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A61K 39/245 (2006.01)	***A61K 38/17*** (2006.01)
C07K 7/00 (2006.01)	***A61P 35/00*** (2006.01)
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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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, 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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— *of inventorship (Rule 4.17(iv))*

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(88) Date of publication of the international search report:
01 February 2018 (01.02.2018)

WO 2017/203370 A3

(54) Title: CMV EPITOPES

(57) Abstract: Provided herein are compositions and methods related to the treatment of a CMV infection and/or cancer in a subject. In particular, CMV epitopes KARAKKDELR, ARAKKDELR, KARAKKDELK, ARAKKDELK, RRKMMYMYCR, KRKMIYMYCR, VLEETSVML, YILEETSVML, DELRRKMMY, ELKRKMIY, EEAIAVAYL, EDAIAAYTL, ELRRKMMYM, ELKRKMIYM, AYAQKIFKIL, TYSQKIFKIL, FMDILTTCV, NLVPMVATV, RPHERNGFTVL, TPRVTGGGAM, VTEHDTLLY, QIKVRVDMV and YSEHPTFTSQY are provided. Additionally, antibodies binding to such epitopes, peptide and nucleic acid equivalents of such epitopes, T cells expressing a T cell receptor (TCR) that bind to such epitopes, vaccines incorporating such epitopes, antigen presenting cells (APC) with such epitopes presented on Class I MHC, as well as methods of treating and/or preventing cancer or cytomegalovirus (CMV) infection thereof are further provided.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2017/000849

A. CLASSIFICATION OF SUBJECT MATTER

[See Supplemental Sheet]

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)

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)

Databases: EPOQUE: PATENW; STN: REGISTRY, HCAPLUS, BIOSIS, EMABSE, MEDLINE; GENOMEQUEST; Public: ESPACENET, PUBMED. Keywords: Cytomegalovirus, CMV, HCMV, herpesvirus 5, epitope, antigen, T cell, cytotoxic T cell, T killer cell, CD8+ T cell, adoptive immunotherapy, adoptive cellular therapy, antigen presenting cell, dendritic cell, antibody, mmunoglobulin, cancer, tumour, carcinoma, KARAKKDELR, ARAKKDELR, KARAKKDELK, ARAKKDELK, RRKMMYMYCR, KRKMIYMYCR, DELRRKMMY, DELKRKMIY and like terms. Applicant and Inventor name searches were also carried out using internal IPA databases (PAMS NOSE & INTESS) and using ESPACENET and PUBMED.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[X] Further documents are listed in the continuation of Box C

[X] 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 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	Date of mailing of the international search report
11 December 2017	11 December 2017
Name and mailing address of the ISA/AU	**Authorised officer**
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustralia.gov.au	Holly Thomas AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. +61262256157

