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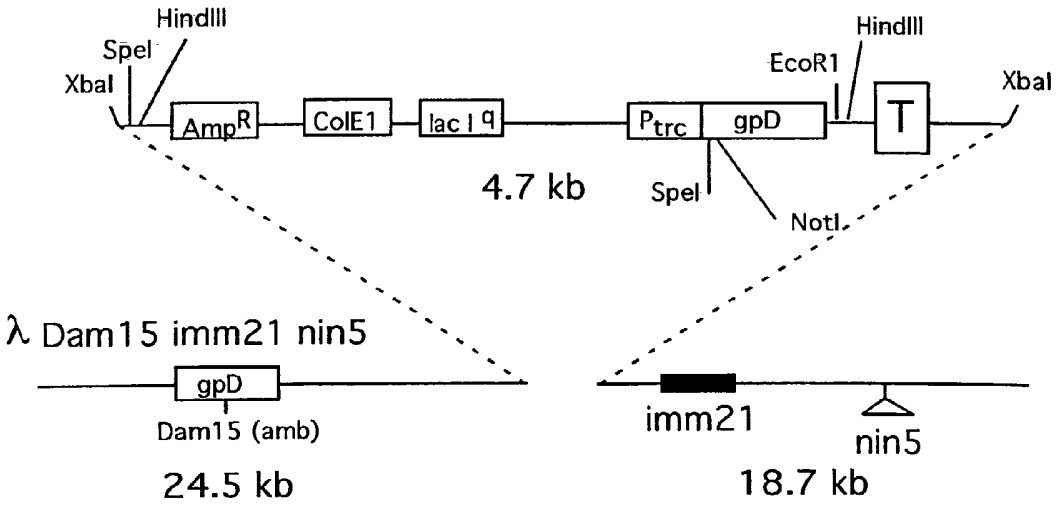
2 October 2003

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: IDENTIFICATION OF SPECIFIC TUMOUR ANTIGENS BY MEANS OF THE SELECTION OF CDNA LIBRARIES WITH SERA AND THE USE OF SAID ANTIGENS IN DIAGNOSTIC IMAGING TECHNIQUES



(57) Abstract: A method is described for the identification of specific tumour antigens by means of the selection of cDNA display libraries by using sera characterised in that said selection is accomplished with the phage display technique, and in particular said selection is accomplished by means of the SEREX technique (serological analysis of autologous tumour antigens through the expression of recombinant cDNA). The method according to the invention described herein advantageously combines the SEREX approach with the potency of the phage display technique defined above, at the same time avoiding the drawbacks characteristic of the SEREX technique.

WO 03/010199 A3

INTERNATIONAL SEARCH REPORT

Intern al Application No
PCT/IT 02/00491

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C07K14/47 C07K16/18 G01N33/574

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)
IPC 7 C07K C12N G01N

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)

BIOSIS, EPO-Internal, WPI Data, PAJ, SEQUENCE SEARCH, MEDLINE, CHEM ABS Data, EMBASE, EMBL

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	SIOUD MOULDY ET AL: "Profiling the immune response in patients with breast cancer by phage-displayed cDNA libraries." EUROPEAN JOURNAL OF IMMUNOLOGY, vol. 31, no. 3, March 2001 (2001-03), pages 716-725, XP002193380 ISSN: 0014-2980	1-3,5,6, 13
Y	relevant to invention 1 the whole document	4,10, 14-16,19
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in 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	Date of mailing of the international search report
8 January 2003	11. 02. 03

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, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Morawetz, R

