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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/629,997	01/10/2020	Andrea Aliverti	1732-243	4531

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EXAMINER	
AGAHI, PUYA	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
09/24/2020	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):

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Office Action Summary	**Application No.** 16/629,997	**Applicant(s)** Aliverti et al.	
	Examiner PUYA AGAHI	**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 9/10/2020.
☐ 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) 1-11 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) 1-11 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

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

1. Applicant's arguments filed in the reply on September 10, 2020 were received and fully considered. Claims 1 and 4-11 were amended. The current action is FINAL. Please see corresponding rejection headings and response to arguments section below for more detail.

Claim Rejections - 35 USC § 101

2. 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.

3. Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim(s) as a whole, considering all claim elements both individually and in combination, do not amount to significantly more than an abstract idea. A streamlined analysis of claim 1 follows.

Regarding claim 1, the claim recites a wearable device for continuous monitoring of the respiratory rate of a patient. Thus, the claim is directed to a machine, which is one of the statutory categories of invention.

The claim is then analyzed to determine whether it is directed to any judicial exception. The following limitations set forth a judicial exception:

"...processing the abdominal quaternions and thoracic quaternions received so that the abdominal quaternion and the thoracic quaternion are referenced to the reference quaternion, said control centre comprising a band-pass adaptive filter, which filters signals represented by the abdominal quaternion and by the thoracic quaternion to eliminate residual components linked to movements of the patient, said control centre being configured for calculating respiratory rate from signals represented by a filtered abdominal quaternion and by a filtered thoracic quaternion."

These limitations describe a mathematical calculation and/or mental process. Further, the limitations are capable of being performed mentally by looking at measurements and making a mental assessment.

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. Besides the mathematical calculation and/or mental process, the claim recites the following additional limitations:

"A wearable device for continuous monitoring of a respiratory rate of a patient, comprising: three inertial sensors, a first inertial sensor being positioned on an abdomen, a second inertial sensor being positioned on a thorax, and a third, reference, inertial sensor being positioned on a part of a body not subject to respiratory movements, fixed with respect to a torso, each inertial sensor comprising an accelerometer, a magnetometer, and a gyroscope, each inertial sensor of the three inertial sensors comprising a microprocessor connected to said accelerometer, magnetometer, and gyroscope, said microprocessor being connected to a transmitter, and being configured for processing a signals and for supplying to said transmitter a signal represented by a quaternion that describes an orientation of said three inertial sensors with respect to Earth's reference system; a receiver connected to a control centre and configured for receiving an abdominal quaternion of the first inertial sensor, a thoracic quaternion of the second inertial sensor, and a reference quaternion of the third inertial sensor, and for sending them to said control centre"

These additional (structural) limitations are each recited at a high level of generality such that it amounts to insignificant presolution activity, e.g., mere data gathering steps necessary to perform the mathematical calculation and/or mental process. When recited at this high level of generality, there is no meaningful limitation, such as a particular or unconventional step that distinguishes it from well-understood, routine, and conventional data gathering and measuring activity used in respiratory rate monitoring methods prior to Applicant's invention. The limitations recited in claim 1 are recited at such a broad level of generality that they would tie up any technology directed to calculating respiratory rate from conventional inertial sensors. Furthermore, it is well established that the mere physical or tangible nature of additional elements such as the obtaining and measuring steps do not automatically confer eligibility on a claim directed to an abstract idea (see, e.g., *Alice Corp. v. CLS Bank Int'l, 134 S.Ct. 2347, 2358-59 (2014)*).

Consideration of the additional elements as a combination also adds no other meaningful limitations to the exception not already present when the elements are considered separately. Unlike the eligible claim in *Diehr* in which the elements limiting the exception are individually conventional, but taken together act in concert to improve a technical field, the claim here does not provide an improvement to the technical field. Even when viewed as a combination, the additional elements fail to transform the exception into a patent-eligible application of that exception. Thus, the claim as a whole does not amount to significantly more than the exception itself. The claim is therefore drawn to non-statutory subject matter.

Independent claim 5 is also not patent eligible for substantially similar reasons.

Dependent claims 2-4 and 6-11 also fail to add something more to the abstract independent claims as they merely further limit the abstract idea.

Therefore, claims 1-11 are not patent eligible under 35 USC 101.

