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Bogotá D.C., 6 de mayo de 2015

Señores
DIVISION DE NUEVAS CREACIONES
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Ciudad

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
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REFERENCIA: Expediente No. 14 – 058.169

TÍTULO: “PROCEDIMIENTO PARA PREPARAR 5-(2-{[6-(2,2-DIFLUORO-2-FENILETOXI)HEXIL]-AMINO}-1(R)-HIDROXIETIL)-8-HIDROXIQUINOLIN-2(1H)-ONA VÍA UN NUEVO INTERMEDIO”

SOLICITANTE: ALMIRALL S.A.

TRÁMITE: Respuesta a Concepto Técnico notificado mediante Oficio No. 3.282 del 31 de marzo de 2015.

JAIME EDUARDO DELGADO VILLEGAS, en mi condición de apoderado de la sociedad **ALMIRALL S.A.**, dentro del término legal, presento respuesta a Concepto Técnico notificado mediante Oficio No. 3.282 del 31 de marzo de 2015.

1. DE LA SOLICITUD DE PATENTE

REIVINDICACIONES (ART 30 D 486, ART 22 PCT)

El Examinador Técnico manifiesta:

“Las reivindicaciones 1 y 2 no son concisas, porque no establecen las posibilidades de grupos protectores P1 y P3, la descripción solo soporta procesos en los cuales el grupo protector de amino es bencilo o alilo, y el grupo protector de hidroxí es bencilo. Se sugiere hacer una generalización razonable de la materia que cuenta con soporte descriptivo”.

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“Adicionalmente, las reivindicaciones 1 y 2 no son concisas porque no establecen claramente como se lleva a cabo la reducción del resto aminocetona, ya que solamente señalan que se realiza en presencia de un catalizador de rodio o rutenio, y la descripción solo soporta procesos en los cuales la reducción del resto aminocetona se efectúa usando un catalizador de rutenio como es el (R)-tol-BINAP RuCl₂ DAIPEN en isopropanol, en presencia de terc-butóxido de potasio y t-butanol. Por otro lado, la reivindicación 1 no establece como se desprotege el compuesto obtenido después de la reacción del compuesto de fórmula (Ap). Se sugiere restringir la reivindicación a una generalización razonable de la materia que cuenta con soporte descriptivo”.

La reivindicación 5 no se encuentra enteramente soportada en la descripción porque la descripción solo soporta proceso en los cuales la reducción del grupo aminocetona se lleva a cabo en presencia de un catalizador de rutenio”.

La reivindicación 8 no es concisa porque reclama rangos muy amplios de temperatura y de presión para la etapa de reducción del resto aminocetona, los ejemplos de la descripción se efectúan a 65°C y una presión de 25 bares. se sugiere hacer una generalización razonable de la materia que efectivamente cuenta con soporte descriptivo”.

Adicionalmente, la reivindicación 8 no es concisa porque no establece las posibilidades de base a usar en la etapa de reducción de acuerdo a lo soportado en la descripción. Se sugiere incorporar el contenido de las reivindicaciones dependientes 9 y 10 para dar concisión”.

“La reivindicación 12 no es clara, ni se encuentra totalmente soportada en la descripción, porque establece que los dos grupos protectores P1 y P3 representan el mismo grupo protector...”

R/: El solicitante de acuerdo a lo expresado por el Examinador Técnico de Patentes, con respecto a las Reivindicaciones como sigue:

Se adjunta un nuevo pliego de reivindicaciones en el que se ha introducido varias modificaciones para subsanar la falta de claridad y concisión objetada por el Examinador.

Básicamente, se han realizado las siguientes modificaciones:

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- Se ha incluido el contenido de las reivindicaciones 2, 5, 9 y 10 en la reivindicación 1,
- Se han combinado las reivindicaciones 17 y 18,
- Se han eliminado las reivindicaciones 3-5, 8-10, 12, y 21,
- Se han reenumerado el resto de las reivindicaciones.

Por lo anterior, el solicitante pone a consideración del Examinador Técnico de Patentes un **NUEVO CAPITULO REIVINDICATORIO**, el cual consta de **doce (12) nuevas reivindicaciones** en cuatro folios.

2. UNIDAD DE INVENCION (ART 25 D 486)

El Examinador objeto la Unidad de Invención de la solicitud porque:

“La Solicitud no cumple con el Requisito de Unidad de Invención porque se refiere a 4 Grupos Inventivos”.

