UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/071,957	10/15/2020	Dinesh SEEMAKURTY	59419-701.201	1868

21971   7590   04/16/2021
WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER
BARR, MARY EVANGELINE

ART UNIT	PAPER NUMBER
3626	

NOTIFICATION DATE	DELIVERY MODE
04/16/2021	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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-- 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 <u>3</u> 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 <u>03/22/2021</u>.
   ☐ 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) <u>1,3-5 and 7-20</u> 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   5a) Of the above claim(s) _____ is/are withdrawn from consideration.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) <u>1,3-5 and 7-20</u> 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 <u>allowable</u>, 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: _____.

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.

DETAILED ACTION

Status of the Application

2.   **Claims 1, 3-5 and 7-20** are currently pending in this case and have been examined and

addressed below. This communication is a Final Rejection in response to the Arguments and

Amendment to the Claims filed on 03/22/2021.

- **Claims 1, 3-5, 12-13 and 15-20** have been amended.

- **Claims 2 and 6** have been cancelled and are not considered at this time.

Claim Rejections - 35 USC § 101

3.   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.

4.   **Claims 1, 3-5 and 7-20** are rejected under 35 U.S.C. 101 because the claimed invention is

directed to an abstract idea without significantly more. The claims recite monitoring patient

data and predicting future health events.

Claim 1 falls within the statutory category of a system. The data processing including

creating a predetermined dimensional matrix representative of a plurality of samples obtained

which represent health parameters of patient in a predefined time interval and processing

samples selected based on a predefined condition, as drafted, are steps executed by a system

that, under its broadest reasonable interpretation, covers managing interactions between

people but for the recitation of generic computer components. That is, other than reciting "a data analytics subsystem comprising: a data processing module," nothing in the claim elements precludes the step from being a function which manages personal behavior or interactions between people including following rules or instructions. For example, data processing including creating data representative of the samples of health parameters and processing those samples based on a predefined condition involves a person conducting data manipulation and interaction with the patient information which includes following rules or instructions. Similarly, the claim includes labelling the predetermined dimensional matrix upon processing samples using a clinical scoring technique, analyzing the labelled predetermined dimensional matrix to generated a prediction of a future event using an ensemble modelling technique, which covers managing interactions between people but for the recitation of computer components, i.e. a future event prediction module. The labelling of the matrix which results from the data processing is a categorization of information which is a certain method of organizing human activity. Additionally, predicting a future event using an ensemble modelling technique and using a rule-based decision logic to integrate individual predictions generated by the first and second models into the predicted health status are also certain methods of organizing human activity which includes the user following rules or instructions to apply the data to the rules of the modelling technique and follow rules for decision logic. If a claim limitation, under its broadest reasonable interpretation, covers managing personal behavior or relationships or interactions between people including teaching and following rules or instructions, but for the recitation of generic computer components, then it falls within the "Certain Methods of Organizing Human Behavior" grouping of abstract ideas. Additionally,

analyzing a matrix using an ensemble modelling technique which is an aggregate of more than

one model and using a rule-based decision logic to integrate predictions into a predicted health

status can also fall into the grouping of mathematical concepts where the use of mathematical

calculations or relationships is used to carry out the using an ensemble modelling technique to

predict the future event. Accordingly, the claim recites an abstract idea.

This judicial exception is not integrated into a practical application because the

additional elements and combination of additional elements do not impose meaningful limits

on the judicial exception. In particular, the claims only recite the additional elements – a

computing device comprising a processor, memory, and operating system to perform the steps

of the claim. The subsystem comprising the processor, memory, and operating system in these

steps is recited at a high-level of generality such that it amounts to 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 use of the

computing device to execute the steps of the abstract idea, including real-time execution of

integrating predications amounts to mere instructions to apply the exception. As per MPEP

2106.05(f)(2), claiming the improved speed or efficiency inherent with applying the abstract

idea on a computer does not integrate the abstract idea into a practical application. The claim

also recites the additional element of filtering the electronic signal comprising the health data

to eliminate outliers which amounts to mere instructions to apply the exception because, as per

MPEP 2106.05(f)(2), the courts have found requiring the use of software to tailor information

and provide it to the user on a generic computer to be mere instructions to apply the

exception, because they do no more than merely invoke computers or machinery as a tool to

perform an existing process. The use of an ensemble modelling technique to generate a

prediction of a future event also amounts to mere instructions to apply the exception as it is

invoking computers as a tool to perform the abstract idea, as per MPEP 2106.05(f)(2), where

the courts have found a commonplace business method or mathematical algorithm being

applied on a general purpose computer (*Alice Corp. Pty. Ltd. V. CLS Bank Int'l,* 573 U.S. 208, 223,

110 USPQ2d 1976, 1983 (2014); *Gottschalk v. Benson,* 409 U.S. 63, 64, 175 USPQ 673, 674

(1972); *Versata Dev. Group, Inc. v. SAP Am., Inc.,* 793 F.3d 1306, 1334, 115 USPQ2d 1681, 1701