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	KERN, F. et al. "Target Structures of the CD8+-T-Cell Response to Human Cytomegalovirus: the 72-Kilodalton Major Immediate-Early Protein Revisited", JOURNAL OF VIROLOGY, Oct. 1999, Vol. 73, No. 10, p. 8179–8184.	
X	Abstract; 'Results and Discussion' starting Page 8180, especially, Page 8180, Col. 2, Para. 2.	1-57
Y	Abstract; 'Results and Discussion' starting Page 8180, especially, Page 8180, Col. 2, Para. 2.	1-57
	US 2004/0106159 A1 (KERN, F. et al.) 03 June 2004	
X	Abstract; [0012]-[0020]; Fig. 1; Example.	1-57
Y	Abstract; [0012]-[0020]; Fig. 1; Example.	1-57
	US 2006/0165714 A1 (KERN, F. et a.) 27 July 2006	
X	Abstract; [0056]-[0073]; Examples.	1-57
Y	Abstract; [0056]-[0073]; Examples.	1-57
	GIBSON, L. et al. "Cytomegalovirus (CMV) IE1- and pp65-Specific CD8+ T Cell Responses Broaden over Time after Primary CMV Infection in Infants", Journal of Infectious Diseases, 15 June 2007, Vol. 195, Pages 1789-98.	
X	Abstract; Table 2; 'Results', Starting page 179.	1-57
Y	Abstract; Table 2; 'Results', Starting page 179.	1-57
	WO 2010/037397 A1 (DAKO DENMARK A/S) 08 April 2010	
X	Abstract; Page 3, Lines 14-17; Page 26, Line 29 – Page 27, Line 9; Table 9.	1-57
Y	Abstract; Page 3, Lines 14-17; Page 26, Line 29 – Page 27, Line 9; Table 9.	1-57
	WO 2005/007689 A1 (ALPHAVAX, INC.) 27 January 2005	
X	Abstract; Page 19, Line 32 – Page 20, Line 3; Page 17, Lines 24-30.	1-57
Y	Abstract; Page 19, Line 32 – Page 20, Line 3; Page 17, Lines 24-30.	1-57
	BRAENDSTRUP, P. et al. "Identification and HLA-Tetramer-Validation of Human CD4+ and CD8+ T Cell Responses against HCMV Proteins IE1 and IE2", PLOS ONE, April 2014, Vol. 9, No. 4, e94892 (Pages 1-16).	
X	Abstract; Table 2.	1-57
Y	Abstract; Table 2.	1-57
	WO 2015/142671 A2 (FLUGEN, INC.) 24 September 2015	
X	Abstract; [0165]; Table A; Table B, Page 23.	1-57
Y	Abstract; [0165]; Table A; Table B, Page 23.	1-57
	KHAN, N. et al. "T Cell Recognition Patterns of Immunodominant Cytomegalovirus Antigens in Primary and Persistent Infection", The Journal of Immunology, 2007, Vol. 178, Pages 4455-4465.	
X	Abstract; Page 4457, Col. 1, Para. 3; Page 4458, Col. 1, Para. 2; Table 1, Page 4459.	1-57
	ALP, N. J. et al. "Fine Specificity of Cellular Immune Responses in Humans to Human Cytomegalovirus Immediate-Early Protein", JOURNAL OF VIROLOGY, Sept. 1991, Vol. 65, No. 9, p. 4812-4820.	
X	Abstract; Page 4813, Col. 1, Para. 2; Page 4814, Col. 1, Para. 2; Figure 2.	1-57
	WO 2015/001361 A1 (THE UNIVERSITY OF BIRMINGHAM) 08 January 2015	
X	Abstract; Pages 10-12.	1-57
	WO 2010/014567 A2 (MERCK & CO., INC.) 04 February 2010	

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Abstract; Page 2, Line 16 – Page 3, Line 12; SEQ ID NO: 40; Table 3, Page 29.	1-57
	SMITH, C. et al. "Molecular Imprint of Exposure to Naturally Occurring Genetic Variants of Human Cytomegalovirus on the T cell Repertoire", Scientific Reports, 2014, Vol. 4, Article 3993 (Pages 1-10), DOI: 10.1038/srep03993.	
X	Abstract; Page 2, Col. 1, Para. 2; Page 2, Col. 1, Para. 3.	1-57
Y	Abstract; Page 2, Col. 1, Para. 2; Page 2, Col. 1, Para. 3.	1-57
	WO 2003/000720 A1 (THE COUNCIL OF THE QUEENSLAND INSTITUTE OF MEDICAL RESEARCH) 03 January 2003	
A	Abstract; Page 8, Line 30 - Page 9, Line 34; Page 10, Lines 19-26; Page 12, Line 7 - Page 14, Line 13; Page 26, Lines 18-31; Page 27, Lines 13-34; Page 31, Lines 31-34; Page 50, Lines 1-4; Page 54, Lines 15-22; Page 59, Lines 13-19; Page 64, Lines 20-28; Examples.	1-57
	WO 2013/119947 A1 (BAYLOR COLLEGE OF MEDICINE) 15 August 2013	
A	Whole document, particularly Abstract; [0008]; [0012]-[0014].	1-57
	AU 2012227280 B2 (THE COUNCL OF THE QUEENSLAND INSTITUTE OF MEDICAL RESEARCH) 11 October 2012	
A	Whole document, particularly Abstract; Page 2, Line 26 - Page 6, Line 11.	1-57

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2017/000849

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:
the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including

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 Supplemental Box for Details

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.:
1-57, in so far as they relate to Inventions 1, 2 and 4 as defined in the unity objection.

