

CAVELIER

ABOGADOS

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Señor Director
DIRECCION DE NUEVAS CREACIONES
Superintendencia de Industria y Comercio
E. S. D.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 11-177480- -00002-0000

Fecha: 2012-03-21 16:24:06 Dep. 2020 DIR.NUEVASCR
Tra. 11 PATENTEIYII Eve: 378 FASENACIONALI
Act. 444 RESPUESTAREQUE Folios: 20

Trámite : 011
Evento : 378
Actuación : 444

Referencia : Expediente No. 11.177.480
Asunto : Solicitud de patente para **PROCEDIMIENTO PARA LA PRODUCCION DE BENZOFURANOS**
Solicitante : **SANOFI**
Clase : A61K 031/343, A61P 009/006, C07C 205/043, C07D 307/080
Fecha de solicitud : 23 de diciembre de 2011

CONTESTACION OFICIO No. 1990

1. Yo, Luz Clemencia de PÁEZ, obrando como apoderada del solicitante en el asunto de la referencia, doy respuesta al Oficio No. **1990**, notificado por fijación en lista de fecha 10 de febrero de 2012.

2. Mediante el Oficio No. **1990** se puso en conocimiento del solicitante el resultado del examen de forma realizado por ese Despacho, requiriéndole para completar el siguiente requisito:

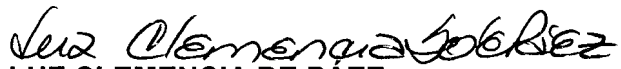
2.1. Documento de cesión de derechos de los inventores: Acompaño con este escrito un (1) documento en que consta la cesión de derechos de los cuatro (4) inventores a favor de la sociedad solicitante, debidamente notariado, legalizado por Apostilla y traducido al español.

3. Adicionalmente presento copia del Informe Preliminar Internacional sobre patentabilidad expedido en el trámite de la solicitud internacional PCT/EP2010/057270, correspondiente a la presente fase nacional.

Solicito a ese Despacho tener en cuenta que el examen efectuado por la Administración encargada fue favorable, esto es que la invención es novedosa, tiene nivel inventivo y aplicación industrial.

4. Puesto que se han atendido a cabalidad las observaciones hechas por ese Despacho sobre la presente solicitud de patente, atentamente solicito que se continúe su tramitación.

Señor Director,


LUZ CLEMENCIA DE PÁEZ
C.C. No. 35.456.344 de Usaquén
T.P.A. 23.555

COLO-00751-841-031-6
SDC\JGG\ID-213293\WPCL0751
No. M-2012-213293\SDC

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Co
3

ASSIGNMENT AND AGREEMENT

For value received and intending to be legally bound, I/we, the undersigned joint inventor(s) (Assignor(s)), sell, assign and transfer to **SANOFI** (Assignee), **174 avenue de France, 75013 Paris, France** and its successors, assigns and legal representatives, the entire right, title and interest in and to my/our invention and any improvements thereon for all countries of the world, relating in and to the application for United States Letters Patent therefore, assigned Attorney Docket No. **DE2009/069**, entitled

Process for the production of benzofurans

And for all patent applications which claim priority to or are derived from said priority applications:

European Patent (EP): EP Application Filing Date: **May 27, 2009**
EP Application Filing No.: **09290395.4**

USA (US): US Application Filing Date: **September 22, 2009**
US Application Filing No.: **61/244550**

and all the rights and privileges, including any and all benefits under the International Convention for the Protection of Industrial Property, including the right to claim priority based on said application(s), and under any and all Letters Patent which may be granted therefore, and all right, title and interest in and to every patent application filed or to be filed on said invention in any other country or patent organization, including continuations, divisions, renewals, revivals, and any substitute applications of said United States application, and any and all patents which may issue thereon, and any reissues, pipelines and extensions, and governmental exclusivity rights of the same.

I/we authorize and request competent authorities to grant and issue any and all patents on said invention to said assignee or its successor, assigns and legal representatives, or to such nominees as said assignee may designate.

I/we agree that, when requested, I/we will, without charge to said assignee but at its expense, sign all papers, take all rightful oaths, and do all acts which may be necessary, desirable or convenient for securing and maintaining patents for said invention in any and all countries and for vesting title thereto in said assignee, its successors, assigns, legal representatives or nominees.

I/we covenant with said assignee, its successors, assigns and legal representatives, that the rights and property herein conveyed are free and clear of any encumbrance, and that I/we have full right to convey the same as herein expressed.

