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(54) Title: NOVEL FORMULATIONS COMPRISING L	IPID–F	REG	FULATING AGENTS			
(57) Abstract						
The present invention is directed to a formulation comprising a lipid-regulating agent dissolved in at least one propylene glycol fatty acid ester as the primary solvent medium for said agent. One or more emulsifiers may be added to the formulation.						

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#### INTERNATIONAL SEARCH REPORT

Inte onal Application No PCT/US 99/29696

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/48 A61K47/14 A61P3/04

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

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, WPI Data, PAJ, BIOSIS, CHEM ABS Data

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 92 10996 A (MERRELL DOW PHARMA) 9 July 1992 (1992-07-09)	1,6,7, 12,17, 22,23, 28-30
	page 1, line 5 - line 8	
	page 2, line 1 - line 12 page 3, line 14 - line 26	
	page 4, line 21 - line 28	
	page 6, line 35 -page 7, line 5; table II claims; example 1	
	-/	
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X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
<ul> <li>Special categories of cited documents:</li> <li>"A" document defining the general state of the art which is not considered to be of particular relevance</li> <li>"E" earlier document but published on or after the international filing date</li> <li>"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)</li> <li>"O" document referring to an oral disclosure, use, exhibition or other means</li> <li>"P" document published prior to the international filing date but later than the priority date claimed</li> </ul>	"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
7 August 2000	18/08/2000
Name and mailing address of the ISA	Authorized officer
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	Marttin, E

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# INTERNATIONAL SEARCH REPORT

inte onal Application No PCT/US 99/29696

		I
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; KOUJI, MINORU ET AL: "Composition of pharmaceutical preparation improved in peroral absorbability" retrieved from STN Database accession no. 123:152928 XP002144199 abstract & WO 95 14463 A (TAISHO PHARMACEUTICAL CO., LTD., JAPAN) 1 June 1995 (1995-06-01)	1,6,9, 12,17, 22,23
A	US 5 645 856 A (LACY JONATHAN ERNEST ET AL) 8 July 1997 (1997-07-08) cited in the application  column 1, line 4 - line 7 column 3, line 56 -column 4, line 14 column 4, line 36 -column 5, line 51 column 6, line 34 -column 7, line 55 column 8, line 45 -column 9, line 14 column 12, line 22 - line 23 column 12, line 54 -column 13, line 7 column 13, line 47 - line 57; claims 1-8,15-17; example 7	1-3, 6-14, 17-19, 22-25,30
Ε	EP 0 998 927 A (FUJIREBIO KK) 10 May 2000 (2000-05-10)  page 2, paragraph 2 - paragraph 4 page 2, last paragraph -page 3, paragraph 1 page 3, paragraph 10 - paragraph 13 claims; examples 2,3,10-12,14	1,6-10, 12,17, 22,23, 30-32

#### FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

#### Continuation of Box I.2

Present claims 1-32 relate to a compound defined by reference to a desirable characteristic or property, namely a "lipid-regulating agent". The term "lipid-regulating agent" as used in the present independent claims 1, 17, 22 and 23 in dependent claims 2-16, 18-21, and 24-32 defines the active agent by its pharmacological effect. However, a compound canot be sufficiently characterised by its pharmacological effect as it is done by an expression like "lipid-regulating agent", because it is impossible to know which substances are encompassed in this expression. Moreover, a compound cannot be sufficiently characterised by the term "regulating", because this term has no well-recognised meaning and is therefore unclear.

The claims cover all compounds having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such compounds. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the compound by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for the concept of "lipid-regulating agent" and those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the compounds mentioned in claims 2-5.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

## INTERNATIONAL SEARCH REPORT

information on patent family members

Inte. onal Application No PCT/US 99/29696

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EP 0998927	Α	10-05-2000	NONE		