

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

|                                                    |                                                                                                  |                                                                                    |
|----------------------------------------------------|--------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| Applicant's or agent's file reference<br>25154     | <b>FOR FURTHER ACTION</b><br>see Form PCT/ISA/220<br>as well as, where applicable, item 5 below. |                                                                                    |
| International application No.<br>PCT/US2022/014812 | International filing date ( <i>day/month/year</i> )<br>2 February 2022 (02-02-2022)              | (Earliest) Priority Date ( <i>day/month/year</i> )<br>4 February 2021 (04-02-2021) |
| Applicant<br><br>MERCK SHARP & DOHME CORP.         |                                                                                                  |                                                                                    |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed  
☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant  
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant  
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 4  
☒ as suggested by the applicant  
☐ as selected by this Authority, because the applicant failed to suggest a figure  
☐ as selected by this Authority, because this figure better characterizes the invention  
b. ☐ none of the figures is to be published with the abstract

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2022/014812

| <b>A. CLASSIFICATION OF SUBJECT MATTER</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| INV.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>A61K39/09</b>                                                                                                                                                                                                                                                                                                                                                                                | <b>A61K39/385</b>                                                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>A61K39/39</b>                                                                                                                                                                                                                                                                                                                                                                                | <b>A61P11/00</b>                                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>A61P31/04</b>                                                                                                                                                                                                                                                                                                                                                                                | <b>A61P37/04</b>                                                        |
| <b>ADD.</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                         |
| According to International Patent Classification (IPC) or to both national classification and IPC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                         |
| <b>B. FIELDS SEARCHED</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                         |
| Minimum documentation searched (classification system followed by classification symbols)<br><b>A61K A61P</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                         |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                         |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br><b>EPO-Internal, WPI Data, BIOSIS, EMBASE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                         |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                         |
| Category*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                                                                                                                                                                              | Relevant to claim No.                                                   |
| <b>X</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>ARADOTTIR PIND AUDUR ANNA ET AL:</b><br><b>"Adjuvants Enhance the Induction of</b><br><b>Germinal Center and Antibody Secreting</b><br><b>Cells in Spleen and Their Persistence in</b><br><b>Bone Marrow of Neonatal Mice",</b><br><b>FRONTIERS IN IMMUNOLOGY,</b><br><b>vol. 10, 1 January 2019 (2019-01-01), page</b><br><b>2214, XP055911943,</b><br><b>DOI: 10.3389/fimmu.2019.02214</b> | <b>1, 2, 6-22</b>                                                       |
| <b>Y</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>abstract</b><br><b>page 3, left-hand column, paragraph 3</b><br>-----<br>-/--                                                                                                                                                                                                                                                                                                                | <b>3-5</b>                                                              |
| <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                         |
| * Special categories of cited documents :<br>"A" document defining the general state of the art which is not considered to be of particular relevance<br>"E" earlier application or patent but published on or after the international filing date<br>"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)<br>"O" document referring to an oral disclosure, use, exhibition or other means<br>"P" document published prior to the international filing date but later than the priority date claimed<br>"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<br>"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<br>"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<br>"&" document member of the same patent family |                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                         |
| Date of the actual completion of the international search<br><b>29 April 2022</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                 | Date of mailing of the international search report<br><b>10/05/2022</b> |
| Name and mailing address of the ISA/<br>European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                 | Authorized officer<br><b>Irion, Andrea</b>                              |

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2022/014812

| C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT |                                                                                                                                                                                                                                                                                                                                                                                                              |                       |
|------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Category*                                            | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                                                                                                                                                                                           | Relevant to claim No. |
| A                                                    | <p>LEROUX-ROELS GEERT ET AL: "A randomized, observer-blind Phase Ib study to identify formulations and vaccine schedules of a trivalent Group B Streptococcus vaccine for use in non-pregnant and pregnant women",<br/>VACCINE,<br/>vol. 34, no. 15, 5 March 2016 (2016-03-05)<br/>, pages 1786-1791, XP029463429,<br/>ISSN: 0264-410X, DOI:<br/>10.1016/J.VACCINE.2016.02.044<br/>abstract</p> <p>-----</p> | 1-22                  |
| X,P                                                  | <p>EP 3 919 076 A1 (MAX PLANCK GESELLSCHAFT [DE]) 8 December 2021 (2021-12-08)<br/>paragraph [0322] - paragraph [0325]<br/>table 1<br/>paragraph [0348]<br/>paragraph [0354] - paragraph [0358]</p> <p>-----</p>                                                                                                                                                                                             | 1, 2, 7,<br>21, 22    |
| Y                                                    | <p>OTT G ET AL: "A cationic sub-micron emulsion (MF59/DOTAP) is an effective delivery system for DNA vaccines",<br/>JOURNAL OF CONTROLLED RELEASE, ELSEVIER, AMSTERDAM, NL,<br/>vol. 79, no. 1-3,<br/>19 February 2002 (2002-02-19), pages 1-5,<br/>XP004340908,<br/>ISSN: 0168-3659, DOI:<br/>10.1016/S0168-3659(01)00545-4<br/>the whole document</p> <p>-----</p>                                         | 3, 5                  |
| Y                                                    | <p>ELIZABETH THORYK ET AL:<br/>"Co-Administration of Lipid Nanoparticles and Sub-Unit Vaccine Antigens Is Required for Increase in Antigen-Specific Immune Responses in Mice",<br/>VACCINES,<br/>vol. 4, no. 4,<br/>6 December 2016 (2016-12-06), page 47,<br/>XP55407769,<br/>DOI: 10.3390/vaccines4040047<br/>abstract<br/>page 2, paragraph 6 - page 3, paragraph 1</p> <p>-----</p>                      | 3-5                   |

## INTERNATIONAL SEARCH REPORT

### Information on patent family members

International application No

PCT/US2022/014812

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
|-------------------------------------------|---------------------|----------------------------|---------------------|
| <b>EP 3919076 A1</b>                      | <b>08-12-2021</b>   | <b>EP 3919076 A1</b>       | <b>08-12-2021</b>   |
|                                           |                     | <b>WO 2021244996 A1</b>    | <b>09-12-2021</b>   |
| -----                                     |                     |                            |                     |