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(74) Agent: INSPICOS A/S; Bøge Allé 5, P.O. Box 45, DK-2970 Hørsholm (DK).

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(71) Applicant (for all designated States except US):
ADITECH PHARMA AB [SE/SE]; Medeon - Malmö Science Park, P.A. Hanssonsväg 41, S-205 12 Malmö (SE).

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(72) Inventors; and

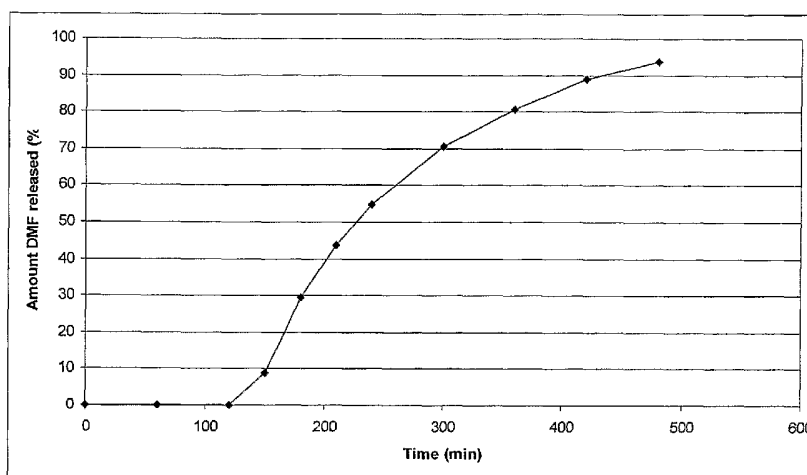
(75) Inventors/Applicants (for US only): NILSSON, Henrik [SE/DK]; Cort Adelersgade 4, st.th., DK-1053 Copenhagen (DK). SCHÖNHARTING, Florian [DK/SE]; Sundspromenaden 27, 3, s., S-211 16 Malmö (SE). MÜLLER, Bernd, W. [DE/DE]; Schlotfeldtsberg 14a, D-24220 Flintbek (DE). ROBINSON, Joseph, R.

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[Continued on next page]

(54) Title: CONTROLLED RELEASE PHARMACEUTICAL COMPOSITIONS COMPRISING A FUMARIC ACID ESTER



(57) Abstract: The present invention relates to controlled release pharmaceutical compositions comprising fumaric acid ester(s) as active substance(s). The compositions are suitable for use in the treatment of e.g. psoriasis or other hyperproliferative, inflammatory or autoimmune disorders and are designated to release the fumaric acid ester in a controlled manner so that local high concentrations of the active substance within the gastrointestinal tract upon oral administration can be avoided and, thereby, enabling a reduction in gastro-intestinal related side-effects.



— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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.

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INTERNATIONAL SEARCH REPORT

International application No

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A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K9/20

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, 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	US 4 959 389 A (SPEISER ET AL) 25 September 1990 (1990-09-25) column 1, lines 44-65; claim 1; examples 1-4	14-29, 34-39, 43,45
X	US 5 424 332 A (SPEISER ET AL) 13 June 1995 (1995-06-13) example 1	14-29, 34-39, 43,45
X	US 2003/013761 A1 (JOSHI RAJENDRA KUMAR ET AL) 16 January 2003 (2003-01-16) paragraphs [0012] - [0015], [0019]; examples 1-3 ----- -/--	14-29, 34-39, 43,45

☒ 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
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- *&* document member of the same patent family

Date of the actual completion of the international search

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23/05/2006

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

Uh1, M

INTERNATIONAL SEARCH REPORT

International application No

PCT/DK2005/000648

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 6 355 676 B1 (JOSHI RAJENDRA KUMAR ET AL) 12 March 2002 (2002-03-12) column 5, lines 1-59; claims 1-3,19,37; examples 1,2; table 1 -----	14-29, 34-39, 43,45
X	US 6 359 003 B1 (JOSHI RAJENDRA KUMAR ET AL) 19 March 2002 (2002-03-19) column 2, line 54 - column 3, line 13; claims 1,8,10,11; example 8 -----	14-29, 34-39, 43,45
A	KREUTER A ET AL: "TREATMENT OF DISSEMINATED GRANULOMA ANNULARE WITH FUMARIC ACID ESTERS" BMC DERMATOLOGY, BIOMED CENTRAL,, US, vol. 2, no. 5, 19 March 2002 (2002-03-19), XP008047020 ISSN: 1471-5945 the whole document -----	14-29, 34-39, 43,45

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 1-13, 30-33, 40-42,44

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy is the reason why claim 44 is not searched.

Continuation of Box II.2

Claims Nos.: 1-13, 30-33, 40-42

pharmakokinetic parameters are aims to be achieved but can not replace the technical features necessary to achieve them, the same applies for a comparison of unspecified GI related side effects in comparison to a prior art fumaderm tablet. These pharmakokinetic parameters or comparison tests can not be taken into account as features which results in a very large number of documents relevant to the issue of novelty. So many documents were retrieved that it is impossible to determine which parts of the claims 1-13 may be said to define subject-matter for which protection might legitimately be sought (Article 6 PCT). The characterisation of a medicament only by indicating how often it should be taken per day is in absence of any further technical features characterising the tablet as such is considered to be meaningless (claims 30-33). The same applies to the features of claims 40-42 where relative terms are used to characterise tablets.

The applicant's attention is drawn to the fact that 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. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK2005/000648

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.: 1-13, 30-33, 40-42, 44
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by therapy is the reason why claim 44 is not searched.
2. ☒ Claims Nos.: 1-13, 30-33, 40-42
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:
see FURTHER INFORMATION sheet PCT/ISA/210
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:

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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/DK2005/000648

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INTERNATIONAL SEARCH REPORT

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