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(71) Applicant: **IMMUNOMIC THERAPEUTICS, INC.** [US/US]; 15010 Broschart Road, Suite 250, Rockville, MD 20850 (US).

(72) Inventors: **HEARL, William**; 9611 Greenel Road, Damascus, MD 20872 (US). **HEILAND, Teri**; 6241 Sawyer Road, New Market, MD 21774 (US).

(74) Agents: **ROSEDALE, Jeffrey, H.** et al.; Baker & Hostetler LLP, 2929 Arch Street, Cira Centre, 12th Floor, Philadelphia, PA 19104-2891 (US).

(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, 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, KN, KP, KR, 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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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *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))*

(88) Date of publication of the international search report:
21 April 2016

(54) Title: NUCLEIC ACIDS FOR TREATMENT OF PEANUT ALLERGIES

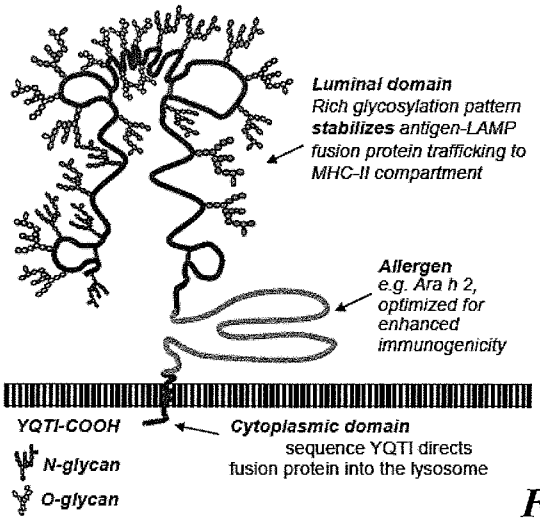


Fig. 1

(57) Abstract: Provided herein are DNA vaccines for the treatment of peanut allergies. The vaccines comprise the coding sequence for one or more peanut allergenic epitopes fused in-frame with the luminal domain of the lysosomal associated membrane protein (LAMP) and the targeting sequence of LAMP. The vaccines can be multivalent molecules and/or can be provided as part of a multivalent vaccine comprising two or more DNA constructs.

WO 2015/200357 A3

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/037240

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K39/35 C07K14/415 A61K39/00
ADD.

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)
A61K C07K

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)
EPO-Internal, BIOSIS, FSTA, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2013/187906 A1 (IMMUNOMIC THERAPEUTICS INC [US]; HEARL WILLIAM [US]; HEILAND TERI [US]) 19 December 2013 (2013-12-19)	1-30,32, 33,35-49
Y	See e.g. claims 1-4, in particular claim 1; SEQ ID NO: 7; Figures 6A, 6B, 18 and 19; paragraphs [022] and [158]-[160]; page 45, lines 7 and 8	1-50

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[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
17 February 2016	09/03/2016

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Valcárcel, Rafael

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/037240

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:

see additional 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 an 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.:

1-25, 27-50(completely); 26(partially)

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.