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.

Supplemental Box

Continuation of: **Box III**

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Invention 1: Claims 1-16 and 20-57 in part, and claims 17-18 in full, directed to methods of treating cancer by administering a CTL comprising a TCR that specifically binds to an epitope of CMV, methods of treating CMV infection by administering a composition comprising CTLs comprising a TCR that specifically binds to a CMV epitope presented in class I MHC, methods of inducing proliferation of CMV-specific CTLs by incubating a sample comprising CTLs and APCs that present a CMV peptide comprising an epitope, peptides comprising a CMV epitope, wherein the peptide does not comprise more than 30 contiguous amino acids of a CMV protein, antibodies and antigen binding fragments thereof that bind to a CMV epitope and T cells expressing a TCR that binds to an epitope of CMV presented on a MHC, wherein the CMV epitope is KARAKKDELR, ARAKKDELR, KARAKKDELK or ARAKKDELK. The feature of the KARAKKDELR, ARAKKDELR, KARAKKDELK or ARAKKDELK epitope is specific to this group of claims.
- Invention 2: Claims 1-16 and 20-57 in part, and claim 19 in full, directed to the same as invention 1, wherein the CMV epitope is RRKMMYMYCR or KRKMIYMYCR.
- Invention 3: Claims 1-16 and 20-57 in part, directed to the same as invention 1, wherein the CMV epitope is VLEETSVML or YILEETSVML.
- Invention 4: Claims 1-16 and 20-57 in part, directed to the same as invention 1, wherein the CMV epitope is DELRRKMMY or DELKRKMIY.
- Invention 5: Claims 1-16 and 20-57 in part, directed to the same as invention 1, wherein the CMV epitope is EEAIAVAYL or EDAIAAYTL.
- Invention 6: Claims 1-16 and 20-57 in part, directed to the same as invention 1, wherein the CMV epitope is ELRRKMMYM or ELKRKMIYM.
- Invention 7: Claims 1-16 and 20-57 in part, directed to the same as invention 1, wherein the CMV epitope is AYAQKIFKIL or TYSQKIFKIL.
- Invention 8: Claims 1-16 and 20-57 in part, directed to the same as invention 1, wherein the CMV epitope is FMDILTTCV.
- Invention 9: Claims 1-16 and 20-57 in part, directed to the same as invention 1, wherein the CMV epitope is NLVPMVATV.
- Invention 10: Claims 1-16 and 20-57 in part, directed to the same as invention 1, wherein the CMV epitope is RPHERNGFTVL.
- Invention 11: Claims 1-16 and 20-57 in part, directed to the same as invention 1, wherein the CMV epitope is TPRVTGGGAM.
- Invention 12: Claims 1-16 and 20-57 in part, directed to the same as invention 1, wherein the CMV epitope is VTEHDTLLY.
- Invention 13: Claims 1-16 and 20-57 in part, directed to the same as invention 1, wherein the CMV epitope is QIKVRVDMV.
- Invention 14: Claims 1-16 and 20-57 in part, directed to the same as invention 1, wherein the CMV epitope is YSEHPTFTSQY.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. The only feature common to all of the claimed inventions and which provides a technical relationship among them is CMV T cell epitopes.

However this feature does not make a contribution over the prior art because it is disclosed in:

KHAN N. et al. "Comparative Analysis of CD8+ T Cell Responses against Human Cytomegalovirus Proteins pp65 and Immediate Early 1 Shows Similarities in Precursor Frequency, Oligoclonality, and Phenotype", The Journal of Infectious Diseases, 2002, Vol. 185, Pages 1025–34, or

Supplemental Box

SMITH C. et al. "Molecular Imprint of Exposure to Naturally Occurring Genetic Variants of Human Cytomegalovirus on the T cell Repertoire", Scientific Reports, 2014, Vol 4: 3993, Pages 1-10.

