



(43) International Publication Date
17 July 2014 (17.07.2014)

(10) International Publication Number
WO 2014/108809 A3

(51) International Patent Classification:

A61K 31/57 (2006.01) A61P 25/00 (2006.01)
A61K 31/197 (2006.01)

(21) International Application Number:

PCT/IB2014/000609

(22) International Filing Date:

5 January 2014 (05.01.2014)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/750,745 9 January 2013 (09.01.2013) US
14/055,604 16 October 2013 (16.10.2013) US

(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,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM,
ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
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,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(88) Date of publication of the international search report:

30 October 2014

(54) Title: MULTIPLE-COMPONENT PHARMACEUTICAL FORMULATIONS AND METHODS FOR THEIR USE IN
TREATING NEUROPATHOLOGY AND NEURODEGENERATION CAUSED BY TRAUMATIC INJURY

(57) Abstract: Novel two-component formulations, procedures and methods for use in treating neuropathology and neurodegenera-
tion incident to trauma are provided. Two- component formulations of the invention comprise biologically active forms of at least
one neurosteroid or neuroactive steroid, such as progesterone or synthetic progestin, and at least one anti-epileptic or anticonvulsant,
such as pregabalin. The provided formulations are configured or adapted to prevent or reduce the incidence and severity of neurolo-
gical damage caused by trauma. 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.



WO 2014/108809 A3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2014/000609

A. CLASSIFICATION OF SUBJECT MATTER

IPC: **A61K 31/57** (2006.01), **A61K 31/197** (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)
TotalPatent, Canadian Patent Database

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)
TotalPatent, Canadian Patent Database, EPOQUE: anticonvulsant, antiepileptic, neurosteroid, trauma, gabapentin, pregabalin, valproic, progesterone, methylprednisolone, medroxyprogesterone, trauma, neuro

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/0288059 A1 (MARX, et al.) 24 November 2011 (24-11-2011) Claim 9, abstract	1-3, 6-12, 15-24
X	WO 2010/107815 A1 (ROSE, et al.) 23 September 2010 (23-09-2010) claims 17, 20	1-3, 6-12, 15-24
X	US 2011/0301133 A1 (WU, et al.) 8 December 2011 (08-12-2011) claims 25, 28	1-3, 6-12, 15-24
X	WO 2010/077680 A2 (WU, et al.) 8 July 2010 (08-07-2010) claims 25, 28	1-3, 6-12, 15-24
X	US 2011/0046090 A1 (BARLOW, et al.) 24 February 2011 (24-02-2011) claims 1, 4, 5, page 146, paragraph [1160] to page 147	1-3, 6-12, 15-24
X	WO 2012/112340 A2 (PAN) 23 August 2012 (23-08-2012) claims 1, 9, 39-46	1-3, 6-12, 15-24
X	WO 2009/089024 A1 (MARX, et al.) 16 July 2009 (16-07-2009) claim 4, page 93, line 8, example 16; claim 8, abstract	1-3, 6-12, 15-24

 Further documents are listed in the continuation of Box C.

 See patent family annex.

* "A" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance earlier application or patent but published on or after the international filing date 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 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	"T" "X" "Y" "&"	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 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 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 document member of the same patent family
--------------------------------------	--	--------------------------	--

Date of the actual completion of the international search
4 June 2014 (04-06-2014)

Date of mailing of the international search report
24 July 2014 (24-07-2014)