Claim Rejections - 35 USC § 103

4. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

5. Claims 1-9 are rejected under 35 U.S.C. 103 as being unpatentable over Belanger et al. (US PG Pub. No. 2015/0173654 A1) (hereinafter "Belanger") in view of Ferber et al. (US PG Pub. No. 2017/0156593 A1) (hereinafter "Ferber").

Belanger and Ferber were applied in the previous office action.

With respect to claims 1 and 5, Belanger teaches a wearable device for continuous monitoring of the respiratory rate of a patient (abstract "determining... a respiratory rate"; sensors worn on patient's body as depicted in Fig. 1), comprising: inertial sensors, a first inertial sensor (interial sensor 14 in Fig. 1), a second inertial sensor being positioned on the thorax (inertial sensor 12 positioned on thorax area as depicted in Fig. 1), each inertial sensor of the three inertial sensors comprising an accelerometer, a magnetometer, and a gyroscope (par.0044 "each comprise a combination of a 3-axis accelerometer and a 3-axis gyroscope"; par.0047 "may also comprise a magnetometer"), each inertial sensor comprising a microprocessor connected to said accelerometer, magnetometer, and gyroscope (par.0054 "filtered and <u>processed</u>" implies the use of a microprocessor or some equivalent structure), said microprocessor being connected to a transmitter, and being configured for processing said signals (par.0052 "wireless communication protocol... transmitting data received") and for supplying to said transmitter a signal represented by a quaternion that describes the orientation of said three inertial sensors with respect to the Earth's reference system (par.0054 “quaternions q1 and q2 corresponding to spatial orientations of the sensing units 12 and 14 respectively”); a receiver connected to a control centre and configured for receiving the quaternion of the first inertial sensor, the thoracic quaternion of the second inertial sensor, and for sending them to said control centre (par.0052 “data received from the sensing units to a PC”), said contro centre being configured for processing the abdominal quaternions and thoracic quaternions received so that the abdominal and the thoracic quaternion are referenced to the reference quaternion (par.0061 “analysis program, either embedded in the recorder (FIG. 3c) or not (FIG. 3b) processes the acceleration vectors A1 and A2 in the respective referential of the sensing units 12 and 14”); said control centre comprising a filter, which filters the signals represented by the abdominal quaternion and by the thoracic quaternion to eliminate the residual components linked to the movements of the patient (par.0054 “filtered and processed to determine acceleration vectors A1 and A2 in the respective referential of the sensing units 12 and 14, quaternions q1 and q2 corresponding to spatial orientations of the sensing units 12 and 14 respectively”), said control centre being configured for calculating respiratory rate from signals represented by a filtered quaternions (abstract “determining... a respiratory rate”).

However, Belanger does not explicitly teach the first inertial sensor being positioned on an abdomen, a third, reference, inertial sensor being positioned on a part of the body not subject to respiratory movements, fixed with respect to the torso; the reference quaternion of the third inertial sensor; and a band-pass adaptive filter.

Belanger also teaches:

[0052].... signals collected by the sensing units 12, 14 along the three axis x, y of the body frame of the sensing units 12, 14 respectively, z are **filtered** and processed to determine acceleration vectors A1 and A2 in the respective referential of the sensing units 12 and 14, quaternions q1 and q2 corresponding to spatial orientations of the sensing units 12 and 14 respectively.

[0062]... spatial positioning (SP) **may include the relative position**, i.e. a height from a ground reference or a distance from a reference, and a height of a vertical movement in case of a fall.

Ferber teaches:

Systems and method for non-invasive respiratory rate measurement (title)

