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(54) Title: METHODS FOR DIAGNOSING MYOCARDIAL INFARCTION

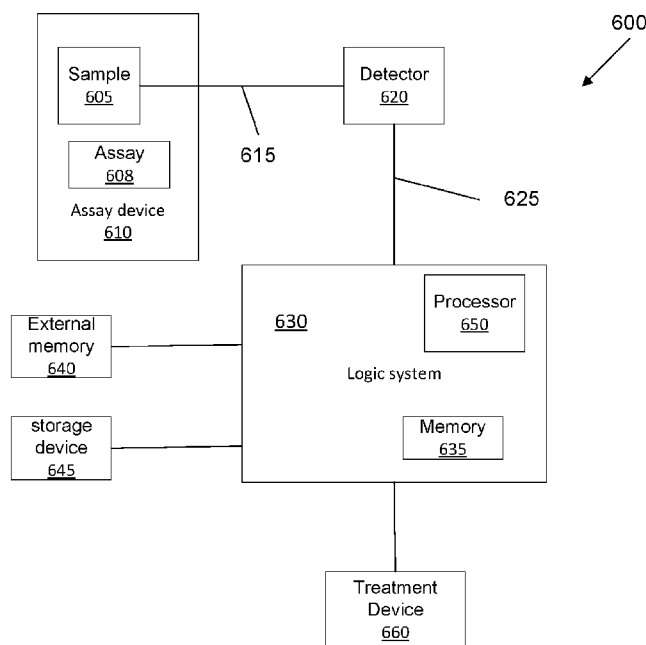


FIG. 6

(57) Abstract: Systems, methods, compositions, apparatuses, and kits for determining whether a subject is undergoing myocardial infarction (MI) using biological samples obtained from the subject, are provided herein. The disclosed methods and compositions involve biomarkers identified from the transcriptomic data of biological samples from subjects with MI. The biomarkers allow the calculation of a composite biomarker value that can be used to determine whether the subject is undergoing MI.

RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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11 January 2024 (11.01.2024)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US23/14600

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. G16H 50/20; A61B 5/00; A61B 5/145; C12Q 1/68 (2023.01)

ADD.

CPC - INV. G16H 50/20; A61B 5/00; A61B 5/145; C12Q 1/68

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic database consulted during the international search (name of database and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2021/0072260 A1 (PREVENCIO INC.) 11 March 2021; [0007], [0008], [0012], [0172], [0255], [0265], [0266], [0271]	1, 3-4, 6-8, 33-35, and 44-47
Y	CN 109735616 A (JILIN UNIV) 10 May 2019; Claim 3	1, 3-4, 6-8, 33-35, and 44-47
Y	US 9,540,684 B2 (MINDERA CORPORATION) 10 January 2017; [0069]; Claim 8	34 and 35/34
E,X	WO 2023/192004 A2 (INFLAMMATIX INC.) 05 October 2023; entire document	1, 3-4, 6-8, 33-35, and 44-47



Further documents are listed in the continuation of Box C.



See patent family annex.

*

Special categories of cited documents:

"A"

document defining the general state of the art which is not considered to be of particular relevance

"D"

document cited by the applicant in the international application

"E"

earlier application or patent but published on or after the international filing date

"L"

document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O"

document referring to an oral disclosure, use, exhibition or other means

"P"

document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

18 October 2023 (18.10.2023)

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US23/14600

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 9-10, 14-32, 36-43
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
-***-Please See Supplemental Page-***-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Group I+, Claims 1-8, 11-13, 33-35, 44-47; SOCS3 (biomarker)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US23/14600

-Continued From Box No. III: Observations where unity of invention is lacking-

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I+, Claims 1-8, 11-13, 33-35, 44-47 and SOCS3 (biomarker) are directed towards methods and kits for determining whether a subject is undergoing myocardial infarction (MI) using biological samples obtained from the subject.

The methods and kits of Claims 1 (in-part), 3-4 (each in-part), 6-8 (each in-part), 33-35 (each in-part), and 44-47 (each in-part) are believed to encompass the first named invention of Group I+ and are the claims that will be searched without fee to the extent that they encompass SOCS3 (first exemplary biomarker). This first named invention of Group I+ has been selected to encompass the first species of each of the genera found in claims 1, 3-4, 33, 35, 44 and 45 based on the guidance set forth in section 10.54 of the PCT International Search and Preliminary Examination Guidelines.