For example, SMITH et al. discloses the ELRRKMMYM and ELKRKMIYM epitope variants and how CMV infection with genotypic variants impacts on the T cell repertoire in a subject and KHAN et al. discloses the human CMV-derived CD8+T cell epitope VLEETSVML; stating that as many as one third of HLA-A*0201-positive HCMV-seropositive donors make responses to this peptide and further teaches use in vaccines.

Therefore in the light of this document this common feature cannot be a special technical feature. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied *a posteriori*.

Ultimately, the application discloses the amino acid sequence of 23 distinct peptides comprising epitopes from the CMV immediate early 1 protein which are recognized by cytotoxic T lymphocytes (CTLs) (see Table 1). The application suggests that these epitopes can be the basis of T cell immunotherapy for the treatment of CMV infections and cancers.

Although all the claimed inventions relate to CMV epitopes and methods of their use, this is not considered to be a special technical feature (and thereby a feature that unites the all claims) because at least some of the 23 epitopes are known in the art.

Therefore the requirements for unity of invention are not satisfied a posteriori, and the claims cover multiple inventions: there are 14 separate inventions (see above) when all 23 distinct epitopes of Table 1 are grouped according to their amino acid homology.

Search and examination has been completed on claims 1-57 in so far as they relate to Inventions 1, 2 and 4, as requested by the applicant in their response to the Invitation to Pay (ITP).

Supplemental Box – IPC Marks

A61K 35/17 (2015.01)

C07K 16/00 (2006.01)

C07K 16/28 (2006.01)

A61K 39/00 (2006.01)

A61K 39/245 (2006.01)

C07K 7/00 (2006.01)

C07K 7/06 (2006.01)

C07K 14/00 (2006.01)

C07K 14/705 (2006.01)

A61K 38/00 (2006.01)

A61K 38/08 (2006.01)

A61K 38/10 (2006.01)

A61K 38/16 (2006.01)

A61K 38/17 (2006.01)

A61P 35/00 (2006.01)

A61P 31/12 (2006.01)

A61P 31/22 (2006.01)

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/IB2017/000849**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		**Patent Family Member/s**	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
US 2004/0106159 A1	03 June 2004	US 2004106159 A1	03 Jun 2004
		US 7994096 B2	09 Aug 2011
		AU 4644401 A	03 Sep 2001
		DE 10009341 A1	06 Sep 2001
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		AU 5963500 A	28 Dec 2000
		DE 19927039 A1	07 Dec 2000
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		EP 1181313 A2	27 Feb 2002
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		JP 2003501076 A	14 Jan 2003
		US 7041442 B1	09 May 2006
		WO 0075180 A2	14 Dec 2000
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		AU 2004257214 A1	27 Jan 2005
		AU 2004257214 B2	22 Apr 2010
		EP 1651666 A1	03 May 2006
		EP 1651666 B1	27 May 2009
		US 2005054107 A1	10 Mar 2005
		US 7419674 B2	02 Sep 2008

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/IB2017/000849**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
WO 2015/142671 A2	24 September 2015	WO 2015142671 A2	24 Sep 2015
		EP 3119883 A2	25 Jan 2017
		US 2017106077 A1	20 Apr 2017
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		CN 105392798 A	09 Mar 2016
		EP 3016969 A1	11 May 2016
		EP 3016969 B1	30 Aug 2017
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		JP 2016523888 A	12 Aug 2016
		US 2016206726 A1	21 Jul 2016
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		US 7524503 B2	28 Apr 2009
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		EP 2812431 A1	17 Dec 2014

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/IB2017/000849**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
		US 2015010519 A1	08 Jan 2015
AU 2012227280 B2	11 October 2012	AU 2012227280 A1	11 Oct 2012
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		AU 2005309341 A1	01 Jun 2006
		US 2008107620 A1	08 May 2008
		US 7976845 B2	12 Jul 2011
		WO 2006056027 A1	01 Jun 2006

End of Annex

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.