

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 March 2006 (30.03.2006)

PCT

(10) International Publication Number
WO 2006/033675 A3

(51) International Patent Classification:

C07K 16/12 (2006.01) G01N 33/569 (2006.01)
A61K 39/395 (2006.01) G01N 33/577 (2006.01)

(21) International Application Number:

PCT/US2005/016567

(22) International Filing Date: 11 May 2005 (11.05.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/570,798 12 May 2004 (12.05.2004) US

(71) Applicant (for all designated States except US): TETRA-CORE, INC. [US/US]; 11 Firstfield Road, Suite C, Gaithersburg, MD 20878 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): MANGOLD, Beverly, L. [US/US]; 734 College Parkway, Rockville, MD 20850 (US). ALDRICH, Jennifer, L. [US/US]; 3 West 9th Street, Frederick, MD 21701 (US).

(74) Agents: LAU, Kawai et al.; Townsend and Townsend and Crew LLP, 12730 High Bluff Drive, Suite 400, San Diego, CA 92130 (US).

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

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

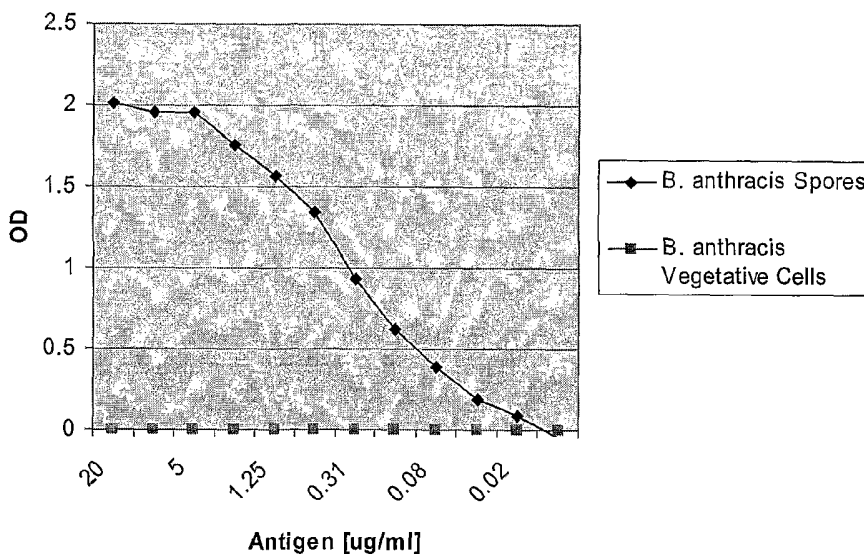
— with international search report

(88) Date of publication of the international search report:
18 May 2006

[Continued on next page]

(54) Title: BACILLUS ANTHRACIS SPORE SPECIFIC ANTIBODIES

Capture ELISA: 23a-14G9 Monoclonal Antibody



(57) Abstract: The invention relates to spore specific antibodies. Compositions and methods relating to the antibodies are provided along with the hybridomas that produce the antibodies. The antibodies are specific for the spores of *B. anthracis* relative to the vegetative form of the cells. The antibodies are also specific for the spores relative to other *Bacillus* spores and cells. The antibodies may be used to detect the presence of *B. anthracis* spores by use of methods provided herein. The invention also relates to articles of manufacture as well as kits comprising these antibodies which may be used in the detection methods of the invention.

WO 2006/033675 A3



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.

INTERNATIONAL SEARCH REPORT

national application No
PCT/US2005/016567

A. CLASSIFICATION OF SUBJECT MATTER
C07K16/12 A61K39/395 G01N33/569 G01N33/577

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)
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 practical, search terms used)
EPO-Internal, WPI Data, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DANG JESSICA L ET AL: "Bacillus spore inactivation methods affect detection assays" APPLIED AND ENVIRONMENTAL MICROBIOLOGY, vol. 67, no. 8, August 2001 (2001-08), pages 3665-3670, XP002366679 ISSN: 0099-2240 page 3666, column 1	1,3-5, 10-20
X	WO 03/103481 A (BIOSITE DIAGNOSTICS, INC) 18 December 2003 (2003-12-18) page 47 - page 54; examples 4,5 ----- -/--	1,3-5

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.
 - *Z* document member of the same patent family

Date of the actual completion of the international search 15 February 2006	Date of mailing of the international search report 27/02/2006
---	--

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 Bumb, P
---	-----------------------------------

INTERNATIONAL SEARCH REPORT

national application No
PCT/US2005/016567

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WILLIAMS DAVID D ET AL: "Surface layer protein EA1 is not a component of Bacillus anthracis spores but is a persistent contaminant in spore preparations." JOURNAL OF BACTERIOLOGY, vol. 186, no. 2, January 2004 (2004-01), pages 566-569, XP002366678 ISSN: 0021-9193 the whole document -----</p>	1-5, 10-20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/016567

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:

2. Claims Nos.: 6-9 (completely)
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 6-9 (completely)

The present claims 6-9 relate to an extremely large number of possible compounds. Support and disclosure in the sense of Article 6 and 5 PCT is to be found however for only a very small proportion of the compounds claimed, see examples 1 & 2. The non-compliance with the substantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search of claim 6-9 (PCT Guidelines 9.19 and 9.23).

As the present application fails to disclose the spore-specific antigen bound by the antibody of claim 1, no meaningful search could be carried out over any of the subject-matter covered by claims 6-9.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2005/016567

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 03103481 A	18-12-2003	AU 2003267935 A1	22-12-2003