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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.



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(54) Title: COMPOSITIONS AND METHODS FOR THE THERAPY AND DIAGNOSIS OF KIDNEY CANCER

(57) Abstract: Compositions and methods for the therapy and diagnosis of cancer, particularly kidney cancer, are disclosed. Illustrative compositions comprise one or more kidney tumor polypeptides, immunogenic portions thereof, polynucleotides that encode such polypeptides, antigen presenting cell that expresses such polypeptides, and T cells that are specific for cells expressing such polypeptides. The disclosed compositions are useful, for example, in the diagnosis, prevention and/or treatment of diseases, particularly kidney cancer.

INTERNATIONAL SEARCH REPORT

International application No.

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A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 1/68; G01N 33/53; C07K 14/00, 16/00
 US CL : 435/6, 7.1; 530/350, 387.1

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. : 435/6, 7.1; 530/350, 387.1

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.
X	Database SPTREMBL_19, Accession number BAA95969. October 2000.	14
X	Database NCBI, Accession number BAA95969. February 2001.	14
X	Database Geneseq, Accession Number AAY94990, SEQ ID NO 20 from WO 00/11015. 02 March 2000.	14
X	WO 00/11015 (ALPHAGENE, INC.) 02 March 2000, see especially SEQ ID NO 20, pages 33, 189-194, 201-203, 204-209.	1-2, 4-5, 7, 9-10, 14, 17-18, 22(a), 22(c)-(d), 24

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 application or patent 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

24 September 2002 (24.09.2002)

Date of mailing of the international search report

30 OCT 2002

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

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Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claim 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. Claim 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:
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 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.: 1-2, 4-5, 7, 9-10, 14, 17-18, 22(a), 22(c-d), and 24, SEQ ID NO 1852
- Remark on Protest**
- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Groups 1-1855, claim(s) 1-2, 4-5, 7, 9-10, 14, 17-18, 22(a), 22(c-d), and 24 in part, drawn to polypeptides, antibodies that bind to them, fusion proteins, methods for detecting the presence of cancer in a patient comprising contacting the sample with a binding agent that selectively binds to a polypeptide encoded by one of the polynucleotides in the claim, methods for stimulating an immune response with polypeptides or antibodies, and methods of treating cancer with polypeptides or antibodies. It is noted that Groups 1-1855 correspond to the polynucleotides listed in the claims, in the order they are listed. Therefore the first mentioned invention is the methods and products of the claims to the extent that they apply to SEQ ID NO 1852. Group 1, the first mentioned invention, is the invention which will be searched in accordance with PCT Article 17(3)(a). Additional groups may be elected. For example, if Group 2 is elected, and the proper fees are paid, then the claims will be searched to the extent that they apply to methods and products using a polypeptide encoded by SEQ ID NO 1. Upon election of an invention to be searched in addition to group 1, please identify the SEQ ID NO to be searched.

Groups 1856-3710, claims 3, 8, 12-13, 15-16, 19, 22(b), and 23, in part drawn to polynucleotides, vectors and host cells, and methods of stimulating an immune response, methods of diagnosing cancer, and methods for the treatment of cancer using the polynucleotides recited in the claims. It is noted that Groups 1856-3710 correspond to the polynucleotides listed in the claims, in the order they are listed. Therefore the first mentioned invention is the methods and products of the claims to the extent that they apply to SEQ ID NO 1852, which will be searched if group 1856 is elected. Upon election of one or more inventions in this group, please specify the SEQ ID NO requested for search.

Groups 3711-5566, claims 6, 11, and 22(f) drawn to antigen presenting cells that express a polypeptide and a method of stimulating an immune response and methods of treating cancer using the antigen presenting cells. It is noted that groups 3711-5566 correspond to the polynucleotides listing in the claims in the order they are listed. Therefore the first mentioned invention is the methods and products of the claims to the extent that they apply to SEQ ID NO 1852, which will be searched if group 3711 is elected. Upon election of one or more inventions in this group, please specify the SEQ ID NO requested for search.

Groups 5567-7421, claims 20-21, 22(e) and 25 drawn to a method for stimulating T cells, a T cell population, and a method of treating kidney cancer using T cells. It is noted that groups 5567-7421 correspond to the polynucleotides listing in the claims in the order they are listed. Therefore the first mentioned invention is the methods and products of the claims to the extent that they apply to SEQ ID NO 1852, which will be searched if group 7421 is elected. Upon election of one or more inventions in this group, please specify the SEQ ID NO requested for search.

The inventions listed as Groups 1-5566 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 first claimed invention, claims 1-2, 4-5, 7, 9-10, 14, 17-18, 22(a), 22(c-d), and 24 (Groups 1-1855) lack unity because they represent nucleic acids which have different structures and functions depending on the nucleic acid present in the sample and have a different special technical feature. That is, depending on the nucleic acid present, the special technical feature of each part of the invention would be the specific SEQ ID NO of the nucleic acid listed in the claims. Since these nucleic acids have different structures and functions, they lack unity with one another. Accordingly, the claims have been separated into a number of groups corresponding to the number of different inventions encompassed by the claims, and the claims will be searched only as they read upon the invention of the elected group. For the same reasons, the remainder of the claims have been separated in a number of groups corresponding to the number of different inventions encompassed thereby.

The groups comprising polynucleotides (Groups 1856-3710), polypeptides (1-1855), antigen presenting cells (3711-5566) and T cells (5567-7421) are additionally drawn to multiple, distinct products lacking the same or corresponding special technical features. The nucleic acids are composed of nucleotides and function in, e.g., methods of nucleic acid hybridization or amplification. These groups are directed to different combinations of nucleic acids which are different from one another and may be employed in different methods. The polypeptides differ in both structure and function from either the nucleic acids, the antigen presenting cells, or the T cells. The polypeptides are composed of amino acids linked by peptide bonds and arranged in a complex combination of alpha helices, beta pleated sheets, hydrophobic and hydrophilic domains. The antigen presenting cells are made up of complex biological systems and have different functions than either the nucleic acids or polypeptides. The T cells are also made up of complex biological systems, but they have different structural features than the antigen presenting cells and have different functions than either the antigen presenting cells, the polynucleotides or the polypeptides. Accordingly, the products differ structurally and functionally from one another. As products of

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different sets of Groups differ from each other in structure, function, and effect, they do not belong to a recognized class of chemical compound, or have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature".

Continuation of B. FIELDS SEARCHED Item 3:

STN, Medline, Caplus, Genbank, West

SEQ ID NO 1852

search terms: cancer, kidney, renal, KIAA1445