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	SIOUD M ET AL: "Profiling the immune responses in patient sera with peptide and cDNA display libraries (review)." INTERNATIONAL JOURNAL OF MOLECULAR MEDICINE, vol. 6, no. 2, August 2000 (2000-08), pages 123-128, XP001062909 ISSN: 1107-3756	1-3,5,6, 13
Y	relevant to invention 1 the whole document	4,10, 14-16,19
X	JAEGER D ET AL: "IDENTIFICATION OF A TISSUE-SPECIFIC PUTATIVE TRANSCRIPTION FACTOR IN BREAST TISSUE BY SEROLOGICAL SCREENING OF A BREAST CANCER LIBRARY" CANCER RESEARCH, AMERICAN ASSOCIATION FOR CANCER RESEARCH, BALTIMORE, MD, US, vol. 61, no. 5, 1 March 2001 (2001-03-01), pages 2055-2061, XP001053562 ISSN: 0008-5472 relevant to invention 1 the whole document	6,10, 13-16
X	TURECI O ET AL: "SEROLOGICAL ANALYSIS OF HUMAN TUMOR ANTIGENS: MOLECULAR DEFINITION AND IMPLICATIONS" MOLECULAR MEDICINE TODAY, ELSEVIER, CAMBRIDGE, GB, vol. 3, no. 8, August 1997 (1997-08), pages 342-349, XP000985587 ISSN: 1357-4310	6
Y	relevant to invention 1 the whole document	10,13-16
X	SAHIN UGUR ET AL: "Human neoplasms elicit multiple specific immune responses in the autologous host." PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES, vol. 92, no. 25, 1995, pages 11810-11813, XP002193381 1995 ISSN: 0027-8424	6
Y	relevant to invention 1 the whole document	1-5,10, 13-16
X	OLD LLOYD J ET AL: "New paths in human cancer serology." JOURNAL OF EXPERIMENTAL MEDICINE, vol. 187, no. 8, 20 April 1998 (1998-04-20), pages 1163-1167, XP002193786 ISSN: 0022-1007	6
Y	relevant to invention 1 the whole document	1-5,10, 13-16

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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	MIKAWA Y G ET AL: "Surface display of proteins on bacteriophage lambda heads." JOURNAL OF MOLECULAR BIOLOGY, vol. 262, no. 1, 1996, pages 21-30, XP002203952 ISSN: 0022-2836	18
Y	relevant to invention 1 the whole document	19
Y	STERNBERG NAT ET AL: "Display of peptides and proteins on the surface of bacteriophage lambda." PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES, vol. 92, no. 5, 1995, pages 1609-1613, XP002203953 1995 ISSN: 0027-8424 relevant to invention 1 the whole document	18,19
Y	SANTINI CLAUDIA ET AL: "Efficient display of an HCV cDNA expression library as C-terminal fusion to the capsid protein D of bacteriophage lambda." JOURNAL OF MOLECULAR BIOLOGY, vol. 282, no. 1, pages 125-135, XP002203954 ISSN: 0022-2836 relevant to invention 1 the whole document	18,19
Y	YANG F ET AL: "NOVEL FOLD AND CAPSID-BINDING PROPERTIES OF THE LAMBDA-PHAGE DISPLAY PLATFORM PROTEIN GPD" NATURE STRUCTURAL BIOLOGY, NEW YORK, NY, US, vol. 3, no. 7, March 2000 (2000-03), pages 230-237, XP001063314 ISSN: 1072-8368 relevant to invention 1 the whole document	18,19
Y	WO 00 61790 A (MERRIL CARL R ;US HEALTH (US)) 19 October 2000 (2000-10-19) relevant to invention 1 example 1	18,19