[0254] Typically, respiration is a slowly varying signal, often not more than 40 BPM (or 0.67 Hz), and the signal may need to be measured over longer durations (e.g., relative to pulse rate, which can usually be measured at an interval of 1 second) before a respiratory rate can be determined. For example, a 30 second window may be used over a PPG window, sampled upwards of 50 Hz. In some embodiments, the respiration signal may include information less than 1 Hz, and it can be decimated up to 2 Hz before processing (e.g., for computational efficiency). In some embodiments, pre-processing **may apply a high pass filter** (e.g., at cut-off 0.1 Hz) to eliminate, reduce, remove and/or attenuate (or, collectively, "remove") low frequency drift inherit to signals. In some embodiments, the high pass filter **may have a narrow transition band** (e.g., 0.05 Hz). In some embodiments, **Savitzky-Golay filtering may be both computationally efficient and effective in eliminating low-frequency drift**. In some embodiments, if the filter order is high, it may **also eliminate some useful high frequency components of the signal**. In some embodiments, a classifier may be used to determine appropriate or optimized filter parameters.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art when the invention was filed to modify Belanger such that inertial sensor 14 is placed on the user's abdomen (as opposed to the user's limb as depicted in Belanger's Fig.1) since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Additionally, it would appear from Bellanger that the user has the capability to reposition first inertial sensor 14 on his/her abdomen (Fig. 1 shows that sensor 14 is attached via flexible cable). Also, one of ordinary skill in the art when the invention was filed would also have predictable success utilizing a reference inertial sensor placed on part of the body not subject to respiratory movements in order to provide a reference/ground to assess spatial positioning in case of a fall, as suggested by Belanger (par.0062). Furthermore, modifying Belanger such that an additional inertial sensor is utilized would be further obvious to POSITA when the invention was filed since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Also, one of ordinary skill in the art when the invention was filed would have had predictable success modifying Belanger's filtering such that an adaptive band-pass filter (e.g. Savitzky-Golay filter) is utilized in order to eliminate low-frequency and high-frequency components, as evidence by Ferber. Lastly, POSITA would have additional motivation to combine Belanger and Ferber as they both deal with the same narrow field of endeavor, i.e. non-invasive respiratory rate detection.

With respect to claim 2, Belanger renders obvious three inertial sensors (see obviousness rationale in claim 1) each comprise a transmitter that sends abdominal quaternion, said thoracic quaternion, and said reference quaternion to said control centre (par.0052 "data received from the sensing units to a PC").

With respect to claim 3, Belanger renders obvious said control centre synchronises said abdominal quaternion, said thoracic quaternion, and said reference quaternion with one another (par.0054 "quaternions q1 and q2 corresponding to spatial orientations of the sensing units 12 and 14 respectively"; par.0062; implied that the signals are utilized together, i.e. synchronized, in order to determine various physiological information such as respiration rate).

With respect to claim 4, Belanger does not explicitly teach calculating the inspiratory time and the expiratory time from the signals represented by the filtered abdominal quaternion and by the filtered thoracic quaternion. However, this would be obvious as it is widely known in the art to derive inspiratory/expiratory information from respiratory rate (glancing at respiratory output, POSITA would be capable of deriving more specific information from the waveforms corresponding to inhalation/exhalation).

With respect to claim 6, Belanger teaches in order to determine the bandpass of said adaptive filter, the method comprises: determining a principal component of said fourth and fifth quaternions; determining peaks of said principal component; determining a peak of a spectral density of said principal component; determining cutoff frequencies of said adaptive filter as the frequency of said peak of the spectral density +-0.4 Hz; filtering the principal components of said fourth and fifth quaternions with said adaptive filter; determining minimum and maximum values of the principal component of said fourth and fifth quaternions filtered with said adaptive filter; and determining the respiratory rate (See Belanger, peak information and minimum/maximum values can be assessed by output depicted in Figs. 5A-5D; Ferber also provides motivation for utilizing adaptive bandpass filter as set forth above).

With respect to claim 7, Ferber teaches determining the peaks of said principal component comprises filtering said fourth and fifth quaternions with a filter of the Savitzky-Golay type (par.0254). One of ordinary skill in the art when the invention was filed would have had predictable success modifying Belanger’s filtering such that an adaptive band-pass filter (e.g. Savitzky-Golay filter) is utilized in order to eliminate low-frequency and high-frequency components, as evidence by Ferber.

With respect to claim 8, Ferber teaches determining minimum and maximum values of said fourth and fifth quaternions filtered with said adaptive filter comprises filtering said fourth and fifth quaternions with a filter of a Savitzky-Golay type (par.0254). One of ordinary skill in the art when the invention was filed would have had predictable success modifying Belanger's filtering such that an adaptive band-pass filter (e.g. Savitzky-Golay filter) is utilized in order to eliminate low-frequency and high-frequency components, as evidence by Ferber.

With respect to claim 9, Belanger and Ferber do not explicitly teach determining the peak of the spectral density of said principal component comprises the step of determining the peak of the spectral density above a threshold frequency calculated by calculating a difference between peaks of said principal component and computing a reciprocal. However, performing peak detection in an alternative manner is understood to be routine in the art of respiratory rate detection. Accordingly, POSITA would have had predictable success modifying Belanger and Ferber such that the peak is determined by utilizing a threshold and calculating difference between the peaks and computing the reciprocal.

