01537 APPLE-1047, ¶¶ 22-23.

Ohsaki

3. A pulse wave sensor for detecting a pulse wave of a human body comprising:

a detecting element including a light emitting element and a light receiving element; and

a sensor body including a circuit connected to the detecting element via a signal line,

wherein the detecting element is constructed to be worn on a user's wrist or a user's forearm,

the pulse wave sensor further comprising:

a first belt for fixing the detecting element to the user's wrist or the user's forearm; and

a second belt for fixing the sensor body to the user's wrist or the user's forearm.

IPR2020-01537 APPLE-1009, claim 3.

FISH.

Ohsaki Does Not Limit its Sensor to the Backside of the Wrist

Dr. Kenny's Second Declaration

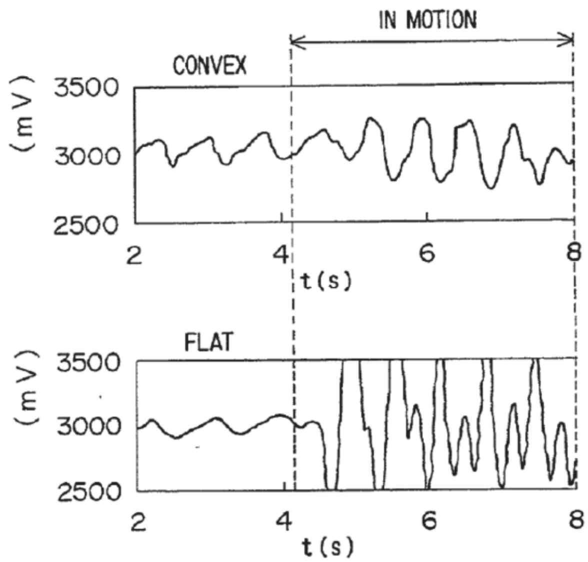
side of a user's wrist or a user's forearm. *See* POR, 27-39. Because Ohsaki requires no such location for the translucent board 8, these arguments fail.

25. Moreover, even assuming for the sake of argument alone that a POSITA would have understood Aizawa's sensor as being limited to placement on the palm side of the wrist, and would have understood Ohsaki's sensor's "tendency to slip" when arranged on the front side as informing consideration of Ohsaki's teachings with respect to Aizawa, that ***would have further motivated*** the POSITA to implement a light permeable convex cover in Aizawa's sensor, to improve detection efficiency of that sensor when placed on the palm side. POR, 33-36; APPLE-1009, ¶¶[0015], [0017], [0023], [0025], FIGS. 1, 2, 3A, 3B, 4A, 4B.

26. When describing advantages associated with its translucent board, Ohsaki explains with reference to FIGS. 4A and 4B (reproduced below) that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist," but that if the board "has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed." APPLE-1003, ¶¶86, 149; APPLE-1009, ¶¶[0015], [0017], [0025].

IPR2020-01537 APPLE-1047, ¶¶ 24-26.

Ohsaki



IPR2020-01537 APPLE-1009, FIGS. 4A, 4B.

[0015] **FIGS. 4A and 4B** are graphs of the pulse wave detected by a pulse wave sensor including a convex detecting surface and the pulse wave detected by a pulse wave sensor including a flat detecting surface, respectively.

IPR2020-01537 APPLE-1009 ¶ [0015].

FISH.

21

Ohsaki Does Not Limit its Sensor to the Backside of the Wrist

Dr. Kenny's Second Declaration

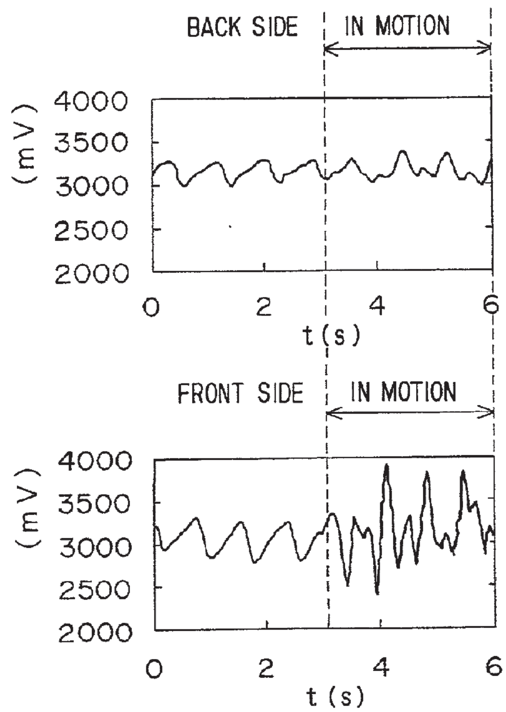
27. In my opinion, contrary to Masimo's contentions, a POSITA would not have understood these benefits of a convex surface over a flat surface to be limited to one side or the other of the user's wrist.[2] Rather, a POSITA would have understood that, by promoting "intimate contact with the surface of the user's skin," a light permeable convex cover would have increased adhesion and reduced slippage of Aizawa's sensor when placed on the palm side of a user's wrist, with associated improvements in signal quality. APPLE-1009, ¶¶[0015], [0017], [0025]; FIGS. 1, 2, 4A, 4B, Claims 3-8; *see also* APPLE-1019, 87, 91. Indeed, a

IPR2020-01537 APPLE-1047, ¶ 27.

[2] Indeed, from Ohsaki's explanation of FIGS. 3A and 3B, the POSITA would have understood that the problem of the "detected pulse wave [being] adversely affected by the movement of the user's wrist," the very problem that Ohsaki seeks to alleviate through a convex detecting surface, is present with respect to *both* sides of the wrist. APPLE-1009, [0023]-[0025].

IPR2020-01537 APPLE-1047 FN 2.

Ohsaki



IPR2020-01537 APPLE-1009, FIGS. 3A, 3B.

FISH.

Reasonable Expectation of Success

Patent Owner's Sur-Reply

Lacking any credible basis to change the shape of Ohsaki's board, Petitioner asserts that Ohsaki's board has ***no*** particular shape. Reply 13-15. Petitioner thus embraces the vague testimony of its declarant, Dr. Kenny, who testified he did not ***know*** the shape of Ohsaki's board and that the board could be "circular or square or rectangular." Ex. 2008 68:21-70:1, 71:7-72:10; Ex. 2027 162:15-20. But Petitioner cannot allege that Ohsaki's board has ***no*** geometry while also arguing Aizawa's cover would be modified "to include a lens/protrusion…similar to Ohsaki's translucent board 8." Pet. 27.

IPR2020-01538 Pap. 32 (Sur-Reply), 4
(citing Ex. 2027, 162:15-20).

Ex. 2027

Q. Okay. So Ohsaki doesn't tell you anything about the shape of the board, correct?

A. That's correct. It merely says that if the board has a convex surface, it provides these benefits of, of improved adhesion and, and prevention of light from scattering inside.

Ex. 2027, 162:15-20.

And that in view of the references that are part of this combination, that one of ordinary skill in the art would consider combining the sensor of Aizawa with a convex protrusion, such as in Ohsaki, and could carry out that combination in a way that would be able to deliver the benefits being sought.

Ex. 2027, 158:4-10.

FISH.

Reasonable Expectation of Success

Dr. Kenny's First Declaration

89. Furthermore, one of ordinary skill would have understood how to incorporate the shape of Ohsaki's cover into Aizawa's cover, and further would have expected such a modification to succeed given the high degree of overlap between the two references. For example, as discussed above, Ohsaki teaches that its light permeable cover can be flat or alternatively be in the shape of a convex lens to prevent "disturbance light from the outside" from penetrating translucent board 8. *Id.* Thus, when a convex cover is used, "the pulse wave can be detected without being affected by the movement of the user's wrist 4 as shown in FIG. 4A." *Id.* That is, depending on the desired objective of the user (e.g., simplicity or reduced variation in the amount of reflected light reaching the detector and improved adhesion to the user's wrist), the shape of the cover can be readily modified.

IPR2020-01537 APPLE-1003, ¶ 89.

90. One of ordinary skill would have further recognized that the acrylic material used to make Aizawa's "acrylic transparent plate 6" can be easily formed to include a convex protrusion. APPLE-1006, 3:46-41, FIG. 1; APPLE-1026, ¶¶[0022], [0032], [0035], FIG. 6. Indeed, many prior art references of this period, such as Nishikawa (shown below) demonstrate exactly how such a convex shape may be incorporated into a molded cover. APPLE-1026, ¶¶[0022], [0032], [0035], FIG. 6. In other words, one of ordinary skill would have known that acrylic is a transparent material that can be readily transformed into various shapes, including a lens shape, as needed due to its easy molding properties. Thus, one of ordinary skill preferring improved adhesion to a user's tissue and the ability to detect a pulse wave "without being affected by the movement of the user's wrist" (APPLE-1009, ¶[0025]) could have been able to easily modify Aizawa's cover to have a lens shape as per Ohsaki. Indeed, only a routine knowledge of sensor design and assembly, which were well within the abilities of one of ordinary skill in the art, would be required to perform such modifications. Thus, to achieve the goal of improved adhesion and detection, one of ordinary skill would have been able to, with a reasonable expectation of success, modify Aizawa's light permeable cover to have a convex protrusion as taught by Ohsaki.

IPR2020-01537 APPLE-1003, ¶ 90.

FISH.

Issue 1B

The Cover's Protruding Convex Surface would Enhance Light-Gathering Ability

FISH.

A POSITA Would Have Found Modified Aizawa's Flat Cover

Dr. Kenny's Declarations

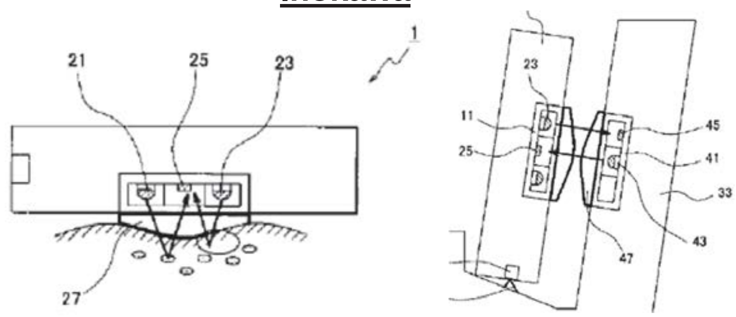
3. As I previously explained in the Original Declaration, Inokawa ***very generally*** describes a "lens [that] makes it possible to increase the light-gathering ability" of a reflectance type pulse sensor. APPLE-1008, [0015], [0058], FIG. 2, and, based on this disclosure, a POSITA would have been motivated to incorporate "an Inokawa-like lens into the cover of Aizawa to increase the light collection efficiency...." APPLE-1003, ¶¶94-99. In a significant extrapolation from the very

IPR2020-01520, APPLE-1047, ¶ 3.

97. In more detail, a POSITA would have found it obvious to combine the teachings of Aizawa and Inokawa such that the flat cover (left) of Aizawa is modified to include a lens/protrusion (right) as per Inokawa in order to "increase the light-gathering ability." APPLE-1008, [0015]. Indeed, by positioning a lens above the optical components of Aizawa, as shown below, the modified cover will allow more light to be gathered and refracted toward the light receiving cavities of Aizawa, thereby further increasing the light-gathering ability of Aizawa beyond what is achieved through the tapered cavities. APPLE-1006, [0012], [0024].

IPR2020-01520, APPLE-1003, ¶ 97.

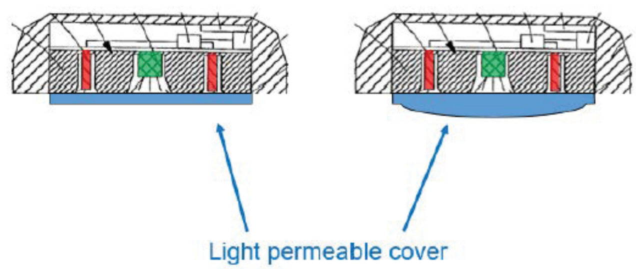
Inokawa



(8) In the invention in Claim 8, a lens is placed on the surface of the sensor-side light-emitting means.
This lens makes it possible to increase the light-gathering ability of the LED as well as to protect the LED or PD.

IPR2020-01520, APPLE-1008 FIGS. 2, 3, ¶ [0015].

Aizawa



IPR2020-01520, APPLE-1006, FIG. 1(b)
(as annotated at APPLE-1003, ¶ 97).

FISH.

Inokawa's Lens Improves Light-Gathering Ability at All Locations

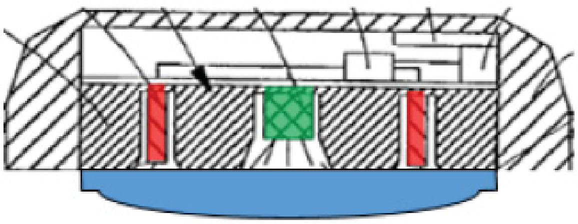
Dr. Kenny's Declarations

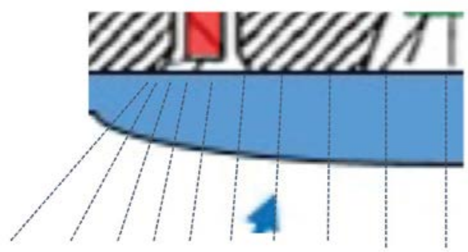
19. As I explained during my deposition, "given the arrangement of the corpuscles as the reflecting objects in the space all around underneath [Inokawa's lens]...there would be some improvement in the light concentration at pretty much all of the locations under the curvature of the lens." Ex. 2006, 164:8-16. As explained further below, this improvement—which a POSITA would understand is what Inokawa is referring to—is based on the convex shape of the lens and application of the most basic of optical concepts, namely Snell's law. Thus, Inokawa's lens "provides an opportunity to capture some light that would otherwise not be captured." *Id.*, 204:21-205:12. In short, Inokawa's lens improves the light-gathering ability of Aizawa's sensor by allowing a larger fraction of the backscattered light to reach the areas covered by the lens. *See* Ex. 2012, 86, 90; APPLE-1046, 803.

IPR2020-01520, APPLE-1047, ¶ 19.

1484. Because of the curvature of the lens, the orthogonal lines positioned at the locations of greatest curvature are more generally oriented towards the detector locations. An elementary understanding of Snell's law, and of the lens shape provided in this illustration, would guide a POSITA to understand that a combination of the teachings of Aizawa and Inokawa as presented in my original declaration, would lead to an improvement in the light concentration at the location of the detectors. Very simply, a POSITA familiar with Snell's law and in view of Aizawa and Inokawa would understand that the placement of the curvature in the region near the locations of the detectors would have the effect of improving the light concentration provided by the lens in these regions.

IPR2020-01520, APPLE-1047, ¶ 21.





IPR2020-01520, APPLE-1006, FIG. 1(b) (as annotated at APPLE-1047, ¶¶ 20, 21).

FISH.

27

Inokawa's Lens Improves Light-Gathering Ability at All Locations

Ex. 2006

Q. How about the, the, the lens in your combination, the figure at the bottom right below Paragraph 97?

A. Yeah, I would say there's some, given the arrangement of the corpuscles as the reflecting objects in the space all around underneath that lens, that there would be some improvement in the light concentration at pretty much all of the locations under the curvature of the lens.

IPR2020-01520, Ex. 2006, 164:8-16.

Q. So it sounds like there's two considerations here. One is the convex lens in general would direct more light to the center; the other is your testimony that a protruding lens overall would capture more light. Am I capturing your testimony correctly?

A. I think one of ordinary skill in the art would appreciate that those are both true, simultaneously, that you have the, the, the general lens-like shape of the convex lens provides refraction which allows additional concentration of light and light-collection efficiency, and that the protrusion provides an opportunity to capture some light that would otherwise not be captured.

IPR2020-01520, Ex. 2006, 204:21-205:12.

FISH.

