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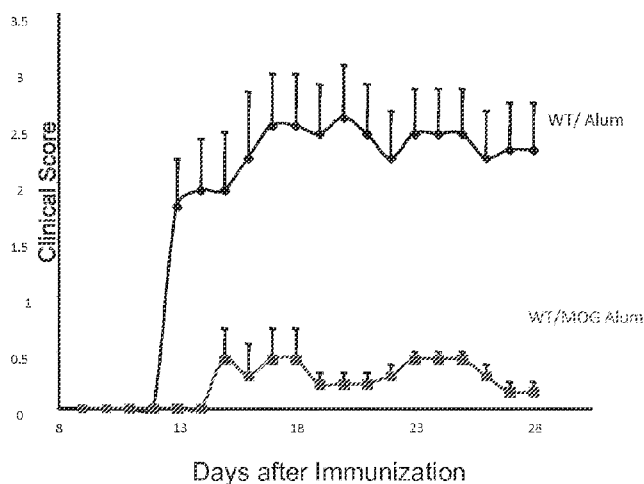
- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
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(88) Date of publication of the international search report:

4 December 2014

(54) Title: COMPOSITIONS AND METHODS FOR TREATING AUTOIMMUNE DISEASES

FIG. 1



(57) Abstract: The present invention provides compositions comprising immunologically effective amounts of one or more autoimmune disease associated antigens or antigenic fragments or derivatives thereof and one or more Th2 promoting adjuvants. The compositions may optionally comprise one or more Th2 promoting TLR2 ligands. The invention further provides methods of treating or preventing an autoimmune disease, such as multiple sclerosis, comprising administering to a subject in need thereof an immunologically-effective amount of an autoimmune disease associated antigen, a Th2 promoting adjuvant and optionally one or more Th2 promoting TLR2 ligands which overall causes re-routing of the harming immune cells to places where they can be of no harm.

INTERNATIONAL SEARCH REPORT

014/024615 19.09.2014

International application No.

PCT/US14/24615

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 39/00 (2014.01)

USPC - A61K 39/00

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)

IPC(8): A61K 39/00 (2014.01)

USPC: 424/185.1, 184.1, 130.1; CPC: A61K 38/00, 39/00; C07K 2319/00

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)

MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); Google Scholar; Pubmed; ScienceDirect; composition, antigen, adjuvant, 'MOG,' 'Th2,' 'multiple sclerosis'

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	SINHA, S et al. A Promising Therapeutic Approach For Multiple Sclerosis: Recombinant T-Cell Receptor Ligands Modulate Experimental Autoimmune Encephalomyelitis By Reducing Interleukin-17 Production And Inhibiting Migration Of Encephalitogenic Cells Into The CNS. Journal of Neuroscience. 14 November 2007; Vol. 27, No. 46; pages 12531-12539; abstract; page 12532, right column, first paragraph; page 12535, Table 1.	1, 3-5, 11-14 ----- 2, 6/1-6/5, 15/11-15/14
Y	ROMAGNANI, S. The Th1/Th2 Paradigm. Immunology Today. June 1997; Vol. 18, No. 6; pages 263-266. page 263, left column, first paragraph.	1-6, 11-15
Y	JIANG, Z. MOG35-55 i.v Suppresses Experimental Autoimmune Encephalomyelitis Partially Through Modulation Of Th17 And JAK/STATs Pathways. European journal of Immunology. March 2009, Vol. 39, No. 3; pages 789-799; page 789, second paragraph. DOI:10.1002/eji.200838427.	3-5, 6/3-6/5
Y	SHAKYA, A. Adjuvant Properties Of A Biocompatible Thermo-Responsive Polymer Of N-Isopropylacrylamide In Autoimmunity And Arthritis. J. R. Soc. Interface. 07 December 2011, Vol. 8, No. 65; pages 1748-1759; abstract; page 1751, right column, first paragraph. DOI: 10.1098/rsif.2011.0114.	6/1-6/5, 15/11-15/14

☐ 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

05 September 2014 (05.09.2014)

Date of mailing of the international search report

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Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

014/024615 19.09.2014

International application No.

