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EXAMINER
BARR, MARY EVANGELINE

ART UNIT	PAPER NUMBER
3626	

NOTIFICATION DATE	DELIVERY MODE
07/20/2020	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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PTOL-90A (Rev. 04/07)

		Application No.	**Applicant(s)**
		15/022,711	Liu et al.
Office Action Summary		**Examiner**	**Art Unit**	**AIA (FITF) Status**
		Evangeline Barr	3626	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 03/23/2020 and 07/14/2020.
   ☐ 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) 1-20 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   5a) Of the above claim(s) ____ is/are withdrawn from consideration.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) 1-20 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
<u>http://www.uspto.gov/patents/init_events/pph/index.jsp</u> 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)   3) ☐ Interview Summary (PTO-413)
                                                                  Paper No(s)/Mail Date _____.
2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)   4) ☐ Other: _____.
   Paper No(s)/Mail Date _____.

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

Continued Examination Under 37 CFR 1.114

2.   A request for continued examination under 37 CFR 1.114, including the fee set forth in

37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible

for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been

timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR

1.114. Applicant's submissions filed on 03/23/2020 and 07/14/2020 have been entered.

Status of the Application

3.   **Claims 1-20** are currently pending in this case and have been examined and addressed

below. This communication is a Non-Final Rejection in response to the Amendment to the

Claims and Remarks filed on 03/23/2020 and 07/14/2020.

- Claims 1, 4-10, 13-15 and 18-20 are currently amended.

- Claims 2-3, 11-12 and 16-17 are as previously presented.

Priority

4.   Receipt is acknowledged of certified copies of papers required by 37 CFR 1.55 for the

national stage application.

Claim Rejections - 35 USC § 101

5.   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.

6.   **Claims 1-20** are rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more. Claims 1-20 are directed to the abstract idea of determining a disease state transition path which is a method of organizing human activity.

As per Claims 1, 10 and 15, the limitations of identifying a first and second disease state of a plurality of non-overlapping disease states, as drafted, is a step executed by a system that, under its broadest reasonable interpretation, covers mental processes but for the recitation of generic computer components. That is, other than reciting "a storage device for storing instructions" and "a processor configured to execute the instructions to" and "by the first processor", nothing in the claim elements precludes the step from being a function which can be performed in the human mind by evaluating the patient data and predetermined range of functional and structural degeneration values associated with the disease states. Similarly, the limitation of predicting a most probable path between the first disease state and the second disease state, as drafted, under its broadest reasonable interpretation, covers a mental process as it can be performed in the human mind using evaluation, judgement and/or opinion to predict the most probable path between states. That is, other than reciting "using a two dimensional continuous-time hidden Markov model," nothing in the claim elements precludes the step from being a function which is a mental process. Claim 10 also includes the limitations of determining a most probable next disease state along the probable path, comparing the most probably next disease state to the second disease state, and determining a transition

between states has a fast structural and/or functional progression based on the comparison. These steps, under their broadest reasonable interpretation are also mental processes for similar reasons to that described above. The determining, comparing, and determining based on the comparing comprise a person using evaluation and judgement to determine the result that a transition between states has a fast structural and/or functional progression. If a claim limitation, under its broadest reasonable interpretation, covers concepts which can be performed in the human mind using observation, evaluation, judgement and/or opinion, but for the recitation of generic computer components, then it falls within the "Mental Processes" grouping of abstract ideas. 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 recite the additional elements – "a storage device", and "a processor" to execute the instructions in the storage device. The storage device and processor in these steps are recited at a high-level of generality and are recited as generic computer components that perform routine functions that are well-known in the industry such that it amounts to no more than mere instructions to apply the exception using a generic computer component. The claims also include a first processor of a disease progression model which carries out the identifying and predicting steps which amounts to no more than mere instructions to apply the exception, as per MPEP 2106.05(f), simply adding a general purpose computer or computer components after the fact to an abstract idea does not integrate a judicial exception into a practical application. The claim also recites the additional elements of "using a two-dimensional continuous-time hidden Markov model" which also amounts to no

more than mere instructions to apply the exception, as it is a known mathematical algorithm.

As per MPEP 2106.05(f)(2), the courts have found the following to be mere instructions to apply

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

perform an existing problem: a commonplace business method or mathematical algorithm

being applied on a general purpose computer, *Alice Corp. Pty. Ltd. V. CLS Bank Int'l*, 134 S. Ct.

