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Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

Published:

— with international search report (Art. 21(3))

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

28 January 2010

(54) Title: POLYVALENT VACCINE

(57) Abstract: The present invention relates, in general, to an immunogenic composition (e.g., a vaccine) and, in particular, to a polyvalent immunogenic composition, such as a polyvalent HIV vaccine, and to methods of using same. The invention further relates to methods that use a genetic algorithm to create sets of polyvalent antigens suitable for use, for example, in vaccination strategies.



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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/32907

A. CLASSIFICATION OF SUBJECT MATTER
 IPC: A61K 39/21(2006.01),39/12(2006.01),39/00(2006.01),38/00(2006.01)

 USPC: 424/188.1,187.1,186.1,185.1,184.1;514/2
 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)
 U.S. : 424/188.1, 187.1, 186.1, 185.1, 184.1; 514/2

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	SHINODA et al. Polygene DNA vaccine induces a high level of protective effect against HIV-vaccinia virus challenge in mice. Vaccine. 2004, Vol. 22, pages 3676-3690.	1, 2, 4, 5 and 7-12
A	US 2003/0147888 A1 (HAYNES et al.) 7 August 2003 (07.08.2003), whole document.	1, 2, 4, 5 and 7-12
A	US 2003/0044421 A1 (EMINI et al.) 6 March 2003 (06.03.2003), whole document.	1, 2, 4, 5 and 7-12
A	US 2003/0104011 A1 (RIOS) 5 June 2003 (05.06.2003), whole document.	1, 2, 4, 5 and 7-12

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	"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
"E" earlier application or patent published on or after the international filing date	"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
"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)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search: 31 January 2008 (31.01.2008)
 Date of mailing of the international search report: 27 AUG 2008

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
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US06/32907

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:
Please See Continuation 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 any 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.: 1-2 (in part), 4-5 (in part), and 7-12 (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.

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

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, claim(s) 1-2 (in part), 4-5, (in part), 7-12 (in part), drawn to synthetic peptides comprising theoretical HIV-1 *nef*-encoded antigenic epitopes.

Group II, claim(s) 1-2 (in part), 4-5, (in part), 7-12 (in part), drawn to synthetic peptides comprising theoretical HIV-1 *gag*-encoded antigenic epitopes

Group III, claim(s) 1 (in part), 3-4 (in part), 6-12 (in part), drawn to synthetic peptides comprising theoretical HIV-1 *env*-encoded antigenic epitopes.

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 claims are drawn to "Markush" type groups of synthetic polypeptides and polynucleotide compositions capable of encoding the polypeptides. Under PCT Rule 13.2, the "Markush" grouping possess unity if:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)(2) In the cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In the instant case, neither criteria A or B1 or B2 is met between the groups. Only within each groups do the alternatives have a common property; *nef*-, *gag*-, or *env*-encoded epitopes each and independently have the capacity to induce an immune response to respective class of epitopes because to the significantly different structure of the epitope.