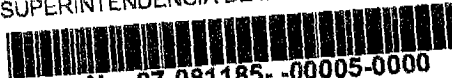


Señora Jefe

DIVISIÓN DE NUEVAS CREACIONES
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Bogotá D.C.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 07-081185-00005-0000

Fecha: 2009-02-12 10:08:15 Dep. 2020 NUECREACIONES
Tra. 11 PATENTEIYII Eve: 378 FASENACIONALI
Act. 449 RESPUESOPOSICI Folios: 14

Ref.: Radicación: 07-81.185

Fase Nacional Solicitud de Patente PCT
a nombre de EURO-CELTIQUE S.A.
RESPUESTA A OPOSICIÓN

En relación con el asunto de la referencia, y estando dentro del término legal fijado para el efecto, procedo a responder a la oposición presentada por GYNOPHARM S.A. en los siguientes términos:

1. El opositor alega que los documentos EP 1 348 429 (D1) y WO03004009 afectan el nivel inventivo de esta solicitud.

No obstante, ni D1 ni D2 sugieren una formulación para obtener formas de dosificación resistentes al alcohol. Por ello, no es cierto que los documentos citados afecten el nivel inventivo de la presente solicitud.

2. Afirma el opositor que la combinación de D1 y D2 podría llevar fácilmente a una persona versada en la técnica, a un polímero termoplástico o a un polímero hidrofóbico como material de matriz de liberación controlada en la fabricación de una formulación matriz opioide de liberación controlada para impartir resistencia a la extracción de alcohol del opioide.

El D1 describe composiciones farmacéuticas que contienen varios polímeros y copolímeros y un ingrediente activo (preferiblemente un opioide). Por su parte, el D2 describe composiciones farmacéuticas que

contienen un acrilato poli (etil acrilato, metil metacrilato) neutro, y un ingrediente activo. Sin embargo, nótese que ni D1 ni D2 divulgan una composición farmacéutica resistente a extracción de alcohol del compuesto activo. Por lo tanto, no hay ningún motivo para que la persona versada en la técnica combine D1 y D2 con el fin de llegar a la presente invención.

Es importante resaltar, además, que ni D1 ni D2 sugieren una formulación para obtener formas de dosificación resistentes a alcohol, y que la persona versada, aún si combina D1 y D2, no llegaría a la presente invención, es decir, a una formulación para obtener formas de dosificación resistentes a alcohol.

3. El examen de la solicitud PCT establece claramente que el objeto materia de la presente solicitud no solo es nuevo, sino que implica nivel inventivo. Dicho examen tuvo en consideración el estado de la técnica anterior, que en efecto comprende los documentos D1 y D2 que menciona el Oponente. Estoy adjuntando una copia del Reporte Internacional de Búsqueda y de la Opinión Escrita de la Autoridad de Búsqueda Internacional del 7 de agosto de 2006, en donde constan estas opiniones expertas.

Así las cosas, les solicito otorgar el privilegio de patente de invención aquí tramitado.

De Ustedes Atentamente,


LUIS FELIPE CASTILLO GIBSONE
C.C.79.397.879 de Bogotá
TP. 68995 del CSJ

PATENT COOPERATION TREATY

219
3

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

To: MAIWALD PATENTANWALTS GMBH Attn. Ehlich, Eva Susanne Elisenhof Elisenstrasse 3 80335 München ALLEMAGNE	MAIWALD Patentanwälte GmbH 12. Sep. 2006 MÜNCHEN
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(PCT Rule 44.1)

Applicant's or agent's file reference <i>12.11.2006 N (WIC) / E</i> E 8355 / ES	Date of mailing (day/month/year) 12/09/2006
International application No. PCT/EP2006/000727	International filing date (day/month/year) 27/01/2006
Applicant EURO-CELTIQUE S.A.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority 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 Natalia Morancho Alcaine
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These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

MATWALD Patentanwalts GmbH	
12. Sep. 2006	
MÜNCHEN	
FRIST	

Applicant's or agent's file reference E 8355 / ES	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/EP2006/000727	International filing date (day/month/year) 27/01/2006	(Earliest) Priority Date (day/month/year) 28/01/2005
Applicant EURO-CELTIQUE S.A.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out 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))

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (See Box No. II)