(Fed. Cir. 2015)) to be mere instructions to apply the exception. The claim also recites the

additional elements of receiving an electronic signal comprising health data of patients from

medical data acquisition devices which is insignificant extra-solution activity, as in MPEP

2106.05(g), because the step of receiving electronic patient information from at least one

terminal is mere data gathering in conjunction with the abstract idea where the limitation

amounts to necessary **data gathering and outputting,** (*i.e.,* all uses of the recited judicial

exception require such data gathering or data output). See *Mayo,* 566 U.S. at 79, 101 USPQ2d

at 1968; *OIP Techs., Inc. v. Amazon.com, Inc.,* 788 F.3d 1359, 1363, 115 USPQ2d 1090, 1092-93

(Fed. Cir. 2015) (presenting offers and gathering statistics amounted to mere data gathering).

Because the additional elements do not impose meaningful limitations on the judicial

exception, the claim is directed to an abstract idea.

The claims 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 elements of a computing device

comprising a processor, memory, and operating system to perform the steps of the claim

amounts to no more than mere instructions to apply the exception using a generic computer

component. The modules are generic computing system, as they are described in the

specification as a subsystem which is hosted on a server or device ([0005]) where the device is a

general purpose computing device such as a tablet, mobile phone, etc. ([0029]) and the server

includes a processor and memory which includes the modules as executable programs ([0082]).

The additional element of filtering health data is also mere instructions to apply the exception

because it is applied to the subsystem above which is described as a routine computer

components. Mere instructions to apply an exception using a generic computer component

cannot provide an inventive concept. The additional element of receiving health data of a

patient from a medical data acquisition device is insignificant extra-solution activity which is no

more than well-understood, routine, conventional activities previously known to the industry

including mere data gathering similar to receiving or transmitting data over a

network, *e.g.,* using the Internet to gather data, *Symantec,* 838 F.3d at 1321, 120 USPQ2d at

1362 (utilizing an intermediary computer to forward information); *TLI Communications LLC v.*

AV Auto. LLC, 823 F.3d 607, 610, 118 USPQ2d 1744, 1745 (Fed. Cir. 2016) (using a telephone for

image transmission); *OIP Techs., Inc., v. Amazon.com, Inc.,* 788 F.3d 1359, 1363, 115 USPQ2d

1090, 1093 (Fed. Cir. 2015) (sending messages over a network); *buySAFE, Inc. v. Google,*

Inc., 765 F.3d 1350, 1355, 112 USPQ2d 1093, 1096 (Fed. Cir. 2014) (computer receives and

sends information over a network); but see *DDR Holdings, LLC v. Hotels.com, L.P.,* 773 F.3d

1245, 1258, 113 USPQ2d 1097, 1106 (Fed. Cir. 2014) ("Unlike the claims in *Ultramercial,* the

claims at issue here specify *how* interactions with the Internet are manipulated to yield a

desired result--a result that overrides the routine and conventional sequence of events

ordinarily triggered by the click of a hyperlink." (emphasis added)), as per MPEP 2106.05(d)(II).

As the additional elements are well-understood, routine and conventional functionalities in the

art, the claims do not amount to significantly more than the abstract idea and are not patent

eligible.

Dependent claims 3-5 and 7-20 add additional limitations. Claims 3-5 and 7-14 include

limitations which further specify or limit the elements of the independent claim, and hence are

nonetheless directed towards fundamentally the same abstract idea as independent Claim 1.

Claim 15 includes implementing a training technique to update a model based on requirements

which amounts to following rules and instructions and thus is directed to certain methods of

organizing human activity. Claims 16-20 include features for generating and transmitting alerts

regarding the prediction of the health status of the patient. This involves managing personal

behavior and interactions and falls into the grouping of certain methods of organizing human

activity. These limitations only serve to further limit or specify the limitations of the

independent claims, and hence are nonetheless directed towards fundamentally the same

abstract idea as independent claim 1.

The dependent claims do not include any additional elements that integrate the

abstract idea into a practical application or amount to significantly more than the abstract idea.

Claim 11 also includes collecting health data using sensors and displaying collected data which

are insignificant extra-solution activity because they amount to mere data gathering and data

outputting (MPEP 2106.05(g)(3)), similar to the independent claim. Therefore, when taken

individually or as an ordered combination, Claims 1, 3-5 and 7-20 are nonetheless rejected

under 35 U.S.C. 101 as being directed to non-statutory subject matter.

Response to Arguments

5.   Applicant's arguments, see Pages 8-9, "Claim Rejections - 35 USC §112", filed

03/22/2021 with respect to claims 1-20 have been fully considered and they are persuasive.

The 112(a) and 112(b) rejections of 12/22/2020 have been withdrawn.

