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(71) Applicant (for all designated States except US):

METABOLOUS PHARMACEUTICALS, INC.
[US/US]; c/o Third Rock Ventures, 29 Newbury Street,
Boston, MA 02116 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **ARONNE, Louis, J.**
[US/US]; 34 Sherwood Avenue, Greenwich, CT 06831 (US).(74) Agents: **GORDON, Dana, M.** et al.; Foley Hoag LLP,
Seaport World Trade Center West, 155 Seaport Blvd.,
Boston, MA 02210-2600 (US).(81) Designated States (unless otherwise indicated, for every
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DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
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- with international search report (Art. 21(3))
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(88) Date of publication of the international search report:

22 July 2010

(54) Title: COMBINATION THERAPIES FOR THE TREATMENT OF OBESITY

Figure 1

tenuate (diethylpropion) + metformin er	Age Range	Sex	Initial Weight (lb)	Height (in)	Initial BMI	% Loss
tenuate 25 mg qd + metformin er 500 mg qd	51-55	F	194.4	63	35	11.0%
tenuate 25 mg qd + metformin er 500 mg qd	41-45	M	253.5	72	35	24.1%
tenuate 37.5 mg qd + metformin er 500 mg qd	61-65	F	161.3	63	29	5.8%
tenuate 75 mg qd + metformin er 500 mg bid	51-55	F	154.2	62	28	8.0%
						12.2%

(57) Abstract: Described are pharmaceutical compositions comprising metformin, diethylpropion, and at least one pharmaceutically acceptable carrier or excipient. Another aspect of the present invention relates to a method of treating a patient suffering from obesity or needing to lose weight, comprising the step of co-administering to said patient a therapeutically effective amount of metformin and diethylpropion. In certain embodiments, an aforementioned method is practiced in conjunction or tandem with a medical procedure or the use of a medical device or both.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/061015**A. CLASSIFICATION OF SUBJECT MATTER*****A61K 31/135(2006.01)i, A61K 31/155(2006.01)i, A61P 3/04(2006.01)i, A61P 3/10(2006.01)i***

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)

A61K 31/135; A01N 43/04; A01N 43/54; A01N 46/16; A61K 31/365; A61K 31/415; A61K 31/425; C07D 277/04; C07D 411/00

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

(Chinese Patents and application for patent)

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

eKOMPASS(KIPO internal) & Keywords: "diethylpropion, metformin", USPTO, Pubmed, Google.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007-0244130 A1 (EPPL ROBERT et al.) 18 October 2007 See claims 11-12.	1-6
X	US 2004-0204472 A1 (MICHAEL BRIGGS et al.) 14 October 2004 See claims 1, 2 and 9.	1-6
X	US 7115640 B2 (MARTIN RICHARD et al.) 03 October 2006 See claims 18, 20, 25 and 26.	1-6
X	US 6686337 B2 (CONNOR; GREGORY S.) 03 February 2004 See column 1, line 35 - column 3, line 33.	1-6
X	KLONOFF D.C. et al., "Drugs in the Pipeline for the Obesity Market", Journal of Diabetes Science and Technology, September 2008, Vol.2, No.5, pp.913-918 See abstract, page 914, "Current Available Drugs" and page 916, "Combination Drugs in Late Stage Development".	1-6

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

* 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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of 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

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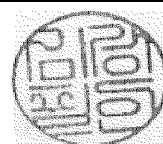
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Government Complex-Daejeon, 139 Seonsa-ro, Seo-
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KANG-PIL KIM

Telephone No. 82-42-481-8393



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2009/061015**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.: 11-63
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 11 to 63 pertain to methods for treatment of the human body by therapy, and thus relate to a subject-matter which International Searching Authority is not required to search Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulation under the PCT.
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.: 7-10
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 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/US2009/061015

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007-0244130 A1	18.10.2007	AR049186A1 AU 2005-247930 A1 AU 2005-247930 B2 AU 2005-247930 B2 AU 2005-247931 A1 AU 2005-247931 B2 AU 2009-202673 A1 BR P10511527A CA 2563818-A1 CA 2563819-A1 CN 1980906 A CN 1980906 C0 CN 1980919 A CN 1980919 C0 ECSP067019A EP 1748993 A1 EP 1749003 A1 JP 2008-500354 A JP 2008-500354 T JP 2008-500355 A KR 10-2007-0030791 A KR 10-2007-0043705 A MXPA06013589A NO20065983A RU2006145893A US 2007-0203155 A1 WO 2005-116000 A1 WO 2005-116016 A1	05.07.2006 08.12.2005 02.04.2009 02.04.2009 08.12.2005 23.10.2008 23.07.2009 02.01.2008 08.12.2005 08.12.2005 13.06.2007 13.06.2007 13.06.2007 13.06.2007 29.12.2006 07.02.2007 07.02.2007 10.01.2008 10.01.2008 10.01.2008 16.03.2007 25.04.2007 15.03.2007 05.02.2007 27.06.2008 30.08.2007 08.12.2005 08.12.2005
US 2004-0204472 A1	14.10.2004	None	
US 7115640 B2	03.10.2006	US 2003-0212111 A1 US 2004-0180942 A1 US 6696473 B2	13.11.2003 16.09.2004 24.02.2004
US 6686337 B2	03.02.2004	US 2002-0147157 A1 US 2004-0157785 A1	10.10.2002 12.08.2004