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

Petitioner Demonstratives

Case No. IPR2020-01526
U.S. Patent No. 6,771,994
Before Hon. Josiah Cocks, Robert Kinder, Amanda Wieker
Administrative Patent Judges

FISH.

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Obviousness over Diab, Benjamin, and Melby

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Issue 1A

Light Control Film Improves Diab's Consistency and Accuracy

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Diab Describes an Optical Sensor with a Scattering Medium

Dr. Anthony's Declaration

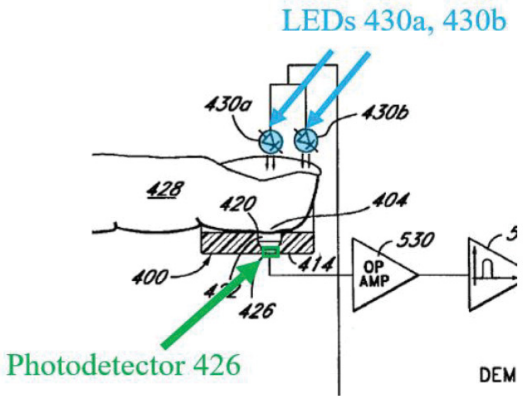
41. Diab describes an "optical probe for measurements" (APPLE-1006, Abstract) for use in "non-invasive energy absorption (or reflection)" detection methods such as pulse oximetry. APPLE-1006, 3:12-43. The device includes a "light source, such as an LED" and a "detector, such as a photodetector." APPLE-1006, 3:12-43. Diab's light source includes, for example, two "LEDs 430a and 430b," one which emits "red wavelengths" and one which emits "infrared wavelengths." APPLE-1006, 18:8-22.

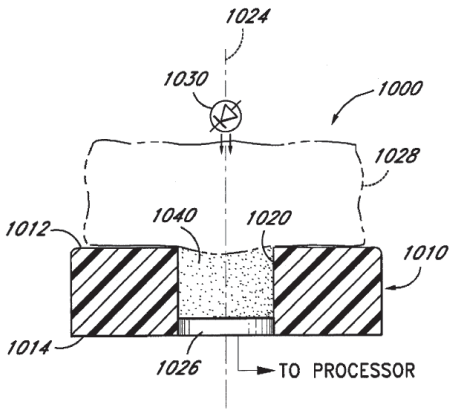
APPLE-1003, ¶ 41.

58. Diab further describes the use of a scattering medium positioned over the photodetector to provide an "improved optical signal-to-noise ratio" by minimizing the effects of local artifacts resulting from scattering as a result of motion. *Id.*, 3:63-4:13. For example, Diab's system can include a scattering medium "between the material [being tested] and the photodetector," "result[ing] in an improved optical signal-to-noise ratio." *Id.*

APPLE-1003, ¶ 58.

Diab





APPLE-1006, FIGS. 24 (top, annotated), 25 (bottom).

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Diab Discloses Removing the Scattering Medium from its Photodetector

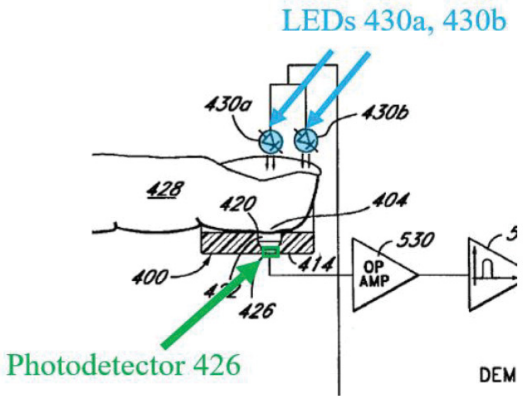
Diab

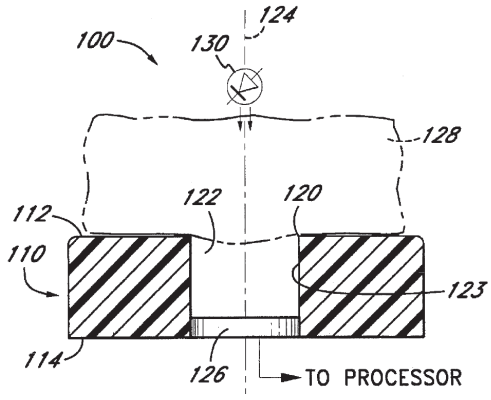
In one preferred embodiment of the present invention, the chamber is filled with a scattering medium. The scattering medium is advantageously formed of a conformable plastic or a highly compressible material so that the material on which measurements are to be made is not compressed upon contact with the scattering medium. The scattering medium helps to minimize the effects of local artifacts and perturbations within the material. Thus, an increased optical signal-to-noise ratio is observed. The scattering medium also improves the optical coupling with the material.

In another preferred embodiment, the scattering medium is interposed between the light source and the material, and in yet another preferred embodiment, the scattering medium is interposed between the light source and the material as well as between the material and the photodetector. Each of these embodiments results in an improved optical signal-to-noise ratio.

APPLE-1006, 3:63-4:12.

Diab





APPLE-1006, FIGS. 24 (top, annotated), 4 (bottom).

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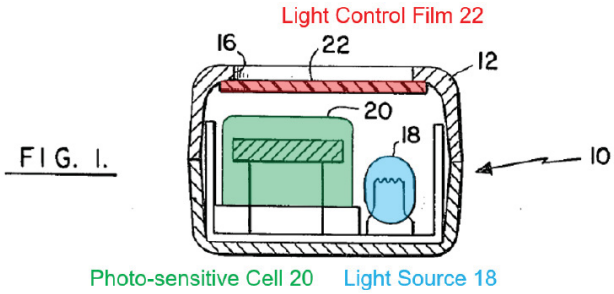
Benjamin Describes an Optical Sensor with Light Control Film

Dr. Anthony's Declaration

43. Benjamin describes an improved "photoplethysmograph," or device that uses a "light source and a specifically selected photo-sensitive cell that responds to light absorbed by the arterial blood in the peripheral vascular bed over which the sensor is placed." APPLE-1007, 1:5-15. The photo-sensitive cell responds to the light absorbed by the blood such that the "amount of pulsating light it registers is proportional to the amount of pulsating arterial blood" within its field of detection and thus provides a measure of "pulsatile blood flow." APPLE-1007, 1:5-15. In order to "improve the accuracy of the photoplethysmographic pickup of the blood flow pulse," Benjamin employs a "light control film" to collimate light passing through and "thereby make the photosensitive cell…more nearly dependent only upon the light beam directly reflected from the field being measured." APPLE-1007, 2:42-61. Such light films were "known in the art and…commercially available."

APPLE-1003, ¶ 43.

Benjamin



APPLE-1007, FIG. 1
(as annotated at APPLE-1003, ¶ 61).

FISH.

Light Control Film Improves Consistency and Accuracy

Dr. Anthony's Declaration

58. Diab further describes the use of a scattering medium positioned over the photodetector to provide an "improved optical signal-to-noise ratio" by minimizing the effects of local artifacts resulting from scattering as a result of motion. *Id.*, 3:63-4:13. For example, Diab's system can include a scattering medium "between the material [being tested] and the photodetector," "result[ing] in an improved optical signal-to-noise ratio." *Id.*

59. Benjamin also recognizes the problem of variations in the amount of scattered light reaching the detector as well. APPLE-1007, 1:35-49. Benjamin describes a device that "senses blood flow by means of a probe placed on the surface of the skin of any part of the body." APPLE-1007, 1:5-15. Benjamin's probe "contains a tiny ***light source*** and a specifically selected ***photo-sensitive cell*** that responds to light absorbed by the arterial blood in the peripheral vascular bed over which the sensor is placed." *Id.*, *see also id.*, 2:26-61. The motivating factor behind Benjamin's invention is that "***variations in the amount of scattered light reaching the photocell cause variations in the operating point of the photocell***," which "adversely affects the accuracy of the measurement." *Id.*, 1:35-49.

60. As a solution, Benjamin identifies, as one of its main improvements, the addition of light control film to stabilize the amount of scattered light that reaches the detector:

APPLE-1003, ¶¶ 58-60.

Benjamin

SUMMARY OF THE INVENTION

It is the general object of this invention to provide improvements in photoplethysmographs and, more particularly, to improve the accuracy of the photoplethysmographic pickup of the blood flow pulse.

