UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

OMNI MEDSCI, INC.,
Patent Owner.

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

Case No.: IPR2019-00916

PATENT OWNER'S RESPONSE TO PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.220

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No.	Description
2101	Apple Inc.'s Final Election of Asserted Prior Art, filed in *Omni MedSci, Inc. v. Apple Inc*., Case No. 2:18-cv-134-RWS (E.D. Tex.), May 24, 2019
2102	Scheduling Order, filed in *Omni MedSci, Inc. v. Apple Inc*., Case No. 2:18-cv-134-RWS (E.D. Tex.), June 19, 2018
2103	Reserved
2104	Reserved
2105	Reserved
2106	Reserved
2107	Claim Construction Memorandum Opinion and Order, filed in *Omni MedSci, Inc. v. Apple Inc*., Case No. 2:18-cv-134-RWS (E.D. Tex.), June 24, 2019
2108	Reserved
2109	Reserved
2110	District Court Scheduling Notice, issued in *Omni MedSci, Inc. v. Apple Inc*., Case No. 2:18-cv-134-RWS (E.D. Tex.), July 12, 2019
2111	Omni MedSci's Amended Final Election of Asserted Claims, served in Omni MedSci, Inc. v. Apple Inc., Case No. 2:18-cv-134-RWS (E.D. Tex.), May 7, 2019
2112	Reserved
2113	District Court Docket Sheet, *Omni MedSci, Inc. v. Apple Inc*., Case No. 2:18-cv-134-RWS (E.D. Tex), October 3, 2019
2114	Amend Docket Control, filed in *Omni MedSci, Inc. v. Apple Inc*., Case No. 2:18-cv-134-RWS, Dkt. 142 (E.D. Tex), March 29, 2019
2115	Petition challenging U.S. 8,888,701 to LeBoeuf et al., *Apple Inc. v. Valencell, Inc*., IPR2017-01704, Paper 2 (PTAB) June 30, 2017
2116	Order, *Apple Inc. and ZTE (USA) Inc., v. INVT SPE LLC*, IPR2018-01478, Paper 8 (PTAB) January 30, 2019

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2117	Civil Minutes, issued in *Windy City Innovations, LLC v. Facebook, Inc*., Case No. 16-cv-01730-YGR, Dkt. 148 (N.D. Cal) January 28, 2019
2118	Case Management and Pretrial Order, issued in *Intri-Plex Technologies, Inc., v. NHK Intl. Corp*., Case No. 17-cv-01097-EMC, Dkt. 114 (N.D. Cal) May 23, 2019
2119	Email Correspondence regarding Motion to Dismiss, *Omni MedSci, Inc. v. Apple Inc.*, No. 19-cv-05924 (N.D. Cal.) and No. 19-cv-05673 (N.D. Cal.) (Nov. 1, 2019)
2120	PCT Application Serial No. PCT/US2013/075767 (Publication No. WO/2014/143276)
2121	U.S. Patent Application Serial No. 14/109,007 (Publication No. 2014/0236021)
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2123	Curriculum Vitae of Duncan L. MacFarlane, Ph.D, P.E.

I. Introduction

Petitioner challenges claims 5, 7-10, 13, and 15-17 of U.S. Patent No. 9,651,533 ("the '533 Patent") as obvious on two grounds. In Ground 1, Petitioner asserts that a combination of U.S. Patent No. 9,241,676 ("Lisogurski") (Ex. 1011) and U.S. Patent Pub. 2005/0049468 ("Carlson") (Ex. 1009) render claims 5, 7-10, 13, and 15-17 obvious under 35 U.S.C. § 103. In Ground 2, Petitioner asserts that a combination of Lisogurski, Carlson, and U.S. 5,746,206 ("Mannheimer") (Ex. 1008) render claims 8-9 and 16-17 obvious.

The Board should deny the Petition for *inter partes* review as to both Grounds because the Petition fails to establish *prima facie* obviousness for the challenged claims. The Petition relies solely on two references, Lisogurski and Carlson, to disclose the "increasing a pulse rate" limitation recited in challenged independent claims 5 and 13. Yet, neither reference discloses the limitation, alone or in combination. Petitioner, therefore, failed to establish *prima facie* obviousness.

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.

Pursuant to 35 U.S.C. § 312(a)(3) and Federal Circuit law, the Board cannot find patent claims unpatentable based on an improper claim construction and an unsupported argument the Petition did not make.

A. The '533 Patent discloses innovative systems for making accurate non-invasive physiological measurements

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.)

Figure 24 of the '533 Patent, reproduced below (color added), illustrates an exemplary physiological measurement system 2400.

