

See MPEP §2163(I)(A) which states:

"The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence."

In this case, the claims are a method of treatment where the treatment is defined solely by function to encompass all possible "therapeutic agents". Written description may be met by providing sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, therapeutic agent, neuroprotective drug, anti-oxidant, etc., are all classes described solely by a function/result with no corresponding structure. This is insufficient to meet the written description requirement.

Alternately, species representative of the genus may be disclosed. However, the specification does not appear to provide any individual species of the claimed genera (see p. 16) and thus does not convey to the artisan that Applicant was in possession of species sufficient to warrant a claim to using the breadth of the genus.

Therefore, claims 111-113 do not meet the written description requirement.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s)

because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 12-13, 21-24, 92-95, 97-103, and 105-120 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 11, 24-30, and 100-134 of copending Application No. 14111331 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because the reference application is directed to the same methodology:

- detection of a protein in blood to determine prognosis
- the same detection limit e.g., claim 109

- using an area under the curve analysis (e.g., claim 105)
- plurality of samples within 96 hours

The difference is in the reference application being drawn to beta-amyloid rather than tau. However, in turning to the specification of the reference application for support of this limitation, the specification clearly indicates tau is an alternate biomarker (p. 12), making such a method an obvious variation of the instant method.

The specification, in support of selecting samples within 96 hours, also discloses those under 12 hours (e.g., specification p.8).

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 11/14/18 have been fully considered but they are not persuasive.

Applicant has not argued the merits of the double patenting rejection and it is maintained for reasons of record.

Regarding the §101 rejection, Applicant argues that using blood represents a non-conventional method and as such the claims should be eligible, noting that there is no evidence that tau could be reliably measured from blood samples (remarks 11/14/18 p. 13). This is not persuasive. The Examiner has set forth multiple documents which constitute prior art that disclose a method for doing so, including at least one document that explicitly teaches measuring tau in blood. Further, selection of the sample (blood) does not need to be routine and/or conventional as this is the judicial exception itself. In other words, as noted, the exception is the relationship between tau levels in blood within 12 hours of a brain injury and the prognosis such levels are indicative of. Thus, that the measurements are made in blood must be set aside when determining "routine and conventional".

Applicant argues the specification characterizes the assay as unconventional (remarks 11/14/18) and thus the Examiner should consider the assay unconventional. Mere statements by Applicant with no corresponding evidence is not persuasive.

Applicant argues that performing mathematical manipulations on data amounts to transformation into a different state or thing and that the "Examiner admits, transformation of gathered data into different state or thing is an important consideration with regard to the patent-eligibility of the claim" (remarks 11/14/18 spanning p. 13-14). It is unclear what statement Applicant is relying on for this admission and the Examiner does not view mathematical manipulation as meeting the transformation test, e.g., it is still the same data useful for the same reasons irrespective of the particular visual representation of that data.

Applicant argues, and the Examiner agrees, that using tau levels in blood within 12 hours of an injury was excluded and deemed non-indicative of future prognosis; such was stated the reasons for withdrawing the §103 rejection. However, Applicant argues that this must also indicate that the method is non-routine and non-conventional. Applicant further argues that the 12 hour limitation is not a description of the natural law. This is not persuasive. Rather, the relationship of tau specifically in this time frame in blood is part of the natural phenomenon being observed over other time frames indicative of prognosis (see previous art rejections). Thus, the judicial exception is informing the artisan that tau levels in blood within 12 hours of the injury is correlated/indicative of prognosis and thus the time frame itself is definitively part of the exception. Moreover, regarding such being excluded or counter-intuitive, this weighs against the obviousness of the claim. However, eligibility is concerned with, once informed of the judicial exception, what would or would not have been routine and conventional. This requirement and level of analysis has been set forth by the Courts. The Court in *Ameritox v Millennium* 88 F.Supp.3d 885 (2015) determined that while the decision in *Mayo* tied the notion of well-understood and conventional steps to "activity already engaged in by the scientific community", the Court when deciding *Myriad v Ambry* couched the question as "techniques that a scientist would have thought" to use. Thus, the relevant question when determining whether or not a technique was routine and conventional is not necessarily that the steps were strictly practiced in the art prior to the invention as in *Mayo*, but whether the techniques are those that would have been thought of by the artisan given the relevant information. This conclusion is supported not only by the *Ameritox* case, but also by the decision in *Ariosa v Sequenom*, where the sample was clearly unconventional (maternal plasma had routinely been disregarded as medical waste) but when provided with information regarding the natural relationship between cfDNA in maternal plasma and a diagnosis, the remaining portion of the claim was drawn to no

more than "known laboratory techniques". This is also supported by the decision in *Myriad v Ambry*, where the probes for *BRCA1* were previously unknown, but represented no more than a standard technique for detection; "any scientist engaged in obtaining the sequence of a gene in a patient sample would rely on these techniques".

In this case, the fact pattern is similar to that in *Ariosa*. The sample itself (maternal plasma; plasma) was previously disregarded as having any important information (disregarded as medical waste; demonstrated that within 12 hours, tau did not inform a prognosis). However, once informed, the claim uses no more than those laboratory techniques known to provide the necessary data, in this case highly sensitive assays routinely used by the art to detect low levels of a protein when the discovered natural phenomenon was that low levels of tau appearing early after injury in blood was indicative of prognosis.

Regarding the method of treatment, Applicant argues the claims are eligible because of the addition of a treatment step; this is not persuasive as appending a treatment step that includes any and all possible treatments is no more than generic instructions to treat/apply it, which does not confer eligibility. However, these claims are eligible for the reasons discussed above, e.g., the combination of the sensitive assay and the data analysis steps.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM M WEIDNER whose telephone number is (571)272-3045. The examiner can normally be reached on M-F 9-16.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Adam Weidner/
Primary Examiner, Art Unit 1649

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 15/269,142		ATTY. DOCKET NO.: Q0052.70018US02	
				FILING DATE: September 19, 2016		CONFIRMATION NO.: 6662	
				FIRST NAMED INVENTOR: David Wilson			
				GROUP ART UNIT: 1649		EXAMINER: A. M. Weidner	
Sheet	1	of	1				

U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
		9,482,622	B2	Sato et al.	11-01-2016
		9,809,838		Walt et al.	11-07-2017
		9,846,155	B2	Rissin et al.	12-19-2017
		9,932,626	B2	Duffy et al.	04-03-2018
		9,952,237	B2	Fournier et al.	04-24-2018
		2003-0096227	A1	Shinitzky et al.	05-22-2003
		2004-0018561	A1	Decrescenzo et al.	01-29-2004
		2005-0053996	A1	Tong	03-10-2005
		2018-0003703	A1	Duffy et al.	01-04-2018
		2018-0017552	A1	Duffy et al.	01-18-2018
		2018-0224451	A1	Rissin et al.	08-09-2018
		2018-0306830	A1	Fournier et al.	10-25-2018

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD- YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			

OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)

[NOTE - No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR § 1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR § 1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR § 1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. § 120.]

