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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 December 2018 (27.12.2018)

WIPO | PCT

(10) International Publication Number
WO 2018/237010 A3

(51) International Patent Classification:
C07K 14/40 (2006.01) *A61K 39/395* (2006.01)
C07K 14/37 (2006.01) *A61K 39/02* (2006.01)
C07K 16/14 (2006.01) *A61K 39/00* (2006.01)
C07K 7/08 (2006.01) *C12N 1/14* (2006.01)

(21) International Application Number:
PCT/US2018/038512

(22) International Filing Date:
20 June 2018 (20.06.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/522,217 20 June 2017 (20.06.2017) 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, 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, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, 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).

(54) Title: VACCINE COMPOSITIONS AND METHODS OF USING THE SAME

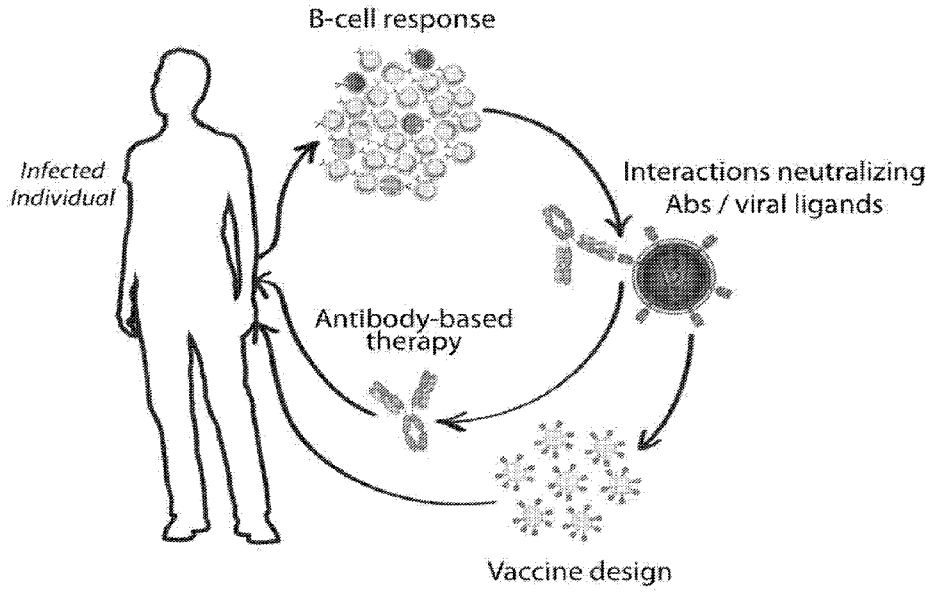

FIG. 8

(57) Abstract: This invention is directed to vaccine compositions and methods of using the same to prevent infection.

WO 2018/237010 A3

[Continued on next page]

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))*

(88) Date of publication of the international search report:
31 January 2019 (31.01.2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US18/38512

A. CLASSIFICATION OF SUBJECT MATTER

IPC - C07K 14/40, 14/37, 16/14, 7/08; A61K 39/395, 39/02, 39/00; C12N 1/14 (2018.01)

CPC - C07K 14/40, 14/37, 16/14, 7/08; A61K 39/0002, 39/02, 39/39575, 39/395; C12N 1/14

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	US 2017/0137476 A1 (XIN, H.) 18 May 2017; abstract; paragraphs [0013]-[0016], [0029]-[0035], [0039], [0042], [0044], [0046]-[0047], [0052]-[0054], [0057], [0062], [0090]-[0091]; claims 19, 20.	1, 3-8, 11, 13/11, 14/13/11, 15/14/13/11, 26-28, 33-36, 41-43, 48-50/41, 62/1, 62/11, 62/41, 63/1, 63/11, 63/41, 64/63/1, 64/63/11, 64/63/41, 77/1, 77/11, 78/1, 78/11, 79/41, 80/41, 90 --- 9, 12, 13/12, 14/13/12, 15/14/13/12, 16/11-12, 40, 44/40, 45/40, 48/40, 49/40, 50/40, 53/40, 54/53/40, 55/53/40, 56/54/53/40, 57-58, 60/57-58, 62/40, 62/57-58, 63/40, 63/57-58, 64/63/40, 64/63/57-58, 68, 69/11-12, 70/40-41, 71/57-58, 72/71/57-58, 73/72/71/57-58, 79/40, 79/57-58, 80/40, 80/57-58, 84-89