In accordance with one feature of the invention means are provided for holding the operating point of the photocell constant by overcoming the adverse affects of the scattered light reaching the photocell. To this end, the amount of scattered light reaching the photocell can be made closer to constant by placing in front of the photocell and light source a small piece of light control film. This film has the effect of collimating the light thereby to make the sensor more nearly dependent only upon the light beam directly reflected from the pulsating blood field.

APPLE-1007, 1:50-66.

FISH.

Benjamin would have Motivated Use of Light Control Film in Diab

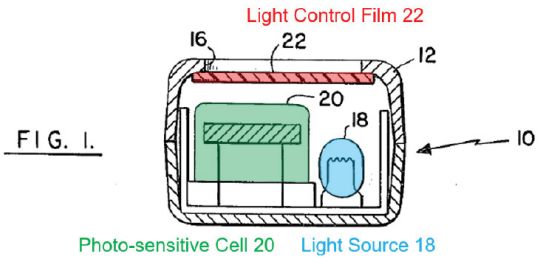
Dr. Anthony's Declaration

61. For example, as shown in FIG. 1 of Benjamin, reproduced below, "***a light control film 22 is mounted*** within the casing 12 to extend across the window 16" such that "the light emitted from the light source 18 ***passes through the light control film 22*** to the field to be measured and light is reflected from this field back through the light control film 22 to the photo-sensitive cell 20." *Id.*, 2:26-61. In further detail, the film "is known in the art and is commercially available," and "***has the effect of collimating the light passing therethrough [sic] to thereby make the photo-sensitive cell 20 more nearly dependent only upon the light beam directly reflected from the field being measured.***" *Id.*

62. One of ordinary skill would have been motivated by the disclosure of Benjamin to modify Diab's sensor to include a light control film in place of Diab's scattering medium. Indeed, one of ordinary skill would have been motivated and would have found it obvious to combine Diab and Benjamin to provide an optical physiological sensor that reduces variations in the amount of light detected by the photodetectors of the sensor in order to "collimat[e] the light emitted from the light source and reflected back to the photo-sensitive cell," which would lead to a more consistent and accurate measurement of blood oxygen saturation. *Id.*; *see, e.g.*, APPLE-1007, Abstract.

APPLE-1003, ¶¶ 58-60.

Benjamin



APPLE-1007, FIG. 1 (annotated).

In accordance with a feature of the invention, a light control film **22** is mounted within the casing **12** to extend across the window **16.** Accordingly, the light emitted from the light source **18** passes through the light control film **22** to the field to be measured and light is reflected from this field back through the light control film **22** to the photo-sensitive cell **20.** The light control film **22** is made of a 0.030 inch thick clear cellulose acetate butyrate film. Light control film of this type is known in the art and is commercially available, such as from the Edmund Scientific Company. The light control film **22** has the effect of collimating the light passing therethrough to thereby make the photo-sensitive cell **20** more nearly dependent only upon the light beam directly reflected from the field being measured. Thus, the amount of scattered light reaching the photo-sensitive cell is made closer to constant. This serves to hold the operating point of the photo-sensitive cell more constant which improves the accuracy of the measurement.

APPLE-1007, 2:42-61.

FISH.

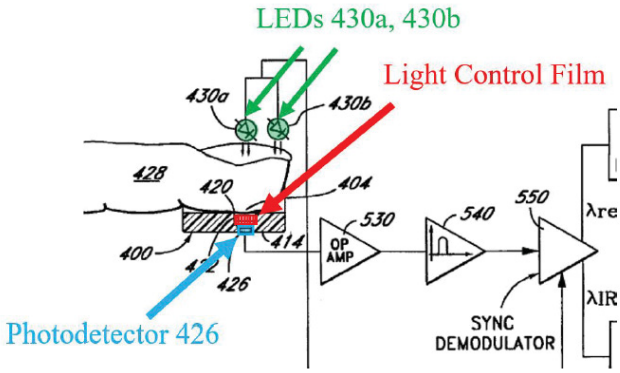
Light Control Film Improves Diab's Consistency and Accuracy

Dr. Anthony's Declaration

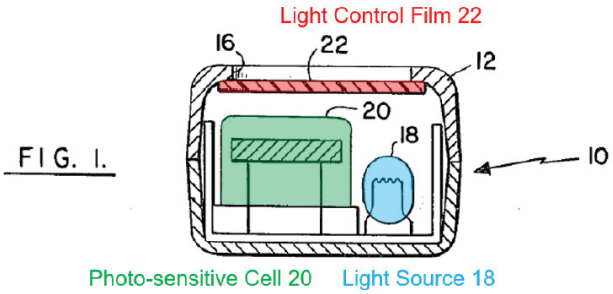
64. One of ordinary skill would have understood that the beneficial effects of a particular component as used within Benjamin's system would have applied in a predictable manner to Diab's system. For example, both Diab and Benjamin describe photoplethysmograph (PPG) devices and relate to reducing the effects of noise in detected signals resulting from describes a pulse oximeter, which measures oxygen saturation level (SpO_2) and is also a PPG. APPLE-1006, 17:62-18:22. Diab's device can measure the change in the volume of arterial blood with each pulse beat, and while it is more complex than Benjamin's device, it operates according to similar principles. Thus, one of ordinary skill would have understood that Benjamin's teachings as applied to its own system and resulting advantages would have been clearly applicable to Diab as well. One of ordinary skill would would have been motivated to use the well-known component of a light control film to cause Diab's pulse oximeter to include such features to achieve the predictable benefits offered by Benjamin's description of the same. *Id.*; *see, e.g.*, APPLE-1006, 3:63-4:13; APPLE-1007, 1:5-49, 2:26-61. Indeed, one of ordinary skill would have had a reasonable expectation of success in making this modification, and would have reasonably expected to reap benefits of collimating light on its way to the detector "to thereby make the photo-sensitive cell…more nearly dependent only upon the light beam directly reflected from the field being measured." APPLE-1007, 2:42-61. Diab and Benjamin describe the same types of

APPLE-1003, ¶ 64.

Diab (top) and Benjamin (bottom)



APPLE-1006, FIG. 24 (annotated).



APPLE-1007, FIG. 1 (annotated).

Melby Describes Details of Light Control Film

Dr. Anthony's Declaration

44. Melby, a patent from nearly 30 years ago and almost 6 years prior to the Critical Date, assigned to the Minnesota Mining and Manufacturing Company (3M), discloses a light control film, or a "louvered plastic film." APPLE-1008,

APPLE-1003, ¶ 44.

70. As shown in FIGS. 1 and 2 (reproduced below), Melby explains the mechanism by which the louvers control light. Melby teaches that "*a louvered plastic film has a plurality of clear regions separated by louvers*," where each louver has "a central region with a relatively high coefficient of extinction and outer regions, adjacent said clear regions, having relatively low coefficients of extinction." APPLE-1008, 3:1-8.

APPLE-1003, ¶ 70.

this type is known in the art and is commercially available"). A POSITA would have been motivated to make this modification to further increase the directionality of the light signal received in the combined device, thereby leading to a device that is less susceptible to the influence of ambient light and thus provides more accurate readings. *Id.*, 3:65-4:10.

APPLE-1003, ¶ 69.

Melby

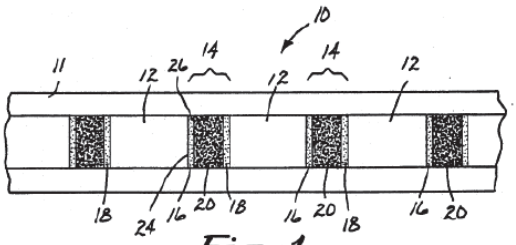


Fig. 1

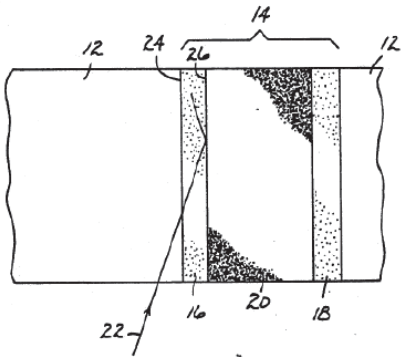


Fig. 2

APPLE-1008, FIGS. 1, 2.