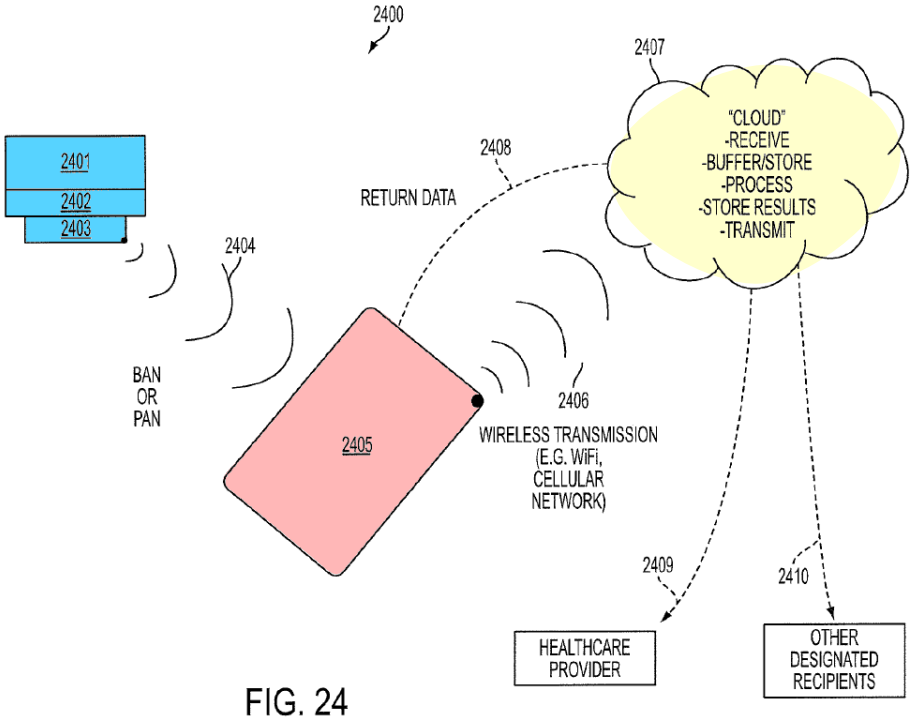


FIG. 24

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.)

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.)

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.”.)

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.”

[1] Throughout this Response, all emphasis added unless noted otherwise.

(*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 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].)

The wearable measurement device also includes a plurality of lenses that receive a portion of the output optical beam from the light source and deliver an analysis beam to a sample. (Ex. 1001 at 5:47–50.)

Lastly, the wearable measurement device includes a receiver that receives at least a portion of the analysis beam that has been reflected from or transmitted through the sample, and processes that signal to generate an output signal. (*Id.* at 5:51–54.)

The Challenged Claims include independent claims 5 and 13. Independent claim 5 is representative and reproduced below with emphasis added to illustrate the "light source . . . increasing a pulse rate" limitation at issue in this Response:

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***;

an apparatus comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample

a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal, wherein the receiver is configured to be synchronized to the light source;

a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen, the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal, and wherein at least a portion of the processed output signal is

configured to be transmitted over a wireless transmission link; and

a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data.

(Ex. 1001, 29:43-30:11.)

B. Effective filing date and AIA status

The ’533 Patent was filed as U.S. application No. 14/875,709 on October 6, 2015 and issued on May 16, 2017. (Ex. 1001 at 1.) The ‘709 Application is a continuation of U.S. application No. 14/108,986 which was filed on December 17, 2013 and issued as U.S. Patent No. 9,164,032. The ‘709 Application also claims the benefit of, and priority to, Provisional application No. 61/747,487 filed on December 31, 2012. (Ex. 1001 at 1-2.)

Patent Owner disagrees with the effective filing date arguments advanced by Petitioner in § IV.A. of the Petition. Nevertheless, because the disagreement over the effective filing date is not relevant to and does not impact the analysis below, Patent Owner does not contest, for purposes of this proceeding only, Petitioner’s claims that the ’533 Patent’s effective filing date is “not earlier than October 6, 2015” and that the ’533 Patent is subject to the America Invents Act.

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.*)

D. Claim construction

1. "pulse rate"

Petitioner proposed construing the term "pulse rate" in claims 5 and 13 to mean a "number of pulses of light per unit of time." (Pet. at 20.) In its Institution Decision, the Board determined that construction of the term "is not needed to resolve the fundamental controversy between the parties, i.e., whether Petitioner has demonstrated a reasonable likelihood of showing the unpatentability of claims 5, 7–10, 13, and 15–17." (DI at 9.) Patent Owner agrees that no construction is needed to decide the issues raised in the Petition.