6.   Applicant's arguments, see Pages 9-20, "Claim Rejections - 35 U.S.C. 101", filed

03/22/2021 with respect to claims 1-20 have been fully considered but they are not persuasive.

Applicant argues that the present claims do not fall into one of the enumerated groupings of

abstract ideas. Examiner respectfully disagrees. Applicant argues that the claims do not recite a

mental process because the receive and filter steps are performed on an electronic signal which

cannot practically be performed by the human mind. Examiner notes that the receiving an

electronic signal comprising health data is not identified as part of the abstract idea but is an

additional element which amounts to insignificant extra-solution activity as mere data

gathering. As per MPEP 2106.05(g), mere data gathering includes gathering data which is

transmitted electronically, therefore, the receiving of the data in form of an electronic signal

still falls into insignificant extra-solution activity. Similarly, the filtering the electronic signal

comprising health data is carried out by a computing device and is not identified as part of the

abstract idea, but rather as an additional element which is mere instructions to apply the

exception similar to using software to tailor information, as per MPEP 2106.05(f). Applicant

additionally argues that generating predictions in real-time could not be done mentally.

Examiner notes that the use of a computer to carry out the abstract idea, which in this case

includes the method of organizing human activity of predicting future events, amounts to mere

instructions to apply the exception because the increased speed or efficiency that results from

the use of a computer has been found to be mere instructions to apply the exception, as per

MPEP 2106.05(f).

Applicant argues that the present claims do not include activity which falls into the

abstract grouping of certain methods of organizing human activity. Examiner respectfully

disagrees. The creation of a matrix from the health data, processing samples from the matrix

based on predefined conditions, labelling the matrix upon processing of samples, and analyzing

the matrix to generate a prediction of a future event is activity which falls into the certain

methods of organizing human activity sub-grouping because it is certain activity of a person

both following rules and instructions and also interacting with a computer which is managing

personal behavior. As per the *October 2019 Update on Subject Matter Eligibility*, certain

activity between a person and a computer may fall within the "certain methods of organizing

human activity" grouping Therefore, as per the rejection above, the claims recite an abstract

idea. Applicant argues that because the claims include the prediction generated in real-time

based on electronic signals obtained from data acquisition devices that the claims are not

certain methods of organizing human activity. Examiner notes, as described above, the use of a

computer to carry out the steps in real-time amounts to mere instructions to apply the

exception, and the receiving of electronic signals comprising data amounts to mere data

gathering and thus the claim recites an abstract idea.

Applicant argues that the present claims are eligible subject matter similar to Example

39. Examiner respectfully disagrees. The claims of Example 39 include the training of the

neural network using a first training set and creating a second training set, and training the

neural network in a second stage using the second training set. The claim recites the training of

a machine learning model and includes the data set which is used to train the model, applying

the model to generate an output (the second training set), and use of the trained model output

which is to train in a second stage. This training of a machine learning model is considered to

be an additional element which integrates the abstract idea into a practical application. In the

present claims, there is not training or development or generation of a model, including the

inputs used to generate the model, the actual positive step of training a model, and the

recitation of use of the output of the trained model. Therefore, the claims are not eligible

similar to Example 39. The present claims merely apply ensemble modelling techniques to

generate an output which is a prediction of a future event. The use of an algorithm by a

general purpose computer to analyze data amounts to mere instructions to apply the

exception, as per MPEP 2106.05(f)(2). Therefore, the present claims recite an abstract idea.

Applicant argues that the present claims integrate the abstract idea into a practical

application because they provide an improvement in a technical field, as a technical solution to

a technical problem. Applicant further argues that the technical solution includes enabling

prediction of near future events in a shorter duration time window to provide early warning to

healthcare professionals, which is accomplished by building a robust AI algorithm that can

operate in real-time. Examiner respectfully disagrees that the present claims recite this

technical solution. The present claims do not positively recite the building of the AI algorithm,

but rather reflect the application of an algorithm to the collected data. As described above, the

application of a mathematical algorithm to collected data is mere instructions to apply the

exception and does not provide an inventive concept. Therefore, the claims do not provide a

technical solution of the actual building, i.e. training, of the AI algorithm or model to be used to

predict future events.

Applicant argues that the present claims are eligible similar to Example 40 because the

present claims provide an improvement in clinical health event prediction similar to the

improvement in network monitoring of Example 40. Examiner respectfully disagrees. The

collecting step of Example 40 provides a specific manner of collecting protocol data which

results in a savings of traffic volume on the network. The present claims include collecting data

via an electronic signal, but the data collection does not result in a technical or computer

improvement itself. Therefore, the claims do not integrate the abstract idea into a practical

application similar to Example 40.

Applicant argues that the present claims provide additional elements which amount to

significantly more than the abstract idea because the additional elements recite a combination

which is unconventional. Examiner respectfully disagrees. The description of the ensemble

model as a first model configured for higher recall and a second model configured for higher

precision is a description of the ensemble model and not an active functional step in the

process. The consideration for whether this is well-known is a consideration of novelty, which

is separate and distinct from the consideration of eligibility. Therefore, the present claims do

not amount to significantly more and are directed to an abstract idea.