EXAMINER: /Adam Weidner/	DATE CONSIDERED: 12/21/2018
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.
6767621.1

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMW/

EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L4	10	L3 and tau.clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2018/12/21 15:24
L3	7678	L1 or L2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2018/12/21 15:24
L2	7645	((wilson near2 david) or (john near2 zetterber) or (kaj near2 blennow) or (jeffrey near2 randall)).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2018/12/21 15:24
L1	43	quanterix.as.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2018/12/21 15:24

EAST Search History (Interference)

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12/ 21/ 2018 3:25:00 PM**C:\Users\aweidner\Documents\EAST\Workspaces\15269142.wsp**

Search Notes 	Application/Control No. 15/269,142	Applicant(s)/Patent Under Reexamination Wilson et al.
	Examiner ADAM M WEIDNER	Art Unit 1649

CPC - Searched*		
Symbol	Date	Examiner

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
inventor/assignee east	3/17/17	amw
text/claims east/internet	3/17/17	amw
inventor/assignee east update	12/11/2017	amw
inventor/assignee east update	12/21/2018	amw

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

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Docket No.: Q0052.70018US02
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: David Wilson
Application No.: 15/269,142
Confirmation No.: 6662
Filed: September 19, 2016
For: METHODS OF DETERMINING A TREATMENT PROTOCOL FOR
AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A
BRAIN INJURY
Examiner: A. M. Weidner
Art Unit: 1649

Certificate of Electronic Filing under 37 C.F.R. § 1.8

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office's electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).

Dated: ____ March 1, 2019 ____

Electronic Signature for Ellen J. Paul: /Ellen J. Paul/

RESPONSE TO NON-FINAL OFFICE ACTION UNDER 37 C.F.R. § 1.111

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

In response to the Office Action dated December 31, 2018, please amend the above-identified U.S. patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 8 of this paper.

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AMENDMENTS TO THE CLAIMS

1-11. (Cancelled)

12. (Previously Presented) A method of determining a prognosis of a patient's recovery from a brain injury comprising:

(a) performing an assay on each of a plurality of blood samples obtained from the patient following the brain injury and/or plasma and/or serum derived from each of the blood samples to determine a measure of the tau protein molecule concentration in each sample,

wherein the plurality of samples are obtained from the patient over a period of time of at least about 48 hours,

wherein at least one of the plurality of samples is obtained within 12 hours of the brain injury,

wherein the assay is characterized by a limit of detection of tau protein molecules that is less than about 0.2 pg/mL; and comprises:

- i. exposing a plurality of capture objects that each include a binding surface having affinity for tau protein molecules to the blood sample;
- ii. immobilizing at least a portion of the tau protein molecules with respect to the plurality of capture objects such that at least some of the capture objects associate with at least one tau protein molecule and a statistically significant fraction of the capture objects do not associate with any tau protein molecules;
- iii. determining a proportion of the plurality of capture objects that associated with a tau protein molecule in step ii; and
- iv. determining a measure of tau protein molecule concentration in the blood sample based at least in part on the proportion determined in step iii;

- (b) determining an area under a curve of a graph of the measure of the tau protein molecule concentration in the plurality of samples versus time, wherein the area is determined for the total period of time and/or a second peak in the tau protein molecule concentration; and
- (c) determining a prognosis of the patient's recovery from the brain injury and/or a method of treatment based on the area under the curve determined in step (b).

13. (Original) The method of claim 12, wherein the brain injury results from a hypoxic event.

14-20. (Cancelled)

21. (Previously presented) The method of claim 12, wherein the brain injury comprises a hypoxic event caused by cardiac arrest.

22. (Previously presented) The method of claim 12, wherein the brain injury comprises a hypoxic event caused by stroke.

23. (Previously presented) The method of claim 12, wherein the brain injury comprises a hypoxic event caused by an ischemic event.

24. (Previously presented) The method of claim 12, wherein the brain injury comprises a hypoxic event caused by a thrombosis.

25- 91. (Cancelled)

92. (Previously Presented) The method of claim 12, further comprising determining a method of treatment based at least in part on the area under the curve determined in step (b).

93. (Previously presented) The method of claim 12, wherein tau protein molecules are spatially segregated into a plurality of locations, wherein a statistically significant fraction of the locations

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contain a single tau protein molecule and a statistically significant fraction of the locations do not contain any tau protein molecules

94. (Previously presented) The method of claim 93, wherein the plurality of locations comprises a plurality of reaction vessels.

95. (Previously presented) The method of claim 93, wherein the plurality of locations comprises plurality of droplets.

96. (Canceled)

97. (Previously presented) The method of claim 12, wherein the plurality of capture objects comprises a plurality of beads.

98. (Previously presented) The method of claim 12, further comprising plotting the measure of the tau protein molecule concentration versus time on a graph to determine the area under the curve.

99. (Previously presented) The method of claim 12, wherein each of the tau protein molecule is selected from the group consisting of tau 23 (352, 0N3R), tau 24 (383, 0N4R), tau 37 (381, 1N3R), tau 34 (412, 1N4R), tau 39 (410, 2N3R), and tau 40 (441, 2N4R).

100. (Previously presented) The method of claim 99, wherein at least a portion of the tau protein molecules are phosphorylated.

101. (Previously presented) The method of claim 12, wherein the patient's prognosis is correlated with a Cerebral Performance Category (CPC) score including classifications of good or poor,

wherein a good CPC score indicates a prognosis of the patient being conscious and alert with normal function or only slight disability or conscious and alert with moderate disability after a selected period of time, and

wherein a poor CPC score indicates a prognosis of the patient being conscious with the patient having a severe disability, being comatose or in a persistent vegetative state, or being brain dead or suffering death from other causes after a selected period of time.

102. (Previously presented) The method of claim 101, wherein the prognosis is good for the recovery from the brain injury if the area under the curve is less than about 800.

103. (Previously presented) The method of claim 101, wherein the prognosis is poor for the recovery from the brain injury if the area under the curve is greater than about 800.

