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(54) Title: OMEGA-3 FATTY ACIDS OR OMEGA-3 PHOSPHATIDYLCHOLINE IN THE TREATMENT OF DEPRESSION

(57) Abstract: The present invention is directed to a method of treating patients with major depression by administering omega-3 fatty acids. These may be administered in a substantially purified form, as part of a pharmaceutical composition, or as part of a larger molecule, e.g., triacylglycerol, which releases free fatty acid after ingestion by a patient. The present invention is also directed to triacylglycerols which are esterified at the gamma carbon of glycerol to phosphocholine and at either the alpha or beta carbon of glycerol to an omega-3 fatty acid. These "omega-3 phoshatidylcholines" are also used in the treatment of patients with major depression.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/05926

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61K31/685 A61K31/202 A61K33/14 A61K31/00 A61P25/24				
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 7 A61K A61P				
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 practical, search terms used) CHEM ABS Data, EPO-Internal, PAJ, WPI Data, MEDLINE, BIOSIS, EMBASE				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
7 X	PURI BASANT K ET AL: "Eicosapentaenoic acid in treatment-resistant depression." ARCHIVES OF GENERAL PSYCHIATRY. UNITED STATES JAN 2002, vol. 59, no. 1, January 2002 (2002-01), pages 91-92, XP009014589 ISSN: 0003-990X the whole document.	1-8		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.				
° Special categories of cited documents :				
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "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) "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 </td> <td style="width: 50%; border: none; vertical-align: top;"> "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 "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 "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. "&" document member of the same patent family </td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "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) "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	"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 "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 "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. "&" document member of the same patent family
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "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) "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	"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 "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 "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. "&" document member of the same patent family			
Date of the actual completion of the international search <p style="text-align: center; font-size: 1.2em;">28 July 2003</p>		Date of mailing of the international search report <p style="text-align: center; font-size: 1.2em;">29.01.04</p>		
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer <p style="text-align: center; font-size: 1.2em;">Luangkhot, N</p>		

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/05926

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
10	X JAMES B. ADAMS: "Literature Review of Essential Fatty Acids" HTTP://PUTERAKEMBARA.ORG, [Online] pages 1-4, XP002248820 Retrieved from the Internet: <URL:http://puterakembara.org/rm/EFA.htm> [retrieved on 2003-07-23] the whole document page 3, paragraph 8 * page 4 citations [24], [25] and [26] * ---	1-8
8	X MAIDMENT IAN D: "Are fish oils an effective therapy in mental illness: An analysis of the data." ACTA PSYCHIATRICA SCANDINAVICA, vol. 102, no. 1, July 2000 (2000-07), pages 3-11, XP009014516 ISSN: 0001-690X the whole document abstract page 4, column 1, paragraph 4 page 5, column 2, paragraph 6 ---	1-8
9	X MISCHOULON D ET AL: "Docosahexanoic acid and [omega]-3 fatty acids in depression" PSYCHIATRIC CLINICS OF NORTH AMERICA 2000 UNITED STATES, vol. 23, no. 4, 2000, pages 785-794, XP009014518 ISSN: 0193-953X the whole document page 791, paragraphs 3,4 ---	1-8
6	X WO 97 39759 A (SEVERUS WOLFRAM E ;BRIGHAM & WOMENS HOSPITAL (US); STOLL ANDREW L) 30 October 1997 (1997-10-30) the whole document claims 1-7 ---	1-8
7	X STOLL A L ET AL: "Omega 3 fatty acids in bipolar disorder: a preliminary double-blind, placebo-controlled trial." ARCHIVES OF GENERAL PSYCHIATRY. UNITED STATES MAY 1999, vol. 56, no. 5, May 1999 (1999-05), pages 407-412, XP009014568 ISSN: 0003-990X cited in the application the whole document ---	1-8
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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/05926

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
7	X STOLL A L ET AL: "Omega-3 fatty acids and bipolar disorder: a review." PROSTAGLANDINS, LEUKOTRIENES, AND ESSENTIAL FATTY ACIDS. SCOTLAND 1999 MAY-JUN, vol. 60, no. 5-6, May 1999 (1999-05), pages 329-337, XP009014567 ISSN: 0952-3278 cited in the application the whole document ---	1-8
7	X LOCKE C A ET AL: "Omega-3 fatty acids in major depression." WORLD REVIEW OF NUTRITION AND DIETETICS. SWITZERLAND 2001, vol. 89, 2001, pages 173-185, XP009014587 ISSN: 0084-2230 the whole document * Introduction on p.173 * page 174, paragraph 4 * Conclusion on p.183 * page 175, paragraph 1 ---	1-8
7	A STOLL A L ET AL: "Methodological considerations in clinical studies of omega 3 fatty acids in major depression and bipolar disorder." WORLD REVIEW OF NUTRITION AND DIETETICS. SWITZERLAND 2001, vol. 88, 2001, pages 58-67, XP009014586 ISSN: 0084-2230 page 58 -----	1
7		

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/05926

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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:
see FURTHER INFORMATION sheet PCT/ISA/210
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.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

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.:

1-8

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-8

Use of an omega-3 fatty acid such as eicosapentaenoic acid (EPA) or docosahexaenoic acid (DHA) or alpha-linolenic acid (ALA) for the treatment of unipolar major depression

2. Claims: 9,21,22

use of a combination of an omega-3 fatty acid with an antidepressant for the treatment of unipolar major depression

3. Claims: 10-19,23-27

use of an omega-3 phosphatidylcholine and/or combination thereof with an other antidepressant for the treatment of unipolar major depression; and said pharmaceutical compositions are claimed a such

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claims 1-9 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/05926

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
WO 9739759	A	30-10-1997	AU	2738497 A	12-11-1997
			WO	9739759 A2	30-10-1997
