Propylactic GP studies

Saline
Ag85B-ESAT6-Rv2660
BCG
Ag85B-ESAT6

(54) Title: TUBERCULOSIS VACCINES COMPRISING ANTIGENS EXPRESSED DURING THE LATENT INFECTION PHASE

(57) Abstract: The invention is related to an immunogenic composition, vaccine or pharmaceutical composition for preventing, boosting or treating infection caused by a species of the tuberculosis complex (M. tuberculosis, M. bovis, M. africanum, M. microti). The immunogenic composition, vaccine or pharmaceutical composition comprise a fusion polypeptide, which comprises one or more starvation antigens from M. tuberculosis, the units of the fusion polypeptide being M. tuberculosis antigens. Further, the invention is related to the use of a vaccine comprising a fusion polypeptide sequence or nucleic acid sequence of the invention given at the same time as BCG, either mixed with BCG or administered separately at different sites or routes for preparing said immunogenic composition, vaccine, or pharmaceutical composition.
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:
15 November 2007

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.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. C07K14/35 A61K39/04 A61P31/06

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)
A61K A61P C07K

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, BIOSIS, EMBASE, MEDLINE, SCISEARCH, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
</tr>
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<tbody>
<tr>
<td>X</td>
<td>WO 2004/006952 A (STATENS SERUMINSTITUT [DK]; ANDERSEN PETER [DK]; ROSENKRANDS IDA [DK]); 22 January 2004 (2004-01-22) page 5, lines 11-15 page 30, lines 5-9 page 44, lines 1-5 claims 9,10,13 sequence 33</td>
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<td>WO 03/004520 A (MICROBIOLOGICAL RES AUTHORITY [GB]; JAMES BRIAN WILLIAM [GB]; MARSH PH) 16 January 2003 (2003-01-16) page 13 page 30 claim 25 sequence 189</td>
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</table>

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

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*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

*"* 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.

*S* document member of the same patent family

Date of the actual completion of the international search

4 July 2007

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HN Rijswijk Tel. (+31-70) 940-2040, Tx. 31 651 epo nl, Fax (+31-70) 940-3016

Date of mailing of the International search report

24/09/2007

Authorized officer

Domingues, Helena
<table>
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<td>Y,P</td>
<td>AGER ET AL: &quot;Protective immunity to tuberculosis with Ag85B-ESAT-6 in a synthetic cationic adjuvant system IC31&quot; VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 24, no. 26, 29 June 2006 (2006-06-29), pages 5452-5460, XP005489318 ISSN: 0264-410X the whole document</td>
<td>1-9, 11-14, 19, 20</td>
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INTERNATIONAL SEARCH REPORT

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. [X] Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

   Although claims 19 and 20 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

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. [X] 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.:

   1-9 (all partially), 11-17 (all partially), 18, 19 and 20 (both partially)

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.
This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-9 (all partially), 11-17 (all partially), 18, 19 and 20 (both partially)
   Concerns aspects linked to an immunogenic composition, vaccine or pharmaceutical composition comprising a starvation induced antigen of SEQ ID NO: 2 or one or more fragments thereof.

2. claims: 1-9 (all partially), 11-17 (all partially), 19 and 20 (both partially)
   Concerns aspects linked to an immunogenic composition, vaccine or pharmaceutical composition comprising a starvation induced antigen of SEQ ID NO: 4 or one or more fragments thereof.

3. claims: 1-9 (all partially), 11-17 (all partially), 19 and 20 (both partially)
   Concerns aspects linked to an immunogenic composition, vaccine or pharmaceutical composition comprising a starvation induced antigen of SEQ ID NO: 6 or one or more fragments thereof.

4. claims: 1-9 (all partially), 11-17 (all partially), 19 and 20 (both partially)
   Concerns aspects linked to an immunogenic composition, vaccine or pharmaceutical composition comprising a starvation induced antigen of SEQ ID NO: 8 or one or more fragments thereof.

5. claims: 1-10 (all partially), 11-17 (all partially), 19 and 20 (both partially)
   Concerns aspects linked to an immunogenic composition, vaccine or pharmaceutical composition comprising a starvation induced antigen of SEQ ID NO: 10 or one or more fragments thereof.

6. claims: 1-10 (all partially), 11-17 (all partially), 19 and 20 (both partially)
   Concerns aspects linked to an immunogenic composition, vaccine or pharmaceutical composition comprising a starvation induced antigen of SEQ ID NO: 12 or one or more fragment thereof.
7. claims: 1-9 (all partially), 11-17 (all partially), 19 and 20 (both partially)

Concerns aspects linked to an immunogenic composition, vaccine or pharmaceutical composition comprising a starvation induced antigen of SEQ ID NO: 14 or one or more fragments thereof.

8. claims: 1-9 (all partially), 11-17 (all partially), 19 and 20 (both partially)

Concerns aspects linked to an immunogenic composition, vaccine or pharmaceutical composition comprising a starvation induced antigen of SEQ ID NO: 16 or one or more fragments thereof.

9. claims: 1-9 (all partially), 11-17 (all partially), 19 and 20 (both partially)

Concerns aspects linked to an immunogenic composition, vaccine or pharmaceutical composition comprising a starvation induced antigen of SEQ ID NO: 18 or one or more fragments thereof.
<table>
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<th>Publication date</th>
<th>Patent family member(s)</th>
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<tr>
<td>WO 2004006952 A</td>
<td>22-01-2004</td>
<td>AU 2003242504 A1</td>
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