2347, 1357, 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). Additionally, the claim recites the additional elements of receiving

patient data comprising structural and functional data related to a patient, via a secure

interface, from a second processor associated with a healthcare provider terminal which

amounts to insignificant extra-solution activity. As in MPEP 2106.05(g), insignificant extra-

solution activity does not integrate the abstract idea into a practical application because the

step of receiving patient data is mere data gathering in conjunction with the abstract idea. The

additional limitation of outputting the most probable path to cause the healthcare provider

terminal to display the path as a graphical user interface also amounts to insignificant extra-

solution activity because the outputting of the result of the abstract idea to present to a

provider device amounts to necessary data outputting as per MPEP 2106.05(g). The receiving

and outputting limitations amount 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). Accordingly, the additional elements do not integrate the abstract idea

into a practical application because they do not impose any meaningful limits on practicing the

abstract idea. 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 because the additional elements when considered

both individually and as an ordered combination do not amount to significantly more than the

abstract idea. As discussed above with the respect to integration of the abstract idea into a

practical application, the additional elements of "a storage device" and "a processor" to

execute the functions of the invention amounts to no more than mere instructions to apply the

exception using a generic computing component. The system including the storage device and

processor are recited at a high level of generality and are recited as generic computer

components that perform routine functions that are well-known in the industry (i.e., receiving

data, analyzing data, comparing data, determining data, etc.). These elements recite a generic

computing system by reciting a storage device that may be volatile or non-volatile, magnetic,

semiconductor, etc. (Specification [0048]), and a processor which may be a known processing

device such as a Pentium microprocessor, single or multiple core processor, etc. which executes

the instructions or programs to carry out the tasks of the claims (Specification [0047]), which do

not add meaningful limitations to the abstract idea beyond mere instructions to apply an

exception. The claims also include the additional element of using a two dimensional

continuous-time Markov model which also amounts to no more than mere instructions to apply

the exception, as discussed above. Mere instructions to apply an exception using a generic

computer component cannot provide an inventive concept. The use of continuous-time

Markov modeling to determine disease progression amounts to no more than well-understood,

routine, conventional activity previously known in the healthcare arts as shown in the

Statistician publication which demonstrates the well-understood, routine and conventional

nature of using continuous time hidden Markov models for disease progression. As on Page

193 of *The Statistician*, the Summary describes models based on Markov processes are a well-

established method of estimating transition between stages of disease. As this is shown to be a

functionality supported in healthcare analysis prior to the time the invention was filed, it would

be obvious to a person of ordinary skill in the art that the functions are well-understood,

routine and conventional in the art. The claims also include the additional elements of receiving

patient data and outputting the most probable path to a healthcare provider terminal graphical

user interface which are functions that are well-understood, routine and conventional

computer functions in the field of data management because they are claimed at a high level of

generality and include receiving or transmitting data, which has been found to be well-

understood, routine and conventional computer functions by the Court (MPEP 2106.05(d)(II)(i)

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)). Looking at the limitations as an ordered combination adds nothing that is not already

present when looking at the elements taken individually. There is no indication that the

combination of elements improves the functioning of the computer or improves another

technology. The claims do not amount to significantly more than the underlying abstract idea.

Claims 2-9, 11-14 and 16-20 are dependent from Claims 1, 10 and 15 and include all the

limitations of Claims 1, 10 and 15. The dependent claims recite additional steps such as Claims

2, 11 and 16 further specify the type of disease states. Claims 3, 12, and 17 further limit the

disease states. Claims 4 and 13 include updating the parameters of the Markov model, which is

also directed to the same abstract idea because it involves following rules or instructions. Claim

5 further specifies the determining of the most probable path, which is directed to the same

abstract idea. Claims 6-7 include similar steps to those addressed in Claim 10, as above, and

thus are directed to the same abstract idea. Claims 8 and 19 further include determining an

expected time to transition to the most probable next state which similar to the independent

claims involves following rules or instructions based on the patient data and thus are directed

to the same abstract idea. Claims 9, 14 and 20 include steps which, similar to the independent

claims, involve following rules or instructions to result in determine whether a patient has an

attribute by determining an updated path, determining a disease progression rate, and

comparing the progression rate with a predetermined progression rate and thus are directed to

certain methods of organizing human activity. Claim 18 also involves determining a probable

future disease state, similar to the claims above and is directed to the same abstract idea 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 claims 1, 10 and 15.

