



No. 13-111250- -00011-0000

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Señor

SUPERINTENDENTE DE INDUSTRIA Y COMERCIO

E.

S.

D.

REF: Expediente No. PCT/13-111250

TÍTULO SOLICITADO: "PROCESO PARA PRODUCIR NALTREXONA Y
NALMAFENO"

PUBLICACIÓN: Gaceta 670 del 28/06/2013, N° de publicación 868.

SOLICITANTE: H. LUNDBECK A/S.

APODERADO: LUZ CLEMENCIA DE PÁEZ.

TRÁMITE: Recurso de Reposición y en subsidio el de apelación en
contra de la Resolución 61494 de octubre 14 de 2014 por
la cual se concede una patente de invención tramitada
bajo el número de expediente PCT/13-111250.

TITO NOÉ PARRA MURILLO, mayor de edad, identificado como aparece al pie de mi
firma, reconocido apoderado de la sociedad LAFRANCOL S.A.S. en el asunto de la
referencia, de manera respetuosa, y dentro de los términos de ley, presento Recurso de
Reposición y en subsidio de apelación contra la Resolución 61494 de octubre 14 de 2014
por la cual se concedió a la solicitud PCT/13-111250 el privilegio de patente de invención.

I. PETICIÓN

Sírvase, Señor Superintendente, reponer íntegramente la Resolución 61494 de octubre 14
de 2014, por la cual se declaró infundada la oposición presentada y se otorgó el privilegio
de patente solicitado en el expediente de la referencia, y en su remplazo emitir otra que, con
fundamento en los argumentos expuestos en el escrito de observación y en el presente
escrito, declare fundada dicha oposición y niegue el privilegio de patente mencionado,

procediendo luego al definitivo archivo del expediente en cuestión.

II. ARGUMENTOS SOBRE LOS FUNDAMENTOS DE LA CONCESIÓN Y MOTIVOS DE INCONFORMIDAD

La Resolución 61494 de octubre 14 de 2014, que concede el privilegio de patente de invención solicitado para el capítulo reivindicatorio del expediente 13-111250 titulado “**Proceso para producir Naltrexona y Nalmafeno**”, viola flagrantemente la Decisión 486 si se tiene en cuenta que existían motivos suficientes para afectar los requisitos de novedad y nivel inventivo de la solicitud en mención. Es evidente que el solicitante y la Resolución cometen un error cuando afirman que la oposición presentada por mi representada no muestra ningún tipo de argumento soportado técnicamente, ni desvirtúa la patentabilidad del objeto de estudio, declarándola infundada por cuanto, al momento de presentación del escrito de oposición se dejó en claro que para el presente caso nos encontramos frente a una combinación de compuestos, lo cual indudablemente afecta el requisito de nivel inventivo, éste mismo indispensable para acceder a cualquier beneficio patentario.

Así las cosas, me permito reiterar que la concesión de patente objeto del presente escrito se ve afectada por los documentos del estado del arte que fueron presentados inicialmente en el escrito de observación, por lo cual, basado en lo siguiente, solicito respetuosamente a ese Despacho dar análisis completo y a cabalidad sobre los siguientes documentos, los cuales sin lugar a dudas objetan la concesión en mención, toda vez que develan de manera expresa y sucinta lo que se pretende proteger en la presente solicitud.

Dicho así, me permito manifestar que agentes tales como Naltrexona, han sido ampliamente divulgados en el sector químico-farmacéutico, y concretamente se han develado materias muy similares, las cuales ruego a ese Despacho analizar, en los siguientes documentos:

- **US 3332950**

Así como resulta imprescindible manifestar que los anteriores documentos deben ser analizados a profundidad y cabalidad para así determinar finalmente si afectan o no la novedad y nivel inventivo de la presente solicitud, toda vez que en nuestra opinión se revelan materias muy similares, también es necesario reiterar que la solicitud de la referencia pretende proteger mediante el derecho patentario objetos que no son considerados invenciones. Es claro que una invención es toda creación humana que permita

transformar la materia o energía que existe en la naturaleza, para su aprovechamiento por los seres humanos y satisfacer sus necesidades concretas. De igual modo, como ya se mencionó, según los parámetros de la Decisión 486 y normas concordantes, serán patentables las invenciones que cumplan con los requisitos de novedad, nivel inventivo y aplicación industrial. No obstante, puede observarse que la solicitud en comento pretende reivindicar combinaciones, las cuales no se consideran invenciones. En este sentido, la mezcla (Combinaciones) de productos (Moléculas) conocidos y su variación, bien sea en uso, forma, dimensión o de materia, NO se consideran invenciones por cuanto no son susceptibles de aplicación industrial, nivel inventivo y novedad, luego NO pueden acceder a beneficios patentarios. Por lo tanto, se suma una circunstancia más que imposibilita definitivamente la concesión de la solicitud en mención.

