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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Ned: 06-098506-00003-0000
Rec: 2007-01-30 15:08:20 Dep. 2006 NUEVAS CREACIONES
Id. 11 PATENTE/ITR
Evr: 3/4 TABENALXNALH
Act 444 RESPUESTA/NEUR Folio: 12

Re.: Expediente No. 06 098506

Solicitud de patente PCT fase nacional

Solicitud internacional No. PCT/US2005/010371

Titular: AVENTIS PHARMACEUTICALS INC.

Yo, LUIS PATIÑO LEYVA, vecino de Bogotá D.C., portador de la tarjeta profesional No. 2698, obrando como apoderado en este negocio, manifiesto a usted que doy respuesta al Oficio No. 14628 notificado por estado del 22 de Diciembre de 2006, en los siguientes términos:

- Acompaño documento de Reporte de Examen Preliminar Internacional junto con su traducción al español.

Señor Superintendente,


LUIS PATIÑO LEYVA

C.C. No. 2.930.616 de Bogotá

T.P. No. 2698

30 ENE. 2007

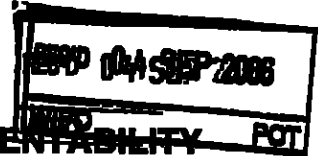
PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



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Applicant's or agent's file reference UAS V2002/0240	FOR FURTHER ACTION See Form PCT/PEA/418	
International application No. PCT/US2005/010371	International filing date (day/month/year) 29.03.2005	Priority date (day/month/year) 01.04.2004
International Patent Classification (IPC) or national classification and IPC INV. A61K31/192 A61K31/426 A61P25/02 A61P25/28		
Applicant AVENTIS PHARMACEUTICALS INC. et al		
1. This report is the International preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 7 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☒ sent to the applicant and to the International Bureau a total of 2 sheets, as follows: ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 807 of the Administrative Instructions). ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. ☐ (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).		
4. This report contains indications relating to the following items: ☒ Box No. I Basis of the report ☐ Box No. II Priority ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☐ Box No. IV Lack of unity of invention ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited ☐ Box No. VII Certain defects in the international application ☐ Box No. VIII Certain observations on the international application		
Date of submission of the demand 02.01.2006	Date of completion of this report 30.08.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tlx 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer A. Jakobs Telephone No. +31 70 340-2617 	

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**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/US2005/010371

Box No. I Basis of the report

1. With regard to the language, this report is based on

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements* of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-33 as originally filed

Claims, Numbers

1-8 received on 08.08.2006 with letter of 08.08.2006

Drawings, Sheets

1/7-7/7 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☒ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☒ the claims, Nos. 8,7
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify):*
- ☐ any table(s) related to sequence listing *(specify):*

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify):*
- ☐ any table(s) related to sequence listing *(specify):*

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 1-3,6,8 (partially)

because:

- ☒ the said international application, or the said claims Nos. 1-3,6,8 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*).
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*).
- ☐ no international search report has been established for the said claims Nos.
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
 - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
 - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

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**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/US2005/010371

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-8
Inventive step (IS)	Yes: Claims	
	No: Claims	1-8
Industrial applicability (IA)	Yes: Claims	see separate sheet
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/US2005/010371

Re Item III.

Claims 1-3,6,8 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no report will be established with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

No report will be established with respect to subject matter which is not covered by the search report.

Re Item V.

1 Reference is made to the following documents:

D1 : WO 02/28434 A (GLAXO GROUP LIMITED; BUCHAN, KEVIN, WILLIAM) 11 April 2002 (2002-04-11)

D2 : WO 02/28433 A (GLAXO GROUP LIMITED; BUCHAN, KEVIN, WILLIAM) 11 April 2002 (2002-04-11)

D3 : WO 02/13812 A (PERSHADSINGH, HARRIHAR, A) 21 February 2002 (2002-02-21)

2 CLAIMS 1-8

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1-8 is not new in the sense of Article 33(2) PCT.
Document D1 discloses (see the passages cited in the search report and page 7, line 5-6) the use of the PPAR delta agonist {2-methyl-4- [4-methyl-2- (4- trifluoromethyl phenyl) thiazol-5-ylmethylthio] phenoxy}-acetic acid for treating multiple sclerosis and pharmaceutical compositions per se comprising {2-methyl-4- [4-methyl-2- (4- trifluoromethyl phenyl) thiazol-5-ylmethylthio] phenoxy}-acetic acid.

2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1-8 is not new in the sense of Article 33(2) PCT.

