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13 November 2014

(54) Title: FORMULATIONS, METHODS AND PROCEDURES FOR REDUCING OR PREVENTING THE DEVELOPMENT, OR THE RISK OF DEVELOPMENT, OF NEUROPATHOLOGY AS A RESULT OF TRAUMA

(57) Abstract: Novel formulations, procedures and methods for their use in treating neuropathology incident to trauma are provided. Multiple-component formulations of the invention, and especially those having four components, comprise biologically active compounds configured for preventing or reducing the incidence and severity of damage caused by neurotrauma. Formulations, methods and procedures of the invention effect both neuroprotective actions to prevent or reduce secondary injuries, and neurotrophic actions to repair and restore cells and tissues affected by the trauma. Formulations, procedures and methods of the invention are especially useful in treating neurological trauma, such as those caused by sports injuries and improvised explosive devices in combat.



WO 2014/108807 A3

## INTERNATIONAL SEARCH REPORT

International application No.

**PCT/IB2014/000594**

| <b>A. CLASSIFICATION OF SUBJECT MATTER</b><br>IPC: <b>A61K 33/00</b> (2006.01) , <b>A61K 31/197</b> (2006.01) , <b>A61K 31/5377</b> (2006.01) , <b>A61K 31/57</b> (2006.01) ,<br><b>A61P 25/00</b> (2006.01)                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| <b>B. FIELDS SEARCHED</b><br><br>Minimum documentation searched (classification system followed by classification symbols)<br>IPC: A61K 33/00 (2006.01) , A61K 31/197 (2006.01) , A61K 31/5377 (2006.01) , A61K 31/57 (2006.01) ,<br>A61P 25/00 (2006.01)<br><br>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)<br>Databases: Total Patent, Espacenet, Canadian Patents Database, Google Scholar<br>Keywords: <u>neuropathology, gabapentin, progesterone, aprepitant, lithium carbonate</u>                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                   |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                   |
| Category <sup>*</sup>                                                                                                                                                                                                                                                                                                                                                                          | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Relevant to claim No.                                                             |
| P,X                                                                                                                                                                                                                                                                                                                                                                                            | CA 2 831 054 HENRY<br>26 December 2013 (26-12-2013)<br>the whole document                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 1-29                                                                              |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                   |
| *<br>"A"<br>"E"<br>"L"<br>"O"<br>"P"                                                                                                                                                                                                                                                                                                                                                           | Special categories of cited documents:<br>document defining the general state of the art which is not considered to be of particular relevance<br>earlier application or patent but published on or after the international filing date<br>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>document referring to an oral disclosure, use, exhibition or other means<br>document published prior to the international filing date but later than the priority date claimed | "T"<br>"X"<br>"Y"<br>"&"                                                          |
| Date of the actual completion of the international search                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Date of mailing of the international search report<br>22 August 2014 (22-08-2014) |
| Name and mailing address of the ISA/CA<br>Canadian Intellectual Property Office<br>Place du Portage I, CI 14 - 1st Floor, Box PCT<br>50 Victoria Street<br>Gatineau, Quebec K1A 0C9<br>Facsimile No.: 001-819-953-2476                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Authorized officer<br><br>Charles Greenough (819) 994-0243                        |

## INTERNATIONAL SEARCH REPORT

International application No.

**PCT/IB2014/000594****Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the 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.  Claim Nos.: 18-29  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claims 18-29 are directed to a method for treatment of the human or animal body by surgery or therapy, which the International Searching Authority is not required to search under Rule 39.1(iv) of the PCT. However, this Authority has carried out a search based on the alleged effect or purpose/use of the product defined in claims 18-29.
2.  Claim 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.  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. 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:

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 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**  
Information on patent family members

International application No.

**PCT/IB2014/000594**

| Patent Document<br>Cited in Search Report | Publication<br>Date           | Patent Family<br>Member(s) | Publication<br>Date           |
|-------------------------------------------|-------------------------------|----------------------------|-------------------------------|
| CA2831 054A1                              | 26 December 2013 (26-12-2013) | CA2831 054A1               | 26 December 2013 (26-12-2013) |
|                                           |                               | US2014 193523A1            | 10 July 2014 (10-07-2014)     |
|                                           |                               | US2014 193526A1            | 10 July 2014 (10-07-2014)     |
|                                           |                               | US2014 193527A1            | 10 July 2014 (10-07-2014)     |
|                                           |                               | US2014 193528A1            | 10 July 2014 (10-07-2014)     |
|                                           |                               | US2014 194394A1            | 10 July 2014 (10-07-2014)     |
|                                           |                               | US2014 194397A1            | 10 July 2014 (10-07-2014)     |