

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property

Organization

International Bureau

(43) International Publication Date

23 December 2021 (23.12.2021)



(10) International Publication Number

WO 2021/257816 A3

(51) International Patent Classification:

A61K 38/08 (2019.01) A61P 11/00 (2006.01)

A61K 38/10 (2006.01) C07K 7/06 (2006.01)

A61K 38/17 (2006.01) C07K 7/08 (2006.01)

(21) International Application Number:

PCT/US2021/037812

(22) International Filing Date:

17 June 2021 (17.06.2021)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/041,396 19 June 2020 (19.06.2020) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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))

Published:

- 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))
- with sequence listing part of description (Rule 5.2(a))

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

20 January 2022 (20.01.2022)

(54) Title: MODIFIED CAVEOLIN-1 PEPTIDES FOR THE TREATMENT OF PATHOGEN-INDUCED LUNG INJURY

(57) Abstract: Provided herein are methods of using modified caveolin-1 (Cav-1) peptides to treat or prevent pathogen-induced lung injury and disrepair. In particular, provided are methods of using the modified Cav-1 peptides for the treatment of pathogen-induced lung injury and disrepair caused by a coronavirus, such as, for example, SARS-CoV-2.



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INTERNATIONAL SEARCH REPORT

International application No.

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A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 38/08; A61K 38/10; A61K 38/17; A61P 11/00; C07K 7/06; C07K 7/08 (2021.01)

CPC - A61K 38/00; A61K 38/08; A61K 38/10; A61K 38/17; A61P 11/00; C07K 7/00 (2021.08)

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	WO 2020/055824 A1 (BOARD OF REGENTS THE UNIVERSITY OF THE TEXAS SYSTEM et al) 19 March 2020 (19.03.2020) entire document	1, 2, 14, 26, 43-58 --- 3-13
Y	HOCKE et al. "Emerging human middle East respiratory syndrome coronavirus causes widespread infection and alveolar damage in human lungs," Am J Respir Crit Care Med, 01 October 2013 (01.10.2013), Vol. 188, Pgs. 882-6. entire document	3-13
Y	GRALINSKI et al. "Mechanisms of severe acute respiratory syndrome coronavirus-induced acute lung injury," mBio, 06 August 2013 (06.08.2013), Vol. 4, e00271-13, Pgs. 1-12. entire document	7, 8
Y	GALLELLI et al. "Severe Acute Lung Injury Related to COVID-19 Infection: A Review and the Possible Role for Escin," J Clin Pharmacol, 22 May 2020 (22.05.2020), Vol. 60, Pg. 815-825. entire document	9, 10
Y	HEROLD et al. "Influenza virus-induced lung injury: pathogenesis and implications for treatment," Eur Respir J, 18 March 2015 (18.03.2015), Vol. 45, Pgs. 1463-78. entire document	13
A	WO 2020/055812 A1 (LUNG THERAPEUTICS INC) 19 March 2020 (19.03.2020) entire document	1-14, 26, 43-58

 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

04 November 2021

Date of mailing of the international search report

DEC 07 2021

Name and mailing address of the ISA/US

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P.O. Box 1450, Alexandria, VA 22313-1450

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2021/037812

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of a sequence listing:

a. forming part of the international application as filed:

in the form of an Annex C/ST.25 text file.

on paper or in the form of an image file.

b. furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

c. furnished subsequent to the international filing date for the purposes of international search only:

in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).

on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).

2. In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

SEQ ID NOs: 4-20 were searched.

INTERNATIONAL SEARCH REPORT

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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.:
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 extra sheet(s).

- 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.:
1-14, 26, 43-58

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.

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Continued from 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 need to be paid.

Group I+: claims 1-60 are drawn to methods for treating pathogen-induced lung injury by administering a modified Cav-1 peptide.

The first invention of Group I+ is restricted to a method of treating or preventing pathogen-induced lung injury in a subject comprising administering to the subject a therapeutically effective amount of a modified Cav-1 peptide, wherein the modified Cav-1 (Caveolin-1) peptide is selected to be SEQ ID NO:4. It is believed that claims 1-14, 26, and 43-58 read on this first named invention and thus these claims will be searched without fee to the extent that they read on SEQ ID NO:4.

Applicant is invited to elect additional Cav-1 peptides, amino acid substitutions, insertions, deletions, or modifications, and corresponding SEQ ID NO to be searched in a specific combination by paying additional fee for each set of election. An exemplary election would be a method of treating or preventing pathogen-induced lung injury in a subject comprising administering to the subject a therapeutically effective amount of a modified Cav-1 peptide, wherein the modified Cav-1 (Caveolin-1) peptide is selected to be SEQ ID NO:5. Additional Cav-1 peptides, amino acid substitutions, insertions, deletions, or modifications, and corresponding SEQ ID NO will be searched upon the payment of additional fees. Applicants must specify the claims that read on any additional elected inventions. Applicants must further indicate, if applicable, the claims which read on 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.

The inventions listed in Groups I+ 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 Groups I+ formulas do not share a significant structural element responsible for treating or preventing pathogen-induced lung injury requiring the selection of alternative Cav-1 peptides where "A method of treating or preventing pathogen-induced lung injury in a subject comprising administering to the subject a therapeutically effective amount of a modified Cav-1 peptide: (i) consisting of any one of the amino acid sequences of SEQ ID NOs: 4-20; or (ii) comprising any one of the amino acid sequences of SEQ ID NOs: 4-20 with one or more amino acid substitutions, insertions, deletions, or modifications."

Additionally, even if Groups I+ were considered to share the technical features of a method of treating or preventing pathogen-induced lung injury in a subject comprising administering to the subject a therapeutically effective amount of a modified Cav-1 peptide with one or more amino acid substitutions, insertions, deletions, or modifications. However, these shared technical features do not represent a contribution over the prior art.

Specifically, WO 2020/055812 A1 to Lung Therapeutics Inc. discloses a method of treating or preventing pathogen-induced lung injury in a subject (a method of treating lung injuries and diseases, Para. [0021]; [l]ung diseases include ...bronchiolitis, Para. [00124]; Bronchiolitis is most commonly caused by viral lower respiratory tract infections, Para. [00129]; lung infection or lung disease in a subject, Para. [0016]) comprising administering to the subject a therapeutically effective amount of a modified Cav-1 peptide with one or more amino acid substitutions, insertions, deletions, or modifications (a method of treating lung injuries and diseases, by administering to the subject (e.g., via the airway) a therapeutically effective amount of a modified Cav-1 peptide, Para. [0021]).

The inventions listed in Groups I+ therefore lack unity under Rule 13 because they do not share a same or corresponding special technical features.