Y sobre el particular, es imprescindible señalar que un efecto sinérgico nuevo no se considera inventivo como tal, dado que puede ser obvio para una persona versada en la materia, cosa que sucede en el presente caso. En palabras del Doctor Carlos Correa, *“El efecto sinérgico entre dos o más drogas se puede considerar un “descubrimiento” y no una “invención”, dado que la sinergia ocurre en el cuerpo y se descubre a través de ensayos clínicos. Asimismo, cabe destacar que, en algunos casos, las reivindicaciones de combinaciones pueden equivaler, en términos prácticos, a reivindicaciones sobre tratamientos médicos (cuya patentabilidad está excluida en la mayoría de los países), cuando sólo brindan un método para administrar una combinación de drogas conocidas. Asimismo, la combinación de drogas para evitar la resistencia particular a una de ellas es una práctica normal en el desarrollo farmacéutico y, por lo general, es evidente para el hombre del oficio de nivel medio”* (Pautas para el examen de patentes farmacéuticas, CEIDIE, Pág. 8). En estos términos, está claro que nos encontramos frente a un tema totalmente sensible que merece toda la evaluación por cuanto las combinaciones deben considerarse excluidas de beneficios de patente.

Y en caso que ese Despacho decidiera insistir en el cabal cumplimiento de los requisitos exigidos para acceder al beneficio de patente, me permito allegar copia del International Search Report y el respectivo Written Opinion Of The International Searching Authority, documentos en los cuales se resalta que la presente invención no cumple con los requisitos de novedad y nivel inventivo por cuanto existen documentos citados del estado del arte que afectan de manera definitiva tales exigencias. Lo anterior deja entrever, sin lugar a equívocos, que la presente solicitud no debió ser concedida, por lo cual es procedente la revocatoria de la Resolución objeto de este escrito.

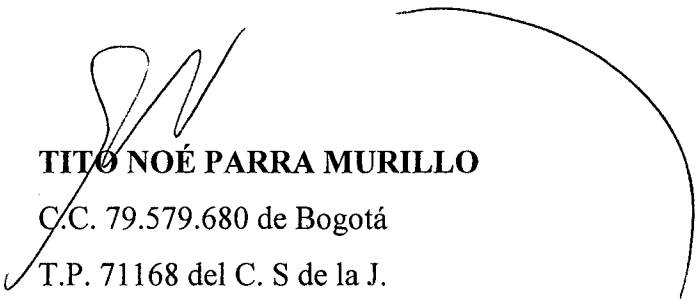
En este sentido, reitero con el debido respeto la necesidad de analizar a profundidad los requisitos de novedad y nivel inventivo para así determinar si la presente solicitud es merecedora de concesión de privilegio de patente.

ANEXOS

International Search Report y el Written Opinion Of The International Searching Authority de la equivalente internacional WO 2012/059103

En subsidio apelo.

Señor Superintendente,



TITO NOÉ PARRA MURILLO

C.C. 79.579.680 de Bogotá

T.P. 71168 del C. S de la J.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 13 and Rules 43 and 44)

Applicant's or agent's file reference 0799 - WO - PCT	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/DK2011/000128	International filing date (day/month/year) 04/11/2011	(Earliest) Priority Date (day/month/year) 05/11/2010
Applicant H. LUNDBECK A/S		

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 3 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. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ 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. _____
☐ 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

INTERNATIONAL SEARCH REPORT

International application No

PCT/DK2011/000128

A. CLASSIFICATION OF SUBJECT MATTER

INV. C07D489/12 C07D489/08
ADD.

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)
C07D

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, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2010/039209 A2 (MALLINCKRODT INC [US]; WANG PETER X [US]; JIANG TAO [US]; BERBERICH DA) 8 April 2010 (2010-04-08) cited in the application	14
A	paragraph [0028]; claim 7; examples 1-12	1-11
X	WO 91/05768 A1 (US HEALTH [US]) 2 May 1991 (1991-05-02) cited in the application	14,15
A	Chart 3	1-13

☐ 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

14 December 2011

Date of mailing of the international search report

21/12/2011

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Gregoire, Ariane

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/DK2011/000128

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2010039209	A2	08-04-2010	AU 2009300379 A1 08-04-2010
		CA 2738246 A1 08-04-2010	
		CN 102227433 A 26-10-2011	
		EP 2344506 A2 20-07-2011	
		US 2010081819 A1 01-04-2010	
		WO 2010039209 A2 08-04-2010	

