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14/840,468	08/31/2015	Jana M. Kainerstorfer	70011-044001	8844

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EXAMINER	
KINGSLEY, SARAH R	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
06/19/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORPATENT.COM

Office Action Summary	Application No. 14/840,468	Applicant(s) Kainerstorfer et al.	
	Examiner SARAH KINGSLEY	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 06/03/2020.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-6,8-15,18-19,21 and 25-28 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-6,8-15,18-19,21 and 25-28 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Response to Amendment

2. Applicant's amendment to Claim 28 has overcome the claim objections previously set forth in the Final Office Action mailed March 3rd, 2020. The claim objection is withdrawn.

3. Applicant's cancellation of claim 20 has overcome the 35 U.S.C. 112, Fourth Paragraph, rejection previously set forth in the Final Office Action mailed March 3rd, 2020. The 35 U.S.C. 112(d) rejection is withdrawn.

Response to Arguments

4. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

5. Applicant's arguments filed 06/03/2020 have been fully considered but they are not persuasive. Regarding the argument that the instant claims cannot be practically performed in the human mind, and would not recite a mental process, the Examiner respectfully disagrees. As indicated in the updated Subject Matter Eligibility guidance issued October 2019, a claim that requires a computer may still recite a mental process. Although the instant claims do recite several steps of receiving and manipulating data, and determining a hemoglobin saturation using a computer, the steps of determining a hemoglobin saturation to exclude an effect of an oscillating rate of supply of oxygenated blood to a portion of the tissue by removing a measured phase offset of the oscillating hemoglobin saturation, and providing the determined

hemoglobin saturation for use in a medical setting could still be performed in the mind, as the instant claims merely use a computer as a tool to perform the concept. Therefore, the 35 U.S.C. 101 rejection of record is proper, and has not been withdrawn.

6. Applicant's arguments with respect to the 35 U.S.C. 103 rejection of claims 1 and 18 have been considered but are moot in view of a new grounds of rejection.

Claim Rejections - 35 USC § 112

7. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

> The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claim 21 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.**

9. Claim 21 recited "The system of claim 20". It is unclear what the system of claim 20 would be, as claim 20 is a canceled claim. For Examination purposes, claim 21 has been interpreted to be dependent upon claim 18.

Claim Interpretation

> The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

> The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Use of the word "means" (or "step for") in a claim with functional language creates a rebuttable presumption that the claim element is to be treated in accordance with 35 U.S.C. 112(f) (pre-AIA 35 U.S.C. 112, sixth paragraph). The presumption that 35 U.S.C. 112(f) (pre-AIA 35 U.S.C. 112, sixth paragraph) is invoked is rebutted when the function is recited with sufficient structure, material, or acts within the claim itself to entirely perform the recited function.

Absence of the word "means" (or "step for") in a claim creates a rebuttable presumption that the claim element **is not** to be treated in accordance with 35 U.S.C. 112(f) (pre-AIA 35 U.S.C. 112, sixth paragraph). The presumption that 35 U.S.C. 112(f) (pre-AIA 35 U.S.C. 112, sixth paragraph) is not invoked is rebutted when the claim element recites function but fails to recite sufficiently definite structure, material or acts to perform that function.

Claim elements in this application that use the word "means" (or "step for") are presumed to invoke 35 U.S.C. 112(f) except as otherwise indicated in an Office action. Similarly, claim elements that do not use the word "means" (or "step for") are presumed not to invoke 35 U.S.C. 112(f) except as otherwise indicated in an Office action.

10. Claim limitation "oximetry processing module", "first input for receiving data" and "second input for receiving a representation of a phase offset" , and "output for providing the determined hemoglobin saturation" Claim 18) has been interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because it uses/they use a generic placeholders "module", "input", and "output" coupled with functional language "oximetry processing",

"receiving data", "providing the determined hemoglobin saturation" without reciting sufficient structure to achieve the function. Furthermore, the generic placeholder is not preceded by a structural modifier, and the generic placeholder does not convey any information about the structure of the claim limitations.