The dependent claims do not integrate the judicial exception into a practical application

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

on the judicial exception. The dependent claims include the additional element of "using the

hidden Markov model", similar to that of the independent claims. As described in relation to

the independent claims above, the use of the hidden Markov model amounts to no more than

mere instructions to apply the exception and does not integrate the abstract idea into a

practical application and additionally, does not provide significantly more than the abstract

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

exception, the claim is directed to an abstract idea. The dependent claims do not include any

additional elements that provide an inventive concept by reciting significantly more than the

abstract idea. Therefore, when taken individually or as an ordered combination, Claims 1-20

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

Response to Arguments

7.   Applicant's arguments, see Pages 8-11, "Rejections under 35 U.S.C. §101", filed

03/23/2020 and Pages 8-10 of the response filed 07/14/2020 with respect to claims 1-20 have

been fully considered but they are not persuasive. The rejection is being maintained.

Applicant argues that the claims do not recite a judicial exception. Examiner

respectfully disagrees. Upon consideration of the amended claims, the claims contain

limitations which are directed to the abstract idea of mental processes as per the rejection

above. Identifying disease state based on patient data and predicting a most probable path

between disease states are concepts which can be performed in the human mind. Applicant

argues that the claims do not recite a mental process because they cannot be practically

performed in the human mind. Examiner notes that executing the predicting step by applying

the data to a two dimensional continuous-time hidden Markov model amounts to mere

instructions to apply the exception because as per MPEP 2106.05(f)(2), a mathematical

algorithm being applied on a general purpose computer has been found by the courts to merely

invoke computers or machinery as a tool to perform an abstract idea. The predicting a most

probable path between a first disease state and second disease state is a mental process which

is applied to a mathematical algorithm. Therefore, the claims are directed to an abstract idea

as per Step 2A, Prong One.

Applicant argues that the claims cannot be performed without computer technology

and thus are inextricably tied to computer technology. Applicant further argues that the

elements of the claims cannot be performed by a human because of the laborious and time-

consuming nature of the data analysis. As per MPEP 2106.05(f)(2), claiming the improved

speed or efficiency inherent with applying the abstract idea on a computer does not provide an

inventive concept. Therefore, requiring the use of a computer to perform the laborious

and time-consuming calculations argued by the Applicant are mere instructions to apply the

exception and does not amount to significantly more than the abstract idea.

Applicant argues (as in the supplemental response of 07/14/2020) that the use of a

continuous-time hidden Markov model in the field is not routine or well-known and thus the

claims amount to significantly more than the abstract idea. Examiner respectfully disagrees.

The Statistician article provides evidence that using continuous hidden Markov models for

disease progression analysis is well established. Additionally, the specification describes the

improvements of the invention as improvements to the accuracy of a disease progression

model ([0087]/[0098]) and improved analysis ([0118]) which does not provide for an

improvement in technology or a technological field. Therefore, as per the rejection above, the

claims do not amount to significantly more than the abstract idea because the use of a

continuous hidden Markov model for disease progression analysis is well-understood, routine

and conventional in the field of healthcare data analysis. Therefore, the rejection is

maintained.

Conclusion

8.   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

This *Response* is filed in reply to an *Office Action* issued by Examiner Barr on July 20, 2020. Claims 1-20 are pending in the Application, and all stand rejected. Applicant thanks the Examiner with appreciation for the careful examination.

Applicant submits this *Response* solely to facilitate prosecution. As such, Applicant reserves the right to present new or additional claims in this Application that have similar or broader scope as originally filed. Applicant also reserves the right to present additional claims in a later-filed continuation application that have similar or broader scope as originally filed. Also, Applicant presents this submission to clarify Applicant's claimed invention and Applicant does not concede that the current or past rejections are correct and reserves the right to challenge such rejections later in prosecution or on appeal. Accordingly, any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter. The submission of amendments, claim cancellations and/or new claims, and arguments in support thereof, is not to be construed as an indication of Applicant's agreement with, or acquiescence to, the rejections of record. As certain of the current amendments may include broadening amendments, Applicant respectfully requests Examiner to revisit any previously reviewed references cited in this Application to further ensure that the currently pending claims remain patentable over any previously reviewed references.

