APPLE INC.,
Petitioner,

v.

OMNI MEDSCI, INC.,
Patent Owner.

Omni MedSci's Demonstrative Exhibits

U.S. Patent No. 9,651,533

Case No.: IPR2019-00916

July 16, 2020

BROOKS KUSHMAN
INTELLECTUAL PROPERTY AND TECHNOLOGY LAW

Apple advances new evidence and argument in Reply

- Petition: Obvious given Carlson's teaching:

> Consequently, a skilled person would have found it obvious to configure Lisogurski to increase the firing rate (frequency) of LEDs as taught by Carlson, given that Carlson teaches that increasing the modulation frequency of the pulsed LEDs improves the signal-to-noise ratio. Ex.1009, [0069]; Ex.1003, ¶¶120-21.

Petition at 39

- Reply: Obvious because increasing pulse rate "generally" increases SNR:

> Dr. MacFarlane admits that increasing the pulse rate of an LED generally increases the signal-to-noise ratio ("SNR") (Ex.1060, 37:17-22). Those admissions are fatal to Omni's assertions in its Response. That is because the Lisogurski device will, in certain physiological situations, increase the pulse rate of an LED and that increase will necessarily increase SNR as well.

Reply at 1

Apple's new Reply evidence and argument is improper

Response at 34

- The ***petition*** must identify, "***with particularity***, . . . ***the grounds*** on which the challenge to each claim is based, ***and the evidence that supports the grounds*** for the challenge to each claim."
  - 35 U.S.C. § 312(a)(3)

- "Petitioner's ***new rationale*** explaining its claim mapping in the Reply ***is not based on a previous position*** Petitioner put forth in the Petition; rather, Petitioner posits a rationale about ***an ordinarily skilled artisan's perspective where none existed previously***."
  - *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-00582, Paper No. 34 at 30-31 (PTAB Aug. 5, 2019) (Informative)

- "Petitioner ***may not submit new evidence or argument*** in reply that it could have presented earlier, *e.g.* to make out a *prima facie* case of unpatentability."
  - Consolidated Trial Practice Guide (Nov. 2019) at 73

Claim limitation missing from the prior art*

- Independent Claims 5 and 13
  - "***the light source configured to increase signal-to-noise ratio*** by increasing a light intensity from at least one of the plurality of semiconductor sources and ***by increasing a pulse rate of at least one of the plurality of semiconductor sources***"

Required functionality: increase SNR

Required way: by increasing an LED's pulse rate

* Omni MedSci's focus on the missing "pulse rate" limitation, is not an admission regarding the other limitations

The Petition does not make a *prima facie* case for the "pulse rate" limitation

- Apple's "pulse rate" limitation argument relies solely on the *express disclosures* of Lisogurski and Carlson
- Neither Lisogurski nor Carlson disclose a device configured to increase SNR by increasing an LED's pulse rate
  - So, not "obvious to configure Lisogurski to increase the firing rate (frequency) of LEDs ***as taught by Carlson***" (Pet. at 39)
- Apple and its expert do **not** rely on:
  - "Inherency"
  - "Common Sense"
  - "General knowledge of those skilled in the art"
  - "Industry trends"

CLAIM CONSTRUCTION

- "light source . . . configured to increase signal-to-noise ratio by . . . increasing a pulse rate
- "pulse rate"

"light source"

Claim limitation

- "***a light source*** comprising a plurality of semiconductor sources that are light emitting diodes . . . ***configured to increase signal-to-noise ratio*** by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources"

Preliminary construction

- "a light source containing two or more light emitting diodes (semiconductor sources), wherein at least ***one of the light emitting diodes is capable of having its pulse rate increased*** to increase a signal-to-noise ratio."

The claims

"***a light source*** comprising a plurality of semiconductor sources that are light emitting diodes . . . ***configured to increase signal-to-noise ratio*** by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources"

1. The Board replaces "***configured to***" **requirement** with an "***is capable of***" **option**

2. The light source must be "configured to" increase SNR
   - The Board's construction:
     - Focuses on ***increasing the pulse rate***; the claim focuses on ***increasing SNR***
     - Removes the ***claimed actor***

The specification

- "The light source is configured to increase signal-to-noise ratio by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources" (Ex. 1001 at 5:11–15.)

- "By use of an active illuminator, a number of advantages may be achieved" including "higher signal-to-noise ratios." (Ex. 1001 at 16:54-58.)

- Use of an "active illuminator" to achieve "higher signal-to-noise ratios" despite "variations due to sunlight" and the "effects of the weather, such as clouds and rain." (US2013/075767, Ex 2120 at 25-26, ¶[0079] inc'd. by ref. at Ex. 1001 at 1:33-37.)

"capable of" is not a substitute for "configured to"

- "[C]onfigured to" has a narrower meaning than "capable of"
  - *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012)
- "[P]lain and ordinary meaning" of "configured to" "requires that the device be actually configured to do the function"
  - *Centripetal Networks, Inc. v. Cisco Sys., Inc.*, No. 2:18-CV-94, 2020 WL 863976, at *7 (E.D. Va. Feb. 20, 2020)
- "[N]one of the general-usage dictionaries consulted by the Court defines 'configure' as to render merely 'capable of.'"
  - *Perdiem Co, LLC v. IndusTrack LLC*, No. 2:15-CV-727-JRG-RSP, 2016 WL 3633627, at *41 (E.D. Tex. July 7, 2016)
- "[T]he claim language 'configured to' requires structure designed to perform the function, not merely structure capable of performing the function."
  - *Cook Grp. Inc. v. Boston Sci. Scimed, Inc.*, IPR2017-00132, Paper No. 71 at 17 (PTAB Nov. 14, 2018)

The light source must be "configured to" increase SNR

- A light source that "sometimes" increases SNR is not "configured to" increase SNR
- Apple's citations to Dr. MacFarlane's testimony focus on increasing pulse rate
  - The testimony merely shows that increasing pulse rate may (or may) not increase SNR
- Apple's petition did not make these "capable of" or "sometimes increase" arguments.

Dr. MacFarlane's testimony:

Q. [by Apple] . . . Dr. MacFarlane, when you increase a pulse rate of an LED, in some circumstances, you'll increase the signal-to-noise ratio; is that correct?

THE WITNESS: Increasing the -- increasing the frequency can ***sometimes*** increase the signal-to-noise ratio.

Q. In general, does increasing the pulse rate of an LED increase the signal-to-noise ratio?

* * *

Q. Do you agree that if you increase the pulse rate of an LED, sometimes the signal-to-noise ratio will increase?

THE WITNESS: ***Sometimes*** increasing the modulation or the pulse rate of a -- of a -- of an LED can increase the signal-to-noise ratio of -- of the measurement.

Ex. 1060 at 82, 84-85

Why increasing pulse rate only "sometimes" increases SNR

Q. Could you give me an example of when increasing the pulse rate of an LED does not increase the signal-to-noise ratio?

A. If -- if increasing the band -- the -- if increasing the pulse rate of the LED changes the signal or moves you into a regime where there's more noise, then the net effect on a signal-to-noise ratio may not be an increase.

Ex. 1060 at 84-85.

Dr. MacFarlane's testimony (con't)

Q. [by Apple] Will you agree that ***in general***, when you increase the pulse rate of an LED, you will increase the signal-to-noise ratio, ***though that won't always happen***?

THE WITNESS: Yes.

* * *

THE WITNESS: [on redirect] . . . The -- the question was -- was -- was poorly phrased, in my opinion. I mis- -- I misunderstood it. The beginning of it was "***in general***"; the end of it was "***not always***," making the question contradictory -- ***those two pieces are contradictory***, and so I answered erroneously. I'd like to change my answer from a yes to a no.

(Ex. 1060, 37:12-17; 81:4-18).

Q. In general, does increasing the pulse rate of an LED increase the signal-to-noise ratio?

THE WITNESS: I can't -- ***I can't say that in general***.

Q. Why not?

A. There may be instances where that doesn't happen.

* * *

Q. Do you agree that if you increase the pulse rate of an LED, typically, the signal-to-noise ratio will increase?

THE WITNESS: ***I neither agree nor disagree with that***.

Q. Do you agree that if you increase the pulse rate of an LED, sometimes the signal-to-noise ratio will increase?

THE WITNESS: ***Sometimes*** increasing the modulation or the pulse rate of a -- of a -- of an LED can increase the signal-to-noise ratio of -- of the measurement.

(*Id.* at 82:8-85:7, objections to form omitted.)

Active voice vs. passive voice

- The claims say:
  - "***the light source*** configured to increase signal-to-noise ratio . . . by increasing a pulse rate of at least one of the plurality of semiconductor sources"
- The specification says:
  - "***The light source*** is configured to increase signal-to-noise ratio by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources." (5:11–15)
  - "[b]y use of ***an active illuminator***, a number of advantages may be achieved" including "higher signal-to-noise ratios." (16:54-58)
- The Board's construction permits, *e.g.*, ***a human***, to increase the pulse rate

"pulse rate"

"pulse rate" = "number of pulses of light per unit of time"

C. "pulse rate"

The parties agreed in district court that a skilled artisan would have understood that "*pulse rate*" means "number of pulses of light per unit of time." The specification describes the pulse repetition rate of a light source and measuring the pulsed output rate using Hertz. Ex.1001, 21:55-59 ("a pulse repetition rate between one kilohertz to about 100 MHz or more"), 25:65-26:1. Hertz is the International System of Units unit for frequency or number of cycles per second. Ex.1003, ¶66. Thus, a skilled person would have understood this term to refer to the number of pulses of light per unit of time. Ex.1003, ¶66.

