(51) International Patent Classification: A61K 31/47, 31/19, 31/519

(21) International Application Number: PCT/US2004/013308

(22) International Filing Date: 19 May 2004 (19.05.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data: 60/473,378 23 May 2003 (23.05.2003) US


(72) Inventors; and


(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(54) Title: CARBOSTYRIL DERIVATIVES AND MOOD STABILIZERS FOR TREATING MOOD DISORDERS

(57) Abstract: The pharmaceutical composition of the present invention comprises a carbostyril derivative which is a dopamine-serotonin system stabilizer and a mood stabilizer in a pharmaceutically acceptable carrier. The carbostyril derivative may be aripiprazole or a metabolite thereof. The mood stabilizer may include but is not limited to lithium, valproic acid, divalproex sodium, carbamazepine, oxcarbazepine, zonisamide, lamotrigine, topiramate, gabapentin, levetiracetam or clonazepam. These compositions are used to treat patients with mood disorders, particularly bipolar disorder with or without psychotic features, mania or mixed episodes. Methods are provided for separate administration of a carbostyril derivative and a mood stabilizer to a patient with a mood disorder.
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 31/47; A61K 31/19; A61K 31/519
US CL : 514/310

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)

U.S. : 514/310; 514/557; 514/299

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

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

CAPLUS; MEDLINE; EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>WO 02/087590 A1 (ORTHO-MCNEIL PHARMACEUTICAL, INC.) 7 November 2002 (07.11.2002 page 4, lines 17-21; page 5 lines 5-10, 31-32; page 6, lines 4-11.</td>
<td>1-5, 12-16</td>
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<td>X</td>
<td>US 2003/0109546 A1 (FENTON) 12 June 2003 (12.06.2003), see entire document, page 2 [0013]; [0017]; [0032].</td>
<td>1-5, 12-16</td>
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<tr>
<td>P</td>
<td>WO 03/066039 A1 (ABBOT LABORATORIES) 14 August 2003 (14.08.2003), page 5, lines 33-35; page 16 lines 40-42; page 15, lines 10-13.</td>
<td>1-5, 12-16</td>
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<td>P</td>
<td>WO 00/59489 A2 (SEPRACOR, INC.) 12 October 2000 (12.10.2000), page 4, lines 7-12; page 6, lines 14-18; page 7, lines 5-10</td>
<td>1-5, 12-16</td>
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<td>Y</td>
<td>GORDON et al. Mood Stabilization and weight loss with Topiramate, American Journal of Psychiatry, June 1999, Vol. 156, No. 6, pages 968-969, see pages 1 and 2.</td>
<td>1-5, 12-16</td>
</tr>
<tr>
<td>Y</td>
<td>WO 97/35584 A1 (ELI LILLY AND COMPANY) 2 October 1997 (02.10.1997), see page 2, lines 9-15, and lines 34-36.</td>
<td>1-5, 12-16</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C. See patent family annex.

Date of the actual completion of the international search

05 December 2004 (05.12.2004)

Authorized officer

Sreeni Padmanabhan

Telephone No. 571-272-1600

Form PCT/ISA/210 (second sheet) (July 1998)
### C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
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</tr>
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</table>
INTERNATIONAL SEARCH REPORT

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.: 6-11
   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 an additional fee, this Authority did not invite payment of any additional fee.
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.
☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet(2)) (January 2004)