Inokawa's Lens Improves Light-Gathering Ability at All Locations

Patent Owner's Response

B. Ground 1A Does Not Establish Obviousness

1. A POSITA Would Not Have Been Motivated To Combine Inokawa's Lens With Aizawa's Sensor

a) Petitioner Admits Inokawa's Lens Directs Light To The Center Of The Sensor

There can be no legitimate dispute that Petitioner's proposed convex lens would direct light toward the center. Petitioner admits that "the lens/protrusion of

IPR2020-01520, Pap. 21 (POR), 15.

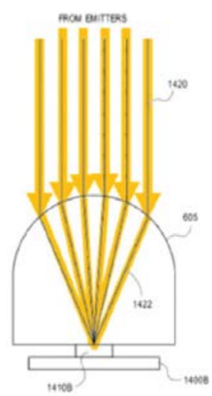
The '265 Patent further confirms that a POSITA would have this understanding. Figure 14B (below) "illustrates how light from emitters (not shown) can be focused by the protrusion 605 onto detectors." Ex. 1001 36:11-14.

IPR2020-01520, Pap. 21 (POR), 17.

Dr. Madisetti's Deposition Transcript

A. In certain context, yes. You would,
for example, as I describe in my Declaration, as
confirmed by Dr. Kenny, if you have a convex surface,
a convex surface, light would be, all light reflected
or otherwise would be condensed or directed towards
the center.

IPR2020-01520, APPLE-1041, 40:6-11.



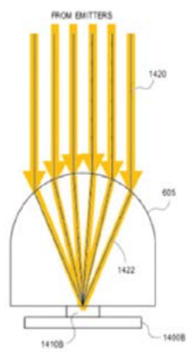
IPR2020-01520, APPLE-1001 FIG. 14B
(as annotated at Pap. 21, 17).

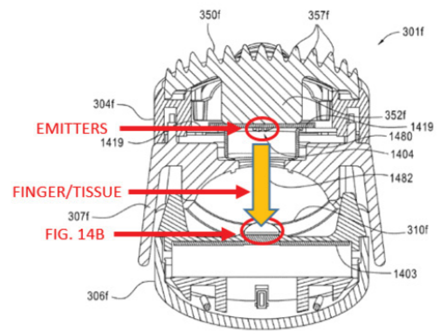
Inokawa's Lens Improves Light-Gathering Ability at All Locations

Dr. Kenny's Second Declaration

26. Patent Owner and Dr. Madisetti's reliance on FIG. 14B for justification of their understanding of Inokawa is severely misplaced. While each of Inokawa, Aizawa, and Mendelson-1988 are directed to a reflectance-type pulse sensor that detects light that has been backscattered from the measurement site, the scenario depicted in FIG. 14B shows a transmittance-type configuration where collimated or nearly-collimated light is "attenuated by body tissue," not backscattered by it. APPLE-1001, 36:19-21. Indeed, FIG. 14I of the '265 patent puts FIG. 14B in proper context, showing how light from the emitters is transmitted through the entire finger/tissue before being received by the detectors on the other side:

IPR2020-01520, APPLE-1047, ¶ 26.

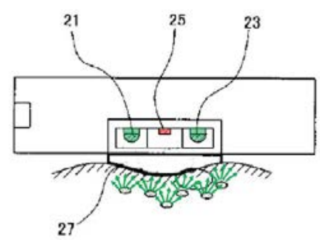




IPR2020-01520, APPLE-1001 FIGS 14B (left) and 14I (right) (as annotated at Pap. 21, 17 and APPLE-1047 ¶ 26).

7. As I further show using green arrows below, light emitted from Inokawa's LEDs 21, 23 is backscattered from many locations throughout the measurement site, each scattered return ray propagating towards the lens with a very wide range of positions and orientations before it can go through the lens 27:

IPR2020-01520, APPLE-1047, ¶ 7.



IPR2020-01520, APPLE-1008 FIG. 2 (as annotated at APPLE-1047, ¶ 7).

FISH.

Inokawa's Lens Improves Light-Gathering Ability at All Locations

Dr. Kenny's Second Declaration

46. Far from ***focusing*** light to the center as Masimo contends, Ohsaki's convex cover provides at best a slight refracting effect, such that some light rays that otherwise would have missed the detection area are instead directed toward that area as they pass through the interface provided by the cover. This is especially the case in configurations like Aizawa's where light detectors are arranged symmetrically about a central light source, so as to enable backscattered light to be detected within a circular active detection area surrounding that source. Ex. 1019, 86, 90. The slight refracting effect is further confirmed by the similar indices of refraction between human tissue and a typical cover material (e.g., acrylic). APPLE-1044, 1486; APPLE-1045, 1484.

IPR2020-01537, APPLE-1047, ¶ 46.

47. As I clarified during my deposition, "given the arrangement of the corpuscles as the reflecting objects in the space all around underneath [a convex lens]...there would be some improvement in the light concentration at pretty much all of the locations under the curvature of the lens." Ex. 2006, 164:8-16. Moreover, due to its protruded shape, as convex cover "provides an opportunity to capture some light that would otherwise not be captured." *Id.*, 204:21-205:12. In short, a convex cover improves the light-gathering ability of Aizawa's sensor by allowing a larger fraction of the backscattered light to reach the areas covered by the lens. Ex. 2012, 86, 90; APPLE-1046, 803.

IPR2020-01537, APPLE-1047, ¶ 47.

Ex. 1019 (Webster)

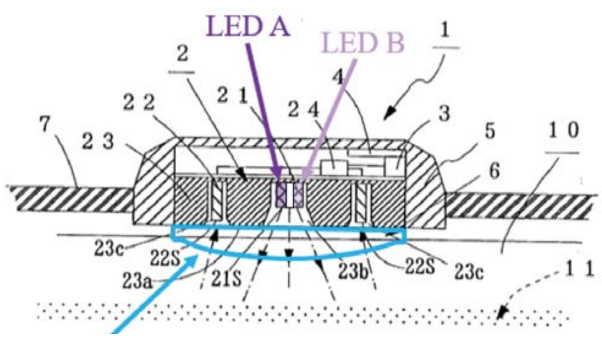
7.2.3 Effect of multiple photodiode arrangement

In a reflectance oximeter, the incident light emitted from the LEDs diffuses through the skin and the back scattered light forms a circular pattern around the LEDs. Thus if we use multiple photodiodes placed symmetrically with respect to the emitter instead of a single photodiode, a large fraction of back scattered light can be detected and therefore larger plethysmograms can be obtained.

To demonstrate this, Mendelson and Ochs (1988) used three photodiodes mounted symmetrically with respect to the red and infrared LEDs; this enabled them to triple the total active area of the photodiode and thus collect a greater fraction of the back scattered light from the skin. The same result can be obtained using a photodiode with three times the area.

IPR2020-01537, APPLE-1019, 90.

Aizawa



IPR2020-01537 APPLE-1006, FIG. 1(b)
(annotated with protruding cover)(APPLE-1003, ¶ 88).

FISH.

Masimo Ignores the Behavior of Scattered Light

Patent Owner's Sur-Reply

Id. Even if the theory had merit, it would be unavailing because it fails to consider the greater ***decrease*** in light at the detectors due to light redirection to a ***more*** central location. *See* Ex. 2027 19:16-21:8. As Dr. Kenny confirmed, the circle of backscattered light's intensity "***decreases*** with the ***square of the distance***" between the central emitter and peripheral detectors. Ex. 2027 49:17-50:13, 57:10-22; *see also* Ex. 2003 at 4 ("backscattered light intensity measured is inversely related to the separation distance between the PD and the LEDs"). Thus, any purported signal obtained from light redirected from the sensor's ***edge*** would be relatively weak and fail to make up for the much greater loss of signal strength when light is redirected away from the detectors and towards a more central position. *See id.*

IPR2020-01537 Pap. 31 (Sur-Reply), 21
(citing Ex. 2027, 19:16-21:8).

Ex. 2027

Q. So there, there is some light that would have been captured by the detectors that is redirected and no longer hits the detectors; is that correct?

MR. SMITH: Objection; form.

A. So of all of the photons scattered backwards from all of these sites --

Q. Correct.

A. -- and interacting with this curved optical surface that we're calling the lens, some of those rays are diff- -- sorry -- refracted in a way that directs them toward the detectors which otherwise might have missed, and there would be some other rays that would have hit the detectors that are refracted away from the detectors; that's correct.

Ex. 2027, 19:16-21:8.

FISH.

Masimo Ignores the Behavior of Scattered Light

Patent Owner's Sur-Reply

Id. Even if the theory had merit, it would be unavailing because it fails to consider the greater ***decrease*** in light at the detectors due to light redirection to a ***more*** central location. *See* Ex. 2027 19:16-21:8. As Dr. Kenny confirmed, the circle of backscattered light's intensity "***decreases*** with the ***square of the distance***" between the central emitter and peripheral detectors. Ex. 2027 49:17-50:13, 57:10-22; *see also* Ex. 2003 at 4 ("backscattered light intensity measured is inversely related to the separation distance between the PD and the LEDs"). Thus, any purported signal obtained from light redirected from the sensor's ***edge*** would be relatively weak and fail to make up for the much greater loss of signal strength when light is redirected away from the detectors and towards a more central position. *See id.*

IPR2020-01537 Pap. 31 (Sur-Reply), 21
(citing Ex. 2027, 19:16-21:8).

Ex. 2027

Q. The indication in this figure, "Toward the center," does that indicate the redirection that leads to the detector capturing light that otherwise would have been missed --

MR. SMITH: Objection; form.

Q. -- for a particular ray?

MR. SMITH: Same objection.

A. So just again, reading from Paragraph 42, the "lens' ability to direct light 'toward the center' would allow the detector to capture light that would otherwise have been missed by the detectors, regardless of their location within the sensor device."

Ex. 2027, 19:3-15
(cited at IPR2020-01537 Pap. 37, 1).

FISH.

Masimo Ignores the Behavior of Scattered Light

Ex. 2027

9/18/2021 Apple, Inc. v. Masimo Corp. Thomas Kenny Jr., Ph.D.

Page 21

the references.

What I've stated throughout the earlier Declaration and throughout the earlier deposition is that a person of ordinary skill in the art would understand how to take advantage of the detector locations and the shape of this convex surface so as to obtain an improvement in the amount of light arriving at the detectors.

Q. The improvement in the light arriving at the detectors depends on the dimensions and shapes of the objects in the final design; is that correct?

MR. SMITH: Objection; form.

A. Yes, yes.

Q. And in this Declaration, there was no detailed calculation presented for dimensions and shapes that establish that relatively more light reaches the detectors for a convex surface than for a flat or no surface; is that correct?

MR. SMITH: Objection; form.

A. So we could read from Paragraph 44, "As I made clear during my deposition," and following that is a quote, I think, from the transcript of the

9/18/2021 Apple, Inc. v. Masimo Corp. Thomas Kenny Jr., Ph.D.

Page 22

deposition, "'The convex shape [of Inokawa's lens] allows light that might have been just specularly reflected off of a flat plate to be captured and refracted inwards. And in the region where there's curvature, it allows the light to be concentrated, and in this case, roughly speaking, in the neighborhood of the detectors and inwards.' That is, that the addition of a convex lens allows the detectors to capture some of the reflected light that...would have missed them completely, and to provide some concentration of the light towards the location of the detectors."

And again, as I explained in the deposition and, and since then in these Declarations, it's within the skill of one of ordinary skill in the art to appreciate how to arrange the position of the detectors and to arrange the shape of the lens so as to obtain some benefit as described here.

Q. Determining whether there is a benefit as described in your Declaration, would have required detailed calculations for dimensions, for particular dimensions and shapes of that lens and

FISH.

Ex. 2027, 21:2-22:18 (cited at IPR2020-01537 Pap. 37, 1).

The Principle of Reversibility Confirms Inokawa's Optical Benefits

Dr. Kenny's Second Declaration

principle of reversibility, which comes from the even more fundamental Fermat's principle, APPLE-1049, 87-92, trivially dispels Patent Owner's claim that reversing the LED/detector configuration of Inokawa (as in Aizawa) by placing the detectors around centrally located LEDs would cause Inokawa's lens to send less light to the detectors, thereby rendering Inokawa's lens ineffective when applied to Aizawa. POR, 15-20. As I noted above, Fermat's principle states that a path taken by a light ray between two points is one that can be traveled in the least time. *See* APPLE-1040, 87-92; APPLE-1049, 106-111. It is one of the most fundamental concepts in optics (and physics for that matter) and readily explains the principle of reversibility. Simply put, the speed of light is independent of the direction of propagation for these simple materials, which can be represented by an index of refraction. Therefore the shortest path between two points is the same regardless of the direction traveled along the path.

IPR2020-01520, APPLE-1047, ¶ 32.

39. In short, further based on the principle of reversibility, which is an absolute requirement of the simple expression of Snell's law, a POSITA would have understood that both configurations of LEDs and detectors—*i.e.*, with the LED at the center as in Aizawa or with the detector at the center as in Inokawa—would benefit from the enhanced light-gathering ability of an Inokawa-like lens.

IPR2020-01520, APPLE-1047, ¶ 39.

FISH.

The Principle of Reversibility Confirms Inokawa's Optical Benefits

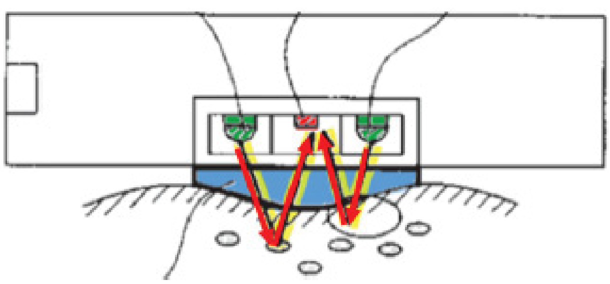
Dr. Kenny's Second Declaration

34. To illustrate the relevance of this principle, with reference to Patent Owner's annotated version of Inokawa FIG. 2 as shown below, two example ray paths from the LEDs (green) to the detector (red) can be seen. In this case, the rays originate from the peripheral LEDs (green) and arrive at the central detector (red).

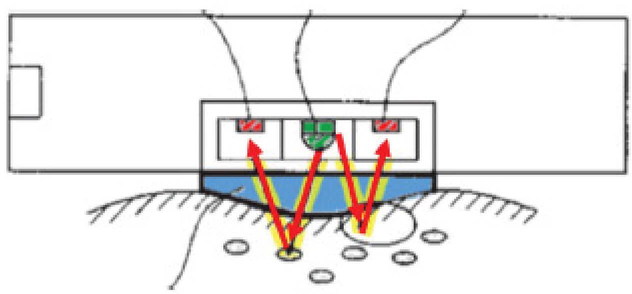
IPR2020-01520, APPLE-1047, ¶ 34.

35. Now, by flipping the LED/detector configuration, as in Aizawa, and applying the principle of reversibility, it is readily observed that the two exemplary paths shown above simply reverse their direction—such that any condensing/directing/focusing benefit achieved by Inokawa's lens (blue) under the original configuration would be identically achieved under the reversed configuration:

IPR2020-01520, APPLE-1047, ¶ 35.



IPR2020-01520, APPLE-1008 FIG. 2
(as annotated at APPLE-1047, ¶ 34).



IPR2020-01520, APPLE-1008 FIG. 2
(as annotated at APPLE-1047, ¶ 35).

FISH.

Masimo Ignores the Principle of Reversibility

Patent Owner's Sur-Reply

absorbs light. Even Petitioner admits that tissue randomly scatters and absorbs light rays, which would cause forward and reverse light paths to be unpredictable and very likely different. *See id.* 23 (reflectance-type sensors measure "random" light that was "reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector"); Ex. 2027 188:6-17, 29:11-30:7, 31:8-32:3, 38:17-42:6. Petitioner never explains how the principle of reversibility could apply to such "random" scattered and absorbed light.