Signed at _____ on this 1.11 day of _____, 2011
(City and Nation)

Signature: _____

Inventor's Name: **Gerhard Kretzschmar**

Residential Address: **c/o Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main, Germany**

Witnessed by: _____

4

Signed at _____ on this 1 day of November, 2011
(City and Nation)

Signature: [Signature]
Inventor's Name: **Volker Kraft**
Residential Address: **c/o Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main, Germany**

Witnessed by: [Signature] [Signature]

Signed at _____ on this 01 day of November, 2011
(City and Nation)

Signature: [Signature]
Inventor's Name: **Thomas Olpp**
Residential Address: **c/o Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main, Germany**

Witnessed by: [Signature] [Signature]

Signed at Frankfurt on this 1 day of Nov, 2011
(City and Nation)

Signature: [Signature]
Inventor's Name: **Kai Rossen**
Residential Address: **c/o Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main, Germany**

Witnessed by: [Signature] [Signature]

I, the undersigned Dr. Michael Baumgartl, Notary in Frankfurt am Main (Federal Republic of Germany) hereby certify that

1. Dr. Gerhard Manfred Kretzschmar, date of birth: June 24, 1954, having his business address at: Industriepark Höchst, Building K 801, 65926 Frankfurt am Main (Germany), who identified himself by submission of his German identity card No. 414443360,

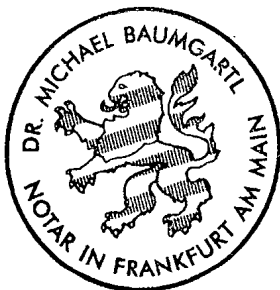
has subscribed the signature on the first page of the annexed document in my presence and

2. Volker Kraft, date of birth: January 12, 1978, having his business address at: Industriepark Höchst, Building K 801, 65926 Frankfurt am Main (Germany), who identified himself by submission of his German identity card No. 411625555,
3. Mr. Thomas Olpp, date of birth: May 10, 1975, having his business address at: Industriepark Höchst, Building K 801, 65926 Frankfurt am Main (Germany), who identified himself by submission of his German identity card No. L5R9JVZJZ,
4. Dr. Kai Rossen, date of birth: December 16, 1958, having his business address at: Industriepark Höchst, Building K 801, 65926 Frankfurt am Main (Germany), who identified himself by submission of his German identity card No. 412475417,

have subscribed the signatures on the second page of the annexes document in my presence.

The Notary has informed the persons appearing about the provision of Section 3, Subsection 1, No. 7 of the Recording Act (Beurkundungsgesetz). The persons appearing thereupon have stated that the Notary is not prevented from recording under such provision.

Frankfurt am Main, November 1, 2011




Michael Baumgartl
Notary

Statement of Fees

Value: EUR 38,000.00 pursuant to § 30 I KostO

Fee pursuant to §§ 141, 32, 45 I S. 1 KostO	EUR	27.00
Fee pursuant to §§ 141, 32, 58 I KostO	EUR	27.00
Flat fee for copies pursuant to §§ 141, 136 I No. 1, No. 2, II KostO	EUR	1.50
Postage pursuant to § 152 II Nr. 1 a) KostO	EUR	1.45
Subtotal	EUR	56.95
VAT 19 % pursuant to § 151a KostO	EUR	10.82
Total	EUR	67.77



Michael Baumgartl
Notary

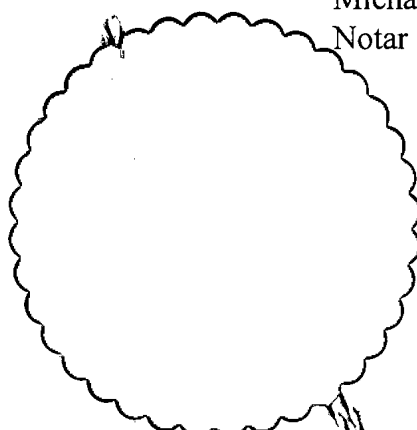
Die wörtliche Übereinstimmung der vorstehenden Abschrift mit der mir vorliegenden Urschrift beglaubige ich hiermit.

I herewith certify that the foregoing copy is a true copy of the original which has been presented to me.

