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(54) Title: METHODS AND COMPOSITIONS FOR DIAGNOSIS AND/OR PROGNOSIS IN SYSTEMIC INFLAMMATORY RESPONSE SYNDROMES

(57) Abstract: The present invention relates to methods and compositions for diagnosing SIRS, sepsis, severe sepsis, septic shock, or MODS in a subject, or assigning a prognostic risk for one or more clinical outcomes for a subject suffering from SIRS, sepsis, severe sepsis, septic shock, or MODS, the method comprising performing an immunoassay for CCL23 splice variant.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/68667

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - G01N 33/53 (2009.01)
USPC - 436/501; 435/7.1
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)
IPC(8) - G01N 33/53 (2009.01)
USPC - 436/501; 435/7.1

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (USPT, PGPB, EPAB, JPAB), Google Patent/Scholar. Search terms - sepsis, septic shock, systemic inflammatory shock syndrome (SIRS), multiple organ dysfunction syndrome (MODS), diagnosis, detection, prognosis, indicators, markers, splice variant, immunoassay, CCL23, sensitive or insensitive assay, pharmaceutical.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	2007/0092911 A1 (BUECHLER et al.) 26 April 2007 (26.04.2007) - see Table 2; para [0022]; para [0028]- [0030]; para [0036] - para [0040]; para [0054]; para [0069]; para [0071]; para [0112]; para [0224].	1-2, 9(4), 12-19, 26, 27(4) 28-30
Y	US 2006/0063223 A1 (BERAHOVICH et al.) 23 March 2006 (23.03.2006) - see para [0168].	1-2, 9(4), 12-19, 26, 27(4) 28-30
Y	US 2004/0106142 A1 (IVEY et al.) 03 June 2004 (03.06.2004) - see para [0042]; para [0045] - para [0047].	26, 27(4), 28-30

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"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	Date of mailing of the international search report
13 January 2008 (13.01.2008)	29 JAN 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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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.:
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:

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, 2, 9 (restricted to option(4)), 12-19, 26, 27 (restricted to option (4)), and 28-30, directed to a method of diagnosing or assigning a prognostic risk to a subject suffering from SIRS, sepsis, septic shock or MODS, comprising performing an immunoassay that detects CCL23 splice variant (SEQ ID NO: 1), but not wild type CCL23.

- Please see extra sheet for continuation -

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.:
1, 2, 9 (restricted to option(4)), 12-19, 26, 27 (restricted to option (4)), and 28-30

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

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Continuation of Box III:

Group II: claims 1, 3-11, and 20-27, directed to a method of diagnosing or assigning a prognostic risk to a subject suffering from SIRS, sepsis, septic shock or MODS, comprising performing an immunoassay that detects CCL23 splice variant as well as CCL23 wild type (SEQ. ID NO: 2).

The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the Group I claims is providing a method of diagnosing or assigning a prognostic risk to a subject suffering from SIRS, sepsis, septic shock or MODS, comprising performing an immunoassay that detects CCL23 splice variant (SEQ ID NO: 1), but not wild type CCL23 - not required by the claims of Group II. The special technical feature of the Group II claims is a method of diagnosing or assigning a prognostic risk to a subject suffering from SIRS, sepsis, septic shock or MODS, comprising performing an immunoassay that detects CCL23 splice variant as well as CCL23 wild type (SEQ. ID NO: 2) - not required by the claims of Group I.

The common technical element shared by the above groups is that they are related to diagnosing or assigning a prognostic risk to a subject suffering from SIRS, sepsis, septic shock or MODS by performing an immunoassay. However, this common technical element does not represent an improvement over the prior art of US 2007/0092911 A1 to Buechler et al. (see abstract, para [0016], [0069]). Therefore, the inventions of Group I and Group II lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.