3. ☐ Unity of invention is lacking (see Box No. III)

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1
☐ as suggested by the applicant
☒ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
 b. ☐ none of the figures is to be published with the abstract

2296

A. CLASSIFICATION OF SUBJECT MATTER INV. A61K9/16 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, EMBASE, PAJ		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 1 348 429 A (EURO-CELTIQUE S.A) 1 October 2003 (2003-10-01) the whole document	
A	WO 03/004009 A (GENEVA PHARMACEUTICALS, INC; MATHARU, AMOL, SINGH; PATEL, MAHENDRA, R) 16 January 2003 (2003-01-16) the whole document	1-115
A	US 5 958 452 A (OSHLACK ET AL) 28 September 1999 (1999-09-28) cited in the application the whole document	1-115
☐ 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 "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 2006		12/09/2006
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 Felder, C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2006/000727

273
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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.: —
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 63, 111 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims 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. ☐ 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.

ZRA

8

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 1348429	A	01-10-2003	NONE	
WO 03004009	A	16-01-2003	NONE	
US 5958452	A	28-09-1999	AT 257375 T	15-01-2004
			AU 705894 B2	03-06-1999
			AU 4157096 A	31-05-1996
			DE 69532415 D1	12-02-2004
			DE 69532415 T2	30-12-2004
			DK 785775 T3	24-05-2004
			EP 0785775 A1	30-07-1997
			ES 2214512 T3	16-09-2004
			HU 77626 A2	29-06-1998
			IL 115871 A	17-08-1999
			JP 3186064 B2	11-07-2001
			JP 10508608 T	25-08-1998
			KR 232945 B1	01-12-1999
			PT 785775 T	30-04-2004
			TW 425288 B	11-03-2001
			WO 9614058 A1	17-05-1996
			US 5965161 A	12-10-1999
			US 2001033865 A1	25-10-2001
			ZA 9509367 A	13-06-1996

225

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

9

To:

see form PCT/ISA/220

MATWALD
Patentanwalts GmbH

12. Sep. 2006

MÜNCHEN

FRIST

12.12.2006 N (HRI) 1/2

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

12.11.06 N (A-19) 1/2

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2006/000727

International filing date (day/month/year)
27.01.2006

Priority date (day/month/year)
28.01.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61K9/16 A61K9/20

Applicant
EURO-CELTIQUE S.A.

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
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Felder, Christian

Telephone No. +49 89 2399-7852



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2006/000727

226

10

Box No. I 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

227
International application No.
PCT/EP2006/000727 11

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. -

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. 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 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 13ter.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

Re Item III.

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
Claims 63 and 111 relate to subject-matter considered by this Authority to be covered
by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated
with respect to the industrial applicability of the subject-matter of these claims (Article
34(4)(a)(I) PCT).

Re Item V.

Reference is made to the following documents:

- D1: EP-A-1 348 429 (EURO-CELTIQUE S.A) 1 October 2003 (2003-10-01)
- D2: WO 03/004009 A (GENEVA PHARMACEUTICALS, INC; MATHARU, AMOL,
SINGH; PATEL, MAHENDRA, R) 16 January 2003 (2003-01-16)
- D3: US-A-5 958 452 (OSHLACK ET AL) 28 September 1999 (1999-09-28) cited in
the application

The present application discloses pharmaceutical compositions resistant to alcohol
extraction of the active compound (in particular opoids).

1. Novelty

The subject-matter of claims 1-115 is novel (Article 33(2) PCT). None of the cited
documents **D1-D3** discloses a pharmaceutical composition resistant to alcohol
extraction of the active compound.

D1 discloses pharmaceutical composition containing various polymers and
copolymers and an active ingredient (preferred an opoid). D2 discloses
pharmaceutical composition containing a neutral poly(ethyl acrylate, methyl
methacrylate) copolymer and an active ingredient. D3 discloses pharmaceutical
composition containing various polymers and copolymers and an active ingredient
(preferred an opoid).

230
14

Therefore, the subject-matter of claims 1-115 is novel over the prior art.

2. Inventive step

The subject-matter of claims 1-115 of the present application is considered as involving an inventive step (Article 33(3) PCT) since none of the cited documents suggest a formulation to obtain alcohol resistant dosage forms.

3. Industrial applicability

For the assessment of the present claims 63 and 111 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.