Petition at 20

Pulse rate examples in '533 specification have non-zero lower limits

- The patent distinguishes "continuous" from "pulsed" light:
  - "the LED provides **the option of continuous wave or pulsed mode** of operation." (Ex. 1001 at 19:67-20:2.)

- "**a pulse repetition rate between one kilohertz** to about 100 MHz or more." (Ex. 1001 at 21:57-59.)

- Modulation frequency between "**0.1-100kHz.**" ('U.S. Pub. 2014/0236021, Ex 2121 at 4, ¶[0045] inc'd. by ref. at Ex. 1001, 1:40-42.)

APPLE FAILED TO MAKE A *PRIMA FACIE* CASE OF OBVIOUSNESS

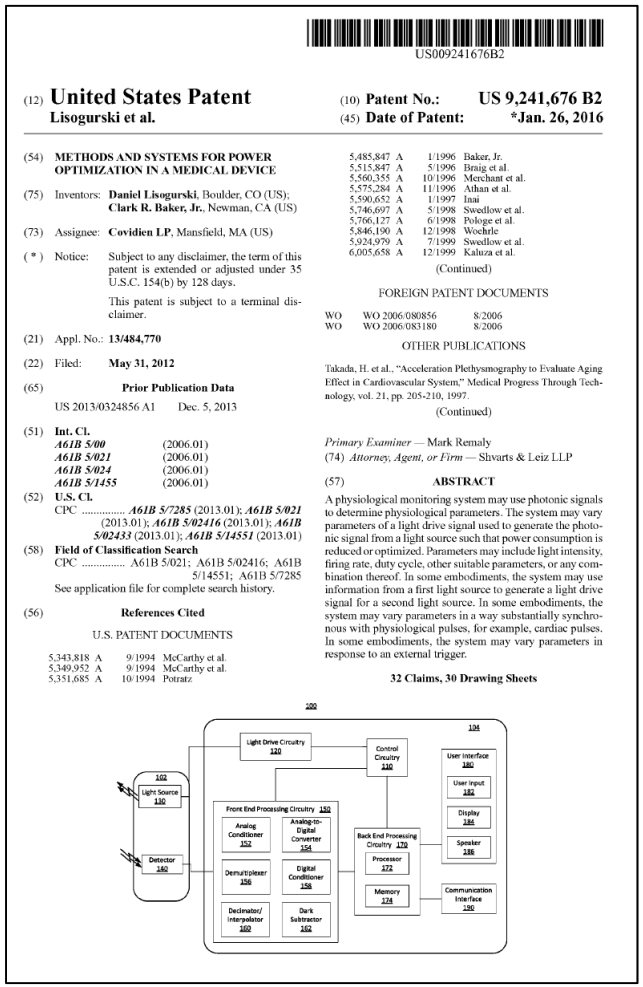
A missing limitation is fatal to the proposed combination

- *Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1345 (Fed. Cir. 2013)
  - Reversing the Board's obviousness determination, finding that neither of the asserted prior art references disclose a claim limitation.

- *Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1378 (Fed. Cir. 2018)
  - Affirming the Board's conclusion of non-obviousness where neither prior art reference disclosed a claim.

- *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.,* 688 F.3d 1342, 1366 (Fed. Cir. 2012)
  - Reversing district court's JMOL of invalidity for obviousness where the prior art references, even if combined, failed to disclose a claim limitation.

Apple's obviousness combination for the independent claims



US009241676B2

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

(10) **Patent No.: US 9,241,676 B2**
(45) **Date of Patent: *Jan. 26, 2016**

(54) **METHODS AND SYSTEMS FOR POWER OPTIMIZATION IN A MEDICAL DEVICE**

(75) Inventors: **Daniel Lisogurski**, Boulder, CO (US); **Clark R. Baker, Jr.**, Newman, CA (US)

(73) Assignee: **Covidien LP**, Mansfield, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 128 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/484,770**

(22) Filed: **May 31, 2012**

(65) **Prior Publication Data**

US 2013/0324856 A1 Dec. 5, 2013

(51) **Int. Cl.**

A61B 5/00	(2006.01)
A61B 5/021	(2006.01)
A61B 5/024	(2006.01)
A61B 5/1455	(2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/7285*** (2013.01); ***A61B 5/021*** (2013.01); ***A61B 5/02416*** (2013.01); ***A61B 5/02433*** (2013.01); ***A61B 5/14551*** (2013.01)

(58) **Field of Classification Search**
CPC A61B 5/021; A61B 5/02416; A61B 5/14551; A61B 5/7285
See application file for complete search history.

(56) **References Cited**

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5,349,952	A	9/1994	McCarthy et al.
5,351,685	A	10/1994	Potratz
5,485,847	A	1/1996	Baker, Jr.
5,515,847	A	5/1996	Braig et al.
5,560,355	A	10/1996	Merchant et al.
5,575,284	A	11/1996	Athan et al.
5,590,652	A	1/1997	Inai
5,746,697	A	5/1998	Swedlow et al.
5,766,127	A	6/1998	Pologe et al.
5,846,190	A	12/1998	Woehrle
5,924,979	A	7/1999	Swedlow et al.
6,005,658	A	12/1999	Kaluza et al.

(Continued)

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WO	WO 2006/083180	8/2006

OTHER PUBLICATIONS

Takada, H. et al., "Acceleration Plethysmography to Evaluate Aging Effect in Cardiovascular System," Medical Progress Through Technology, vol. 21, pp. 205-210, 1997.

(Continued)

Primary Examiner — Mark Remaly
(74) *Attorney, Agent, or Firm* — Shvarts & Leiz LLP

(57) **ABSTRACT**

A physiological monitoring system may use photonic signals to determine physiological parameters. The system may vary parameters of a light drive signal used to generate the photonic signal from a light source such that power consumption is reduced or optimized. Parameters may include light intensity, firing rate, duty cycle, other suitable parameters, or any combination thereof. In some embodiments, the system may use information from a first light source to generate a light drive signal for a second light source. In some embodiments, the system may vary parameters in a way substantially synchronous with physiological pulses, for example, cardiac pulses. In some embodiments, the system may vary parameters in response to an external trigger.

32 Claims, 30 Drawing Sheets

(Ex. 1011)

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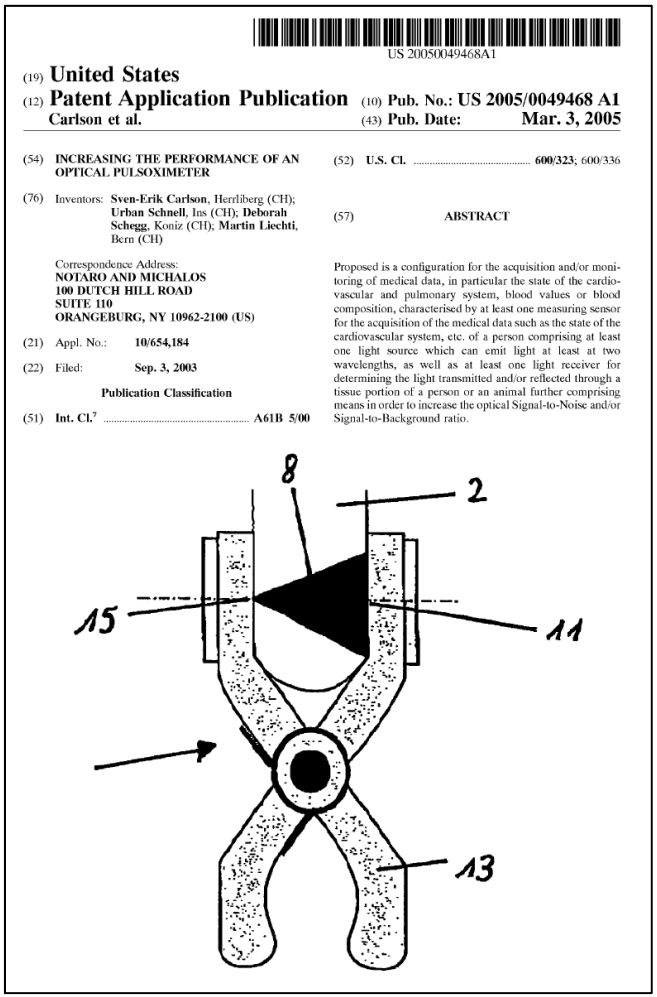

US 20050049468A1

(19) **United States**
(12) **Patent Application Publication**
Carlson et al.