“Los Grupos Inventivos están definidos por las siguientes características esenciales:

“1° Proceso de las reivindicaciones 1 y 2 para preparar el compuesto 5-(2-{{6-(2,2-difluoro-2-fenilettoxihexil)amino}-1(R)-hidroxietil)-8-hidroxiquinolin-2(1H)-ona de fórmula (I)”.

“2° Proceso de las reivindicaciones 3 y 4 para preparar el compuesto 5-(2-{{6-(2,2-difluoro-2-fenilettoxihexil)amino}-1(R)-hidroxietil)-8-hidroxiquinolin-2(1H)-ona de fórmula (I)”.

“3° Proceso de la reivindicación 14 para preparar el compuesto 5-(2-{{6-(2,2-difluoro-2-fenilettoxihexil)amino}-1(R)-hidroxietil)-8-hidroxiquinolin-2(1H)-ona de fórmula (I) que comprende las etapas (i) y (ii)”.

4° Compuesto A1 de la reivindicación 20 y su proceso de preparación de la reivindicación 22”.

“Se sugiere presentar las Solicitudes Divisionales que considere necesarias, ó limitar la solicitud inicial a una sola invención, eliminando de ella las otras invenciones”.

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R/. El solicitante de acuerdo a lo expresado por el Examinador Técnico de Patentes, con respecto a la Unidad de Invención se permite manifestar:

El grupo de invención 2 ya no aplica ya que se han eliminado las reivindicaciones 3 y 4.

El grupo de invención 3 descrito en la reivindicación 14 (nueva reivindicación 6) se refiere al proceso de síntesis para preparar el compuesto de fórmula (I) que comprende la etapa i) y ii). Cabe destacar que primero esta reivindicación es dependiente de la reivindicación 1. De hecho la etapa ii) descrita en la reivindicación 14 (nueva reivindicación 6) es exactamente la misma etapa ya descrita en la reivindicación 1, lo único nuevo y limitante en la presente reivindicación es la descripción de cómo se obtiene el compuesto de fórmula (Ap) mediante las enseñanzas de la etapa i). Por lo cual ambas reivindicaciones 1 y 14 (ahora renumerada 6) comparten un concepto común y novedoso que es la etapa ii) y por lo tanto benefician del concepto de unidad de invención.

Del mismo modo, tanto el compuesto A1 como su proceso de preparación a partir del compuesto Ap también forman parte del proceso de la presente invención. Es cierto que la reivindicación 20 (ahora renumerada 11) está en forma de reivindicación de producto y no de proceso como el resto de las reivindicaciones pero no deja de ser un intermedio novedoso útil para el proceso de la presente invención.

Por otro lado, cabe mencionar que tanto la EPO en el informe internacional de búsqueda así como la mayoría de las oficinas ya reconocen la unidad de invención de la presente solicitud.

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3. EXAMEN DE PATENTABILIDAD (Art 14 D486)

Nivel Inventivo (art. 18 D 486)

El Examinador objeta el nivel inventivo para las reivindicaciones 1-22 con los documentos D1 (WO2008093188) y D2 (WO2010102831) porque:

“(…)”

“La diferencia entre la invención, definida en la reivindicación 1 y el procedimiento divulgado en el documento D1 consiste en que en el procedimiento del documento D1 se obtiene un agonista Beta 2 adrenérgico diferente y en que la reducción del resto aminocetona no se realiza en presencia de un catalizador de rodio o rutenio”.

“(…)”

“La diferencia entre la invención, definida en la reivindicación 1 y el procedimiento del documento D2 consiste en que en el proceso del documento D2 no se lleva a cabo una etapa de reducción usando un catalizador de rodio o rutenio”.

“En consecuencia, la persona del oficio normalmente versada en la materia, se vería motivada a usar un procedimiento de síntesis como el divulgado en el documento D1, usando un catalizador de rutenio durante la etapa de reducción como es de su conocimiento², con el fin de obtener un procedimiento alternativo al divulgado en el documento D2 en la obtención del compuesto 5-(2-{{6-(2,2-difluoro-2-feniletioxi)hexil}amino}-1(R)-hidroxietil)-8-hidroxiquinolin-2(1H)-ona, con la expectativa razonable de éxito porque a pesar que el compuesto del documento D1 no es exactamente igual, si comprende los mismos grupos que participan en la reacción. Por lo cual el objeto de la reivindicación 1 se considera obvio”.