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The POSITA would have Incorporated Light Control Film into Diab

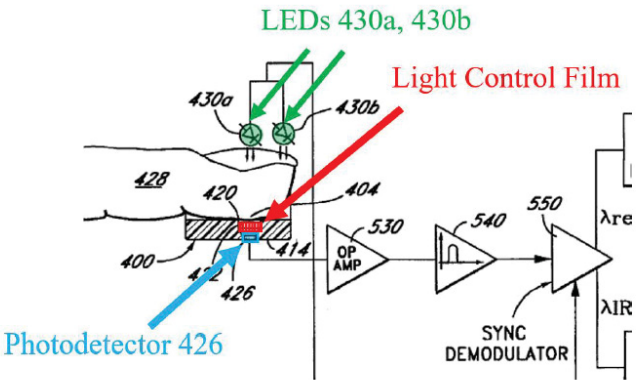
Dr. Anthony's Declaration

73. Thus, one of ordinary skill viewing the disclosure of Diab/Benjamin would have recognized that Melby's film could be used in the Diab/Benjamin device to control light such that only light originating from the direction of the light emitters reaches the detector. APPLE-1007, 2:42-61; APPLE-1008, Abstract, 3:1-9, 3:46-4:52. One of ordinary skill would have found it obvious to look to Melby for details regarding the implementation of the light control film. *Id.* Indeed, Benjamin teaches that light control film was "known in the art and…commercially available." APPLE-1007, 2:42-61. Incorporating Melby's details regarding the implementation of Benjamin's light control film would have been obvious to one of ordinary skill because doing so entails the use of known solutions to improve similar systems and methods in the same way. One of this type is known in the art and is commercially available"). A POSITA would have been motivated to make this modification to further increase the directionality of the light signal received in the combined device, thereby leading to a device that is less susceptible to the influence of ambient light and thus provides more accurate readings. *Id.*, 3:65-4:10.

APPLE-1003, ¶¶ 72-73.

APPLE-1003, ¶ 69.

Diab



APPLE-1006, FIG. 24
(as annotated at APPLE-1003, ¶ 74).

Issue 1B

Incorporation of Light Control Film
is Consistent with Diab's Teachings

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Diab Seeks Improved Optical Signal-to-Noise Ratio

Patent Owner's Response

In combining Diab and Benjamin, the Board accepted Apple's assertion that the combination provides "an optical physiological sensor that reduces variations in the amount of light detected by the photodetectors of the sensor in order to collimate the light emitted from the light source and reflected back to the photo-sensitive cell." Institution at 18. However, neither Apple nor the Board explains why a POSITA explicitly seeking to scatter light as the critical teaching of Diab would make modifications to eliminate this core feature and cause the light to be uniform in direction.

Paper 12 (POR), 30-31.

Specifically, were a POSITA to replace the scattering medium in Diab with the light control film of Benjamin, the modified optical probe would no longer scatter light across the photodetector to decrease the effect of motion artifacts. *See* EX1006 at 3:4-8, 20:9-12; EX2001 ¶ 75. To the extent Apple suggests Diab and

Paper 12 (POR), 31.

Diab

In one preferred embodiment of the present invention, the chamber is filled with a scattering medium. The scattering medium is advantageously formed of a conformable plastic or a highly compressible material so that the material on which measurements are to be made is not compressed upon contact with the scattering medium. The scattering medium helps to minimize the effects of local artifacts and perturbations within the material. Thus, an increased optical signal-to-noise ratio is observed. The scattering medium also improves the optical coupling with the material.

In another preferred embodiment, the scattering medium is interposed between the light source and the material, and in yet another preferred embodiment, the scattering medium is interposed between the light source and the material as well as between the material and the photodetector. Each of these embodiments results in an improved optical signal-to-noise ratio.

APPLE-1006, 3:63-4:12.

FISH.

Diab Discloses Use of a Scattering Medium at its LEDs

Petitioner's Reply

direction." *See id.*, 30-31. Masimo argues that this purportedly "critical teaching" of Diab is its "scattering medium…interposed between the" user tissue "and the photodetector," which the Petition proposes replacing in the combination. *See id.*, 29-31; APPLE-1006, 4:8-10. But Diab explicitly discloses examples in which the scattering medium is "interposed" only "between the light source and the" the user tissue, and describes these examples as "result[ing] in an improved optical signal-to noise ratio." APPLE-1006, 4:6-12. Accordingly, based on Diab's explicit disclosure, Masimo's argument fails.

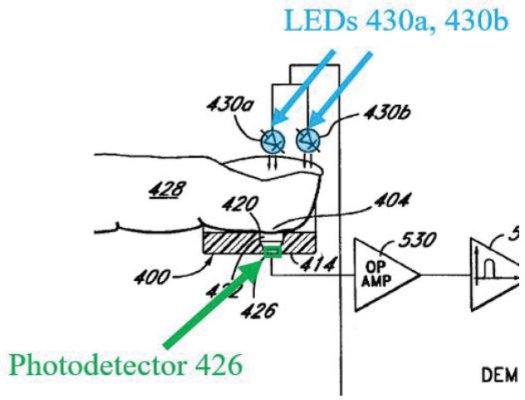
Paper 17 (Pet. Reply), 1-2.

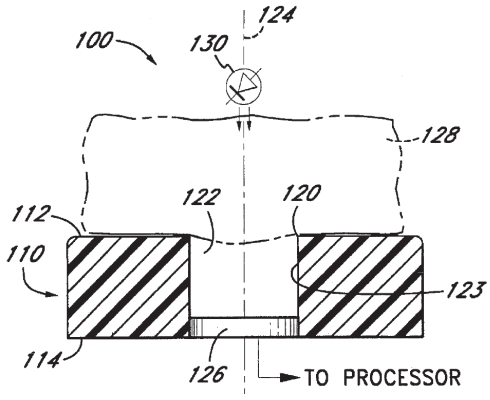
Diab

In another preferred embodiment, the scattering medium is interposed between the light source and the material, and in yet another preferred embodiment, the scattering medium is interposed between the light source and the material as well as between the material and the photodetector. Each of these embodiments results in an improved optical signal-to-noise ratio.

APPLE-1006, 4:6-12.

Diab





APPLE-1006, FIGS. 24 (top, annotated), 4 (bottom).

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Incorporation of Light Control Film Improves Signal-to-Noise Ratio

Dr. Anthony's Declaration

28. The detected signal may include signal and noise from, for example, ambient light or motion induced artifacts. It has been long recognized that noise sources such as stray and ambient light and movement of the subject corrupt the information that is obtained from non-invasive optical biosensors. Motion artifacts arise from kinematic variations, variable mechanical forces, changes in the coupling of the sensor to the subject, local variation in patient anatomy, optical properties of tissue due to geometric realignment or compression, or combinations of these effects.

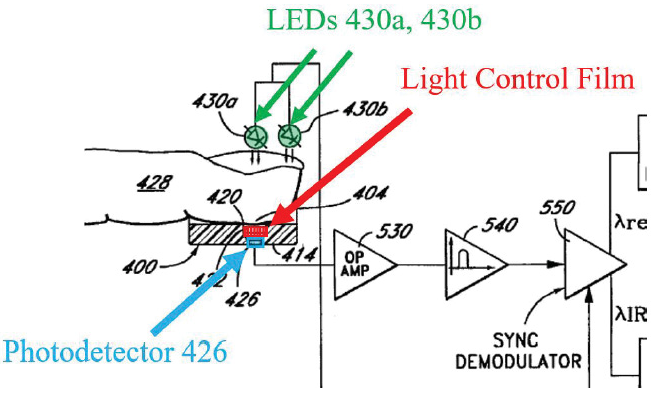
APPLE-1003, ¶ 28.

73. Thus, one of ordinary skill viewing the disclosure of Diab/Benjamin would have recognized that Melby's film could be used in the Diab/Benjamin device to control light such that only light originating from the direction of the light emitters reaches the detector. APPLE-1007, 2:42-61; APPLE-1008, Abstract, this type is known in the art and is commercially available"). A POSITA would have been motivated to make this modification to further increase the directionality of the light signal received in the combined device, thereby leading to a device that is less susceptible to the influence of ambient light and thus provides more accurate readings. *Id.*, 3:65-4:10.

APPLE-1003, ¶ 73.

APPLE-1003, ¶ 69.

Diab



APPLE-1006, FIG. 24
(as annotated at APPLE-1003, ¶ 74).