Since the claim limitation(s) invokes 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, claim(s) 18-24 have been interpreted to cover the corresponding structure described in the specification that achieves the claimed function, and equivalents thereof.

A review of the specification shows that the following appears to be the corresponding structure described in the specification for the 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph limitation: a computing device comprising a processor and algorithm for operating the computer device acting as the oximetry processing module, described on page 21, sections [0084]-[0088] of the specification, and input device comprising a near-infrared sensor acting as the first input (Page 8, section [041]; Page 21, sections [085]-[087]), a processor and algorithm acting as the second input (Page 6, sections [020]-[021]) and a display acting as the output (Page 6, section [023]; Page 21, section [087]).

If applicant wishes to provide further explanation or dispute the examiner's interpretation of the corresponding structure, applicant must identify the corresponding structure with reference to the specification by page and line number, and to the drawing, if any, by reference characters in response to this Office action.

If applicant does not intend to have the claim limitation(s) treated under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112 , sixth paragraph, applicant may amend the claim(s) so that it/they will clearly not invoke 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, or present a

sufficient showing that the claim recites/recite sufficient structure, material, or acts for performing the claimed function to preclude application of 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

For more information, see MPEP § 2173 *et seq.* and *Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications*, 76 FR 7162, 7167 (Feb. 9, 2011).

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6, 8-15, and 18-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to an abstract idea without significantly more. Claims 1 and 18 recite a step of determining a hemoglobin saturation to exclude an effect of an oscillating rate of supply of oxygenated blood to a portion of the tissue by removing a measured phase offset of the oscillating hemoglobin saturation.

The limitation of determining a hemoglobin saturation, as drafted, is a process that, under its broadest reasonable interpretation, covers performance of the limitation in the mind but for the recitation of generic computer components. That is, other than reciting an oximetry processing module, nothing in the claim element precludes the step from practically being performed in the mind. For example, "determining" in the context of this claim encompasses the user manually determining the hemoglobin saturation using a measured phase offset and a set of data representing an oscillating hemoglobin concentration. If a claim limitation, under its broadest reasonable interpretation, covers performance of the limitation in the mind but for

the recitation of generic computers components, then it falls within the "Mental Process" grouping of abstract ideas. Accordingly the claim recites an abstract idea.

This judicial exception is not integrated into a practical application. In particular, the claim only recites one additional element – an oximetry processing module. These elements are well-known, routine, and conventional in the art for monitoring a hemoglobin concentration of a vascular compartment, see at least Wang (US 6430513), Fantini (CA 2934869 A1), Pautot (US 2014/0219532), and Zhang (US 2015/0157271), such that it amounts no more than mere instructions to apply the exception using a generic computer component. Accordingly, this additional element does not integrate the abstract idea into a practical application because it does not impose any meaningful limits on practicing the abstract idea. The claim is directed to an abstract idea.

Regarding claims 2-6 and 8-15, the additional recitations in the claims (describing the frequencies at which the hemoglobin concentrations oscillate, the frequencies being a cardiac, respiratory, or physically induced frequency, describing the effect of the oscillating rate of supply of oxygenated blood, indicating that the oscillation on the oscillations are due to a diffusion of oxygen, describing the portion of the tissue being monitored, the portion of tissue being an arterial compartment, a venous compartment, a capillary compartment, or both an arterial and venous compartment, determining a first and second fraction of hemoglobin saturation, the first and second fraction being hemoglobin saturations associated with the venous and arterial compartments, determining hemoglobin saturation based on a blood pressure measurement, determining the second fraction using an empirically determined ratio) fail to add something significantly more to the abstract idea itself as they further describe the

abstract idea by reciting extra-solution activity. Regarding claims 19-20, the additional recitations in the claims (using a sensor for acquiring data, incorporating an output for providing the determined hemoglobin saturation, displaying the data) fails to add significantly more to the abstract idea as these elements are well-known, routine, and conventional, see Wang, Fantini, Pautot, and Zhang.