“(…)”

“La diferencia entre la invención, definida en la reivindicación 14 y el procedimiento divulgado en el documento D1 consiste en que en el procedimiento del documento D1 se obtiene un agonista Beta 2 adrenérgico diferente, en consecuencia, se usan intermediarios diferentes. Adicionalmente, la reducción del resto aminocetona no se realiza en presencia de un catalizador de rodio o rutenio”.

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“(…)”

“En consecuencia, la persona del oficio normalmente versada en la materia, se vería motivada a usar un procedimiento de síntesis como el divulgado en el documento D1, usando un catalizador de rutenio durante la etapa de reducción como es de su conocimiento⁴, con el fin de obtener un procedimiento alternativo al divulgado en el documento D2 para la obtención del compuesto 5-(2-([6-(2,2-difluoro-2-feniletioxi)hexil]amino)-1(R)-hidroxietil)-8-hidroxiquinolin-2(1H)-ona, con la expectativa razonable de éxito porque a pesar que el compuesto del documento D1 no es exactamente igual, si comprende los mismos grupos que participan en la reacción. Por lo cual el objeto de la reivindicación 14 se considera obvio”.

R/: Con relación a las objeciones del Examinador de Patentes respecto a la falta de **Nivel Inventivo** de la invención en estudio, el solicitante de acuerdo al Nuevo Capítulo Reivindicatorio, procede a analizar el estado de la técnica más relevante por los siguientes motivos:

Antes de presentar los argumentos, se describe a continuación un esquema resumiendo los diferentes procesos sintéticos descritos en los documentos **D1 y D2:**

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Nombres Comerciales – Enseñas
Propiedad Intelectual
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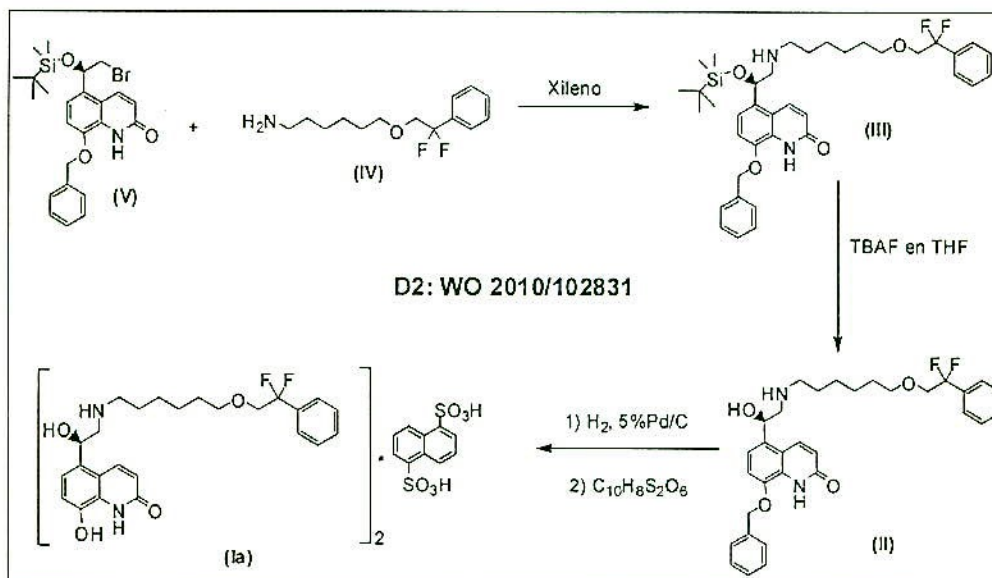
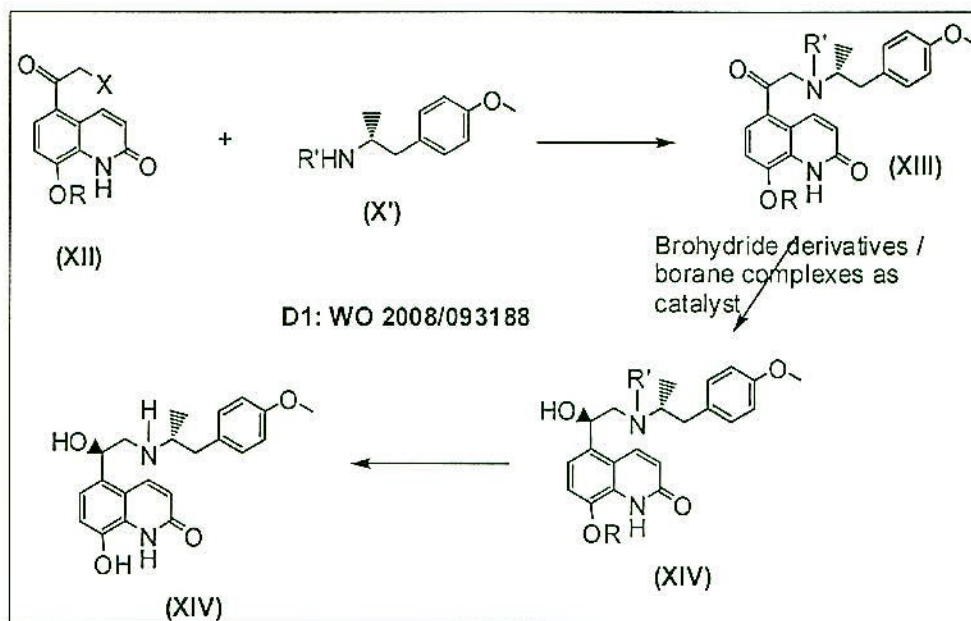
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El documento D2 describe un proceso para preparar compuesto de fórmula (Ia) haciendo reaccionar compuesto intermedio de fórmula (V) con un compuesto intermedio de fórmula (IV) utilizando xileno como disolvente, seguido de una desprotección del grupo hidroxilo y finalmente **seguido de un**

