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- (81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
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Published:

- with international search report (Art. 21(3))
- with sequence listing part of description (Rule 5.2(a))

- (88) **Date of publication of the international search report:**
6 March 2014

(54) **Title:** NUCLEIC ACID MOLECULES ENCODING NOVEL HERPES ANTIGENS, VACCINE COMPRISING THE SAME, AND METHODS OF USE THEREOF

(57) **Abstract:** Provided herein are nucleic acid sequences that encode novel consensus amino acid sequences of herpes virus antigens, as well as genetic constructs/vectors and vaccines expressing the sequences. Also provided herein are methods for generating an immune response against herpes virus using the vaccines that are provided.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/23398

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - C07H 21/00; C07K 14/03 (2012.01)

USPC - 536/23.72; 530/350; 435/320.1

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): C07H 21/00; C07K 14/03 (2012.01)

USPC: 536/23.72; 530/350; 435/320.1

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

USPC: 536/23.72; 530/350; 435/320.1, 424/186.1 (text search)

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

Electronic data bases: PubWEST (USPT, EPAB, JPAB, PGPB); Google Scholar; GenCore sequence search (AA, NT)

Search terms: human cytomegalovirus (hCMV or HHV-5), vaccine, nucleic acid vaccine, expression vector, antigen, operably linked, regulatory elements, hCMV glycoprotein B (hCMV gB), hCMV gH, hCMV gL

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y --- A	US 2004/0228842 A1 (LU et al.) 18 November 2004 (18.11.2004). Especially SEQ ID NOs: 1,2,7,8,9,10; para [0005], [0007], [0008], [0013], [0058], [0068], [0076], [0093].	1, 6, 7, 12-19, 21, 22 ----- 2 ----- 3-5
X --- Y	MILNE et al. Uniprot Q68671. (GL_HCMV5); 11 January 2011. [online] Available on the internet: <URL: http://www.uniprot.org/uniprot/Q68671.txt?version=40 >. [retrieved 3 August 2012]; Especially pg 1.	19, 20 ----- 2



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

3 August 2012 (03.08.2012)

Date of mailing of the international search report

10 AUG 2012

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/23398

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)

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:

a. (means)

☐

on paper

☒

in electronic form

b. (time)

☐

in the international application as filed

☒

together with the international application in electronic form

☐

subsequently to this Authority for the purposes of search

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:

GenCore ver 6.3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/23398

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:

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.

Groups I+: claims 1-22, directed to a nucleic acid molecule comprising a coding sequence for a herpes virus antigen encoding one or more proteins selected from the group consisting of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 85, 87, 89, 91, 93, 95, 97, 99, 101, 103, 105, 107, 109, 11 and 113, or sequences at least 95% identical thereto, or a polypeptide encoded by said sequences; wherein the first invention is limited to a nucleic acid encoding SEQ ID NO: 2, or the protein comprising said sequence. (Applicants may opt for additional polypeptides to be searched by specifying the SEQ ID NO: and paying an additional invention search fee for each elected sequence).

- 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.:
Claims 1-7 and 12-22: restricted to SEQ ID NOs: 2, 8 and 10.
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/US 12/23398

Continuation of Box III: Lack of Unity of Invention

The inventions listed as Groups I+ 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+ is indicated above in the Group description. Each subgroup is directed to a different encoded polypeptide.

The only common technical element shared by the above groups is that they are related to herpes virus polypeptides, and nucleic acids encoding said polypeptides. This common technical element does not represent an improvement over the prior art of US 2010/0160419 A1 to Vilalta et al., which discloses a polynucleotide encoding a herpes virus protein (para [0027]), as well as administration thereof to a subject, wherein the administered polypeptide has an immunogenic effect on the vertebrate (para [0024]), and pharmaceutical formulations comprising said polynucleotide (para [0028]), further wherein the polynucleotide may encode two or more joined nucleic acid fragments, wherein each encodes a single HSV polypeptide (para [0047]). Vilalta further discloses isolated hsv polypeptides or fragments thereof (para [0051]).

Therefore, the inventions of Groups I+ lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.