

Clarke, Modet & Cº

COLOM

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

P-2903

SUPERINTENDENCIA DE INDUSTRIA Y
DIVISION DE NUEVAS CREACIONES

E. S. D.

No. 11-056556-00002-0000

Fecha: 2011-08-31 15:04:41 Dep. 2020 DIR.NUEVASCR
Tra. 11 PATENTEIYII Eve: 378 FASENACIONALI
Act. 444 RESPUESTAREQUE Folios: 14

Ref.: Expediente No. 11.056.556
Solicitud de Patente a nombre de
THERAVANCE, INC.

Yo, DILIA MARÍA RODRÍGUEZ D'ALEMAN, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 No. 86-53, piso 6, obrando como apoderada de la sociedad **THERAVANCE, INC.**, solicitante de la patente de la referencia, en respuesta al oficio No. 11478 notificado por fijación en lista el día 22 de Julio de 2011, atentamente me permito presentar:

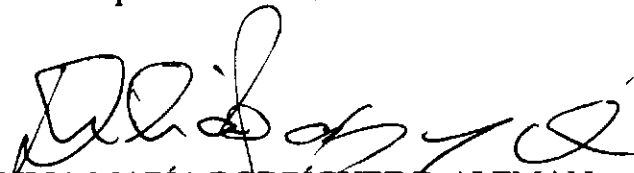
1. Documentos donde consta la cesión del derecho a la patente otorgada por los inventores a favor de mi mandante.

Sobre el particular, es importante resaltar que de conformidad con las normas legales vigentes, numeral 1.2.1.1 del Capítulo Primero, Título X de la Circular Única expedida por la Superintendencia de Industria y Comercio, y artículo 2 de la Convención de la Haya, el documento en inglés que se pretenda aportar como parte de los trámites de propiedad industrial ante la Superintendencia de Industria y Comercio no requiere traducción. Por otro lado, la legalización consular y/o diplomática de los documentos expedidos en el extranjero no es necesaria. Por lo tanto, los documentos anexos a este memorial son válidamente presentados en idioma inglés y con la correspondiente apostilla.

2. Copia simple del Informe Preliminar Internacional sobre Patentabilidad (IPRP) expedido en fase internacional del PCT, para su pronta referencia, en caso de ser necesario.

Espero con esto haber dado cabal cumplimiento a lo solicitado por ese despacho y de conformidad con lo indicado en los artículos 3º, inciso 3, 35 inciso 2 y 59 inciso 2 del CCA, al analizar este memorial, atentamente ruego se traten todas las cuestiones planteadas con motivo del mismo.

Señor Superintendente,


DILIA MARÍA RODRÍGUEZ D'ALEMAN
C.C. 41.654.882 de Bogotá
T.P. 20824 CSJ

State of California



SECRETARY OF STATE

This Apostille only certifies the authenticity of the signature and the title of the public official who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the authenticity of the underlying document for which it was issued. This Apostille is not valid for use anywhere within the United States of America, its territories or possessions. To verify the issuance of this Apostille, go to www.sos.ca.gov/business/notary/apostille-search/

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America
This public document
2. has been signed by Maria Chuakay
3. acting in the capacity of Notary Public, State of California
4. bears the seal/stamp of Maria Chuakay, Notary Public, State of California
CERTIFIED
5. At Sacramento, California
6. the 17th day of August 2011
7. by Deputy Secretary of State, State of California
8. No. 90144
9. Seal/Stamp:



10. Signature

Jana Bowen
Secretary of State

BY *[Signature]*



P-263-CO

ACKNOWLEDGMENT

State of California
County of San Mateo

On 16 August 2011 before me, Maria Chuakay, Notary Public
(insert name and title of the officer)

personally appeared Robert Chao and Jeffrey A. Hagenah
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are
subscribed to the within instrument and acknowledged to me that he/she/they executed the same in
~~his/her~~ their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the
person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing
paragraph is true and correct.

WITNESS my hand and official seal.