By the present *Response*, Claims 1-20 are pending in the Application. Claims 1, 10, and 15 are currently amended, Claims 2, 11, and 16 are canceled, Claims 3 and 12 are in their original format, and Claims 4-9, 13-14, and 17-20 are previously presented. Applicant amends certain claims in this *Response* to clarify the currently claimed embodiments of the invention. No new matter is believed introduced by this *Response* as the amendments are fully supported by the *Specification* and figures as originally submitted. *See, e.g.,* U.S. Patent Publication No. US 2016/1232324, *Specification,* ¶¶ [00141]-[00143]. Applicant respectfully asserts that the pending claims are in condition for allowance, and respectfully requests reconsideration of the claims in light of this *Response*. Applicant believes that the Application is allowable for at least the following reasons.

I. Rejections under 35 U.S.C. § 101

The *Office Action* rejects Claims 1-20 under 35 U.S.C. § 101 as allegedly being directed to a judicial exception without significantly more. *Office Action* at 3. Applicant respectfully disagrees and maintains the arguments presented in the Response to the Final Office Action and the Supplemental Response (collectively, the "*Previous Responses*"). Applicant further contends that (1) Claims 1-20 do not recite the alleged judicial exception under Step 2A Prong One; (2) even if they do, the judicial exception is integrated into a practical application at Step 2A Prong Two; and (3) even if the additional limitations of Claims 1-20 do not integrate the alleged judicial exception under Step 2A Prong Two, the Claims, when analyzed as a whole, amount to significantly more than the recited alleged exception under Step 2B because they recite a specific and unconventional step that amounts to significantly more than the alleged exceptions.

Therefore, Applicant respectfully requests withdrawal of the 35 U.S.C. § 101 rejection of Claims 1-20 and requests reconsideration. Applicant respectfully submits that the claims are directed to patentable subject matter.

A. The Claims Do Not Recite the Alleged Judicial Exception (Abstract Idea)

1. The Claims Are Not Directed to a Method of Organizing Human Activity

Examiner first alleges that "Claims 1-20 are directed to the abstract idea of determining a disease state transition path which is a method of organizing human activity." *Office Action*, 3. The October 2019 Update: Subject Matter Eligibility ("*October 2019 Update*") published by the USPTO specifically addresses judicial exceptions related to "Certain Methods of Organizing Human Activity." October 2019 Update, 4-6. Specifically, it states, "this grouping is limited to activity that falls within the enumerated sub-groupings of fundamental economic principles or practices, commercial or legal interactions, managing personal behavior, and relationships or interactions between people, *and is not to be expanded beyond these enumerated sub-groupings except in rare circumstances* . . . ." Id., 4 (emphasis added). The instant claims, however, do not fall into any of these specific sub-groupings, nor has Examiner alleged that the claims do so.

According to the October 2019 Update, "'fundamental economic principles or practices' . . . describe subject matter relating to the economy and commerce." Id. The pending claims do not relate to the economy and commerce.

Further, "'commercial interactions' or 'legal interactions' include subject matter relating to agreements in the form of contracts legal obligations, advertising, marketing or sales activities or behaviors, and business relations." Id. The pending claims are not directed to any of these topics.

"'[M]anaging personal behavior or relationships or interactions between people' includes social activities, teaching, and following rules or instructions." The pending claims, however, do not relate to social activities or teaching and contain no "rules or instructions" to be followed.

For at least these reasons, Applicant respectfully submits the claims are not directed to a method of organizing human activity. To the extent Examiner disagrees, Applicant respectfully requests Examiner provide evidence that the present claims fall into one of the enumerated sub-groupings.

2. The Claims Are Not Directed to a Mental Process

Examiner also alleges that the limitation in Claims 1, 10, and 15, "is a step executed by a system that, under its broadest reasonable interpretation, covers mental processes." *Office Action*, 3. Applicant respectfully disagrees. The October 2019 Update expressly states, "[c]laims do not recite a mental process when they do not contain limitations that can practically be performed in the human mind, for instance when the human mind is not equipped to perform the claim limitations." Id., 7. For example, amended Claim 1 recites the step of "predicting, by the first processor using a two dimensional continuous-time hidden Markov model, a most probable path between the first disease state and the second disease state." This is a step that cannot be practically performed in the human mind for determining glaucoma. Indeed, Examiner essentially admits as much in the Office Action: "That is, *other than reciting 'using a two dimensional continuous-time hidden Markov model,'* nothing in the claim elements precludes the step from being a function which is a mental process." *Office Action*, 3 (emphasis added). Applicant submits that the claim must be considered as a whole, such that the limitation of "using a two dimensional continuous-time hidden Markov model" cannot be disregarded in arguing the claims are directed to a mental process.

