



(51) International Patent Classification:

A61K 8/64 (2006.01) C07K 16/18 (2006.01)
C07K 16/12 (2006.01) A61L 29/16 (2006.01)
A61L 27/54 (2006.01)

(21) International Application Number:

PCT/US2022/011853

(22) International Filing Date:

10 January 2022 (10.01.2022)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/135,876 11 January 2021 (11.01.2021) US
63/221,394 13 July 2021 (13.07.2021) US

(71) Applicants: **KEYSTONE BIO, INC.** [US/US]; Cambridge Innovation Center, 4220 Duncan Ave., Suite 200, St. Louis, Missouri 63110 (US). **UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC.** [US/US]; 300 E. Market St., Suite 300, Louisville, Kentucky 40202 (US).

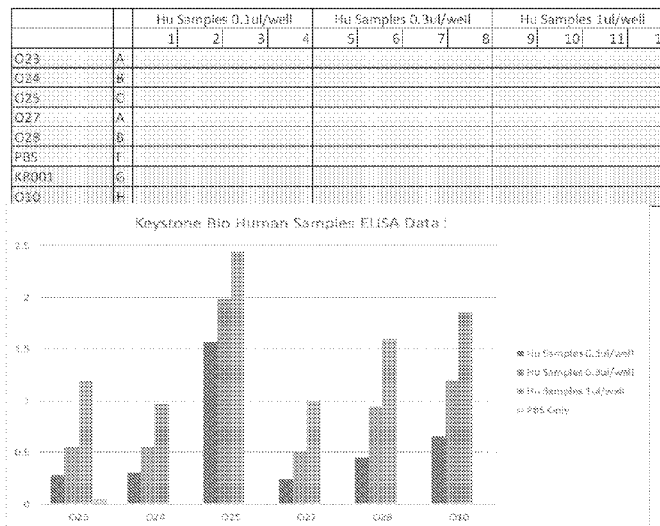
(72) Inventors: **NARA, Peter L.**; c/o Keystone Bio, Inc., Cambridge Innovation Center, 4220 Duncan Ave., Suite 200, St. Louis, Missouri 63110 (US). **POTEMPA, Jan Stanislaw**; c/o University of Louisville Research Foundation, Inc., 300 E. Market St., Suite 300, Louisville, Kentucky 40202 (US). **TOBIN, John Knox**; c/o Keystone Bio, Inc., Cambridge Innovation Center, 4220 Duncan Ave., Suite 200, St. Louis, Missouri 63110 (US). **TOBIN, Gregory John**; c/o Keystone Bio, Inc., Cambridge Innovation Center, 4220 Duncan Ave., Suite 200, St. Louis, Missouri 63110 (US).

(74) Agent: **MALLON, Joseph J.**; Knobbe Martens Olson & Bear LLP, 2040 Main Street, Fourteenth Floor, Irvine, California 92614 (US).

(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,

(54) Title: ANTIGENIC COMPOSITION(S) AND METHOD(S) AGAINST PORPHYROMONAS GINGIVALIS FOR THE PREVENTION AND/OR TREATMENT OF INFECTION AND/OR DISEASES

FIG. 22
rGP-1 ELISA Human Plasma



(57) Abstract: Vaccines for *Porphyromonas gingivalis* are described. Also provided are methods of treating or preventing a disorder or disease by administering the vaccine.



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).

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:

18 August 2022 (18.08.2022)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US22/11853

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61K 8/64; C07K 16/12; A61L 27/54; C07K 16/18; A61L 29/16 (2022.01)

CPC - A61K 8/64; C07K 16/12; A61L 27/54; C07K 16/18; A61L 29/16

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	WO 9734629 A1 (UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC.) 25 September 1997; page 4, lines 16-37; page 15, lines 5-17; page 23, lines 7-14; page 44, lines 25-33; page 45, lines 9-21; claims 1, 3; figures 3F, 4	1-7, 77-79
X	US 2011/0280880 A1 (REYNOLDS, EC et al.) 17 November 2011; paragraph [0131], [0132], [0134]; claims 73-74, 86	71, 83
A	WO 2008/000028 A1 (THE UNIVERSITY OF MELBOURNE) 03 January 2008; entire document	1-7, 71, 77-79, 83
E,X	WO 2022/098661 A1 (KEYSTONE BIO, INC.) 12 May 2022; entire document	1-7, 71, 77-79, 83

 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

06 June 2022 (06.06.2022)

Date of mailing of the international search report

JUN 21 2022

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US22/11853

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:

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US22/11853

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.: 8-22, 23-66, 72-76, 80-82, 84
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:
-***-Please See Supplemental Page-***-

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.:
Group I, Claims 1-7, 71, 77-79, 83

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.

-***-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 must be paid.

Group I, Claims 1-7, 71, 77-79, 83 are directed towards a composition comprising an effective amount of an isolated and purified peptide and/or protein, wherein the isolated and purified peptide and/or protein comprises an epitope that is bound by the antigen binding molecule KB001, and wherein the epitope includes at least one of the residues in YTYTVYRDGTKIK (SEQ ID NO: 6).

Group II, Claims 67-70 are directed toward a method of screening for a vaccine, the method comprising: providing an antibody that binds to a Porphyromonas gingivalis protein PG0495, determining an epitope to which the antibody binds; and providing a fragment of the Porphyromonas gingivalis protein PG0495 as a protein fragment.

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 special technical features of Group I include YTYTVYRDGTKIK, not present in Group II; the special technical features of Group II include providing an antibody that binds to a Porphyromonas gingivalis protein PG0495, determining an epitope to which the antibody binds; and providing a fragment of the Porphyromonas gingivalis protein PG0495 as a protein fragment, not present in Group I.

Groups I and II share the technical features including: a binding molecule and Porphyromonas gingivalis.

However, these shared technical features are previously disclosed by the WO 2008/000028 A1 (THE UNIVERSITY OF MELBOURNE) (hereinafter 'Melbourne').

Melbourne discloses a binding molecule (a binding molecule; page 4, lines 4-6) and Porphyromonas gingivalis (abstract).

Since none of the special technical features of the Groups I and II inventions are found in more than one of the inventions, and since all of the shared technical features are previously disclosed by the Melbourne reference, unity of invention is lacking.