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.*)

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.

When construing claims, the Board must apply the standard of *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). *See* 37 CFR §42.100(b); 83 CFR

51340-59. Unlike the "broadest reasonable interpretation" standard used in prosecution, under the *Phillips* standard, the Board must discern the meaning of the claims using the claims themselves and the intrinsic record. *Phillips*, 415 F.3d at 1313. The proper construction is the one that stays true to the claim as written. *Phillips*, 415 F.3d at 1316 ("The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction."). A construction that broadens the claim is improper. *See Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419 (1908) ("In making his claim the inventor is at liberty to choose his own form of expression, and while the courts may construe the same in view of the specifications and the state of the art, they may not add to or detract from the claim."); *Phillips*, 415 F.3d at 1312 quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("we look to the words of the claims themselves . . . to define the scope of the patented invention.").

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.

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.

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.

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.

The ’533 Patent specification makes clear that the change in pulse-rate is done by the device, not a manual adjustment. (Ex. 2122, MacFarlane Decl., ¶35.) *Phillips*, 415 F.3d at 1315 (“the specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’”), quoting *Vitronics*, 90 F.3d at 1582. 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.) 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 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].)

For these reasons, the Board should adopt the following construction of "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":

> a light source, containing two or more light emitting diodes (semiconductor sources), where the light source is configured to increase the pulse rate of at least one of the light emitting diodes to increase signal-to-noise ratio.

II. Summary of Patent Owner Response

Independent claims 5 and 13, from which all other challenged claims depend, require: "*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 . . .*." Petitioner asserts that Lisogurski discloses this limitation, and if not disclosed in Lisogurski, it would have been obvious to modify Lisogurski to implement the "technique" disclosed in Carlson. (Pet. at 35-39.) The Petition asserts no other basis for finding the "increasing a pulse rate" limitation obvious.

Neither Lisogurski nor Carlson disclose a system where the device itself is "configured to" "increase a pulse rate of at least one of the plurality of semiconductor sources" so as to "increase signal-to-noise ratio." In the Institution Decision, the

Board explained that Lisogurski does not disclose this limitation and stopped short of finding that Carlson discloses the limitation. (DI at 29-35.)

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.

For these reasons, the Petition fails to establish *prima facie* obviousness and the Board should confirm the patentability of the challenged claims.

III. Argument

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.)

Lisogurski teaches three different techniques for improving SNR: (i) by increasing the "brightness" of the light source, (ii) by operating in a "high power mode without cardiac cycle modulation," and (iii) by modulating the light signal to correlate with "physiological pulses" such as a "cardiac pulse," *e.g.*, "diastole period cardiac modulation" or "systole period cardiac cycle modulation." (Ex. 1011, Lisogurski at 6:3-6; 9:4-7; 9:46-60; 25:66-26:14; 42:45-58.) Nowhere does Lisogurski disclose the claimed configuration of increasing the pulse rate to improve SNR. (Ex. 2122, MacFarlane Decl., ¶¶63-73).)

Petitioner asserts that Lisogurski "describes embodiments where the firing rate of an LED is correlated to the sampling rate of an analog-to-digital converter in the detector," and that Lisogurski "teaches that as the sample rate increases, the firing rate of the LED also increases." (Pet. at 36 citing Lisogurski at 11:43-46; 11:52-55; 33:47-49; 33:56-58; 35:7-9; 35:27-31.) Petitioner has it backwards. The cited passages of Lisogurski disclose setting the sampling rate based on the modulation of the light drive signal—not vice-versa as Petitioner asserts. (Ex. 2122, MacFarlane Decl., ¶¶67-68.) Regardless, Lisogurski discloses varying the *sampling rate* of the *detector* to "optimize power consumption"—***not*** to increase SNR by increasing the

pulse rate of the *light source* as claimed. (*Id*., ¶68; Ex. 1011, Lisogurski at 10:23-26.)

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.)

In its Institution Decision, the Board correctly found that Lisogurski fails to disclose increasing SNR by increasing a pulse rate as claimed. (DI at 30-31; Ex. 2122, MacFarlane Decl., ¶73.) 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***." (DI 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, with regard to Petitioner'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.)