For at least these reasons, Applicant respectfully submits the pending claims do not recite a judicial exception under Step 2A Prong One.

B. Even if the Claims Recite a Judicial Exception, the Judicial Exception is Integrated into a Practical Application, Particularly the "Improvements to Technology" and "Other Meaningful Limitations" Considerations

Even assuming *arguendo* that the claims recite the alleged judicial exception, the claims are not directed to the judicial exception because the judicial exception is integrated into a practical application. October 2019 Update, 10 ("[U]nder Prong Two, a claim that recites a judicial exception is not directed to that judicial exception, if the claim as a whole 'integrates the recited judicial exception into a practical application of that exception.'").

For example, Claim 1 recites the step of "predicting, by the first processor using a two dimensional continuous-time hidden Markov model, a most probable path between the first disease state and the second disease state." This Claim adds the additional limitation that specifies the "two dimensional continuous-time hidden Markov model" predicts the most probable path among a plurality of disease states to determine the path of glaucoma, thereby integrating the alleged exception into a practical application. The additional limitation does not only link the alleged judicial exception to a technical field, but also adds a meaningful limitation in that it employs the information provided by the alleged judicial exception (a known mathematical algorithm) to generate a modeled prediction of a patient's glaucoma disease progression.

In the Interview Summary, Examiner recommended Applicant explain "how the Markov model is applied in ways that are not routine or well-known in the field." Applicant notes that Step 2A Prong Two analysis excludes considerations of whether a limitation is well-understood, routine, or conventional activity. Id., 15. Applicant, however, submits the field is completely silent as to the use of a *two dimensional continuous-time* hidden Markov model *in the field of glaucoma*. Thus, any use of such a model as recited in the claims is necessarily "not routine or well-known." Indeed, there is no evidence in the record indicating such a model, specifically a two dimensional continuous-time hidden Markov model or even a discrete-time hidden Markov model, has ever been used *in the field of glaucoma*.

Further, Applicant points Examiner to paragraphs [0069]-[0079] of the published application in which the specification goes into detail as to how the two dimensional continuous-time hidden Markov model can be used to predict a probable path between disease states, particularly where "the most probable path comprises one or more intermediary disease states," as also recited in Claim 1. Applicant submits this entire process, i.e., the use of a two dimensional continuous-time hidden Markov model, is not routine or well-known.

In the *Office Action*, Examiner points to *The Statistician* reference as describing models based on Markov processes as being used in healthcare analysis. On page 196, *The Statistician* teaches "In engineering and biological sequencing applications, the Markov process usually evolves over an equally spaced discrete 'time' space. Therefore, most of the theory of hidden Markov model estimation was developed for discrete time models. *Hidden Markov models have less frequently been used in medicine,* where continuous time processes are often more suitable. A disease process evolves in continuous time, and patients are often monitored at irregular and differing intervals." (emphasis added). Thus, *The Statistician*, itself, admits that the use of hidden Markov models in medical fields are not routine and conventional.

Further, Applicant contends that *The Statistician* does not make use of both functional degeneration data and structural degeneration data. Applicant points Examiner to paragraphs [0057]-[0058] of the published application in which the specification goes into detail of both structural degeneration data and functional degeneration data for glaucoma. Indeed, the model used in The Statistician looks solely at "Aortic diameter," which is structural degeneration data (*The Statistician*, Table 1)—it does not also consider functional degeneration data as recited in the pending claims.

Applicant further contends that *The Statistician* does not teach the use of multiple non-overlapping states in a two dimensional continuous-time hidden Markov model, nor does it describe the use of any hidden Markov model for glaucoma. Importantly, paragraphs [0007]-[0009] and [0059]-[0061] of the published application illustrate how multiple non-overlapping disease states within each medical factor (i.e. 100 or more disease states may be used) are incorporated into this two-dimensional based model. Therefore, Applicant submits there is no evidence in the record indicating such a model, specifically a two dimensional continuous-time hidden Markov model, as recited in Claim 1, has been used in the field for the prediction of glaucoma disease states.