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Document D2 discloses (see the passages cited in the search report) the use of the PPAR delta agonist (2-methyl-4- [4-methyl-2- (4- trifluoromethyl phenyl) thiazol-5-ylmethylthio] phenoxy)-acetic acid and pharmaceutically acceptable salts to treat multiple sclerosis and pharmaceutical compositions per se comprising (2-methyl-4- [4-methyl-2- (4- trifluoromethyl phenyl) thiazol-5-ylmethylthio] phenoxy)-acetic acid.

- 2.3 The attention of the applicant is drawn to the fact that the disclosure of a document has to be considered as a whole and not only on the basis of the examples thereof. It is the overall disclosure which the skilled person can unambiguously take from a document which is decisive for establishing whether such disclosure is novelty destroying or not. This means that, when examining novelty, different passages of one document (here D1 or D2) may be combined provided that there are no reasons which would prevent a skilled person from such a combination. In general the technical teaching of examples may be combined with that disclosed elsewhere in the same document, e.g. in the description of a patent document, provided that the example concerned is indeed representative for the general technical teaching disclosed in the respective document.

3 CLAIMS 1-8

Claims 1-8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

- 3.1. The subject-matter of claims 1-8 consists in the selection of a disease to be treated, in particular multiple sclerosis from the range of diseases described in document D1, D2, including inflammatory conditions and immune disorders like arthritis (e. g. rheumatoid arthritis, osteoarthritis, prosthetic joint failure), or the gastrointestinal tract (e. g. ulcerative colitis, Crohn's disease, and other inflammatory bowel and gastrointestinal diseases, gastritis and mucosal inflammation resulting from infection, the enteropathy provoked by non-steroidal anti-inflammatory drugs), of the lung (e. g. adult respiratory distress syndrome, asthma, cystic fibrosis, or chronic obstructive pulmonary disease), of the heart (e. g. myocarditis), of nervous tissue (e. g. multiple sclerosis), of the pancreas, (e. g. inflammation associated with diabetes melitus and

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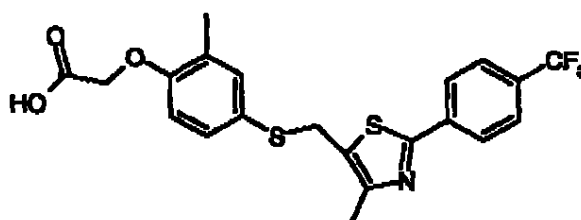
complications thereof of the kidney (e. g. glomerulonephritis), of the skin (e. g. dermatitis, psoriasis, eczema, urticaria and burn injury), of the eye (e. g. glaucoma) as well as of transplanted organs (e. g. rejection) and multi-organ diseases (e. g. systemic lupus erythematosus), inflammatory sequelae of viral or bacterial infections and inflammatory conditions associated with atherosclerosis and following hypoxic or ischaemic insults (with or without reperfusion), for example in the brain or in ischaemic heart disease. Such a selection, even if it could be rendered novel, can only be regarded as inventive, if the use of the specified compounds for treating multiple sclerosis presents unexpected effects or properties in relation to the rest of the range. However, no such effects or properties are indicated in the application. Hence, no inventive step is present in the subject-matter of claims 1-8. From D1, D2, the skilled person would immediately derive their usefulness for treating multiple sclerosis without exerting inventive skills.

- 4 For the assessment of the present claims 1-8 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

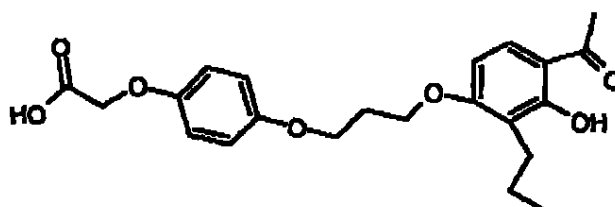
CLAIMS

What is claimed is:

- 5 1. A method for the treatment of demyelinating diseases in a patient comprising the administration of a therapeutically effective amount of a compound selected from the group consisting of compound of formula (1) and formula (2)



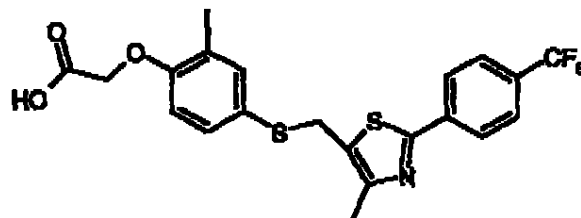
(1)



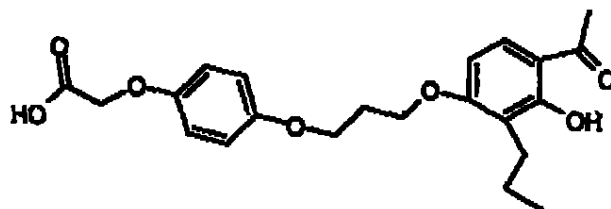
(2).