7.   Applicant's arguments, see Pages 20-24, "Claim Rejections - 35 U.S.C. 103", filed

03/22/2021 with respect to claims 1-20 have been fully considered and they are persuasive.

The rejections of 12/22/2020 have been withdrawn. The prior art does not teach the ensemble

modelling technique comprises a first model configured for higher recall than precision and a

second model configured for higher precision than recall, wherein the ensemble modelling

technique has a higher precision than the first model and a higher recall than the second model

as per Claim 1.

Conclusion

8.   **THIS ACTION IS MADE FINAL.** 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 mailing date of this final

action.

9.   Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Evangeline Barr whose telephone number is (571)272-0369.

The examiner can normally be reached on Monday to Friday 8:00 am to 4:00 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, Fonya Long can be reached on 571-270-5096.   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.

/EVANGELINE BARR/
Primary Examiner, Art Unit 3626

REMARKS

Claims 1, 3-5 and 7-20 were pending in this application prior to entry of the aforementioned amendments. With this amendment, claim 1 is amended. Support for the amendments to the claims can be found throughout the as-filed application and claims including at least at paragraphs [0004], [0007], and [0047]. No new matter is believed to be introduced.

Upon entry of this amendment, claims 1, 3-5 and 7-20 are pending and under examination. Entry of the claim amendments and allowance of the application is respectfully requested.

Comment on AFCP2.0 Request

Applicant notes that this response provides arguments directed to Step 2B of the Alice/Mayo analysis under 35 U.S.C. 101 in accordance with the Office's suggestion during the Interview conducted July 10, 2021. The Step 2B analysis raises the question of whether the combination of additional recited elements is routine and conventional or provides something more that constitutes an inventive concept.

Due to the Office's conclusion that the instant claims (even before further amendment) are novel and nonobvious, Applicant submits that the request under AFCP2.0 is appropriate and provides the Office with sufficient time for additional search and/or consideration of this sole remaining issue under 35 U.S.C. 101. Thus, Applicant submits that an RCE is not necessary for full consideration of this response under the AFCP2.0 program and requests swift allowance of the instant application.

I)   Claim Rejections – 35 USC § 101

The Office Action rejects claims 1, 3-5 and 7-20 under 35 U.S.C. 101, on grounds the claimed invention is allegedly directed to an abstract idea without significantly more.

Without conceding to the rejection, and solely to expedite the prosecution of this application, Applicant has amended claim 1.

Applicant submits that the instant claims are eligible under 35 U.S.C. 101 in view of the 2019 Revised Patent Subject Matter Eligibility Guidance (January 7, 2019) (hereinafter "Revised Guidance") and the October 2019 Update: Subject Matter Eligibility (hereinafter "October Update") for at least the following reasons.

(A) The Claims Are Eligible Under Step 2B of the Alice/Mayo Test

Based on the Examiner's feedback during the Interview conducted on July 10, 2021, Applicant submits the instant claim amendment recites a combination of additional elements that is not routine or conventional.

The Revised Guidance states that in the event that "a claim has been determined to be directed to a judicial exception under revised Step 2A, examiners should then evaluate the **additional elements individually and in combination** under Step 2B to determine whether they provide an inventive concept." [Emphasis added] See page 56, left column. The Revised Guidance specifies that considerations the examiner should consider "whether an additional element or combination of elements... [a]dds a specific limitation or **combination of limitations that are not well-understood, routine, conventional activity in the field**, which is indicative that an inventive concept may be present". Id.

The system recited in amended claim 1 provides a solution to the technical problem of providing a clinical predictive triage system that effectively generates predictions of near future health events despite low data sufficiency. The instant application states that "[c]onventional health monitoring systems record the health data of one or more patients by tracking one or more health parameters through multiple body sensors" but recognizes that "such conventional systems are simplistic and less reactive, wherein monitors track information of the patient/s and generate one or more alarms only if the one or more health parameters are inside or outside of a set limit" (see paragraph [0003]). Given the limits to conventional systems, the result is that the "frequency of the alarms generated by such conventional systems are ambiguous and there is a high probability of false alarms among other factors, which may lead to incorrect decision making by the healthcare practitioners in case of patient care prioritizing" (see paragraph [0003]).

Furthermore, the instant application recognizes that "such conventional systems notify the healthcare practitioners only upon deterioration of the health condition of the patient/s with little or no predictive elements, and therefore provides a very limited amount of reaction time to the healthcare practitioners for adequate or appropriate patient care" (see paragraph [0003]). This unique context of health monitoring and alarm generation means (a) there is a heightened need for a proactive approach to health monitoring and alarm generation as opposed to a reactive one (b) coupled with a need for increased accuracy and timeliness in alarm detection/generation as compared to more general applications.

