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EXAMINER	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL SIMMS SHULER

Appeal 2020-000675
Application 15/088,220
Technology Center 3700

Before CARL M. DEFRANCO, GEORGE R. HOSKINS, and LISA M. GUIJT, *Administrative Patent Judges.*

DEFRANCO, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 5, 9, 11, 13, 17, 19–22, and 25–30. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as J&M Shuler, Inc. Appeal Br. 2.

CLAIMED SUBJECT MATTER

Of the claims on appeal, claims 5 and 13 are independent. Claim 5 is directed to a method for automatically monitoring oxygenation levels of injured tissue in the human body in order to detect conditions of an acute compartment syndrome ("CS"), while claim 13 is directed to a system for doing the same. Claim 5 is illustrative and reproduced below.

> 5. A computer-implemented method for automatically monitoring oxygenation levels of injured tissue of a human body for automatically detecting conditions of an acute compartment syndrome, comprising:
>
> automatically monitoring oxygenation levels of injured tissue in a continuous manner with a first non-invasive sensor;
>
> automatically monitoring oxygenation levels of healthy tissue in a continuous manner with a second non-invasive sensor, the second non-invasive sensor detecting systemic perfusion of the human body from the healthy tissue;
>
> automatically calculating a difference between the oxygenation levels from the first non-invasive sensor relative to the non-invasive second sensor and displaying this difference on a display device proximate to the oxygenation levels of the first non-invasive sensor and second non-invasive sensor also being displayed on the display device; and
>
> automatically activating an alarm with a computing device indicating a potential acute compartment syndrome when oxygenation levels of the first non-invasive sensor for the injured tissue start decreasing in value compared to the oxygenation levels of the second non-invasive sensor for the healthy tissue, the second non-invasive sensor providing a basis for comparison for relative oxygenation levels of the injured tissue.

EVIDENCE OF RECORD

Name	Reference	Date
Chance	US 5,873,821	Feb. 23, 1999
Friedman	US 6,050,951	Apr. 18, 2000
Ortner	US 7,596,397 B2	Sep. 29, 2009
Shehada	US 2004/0254432 A1	Dec. 16, 2004
Baker	US 2008/0146906 A1	June 19, 2008
Li	US 2010/0145169 A1	June 10, 2010
Tsien	*Reducing False Alarms in the Intensive Care Unit: A Systematic Comparison of Four Algorithms*	1997

EXAMINER'S REJECTIONS

Appellant appeals from the Examiner's Final Office Action, dated November 15, 2018, which includes the following rejections:

Claims Rejected	35 U.S.C. §	Basis
5, 11, 13, 22, 25, 28	103(a)	Li, Chance
9	103(a)	Li, Chance, Ortner
17	103(a)	Li, Chance, Friedman
19, 20	103(a)	Li, Chance, Baker
21	103(a)	Li, Chance, Tsien
26, 27, 29, 30	103(a)	Li, Chance, Shehada

ANALYSIS

A. Independent Claims 5 and 13

Appellant argues independent claims 5 and 13 separately, but advances the same arguments with respect to both claims. *See* Appeal Br. 39 (remarking that Appellant's arguments for claim 13 are "[s]imilar to the arguments presented above for independent Claim 5"). In particular, Appellant argues that claims 5 and 13 are allowable because the combination of Li and Chance fails to teach the claim limitations of *calculating a difference between the oxygenation levels* from the non-invasive compartment sensor relative to the non-invasive healthy tissue sensor *and displaying this difference on a display device proximate to the oxygenation levels* of the non-invasive compartment sensor and the non-invasive healthy tissue sensor also being displayed on the display device. *Id.* at 13 (claim 5); *see also id.* at 39–40 (arguing that combination of Li and Chance fails to teach essentially the same limitations in claim 13). According to Appellant,

> [t]here is no difference between oxygenation levels of a first sensor and a second sensor being calculated by the Li reference whatsoever. The Li reference never teaches or suggests displaying sensor data for individual sensors as recited in Claim 5. Furthermore, there is no display of such a difference being taught or suggested by the Li reference NOR is there a display of an oxygenation level for a first sensor and an oxygenation level for a second sensor that *are both displayed proximate to the difference*.