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Issue 1C

Incorporation of Light Control Film Reduces Noise from Ambient Light

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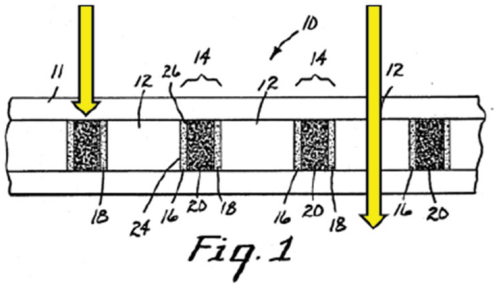
Light Control Film Reduces Ambient Light at Photodetector

Patent Owner's Response

A POSITA would have also understood that the proposed modifications would cause Diab to perform worse. EX2001 ¶ 80. For example, the combination of Diab's absorbing chamber wall and Melby's light control film would reduce the total light received by the photodetector 426. *Id.* As indicated by the arrows below, the carbon black layers absorb at least some of the light approaching Melby's film from a direction that would pass through the transparent layers 12. *Id.* Adding Melby's film to Diab would make the signal more difficult to interpret. *Id.*

Paper 12 (POR), 35.



APPLE-1008 (Melby), FIG. 1 (as annotated at POR, 36)

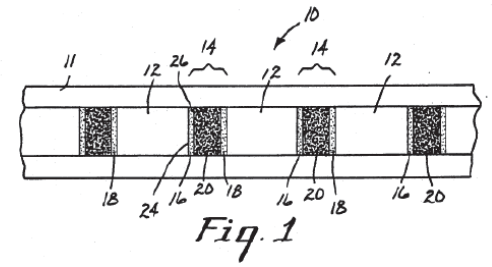
Light Control Film Reduces Noise from Ambient Light

Petitioner's Reply

Masimo argues that "the combination of Diab's absorbing chamber wall and Melby's light control film would reduce the total light received by the photodetector 426" and "make the signal more difficult to interpret." POR, 35. As explained in the Petition, in the combination, the light control film blocks ambient light (*i.e.*, light that has not passed through the tissue). Petition, 19-29. This ambient light is noise not signal, because it cannot be used to calculate oxygen saturation. *See* Petition, 22; APPLE-1006, 17:62-18:22 Thus, even if the "total light received by the photodetector 426" were reduced by the introduction of the light control film, much of the light constituting the reduction would be ambient light, thereby increasing the signal to noise ratio and, contrary to Masimo's argument, making the signal easier to interpret. *See* Petition, 28; APPLE-1008, 3:65-4:10; APPLE-1003, [0069]-[0073]. Accordingly, Masimo's argument fails.

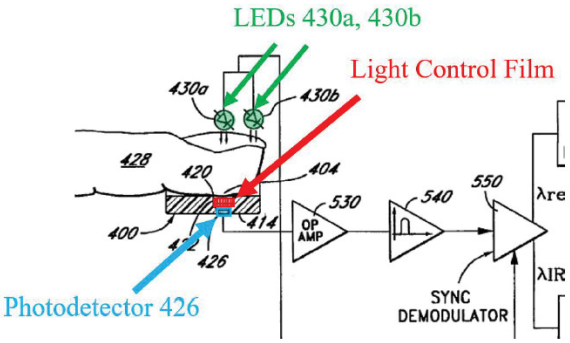
Paper 17 (Pet. Reply), 2.

Melby



APPLE-1008, FIG. 1.

Diab



APPLE-1006, FIG. 24.

FISH.

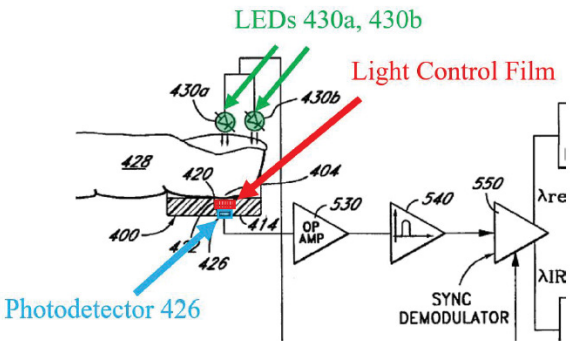
Light Control Film Improves Signal-to-Noise Ratio

Dr. Anthony's Declaration

69. Also in the combination, Melby describes a light control film that can be used with the combined Diab/Benjamin system. In further detail, Melby describes a "***louvered plastic film [that] has louvers*** including central regions with a relatively high coefficient[] of extinction and outer regions with relatively low coefficients of extinction." APPLE-1008, Abstract. Melby is a 3M patent that describes a commercially available louvered light film made of "cellulose acetate butyrate (CAB)". *See, e.g.*, APPLE-1007, 2:42-57 (describing light control film made of "cellulose acetate butyrate film" and stating that "[l]ight control film of this type is known in the art and is commercially available"). A POSITA would have been motivated to make this modification to further increase the directionality of the light signal received in the combined device, thereby leading to a device that is less susceptible to the influence of ambient light and thus provides more accurate readings. *Id.*, 3:65-4:10.

APPLE-1003, ¶ 69.

Diab



APPLE-1006, FIG. 24
(as annotated at APPLE-1003, ¶ 74).

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Issue 1D

Regulatory Approval Processes would not have Dissuaded the POSITA from Improving Diab

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Masimo's Relied-Upon Reference is Irrelevant

Patent Owner's Response

Combining Melby's light control film with Diab's sensor introduces a component in Diab's light path. EX2001 ¶ 86.

FDA Guidance explains that a pulse oximeter system "that has undergone a significant change or modification *(from its currently cleared configuration)* that could significantly affect the safety or effectiveness of the device" requires a new 510(k). EX2005 at 5. Examples of significant modifications include:

- significant electro-optical sensor modifications (e.g., ***component*** or bandage material ***in the light path***, extensive re-design where a device is miniaturized); or
- significant SpO_2 algorithm modifications.

Id.

Without a compelling motivation to modify Diab's optical system, a POSITA would not risk the costly and time-consuming drawbacks of updating the calibration curve and preparing a new 510(k) submission. EX2001 ¶ 87.

Paper 12 (POR), 37-38.

Ex. 2005

Pulse Oximeters - Premarket Notification Submissions [510(k)s]
Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 4, 2013

This document supersedes Non-invasive Pulse Oximeter General Guidance Document, September 7, 1992
The draft of this document was issued on July 19, 2007.

For questions regarding this document contact Neel Patel at 301-796-5580 or neel.patel@fda.hhs.gov.

Center for Devices and Radiological Health
CDRH

Ex. 2005, 1.

FISH.

Masimo's Relied-Upon Reference is Irrelevant

Petitioner's Reply

Masimo argues that the Diab-Melby-Benjamin combination would not have led to predictable results because "the FDA considers introducing a component in the light path a significant modification that should undergo further regulatory review." POR, 37-38. For support, Masimo and cites to a document (Ex-2005) it refers to as "FDA Guidance," which is dated "March 4, 2013." *See* Ex-2005, 1; POR, Exhibit List (confirming March 2013 date for Ex-2005). As noted in the Petition, the '994 patent claims an earliest priority date of June 18, 1999 (the "Critical Date"). *See* APPLE-1001, Face; Petition, 1. Masimo fails to explain what relevance, if any, this purported FDA Guidance document from ***over a decade after the Critical Date*** of the '994 patent has to the present obviousness analysis.

Paper 17 (Pet. Reply), 2-3.

Ex. 2005

Pulse Oximeters - Premarket Notification Submissions [510(k)s]

Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 4, 2013

Document issued on: March 4, 2013

Ex. 2005, 1 (annotated)

FISH.

Masimo's Relied-Upon Reference is Irrelevant

Petitioner's Reply

Even if the FDA Guidance cited by Masimo were from the relevant timeframe for our present analysis (which they are not), Masimo cites no case law or other authority standing for its proposition that the possibility of burdensome or expensive regulatory processes can dissuade a POSITA from arriving at a claimed invention. *See* POR, 37-38. Petitioner is similarly unaware of any authority endorsing such an approach. And because obtaining regulatory approval is neither a requirement for patentability, nor recited as an element of the present claims, it seems irrelevant to the issue of whether claim 15 is unpatentable.

Paper 17 (Pet. Reply), 3.

