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- as to applicant's entitlement to apply for and be granted a
patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the
earlier application (Rule 4.17(iii))

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For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: COMPOSITIONS CONTAINING POLICOSANOL AND B VITAMINS AND THEIR PHARMACEUTICAL USES

(57) Abstract: A composition is provided which contains policosanol and B vitamins and which may be used for treating and or reducing hypercholesterolemia and hyperhomocysteinemia diseases, total cholesterol, LDL-cholesterol, LDL/HDL ratio, Lp(a), triglycerides, homocysteine, coronary heart disease (heart attacks and strokes), carotid artery disease, inflammation, deep-vein thrombosis, immunoregulatory diseases, cardiovascular diseases, anxiety, depression, neurodegenerative disorders (such as but not limited to Alzheimers), and/or raise HDL cholesterol in humans and animals. The method comprises administering policosanol and B vitamins which together effectively lower the risk of heart disease. Typically, the administered composition includes about 0.1-10:1 parts by weight of policosanol to B vitamins.



WO 2006/014787 A3

INTERNATIONAL SEARCH REPORT

International application No

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A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K31/714 A61K31/525 A61K31/4415 A61K31/045 A61P3/00

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, EMBASE, BIOSIS, CHEM ABS Data, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/020260 A (METAPROTEOMICS, LLC) 13 March 2003 (2003-03-13) abstract table 4	1,2, 5-11, 28-30, 32-34
X	FR 2 693 876 A (VANI) 28 January 1994 (1994-01-28) claims 1-3 page 7, line 19 - line 25 ----- -/--	1,5-7, 11,32-34

☒ 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 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

10 August 2006

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Authorized officer

Leherte, Chantal

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/025943

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 8-10, 14-23, 28-30, 38 and 42-45 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: 14-25, 28-30. 39, 43-45 (all partially), 1-13, 31-38, 40-42, 46, 47

A composition comprising policosanol and one or more B vitamins and is use for the treatment of hypercholesterolemia, hyperhomocysteinemia related diseases, for reducing total cholesterol, LDL-cholesterol, homocysteine levels, for increasing HDL-cholesterol levels, for improving LDL-cholesterol/HDL-cholesterol ratio, for treating coronary heart disease (heart attacks and strokes), carotid artery disease, deep-vein thrombosis and cardiovascular diseases

2. claims: 14-25, 39, 43-45 (all partially)

A composition comprising policosanol and one or more B vitamins and is use for the treatment of inflammation

3. claims: 14-25. 39, 43-45 (all partially)

A composition comprising policosanol and one or more B vitamins and is use for the treatment of immunoregulatory diseases

4. claims: 14-25, 39, 43-45 (all partially)

A composition comprising policosanol and one or more B vitamins and is use for the treatment of anxiety, depression and neurodegenerative disorders (Alzheimers)

5. claim: 26 and 27

An article of manufacture comprising:
(a) a stent body comprising a surface; and (b) a coating comprising at least one layer disposed over at least a portion of the stent body, wherein the said layer comprises polymer film having at least one biologically active agent dispersed therein

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2005/025943

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DAVIDSON M H ET AL: "Efficacy of over-the-counter nutritional supplements" CURRENT ATHEROSCLEROSIS REPORTS 2003 UNITED KINGDOM, vol. 5, no. 1, 2003, pages 15-21, XP008067165 ISSN: 1523-3804 page 17, column 1, paragraph 2 - page 18, column 1, paragraph 1	1-25, 28-47
Y	page 19, column 1, paragraph 2	1-25, 28-47
Y	----- WO 02/088060 A (HAUSER, INC) 7 November 2002 (2002-11-07) page 5, line 16 - page 6, line 5; claims 4-9,12-17	1-25, 28-47
Y	----- GOUNI-BERTHOLD I ET AL: "Policosanol: Clinical pharmacology and therapeutic significance of a new lipid-lowering agent" AMERICAN HEART JOURNAL, MOSBY- YEAR BOOK INC., ST. LOUIS, MO, US, vol. 143, no. 2, February 2002 (2002-02), pages 356-365, XP002263555 ISSN: 0002-8703 cited in the application the whole document	1-25, 28-47
Y	----- US 5 856 316 A (LAGUNA GRANJA ET AL) 5 January 1999 (1999-01-05) claims	1-25, 28-47

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2005/025943

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 03020260	A	13-03-2003	NONE	
FR 2693876	A	28-01-1994	NONE	
WO 02088060	A	07-11-2002	BR 0209240 A CN 1522239 A EP 1390331 A1 NZ 529653 A	16-08-2005 18-08-2004 25-02-2004 19-12-2003
US 5856316	A	05-01-1999	NONE	