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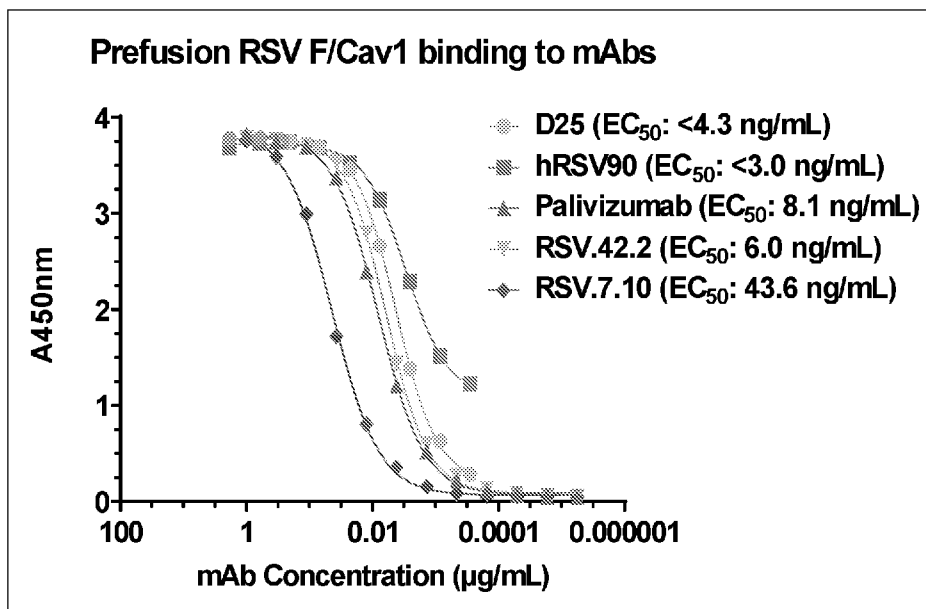
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(54) Title: RSV F VACCINE FORMULATIONS

FIG. 1



(57) Abstract: Disclosed herein are RSV F glycoproteins and nanoparticles comprising the same, which are suitable for use in vaccines. The nanoparticles present antigens from pathogens surrounded to and associated with a detergent core resulting in enhanced stability and good immunogenicity. Dosages, formulations, and methods for preparing the vaccines and nanoparticles are also disclosed.



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

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

03 October 2024 (03.10.2024)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 24/14509

A. CLASSIFICATION OF SUBJECT MATTER
 IPC - INV. A61K 39/155, A61K 39/12, C07K 14/005, C12N 7/00, A61K 39/39, A61K 39/00 (2024.01)
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 CPC - INV. A61K 39/155, A61K 39/12, A61K 39/39, C07K 14/005, C12N 7/00, A61K 39/00
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 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	US 11,446,374 B2 (NOVAVAX, INC.) 20 September 2022 (20.09.2022); abstract; col 4, ln 24-26; col 38, ln 1-4; claim 1, 11	1-3
A	US 9,060,975 B2 (MUCOSIS BV) 23 June 2015 (23.06.2015); entire document	1-3

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 07 June 2024	Date of mailing of the international search report JUL 11 2024
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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 Kari Rodriguez Telephone No. PCT Helpdesk: 571-272-4300
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 24/14509

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.
 - b. furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(a)),
 accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this report has been established to the extent that a meaningful search could be carried out without a WIPO Standard ST.26 compliant sequence listing.
3. Additional comments:

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 24/14509

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.: 4-102
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 Supplemental Box---

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.:
1-3, limited to a deletion of one or more of amino acids 137-146

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/US 24/14509

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 searched, the appropriate additional search fees must be paid.

Group I+: Claims 1-3, directed to a respiratory syncytial virus (RSV) fusion (F) glycoprotein. The respiratory syncytial virus (RSV) fusion (F) glycoprotein will be searched to the extent that the RSV fusion glycoprotein encompasses a deletion of one or more of amino acids 137-146. The first named invention was determined based on first claim modification (claim 1). This first named invention has been selected based on the guidance set forth in section 10.54 of the PCT International Search and Preliminary Examination Guidelines. It is believed that claims 1 and 3(in part), encompass this first named invention, and thus these claims will be searched without fee to the extent that they encompass an RSV fusion glycoprotein comprising a deletion of one or more of amino acids 137-146. Additional RSV fusion glycoproteins comprising additional modifications will be searched upon the payment of additional fees. Applicants must specify the claims that encompass any additionally elected RSV fusion glycoproteins. 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. An exemplary election would be an RSV fusion glycoprotein comprising an inactivated primary furin cleavage site (claim 1).

The inventions listed as 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:

Special Technical Features

The technical feature of each of the inventions listed as Group I+ is a respiratory syncytial virus (RSV) fusion (F) glycoprotein with the specific modification recited therein. Each invention requires a specific modification not required by any of the other inventions.

Common Technical Features

Groups I+ share the technical features of a respiratory syncytial virus (RSV) fusion (F) glycoprotein, comprising an F1 domain, an F2 domain, and p27; wherein the glycoprotein comprises one or more modifications.

However, these shared technical features do not represent a contribution over prior art, because the shared technical features are anticipated by US 11,446,374 B2 to Novavax, Inc. (hereinafter "Novavax").

Novavax discloses a respiratory syncytial virus (RSV) fusion (F) glycoprotein (abstract - "The present invention is generally related to modified or mutated respiratory syncytial virus fusion (F) proteins"), comprising an F1 domain, an F2 domain, and p27 (claim 1 - "wherein the RSV F glycoprotein is cleaved into F1 and F2 subunits which are disulfide linked, and wherein a p27 protein is connected to the F1 subunit via an amide bond"); wherein the glycoprotein comprises one or more modifications selected from the group consisting of: (a) deletion of one or more of amino acids 137-146 (col 4, ln 24-26 - "the RSV F protein further comprises a deletion in the N-terminal half of the fusion domain corresponding to amino acids 137-146").

As the technical features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Groups I+ therefore lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.

Continuation of item 4 above: claims 4-102 are held unsearchable because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 24/14509

Continuation of: A. CLASSIFICATION OF SUBJECT MATTER

CPC - ADD. C12N 2760/18562