Indeed, Dr. Kenny testified that "light backscattered from the tissue can go in a large number of possible directions, not any single precise direction." Ex. 2027 17:12-18; *see also id.* 17:19-19:2 (reiterating random path and absorbance), 38:17-40:13, 40:14-42:6 ("Every photon tracing that particular path…would have a potentially different interaction with the tissue and it would be scattered, potentially, in a different direction than the photon arriving before and after it."). In contrast, the principle of reversibility provides that "a ray going from P to S [in one direction] will trace the ***same route*** as one going from S to P [the opposite direction]" assuming there is ***no*** absorption or scattering. Ex. 1040 at 51 (illustrating diffuse reflection), 53 (defining principle of reversibility), 207 (principle of reversibility requires no absorption). Dr. Kenny also testified that the principle of reversibly applies to a light ray between two points and admitted it does ***not*** apply to randomly scattered light in bulk. Ex. 2027 207:9-208:22. In that

IPR2020-01537 Pap. 31 (Sur-Reply), 17 (citing Ex. 2027, 207:9-208:22).

Ex. 2027

9/18/2021 Apple, Inc. v. Masimo Corp. Thomas Kenny Jr., Ph.D.

Page 208

with the random scattering, even two different photons entering along the same axis are likely to be scattered in, in different exact ways.

But the point of the principle is that any particular pathway of any particular photon is -- can be traversed in the opposite direction and that overall, there's no reason that one would expect that swapping the locations of the emitters and the detectors in a system like this would lead to all the light suddenly being directed in the wrong place for success.

The light paths are capable of being reversed exactly and that in general, one would expect that light that is likely to go in one direction could go in the exact opposite direction.

Q. Fermat's principle, as you stated it, applies to a light ray between two points, correct?

A. Yes.

Q. It doesn't apply to randomly scattered light in bulk, correct?

MR. SMITH: Objection.

A. In its simplest form, no --

Ex. 2027, 208:1-22.

FISH.

Masimo Ignores the Principle of Reversibility

Ex. 2027

9/18/2021 Apple, Inc. v. Masimo Corp. Thomas Kenny Jr., Ph.D.

Page 208

with the random scattering, even two different photons entering along the same axis are likely to be scattered in, in different exact ways.

But the point of the principle is that any particular pathway of any particular photon is -- can be traversed in the opposite direction and that overall, there's no reason that one would expect that swapping the locations of the emitters and the detectors in a system like this would lead to all the light suddenly being directed in the wrong place for success.

The light paths are capable of being reversed exactly and that in general, one would expect that light that is likely to go in one direction could go in the exact opposite direction.

Q. Fermat's principle, as you stated it, applies to a light ray between two points, correct?
A. Yes.
Q. It doesn't apply to randomly scattered light in bulk, correct?
MR. SMITH: Objection.
A. In its simplest form, no --

Ex. 2027, 208:1-22 (cited at Pap. 31, 17).

9/18/2021 Apple, Inc. v. Masimo Corp. Thomas Kenny Jr., Ph.D.

Page 209

MR. SMITH: Objection; form.
A. -- but one could look at any particular randomly scattered path which would be little pieces of light paths separated by changes in direction with scattering events and the reversibility principle applies to all of the pieces and, therefore, it applies to the aggregate. Light that can go in one direction through this system could go in the exact opposite direction along the exact same path.

And I think maybe the more important point here is that when we're considering what happens to this light as it encounters this convex surface and is refracted by that surface, it is absolutely the case that the light encountering that, that refractive experience is absolutely able to go in either direction along that path. That's fundamental to the principles that underlie the concepts of refraction. So if we're concerned with the impact of the lens on the system, it's absolutely reversible.
Q. Looking at the incoming light, does

Ex. 2027, 209:1-21 (cited at IPR2020-01537 Pap. 37, 1).

FISH.

Masimo Ignores the Principle of Reversibility

Patent Owner's Sur-Reply

circumstance. Dr. Kenny merely testified that light "can go" or "could go" along the same path. *Id.* 207:17-209:21, 210:8-211:6. That hardly supports Petitioner's argument that light will necessarily travel the same paths regardless of whether the LEDs and detectors are reversed.

Petitioner accordingly misapplies the principle of reversibility to the proposed combination. The principle of reversibility does not even address the relevant issue: whether changing Aizawa's flat surface to a convex surface results in more light on Aizawa's peripherally located detectors. *See* Ex. 2027 212:3-14. Petitioner attempts to use the theory of reversibility to argue that one could simply reverse the LEDs and detectors and obtain the same ***benefit*** from a convex surface. Reply 21-22. However, the principle of reversibility does not indicate that one could reverse ***sensor components*** and still obtain the same ***benefit*** from a convex—as opposed to a flat—surface. Dr. Kenny specifically testified that the benefit of a convex surface would ***not*** be "obvious" if one moves the "LEDs and detectors around…." Ex. 2006 86:19-87:6.[6]

IPR2020-01537 Pap. 31 (Sur-Reply), 18
(citing Ex. 2027, 207:17-209:21).

Ex. 2027

And I think maybe the more important point here is that when we're considering what happens to this light as it encounters this convex surface and is refracted by that surface, it is absolutely the case that the light encountering that, that refractive experience is absolutely able to go in either direction along that path. That's fundamental to the principles that underlie the concepts of refraction. So if we're concerned with the impact of the lens on the system, it's absolutely reversible.

Ex. 2027, 209:11-21.

FISH.

Masimo Ignores the Principle of Reversibility

Patent Owner's Sur-Reply

circumstance, Dr. Kenny merely testified that light "can go" or "could go" along the same path. *Id.* 207:17-209:21, 210:8-211:6. That hardly supports Petitioner's argument that light will necessarily travel the same paths regardless of whether the LEDs and detectors are reversed.

Petitioner accordingly misapplies the principle of reversibility to the proposed combination. The principle of reversibility does not even address the relevant issue: whether changing Aizawa's flat surface to a convex surface results in more light on Aizawa's peripherally located detectors. *See* Ex. 2027 212:3-14. Petitioner attempts to use the theory of reversibility to argue that one could simply reverse the LEDs and detectors and obtain the same ***benefit*** from a convex surface. Reply 21-22. However, the principle of reversibility does not indicate that one could reverse ***sensor components*** and still obtain the same ***benefit*** from a convex—as opposed to a flat—surface. Dr. Kenny specifically testified that the benefit of a convex surface would ***not*** be "obvious" if one moves the "LEDs and detectors around…." Ex. 2006 86:19-87:6.[6]

IPR2020-01537 Pap. 31 (Sur-Reply), 18
(citing Ex. 2006, 86:19-87:6).

Ex. 2006

I think one of ordinary skill in the art would understand that in Inokawa the objective is to concentrate light at the detector, which is in the center axis of the drawing and that the lens is capable of providing that benefit.

If we're going to move the lenses and the LEDs and detectors around and ask different questions, it's -- it isn't so obvious that Inokawa is specifically considering those scenarios. It's a little more hypothetical.

Ex. 2006, 86:19-87:6.

FISH.

A POSITA would have Modified Mendelson-1988 to Include a Protruding Lens-Like Cover

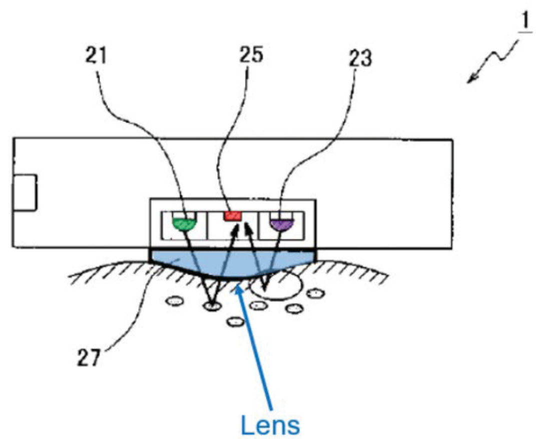
Dr. Kenny's First Declaration

174. Indeed, as I described above, Inokawa teaches a similarly configured pulse sensor as in Mendelson-1988 but one in which a lens is positioned over the detectors to "increase the light-gathering ability of the LED as well as to protect the LED or [detector]." APPLE-1008, [0015], [0058].

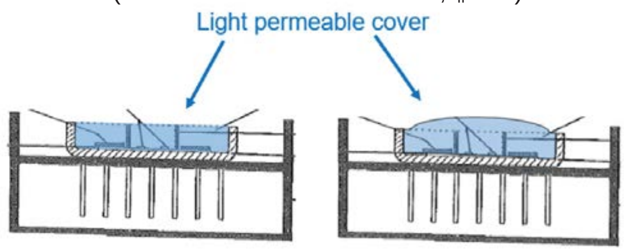
175. Accordingly, a POSITA would have been motivated to incorporate the lens of Inokawa into to cover of Mendelson-1988 in order to increase the light collection efficiency. A POSITA would have been particularly interested in making such a modification because Mendelson-1988 shares a similar goal of maximizing "reflectance photoplethysmographic signals." APPLE-1015, 173. The lens of Inokawa provides precisely this benefit to Mendelson'1988's device by providing a protective cover that further refracts and concentrates the incoming light beams to thereby enhance the light collection efficiency and, by extension, the signal to noise ratio. APPLE-1008, [0015], [0058].

176. Indeed, as illustrated below, the device resulting from this combination of Mendelson-1988 and Inokawa would have modified the flat epoxy cover (left) with a curved one as per Inokawa (right) to thereby "increase the light-gathering ability." APPLE-1008, [0015].

IPR2020-01520, APPLE-1003, ¶¶ 174-176.



IPR2020-01520, APPLE-1008, FIG 2 (as annotated at APPLE-1003, ¶ 176).



IPR2020-01520, APPLE-1015, FIG 2(B) (as annotated at APPLE-1003, ¶ 176).

FISH.

Issue 1C

The Cover's Protruding Convex Surface would Protect Sensor Elements

FISH.

A POSITA would have Recognized that a Convex Cover would Protect Sensor Elements

Dr. Kenny's Second Declaration

13. As I explained at length in my first declaration, "Ohsaki would have motivated one of ordinary skill to add a light permeable protruding convex cover to Mendelson '799's sensor, to [1] improve adhesion between the sensor and the user's tissue, to [2] improve detection efficiency, and to [3] provide additional protection to the elements accommodated within sensor housing 17." APPLE-1003, [87] (citing APPLE-1009, [0015], [0017], [0025], FIGS. 1, 2, 4A, 4B).

IPR2020-01536 APPLE-1047, ¶ 9.

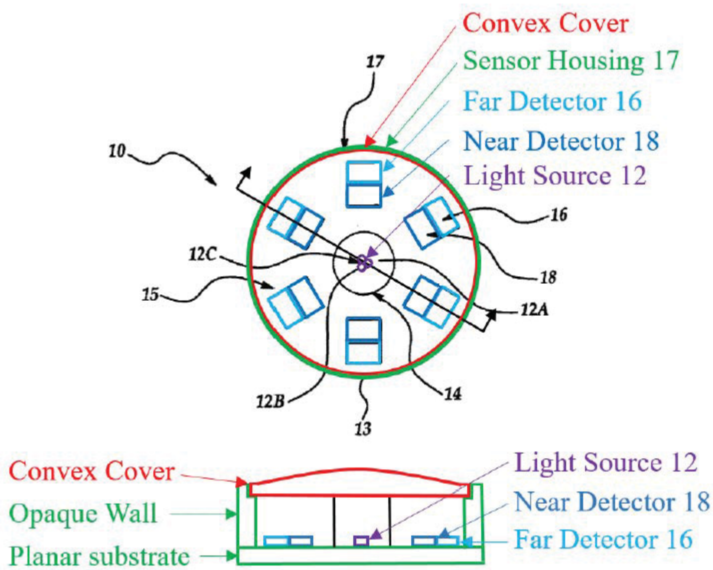
Dr. Kenny's First Declaration

1. *Light permeable cover comprising a protruding convex surface*

81. Mendelson '799 does not describe a cover configured to be located between user tissue and the components accommodated within sensor housing 17 when the sensor is worn, but one of ordinary skill would have recognized that a light permeable cover with a protruding convex surface would improve adhesion between the sensor and the user's tissue, improve detection efficiency, and protect the elements within sensor housing 17. APPLE-1009, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B; *see also* APPLE-1008, ¶¶14-15, FIG. 1 (depicting a convex lens that enhances signal strength and protects a LED and photodetector); APPLE-1024, ¶¶[0033], [0035], FIG. 6 (depicting an LED featuring a convex lens).

IPR2020-01536 APPLE-1003, ¶ 81.

Mendelson '799



IPR2020-01536 APPLE-1012 FIG. 7 (annotated with additional section view) (APPLE-1003, ¶ 88).

FISH.

A Convex Cover would Protect Sensor Elements

Dr. Kenny's First Declaration

1. *Light permeable cover comprising a protruding convex surface*

81. Mendelson '799 does not describe a cover configured to be located between user tissue and the components accommodated within sensor housing 17 when the sensor is worn, but one of ordinary skill would have recognized that a light permeable cover with a protruding convex surface would improve adhesion between the sensor and the user's tissue, improve detection efficiency, and protect the elements within sensor housing 17. APPLE-1009, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B; *see also* APPLE-1008, ¶¶14-15, FIG. 1 (depicting a convex lens that enhances signal strength and protects a LED and photodetector); APPLE-1024, ¶¶[0033], [0035], FIG. 6 (depicting an LED featuring a convex lens).

IPR2020-01536 APPLE-1003, ¶ 81.

Ohsaki

FIG. 1

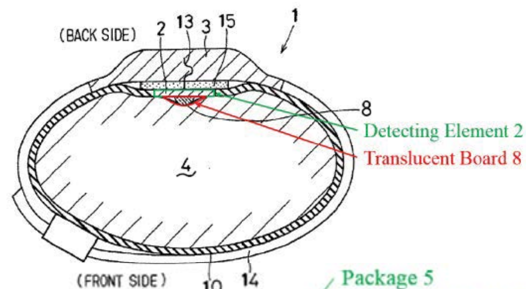
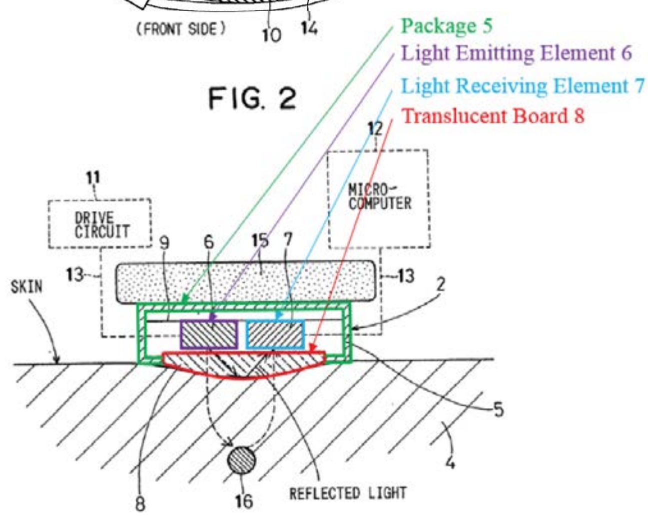


FIG. 2



IPR2020-01536 APPLE-1009, FIGS. 1, 2 (APPLE-1003, ¶¶ 67-68). 44

FISH.

A Convex Cover would Protect Sensor Elements

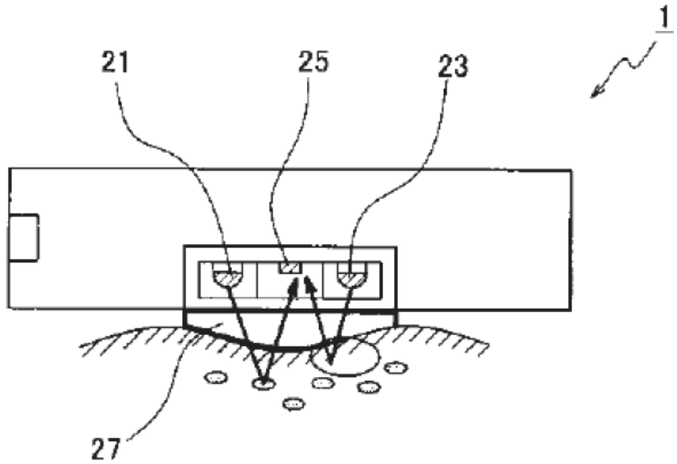
Dr. Kenny's First Declaration

1. *Light permeable cover comprising a protruding convex surface*

81. Mendelson '799 does not describe a cover configured to be located between user tissue and the components accommodated within sensor housing 17 when the sensor is worn, but one of ordinary skill would have recognized that a light permeable cover with a protruding convex surface would improve adhesion between the sensor and the user's tissue, improve detection efficiency, and protect the elements within sensor housing 17. APPLE-1009, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B; *see also* APPLE-1008, ¶¶14-15, FIG. 1 (depicting a convex lens that enhances signal strength and protects a LED and photodetector); APPLE-1024, ¶¶[0033], [0035], FIG. 6 (depicting an LED featuring a convex lens).