104-113. (Canceled)

114. (Previously Presented) A method for determining a measure of tau protein from a plurality of blood or blood derived samples obtained from a patient following a brain injury, comprising:

(a) performing an assay on each of the plurality of samples obtained from the patient following the brain injury and/or plasma and/or serum derived from each of the samples to determine a measure of the tau protein molecule concentration in each sample,

wherein the plurality of samples are obtained from the patient over a period of time of at least about 48 hours,

wherein at least one of the plurality of samples is obtained within 12 hours of the brain injury,

wherein the assay comprises

- i. detecting tau protein molecules in each sample with single molecule resolution such that the limit of detection of tau protein molecules of the assay is less than about 0.2 pg/mL; and

- ii. determining the measure of tau protein molecule concentration in each blood sample based on the results of the detecting step; and
- (b) determining an area under a curve of a graph of the measure of the tau protein molecule concentration in the plurality of samples versus time, wherein the area is determined for the total period of time and/or a second peak in the tau protein molecule concentration.

115. (Previously Presented) The method of claim 114, wherein the assay further comprises:

- a) exposing a plurality of capture objects that each include a binding surface having affinity for tau protein molecules to the sample;
- b) immobilizing at least a portion of the tau protein molecules with respect to the plurality of capture objects such that at least some of the capture objects associate with at least one tau protein molecule and a statistically significant fraction of the capture objects do not associate with any tau protein molecules;
- c) determining a proportion of the plurality of capture objects that associated with a tau protein molecule in step b; and
- d) determining a measure of tau protein molecule concentration in the blood sample based at least in part on the proportion determined in step c.

116. (Previously Presented) The method of claim 115, wherein the assay comprises, between step b and step c, spatially segregating at least a portion of the capture objects subjected to the immobilizing step into a plurality of locations.

117. (Previously Presented) The method of claim 116, further comprising addressing at least a portion of the plurality of locations subjected to the spatially segregating step and determining the number of said locations containing a tau protein molecule.

118. (Previously Presented) The method of claim 115, wherein the plurality of capture objects comprises a plurality of paramagnetic beads covalently attached to anti-tau antibodies.

119. (Previously Presented) The method of claim 116, wherein the plurality of locations comprises a plurality of reactions vessels.

120. (Currently Amended) The method of claim 119, wherein the average volume of the plurality of reaction vessels is between about 10 attoliters and about 100 picoliters, ~~or between about 1 femtoliter and about 1 picoliter.~~

121. (New) The method of claim 119, wherein the average volume of the plurality of reaction vessels is between about 1 femtoliter and about 1 picoliter.

REMARKS

Claims 12-13, 21-24, 92-95, 97-103 and 105-120 were pending in the application. Claims 105-113 have been cancelled without prejudice or disclaimer. Claim 120 has been amended to remove alternative limitations, which limitations have now been made the subject of new claim 121. No new matter has been added.

Claims 12-13, 21-24, 92-95, 97-103, and 114-121 are now pending in this application with claims 12 and 114 being independent claims.

Notice

In the Office Action, Notice was made by the Patent Office asserting that “[N]owhere in the Remarks filed 11/14/18 does Applicant provide any substantive argument against the double patenting rejection, instead asking that the rejection be deferred until the Application is otherwise allowable,” and stating that resolution of the double patenting rejection is necessary and that future correspondence must provide a complete response to the double patenting rejections.

As described in the Remarks below, Applicant is filing a terminal disclaimer to address the double patenting rejection. Therefore, the double patenting rejection has been resolved and a complete response to the double patenting rejections has been provided.

Claim Rejections-35 USC § 101

Claims 105-110 were rejected under 35 U.S.C. §101 because the claims as a whole are allegedly not directed to patent eligible subject matter. That Patent Office has asserted that, based upon an analysis with respect to the claim as a whole, these claims do not recite something significantly more than a judicial exception.

Without acceding to the merits of the rejections, claims 105-110 have been canceled without prejudice or disclaimer. Therefore, the rejections based on this ground have been rendered moot.

Accordingly, withdrawal of the claim rejection is requested.

Claim Rejections-35 USC § 112

Claims 111-113 were rejected under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-A IA), first paragraph, as allegedly failing to comply with the written description requirement.

Without acceding to the merits of the rejections, claims 111-113 have been canceled without prejudice or disclaimer. Therefore, the rejections based on this ground have been rendered moot.

Accordingly, withdrawal of the claim rejection is requested.

Double Patenting

Claims 12-13, 21-24, 92-95, 97-103, and 105-120 were provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 11, 24-30, and 100-134 of copending Application No. 14111331 (reference application).

Without acceding to the merits of this rejection, Applicant submits a Terminal Disclaimer to overcome this rejection.

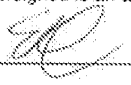
Accordingly, withdrawal of the double patenting rejection is requested.

In view of the foregoing, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this response, the application is not in condition for allowance, the Examiner is requested to call the undersigned at the telephone number indicated below to discuss any outstanding issues.

Dated: March 1, 2019

Respectfully submitted,

Electronic signature: /Michael J. Pomianek/
Michael J. Pomianek
Registration No.: 46,190
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Boston, Massachusetts 02210-2206
617.646.8000

TERMINAL DISCLAIMER TO OBTAIN A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION		Docket Number (Optional) Q0052.70018US02
In re Application of: David Wilson et al.		
Application No.: 15/269,142-Conf. #6662		
Filed: September 19, 2016		
For: METHODS OF DETERMINING A TREATMENT PROTOCOL FOR AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A BRAIN INJURY		
The applicant, <u>Quanterix Corporation</u> , owner of <u>100</u> percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending <u>reference</u> Application Number <u>14/111,331</u> , filed, <u>December 18, 2013</u> , as the term of any patent granted on said <u>reference</u> application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending <u>reference</u> application. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the <u>reference</u> application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.		
In making the above disclaimer, the applicant does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said <u>reference</u> application, "as the term of any patent granted on said <u>reference</u> application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending <u>reference</u> application," in the event that: any such patent granted on the pending <u>reference</u> application expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.		
Check either box 1 or 2 below, if appropriate.		
1. ☒ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.		
I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.		
2. ☐ The undersigned is an attorney or agent of record. Reg. No. _____		
		<u>2/14/19</u>
Signature		Date
E. Kevin Hrusovsky		
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CEO		Telephone Number
Title		
☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included.		
WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.		