WO 9105768	A1	02-05-1991	AT 178329 T 15-04-1999
		AU 642447 B2 21-10-1993	
		CA 2067200 A1 17-04-1991	
		DE 69033035 D1 06-05-1999	
		DE 69033035 T2 05-08-1999	
		DK 0496830 T3 11-10-1999	
		EP 0496830 A1 05-08-1992	
		ES 2129395 T3 16-06-1999	
		GR 3030101 T3 30-07-1999	
		JP 2694156 B2 24-12-1997	
		JP H04504861 A 27-08-1992	
		WO 9105768 A1 02-05-1991	

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

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/DK2011/000128	International filing date (day/month/year) 04.11.2011	Priority date (day/month/year) 05.11.2010
International Patent Classification (IPC) or both national classification and IPC INV. C07D489/12 C07D489/08		
Applicant H. LUNDBECK A/S		

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 and 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 or 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 Fax: +49 89 2399 - 4465	Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Gregoire, Ariane Telephone No. +49 89 2399-2994 
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/DK2011/000128

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. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
- a. (means)
- ☐ on paper
 - ☐ in electronic form
- b. (time)
- ☐ in the international application as filed
 - ☐ together with the international application in electronic form
 - ☐ subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing 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.
5. Additional comments:

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	<u>1-13</u>
	No: Claims	<u>14, 15</u>
Inventive step (IS)	Yes: Claims	<u>1-13</u>
	No: Claims	<u>14, 15</u>
Industrial applicability (IA)	Yes: Claims	<u>1-15</u>
	No: Claims	

2. Citations and explanations

see separate sheet

3

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/DK2011/000128

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 V

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

Reference is made to the following documents:

- D1 WO 2010/039209 A2 (MALLINCKRODT INC [US]; WANG PETER X [US]; JIANG TAO [US]; BERBERICH DA) 8 April 2010 (2010-04-08) cited in the application
- D2 WO 91/05768 A1 (US HEALTH [US]) 2 May 1991 (1991-05-02) cited in the application

Novelty (Art. 33 (1) and (2) PCT) :

The synthesis of naltrexone from noroxymorphone is reported in the art (e.g. in D1 or D2) but not in the presence of N-ethyl-2-pyrrolidine as presently claimed. Present claims 1-13 do thus comply with Art. 33(2) PCT.

Claims 14 and 15 are products by process claims which can not be considered novel over the art (e.g. over D2) since the product they referred to is a clearly defined chemical compound (Naltrexone or Nalmefene). Their structure do not depend on the process used to prepare them so that product by the process claims are considered as product claims. Both compounds referred to in claims 14 and 15 are well-known compounds. Claims 14 and claim 15 do not comply with Art. 33(2) PCT.

Inventive Step (Art. 33 (1) and (3) PCT) :

D1 is considered as the closest prior art since it discloses a process for the preparation of naltrexone from noroxymorphone. The solvent used in this document is either N-methyl-2-pyrrolidine, Dimethylformamide N,N-dimethylacetamide.

The present process differs from D1 in that N-ethyl-2-pyrrolidine is present.

The technical problem raised by the application is the provision of an improved process for the preparation of naltrexone.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/DK2011/000128

The examples provided in the application show that the problem raised was solved.

Although the N-ethyl-2-pyrrolidone is structurally close to the N-methyl-2-pyrrolidone used in the art, the skilled person looking for an alternative process had no incentive to change this specific parameter and would not have expected the high yield (around 90% see e.g. examples 5 and 7) obtained for the present process.

The presence of an inventive step can thus be acknowledged for the process of claims 1-13.

Re Item VIII

Certain observations

The present description discloses subject-matter (page 5 lines 8 and the following and also point E44 page 13) not included in the scope of the claims which renders the scope of the present invention unclear (Art. 6 PCT). This also applies to the passage starting page 5 line 25 to page 6 line 6.

The applicant has acknowledged documents on page 7, lines 20-24, by the term "incorporated herein by reference". This gives rise to clarity objections under Art. 6 PCT since it is vague and ambiguous which technical features are referred to. Furthermore, it should be noted that this kind of reference contravenes the basic requirement of each application that the invention must be comprehensible from the specification by itself. In order to overcome the clarity objection, either the phrase "incorporated herein by reference" could simply be deleted or the cited prior art under Art. 5.1 (a) (ii) could be discussed in a short summary (see also Guidelines II-4.17 PCT).