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1 November 2007

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(54) Title: A METHOD FOR DIAGNOSIS AND PROGNOSIS OF MULTIPLE SCLEROSIS SUBTYPES

(57) Abstract: This invention provides methods of assessing autoantibodies to specific epitopes of myelin components (e.g. to conformational epitope of myelin/oligodendrocyte glycoprotein) for the diagnosis and/or prognosis of multiple sclerosis.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/15198

Box No. 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.:
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. ☐ 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 No. 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:
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 additional fees, this Authority did not invite payment of any additional fees.
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.: 1-9

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/15198

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8): **G01N 33/53**(2006.01)

USPC: 435/7.1
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. : 435/7.1

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)
EAST, Pubmed, Dialog

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	MENGE, T. Detection of Anti-Galactocerbroside Antibodies by a New Assay That is Specific for Patients With Multple Sclerosis: P06.066. Neurology 62(7) Supplement S5, April 2004, p A482	1-9
X	MENGE T. Time course of antibody responses to myelin proteins and galactocerebroside in marmoset experimental allergic encephalomyelitis and multiple sclerosis. Annals of Neurology 2003 54(suppl 7), p. S38	1,6-8
P	MENGE T. Antibody responses against galactocerebroside are potential stage-specific biomarkers in multiple sclerosis. J Allergy Clin Immunol 2005 116:453-459. Available online May 16 2005.	1-8

☐ 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

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INTERNATIONAL SEARCH REPORT

International application No.
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BOX III. 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.

Group 1, claim(s) 1 - 9, drawn to methods comprising detecting antibodies that bind to galactocerebroside.

Group 2, claim(s) 10 - 36, drawn to methods comprising detecting antibodies that bind to MOG.

The inventions listed as Groups 1-2 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:

Group 1 is directed to methods comprising detection of antibodies that bind galactocerebreside (alpha-GalC) for diagnosis of multiple sclerosis. However, because Menge (2004. Neurology 62(7) Supplement S5:A482) teaches detection of alpha-GalC for diagnosis of multiple sclerosis, no special technical feature exists for Group 1 as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Furthermore, Group 2 does not share the same technical feature as Group 1, as Group 2 requires detection of antibodies that bind MOG whereas Group 1 requires detection of antibodies that bind GalC. The technical features of Groups 1 and 2 are drawn to methods which require different starting materials and as such do not share the same or corresponding technical feature. Note that PCT Rule 13 does not provide for multiple products or methods within a single application. Because the technical feature of Group 1 is not a special technical feature and because Groups 1 and 2 do not share the same or corresponding technical feature, unity of invention is lacking.