IPR2020-01536 APPLE-1003, ¶ 81.

Inokawa



IPR2020-01536, -01537 APPLE-1008, FIG. 2.

(0015)
(8) In the invention in Claim 8, a lens is placed on the surface of the sensor-side light-emitting means. This lens makes it possible to increase the light-gathering ability of the LED as well as to protect the LED or PD.

IPR2020-01536 APPLE-1008, [0015].

FISH.

Masimo Fails to Rebut that a Convex Cover would Protect Sensor Elements

Patent Owner's Response

c) **A POSITA Would Not Have Selected A Convex Cover To Protect The Optical Elements**

Petitioner also asserts a POSITA would have been motivated to combine Ohsaki and Mendelson '799 because a convex cover would have protected the optical components. Pet. 25. But, as Dr. Kenny acknowledged, a convex cover is just one of many different alternatives for protecting the components of a sensor. Ex. 2009 394:18-396:17. For example, as Dr. Kenny acknowledged, a layer of sealing resin could protect the optical elements. Ex. 2009 395:22-396:4. Dr. Kenny confirmed encapsulation was a "widely used" way of protecting components. Ex. 2009 395:22-396:8. Other Mendelson references upon which Petitioner relies protect the optical components with a flat layer of epoxy encapsulation. Pet. 12-16 (illustrating Exs. 1017 and 1018); *see also* Ex. 2004 ¶¶80-81.

IPR2020-01536 Pap. 24 (POR), 38-39.

Ex. 2009

Q. Are there other ways a person of ordinary skill in the art could design a sensor to protect the components within?

A. I think by selection of other elements of the package, the housing.

Q. Do you mean that the other elements of the package of the housing could be designed to protect the components on the inside?

A. Yes. For example, you know, if we look at my illustration on below Paragraph 88, I think the combination of the cover and other elements of the housing would be -- could be selected so as to provide that protection.

Q. And what other, what elements of the housing other than the cover are providing protection?

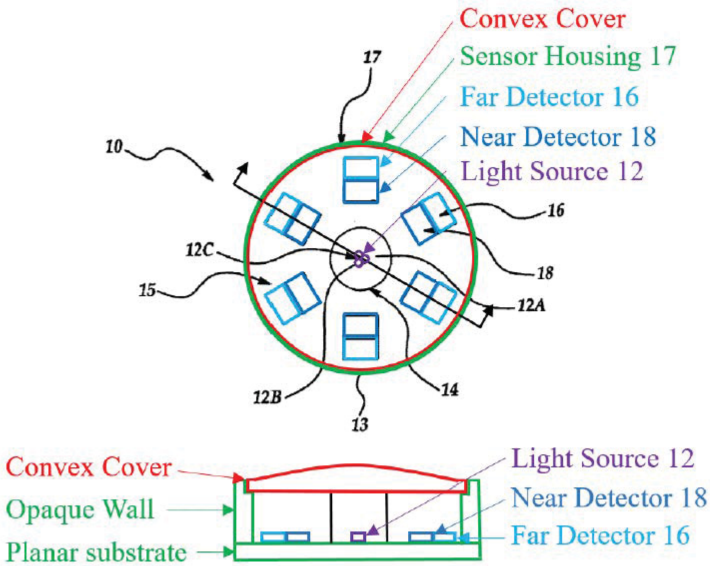
A. Well, in this illustration we have the wall, and the planar substrate together providing protection.

IPR2020-01536 Ex. 2009, 395:3-21 (cited at Pap. 24, 38-39).

FISH.

Masimo Fails to Rebut that a Convex Cover would Protect Sensor Elements

Mendelson '799



IPR2020-01536 APPLE-1012 FIG. 7 (annotated with additional section view) (APPLE-1003, ¶ 88).

Ex. 2009

Q. Are there other ways a person of ordinary skill in the art could design a sensor to protect the components within?

A. I think by selection of other elements of the package, the housing.

Q. Do you mean that the other elements of the package of the housing could be designed to protect the components on the inside?

A. Yes. For example, you know, if we look at my illustration on below Paragraph 88, I think the combination of the cover and other elements of the housing would be -- could be selected so as to provide that protection.

Q. And what other, what elements of the housing other than the cover are providing protection?

A. Well, in this illustration we have the wall, and the planar substrate together providing protection.

IPR2020-01536 Ex. 2009, 395:3-21.

FISH.

A POSITA would have Understood the Multiple Advantages of a Convex Cover to Outweigh Possible Scratching

Patent Owner's Response

Indeed, a POSITA would have understood that a flat cover would provide *better protection* than a convex surface because, as Petitioner's cited art teaches, it would be less prone to scratches. Ex. 1008 ¶[0106]. Petitioner's relied-upon references indicate that a flat surface actually improves adhesion and detection efficiency for more relevant measurement locations such as the palm-side of the wrist, next to the artery. *See* Ex. 1006 ¶[0013] ("[A] transparent plate-like member…makes it possible to improve adhesion between the sensor and the wrist and thereby further improve the detection efficiency of pulse waves."). There would have been no reason for a POSITA to select a convex surface from the many other available options, which provide similar or better protection without the complications and concerns arising from the convex shape. Accordingly, a POSITA

IPR2020-01536 Pap. 24 (POR), 39

Relevant Case Law

"The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another."

Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1349, n. 8 (Fed. Cir. 2000).

Dr. Kenny's Second Declaration

D. A POSITA would have found the advantages of using a convex cover to outweigh the slight possibility of scratching the cover

52. Masimo claims that "a POSITA would not have been motivated to combine Ohsaki's convex board with Mendelson '799's sensor" because "a POSITA would have understood that a flat cover would provide better protection than a convex surface because, as a Petitioner's cited art teaches, it would be less prone to scratches." POR, 39-40. Even assuming this to be true, it is my understanding that one possible disadvantage that competes with the known advantages of applying Ohsaki's teachings to Mendelson-799's sensor would not have negated a POSITA's motivation to combine. *In re Fulton,* 391 F.3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004). In that regard, in my opinion, the POSITA would have understood the ***multiple*** advantages of a convex cover described in the Petition to outweigh any possibility of scratching.

IPR2020-01536 APPLE-1047 ¶ 52.

"[M]ere disclosure of alternative designs does not teach away."

In re Fulton, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

FISH.

Issue 2

Adding a Second Emitter to Aizawa

Case Nos. IPR2020-01520, -01537, -01539
U.S. Patent Nos. 10,258,265, 10,588,553, 10,588,554

FISH.

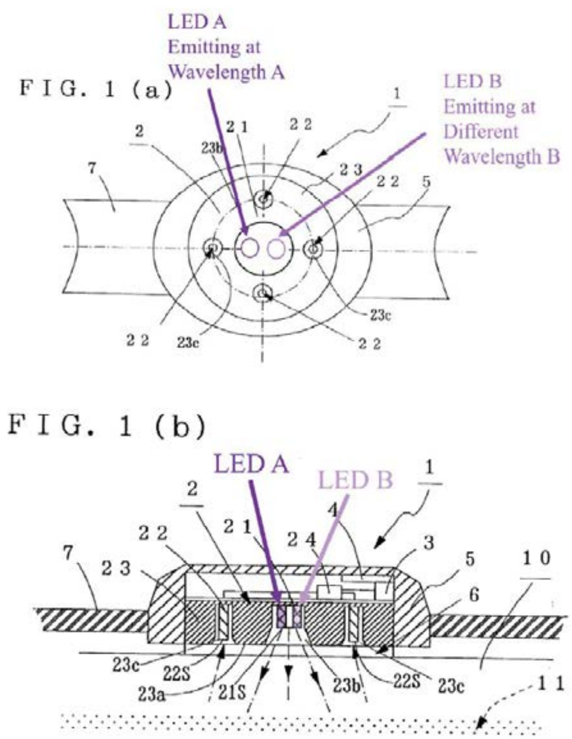
A POSITA would have Modified Aizawa to Feature Two Emitters

Dr. Kenny's Second Declaration

7. As I explained at length in my first declaration, "one of ordinary skill would have found it obvious to modify the [Aizawa] sensor's flat cover…to include a lens/protrusion…similar to Ohsaki's translucent board 8, so as to [1] improve adhesion between the user's wrist and the sensor's surface, [2] improve detection efficiency, [3] and protect the elements within the sensor housing." APPLE-1003, ¶¶84-91 (citing to APPLE-1014, [0025]; APPLE-1006, [0012], [0024]; APPLE-1024, ¶¶[0022]; [0032]-[0033], [0035], FIG. 6). I further explained that a POSITA would have found it obvious in view of Inokawa to include an additional LED in Aizawa's sensor, to [1] "improve the detected pulse wave by distinguishing between blood flow detection and body movement, in addition to [2] enabling wireless communication between the sensor and a base station". APPLE-1003, ¶¶[0068]-[0083] (citing to APPLE-1008, ¶¶[0058]-[0059], [0014], [0040], [0076]-[0077], [0111], [0044], [0048], [0003], [0067], [0075], FIG. 2; APPLE-1006, ¶¶[0006], [0023], [0028], [0032]-[0033], [0035], FIGS. 1(a)-1(b)).

IPR2020-01537 APPLE-1047, ¶ 7.

Aizawa



IPR2020-01537 APPLE-1006, FIGS. 1(a), 1(b)
(as annotated at APPLE-1003 ¶¶ 74-75).

FISH.

Two Emitters would Enable Aizawa to Account for Motion Load

Dr. Kenny's First Declaration

Although Aizawa emphasizes the desirability of disposing photodetectors "on a circle concentric to" a light source, so as to enable accurate pulse wave detection "even when the attachment position of the pulse rate detector 1 is dislocated," Aizawa describes alternative arrangements in which "a plurality of light emitting diodes 21" are employed. *Id.*, ¶¶[0032]-[0033].

IPR2020-01537 APPLE-1003, ¶ 68.

69. One of ordinary skill would have combined the teachings of Aizawa and Inokawa such that Aizawa's pulse wave sensor would be modified to include an additional LED as taught by Inokawa to improve the detected pulse wave by distinguishing between blood flow detection and body movement. APPLE-1008, ¶(0059) (describing the use of the "S-side green LED 21…to sense the pulse from the light reflected off of the body (i.e. change in the amount of hemoglobin in the capillary artery), while the S-side infrared LED 23 serves to sense body motion from the change in this reflected light"); APPLE-1006, ¶[0006] (recognizing the problem of weak signals from a wearable sensor because the sensor "detects the motion of a red corpuscle…and is easily affected by noise caused by the shaking of the body of the subject), ¶[0028] (describing a device for "computing the amount of motion load" such that the motion can be compensated for).

IPR2020-01537 APPLE-1003, ¶ 69.

Aizawa

[0006] However, although the conventional pulse wave sensor to be attached to the finger or ear is small in size, a signal from the sensor is weak because it detects the motion of a red corpuscle in the capillary and is easily affected by noise caused by the shaking of the body of the subject. Also, as some pressure is applied to the measurement site at the time of detection, the subject cannot carry the detector for a long time when walking or the like.

IPR2020-01537 APPLE-1006, ¶ [0006].

[0028] **FIG. 3** schematically shows the waveform of a pulse wave which is the output of the above photodetector **22**. The detected pulse wave data is amplified by the drive detection circuit **24** and the amplified pulse wave data is transmitted to the arithmetic circuit **3**. The arithmetic circuit **3** has a threshold value and computes the number of outputs above the threshold value per unit time so as to calculate a pulse rate and the transmitter**4** transmits the pulse rate to a display for displaying the above pulse rate data and a device for computing the amount of motion load. Since the output of the above photodetector **22** is generally low, after the output is amplified, the amplified output is converted into a digital signal for the computation of a pulse rate in this embodiment.

IPR2020-01537 APPLE-1006, ¶ [0028].

FISH.

Two Emitters would Enable Aizawa to Account for Motion Load

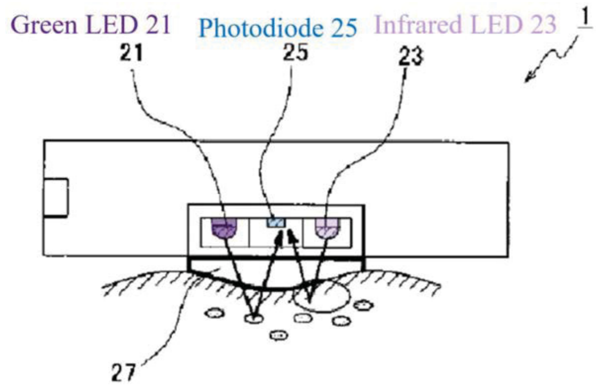
Dr. Kenny's First Declaration

72. In addition to enabling optical communication, the use of multiple LEDs emitting light at different wavelengths—e.g. infrared and green LEDs—enables Inokawa's sensor to detect body motion. APPLE-1008, ¶[0014]. As Inokawa explains, "when using sensor-side light-emitting means of various kinds…the manner of use can be adjusted according to the properties of each respective means" such that "work can be divided between the various means, with an infrared LED used to **detect vital signs** and **transmit** vital sign information, and a green LED used to **detect pulse**." APPLE-1008, ¶¶[0014], [0040].

73. More specifically, and as shown in Inokawa's FIG. 2, Inokawa's pulse sensor includes "a green light-emitting diode (S-side green LED) 21 and an infrared light-emitting diode (S-side infrared LED) 23, [and] a single photodiode (S-side PD) 25 that receives the reflected light from these." *Id.*, ¶[0058]. The green LED senses "the pulse from the light reflected off of the body (i.e. change in the amount of hemoglobin in the capillary artery)" and the infrared LED senses "body motion from the change in this reflected light." *Id.*, ¶[0059].

IPR2020-01537 APPLE-1003, ¶¶ 72-73.

Inokawa



(0014)
(7) In the invention in Claim 7, two or more light-emitting means such as LEDs are provided as the sensor-side light-emitting means.
Accordingly, by transmitting the vital sign information using a plurality of sensor-side light-emitting means, it is possible transmit efficiently. It is also possible to distinguish between the roles performed by the light-emitting means, e.g. with one means used to transmit vital sign information and another means used to transmit information used to check a checksum or the like. Furthermore, when using sensor-side light-emitting means of various kinds, such as an infrared LED or a green LED, the manner of use can be adjusted according to the properties of each respective means. For example, work can be divided between the various means, with an infrared LED used to detect vital signs and transmit vital sign information, and a green LED used to detect pulse.

(0058)
As shown in FIG. 2, the pulse sensor 1 is comprised of a pair of light-emitting elements, i.e. a green light-emitting diode (S-side green LED) 21 and an infrared light-emitting diode (S-side infrared LED) 23, a single photodiode (S-side PD) 25 that receives the reflected light from these, and an S-side lens 27.
(0059)
Among these, the basic function of the S-side green LED 21 is to sense the pulse from the light reflected off of the body (i.e. change in the amount of hemoglobin in the capillary artery), while the S-side infrared LED 23 serves to sense body motion from the change in this reflected light.

APPLE-1008, ¶¶ [0014], [0058]-[0059], FIG. 2.

FISH.