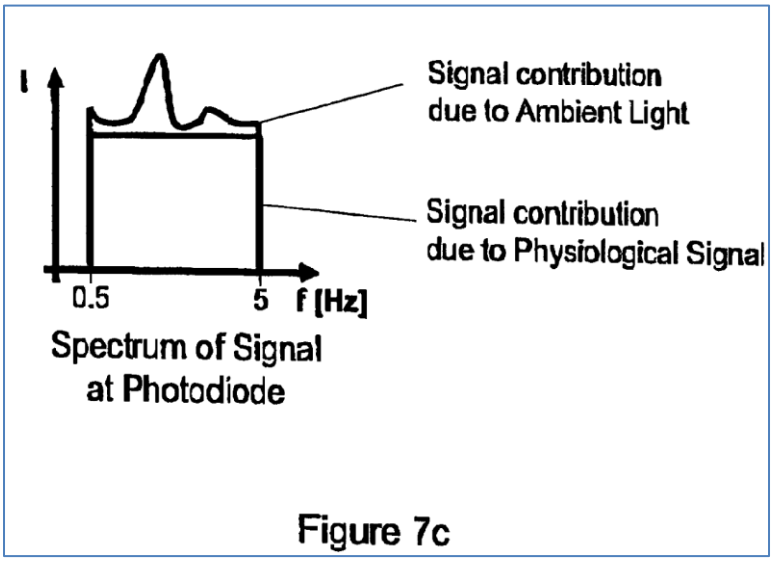
B. The Board correctly stopped short of finding that Carlson discloses increasing SNR by "*increasing a pulse rate*" as claimed—it does not

Petitioner asserts that Carlson "teaches that increasing the modulation frequency of the pulsed LEDs improves the signal-to-noise ratio" and 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. at 39.) But contrary to Petitioner's assertion, Carlson does ***not*** disclose increasing a pulse rate of a light source to increase SNR as claimed. (Ex. 2122, MacFarlane Decl., ¶84.) Carlson discloses, instead, designing the system to modulate the LED at a fixed, ***specific*** carrier frequency, f_c/f_0 (as distinct from "current or continuous light") "in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range where environmental radiation is unlikely." (Ex. 1009, Carlson at [65] and [69]; Ex. 2122, MacFarlane Decl., ¶¶77-79.) Carlson thus teaches modulating the light source at a chosen single, fixed pulse rate, not ***increasing*** the pulse rate to increase SNR as claimed. (Ex. 2122, MacFarlane Decl., ¶79.) Carlson makes clear that the (single) carrier frequency f_c/f_0 is "chosen"—not "increased"—as claimed.

- "The frequency is ***chosen*** in such a way that it is outside the frequency spectrum of sunlight and of ambient light . . .." (Ex. 1009, Carlson at [69].)
- "f_0 is the ***chosen*** frequency of the emitted light" (*Id.*)

- "f_0 of course can be ***chosen*** at any other frequency, as e.g. 2000 Hz or even higher" (*Id.*)

Petitioner states, incorrectly, that "Figure 8 of Carlson shows increasing the operating frequency F_0 of the LEDs as compared to Fig. 7c." (Pet. at 38, citing Carlson at [69] and Ex. 1003, ¶119; Ex. 2122, MacFarlane Decl., ¶80.) *First*, Carlson does not disclose what Petitioner describes as an "operating frequency F_0" for the LEDs. (Ex. 2122, MacFarlane Decl., ¶81.) To the extent the Petitioner is referring to Carlson's "carrier frequency" f_c, Figure 7c does not disclose a carrier frequency either. (*Id.*) Instead, as shown below, Figure 7c discloses "a basic signal contribution due to physiological signal and additional signal contribution due to ambient light." (Ex. 1009, Carlson at [67].)



Carlson explains that Figure 7c illustrates what "would be ***detected*** by a photo diode ***without*** the use of any means as described above in relation to FIGS. 1 to 6."

(Ex. 1009, Carlson at [67]; Ex. 2122, MacFarlane Decl., ¶76.) Figure 7c thus illustrates detection of "current or continuous light" (Ex. 1009, Carlson at [69]; Ex. 2122, MacFarlane Decl., ¶76), not light modulated or "pulsed" at a carrier frequency f_c. (Ex. 1009, Carlson at [64-65]; Ex. 2122, MacFarlane Decl., ¶76).

Because Figure 7c of Carlson does not disclose a carrier frequency f_c (or Petitioner's "operating frequency f_0"), Figure 8 of Carlson cannot disclose "***increasing*** the operating frequency F_0 of the LEDs as compared to Fig. 7c," as Petitioner incorrectly asserts. (Pet. at 38; Ex. 2122, MacFarlane Decl., ¶82.) As explained above, in Fig. 8, Carlson discloses a ***single*** "chosen" carrier frequency f_0, (Ex. 2122, MacFarlane Decl., ¶79), which is a fixed frequency, shown in Figure 8 (reproduced below) but not Figure 7c.