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proceso en una sola etapa de desprotección y salificación con una sal farmacéuticamente aceptable. Cabe mencionar que en el documento **D1** el proceso de reducción del radical aminoacetona se realiza bastante antes de acoplamiento de los reactivos de fórmula (V) y (IV)

El documento **D1** describe un proceso de preparación de un compuesto de formula (XIV), en el que el proceso de reducción del radical aminoacetona se realiza después del acoplamiento de los dos intermedios (XII) y (X'). Dicha reducción, de acuerdo con el documento **D1**, se realiza en presencia de agentes catalizadores del tipo derivado de borohidruros tales como borohidruro de litio, borohidruro de sodio, cianoborohidruro sódico monoacetoxiborohidruro sódico (ver página 9, líneas 10-14 del documento **D2**). **No existe ninguna mención ni siquiera una indicación en el documento D1 sobre catalizadores basados en rodio o rutenio.** Por otro lado, cabe mencionar que el documento **D1** describe exclusivamente una única secuencia de reacciones en el que la desprotección tiene lugar después de la reducción de la aminoacetona al amino alcohol. En cambio la **presente invención describe que la preparación del compuesto de formula (I) se puede realizar en ambas secuencias de las reacciones, es decir en el que la desprotección tiene lugar tanto antes como después de la reducción del aminoacetona al amino alcohol.**

Es muy importante mencionar las **ventajas asociadas al nuevo proceso para obtener el compuesto de fórmula (I).** De hecho, a diferencia de los métodos de los documentos **D1** y **D2**, el **procedimiento de la invención permite la producción del compuesto de fórmula (I) por un camino muy corto, lo que reduce considerablemente el tiempo de reacción.** Además, el compuesto (I) y sus sales se pueden preparar fácilmente a partir del nuevo

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Modelos – Diseños
Nombres Comerciales – Enseñas
Propiedad Intelectual
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intermedio (Ap) a través de solamente dos etapas de síntesis mejorando al mismo tiempo el rendimiento y la pureza del compuesto final (ver Tabla 1 de la memoria descriptiva).

Por otro lado, es muy importante destacar que la reducción de la aminocetona se lleva a cabo usando un catalizador basado en rodio o rutenio. De este modo se evita el uso del complejo derivado de boranos tal como se describen tanto en el documento D1 como en el documento D2, y así se evitan todos los inconvenientes generados dentro del uso de este tipo de catalizador.

El nuevo proceso de la presente invención permite obtener el compuesto de fórmula (I) utilizando solamente 3 etapas de reacción dando lugar al producto final con niveles de impurezas mucho más bajos que el descrito en el documento D2. Esto se consigue utilizando un nuevo compuesto intermedio (Ap), simplificando así las etapas de reacción y evitando el uso y la manipulación de otras sustancias conocidas por su alta toxicidad.