- 15 2. The method according to claim 1 wherein said demyelinating disease is selected from the group consisting of multiple sclerosis, Charcot-Marie-Tooth disease, Pelizaeus-Merzbacher disease, encephalomyelitis, neuromyelitis optica, adrenoleukodystrophy, Guillian-Barre syndrome and disorders in which myelin forming glial cells are damaged including spinal cord injuries, neuropathies and nerve injury.
- 20 3. The method according to claim 2 wherein the demyelinating disease is multiple sclerosis.

4. A pharmaceutical composition comprising a compound selected from the group consisting of compound of formula (1) and formula (2) in an amount effective for treating multiple sclerosis, Charcot-Marie-Tooth disease, Pelizaeus-Merzhauser disease, encephalomyelitis, neuromyelitis optica, adrenoleukodystrophy, Guillian-Barre syndrome and disorders in which myelin forming glial cells are damaged including spinal cord injuries, neuropathies and nerve injury in combination with at least one pharmaceutically acceptable carrier



(1)

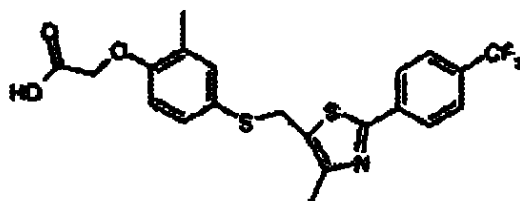


(2)

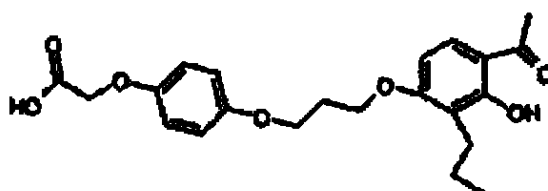
5. The pharmaceutical composition according to claim 4 comprising an amount effective for treating multiple sclerosis.

REIVINDICACIONES

1. Un método para tratar enfermedades de desmineralización en un paciente, que comprende la administración de una cantidad terapéuticamente efectiva de un compuesto seleccionado del grupo que consiste de los compuestos de fórmula (1) y fórmula (2)



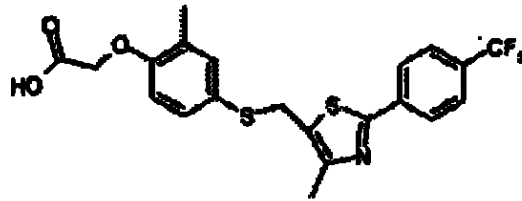
(1)



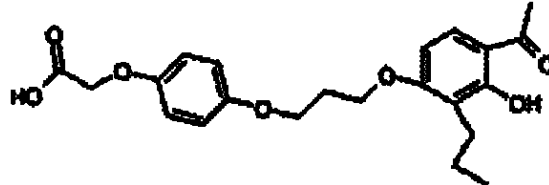
(2).

2. El método de acuerdo con la reivindicación 1 en donde dicha enfermedad de desmineralización es seleccionada del grupo que consiste de esclerosis múltiple, enfermedad de Charcot-Marie-Tooth, enfermedad de Pelizaeus-Merzbacher, encefalomiелitis, neuromielitis óptica, adrenoleucodistrofia, síndrome de guillan-Barre y desordenes en los que las células gliales formadoras de la mielina, incluyendo lesiones de la médula espinal, neuropatías y lesiones nerviosas.
3. El método de acuerdo con la reivindicación 2 caracterizado porque la enfermedad de desmineralización es esclerosis múltiple.
4. Una composición farmacéutica que comprende un compuesto seleccionado del grupo que comprende compuestos de la fórmula (1) y de la fórmula (2) en una cantidad eficaz para tratar la esclerosis múltiple, enfermedad de Charcot-Marie-Tooth, enfermedad de Pelizaeus-Merzbacher, encefalomiелitis, neuromielitis óptica, adrenoleucodistrofia, síndrome de guillan-Barre y desordenes en los que las células gliales formadoras de la mielina, incluyendo

lesiones de la médula espinal, neuropatías y lesiones nerviosas, en combinación con por lo menos un vehículo farmacéuticamente aceptable



(1)



(2).

- 5. La composición farmacéutica de acuerdo con la reivindicación 4 caracterizada porque comprende una cantidad efectiva para tratar la esclerosis múltiple.**