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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	FOLGORI A ET AL: "SELECTION OF EPITOPES FROM PHAGE DISPLAYED PEPTIDE LIBRARIES BY USING HUMAN SERA: A NEW TOOL FOR THE IDENTIFICATION OF ANTIGENIC AND IMMUNOGENIC MIMOTOPES" FEMS SYMPOSIUM, ACADEMIC PRESS, LONDON, GB, 1994, pages 415-425, XP000652429 ISSN: 0163-9188 relevant to invention 1 the whole document ---	1-5
P,X	BEGHETTO ELISA ET AL: "Identification of a human immunodominant B-cell epitope within the GRA1 antigen of Toxoplasma gondii by phage display of cDNA libraries." INTERNATIONAL JOURNAL FOR PARASITOLOGY, vol. 31, no. 14, December 2001 (2001-12), pages 1659-1668, XP001063313 ISSN: 0020-7519 relevant to invention 1 page 1660, left-hand column, paragraph 3 -right-hand column, paragraph 1 ---	18,19
A	HALUSKA PAUL JR ET AL: "Interaction between human topoisomerase I and a novel RING finger/arginine-serine protein." NUCLEIC ACIDS RESEARCH, vol. 27, no. 12, 15 June 1999 (1999-06-15), pages 2538-2544, XP002193382 ISSN: 0305-1048 cited in the application relevant to invention 1 the whole document ---	8,10, 13-16
A	NAGASE T ET AL: "PREDICTION OF THE CODING SEQUENCES OF UNIDENTIFIED HUMAN GENES. XIX. THE COMPLETE SEQUENCES OF 100 NEW CDNA CLONES FROM BRAIN WHICH CODE FOR LARGE PROTEINS IN VITRO" DNA RESEARCH, UNIVERSAL ACADEMY PRESS, JP, vol. 7, no. 6, 31 December 2000 (2000-12-31), pages 347-355, XP001068355 ISSN: 1340-2838 see KIAA1735; relevant to invention 4 --- -/--	8,10, 13-16

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
P,A	DATABASE GENESEQ 'Online! 18 February 2002 (2002-02-18) DRMANAC RT, ET AL.,: "Novel human diagnostic protein #23359" Database accession no. ABG23368 XP002226213 relevant to invention 4 the whole document	8,10, 13-16
P,A	-& WO 01 75067 A (HYSEQ INC ;LIU CHENGHUA (US); TANG Y TOM (US); DRMANAC RODOJE T (U) 11 October 2001 (2001-10-11) the whole document	8,10, 13-16
P,A	WO 01 57209 A (NAHMIAS CLARA ;NOUET SANDRINE (FR); CENTRE NAT RECH SCIENT (FR); S) 9 August 2001 (2001-08-09) see hATIP3, hATIP6; relevant to invention 9	8,10, 13-16
A	NAGASE T ET AL: "PREDICTION OF THE CODING SEQUENCES OF UNIDENTIFIED HUMAN GENES XV. THE COMPLETE SEQUENCES OF 100 NEW CDNA CLONES FROM BRAIN WHICH CODE FOR LARGE PROTEINS IN VITRO" DNA RESEARCH, UNIVERSAL ACADEMY PRESS, JP, vol. 6, 1999, pages 337-345, XP002943288 ISSN: 1340-2838 see KIAA1288; relevant to invention 9	8,10, 13-16
P,A	DATABASE GENESEQ 'Online! 13 February 2002 (2002-02-13) DRMANAC RT, ET AL.,: "Novel human diagnostic protein #5905" Database accession no. ABG05914 XP002226214 relevant to invention 10 the whole document	8,10, 13-16
P,A	-& WO 01 75067 A (HYSEQ INC ;LIU CHENGHUA (US); TANG Y TOM (US); DRMANAC RODOJE T (U) 11 October 2001 (2001-10-11) the whole document	8,10, 13-16
A	KUSSEL-ANDERMANN POLONCA ET AL: "Vezatin, a novel transmembrane protein, bridges myosin VIIA to the cadherin-catenins complex." EMBO (EUROPEAN MOLECULAR BIOLOGY ORGANIZATION) JOURNAL, vol. 19, no. 22, 15 November 2000 (2000-11-15), pages 6020-6029, XP002226212 ISSN: 0261-4189 relevant to invention 13 the whole document	8,10, 13-16

