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61/642,844 4 May 2012 (04.05.2012) US(71) Applicant: **PFIZER INC.** [US/US]; 235 East 42nd Street,
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East 42nd Street, New York, NY 10017 (US).(81) Designated States (unless otherwise indicated, for every
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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,
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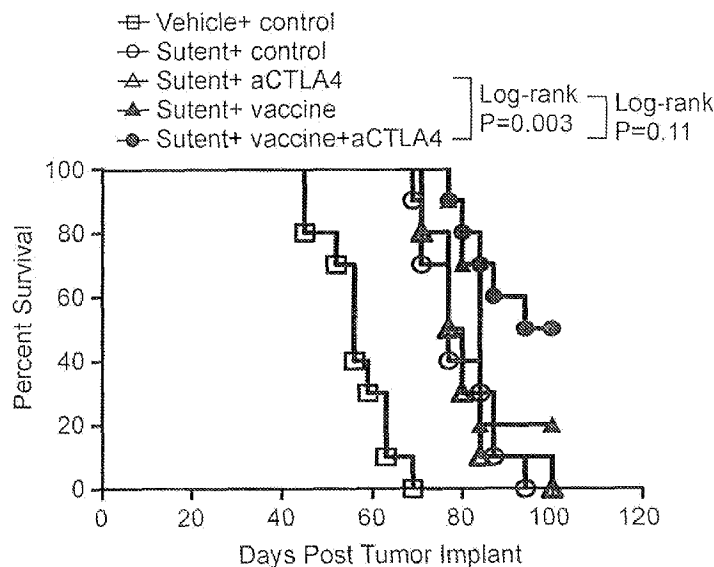
Declarations under Rule 4.17:

— as to the identity of the inventor (Rule 4.17(i))

[Continued on next page]

(54) Title: PROSTATE-ASSOCIATED ANTIGENS AND VACCINE-BASED IMMUNOTHERAPY REGIMENS

FIG. 37



(57) Abstract: The present disclosure provides (a) isolated immunogenic PAA polypeptides; (b) isolated nucleic acid molecules encoding immunogenic PAA polypeptides; (c) vaccine compositions comprising an immunogenic PAA polypeptide or an isolated nucleic acid molecule encoding an immunogenic PAA polypeptide; (d) methods relating to uses of the polypeptides, nucleic acid molecules, and compositions; and (e) vaccine-based immunotherapy regimens which involve co-administration of a vaccine in combination with an immune-suppressive-cell inhibitor and an immune-effector-cell enhancer.



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|---|--|
| — as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) | — 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)) |
| — as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) | — with sequence listing part of description (Rule 5.2(a)) |

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
INV. 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

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)

EP0-Internal, Sequence Search, WPI Data, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE UniProt [Online] 1 June 1994 (1994-06-01), "Glutamate carboxypeptidase 2; EC=3.4.17.21; Cell growth-inhibiting gene 27 protein;Folate hydrolase 1; Folypoly-gamma-glutamate carboxypeptidase; FGCP;", XP002713616, retrieved from EBI accession no. UNIPROT:Q04609 Database accession no. Q04609 sequence	1-5, 10-14, 33,34
A	----- -/--	6-9, 15-20, 35-41

☒ 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 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

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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/053377

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	OLSON WILLIAM C ET AL: "Clinical trials of cancer therapies targeting prostate-specific membrane antigen.", REVIEWS ON RECENT CLINICAL TRIALS SEP 2007, vol. 2, no. 3, September 2007 (2007-09), pages 182-190, XP007922264, ISSN: 1574-8871 abstract page 183, right-hand column, last paragraph page 186, left-hand column, paragraph 3 - page 187, right-hand column, last line -----	6,14, 18-20, 33,34
X	FERRARO BERNADETTE ET AL: "Co-delivery of PSA and PSMA DNA vaccines with electroporation induces potent immune responses.", HUMAN VACCINES 2011 JAN-FEB, vol. 7 Suppl, January 2011 (2011-01), pages 120-127, XP007922265, ISSN: 1554-8619 abstract page 121, left-hand column, paragraph 3 - right-hand column, paragraph 2 page 122, right-hand column, paragraph 2 - page 123, right-hand column, paragraph 2 figure 2 -----	6-9,15, 35,38
X	YING WAECKERLE-MEN ET AL: "Dendritic cell-based multi-epitope immunotherapy of hormone-refractory prostate carcinoma", CANCER IMMUNOLOGY, IMMUNOTHERAPY, SPRINGER, BERLIN, DE, vol. 55, no. 12, 13 April 2006 (2006-04-13), pages 1524-1533, XP019422513, ISSN: 1432-0851, DOI: 10.1007/S00262-006-0157-3 abstract page 1527, left-hand column, paragraph 1 page 1531, left-hand column, line 1 - right-hand column, line 3 ----- -/--	16,17, 19,36-41