A POSITA would have Modified Aizawa to Feature Two Emitters to Account for Motion Load

Dr. Kenny's First Declaration

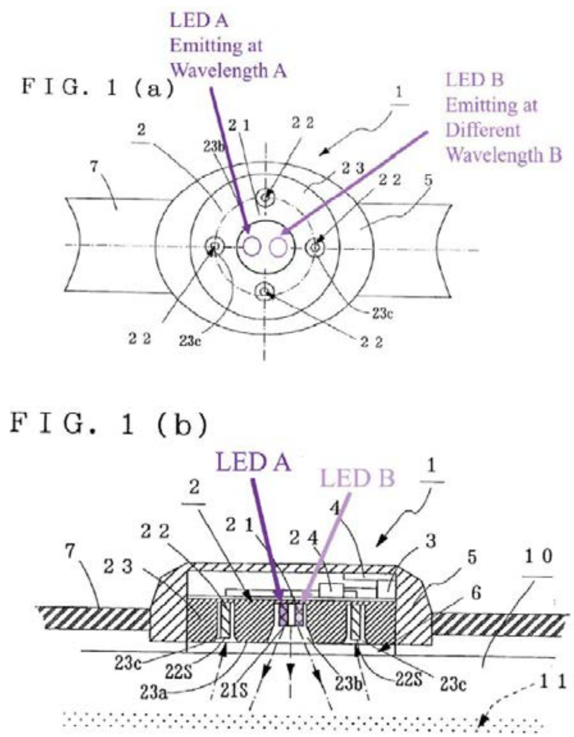
74. To obtain the advantages described by Inokawa (e.g., to improve the detected pulse wave by enabling the sensor to distinguish between blood flow detection and body movement, in addition to enabling wireless communication between the sensor and a base station), one of ordinary skill would have been motivated to configure Aizawa's pulse wave sensor to include at least two LEDs. APPLE-1008, ¶¶[0058]-[0059]; APPLE-1008, ¶¶[0006], [0028].

75. As I illustrate below, the Aizawa-Inokawa sensor would have featured two LEDs in place of Aizawa's LED 21.

76. Aizawa-Inokawa would utilize two LEDs that emit two different wavelengths. LED 21 in the implementation shown in Aizawa's FIG. 1(b) would simply be replaced with two LEDs. In this manner, Aizawa's sensor would have been improved through the implementation of a separate LED to account for motion load which the system records and accounts for. APPLE-1006, ¶¶[0006], [0028], [0035].

IPR2020-01537 APPLE-1003, ¶¶ 74-76.

Aizawa



IPR2020-01537 APPLE-1006, FIGS. 1(a), 1(b)
(as annotated at APPLE-1003 ¶¶ 74-75).

FISH.

Two Emitters would Enable Wireless Communication

Dr. Kenny's First Declaration

78. One of ordinary skill would have looked to Inokawa's disclosure of two LEDs emitting light of different wavelengths, in part, because it provides additional functionality, including that of wireless communication with a base station. *Id.* Inokawa's base device 17 receives, for example, "pulse and body motion" data through "the S-side infrared LED 23 of the pulse sensor 1 and the B-side PD 45 of the base device 17." *Id.*, ¶(0076). "As a result, there is no need to use a special wireless communication circuit or a communication cable as previously, which makes it possible to transmit vital sign information to the base device 17 accurately, easily, and without malfunction." *Id.*, ¶[0077]. In other words, the LEDs provided on the sensor can be used not only to detect pulse rate but also to "accurately, easily, and without malfunction" transmit the sensed data to a base station.

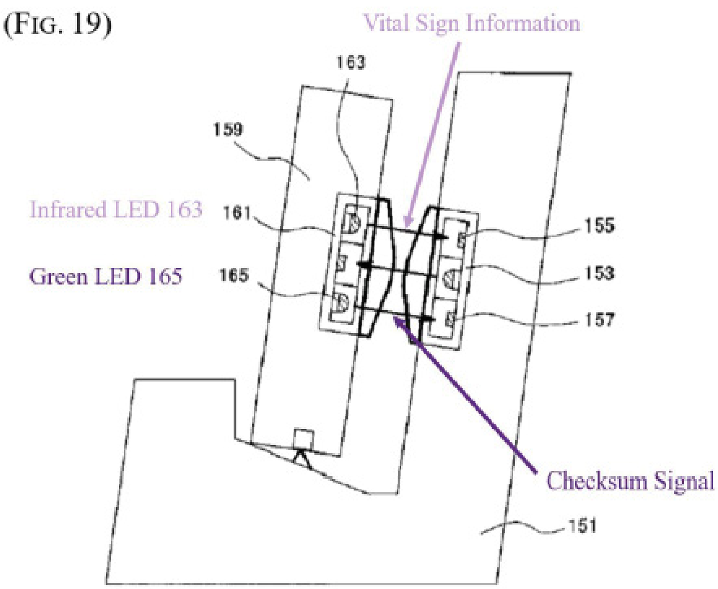
IPR2020-01537 APPLE-1003, ¶ 78.

80. With reference to FIG. 19 below, Inokawa further teaches that the use of two LEDs instead of one further helps improve data transmission accuracy by using the second LED to transmit checksum information. For example, Inokawa describes that "the presence of two pairs of light-emitting and light-receiving elements makes it possible to efficiently transmit information," including increasing the "**accuracy of data**…by transmitting and receiving a **checksum signal** using, for example, the S-side green LED 165 and the other B-side PD 157." APPLE-1008, ¶¶[0111], [0044], [0048].

IPR2020-01537 APPLE-1003, ¶ 80.

Inokawa

(FIG. 19)



IPR2020-01537 APPLE-1008, FIGS. 1(a), 1(b)
(as annotated at APPLE-1003 ¶ 80).

FISH.

A POSITA would have Modified Aizawa to Feature Two Emitters to Enable Wireless Communication

Dr. Kenny's First Declaration

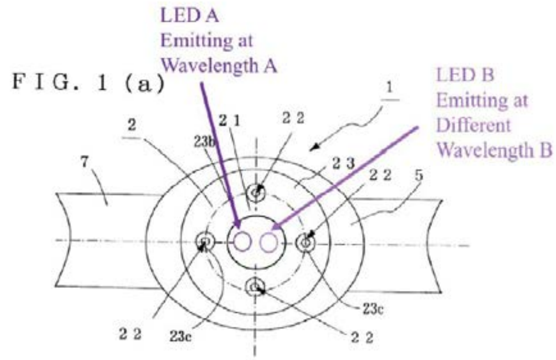
78. One of ordinary skill would have looked to Inokawa's disclosure of two LEDs emitting light of different wavelengths, in part, because it provides additional functionality, including that of wireless communication with a base station. *Id.* Inokawa's base device 17 receives, for example, "pulse and body motion" data through "the S-side infrared LED 23 of the pulse sensor 1 and the B-side PD 45 of the base device 17." *Id.*, ¶(0076). "As a result, there is no need to use a special wireless communication circuit or a communication cable as previously, which makes it possible to transmit vital sign information to the base device 17 accurately, easily, and without malfunction." *Id.*, ¶[0077]. In other words, the LEDs provided on the sensor can be used not only to detect pulse rate but also to "accurately, easily, and without malfunction" transmit the sensed data to a base station.

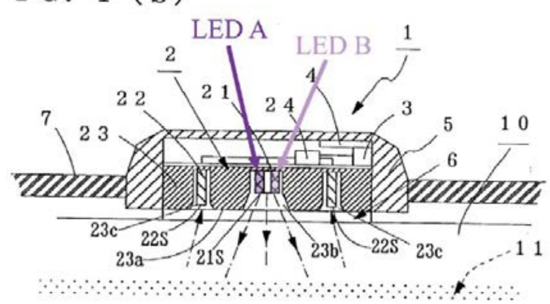
IPR2020-01537 APPLE-1003, ¶ 78.

80. With reference to FIG. 19 below, Inokawa further teaches that the use of two LEDs instead of one further helps improve data transmission accuracy by using the second LED to transmit checksum information. For example, Inokawa describes that "the presence of two pairs of light-emitting and light-receiving elements makes it possible to efficiently transmit information," including increasing the "**accuracy of data**…by transmitting and receiving a **checksum signal** using, for example, the S-side green LED 165 and the other B-side PD 157." APPLE-1008, ¶¶[0111], [0044], [0048].

IPR2020-01537 APPLE-1003, ¶ 80.

Aizawa





IPR2020-01537 APPLE-1006, FIGS. 1(a), 1(b)
(as annotated at APPLE-1003 ¶¶ 74-75).

FISH.

Masimo Fails to Rebut that a POSITA would have Added a Second Emitter to Aizawa to Account for Motion Load

Patent Owner's Response

Petitioner nonetheless argues that Inokawa would have motivated a POSITA to add a second LED to Aizawa's multiple detectors for two reasons, neither of which is persuasive. First, Petitioner argues a second LED would have "improve[d] the detected pulse wave by distinguishing between blood flow detection and body movement." Pet. 17. Petitioner bases its argument on Dr. Kenny's erroneous belief that Aizawa could not calculate a motion wave because Aizawa uses a single LED. Ex. 2007 400:7-401:10. Specifically, Dr. Kenny incorrectly believed Aizawa's sensor attempts to prevent motion rather than account for it. *Id.* 400:7-11. However, Aizawa expressly states that it already provides a "device for ***computing*** the ***amount*** of motion load from the pulse rate" based on its measured data. Ex. 1006 ¶15. Accordingly, Aizawa's sensor already includes a means for detecting body movement. Ex. 2004 ¶104.

IPR2020-01537 Pap. 24 (POR), 50-51.

Dr. Kenny's Second Declaration

60. Masimo, however, suggests that such motivation is flawed because "Aizawa...expressly states that it provides a 'device for ***computing*** the ***amount*** of motion load from the pulse rate.'" POR, 50. Yet Masimo fails to explain—and Aizawa itself is certainly silent—regarding how Aizawa senses and computes motion load. Moreover, while Masimo contends that Aizawa "account[s] for" motion, Aizawa is silent on whether it uses the computed motion load to improve the detection signal. Masimo further does not rebut that adding a second LED having a second wavelength, as per Inokawa, will "enabling the sensor to distinguish between blood flow detection and body movement." Petition, 22; APPLE-1003, ¶¶80, 113. Indeed, as I explained during my deposition, adding a second LED at a different wavelength to Aizawa's single LED design would allow it to obtain a more reliable pulse measurement by allowing the system to "measur[e] pulse rate and motion load during the same time" by operating a separate LED dedicated to sensing motion. Ex. 2007, 401:11-402:4. In my opinion, having two separate signals that are respectively dedicated to measuring pulse and body motion, as per Inokawa, will allow Aizawa's system to " us[e]

IPR2020-01537 APPLE-1027, ¶ 60.

FISH.

Masimo Fails to Rebut that a POSITA would have Added a Second Emitter to Aizawa to Account for Motion Load

Dr. Kenny's Second Declaration

APPLE-1003, ¶¶80, 113. Indeed, as I explained during my deposition, adding a second LED at a different wavelength to Aizawa's single LED design would allow it to obtain a more reliable pulse measurement by allowing the system to "measur[e] pulse rate and motion load during the same time" by operating a separate LED dedicated to sensing motion. Ex. 2007, 401:11-402:4. In my opinion, having two separate signals that are respectively dedicated to measuring pulse and body motion, as per Inokawa, will allow Aizawa's system to " us[e] multiple LEDs emitting light at different wavelengths—e.g. infrared and green LEDs…to…detect body motion." APPLE-1003, ¶115. Because different wavelengths have different sensitivities to pulse and body motion, collecting two separate signals will allow noise arising from body motion to be better isolated and accounted for.

IPR2020-01537 APPLE-1027, ¶ 60.

61. By using two wavelengths, it is possible to record two independent signal waveforms at the same time from the same site. As explained above, each reflected signal includes some dependence on the physiological parameter, and on the movement of the sensor relative to the measurement site. Because it is possible to choose different wavelengths of light so as to have one signal with strongest dependence on the physiological parameter and the second signal with the strongest dependence on the movement of the sensor, the signals can be processed in a way to compensate for movement and create a more reliable measurement of the physiological parameter. The use of two or more separate wavelengths to obtain independent measures of the physiological parameter and error sources such as body movement, was well-known at the time of the invention, and it would have been obvious for a POSITA to consider the use of a second wavelength LED to capture these benefits.

IPR2020-01537 APPLE-1027, ¶ 61.

FISH.

Masimo Fails to Rebut that a POSITA would have Added a Second Emitter to Aizawa to Improve Accuracy

Dr. Kenny's Second Declaration

[0048]. The fact that "Aizawa already includes the ability to calculate motion load with its ***single*** LED" does not take away from the fact that a POSITA would nevertheless have been motivated to look to the two-LED implementation of Inokawa to further improve accuracy. POR, 3; Petition, 20-22; Ex. 2007, 407:7-408:20. And while Masimo further contends that I "acknowledged that POSITA wanting to maintain a wireless data transmission approach [in Aizawa] would not switch to the base station transmission approach of Inokawa," POR, 39, a full reading of the cited deposition testimony reveals that I made it very clear that if "they've already decided not to use a base station transmission device, then they probably wouldn't switch to one." Ex. 2007, 416:5-15.

Ex. 2007

Q. So you have a picture below Paragraph 81 that shows a base device. You show how additional LED would communicate with the base device. You're relying on an approach for data transmission from Inokawa and saying that would be an additional reason to add LED to Aizawa, correct?

MR. SMITH: Objection; form.

A. So I, I take the combination to include the use of a second LED to transmit data and to provide confirmation of the accuracy of that data, improve data transmission accuracy in particular, without absolutely being bound to the specific details of the base and sensor configuration shown on the bottom of Page 47 or there on the middle of Page 46.

It's one example of how one might use an LED to support data transmission, but it wouldn't absolutely require all of the details of an implementation in order to provide the data transmission.

Ex. 2007, 407:7-408:4.

FISH.

Issue 3

Implementing Wireless Communication

Case Nos. IPR2020-01536, -01537, -01538, -01539
U.S. Patent Nos. 10,588,553, 10,588,554

FISH.

A POSITA would have Enabled Aizawa to Communicate Wirelessly with a Handheld Computing Device

Dr. Kenny's First Declaration

80. When Inokawa's sensor is mounted onto the base station, "vital sign information…such as pulse and body motion, is transmitted to the base device…using the…infrared LED." *Id.*, ¶[0076]. The "base device 17 is connected to a PC 59, and information transmitted from the pulse sensor 1 is downloaded to the PC 59 via the base device 17." *Id.*; *see also id.*, ¶¶[0074] ("in transmission

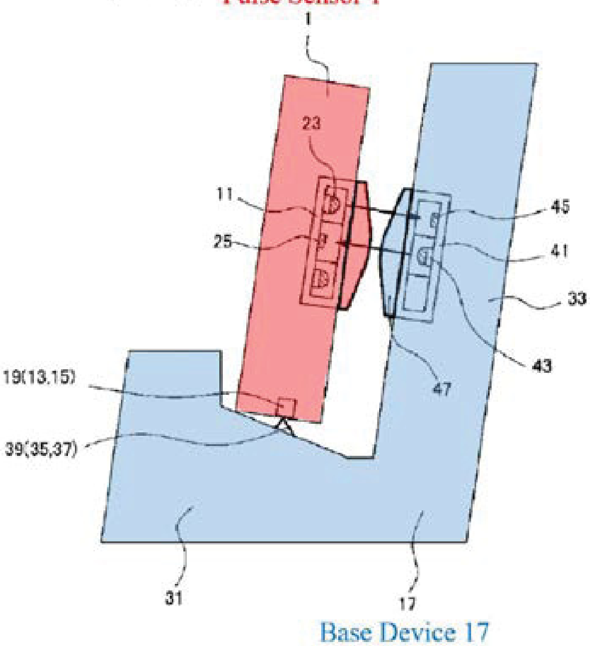
IPR2020-01539 APPLE-1003, ¶ 80.

91. To obtain these and other advantages described by Mendelson-2006, one of ordinary skill would have been motivated to implement Aizawa's pulse wave sensor as part of a physiological measurement system including a handheld computing device, and to enable a physiological sensor device including sensor 1 to communicate wirelessly with the handheld computing device. APPLE-1006, Abstract ("a pulse wave sensor for detecting a pulse wave by detecting light output from a light emitting diode and reflected from the artery of a wrist of a subject "), ¶¶[0002], [0005], [0008]-[0016], [0023] (describing transmitting "pulse rate data to an unshown display"), [0024], [0027]-[0030], [0032]-[0033], FIGS. 1, 2, 3, 4(a); APPLE-1010, 1-4, FIG. 3; *see also* APPLE-1020, 1-4.

