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Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(88) Date of publication of the international search report:

24 September 2009

(54) Title: COMPOSITIONS AND METHODS FOR ASSESSING DISORDERS

(57) Abstract: The present invention relates to compositions and methods for disorder (e.g., hyperproliferative disorders, inflammatory disorders) research, diagnosis, and treatment, including but not limited to, bio-markers specific for a particular disorder (e.g., cancer, systemic lupus erythematosus). In particular, the present invention relates to peripheral blood mononuclear cells (PBMCs) as bio-markers specific for particular disorders.



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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/079609**A. CLASSIFICATION OF SUBJECT MATTER***C12Q 1/68(2006.01)i, G01N 33/577(2006.01)i, A61K 39/395(2006.01)i*

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 C12Q 1/68

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)

NCBI PubMed, eKOMPASS (KIPO internal), "CD11b+, peripheral, blood, mononuclear, PBMC, gene, expression, etc."

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/0209316 A1 (Ritchlin TR et al., US) 21 Oct 2004 - see the whole document, especially Claims 1-4, 13, 18, 22-30; Figures 27-30; Abstract.	1, 2, 13, 14, 16-19
X	US 5426028 A (Levy JA et al., US) 20 Jun 1995 - see the whole document, especially Claims 1-5; Figure 1; Tables 2, 4, 5; Abstract.	1, 2, 13, 14, 16-19
X	Brunialti MK et al., "TLR2, TLR4, CD14, CD11B, and CD11C expressions on monocytes surface and cytokine production in patients with sepsis, severe sepsis, and septic shock" Shock Vol. 25, No. 4, pp351-357, Apr 2006.	1, 2, 13, 14, 16-19
X	US 5567443 A (Kashiwagi N et al., JP) 22 Oct 1996. - see the whole document, especially Claims 1-6; Table 1; Abstract.	1, 2, 13, 14, 16-19
X	Kirveskari J et al., "Modulation of peripheral blood mononuclear cell activation status during Salmonella-triggered reactive arthritis" Arthritis Rheum Vol. 42, No. 10, pp2045-2054, Oct 1999. - see the whole document, especially Abstract; Figure 4; p2049.	1, 2, 13, 14, 16-19
A	US 6423505 B1 (Davis KA, US) 23 Jul 2002. - see the whole document.	1, 2, 13, 14, 16-19

 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

"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 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

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Name and mailing address of the ISA/KR

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2008/079609**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:

See Extra Sheet.

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 an additional fee, this Authority did not invite payment of any additional fee.
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, 13, 14 and 16-19

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

Information on patent family members

International application No.

PCT/US2008/079609

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004-0209316 A1	21. 10. 2004	AU 2004-222231 A1	15. 03. 2004
		AU 2004-222231 A1	30. 09. 2004
		CA 2519182 A1	30. 09. 2004
		EP 1604205 A4	09. 01. 2008
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		WO 2004-082635 A2	30. 09. 2004
		WO 2004-082635 A3	30. 09. 2004
US 05426028 A	20. 06. 1995	US 05426028 A	20. 06. 1995
		US 05538856 A	23. 07. 1996
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		WO 1993-001273 A1	21. 01. 1993
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		EP 1605263 A2	14. 12. 2005
		EP 1605263 A3	06. 12. 2006
		JP 2002-531832 A	24. 09. 2002
		US 2002-0076734 A1	20. 06. 2002
		US 06200766 B1	13. 03. 2001
		US 06376202 B1	23. 04. 2002
		US 06951727 B2	04. 10. 2005
		WO 2000-033082 A2	08. 06. 2000
WO 2000-033082 A3	08. 06. 2000		

Continuation of Box No. III.

Lack of Unity of Invention

This ISA found multiple inventions in this application as follows:

-Group 1: Claims 1, 2, 13, 14 and 16-19 are drawn to an invention featuring a method for assessing a disorder comprising identifying a characteristic associated with CD11b+ peripheral blood mononuclear cells obtained from a patient sample.

-Groups 2-11: Claims 1-4 and 12 (all partial) are drawn to 10 inventions featuring a method for assessing systemic lupus erythematosus comprising comparing an expression of a gene selected from the group consisting of 10 genes (TOP2A, ..., TET2) to a control.

-Groups 12-21: Claims 1-3, 5-7 and 15 (all partial) are drawn to 10 inventions featuring a method for assessing prostate cancer comprising comparing an expression of a gene selected from the group consisting of 10 genes (MRSA, ..., VTIIA) to a control.

-Groups 22-31: Claims 1-3, 5, 6, 8 and 15 (all partial) are drawn to 10 inventions featuring a method for assessing lung cancer comprising comparing an expression of a gene selected from the group consisting of 10 genes (METTL7B, ..., FAM84B) to a control.

-Groups 32-41: Claims 1-3, 5, 6, 9 and 15 (all partial) are drawn to 10 inventions featuring a method for assessing breast cancer comprising comparing an expression of a gene selected from the group consisting of 10 genes (FCRL5, ..., KIAA0125) to a control.

-Groups 42-51: Claims 1-3, 5, 6, 10 and 15 (all partial) are drawn to 10 inventions featuring a method for assessing pancreatic cancer comprising comparing an expression of a gene selected from the group consisting of 10 genes (LGR4, ..., CACNA2D3) to a control.

Groups 52-61: Claims 1-3, 5, 6, 11 and 15 (all partial) are drawn to 10 inventions featuring a method for assessing colon cancer comprising comparing an expression of a gene selected from the group consisting of 10 genes (FAM20A, ..., GAS6) to a control.

Groups 1-61 are related to methods for assessing various disorders comprising identifying a characteristic, such as an altered gene expression, associated with CD11b+ peripheral blood mononuclear cells obtained from a patient sample. The single general concept linking Groups 1-61 together is merely "comparing an altered gene expression associated with CD11b+ peripheral blood mononuclear cells to a control".

This common concept is, however, described in US 2004/0209316 A1 (21 Oct 2004; Ritchlin TR et al., US) and, therefore, does not represent any contribution over the prior art.

Hence the inventions listed as Groups 1-61 do not relate to a single general inventive concept under PCT Rule 13.1 because the above mentioned common concept fails to make a contribution over the prior art within the meaning of PCT Rule 13.2.