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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/322,585	12/28/2016	Krista Toler	5394.A88US1	8947

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EXAMINER
DEJONG, ERIC S

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
10/03/2019	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):

SLW@blackhillsip.com
USPTO@slwip.com

Office Action Summary	Application No. 15/322,585	Applicant(s) Toler et al.	
	Examiner ERIC S DEJONG	Art Unit 1631	AIA (FITF) Status Yes

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

Period for Reply

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

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

Status

1)☑ Responsive to communication(s) filed on 0614/2019.

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

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

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

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

Disposition of Claims*

5) ☑ Claim(s) 1-3,6-9,11-12,14,17 and 48-56 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-3,6-9,11-12,14,17 and 48-56 is/are rejected.

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

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant response filed 06/14/2019 is acknowledged.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-3, 6-9, 11, 12, 14, and 17) in the reply filed on 03/04/2019 is acknowledged.

Claims 22, and 41-43, and 45-47 (now cancelled) were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group of invention, there being no allowable generic or linking claim

Claims 4, 5, 10, 13, 15, 16, 18-47 have been cancelled by applicant.

Claims 48-56 are newly presented.

Claims 1-3, 6-9, 11, 12, 14, 17 and 48-56 are currently under examination.

Claim Rejections - 35 USC § 101

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

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

Claims 1-3, 6-9, 11, 12, 14, 17 and 48-56 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without including additional elements that are sufficient to amount to significantly more than the judicial exception itself. This rejection is further necessitated by applicant amendment to the instant claims.

The instant claims are directed to a method and related device for determining an efficacy ratio associated with an input and output ratio of an anti-inflammatory cytokine. The recited process carried out by the claimed invention comprises obtaining concentrations of inflammatory cytokines and anti-inflammatory cytokines by processing a donor sample, and calculating a first efficacy ratio.

The courts have clearly established that a method directed essentially to a series of algorithmic/mathematical procedures is not a statutory process:

"Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible. "If a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory." *Parker v. Flook*, 437 U.S. 584, 595 (1978) (internal quotations omitted)." (Precedential CAFC decision: Digitech Image Technologies, LLC. v. Electronics for Imaging, Inc., decided July 11, 2014).

"A claim that directly reads on matter in the three identified categories is outside section 101. *Mayo*, 132 S. Ct. at 1293. But the provision also excludes the subject matter of certain claims that by their terms read on a human-made physical thing ("machine, manufacture, or composition of matter") or a human-controlled series of physical acts ("process") rather than laws of nature, natural phenomena, and abstract ideas. Such a claim falls outside section 101 if (a) it is "directed to" matter in one of the three excluded

categories and (b) "the additional elements" do not supply an "inventive concept" in the physical realm of things and acts—a "new and useful application" of the ineligible matter in the physical realm—that ensures that the patent is on something "significantly more than" the ineligible matter itself. *Alice*, 134 S. Ct. at 2355, 2357 (internal quotation marks omitted); *see Mayo*, 132 S. Ct. at 1294, 1299, 1300. This two-stage inquiry requires examination of claim elements "both individually and 'as an ordered combination.'" *Alice*, 134 S. Ct. at 2355." (Precedential CAFC decision: Buysafe Inc. v. Google Inc., decided September 3, 2014).

The instant claims do recite additional elements beyond the judicial exception set forth above. The claims recite the generic steps of processing a donor sample in order to obtain the necessary input data in order to perform the calculations set forth in the claims. The claims, however, do not recite anything special regarding the manner in which data is collected such that the scope of said claims would exclude routine and conventional biological experiments known to produce data required by the instant analysis. As such, this element of the claims only adds a conventional data collection methods as the source of the data to be analyzed. As such, this cannot amount to something beyond the recitation of routine and conventional data gathering activities.

Independent claim 1 has been amended to recite reprocessing an anti-inflammatory composition or repeating steps (a) to (e) if the calculated efficacy ratio is greater than one. The amendment amounts to nothing more than insignificant post solution activity involving additional analysis. Such additional analysis following the determination of a first efficacy ration fails to provide for a practical application of the judicial exception embraced by the instant claims.

Newly presented claims 48-56 introduce an additional final limitation of administering the anti-inflammatory composition to a subject or storing said composition IF the efficacy ration is greater or equal to one or IF the reprocessing of the anti-inflammatory composition if the efficacy ratio is less than one. Again, the newly

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