Frankfurt am Main, 8. November 2011

Frankfurt am Main, November 8, 2011


Michael Baumgartl
Notar



APOSTILLE

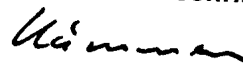
(Convention de la Haye du 5 octobre 1961)

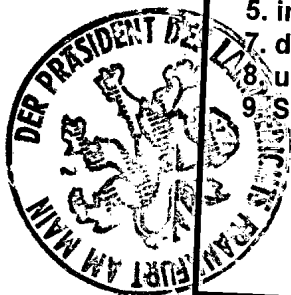
- Land: Bundesrepublik Deutschland
Diese öffentliche Urkunde
2. ist unterschrieben von Dr. Michael Baumgartl
3. in seiner Eigenschaft als amtlich bestellter Notar
4. sie ist versehen mit dem Siegel/Stempel des(der) Notars

Bestätigt

5. in Frankfurt/Main
6. am 10.11.11
7. durch den Herrn Präsidenten des Landgerichts
8. unter Nr. 91 Ea A 10423
9. Siegel/Stempel

10. Unterschrift


i.A. Kämmerer



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Traducción Oficial No. 2011/805 de un documento escrito en inglés el cual para su identificación se sella con el sello del traductor al tiempo con la presente. Esta traducción ha sido preparada por Hilda Aguilera de Piedrahita, traductora oficial debidamente reconocida por el Ministerio de Relaciones Exteriores y autorizada por el Ministerio de Justicia y del Derecho por Resolución No. 323 de 1980.

Expediente sanofi-aventis No. DE2009/069

CESIÓN Y ACUERDO

Por un valor recibido y con la intención de estar legalmente obligado, yo/nosotros, los suscritos inventores conjuntos (cedentes), vendemos, cedemos y transferimos a SANOFI (Cesionario), 174 Avenue de France, 75013 Paris, Francia, y a sus sucesores, cesionarios y representantes legales, mi/nuestro completo y exclusivo derecho, título y participación en y para mi/nuestra invención y cualesquiera mejoras sobre las mismas para todos los países del mundo, en relación con la Solicitud para Certificado de Patente de los Estados Unidos sobre ella, asignada bajo el Expediente de Apoderado No. DE2009/069, y cuyo título es

Procedimiento para la producción de benzofuranos

y para todas las solicitudes de patente que reivindiquen prioridad o se deriven de tal solicitud de prioridad:

Patente (PE)	Europea	Fecha de Presentación de la Solicitud PE:	Mayo 27, 2009
		No. de Presentación de la Solicitud PE:	09290395.4
E.U. (EU)		Fecha de Presentación de la Solicitud EU:	Septiembre 22, 2009
		No. de Presentación de la Solicitud EU:	61/244550

y todos los derechos y privilegios, incluyendo cualesquiera y todos los beneficios bajo la Convención Internacional para la Protección de la Propiedad Industrial, incluyendo el derecho de reivindicar prioridad con base en la solicitud de los Estados Unidos, y bajo cualesquiera y todos los Certificados de Patente que puedan ser otorgados en adelante, y todo derecho, título y participación en y para toda solicitud de patente presentada o que se vaya a presentar sobre la mencionada invención en cualquier otro país u organización de patentes, incluyendo, sin limitación, continuaciones, divisiones, renovaciones, resurgimientos, y cualesquiera solicitudes sustitutas de la mencionada solicitud de prioridad, y cualesquiera y todas las patentes que puedan expedirse sobre ella, y cualesquiera reexpediciones, re-exámenes, proyectos y prorrogas, y derechos de exclusividad gubernamental de las mismas.

Yo/nosotros autorizamos y solicitamos a las autoridades competentes otorgar y expedir cualesquiera y todas las patentes sobre la mencionada invención al mencionado cesionario o a sus sucesores, cesionarios y representantes legales, a cualesquiera nominados como tal cesionario pueda designar.

Yo/nosotros acordamos que, cuando sea solicitado, yo/nosotros procederemos, sin cargo para el mencionado cesionario pero a su gasto, a firmar todos los papeles, tomar todos los juramentos debidos, testificar el procesos legales, y llevar acabo todos los actos que puedan ser necesarios, deseables o convenientes para asegurar, mantener y hacer cumplir las patentes para la mencionada

TRADUCCION OFICIAL No. 2011/805
HILDA AGUILERA DE PIEDRAHITA
INTERPRETE OFICIAL
RES. No. 323 DEL MIN. DE JUSTICIA Y DEL DERECHO

invención en cualesquiera y todos los países y para invertir título de la misma en el mencionado cesionario, sus sucesores, cesionarios, representantes legales o nominados.

Yo/nosotros prometemos al mencionado cesionario, sus sucesores, cesionarios y representantes legales, a que los derechos y propiedad aquí transferida están a paz y salvo de cualquier gravamen, y que yo/nosotros tenemos pleno derecho para transferir el mismo como aquí se expresa.