(10) **Pub. No.: US 2005/0049468 A1**
(43) **Pub. Date: Mar. 3, 2005**

(54) **INCREASING THE PERFORMANCE OF AN OPTICAL PULSOXIMETER**

(76) Inventors: **Sven-Erik Carlson**, Herrliberg (CH); **Urban Schnell**, Ins (CH); **Deborah Schegg**, Koniz (CH); **Martin Liechti**, Bern (CH)

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(21) Appl. No.: **10/654,184**

(22) Filed: **Sep. 3, 2003**

Publication Classification

(51) **Int. Cl.**[7] **A61B 5/00**

(52) **U.S. Cl.** **600/323**; 600/336

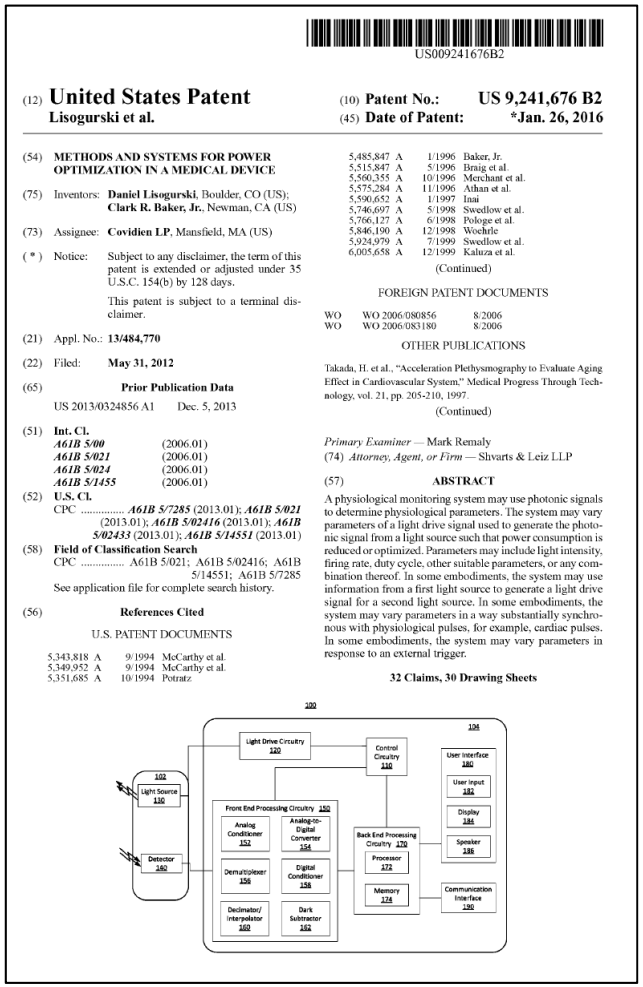
(57) **ABSTRACT**

Proposed is a configuration for the acquisition and/or monitoring of medical data, in particular the state of the cardiovascular and pulmonary system, blood values or blood composition, characterised by at least one measuring sensor for the acquisition of the medical data such as the state of the cardiovascular system, etc. of a person comprising at least one light source which can emit light at least at two wavelengths, as well as at least one light receiver for determining the light transmitted and/or reflected through a tissue portion of a person or an animal further comprising means in order to increase the optical Signal-to-Noise and/or Signal-to-Background ratio.

(Ex. 1009)

LISOGURSKI

Lisogurski: two types of modulation



US009241676B2

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(Continued)

FOREIGN PATENT DOCUMENTS

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(Continued)

Primary Examiner — Mark Remaly
(74) *Attorney, Agent, or Firm* — Shvarts & Leiz LLP

(57) **ABSTRACT**

A physiological monitoring system may use photonic signals to determine physiological parameters. The system may vary parameters of a light drive signal used to generate the photonic signal from a light source such that power consumption is reduced or optimized. Parameters may include light intensity, firing rate, duty cycle, other suitable parameters, or any combination thereof. In some embodiments, the system may use information from a first light source to generate a light drive signal for a second light source. In some embodiments, the system may vary parameters in a way substantially synchronous with physiological pulses, for example, cardiac pulses. In some embodiments, the system may vary parameters in response to an external trigger.

32 Claims, 30 Drawing Sheets

(Ex. 1011)

"cardiac cycle modulation"

- "***aligned with pulses of the heart***" or "other suitable physiological cyclical cycle" (Ex. 1011 at 5:25-47.)
- "***on the order of 1 Hz***" correlating with an average heart rate of 60 beats per minute (Id. at 6:28-29.)
- "firing rate" can be adjusted to track the cardiac cycle. (Id. at 25:45-58; 28:30-39; 29:25-34.)

"drive cycle modulation"

- "***a technique to remove ambient and background signals***" by measuring ambient light while the LED is off and subtracting that measurement from the signals received with the light on (Id. at 6:7-30.)
- Exemplary modulation rate of "***1 kHz***" (Ex. 1011 at 5:48-54; 6:30.)
- ***Apple does not rely on this modulation in Lisogurski***

Lisogurski does not disclose a "light source … configured to increase SNR … by increasing a pulse rate"

- **Uses "drive cycle modulation" to address noise**
  - "1kHz" (6:30)
  - Does ***not*** disclose ***increasing*** **the 1kHz modulation rate to increase SNR**

- **Uses "cardiac cycle modulation" to remain synchronous with heart rate**
  - **"firing rate"** adjustments are **to remain synchronous with heart rate**
    - 2:1-2; 25:54; 27:48; 28:37-38; 29:33; 30:57; 31:51; 32:13-14; 32:58-59; 33:35, etc.
  - Also to reduce power consumption (Abstract; 1:21)

Lisogurski's "cardiac cycle modulation"

As used herein, "cardiac cycle modulation" will refer to the modulation techniques generally correlated to the cardiac cycle. It will be understood that cardiac cycle modulation may include modulation aligned with pulses of the heart, pulses of a particular muscle group, other suitable pulses, any other suitable physiological cyclical function, or any combination thereof. In some embodiments, the system may use a cardiac cycle modulation with a period on the order of the cardiac cycle period. For example, the cardiac cycle modulation may repeat every cardiac cycle. In some embodiments,

(Ex. 1011, col. 5, lines 25-47.)

The system may determine periods of the cardiac cycle and apply a cardiac cycle modulation to a second light source. For example, red light drive signal **556** may be switched on at period **532** during systole period **502**, off during diastole period **504**, on at period **534** during systole period **506**, and off during diastole period **508**. Red light drive signal **556** may, for example, correspond to the second light drive signal generated at step **408** of FIG. **4**. Thus, the cardiac cycle modulation applied to red light drive signal **556** may be substantially synchronous with the systole periods of the cardiac cycle. In some embodiments, the system may determine the timing of the systole periods using information from the attenuated first photonic signal associated with IR light drive signal **558**. In some embodiments, the system may use historical information from multiple cardiac cycles to determine the red light drive signal **556**.

(Ex. 1011, col. 21, lines 44-59.)

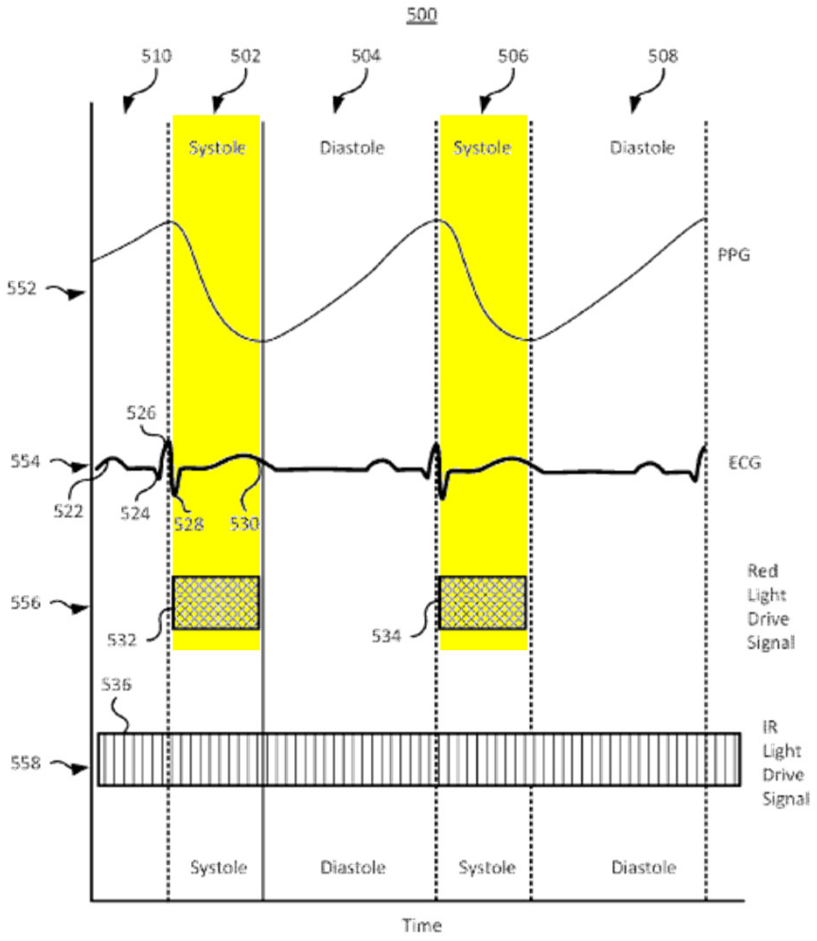


FIG. 5

(Omni's Sur-Reply at 2.)

Lisogurski's optional "drive cycle modulation"

As used herein, "drive cycle modulation" (described below) will refer to a relatively higher frequency modulation technique that the system may use to generate one or more wavelengths of intensity signals. Cardiac cycle modulation may have a period of, for example, around 1 second, while drive cycle modulation may have a period around, for example, 1.6 milliseconds. **(Ex. 1011, col. 5, lines 48-54.)**

In some embodiments, a technique to remove ambient and background signals may be used in addition to or in place of a power saving light modulation scheme. In a drive cycle modulation technique, the system may cycle light output at a rate significantly greater than the cardiac cycle. For example, a drive cycle modulation cycle may include the system turning on a first light source, followed by a "dark" period, followed by a second light source, followed by a "dark" period. The system may measure the ambient light detected by the detector during the "dark" period and then subtract this ambient contribution from the signals received during the first and second "on" periods. **(Ex. 1011, col. 6, lines 7-30.)**

(Ex. 1011, col. 6, lines 26-31.) The cardiac cycle modulation may represent a lower frequency envelope function on the higher frequency drive cycle. For example, cardiac cycle modulation may be an envelope on the order of 1 Hz superimposed on a 1 kHz sine wave drive cycle modulation.