6. Claims 10 and 11 are rejected under 35 U.S.C. 103 as being unpatentable over Belanger and Ferber, as applied to claim 5 above, in further view of Banet et al. (US PG Pub. No. 2011/0257552 A1) (hereinafter "Banet").

Banet was applied in the previous office action.

With respect to claims 10 and 11, Belanger and Ferber teach a method for continuous monitoring of the respiratory rate of a patient.

However, Belanger and Ferber do not teach and/or suggest the limitations recited in claims 10 and 11.

Regarding claim 10, Banet teaches prior to filtering the principal component of said fourth and fifth quaternions with said bandpass adaptive filter, it comprises determining the peak of the spectral density of said third quaternion and of filtering said first and second quaternions with a filter of a notch type centered on the frequency of said peak (par.0129).

Regarding claim 11, Banet teaches in that, prior to determining the principal component of said fourth and fifth quaternions, it comprises subtracting a baseline from a component of the fourth and fifth quaternions, said baseline being calculated by means of a moving-average filter, and in that a size of a window of said bandpass adaptive filter is variable and depends upon activity detected by a signal of the third quaternion corresponding to the reference inertial sensor (par.0095 "removes any low-frequency baseline components from the IP waveform, and additionally generates a clear, well-defined zero-point crossing corresponding to each peak in the IP signal. Each peak corresponds to each respiration event").

Therefore, it would have been prima facie obvious to one of ordinary skill in the art when the invention was filed to modify Belanger and Ferber to utilize a notch filter and baseline subtraction in order to process obtained signals to determine a collection of frequencies corresponding to patient's motion in ultimately determining respiratory rate, as evidence by Banet.

Response to Arguments

7. Applicant's arguments filed with respect to the 35 USC 112B rejections raised in the previous office action were persuasive in view of amendment. These rejections are withdrawn.

8. Applicant's arguments filed with respect to the 35 USC 101 rejections raised in the previous office action have been fully considered, but they are not persuasive. First, applicant appears to argue that claimed invention is not directed to a mathematical equation, or a mental process (steps could not be conducted in the human mind). Examiner respectfully disagrees and maintains that the limitations identified above pertain to mathematical calculations. Also, while a person may not be able to perform the calculations in their mind, it is understood that an individual with ordinary skill could use pen and paper to perform the recited steps (having first obtained the data from the inertial sensors). Applicant appears to also fixate on the additional (structural) elements in arguing that the claimed invention is integrated into a practical application. Examiner argues that the structure (accelerometer, magnetometer, and gyroscope) are conventional sensors and amount to pre-solution activity (data gathering). Accordingly, the additional limitations do not integrate the judicial exception into a practical application. Applicant's "improvement" argument ("improves the function of a respiratory monitoring device and solves a technical problem... evaluation of respiratory rates in dynamic conditions, such as when a patient is walking") is considered, but also not

persuasive. Here, the alleged improvement appears to lie within the judicial exception. However, courts have held that “the judicial exception alone cannot provide the improvement.” See the discussion of *Diamond v. Diehr*, 450 U.S. 175, 187 and 191-92, 209 USPQ 1, 10 (1981). For these reasons, Examiner maintains that claims 1-11 are not patent eligible. Please see corresponding rejection heading above for more detail.

9. Applicant's arguments filed with respect to the 35 USC 103 rejections raised in the previous office action have been fully considered, but they are not persuasive. Applicant argues that Belanger and Ferber do not teach the claimed invention with specific regards to the amended limitation “said control centre comprising a filter, which filters the signals represented by the abdominal quaternion and by the thoracic quaternion to eliminate the residual components linked to the movements of the patient.” Examiner respectfully disagrees. Upon further consideration as necessitated by amendment, Examiner argues that the primary reference teaches this limitation (see underlined portion in the prior art section above). Applicant goes on to argue that Ferber and Belanger utilize two completely different methods of generating respiratory rate via electrocardiographic signal (Belanger), while Ferber uses a method that is based on the transmission and reception of a form of energy through tissue. Examiner respectfully disagrees. Here, the claimed invention recites “comprising” (open) type language (see claim 1, line 2). Accordingly, Belanger’s generating respiratory rate via electrocardiographic signal does not equate to patentable distinction because the claimed invention could encompass the use of ECG. Also, Ferber was relied upon for teaching Savitzky-Golay filtering in a respiratory rate detection method and the Examiner has articulated reasons for why the combination would be obvious to

