Title: COMPOSITIONS AND METHODS FOR THE TREATMENT OF IMMUNE RELATED DISEASES

Abstract: The present invention relates to compositions containing novel proteins and methods of using those compositions for the diagnosis and treatment of immune related diseases.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
   IPC: C07K 17/00 07 K 17/00
   USPC: 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.: 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>National Institutes of Health Mammalian Gene Collection; NIH_MGC_107; contains sequence, lab host, vector.</td>
<td>1-6</td>
</tr>
</tbody>
</table>

☐ 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

  "I" 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
15 August 2006 (15.08.2006)

Date of mailing of the international search report
07 SEP 2006

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Form PCT/ISA/210 (second sheet) (July 1998)
INTERNATIONAL SEARCH REPORT

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.: 1-7, SEQ ID NOS: 1-2

Remark on Protest ☐ The additional search fees were accompanied by the applicant’s protest.  
☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet(1)) (July 1998)
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.

SECTION A: INVENTIVE GROUPS

Group I, claim(s) 1-7, drawn to an isolated nucleic acid having at least 80% identity to a nucleotide that encodes for a polypeptide of any one of SEQ ID NOs: 1-7589, the polypeptide having any one of SEQ ID NOs: 1-7589 and host cells, vectors.

Group II, claim(s) 8-9, drawn to chimeric molecules comprising a polypeptide having at least 80% amino acid sequence identity to any one of SEQ ID NOs: 1-7589 and a heterologous amino acid sequence.

Group III, claim(s) 10-11, drawn to antibodies that specifically bind to a polypeptide having at least 80% amino acid sequence identity any one of SEQ ID NOs: 1-7589.

Group IV, claim(s) 12-15, drawn to a composition of matter and kits comprising a polypeptide having at least 80% amino acid sequence identity any one of SEQ ID NOs: 1-7589, an agonist of said polypeptide, an antagonist of said polypeptide, or an antibody that binds to said polypeptide in combination with a pharmaceutically acceptable carrier.

Group V, claim(s) 16-17 and 25, drawn to a method of treatment comprising administration of a polypeptide having at least 80% amino acid sequence identity any one of SEQ ID NOs: 1-7589, an agonist of said polypeptide, an antagonist of said polypeptide, or an antibody that binds to said polypeptide.

Group VI, claim(s) 18, 20, drawn to a method of detection or diagnosis comprising contacting the sample with a polypeptide having at least 80% amino acid sequence identity any one of SEQ ID NOs: 1-7589.

Group VII, claim(s) 19, 22, 26, drawn to a method of diagnosis or screening comprising detecting the level of gene expression encoding a polypeptide having at least 80% amino acid sequence identity any one of SEQ ID NOs: 1-7589, wherein a higher or lower level of expression of said gene in the test sample as compared to the control sample is indicative of the presence of an immune related disease.

Group VIII, claim(s) 21, 24, drawn to a method of screening that inhibits or mimics the activity of a polypeptide having at least 80% amino acid sequence identity any one of SEQ ID NOs: 1-7589 in a cell, comprising contacting cells with a polypeptide having at least 80% amino acid sequence identity any one of SEQ ID NOs: 1-7589 or a candidate compound and determining the responsiveness of said cells to said candidate compound.

SECTION B: POLYPEPTIDES AND POLYNUCLEOTIDES

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

SEQ ID NOs: 1-7589, claimed in Groups 1-7

SECTION C: DISEASES OR DISORDERS

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

The disease/conditions recited in claim 17.

The inventions listed as Groups I-VIII 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: first, with respect to sections A and B, there are 7589 different polypeptides claimed in each of the Groups. Each polypeptide has a different primary structure and function; success with one does not guarantee success with another. There are eight inventive Groups total so that equals 60,712 possible different inventions (each possible polypeptide multiplied by the total number of inventive groups). Second, under PCT rules, the Applicant is entitled to the examination of the first claimed product, the first claimed method of making the product and the first claimed method of using said product. With the proviso that Applicant elects one of the 7569 different species of polypeptide, Group I encompasses the first claimed product and method of making said product. Group II is drawn to a chimeric molecules comprising a polypeptide having at least 80% sequence identity to any one of SEQ ID NOs: 1-7589 and a heterologous amino acid, thus represents inventions 7590-15,179. Group III is drawn to a composition of matter and kits comprising a polypeptide having at least 80% sequence identity to any one of SEQ ID NOs: 1-7589, an agonist of said polypeptide, an antagonist of said polypeptide, or an antibody that binds to said polypeptide, thus represent inventions 15,180-22,768. Group IV is drawn to compositions and kits having at least 80% amino acid sequence identity to any one of SEQ ID NOs: 1-7589, an agonist of said polypeptide, an antagonist of said polypeptide or an antibody that binds to said polypeptide, thus represents inventions 22,769-30,357. Group V is drawn to a method of treatment comprising administration of a polypeptide having at least 80% amino acid sequence identity to any one of SEQ ID NOs: 1-7589, thus represent inventions 30,358-37,946. Group VI is drawn to a method of detection or diagnosis comprising contacting a sample with a polypeptide having 80% sequence identity to any one of SEQ ID NOs: 1-7589, thus represent inventions 37,947-45,535. Group VII is drawn to a method of diagnosis or screening comprising detecting the level of gene expression encoding a polypeptide having at least 80% sequence identity to any one of SEQ ID NOs: 1-7589, thus represent inventions 45,536-52,124. Group VIII is drawn to a method of screening of a compound that inhibits or mimics the polypeptide having at least 80% sequence identity to any one of SEQ ID NOs: 1-7589, thus represents inventions 53,125-60,712.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: with respect to section C, Diseases or Disorders, the diseases recited in claim 17 represents different diseases with different etiologies and in many cases, different patient populations, success with one does not guarantee success with another.