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(54) Title: LEISHMANIASIS ANTIGEN DETECTION ASSAYS AND VACCINES

FIG. 7

Protein 1: <i>Leishmania infantum</i> iron superoxide dismutase (NCBI accession: XP_001467866.1; Gene ID EuPathDB: LinJ.32.1910) MPFAVQPLPYPIIDALASKGMSKEQVTHIEKIHIGYAVKLNAAESENGLASKSL VDIKSEKGPANCAAQIINIDFWRCLSPRGGLPSGPLASIVDSFGSEAFKKLP IDAANGHIGSGAWAWLYKDKSSGKLKVLQTHDAGPLTEPNLVPIUCDIWEIJAYYI DYKNDASYVNAFWNMVDWDFASSQL (SEQ ID NO: 18) SEQ ID NO: 2 and 4 are underlined respectively.	Protein 2: <i>Leishmania infantum</i> trypanodisin (NCBI accession: XP_001466642.1; Gene ID EuPathDB: LinJ.29.1250) MSGVSKHIGDVLKLOKONDVDMSSLSGKIVELYISASWCPPCRGEIPKLVIEYE KIHINSKNFEHLASWDELEDNGYYSKMPWLSIPTEKRNIVVLEALIKQYKVESIPIL IGLNADIGDIVTIRARHALIQDPEGEQFPWRDE (SEQ ID NO: 20) SEQ ID NO: 6, 8, and 10 are underlined respectively. SEQ ID NO: 12 is embedded within SEQ ID NO: 10.
Protein 3: <i>Leishmania infantum</i> nuclear transport factor 2 (NCBI accession: XP_001463738.1; Gene ID EuPathDB: LinJ.10.0900) MSHEDVGVGVYQHYNYHANQRDLQAGYRPNLELTWOKEQYGVDAIMAR FANLGFTEAFAFKQSDICQPSMSGGVIVVNGEVKLRGDSLSKFNDFHILAQNGGQ WYYSNQVILVGGGGQ (SEQ ID NO: 22) SEQ ID NO: 16 and 14 are underlined respectively.	

(57) Abstract: The present invention relates to isolated Visceral leishmaniasis (VL) antigens that are useful in therapeutic and vaccine compositions for stimulating a VL specific immunological response. The identified antigens are also useful in diagnostic assays to determine the presence of active VL in an individual. Combinations of antibodies raised against these antigens are especially useful in detection of VL infections. Accordingly, the present invention includes polypeptide molecules, nucleic acid molecules, vaccine compositions, diagnostic assays, and methods of diagnosis and monitoring treatment related to these VL antigens.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/029737

A. CLASSIFICATION OF SUBJECT MATTER
INV. C07K14/435
ADD.

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)
C07K

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)

EPO-Internal, Sequence Search

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	MARÍN C ET AL: "The use of an excreted superoxide dismutase in an ELISA and Western blotting for the diagnosis of Leishmania (Leishmania) infantum naturally infected dogs", PARASITOLOGY RESEARCH ; FOUNDED AS ZEITSCHRIFT FÜR PARASITENKUNDE, SPRINGER, BERLIN, DE, vol. 101, no. 3, 12 May 2007 (2007-05-12), pages 801-808, XP019542658, ISSN: 1432-1955, DOI: 10.1007/S00436-007-0551-6 Page 802, left column, last paragraph and Discussion. ----- -/--	1-8, 10-32



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 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

16 May 2013

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24/09/2013

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/029737

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:

see additional 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 an 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.:

1-32(partially)

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/US2013/029737

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	NADA S DAIFALLA ET AL: "Immunogenicity of iron superoxide dismutase B1 and peroxidoxin 4 in BALB/c mice: The contribution of Toll-like receptor agonists as adjuvant", EXPERIMENTAL PARASITOLOGY, NEW YORK, NY, US, vol. 129, no. 3, 1 July 2011 (2011-07-01), pages 292-298, XP028318548, ISSN: 0014-4894, DOI: 10.1016/J.EXPPARA.2011.07.001 [retrieved on 2011-08-03] Results and Discussion -& DATABASE UniProt [Online] 5 July 2004 (2004-07-05), "RecName: Full=Superoxide dismutase; EC=1.15.1.1;", XP002697097, retrieved from EBI accession no. UNIPROT:Q71S89 Database accession no. Q71S89 sequence	1-8, 10-32
X,P	& S. S. KASHINO ET AL: "Identification of Leishmania infantum chagasi proteins in urine of patients with visceral leishmaniasis: a promising antigen discovery approach of vaccine candidates", PARASITE IMMUNOLOGY, vol. 34, no. 7, 7 July 2012 (2012-07-07), pages 360-371, XP055062799, ISSN: 0141-9838, DOI: 10.1111/j.1365-3024.2012.01365.x the whole document	1-32
X,P	----- C. ABEIJON ET AL: "Identification and Diagnostic Utility of Leishmania infantum Proteins Found in Urine Samples from Patients with Visceral Leishmaniasis", CLINICAL AND VACCINE IMMUNOLOGY, vol. 19, no. 6, 18 April 2012 (2012-04-18), pages 935-943, XP055062826, ISSN: 1556-6811, DOI: 10.1128/CVI.00125-12 the whole document	1-32
A	----- SRIVASTAVA P ET AL: "Diagnosis of visceral leishmaniasis", TRANSACTIONS OF THE ROYAL SOCIETY OF TROPICAL MEDICINE AND HYGIENE, ELSEVIER, GB, vol. 105, no. 1, 1 January 2011 (2011-01-01), pages 1-6, XP027538645, ISSN: 0035-9203 [retrieved on 2010-11-30] item 2 -----	1

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-32(partially)

Polypeptides and corresponding nucleic acid molecules comprising an immunogenic protein of an L. infantum or L.donovani antigen, wherein the antigen comprises an amino acid sequence selected from the group consisting of: SEQ ID NO: 1-4, 17, 18. Vector, host cell, antibody, fusion proteins and methods thereof.

2. claims: 1-32(partially)

Polypeptides and corresponding nucleic acid molecules comprising an immunogenic protein of an L. infantum or L.donovani antigen, wherein the antigen comprises an amino acid sequence selected from the group consisting of: SEQ ID NO: 5-12, 19-20. Vector, host cell, antibody, fusion proteins and methods thereof.

3. claims: 1-32(partially)

Polypeptides and corresponding nucleic acid molecules comprising an immunogenic protein of an L. infantum or L.donovani antigen, wherein the antigen comprises an amino acid sequence selected from the group consisting of: SEQ ID NO:13-16, 22. Vector, host cell, antibody, fusion proteins and methods thereof.