☒ 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

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"O" document referring to an oral disclosure, use, exhibition or other means

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"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	Date of mailing of the international search report
13 November 2018 (13.11.2018)	11 DEC 2018
Name and mailing address of the ISA/ 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 PCT Helpdesk: 571-272-4300 PCT OSP: 571 272 7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US18/38512

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2007/0196378 A1 (LOTZ, H. et al.) 23 August 2007; paragraphs [0002], [0006], [0013], [0015]-[0018], [0026]-[0028], [0030], [0035]-[0036], [0043], [0051], [0053], [0063], [0065]-[0066], [0068], [0070], [0072], [0073], [0076], [0078], [0083], [00181]; claims 33, 42.	1-2, 10, 12, 13/12, 14/13/12, 41, 53/41, 54/53/41, 55/53/41, 56/54/53/41, 62/12, 63/12, 64/63/12, 77/10, 77/12, 78/10, 78/12 ---------- 12, 15/14/13/12, 16/12, 44/41, 45/41, 53/40, 54/53/40, 55/53/40, 56/54/53/40, 69/12
Y	Fructose-Biphosphate Aldolase [Candida Albicans SC5314]. GenBank: AOW28947.1. 14 October 2016; downloaded from the internet < https://www.ncbi.nlm.nih.gov/protein/AOW28947.1> on 23 October 2018, pages 1-2.	9, 16/11-12, 40, 44/40, 45/40, 48/40, 49/40, 50/40, 53/40, 54/53/40, 55/53/40, 56/54/53/40, 58, 60/57, 60/58, 62/40, 62/58, 63/40, 63/58, 64/63/40, 64/63/58, 70/40, 71/58, 72/71/58, 73/72/71/58, 79/40, 79/58, 80/40, 80/58
Y	WO 2015/187779 A1 (XBIOTECH, INC.) 10 December 2015; paragraphs [0006], [0014], [0026], [0045].	44/40-41, 45/40/41
Y	US 7,241,613 B1 (WILLINS, D. et al.) 10 July 2007; column 2, line 63-column 3, line 10; column 3, lines 6-15; column 8 , lines 24-29; column 17, lines 40-52; column 26, lines 36-42.	57-58, 60/57-58, 62/57-58, 63/57-58, 64/63/57-58, 68, 69/11-12, 70/40-41, 71/57-58, 72/71/57-58, 73/72/71/57-58, 79/57-58, 80/57-58
Y	WO 02/061113 A2 (THE JOHNS HOPKINS UNIVERSITY) 8 August 2002; abstract; page 2, lines 26-30; page 50, line 16-page 51, line 10.	84-89
Y	WO 2006/076594 A2 (XENCOR, INC.) 20 July 2006; paragraphs [10], [103].	88

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US18/38512

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.: 52, 59, 81-83, 91
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.:
-***-Please See Supplemental Page-***-

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
Information on patent family members

International application No.
PCT/US18/38512

-***-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 1-51, 53-58, 60-80, 84-90; a fungal cell wall fructose-bisphosphate aldolase (Fba) peptide encompassing SEQ ID NO: 26 (universal peptide); an adjuvant (composition component); SEQ ID NO: 53 (antibody target protein); fungi (microorganism); and an anti-fungal agent (antimicrobial agent) are directed toward antigenic universal peptides, vaccine compositions comprising the peptides; nucleic acids encoding the peptides; antibodies binding the peptides or their parent proteins, nucleic acids encoding the antibodies and host cells comprising the nucleic acids, compositions comprising the antibodies, and methods of using the peptides or antibodies to prevent infection.

