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(71) Applicant (for all designated States except US): **THE TEXAS A & M UNIVERSITY SYSTEM** [US/US]; 3369 Tamu, College Station, TX 77843 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **HOOK, Magnus** [US/US]; 4235 Oberlin, Houtin, TX 77005 (US). **LA-BANDEIRA-REY, Maria** [US/US]; 4848 Pin Oak Park #339, Houston, TX 77081 (US). **BOWDEN, M., Gabriela** [US/US]; 111 Sixth Street, Sugar Land, TX 77478 (US).

(74) Agents: **SCHULMAN, B., Aaron** et al.; Stites & Harbison PLLC, 1199 North Fairfax Street, Suite 900, Alexandria, VA 22314 (US).

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6 November 2008

(54) Title: ANTIBODIES RECOGNIZING A HIGHLY EXPRESSED PUTATIVE ANTIGEN OF CA-MRSA AND METHODS OF USE

(57) Abstract: The present invention provides MSCRAMM® proteins from *S. aureus* which are putative highly-expressed antigens from methicillin-resistant *S. aureus*, including communit -associated MRSA (CA-MRSA), and these antigens can thus be utilized in methods of generating antibodies capable of binding these antigens which can be useful in methods of treating or preventing infection from MRSA. The present invention is directed to these proteins, antibodies capable of binding these proteins, methods of generating said antibodies, nucleic acids coding for said proteins, and pharmaceutical compositions or vaccines which include the proteins or antibodies of the present invention in combination with a pharmaceutically acceptable vehicle, carrier or excipient.



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A. CLASSIFICATION OF SUBJECT MATTER IPC: A61K 39/00(2006.01),39/38(2006.01),39/02(2006.01),39/085(2006.01),39/09(2006.01),38/00(2006.01),37/18,38/16(2006.01);C07K 1/00(2006.01),14/00(2006.01),17/00(2006.01) USPC: 424/184.1,190.1,234.1,237.1,243.1;514/2,8;530/350 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) U.S. : 424/184.1, 190.1, 234.1, 237.1, 243.1; 514/2, 8; 530/350 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) Please See Continuation Sheet		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
---	WO 02/094868 A2 (CHIRON SPA) 28 November 2002 (28.11.2002), see entire document.	-----
Y		1-4
X	HOLDEN, M.T.G. Complete genomes of two clinical Staphylococcus aureus strains: Evidence for the rapid evolution of virulence and drug resistance. PNAS. June 29, 2004, Vol 101, No. 26, pages 9786-9791, see entire document.	1, 4
X	BABA, T. Genome and virulence determinants of high virulence community-acquired MRSA. Lancet. 2002, Vol 359, pages 1819-1827, see entire document.	1, 4
X	KURODA, M. Whole genome sequencing of metticillin-resistant Staphylococcus aureus. Lancet. 2001, Vol 357, pages 1225-1240, see entire document.	1, 4
☒ 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	"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
"E"	earlier application or patent published on or after the international filing date	"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
"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)	"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
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search. 15 August 2008 (15.08.2008)		Date of mailing of the international search report 09 SEP 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer N. M. Minnifield Telephone No. 571-272-0500

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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	US 2003/0054436 A1 (KUNSCH et al) 20 March 2003 (20.03.2003) see entire document.	----- 1-4
--- Y	US 2004/0043037 A1 (KUNSCH et al) 04 March 2004 (04.03.2004), see entire document.	----- 1-4
--- Y, P	US 2007/0020746 A1 (KUNSCH et al) 25 January 2007 (25.01.2007), see entire document.	----- 1-4

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BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

Group I, claims 1-4, drawn to an antigen and composition.

Group II, claims 5-13, drawn to an antibody and composition.

Group III, claims 14-16, drawn to a kit and method.

Group IV, claim 17, drawn to a method of treating or preventing an MRSA infection comprising administering an antibody.

Group V, claim 18, drawn to a method of treating or preventing an MRSA infection comprising administering an antigen.

Group VI, claims 19 and 20, drawn to isolated nucleic acid.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of the claimed invention is the isolated antigen from methicillin-resistant *Staphylococcus aureus* (MRSA) comprising a protein selected from the group consisting of amino acid sequences SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 5, SEQ ID NO: 7, SEQ ID NO: 9, and SEQ ID NO: 11. HOLDEN et al (PNAS, June 29, 2004, 101/26:9786-9791) discloses SEQ ID NO: 1 and 3 of the claimed invention. The invention disclosed in this application lacks novelty, therefore the other claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept. Inasmuch as the technical feature does not define a contribution over the art, it is not "special" within the meaning of PCT Rule 13.2. Consequently, Groups I-VI lack unity of invention.

Continuation of B. FIELDS SEARCHED Item 3:

WEST, PALM, STIC/SEQUENCE SEARCH, NPL, PUBMED, SCIENCE DIRECT, MEDLINE, BIOSIS, AGRICOLA, CA, BIOTECHDS

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Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of:

a. type of material



a sequence listing



table(s) related to the sequence listing

b. format of material



on paper



in electronic form

c. time of filing/furnishing



contained in the international application as filed



filed together with the international application in electronic form



furnished subsequently to this Authority for the purposes of search

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

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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:
Please See Continuation 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 additional fees, this Authority did not invite payment of any 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.: 1-4

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.