Id. at 18. As for Chance, Appellant argues that it "relates to a differential spectrophotometer system, which is not related to any compartment syndrome (exertional or acute compartment syndrome) whatsoever" and, thus, "a person skilled in the art would not look at the Chance reference for any teachings about acute compartment syndrome that involves injured tissue [because] . . . [t]he Chance reference never mentions by name any form of compartment syndrome." *Id.* at 19, 24, respectively.

We do not find Appellant's arguments persuasive. As discussed below, the evidence supports the Examiner's findings that the combination of Li and Chance teaches the recited limitations and that a skilled artisan would have been led to combine their respective teachings to arrive at the claimed invention. *See* Exr. Ans. 3–8.

1. The Monitoring and Calculating Limitations

In satisfying the claimed "monitoring" and "calculating" steps, Li teaches a method and system of using a "non-invasive sensor," such as a "near infrared spectrometry (NIRS) sensor," to measure "deoxygenated hemoglobin" and "[o]xygenated [h]emoglobin" levels in human tissue "for detecting and alerting one to a condition of Compartment Syndrome (CS)." Li ¶¶ 2, 9, 14, 17, 30, Claims 1, 11, 19, Fig. 2. This is no different than how Appellant's specification describes the claimed invention, which likewise uses "near-infrared spectroscopy (NIRS) sensors 405A, 405B" to measure "hemoglobin oxygen concentration . . . for the accurate detection of conditions that may be associated with compartment syndrome." *See* Spec. ¶¶ 89, 94–95, Fig. 4.

Also, like the claimed invention, Li compares the measured oxygenation levels with a presumed healthy tissue threshold value and activates an alarm when the difference between the oxygenation levels indicates a condition of compartment syndrome. Li ¶¶ 34–41. More specifically, Li states that—

> the difference between the concentration of HbO_2 and an initial concentration of HbO_2 is compared with a threshold value which corresponds to a value indicating a condition of CS. If the difference is less than the threshold value, then a corresponding alarm is triggered at block 222.

Id. ¶ 40.

As for the claim limitation directed to a healthy tissue sensor for deriving oxygenation levels as a basis for comparison with oxygenation levels of injured tissue, the Examiner acknowledges that Li does not expressly teach a second non-invasive sensor to derive the threshold (i.e., baseline) oxygenation value of healthy tissue. *See* Exr. Ans. 4–5. For that aspect of the claimed invention, the Examiner points to Chance as teaching "a second non-invasive sensor for monitoring oxygenation levels of healthy tissue, or as a reference oxygenation level." *Id.* at 5.

We agree with the Examiner's findings in this regard. For instance, Chance teaches a "non-invasive" system that uses "tissue spectrometry" to measure and monitor "the oxygenation state of a specific area of tissue," be it muscle tissue or brain tissue. Chance, 1:5–11, 1:62–2:16. In one preferred embodiment, Chance's spectrophotometer uses "two sensor modules" for detecting changes in electromagnetic radiation between "two localized tissues of interest." *Id.* at 26:1–36, Fig. 24. According to Chance, the localized tissues of interest may be "regions of the left and right hemisphere of the brain, left and right breast, or left and right arm." *Id.* at 26:15–17. Notably, Chance's first sensor collects reference data from localized tissue that is expected to have normal (i.e., healthy) physiological properties, while Chance's second sensor collects data from localized tissue that is expected to have abnormal (i.e., pathological or pathophysiological) changes, such as from a tumor or bleeding. *Id.* at 26:5–10. The tissue is then evaluated by "comparing" signals from the sensors to detect any pathophysiological changes, which Chance identifies as including "oxygenation/deoxygenation changes." *Id.* at 26:48–27:6; *see also id.* at 29:16–18 ("said pathophysiological change includes . . . hemoglobin oxygenation change of the examined tissue"). Because oxygenation levels should be substantially the same in the absence of an abnormal condition, a significant change in the oxygenation level of the injured tissue as compared to that of the healthy tissue is indicative of an abnormal condition. *See id.* at 26:10–23, 26:48–27:15.

