

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: LAVERY, DE BILLY, LLP 1 Place Ville Marie Suite 4000 MONTREAL, Quebec Canada, H3B 4M4		PCT WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;">Date of mailing <i>(day/month/year)</i></td> <td style="width: 50%; padding: 5px;">16 January 2023 (16-01-2023)</td> </tr> </table>		Date of mailing <i>(day/month/year)</i>	16 January 2023 (16-01-2023)
Date of mailing <i>(day/month/year)</i>	16 January 2023 (16-01-2023)				
Applicant's or agent's file reference BN-10875-00196		FOR FURTHER ACTION See paragraph 2 below			
International application No. PCT/CA2022/051600	International filing date <i>(day/month/year)</i> 28 October 2022 (28-10-2022)	Priority date <i>(day/month/year)</i> 01 November 2021 (01-11-2021)			
International Patent Classification (IPC) or both national classification and IPC IPC: C07H 15/04 (2006.01), A61K 39/09 (2006.01), A61K 39/385 (2006.01), A61P 31/04 (2006.01), A61P 37/04 (2006.01), C07H 3/06 (2006.01), C07H 5/06 (2006.01), C07H 13/00 (2006.01), C08B 37/00 (2006.01) CPC: C07H 15/04 (2020.01), A61K 39/09 (2020.01), A61K 39/385 (2020.01), A61P 31/04 (2020.01), A61P 37/04 (2020.01), C07H 3/06 (2020.01), C07H 13/00 (2020.01), C08B 37/006 (2020.01)					
Applicant UNIVERSITÉ DE MONTRÉAL ET AL					

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Date of completion of this opinion 16 January 2023 (16-01-2023)	Authorized officer Lu Jiang (819) 639-4540
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Box No I

Basis of this opinion

1. With regard to the **language**, this opinion has been established 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)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established 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 only:
- ☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.

4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.

5. Additional comments:

Box No. IV **Lack of unity of invention**

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☒ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:

The claims are directed to a plurality of inventive concepts as follows:

Group A - Claims 1-20 (in part) are directed to a compound of Formulae A0, A, A01, A1, A02, and A2, compound 1, compound 15, and a glycoconjugate, a vaccine formulation, a preparation process for the glycoconjugate and the vaccine formulation, and a use thereof for the prevention of a disease associated to *Streptococcus suis* in a mammal;

Group B - Claims 1-20 (in part) are directed to a compound of Formulae B0, B, B01, B1, B02, and B2, compound 4, compound 16, and a glycoconjugate, a vaccine formulation, a preparation process for the glycoconjugate and the vaccine formulation, and a use thereof for the prevention of a disease associated to *Streptococcus suis* in a mammal;

Group C - Claims 1-20 (in part) are directed to a compound of Formulae C0, C, C01, C1, C02, and C2, compound 7, compound 17, and a glycoconjugate, a vaccine formulation, a preparation process for the glycoconjugate and the vaccine formulation, and a use thereof for the prevention of a disease associated to *Streptococcus suis* in a mammal;

Group D - Claims 1-20 (in part) are directed to a compound of Formulae D0, D, D01, D1, D02, and D2, compounds 10-12, compounds 18-20, and a glycoconjugate, a vaccine formulation, a preparation process for the glycoconjugate and the vaccine formulation, and a use thereof for the prevention of a disease associated to *Streptococcus suis* in a mammal;

Group E - Claims 1-20 (in part) are directed to a compound of Formulae E0, E, E01, E1, E02, and E2, compound 13, compound 21, and a glycoconjugate, a vaccine formulation, a preparation process for the glycoconjugate and the vaccine formulation, and a use thereof for the prevention of a disease associated to *Streptococcus suis* in a mammal; and

Group F - Claims 1-20 (in part) are directed to a compound of Formulae F0, F, F01, F1, F02, and F2, compound 14, compound 22, and a glycoconjugate, a vaccine formulation, a preparation process for the glycoconjugate and the vaccine formulation, and a use thereof for the prevention of a disease associated to *Streptococcus suis* in a mammal.