Present claims 1-62, 64-110 and 112-115 are industrial applicable.

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCIÓN DE NUEVAS CREACIONES**

2020

Abogado
LUIS FELIPE CASTILLO

ASUNTO

Radicación 07 081 185
Trámite 011
Evento 378
Actuación 519
Oficio
Folios 6

008930

Patente de Invención

☒

Patente de Modelo de Utilidad

☐

Vía Nacional

☐

Vía PCT (fase nacional)

☒

Cap. I

☒

Cap. II

☐

No. Solicitud Internacional PCT/EP2006/000727

Fecha de Presentación Internacional 27/Enero/2006

Como resultado del Examen de Fondo realizado, con fundamento en el Artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se comunica:

1. Documentos estudiados

Descripción:	Folios 12 a 73	como se radicó inicialmente.
Reivindicaciones:	Folios 74 a 94	como se radicó inicialmente
Oposiciones:	Folios 134 a 213	GYNOPHARM
Respuesta del solicitante:	Folios 217 a 218	GYNOPHARM

2. Objeto de la invención

Título de la solicitud: "formulaciones opiodes de liberación controlada resistentes a extracción de alcohol" (modificado en el folio 129).

El problema planteado en esta solicitud es la necesidad de una forma de dosificación oral que comprenda un agonista opioide de liberación reducida de opioide al ser expuesto a alcohol..

Para resolver este problema técnico la solicitud en estudio proporciona formulaciones opioides junto con un polímero termoplástico o hidrófobo que presenta una liberación controlada resistente a la extracción con alcohol.

El objeto de la presente Solicitud se relaciona con la Clasificación Internacional de Patentes (CIP): A 61 K 9/16; A 61 K 9/20

Expediente 07 081 185 1er Art 45

3. Excepción a la Patentabilidad (Art 20 D 486 literal d)

El objeto de las reivindicaciones 63 – 64, 111 y 113 no es patentable de acuerdo con el Art citado.

4. Reivindicaciones relativas a un uso o a un segundo uso (Art 14 y 21 D 486)

El uso de la reivindicación 110 no es patentable de acuerdo con los Art citados.

5. De la Solicitud de Patente

Reivindicaciones (Art 30 D 486, Art 22 PCT)

La reivindicación 1 no es clara porque enseña las mismas características técnicas de la invención tanto en el prologo de la reivindicación como en la parte caracterizadora. Se sugiere que se organice de tal manera que la parte caracterizadora revele las características técnicas esencial que identifiquen la invención. Adicionalmente la reivindicación habla de un polímero, una matriz y de una composición, términos que no corresponden a la caracterización del polímero a reivindicar. Se sugiere definir la materia reivindicada y caracterizarla con sus características técnicas esenciales.

La reivindicación 2 corresponde al mismo polímero de la reivindicación 1. Se sugiere establecer la correspondiente dependencia.

Las Reivindicaciones 1 – 62 y 67 – 109 no son claras porque se refieren el perfil de disolución del fármaco desde la formulación, que es un resultado a alcanzar, y la invención queda definida por el resultado a alcanzar, puesto que la reivindicación incluiría no sólo la solución propuesta por el solicitante, sino todas las alternativas presentes o futuras que lleguen a ese resultado. Se sugiere reemplazarlo por las características esenciales, estructurales o funcionales, que contribuyen a la obtención de ese efecto.

Las Reivindicaciones 1 – 62 y 67 – 109 no son claras porque la descripción enseña (folio 27) que tanto el polímero termoplástico como el polímero hidrófobo correaponen a la misma sustancia (alquilcelulosa). Se sugiere caracterizar específicamente la naturaleza de cada polímero.

La reivindicación 114 corresponde al mismo proceso de manufactura de la reivindicación 65. Se sugiere establecer la correspondiente dependencia.

El capítulo reivindicatorio no es conciso porque contiene un excesivo número de reivindicaciones independientes, lo cual hace difícil definir cuál es el objeto que se busca proteger.

Se requiere al Solicitante hacer las aclaraciones necesarias.

