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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHODS FOR DETECTING A MYCOBACTERIUM TUBERCULOSIS INFECTION

(57) Abstract: Methods for detecting an infection with Mycobacterium tuberculosis (Mtb) in a subject are disclosed. The methods include detecting the presence of CD8+ T cells that specifically recognize an Mtb polypeptide. The methods include *in vitro* assays for detecting the presence of CD8+ T cells in a biological sample, and *in vivo* assays that detect a delayed type hypersensitivity reaction. The methods can also include detecting Mtb polypeptides and polynucleotides. Reagents for the detection of an Mtb infection are also disclosed.



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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2007/006534

A. CLASSIFICATION OF SUBJECT MATTER
INV. G01N33/569

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)

G01N

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 practical, search terms used)

EPO-Internal, WPI Data, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	LEWINSOHN DEBORAH A ET AL: "Human dendritic cells presenting adenovirally expressed antigen elicit Mycobacterium tuberculosis-specific CD8+ T cells" AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE, vol. 166, no. 6, 15 September 2002 (2002-09-15), pages 843-848, XP002443626 ISSN: 1073-449X the whole document ----- -/--	1-4, 29-45

☒ 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 document 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

23 July 2007

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02/10/2007

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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2007/006534

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	LEWINSOHN DAVID M ET AL: "Characterization of human CD8+ T cells reactive with Mycobacterium tuberculosis-infected antigen-presenting cells" JOURNAL OF EXPERIMENTAL MEDICINE, vol. 187, no. 10, 18 May 1998 (1998-05-18), pages 1633-1640, XP002443627 ISSN: 0022-1007 the whole document	1-4, 29-45
X	WO 01/62893 A (CORIXA CORP [US]; CAMPOS NETO ANTONIO [US]; SKEIKY YASIR [US]; OVENDAL) 30 August 2001 (2001-08-30) pages 42-52, paragraphs V,VI examples 1,2 sequences 16,18,20,22,24,26,28,30	1-4, 29-45
Y	-----	46-49
X	EP 1 484 405 A (STATENS SERUMINSTITUT [DK]) 8 December 2004 (2004-12-08) page 15, paragraph 102 - page 16, paragraph 110 sequences 179,185	1-4, 29-45
Y	-----	46-49
Y	SMITH S M ET AL: "Human CD8+ CTL specific for the Mycobacterial major secreted antigen 85A" JOURNAL OF IMMUNOLOGY, THE WILLIAMS AND WILKINS CO. BALTIMORE, US, vol. 165, 2000, pages 7088-7095, XP002173902 ISSN: 0022-1767 page 7090, paragraph TETRAMERS	46-49
A	US 2004/141985 A1 (LALVANI AJIT [GB] ET AL) 22 July 2004 (2004-07-22) the whole document	1-4, 29-49
A	----- GROTZKE J E ET AL: "Role of CD8<+> T lymphocytes in control of Mycobacterium tuberculosis infection" MICROBES AND INFECTION, ELSEVIER, PARIS, FR, vol. 7, no. 4, April 2005 (2005-04), pages 776-788, XP004904672 ISSN: 1286-4579 the whole document	1-4, 29-49

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/006534

Box 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:
Although claims 35-39 are directed to a method of diagnosis practised on the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition in in vitro methods.
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 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 additional 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.:
claims 1, 29-49 (partially), 2-4 (fully)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

Invention 1: claims 1, 29-49 [partially], 2-4 [fully]

Methods of detecting Mycobacterium tuberculosis involving
SEQ ID NO 1 or T cells expressing Cd8+ that specifically
bind the Mycobacterium polypeptide with SEQ ID NO 1.

Invention 2-12: claims 1, 29-49 [partially], 5-28 [fully]

Methods of detecting Mycobacterium tuberculosis involving
SEQ ID NO 1 or T cells expressing Cd8+ that specifically
bind the Mycobacterium polypeptide with SEQ ID NO 2
(invention 2), 3 (invention 3) ... up to 12 (invention 12).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0162893	A	30-08-2001	AU 4173801 A	03-09-2001
EP 1484405	A	08-12-2004	NONE	
US 2004141985	A1	22-07-2004	NONE	