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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a
patent (Rule 4.17(ii))*

Published:

— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the
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16 October 2014

(54) Title: TREATMENTS FOR DEPRESSION AND OTHER DISEASES WITH A LOW DOSE AGENT

(57) Abstract: The present invention relates to improved compositions and methods for the treatment or prevention of various dis-
eases, including forms of depression, including, for example, breakthrough depression and treatment-refractory depression, and other
mood disorders, as well as Parkinson's disease, bipolar disorder, attention deficit disorder (ADHD), Restless Leg
Syndrome (RLS), and obesity. In some embodiments, the compositions and methods comprise low dose naltrexone or related opioid
antagonists.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2014/013874

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 31/485 (2014.01)

USPC - 514/282

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(8) - A61K 31/485 ; A61P 25/24, 25/36 (2014.01)

USPC - 514/250, 282

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

CPC - A61K 31/00, 31/428, 31/439, 31/485 (2014.02)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Orbit, Google Patents, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2010/0168119 A1 (BEAR et al) 01 July 2010 (01.07.2010) entire document	1-3, 21-23, 41-43, 62-66, 83-88, 90
		89
Y	US 2003/0087896 A1 (GLOVER) 08 May 2003 (08.05.2003) entire document	89
A	US 2006/0069086 A1 (MICHALOW) 30 March 2006 (30.03.2006) entire document	1-3, 21-23, 41-43, 62-66, 83-90
A	US 5,512,593 A (DANTE et al) 30 April 1996 (30.04.1996) entire document	1-3, 21-23, 41-43, 62-66, 83-90
A	US 5,028,612 A (GLOVER) 02 July 1991 (02.07.1991) entire document	1-3, 21-23, 41-43, 62-66, 83-90

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"&" document member of the same patent family

Date of the actual completion of the international search

25 April 2014

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2014/013874

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of 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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims 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. ☒ Claims Nos.: 4-20, 24-40, 44-61, 67-82
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 claims 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 claims 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.