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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/512,361	10/10/2014	Aris FLORATOS	2003144.00137US2	8776
23483	7590	02/17/2017	EXAMINER	
WILMERHALE/BOSTON 60 STATE STREET BOSTON, MA 02109			SWITZER, JULIET CAROLINE	
			ART UNIT	PAPER NUMBER
			1634	
			NOTIFICATION DATE	DELIVERY MODE
			02/17/2017	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):

whipusptopairs@wilmerhale.com  
teresa.maia@wilmerhale.com

<b>Office Action Summary</b>	<b>Application No.</b> 14/512,361	<b>Applicant(s)</b> FLORATOS, ARIS	
	<b>Examiner</b> JULIET SWITZER	<b>Art Unit</b> 1634	<b>AIA (First Inventor to File) Status</b> 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 2 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 \_\_\_\_\_.  
 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) 1-16 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) 1-16 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](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto: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: \_\_\_\_\_

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

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a method of identifying a subject afflicted with or at risk of developing Drug-Induced Liver Injury, classified in C12Q 1/6883.

II. Claim 16, drawn to a method of identifying a drug agent for the treatment of DILI, classified in G01N 33/48.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are directed to related methods. The related inventions are distinct if:

(1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants.

See MPEP § 806.05(j). In the instant case, the inventions as claimed have different modes of operation, functions and effects, as is evident by the preambles which state the purpose of the methods, and the process steps which share no common process features. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

4. Restriction for examination purposes as indicated is proper because all the inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

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The methods are not commonly classified and do not share common steps. The methods have recognized divergent subject matter and search and examination would not be coextensive.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other invention.

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This application contains claims directed to the following patentably distinct species any combination of "at least one" genetic marker, where there are hundreds of potential combinations of "at least one" genetic marker from those listed in the tables.

Applicant should select a single combination of "at least one" marker from the tables. The combination may be only one marker or any combination of markers supported by the specification.

Upon selecting a species, please identify for each member of the group of "at least one" which table or tables each individual marker in the group is disclosed in.

5. The species are independent or distinct because the different species have mutually exclusive characteristics (based upon their sequences and the phenotypes they are related to) for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims recite species in the alternative.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: Each method which detects or considers each marker or combinations of markers requires a unique search based upon that marker or combination of markers for examination. The search would have to consider the sequence of the marker itself as well as searching the prior art for disclosures related to DILI and the particular different drugs that the markers are disclosed as being indicative of DILI for that

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drug. The search is unique for each marker, and examining each one alone, let alone any possible combination would be an enormous burden on the examiner.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

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6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

A telephone call was made to Colleen Superko on 8/19/15 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Thursday from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached by calling (571) 272-0731.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is **(571)272-0507**.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Juliet C. Switzer/  
Primary Examiner  
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February 14, 2017