Accordingly, the claimed system provides a solution to the above-stated problems that enables more reliable predictions of near future events to be effectively generated when using short data windows because "certain conditions or deteriorations in health status may progress rapidly and require a shorter duration window to be detected in time to provide early warning to healthcare professionals" (see paragraph [0030]). For example, unlike standard approaches that may use 24h of data, the instant application provides a non-limiting illustrative example that generates **accurate** and **reliable** predictions using only a **short data window** (see paragraph [0136]).

Indeed, the technical problem faced by the inventors must be understood within the unique context of building a sufficiently robust AI algorithm that could operate with **real-time** electronic signals with **limited amount of data** and avoid significant amounts of **false positives** while being sufficiently proactive.

Moreover, the instant application recognizes that simply **"[c]ombining individual models in an ensemble approach is not guaranteed to improve performance"** (see paragraph [0043]) (emphasis added). Indeed, the "present disclosure demonstrated that the fundamental problem of **precision and recall being a trade-off** could be compensated for using ensemble modelling" which is of **"critical importance** within the **unique context** of detecting or predicting **near future events** (e.g., health status change) because a highly accurate model is useless if it cannot predict sufficiently far into the future to give healthcare practitioners enough forewarning to prepare for the event before it occurs" (see paragraph [0043]) (emphasis added). Therefore, the unique ensemble modelling approach as integrated into the combination of

elements recited in amended claim 1 provides an innovative solution to this particular technical problem that constitutes an inventive concept for at least the foregoing reasons.

Thus, the instant application recognizes the challenge of balancing accuracy with timeliness for purposes of providing the appropriate treatment, which is not disclosed in any of the prior art references of record. An inaccurate prediction can result in unnecessary waste of time and resources for the healthcare practitioners responding to a false positive medical event or, even worse, fail to flag the medical event which can result in adverse consequences and even death. In response to this challenge, the instant claims recite:

> "analyze, by the computing device, the labelled predetermined dimensional matrix using an ensemble modelling technique to generate a prediction of a future event comprising a predicted health status of the one or more patients in real-time, wherein the future event is predicted to occur at least a minimum period of time after a time period corresponding to the moving window of filtered health data;
>
> wherein the ensemble modelling technique comprises a first model configured for higher recall than precision and a second model configured for higher precision than recall, wherein the ensemble modelling technique has a higher precision than the first model and a higher recall than the second model, wherein the ensemble modelling technique comprises a first model configured for higher recall than precision and a second model configured for higher precision than recall, wherein the ensemble modelling technique has a higher precision than the first model and a higher recall than the second model, **wherein the ensemble modelling technique analyzes the labelled predetermined dimensional matrix using the first model configured for higher recall than precision and the second model configured for higher precision than recall to generate individual predictions and applies a rule-based decision logic to integrate the individual predictions generated by the first model and the second model into the predicted health status of the one or more patients in real-time**."

Accordingly, the recited combination of elements, in particular the ensemble modelling technique that analyzes the predetermined dimensional matrix using the first model configured for higher recall than precision and the second model configured for higher precision than recall to generate individual predictions and then applies a rule-based decision logic to integrate these individual predictions into the predicted health status in real-time constitutes an improved system that **enables** generation of a prediction in **real-time** with a **short window of data**.

For example, one model may be used to broadly flag for positive events, and then the second model provides an effective mechanism for filtering out false positives to **produce predictions are both high precision and recall despite short data windows**. This is important because a long data window may enhance accuracy, but it also effectively renders the system useless in certain scenarios, for example, when a patient has recently been checked in and experiences a medical emergency before the long data window (e.g., 24h) has been filled to enable predictions to be made.

Again, Applicant emphasizes the fact that none of the cited references teaches (1) the unique health monitoring and alarm generation context that prompts the increased need for both higher precision and recall and timeliness of the alarm (as explained with reference to the specification above), and (2) the unique solution in which the predetermined dimensional matrix is generated and then analyzed using the claimed ensemble modeling technique using two different models to generate individual predictions that are then integrated in a decision logic to generate the predicted health status in real-time, which produces increased precision/recall that is also timely. Instead, the conventional approach, as exemplified by the prior art references identified by the Office (e.g., Vaucher and El-Rashidy), are directed to a stacking ensemble technique in which the outputs of individual models selected for some particular performance metric are combined by averaging them, which can be tweaked by weighing the outputs relatively.

Applicant notes that the particular combination of elements recited in claim 1 even before entry of the instant amendment was found to be novel and inventive over the cited references. The requirement for the additional elements to be routine and conventional sets a higher bar than mere disclosure in the prior art, but rather requires the Office to put forth evidence and arguments as to why the elements are actually routine and conventional. Thus, the fact that the Office has concluded none of the closest prior art references teach the combination of elements recited in unamended claim 1 further corroborates the eligibility of amended claim 1 as reciting a combination of additional elements that are not routine and conventional.