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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	15/269,142-Conf. #6662
	Filing Date	September 19, 2016
	First Named Inventor	David Wilson
	Art Unit	1649
	Examiner Name	A. M. Weidner
Total Number of Pages in This Submission	Attorney Docket Number	Q0052.70018US02

ENCLOSURES (Check all that apply)			
☒ Fee Transmittal Form ☐ Fee Attached ☒ Amendment/Reply ☐ After Final ☐ Affidavits/declaration(s) ☐ Extension of Time Request ☐ Express Abandonment Request ☐ Information Disclosure Statement ☐ Certified Copy of Priority Document(s) ☐ Reply to Missing Parts/ Incomplete Application ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53	☐ Drawing(s) ☐ Licensing-related Papers ☐ Petition ☐ Petition to Convert to a Provisional Application ☐ Power of Attorney, Revocation Change of Correspondence Address ☒ Terminal Disclaimer ☐ Request for Refund ☐ CD, Number of CD(s) _____ ☐ Landscape Table on CD	☐ After Allowance Communication to TC ☐ Appeal Communication to Board of Appeals and Interferences ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) ☐ Proprietary Information ☐ Status Letter ☐ Other Enclosure(s) (please Identify below):	Remarks
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	WOLF, GREENFIELD & SACKS, P.C.		
Signature	/Michael J. Pomianek/		
Printed name	Michael J. Pomianek		
Date	March 1, 2019	Reg. No.	46,190

Certificate of Electronic Filing under 37 C.F.R. § 1.8	
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office's electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).	
Dated: March 1, 2019	Electronic Signature for Ellen J. Paul: /Ellen J. Paul/

6986035.1

FEE TRANSMITTAL		Complete if known	
		Application Number	15/269,142-Conf. #6662
		Filing Date	September 19, 2016
☐ Applicant asserts small entity status. See 37 CFR 1.27.		First Named Inventor	David Wilson
☐ Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.		Examiner Name	A. M. Weidner
		Art Unit	1649
TOTAL AMOUNT OF PAYMENT	(\$160.00)	Practitioner Docket No.	Q0052.70018US02

METHOD OF PAYMENT (check all that apply)

☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 23/2825 Deposit Account Name: Wolf, Greenfield & Sacks, P.C.

For the above-identified deposit account, the Director is hereby authorized to (check all that apply):

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☐ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17, **except for any excess claims fees or multiple dependent claim fee** ☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17

☒ Credit any overpayment of fee(s)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES (U = undiscounted fee; S = small entity fee; M = micro entity fee)

	FILING FEES			SEARCH FEES			EXAMINATION FEES			
Application Type	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	Fees Paid (\$)
Utility	300	150*	75	660	330	165	760	380	190	
Design	200	100	50	160	80	40	600	300	150	
Plant	200	100	50	420	210	105	620	310	155	
Reissue	300	150	75	660	330	165	2,200	1,100	550	
Provisional	280	140	70	0	0	0	0	0	0	

* The \$150 small entity status filing fee for a utility application is further reduced to \$75 for a small entity status applicant who files the application via EFS-Web.

2. EXCESS CLAIM FEES

Fee Description	Undiscounted Fee (\$)	Small Entity Fee (\$)	Micro Entity Fee (\$)
Each claim over 20 (including Reissues)	100	50	25
Each independent claim over 3 (including Reissues)	460	230	115
Multiple dependent claims	820	410	205
<u>Total Claims</u> <u>Extra Claims</u> <u>Fee (\$)</u> <u>Fee Paid (\$)</u> <u>Multiple Dependent Claims</u>			
25 - 40 or HP = _____ x _____ = _____			
HP = highest number of total claims paid for, if greater than 20.			
<u>Indep. Claims</u> <u>Extra Claims</u> <u>Fee (\$)</u> <u>Fee Paid (\$)</u>			
2 - 6 or HP = _____ x _____ = _____			
HP = highest number of independent claims paid for, if greater than 3.			

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$400 (\$200 for small entity) (\$100 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
_____	_____	_____	_____	_____

_____ - 100 = _____ / 50 = _____ (round up to a whole number) x _____ = _____

4. OTHER FEE(S)

Non-English specification, \$130 fee (no small or micro entity discount)	
Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, \$400 fee (\$200 small or micro entity)	
Other (e.g., late filing surcharge): 1814 Statutory disclaimer, including terminal ...	160.00
	Fees Paid (\$)

SUBMITTED BY			
Signature	/Michael J. Pomianek/	Registration No. (Attorney/Agent)	46,190
Name (Print/Type)	Michael J. Pomianek	Telephone	617.646.8000
		Date	March 1, 2019

Certificate of Electronic Filing under 37 C.F.R. § 1.8	
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office's electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).	
Dated: March 1, 2019	Electronic Signature for Ellen J. Paul: /Ellen J. Paul/

6986034.1

Electronic Patent Application Fee Transmittal				
Application Number:		15269142		
Filing Date:		19-Sep-2016		
Title of Invention:		METHODS OF DETERMINING A TREATMENT PROTOCOL FOR AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A BRAIN INJURY		
First Named Inventor/Applicant Name:		David Wilson		
Filer:		Michael Pomianek/Ellen Paul		
Attorney Docket Number:		Q0052.70018US02		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
STATUTORY OR TERMINAL DISCLAIMER	1814	1	160	160
Total in USD (\$)				160

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 15/269,142		Filing Date 09/19/2016		☐ To be Mailed		
ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO										
APPLICATION AS FILED - PART I										
		(Column 1)		(Column 2)						
FOR		NUMBER FILED		NUMBER EXTRA		RATE (\$)		FEE (\$)		
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A		N/A		N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))		N/A		N/A		N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A		N/A		N/A				
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 = *				x \$80 =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *				x \$420 =				
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL				
APPLICATION AS AMENDED - PART II										
		(Column 1)		(Column 2)		(Column 3)				
AMENDMENT	03/01/2019		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))		* 25	Minus	** 25	= 0			x \$100 =	0
	Independent (37 CFR 1.16(h))		* 4	Minus	*** 4	= 0			x \$460 =	0
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
								TOTAL ADD'L FEE		0
AMENDMENT			CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))		*	Minus	**	=			x \$0 =	
	Independent (37 CFR 1.16(h))		*	Minus	***	=			x \$0 =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
								TOTAL ADD'L FEE		
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.								SLIE		
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".								/DEIDRE C KING-WOODWARD/		
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".										
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt	
EFS ID:	35303610
Application Number:	15269142
International Application Number:	
Confirmation Number:	6662
Title of Invention:	METHODS OF DETERMINING A TREATMENT PROTOCOL FOR AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A BRAIN INJURY
First Named Inventor/Applicant Name:	David Wilson
Customer Number:	23628
Filer:	Michael Pomianek/Ellen Paul
Filer Authorized By:	Michael Pomianek
Attorney Docket Number:	Q0052.70018US02
Receipt Date:	01-MAR-2019
Filing Date:	19-SEP-2016
Time Stamp:	17:05:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 160
RAM confirmation Number	030419INTEFSW17055000
Deposit Account	232825
Authorized User	Ellen Paul
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.17 (Patent application and reexamination processing fees) 37 CFR 1.21 (Miscellaneous fees and charges)	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Q005270018US02-AMN-MJP.pdf	51928	yes	10
			36f07a55f06627a10ef1f3e4dec0286e95d08f59		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	7	
	Applicant Arguments/Remarks Made in an Amendment		8	10	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	Q005270018US02-FEE-MJP.pdf	32689	no	1
			afb5f4b4b6b82b432bb2235dfda934f8c9148		
Warnings:					
Information:					
3	Terminal Disclaimer Filed	Q005270018US02-TD-MJP.pdf	123332	no	1
			67ce83dc6759d87593d62e85868bb5beeb e5acaf		
Warnings:					
Information:					
4	Miscellaneous Incoming Letter	Q005270018US02-TRN-MJP.pdf	26255	no	1
			3fec339aa5f802a0a48969a4920a6367b3138793		
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	31018	no	2
			8f773fb6e856cdcc0b39fe9c2302752bf6978924		