Dr. Anthony's Declaration

this type is known in the art and is commercially available"). A POSITA would have been motivated to make this modification to further increase the directionality of the light signal received in the combined device, thereby leading to a device that is less susceptible to the influence of ambient light and thus provides more accurate readings. *Id.*, 3:65-4:10.

APPLE-1003, ¶ 69.

Ex. 2005

Pulse Oximeters - Premarket Notification Submissions [510(k)s]
Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 4, 2013

Ex. 2005, 1.

FISH.

Issue 2

Obviousness over Webster and Melby

FISH.

Issue 2A

Light Control Film Improves Webster's Consistency and Accuracy

FISH.

Webster Recommends Protecting Detectors from Ambient Light

Dr. Anthony's Declaration

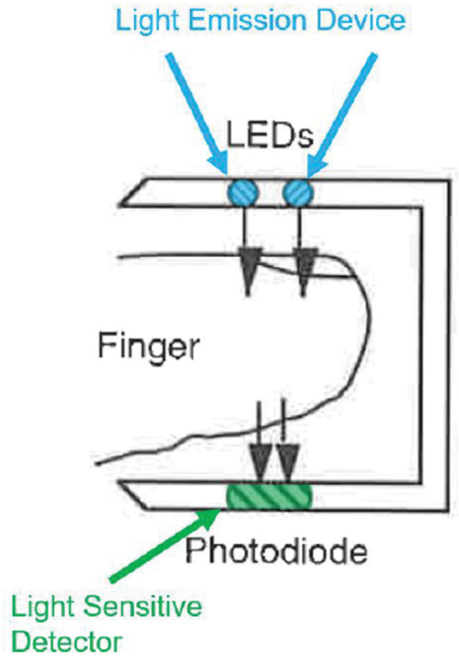
To the extent the preamble is limiting, in the combination, Webster describes devices known as "pulse oximeters," which provide "an empirical measure of arterial saturation." APPLE-1010, 13. These devices operate by shining "light of two wavelengths through a tissue bed such as the finger or earlobe and measures the transmitted light signal." *Id.*

APPLE-1003, ¶ 76.

77. In further detail, and as shown in FIG. 7.1 of Webster, reproduced above, Webster explains that the "probe of a pulse oximeter consists of ***two LEDs*** of selected wavelengths and a detector." APPLE-1010, 86. The LEDs can emit wavelengths of, for example, "***660 nm and 940 nm***," and "the ***detector*** used is a photodiode." *Id.* Because light from the LEDs "is partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector," reducing the amount of light that eventually reaches the detector, the assembly "must be protected from the ambient light for the wavelengths to which the photodiode is sensitive." *Id.* Because the pulse oximeter "uses two specific wavelengths, spectral response, or the ***relative response of the device to different wavelengths*** must be considered." *Id.*, 71.

APPLE-1003, ¶ 77.

Webster



APPLE-1010 (Webster), FIG 7.1
(as annotated at APPLE-1003, ¶ 76)

FISH.

27

Melby's Light Control Film Controls Ambient Light

Dr. Anthony's Declaration

94. Webster proposes that, in order to "minimize the effects from light other than the optical signals of interest," "some type of ***light filter***" can be placed over the detector. APPLE-1010, 79.

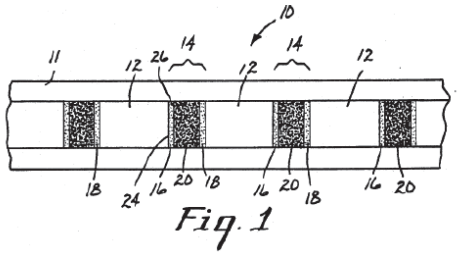
wavelengths to pass through the filter." *Id.* Webster contemplates that in order for the pulse oximeter device to function effectively, "most of the light being transmitted from the LEDs ***must not reach the photodiode unless it has passed through tissue containing arterial blood***." *Id.*

APPLE-1003, ¶ 94.

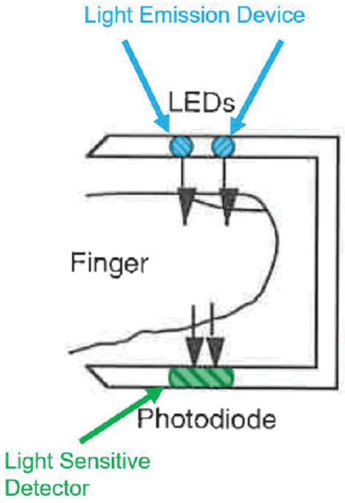
100. Thus, one of ordinary skill viewing the disclosure of Webster would have recognized that Melby's film could be used in the Webster device as the "light filter" to control light such that only light originating from the direction of the light emitters reaches the detector. APPLE-1010, 79.

APPLE-1003, ¶ 100.

Melby (top) and Webster (bottom)



APPLE-1008, FIG. 1.



APPLE-1010, FIG 7.1.

FISH.

Melby's Light Control Film Improves Webster's Signal-to-Noise Ratio

Dr. Anthony's Declaration

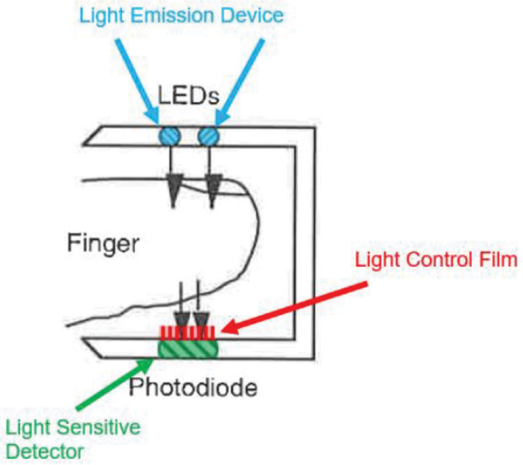
101. One of ordinary skill would have been motivated by Melby to include a light control film in the sensor described by Webster. Indeed, one of ordinary skill would have been motivated and would have found it obvious to combine Webster and Melby to provide a pulse oximeter that "minimize[s] errors" by limiting "the light reaching the photodiode to that which has traveled through tissue containing arterial blood." APPLE-1010, 79.

APPLE-1003, ¶ 101.

104. Indeed, one of ordinary skill would have understood that a light control film placed over the detector could thus accept light from the light emission device from a particular direction based on the angle of the louvers within the light control film. *Id.* As described above, the light from pulse oximeter emitters is directed at, for example, "the tissue of the finger" of a subject (APPLE-1010, 87) and "travels through the tissue, and is detected at the photodiode." *Id.*, 88. Thus,

APPLE-1003, ¶ 104.

Combination of Webster and Melby



APPLE-1010, FIG. 7.1
(as annotated APPLE-1003, ¶ 103).

FISH.

Issue 2B

Incorporation of Light Control Film is Consistent with Webster's Teachings

FISH.

Webster Proposes Limiting Unwanted Light Incident on the Detector

Patent Owner's Response

Apple argues a POSITA would have recognized that Melby's film, which is used with automobile control panels (EX1008 at 2:9-12), "could be used in the Webster device as the 'light filter' to control light such that only light originating from the direction of the light emitters reaches the detector." Pet. at 42. Accordingly, Apple conflates Webster's wavelength filter, one component, with the optical effect of the barrier, a different component. Thus, a POSITA would have had no motivation to position Melby's light film ***over*** the detector, which like Webster's barrier blocks light from reaching the detector.

Accordingly, Webster's light impervious barriers—***not*** Webster's light filters—"limit the light reaching the photodiode to that which has traveled through tissue containing arterial blood." EX1010 at 79; EX2001 ¶¶ 94-99. And Webster's light impervious barriers are not ***over*** the detector, putting them over the detector would make the detector non-functional.

Paper 12 (POR), 37-38.

Dr. Anthony's Declaration

93. Webster describes the importance of preventing light other than the actual signals of interest (e.g., light that has passed through the tissue carrying pulsing blood) from reaching the detector. APPLE-1010, 95, FIG. 7.13.

94. Webster proposes that, in order to "minimize the effects from light other than the optical signals of interest," "some type of ***light filter***" can be placed over the detector. APPLE-1010, 79. Using a light filter allows "light of wavelengths of interest to pass through the filter but does not allow light of other wavelengths to pass through the filter." *Id.* Webster contemplates that in order for the pulse oximeter device to function effectively, "most of the light being transmitted from the LEDs ***must not reach the photodiode unless it has passed through tissue containing arterial blood***." *Id.* Indeed, Webster warns that in order 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***" and suggests the use of "***[l]ight 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." *Id.*

APPLE-1003, ¶¶ 93-94.