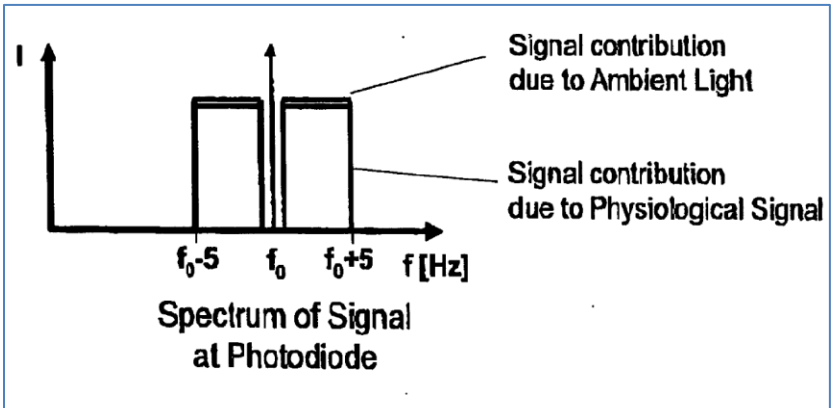


Figure 8

Carlson's "chosen" carrier frequency does not change; it does not increase over time for any purpose, let alone to increase SNR as claimed. (Ex. 2122,

MacFarlane Decl., ¶¶79, 84.) While Carlson teaches that a designer may choose one of several different carrier frequencies (Ex. 1009, Carlson at [69]), the chosen frequency remains fixed. (Ex. 2122, MacFarlane Decl., ¶79.) In this manner, Carlson fails to disclose a ***system*** that ***increases*** a pulse rate to increase SNR as claimed. (Ex. 2122, MacFarlane Decl., ¶85.)

Petitioner also states, incorrectly, that Carlson discloses a "frequency shift, which corresponds to increasing the '*pulse rate*' of the emitter." (Pet. at 38, emphasis in original; Ex. 2122, MacFarlane Decl., ¶82.) Carlson discloses temporarily modulating the LED at a chosen, fixed carrier frequency f_c to ***shift the power spectrum*** of the pulsoximeter signals into a higher frequency range"—***not*** to shift the carrier frequency itself, as Petitioner incorrectly implies. (Ex. 2122, MacFarlane Decl., ¶83.) As explained above, Carlson discloses using either "current or continuous light," or modulating the light using a fixed, "chosen" carrier frequency f_c/f_0. (Ex. 2122, MacFarlane Decl., ¶¶76, 79.)

In its Institution Decision, the Board observed, "Carlson more generally teaches 'shift[ing] the ***power spectrum*** of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely.'" (DI at 35.) Changing the "power spectrum" is different from increasing the pulse rate of the light source to increase SNR. (Ex. 2122, MacFarlane Decl., ¶83.) As Carlson expressly teaches, setting a single, fixed pulse rate, *e.g.*, 1000Hz, is suitable to

achieve Carlson's stated goal of shifting the power spectrum of the pulsoximeter signals (*i.e.*, from the continuous light spectrum shown in Fig. 7c) to a higher frequency range where environmental optical radiation is unlikely. (*Id*., ¶¶83-84.) Carlson achieves this goal by designing the light to pulse at a particular "chosen" frequency—not by using a system that can actively increase the pulse rate to increase SNR. (Ex. 1009, Carlson at [69]; Ex. 2122, MacFarlane Decl., ¶¶84-85.)

C. Taken together, Lisogurski and Carlson do not render the challenged claims obvious

Dr. Anthony asserts that "a person of ordinary skill in the art 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 (Carlson), [0069]." (Ex. 1003 at ¶121.) But, as explained above, Carlson does not teach that "increasing the modulation frequency of the pulsed LEDs improves the signal-to-noise ratio." (Ex. 2122, MacFarlane Decl., ¶86.) Carlson teaches only that, as an alternative to continuous light (Fig. 7c), modulated light at a "chosen" frequency F_0 (Fig. 8) may help avoid interreference caused by sunlight, other ambient light and/or intermittent shade. (*Id*.) Carlson never discloses a ***device*** that ***increases*** the modulation frequency or the pulse rate, let alone to increase SNR as claimed. (*Id*.)