The additional steps when considered both individually and as an ordered combination do not include additional elements that are sufficient to amount to significantly more than the judicial exception. As discussed above with respect to integration of the abstract idea into a practical application, the additional element of an oximetry processing module amounts to no more than mere instructions to apply the exception using a generic computer component. Mere instructions to apply an exception using a generic computer component cannot provide an inventive concept. The claim is not patent eligible.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **Claim 1-6, 8-15, 18-19, and 25-28 are rejected under 35 U.S.C. 103 as being unpatentable over Fantini (CA 2934869 A1) in view of Zheng (Phasor representation of oxy- and deoxyhemoglobin concentrations: what is the meaning of out-of-phase oscillations as measured by near-infrared spectroscopy?).**

14. Regarding claims 1 and 18, Fantini teaches a system and method for determining a hemoglobin saturation of a volume-oscillating vascular compartment in tissue with a non-negligible oscillating rate of supply of oxygenated blood to a portion of the tissue (Page 2, section [006]), the system and method including:

an input for receiving data representing measurements of a plurality of oscillating hemoglobin concentrations from the tissue (Page 7, section [033]); and using an oximetry processing module for determining the hemoglobin saturation of the volume-oscillating vascular compartment (Page 1, section [0076]). Fantini further teaches a system for monitoring the hemoglobin saturation of a vascular compartment using near-infrared spectroscopy (Page 2, section [006]), and monitors the phase of the oscillations (Page 13, section [051]) for determining the hemoglobin concentrations (Page 20, section [073]), wherein an oscillation occurs in the measured concentration of oxygenated hemoglobin and a measured concentration of deoxygenated hemoglobin due to oscillations in blood flow to the portion of the tissue (Page 8, section [037]).

While Fantini teaches a method and system for measuring hemoglobin saturation using a measured phase, the method and system using a computer-implemented computational model (Page 3, section [008]), wherein the model may be used in a medical setting (Pages 6-7, section [032]), Fantini fails to teach a system that excludes an effect on the determined hemoglobin saturation of an oscillating rate of supply of oxygenated blood to the portion of the tissue determines by determining phase offset of one or more oscillating hemoglobin concentration measurements. Zheng teaches a model for measuring oscillating hemoglobin saturation (Page 2, equations 3 and 4), and notes that a phase shift between oxy- and deoxy-

mischaracterizes

Examiner has set up a straw man that is NOT our claim language and has knocked it down.

hemoglobin can be monitored (Page 2, Col. 1), wherein a phase shift other than 0 or π indicates a physiological effect on the tissue region, the physiological effect being a redistribution of background hemoglobin concentration (Page 2, Col. 2). Zheng further teaches that phase shifts typically negatively affect correlation coefficient analysis of oscillating hemoglobin concentrations (Page 3, Col. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was effectively filed that the mathematical model of Fantini exclude a phase offset that reflects a redistribution of background hemoglobin concentration taught by Zheng in order to increase the accuracy of oscillating hemoglobin saturation model.

15. Regarding claim 2, Fantini as modified teaches all the elements of claim 1 as described above. Fantini further teaches a method wherein the plurality of oscillating hemoglobin concentrations from the tissue include a measured concentration of oxygenated hemoglobin, a measured concentration of deoxygenated hemoglobin, and a total hemoglobin concentration (Page 20, section [073]).

16. Regarding claims 3-6, Fantini as modified teaches all the elements of claim 1 as described above. Fantini further teaches a system wherein the plurality of oscillating hemoglobin concentrations oscillate at a frequency associated with a physiological function, the frequency being a cardiac frequency, a respiratory frequency, or a physically induced frequency (Page 12, section [049]).

17. Regarding claim 8, Fantini as modified teaches all the elements of claim 1 as described above. Fantini further teaches a system wherein the oscillations in the measured concentration of oxygenated hemoglobin and the oscillation in the measured concentration of the

deoxygenated hemoglobin are at least in part due to diffusion of oxygen from blood to the portion of the tissue (Page 8, section [037]).