Applicant is invited to elect additional biomarker(s), and where available as an option within at least one searchable claim, to be searched. Additional biomarker(s) will be searched upon the payment of additional fees. Applicants must specify the searchable claims that encompass any additionally elected biomarker(s). Applicants must further indicate, if applicable, the claims which encompass the first named invention, if different than what was indicated above for this group. Failure to clearly identify how any paid additional invention fees are to be applied to the "+" group(s) will result in only the first claimed invention to be searched/examined. An exemplary election would be MACROH2A1 (biomarker).

No technical features are shared between the biomarkers of Groups I+ and, accordingly, these groups lack unity a priori.

Additionally, even if Groups I+ were considered to share the technical features including: a method for a patient suspected of undergoing a myocardial infarction (MI), the method comprising: a) receiving a biological sample obtained from the patient suspected of undergoing the MI; b) measuring one or more expression levels of at least one biomarker; c) determining whether the patient is undergoing the MI based on the one or more expression levels of the at least one biomarker in the biological sample; a test kit for detecting expression levels of one or more biomarkers in a biological sample of a patient suspected of undergoing a myocardial infarction (MI), wherein the one or more biomarkers comprise at least one biomarker; a method for providing an indication for a myocardial infarction (MI) in a subject, the method comprising: (a) measuring expression levels of one or more biomarkers in a biological sample obtained from the subject; (b) evaluating the expression levels of the one or more biomarkers to yield a composite biomarker value, wherein the composite biomarker value exceeding a threshold value indicates that the subject is undergoing the MI; and (c) administering medical care to the subject; these shared technical features are previously disclosed by US 2021/0072260 A1 (PREVENCIO, INC.) (hereinafter 'Prevencio').

Prevencio discloses a method for a patient suspected of undergoing a myocardial infarction (MI) (a method for a patient suspected of undergoing a myocardial infarction; paragraphs [0008], [0012]), the method comprising: a) receiving a biological sample obtained from the patient suspected of undergoing the MI; b) measuring one or more expression levels of at least one biomarker (the method comprising: a) receiving a biological sample obtained from the patient suspected of undergoing the MI; b) measuring one or more expression levels of at least one biomarker; paragraphs [0007], [0008], [0012]); c) determining whether the patient is undergoing the MI based on the one or more expression levels of the at least one biomarker in the biological sample (determining a diagnostic score for the subject based on the level of at least one biomarker (determining whether the patient is undergoing the MI based on the one or more expression levels of the at least one biomarker in the biological sample); paragraphs [0007], [0008], [0012]); a test kit for detecting expression levels of one or more biomarkers in a biological sample of a patient suspected of undergoing a myocardial infarction (MI) (kit comprising a panel of biomarkers for detecting expression levels of one or more biomarkers in a biological sample of a patient suspected of undergoing a myocardial infarction; paragraphs [0008], [0012]), wherein the one or more biomarkers comprise at least one biomarker (paragraph [0032]); a method for providing an indication for a myocardial infarction (MI) in a subject (a method for diagnosing (providing an indication for) a myocardial infarction (MI) in a subject); paragraphs [0007], [0008], [0012]) the method comprising: (a) measuring expression levels of one or more biomarkers in a biological sample obtained from the subject (measuring expression levels of one or more biomarkers in a biological sample obtained from the subject); paragraph [0007]); (b) evaluating the expression levels of the one or more biomarkers to yield a composite biomarker value (calculating a prognostic score (evaluating the expression levels of the one or more biomarkers to yield a composite biomarker value); paragraph [0007], wherein the composite biomarker value exceeding a threshold value indicates that the subject is undergoing the MI (determining a therapeutic or diagnostic intervention regimen based on the positive or negative result (wherein the composite biomarker value exceeding a threshold value indicates that the subject is undergoing the MI); paragraph [0007], [0008], [0012]); and (c) administering medical care to the subject (paragraph [0023]).

Since none of the special technical features of the Groups I+ inventions is found in more than one of the inventions, and since all of the shared technical features are previously disclosed by the Prevencio reference, unity of invention is lacking.