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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: MUTANT VIRAL NUCLEIC ACIDS AND VACCINE CONTAINING SAME

(57) Abstract: The present invention is directed to a nucleic acid comprising a deletion mutant of a PTAP (SEQ ID NO:1) motif and/or PPXY (SEQ ID NO:2) and/or YXXL (SEQ ID NO:3) motif in the late or L domain of a viral protein, where the L domain mediates the budding process. Examples of such viral proteins containing L domains are the retroviral gag proteins and the matrix proteins of rhabdoviruses and filoviruses. In addition, the present invention is directed to a vector containing (a) this nucleic acid or (b) this nucleic acid and one or more nucleic acids encoding other structural and regulatory viral proteins. The present invention is further directed to vaccines containing the nucleic acid or vector for the purpose of augmenting a cellular immune response.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/01226

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 39/12

US CL : 424/204.100

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. : 424/204.100

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)

PubMed

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	HUANG, M. p6 Gag is required for Particle Production from Full-Length Human	1-12
---	Immunodeficiency Virus Type I Molecular Clones Expressing Protease. Journal of Virology	-----
Y	1995, Vol 69, No. 11, pages 6810-6818, especially page 6813.	13-24
Y	KONG et al. Immunogenicity of Multiple Gene and Clade Human Immunodeficiency Virus Type 1 DNA Vaccines. Journal of Virology, December 2003, Vol. 77, No. 23, pages 12764-12772.	13-24

☐ 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 application or patent 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

06 October 2005 (06.10.2005)

Date of mailing of the international search report

06 DEC 2005

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/01226

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.:

- 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. |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/01226

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) 1-12, drawn to a DNA comprising a nucleic acid comprising a deletion mutation of the budding mediating motif of a viral protein, a vector comprising the DNA, a composition comprising the vector, and a composition comprising the DNA.

Group II, claim(s) 13-24, drawn to a method for immunizing a subject, or augmenting a cellular immune response to a virus, which comprises administering the DNA molecule or the composition comprising the DNA, or administering the vector or the composition comprising the vector.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

For each group, Applicant is required to elect the following three species:

- (A) one budding mediating motif as exemplified by claim 2;
- (B) one additional viral protein as exemplified by claim 8;
- (C) one molecular clone as exemplified by claim 9.

The inventions listed as Groups I and II 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 technical feature linking groups I and II appears to be that they all relate to a DNA molecule comprising a nucleic acid comprising a deletion mutation of the budding mediating motif of a viral protein.

However, Gottwein *et al.* (2003) teaches the mutation of the PPPY motif to PGAA where codons PPY are deleted (see abstract, especially page 9476, Materials and Methods), which renders the claimed invention to lack an inventive step.

Thus the claimed inventions do not make a contribution over the prior art and lack unity.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the special technical features for the same reason as stated above for the Groups of Inventions.

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure. The protein species and the molecular clones do not share a common structure, property or activity. Therefore, the species lack unity.