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(54) Title: METHODS OF TREATING SJÖGREN'S SYNDROME

(57) Abstract: Disclosed herein are methods for treating Sjögren's syndrome in a subject in need thereof including administering to the subject a therapeutically effective amount of levocarnitine or a pharmaceutically acceptable salt thereof.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US21/32347

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61K 31/185; A61K 31/205; A61P 27/02; A61P 11/02; A61P 11/04 (2021.01)

CPC - A61K 31/205; A61K 31/185; A61P 27/02; A61P 11/02; A61P 11/04

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)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	(CROFFORD, L) Levocarnitine for Dry Eye in Sjogren's Syndrome. NCT03953703. ClinicalTrials.gov Entry (online). US National Library of Medicine. 4 May 2020 [retrieved on 7 August 2021]. Retrieved from the Internet: [URL: https://web.archive.org/web/20200717024759/https://clinicaltrials.gov/ct2/show/NCT03953703]; page 1, first paragraph; page 2, second and third paragraphs; page 3, third paragraph	1-2, 4/1-2, 12, 15/12 --- 3, 4/3, 13-14 15/13-14, 16/15/12-14
Y	(SAN FILIPPO, CA et al.) Pharmacological Rescue of Carnitine Transport in Primary Carnitine Deficiency. Human Mutation. 2006, Vol. 27, No. 6; pages 513-523; abstract; page 516, second column, second paragraph; page 519, second column, first paragraph; DOI: 10.1002/humu.20314	3, 4/3, 16/15/12-14
Y	US 2019/0194293 A1 (SANABIO, LLC) 27 June 2019; paragraphs [0095], [0099], [0223], [0231], [0492]	13-14, 15/13-14, 16/15/13-14
A	(TANG, NLS et al.) A Founder Mutation (R254X) of SLC22A5 (OCTN2) in Chinese Primary Carnitine Deficiency Patients. Human Mutation. September 2002, Vol. 20, No. 3, article 232; pages 1-7; DOI: 10.1002/humu.9053	2
A	(SEEN, S et al.) Dry eye disease and oxidative stress. Acta Ophthalmologica. June 2018, Vol. 96, No. 4; pages e412-e420; DOI: 10.1111/aos.13526	1

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

"D" document cited by the applicant in the international application

"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

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US21/32347

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.: 5-11, 17-20
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:

- 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.:

- 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.