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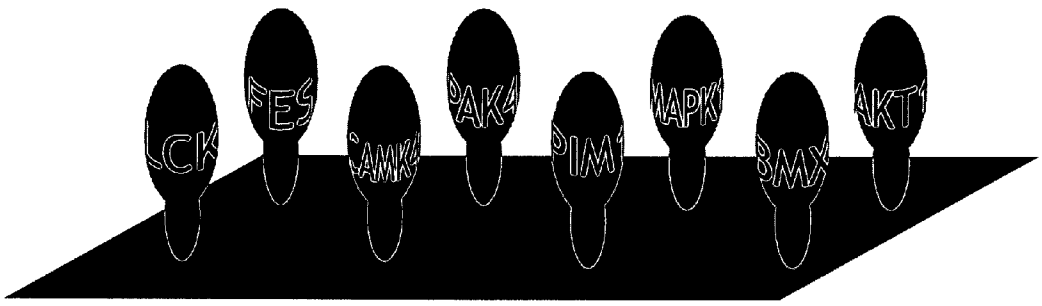
[Continued on next page]

(54) Title: AUTO-ANTIBODY MARKERS OF AUTOIMMUNE DISEASE

Figure 1



(57) Abstract: The present invention encompasses auto-antibodies associated with autoimmune disorders. The auto-antibodies may be used, for example, in methods of treating patients, methods of diagnosing patients, methods of monitoring disease progression of patients, and methods of prognosing patients.

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IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/62639

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - C12N 5/06;C12N 5/16 (2008.04)
USPC - 435/327-328
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)
USPC- 435/327-328

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC- 435/7.1; 435/69.51; 435/320.1; 435/325; 514/12; 514/44; 350/351; 536/23.5 (see search terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST: DB=PGPB,USPT,USOC,EPAB,JPAB: Google: Scholar/patents: auto-antibodies antigens autoimmune ifn inducible genes

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,333,032 B1 (SKURKOVICH et al.) 25 December 2001 (25.12.2001) col 4, ln 15-25, ln 34-43; col 6, ln 17-21; col 7, ln 7-11, ln 16-30; col 8, ln 1-3, ln 22-35; col 9, ln 1-8, ln 15-21, ln 27-32; col 10, ln 53-64; col 11, ln 1-3; col 12, ln 10-15; Table 1; col 17, ln 61-67; col 23, ln 4-7; col 29, ln 11-35; col 30, ln 20-26	1-30, 54-89
Y	US 2005/0261215 A1 (GARREN et al.) 24 November 2005 (24.11.2005) para [0080], [0087], [0090]	1-30, 54-89
Y	US 2007/0092890 A1 (ABBAS et al.) 26 April 2007 (26.04.2007) para [0142], [0171], [0177], [0179], [0183]	3, 19-27, 60-61, 81-89
Y	Medimmune, Inc. MedImmune Expands Anti-Interferon-Alpha Program By Initiating Phase 1 Trial In Patients With Psoriasis. Medical News Today, 24 March 1997, para 1	6, 66-67

☐ Further documents are listed in the continuation of Box C. ☐

* 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 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
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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: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/62639

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.

Group I, claims 1-30, 54-89, drawn to a method of treating a patient having a type I IFN or IFNalpha-related autoimmune disorder by
-- administering an agent that binds to and modulates type I IFN or IFNalpha activity, said patient having the autoimmune disorder comprises autoantibodies that bind auto-antigens of:
(a) Myxovirus (influenza virus) resistance 1, interferon-inducible protein p78; and
(b) surfeit 5, transcript variant c.

Group II+, claims 1-30, 54-89, drawn to a method of treating a patient having a type I IFN or IFNalpha-related autoimmune disorder by
-- administering an agent that binds to and modulates type I IFN or IFN alpha activity, said patient having the autoimmune disorder comprises autoantibody that binds to at least any two of the claimed auto-antigens. Due to the combinatorial nature, said claims contain an exponential number of species because they are directed to a multiplicity of possible combinations the autoantibodies. Applicant is required to make a specific selection of the autoantibodies should additional examination fees be paid.

Group III+, claims 31-37, 50-53, 90-101, 124-136, drawn to a method of diagnosing a patient as having a type I IFN or IFNa-related autoimmune disorder by
-- detecting presence or absence of auto-antibodies in a sample of a patient; wherein the auto-antibodies bind at least any two of the claimed auto-antigens. Applicant is required to make a specific selection of the autoantibodies should additional examination fees be paid.

Group IV+, claims 38-49, 102-117, drawn to a method of monitoring the disorder progression by
-- detecting presence or absence of auto-antibodies in a first sample from a patient; wherein the auto-antibodies bind at least any two of the claimed auto-antigens;
-- administering a therapeutic agent that binds to and modulates type I IFN or IFNalpha activity;
-- identifying the auto-antibodies in the second sample from the patient;
-- comparing the first and the second samples. Applicant is required to make a specific selection of the autoantibodies should additional examination fees be paid.

The inventions listed as Groups I-IV+ 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 technical features for the following reasons:

Groups I and II+ do not include the inventive concept of diagnosing a patient as having a type I IFN or IFN alpha-related autoimmune disorder by detecting presence or absence of auto-antibodies in a sample of a patient, as required by Group III+; while Group III+ does not include the inventive concept of treating a patient having a type I IFN or IFN alpha-related autoimmune disorder by administering an agent that binds to and modulates type I IFN or IFN alpha activity.

As to Groups III+ and IV+, Group III+ does not include the inventive concept of
-- administering a therapeutic agent that binds to and modulates type I IFN or IFNalpha activity;
-- comparing the first and the second samples obtained before and after administering said therapeutic agent, as required by Group IV+.

As to Groups I and II+, each separate species of the auto-antigens is lacking unity of invention with the others because said autoantibody do not share a significant structural element that is essential to the common property or activity and is an improvement over the prior art.

Similarly, each separate species of the auto-antigens of Groups III+ and IV+ is lacking unity of invention with the others.

Groups I-IV+ therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

NOTE:

Claims 118-123 are not drafted in accordance with the second and third sentences of Rule 6.4 (a). These claims are improper multiple dependent claims.