Signature Maria Chuakay (Seal)



THE
STATE

Clarke, Modet & C^o

COLOMBIA

E-MAIL: info@clarkemodet.com.co
SANTAFÉ DE BOGOTÁ, A.A. 92397 COLOMBIA

CESION

El (la) abajo firmante (En adelante EL CEDENTE)

1. PATTERSON, Lori Jean
2. CHAO, Robert
3. RAPTA, Miroslav

en su carácter de inventor /diseñador con domicilios en:
1.3 Whitney Street, San Francisco, California 94131, Estados Unidos de América.
2. 1121 Doyle Circle, Santa Clara, California 95054, Estados Unidos de América.
3. 411 E. Duane Avenue, Sunny-Vale, California 94085, Estados Unidos de América.

por el presente documento declara que cede todos y cada uno de los derechos que le corresponden o puedan corresponderle sobre la siguiente invención, modelo de utilidad, diseño industrial No. PCT/US2009/064306

a: THERAVANCE, INC.

con domicilio en 901 Gateway Boulevard, South, San Francisco, California 94080, Estados Unidos de América.

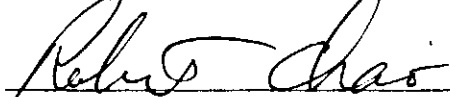
En prueba de la mutua aceptación de esta cesión ambas partes CEDENTE y CESIONARIO firman el presente documento.

Dado y firmado en
A los Días de De

1. PATTERSON, Lori Jean

El Cedente /The Assignor

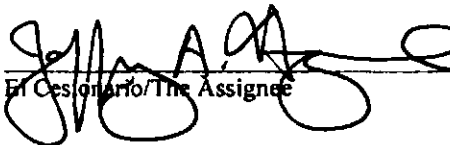
2. CHAO, Robert



El Cedente /The Assignor

3. RAPTA, Miroslav

El Cedente /The Assignor



El Cesionario/The Assignee

Este documento debe ser otorgado ante Notario público y legalizado por el Cónsul de Colombia) o por Apostilla

ASSIGNMENT

The undersigned (Hereinafter THE ASSIGNOR)

1. PATTERSON, Lori Jean
2. CHAO, Robert
3. RAPTA, Miroslav

Inventor /designor

1.3 Whitney Street, San Francisco, California 94131, Estados Unidos de América.
2. 1121 Doyle Circle, Santa Clara, California 95054, Estados Unidos de América.
3. 411 E. Duane Avenue, Sunny-Vale, California 94085, Estados Unidos de América.

do hereby declares that it assigns all and each of his rights and privileges on the following invention, industrial design, utility model No. PCT/US2009/064306

to THERAVANCE, INC.

with domicile in 901 Gateway Boulevard, South, San Francisco, California 94080, United States of America

As a proof of the mutual acceptance of this assignment, both parties ASSIGNOR and ASSIGNEE sign the present document.

Granted and signed at
on this 21 day of JUNE of 2011

1. PATTERSON, Lori Jean

El Cedente /The Assignor

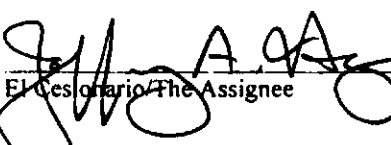
2. CHAO, Robert



El Cedente /The Assignor

3. RAPTA, Miroslav

El Cedente /The Assignor



El Cesionario/The Assignee

JEFFREY A HAGENAH
VICE PRESIDENT &
CHIEF PATENT COUNSEL

(This document must be signed before Notary Public and legalized before the colombian Consul) or by Apostille

(See attached Acknowledgment.)

State of California

SECRETARY OF STATE

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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America
This public document
2. has been signed by Maria Chuakay
3. acting in the capacity of Notary Public, State of California
4. bears the seal/stamp of Maria Chuakay, Notary Public, State of California
- CERTIFIED**
5. At Sacramento, California
6. the 5th day of July 2011
7. by Deputy Secretary of State, State of California
8. No. 76428
9. Seal/Stamp:



10. Signature

John Bowen
Secretary of State

BY *Maige Jones*



Clarke, Modet & C^o

COLOMBIA

E-MAIL: info@clarkemodet.com.co
SANTAFÉ DE BOGOTÁ, A.A. 92397 COLOMBIA

CESION

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El (la) abajo firmante (En adelante EL CEDENTE)

The undersigned (Hereinafter THE ASSIGNOR)