Appellant raises essentially two arguments in response to the Examiner's combination of Li with Chance. First, Appellant argues that Chance "is not related to any compartment syndrome (exertional or acute compartment syndrome) whatsoever."[2] Appeal Br. 19; *see also id.* at 24 ("The Chance reference never mentions by name any form of compartment syndrome."). Although Appellant is correct that Chance does not expressly teach that the abnormal condition may be acute CS, we agree with the Examiner's finding that Li resolves this shortcoming by teaching that, in the presence of acute CS, the oxygenation levels of injured tissue (i.e., tissue where acute CS may develop) decrease with elevated compartment pressure relative to a threshold oxygenation level. *See* Exr. Ans. 7 (citing Li ¶ 40). In other words, Li's use of a threshold oxygenation level corresponds to Chance's use of a healthy tissue oxygenation level in that each is used as a basis for comparison with the oxygenation level of injured tissue in order to detect an abnormal condition.

Appellant further argues that Chance "do[es] not provide any teaching of measuring oxygenation levels." Appeal Br. 25 (emphasis omitted); *see also id.* at 29 (arguing "the Chance reference in no way describes oxygenation levels"). We disagree. Chance states expressly that the "object of the present invention" is "to provide methods and apparatus which allow

[2] Appellant also discusses Figures 2 and 3 of Chance in an attempt to distinguish Chance from the claimed invention. Appeal Br. 19–24. We do not see the relevancy of this discussion given that the Examiner relies on Chance's Figure 24, not Figures 2 and 3. *See* Exr. Ans. 6–7.

a rapid determination of the oxygenation state of tissue." Chance, 2:65–67; *see also id.* at 3:5–9 ("It is also an object of the present invention to provide apparatus which may be attached to a user which would determine the oxygenation state of a portion of the user's body and provide that information in a readily understandable form."). And, with respect to Figure 24, Chance likewise states that the pathophysiological changes detected by the two sensors include "oxygenation/deoxygenation changes." *Id.* at 27:5–6; *see also id.* at 29:16–18 ("said pathophysiological change includes blood volume change or hemoglobin oxygenation change of the examined tissue"). Thus, we reject the notion that Chance fails to teach that the disclosed sensors measure oxygenation levels.

In sum, we agree with the Examiner that Chance suggests a suitable, predictable alternative for deriving Li's threshold or baseline value, namely, using a second sensor to measure oxygenation levels of comparable tissue known to be healthy. Thus, consistent with the Examiner's rejection, the record supports that a skilled artisan would have been led to modify Li's CS detection system to incorporate a healthy tissue sensor, as taught by Chance, for deriving Li's threshold value as a basis for comparison with the measured oxygenation levels of Li's injured tissue sensor to identify the point at which oxygenation levels begin to differ significantly.

2. The Displaying Limitation

Appellant does not dispute that both Li and Chance teach displaying the measured oxygenation levels of the tissue being monitored. For instance, Appellant admits that Li discloses displaying a "plot" of oxygenation data measured from injured tissue over time, as well as "trends" in the measured data. Appeal Br. 18. Nor does Appellant dispute Li's disclosure of displaying "the difference" (or change) between measured oxygenation levels and initial oxygenation levels relative to a threshold value indicative of a CS condition. *See* Li ¶¶ 38–42 ("The concentration values are analysed at block 208 to detect a condition of CS . . . The concentration values and results of the analysis at block 208 may be displayed on a display, as shown at block 230."); *see also id.* ¶¶ 66–69 (describing the information displayed).