Firmado en _____, este día 1.11 de _____ de 2011.
(Ciudad y Nación)

Firma (Firmado)
Nombre del Inventor: Gerhard Kretzschmar
Dirección de Correspondencia: c/o Sanofi-Aventis Deutschland GmbH,
65926 Frankfurt am Main, Alemania
Da fe:
(Firmado) (Firmado)

Firmado en _____, este día 1 de Noviembre de 2011.
(Ciudad y Nación)

Firma (Firmado)
Nombre del Inventor: Volker Kraft
Dirección de Correspondencia: c/o Sanofi-Aventis Deutschland GmbH,
65926 Frankfurt am Main, Alemania
Da fe:
(Firmado) (Firmado)

Firmado en _____, este día 1 de Noviembre de 2011.
(Ciudad y Nación)

Firma (Firmado)
Nombre del Inventor: Thomas Olpp
Dirección de Correspondencia: c/o Sanofi-Aventis Deutschland GmbH,
65926 Frankfurt am Main, Alemania
Da fe:
(Firmado) (Firmado)

Firmado en Frankfurt, este día 1 de Noviembre de 2011.
(Ciudad y Nación)

Firma (Firmado)
Nombre del Inventor: Kai Rossen
Dirección de Correspondencia: c/o Sanofi-Aventis Deutschland GmbH,
65926 Frankfurt am Main, Alemania
Da fe:
(Firmado) (Firmado)

Yo, el suscrito Sr. Michael Baumgartl, Notario en Frankfurt am Main (República Federal de Alemania) por el presente certifico que

- 1. el Dr. Gerhard Kretzschmar, fecha de nacimiento: Junio 24 de 1954, teniendo dirección comercial en: Industriepark Höchst, Building K 801, 65926 Frankfurt am Main (Alemania), quien se identificó presentando su tarjeta de identidad alemana No. 414443360,

ha suscrito la firma en la primera página del documento anexo en mi presencia y

- 2. Volker Kraft, fecha de nacimiento: Enero 12 de 1978, teniendo dirección comercial en: Industriepark Höchst, Building K 801, 65926 Frankfurt am Main (Alemania), quien se identificó presentando su tarjeta de identidad alemana No. 411625555,
- 3. Sr. Thomas Olpp, fecha de nacimiento: Mayo 10 de 1975, teniendo dirección comercial en: Industriepark Höchst, Building K 801, 65926 Frankfurt am Main (Alemania), quien se identificó presentando su tarjeta de identidad alemana No. L5R9JVZJZ,
- 4. Dr. Kai Rossen, fecha de nacimiento: Diciembre 16 de 1958, teniendo dirección comercial en: Industriepark Höchst, Building K 801, 65926 Frankfurt am Main (Alemania), quien se identificó presentando su tarjeta de identidad alemana No. 412475417,

Han suscrito las firmas en la segunda página del documento anexo en mi presencia.

El Notario ha informado que las personas comparecientes acerca de la disposición de la Sección 3, Sub-sección 1, No. 7 de la Ley de Registro (Beurkundungsgesetz). Las personas comparecientes han manifestado que el Notario no esta impedido de registrar bajo tal disposición.

Frankfurt am Main, Noviembre 1 de 2011.

(Firmado)
Michael Baumgartl
Notario
(Sello Notarial a tinta)

Declaración de Derechos

Valor: EUR 38,000.00 de conformidad con § 301 KostO

Derecho de conformidad con §§ 14,32,45 I S.1 KostO	EUR	27.00
Derecho de conformidad con §§ 14,32,58 I KostO	EUR	27.00
Derecho Plano para copias de acuerdo con §§ 141,136 I No. 1, No. 2, II KostO	EUR	1.50
Franqueo de conformidad con §§ 152 II Nr. 1 a) KostO	EUR	1.45
Subtotal	EUR	56.95
IVA 19% de conformidad con §§ 151 a KostO	EUR	10.82

TRADUCCION OFICIAL No. 2011/805
HILDA AGUILERA DE PIEDRAHITA
INTERPRETE OFICIAL
RES. No. 323 DEL MIN. DE JUSTICIA

Total

EUR

67.77

(Firmado)
Michael Baumgartl
Notario

Por el presente certifico que la anterior copia es una copia verdadera del original que ha sido presentado ante mi.

Frankfurt am Main, Noviembre 8 de 2011.