6. Análisis de la(s) Oposicion(es)

Argumentaciones de Gynopharm

1. Dice el oponente " ...Se debe advertir que las reivindicaciones se refieren al uso y a un método de tratamiento y no solo a la composición farmacológica ó a un método de fabricación mediante la cual se obtenga un producto tangible y según la legislación, Decisión 486 de la comunidad andina de naciones, artículo 14 (...), los usos no están contemplados como patentables; y artículo 20 (...). Solo serán patentables los productos o procedimientos. Por lo tanto a la luz de la norma, dicha materia referente al uso y a un método de tratamiento no sería patentable."
2. "(...)el documento D1 (EP1348429), particularmente en la descripción, revela formas biodisponible de liberación sostenida en forma de dosificación orales que incluye opiodes analgésicos, comprendiendo una pluralidad de multiparticulados producidos por técnicas de derretido. Según esta anterioridad, se revela una sostenida liberación de formulación farmacéutica, comprendiendo un derretir en la reivindicación 1 una mezcla expulsada de un agente terapéuticamente activo, uno o varios materiales hidrófobos seleccionados del grupo que consiste en alquilcelulosas, polímeros acrílicos y ácidos metacrílicos y copolímeros, laca, zein, aceite de castor hidrogenado, aceite de verduras hidrogenado y mezclas de ellos así como uno o varios portadores hidrófobos fusibles que proporcionan un remoto efecto retardante y seleccionado del grupo que consiste en ceras naturales o sintéticas, ácidos grasos alcohol grasos y mezclas de ellos y dicho portador fusible hidrófobo. (...) el documento D2 (WO03004009) define un proceso para preparar formas de dosificación en pastilla de agentes farmacéuticos de metformina HCl. Según las reivindicaciones de la anterioridad D2, se revela un proceso para preparar una formulación farmacéutica preparando una mezcla por combinado del agente farmacéutico de difícil compresión, un componente hidrófilo erodible y un componente hidrófobo; se comprime la mezcla en una pastilla. por lo tanto, visto dicho documento D2 en combinación con el documento D1, la presente solicitud carece evidentemente de altura inventiva (...).

Respuestas del Solicitante

" (...)ni D1 ni D2 sugieren una formulación para obtener formas de dosificación resistentes al alcohol."

"D1 describe composiciones farmacéuticas que contienen varios polímeros y copolímeros y un ingrediente activo (preferiblemente un opiode). Por su parte D2 describe composiciones farmacéuticas que contienen un acrilato poli (etil acrilato, metil metacrilato) neutro, y un ingrediente activo. Sin embargo nótese que ni D1 ni D2 divulgan una composición farmacéutica resistente a extracción de alcohol del compuesto activo. Por lo tanto, no hay ningún motivo para que la persona versada en la técnica combina D1 y D2 con el fin de llegar a la presente invención."

Respuesta del Examinador Técnico

La invención queda definida por las características técnicas esenciales de tipo estructural y funcional que aporten a que la formulación sea resistente a la extracción con alcohol, y estas características son las evaluadas para determinar la patentabilidad de la invención. Tanto el documento D1 como el documento D2 enseñan características técnicas esenciales que definen la solicitud.

Por esta razón, los documentos presentados en la Oposición desvirtúan la el Nivel Inventivo del objeto de esta solicitud; por lo cual se considerarán dentro del Examen de Patentabilidad.

7. Determinación del Estado de la Técnica

El Estado de la Técnica se determinó con base en la

Fecha de Presentación de la Solicitud de Prioridad: Enero 28 de 2005

y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

Item	Documento	Título	Fecha de Publicación*
D1	EP 1348429 A2	Melt-extruded orally administrable opioid formulations	01/Octubre/2003

D1 divulga (página 5, párrafo 0037) una forma de dosificación de liberación prolongada que comprende un analgésico como fármaco y un material hidrófobo como alquilcelulosa o polímeros o copolímeros acrílicos.

D1 se encuentra disponible en el link http://worldwide.espacenet.com/publicationDetails/originalDocument?CC=EP&NR=1348429A2&KC=A2&FT=D&date=20031001&DB=EPODOC&locale=en_EP

8. Examen de Patentabilidad (Art 14 D486)

Novedad (Art 16 D486)

La reivindicación 1 consiste en un polímero termoplástico escasamente permeable al agua o un polímero hidrofóbico como material matriz de liberación controlada en la manufacturación de una formulación matriz opioide de liberación controlada para otorgar resistencia a la extracción de alcohol del opioide, CARACTERIZADO porque dicha formulación que tiene un polímero termoplástico escasamente permeable al agua o polímero hidrofóbico como material matriz de liberación controlada libera una menor cantidad de opioide en un análisis de extracción de alcohol en comparación con la misma formulación pero con el polímero termoplástico escasamente permeable al agua o polímero hidrofóbico sustituido totalmente o en parte por otros materiales matrices.