PHOSITA. Applicant also argues that Ferber and Belanger do not contemplate using inertial systems for deriving respiratory rate. Examiner respectfully disagrees. Though Belanger certainly teaches monitory activity and posture of a person via inertial system, it is understood that Belanger also utilizes data from the inertial system (accelerometer, magnetometer, gyroscope) in determining respiratory rate (See par.0089 “spatial positions of the user may be correlated with the user’s activity... and the respiratory rate”). For these reasons, Examiner maintains that the claimed invention is obvious to PHOSITA when the invention was filed. Please see prior art section above for more detail/citations.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PUYA AGAHI whose telephone number is (571)270-1906. The examiner can normally be reached on M-F 8 AM - 5 PM.

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 M Sims can be reached on 5712727540. 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 https://ppair-my.uspto.gov/pair/PrivatePair. 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.

/PUYA AGAHI/
Primary Examiner, Art Unit 3791

<u>REMARKS</u>

Applicant has fully reviewed the final Office Action dated September 24, 2020. In light of the foregoing amendments and the following remarks, it is believed that all pending claims patentably distinguish over the cited references.

Initially, Applicant wishes to thank the examiner for the courtesy shown in the telephone interview dated January 13, 2021, between Applicant's representative, Nick Coleman, and Examiner Agahi. The subject matter of the interview related to the Sections 101 and 103 rejections in the final office action. The examiner also requested certain minor claim amendments to address consistency of language throughout the claims, said amendments being reflected in the claims submitted herewith. While no agreement was reached, the examiner agreed to consider a response under the After Final Pilot Program 2.0, for which Applicant is grateful.

The first issue raised in the final office action is a rejection of all claims under 35 USC 101 as allegedly not being directed to statutory subject matter. Here, the claims are directed to a wearable device with three inertial sensors – one positioned on the abdomen, one positioned on the thorax, and a third reference sensor positioned on a body part not subject to respiratory movements. A control center processes signals from each of the three sensors and calculates a respiratory rate based on data from the abdominal and thoracic sensors, with residual components of said data from the abdominal and thoracic sensors related to movement of the patient being filtered, said filtering being done with data from the third reference sensor.

A particularly instructive case in this matter is <u>Thales Visionix, Inc. v. United States</u>, 850 F.3d 1343 (Fed. Cir. 2017), in which the Federal Circuit conducted a Section 101 analysis of a set of claims to a system for tracking motion of an object including a first inertial sensor at a first location (i.e. on the tracked object), a second inertial sensor at a second location (i.e. mounted on a moving reference frame), and a receiver configured to receive signals from the two inertial sensors and calculate a relative orientation of the object. In <u>Thales</u>, under the first step of the framework established in <u>Alice Corp. Pty. v. CLS Bank</u>

Int'l, 134 S. Ct. 2347, 2354 (2014), the court recognized that "[w]hile the claims utilize mathematical equations to determine the orientation of the object relative to the moving reference frame, the equations—dictated by the placement of the inertial sensors and application of laws of physics—serve only to tabulate the position and orientation information in this configuration." Thales at 1348. The court specifically concentrated on the placement/location of the inertial sensors, stating that this arrangement "result in a system that reduces errors in an inertial system that tracks an object on a moving platform." Id. In finding that the claims were directed toward patentable subject matter, the Federal Circuit ruled as follows:

> The claims specify **a particular configuration of inertial sensors** and a particular method of using the raw data from the sensors in order **to more accurately calculate the position and orientation of an object on a moving platform**. The mathematical equations are a consequence of the arrangement of the sensors and the unconventional choice of reference frame in order to calculate position and orientation. Far from claiming the equations themselves, the **claims seek to protect only the application of physics to the unconventional configuration of sensors as disclosed**. As such, these claims are not directed to an abstract idea and thus the claims survive Alice step one.

Id. at 1348-49 (emphasis added).

Similar to the claims of Thales, Applicant's claims are directed to a particular configuration of inertial sensors used to more accurately calculate respiratory rate of a patient. As noted in Applicant's specification, prior studies have shown the feasibility of measuring respiratory rate using a single accelerometer, and increasingly complex systems set on the thorax and abdomen. Applicant's Specification, p. 1. However, these systems lack the ability to be used in dynamic conditions, and therefore cannot offer reliable measurements during everyday activities. Id., pp. 1-2. The claimed device, however, requires a unique configuration of inertial sensors, including a reference inertial sensor positioned on a part of the body not subject to respiratory movements. Id., p. 2. Through "the application of physics to this unconventional configuration of sensors," certain equations are used to filter residual components of movement (determined with respect to the reference inertial sensor) from the abdominal and thoracic inertial sensors. Therefore, this unconventional configuration of sensors allows for the calculation of respiratory rate in a more accurate manner than had been previously available by way of inertial sensors, in particular within the context of dynamic conditions.

Given the explicit parallels to the Thales decision, Applicant submits that the claims of the present application are not directed to any abstract idea at all. As the court in Thales noted, "[t]hat a mathematical equation is required to complete the claimed method and system does not doom the claims to abstraction." Id. at 1348. Instead, the claims are directed to a system and method that uses inertial sensors in a non-conventional manner to reduce errors in measuring respiratory rate, including during dynamic conditions. As such, the claims are directed toward patentable subject matter under step one of the Alice analysis, and there is no need to proceed to step two.

Substantively, claims 1-9 stand rejected under 35 USC 103 as allegedly obvious over Belanger (US 2015/0173654) in view of Ferber (US 2017/0156593). As was discussed in the telephone interview, Belanger uses inertial sensors 12, 14 exclusively for determining motion and position of the body (but not respiratory rate). Instead, Belanger uses ECG sensors 20 (which do not have inertial sensors) exclusively for determining respiratory rate. There is no indication, suggestion, or motivation to use the inertial sensors of Belanger in any way to monitor anything related to respiratory rate. Furthermore, there is no allegation that Ferber would cause any modification of Belanger to use the inertial sensors in the context of determining respiratory rate. Accordingly, any combination of Belanger and Ferber fails to establish a *prima facie* case of obviousness with respect to claims related to the use of an unconventional configuration of inertial sensors to calculate and determine respiratory rate.

Nevertheless, Applicant amends claims 1 and 5 herein to explicitly require that calculation of respiratory rate is done only from signals represented by a filtered abdominal quaternion and by a filtered thoracic quaternion (claim 1) or only from the fourth and fifth quaternions, corresponding to data filtered from the abdominal and thoracic inertial sensors (claim 5). As discussed in the telephone interview, no combination of Belanger with Ferber discloses or renders obvious determination of respiratory rate in such a way.

It is believed that all issues in the final office action have been addressed that that all claims now stand in condition for allowance. Accordingly, a Notice of Allowability is earnestly requested. If any issues remain, the Examiner is encouraged to contact the Applicant's counsel at the telephone number listed below in order to reduce costs and expedite the prosecution of this patent application. To the extent any fees are due for processing this response, the undersigned authorizes their deduction from Deposit Account 11-0978.

Respectfully submitted,

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Amendments to the Claims:

This below-listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Currently amended) A wearable device for continuous monitoring of a respiratory rate of a patient, comprising: three inertial sensors (10, 11, 12) , a first inertial sensor (10) of the three inertial sensors being positioned on an abdomen (13), a second inertial sensor (11) of the three inertial sensors being positioned on a thorax (14) , and a third[[,]] reference[[,]] inertial sensor (12) of the three inertial sensor being positioned on a part of a body (15) not subject to respiratory movements, fixed with respect to a torso, each inertial sensor (10, 11, 12) of the three inertial sensors comprising an accelerometer, a magnetometer, and a gyroscope, each inertial sensor (10, 11, 12) comprising a microprocessor (21) connected to said accelerometer, magnetometer, and gyroscope, said microprocessor (21) being connected to a transmitter (22) , and being configured for processing signals and for supplying to said transmitter (22) a signal represented by a quaternion that describes an orientation of said three inertial sensors with respect to Earth' s reference system; a receiver (30) connected to a control centre (31) and configured for receiving an abdominal quaternion of the first inertial sensor, a thoracic quaternion of the second inertial sensor, and a reference quaternion of the third reference inertial sensor, and for sending them to said control centre (31) , said control centre (31) being configured for processing the abdominal quaternions and thoracic quaternions received so that the abdominal quaternion and the thoracic quaternion are referenced to the reference quaternion, said control centre (31) comprising a band-pass adaptive filter (55, 56) , which filters signals represented by the abdominal quaternion and by the thoracic quaternion to eliminate residual components linked to movements of the patient,

said control centre (31) being configured for calculating respiratory rate only from signals represented by a filtered abdominal quaternion and by a filtered thoracic quaternion.