(Firmado)
Michael Baumgartl
Notario
(Sello)

APOSTILLA EN ALEMAN No. 91 Ea A 10423 del 10. 11.11.

ES TRADUCCIÓN FIEL Y COMPLETA de la cual se deja copia en los archivos de esta oficina para su confrontación y a la cual me remito, habiendo tenido a la vista el documento original.

Bogotá, Diciembre 26 de 2011.

MINISTERIO DE
RELACIONES EXTERIORES
2011 DIC 26 A 11:38
JEFE DE LEY
BOGOTÁ D.C.

NO SE ASUME
RESPONSABILIDAD
DEL TEXTO
115834
Hilda Aguilar
COPIA FIEL APARECE EN EL
DOCUMENTO DESEMPENA
LAS FUNCIONES INDICADAS.

TRADUCCION OFICIAL No. 2011/805.
HILDA AGUILERA DE PIEDRA
INTERPRETE OFICIAL
RES. No. 323 DEL MIN. DE JUSTICIA

Traducción oficial No. 32 / 2011 al idioma español de un texto escrito en alemán, realizada por Juan Felipe Sarmiento Espinosa, traductor oficial autorizado por resolución No. 0238 del 8 de Agosto de 2007, expedida por la Universidad Nacional de Colombia y debidamente registrado ante el Ministerio de Relaciones Exteriores de Colombia. Se traducen los sellos y apostilla que se encuentran en Alemán de un documento de cesión de la invención Procedimiento para la producción de benzofuranos el cual está escrito en Inglés., Asunto COLO 00751 841 031 6.

[Página 1]

[Sello-
Copia autenticada]

[Página 5]

Mediante el presente documento certifico la correspondencia entre la presente copia y el documento original.
Frankfurt am Main, 8 de Noviembre de 2011

[Firma]
Michael Baumgartl
Notario

[Sello ilegible]

[Sello]
El presidente del Juzgado Regional
Frankfurt am Main
MINISTERIO DE
RELACIONES EXTERIORES
2011 DIA 08 A las 11:38
JEFE DE EJECUCIONES
DICCIA O.C.

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. País: República Federal Alemana
este documento público
2. está firmado por el Dr. Michael Baumgartl
3. en su calidad de notario público
4. y está provisto del sello del notario

Autenticado
5. En Frankfurt am Main 6. El 10 de Noviembre de 2011
7. por el Sr. Presidente del Juzgado Regional
8. con el código 91 Ea A 10423
9. Sello 10. Firma
[Sello] [Firma]
El Presidente del Juzgado Regional En representación del Juzgado
Frankfurt am Main] Kämmerer

115834
Felipe Sarmiento
COPIA FIDELMENTE APARECE EN EL
DOCUMENTO DESFEMPEÑA
LAS FUNCIONES INDICADAS.
NO SE ASUME
RESPONSABILIDAD
DEL TEXTO

-----Fin de la traducción-----

Felipe Sarmiento Espinosa
Felipe Sarmiento Espinosa
Alemán - Español - Alemán
Certif. U. Nal. No. 0238

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 SD 41383 / GBL	FOR FURTHER ACTION		See item 4 below
International application No. PCT/EP2010/057270	International filing date (day/month/year) 26 May 2010 (26.05.2010)	Priority date (day/month/year) 27 May 2009 (27.05.2009)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant SANOFI			

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 8 sheets, including this cover sheet.

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

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

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

	Date of issuance of this report 29 November 2011 (29.11.2011)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Agnès Wittmann-Regis
Facsimile No. +41 22 338 82 70	e-mail: pt06.pct@wipo.int

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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

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/EP2010/057270

International filing date (day/month/year)
26.05.2010

Priority date (day/month/year)
27.05.2009

International Patent Classification (IPC) or both national classification and IPC
INV. C07C205/43 C07D307/80 A61K31/343 A61P9/06

Applicant
SANOFI-AVENTIS

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

Sarakinos, Georgios

Telephone No. +49 89 2399-4857



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2010/057270

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>1-17</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

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2010/057270

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

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

see separate sheet

Re Item V

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

1. The present application relates to a process for the production of benzofurans which can be used to produce the class III antiarrhythmic drug Dronedarone. The key steps in this process are an O- to C- acyl migration followed by acetal formation and dehydration. In addition, intermediates useful in the synthesis of Dronedarone are disclosed.