No existe ninguna indicación ni en el documento D1 ni en el documento D2 que hubiera llevado a un experto en la materia en **modificar las condiciones del proceso sintético de la presente invención** (el uso de un intermedio novedoso (Ap), el uso de catalizador a base de rodio o rutenio, la posibilidad de simplificar las etapas totales de síntesis, y también la posibilidad de escalar el proceso obteniendo un producto final con menor impurezas cuando se compara con los procesos anteriores). Todas estas ventajas ante mencionadas hace que la **presente invención presente tanto**

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Modelos – Diseños
Nombres Comerciales – Enseñas
Propiedad Intelectual
Registros en el Exterior
Registros Sanitarios INVIMA – ICA
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novedad como nivel inventivo con respecto al documento D1 y/o documento D2.

Finalmente, solo a modo indicativo el solicitante respetuosamente indica al Examinador que, el Informe de búsqueda Internacional ya reconoce tanto la novedad como el nivel inventivo de la presente invención así como la unidad y la aplicación industrial de la presente invención. (Ver Anexo). Asimismo, la Oficina de Patentes de Estados Unidos (USPTO) (Ver Adjunto), acaba a emitir una **notificación concediendo la presente solicitud** con reivindicaciones mucho más amplias que las actuales y que en estos momentos se están recibiendo exámenes positivos en la mayoría de las oficinas de patente, incluida la Oficina Europea de Patentes.

Por lo expresado anteriormente, la Reivindicación 1 así como las Reivindicaciones 2 a 12 dependientes de la presente solicitud de invención de nuestro poderdante tiene **NIVEL INVENTIVO**.

Finalmente, el solicitante pone a consideración del Examinador Técnico de Patentes: - Un **NUEVO CAPÍTULO REIVINDICATORIO** el cual incluye **doce (12) nuevas reivindicaciones** en cuatro folios; el cual cumple con los requisitos de **NOVEDAD, NIVEL INVENTIVO Y APLICACIÓN INDUSTRIAL** exigidos por la Decisión 486 del Acuerdo de la Comisión de la Comunidad Andina; además, estamos dando respuesta al Concepto Técnico notificado mediante Oficio No. 3.282 del 31 de marzo de 2015.

Por lo tanto, solicito respetuosamente se proceda a **CONCEDER** la Patente de Invención titulada: **“PROCEDIMIENTO PARA PREPARAR 5-(2-([6-(2,2-DIFLUORO-2-FENILETOXI)HEXIL]-AMINO)-1(R)-HIDROXIETIL) -8-HIDROXIQUINOLIN-2(1H)-ONA VÍA UN**

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Modelos – Diseños
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NUEVO INTERMEDIO” a nombre de la sociedad ALMIRALL S.A., para las nuevas Reivindicaciones 1 a 12 inclusive.

Atentamente,



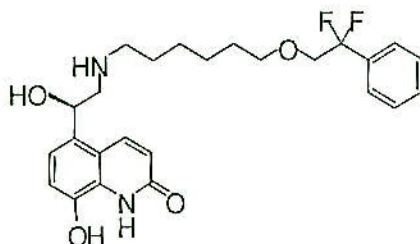
JAIME EDUARDO DELGADO VILLEGAS
C.C. No. 19.270.955 Bogotá
T.P. No. 43.308 C.S.J.

Anexos:

Nuevas Reivindicaciones (12) en cuatro folios.
IPRP en cinco folios.
Notice of Allowance in US en veintitrés folios.

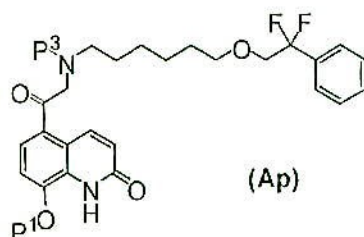
NUEVAS REIVINDICACIONES

1. Un procedimiento para preparar un compuesto de 5-(2-[[6-(2,2-difluoro-2-feniletotoxihexil]amino)-1(R)-hidroxietil]-8-hidroxiquinolin-2(1H)-ona de fórmula (I) o una sal farmacéuticamente aceptable del mismo,



(I)

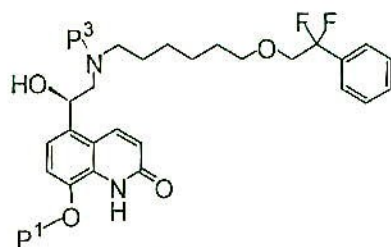
donde dicho procedimiento comprende reducir y desproteger un compuesto de fórmula (Ap), o una sal farmacéuticamente aceptable del mismo,