The vaccines, peptides, nucleic acids, antibodies, host cells, compositions, and methods will be searched to the extent that they encompass a fungal cell wall fructose-bisphosphate aldolase (Fba) peptide encompassing SEQ ID NO: 26 (universal peptide); an adjuvant (composition component); SEQ ID NO: 53 (antibody target protein); fungi (microorganism); and an anti-fungal agent (antimicrobial agent). Applicant is invited to elect additional peptide(s), and/or composition component(s), and/or antibodies by target peptide or protein sequence and/or, where applicable, clone name and/or, where applicable, pair(s) of light and heavy chain sequence (s), with specified SEQ ID NO: for each, or with specified substitution(s) at specified site(s) of a SEQ ID NO:, such that the sequence of each elected species is fully specified (i.e. no optional or variable residues or substituents), to be searched. Aadditional peptide(s), and/or composition component(s), and/or antibodies by target peptide or protein sequence and/or, where applicable, clone name and/or, where applicable, pair(s) of light and heavy chain sequence(s), will be searched upon the payment of additional fees. It is believed that claims 1-6, 7-9 (each in-part), 10-13, 14-16 (each in-part), 26-28, 33 (in-part), 34-36 (each in-part), 40 (in-part), 41-42, 43-45 (each in-part), 48-50 (each in-part), 53-58 (each in-part), 60 (in-part), 62-64 (each in-part), 68-69, 70-73 (each in-part), 77-80 (each in-part), and 84-90 encompass this first named invention and thus these claims will be searched without fee to the extent that they encompass aa fungal cell wall fructose-bisphosphate aldolase (Fba) peptide encompassing SEQ ID NO: 26 (universal peptide); an adjuvant (composition component); SEQ ID NO: 53 (antibody target protein); fungi (microorganism); and an anti-fungal agent (antimicrobial agent). Applicants must specify the claims that encompass any additionally elected peptide(s), and/or composition component(s), antibodies by target peptide and/or, where applicable, clone name and/or, where applicable, pair(s) of light and heavy chain sequence (s). Applicants must further indicate, if applicable, the claims which encompass 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. An exemplary election would be a fungal cell wall 6-methyltetrahydropteroyltriglutamate-homocysteine methyltransferase (Met6) peptide enompassing SEQ ID NO: 1 (universal peptide). (Note: the assignment of SEQ ID NO: 26 as the first exemplary embodiment is based on paragraph [00201] of the instant disclosure, which is the only occurrance of a specified sequence for a Fba peptide within the claimed group of sequences that is indicated in the body of the disclosure.)

No technical features are shared between the peptides and/or nucleic acids, and/or composition components, and/or antibodies of Groups I+ and, accordingly, these groups lack unity a priori.

