

OLARTEMOURE

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Señores

SUPERINTENDENCIA DE INDUSTRIA Y COMER

DIRECCIÓN DE NUEVAS CREACIONES

E. S. D.

Medellín
María Clara Múnera

Re: Expediente N°. 12-073.055

Solicitud de Patente de Invención titulada: “COMPUESTOS DE
ESPIROPIPERIDINA COMO ANTAGONISTAS DEL RECEPTOR”

Solicitante: ELI LILLY AND COMPANY

Nuestra Ref: P2012/000047

RESPUESTA AL OFICIO N° 7767 NOTIFICADO

POR FIJACION EN LISTA No. 253, DE FECHA 16 DE MAYO DE 2012,

(EXAMEN DE FORMA)

CARLOS R. OLARTE, mayor de edad y vecino de Bogotá, D.C., 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 proferido por ese Despacho, dentro del término legal previsto en el artículo 39 de la Decisión 486 en los siguientes términos:

1. En respuesta a la primera observación del Examinador, me permito aclarar al Despacho que la presente solicitud corresponde al capítulo I, ya que por un error tipográfico en el petitorio se indicó capítulo II, para tal efecto adjunto copia del IPRP.

OLARTEMOURE

OLARTE MOURE & ASOCIADOS LTDA.

2. En respuesta a la segunda observación del Examinador, me permito presentar un nuevo resumen según lo dispuesto en el Artículo 31 de la Decisión 486.

Atentamente,



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

Adjunto: IPRP
Resumen

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference X18870	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2010/056180	International filing date (day/month/year) 10 November 2010 (10.11.2010)	Priority date (day/month/year) 16 November 2009 (16.11.2009)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant ELI LILLY AND COMPANY			

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 5 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

☐

Box No. II

☐

Box No. III

☐

Box No. IV☒☐☐☐

Basis of the report

Priority

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

Lack of unity of invention

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Certain documents cited

Certain defects in the international application

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).

	Date of issuance of this report 22 May 2012 (22.05.2012)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Nora Lindner
Facsimile No. +41 22 338 82 70	e-mail: pt03.pct@wipo.int

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

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

To: see form PCT/ISA/220		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/US2010/056180	International filing date (day/month/year) 10.11.2010	Priority date (day/month/year) 16.11.2009	
International Patent Classification (IPC) or both national classification and IPC INV. C07D495/20 A61K31/444 A61P25/00			
Applicant ELI LILLY AND COMPANY			
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 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 Fax: +49 89 2399 - 4465		Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Miniejew, Catherine Telephone No. +49 89 2399-4880 

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/056180

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

2. Citations and explanations

see separate sheet

Reference is made to the following documents:

- D1 YOSHIZUM TAKASHI ET AL., BIOORGANIC & MEDICINAL CHEMISTRY
LETTERS, 18, 2008, 3778-3782 (cited in the application)
- D2 WO 2005/016913 A1
- D3 WO 2005/066183 A1

Subject-matter

The present application discloses spiro piperidine derivatives as ORL-1 receptor antagonists for the treatment of obesity, migraine or depression.

Re Item V.

V.1. Novelty

The subject-matter of the claims is considered to be novel (Article 33(2) PCT).

D1, D2 and D3 are not relevant for the novelty of the present application because they do not disclose piperidines spiro condensed with a dihydro-thienopyran moiety.

V.2. Inventive step

D1 is regarded as being the closest prior art to the present subject-matter. It discloses spiro piperidine derivatives as ORL-1 receptor antagonists (D1, whole document). The difference to D1 resides (i) in that the dihydro-furan of the condensed system is replaced by a dihydro-pyran and (ii) in that the phenyl of the condensed system is replaced by a thienyl.

The technical problem to be solved by the present application is seen in the provision of further ORL-1 antagonists for the treatment of obesity, migraine or depression.

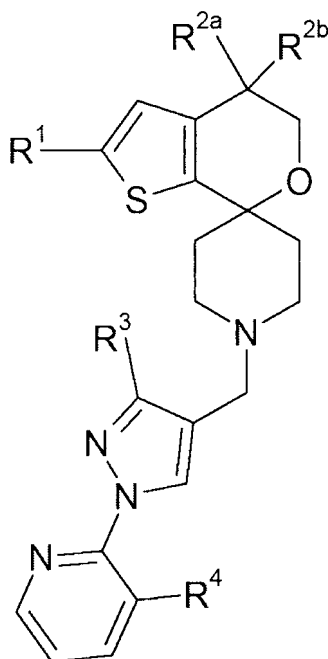
In view of the information provided in the description (pages 91-102), it seems that this problem has been solved for those compounds as disclosed in the claims. D2 discloses spiro piperidine derivatives condensed with a dihydro-pyran as ORL-1 antagonists (D2, claim 1, lines 9-14 on pages 1). However, the derivatives of D2 differ from the present compounds (i) in that the condensed system contains a phenyl instead of a thienyl and (ii) in the substitution pattern of the spiro system. D3 discloses spiro derivatives containing a dihydro-thienopyran moiety as ORL-1 antagonists (D3, claim 1, pages 35-36, example 3). However, the derivatives of D3 differ from the

present compounds (i) in that they are spiro cyclohexyl derivatives, (ii) in that the dihydro-thienopyran moiety is further ortho condensed with a phenyl and (iii) in the substitution pattern of the spiro system. Even combining the teaching of the prior art documents would no lead to the present compounds. Therefore, the present application is considered as involving an inventive step (Article 33(3) PCT).



RESUMEN MODIFICADO

La presente invención se refiere a compuestos derivados de espiropiperidina de la fórmula:



Así como a sus métodos de obtención, y composiciones farmacéuticas donde puedan estar presentes actuando como antagonistas del receptor ORL-1, las cuales tienen aplicación en el tratamiento de enfermedades mediadas por la actividad de dicho receptor, tales como: depresión, migraña y/o obesidad.