18. Regarding claims 9-11, Fantini as modified teaches all the elements of claim 1 as described above. Fantini further teaches a method wherein the portion of the tissue includes a capillary compartment, an arterial compartment, and a venous compartment (Page 8, section [038]).

19. Regarding claim 12, Fantini as modified teaches all the elements of claim 1 as described above. Fantini further teaches a system wherein the volume-oscillating vascular compartment includes a mixture of an arterial compartment and a venous compartment (Page 8, section [038]).

20. Regarding claim 13, Fantini as modified teaches all the elements of claim 12 as described above. Fantini further teaches a method comprising determining a first fraction of the hemoglobin saturation associated with the venous compartment and a second fraction of the hemoglobin saturation associated with the arterial compartment (Page 9, sections [039]-[041]).

21. Regarding claim 14, Fantini as modified teaches all the elements of claim 13 as described above. Fantini further teaches a system wherein the second fraction of hemoglobin saturation is determined based on a blood pressure measurement (Page 5, section [021]; Page 12, section [049]; Page 16, section [0062]).

22. Regarding claim 15, Fantini as modified teaches all the elements of claim 13 as described above. Fantini further teaches a system wherein the first fraction and the second fraction are determined based on an empirically determined ratio (Page 9, section [041])

23. Regarding claim 19, Fantini as modified teaches all the elements of claim 18 as described above. Fantini further teaches a system further comprising a sensor for obtaining the data representing measurements of the plurality of hemoglobin concentrations from the tissue and providing data to the input (Page 7, section [033]; Page 7, section [033]).

24. Regarding claims 25 and 26, Fantini as modified teaches all the elements of claims 1 and 18 as described above. Fantini further teaches a method and system wherein the hemoglobin saturation of the volume-oscillating vascular compartment is determined at least in part using a multi-compartment hemodynamic model (Page 20, section [073]).

25. Regarding claims 27 and 28, Fantini as modified teaches all the elements of claims 1 and 18 as described above. Fantini further teaches a device wherein the phase offset of the first contribution of one or more of the oscillating hemoglobin concentration measurements relative to one or more of the oscillating hemoglobin concentration measurements includes a phase offset between oscillations in an oxy-hemoglobin concentration due to blood flow oscillations and measured oscillations in ox7-hemoglobin concentrations, the measured oscillations in oxy-hemoglobin concentration including contributions from both blood flow oscillation and from blood volume oscillations (Page 13, section [052]).

26. **Claim 21 is rejected under 35 U.S.C. 103 as being unpatentable over Fantini in view of Zheng as applied to claim 20 above, and further in view of Zhang (US 2015/0157271).**

27. Regarding claim 21, Fantini as modified teaches all the elements of claim 1 as described in paragraph 14 above. While Fantini teaches a system capable of monitoring oscillating hemodynamic parameters by monitoring the hemodynamic parameters of three vascular compartments (Page 8, section [037]), Fantini fails to teach whether the system is capable of

displaying the information. Zhang teaches a system for extracting parameters based on vascular compartment (Fig. 2) that displays the extracted parameters (Page 2, section [0026]). It would have been obvious to one of ordinary skill in the art at the time the invention was effectively filed for the system of Fantini in view of Zheng to incorporate the display of Zhang, since Fantini as modified teaches a system capable of measuring hemodynamic parameters of several vascular compartments, but fails to teach whether the collected information can be displayed, and Zhang teaches a system that collects and analyzes data from several vascular compartments that incorporates a display for displaying information.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Wang (Previously cited - US 6430513): directed to a system for monitoring cerebral oxy- and deoxy-hemoglobin concentrations using near-infrared spectroscopy.

Pautot (Previously cited - US 2014/0219532): directed for monitoring hemodynamic oscillations.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH KINGSLEY whose telephone number is (571)272-8435. The examiner can normally be reached on Monday-Friday 9AM-5PM.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jason Sims can be reached on (571) 272-7540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH R KINGSLEY/
Examiner, Art Unit 3791
/CHRISTIAN JANG/
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