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Señores

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIVISIÓN DE NUEVAS CREACIONES

E. _____ S. _____

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 08-002344- -00002-0000

Fecha: 2008-02-20 15:30:45 Dep. 2020 NUECREACION
Tra. 11 PATENTE IYII Eve: 379 FASE NACIONAL II
Act. 444 RESPUESTA REQUE Folios: 8

Re: Expediente No. 08-002.344

Solicitud de Patente de Invención titulada: "AGONISTAS DE PPAR
[ALFA/GAMMA] Y PROCESOS DE PREPARACION".

Solicitante: NOVARTIS AG

Nuestra Ref.: P2007/000226

RESPUESTA AL OFICIO No. 1597 NOTIFICADO
POR FIJACION EN LISTA No. 33, DE FECHA 8 DE FEBRERO DE 2008
(EXAMEN DE FORMA)

CARLOS R. OLARTE, mayor de edad y vecino de Bogotá, identificado tal como aparece al pie de mi firma, en mi carácter de apoderado de la sociedad en referencia, me permito dar respuesta al auto emanado de ese Despacho, dentro del término legal previsto en el Artículo 39 de la Decisión 486, en los siguientes términos:

1. En respuesta a la única observación del Examinador, me permito aclarar al despacho que la presente solicitud entra en Fase Nacional Capítulo I y no Capítulo II como inicialmente se presentó. Para tal efecto adjunto copia del Reporte Preliminar Internacional de Patentabilidad, el cual valga la pena aclarar no contiene anexos.

Atentamente,

CARLOS R. OLARTE
CC: No. 79.782.747 de Bogotá
T.P. 74.295

Adjunto: Reporte Preliminar Internacional de Patentabilidad.

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 34310	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2006/027441	International filing date (<i>day/month/year</i>) 12 July 2006 (12.07.2006)	Priority date (<i>day/month/year</i>) 13 July 2005 (13.07.2005)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant NOVARTIS AG			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. 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 |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Date of issuance of this report 16 January 2008 (16.01.2008)
	Authorized officer Nora Lindner e-mail: pt02.pct@wipo.int

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2006/027441

International filing date (day/month/year)
12.07.2006

Priority date (day/month/year)
13.07.2005

International Patent Classification (IPC) or both national classification and IPC
INV. C07D413/12 A61K31/422 A61P3/06

Applicant
NOVARTIS AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ 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 Rule 43bis.1(a)(i) 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

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - Gitschiner Str. 103
D-10958 Berlin
Tel. +49 30 25901 - 0
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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Hoepfner, Wolfgang

Telephone No. +49 30 25901-337



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2006/027441

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Box No. 1 Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ 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 (Rules 12.3(a) and 23.1 (b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material:

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material:

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing:

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No. 121
PCT/US2006/027441

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

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. 1-11, 18-20, 22-25 (all partially)

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):
- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-11, 18-20, 22-25 (all partially) are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

- ☐ 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 whole application or for 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 Searching 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 Searching 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 13^{ter}.1(a) or (b).
- ☐ 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 Searching 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 Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No. **122**
PCT/US2006/027441

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	5-17,31-33
	No: Claims	1-4,18-30
Inventive step (IS)	Yes: Claims	5-17,31-33
	No: Claims	1-4,18-30
Industrial applicability (IA)	Yes: Claims	1-33
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The target compounds mentioned in the preamble of claim 1 refer to a Markush formula the variable "Z" of which has the meaning "chemical bond", "oxygen" or "sulfur", whereas the claimed process in the characterising part solely addresses the use of reagents, wherein the said variable has the meaning "oxygen".

Consequently, the claim lacks clarity and the search was restricted to a process with "Z=O".

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

D1: WO 03/043985 A (NOVARTIS AG [CH]; NOVARTIS PHARMA GMBH [AT]; BACH ANDREW THOMAS [US];) 30 May 2003 (2003-05-30) cited in the application

Novelty

The document D1 discloses a process for the preparation of PPAR α/γ agonists comprising the same steps a), b), c) as claimed in present claim 1. Likewise, there are contemplated in D1 pharmaceutically acceptable salts of the said antagonists (see page 1, paragraph 1; page 1, Formula (I); page 3, lines 5, 6; page 3, lines 7-9; page 17, line 1 - page 19, line 11; page 23, line 28 - page 24, line 1; page 26, lines 3-19; Example 2 in combination with page 55, Example 6, Compd. No. 6-46).

In view of this prior art, it appears that the subject-matter of independent claim 1 and dependent claims 2-4 and 18-30 is novelty-destroying anticipated by D1.

Even, if D1 refers to potassium salts, the particular hemi-salts of claims are deemed a formally novel selection from D1.

Inventive step

The distinguishing feature between the remaining novel subject-matter and D1 is the provision of a particular potassium salt within the general teachings of D1.

However, in the absence of any evidence for an unexpected technical effect linked to this feature, the objective problem underlying the novel subject-matter can merely be seen as the provision of a pharmaceutically acceptable salt within the ambit of D1 and the provision of a process for its preparation.

The solution underlying the remaining novel subject-matter was the selection of a hemi-salt of the Compd. No. 6-46 and potassium.

However, since this solution is not linked to an unexpected technical effect, it is deemed an arbitrary selection from the prior. Such an arbitrary selection, however, cannot contribute to inventive step.

This applies even more, since the acid 6-46 as such is already crystalline so that the skilled person could expect that it would be possible to obtain mixed crystals.

Industrial applicability

There is no doubt that the subject-matter of the present claims 1-33 is industrially applicable.

Re Item VIII

Certain observations on the international application

Claim 1 and all dependent claims which address the variable "Z" lack clarity, since the claimed process in the characterising part of claim 1 solely addresses the use of reagents, wherein the said variable is restricted to "oxygen".

Substance claims 31-33 appear to address the same compound (see also process claim 5).

However, the presence of three independent claims addressing exactly the same subject-matter does not appear to make much sense.