Lisogurski discloses a pulse oximeter having an adjustable "firing rate," and increasing signal brightness to address interference caused by ambient light. (Ex. 2122, MacFarlane Decl., ¶87.) Carlson, in contrast, teaches that a designer may "choose" a pulse rate above the rate of any anticipated interference, *e.g.*, 1000 Hz. (*Id*.) Thus, if a person of ordinary skill in the art at the time of the invention were to combine the teachings of Lisogurski and Carlson, the result would simply be a pulse oximeter having a single "chosen" firing rate above 1000Hz. (*Id*.) The references lack any disclosure, alone or in combination, of a ***device*** that ***increases*** an ***existing*** pulse rate to increase SNR as recited in the challenged claims of the '533 Patent. (*Id*.)

Dr. Anthony does not advance an obviousness analysis other than modifying Lisogurski using the "Carlson technique" which, as explained above, is not a device that increases pulse rate to increase SNR. Dr. Anthony's analysis is based entirely on his incorrect conclusion that Lisogurski and/or Carlson independently disclose increasing SNR by increasing a pulse rate as claimed. (Ex. 2122, MacFarlane Decl., ¶88.)

D. Because neither Lisogurski nor Carlson disclose increasing SNR by "*increasing a pulse rate*," the Petition fails to establish *prima facie* obviousness

1. Petitioner presents no argument or evidence that "*increasing a pulse rate*" is obvious if that limitation is not disclosed in Lisogurski or Carlson

Apple asserts, incorrectly, that both Lisogurski and Carlson disclose increasing SNR by "increasing a pulse rate." (Pet. at 35-39; Ex. 1003, ¶¶110-121.) Apple, and its expert, make no argument and present no evidence that the limitation is obvious *independent of* Lisogurski or Carlson. (*Id.*) In other words, if Patent Owner (and the Board) is correct that neither Lisogurski nor Carlson disclose the "increasing a pulse rate" limitation (and they do not), the Petition lacks any other basis for asserting obviousness.

2. The Petition lacks a *prima facie* case of obviousness, which cannot be cured in the Reply

As the Board already determined, Lisogurski fails to disclose a system that increases the pulse rate of the light source to increase the signal to noise ratio. (DI at 30-31.) And the Board stopped short of finding that that Carlson discloses "increasing a pulse rate" as claimed. The Board correctly found Carlson discloses pulsing the LED at "a rate" that is "chosen" at "some frequency f_0":

> Carlson teaches pulsing the LEDs at ***a rate*** higher than the frequency spectrum of the noise. *See* Ex. 1011, 9:50–52 ("The system may increase the brightness of the light sources in response to the noise to

> improve the signal-to-noise ratio."); Ex. 1009 ¶69 ("emit[ting] 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 . . . increasing significantly the Signal-to-Noise.").

(DI at 27.)

> Carlson teaches removing such disturbances by pulsing the sensor LEDs at ***a frequency*** that is "outside the frequency spectrum of sunlight and of ambient light" in order to "increas[e] significantly the Signal-to-Noise." *Id.* ¶69. Carlson does not teach pulsing the LEDs at any particular frequency, but instead teaches pulsing at ***some frequency*** f_0 and "using AC-Coupling or Lock-In Amplification . . . to temporarily modulate the optical radiation of the LED at ***the carrier frequency*** f_0 in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely." *Id.* ¶¶65, 69. Although Carlson gives a particular example of pulsing the LEDs at 1000 Hz, that example pertains to sampling pulsed LED light that has been transmitted through or reflected from a sample in the presence of 0 to 120 Hz noise. *Id.* ¶69. Carlson more generally teaches "shift[ing] the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely." *Id.* ¶65.

(DI at 34-35.)

To be clear, choosing a carrier frequency that "shift[s] the ***power spectrum*** of the pulsoximeter signals ***into a higher frequency range*** where environmental optical

radiation is unlikely" does ***not*** disclose "increasing a pulse rate" of the light source. (Ex. 2122, MacFarlane Decl., ¶¶83-84.) Figure 7c shows a power spectrum for what the specification describes as "continuous light." (Ex. 1009, Carlson at [67] and [69]; Ex. 2122, MacFarlane Decl., ¶¶76-77.) Carlson discloses that the frequency of the "power spectrum" (not the pulse rate) may increase through the imposition of the continuous light signal onto a "chosen" carrier frequency. (Ex. 1009, Carlson at [65] and [69].) This is not a disclosure that the Carlson device increases a pulse rate to increase SNR, which would be contrary to Carlson's specification. (Ex. 2122, MacFarlane Decl., ¶¶84-85.)