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2. CHAO, Robert
3. RAPTA, Miroslav

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2. CHAO, Robert
3. RAPTA, Miroslav

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Inventor /designor

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2. 1121 Doyle Circle, Santa Clara, California 95054, Estados Unidos de América.
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por el presente documento declara que cede todos y cada uno de los derechos que le corresponden o puedan corresponderle sobre la siguiente invención, modelo de utilidad, diseño industrial No. PCT/US2009/064306

do hereby declares that it assigns all and each of his rights and privileges on the following invention, industrial design, utility model No. PCT/US2009/064306

a: THERAVANCE, INC.

to THERAVANCE, INC.

con domicilio en 901 Gateway Boulevard, South, San Francisco, California 94080, Estados Unidos de América.

with domicile in 901 Gateway Boulevard, South, San Francisco, California 94080, United States of America.

En prueba de la mutua aceptación de esta cesión ambas partes CEDENTE y CESIONARIO firman el presente documento.

As a proof of the mutual acceptance of this assignment, both parties ASSIGNOR and ASSIGNEE sign the present document.

Dado y firmado en

A los Días de De

Granted and signed at

on this 21 day of JUNE of 2011

1. PATTERSON, Lori Jean

1. PATTERSON, Lori Jean


El Cedente /The Assignor


El Cedente /The Assignor

2. CHAO, Robert

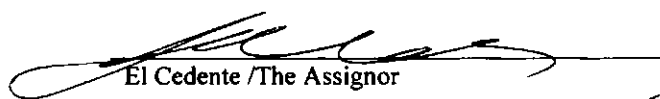
2. CHAO, Robert

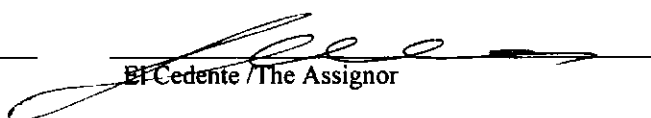
El Cedente /The Assignor

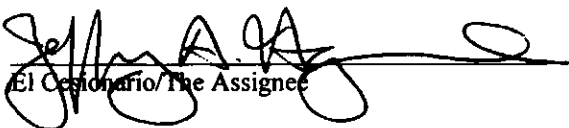
El Cedente /The Assignor

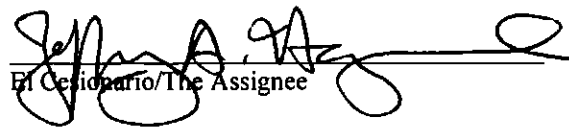
3. RAPTA, Miroslav

3. RAPTA, Miroslav


El Cedente /The Assignor


El Cedente /The Assignor


El Cesionario /The Assignee


El Cesionario /The Assignee

Este documento debe ser otorgado ante Notario público y legalizado por el Cónsul de Colombia) o por Apostilla

(This document must be signed before Notary Public and legalized before the colombian Consul) or by Apostille

(See attached Acknowledgment)

ACKNOWLEDGMENT

State of California
County of San Mateo

On 21 June 2011 before me, Maria Chuakay, Notary Public
(insert name and title of the officer)

personally appeared Lori Jean Patterson, Miroslav Rapta & Jeffrey A. Hagenah
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are
subscribed to the within instrument and acknowledged to me that he/she/they executed the same in
his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the
person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing
paragraph is true and correct.

WITNESS my hand and official seal.

Signature Maria Chuakay (Seal)



PCT

**NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)**

(PCT Rule 44bis.1(c))

To:

HAGENAH, Jeffrey A.
Theravance, Inc.
901 Gateway Boulevard
South San Francisco, California 94080
ETATS-UNIS D'AMERIQUE

ORIGINAL

Date of mailing (day/month/year)

26 May 2011 (26.05.2011)

Applicant's or agent's file reference

P-263-PCT

IMPORTANT NOTICE

International application No.

