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(72) Inventor; and

(71) Applicant : HENRY, James, Lorne [CA/CA]; 132 North
Shore Boulevard East, Burlington, Ontario L7T 1W4 (CA).

(74) Agent: BERESKIN & PARR LLP/S.E.N.C.R.L., s.r.l.;
40 King Street West, 40th Floor, Toronto, Ontario M5H
3Y2 (CA).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,

DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR,
KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM,
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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, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
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KM, ML, MR, NE, SN, TD, TG).

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(54) Title: THREE-COMPONENT FORMULATIONS, METHODS AND PROCEDURES, AND COMBINATIONS THEREOF, FOR REDUCING OR PREVENTING THE DEVELOPMENT, OR THE RISK OF DEVELOPMENT, OF NEUROPATHOLOGY RESULTING FROM TRAUMA

(57) Abstract: Novel three-component formulations, procedures and methods for use in treating neuropathology incident to trauma are provided. Three-component formulations of the invention comprise biologically active forms of at least one neurosteroid, at least one anti-epileptic or anticonvulsant, and at least one lithium-containing or lithium-related compound. The provided formulations are configured or adapted to prevent or reduce the incidence and severity of neurological damage caused by neurotrauma. Formulations, procedures and methods of the invention advantageously effect both neuroprotective actions to prevent or reduce secondary injuries, and neurotrophic actions to repair and restore cells and tissues affected by the trauma, and are especially useful in treating neurological trauma, such as those caused by sports injuries, chemical weapons, vehicle collisions and improvised explosive devices in combat.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2014/000764

A. CLASSIFICATION OF SUBJECT MATTER

IPC: **A61K 33/00** (2006.01), **A61K 31/197** (2006.01), **A61K 31/57** (2006.01), **A61P 25/00** (2006.01)

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)

IPC: **A61K 33/00** (2006.01), **A61K 31/197** (2006.01), **A61K 31/57** (2006.01), **A61P 25/00** (2006.01)

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)

Total Patent; Intellect; PubMed (gabapentin, progesterone, trauma, lithium, carbonate) (James L. Henry) (Sapna Life Sciences)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	CA 2831054 A1 (HENRY, J.L.) 26 December 2013 (26-12-2013) *whole document*	1-28
X	WO 2009/089024 A1 (MARX, C.E. et al) 16 July 2009 (16-07-2009) *abstract, examples and claim 1 and 8*	1-28
X	WO 2010/1070815 A1 (ROSE, J. E. et al.) 23 September 2010 (23-09-2013) *abstract, examples and claim 1 and 8*	1-28
X	US 2011/0046090 A1 (BARLOW, C. et al) 24 February 2011 (24-02-2011) *whole document, see especially claims 21 and 31, [1070] and [1147]*	1-28

 Further documents are listed in the continuation of Box C.	 See patent family annex.
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* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search 25 September 2014 (25-09-2014)	Date of mailing of the international search report 08 October 2014 (08-10-2014)
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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	Authorized officer Karla Randell (819) 956-6118
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2014/000764**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.: 17-28
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 17-28 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 composition defined in claims 17-28.

2. ☒ Claim Nos.: 13
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:

The International Searching Authority has not carried out a search for claim 13, under Article 17.2(b) of the PCT. The description, claims, and/or drawings fail to comply with the prescribed requirements to such an extent that a meaningful search could not be carried out. Claim 13 so lacks clarity and/or support that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been established for the parts of the application which appear to be clear and supported, namely a composition of gabapentin, progesterone and lithium carbonate.

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/IB2014/000764

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
CA2831054A1	26 December 2013 (26-12-2013)	CA2831054A1 US2014193523A1 US2014193526A1 US2014193527A1 US2014193528A1 US2014194394A1 US2014194397A1 US2014272159A1 WO2014107794A1 WO2014108807A2 WO2014108808A2 WO2014108809A2 WO2014138874A1 WO2014140802A2	26 December 2013 (26-12-2013) 10 July 2014 (10-07-2014) 10 July 2014 (10-07-2014) 10 July 2014 (10-07-2014) 10 July 2014 (10-07-2014) 10 July 2014 (10-07-2014) 10 July 2014 (10-07-2014) 18 September 2014 (18-09-2014) 17 July 2014 (17-07-2014) 17 July 2014 (17-07-2014) 17 July 2014 (17-07-2014) 17 July 2014 (17-07-2014) 18 September 2014 (18-09-2014) 18 September 2014 (18-09-2014)
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