2. (Original) The device according to Claim 1, characterized in that said three inertial sensors (10, 11, 12) each comprise a transmitter (22) that sends said abdominal quaternion, said thoracic quaternion, and said reference quaternion to said control centre (31) .

3. (Previously Presented) The device according claim 1, characterized in that said control centre (31) synchronises said abdominal quaternion, said thoracic quaternion, and said reference quaternion with one another.

4. (Previously Presented) The device according claim 1, characterized in that said control centre (31) calculates an inspiratory time and an expiratory time from the signals represented by the filtered abdominal quaternion and by the filtered thoracic quaternion.

5. (Currently amended) A method for continuous monitoring of a respiratory rate of a patient comprising: positioning a first inertial sensor (10) on an abdomen (13); positioning a second inertial sensor (11) on a thorax (14) ; positioning a third[[,]] reference[[,]] inertial sensor (12) on a part of a body (15) not subject to respiratory movements, fixed with respect to a torso, where each inertial sensor (10, 11, 12) of the three inertial sensors comprises an accelerometer, a magnetometer, and a gyroscope, and a microprocessor (21) that receives signals from said accelerometer, magnetometer, and gyroscope, and where microprocessors (21) process said signals and supplies a signal represented by a quaternion that describes an orientation of said three inertial sensors with respect to Earth' s reference system; sending a first quaternion representing a spatial orientation of said first inertial sensor (10) to a control centre (31) ; sending a second quaternion representing a spatial orientation of said second inertial sensor (11) to said control centre (31) ; sending a third quaternion representing a spatial orientation of said third[[,]] reference[[,]] inertial sensor (12) to said control centre (31); referencing an orientation of said first quaternion (40) and said second quaternion (41) to said third quaternion (42) , to provide a fourth quaternion (43) and a fifth quaternion (44) ,

respectively; filtering said fourth and fifth quaternions by means of a bandpass adaptive filter (55, 56) to eliminate residual components linked to movements of the patient; and calculating the respiratory rate from only said fourth and fifth quaternions.

6. (Previously presented) The method according to Claim 5 , characterized in that, in order to determine the bandpass of said adaptive filter (55, 56), the method comprises: determining a principal component of said fourth and fifth quaternions; determining peaks of said principal component; determining a peak of a spectral density of said principal component; determining cutoff frequencies of said adaptive filter (55, 56) as the frequency of said peak of the spectral density +-0.4 Hz; filtering the principal components of said fourth and fifth quaternions with said adaptive filter (55, 56) ; determining minimum and maximum values of the principal component of said fourth and fifth quaternions filtered with said adaptive filter (55, 56); and determining the respiratory rate.

7. (Previously presented) The method according to Claim 5 , characterized in that determining the peaks of said principal component comprises filtering said fourth and fifth quaternions with a filter (60, 61) of a Savitzky-Golay type.

8. (Previously presented) The method according to Claim 5, characterized in that determining minimum and maximum values of said fourth and fifth quaternions filtered with said adaptive filter (55, 56) comprises filtering said fourth and fifth quaternions with a filter (60, 61) of a Savitzky-Golay type.

9. (Previously presented) The method according to Claim 5, characterized in that determining the peak of the spectral density of said principal component comprises the step of determining the peak of the spectral density above a threshold frequency calculated by calculating a difference between peaks of said principal component and computing a reciprocal.

10. (Previously presented) The method according to Claim 5, characterized in that, prior to filtering the principal component of said fourth and fifth quaternions with said bandpass adaptive filter (55, 56), it comprises determining the peak of the spectral density of said third quaternion and of filtering said first and second quaternions with a filter of a notch type centred on a frequency of said peak.

11. (Previously presented) The method according to Claim 5, characterized in that, prior to determining the principal component of said fourth and fifth quaternions (45, 46), it comprises subtracting a baseline from a component of the fourth and fifth quaternions (43, 44), said baseline being calculated by means of a moving-average filter, and in that a size of a window of said bandpass adaptive filter is variable and depends upon activity detected by a signal of the third quaternion (42) corresponding to the reference inertial sensor (12) .