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Published:

- with international search report (Art. 21(3))
- (88) Date of publication of the international search report: 17 October 2013



(54) Title: COMPOSITIONS AND METHODS FOR TREATING VIRAL INFECTIONS

(57) Abstract: The present disclosure provides compositions and methods useful for treating viral infections. As described herein, the compositions and methods are based on the development of immunogenic compositions that include an inactivated virus in combination with a non-ionic surfactant vesicle (NISV). In certain embodiments at least a portion of the antigen present in the composition is physically associated with the NISV. In certain embodiments the compositions are lyophilized and subsequently rehydrated after a period of storage. In certain embodiments the rehydrated compositions exhibit greater potency as compared to otherwise equivalent compositions that lack the NISV. In certain embodiments the lyophilized compositions are stored at temperatures in excess of 8°C prior to rehydration. In certain embodiments the rehydrated compositions exhibit greater potency as compared to otherwise equivalent compositions that lack the NISV and that were also stored at temperatures in excess of 8°C prior to rehydration. In certain embodiments the antigen is taken from a licensed vaccine and the administered dose of antigen is less than the standard human dose for the licensed vaccine.

INTERNATIONAL SEARCH REPORT

International application No. PCT/IB2013/000453

A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61K 47/14 (2006.01), A61K 39/12 (2006.01), A61K 39/13 (2006.01), A61K 39/205 (2006.01), A61K 39/29 (2006.01), A61K 47/08 (2006.01) (more IPCs on the last page)

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)

 $\mathrm{IPC}^8: A61K\ 47/14\ , A61K\ 39/12\ , A61K\ 39/13\ , A61K\ 39/205\ , A61K\ 39/29\ , A61K\ 47/08\ , A61K\ 47/12\ , A61K\ 47/20\ , A61K\ 47/28\ , A61K\ 9/19\ , A61P\ 31/12\ , A61P\ 37/04\ , A61K\ 47/28\$

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used) STN CAPlus (keywords = non-ionic surfactant, viral, virus, antigen, vesicle, lipid, vaccine, lyophilize, rehydration, immunogenic); Canadian Patent Database (IPC + keywords)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X | CA 2,767,392 A1 (Anderson et al.) 13 January 2011 (13-01-2011) *Claims* | 1-19, 28-43 |
| X | CA 2,803,282 A1 (Anderson et al.) 13 January 2011 (13-01-2011) *Claims'' | 1-19, 28-43 |
| X | US 2010/0226932 A1 (Smith et al.) 9 September 2010 (09-09-2010) *paragraphs [0029]-[0043], [0047]-[[0070], [0105]* | 1-19, 28-43 |
| Р, Х | WO 2012/006368 A2 (Anderson et al.) 12 January 2012 (12-01-2012) *entire document* | 1–19, 28-43 |
| P, X | WO 2012/097346 A1 (Anderson et al.) 19 July 2012 (19-07-2012) *entire document* | 1–19, 28–43 |
| | | |

| [] F | Further documents are listed in the continuation of Box C. | [X] See patent family annex. | |
|---|---|--|--|
| * "A" | Special categories of cited documents: document defining the general state of the art which is not considered | "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 | |
| "E" | to be of particular relevance earlier application or patent but published on or after the international filing date | "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 | |
| "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) | "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 | |
| "P" | document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed | "&" document member of the same patent family | |
| Date of the actual completion of the international search | | Date of mailing of the international search report | |
| 12 June 2013 (12-06-2013) | | 09 July 2013 (09-07-2013) | |
| Name and mailing address of the ISA/CA Canadian Intellectual Property Office | | Authorized officer | |
| Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street | | Tung Siu (819) 934-6735 | |
| Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476 | | | |
| Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 | | Tung Siu (819) 934-6735 | |

INTERNATIONAL SEARCH REPORT Information on patent family members

International application No. PCT/IB2013/000453

| Patent Document Cited in Search Report | Publication Date | Patent Family Member(s) | Publication Date |
|---|-------------------------------|---|--|
| CA2767392A1 | 13 January 2011 (13-01-2011) | AU2010270722A1 CN102482666A EP2451950A1 IL217375D0 JP2012532200A MX2012000372A US2012156240A1 WO2011005769A1 | 01 March 2012 (01-03-2012) 30 May 2012 (30-05-2012) 16 May 2012 (16-05-2012) 29 February 2012 (29-02-2012) 13 December 2012 (13-12-2012) 28 February 2012 (28-02-2012) 21 June 2012 (21-06-2012) 13 January 2011 (13-01-2011) |
| CA2803282A1 | 13 January 2011 (13-01-2011) | CA2803282A1 US2012177683A1 WO2011005772A1 | 13 January 2011 (13-01-2011) 12 July 2012 (12-07-2012) 13 January 2011 (13-01-2011) |
| US2010226932A1 | 09 September 2010 (09-09-2010 | D) EP1988918A2 EP1988918A4 WO2007098186A2 WO2007098186A3 | 12 November 2008 (12-11-2008) 28 April 2010 (28-04-2010) 30 August 2007 (30-08-2007) 05 June 2008 (05-06-2008) |
| WO2012006368A2 | 12 January 2012 (12-01-2012) | WO2012006368A2 WO2012006368A3 | 12 January 2012 (12-01-2012) 15 March 2012 (15-03-2012) |
| WO2012097346A1 | 19 July 2012 (19-07-2012) | None | |

INTERNATIONAL SEARCH REPORT

International application No. PCT/IB2013/000453

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)

| Thi reas | | | ernational search report has not been established in respect of certain claims under Article 17(2)(a) for the following |
|-------------|------|-----|--|
| 1. | [] | ζ] | Claim Nos.: 20-27 |
| | | | because they relate to subject matter not required to be searched by this Authority, namely : |
| | | | Claims 20-27 are directed to a method for treatment of the human or animal body by surgery or therapy which the International Search Authority is not required to search. However, this Authority has carried out a search based on the alleged effects or purposes/uses of the product defined in claims 20-27. |
| 2. | ſ | 1 | Claim Nos. : |
| | ı | | 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. | ſ | 1 | Claim Nos. : |
| | | _ | because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a). |
| Box | No | Э. | III Observations where unity of invention is lacking (Continuation of item 3 of first sheet) |
| This | s In | ter | national Searching Authority found multiple inventions in this international application, as follows: |
| 1 | r | 7 | As all manifed additional growth for grown timely said by the applicant this intermetional growth growth course all |
| 1. | l | J | 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 claim 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 claim Nos. : |
| | | | 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/IB2013/000453

| A61K 47/12 (2006.01), A61K 47/20 (2006.01), A61K 47/24 (2006.01), A61K 47/28 (2006.01), A61K 9/19 (2006.01), A61P 31/12 (2006.01), A61P 37/04 (2006.01) | | | | |
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