(Omni's Sur-Reply at 2.)

Intentionally blank

Lisogurski also discloses using "conventional servo algorithms"

In some embodiments, conventional servo algorithms may be used in addition to any combination of cardiac cycle modulation and drive cycle modulation. Conventional servo algorithms may adjust the light drive signals due to, for example, ambient light changes, emitter and detector spacing changes, sensor positioning, other suitable parameters, or any combination thereof. Generally, conventional servo algorithms vary parameters at a slower rate than cardiac cycle modulation. For example, a conventional servo algorithm may adjust drive signal brightness due to ambient light every several seconds. The system may use conventional servo algorithms in part to keep received signal levels within the range of an analog to digital converter's dynamic range. For example, a signal with amplitudes that are large may saturate an analog to digital convertor. In response to a signal with high amplitudes, the system may reduce emitter brightness. In a further example, the quality of a low amplitude signal may be degraded by quantization noise by an analog to digital converter. In response, the system may increase the emitter brightness.

('676 Patent, 5:55-6:6.)

- Discloses increasing emitter *brightness* to address noise
- Does not disclose increasing *pulse rate* (for any reason)
- ***Apple does not assert that a conventional servo algorithm increases pulse rate***

The Board: Apple failed to show how Lisogurski increases pulse rate to increase SNR

At this stage of the proceeding, Petitioner has failed to sufficiently demonstrate how Lisogurski teaches increasing LED firing rate to increase signal-to-noise. The passages of Lisogurski identified by Petitioner teach generating a light drive signal that "varies with a period the same as or closely related to the period of the cardiac cycle" by varying parameters "related to the light drive signal including drive current or light brightness, duty cycle, firing rate . . . [and] other suitable parameters." Ex. 1011, 25:49–55. That is, the LED firing rate is varied to become or remain synchronous with a cardiac cycle, not to increase signal-to-noise. Although Lisogurski teaches "alter[ing] the cardiac cycle modulation technique based on the level of noise [or] ambient light," Lisogurski teaches doing this by "increasing the brightness of the light sources" or by changing "from a modulated light output to a constant light output." *Id.* at 9:46–60.

(Paper No. 16, ID at 30-31.)

The Board: Rejected Apple's "sampling rate" argument

Similarly, although Lisogurski teaches light output variations may also apply to sampling rate, this teaching in Lisogurski is provided in the context of modifying the sampling rate, light output, and other parameters to be synchronous with cardiac cycles:

> It will also be understood that sampling rate is one of the components that may be modulated in cardiac cycle modulation as described above. It will also be understood that the earlier described embodiments relating to varying light output may also apply to sampling rate.

Id. at 35:5–9. Throughout the specification, Lisogurski teaches varying light intensity to be synchronous with features of a cardiac cycle. *See id.* at 20:64–67 ("us[ing] a first light drive signal to identify systole periods of the cardiac cycle and modulat[ing] a second light drive signal to increase light intensity concurrent with the systole periods"); 22:14–17 ("us[ing] a first light drive signal to identify diastole . . . periods of the cardiac cycle and modulat[ing] a second light drive signal to increase light intensity concurrent with diastole period[s]"); 22:51–54 ("us[ing] a first light drive signal to identify a dicrotic notch . . . in the cardiac cycle and modulat[ing] a second light drive signal to increase light intensity concurrent with the dicrotic notch"). Thus, when Lisogurski teaches "varying light output may also apply to sampling rate," Lisogurski is teaching varying the sampling rate to be synchronous with the cardiac cycle, not to improve signal-to-noise. *Id.* at 35:5–9.

(Paper No. 16 , ID at 30.)

CARLSON

Carlson teaches an optional modulation at a "chosen" frequency beyond ambient noise

[0018] Again, in addition to the above mentioned two configurations, or as an alternative, a further configuration is proposed which comprises at least the following components:

[0020] at least one light source frequency modulating means to frequency modulate the optical radiation of the light source at a carrier frequency in order to shift the power spectrum of the pulsoximeter signals. The basic idea of using AC-Coupling or Lock-In Amplification (synchronous detection), is to temporarily modulate the amplitude of the optical radiation of, e.g., the LED at a carrier frequency f_c in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely and electronic band pass filtering is technologically less stringent. Thus, the pulsoximeter signals are readily discriminated from electronic and parasitic contributions of environmental optical radiation outside the frequency range of, e.g. f_c +/−5 Hz, increasing significantly the S/N (Signal/Noise)- and S/B ratio.

[0069] As a consequence, it is therefore proposed to emit light by the LEDs not as current or continuous light but as pulsed light. The frequency is chosen in such a way that it is outside the frequency spectrum of sunlight and of ambient light which, according to **FIG. 7***b*, is in the range of above approximately 1000 Hz. Thus, the pulsoximeter signals are readily discriminated from electronic and parasitic contributions of environmental optical radiation outside the frequency f_c+/−5 Hz increasing significantly the Signal-to-Noise and Signal-to-Background ratio. **FIG. 8** shows the shift spectrum of signal to a region where there is little influence, e.g. of ambient light. F_0 is the chosen frequency of the emitted light to operate the pulsoximeter sensor and the range between f_0−5 Hz and f_{0+5} Hz is the consequence of the influence of the frequency due to physiological signal. Therefore, as shown in **FIG. 8**, the frequency spectrum of signal at the photo diode does have a basic signal contribution due to physiological signal. The signal contribution which is shown at the top of the signal contribution due to physiological signal and which is due to ambient light, is very small and as a consequence is approximately neglectable. Any noise or sunlight within the range of 0 to 120 Hz, while the light beam for the pulsoximetric measurement is within the range of approximately f_0−5 Hz to f_0+5 Hz, will not influence the measurement of the pulsoximetric sensor. F_0 could be e.g., as mentioned, 1000 Hz which of course is a frequency far outside of any indoor light source, as e.g. halogen light, conventional light, etc. f_0 of course can be chosen at any other frequency, as e.g. 2000 Hz or even higher. By using light source modulation, it is even possible to use an additional filter removing a certain frequency spectrum. Looking e.g. at **FIG. 9**, it is possible to arrange a filter band pass **51** which is e.g. removing any frequencies in the range of 0 to 120 Hz. The respective filter is shown in form of the dashed line **51**. As a result, we end up by a diagram according to **FIG. 9***b* only showing any measurements in the range of f_0−5 Hz to f_0+5 Hz.

Carlson's optional modulation at the "chosen" f_0

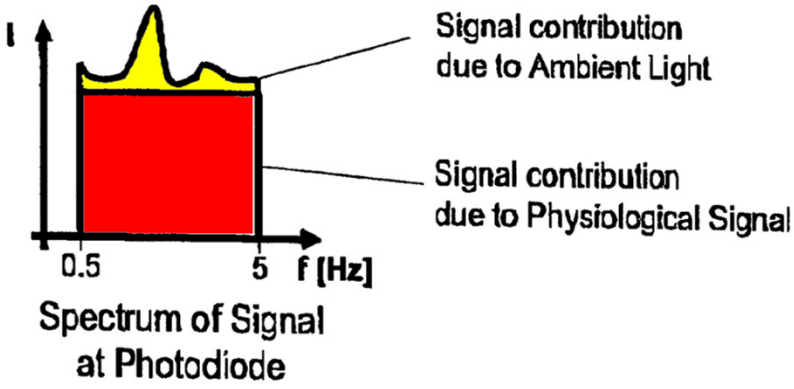


Figure 7c

(Continuous Light Source; no modulation)

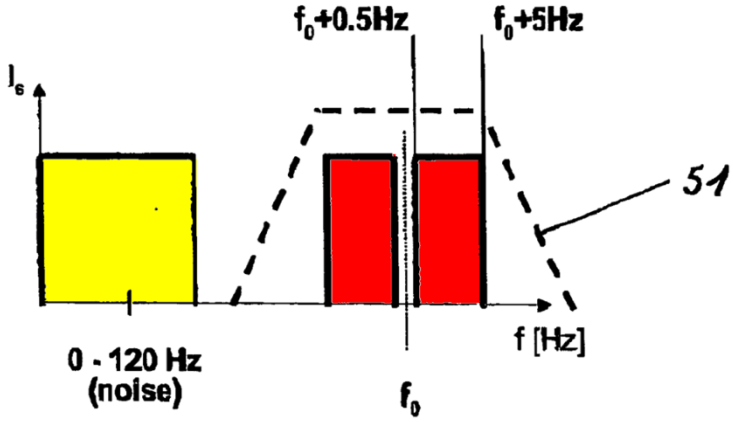


Figure 9

(Temporarily Modulated Light Source)

Carlson does ***not*** teach:

"***the light source configured to increase signal-to-noise ratio*** by increasing a light intensity from at least one of the plurality of semiconductor sources and ***by increasing a pulse rate of at least one of the plurality of semiconductor sources***"

The Board incorrectly described the Lisogurski and Carlson in its obviousness analysis

Together, the references teach that a pulsoximeter can detect a change in background noise and modify the LED firing rate based on the detected change (as taught by Lisogurski), and can modify the frequency of the LED firing rate to be greater than the frequency of the background noise (as taught by Carlson). *See* e.g., Ex. 1011, 37:6–9, 1:67–2:3; Ex. 1009 ¶¶ 65, 69. For these reasons, at this stage of the proceeding, Petitioner has sufficiently demonstrated that "a skilled person would have found it obvious to configure Lisogurski to increase the firing rate (frequency) of LEDs as taught by Carlson." Pet. 39.

(Paper No. 16 , ID at 36.)