Instead, Appellant merely disputes the "relative placement" of Li's data "on the display." Appeal Br. 18 (emphasis omitted). We note, however, that claims 5 and 13 only require that the calculated "difference" value be displayed "proximate to" (i.e., close to, or nearby) the measured oxygenation levels, not "[u]nderneath" them as Appellant seemingly argues. Appeal Br. 11. Because Li discloses that both the plot of measured oxygenation values and the resulting analysis of differences between measured and threshold oxygenation levels are shown on the same display, we agree with the Examiner's finding that Li's display meets the "proximate to" limitation of the displaying step of claims 5 and 13. *See* Exr. Ans. 5.

That said, however, we agree with Appellant that Li does not teach or suggest displaying oxygenation data from a healthy tissue sensor. *See* Appeal Br. 17–18. Nonetheless, Chance teaches a "display module" for monitoring the oxygenation levels measured by both a healthy tissue sensor and an injured tissue sensor. Chance, 26:24–28, 26:48–52. According to Chance, the display may be "a digital display, a bar graph or a series of deoxyhemoglobin levels, placed on a time scale." *Id.* at 2:55–61. Nowhere does Appellant dispute those teachings by Chance. *See* Appeal Br. 19–29 (arguing only that Chance is not directed to the detection of compartment syndrome). Given that both Li and Chance teach the display of measured oxygenation levels to assist in monitoring and treating injured tissue, we agree with the Examiner that a skilled artisan, upon modifying Li's system to incorporate Chance's healthy tissue sensor for determining Li's threshold oxygenation value, also would have been led to modify Li's display to show not only the oxygenation level of the injured tissue sensor but also the oxygenation level of the baseline sensor taught by Chance, in order to permit visualization of the healthy tissue oxygenation levels relative to the injured tissue oxygenation levels for purposes of detecting an abnormal CS condition. *See* Exr. Ans. 4–5.

Finally, we have considered Appellant's evidence of non-obviousness consisting of two peer review articles purporting to show skepticism of experts. *See* Appeal Br. 29–38. We do not find this evidence persuasive. Rather, we agree with the Examiner's reasoning that, although the two peer review articles "suggest that using a single NIRS sensor or spectrometer to monitor oxygenation levels of injured tissue is not sufficient to detect acute CS," neither of them appears skeptical of using a second reference sensor as the indicator of healthy oxygenation levels and the basis for comparison to those of injured tissue. Exr. Ans. 8. Indeed, from our review of the two peer review articles, they actually support Chance's teaching that a skilled artisan would have been led to provide a second sensor of known healthy oxygenation levels as a baseline for comparison to the NIRS sensor monitoring oxygenation levels of injured tissue. Accordingly, we find unpersuasive Appellant's evidence of non-obviousness.

Having considered Appellant's arguments and the prior art of record, we sustain the Examiner's rejection of independent claims 5 and 13 as unpatentable over the combined teachings of Li and Chance.

B. Dependent Claims 9, 11, 17, 19–22, and 25–30

To refute the rejection of dependent claims 9, 11, 17, 19–22, and 25–30, Appellant relies on the arguments it presented for patentability of claims 5 and 13, and argues that the additional prior art (Ortner, Tsien, Friedman, Baker, and Shehada) used to reject these claims does not cure the deficiencies of Li and Chance. Appeal Br. 40. For the same reasons provided above in our analysis of the rejection of claims 5 and 13, we do not find these arguments persuasive. Accordingly, we sustain the Examiner's rejection of dependent claims 9, 11, 17, 19–22, and 25–30.

CONCLUSION

The Examiner's rejections are AFFIRMED.

DECISION SUMMARY

Claims Rejected	**35 U.S.C. §**	**Basis**	**Affirmed**	**Reversed**
5, 11, 13, 22, 25, 28	103(a)	Li, Chance	5, 11, 13, 22, 25, 28	
9	103(a)	Li, Chance, Ortner	9	
17	103(a)	Li, Chance, Friedman	17	
19, 20	103(a)	Li, Chance, Baker	19, 20	
21	103(a)	Li, Chance, Tsien	21	
26, 27, 29, 30	103(a)	Li, Chance, Shehada	26, 27, 29, 30	
Overall Outcome			5, 9, 11, 13, 17, 19–22, 25–30	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED