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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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(88) Date of publication of the international search report:
23 August 2007

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: RECOMBINANT METHOD FOR THE PRODUCTION OF A MONOCLONAL ANTIBODY TO CD52 FOR THE TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA

(57) Abstract: The present invention relates to the recombinant method used for the production of soluble form monoclonal antibody that binds to CD52. The procedure describes the de novo synthesis of the nucleic acid sequence encoding anti-CD 52, transformation of the constructed nucleic acid sequences into competent bacteria and the sub-cloning of the same into mammalian expression vectors for expression of the desired protein. DNA constructs comprising the control elements associated with the gene of interest has been disclosed. The nucleic acid sequence of interest has been codon optimized to permit expression in the suitable mammalian host cells.



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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2006/001356

A. CLASSIFICATION OF SUBJECT MATTER

INV. C07K16/28
ADD. A61K39/395

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>HUTCHINS J T ET AL: "Improved biodistribution, tumor targeting, and reduced immunogenicity in mice with a gamma4 variant of Campath-1H" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, NATIONAL ACADEMY OF SCIENCE, WASHINGTON, DC, US, vol. 92, December 1995 (1995-12), pages 11980-11984, XP002234019 ISSN: 0027-8424 page 11980 figure 4 table 1 page 11983 - page 11984</p> <p style="text-align: center;">----- -/--</p>	1,6-9

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

3 May 2007

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21/05/2007

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2006/001356

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	RIECHMANN L ET AL: "RESHAPING HUMAN ANTIBODIES FOR THERAPY" NATURE, NATURE PUBLISHING GROUP, LONDON, GB, vol. 332, no. 6162, 24 March 1988 (1988-03-24), pages 323-327, XP000020414 ISSN: 0028-0836 cited in the application figure 1 pages 324-325	1,6-8
X	HALE G ET AL: "REMISSION INDUCTION IN NON-HODGKIN LYMPHOMA WITH RESHAPED HUMAN MONOCLONAL ANTIBODY CAMPATH-1H" LANCET THE, LANCET LIMITED. LONDON, GB, vol. 2, no. 8625, 17 December 1998 (1998-12-17), pages 1394-1399, XP009028211 ISSN: 0140-6736 the whole document	8,9
X	GILLILAND L K ET AL: "Elimination of the Immunogenicity of Therapeutic Antibodies" JOURNAL OF IMMUNOLOGY, THE WILLIAMS AND WILKINS CO. BALTIMORE, US, vol. 162, 1999, pages 3663-3671, XP002212906 ISSN: 0022-1767 page 3664 page 3666 - page 3670	8,9
A	MONE ANDREW P ET AL: "ALEMTUZUMAB INDUCES CELL DEATH IN HUMAN CHRONIC LYMPHOCYTIC LEUKEMIA CELLS THROUGH A LIPID RAFT-DEPENDENT MECHANISM" BLOOD, W.B.SAUNDERS COMPANY, ORLANDO, FL, US, vol. 104, no. 11, 7 December 2004 (2004-12-07), page 687A, XP008077237 ISSN: 0006-4971 abstract	1
A	NISHIURA HIROSHI ET AL: "S19 ribosomal protein dimer augments metal-induced apoptosis in a mouse fibroblastic cell line by ligation of the C5a receptor." JOURNAL OF CELLULAR BIOCHEMISTRY 15 FEB 2005, vol. 94, no. 3, 15 February 2005 (2005-02-15), pages 540-553, XP002430858 ISSN: 0730-2312 page 540, column 1, last paragraph	7
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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2006/001356

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>LIM L H ET AL: "High-level expression of a codon optimized recombinant dust mite allergen, Blo t 5, in Chinese hamster ovary cells" BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, ACADEMIC PRESS INC. ORLANDO, FL, US, vol. 316, no. 4, 16 April 2004 (2004-04-16), pages 991-996, XP004496886 ISSN: 0006-291X the whole document</p> <p style="text-align: center;">-----</p>	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2006/001356

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.: 2-5, 8
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.: 2-5,8

The International Search Authority has not carried out a search with respect to the subject-matter relating to SEQ ID NOs: 1-4 (claims 2-5), as the relevant late filing fee has not been furnished .

The subject-matter of claim 8 refers to a vector construct as depicted in the figures, but then fails to define as to which figure is meant. It is thus not possible to discern what this technical feature is supposed to be. Consequently, the search with respect to the subject-matter of claim 8 cannot be carried out.

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.