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	STEINKE JOHN W ET AL: "T-cell biology in immunotherapy", ANNALS OF ALLERGY, ASTHMA & IMMUNOLOGY, ARLINGTON HEIGHTS, IL, US, vol. 112, no. 3, 14 January 2014 (2014-01-14), pages 195-199, XP028666084, ISSN: 1081-1206, DOI: 10.1016/J.ANAI.2013.12.020 The whole document but see e.g. on page 196 the section "Immunology of SCIT"	1-50
Y	KOPPELMAN S J ET AL: "Relevance of Ara h1, Ara h2 and Ara h3 in peanut-allergic patients, as determined by immunoglobulin E Western blotting, basophil-histamine release and intracutaneous testing: Ara h2 is the most important peanut allergen", CLINICAL & EXPERIMENTAL ALLERGY : JOURNAL OF THE BRITISH SOCIETY FOR ALLERGY AND CLINICAL IMMUNOLOGY, WILEY INTERSCIENCE, UK, vol. 34, no. 4, 1 April 2004 (2004-04-01), pages 583-590, XP009188453, ISSN: 0954-7894 See e.g. the abstract	1-49
Y	OBERMUELLER STEFANIE ET AL: "The tyrosine motifs of Lamp 1 and LAP determine their direct and indirect targetting to lysosomes", JOURNAL OF CELL SCIENCE, CAMBRIDGE UNIVERSITY PRESS, LONDON, GB, vol. 115, no. 1, 1 January 2002 (2002-01-01), pages 185-194, XP009188470, ISSN: 0021-9533 See e.g. the abstract; page 185, left column, first paragraph; Figure 4 on page 189.	1-50
Y	CHUA KAW YAN ET AL: "DNA vaccines for the prevention and treatment of allergy", CURRENT OPINION IN ALLERGY AND CLINICAL IMMUNOLOGY, LIPPINCOTT WILLIAMS AND WILKINS, US, vol. 9, no. 1, 1 February 2009 (2009-02-01), pages 50-54, XP008122624, ISSN: 1528-4050, DOI: 10.1097/ACI.0B013E3283207AD8 See e.g. page 52, left column, second paragraph	1-50

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	H. WU: "YXXM Motifs in the PDGF-Receptor Serve Dual Roles as Phosphoinositide 3-Kinase Binding Motifs and Tyrosine-based Endocytic Sorting Signals", JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 278, no. 42, 31 July 2003 (2003-07-31), pages 40425-40428, XP55248893, US ISSN: 0021-9258, DOI: 10.1074/jbc.C300225200 see e.g. the abstract; page 40425 , right column, third line from the bottom	1-49
Y	Shigenori Ogata ET AL: "THE JOURNAL OF BIOWCICAL CHEM˜STRY 0 1994 by The American Society for Biochemistry and Molecular Biology Lysosomal Targeting of Limp I1 Membrane Glycoprotein Requires a Novel Leu-Ile Motif at a Particular Position in Its Cytoplasmic Tail*", , 18 February 1994 (1994-02-18), pages 5210-5217, XP055250027, Retrieved from the Internet: URL:http://www.jbc.org/content/269/7/5210.full.pdf [retrieved on 2016-02-15] See e.g. the abstract; figure 1 and Figure 3	1-18,50
X,P	XIU-MIN LI ET AL: "Immunization with ARAh1,2,3-Lamp-Vax Peanut Vaccine Blocked IgE Mediated-Anaphylaxis in a Peanut Allergic Murine Model", JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, vol. 135, no. 2, 1 February 2015 (2015-02-01), page AB167, XP055249591, AMSTERDAM, NL ISSN: 0091-6749, DOI: 10.1016/j.jaci.2014.12.1482	1-49
Y,P	abstract	1-49

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	KANG ET AL: "Cloning and characterization of a novel peanut allergen Ara h 3 isoform displaying potentially decreased allergenicity", PLANT SCIENCE, ELSEVIER IRELAND LTD, IE, vol. 172, no. 2, 12 January 2007 (2007-01-12), pages 345-353, XP005827707, ISSN: 0168-9452, DOI: 10.1016/J.PLANTSCI.2006.09.014 See e.g. the abstract	1-49
Y	RABJOHN PAT ET AL: "Modification of peanut allergen Ara h 3: Effects on IgE binding and T cell stimulation", INTERNATIONAL ARCHIVES OF ALLERGY AND IMMUNOLOGY, KARGER AG, CH, vol. 128, no. 1, 1 May 2002 (2002-05-01), pages 15-23, XP009163090, ISSN: 1018-2438, DOI: 10.1159/000057999 see e.g. the abstract	1-49
Y	SARA R PRICKETT ET AL: "Ara h 2 peptides containing dominant CD4T-cell epitopes: Candidates for a peanut allergy therapeutic", JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, ELSEVIER, AMSTERDAM, NL, vol. 127, no. 3, 23 September 2010 (2010-09-23), pages 608-615.e5, XP028196570, ISSN: 0091-6749, DOI: 10.1016/J.JACI.2010.09.027 [retrieved on 2010-10-04] See e.g. the abstract	1-49