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

Karol Gajewski (819) 934-6734

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/IB2014/000609

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
US2011288059A1	24 November 2011 (24-11-2011)	US2011288059A1 AU2009204429A1 CA2711605A1 EP2249840A1 US2009074677A1 US2009203658A1 WO2009089024A WO2009089024A8 WO2010107815A1 US2013210783A1	24 November 2011 (24-11-2011) 16 July 2009 (16-07-2009) 16 July 2009 (16-07-2009) 17 November 2010 (17-11-2010) 19 March 2009 (19-03-2009) 13 August 2009 (13-08-2009) 16 July 2009 (16-07-2009) 21 October 2010 (21-10-2010) 23 September 2010 (23-09-2010) 15 August 2013 (15-08-2013)
WO2010107815A1	23 September 2010 (23-09-2010)	WO2010107815A1 AU2009204429A1 CA2711605A1 EP2249840A1 US2009074677A1 US2009203658A1 WO2009089024A WO2009089024A8 US2011288059A1 US2013210783A1	23 September 2010 (23-09-2010) 16 July 2009 (16-07-2009) 16 July 2009 (16-07-2009) 17 November 2010 (17-11-2010) 19 March 2009 (19-03-2009) 13 August 2009 (13-08-2009) 16 July 2009 (16-07-2009) 21 October 2010 (21-10-2010) 24 November 2011 (24-11-2011) 15 August 2013 (15-08-2013)
US2011301133A1	08 December 2011 (08-12-2011)	US2011301133A1 AU2009333537A1 CA2746220A1 CN102292338A EP2376495A2 EP2376495A4 JP2012511054A KR20110114565A MX2011006108A RU2011128013A WO2010077680A2 WO2010077680A3	08 December 2011 (08-12-2011) 28 July 2011 (28-07-2011) 08 July 2010 (08-07-2010) 21 December 2011 (21-12-2011) 19 October 2011 (19-10-2011) 31 October 2012 (31-10-2012) 17 May 2012 (17-05-2012) 19 October 2011 (19-10-2011) 18 November 2011 (18-11-2011) 20 January 2013 (20-01-2013) 08 July 2010 (08-07-2010) 14 October 2010 (14-10-2010)
WO2010077680A2	08 July 2010 (08-07-2010)	WO2010077680A2 WO2010077680A3 AU2009333537A1 CA2746220A1 CN102292338A EP2376495A2 EP2376495A4 JP2012511054A KR20110114565A MX2011006108A RU2011128013A US2011301133A1	08 July 2010 (08-07-2010) 14 October 2010 (14-10-2010) 28 July 2011 (28-07-2011) 08 July 2010 (08-07-2010) 21 December 2011 (21-12-2011) 19 October 2011 (19-10-2011) 31 October 2012 (31-10-2012) 17 May 2012 (17-05-2012) 19 October 2011 (19-10-2011) 18 November 2011 (18-11-2011) 20 January 2013 (20-01-2013) 08 December 2011 (08-12-2011)
US2011046090A1	24 February 2011 (24-02-2011)	US2011046090A1 AU2006308889A1 CA2625210A1 EP1942879A1 EP2314289A1 JP2009513672A US2007112017A1 WO2007053596A1	24 February 2011 (24-02-2011) 10 May 2007 (10-05-2007) 10 May 2007 (10-05-2007) 16 July 2008 (16-07-2008) 27 April 2011 (27-04-2011) 02 April 2009 (02-04-2009) 17 May 2007 (17-05-2007) 10 May 2007 (10-05-2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2014/000609

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
WO2012112340A2	23 August 2012 (23-08-2012)	WO2012112340A2 WO2012112340A3 AU2012218094A1 CA2827715A1 CN103764136A EP2675447A2 JP2014514248A MX2013009544A US2013324608A1	23 August 2012 (23-08-2012) 17 April 2014 (17-04-2014) 29 August 2013 (29-08-2013) 23 August 2012 (23-08-2012) 30 April 2014 (30-04-2014) 25 December 2013 (25-12-2013) 19 June 2014 (19-06-2014) 26 September 2013 (26-09-2013) 05 December 2013 (05-12-2013)
WO2009089024A1	16 July 2009 (16-07-2009)	WO2009089024A1 WO2009089024A8 AU2009204429A1 CA2711605A1 EP2249840A1 US2009074677A1 US2009203658A1 US2011288059A1 US2013210783A1 WO2010107815A1	16 July 2009 (16-07-2009) 21 October 2010 (21-10-2010) 16 July 2009 (16-07-2009) 16 July 2009 (16-07-2009) 17 November 2010 (17-11-2010) 19 March 2009 (19-03-2009) 13 August 2009 (13-08-2009) 24 November 2011 (24-11-2011) 15 August 2013 (15-08-2013) 23 September 2010 (23-09-2010)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2014/000609

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.: 14-20
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 14-20 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 14-20.
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.