(Ap)

en donde P¹ y P³ independientemente se seleccionan del grupo que consiste en un grupo bencilo y un grupo alilo, para dar un compuesto de fórmula (I) o una sal farmacéuticamente aceptable del mismo, en donde el resto aminocetona se reduce en presencia de un catalizador a base de rodio o rutenio, a una temperatura en el intervalo de 65-70°C, a una presión de 25 bar y en presencia de una base que es terc-butóxido de potasio, dicho proceso comprende:

- b1) la reducción del resto aminocetona del compuesto de fórmula (Ap) o una sal farmacéuticamente aceptable del mismo, para dar un compuesto de fórmula (Bp) o una sal farmacéuticamente aceptable del mismo,

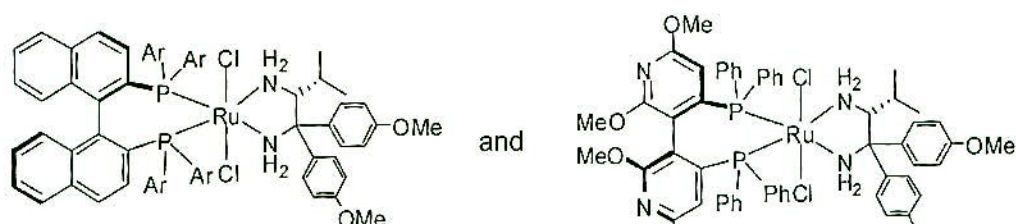


(Bp)

y luego

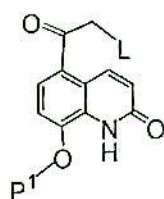
- c1) la separación de los grupos protectores P¹ y P³ del compuesto de fórmula (Bp) o una sal farmacéuticamente aceptable del mismo.

2. Un procedimiento según la Reivindicación 1, en donde el resto aminocetona se reduce en presencia de un catalizador a base de rutenio.
3. Un procedimiento según la Reivindicación 2, en donde el catalizador a base de rutenio se selecciona de:



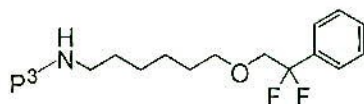
en donde los grupos Ar son iguales y se seleccionan de grupo fenilo y grupo toliilo.

4. Un procedimiento según una cualquiera de las Reivindicaciones precedentes, en donde los grupos protectores P¹ y P³ representan un grupo bencilo.
5. Un procedimiento según una cualquiera de las Reivindicaciones precedentes, en donde los grupos protectores P¹ y P³ se separan en una sola etapa.
6. Un procedimiento para preparar un compuesto de 5-(2-{{6-(2,2-difluoro-2-feniletotoxi)hexil}amino}-1(R)-hidroxietil)-8-hidroxiquinolin-2(1H)-ona de fórmula (I) o una sal farmacéuticamente aceptable del mismo, que comprende
 - (i) preparar un compuesto de fórmula (Ap) como se define en una cualquiera de las Reivindicaciones 1 o 4 o una sal farmacéuticamente aceptable del mismo mediante a) hacer reaccionar un intermedio de fórmula (VII)



(VII)

en donde L es un átomo halógeno, con un derivado de 6-(2,2-difluoro-2-feniletotoxi)hexan-1-amina de fórmula (X),

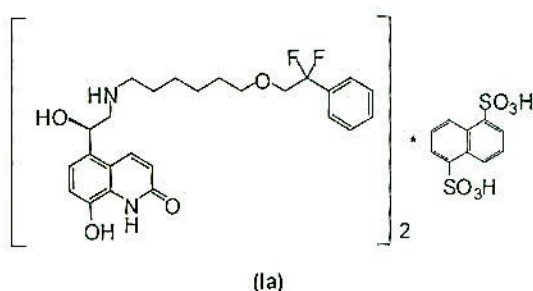


(X)

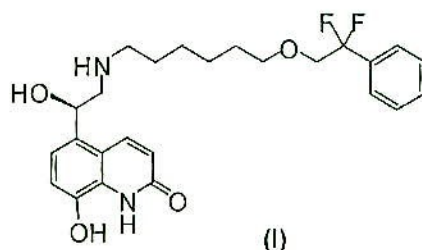
en presencia de una base, en donde P^1 y P^3 son como se definen en una cualquiera de las Reivindicaciones 1 o 4, en donde la base se selecciona de trietilamina, diisopropiletilamina o carbonato de potasio, y después

- (ii) reducir y desproteger el compuesto de fórmula (Ap), o una sal farmacéuticamente aceptable del mismo, por un procedimiento como se define en una cualquiera de las Reivindicaciones 1 a 5, para dar un compuesto de fórmula (I) o una sal farmacéuticamente aceptable del mismo.

