Abstract: Immunologically active agents are described, including isolated Pneumocystis A12 protein or polypeptides: immunogenic conjugates containing Pneumocystis A12 protein or polypeptide of the present invention; antibodies recognizing the Pneumocystis A12 protein or polypeptide or the immunogenic conjugates of the present invention; and nucleic acid molecules that encode the Pneumocystis A12 protein or polypeptide of the present invention, as well as DNA constructs, expression vectors, and host cells that contain the nucleic acid molecules. Disclosed uses of the antibodies, immunogenic conjugates, and DNA constructs include inducing passive or active immunity to treat or prevent pathogen infections, particularly by a Pneumocystis organism, in a subject.
**INTERNATIONAL SEARCH REPORT**

A. **CLASSIFICATION OF SUBJECT MATTER**

IPC(8) - A61K 36/06 (2013.01)

USPC - 424/185.1

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) - A61 K 36/06, 38/00 39/00, 39/09, 39/39, 39/395; A61 P 31/04, 31/10; C12N 15/09 (201) 3.01 )

USPC - 424/144.1 , 165.1 , 184.1 , 185.1 , 190.1 , 274.1

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

CPC - A61 K 36/06, 39/0002; C07K 14/37

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

PatBase, Google Patents, PubMed, Google Scholar, Google

**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>
<th>Relevant to claim No.</th>
</tr>
</thead>
</table>

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**

21 January 2013

**Date of mailing of the international search report**

25 MAR 2013

**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:**

Blaine R. Copenhaver

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774
Box No. I  Nucleotide and/or amino acid sequence(s) (Continuation of item 1c of the first sheet)

<p>| | |</p>
<table>
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<tr>
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<tr>
<td>1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of a sequence listing filed or furnished:</td>
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<td>a. (means)</td>
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<td>in electronic form</td>
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<td>b. (time)</td>
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<td>in the international application as filed</td>
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<td>X</td>
<td>together with the international application in electronic form</td>
</tr>
<tr>
<td></td>
<td>subsequently to this Authority for the purposes of search</td>
</tr>
</tbody>
</table>

2. In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

SEQ ID NOs: 1 and 4 were searched.
**INTERNATIONAL SEARCH REPORT**

**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 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.: 1-3, 14-20, 25-30 (in part)

**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.

Form PCT/ISA/2 20 (continuation of first sheet (2)) (July 2009)
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 need to be paid.

Group I: claims 1-3, 14-20, and 25-30 (in part) are drawn to an isolated Pneumocystis A12 protein comprising an amino acid sequence that is at least 20% identical to SEQ ID NO:1.

Group II: claims 4-6 and 25-29 (in part) are drawn to an isolated nucleic acid molecule that encodes a Pneumocystis A12 protein comprising an amino acid sequence that is at least 20% identical to SEQ ID NO:1.

Group III: claims 7-13 and 25-30 (in part) are drawn to a fusion protein comprising: a first protein or protein fragment comprising an N-terminal region of Pneumocystis A12 and a second protein or protein fragment linked to the first protein or protein fragment.

Group IV: claims 21-24 and 25-30 (in part) are drawn to an isolated Pneumocystis A12 protein or polypeptide fragment comprising an amino acid sequence that is at least 20% identical to a 25 contiguous amino acid sequence of SEQ ID NO:2.

Group V: claims 31-33 are drawn to a method of immunizing a subject against infection of Pneumocystis.

Group VI: claim 34 is drawn to a pharmaceutical composition comprising a Pneumocystis A12 protein.

Group VII: claims 35-41 are drawn to an immunogenic conjugate comprising a Pneumocystis A12 protein.

Group VIII: claims 42-55 are drawn to an antibody that specifically binds to an epitope comprising amino acid residues within a region of 1-821 of SEQ ID NO:1.

Group IX: claim 56 is drawn to a diagnostic kit.

The inventions listed in Groups I-IX 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 features of Group I, an isolated Pneumocystis A12 protein comprising an amino acid sequence that is at least 20% identical to SEQ ID NO:1, is not present in Groups II-IX; the special technical features of Group II, an isolated nucleic acid molecule that encodes a Pneumocystis A12 protein comprising an amino acid sequence that is at least 20% identical to SEQ ID NO:1, is not present in Groups I and III-IX; the special technical feature of Group III, a fusion protein, is not present in Groups I, II, and IV-IX; the special technical feature of Group IV, an isolated Pneumocystis A12 protein or polypeptide fragment comprising an amino acid sequence that is at least 20% identical to a 25 contiguous amino acid sequence of SEQ ID NO:2, is not present in Groups I-III and V-IX; the special technical feature of Group V, a method of immunizing a subject against infection of Pneumocystis, is not present in Groups I-IV and VI-IX; the special technical feature of Group VI, a pharmaceutical composition comprising a Pneumocystis A12 protein, is not present in Groups I-V and VII-IX; the special technical feature of Group VII, an immunogenic conjugate comprising a Pneumocystis A12 protein, is not present in Groups I-VI, VIII, and IX; the special technical feature of Group VIII, an antibody that specifically binds to an epitope comprising amino acid residues within a region of 1-821 of SEQ ID NO:1, is not present in Groups I-VII and IX; the special technical feature of Group IX, a diagnostic kit, is not present in Groups I-VIII.

Groups I-IX share the technical features of an isolated Pneumocystis A12 protein, an antibody that binds to a Pneumocystis A12 protein, and administering to a subject an isolated Pneumocystis A12 protein or an antibody that binds to a Pneumocystis A12 protein to prevent or treat a Pneumocystis infection. However, these shared technical features do not represent a contribution over the prior art.

Specifically, US 7,815,918 B2 to Gigliotti et al. teach an isolated Pneumocystis A12 protein (the isolated protein or polypeptide of this embodiment are encoded by a nucleic acid molecule that contains the nucleotide sequence of 1-837 of the Pneumocystis A12 clone, Col. 8, Lns. 28-31; a Pneumocystis protein or polypeptide having the amino acid sequence of clone A12, Col. 4, Lns. 66-67), an antibody that binds to a Pneumocystis A12 protein (an antibody that recognizes Pneumocystis kexin and the protein of clone A12, Col. 4, Lns. 11-12), and administering to a subject an isolated Pneumocystis A12 protein (a method of treating or preventing infection in a patient by a Pneumocystis organism... administering to a patient an amount of a Pneumocystis protein or polypeptide comprising the amino acid sequence of clone A12, Col. 4, Lns. 17-22) or an antibody that binds to a Pneumocystis A12 protein to prevent or treat a Pneumocystis infection (administering to a patient an amount of... an antibody that recognizes Pneumocystis kexin and the protein of clone A12... wherein the amount of the one or more antibodies is effective to treat or prevent infection by a Pneumocystis organism, Col. 4, Lns. 8-15).

Since none of the special technical features of the Groups I-IX inventions are found in more than one of the inventions, unity is lacking.