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2013/053377

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	SUTMULLER R P M ET AL: "SYNERGISM OF CYTOTOXIC T LYMPHOCYTE-ASSOCIATED ANTIGEN 4 BLOCKADE AND DEPLETION OF CD25+ REGULATORY T CELLS IN ANTITUMOR THERAPY REVEALS ALTERNATIVE PATHWAYS FOR SUPPRESSION OF AUTOREACTIVE CYTOTOXIC T LYMPHOCYTE RESPONSES", THE JOURNAL OF EXPERIMENTAL MEDICINE, ROCKEFELLER UNIVERSITY PRESS, US, vol. 194, no. 6, 17 September 2001 (2001-09-17), pages 823-832, XP008040742, ISSN: 0022-1007, DOI: 10.1084/JEM.194.6.823 abstract page 824, left-hand column, paragraph 3 page 829, left-hand column, paragraph 2 - right-hand column, paragraph 1; figure 8 -----	21-32, 42-48
X	MANGSBO SARA M ET AL: "Enhanced Tumor Eradication by Combining CTLA-4 or PD-1 Blockade With CpG Therapy", JOURNAL OF IMMUNOTHERAPY, LIPPINCOTT WILLIAMS & WILKINS, HAGERSTOWN, MD, US, vol. 33, no. 3, 1 April 2010 (2010-04-01), pages 225-235, XP009144370, ISSN: 1524-9557 abstract page 225, left-hand column, last paragraph - page 226, left-hand column, paragraph 1 page 229, right-hand column, paragraph 2 - page 231, left-hand column, paragraph 2 page 234, right-hand column, last paragraph -----	21-32, 42-48
X	R. HOUOT ET AL: "T-cell modulation combined with intratumoral CpG cures lymphoma in a mouse model without the need for chemotherapy", BLOOD, vol. 113, no. 15, 9 April 2009 (2009-04-09), pages 3546-3552, XP055097924, ISSN: 0006-4971, DOI: 10.1182/blood-2008-07-170274 abstract page 3547, right-hand column, last paragraph - page 3549, left-hand column, paragraph 1 ----- -/--	21-32, 42-48

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/053377

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	AHLERS JEFFREY D ET AL: "A push-pull approach to maximize vaccine efficacy: abrogating suppression with an IL-13 inhibitor while augmenting help with granulocyte/macrophage colony-stimulating factor and CD40L", PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES, NATIONAL ACADEMY OF SCIENCES, US, vol. 99, no. 20, 1 October 2002 (2002-10-01), pages 13020-13025, XP002489213, ISSN: 0027-8424, DOI: 10.1073/PNAS.192251199 abstract page 13021, right-hand column, last paragraph - page 13022, left-hand column, paragraph 1 page 13023, right-hand column, paragraph 2 -----	21-32, 42-48
A	BERZOFISKY JAY A ET AL: "Progress on new vaccine strategies for the immunotherapy and prevention of cancer", JOURNAL OF CLINICAL INVESTIGATION, AMERICAN SOCIETY FOR CLINICAL INVESTIGATION, US, vol. 113, no. 11, 1 June 2004 (2004-06-01), pages 1515-1525, XP002420765, ISSN: 0021-9738, DOI: 10.1172/JCI200421926 page 1515, right-hand column, paragraph 3 page 1522, left-hand column, paragraph 2 - paragraph 3 -----	21-32, 42-48
X,P	WO 2012/065164 A2 (UNIV PENNSYLVANIA [US]; INOVIO PHARMACEUTICALS INC [US]; WEINER DAVID) 18 May 2012 (2012-05-18) the whole document -----	1-20, 33-41
X,P	WO 2013/006050 A1 (ISA PHARMACEUTICALS B V [NL]; PLATENBURG GERARDUS JOHANNES [NL]; KREBB) 10 January 2013 (2013-01-10) the whole document -----	1-20, 33-41

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2013/053377

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2012065164 A2	18-05-2012	AU 2011325893 A1	30-05-2013
		CA 2817709 A1	18-05-2012
		CN 103314002 A	18-09-2013
		EA 201390689 A1	29-11-2013
		EP 2638055 A2	18-09-2013
		US 2013302361 A1	14-11-2013
		WO 2012065164 A2	18-05-2012

WO 2013006050 A1	10-01-2013	NONE	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2013/053377

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.:
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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-20, 33-41

PSMA polypeptides and there medical use for vaccination or therapy, either alone or in combination with PSA (and PSCA).

2. claims: 21-32, 42-48

Methods of enhancing the therapeutic effect of a vaccine for the treatment of a neoplastic disorder.
