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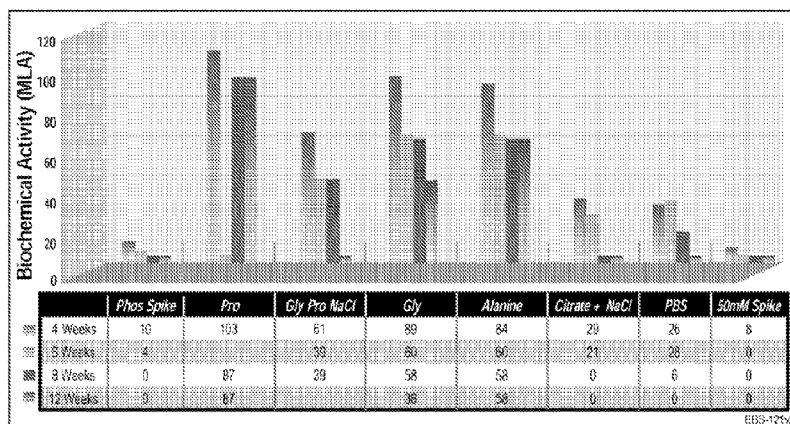
- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
- with sequence listing part of description (Rule 5.2(a))

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

5 August 2010

(54) Title: STABLE ANTHRAX VACCINE FORMULATIONS

Figure 5.



(57) Abstract: Formulations of anthrax protective antigen are provided that are stable in storage for prolonged periods. Methods of using the formulations to prepare vaccine are also provided. Vaccines comprising the formulations are useful, for example, to protect against anthrax infection.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/52279

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 39/07, A61K 47/00 (2010.01)

USPC - 424/246.1, 514/772

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)

USPC -- 424/246.1, 514/772

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)

WEST -- PGPB, USPT, USOC, EPAB, JPAB; Dialog Classic Files -- 654, 652, 351, 349, 6, 35, 65, 155; Google Scholar; USPTO Web Page; Search terms -- stable anthrax vaccine, B. anthracis protective antigen, sodium phosphate, alanine, Tween-80

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2006/0257426 A1 (BAKER et al.) 16 November 2006 (16.11.2006) para [0007], [0009], [0022], [0064], [0082], [0086], [0110], [0145], [0157], [0175], [0207], [0213], [0232], [0233], [0289]	1, 2 ----- 3
Y	US 2003/0162167 A1 (HOUGHTON et al.) 28 August 2003 (28.08.2003) para [0129], [0142], [9340], [0754], [0883], [1016]	3
A	US 2005/0276756 A1 (HOO et al.) 15 December 2005 (15.12.2005) para [0026], [0055], [006], [0068], [0109]	1-3

☐ 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

30 May 2010 (30.05.2010)

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Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/52279

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.: 4-7, 12-16 and 20-49
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 1-3, directed to a stable vaccine for the prevention or treatment of a B. anthracis infection comprising a B. anthracis protective antigen protein and an alanine formulation buffer.

Group II: claims 8-11, directed to a stable vaccine for the prevention or treatment of a B. anthracis infection comprising a B. anthracis protective antigen protein and an proline formulation buffer.

Group III: claims 17-19, directed to a stable vaccine for the prevention or treatment of a B. anthracis infection comprising a B. anthracis protective antigen protein and a glycine formulation buffer.

- 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.:
1-3

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.

Continuation of Box III: Lack of Unity of Invention

The inventions listed as Groups I - III 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 claims of Groups I - III is a stable vaccine for the prevention or treatment of a B. anthracis infection comprising a B. anthracis protective antigen protein, wherein the composition further comprises a buffer comprising an amino acid, wherein each Group is directed to a different amino acid.

The only common technical element shared by the above groups is that they are related to vaccine formulations comprising immunogenic B. anthracis proteins and a buffer formulation comprising an amino acid. These common technical elements do not represent an improvement over the prior art of US 2005/0276756 A1 to Hoo et al. (see abstract, para [0026], [0055], [0065], [0068], [0109]). Therefore, the inventions of Groups I - III lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.