Incorrect: Lisogurski teaches only increasing ***brightness*** to address noise

Incorrect: Carlson teaches only introducing modulation at a "***chosen" rate***

The Board's obviousness position on Lisogurski is inconsistent with its earlier finding

Board's Correct Statement:

At this stage of the proceeding, Petitioner has failed to sufficiently demonstrate how Lisogurski teaches increasing LED firing rate to increase signal-to-noise. The passages of Lisogurski identified by Petitioner teach generating a light drive signal that "varies with a period the same as or closely related to the period of the cardiac cycle" by varying parameters "related to the light drive signal including drive current or light brightness, duty cycle, firing rate . . . [and] other suitable parameters." Ex. 1011, 25:49–55. That is, the LED firing rate is varied to become or remain synchronous with a cardiac cycle, not to increase signal-to-noise. Although Lisogurski teaches "alter[ing] the cardiac cycle modulation technique based on the level

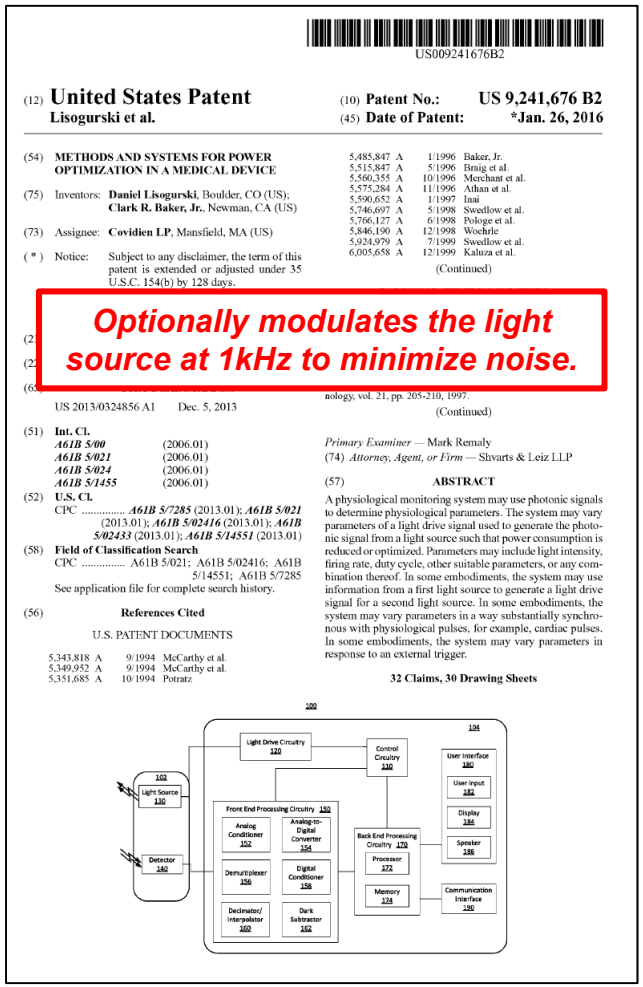
(Paper No. 16, ID at 30.)

Board's Incorrect Statement:

Together, the references teach that a pulsoximeter can detect a change in background noise and modify the LED firing rate based on the detected change (as taught by Lisogurski), and can modify the frequency of the LED firing rate to be greater than the frequency of the background noise (as taught by Carlson). *See* e.g., Ex. 1011, 37:6–9,

(Paper No. 16, ID at 36.)

Adding Carlson does not enhance Lisogurski, which the Board already determined is ***not*** the claimed invention



US009241676B2

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

(10) **Patent No.: US 9,241,676 B2**
(45) **Date of Patent: *Jan. 26, 2016**

(54) **METHODS AND SYSTEMS FOR POWER OPTIMIZATION IN A MEDICAL DEVICE**

(75) Inventors: **Daniel Lisogurski**, Boulder, CO (US); **Clark R. Baker, Jr.**, Newman, CA (US)

(73) Assignee: **Covidien LP**, Mansfield, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 128 days.

Optionally modulates the light source at 1kHz to minimize noise.

US 2013/0324856 A1 Dec. 5, 2013

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/021 (2006.01)
A61B 5/024 (2006.01)
A61B 5/1455 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/7285*** (2013.01); ***A61B 5/021*** (2013.01); ***A61B 5/02416*** (2013.01); ***A61B 5/02433*** (2013.01); ***A61B 5/14551*** (2013.01)

(58) **Field of Classification Search**
CPC A61B 5/021; A61B 5/02416; A61B 5/14551; A61B 5/7285
See application file for complete search history.

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nology, vol. 21, pp. 205-210, 1997.
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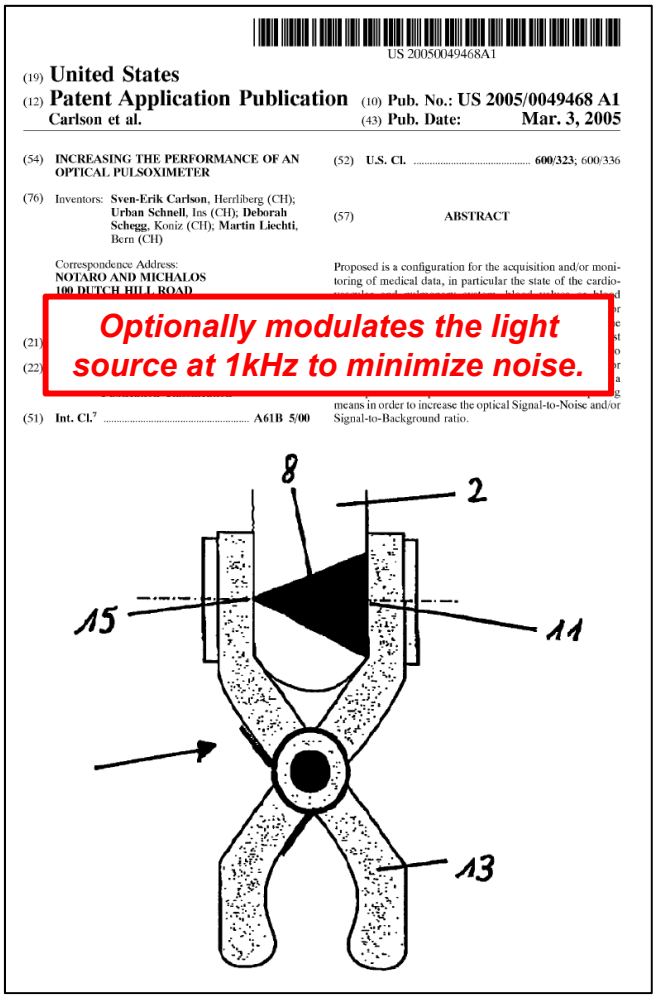
Primary Examiner — Mark Remaly
(74) *Attorney, Agent, or Firm* — Shvarts & Leiz LLP

(57) **ABSTRACT**

A physiological monitoring system may use photonic signals to determine physiological parameters. The system may vary parameters of a light drive signal used to generate the photonic signal from a light source such that power consumption is reduced or optimized. Parameters may include light intensity, firing rate, duty cycle, other suitable parameters, or any combination thereof. In some embodiments, the system may use information from a first light source to generate a light drive signal for a second light source. In some embodiments, the system may vary parameters in a way substantially synchronous with physiological pulses, for example, cardiac pulses. In some embodiments, the system may vary parameters in response to an external trigger.

32 Claims, 30 Drawing Sheets

(Ex. 1011)



US 20050049468A1

(19) **United States**
(12) **Patent Application Publication**
Carlson et al.

(10) **Pub. No.: US 2005/0049468 A1**
(43) **Pub. Date: Mar. 3, 2005**

(54) **INCREASING THE PERFORMANCE OF AN OPTICAL PULSOXIMETER**

(76) Inventors: **Sven-Erik Carlson**, Herrliberg (CH); **Urban Schnell**, Ins (CH); **Deborah Schegg**, Koniz (CH); **Martin Liechti**, Bern (CH)

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Optionally modulates the light source at 1kHz to minimize noise.

(51) **Int. Cl.**[7] **A61B 5/00**

(52) **U.S. Cl.** **600/323**; 600/336

(57) **ABSTRACT**

Proposed is a configuration for the acquisition and/or monitoring of medical data, in particular the state of the cardio-

means in order to increase the optical Signal-to-Noise and/or Signal-to-Background ratio.

(Ex. 1009)

In re Merck and *In re Keller* are inapposite

- "**Accepting as true**" that Carlson discloses selecting a single pulse rate, the Board cited:
  - *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.")
  - *In re Keller,* 642 F.2d 413, 425 (Fed. Cir. 1981) (the test for obviousness is "what the combined teachings of the references would have suggested to those of ordinary skill in the art").
- But neither case dealt with a ***missing limitation*** in the combination:
  - In *Merck*, the Board rejected the applicant's assertion that there was no "motivation" in the prior art to arrive at the invention
  - In *Keller*, the issue was whether the two prior art references were properly combinable

THE '533 PATENT

'533 Patent: Overview

The '533 Patent is directed to measurement systems for making accurate non-invasive physiological measurements of a material or substance, including human tissue and blood. (*See, e.g.*, Ex. 1001, 8:30–34; 3:66-4:32.) For example, the '533 Patent discloses inspecting a sample "by comparing different features, such as wavelength (or frequency), spatial location, transmission, absorption, reflectivity, scattering, fluorescence, refractive index, or opacity." (*Id.* at 8:29–34.) This may entail measuring various optical characteristics of the sample as a function of the wavelength of the source light by varying the wavelength of the source light or by using a broadband source of light. (*Id.* at 8:34–46.)