-***-Continued Within the Next Supplemental Box-***-

-***-Continued from Previous Supplemental Box -***-

Additionally, even if Groups I+ were considered to share the technical features including: an antigenic universal peptide comprising a peptide that is at least 70% identical in two or more different microorganisms, wherein the peptide comprises at least nine consecutive amino acid residues, and wherein the peptide is modified for use as a vaccine in a mammal; a nucleic acid encoding an antigenic universal peptide comprising a peptide that is at least 70% identical in two or more different microorganisms, wherein the peptide comprises at least nine consecutive amino acid residues, and wherein the peptide is modified for use as a vaccine in a mammal; a vaccine composition comprising an antigenic universal peptide and a pharmaceutically acceptable carrier, wherein the amino acid sequence of the antigenic universal peptide is at least 70% identical in two or more different microorganisms, and wherein the peptide comprises at least nine consecutive amino acid residues; a vaccine composition comprising a nucleic acid encoding an amino acid sequence of an antigenic universal peptide and a pharmaceutically acceptable carrier, wherein the amino acid sequence of the antigenic universal peptide is at least 70% identical in two or more different microorganisms, and wherein the peptide comprises at least nine consecutive amino acid residues; a vaccine composition comprising at least two antigenic universal peptides and a pharmaceutically acceptable carrier, wherein the amino acid sequence of the first antigenic universal peptide is at least 70% identical in two or more different microorganisms, and optionally, wherein the amino acid sequence of the second antigenic universal peptide is at least 70% identical in two or more different microorganisms, and wherein each peptide comprises at least nine consecutive amino acid residues; an isolated antibody or binding fragment thereof that specifically binds to a peptide with an amino acid sequence that is at least 80% identical in two or more different microorganisms, wherein the peptide comprises the amino acid sequence; an isolated antibody or binding fragment thereof that specifically binds to at least one synthetic cell wall peptide with an amino acid sequence that is at least 70% identical in two or more different microorganisms; an isolated nucleic acid encoding the antibody; a recombinant expression vector comprising the isolated nucleic acid; a host cell comprising the nucleic acid; a host cell transformed with the recombinant expression vector; a composition for passive protection against an infection comprising an immunologically effective amount of at least one recombinant antibody or binding fragment thereof that specifically binds to a peptide with an amino acid sequence that is at least 80% identical in two or more microorganisms, and a pharmaceutically acceptable carrier; a composition for passive protection against an infection comprising an immunologically effective amount of at least one recombinant antibody or binding fragment thereof that specifically binds to a peptide with an amino acid sequence that is at least 80% identical in two or more microorganisms, and a pharmaceutically acceptable carrier, wherein the peptide comprises the amino acid sequence; a method for active immunization against a microbial infection, the method comprising administering the composition; a method for active protection against a microbial infection comprising administering the composition to a subject in need thereof; a method for passive immunization against a microbial infection comprising administering the composition to a subject in need thereof; a method for passive protection against a microbial infection comprising administering the composition to a subject in need thereof; a method for selecting a peptide vaccine, the method comprising aligning the amino acid sequences of two or more cell wall proteins, and selecting a peptide vaccine, wherein the amino acid sequence of the peptide vaccine is at least 80% identical in the two or more cell surface proteins; a therapeutic composition, wherein the composition comprises: a. an antibody mixture, a peptide mixture, or a combination thereof, and b. optionally, an antimicrobial agent wherein the therapeutic composition is effective to stimulate an immune response in a patient against a pathogenic/microbial infection; these shared technical features are previously disclosed by US 2017/0137476 A1 (XIN) in view of WO 2002/061113 A2 (THE JOHNS HOPKINS UNIVERSITY) (hereinafter 'Hopkins') and US 7,241,613 B1 to Willins, et al. (hereinafter 'Willins').