Webster Proposes Decreasing Angle of Incidence to the Detector

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.

6.3.2 Optical interference

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.

There are two types of optical interference that may cause problems for the photodiode. The first is excessive ambient light.

APPLE-1010 (Webster), 79
(cited and quoted at Petition, 39).

See also Pet. Reply, 4-5.

FISH.

Melby's Light Control Film Decreases Angle of Incidence to the Detector

Petitioner's Reply

42-46 (Sections C.1, C.2). But the Petition merely relies on the explicit disclosure of Webster. *See* Petition, 39. For example, Webster states that "it is important to minimize the effects from light other than the optical signals of interest." APPLE-1010, 79. "One way to minimize unwanted light incident upon the detector is to place ***some type of light filter*** over the detector." *Id.* Webster describes that one type of "unwanted light" that should be minimized is "ambient light"—which is the type of light the light control film of Melby is designed to minimize. *See id.*; APPLE-1008, Abstract, 3:1-8, 3:46-4:25, FIGS. 1-2; Petition, 39-44; APPLE-1003, [0092]-[0105].

Masimo's arguments appear to characterize Webster as requiring a wavelength filter, when in fact Webster's disclosure provides this only as one example mechanism for limiting unwanted light. *See* APPLE-1010, 79. Webster even makes clear that it requires no such thing, stating that such wavelength filters "do not appear to be used much in actual pulse oximetry designs." *Id.* Thus, Masimo's arguments mischaracterize Webster's disclosure and fail to address the Petition arguments.

Pet. Reply, 4-5.

Dr. Anthony's Declaration

104. Indeed, one of ordinary skill would have understood that a light control film placed over the detector could thus accept light from the light emission device from a particular direction based on the angle of the louvers within the light control film. *Id.* As described above, the light from pulse oximeter emitters is directed at, for example, "the tissue of the finger" of a subject (APPLE-1010, 87) and "travels through the tissue, and is detected at the photodiode." *Id.*, 88. Thus, in the combination, one of ordinary skill would have understood Webster to render obvious light that originated from a general direction of the light emission devices, transmitted through body tissue carrying pulsing blood. In the combination, one of ordinary skill would have understood the light control film to restrict the amount of light that reaches the detector from a particular direction, and therefore that the louvers accept the light when the sensor is properly applied to the patient's body.

APPLE-1003, ¶ 104.

FISH.

Issue 3

Obviousness over Fine

FISH.

Fine's Complexity and Price are Irrelevant

Petitioner's Reply

Masimo argues that "Fine's expensive and complex fetal sensor design would not form the basis for a POSITA looking to design a pulse oximetry sensor." POR, 47 (Section C.1). But regardless of how "complex" or "expensive" Fine's invention would be to implement, Fine's disclosure is nonetheless prior art with respect to the '994 patent. *See Raytheon v. General Electric,* 993 F. 3d 1374, 1380 (Fed. Cir. 2021) (A reference "is prior art for all that it teaches.") (quoting *Beckman Instruments v. LKB Produkter*, 892 F.2d 1547, 1551 (Fed. Cir. 1989)). Masimo does not cite, and Petitioner is not aware of, any authority for disqualifying a prior art reference from an obviousness analysis due to its complexity or the cost to implement the invention it describes. Accordingly, these arguments fail.

Pet. Reply, 5.

FISH.

Fine's Optical Fiber Bundles Teach the Claimed Louvers

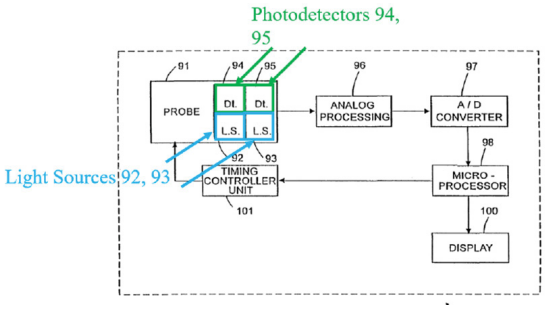
Petition

Fine describes sensor "for optical blood oximetry" that uses "two point-like light emitters positioned in the center of the device" and in proximity to "annular detector terminals" that lead to detectors such as "photodiodes." APPLE-1009, Abstract.

Fine's sensor is applied to a subject's skin and illuminates tissue "via the light emitting terminal by the two light sources" such that the light is "absorbed and partially reflected by the tissue and the pulsatile changes of the light absorption" within the portion of the tissue that is illuminated. APPLE-1009, 16:17-26. The intensities of integral light signals received by the two light detector terminals can be used to determine "a degree of attenuation of the light" within the tissue and parameters such as "the oxygen saturation of the blood in the tissue." *Id.*, 16:26-30. Fine uses optical fiber bundles that "constitute first and second detector terminals" for the sensor to direct the light to the detectors. APPLE-1009, 16:31-17:5. The oblique cut of the ends of the fibers define the scope of the direction of light (annotated in yellow) that will reach the detectors at the other end of the fibers. APPLE-1009, 17:21-18:7, 18:7-18; APPLE-1003, [0107]-[0108]

Petition, 45-46.

Fine



APPLE-1009, FIG. 7
(as annotated at Petition, 45)

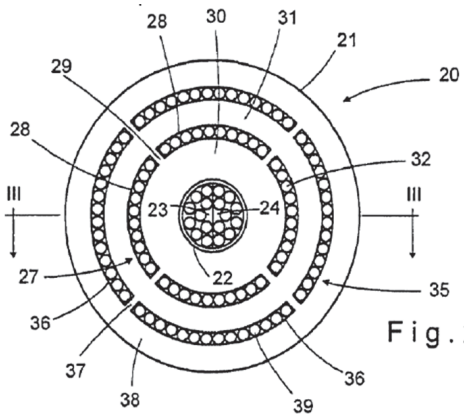


Fig. 2

APPLE-1009, FIG. 2.

FISH.

Fine's Optical Fiber Bundles Teach the Claimed Louvers

Petitioner's Reply

As explained at length in the Petition, "Fine's fiber bundles 63 and 64 teach a plurality of louvers positioned over its detector that accept light from the LEDs originating from the LEDs through tissue." *See* APPLE-1009, 16:31-17:5; Petition, 54; APPLE-1003, [0126]. The Petition explains that each fiber in the bundles "terminate[s] with an oblique cut." APPLE-1009, 17:14-18; Petition, 54. Due to the oblique cut on the end of the fiber, "the specular reflection and shunted light which mostly come to the 30 surface 72 from left of the ray 74 will not be perceived by the detector," while light arriving from the reflective deep layers of the tissue in directions substantially perpendicular to surface 71 in a rather wide area confined between rays 74 and 75" will be perceived by the detector. *See* APPLE-1009, 17:28-18:1; Petition, 55-56; APPLE-1003, [0128]. This is shown in the following annotated FIG. 5 from Fine included in the Petition:

Pet. Reply, 6.

Fine

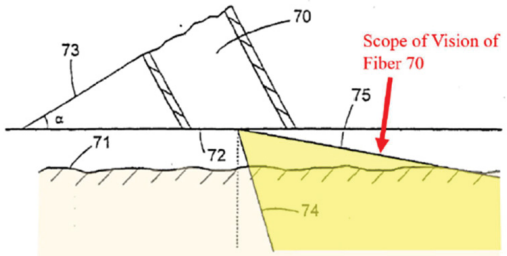


Fig. 5

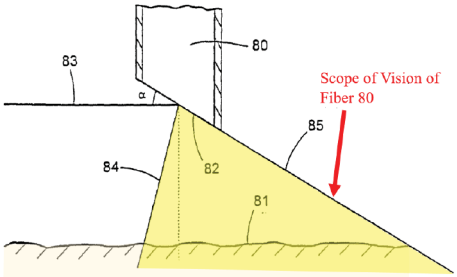


Fig. 6

APPLE-1009, FIGS. 5, 6
(as annotated at Petition, 56, 72)

FISH.