Warnings:	
Information:	
Total Files Size (in bytes):	265222
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.	

Application Number * 15/269,142 *	Application/Control No. 15/269,142	Applicant(s)/Patent under Reexamination Wilson et al.	
	Examiner WEIDNER, ADAM M	Art Unit 1649	
Document Code - DISQ		Internal Document - DO NOT MAIL	

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed: <u>01 March 2019</u>	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
/JEAN PROCTOR/ Technology Center: OPLC Telephone: (571)272-1040



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

23628 7590 04/25/2019
WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER

WEIDNER, ADAM M

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 04/25/2019

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/269,142	09/19/2016	David Wilson	Q0052.70018US02	6662

TITLE OF INVENTION: METHODS OF DETERMINING A TREATMENT PROTOCOL FOR AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A BRAIN INJURY

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	07/25/2019

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

23628 7590 04/25/2019
WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/269,142	09/19/2016	David Wilson	Q0052.70018US02	6662

TITLE OF INVENTION: METHODS OF DETERMINING A TREATMENT PROTOCOL FOR AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A BRAIN INJURY

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	07/25/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
WEIDNER, ADAM M	1649	435-007900

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

- ☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/269,142	09/19/2016	David Wilson	Q0052.70018US02	6662
23628	7590	04/25/2019	EXAMINER	
WOLF GREENFIELD & SACKS, P.C.			WEIDNER, ADAM M	
600 ATLANTIC AVENUE			ART UNIT	PAPER NUMBER
BOSTON, MA 02210-2206			1649	
DATE MAILED: 04/25/2019				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.** Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b) (2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 15/269,142	Applicant(s) Wilson et al.	
	Examiner ADAM M WEIDNER	Art Unit 1649	AIA (FITF) Status No

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/1/19.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ 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.

3. ☒ The allowed claim(s) is/are See Continuation Sheet. As a result of the allowed claim(s), 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**.

4. ☐ 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)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☐ Examiner's Amendment/Comment
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.	6. ☐ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. ☐ Other _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.	

/Adam Weidner/ Primary Examiner, Art Unit 1649	
---	--

Continuation of 3. The allowed claim(s) is/are: 12-13,21-24,92-95,97-103 and 114-121

EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L4	10	L3 and tau.clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2019/04/18 11:39
L3	7776	L1 or L2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2019/04/18 11:39
L2	7743	((wilson near2 david) or (john near2 zetterber) or (kaj near2 blennow) or (jeffrey near2 randall)).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2019/04/18 11:39
L1	43	quanterix.as.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	ADJ	ON	2019/04/18 11:39

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L6	11	5 and hours.clm. and tau.clm. and blood.clm.	US-PGPUB; USPAT	ADJ	ON	2019/04/18 11:40
L5	13495	(g01n33/6896 or g01n28/47 or g01n2333/47 or g01n2800/52).cpc.	US-PGPUB; USPAT	ADJ	ON	2019/04/18 11:40

4/ 18/ 2019 11:42:00 AM

C:\Users\aweidner\Documents\EAST\Workspaces\15269142.wsp

Search Notes 	Application/Control No. 15/269,142	Applicant(s)/Patent Under Reexamination Wilson et al.
	Examiner ADAM M WEIDNER	Art Unit 1649

CPC - Searched*		
Symbol	Date	Examiner

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
inventor/assignee east	3/17/17	amw
text/claims east/internet	3/17/17	amw
inventor/assignee east update	12/11/2017	amw
inventor/assignee east update	12/21/2018	amw
inventor/assignee east update	04/18/2019	amw

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	see east notes	04/18/2019	amw

--	--

Issue Classification 	Application/Control No. 15/269,142	Applicant(s)/Patent Under Reexamination Wilson et al.
	Examiner ADAM M WEIDNER	Art Unit 1649

CPC						
Symbol					Type	Version
G01N	/	33	/	6896	F	2013-01-01
G01N	/	33	/	54306	I	2013-01-01
G01N	/	2333	/	4709	A	2013-01-01
G01N	/	2800	/	28	A	2013-01-01
G01N	/	2333	/	47	A	2013-01-01
G01N	/	2800	/	52	A	2013-01-01

CPC Combination Sets				
Symbol	Type	Set	Ranking	Version
/				

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	25	
/Adam Weidner/ Primary Examiner, Art Unit 1649	18 April 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

Issue Classification 	Application/Control No. 15/269,142	Applicant(s)/Patent Under Reexamination Wilson et al.
	Examiner ADAM M WEIDNER	Art Unit 1649

INTERNATIONAL CLASSIFICATION			
CLAIMED			
G01N33/68	/	33	/ 68
G01N33/543	/	33	/ 543
NON-CLAIMED			
	/		/

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	25	
/Adam Weidner/ Primary Examiner, Art Unit 1649	18 April 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

Issue Classification 	Application/Control No. 15/269,142	Applicant(s)/Patent Under Reexamination Wilson et al.
	Examiner ADAM M WEIDNER	Art Unit 1649

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 25	
/Adam Weidner/ Primary Examiner, Art Unit 1649 (Primary Examiner) _____ (Date) _____		O.G. Print Claim(s) 1	O.G. Print Figure none

Bibliographic Data

Application No: 15/269,142

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☐ No ☐ Met After Allowance

Verified and Acknowledged:

Examiner's Signature

Initials

Title:

METHODS OF DETERMINING A TREATMENT PROTOCOL FOR
AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A
BRAIN INJURY

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/19/2016	435	1649	Q0052.70018US02
RULE			

APPLICANTS

Quanterix Corporation, Lexington, MA, UNITED STATES

INVENTORS

David Wilson Boxborough, MA, UNITED STATES

John Henrik Zetterberg Molnlycke, SWEDEN

Kaj Blennow Kungsbacka, SWEDEN

Jeffrey D. Randall Canton, MA, UNITED STATES

CONTINUING DATA

This application is a CON of 14111326 06/24/2014ABN

14111326 is a 371 of PCT/US2012/033343 04/12/2012

PCT/US2012/033343 has PRO of 61524693 08/17/2011

PCT/US2012/033343 has PRO of 61474315 04/12/2011

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

09/28/2016

STATE OR COUNTRY

UNITED STATES

ADDRESS

WOLF GREENFIELD & SACKS, P.C.