Xin discloses an antigenic universal peptide (chimeric peptides impart active immunity against C. albicans, C. glabrata, C. tropicalis, C. gulliermodii, and C. lusitaniae; paragraph [0030]) comprising a peptide that is at least 70% identical in two or more different microorganisms (comprising a peptide that is at least 70% identical to Fba and Met6 of C. albicans, C. glabrata, C. tropicalis, C. gulliermodii, and C. lusitaniae (in two or more different microorganisms); abstract; paragraphs [0013], [0030]), wherein the peptide comprises at least nine consecutive amino acid residues (wherein the peptide comprises at least nine consecutive amino acid residues; paragraph [0015]), and wherein the peptide is modified for use as a vaccine in a mammal (wherein the peptide is modified for use as a vaccine in a mammal; paragraph [0030]); a vaccine composition (abstract) comprising an antigenic universal peptide (chimeric peptides impart active immunity against C. albicans, C. glabrata, C. tropicalis, C. gulliermodii, and C. lusitaniae; paragraph [0030]) and a pharmaceutically acceptable carrier (paragraph [0033]), wherein the amino acid sequence of the antigenic universal peptide is at least 70% identical in two or more different microorganisms (comprising a peptide that is at least 70% identical to Fba and Met6 of C. albicans, C. glabrata, C. tropicalis, C. gulliermodii, and C. lusitaniae (in two or more different microorganisms); abstract; paragraphs [0013], [0030]), and wherein the peptide comprises at least nine consecutive amino acid residues; paragraph [0015]); a vaccine composition (abstract) comprising at least two antigenic universal peptides (comprising a chimeric peptide (at least two) that is at least 70% identical to Fba and Met6 of C. albicans, C. glabrata, C. tropicalis, C. gulliermodii, and C. lusitaniae (in two or more different microorganisms); abstract; paragraphs [0013], [0030]) and a pharmaceutically acceptable carrier (paragraph [0033]), wherein the amino acid sequence of the first antigenic universal peptide is at least 70% identical in two or more different microorganisms (comprising a peptide that is at least 70% identical to Fba of C. albicans, C. glabrata, C. tropicalis, C. gulliermodii, and C. lusitaniae (in two or more different microorganisms); abstract; paragraphs [0013], [0030]), and wherein each peptide comprises at least nine consecutive amino acid residues (wherein the peptide comprises at least nine consecutive amino acid residues; paragraph [0015]); an isolated antibody or binding fragment thereof that specifically binds to a peptide with an amino acid sequence that is at least 80% identical in two or more different microorganisms (antibodies raised against a peptide that is at least 70% identical to Fba and Met6 of C. albicans, C. glabrata, C. tropicalis, C. gulliermodii, and C. lusitaniae (in two or more different microorganisms); abstract; paragraphs [0013], [0030]), wherein the peptide comprises the amino acid sequence (paragraph [0015]);]); an isolated antibody or binding fragment thereof that specifically binds to at least one synthetic cell wall peptide with an amino acid sequence that is at least 70% identical in two or more different microorganisms (an isolated antibody or binding fragment thereof that specifically binds to at least one chimeric (synthetic) cell wall peptide with an amino acid sequence that is at least 70% identical in two or more different microorganisms; paragraphs [0013], [0030]); a composition for passive protection against an infection (a composition for passive protection against an infection; paragraphs [0013], [0032]) comprising an immunologically effective amount of at least one antibody that specifically binds to a peptide with an amino acid sequence that is at least 80% identical in two or more microorganisms (comprising an immunologically effective amount of at least one antibody that specifically binds to a peptide with an amino acid sequence that is at least 80% identical in two or more microorganisms; paragraphs [0013], [0030], [0031]), and a pharmaceutically acceptable carrier (paragraph [0033]);

-***-Continued Within the Next Supplemental Box-***-

-***-Continued from Previous Supplemental Box-***-

a composition for passive protection against an infection (a composition for passive protection against an infection; paragraphs [0013], [0032]) comprising an immunologically effective amount of at least one antibody or binding fragment thereof that specifically binds to a peptide with an amino acid sequence that is at least 80% identical in two or more microorganisms (comprising an immunologically effective amount of at least one antibody that specifically binds to a peptide with an amino acid sequence that is at least 80% identical in two or more microorganisms; paragraphs [0013], [0030], [0031]), and a pharmaceutically acceptable carrier (paragraph [0033]), wherein the peptide comprises the amino acid sequence (paragraph [0015]); a method for active immunization against a microbial infection (a method for active immunization against a microbial infection; abstract; paragraphs [0035], [0039]), the method comprising administering the composition (the method comprising administering the composition; paragraph [0030]); a method for active protection against a microbial infection (a method for active protection against a microbial infection; abstract; paragraphs [0035], [0039]) comprising administering the composition to a subject in need thereof (the method comprising administering the composition; paragraph [0030]); a method for passive immunization against a microbial infection comprising administering the composition to a subject in need thereof (a method for passive immunization against a microbial infection comprising administering the composition to a subject in need thereof; paragraphs [0032], [0057]); a method for passive protection against a microbial infection comprising administering the composition to a subject in need thereof (a method for passive protection against a microbial infection comprising administering the composition to a subject in need thereof; paragraphs [0032], [0057]); a therapeutic composition (vaccine (therapeutic composition); abstract), wherein the composition comprises: a peptide mixture (abstract; paragraph [0044]) and wherein the therapeutic composition is effective to stimulate an immune response in a patient against a pathogenic/microbial infection (Mice immunized with the two peptide mixture showed greatly reduced or even non-detectable fungal CFUs in kidneys (wherein the therapeutic composition is effective to stimulate an immune response in a patient against a pathogenic/microbial infection); abstract; paragraph [0044]).