IPR2020-01539 APPLE-1003, ¶ 91.

Inokawa

(FIG. 3)



IPR2020-01539 APPLE-1008, FIG. 3
(as annotated at APPLE-1003 ¶ 80).

FISH.

A POSITA would have Enabled Wireless Communication with a Handheld Computing Device

Dr. Kenny's First Declaration

82. Inokawa does not explicitly describe wireless communication between the base station and a computer, but one of ordinary skill would have found it obvious to implement the physiological sensor device resulting from the combined teachings of Aizawa, Inokawa, and Ohsaki as part of a physiological measurement system including a handheld computing device, and to enable the physiological sensor device to communicate wirelessly with the handheld computing device. APPLE-1006, Abstract, [0002], [0005], [0008]-[0016], [0023]-[0024], [0027]-[0030], [0032]-[0033], FIGS. 1, 2, 3, 4(a); APPLE-1008, ¶¶[0002], [0003], [0067] [0074]-[0077]; APPLE-1010, 1-4, FIG. 3.

IPR2020-01539 APPLE-1003, ¶ 8

84. Indeed, by the '554 patent's 2008 earliest effective filing date, physiological monitoring devices commonly employed touch-screen displays. Yitzhak Mendelson's 2006 paper "A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring," for example, describes a "body-worn" pulse oximetry system that includes a sensor module, a receiver module, and a PDA. APPLE-1010, 3.

IPR2020-01539 APPLE-1003, ¶ 84.

Mendelson-2006

Fig. 1. (Top) Attachment of Sensor Module to the skin; (Bottom) photograph of the Receiver Module (left) and Sensor Module (right).

IPR2020-01539 APPLE-1010, FIG. 1
(as annotated at APPLE-1003 ¶ 68).

FISH.

Mendelson-2006 Teaches Wireless Communication with a Handheld Computing Device

Dr. Kenny's First Declaration

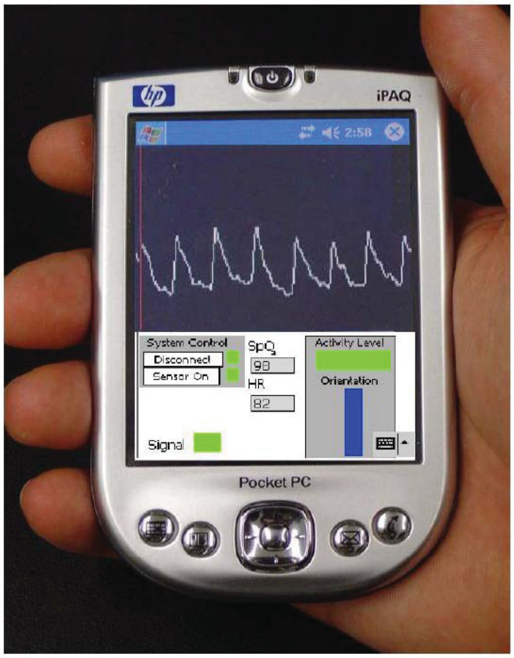
85. As discussed above in Section VI.D and incorporated herein, Mendelson-2006's system includes a sensor module that transmits signals wirelessly to a PDA through a receiver module. *Id.*, 913, FIGS. 1-3.

86. The PDA is said to "provide[] a low-cost touch screen interface." *Id.*, 3-4; *see also* APPLE-1020, 1-4 (depicting and describing the touch-screen display included within the HP iPAQ h4150 Pocket PC PDA utilized in Mendelson-2006's system); APPLE-1021, Cover, xvii-xviii, 10-12, 17, 63, 363; APPLE-1022, 4-11, 30-3. In more detail, and as shown in Mendelson-2006's FIG. 3 (reproduced below), the PDA's "simple GUI" is "configured to present … input and output information to the user" and to allow "easy activation of various functions." *Id.*, 4.

IPR2020-01539 APPLE-1003, ¶¶ 85-86.

90. Wireless communication with the handheld PDA is, moreover, said to enable transfer of information pertaining to physiological and wellness parameters such as "SpO_2, HR, body acceleration, and posture information" to the PDA; and, when the PDA is "carried by medics or first responders," this information is said to enhance their ability "to extend more effective medical care, thereby saving the lives of critically injured persons." *Id.*

Mendelson-2006



IPR2020-01537 APPLE-1010, FIG. 3.

FISH.

62

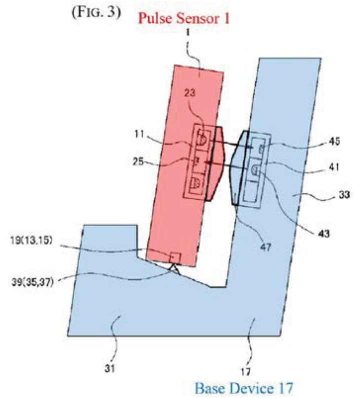
A POSITA would have Recognized that Aizawa's LED could be Used for Data Communication to a Computing Device

Dr. Kenny's Second Declaration

59. For example, the POSITA would have found it obvious to implement the "unshown display" of Aizawa's pulse rate detector as a touch-screen display to provide "a simple GUI" "configured to present…input and output information to the user" in real time, and to allow "easy activation of various functions." APPLE-1006, [0023]; APPLE-1010, 3; *see also* POR, 57 (describing "eliminat[ing] real time monitoring"); APPLE-1051, [0082]-[0095] (describing a user-worn heart rate monitoring device including "a touchscreen display" that displays data received "from a sensor transmitter on the patient's skin"), FIG. 9A. Further, the POSITA would have found it obvious to enable Aizawa's sensor to "accurately, easily, and without malfunction" transmit physiological information to a base station, and would have found it obvious to wirelessly transmit this information from the base station to a PDA featuring a touch-screen display. APPLE-1003, ¶¶73, 122, 167.

IPR2020-01539, APPLE-1003, ¶ 59.

Inokawa and Mendelson-2006



IPR2020-01539 APPLE-1008, FIG. 3;
APPLE-1010, FIG. 3.

FISH.

63

Masimo Fails to Address the Motivation to Add Wireless Communication to the Proposed Sensor

Dr. Kenny's Second Declaration

60. And, contrary to Masimo's contention that "Petitioner identifies no valid motivation," I previously testified to several, including: (1) that "[t]he PDA is used 'as a local terminal' and it 'also provides a low-cost touch screen interface'"; (2) that the PDA's "'simple GUI' is 'configured to present…input and output information to the user' and to allow 'easy activation of various functions'"; and (3) that wireless communication with the handheld PDA enables medical personnel to "extend more effective medical care." APPLE-1003, ¶¶80-93; *see also* APPLE-1010, FIG. 3 (reproduced below)(depicting a "Sample PDA Graphical User Interface"). For at least these reasons, Masimo's arguments fail.

IPR2020-01539, APPLE-1003, ¶ 60.

Mendelson-2006

PDA: The PDA was selected based on size, weight, and power consumption. Furthermore, the ability to carry the user interface with the medic also allows for greater flexibility during deployment. We chose the HP iPAQ h4150 PDA because it can support both 802.11b and Bluetooth™ wireless communication. It contains a modest amount of storage and has sufficient computational resources for the intended application. The use of a PDA as a local terminal also provides a low-cost touch screen interface. The user-friendly touch screen of the PDA offers additional flexibility. It enables multiple controls to occupy the same physical space and the controls appear only when needed. Additionally, a touch screen reduces development cost and time, because no external hardware is required. The data from the wireless-enabled PDA can also be downloaded or streamed to a remote base station via Bluetooth or other wireless communication protocols. The PDA can also serve to temporarily store vital medical information received from the wearable unit.

IPR2020-01539 APPLE-1010, 3.

The GUI was configured to present the input and output information to the user and allows easy activation of various functions.

IPR2020-01539 APPLE-1010, 3-4.

FISH.

A POSITA would have Recognized that Aizawa's LED could be Used for Data Communication to a Computing Device

Dr. Kenny's Second Declaration

57. More specifically, Inokawa describes that a base station receives information transmitted from a pulse sensor wirelessly via LED, and that the base station transmits signals to a computer, via a network interface. APPLE-1003, ¶¶71-93; APPLE-1008, [0002], [0003], [0067], [0074]-[0077]. Similarly, Mendelson-2006 describes that a receiver module receives information transmitted from a sensor module, and that the receiver module wirelessly transmits signals to a PDA. APPLE-1003, ¶¶80-93, 166-180; APPLE-1010, 1-4, FIGS. 2, 3.

58. Thus, contrary to Masimo's contentions, including that "Petitioner's proposed combination frustrates both Aizawa and Mendelson-2006's goal of real-time display of data by requiring a base device," Petitioner's proposed combination does not "eliminate Aizawa's existing transmitter" and then "add back in a separate communications circuit," and does not "eliminate the ability to take and display real-time measurements."[1] POR, 4, 60. Rather, "a POSITA would have been motivated to implement Aizawa's pulse wave sensor as part of a physiological measurement system including a handheld computing device, and to enable a physiological sensor device including [Aizawa's] sensor 1 to communicate wirelessly with the handheld computing device." Pet., 31-33; APPLE-1006, [0023] [0028], [0035], APPLE-1010, 1-4, FIGS. 1-3.

IPR2020-01539, APPLE-1003, ¶¶ 57-58.

Inokawa

...base device 17 receives the information transmitted from the pulse sensor 1 by means of the B-side optical device component 41. Note that the base device 17 is connected to a PC 59, and information transmitted from the pulse sensor 1 is downloaded to the PC 59 via the base device 17.

APPLE-1008, [0067]; Pet., 23-24.

Mendelson-2006

The prototype system, depicted in Fig. 1, consists of a body-worn pulse oximeter that receives and processes the PPG signals measured by a small (ϕ = 22mm) and lightweight (4.5g) optical reflectance transducer. The system consists of three units: A Sensor Module, consisting of the optical transducer, a stack of round PCBs, and a coin-cell battery. The information acquired by the Sensor Module is transmitted wirelessly via an RF link over a short range to a body-worn Receiver Module. The data processed by the Receiver Module can be transmitted wirelessly to a PDA.

IPR2020-01537 APPLE-1010, 2.

FISH.

Masimo Fails to Address the Motivation to Add Wireless Communication to the Proposed Sensor

Dr. Kenny's Second Declaration

55. Rather than attempting to rebut my testimony on these points, Masimo alleges that (1) "Petitioner identifies no valid motivation to add Mendelson 2006 to [its combination]" and that (2) "Petitioner's addition of Mendelson-2006's wireless approach makes no sense given that….Petitioner's combination already replaced Aizawa's wireless transmitter with Inokawa's base station approach." *See* POR, 58-62 (emphasis omitted). The POR additionally states that Mendelson-2006 "is not a multi-emitter/multi-detector sensor," which is simply irrelevant. POR, 61.

56. First, although Aizawa explains that its sensor transmits data to an "unshown display," and can be "coupled to devices making use of bio signals," it is silent about how such transmission would be implemented. APPLE-1003, ¶63; APPLE-1006, [0023], [0028], [0035]. As I previously explained, the POSITA "would have recognized that the LED of Aizawa could be used for data communication to a computing device for further analysis in a way that is wireless…and that does not require a separate RF circuit, as taught by Inokawa." APPLE-1003, ¶74; APPLE-1008, [0003], [0067], [0075].

IPR2020-01539, APPLE-1003, ¶¶ 55-56.

Aizawa

to know the quantity of motion. There has recently been proposed a method of estimating a burden on the heart of a person who takes exercise by real-time measuring his/her heart rate at the time of exercise.

[0015] According to a seventh aspect of the present invention, there is provided a pulse rate detector which comprises a transmitter for transmitting the measured pulse rate data to a display for displaying the pulse rate data and a device for computing the amount of motion load from the pulse rate.

In these figures, reference numeral **2** denotes a pulse wave sensor which comprises an LED **21** (to be referred to as "light emitting diode" hereinafter) for emitting light having a wavelength of a near infrared range, four phototransistors **22** (to be referred to as "photodetectors" hereinafter) disposed around the light emitting diode **21** symmetrically on a circle concentric to the light emitting diode **21**, a holder **23** for storing the above light emitting diode **21** and the photodetectors **22**, and a drive detection circuit **24** for detecting a pulse wave by amplifying the outputs of the photodetectors **22**, **3** is an arithmetic circuit for computing a pulse rate from the detected pulse wave data, **4** a transmitter for transmitting the above pulse rate data to an unshown display, **5** an outer casing for storing the above pulse wave sensor **2**, the arithmetic circuit **3** and the transmitter **4**, **6** an acrylic

IPR2020-01539 APPLE-1008, ¶¶ [0004], [0015], [0023].

FISH.

A POSITA would have Enabled Mendelson ’799 to Communicate Wirelessly with a Handheld Computing Device

Dr. Kenny’s First Declaration

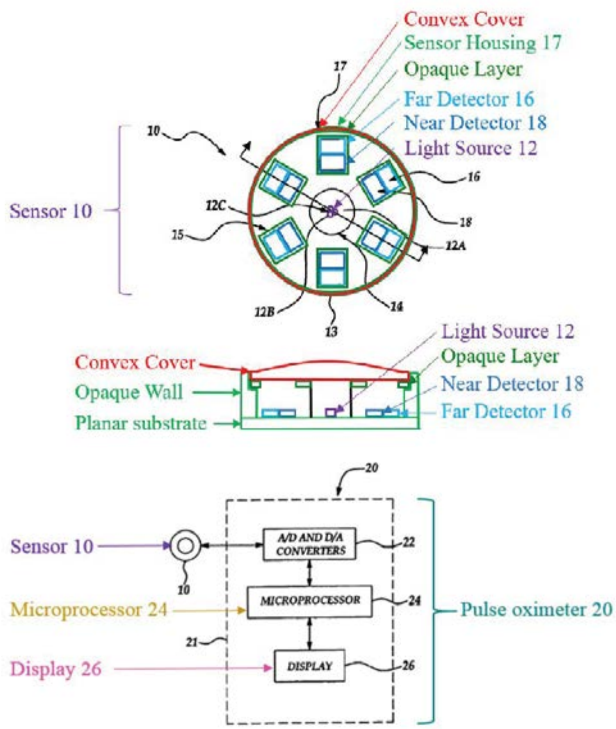
171. To obtain these and other advantages described by Mendelson 2006, one of ordinary skill would have been motivated to implement Mendelson ’799’s sensor 10 and pulse oximeter 20 as part of a physiological measurement system including a handheld computing device, and to enable a physiological sensor device including sensor 10 and pulse oximeter 20 to communicate wirelessly with the handheld computing device. APPLE-1012, Abstract, 8:37-41, 9:22-10:30, FIGS. 7, 8; APPLE-1010, 1-4, FIG. 3; *see also* APPLE-1020, 1-4.

IPR2020-01538 APPLE-1003, ¶ 171.

175. Mendelson ’799 and Mendelson 2006 describe similar pulse oximetry sensors and, indeed, were authored by the same person. *Id.* In combination, Mendelson 2006’s features are implemented in Mendelson-Ohsaki-Schulz’s pulse oximetry system just as they are in Mendelson 2006’s system. *see, e.g.*, APPLE-1008, 1-4, FIGS. 1-3; APPLE-1012, 10:16-30, FIG. 8. Accordingly, implementing Mendelson 2006’s teaching of transmitting data to a handheld device in a pulse oximetry device as taught by Mendelson ’799 would have been routine and straightforward to one of ordinary skill, and it would have been clear that such a combination would predictably work and provide the expected functionality.

IPR2020-01538 APPLE-1003, ¶ 175.

Mendelson ’799



IPR2020-01538 APPLE-1012, FIGS. 7, 8 (as annotated at APPLE-1003 ¶¶ 163, 164).

FISH.