Fine's Optical Fiber Bundles Teach the Claimed Louvers

Dr. Anthony's Declaration

130. One of ordinary skill would have understood that each of Fine's fibers in its fiber optic bundle is connected to its detectors, and thus is positioned over a light detector of Fine's probe. Indeed, one of ordinary skill would have recognized that each of the separate fibers within the fiber optic bundle 57 acts as a louver positioned over a light detector of Fine's probe. For example, one of ordinary skill would have understood fibers 70 and 80 to teach separate louvers because the walls of the fibers serve to direct light and control the scope of vision of the fibers.

APPLE-1003, ¶ 130.

Fine

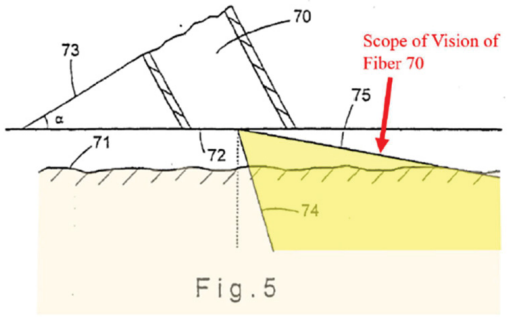


Fig. 5

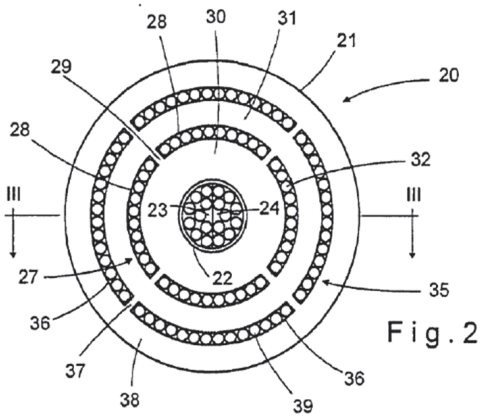


Fig. 2

APPLE-1009, FIGS. 2, 5 (annotated).

FISH.

Issue 4

Obviousness over Fine, Benjamin, and Melby

FISH.

Masimo Mischaracterizes the Proposed Combination

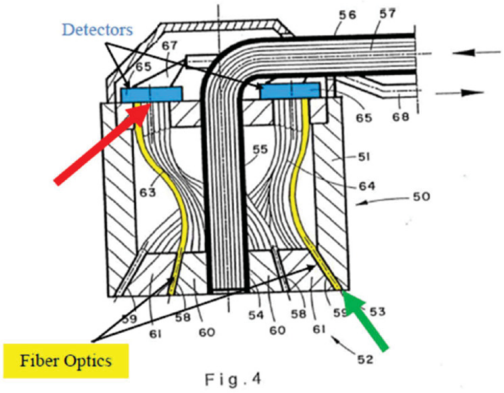
Petitioner's Reply

Masimo argues that the Petition proposes "implement[ing] a light control film over Fine's detectors 65 at the termination of the optical fibers 63, 64", and indicates this supposed location of the light control film with a red arrow in the following annotated FIG. 4 from Fine in the POR. POR, 53; *see* APPLE-1038, 53:5-56-14:

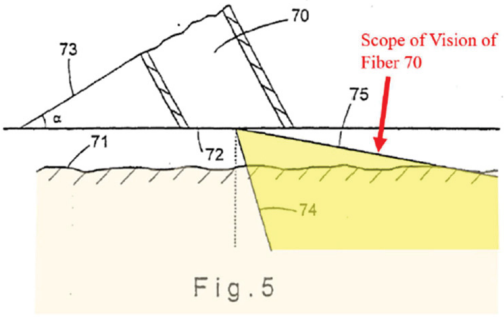
In fact, the Petition proposes incorporating the light control film not at the "termination" of the fibers as Masimo states, but at the origination side of the fiber (i.e., the green arrow in the above figure). *See* Petition, 67. Specifically, the Petition states that "a POSITA would have understood that the ***fibers could thus accept light*** from the light emission device from a particular direction ***based on the angle of the louvers within the light control film***." *Id.* Thus, in the combination, the light control film is implemented at the originating side of the fibers (*i.e.*, where the fibers "accept" light), not at the "termination" of the fibers near the detector as Masimo argues. *Id.*

Pet. Reply, 8-9.

Fine



APPLE-1009, FIG. 4
(as annotated at POR, 53).



APPLE-1009, FIG. 5 (annotated).

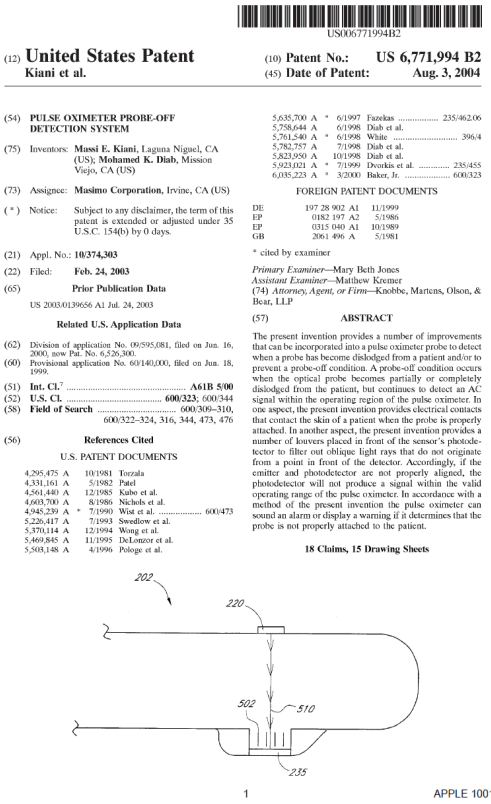
40

FISH.

Overview of the ’994 Patent

FISH.

’994 Patent Overview



US006771994B2

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

(10) **Patent No.: US 6,771,994 B2**
(45) **Date of Patent: Aug. 3, 2004**

(54) **PULSE OXIMETER PROBE-OFF DETECTION SYSTEM**

(75) Inventors: **Massi E. Kiani**, Laguna Niguel, CA (US); **Mohamed K. Diab**, Mission Viejo, 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.

(21) Appl. No.: **10/374,303**

(22) Filed: **Feb. 24, 2003**

(65) **Prior Publication Data**

US 2003/0139656 A1 Jul. 24, 2003

Related U.S. Application Data

(62) Division of application No. 09/595,081, filed on Jun. 16, 2000, now Pat. No. 6,526,300.
(60) Provisional application No. 60/140,000, filed on Jun. 18, 1999.

(51) **Int. Cl.**[7] **A61B 5/00**
(52) **U.S. Cl.** **600/323**; 600/344
(58) **Field of Search** 600/309–310, 600/322–324, 316, 344, 473, 476

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* cited by examiner

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(57) **ABSTRACT**

The present invention provides a number of improvements that can be incorporated into a pulse oximeter probe to detect when a probe has become dislodged from a patient and/or to prevent a probe-off condition. A probe-off condition occurs when the optical probe becomes partially or completely dislodged from the patient, but continues to detect an AC signal within the operating region of the pulse oximeter. In one aspect, the present invention provides electrical contacts that contact the skin of a patient when the probe is properly attached. In another aspect, the present invention provides a number of louvers placed in front of the sensor's photodetector to filter out oblique light rays that do not originate from a point in front of the detector. Accordingly, if the emitter and photodetector are not properly aligned, the photodetector will not produce a signal within the valid operating range of the pulse oximeter. In accordance with a method of the present invention the pulse oximeter can sound an alarm or display a warning if it determines that the probe is not properly attached to the patient.

18 Claims, 15 Drawing Sheets

1 APPLE 1001

IPR2020-01526, APPLE-1001
(U.S. Patent No. 6,771,994)(“’994 Patent”).

- The ’994 Patent’s earliest effective filing date is June 18, 1999.
- The ’994 Patent includes 18 claims, of which claims 1, 9, 15, and 16 are independent.
- Independent claim 15 recites:

“**A sensor** which generates at least first and second intensity signals from a light-sensitive detector which detects light of at least first and second wavelengths transmitted through body tissue carrying pulsing blood; the sensor comprising: … **a plurality of louvers positioned over the light sensitive detector** ….”