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2015/037240

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2013187906 A1	19-12-2013	AU 2012382406 A1	18-12-2014
		CA 2876824 A1	19-12-2013
		CN 104519896 A	15-04-2015
		EP 2861240 A1	22-04-2015
		JP 5807994 B2	10-11-2015
		JP 2015521467 A	30-07-2015
		KR 20150032286 A	25-03-2015
		WO 2013187906 A1	19-12-2013

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-18, 21-30, 32, 33, 35-49(all partially)

A nucleic acid molecule as defined in claim 1. An embodiment of said nucleic acid is a nucleic acid sequence encoding SEQ ID NO: 1. A polypeptide comprising the amino acid sequence of SEQ ID NO: 1 referred to in e.g. claim 21. Compositions and methods involving said sequences.

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2. claims: 1-18, 21-49(all partially)

A nucleic acid molecule as defined in claim 1 but wherein the Ara antigen included is the AraH3 deletion corresponding to SEQ ID NO: 5. It is noted that SEQ ID NO: 5 is comprised in the full length Ara H3 (SEQ ID NO: 4 of the present application). For the sake of clarity, the embodiment wherein the AraH3 is the deleted form, consisting of SEQ ID NO: 5 and not the complete AraH3 is here listed as a potential separate invention. The nucleic molecule of claim 1 comprising a nucleic acid encoding SEQ ID NO: 6 (AraH3del LAMP). A pharmaceutical composition according to claim 30 comprising a nucleic acid encoding SEQ ID NO: 6. The composition of claim 33 comprising a vector comprising SEQ ID NO: 6. Compositions and methods involving said sequences.

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3. claims: 19, 20(completely); 1-18, 21-49(partially)

A nucleic acid as defined in claims 19 and 20, i.e. wherein the endosomal/lysosomal targeting domain comprises a YXXO signal (which is disclosed in the description to be a tyrosine recognition sequence). Compositions and methods involving said sequences.
It is noted that claims 19 and 20 are dependent on any of claims 1-18, which refer to both inventions 1 and 2. Depending on the prior art found in case of additional search fee is eventially paid, further lack of unity may arise within this invention.

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4. claims: 1, 21-49(all partially)

The nucleic acid of claim 1 comprising a nucleic acid sequence encoding SEQ ID NO: 7 (AraH2 LAMP). A pharmaceutical composition according to claim 30 comprising a nucleic acid encoding SEQ ID NO: 7. The composition of claim 33 comprising a vector comprising SEQ ID NO: 7. A polypeptide comprising the amino acid sequence of SEQ ID NO: 7. Compositions and methods involving said sequences.

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5. claims: 1, 21-49(all partially)

The nucleic acid of claim 1 comprising a nucleic acid sequence encoding SEQ ID NO: 8 (AraH1 LAMP). A pharmaceutical composition according to claim 30 comprising a nucleic acid encoding SEQ ID NO: 8. The composition of claim 33 comprising a vector comprising SEQ ID NO: 8. A polypeptide comprising the amino acid sequence of SEQ ID NO: 8. Compositions and methods involving said sequences.

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6. claims: 1, 26, 34-49(all partially)

A polypeptide comprising the amino acid sequence of SEQ ID NO: 28. The composition of claim 33 comprising a vector comprising SEQ ID NO: 28 (AraH3-LAMP). Compositions and methods involving said sequences.

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7. claim: 26(partially)

A polypeptide comprising the amino acid sequence of SEQ ID NO: 5.

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8. claims: 50(completely); 1-18(partially)

A nucleic acid as defined in claim 50, wherein the endosomal/lysosomal targeting domain comprises the amino acid sequence LIRT. It is noted that claim 50 is dependent on any of claims 1-18, which refer to both inventions 1 and 2. Depending on the prior art found in case of additional search fee is eventially paid, further lack of unity may arise within this invention.