600 ATLANTIC AVENUE

BOSTON, MA 02210-2206

UNITED STATES

FILING FEE RECEIVED

\$3,140



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/269,142	09/19/2016	David Wilson	Q0052,70018US02	6662
23628 7590 06/03/2019 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER WEIDNER, ADAM M	
			ART UNIT 1649	PAPER NUMBER
			NOTIFICATION DATE 06/03/2019	DELIVERY MODE 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):

Patents_eOfficeAction@WolfGreenfield.com
WGS_eOfficeAction@WolfGreenfield.com



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 15269142
Applicant : Wilson
Filing Date : 09/19/2016
Date Mailed : 06/03/2019

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

*A copy of this notice **MUST** be returned with the reply. Please address response to
"Mail Stop Issue Fee, Commissioner for Patents,
P.O. Box 1450, Alexandria, VA 22313-1450".*

/Nran Hem/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. **15269142**

NON-COMPLIANT ILLUSTRATIONS IN SPECIFICATION OR CLAIMS

☐ The illustration(s) in the location(s) referenced below do not come within the exceptions of 37 CFR 1.58(a). Please delete the illustration(s) from the specification or claims, provided the illustration(s) as part of the formal drawing(s) in accordance with 37 CFR 1.84, and amend the specification to provide a brief description of the drawings in accordance with 37 CFR 1.74. Please see the following item(s):

☐ Specification document coded _____ dated _____, page(s) _____.

☐ Claims document coded _____ dated _____, claim(s) _____.

☐ Amendment document coded _____ dated _____.

☐ Other: _____.

☒ The chemical formula(s), mathematical formula(s), or table(s) in the location(s) referenced below contain shading (color/grayscale) and therefore do not comply with 37 CFR 1.52 and do not come within the exceptions of 37 CFR 1.58(a). Please delete chemical formula(s), mathematical formula(s), or table(s) with shading from the specification or claims, provide them as formal color drawing(s) in accordance with 37 CFR 1.84, including petition, fee, and amendment in accordance with 37 CFR 1.84(a)(2), and amend the specification to provide a brief description of the drawings in accordance with 37 CFR 1.74. Please see the following item(s):

☒ Specification document coded SPEC dated 09/19/2016, page(s) 43.

☐ Claims document coded _____ dated _____, claim(s) _____.

☐ Amendment document coded _____ dated _____.

☐ Other: _____.

Docket No.: Q0052.70018US02
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: David Wilson
Application No.: 15/269,142
Confirmation No.: 6662
Filed: September 19, 2016
For: METHODS OF DETERMINING A TREATMENT PROTOCOL FOR
AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A
BRAIN INJURY
Examiner: A. M. Weidner
Art Unit: 1649

Certificate of Electronic Filing under 37 C.F.R. § 1.8

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office's electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).

Dated: July 25, 2019

Electronic Signature for Ellen J. Paul: /Ellen J. Paul/

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice to File Corrected Application Papers mailed June 3, 2019,
Applicant submits an Amendment After Allowance Under 37 C.F.R. § 1.312.

Applicant believes no fee is due with this Response to Notice to File Corrected Application Papers. However, if a fee is due with this Response, please charge our Deposit Account No. 23/2825, under Docket No. Q0052.70018US02 from which the undersigned is authorized to draw.

7347212.1

Application No.: 15/269,142

2

Docket No.: Q0052.70018US02

Dated: July 25, 2019

Respectfully submitted,

Electronic signature: /Michael J. Pomianek/
Michael J. Pomianek
Registration No.: 46,190
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
617.646.8000

7347212.1

Docket No.: Q0052.70018US02
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: David Wilson
Application No.: 15/269,142
Confirmation No.: 6662
Filed: September 19, 2016
For: METHODS OF DETERMINING A TREATMENT PROTOCOL FOR
AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A
BRAIN INJURY
Examiner: A. M. Weidner
Art Unit: 1649

Certificate of Electronic Filing under 37 C.F.R. § 1.8

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office's electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).

Dated: July 25, 2019

Electronic Signature for Ellen J. Paul: /Ellen J. Paul/

AMENDMENT AFTER ALLOWANCE UNDER 37 C.F.R. § 1.312

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

Prior to issuance of the patent, applicant requests entry of this Amendment under 37 C.F.R. § 1.312.

Amendments to the Specification begin on page 2 of this paper.

Remarks begin on page 3 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please replace Table 2 on page 43 of the specification with the following new Table 2:

Table 2.

Patient	AUC $\leq$ 24 hr		AUC all		AUC 2 nd peak only	
	Good	Poor	Good	Poor	Good	Poor
2		1590		4759		1440
3	708.9		2145		0	
4	748.3		2861		154.2	
5		625.2		3007		1890
6		179.9		1232		897.5
7	4.72		92.86		54.5	
8		11.19		1646		1545
9	59		1141		0	
10		109.7		9336		8206
11	14.63		84.56		0	
12		52.15		848.2		567.8
13	26.01		288.5		215.8	
14	12.93		431.5		393	
15	12.31		184.4		168.2	
17	0.02		30.68		30.9	
18	15.78		46.62		0	
20		334.6		6827		5511
21		580.8		19875		18051
23		1039		26150		23935
24		12.92		72.9		35.94
25		9.37		8987		8842
AVG	160.26	413.17	730.61	7521.83	101.66	6447.39
t-test (p)	0.090609467		0.011726946		0.01197362	

REMARKS

The Specification has been amended to replace Table 2 on page 43 in response to the Notice to File Corrected Application Papers mailed on June 3, 2019. No new matter has been added.

This application is believed to be in condition for allowance. If the Examiner believes, after this amendment, the application is not in condition for allowance, the Examiner is requested to call the undersigned at the telephone number indicated below to discuss any outstanding issues.

Applicant believes no fee is due with this Amendment. However, if a fee is due with this Amendment, please charge our Deposit Account No. 23/2825, under Docket No. Q0052.70018US02 from which the undersigned is authorized to draw.