’994 Patent: Challenged Claim 15

15. A sensor which generates at least first and second intensity signals from a light-sensitive detector which detects light of at least first and second wavelengths transmitted through body tissue carrying pulsing blood; the sensor comprising:

at least one light emission device;

a light sensitive detector; and

a plurality of louvers positioned over the light sensitive detector to accept light from the at least one light emission device originating from a general direction of the at least one light emission device and then transmitting through body tissue carrying pulsing blood, wherein the louvers accept the light when the sensor is properly applied to tissue of a patient.

IPR2020-01526, APPLE-1001, 8:21-36 (independent claim 1).

FISH.

’994 Patent: Pulse Oximetry Sensor

Dr. Anthony’s Declaration

30. The ’994 Patent relates to a “pulse oximetry monitor (pulse oximeter).” APPLE-1001, 1:44-46. Specifically, the ’994 Patent is directed to a pulse oximetry sensor that includes a first LED, a second LED, and a photodetector, as shown in FIG. 1 (reproduced below). APPLE-1001, 3:21-55, FIG. 1.

31. The two LEDs are “preferably configured to produce different wavelengths of light.” *Id.* Pulse oximetry “relies on the differential light absorption of oxygenated hemoglobin, HbO_2, and deoxygenated hemoglobin, Hb” that is measured using two different wavelengths of light. *Id.*, 3:3-20. For example, blood oxygen saturation measurements can be “based upon a ratio of the time-varying or AC portion” of the detected signals. *Id.*

32. The ’994 Patent describes and depicts its photodetector as being placed opposite the light emitters to detect transmitted light as it emerges from the user’s body tissue. APPLE-1001, 1:41-43 (describing the configuration of known pulse oximetry probes as positioning the detector “opposite the LED”), 4:19-25 (“the emitters located within the probe are spaced opposite the detector assembly 235…such that the light from the emitters passes…through the finger 250 and is incident upon the detector assembly 235”), FIGS. 2A-B, 4, 5A-B.

IPR2020-01526, APPLE-1003, ¶¶ 30-32.

’994 Patent

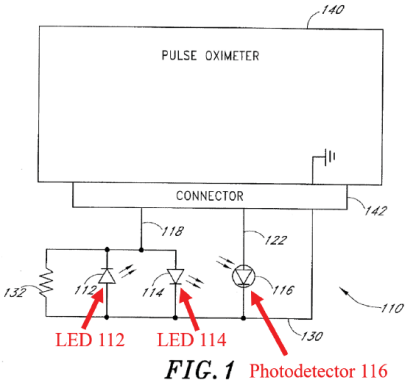

FIG. 1

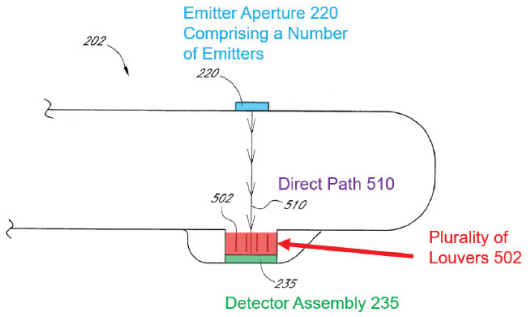

FIG.5B

IPR2020-01526, APPLE-1001, FIGS. 1, 5B (as annotated at APPLE-1003, ¶¶ 30, 33).

’994 Patent: “a plurality of louvers”

Dr. Anthony’s Declaration

32. The ’994 Patent describes and depicts its photodetector as being placed opposite the light emitters to detect transmitted light as it emerges from the user’s body tissue. APPLE-1001, 1:41-43 (describing the configuration of known pulse oximetry probes as positioning the detector “opposite the LED”), 4:19-25 (“the emitters located within the probe are spaced opposite the detector assembly 235…such that the light from the emitters passes…through the finger 250 and is incident upon the detector assembly 235”), FIGS. 2A-B, 4, 5A-B.

33. The ’994 Patent also includes a number of louvers placed in front of the sensor’s photodetector. *Id.*, 6:24-41. The louvers “block light rays travelling along an oblique path 410 (i.e., light that does not originate from in front of the detector assembly 235….)” *Id.* By blocking light travelling along an oblique path, or at an angle, from reaching the detector, the louvers prevent inaccurate reads that can occur when rays of light travelling along the oblique path “generate an AC signal that could be interpreted by the pulse oximeter 140 as a physiological signal” (*id.*) even though the probe is not properly attached, which can lead to missed desaturation events. *Id.*, 4:35-45. The louvers are, “[i]n a preferred embodiment…created from commercially available ‘3M Light Control Film.’” *Id.*, 6:39-41.

IPR2020-01526, APPLE-1003, ¶¶ 32-33.

’994 Patent

FIG. **5**C illustrates a top plan view of a preferred embodiment of this aspect of the present invention. The detector aperture **2**o**3** is formed in a plastic body **504** having slots **506** to hold the louvers **502** in place across the detector aperture **203**. In a preferred embodiment of the present aspect, the louvers **502** can be created from commercially available “3M Light Control Film.”

IPR2020-01526, APPLE-1001, 6:35-41.

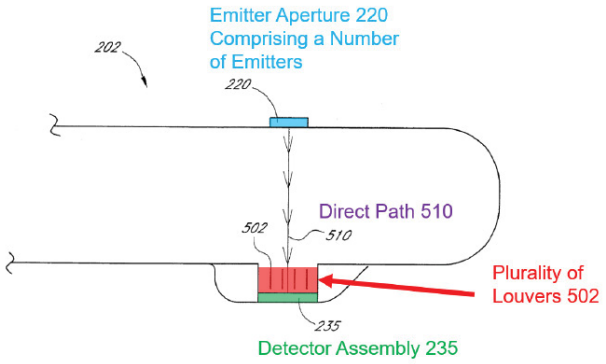

FIG. 5B

IPR2020-01526, APPLE-1001, FIG. 5B
(as annotated at APPLE-1003, ¶ 33).

FISH.

’994 Patent: “a plurality of louvers”

Dr. Anthony’s Declaration

39. In my opinion, one of ordinary skill would have construed this claim limitation as requiring the light sensitive detector to be positioned opposite the at least one light emission device such that the body tissue carrying pulsing blood positioned between the light sensitive detector and the at least one light emission device. This construction is consistent with the specification and figures of the ’994 Patent, which only depict and describe the placement of the body tissue carrying pulsing blood between the at least one light emission device and the light sensitive detector. APPLE-1001, 1:41-43 (the “photodiode is positioned opposite the LED so as to detect the LED transmitted light as it emerges from the [body] tissue.”)

40. Indeed, one of ordinary skill would have understood the plain language of the claim to require such a configuration, as the light that is accepted by the louvers must originate “from a general direction of the at least one light emission device,” and then transmit through the body tissue before “pass[ing] directly through the louvers 502 along a direct path 510.” *Id.*, 6:30-34.

IPR2020-01526, APPLE-1003, ¶¶ 39-40.

’994 Patent

a plurality of louvers positioned over the light sensitive detector to accept light from the at least one light emission device originating from a general direction of the at least one light emission device and then transmitting through body tissue carrying pulsing blood, wherein the louvers accept the light when the sensor is properly applied to tissue of a patient.

IPR2020-01526, APPLE-1001, 8:21-36 (independent claim 1).

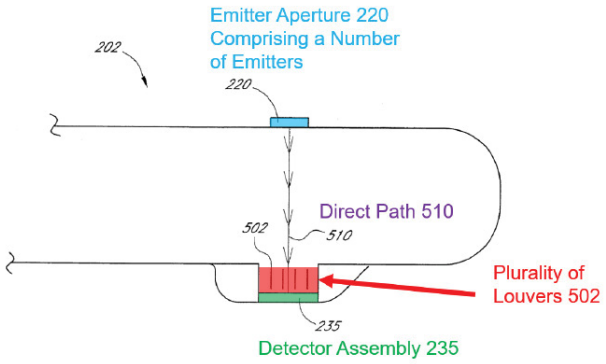

FIG.5B

IPR2020-01526, APPLE-1001, FIG. 5B
(as annotated at APPLE-1003, ¶ 39).

FISH.

Overview of the Instituted Grounds

FISH.

Instituted Grounds

Ground	Basis	Claim
1	Obvious over Diab in view of Benjamin and Melby	15
2	Obvious over Webster in view of Melby	15
3	Obvious over Fine	15
4	Obvious over Fine in view of Benjamin and Melby	15