Response at 2

'533 Patent: Fig. 24

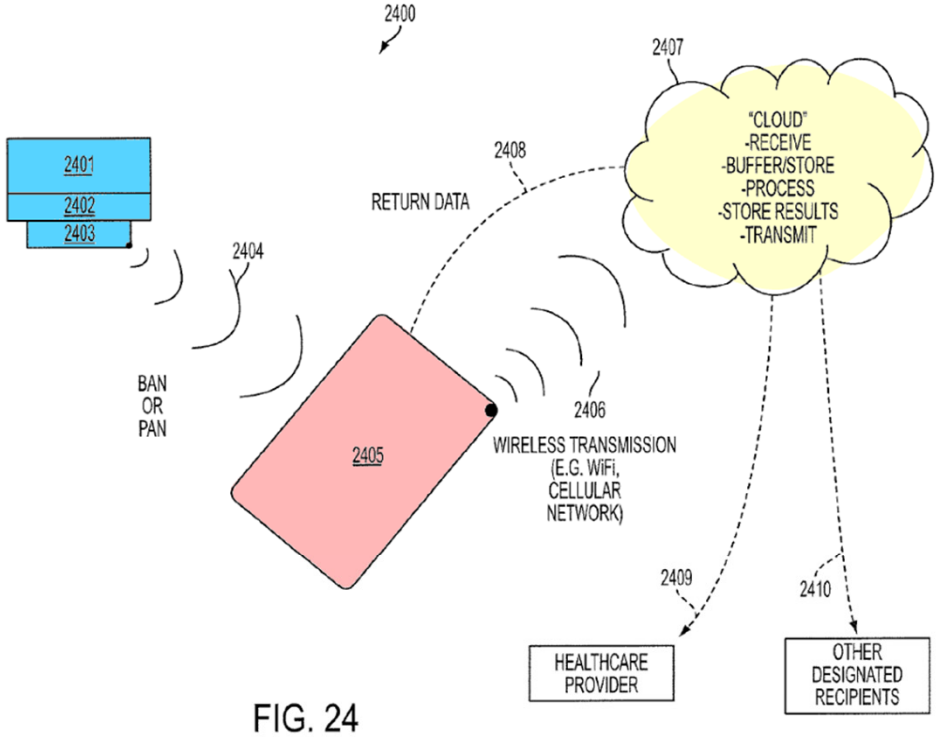

FIG. 24

The system includes a wearable measurement device 2401, 2402, and 2403 (blue), a personal device 2405 (red), and a cloud-based server 2407 (yellow). (*Id.* at 26:49–27:20.) The "wearable measurement device [is] for measuring one or more physiological parameters." (*Id.* at 5:35–37.)

Response at 3

'533 Patent: Two operating modes

Wearable measurement device includes light source 1801 made from a plurality of light emitting diodes that generate an output optical beam at one or more optical wavelengths, wherein at least one of the optical wavelengths is between 700 and 2500 nanometers. (*Id.* at 5:37–43; 18:46–48.) The '533 specification discloses two operating modes for the LEDs: "continuous wave or pulsed mode of operation." (*Id.* at 19:66-20:2.)

Response at 3

'533 Patent: Increasing SNR

The '533 Patent describes various techniques for improving the signal-to-noise ratio ("SNR") of the measurement. For example, the SNR may be improved by increasing the light intensity from the light source. (*See, e.g.*, Ex. 1001 at 4:15–17: "More light intensity can help to increase the signal levels, and, hence, the signal-to-noise ratio."). And in the "pulsed mode of operation," the light source can increase the pulse rate to improve the signal-to-noise ratio. (*See, e.g., id.* at 5:11–15: "The light source is configured to increase signal-to-noise ratio by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources," and 19:67-20:2: "the LED output may more easily be modulated" and provides the option of a "pulsed mode of operation.".)

Response at 4

'533 Patent: Active illuminator

The '533 Patent specification explains that the change in pulse-rate is done by the device, not a manual adjustment. The '533 specification discloses that the LEDs may operate in a "pulsed mode of operation" during which a "pulse rate" is "increased" to increase SNR. (Ex. 1001 at 5:11–15; 19:67-20:2.) The specification states, "***The light source*** is configured to increase signal-to-noise ratio by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources." (*Id.* at 5:11–15.)[1] The specification states that "[b]y use of ***an active illuminator***, a number of advantages may be achieved" including "higher signal-to-noise ratios." (*Id.* at 16:54-58.) PCT Application Serial No. PCT/US2013/075767 (Publication No. WO/2014/143276), which is incorporated by reference into the '533 specification, describes the use of an "active illuminator" to achieve "higher signal-to-noise ratios" despite "variations due to sunlight" and the "effects of the weather, such as clouds and rain." (Ex. 1001 at 1:33-37; Ex 2120 at 25-26, ¶[0079].) This is

Response at 4-5

'533 Patent: Non-zero pulse rate

This is consistent with U.S. Patent Application Serial No. 14/109,007 (Publication No. 2014/0236021), also incorporated by reference into the '533 specification, which discloses that the modulation frequency of the light source is non-zero and can range between "0.1-100kHz." (Ex. 1001 at 1:40-42; Ex 2121 at 4, ¶[0045].)

Response at 5

Claim 5: the "pulse rate" limitation

5. A measurement system comprising:

a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths, wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers,

the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and ***by increasing a pulse rate of at least one of the plurality of semiconductor sources***;

LEVEL OF SKILL

Level of ordinary skill in the art

C. Level of ordinary skill in the art

For the purposes of this proceeding, Patent Owner does not dispute Petitioner's description of a person of ordinary skill in the art as someone who would have had a good working knowledge of optical sensing techniques and their applications, and familiarity with optical system design and signal processing techniques. (Pet. at 16.) Such a person would have obtained such knowledge through an undergraduate education in engineering (electrical, mechanical, biomedical, or optical) or a related field of study, along with relevant experience studying or developing physiological monitoring devices in industry or academia. (*Id.*)

Response at 8

CLAIM CONSTRUCTION

The Board's construction

2. "a light source comprising a plurality of semiconductor sources that are light emitting diodes . . . configured to increase signal-to-noise ratio by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources"

Petitioner did not propose a construction for the claim limitation "a light source comprising a plurality of semiconductor sources that are light emitting diodes . . . configured to increase signal-to-noise ratio by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources." In the Institution Decision, the Board determined "construction of the term is necessary, however, to resolve the parties' dispute about whether Lisogurski alone or in combination with Carlson discloses such a light source." (DI at 10.) The Board construed the claim limitation to mean "a light source containing two or more light emitting diodes (semiconductor sources), wherein at least one of the light emitting diodes ***is capable of*** having its pulse rate increased to increase a signal-to-noise ratio." (*Id.*)

Response at 9

Two issues with the Board's construction

The Board's construction replaces the claim term "configured to" with the broader phrase "is capable of." The Board also substitutes passive voice for the active voice of the claim, eliminating the claimed "actor" that increases the pulse rate, *i.e.*, the device. Those substitutions are improper because they broaden the claim and create ambiguity.

Response at 9

The Board removed "configured to"

In a patent claim, the phrase "is capable of" is broader than "configured to." *See, e.g.*, *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012); *Cook Group Inc. v. Boston Scientific Scimed, Inc.*, IPR2017-00132, Paper No. 71 at 24-25 (PTAB Nov. 14, 2018). In *Aspex*, the Federal Circuit held that terms such as "configured to" and "adapted to" describe devices that are "designed or configured to accomplish the specified objective, ***not simply that they can be made to serve that purpose***." In *Cook Group*, the Board similarly held that "the claim language 'configured to' requires structure designed to perform the function, not merely structure capable of performing the function." *See Cook Group*, Paper 71 at 17.

Response at 10-11

The Board broadened the claims

A device can be "capable of" operations even if it is not "configured to" perform those operations. By replacing the claim term "configured to" with the phrase "is capable of," the Board improperly broadened the claim. A proper construction does not change the term "configured to," which is a common, well-understood term in patent claims. *See Cook Group*, IPR2017-00132, Paper No. 71 at 24-25.

Response at 11

"capable of" ≠ "configured to"

The Board's construction replaces the claim term "configured to" with the broader phrase "is capable of." The Board also substitutes passive voice for the active voice of the claim, eliminating the claimed "actor" that increases the pulse rate, *i.e.*, the device. Those substitutions are improper because they broaden the claim and create ambiguity.

Response at 9

Other claims use "capable of"

In addition, as in *Aspex*, other limitations of the '533 Patent claims use the term "capable of." (Ex. 1001, '533 Patent, claim 7: "the remote device is ***capable of*** transmitting information"; claims 10 and 13: "the remote device is ***capable of*** storing a history".) This gives rise to the presumption that the term "configured to" recited in challenged independent claims 5 and 13 has a different, *i.e.*, narrower, meaning than "configured to." *Aspex*, 672 F.3d at 1349.

Response at 11

The Board's passive voice construction creates ambiguity

The Board's construction also creates ambiguity because it uses passive voice, whereas the claims state that ***the device*** increases the pulse rate. The Board's construction improperly broadens the limitation permitting, *e.g.*, a human, to increase the pulse rate. That is contrary to the express language of the claims.