Xin does not disclose a nucleic acid encoding an antigenic universal peptide comprising a peptide that is at least 70% identical in two or more different microorganisms, wherein the peptide comprises at least nine consecutive amino acid residues, and wherein the peptide is modified for use as a vaccine in a mammal; a vaccine composition comprising a nucleic acid encoding an amino acid sequence of an antigenic universal peptide and a pharmaceutically acceptable carrier, wherein the amino acid sequence of the antigenic universal peptide is at least 70% identical in two or more different microorganisms, and wherein the peptide comprises at least nine consecutive amino acid residues; an isolated nucleic acid encoding the antibody; a recombinant expression vector comprising the isolated nucleic acid; a host cell comprising the nucleic acid; a host cell transformed with the recombinant expression vector; a method for selecting a peptide vaccine, the method comprising aligning the amino acid sequences of two or more cell wall proteins, and selecting a peptide vaccine, wherein the amino acid sequence of the peptide vaccine is at least 80% identical in the two or more cell surface proteins; and a recombinant antibody.

Hopkins discloses a nucleic acid encoding an antigenic peptide (a nucleic acid encoding an antigenic peptide; claim 1); a vaccine composition comprising a nucleic acid encoding an amino acid sequence of an antigenic peptide (a vaccine composition comprising a nucleic acid encoding an amino acid sequence of an antigenic peptide; abstract) ; an isolated nucleic acid encoding an antibody (a nucleic acid encoding an antigenic peptide; claim 1); a recombinant expression vector comprising the isolated nucleic acid (a recombinant expression vector comprising the isolated nucleic acid; abstract; page 6, lines 4-7; page 41, lines 30-33); a host cell comprising the nucleic acid (page 42, lines 14-27; page 43, lines 30-34); a host cell transformed with the recombinant expression vector (a host cell transformed with the recombinant expression vector; page 42, lines 14-27; page 43, lines 30-34); and a method for selecting a peptide vaccine (aligning sequences for use in vaccine wherein non-homologous sequences can be disregarded (method of selecting a peptide vaccine); abstract; page 50, line 16 – page 51, line 10), the method comprising aligning the amino acid sequences of two or more proteins (the method comprising aligning the amino acid sequences of two or more proteins; page 50, line 16 – page 51, line 10), and selecting a peptide vaccine (aligning sequences for use in vaccine wherein non-homologous sequences can be disregarded (selecting a peptide vaccine); abstract; page 50, line 16 – page 51, line 10).

Willins discloses a recombinant antibody (column 17, lines 40-52).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Xin, to include a nucleic acid encoding an antigenic peptide; a vaccine composition comprising a nucleic acid encoding an amino acid sequence of an antigenic peptide; an isolated nucleic acid encoding the antibody; a recombinant expression vector comprising the isolated nucleic acid; a host cell comprising the nucleic acid; a host cell transformed with the recombinant expression vector; and a method for selecting a peptide vaccine, the method comprising aligning the amino acid sequences of two or more proteins, and selecting a peptide vaccine, as disclosed by Hopkins, in order to provide improved molecular vaccines resulting in enhanced immune responses against multiple pathogenic microorganisms and can be used in the prevention or treatment of diseases that include microbial infections. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Xin, to include a recombinant antibody, as disclosed by Willins, in order to provide antibodies that are not antigenically rejected upon administration in humans, providng high affinity monoclonal antibodies directed to cell Surface antigens useful in treating and preventing microbial infections.

Since none of the special technical features of the Groups I+ inventions is found in more than one of the inventions, and since all of the shared technical features are previously disclosed by a combination of the Xin, Hopkins and Willins references, unity of invention is lacking.