PCT/US2009/064306

International filing date (day/month/year)

13 November 2009 (13.11.2009)

Priority date (day/month/year)

14 November 2008 (14.11.2008)

Applicant

THERAVANCE, INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

2011 06 2011

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Gijsbertus Beijer

Facsimile No. (+41 22 338 82 70)

e-mail: pf02.pct@wipo.int

AGENTE REF.	NTRA REF.	SOLICITANTE	SOLICITUD NR.	DESCRIPCION	PUBLICACION GACETA	PAGINA
P113307CO	P-1096	WORLD-TRADE IMPORT- EXPORT, WTIE, AG	08-012.143	PCT/MX2006/000047	604/Nov. 29, 2009	427
P100408CO	P-1092	WORLD-TRADE IMPORT- EXPORT, WTIE, AG	08-011.002	PCT/MX2006/000047	605/Dic. 29, 2009	300
P116108CO	P-1309	WORLD-TRADE IMPORT- EXPORT, WTIE, AG	08-067.107	PCT/MX2006/000069	610/Sept. 20, 2010	373
P116808CO	P-1311	WORLD-TRADE IMPORT- EXPORT, WTIE, AG	08-067.095	PCT/MX2006/000070	606/Ene. 30, 2010	420
P129608CO	P-1512	WORLD-TRADE IMPORT- EXPORT, WTIE, AG	08-094.845	PCT/MX2006/000081	603/Oct. 30, 2009	484

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

(PCT Rule 44bis)

Applicant's or agent's file reference P-263-PCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2009/064306	International filing date (day/month/year) 13 November 2009 (13.11.2009)	Priority date (day/month/year) 14 November 2008 (14.11.2008)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant THERAVANCE, INC			

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 6 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. <table border="0"> <tr> <td>☒</td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td>☒</td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td>☐</td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>☐</td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td>☒</td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td>☒</td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td>☐</td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td>☒</td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>			☒	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
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☐	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 Form PCT/ISA/73 (January 2004)	Date of issuance of this report 17 May 2011 (17.05.2011)
	Authorized officer Gijsbertus Beijer e-mail: p02.pct@wipo.int

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/US2009/064306

International filing date (day/month/year)
13.11.2009

Priority date (day/month/year)
14.11.2008

International Patent Classification (IPC) or both national classification and IPC
INV. C07D211/22 A61K31/4409 A61P25/00

Applicant
THERAVANCE, INC.

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
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Bérillon, Laurent

Telephone No. +49 89 2399-7078



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2009/064306

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 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.
4. ☐ 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.
5. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2009/064306

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>1-17</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-17</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-17</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

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

1 Prior art

Reference is made to :

D1: WO 2004/087155

2 Novelty (Article 33(2) PCT)

The claimed crystalline hydrochloride salt of 4-[2-(2,4,6-trifluorophenoxy)methylphenyl]-piperidine is not disclosed in D1. The present invention is therefore novel.

3 Inventive step (Article 33(3) PCT)

The present application is directed to a crystalline hydrochloride salt of 4-[2-(2,4,6-trifluorophenoxy)methylphenyl]-piperidine having properties such as low hygroscopicity and high melting point (see pages 2, first paragraph) and use thereof as serotonin and norepinephrine reuptake inhibitors.

D1 which represents the closest prior art equally relates to norepinephrine reuptake inhibitors (see D1, page 1, line 32 to page 2, line 4) and salts thereof.

The compounds disclosed in D1 differ however from the claimed crystalline hydrochloride salt of 4-[2-(2,4,6-trifluorophenoxy)methylphenyl]-piperidine in view of their one atom -O- linker between the two phenyl rings.

The technical problem underlying the present application is regarded as the provision of a further serotonin and norepinephrine reuptake inhibitor having properties such as low hygroscopicity and high melting point.

Since no incentive can be found in the prior art for replacing the one atom -O- linker of the D1 compounds by a -CH₂-O- linker an inventive step can be acknowledged for the claimed crystalline hydrochloride salt of 4-[2-(2,4,6-trifluorophenoxy)methylphenyl]-piperidine.

Re Item VI

Certain documents cited

The priority document pertaining to the present application was not available at the time of establishing this international preliminary examination report. Hence, it is based on the assumption that all claims enjoy priority rights from the filing date of the priority document. If it later turns out that this is not correct, the P-document cited in the international search report could become relevant to assess whether the claims satisfy the criteria set forth in Article 33(1) PCT.

Re Item VIII

Certain observations on the international application

References to figures should be avoided in the claims for sake of clarity (Article 6 PCT).