Therefore, Applicant respectfully submits claim 1 and its dependent claims are eligible subject matter under 35 U.S.C. 101.

(B) Applicant Comments on The Office's response to Applicant Arguments

The Office stated that Applicant's amendments and arguments in the response to Non-Final Office Action filed on March 22, 2021 were not persuasive. Applicant reiterates the arguments set forth in the previous response.

Moreover, Applicant respectfully disagrees with the Office for the following reasons.

Prong One: Judicial Exception is Not Recited

The Office alleges that the claims of Example 39 are eligible subject matter because they recite the training of the neural network using training sets, the applying of the model to generate output, and use of the trained model output to train a second stage (see Office Action, dated April 16, 2021, at page 10). The Office then concludes that the "training of a machine learning model is considered to be an additional element which integrates the abstract idea into a practical application" which is not recited in the instant claims (Office Action, at page 10).

However, Applicant points out that the Office's analysis erroneously interprets the Example 39 analysis as being directed to Prong Two analysis when, in fact, Example 39 was determined to be "eligible because it does not recite a judicial exception." (see page 9). Thus, there was no need to determine the integration into a practical application because a judicial exception could not be identified within the body of the claim.

Claim 1 of Example 39 is reproduced below:

A computer-implemented method of training a neural network for facial detection comprising:

collecting a set of digital facial images from a database;

applying one or more transformations to each digital facial image including mirroring, rotating, smoothing, or contrast reduction to create a modified set of digital facial images;

creating a first training set comprising the collected set of digital facial images, the modified set of digital facial images, and a set of digital non-facial images;

training the neural network in a first stage using the first training set; creating a second training set for a second stage of training comprising the first training set and digital non-facial images that are incorrectly detected as facial images after the first stage of training; and

training the neural network in a second stage using the second training set.

Applicant submits that, according to the Office's interpretation of subject matter eligibility, the "collecting" and "creating" steps of Example 39 represent judicial exceptions. For example, the Office stated on page 9 of the Final Office Action:

> The creation of a matrix from the health data, processing samples from the matrix based on predefined conditions, labelling the matrix upon processing of samples, and analyzing the matrix to generate a prediction of a future event is activity which falls into the certain methods of organizing human activity sub-grouping because it is certain activity of a person both following rules and instructions and also interacting with a computer which is managing personal behavior.

The Office then goes on to state that "certain activity between a person and a computer may fall within the "certain methods of organizing human activity" grouping" and concludes that this is the case for the instant claims (Office Action, at page 9).

However, Applicant submits the Office's conclusion is contradicted by Example 39, for example, "collecting a set of digital facial images from a database" would be considered a judicial exception according to the Office's analysis. Specifically, Applicant submits the Office's analysis would consider this step to be "a person... interacting with a computer" since a human could simply use a computer to collect digital facial images from a database. And yet, Example 39 found that "[t]he claim does not recite any of the judicial exceptions enumerated in the 2019 PEG." (Examples at page 9). Therefore, Applicant submits that amended claim 1 does not recite a judicial exception as alleged by the Office because the claim does not recite mental steps, a mathematical concept, or certain methods of organizing human activity for at least the reasons stated in the response filed on March 22, 2021.

Prong Two: Integration into a Practical Application

The Office alleges that the present claims do not integrate the abstract idea into a practical application via an improvement in a technical field on grounds that the claims "do not positively recite the building of the AI algorithm, but rather reflect the application of an algorithm to the collected data".

However, Applicant points out that nowhere does the MPEP or USPTO guidance on subject matter eligibility require AI algorithm claims to positively recite the building of the AI algorithm in order to satisfy Prong Two. The Office's position adopts an overly narrow interpretation of subject matter eligibility that forces claims to be tied to a particular illustrative example and does not account for alternative means for an algorithm to be practically integrated.

As noted above with respect to Example 39, Applicant notes that the USPTO guidance does not corroborate the Office's narrow interpretation of the subject matter eligibility analysis for AI algorithms or models. Specifically, nowhere does the USPTO description of Example 39 mention that the claim must positively recite the construction of the AI algorithm/model. Rather, the analysis provided for Example 39 suggests AI algorithm steps that cannot be practically performed by the human mind are not judicial exceptions at all (see Analysis column for Step 2A Prong 1 on page 9).

Instead, Applicant submits that the Prong Two analysis finds software algorithm-based claims to be in integrated into a practical application when they provide a technical solution even if the claims are recited at a relatively high level of generality.

For example, Applicant claim 1 of Example 37 recites:

A method of rearranging icons on a graphical user interface (GUI) of a computer system, the method comprising:

receiving, via the GUI, a user selection to organize each icon based on a specific criteria, wherein the specific criteria is an amount of use of each icon;

determining, by a processor, the amount of use of each icon over a predetermined period of time; and

automatically moving the most used icons to a position on the GUI closest to the start icon of the computer system based on the determined amount of use.

