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Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

Published:

- with international search report (Art. 21(3))
- with sequence listing part of description (Rule 5.2(a))

(88) Date of publication of the international search report:

27 December 2012

(54) Title: GLUCOCORTICOID INDUCED LEUCINE ZIPPER MIMETICS AS THERAPEUTIC AGENTS IN MULTIPLE SCLEROSIS

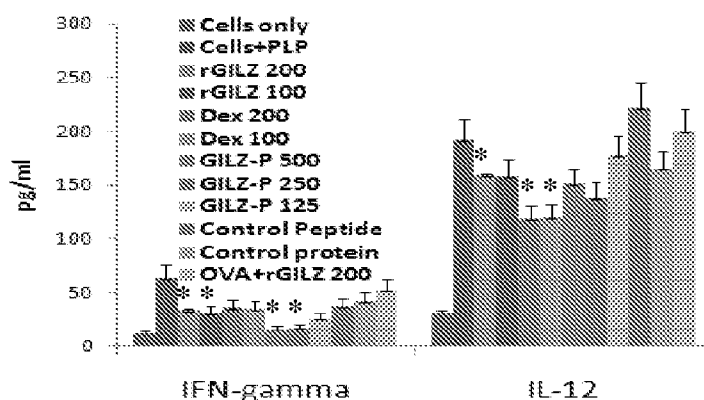


FIGURE 5

(57) Abstract: Polypeptide compositions that mimic the activity of glucocorticoid induced leucine zipper (GILZ) on the immune system are described. Also described is a method of treating multiple sclerosis using compositions comprising GILZ or lower molecular weight polypeptides with structural relationships to GILZ.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/26962

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(8) - A61K 38/10, A61K 38/00, A61K 38/16
 USPC - 514/21.4

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: 514/21.4; IPC: A61K 38/10, A61K 38/00, A61K 38/16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
 USPC: 530/326 (text search, see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 PubWEST -- PGPB,USPT,USOC,EPAB,JPAB; Dialog Classic Files -- 654, 652, 349, 348, 340, 35, 65, 155; USPTO Web Page; Google Scholar; Search terms -- PXXP peptide, polyproline helix, cell penetration peptide, PEP-1, Th-2 stimulation, carrier, powder, pharmaceutical formulation

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Ayrolidi et al. 'Glucocorticoid-induced leucine zipper (GILZ): a new important mediator of glucocorticoid action' The FASEB Journal (2009) vol 23 pg 3649-3658; pg 3654, col 1, para 2, Fig. 1	1, 2, 6-9, 18-20
Y	US 2004/0194160 A1 (RICCARDI) 30 September 2004 (30.09.2004) para [0030], [0051], [0074] -[0079], [0218], SEQ ID NO: 12	1, 2, 6-9, 18-20
Y	US 2009/0061462 A1 (MICHELITSCH et al.) 05 March 2009 (05.03.2009) para [0099], [0101], [0288], Table 2	6,20
Y	US 2010/0055701 A1 (TONG et al.) 04 March 2010 (04.03.2010) para [0004], [0048], [0051]	7-8



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

31 July 2012 (31.7.2012)

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/26962

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:

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 1-9, 18-20, drawn to a pharmaceutical composition comprising a polypeptide from about 6 to about 35 amino acid residues, the polypeptide comprising 1 to 3 tetrapeptides having the sequence of PXXP, wherein P is proline; and

X is any amino acid. The first invention (claims 1, 2, 6-9, 18-20) is restricted to SEQ ID NO:3. Should an additional fee(s) be paid, Applicant is invited to effect an additional SEQ ID NO(s) to be searched.

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 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, 2, 6-9 and 18-20, restricted to SEQ ID NO: 3

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/US 12/26962

Continuation of Box III

Group II: claims 10-17, drawn to a method of treating multiple sclerosis, the method comprising the step of administering to a patient in need thereof a therapeutically effective amount of the pharmaceutical composition of claim 1.

The inventions listed as Groups I+ and II 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 inventions of Group I+ do not include the inventive concept of a method of treating multiple sclerosis, as required by Group II.

The inventions of Group I+ share the technical feature of a pharmaceutical composition of claim 1. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2002/0107187 A1 to KINGSTON, et al. (hereinafter "Kingston") that discloses a pharmaceutical composition comprising a polypeptide (para [0061], also para [0139]-[0160], Examples 3-5) from about 6 to about 35 amino acid residues, the polypeptide comprising 1 to 3 tetrapeptides having the sequence of PXXP, wherein P is proline; and

X is any amino acid (para [0037], "... a peptide having the following sequence ... SEQ ID NO: 26, AISPTPPL; SEQ ID NO:32, PLPEEPAF; SEQ ID NO: 35, PLPEEPAF; SEQ ID NO: 38, PLPEEPAF (see also EXAMPLE 8-11); SEQ ID NO: 39, MSAPSTLPP; SEQ ID NO: 45, MEPLFPA; SEQ ID NO: 47, ALPQEPAS; SEQ ID NO: 50, TLPEEPTS (see also EXAMPLE 8-10). As said pharmaceutical composition was known in the art at the time of the invention, this cannot be considered a special technical feature that would otherwise unify the groups.

Another special technical feature of the inventions listed as Group I+ is the specific amino acid sequence recited therein. The inventions do not share a special technical feature, because Kingston further discloses the claimed SEQ ID NO: 3 (SEQ ID NO: 35, amino acids 3-6). Without a shared special technical feature, the inventions lack unity with one another.

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