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Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv))

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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.

(54) Title: LYCOPENE FOR THE TREATMENT OF METABOLIC DYSFUNCTION

(57) Abstract: This invention relates to the treatment of metabolic dysfunction and disorders associated with metabolic dysfunction using lycopene compounds. Methods of treatment and uses of lycopene compounds in such methods are provided.



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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER		
INV.	A23L1/30	A61K31/01
	A61P3/06	A61P3/10
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		A61K31/40
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		A61P1/16
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		
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)		
EPO-Internal, CHEM ABS Data, WPI Data, BIOSIS, EMBASE		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	RU 2 246 239 C (URALAVIASPETSTEKHOLOGIYA CO LTD) 20 February 2005 (2005-02-20) abstract claim 2 ----- -/--	1-3, 8, 9, 12-14, 19, 20, 77-80, 82-85
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> 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 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		Date of mailing of the international search report
19 July 2007		19/11/2007
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 Olausson, Jenny

INTERNATIONAL SEARCH REPORT

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	PARAN E ET AL: "Effect of standardized tomato extract on blood pressure, endothelial function and plasma lycopene levels in treated hypertensive patients" AMERICAN JOURNAL OF HYPERTENSION, ELSEVIER, vol. 18, no. 5, May 2005 (2005-05), page A213, XP004896213 ISSN: 0895-7061	1-3,7, 12-14, 18, 23-25, 29, 34-36,40
Y	the whole document	1-9, 12-20, 23-31, 34-42, 77-80, 82-85
X	----- EP 0 759 294 A2 (FUJIWARA MUTSUMORI [JP]) 26 February 1997 (1997-02-26) page 3, line 9 - line 22 page 5, line 16 - line 30 page 7, line 52 - line 57 -----	1-3,5,7, 12-14, 16,18, 23-25, 27,29, 34-36, 38,40
X	FUHRMAN B ET AL: "Hypocholesterolemic effect of lycopene and b-carotene is related to suppression of cholesterol synthesis and augmentation of LDL receptor activity in macrophages" BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, ACADEMIC PRESS INC. ORLANDO, FL, US, vol. 233, 1997, pages 658-662, XP002082199 ISSN: 0006-291X page 659, column 1, paragraph 2 page 660, column 1, paragraph 1 - column 2, paragraph 1 -----	1-3, 12-14, 23-25, 34-36
X	WO 2004/052351 A (DSM IP ASSETS BV [NL]; BARELLA LUCA [CH]; GORALCZYK REGINA [DE]; SILER) 24 June 2004 (2004-06-24) page 14, line 5 - line 7 -----	1-3,7, 12-14,18
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INTERNATIONAL SEARCH REPORT

International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/155163 A1 (BENJAMIN SAMUEL D [US] ET AL) 24 October 2002 (2002-10-24) claim 10	1-3,7, 12-14,18
X	JP 2004 035510 A (KIKKOMAN CORP) 5 February 2004 (2004-02-05) abstract	1-3,7, 12-14,18
X	WO 2006/016357 A1 (ENZYMOTEC LTD [IL]; SHULMAN AVIDOR [IL]; PELLED DORI [IL]; COHEN TZAFR) 16 February 2006 (2006-02-16) page 9, paragraph 2 page 45 - page 46; example 7	1-3,8,9, 12-14, 19,20, 77-80, 82-85
X	WO 01/91588 A (NESTLE SA [CH]; BORTLIK KARLHEINZ [CH]; SAUCY FRANCOISE [CH]; DURUZ EL) 6 December 2001 (2001-12-06) page 9; example 1 page 10; example 2	77-80, 82-85
Y	RICHELLE M ET AL: "A Food-Based Formulation Provides Lycopene with the Same Bioavailability to Humans as That from Tomato Paste" JOURNAL OF NUTRITION, WISTAR INSTITUTE OF ANATOMY AND BIOLOGY, PHILADELPHIA, PA,, US, vol. 132, no. 3, March 2002 (2002-03), pages 404-408, XP003001332 ISSN: 0022-3166 cited in the application page 408, column 1, paragraph 3	1-9, 12-20, 23-31, 34-42, 77-80, 82-85
P,X	WO 2006/046222 A (LYCORED NATURAL PROD IND LTD [IL]; ZELKHA MORRIS [IL]; SEDLOV TANYA [I]) 4 May 2006 (2006-05-04) page 5, line 26 - line 34 page 6 - page 9; examples 1-7	77-80, 82-85

INTERNATIONAL SEARCH REPORT

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Box 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:

Although claims 1-9, 23-31 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.
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 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:

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.:

see annex

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: 82-85 completely and claims 1-9, 12-20, 23-31, 34-42, 77-80 partially

Compositions (according to claim 77) comprising a lycopene compound alone, methods for making such compositions (according to claim 82) and their use (according to claims 1, 12, 23 and 34) in treating metabolic dysfunction and conditions associated with metabolic dysfunction.

2. claims: 10, 11, 21, 22, 32, 33, 43, 44, 45-76, 81 completely and claims 1-9, 12-20, 23-31, 34-42, 77-80 partially

Compositions (according to claims 45, 52 and 77) comprising a combination of a lycopene compound and a statin and their use (according to claims 1, 12, 23, 34, 59, 68) in treating metabolic dysfunction and conditions associated with metabolic dysfunction.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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