Dated: July 25, 2019

Respectfully submitted,

Electronic signature: /Michael J. Pomianek/
Michael J. Pomianek
Registration No.: 46,190
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
617.646.8000

PART B-FEE(S) TRANSMITTAL

Complete and send this form, together with the applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By fax, send to: (571) 273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

Ellen J. Paul	(Typed or printed name)
/Ellen J. Paul/	(Signature)
July 25, 2019	(Date)

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
15/269,142	09/19/2016	David Wilson	Q0052.70018US02	6662

TITLE OF INVENTION: METHODS OF DETERMINING A TREATMENT PROTOCOL FOR AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A BRAIN INJURY

APPLN: TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1,000.00			\$1,000.00	07/25/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
A. M. Weidner	1649	

- | | | |
|--|--|--|
| <p>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363)</p> <p>☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p>☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. Use of a Customer Number is required.</p> | <p>2. For printing on the patent front page, list</p> <p>(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,</p> <p>(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.</p> | <p>1. Wolf, Greenfield & Sacks, P.C.</p> <p>2.</p> <p>3.</p> |
|--|--|--|

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE or COUNTRY)

Quanterix Corporation

Lexington, Massachusetts

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. Fees Submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment (Please first reapply any previously paid fee shown above):

☒ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 23/2825

5. Change of Entity Status (from status indicated above)

- | | |
|---|---|
| ☐ Applicant certifying micro entity status. See 37 CFR 1.29. | NOTE: Absent a valid Certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. |
| ☐ Applicant asserting small entity status. See 37 CFR 1.27. | NOTE: If the application was previously under micro entity status, checking this box will be taken as a notification of loss of entitlement to micro entity status. |
| ☐ Applicant changing to regular undiscounted fee status. | NOTE: Checking this box will be taken as a notification of loss of entitlement to small or micro entity status, as applicable. |

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____/Michael J. Pomianek/
Typed or printed name _____Michael J. Pomianek

Date _____July 25, 2019
Registration No. _____46,190

7399091.1

Electronic Patent Application Fee Transmittal				
Application Number:		15269142		
Filing Date:		19-Sep-2016		
Title of Invention:		METHODS OF DETERMINING A TREATMENT PROTOCOL FOR AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A BRAIN INJURY		
First Named Inventor/Applicant Name:		David Wilson		
Filer:		Michael Pomianek/Ellen Paul		
Attorney Docket Number:		Q0052.70018US02		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	1501	1	1000	1000

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1000

TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	15/269,142-Conf. #6662	
	Filing Date	September 19, 2016	
	First Named Inventor	David Wilson	
	Art Unit	1649	
	Examiner Name	A. M. Weidner	
Total Number of Pages in This Submission		Attorney Docket Number	Q0052.70018US02

ENCLOSURES (Check all that apply)			
☐ Fee Transmittal Form ☐ Fee Attached ☒ Amendment/Reply ☐ After Final ☐ Affidavits/declaration(s) ☐ Extension of Time Request ☐ Express Abandonment Request ☐ Information Disclosure Statement ☐ Certified Copy of Priority Document(s) ☐ Reply to Missing Parts/ Incomplete Application ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53	☐ Drawing(s) ☐ Licensing-related Papers ☐ Petition ☐ Petition to Convert to a Provisional Application ☐ Power of Attorney, Revocation Change of Correspondence Address ☐ Terminal Disclaimer ☐ Request for Refund ☐ CD, Number of CD(s) _____ ☐ Landscape Table on CD	☐ After Allowance Communication to TC ☐ Appeal Communication to Board of Appeals and Interferences ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) ☐ Proprietary Information ☐ Status Letter ☒ Other Enclosure(s) (please Identify below): -PTOL-85 Part B Issue Fee Transmittal -Response to Notice to File Corrected Application Papers	
<table border="1"><tr><td>Remarks</td></tr></table>			Remarks
Remarks			

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	WOLF, GREENFIELD & SACKS, P.C.		
Signature	/Michael J. Pomianek/		
Printed name	Michael J. Pomianek		
Date	July 25, 2019	Reg. No.	46,190

Certificate of Electronic Filing under 37 C.F.R. § 1.8	
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office's electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).	
Dated: July 25, 2019	Electronic Signature for Ellen J. Paul: /Ellen J. Paul/

7347162.1

Electronic Acknowledgement Receipt	
EFS ID:	36687448
Application Number:	15269142
International Application Number:	
Confirmation Number:	6662
Title of Invention:	METHODS OF DETERMINING A TREATMENT PROTOCOL FOR AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A BRAIN INJURY
First Named Inventor/Applicant Name:	David Wilson
Customer Number:	23628
Filer:	Michael Pomianek/Ellen Paul
Filer Authorized By:	Michael Pomianek
Attorney Docket Number:	Q0052.70018US02
Receipt Date:	25-JUL-2019
Filing Date:	19-SEP-2016
Time Stamp:	14:22:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 1000
RAM confirmation Number	072619INTEFSW14231801
Deposit Account	232825
Authorized User	Ellen Paul
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.17 (Patent application and reexamination processing fees) 37 CFR 1.21 (Miscellaneous fees and charges)	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	Q005270018US02-TRN-MJP.pdf	26352	no	1
			31bf6351621e7f45e92f5181828e9e9ad57c cbe1		
Warnings:					
Information:					
2	Applicant Response to Pre-Exam Formalities Notice	Q005270018US02-RCAP-MJP. pdf	25124	no	2
			8f233122d5e7c9b15ee00fb378b1c894066 ef2b7		
Warnings:					
Information:					
3		Q005270018US02-312AMN- MJP.pdf	64363	yes	3
			5b3639c42036830b9e7a7591a2741cd2452 808f9		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment after Notice of Allowance (Rule 312)		1	1	
	Specification		2	2	
	Applicant Arguments/Remarks Made in an Amendment		3	3	
Warnings:					
Information:					
4	Issue Fee Payment (PTO-85B)	Q005270018US02-ISSFEE-MJP. pdf	37047	no	1
			5f6c29573635a92fb7b7c0565cc82c0fa3ff8 5f7		
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30901	no	2
			d1b023575e226785666d3e5570ca4c5e762 7359a		

Warnings:	
Information:	
Total Files Size (in bytes):	183787
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.	