C. Even if the Claims Do Not Integrate the Judicial Exception, the Limitation Recites a Specific and Unconventional Step That Amounts to Significantly More Than the Alleged Exception

Even assuming *arguendo* that the claims do not integrate the alleged judicial exception, the claims include additional limitations that amount to significantly more than the judicial exception.

Under Step 2B, the claim, as a whole, is evaluated for whether any additional element or combination of additional elements add an inventive concept to the claim. *See* MPEP 2106.05(g). As discussed above, Step 2A Prong Two analysis excludes considerations of whether a limitation is well-understood, routine, or conventional activity. October 2019 Update, 15. Under Step 2B, however, the evaluation of the alleged insignificant extra-solution activity consideration takes into account whether the extra-solution activity is well-known.

Accordingly, Applicant points out that while continuous-time hidden Markov models are known, mere knowledge of this type of model does not make its use in medicine, or more specifically in determining glaucoma disease progression, routine or conventional. The additional limitation of employing a two dimensional continuous-time hidden Markov model is therefore no longer to be considered insignificant because the use of such hidden Markov model would be beneficial in predicting a patient's glaucoma disease progression. As a result, this unconventional prediction step to perform the limitation using the two dimensional continuous-time hidden Markov model, as recited in the Claims, as a whole, amount to significantly more than the alleged exception itself.

III. Fees

Applicant believes no claims fees or additional fees are due. Nevertheless, Applicant authorizes the Commissioner to charge deposit account No. 20-1507 for any fees deemed due to keep the application pending or credit any overpayment.

CONCLUSION

Applicant respectfully submits that all claims are in condition for allowance and that Applicant has fully addressed each point raised in the *Office Action*. By the present *Response*, therefore, the *Application* has been placed in full condition for allowance. Accordingly, Applicant respectfully requests early and favorable action.

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I hereby certify that this correspondence is being submitted by e-filing to the US Patent and Trademark Office in accordance with §1.8 on this date via the EFS-Web electronic filing system.

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AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions, and listings, of claims in the application.

1. (Currently Amended) A method for determining a disease state transition path **of glaucoma, said method** comprising:

receiving, by a first processor of a disease progression model, patient data comprising ~~one or both of~~ structural **degeneration** data and functional **degeneration** data related to a patient, via a secure interface, from a second processor associated with a healthcare provider terminal;

identifying, by the first processor, based on the patient data, a first disease state of a plurality of non-overlapping disease states **of glaucoma** each associated with a predetermined range of one or both of functional and structural degeneration values;

identifying, by the first processor, based on the patient data, a second disease state of the plurality of disease states, wherein the second disease state is non-adjacent to the first disease state;

predicting, by the first processor using a two dimensional continuous-time hidden Markov model, a most probable path between the first disease state and the second disease state, wherein the most probable path comprises one or more intermediary disease states of the plurality of disease states,

wherein each intermediary disease state is adjacent to one or more of the first disease state, the second disease state, and another intermediary disease state; and

outputting, by the first processor, the most probable path between the first disease state and the second disease state to cause the healthcare provider terminal to display the most probable path as a graphical user interface.

2. (Cancelled)

3. (Original) The method of Claim 1, wherein each sequential disease state is associated with one or both of increased structural and functional degeneration values as time progresses.

4. (Previously Presented) The method of Claim 1 further comprising iteratively updating, by the first processor, one or more parameters of the hidden Markov model based on the determined most probable path until the most probable path remains substantially constant.

5. (Previously Presented) The method of Claim 1, wherein predicting the most probable path further comprises:

predicting the most probable path, with the first processor using hidden Markov model and assigning, by the first processor, a uniform time spent in each intermediary state along the most probable path;

updating, by the first processor, one or more parameters of the hidden Markov model based on the determined most probable path;

predicting, by the first processor, the most probable path using the hidden Markov model; and

alternating, by the first processor, the updating and redetermining steps until the redetermined most probable path substantially matches a previously determined most probable path.

6. (Previously Presented) The method of Claim 1 further comprising predicting, with the first processor, a most probable next disease state for one or more disease states along the most probable path or for the second disease state using the hidden Markov model.

7. (Previously Presented) The method of Claim 6 further comprising:

comparing, by the first processor, the most probable next disease state with the second disease state; and

predicting, with the first processor, that a transition between disease states along the most probable path has a fast structural and/or functional progression based on the comparison.