The USPTO guidance states that the "determining" step recites a judicial exception, but then concludes that the combination of merely three high-level steps of receiving, determining, and moving together is sufficient to "recite a specific manner of automatically displaying icons to the user based on usage which provides a specific improvement over prior systems, resulting in an improved user interface or electronic devices" (see pages 2-3).

In other words, although the claimed steps in Example 37 are broadly worded and recite a judicial exception, the combination of these steps is sufficient to constitute integration into a practical application simply because they provided an improved graphical user interface on a general purpose "computer system". Applicant emphasizes that a GUI and a computer system are well-known concepts and yet an improvement in icon placement on the GUI constitutes a technical improvement under Prong Two according to Example 37.

Similarly, even assuming *arguendo* that the recited ensemble modelling technique of claim 1 is a judicial exception, the overall combination of the receive, filter, create, process, label, and analyze steps of instant claim 1, which are recited at a far higher level of detail than Example 37, provide a specific manner of automatically generating a predicted health status of one or more patients in real-time which is a specific improvement over prior systems, resulting in an improved patient health monitoring system that is capable of generating predictions/alerts that have a combination of timeliness and accuracy while using a smaller window of data than prior systems.

Moreover, the Office states that the instant claims do not provide an improvement in a technical field on grounds that they merely recite "the application of an algorithm to the collected data" instead of reciting the construction of the algorithm – but this analysis contradicts the USPTO guidance on claim 1 of Example 37, which essentially recites a software algorithm step for "determining... the amount of use of each icon over a predetermined period of time" (i.e., an algorithm is typically defined as a sequence of computer implemented instructions). However, there is no recitation of how this algorithm was constructed; rather the claim simply recites an application of the algorithm. Yet this claim satisfies Prong Two according to the USPTO.

Accordingly, Applicant respectfully submits that instant claim 1 also satisfies Prong Two for at least the same reasons as claim 1 of Example 37.

To the extent the Office alleges that claim 1 of Example 37 is different because it recites an active step of moving the icons, Applicant notes that:

(a) instant claim 1 also recites an active step of "generate a prediction of a future event comprising a predicted health status of the one or more patients in real-time" and

(b) instant claim 20 likewise recites an active step of transmitting the predictive alert/health status to one or more patient or stakeholder devices for display, thus alerting them to the predicted health status.

In addition, to the extent the Office alleges USPTO Example 37 is different from the instant claims because it requires operation of a processor to carry out the recited steps, Applicant notes that the Office has characterized the generic recitation of a processor as having "a high-level of generality such that it amounts to no more than mere instructions to apply the exception using a generic computer component" (see Office Action, dated April 16, 2021, at page 4). Of course, such a finding would be contradicted in the case of Example 37. Indeed, Applicant submits the steps recited in the instant claims require operation of a processor in order to be practically performed just as much as the steps of Example 37. Therefore, the instant claims cannot be reasonably differentiated from claim 1 of Example 37 on this basis, and satisfies Prong Two of Step 2A.

Summary

For at least the foregoing reasons, amended claim 1 does not recite a judicial exception under Prong One and/or provides an improvement in a technical field, and therefore, integrates any alleged judicial exception into a practical application under Prong Two of the Revised Step 2A analysis, and are therefore eligible subject matter under 35 U.S.C. 101. Moreover, amended claim 1 recites a combination of elements that are unconventional compared to existing methods, for example, that are disclosed in the same prior art references relied upon by the Office.

In accordance with MPEP 2106 and the 2019 Revised Patent Subject Matter Eligibility Guidance, a rejection of amended claim 1 under 35 U.S.C. 101 should not be maintained.

Applicant, therefore, requests withdrawal of this rejection with allowance of claim 1 along with claims 3-5, and 7-20 that depend therefrom.

CONCLUSION

Applicant respectfully solicits the Examiner to expedite examination of this application to issuance. Should the Examiner have any questions, Applicant requests that the Examiner contact the undersigned at 858-350-2348. The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment to Deposit Account No. 23-2415, referencing Attorney Docket No. 59419-701.201.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI
A Professional Corporation

Date: July 15, 2021   By: /Qiming Deng/
                                              Qiming Deng
                                              Registration No. 74051

650 Page Mill Road
Palo Alto, CA 94304
(858) 350-2348
Customer No. 021971

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions and listing of claims in the above-referenced patent application. The following amendments do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed. Amendments to the claims were made for purposes of more clearly stating the claimed subject matter and do not add new matter or alter the scope of the claims. Deletions are denoted by [strikethrough] and additions are denoted by underline.