67

Issue 4

Guarding against Saturation

Case Nos. IPR2020-01536, -01538
U.S. Patent Nos. 10,588,553, 10,588,554

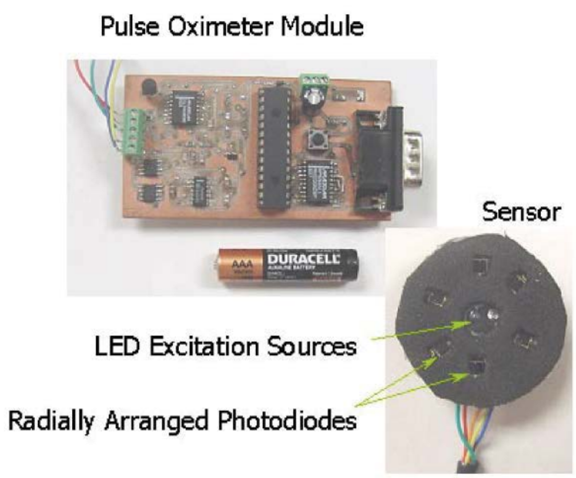
FISH.

A POSITA would have Added an Opaque Layer to Mendelson '799's Sensor

Dr. Kenny's First Declaration

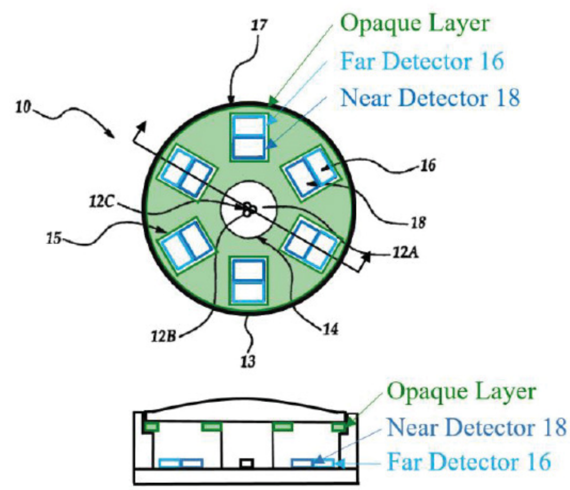
221. Similar to these and other known configurations, and as shown below, Schulz would have motivated one of ordinary skill to modify the Mendelson-Ohsaki combination to include an opaque layer that would have blocked light other than at windows corresponding to the sensor's photodiodes. APPLE-1013, ¶[0073], FIGS. 19A-19C; APPLE-1023, 1-14, FIG. 11; APPLE-1019, 79-80, 86, 94, FIG. 6.6; APPLE-1006, ¶¶[0012], [0023], [0024], FIGS. 1(a), 1(b).

IPR2020-01536, APPLE-1003, ¶ 221.



IPR2020-01536, APPLE-1023 (Yao) FIG. 11.

Mendelson '799



IPR2020-01536, APPLE-1012, FIG. 7 (as annotated at APPLE-1003 ¶ 221).

FISH.

Schulz Teaches that an Opaque Layer would Shield Detectors from Ambient Light

Dr. Kenny's First Declaration

214. As detailed below, one of ordinary skill would have been motivated to combine Mendelson '799 and Ohsaki with Schulz (hereinafter "Mendelson-Ohsaki-Schulz combination" or "Mendelson-Ohsaki-Schulz") to obtain additional benefits. More specifically, one of ordinary skill would have recognized that the Mendelson-Ohsaki opaque wall would partially shield the detectors from ambient light, but would have understood from Schulz that additional measures could be taken to guard against saturation. APPLE-1019, 79, 86, 94.

IPR2020-01536, APPLE-1003, ¶ 214.

218. From Schulz's description, one of ordinary skill would have understood that, in line with textbook recommendations, Schulz's opaque layer limits errors by decreasing the angle of incidence to the photodiode to that enabled by the window included within the layer, and by otherwise preventing ambient light from reaching the photodiode. APPLE-1013, ¶[0073], APPLE-1019, 79-80, 94, FIG. 6.6.

IPR2020-01536, APPLE-1003, ¶ 218.

Schulz

[0073] In an embodiment, a thin sheet of opaque material can be placed inside either housing **1902** or **1903** between the optical components and the inward facing shell **1905** or **1906**. The thin sheet of opaque material is located beneath window **1919** or **1924**, and a window in the opaque material provides an aperture for transmission of optical energy to or from the tissue site. The opaque material blocks light, and the window in the opaque material can be sized as needed to block the proper amount of light from entering the aperture to, for example, avoid saturation of the light detector. In one

IPR2020-01536, APPLE-1013, ¶ 0073.

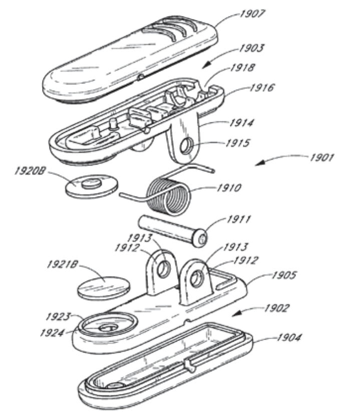


FIG. 19C

IPR2020-01536, APPLE-1013, FIG. 19C (as annotated at APPLE-1003 ¶ 70).

FISH.

Schulz Teaches that an Opaque Layer would Shield Detectors from Ambient Light

Dr. Kenny's First Declaration

218. From Schulz's description, one of ordinary skill would have understood that, in line with textbook recommendations, Schulz's opaque layer limits errors by decreasing the angle of incidence to the photodiode to that enabled by the window included within the layer, and by otherwise preventing ambient light from reaching the photodiode. APPLE-1013, ¶[0073], APPLE-1019, 79-80, 94, FIG. 6.6.

219. One of ordinary skill would also have readily understood that Schulz's teachings would apply to pulse oximetry sensors featuring multiple photodiodes and that, in such sensors, errors could be limited through the use of an opaque layer with multiple windows, the windows being configured to decrease the angles of incidence to the photodiodes. APPLE-1013, ¶[0073], APPLE-1019, 79-80, 94, FIG. 6.6; APPLE-1006, ¶¶[0012], [0023], [0024], FIGS. 1(a), 1(b); APPLE-1023,

IPR2020-01536, APPLE-1003, ¶¶ 218-219.

Webster

Since this is a system with an optical interface, it is important to minimize the effects from light other than the optical signals of interest. One way to minimize unwanted light incident upon the detector is to place some type of light filter over the detector. This allows light of wavelengths of interest to pass through the filter but does not allow light of other wavelengths to pass through the filter. For the pulse oximeter to work effectively, most of the light being transmitted from the LEDs must not reach the photodiode unless it has passed through tissue containing arterial blood.

IPR2020-01536, APPLE-1019, 76.

To minimize errors, the pulse oximeter designer must attempt to limit the light reaching the photodiode to that which has traveled through tissue containing arterial blood (Nellcor 1993). This can be accomplished through thoughtful LED/photodiode placement. Light impervious barriers should be placed between LEDs and the photodiode in all areas where the emitted light could reach the photodiode without passing through tissue (New and Corenman 1987). Two additional measures can be taken to ensure this (figure 6.6). One is to decrease the angle of incidence to the photodiode. The second is to coat the housing around the photodiode with a material that does not scatter or reflect light.

IPR2020-01536, APPLE-1019, 79-80.

Ambient light from sources such as sunlight, surgical lamps etc may cause errors in S_aO_2 readings. In order to prevent this, the simple solution is to cover the sensor site with opaque material which can prevent ambient light from reaching the photodiode.

IPR2020-01536, APPLE-1019, 94.

FISH.

A POSITA would have Modified the Combined Sensor to Guard Against Detector Saturation as taught by Schulz

Patent Owner's Response

First, Schulz is directed to an ear sensor. Pet. 62-63. In contrast, Ohsaki requires that its sensor be used on the backhand side of the wrist. *See, e.g.*, Ex. 1009 Title, Abstract; Sections VII.A, VII.B.1-2, *supra*. Mendelson '799 does not indicate its sensor can be used on the ear and instead ***contrasts*** its reflectance sensor with transmission sensors attached on an earlobe. Ex. 1012 2:8-13; Ex. 2004 ¶90.

IPR2020-01536 Pap. 24 (POR), 44.

Cited Portion of Mendelson '799

Pulse oximeters are of two kinds operating, respectively, in transmission and reflection modes. In transmission-mode pulse oximetry, an optical sensor for measuring SaO_2 is usually attached across a fingertip, foot or earlobe, such that the tissue is sandwiched between the light source and the photodetector.

APPLE-1012, 2:8-13; IPR2020-01536 (cited at POR, 44; APPLE-1027, ¶ 60; Petition, 22-23).

Dr. Kenny's Second Declaration

60. Masimo mischaracterizes the Mendelson-799 reference as "contrast[ing] its reflectance sensor with transmission sensors attached on an earlobe." POR, 44 (citing APPLE-1012 (Mendelson-799), 2:8-13). But the cited portion of Mendelson-799, from the "Background of the Invention" section, describes prior art reflectance and transmission sensors, and, contrary to the POR's characterization, does not describe Mendelson's sensor. *See* APPLE-1012, 2:8-13. Further, the cited passage does not "contrast" reflectance and transmission sensors, but merely describes areas of the body to which transmission sensors are "usually attached," specifically the "fingertip, foot or earlobe." *See id.* The passage contains no indication that these body parts are unsuitable for use with a reflectance sensor, and at least one of the listed body parts (the fingertip) is described as suitable in the '553 patent's description of the prior art. *See id.*;

IPR2020-01536, APPLE-1047, ¶ 60.

FISH.

A POSITA would have Modified the Combined Sensor to Guard Against Detector Saturation as taught by Schulz

Patent Owner's Response

First, Schulz is directed to an ear sensor. Pet. 62-63. In contrast, Ohsaki requires that its sensor be used on the backhand side of the wrist. *See, e.g.*, Ex. 1009 Title, Abstract; Sections VII.A, VII.B.1-2, *supra*. Mendelson '799 does not indicate its sensor can be used on the ear and instead ***contrasts*** its reflectance sensor with transmission sensors attached on an earlobe. Ex. 1012 2:8-13; Ex. 2004 ¶90.

IPR2020-01536, Pap. 24 (POR), 44.

Dr. Kenny's Second Declaration

61. In fact, Mendelson-799 does not describe its sensor as limited to use in any particular location on the body, and it wouldn't have been understood as such. *See generally*, APPLE-1012. Indeed, it was well-known before the Critical Date (and thus a POSITA would have understood) that reflectance probes, like those described in Mendelson-799, could be applied "virtually any place on the human body." APPLE-1019, 87 ("The idea of using skin reflectance spectrophotometry

IPR2020-01536, APPLE-1047, ¶ 61.

Webster

In reflectance pulse oximetry, the LEDs and the photodiode are placed on the same side of the skin surface as shown in figure 7.2. Normally the reflectance probe is placed on the forehead or temple, but is not restricted to only those two places. Reflectance probes can be used to measure arterial oxygen saturation at virtually any place on the human body where the probe can be placed.

IPR2020-01536, APPLE-1019, 88; Reply, 5.

FISH.

A POSITA would have Modified the Combined Sensor to Guard Against Detector Saturation as taught by Schulz

Patent Owner's Response

Second, Petitioner's sole provided motivation is that a POSITA would have combined Schulz with Mendelson '799 and Ohsaki "to guard against saturation." Pet. 65. But there is no evidence over-saturation was a problem for the detectors in either Mendelson '799 or Ohsaki. Indeed, if over-saturation were an issue, it would materially undermine Petitioner's Ground 1 combination, which relies on the incorrect assumption that Ohsaki's board *increases* signal strength. *See, e.g.,* Pet.

IPR2020-01536 Pap. 24 (POR), 44.

Dr. Kenny's Second Declaration

the detectors in either Mendelson '799 or Ohsaki." POR, 44. This argument ignores my First Declaration's explanation of Schulz's disclosure of the benefits of avoiding detector saturation in pulse oximetry sensors, and the corroborating disclosures from Webster and Yao regarding the desirability of blocking ambient light to improve detection in such sensors. APPLE-1003, [214]-[222] (citing

IPR2020-01536, APPLE-1047, ¶ 64.

Schulz

from the tissue site. The opaque material blocks light, and the window in the opaque material can be sized as needed to block the proper amount of light from entering the aperture to, for example, avoid saturation of the light detector. In one

IPR2020-01536, APPLE-1013, ¶73
(cited at Pet. 66).

FISH.

A POSITA would have Modified the Combined Sensor to Guard Against Detector Saturation as taught by Schulz

Dr. Kenny's Second Declaration

65. Masimo further misunderstands or mischaracterizes the teachings of Schulz (and the corroborating teachings of Webster and Yao), and argues, supported only by uncorroborated expert testimony, that "a POSITA would not have been motivated" to implement the features described in Schulz in the combined sensor of Mendelson-799 and Ohsaki, because those features would "make an already weak signal even weaker." POR, 44. This argument assumes that all light reaching the combined sensors detectors represents useful contribution to the "signal." *See id.* But only light from the LEDs "which has traveled through tissue containing arterial blood" can be used for determination of physiological parameters in pulse oximetry measurements. APPLE-1023, 1-14, FIG. 11; APPLE-1019, 76, 79-80, 86, 94, FIG. 6.6. Therefore, only light from the LEDs that has travelled through tissue represents a "signal" to the combined sensor. *See* APPLE-1019, 79-80, 94, FIG. 6.6.). By blocking noise while allowing signal to reach the detectors, the features of Schulz lead to increased signal-to-noise ratio (*i.e.*, a stronger signal and/or weaker background noise) at the detectors in the proposed combination, rather than leading to a "weaker signal" as Masimo alleges.

IPR2020-01536, APPLE-1047, ¶ 65.

Dr. Madisetti's Deposition Transcript

A. An example of -- again, a nonlimiting example of noise could be interference due to light, due to ambient light as an example, a nonlimiting example.

IPR2020-01536, APPLE-1041, 25:10-17 (cited at Reply, 25).

FISH.

Overview of the Challenged ’265, ’553, and ’554 Patents

FISH.

’553 Patent Overview

US010588553B2

(12) **United States Patent**
Poeze et al.

(10) **Patent No.: US 10,588,553 B2**
(45) **Date of Patent: *Mar. 17, 2020**

(54) **MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS**

(71) Applicant: **Masimo Corporation**, Irvine, CA (US)

(72) Inventors: **Jeroen Poeze**, Rancho Santa Margarita, CA (US); **Marcelo Lamego**, Cupertino, CA (US); **Sean Merritt**, Lake Forest, CA (US); **Cristiano Dalvi**, Lake Forest, CA (US); **Hung Vo**, Fountain Valley, CA (US); **Johannes Bruinsma**, Opeinde (NL); **Ferdyan Lesmana**, Irvine, CA (US); **Massi Joe E. Kiani**, Laguna Niguel, CA (US); **Greg Olsen**, Lake Forest, CA (US)

(73) Assignee: **Masimo Corporation**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **16/534,949**

(22) Filed: **Aug. 7, 2019**

(65) **Prior Publication Data**

US 2019/0357812 A1 Nov. 28, 2019

Related U.S. Application Data

(63) Continuation of application No. 16/409,515, filed on May 10, 2019, now Pat. No. 10,376,191, which is a
(Continued)

(51) **Int. Cl.**
A61B 5/1455 (2006.01)
A61B 5/145 (2006.01)
A61B 5/00 (2006.01)

(52) **U.S. Cl.**
CPC *A61B 5/1455* (2013.01); *A61B 5/14532* (2013.01); *A61B 5/14546* (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 5/1455; A61B 5/14551; A61B 5/14552; A61B 5/14532; A61B 5/14546;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,910,701 A 10/1975 Henderson et al.
4,114,604 A 9/1978 Shaw et al.
(Continued)

FOREIGN PATENT DOCUMENTS

CN 1270793 A 10/2000
CN 101484065 B 11/2011
(Continued)

OTHER PUBLICATIONS

US 8,845,543 B2, 09/2014, Diab et al. (withdrawn)
(Continued)

Primary Examiner — Eric F Winakur
Assistant Examiner — Chu Chuan Liu
(74) *Attorney, Agent, or Firm* — Knobbe Martens Olson & Bear LLP

(57) **ABSTRACT**

The present disclosure relates to noninvasive methods, devices, and systems for measuring various blood constituents or analytes, such as glucose. In an embodiment, a light source comprises LEDs and super-luminescent LEDs. The light source emits light at at least wavelengths of about 1610 nm, about 1640 nm, and about 1665 nm. In an embodiment, the detector comprises a plurality of photodetectors arranged in a special geometry comprising one of a substantially
(Continued)

1 APPLE 1001

- The ’553 Patent’s earliest effective filing date is July 3, 2008.
- The ’553 Patent includes 30 claims, of which claims 1, 10, and 20 are independent.
- Independent claim 1, e.g., recites: “A noninvasive optical physiological sensor comprising … a plurality of emitters configured to emit light into tissue of a user … at least four detectors, wherein at least one of the at least four detectors is configured to detect light that has been attenuated by tissue of the user … a wall … and **a cover … compris[ing] a single protruding convex surface operable to conform tissue of the user**….”