Dr. Anthony never asserted obviousness "accepting as true Patent Owner's argument that Carlson teaches selecting a single (e.g., 1000 Hz) LED pulse rate when designing the pulsoximeter." (Ex. 2122, MacFarlane Decl., ¶¶89-90.) On the contrary he asserted, incorrectly, that both Lisogurski and Carlson disclosed that limitation. (*Id.*) His obviousness conclusion is based on this (incorrect) statement that "Carlson teaches that increasing the modulation frequency of the pulsed LEDs improves the signal-to-noise ratio." (Ex. 1003, ¶121; Ex. 2122, MacFarlane Decl., ¶89.)

Dr. Anthony neither advanced nor supported an obviousness argument based on the reality the Board accepted "as true" – that neither Carlson nor Lisogurski disclosed the claimed configuration. (Ex. 2122, MacFarlane Decl., ¶90.) Given that

neither reference teaches nor suggests a device configured to increase a pulse rate to increase SNR, as claimed, the combined teachings of Lisogurski and Carlson could not have rendered obvious the claimed configuration in which a device increases the pulse rate to increase SNR. (*Id.*)

Because the required teaching is completely absent from the two prior art references Petitioner cites, the Petition does not establish *prima facie* obviousness. (Ex. 2122, MacFarlane Decl., ¶91.) *See Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1345 (Fed. Cir. 2013). In *Focarino*, the Federal Circuit reversed the Board's obviousness determination, finding that neither of the asserted prior art references disclose a limitation of the challenged independent claims and that the Board misread the prior art references. (*Id.*) The Federal Circuit held that the Board failed to carry its burden to establish *prima facie* obviousness. *Id.*, citing *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). More recently, in *Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1378 (Fed. Cir. 2018), the Federal Circuit affirmed the Board's conclusion of non-obviousness where neither prior art reference disclosed a limitation of each independent claim. *See also Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1366 (Fed. Cir. 2012) (reversing district court's Judgment as a Matter of Law of invalidity for obviousness where the prior art references, even if combined, failed to disclose an independent claim limitation).

In addition, Petitioner cannot "fix" this flaw in its Reply. 35 U.S.C. § 312(a)(3) requires that 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." A *prima facie* case of obviousness is absent from the Petition; thus, there is no *prima facie* case of obviousness to fix. And § 312(a)(3) bars any Reply argument or evidence to add a missing *prima facie* case of obviousness where none previously existed. *See also* Consolidated Trial Practice Guide (Nov. 2019) at 73 ("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."); *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-00582, Paper No. 34 at 30-31 (PTAB Aug. 5, 2019) (Informative) (rejecting Petitioner's new argument and evidence asserting obviousness in its reply that was not presented in the petition).

3. The Board instituted based on an unsupported argument that neither the Petition nor the Petitioner's expert made.

As explained above, the Board correctly determined that Lisogurski did not disclose the "increasing a pulse rate" limitation, and the Board correctly stopped short of stating that Carlson disclosed the limitation. (DI at 30-31 and 33-35.) The Board nonetheless concluded that the independent claims may be obvious "***even accepting as true*** Patent Owner's argument that Carlson teaches selecting a single

(e.g., 1000 Hz) LED pulse rate when designing the pulsoximeter." (DI at 35.) This conclusion is erroneous for several reasons.

First, the Board stated that Patent Owner "fail[ed] to consider the combined teachings of Carlson and Lisogurski." *Id. citing In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) and *In re Keller*, 642 F.2d 413, 425 (Fed. Cir. 1981). But neither reference teaches nor suggests a ***device*** "configured to" ***increase*** a pulse rate to increase SNR, as claimed. So, even taken together, there is no teaching or suggestion of this missing limitation. *Merck* and *Keller* are inapposite because neither case dealt with the scenario here in which the asserted prior art references, even when combined, fail to disclose or suggest a key claim limitation. In *Merck*, the Board rejected the applicant's assertion that there was no "motivation" in the prior art to arrive at the invention, as well as the applicant's assertions of secondary indicia of non-obviousness. *See Merck*, 800 F.2d at 1097-1098. In *Keller*, the issue was whether the two prior art references were properly combinable. *See Keller*, 642 F.2d at 425.

The more relevant authorities are *Focarino*, 738 F.3d at 1345, *Medtronic*, 891 F.3d at 1378, and *Kinetic Concepts*, 688 F.3d at 1366. In those cases, the invalidity challenge was rejected because the asserted prior art, even taken in combination, failed to disclose or suggest an express claim limitation.