Response at 11

The specification supports the claimed "light source" as the "actor"

The specification states, "***The light source*** is configured to increase signal-to-noise ratio by . . . increasing a pulse rate of at least one of the plurality of semiconductor sources." (*Id.* at 5:11–15.) The specification states that "[b]y use of an ***active illuminator***, a number of advantages may be achieved" including "higher signal-to-noise ratios." (*Id.* at 16:54-58.) PCT Application Serial No. PCT/US2013/075767 (Publication No. WO/2014/143276), which is incorporated by reference into the '533 specification, describes the use of an "active illuminator" to achieve "higher signal-to-noise ratios" despite "variations due to sunlight" and the "effects of the weather, such as clouds and rain." (Ex. 1001 at 1:33-37; Ex 2120 at 25-26, ¶[0079].)

Response at 12

Apple rewrites the "pulse rate" limitation

Apple argues that its references satisfy the claims merely because, if the pulse rate of the light source increases, the SNR may increase, too. (Reply at 1, 3-4.) To make that argument, Apple rewrites the "pulse rate" limitation. Apple wrongly asserts:

> there is: (i) an action that the device must take (increasing the pulse rate of an LED) and (ii) a result of that action (an increased SNR).

(Reply at 6-7.)

Sur-reply at 3

Apple sets up a strawman argument

Apple's summary of the "pulse rate" limitation is wrong because it is backward. The claim requires a light source "configured to increase SNR," not a light source "configured to increase a pulse rate." So, when Apple says, "Lisogurski teaches a device that is ***'configured to' take the action specified by the claim***: ***increasing the pulse rate of an LED***" (Reply at 7), Apple distorts the claim. Apple has set up a strawman. It is irrelevant that Lisogurski discloses a device that varies a pulse rate because that is not the claimed configuration. As Apple aptly summarized, "[t]he Board preliminarily found that Lisogurski alone does not disclose increasing pulse rate ***for the purpose of increasing SNR***." (Reply at 7, n. 2, citing ID at 30.)[3] Apple has not shown Lisogurski and Carlson—separately or together—are "configured to increase SNR" by "increasing a pulse rate."

Sur-reply at 4

Omni MedSci's construction is not based on "intent"

Apple also asserts that Omni MedSci's "configured to" construction injects an improper "intent" requirement. (Reply at 6-8.)[4] But Omni MedSci's construction is not based on "intent," it is based on the express claim language: a "light source ***configured to*** increase signal-to-noise ratio . . . ." (Ex. 1001 29:51-11.) This express claim language is always relevant to the proper construction. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005).

Sur-reply at 5

Apple does not defend the Board's substitution of "capable of"

Apple does not rebut Omni MedSci's arguments or defend the Board's substitution of "capable of" for the claims' "configured to." In its Response (pp. 10-11), Omni MedSci cited and discussed *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012) ("configured to" has a narrower meaning than "capable of") and *Cook Grp. Inc. v. Boston Sci. Scimed, Inc.*, IPR2017-00132, Paper No. 71 at 17 (PTAB Nov. 14, 2018) ("the claim language 'configured to' requires structure designed to perform the function, not merely structure capable of performing the function.").[5] *Aspex Eyeware* is controlling Federal Circuit law. Apple does not address either decision in its Reply.

Sur-reply at 5

The '533 Patent does not claim mere happenstance

Substituting "capable of" for "configured to" would render the "pulse rate" limitation meaningless and irrelevant. But the '533 Patent does not claim mere happenstance. The device must be "configured to"—*i.e.*, designed to—increase SNR in the manner claimed.

Sur-reply at 7

No evidence that "increase the pulse rate of an LED and that increase will ***necessarily*** increase SNR as well."

On page 1, Apple's attorneys assert, "increase the pulse rate of an LED and that increase will ***necessarily*** increase SNR as well." Apple cites no evidence to support that assertion and no evidence exists. But Apple's obviousness argument hinges on Apple proving that increasing a pulse rate ***necessarily*** increases SNR because the claims require a light source "configured to" increase SNR.

Sur-reply at 7

MacFarlane repeatedly disagreed when Apple suggested increasing a pulse rate would necessarily increase SNR

Apple selectively quotes Omni MedSci's expert, Dr. MacFarlane, but he repeatedly disagreed when Apple suggested increasing a pulse rate would necessarily increase SNR. (Ex. 1060 at 37:17-22; 38:4-7; 38:19-39:1; 39:12-17; 82:8-83:4.) Dr. MacFarlane acknowledged, in general, that increasing a pulse rate may increase SNR, but he consistently refuted Apple's suggestion that it necessarily does so.

Sur-reply at 7-8

MacFarlane gave Apple an example when asked

Apple also asserts that Dr. MacFarlane could not name a scenario in which SNR would ***not*** increase with an increase in pulse rate. (Reply at 5.) Not true. In response to Apple's request for "an example of when increasing the pulse rate of an LED does not increase the [SNR]," Dr. MacFarlane gave Apple a specific example. (*Id.* at 83:19-84:13.) Apple's Reply ignores, and does not rebut, the example Dr. MacFarlane provided, and Apple did not ask Dr. MacFarlane to give other examples, which he could have done.

Sur-reply at 9-10

The fallacy of Apple's argument

Dr. MacFarlane's testimony—that increasing pulse rate may or may not increase SNR—highlights the fallacy of Apple's argument. The claims do not say "perhaps increase SNR"—the light source must be "***configured*** to increase [SNR]." Lisogurski, alone or combined with Carlson, does not meet that requirement because, at best, they teach a varying pulse rate that is not "configured to" increase SNR.

Sur-reply at 10

The claims do not recite increasing a "sampling rate"

Apple also asserts Lisogurski discloses "increasing the sampling rate" to increase accuracy. (Reply at 11.) But the challenged claims do not recite increasing a "sampling rate" (*i.e.*, the detection rate), they recite increasing a "pulse rate" of the light source. As the Board explained, "when Lisogurski teaches 'varying light output may also apply to sampling rate,' Lisogurski is teaching varying the sampling rate to be synchronous with the cardiac cycle, ***not to improve signal-to-noise***." (Paper No. 16, ID at 31 *citing* Ex. 1011 at 35:5–9.) Thus, Lisogurski, alone, does not disclose the "pulse rate" limitation.

Sur-reply at 11

CLAIM CONSTRUCTION: PETITION/REPLY

Pulse rate construction

C. "pulse rate"

The parties agreed in district court that a skilled artisan would have understood that "*pulse rate*" means "number of pulses of light per unit of time." The specification describes the pulse repetition rate of a light source and measuring the pulsed output rate using Hertz. Ex.1001, 21:55-59 ("a pulse repetition rate between one kilohertz to about 100 MHz or more"), 25:65-26:1. Hertz is the International System of Units unit for frequency or number of cycles per second. Ex.1003, ¶66. Thus, a skilled person would have understood this term to refer to the number of pulses of light per unit of time. Ex.1003, ¶66.

Petition at 20

Apple says: "increase SNR" construction only relevant to Lisogurski alone

B. The Construction of "*Increas[ing] Signal-to-Noise Ratio by… Increasing a Pulse Rate of at Least One [LED]*"

Ultimately, the precise construction of this term is irrelevant to the petition's obviousness grounds because the combination of Lisogurski and Carlson suggest this claim element under the Board's construction, Omni's construction, and the claim's plain and ordinary meaning. However, the Board's interpretation of this term could affect its determination as to whether Lisogurski alone teaches this claim element, and thus, its meaning is analyzed below.

Reply at 5-6

Apple on the Board's passive voice construction

First, Omni asserts the claim requires the light source to increase the pulse rate while the Board's construction allows another entity to do so. Resp., 11 ("The Board's construction improperly broadens the limitation permitting, e.g., a human, to increase the pulse rate."). But Omni's criticism is irrelevant—it does not dispute that Lisogurski's device can increase the pulse rate of an LED, and thus meets even Omni's narrower reading.

Reply at 6

Apple on the Board's "is capable of" construction

Second, Omni contends the Board's use of the phrase "capable of" was incorrect, and that the claim instead requires a device that is "configured to" increase a pulse rate of an LED to increase SNR. Resp. 11. Omni does this based on its erroneous belief that the "intent" of a device must be considered, rather than what the device actually does.

Reply at 6

Apple rewrites the claim limitation

Importantly, under both the Board's and Omni's constructions, there is no dispute that there is: (i) an action that the device must take (increasing the pulse rate of an LED) and (ii) a result of that action (an increased SNR). There also is no dispute that Lisogurski teaches a device that is "configured to" take the action specified by the claim: increasing the pulse rate of an LED. Ex.1060, 59:1-5 ("Q… Do you agree that Lisogurski describes a device that is configured to increase the emitter firing rate in some circumstances?... A. I believe so."); Resp., 22 ("Lisogurski discloses a pulse oximeter having an adjustable 'firing rate'"); Ex.1011, 35:29-31 ("decreasing the duration of the 'off' periods (i.e., increasing the emitter firing rate) relates to an increased sampling rate.").

Reply at 6-7

OBVIOUSNESS

Two reasons why Board should not have instituted

In its Institution Decision ("DI") (Paper 16), the Board properly determined that Lisogurski fails to teach the "increasing a pulse rate" limitation, and properly stopped short of finding that Carlson discloses the limitation. The Board nonetheless instituted review despite "accepting as true" Patent Owner's assertion that neither reference disclosed the missing limitation. In doing so, the Board improperly instituted review ***based on an obviousness argument the Petition did not make and which lacked evidentiary support.*** In addition, the Board instituted review ***based on an erroneous construction of the "increasing a pulse rate" limitation***, which, *inter alia*, replaced the claim term "configured to" with "capable of" – improperly broadening the claims.