2. Reference is made to the following documents:

- D1 WO 03/040120 A (ISP INVESTMENTS INC [US]; GUTMAN ARIE L [IL]; NISNEVICH GENNADY [IL];) 15 May 2003 (2003-05-15)
- D2 MAJDIK ET AL: "Cyclization of hydroxybenzyl phenyl ketones in benzofuran derivatives /// Studiul reactiei de ciclizare a orto-hidroxibenzilfenilketonelor in benzofuran derivati"REVISTA DE CHIMIE, BUCHAREST, RO, vol. 36, no. 8, 1 January 1985 (1985-01-01) , pages 760-761, XP009124131ISSN: 0034-7752
- D3 ROGER ADAMS ET AL: "Quinone Imides. XXXIX. Adducts of Quinone Monoimides and Conversion of Active Methylene Adducts to Benzofurans"JOURNAL OF THE AMERICAN CHEMICAL SOCIETY, vol. 78, no. 3, 1956 , pages 658-663, XP002550683
- D4 WO 2009/044143 A (CAMBREX KARLSKOOGA AB [SE]; EKLUND LARS [SE]) 9 April 2009 (2009-04-09)

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3. Novelty [Article 33(2) PCT]

Document D1 discloses a process for synthesizing benzofuran intermediates useful for the production of Dronedarone. The disclosed process relies on an intramolecular ring-closure reaction between a phenoxy anion and a secondary bromide. This process is different from the process disclosed in the application. Furthermore, document D1 does not disclose compounds that fall within Markush formulas VII, VIII or V of the present application.

Document D2 discloses in Table 2, where X=F or X=Cl, the protonated forms of two of the phenoxide salts of formula V of the present application.

Document D3 discloses a method of synthesizing benzofurans. More specifically, the acid-catalysed conversion of ethyl α -(5-benzenesulfonamido-2-hydroxyphenyl)-benzoyl acetate to ethyl 5-benzenesulfonamido-2-phenylbenzofuran-3-carboxylate presents some mechanistic similarities to the cyclization step disclosed in the present application. None of the compounds disclosed in document D3 fall within Markush formulas VII, VIII or V of the present application.

Document D4 discloses a process for the synthesis of benzofuran intermediates useful for the production of Dronedarone. The key step involves a phenoxyimino intermediate. This process is different from the process disclosed in the present application and none of the compounds of document D1 fall within Markush formulas VII, VIII or V of the present application.

Claims 1-17 are therefore novel over the prior art and thus claims 1-17 meet the requirements of Novelty [Article 33(2) PCT].

4. Inventive step [Article 33(3) PCT]

Document D1 is considered to be the closest prior art to the present application as it discloses a process for synthesizing benzofuran intermediates useful for the production of Dronedarone. Thus, starting from document D1, the problem to be solved by the present application appears to be the provision of an alternative synthesis of Dronedarone. The applicant describes in claims 2, 5 and 9 a new process, whereby starting from acylated nitrophenol VII, an unprecedented O- to C-acyl migration takes place (compound VII to compound VIII) followed by ring-closure and dehydration leading to the benzofuran skeleton (compound I) which can be further

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easily converted to Dronedarone. The reaction conditions and reagents employed are practical and the reaction yields are high. Therefore, starting from document D1 and taking into account the whole of the prior art, it would not be obvious to the person skilled in the art to provide the process for the synthesis of key intermediate I in order to synthesize Dronedarone. Therefore the processes described in claims 2, 5, 9, 14 and 16 are considered to be inventive. In addition, intermediates of formulas VII (claim 1) and VIII (claim 4) are considered to be inventive.

Compounds of formula V of claim 15 can not be considered inventive because they are intermediates that lack essential structural features with respect to product I and Dronedarone.

Claims 1-14 and 16-17 are hence inventive and therefore claims 1-14 and 16-17 meet the requirements of Inventive Step (Art 56 EPC). Claim 15 does not meet the requirements of Inventive step and is thus not considered to be inventive.

5. The Claims (Art 6 PCT)

In claim 9, a Base B followed by Base C + Lewis acid lead to formation of compound I. It is not understood what purpose the use of two different bases in sequence serves, as the use of only one base results in a high-yielding process, as shown by the examples in the description.

Re Item VII

Certain defects in the international application

The Claims (Rule 6 PCT)

In the present application, there are three independent compound claims (claims 1, 4 and 15) and five independent process claims (claims 2, 5, 9, 14 and 16). This does not comply with the requirements of Rule 6.1(a) PCT.

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Re Item VIII

Certain observations on the international application

In claim 17, the clause that begins with *In one embodiment* does not belong in this claim.