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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.
P,A	WO 01 62783 A (MAO YUMIN ;XIE YI (CN); BIODOOR GENE TECHNOLOGY LTD SH (CN)) 30 August 2001 (2001-08-30) see SEQ ID NO: 2; relevant to invention 13	8,10, 13-16
A	ISHIKAWA K-I ET AL: "PREDICTION OF THE CODING SEQUENCES OF UNIDENTIFIED HUMAN GENES X. THE COMPLETE SEQUENCES OF 100 NEW CDNA CLONES FROM BRAIN WHICH CAN CODE FOR LARGE PROTEINS IN VITRO" DNA RESEARCH, UNIVERSAL ACADEMY PRESS, JP, vol. 5, 1998, pages 169-176, XP002943574 ISSN: 1340-2838 see KIAA0697; relevant to invention 14	8,10, 13-16
T	DATABASE GENESEQ 'Online! 22 August 2002 (2002-08-22) BIRSE, CE ET AL.,: "Human ovarian antigen HE8MH38, SEQ ID NO:2829" Database accession no. ABP41697 XP002226215 relevant to invention 14 the whole document	
P,A	& WO 02 00677 A (HUMAN GENOME SCIENCES INC ;ROSEN CRAIG A (US); BIRSE CHARLES E (US) 3 January 2002 (2002-01-03)	8,10, 13-16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IT 02/00491

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 8,12
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 II Observations where unity of invention is lacking (Continuation of item 2 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 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.:

inventions 1, 4, 9, 10, 13 and 14

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

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

Invention 1: claims 1-7,
18 and 19 (all completely), 8, 10,
12-16 (all partially)

1.1. Claims: 1-7 (all completely), 10,
12-16 (all partially)

Method for the identification of specific tumour antigens; tumour antigens; and subject-matter related thereto.

1.2. Claim : 18 and 19
Expression/display vector (lambdaKM4), and subject-matter related thereto.

1.3. Claims: 8, 10, 12-16 (all partially)
Use as a tumor antigen of the sequence or of the entire or part of the product of the gene encoding for said sequence selected from the group consisting of T1-52; and subject-matter related thereto.

Inventions 2-16: claims 8, 10,
12-16 (all partially)

Use as a tumor antigen of the sequence or of the entire or part of the product of the gene encoding for said sequence selected from the group consisting of T5-8(Invention 2) to T5-19 (Invention 16); and subject-matter related thereto.

Inventions 17 and 18: claims 9-17 (all partially)

Use of the antigen or of the entire or part of the product of the gene encoding for said sequence selected from the group consisting of T6-1 (Invention 17) and T1-17 (Invention 18) as a breast cancer tumour antigen; and subject-matter related thereto.

Please note that all inventions mentioned under item 1, although not necessarily linked by a common inventive concept, could be searched without effort justifying an additional fee.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 8,12

Present claim 8 relates to a compound defined by reference to a desirable characteristic or property, namely to be the entire or part of the product of the gene encoding for a given antigen sequence.
The claim covers the use of all compounds having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such compounds. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claim also lacks clarity (Article 6 PCT). An attempt is made to define the compound by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claim which appear to be clear, supported and disclosed, namely those parts relating to the specific antigen sequences.

Present claim 12 relates to a product defined by reference to a desirable characteristic or property, namely to be a specific ligand of an antigen of claims 6-7. The claim covers all products having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for none of such products. In the present case, the claim so lacks support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claim also lacks clarity (Article 6 PCT). An attempt is made to define the product by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Claims 14-16 relate inter alia to the use of the ligand of claim 12. Consequently, the search has been carried out for those parts of claims 14-16 which appear to be clear, supported and disclosed, namely those parts relating to the use of an antibody or antigen.

The applicant's attention is drawn to the fact that claims, or parts of 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.

INTERNATIONAL SEARCH REPORT

Interi al Application No
PCT/IT 02/00491

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INTERNATIONAL SEARCH REPORT

Inter nal Application No
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