Response at 1-2

Why the Board's institution decision was incorrect

The Board nonetheless instituted review "even accepting as true" Patent Owner's assertion that Carlson fails to disclose increasing SNR "by increasing a pulse rate." (*Id.* at 35-36.) In doing so, the Board (1) relied on its incorrect "capable of," passive voice claim construction, and (2) improperly advanced, without supporting evidence, an obviousness argument the Petition did not make. Nowhere does the Petition assert, let alone support, that the challenged claims are obvious if neither Lisogurski nor Carlson disclose a light source that is configured to increase the pulse rate to increase signal-to-noise ratio.

Response at 13

LISOGURSKI

THE BOARD'S PRELIMINARY LISOGURSKI CONCLUSIONS

The Board's preliminary findings

The Board determined that Lisogurski discloses varying the "firing rate" only "to become or remain synchronous with a cardiac cycle, not to increase signal-to-noise." *Id.* at 30. The Board also correctly determined that "changing from a modulated light output to a constant light output" in response to noise or ambient light is not "increasing a pulse rate" as claimed. *Id.* at 30-31. Finally, regarding Apple's "sampling rate" argument, the Board determined "Lisogurski is teaching varying the sampling rate to be synchronous with the cardiac cycle, not to improve signal-to-noise." *Id.* at 31.

Ex. 2122, ¶ 73

Apple does not dispute the Board's findings

[3] The Board found, and Apple does not dispute, that Lisogurski's "LED firing rate is varied to become or remain synchronous with a cardiac cycle, not to increase signal-to-noise." (Paper No. 16, ID at 30.) The Board also found, and Apple does not dispute, that "Lisogurski is teaching varying the sampling rate to be synchronous with the cardiac cycle, not to improve signal-to-noise." (*Id.* at 31.)

Sur-reply at 4

Lisogurski does not disclose increasing SNR by increasing pulse rate

A. The Board correctly determined that Lisogurski fails to disclose increasing SNR by "increasing a pulse rate" as claimed

Petitioner asserts, incorrectly, that Lisogurski discloses adjusting LED "firing rate" to "ensure an adequate signal-to-noise ratio." (Pet. at 35 citing Lisogurski at 8:29-35, 25:49-55 and 27:44-52.) But as the Board determined, none of the Lisogurski passages cited in the Petition disclose increasing the pulse rate of the light source to improve SNR as claimed: "Petitioner has failed to sufficiently demonstrate how Lisogurski teaches increasing LED firing rate to increase signal-to-noise." (DI at 29-31.)

Response at 13-14

Lisogurski discloses two types of modulation

Lisogurski discloses two forms of light source modulation, neither of which is configured to increase SNR by increasing a pulse rate as claimed. ***First***, Lisogurski discloses "cardiac cycle modulation" which is "aligned with pulses of the heart" or "other suitable physiological cyclical cycle." (Ex. 1011 at 5:25-47.) This cardiac cycle modulation is "on the order of 1 Hz" correlating with an average heart rate of 60 beats per minute. (*Id.* at 6:28-29.) This is shown, for example, by blocks

* * *

Second, Lisogurski also describes "a technique to remove ambient and background signals" by measuring ambient light while the LED is off and subtracting that measurement from the signals received with the light on. (*Id.* at 6:7-30.) Lisogurski says this can be done at an exemplary modulation rate of "1 kHz" using separate "drive cycle modulation." (Ex. 1011 at 5:48-54; 6:30.) Apple ignores

Sur-reply at 1-2

ANTHONY'S CITATIONS DO NOT SUPPORT LISOGURSKI "ALONE"

FIRING RATE

Anthony's citations do not support that Lisogurski increases pulse rate for SNR

63. Dr. Anthony asserts, incorrectly, that "Lisogurski explains that the light drive parameters (e.g., brightness, duty cycle, ***firing rate***) can be varied to adapt to changes in the environment, which allows the signal-to-noise ratio of the device to be increased when interference is encountered." (¶75, emphasis added.) He cites Lisogurski at 5:55-61, 9:46-52, 27:44-49. But none of the cited passages disclose increasing signal to noise ratio by increasing the "firing rate."

* * *

as claimed. Thus, none of the cited passages support Dr. Anthony's statement that "Lisogurski explains that the light drive parameters (e.g., brightness, duty cycle, ***firing rate***) can be varied to adapt to changes in the environment, which allows the signal-to-noise ratio of the device to be increased when interference is encountered." (Ex. 1003, ¶75, emphasis added.)

Ex. 2122

Anthony's citations of Lisogurski do not support his conclusions

> 65. In his obviousness analysis, Dr. Anthony states:
>
> Lisogurski explains that its system can ***adjust various parameters of light emitted by the LEDs to ensure an adequate signal-to-noise ratio***. Ex.1011 (Lisogurski), 9:46-52, *id.*, 37:6-22. ***These parameters include*** "drive current or light brightness, duty cycle, [and] ***firing rate***" amongst others. Ex.1011 (Lisogurski), 27:44-52, *id.*, 2:1-2 ("light source firing rate"), 8:29-35, 25:49-55.

(Ex. 1003, ¶112.) (Emphasis added.)

66. Yet, the cited passages do ***not*** state that the Lisogurski system adjusts firing rate to increase SNR as claimed.

No support in Lisogurski for increasing firing rate to increase SNR

Petitioner concludes—without citation to Lisogurski—that "Lisogurski teaches that the system can increase the LED firing rate ('*pulse rate*') to increase signal-to-noise ratio." (Pet. at 36, emphasis in original.) As explained above, however, Lisogurski does ***not*** disclose this limitation. Petitioner cites its expert declaration for support, but the expert's declaration similarly fails to cite any passage of Lisogurski supporting his bare conclusion. (Ex. 1003, ¶116.)

Response at 16

Analysis of Anthony's Lisogurski "support": 5:55-61, 9:46-52, 27:44-49

Lisogurski at 5:55-61 make no mention of firing rate, let alone increasing it to increase SNR as claimed. In the only provided example, "brightness" of the light source (not pulse rate) is changed "every several seconds." (Ex. 1011, Lisogurski at 5:63-64.) Lisogurski at 9:46-52 states "the system may increase the ***brightness*** of the light sources in response to the noise to improve the signal-to-noise ratio." That passage also fails to describe increasing the firing rate to increase SNR. Lisogurski at 27:44-49 describes "modulation of" the firing rate, among other elements of the "light drive signal," but neither teaches not suggests increasing SNR by increasing the pulse rate as claimed. Thus, none of the cited passages support Dr. Anthony's statement that

Ex. 2122, ¶ 63

Analysis of Anthony's Lisogurski "support": 37:6-22, 2:1-2, 8:29-35, 25:49-55

Lisogurski at 37:6-22 makes no mention of increasing the pulse rate to increase SNR. Lisogurski at 2:1-2 mentions varying the light source firing rate "in response to the external trigger" – not for purposes of increasing SNR as claimed. Lisogurski at 8:29-35 similarly fails to describe increasing the pulse rate to increase SNR as claimed. Finally, Lisogurski at 25:49-55 describes "cardiac cycle modulation techniques," not increasing the pulse rate to increase SNR as claimed.

Ex. 2122, ¶ 66

Analysis of Anthony's Lisogurski "support": Anthony ¶ 116

69. Dr. Anthony incorrectly states in ¶116 that Lisogurski discloses increasing the "firing rate" to increase SNR:

> With respect to the light output, Lisogurski states that "[t]he system may increase the brightness of the light sources in response to the noise to improve the signal-to-noise ratio." Ex.1011 (Lisogurski), 9:46-52 (emphases added). Lisogurski states that increasing the sampling rate "may result in more accurate and reliable physiological information." Ex.1011 (Lisogurski), 33:56-58. Therefore, Lisogurski explains that the LED firing rate can be increased to increase signal-to-noise ratio.

70. Yet, the quoted statements pertain to increasing the brightness of the light sources to increase SNR, not increasing the pulse rate as claimed.

Analysis of Anthony's Lisogurski "support": 1:67-2:3, 5:55-61, 9:46-60, 37:6-18

71. Later in his analysis, Dr. Anthony incorrectly states "Lisogurski explains that the ***firing rate*** of the LEDs can be adjusted in response changes in environmental conditions, such as changes in background noise or ambient light." He cites four passages from Lisogurski, but none of them support his statement. Lisogurski at 1:67-2:3 discloses varying the firing rate "in response to the external trigger" – not to increase SNR as claimed. Lisogurski at 5:55-61 discloses "servo algorithms" for adjusting "signal brightness" to address changes in ambient light – not increasing the pulse rate of the light source to increase SNR as claimed. Lisogurski at 9:46-60 and 37:6-18 also address adjusting signal brightness or, as an alternative, changing from pulsed light to a continuous light source – not increasing the pulse rate of the light source to increase SNR as claimed.

Ex. 2122

Lisogurski does not disclose the "pulse rate" limitation

64. Dr. Anthony states "Lisogurski describes several modulation schemes that can be used to vary ***these parameters***" citing Lisogurski at 5:25-6:9. (Ex. 1003, ¶75, emphasis added.) Yet, like his other citations, nothing in this passage teaches or suggests increasing SNR by increasing the pulse rate as claimed. He fails to identify a passage in Lisogurski that teaches that limitation – there is none.

73. In its Institution Decision, the Board correctly found that Lisogurski fails to disclose increasing SNR by increasing a pulse rate as claimed. (Paper No. 16 at 30-31.) The Board determined that Lisogurski discloses varying the "firing rate" only "to become or remain synchronous with a cardiac cycle, not to increase signal-to-noise." *Id.* at 30.

Ex. 2122

ANTHONY'S CITATIONS DO NOT SUPPORT LISOGURSKI "ALONE"

SAMPLING RATE