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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.: 7-10, 16-19
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 Supplemental Page-

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 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.:
Groups I+: Claims 1-4, 5 (in-part), 6 (in-part), 11-13, 14 (in-part), 15 (in-part), SEQ ID NO: 13

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.

Box No. 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.

Groups I+: Claims 1-6, 11-15 are directed toward a composition comprising an immunologically-effective amount of one or more autoimmune disease associated antigens or antigenic fragments or derivatives thereof and one or more Th2 promoting adjuvants, and a method of treating or preventing an autoimmune disease comprising administering to a subject in need thereof said composition.

The composition comprising an immunologically-effective amount of one or more autoimmune disease associated antigens or antigenic fragments or derivatives thereof and one or more Th2 promoting adjuvants, and a method of treating or preventing an autoimmune disease comprising administering to a subject in need thereof said composition will be searched to the extent that they encompass the autoimmune disease associated antigen is MOG35-55 mouse fragment (SEQ ID NO: 13) (autoimmune disease antigen MOG mouse fragment). It is believed that Claims 1-3, 4, 5 (in-part), 6 (in-part), 11, 12, 13, 14 (in-part) and 15 (in-part) encompass this first named invention and these claims will be searched without fee to the extent that they encompass SEQ ID NO: 13 (autoimmune disease antigen MOG mouse fragment). Applicants must specify the claims that encompass any additionally elected antigen sequences. Applicants must further indicate, if applicable, the claims which encompass the first named invention, if different than what was indicated above for this group. Failure to clearly identify how any paid additional invention fees are to be applied to the "+" group(s) will result in only the first claimed invention to be searched/examined. An Exemplary Election would be: SEQ ID NO: 14 (autoimmune disease antigen MOG human fragment).

Groups I+ share the technical features including a composition comprising an immunologically-effective amount of one or more autoimmune disease associated antigens or antigenic fragments or derivatives thereof and one or more Th2 promoting adjuvants and optionally one or more Th2 promoting TLR2 ligands; and a method of treating or preventing an autoimmune disease comprising administering to a subject in need thereof an immunologically-effective amount of one or more autoimmune disease associated antigens or antigenic fragments or derivatives thereof, one or more Th2 promoting adjuvants and optionally one or more Th2 promoting TLR2 ligands.

However, these shared technical features are previously disclosed by US 2007/0003542 A1 to Zimmerman, et al. (hereinafter 'Zimmerman'). Zimmerman discloses a composition (a composition; abstract) comprising an immunologically-effective amount (a pharmacologically effective composition (immunologically effective amount); paragraph [0016]) of one or more antigens for treating autoimmune disease (antigens for treating autoimmune disease (one or more antigens for treating autoimmune disease); abstract) and one or more Th2 promoting adjuvants (adjuvants promoting a T helper cell response, including a Th2 response (Th2 promoting adjuvants); abstract, paragraph [0115]); and a method of treating or preventing an autoimmune disease (a method of treating autoimmune disease; abstract, paragraph [0021]) comprising administering to a subject in need thereof (to a subject in need thereof; paragraph [0021]) an immunologically-effective amount (a pharmacologically effective composition (immunologically effective amount); paragraph [0016]) of one or antigens or antigenic fragments or derivatives thereof (of one or more antigens or antigenic fragments thereof; abstract, paragraph [0017]) and one or more Th2 promoting adjuvants (adjuvants promoting a T helper cell response, including a Th2 response (and one or more Th2 promoting adjuvants); abstract, paragraph [0115]). Zimmerman does not disclose wherein the antigens are autoimmune disease associated antigens. However, it would have been obvious to a person of ordinary skill in the art at the time of the invention, to have administered an antigen specifically associated with a disease, in order to provide effective treatment for or prevention of the disease, such as an autoimmune disease-associated antigen, for the effective treatment of an autoimmune disease, provided the previous disclosure of Zimmerman.

Since none of the special technical features of the Groups I+ inventions is found in more than one of the inventions, and since all of the shared technical features are previously disclosed by the Zimmerman reference, unity of invention is lacking.