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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/269,142	09/19/2016	David Wilson	Q0052.70018US02	6662
23628 7590 07/30/2019 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER WEIDNER, ADAM M	
			ART UNIT 1649	PAPER NUMBER
			NOTIFICATION DATE 07/30/2019	DELIVERY MODE 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):

Patents_eOfficeAction@WolfGreenfield.com
WGS_eOfficeAction@WolfGreenfield.com

Response to Rule 312 Communication	Application No. 15/269142	Applicant(s)
	Examiner	Art Unit
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -- 1. ☒ The amendment filed on <u>25 July 2019</u> under 37 CFR 1.312 has been considered, and has been: a) ☒ entered. b) ☐ entered as directed to matters of form not affecting the scope of the invention. c) ☐ disapproved because the amendment was filed after the payment of the issue fee. Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue. d) ☐ disapproved. See explanation below. e) ☐ entered in part. See explanation below. D. Fisher Publishing Division		



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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/269,142	08/27/2019	10393759	Q0052.70018US02	6662

23628 7590 08/07/2019
WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

David Wilson, Boxborough, MA;
Quanterix Corporation, Lexington, MA;
John Henrik Zetterberg, Molnlycke, SWEDEN;
Kaj Blennow, Kungsbacka, SWEDEN;
Jeffrey D. Randall, Canton, MA;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

IR103 (Rev. 10/09)

Docket No.: Q0052.70018US02
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: David Wilson
Application No.: 15/269,142
Confirmation No.: 6662
Filed: September 19, 2016
Patent No.: 10,393,759
Issued: August 27, 2019
For: METHODS OF DETERMINING A TREATMENT PROTOCOL FOR
AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A
BRAIN INJURY
Examiner: A. M. Weidner
Art Unit: 1649

Certificate of Electronic Filing under 37 C.F.R. § 1.8

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office's electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).

Dated: September 4, 2019

Electronic Signature for Ellen J. Paul: /Ellen J. Paul/

REQUEST FOR CERTIFICATE OF CORRECTION PURSUANT TO 37 CFR 1.322

Attention: Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Upon reviewing the above-identified patent, Patentee noted typographical errors which should be corrected.

In the Specification:

At column 32, line 19, the word "head-based" should read --bead-based--

At column 33, line 35, the words "g/ml for assay" should read --µg/ml for assay--

7533892.1

This request does not involve correction of Applicant errors. Accordingly, no fee is required.

Transmitted herewith is a proposed Certificate of Correction effecting such amendment. Patentee respectfully solicits the granting of the requested Certificate of Correction.

Applicant believes no fee is due with this Request for Certificate of Correction -- PTO Error -- no fee required (37 CFR 1.322). However, if a fee is due with this Request for Certificate of Correction -- PTO Error -- no fee required (37 CFR 1.322), please charge our Deposit Account No. 23/2825, under Docket No. Q0052.70018US02 from which the undersigned is authorized to draw.

Dated: September 4, 2019

Respectfully submitted,

Electronic signature: /Michael J. Pomianek/
Michael J. Pomianek
Registration No.: 46,190
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
617.646.8000

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

Page 1 of 1

PATENT NO. : 10,393,759
APPLICATION NO. : 15/269,142
ISSUE DATE : August 27, 2019
INVENTOR(S) : David Wilson et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification:

At column 32, line 19, the word "head-based" should read --bead-based--

At column 33, line 35, the words "g/ml for assay" should read --µg/ml for assay--

MAILING ADDRESS OF SENDER (Please do not use Customer Number below):

Michael J. Pomianek
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206

1

7533889.1

TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	Patent#: 10,393,759	
	Filing Date	Issued: August 27, 2019	
	First Named Inventor	David Wilson	
	Art Unit	1649	
	Examiner Name	A. M. Weidner	
Total Number of Pages in This Submission		Attorney Docket Number	Q0052.70018US02

ENCLOSURES (Check all that apply)			
☐ Fee Transmittal Form ☐ Fee Attached ☐ Amendment/Reply ☐ After Final ☐ Affidavits/declaration(s) ☐ Extension of Time Request ☐ Express Abandonment Request ☐ Information Disclosure Statement ☐ Certified Copy of Priority Document(s) ☐ Reply to Missing Parts/ Incomplete Application ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53	☐ Drawing(s) ☐ Licensing-related Papers ☐ Petition ☐ Petition to Convert to a Provisional Application ☐ Power of Attorney, Revocation Change of Correspondence Address ☐ Terminal Disclaimer ☐ Request for Refund ☐ CD, Number of CD(s) _____ ☐ Landscape Table on CD	☐ After Allowance Communication to TC ☐ Appeal Communication to Board of Appeals and Interferences ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) ☐ Proprietary Information ☐ Status Letter ☒ Other Enclosure(s) (please Identify below): -Request for Certificate of Correction -Certificate of Correction	
<table border="1"><tr><td>Remarks</td></tr></table>			Remarks
Remarks			

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	WOLF, GREENFIELD & SACKS, P.C.		
Signature	/Michael J. Pomianek/		
Printed name	Michael J. Pomianek		
Date	September 4, 2019	Reg. No.	46,190

Certificate of Electronic Filing under 37 C.F.R. § 1.8	
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office's electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).	
Dated: September 4, 2019	Electronic Signature for Ellen J. Paul: /Ellen J. Paul/

Electronic Acknowledgement Receipt	
EFS ID:	37057676
Application Number:	15269142
International Application Number:	
Confirmation Number:	6662
Title of Invention:	METHODS OF DETERMINING A TREATMENT PROTOCOL FOR AND/OR A PROGNOSIS OF A PATIENT'S RECOVERY FROM A BRAIN INJURY
First Named Inventor/Applicant Name:	David Wilson
Customer Number:	23628
Filer:	Michael Pomianek/Ellen Paul
Filer Authorized By:	Michael Pomianek
Attorney Docket Number:	Q0052.70018US02
Receipt Date:	04-SEP-2019
Filing Date:	19-SEP-2016
Time Stamp:	10:01:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment		no			
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	Q005270018US02-TRN-MJP.pdf	25905	no	1
			3958766049e45a7454300ff400525c9b48b671c5		
Warnings:					

Information:					
2	Request for Certificate of Correction	Q005270018US02-RCOC-MJP. pdf	26319 a484a0ca539fc201071898c483cb2244f05fa494	no	2
Warnings:					
Information:					
3	Request for Certificate of Correction	Q005270018US02-COC-MJP. pdf	18754 91d60e98b282288c6c965dc2d4c09426daae5678	no	1
Warnings:					
Information:					
Total Files Size (in bytes):			70978		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 10,393,759 B2
APPLICATION NO. : 15/269142
DATED : August 27, 2019
INVENTOR(S) : David Wilson et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification

At Column 32, Line 19, the word "head-based" should read --bead-based--

At Column 33, Line 35, the words "g/ml for assay" should read --μg/ml for assay--

Signed and Sealed this
First Day of October, 2019



Andrei Iancu
Director of the United States Patent and Trademark Office