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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))*

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

10 March 2016

(54) Title: IMMUNE MOTIFS IN PRODUCTS FROM DOMESTIC ANIMALS

(57) Abstract: The present invention provides a means to prepare a product from domestic animal milk, blood or eggs which comprises an array of T-cell exposed motifs similar in identity, distribution and concentration to those found in human immunoglobulin variable regions and to prepare and apply the product as an immune modulating agent for administration either as a nutritional supplement or as a pharmaceutical product.



WO 2016/007871 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/39970

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 39/00, A61K 39/38, A61K 38/08, A61K 38/00, C40B 30/04, C40B 30/10, C40B 50/02 (2015.01)

CPC - A61K 38/00, A61K 39/00, A61K 39/0011, A61K 39/39, C07K 2319/00, C07K 7/06, C07K 7/23

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, A61K 39/38, A61K 38/08, A61K 38/00, C40B 30/04, C40B 30/10, C40B 50/02 (2015.01)

CPC - A61K 38/00, A61K 39/00, A61K 39/0011, A61K 39/39, C07K 2319/00, C07K 7/06, C07K 7/23

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

CPC - C07K 7/08, C07K 1/00, C07K 5/1013, C07K 5/0812, C07K 5/1008, B01J 2219/00585, B01J 2219/00659, B01J 2219/00596, B01J 2219/00612, B01J 2219/00722, B01J 19/0046, C40B 40/14, C40B 50/02, G06F 19/16, G06F 19/70

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWEST(PGPB,USPT,USOC,EPAB,JPAB); PatBase, Google/Scholar: T-cell stimulating peptide motifs, epitope, HLA, MHC allele, Groove Exposed Motif, GEM, Immunoglobulin germline, milk, colostrum, frequency, epitope occurrence, representation, Ovomucoid, ovalbumin, ovotransferrin, lysozyme, casein, albumin, T-cell memory, IVIG, database, dataset...

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/0014796 A1 (Carr, et al.) 18 January 2007 (18.01.2007) para [0025], [0027], [0043], [0117]-[0123]	1-25, 31-33, 55-59
Y	Tsabouri, et al. Cow's milk allergenicity. Endocr Metab Immune Disord Drug Targets March 2014, 14(1):16-26; pg 17, Table 1; pg 19, col 2	1-3, 7-18, 24, 25/(1-3,7-18,24), 31, 32,
Y	Konuspayeva, et al. Lactoferrin and immunoglobulin contents in camel's milk (Camelus bactrianus, Camelus dromedarius, and Hybrids) from Kazakhstan. J Dairy Sci. 2007, 90(1):38-46; Abstract, pg 39, col 2; pg 45, col 2	1-4, 6, 19-23, 25/(1-4,6,19-23), 55-59
Y	Shin, et al. Use of Egg Yolk-Derived Immunoglobulin as an Alternative to Antibiotic Treatment for Control of Helicobacter pylori Infection. Clin Diagn Lab Immunol. 2002, 9(5):1061-1066: Abstract	1, 5, 25/(1,5), 33

☐ 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

02 November 2015 (02.11.2015)

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Name and mailing address of the ISA/US

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***** Supplemental Sheet *****

In Continuation of Box III. Observations where unity of invention is lacking:

Group III: claims 75-83, directed to a process comprising orally administering a concentrated domestic animal immunoglobulin polypeptide fraction comprising greater than about 75% w/w immunoglobulin polypeptides.

The inventions listed as Groups I-III 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:

Special Technical Features

The inventions of Group I do not include the shared or common technical feature of an oral formulation comprising a concentrated domestic animal immunoglobulin polypeptide fraction, said fraction comprising greater than about 25% w/w immunoglobulin polypeptides, as required by Groups II and III.

The inventions of Groups II and III do not include the shared or common technical feature of immunoglobulin polypeptides comprising a predetermined frequency of representation of T-cell exposed motifs as compared with a reference database of human T-cell exposed motifs, as required by Group I.

The inventions of Group II do not include the shared or common technical feature of a process comprising orally administering a concentrated domestic animal immunoglobulin polypeptide fraction comprising greater than about 75% w/w immunoglobulin polypeptides, as required by Group III.

Common Technical Features

The inventions of Groups I-III share the technical feature of a product comprising immunoglobulin polypeptides. The inventions of Groups II and III share the technical feature of an oral formulation of a concentrated domestic animal immunoglobulin polypeptide fraction comprising greater than about 25% w/w immunoglobulin polypeptides. However, this shared technical feature does not represent a contribution over prior art as being anticipated by a paper titled "Immunomodulatory effects of bovine colostrum in human peripheral blood mononuclear cells" by Biswas, et al. (New Microbiol. 2007, 30(4):447-54) (hereinafter "Biswas").

Biswas discloses an oral formulation (pg 448, col 1, "volunteers who had ingested immunoglobulin-concentrated BC [bovine colostrum]") comprising a concentrated domestic animal immunoglobulin polypeptide fraction, said fraction comprising greater than about 25% w/w immunoglobulin polypeptides (pg 448, col 2, "The BC used in our study is de-fatted and freeze-dried, containing less than 1% of fat, 85-90% of protein of which about 85% are IgG"). As said technical features were known in the art at the time of the invention, they cannot be considered special technical feature that would otherwise unify the groups.

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

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/39970

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.: 26-30, 37-43, 45-54, 60-74, 84-86
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.

Group I: claims 1-25, 31-33, 55-59, directed to a protein product comprising an immunoglobulin polypeptide fraction derived from a domestic animal wherein said polypeptides comprise a predetermined frequency of representation of T-cell exposed motifs as compared with a reference database of human T-cell exposed motifs (claims 1-25, 31-33), and a method of preparing such a protein product (claims 55-59).

Group II: claims 34-36, 44, directed to an oral formulation comprising a concentrated domestic animal immunoglobulin polypeptide fraction, said fraction comprising greater than about 25% w/w immunoglobulin polypeptides.

***** See Supplemental Sheet to continue *****

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.:
1-25, 31-33, 55-59

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.