In "accepting as true" Patent Owner's argument that Carlson fails to teach increasing SNR by "increasing a pulse rate," the Board summarized what it deemed the most relevant teachings of Lisogurski and Carlson:

> Lisogurski teaches varying a pulsoximeter's light drive signal, including an LED firing rate, based on a received external trigger. Ex. 1011 1:60–2:3. Lisogurski also teaches "detect[ing] a change in background noise [or] ambient light." *Id.* at 37:8–9. Lisogurski further teaches using servo algorithms to "adjust the light drive signals due to, for example, ambient light changes." *Id.* at 5:55–59. Carlson teaches increasing a pulsoximeter's signal-to-noise in the presence of ambient light by ***choosing*** the LED firing rate or pulse frequency to be "outside the frequency spectrum of sunlight and of ambient light." Ex. 1009 ¶69.

(DI at 35-36.)

Neither of these passages disclose a device "configured to" actively "increase a pulse rate" to increase SNR, as claimed. The Board nonetheless concluded:

> Together, the references teach that a pulsoximeter **[1]** can detect a change in background noise and modify the LED firing rate based on the detected change (as taught by Lisogurski), and **[2]** 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.

(DI at 36, reference numerals added.)

Even taking the references together, however, neither statement is true. As explained above, the Board had already correctly determined that Lisogurski does ***not*** detect a change in background noise and modify the LED firing rate based on the detected change. (DI at 30-31, "At this stage of the proceeding, Petitioner has failed to sufficiently demonstrate how Lisogurski teaches increasing LED firing rate to increase signal-to-noise.") And as explained above, Carlson discloses a designer choosing a single, fixed pulse rate, not *increasing* a pulse rate. (Ex. 2122, MacFarlane Decl., ¶79.) Carlson merely discloses "choosing" a suitable firing rate—not a device configured to increase it to increase SNR, as claimed. (*Id*.) Indeed, in this portion of the Board's analysis, the Board is "***accepting as true*** Patent Owner's argument that Carlson teaches selecting a single (e.g., 1000 Hz) LED pulse rate when designing the pulsoximeter." (DI at 35.) In the next sentence, however, the Board essentially ignores that fact and ***erroneously*** concludes that "***[f]or 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***.'" (DI at 36 citing Pet. at 39.) That conclusion was based, at least in part, on the Board erroneous claim construction, which (1) permitted a manual configuration, and (2) read out the requirement of ***the light source*** being "configured to" (not just "capable of") increase the pulse rate to increase SNR.

The Board found that Petitioner had made that argument citing "Pet. 39," but ***the Petitioner did not make the Board's argument***. The Petitioner merely argued, incorrectly, that Carlson "increases the firing rate (frequency) of LEDs." (Pet. at 39.) The Petition does ***not*** identify as a basis for obviousness that the claim limitation would have been obvious "even accepting as true Patent Owner's argument that Carlson teaches ***selecting a single*** (e.g., 1000 Hz) LED pulse rate when designing the pulsoximeter." Similarly, the Petitioner's expert never asserted, as the Board does, that the claimed invention would be obvious "even accepting as true" that Carlson teaches selecting a single pulse rate. (Ex. 2122, MacFarlane Decl., ¶90.) His opinion is based solely on his incorrect belief that Carlson discloses increasing SNR by "increasing a pulse rate"—something he wrongly describes as the "Carlson technique." (Ex. 1003, ¶¶120-121.)

Thus, the Board instituted review "even accepting as true Patent Owner's argument" based on (i) an improper claim construction, (ii) an obviousness argument the Petition did not assert, and (iii) without citation to record evidence (there is none) supporting the institution decision. It was improper for the Board to do so. 35 U.S.C. § 312(a)(3); *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (reversing PTAB's obviousness determination holding that the Board may not "raise, address, and decide unpatentability theories never presented by the petitioner

and not supported by record evidence."); *Rovalma, S.A. v. Bohler-Edelstahl GmbH & Co. KG*, 856 F.3d 1019, 1027 (Fed. Cir. 2017).

The "increasing a pulse rate" limitation is recited in all challenged claims of the '533 Patent. Because the Petition does not identify with particularity any basis for finding this limitation obvious, the Petition fails to establish *prima facie* obviousness.

IV. Conclusion

Because the Petitioner has failed to establish *prima facie* obviousness of the challenged claims, Patent Owner asks the Board to confirm the patentability of all challenged '533 Patent claims.

Respectfully submitted,

Dated: January 31, 2020

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Certificate of Service

The undersigned hereby certifies that on January 31, 2020, a complete and entire copy of **PATENT OWNER'S RESPONSE TO PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.220 and all applicable Exhibits**, were served via electronic mail by serving the correspondence email address of IPRnotices@sidley.com, which delivers to the following lead and back-up counsel:

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