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(71) Applicant (for all designated States except US): **GLAXO GROUP LIMITED** [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **CATCHPOLE, Ian, Richard** [GB/GB]; GlaxoSmithKline, Gunnels Wood Road, Stevenage, Hertfordshire SG1 2NY (GB). **PAPANICOLAOU, Irene** [GB/GB]; GlaxoSmithKline, Gunnels Wood Road, Stevenage, Hertfordshire SG1 2NY (GB).

(74) Agent: **LAWRENCE, Geoffrey, Mark, Prouse**; Glaxo-SmithKline, Corporate Intellectual Property CN925.1, 980 Great West Road, Brentford, Middlesex TW8 9GS (GB).

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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))
- of inventorship (Rule 4.17(iv))

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Previous Correction:

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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: NEW ADJUVANT

(57) Abstract: The present invention provides a novel adjuvant for polynucleotide vaccines, and in particular the present invention provides immunogenic compositions comprising a polynucleotide encoding an antigen capable of eliciting an immune response and an adjuvant comprising an immunostimulatory quantity of a gemini surfactant, or a derivative thereof. The invention further comprises polynucleotide vaccines that comprise, or are administered in association with, a composition that comprises a gemini surfactant compound. The polynucleotide vaccines of the present invention are vaccines that encode an antigen against which it is desired to generate an immune response, and in particular the polynucleotide vaccine may be a DNA vaccine. Also provided by the present invention is the use of gemini surfactants in the manufacture of a polynucleotide vaccine composition for the purpose of enhancing the immune response against the specific antigen that is encoded by the polynucleotide vaccine. Vaccine compositions, kits comprising separate polynucleotide composition and adjuvant compositions for separate or simultaneous administration, methods of manufacture of the vaccines and kits, and methods of treatment of individuals with the immunogenic compositions and vaccines of the present invention, are provided.

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INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K39/21 A61P31/14

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 practical, search terms used)

EPO-Internal, 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	WO 99/29712 A (SMITHKLINE BEECHAM PLC [GB]; CAMILLERI PATRICK [GB]; KREMER ANDREAS [G] 17 June 1999 (1999-06-17) page 1, line 1 - page 2, line 12 page 5, line 8 - line 11 claims; examples	1
X	WO 00/77032 A2 (SMITHKLINE BEECHAM PLC [GB]; UNIV CAMBRIDGE TECH [GB]; CAMILLERI PATRI) 21 December 2000 (2000-12-21) page 1, line 1 - page 2, line 13 claims; examples ----- -/--	1

☒ 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 document 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

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19/04/2007

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Rankin, Robert

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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.
X	WO 03/082809 A (GLAXO GROUP LTD [GB]; UNIV CAMBRIDGE TECH [GB]; CATHOLIC UNIVERSITY OF) 9 October 2003 (2003-10-09) page 1, line 6 - page 2, line 8 page 7, line 20 - line 23 claims; examples -----	1
A	MCGREGOR C ET AL: "Rational approach to the design of cationic gemini surfactants for Gene delivery" JOURNAL OF THE AMERICAN CHEMICAL SOCIETY, AMERICAN CHEMICAL SOCIETY, WASHINGTON, DC, US, vol. 123, no. 26, 2001, pages 6215-6220, XP002252235 ISSN: 0002-7863 abstract -----	1
A	CASTRO MARIANO ET AL: "Effect of chain length on transfection properties of spermine-based gemini surfactants." ORGANIC & BIOMOLECULAR CHEMISTRY 7 OCT 2004, vol. 2, no. 19, 7 October 2004 (2004-10-07), pages 2814-2820, XP002420561 ISSN: 1477-0520 -----	1
P,X	WO 2006/053783 A (GLAXO GROUP LTD [GB]; CASTRO MARIANO JAVIER [GB]; KITSON CHRISTOPHER []) 26 May 2006 (2006-05-26) page 1, line 1 - line 7 page 7, line 31 - line 33 claims 16,17 -----	1-5,7,8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2006/006264

Box 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:

Although claim 11 is directed to a method of treatment of the human body, the search has been carried out and based on the alleged effects of the composition.
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 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:

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 fee, this Authority did not invite payment of any additional fee.
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.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2006/006264

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9929712	A	17-06-1999	CA 2312941 A1 17-06-1999 EP 1037903 A1 27-09-2000 JP 2001525419 T 11-12-2001 US 6693167 B1 17-02-2004
WO 0077032	A2	21-12-2000	AT 349419 T 15-01-2007 AU 5690400 A 02-01-2001 EP 1187806 A2 20-03-2002 JP 2003504311 T 04-02-2003 US 6835712 B1 28-12-2004
WO 03082809	A	09-10-2003	AU 2003217028 A1 13-10-2003 EP 1487788 A1 22-12-2004 JP 2005529860 T 06-10-2005 US 2006148734 A1 06-07-2006
WO 2006053783	A	26-05-2006	NONE