IPR2020-01536, APPLE-1001
(U.S. Patent No. 10,588,553)(“’553 Patent”).

FISH.

’553 Patent: Background

Dr. Thomas Kenny’s Declaration

45. In its background section, the ’553 Patent explains that “[t]he standard of care in caregiver environments includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter,” and that “[d]evices capable of spectroscopic analysis generally include a light source(s) transmitting optical radiation into or reflecting off a measurement site, such as, body tissue carrying pulsing blood.” *Id.*, 2:5-11. “After attenuation by tissue and fluids of the measurement site, a photo-detection device(s) detects the attenuated light and outputs a detector signal(s) responsive to the detected attenuated light.” *Id.*, 2:11-14. “A signal processing device(s)” then “process[es] the detector(s) signal(s) and outputs a measurement indicative of a blood constituent of interest, … other physiological parameters, or other data or combinations of data useful in determining a state or trend of wellness of a patient.” *Id.*, 2:14-20.

IPR2020-01536, APPLE-1003 ¶ 45.

46. In this way, the ’553 Patent confirms that prior art “devices capable of spectroscopic analysis” (“for example, a pulse oximeter”), generally included one or more light sources configured to emit light into user tissue, one or more detectors configured to detect light after attenuation by the user’s tissue and to output responsive signal(s), and one or more signal processors configured to process signals and to output measurements of physiological parameters. *Id.*, 2:5-20.

IPR2020-01536, APPLE-1003 ¶ 46.

’553 Patent

BACKGROUND

The standard of care in caregiver environments includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter. Devices capable of spectroscopic analysis generally include a light source(s) transmitting optical radiation into or reflecting off a measurement site, such as, body tissue carrying pulsing blood. After attenuation by tissue and fluids of the measurement site, a photo-detection device(s) detects the attenuated light and outputs a detector signal(s) responsive to the detected attenuated light. A signal processing device(s) process the detector(s) signal(s) and outputs a measurement indicative of a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, other physiological parameters, or other data or combinations of data useful in determining a state or trend of wellness of a patient.

In noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger.

IPR2020-01536, APPLE-1001, 2:4-25.

FISH.

’553 Patent: Brief Description

Dr. Kenny’s Declaration

47. The system described by the ’553 Patent is said to include, in one embodiment, “a noninvasive sensor and a patient monitor communicating with the noninvasive sensor.” APPLE-1001, 2:38-40. The exemplary data collection system 100 illustrated by the ’553 Patent’s FIG. 1 (reproduced below) includes “a sensor 101 … that is coupled to a processing device or physiological monitor 109.” *Id.*, 5:35-38, 11:47-49.

IPR2020-01536, APPLE-1003 ¶ 47; Pet. 5.

40. The ’553 Patent describes and claims a purported improvement to a “noninvasive optical physiological sensor”: a cover with “a single protruding convex surface” that is configured to be located between “at least four” detectors and user tissue, and that is operable to conform user tissue to the surface when the sensor is worn. APPLE-1001, 14:3-10, 36:30-41, 44:50-67 (claim 1), FIGS. 1, 14D. Each detector “can be implemented using one or more photodiodes, phototransistors, or the like,” “can capture and measure light transmitted from [an] emitter … that has been attenuated or reflected from the tissue,” and can “output a detector signal … responsive to the light ….” *Id.*, 14:3-10. Placement of a cover with a protrusion over the detectors is said to offer multiple benefits; the protrusion may, for example, “penetrate[] into the tissue and reduce[] the path length of the light ….” *Id.*, 14:3-10, 24:16-35, 10:61-11:13.

IPR2020-01536, APPLE-1003 ¶ 40; Pet. 1.

’553 Patent

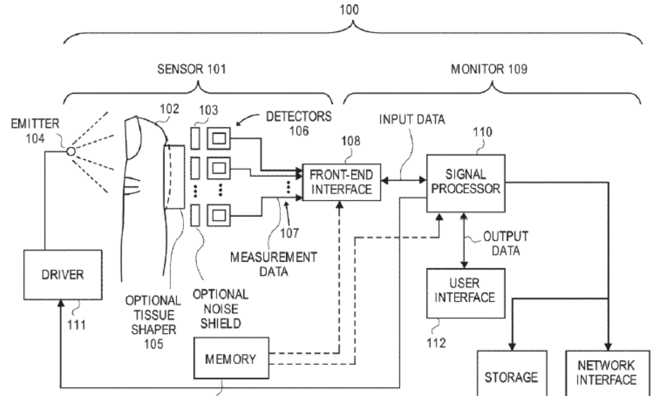


FIG. 1

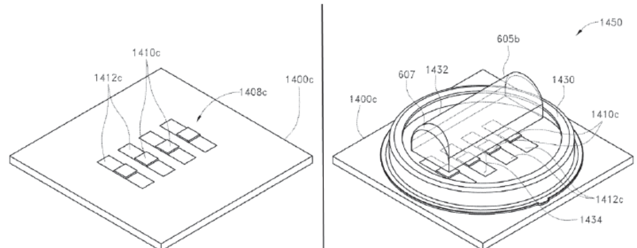


FIG. 14C

FIG. 14D

IPR2020-01536, APPLE-1001 FIGS. 1, 14C, 14D; Pet. 5-6.

’553 Patent: Brief Description

Dr. Kenny’s Declaration

50. As illustrated in FIG. 14D, a housing 1430 including “a transparent cover 1432, upon which the protrusion 605b is disposed” surrounds each of the detectors 1410*c*. APPLE-1001, 36:30-41. Each detector “can be implemented using one or more photodiodes, phototransistors, or the like,” “can capture and measure light transmitted from [an] emitter … that has been attenuated or reflected from the tissue in [a] measurement site,” and can “output a detector signal … responsive to the light ….” *Id.*, 14:3-10.

IPR2020-01536, APPLE-1003 ¶ 50.

51. Placement of a protrusion “over the photodiodes” is said to offer multiple benefits; the protrusion may, for example, “penetrate[] into the tissue and reduce[] the path length of the light ….” *Id.*, 14:3-10, 24:16-35; *see also id.*, 10:61-11:13 (“the system 100 includes an optional tissue thickness adjuster or tissue shaper 105, which can include one or more protrusions, bumps, lenses, or other suitable tissue-shaping mechanisms”), 11:5-12 (“Advantageously, in certain embodiments, the tissue shaper 105 reduces thickness of the measurement site 102 while preventing or reducing occlusion … [r]educing thickness of the site can advantageously reduce the amount of attenuation of the light because there is less tissue through which the light must travel”).

IPR2020-01536, APPLE-1003 ¶ 51.

’553 Patent

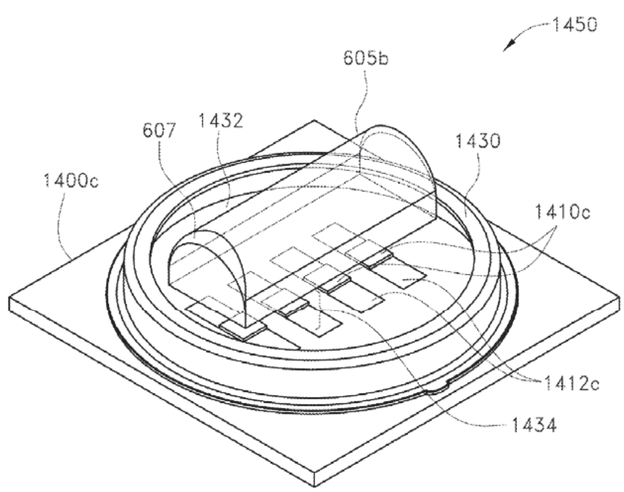


FIG. 14D

IPR2020-01536, APPLE-1001 FIG. 14D; Pet. 6.

FISH.

’553 Patent: Brief Description

Dr. Kenny’s Declaration

41. But the claimed sensor was not new. To the contrary, the ’553 Patent was granted without full consideration to the wide body of applicable prior art. *See generally* APPLE-1002 (no office actions issued during the prosecution of the application from which the ’553 Patent issued). And, as I explain in this declaration with respect to the prior art applied in this Petition, noninvasive optical physiological sensors such as pulse rate detectors and pulse oximeters commonly included covers by the ’553 Patent’s earliest effective filing date, and a sensor including each feature of the Challenged Claims would have been obvious to one of ordinary skill. APPLE-1001, 44:50-47:22.

IPR2020-01536, APPLE-1003 ¶ 41; Pet. 2.

42. For example, Mendelson ’799 (APPLE-1012) discloses a “sensor for use in an optical measurement device” featuring a sensor housing 17 that accommodates a “light source 12” and an array of twelve “discrete detectors (e.g., photodiodes).” APPLE-1012, Title, Abstract, 9:22-40, 10:16-37, FIGS. 7, 8. And, similar to the ’553 Patent, Ohsaki (APPLE-1009) describes an optical sensor that features a cover with a protruding convex surface that is placed “in intimate contact with the surface of the user’s skin” when the sensor is worn. APPLE-1009, Title, Abstract, ¶¶[0016], [0017], FIGS. 1, 2. Ohsaki is not alone, as Inokawa (APPLE-1007, APPLE-1008) and other references likewise disclose covers with protruding convex surfaces for use in optical sensors. APPLE-1008, ¶¶14-15, FIGS. 2, 3. And, in my opinion and as I explain below in the following analysis, one of ordinary skill would have found it obvious to utilize such a cover in Mendelson’s ’799 sensor.

IPR2020-01536, APPLE-1003 ¶ 42; Pet. 2.

FISH.

’553 Patent: Exemplary Claim

’553 Patent

1. A noninvasive optical physiological sensor comprising:
a plurality of emitters configured to emit light into tissue of a user;
at least four detectors, wherein at least one of the at least four detectors is configured to detect light that has been attenuated by tissue of the user, and wherein the at least four detectors are arranged on a substrate;
a wall configured to circumscribe at least the at least four detectors; and
a cover configured to be located between tissue of the user and the at least four detectors when the noninvasive optical physiological sensor is worn by the user, wherein the cover comprises a single protruding convex surface operable to conform tissue of the user to at least a portion of the single protruding convex surface when the noninvasive optical physiological sensor is worn by the user, and wherein the wall operably connects to the substrate and the cover.

IPR2020-01536, APPLE-1001 (’553 Patent), 44:50-67 (Independent Claim 1).

FISH.

’554 Patent: Exemplary Claim

’554 Patent

1. A physiological measurement system comprising:
a physiological sensor device comprising:
a plurality of emitters configured to emit light into tissue of a user;
at least four detectors, wherein each of the at least four detectors has a corresponding window that allows light to pass through to the detector;
a wall that surrounds at least the at least four detectors; and
a cover that operably connects to the wall and that is configured to be located between tissue of the user and the at least four detectors when the physiological sensor device is worn by the user, wherein:
the cover comprises a single protruding convex surface, and
at least a portion of the cover is sufficiently rigid to cause tissue of the user to conform to at least a portion of a shape of the single protruding convex surface when the physiological sensor device is worn by the user; and
a handheld computing device in wireless communication with the physiological sensor device, wherein the handheld computing device comprises:
one or more processors configured to wirelessly receive one or more signals from the physiological sensor device, the one or more signals responsive to at least a physiological parameter of the user;
a touch-screen display configured to provide a user interface,
wherein:
the user interface is configured to display indicia responsive to measurements of the physiological parameter, and
an orientation of the user interface is configurable responsive to a user input; and
a storage device configured to at least temporarily store at least the measurements of the physiological parameter.

IPR2020-01538, APPLE-1001 (’554 Patent), 44:67-45:21 (Independent Claim 1).

FISH.

’265 Patent: Exemplary Claim

’265 Patent

1. A noninvasive optical physiological measurement device adapted to be worn by a wearer, the noninvasive optical physiological measurement device providing an indication of a physiological parameter of the wearer comprising:

a plurality of emitters of different wavelengths;

a housing having a surface and a circular wall protruding from the surface;

at least four detectors arranged on the surface and spaced apart from each other, the at least four detectors configured to output one or more signals responsive to light from the one or more light emitters attenuated by body tissue, the one or more signals indicative of a physiological parameter of the wearer; and

a light permeable cover arranged above at least a portion of the housing, the light permeable cover comprising a protrusion arranged to cover the at least four detectors.

IPR2020-01520, APPLE-1001 (’265 Patent), 44:66-45:15 (Independent Claim 1).

FISH.

Overview of the Instituted Grounds

Instituted Aizawa-based Grounds

Ground	Challenged Claim(s)		
	IPR2020-01537	**IPR2020-01539**	**IPR2020-01520**
Obvious (§ 103) over Aizawa and Inokawa			**1**-4, 6-14, 16, 17, 19-23, **26**-29
Obvious (§ 103) over Aizawa, Inokawa, and Ohsaki	**1**-6, 9, **10**-18, **20**-24, 29		**1**-4, 6-14, 16, 17, 19-23, **26**-29
Obvious (§ 103) over Aizawa, Inokawa, and Mendelson-2006			23, 24
Obvious (§ 103) over Aizawa, Inokawa, Ohsaki, and Mendelson-2006	7, 19	**1**-7, **20**-28	
Obvious (§ 103) over Aizawa, Inokawa, Ohsaki, Mendelson-2006, and Sherman	8, 25-28		
Obvious (§ 103) over Aizawa, Inokawa, Ohsaki, Mendelson-2006, and Bergey		8-19	
Obvious (§ 103) over Aizawa, Inokawa, Goldsmith, and Lo			23, 24
Obvious (§ 103) over Aizawa, Inokawa, Mendelson-2006, and Beyer			25

Instituted Mendelson ’799-based Grounds

Ground	Claim(s) Challenged	
	IPR2020-01536	IPR2020-01538
Obvious (§ 103) over Mendelson ’799 and Ohsaki	**1**-3, 5, 6, 9, **10**-18, **20**-24, and 29	-
Obvious (§ 103) over Mendelson ’799, Ohsaki, and Schulz	4, 18, and 24	-
Obvious (§ 103) over Mendelson ’799, Ohsaki, and Griffin	25	-
Obvious (§ 103) over Mendelson ’799, Ohsaki, and Mendelson 2006	7 and 19	-
Obvious (§ 103) over Mendelson ’799, Ohsaki, Mendelson 2006, and Griffin	8 and 26-28	-
Obvious (§ 103) over Mendelson ’799, Ohsaki, Schulz, and Mendelson 2006	-	**1**-7 and **20**-28

FISH.

Instituted Mendelson-1988-based Grounds

Ground	Claim(s) Challenged
	IPR2020-01520
Obvious (§ 103) over Mendelson-1988 and Inokawa	**1**-4, 6-14, **16**-22, and 26-30
Obvious (§ 103) over Mendelson-1988, Inokawa, and Mendelson-2006	23, 24
Obvious (§ 103) over Mendelson-1988, Inokawa, Mendelson-2006, and Beyer	25

FISH.