Comparación de las características técnicas **esenciales** de la reivindicación 1, con las del Estado de la Técnica:

Características esenciales	D1
polímero termoplástico escasamente permeable al agua	Material hidrofóbico como alquicelulosa o polímero o copilimeros de acrilato
o un polímero hidrofóbico	

Las características **esenciales** de la composición de la reivindicación 1 habían sido divulgadas previamente en D1, el cual enseña un material hidrofóbico como alquicelulosa o polímero o copolímeros de acrilato para liberación controlada (pagina 5, párrafo 0037)

En consecuencia, la reivindicación 1 carece de novedad, según lo divulgado en el documento D1.

La reivindicación 37 consiste en forma de dosis de liberación controlada caracterizada porque comprende:
una matriz que comprende una sal farmacéuticamente aceptable de un analgésico opioide en un material de liberación controlada; en donde menos de un 25% de la sal opioide es liberada luego de 1 hora de disolución in-vitro de la forma de dosis en 900 ml de Fluido Gástrico Simulado con un 20% etanol utilizando un Aparato USP I (cesta) a 100 rpm a 37 grados C°.

Comparación de las características técnicas **esenciales** de la reivindicación 37, con las del Estado de la Técnica:

Características esenciales	D1
Forma de dosis de liberación controlada	Tabletas de liberación controlada
Polímero que comprende una sal farmacéuticamente aceptable de un analgésico opioide en un material de liberación controlada	Fármaco corresponde a oxicodona y contiene un polímero de metacrilato (Eudragit RS30D) y otros excipientes

Las características **esenciales** de la composición de la reivindicación 9 habían sido divulgadas previamente en D1, el cual enseña tabletas de liberación controlada donde el fármaco corresponde a oxicodona y la matriz está hecha con la mezcla de un polímero de metacrilato (Eudragit RS30D) y otros excipientes (página 15, párrafo 0096, ejemplo 14)

En consecuencia, la reivindicación 37 carece de novedad, según lo divulgado en el documento D1.

Las reivindicaciones dependientes 38 – 62 no mencionan alguna característica que haga nueva a la composición de la reivindicación 37, por lo cual se considera que no son nuevas.

La reivindicación 65 consiste en un método para manufacturar una forma de dosis de liberación controlada e las reivindicaciones 37 a 62 caracterizado porque comprende extruir el analgésico opioide y el material de liberación controlada.

Comparación de las características técnicas **esenciales** de la reivindicación 65, con las del Estado de la Técnica:

Características esenciales	D1
Método para manufacturar una forma de dosis de liberación controlada de las reivindicaciones 37 a 62	Método para manufacturar una forma de dosis
Extruir el analgésico opioide y el material de liberación controlada.	Extrusión en caliente del analgésico opioide y el material de liberación controlada

Las características **esenciales** de la composición de la reivindicación 15 habían sido divulgadas previamente en D4, el cual da a conocer un Método para manufacturar una forma de dosis de liberación controlada en forma de pellets a través de la extrusión en caliente del analgésico opioide y el material de liberación controlada (página 12, párrafo 0082)

En consecuencia, la reivindicación 65 carece de novedad, según lo divulgado en el documento D1.

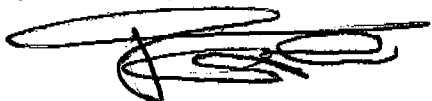
9. Conclusión

Los requisitos de Patentabilidad de la presente Solicitud están afectados así:

Item	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	EP 1348429 A2	1 - 62, 65 - 109, 111 - 115	Novedad

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta (60) días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única No. 10 de 2001.



JOSÉ LUIS SALAZAR LÓPEZ
Director de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por fijación en lista, de fecha

3 JUN. 2011

CONCEPTO TÉCNICO No. 1803	EXAMINADOR TÉCNICO Código No. 202098
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