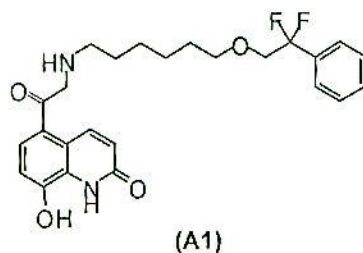
7. Un procedimiento según la Reivindicación 1, en donde el grupo saliente L es un átomo de bromo.
8. Un procedimiento según la Reivindicación 6 o 7, en donde la base es trietilamina.
9. Un procedimiento según una cualquiera de las Reivindicaciones 1 a 8, que comprende además subsiguientemente d) tratar el compuesto de fórmula (I) así obtenido con un ácido farmacéuticamente aceptable, para formar la correspondiente sal farmacéuticamente aceptable, en donde el ácido farmacéuticamente aceptable usado en la etapa d) es el ácido naftaleno-1,5-disulfónico y la sal farmacéuticamente aceptable es la sal napadisilato de fórmula (Ia):



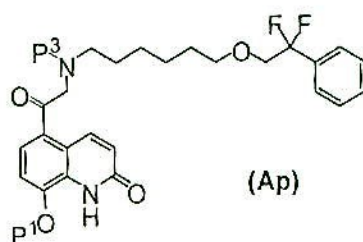
10. Un procedimiento según una cualquiera de las Reivindicaciones 1 a 8, en donde el compuesto (I) se obtiene en forma de base libre.



11. Un compuesto de fórmula (A1) o una sal farmacéuticamente del mismo.



12. Un procedimiento para preparar un compuesto de fórmula (A1) como se define en la Reivindicación 11 o una sal farmacéuticamente aceptable del mismo, donde dicho procedimiento comprende la separación de los grupos protectores P^1 y P^3 de un compuesto de fórmula (Ap)



en donde P^1 representa un grupo protector de hidroxilo y P^3 representa un grupo protector de amino.

PATENT COOPERATION TREATY

PCT/EP2012/069475

From the INTERNATIONAL BUREAU

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:

J A I K E M P

REC'D 25 APR 2014

SRINIVASAN, Ravi Chandran
14 South Square
Gray's Inn
London Greater London WC1R 5JJ
ROYAUME-UNI

Signature by: S E E

Date of mailing (day/month/year)
17 April 2014 (17.04.2014)

Applicant's or agent's file reference
N.117750

IMPORTANT NOTICE

International application No.
PCT/EP2012/069475

International filing date (day/month/year)
02 October 2012 (02.10.2012)

Priority date (day/month/year)
07 October 2011 (07.10.2011)

Applicant
ALMIRALL, S.A.

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

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

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 N.117750	FOR FURTHER ACTION		See item 4 below
International application No. PCT/EP2012/069475	International filing date (day/month/year) 02 October 2012 (02.10.2012)	Priority date (day/month/year) 07 October 2011 (07.10.2011)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant ALMIRALL, S.A.			

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:		
☒	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).		

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland		Date of issuance of this report 08 April 2014 (08.04.2014)
Facsimile No. +41 22 338 82 70		Authorized officer Agnès Wittmann-Regis
		e-mail: pt06.pct@wipo.int

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2012/069475

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: WO2010/102831

D2: WO2008/093188

Novelty

The present claims relate to the preparation of the compound of formula (I) via the intermediate aminoketone (Ap) as well as to intermediates directly prepared from (Ap) and their conversion to (I).

D1 relates to the preparation of the compound of present formula (I) but proceeds via the protected amino alcohol (III) rather than via an aminoketone (present (Ap) or (A1)).