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claim Nos. 1-20 (in part) that relate to **Groups A, C and D**

Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-20 (in part)	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-20 (in part)	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	None	NO

2. Citations and explanations:

Prior Art

D1 WO 2017/062558 A1 (GOTTSCHALK et al.) 13 April 2017 (13-04-2017)

D2 *Angew. Chem. Int. Ed.* **2021**, 60, 14679– 14692

D1 discloses an immunogenic composition comprising polysaccharide-protein conjugates wherein each conjugate contains a capsular polysaccharide prepared from *Streptococcus suis* serotypes 1, 2, 7 and/or 9 or any other serotype conjugated to a carrier protein.

D2 discloses the synthesis of a collection of 30 novel oligosaccharides resembling the capsular polysaccharides related to four major serotypes (2, 3, 9, 14) of the bacterium *Streptococcus suis*.

Summary of Invention relating to Groups A, C and D

The present invention is directed to a compound of Formulae A0, A, A01, A1, A02, A2, C0, C, C01, C1, C02, C2, D0, D, D01, D1, D02, and D2, compounds 1, 7, 10-12, 15, and 17-20, a glycoconjugate, a vaccine formulation, a preparation process for the glycoconjugate and the vaccine formulation, and a use thereof for the prevention of a disease associated to *Streptococcus suis* in a mammal.

Novelty & Inventive Step

Although **D1** discloses an immunogenic composition comprising polysaccharide-protein conjugates wherein each conjugate contains a capsular polysaccharide prepared from *Streptococcus suis* serotypes 1, 2, 7 and/or 9 and **D2** discloses the synthesis of a collection of 30 oligosaccharides resembling the capsular polysaccharides related to four major serotypes (2, 3, 9, 14) of the bacterium *Streptococcus suis*, neither of them discloses or even suggests a compound of Formulae A0, A, A01, A1, A02, A2, C0, C, C01, C1, C02, C2, D0, D, D01, D1, D02, and D2, compounds 1, 7, 10-12, 15, and 17-20, as well as the glycoconjugate thereof. Therefore, claims 1-20 (in part) comply with PCT Articles 33(2) and 33(3) regarding novelty and inventive step.

(Continued in Supplemental Box)

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 7 does not end with a period.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-6 and 9-20 encompass products that are not defined in clear and concise terms as required under PCT Article 6. Moreover, these claims encompass products with insufficient technical features. In view of the complexity of carbohydrate chemistry and oligosaccharide synthesis, Formulae A0, A, A01, A1, A02, A2, B0, B, B01, B1, B02, B2, C0, C, C01, C1, C02, C2, D0, D, D01, D1, D02, D2, E0, E, E01, E1, E02, E2, F0, F, F01, F1, F02, and F2 encompass an extremely large number of compounds, whereas the application provides support within the meaning of PCT Article 6 and/or adequate disclosure within the meaning of Article 5 for only compounds 1, 4, 7, and 10-22. The claims thus lack clarity and/or support and/or lacks disclosure.

Claims 1-6 do not comply with PCT Article 6. The term "glucose" should read "glucose".

Claim 13 does not comply with PCT Article 6. The claim shall be clear and concise. Commercial availability suggests that the vaccine formulation is known.

Claims 19 and 20 do not comply with PCT Article 6. The preamble of a dependent claim should be consistent with the preamble of the claim or claims to which it refers.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Box No. V**

Industrial Applicability

Claims 1-20 define a compound of Formulae A0, A, A01, A1, A02, A2, B0, B, B01, B1, B02, B2, C0, C, C01, C1, C02, C2, D0, D, D01, D1, D02, D2, E0, E, E01, E1, E02, E2, F0, F, F01, F1, F02, and F2, compounds 1, 4, 7, and 10-22, a glycoconjugate, a vaccine formulation, a preparation process for the glycoconjugate and the vaccine formulation, and a use thereof for the prevention of a disease associated to *Streptococcus suis* in a mammal, which comply with the requirements of PCT Article 33(4).

Claims 16-20 relate to a subject matter considered to be a method of medical treatment. Of note, some jurisdictions, such as Canada, do not recognize the patentability of claims to methods of medical treatment; they may, however, permit claims directed to a product, particularly substances or compositions, as well as claims directed to the contemplated medical use of said product.