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(54) Title: SELF-EMULSIFYING FORMULATIONS OF FENOFIBRATE AND/OR FENOFIBRATE DERIVATIVES WITH IMPROVED ORAL BIOAVAILABILITY AND/OR REDUCED FOOD EFFECT

(57) Abstract: A fibrate self-emulsifying oral formulation with improved bioavailability when compared to commercially available formulations containing a therapeutically effective dose of fenofibrate, derivative of fenofibrate or mixtures thereof dissolved in a fibrate solubilizer selected from N-alkyl derivative of 2-pyrrolidone, mono- or di- or polyethylene glycol monoethers, C<sub>8-12</sub> fatty acid mono- or di-esters of propylene glycol, or combinations thereof, one or more surfactants and optionally one or more stabilizers useful in the treatment of hypercholesterolaemia or hypertriglyceridaemia in mammals in the fed or fasted state.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/20236

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : A61K 9/16, 9/20, 9/50  
 US CL : 424/462, 456, 458, 459, 489, 490, 497, 464, 465, 469, 470

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)  
 U.S. : 424/462, 456, 458, 459, 489, 490, 497, 464, 465, 469, 470

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 practicable, search terms used)  
 CAS ONLINE, EAST

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,074,670 A (STAMM et al.) 13 June 2000 (13.06.2000), see entire document.	1-17, 20-22
Y	US 5,545,628 A (DEBOECK et al.) 13 August 1996 (13.08.1996), see entire document.	1-17, 20-22
Y	US 4,895,726 A (CURTET et al.) 23 January 1990 (23.01.1990), see entire document.	1-17, 20-22

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	"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
"E"	earlier application or patent published on or after the international filing date	"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
"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)	"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
"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	"&" document member of the same patent family

Date of the actual completion of the international search

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/20236

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claim 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.  Claim Nos.: 18 and 19  
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:

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.

No protest accompanied the payment of additional search fees.