8. (Previously Presented) The method of Claim 6 further comprising predicting, with the first processor, an expected time to transition from the second disease state to the most probable next disease state using the hidden Markov model.

9. (Previously Presented) The method of Claim 1 further comprising:

training, by the first processor, the hidden Markov model based on patient progression data corresponding to a plurality of patients having an attribute;

predicting, with the first processor using a trained hidden Markov model, an updated most probable path between the first disease state and the second disease state;

predicting, with the first processor, a disease progression rate based on the updated most probable path;

comparing, by the first processor, the predicted disease progression rate with a predetermined disease progression rate; and

predicting, with the first processor, whether a patient has the attribute based on the comparison.

10. (Currently Amended) A method for detecting disease state transitions **of glaucoma** ~~having fast progression,~~ **said method** comprising:

receiving, by a first processor of a disease progression model, patient data comprising ~~one or both of~~ structural **degeneration** data and functional **degeneration** data related to a patient, via a secure interface, from a second processor associated with a healthcare provider terminal;

identifying, by the first processor, based on the patient data, a first disease state of a plurality of non-overlapping disease states **of glaucoma** each associated with a predetermined range of one or both of functional and structural degeneration values;

identifying, by the first processor, based on the patient data, a second disease state of the plurality of disease states, wherein the second disease state is non-adjacent to the first disease state;

determining, with the first processor using a two dimensional continuous-time hidden Markov model, a most probable path between the first disease state and the second disease state, wherein:

the most probable path comprises one or more intermediary disease states of the plurality of disease states, and

each intermediary disease state is adjacent to one or more of the first disease state, the second disease state, and another intermediary disease state;

determining, with the first processor, a most probable next disease state for one or more disease states along the most probable path using the hidden Markov model;

comparing, by the first processor, the most probable next disease state with the second disease state; and

determining, with the first processor, that a transition between disease states along the most probable path has a fast structural and/or functional progression based on the comparison.

11. (Cancelled)

12. (Original) The method of Claim 10, wherein each sequential disease state is associated with one or both of increased functional and structural degeneration values as time progresses.

13. (Previously Presented) The method of Claim 10 further comprising iteratively updating, by the first processor, one or more parameters of the hidden Markov model based on the determined most probable path until the most probable path remains substantially constant.

14. (Previously Presented) The method of Claim 10 further comprising:

when the transition is determined to be the fast structural and/or functional progression, training, by the first processor, the hidden Markov model based on patient progression data corresponding to a plurality of patients having the fast structural and/or functional progression;

redetermining, with the first processor, the most probable next disease state for one or more disease states along the most probable path using the hidden Markov model.

15. (Currently Amended) A system for determining a disease state transition path **of glaucoma, said method** comprising:

a storage device for storing instructions; and

a processor configured to execute the instructions in the storage device to:

receive patient data comprising ~~one or both of~~ structural **degeneration** data and functional **degeneration** data related to a patient;

identify, based on the patient data, two or more disease states of a plurality of non-overlapping disease states **of glaucoma** each associated with a predetermined range of one or both of functional and structural degeneration values; and

predict, using a two dimensional continuous-time hidden Markov model, a most probable path between a sequential pair of non-adjacent disease states of the two or more disease

states, wherein the most probable path comprises one or more intermediary disease states of the plurality of disease states,

wherein each intermediary disease state is adjacent to at least one of the sequential pair of non-adjacent disease states and another intermediary disease state.

16. (Cancelled)

17. (Previously Presented) The system of Claim 15, wherein each of the identified two or more disease states is associated with one or both of increased functional and structural degeneration values as time progresses.

18. (Previously Presented) The system of Claim 15, wherein the processor is further configured to predict a most probable future disease state for the most recent of the identified two or more disease states using the hidden Markov model.

19. (Previously Presented) The system of Claim 18, wherein the processor is further configured to predict an expected time to transition from the most recent of the identified two or more disease state to the most probable future disease state using the hidden Markov model.

20. (Previously Presented) The system of Claim 15, wherein the processor is further configured to:

train the hidden Markov model based on patient progression data corresponding to a plurality of patients having an attribute;

predict, using a trained hidden Markov model, an updated most probable path between the sequential pair of non-adjacent disease states;

predict a disease progression rate based on the updated most probable path;

compare the predicted disease progression rate with a predetermined disease progression rate; and

determine whether a patient has the attribute based on the comparison.