Listing of the Claims

1.   (Currently Amended) A computer-implemented status monitoring and future event prediction system comprising a data analytics subsystem comprising a computing device comprising a processor, a memory, and an operating system configured to perform executable instructions, wherein the computing device is operative to:

receive, by the computing device, an electronic signal comprising health data of one or more patients from one or more medical data acquisition devices; and

filter, by the computing device, the electronic signal comprising the health data to eliminate one or more outliers;

create, using the computing device, a predetermined dimensional matrix representative of a plurality of samples obtained from a moving window of the filtered health data representative of the plurality of health parameters of the one or more patients in a predefined interval; and

process, using the computing device, one or more samples selected from the plurality of samples of the predetermined dimensional matrix based on a predefined condition; and

label, by the computing device, the predetermined dimensional matrix upon processing of the one or more samples using one or more clinical scoring techniques; and

analyze, by the computing device, the labelled predetermined dimensional matrix using an ensemble modelling technique to generate a prediction of a future event comprising a predicted health status of the one or more patients in real-time, wherein the future event is

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predicted to occur at least a minimum period of time after a time period corresponding to the moving window of filtered health data;

wherein the ensemble modelling technique comprises a first model configured for higher recall than precision and a second model configured for higher precision than recall, wherein the ensemble modelling technique has a higher precision than the first model and a higher recall than the second model, wherein the ensemble modelling technique analyzes the labelled predetermined dimensional matrix using the first model configured for higher recall than precision and the second model configured for higher precision than recall to generate individual predictions; and wherein applies a rule-based decision logic is used to integrate the individual predictions generated by the first model and the second model into the predicted health status of the one or more patients in real-time.

2.   (Cancelled)

3.   (Previously Presented) The system of claim 1, wherein the first model comprises a neural network.

4.   (Previously Presented) The system of claim 1, wherein the second model comprises a tree model.

5.   (Previously Presented) The system of claim 1, wherein the minimum period of time is at least 5 minutes after the time period corresponding to the moving window of filtered health data.

6.   (Cancelled)

7.   (Original) The system of claim 1, wherein the data analytics subsystem is hosted on a cloud server, a local server, one or more medical data acquisition devices or a combination thereof.

8.   (Original) The system of claim 1, wherein the plurality of health parameters comprises at least one of heart rate, blood oxygen, electrocardiogram, respiratory rate, blood pressure, temperature or a combination thereof.

9.   (Original) The system of claim 1, wherein the one or more outliers comprises at least one of additional movements of the one or more patients, misplacement of one or more sensors, one or more data artefacts, one or more noises or a combination thereof.

10.   (Original) The system of claim 1, wherein the one or more medical data acquisition devices comprises a bedside monitoring device comprising at least one communication medium to receive the plurality of health parameters from one or more sensors and a display interface.

11.   (Original) The system of claim 10, wherein the one or more medical data acquisition devices are configured to:

collect health data representative of a plurality of health parameters from the one or more patients through the one or more sensors; and

display the health data collected from the one or more patients on the display interface via a predefined icon from a plurality of designated icons.

12.   (Previously Presented) The system of claim 1, wherein the predefined condition comprises selection of the one or more samples having the plurality of health parameters that pass a predefined threshold value for a predefined time period.

13.   (Previously Presented) The system of claim 1, wherein the computing device is further operative to process static information associated with the one or more patients, wherein the static information comprises patient demographics, patient health condition or one or more clinical notes.

14.   (Original) The system of claim 1, wherein the ensemble modelling technique comprises at least one of a dilated causal convolution network, a tree-based gradient boosted technique, a recurrent neural network, a graph neural network, a support vector machine classifier, a logistic regression technique, a k-nearest neighbor classifier, or any combination thereof.

15.   (Previously Presented) The system of claim 1, wherein the computing device is further operative to implement an online training technique to fine-tune a prediction model corresponding to one or more clinical and operational requirements of an area of implementation or a patient health condition.

16.   (Previously Presented) The system of claim 1, wherein the computing device is further operative to generate one or more predictive alerts for the one or more patients based on prediction of the health status of the one or more patients.

17.   (Previously Presented) The system of claim 16, wherein the one or more predictive alerts generated are described with one or more contributing input features using a class activation map technique, wherein the class activation map technique determines the one or more input contributing features responsible for successful prediction of clinical scores in multiclass prediction.

18.   (Previously Presented) The system of claim 16, wherein the computing device is further operative to add hysteresis for providing one or more escalation processes based on a plurality of prediction classes predicted by the future event prediction module.

19.   (Previously Presented) The system of claim 16, wherein the computing device is further operative to:

transmit the one or more predictive alerts to one or more corresponding stakeholders for creating awareness associated with the health status of the one or more patients based on the predictive value; and

prioritize a list of the one or more patients with a predictive value higher than a predetermined predictive value based on transmission of the one or more predictive alerts.

20.   (Previously Presented) The system of claim 1, wherein the computing device is further operative to transmit a signal comprising the predicted health status of the one or more patients and the one or more predictive alerts to one or more handheld computing devices and one or more handheld electronic devices associated with at least one of the one or more patients or one or more stakeholders associated with the one or more patients, wherein the one or more stakeholders comprises at least one of a caregiver, a nurse, a healthcare practitioner, or any combination thereof.