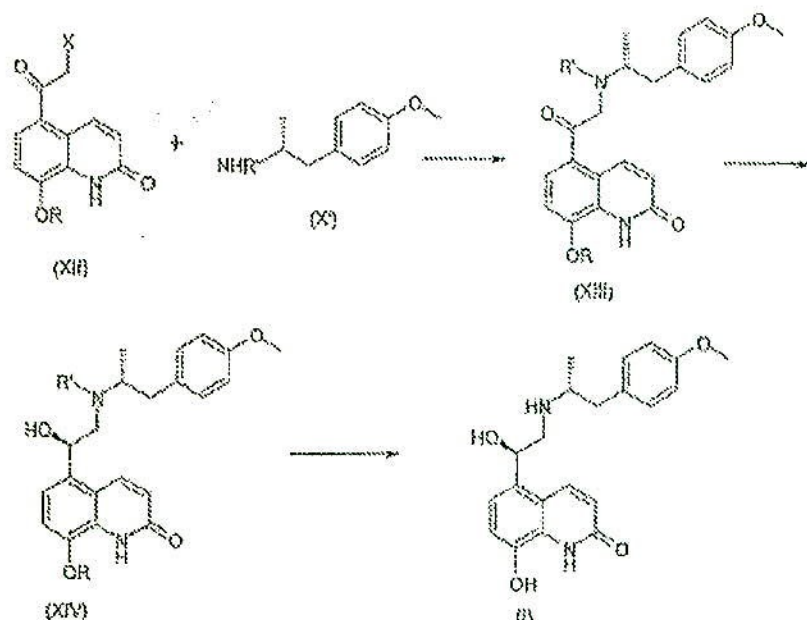
The requirements of novelty are fulfilled.

Inventive step

The technical problem underlying the present application is taken as the provision of an alternative method for preparing present compound (I) as well as an intermediate therefor. D1 is taken as the closest prior art.

The skilled person, starting from D1 and seeking a solution to the above-formulated technical problem, would be motivated to see how structurally very similar compounds have been synthesized in the prior art.

D2 discloses the synthesis of a compound of formula (I), which differs from present formula (I) solely in the nature of the substituent on the amino alcohol nitrogen atom. The compound (I) of D2 is prepared by reacting compound (XII), which corresponds exactly to present compound (VII), with a protected amine of formula (X'), which differs from present compound (X) in the nature of one of the two nitrogen substituents (i.e. the substituent which is not the protecting group) and subsequently reducing the so-obtained aminoketone (XIII) and deprotecting the resulting compound (XIV) to give the desired amino alcohol end product (I) (see Scheme 1).



Present claims 1-3, 5-10 relate to processes in which the reduction is performed in the presence of a rhodium or ruthenium-based catalyst. D2 states that the reduction may be done with a suitable reducing agent such as lithium borohydride, sodium borohydride, sodium cyanoborohydride, sodium monoacetoxyborohydride or borane complexes (p. 9, l. 10-14). No mention is made of a rhodium or ruthenium-based catalyst. Said claims therefore do not appear to be obvious in light of D2.

Present claims 3-5, 20-22 concern reactions and intermediates wherein the deprotection takes place before reduction of the aminoketone to the amino alcohol. As the teaching of D2 deals exclusively with reaction sequences in which the reduction precedes the deprotection, said claims do not appear to be obvious in light of D2.

Present claims 11-19 include the features of one or more of claims 1-10 and are hence inventive for the same reasons as claims 1-10.

The requirements of inventive step are therefore fulfilled.

Re Item VIII

Certain observations on the international application

Claims 9, 11, 15 and 16 contain non-essential preferable features. A claim which contains non-essential features does not comply with the requirement of conciseness. The correct way to claim such preferred embodiments is by use of dependent claims.

21



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

22852 7590 02/02/2015
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

RECEIVED

FEB 06 2015

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER LLP

EXAMINER

SEAMAN, D MARGARET M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 02/02/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/350,108	04/07/2014	Iolanda Marchueta Hereu	09605.0098-00000	9175

TITLE OF INVENTION: PROCESS FOR PREPARING
5-(2-([6-(2,2-DIFLUORO-2-PHENYLETHOXY)HEXYL)AMINO)-1(R)-HYDROXYETHYL)-8-HYDROXYQUINOLIN-2(1H)-ONE VIA A NOVEL
INTERMEDIATE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	05/04/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or **Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the **ISSUE FEE** and **PUBLICATION FEE** (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

22852 7590 02/02/2015
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNE
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
14/350,108	04/07/2014	Iolanda Marchucta Hereu	09605.0098-00000	9175		
TITLE OF INVENTION: PROCESS FOR PREPARING 5-(2-((6-(2,2-DIFLUORO-2-PHENYLETHOXY)HEXYL)AMINO)-1(R)-HYDROXYETHYL)-8-HYDROXYQUINOLIN-2(1H)-ONE VIA A NOVEL INTERMEDIATE						
APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	05/04/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
SEAMAN, D MARGARET M	1625	546-157000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1	_____
2	_____
3	_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/350,108	04/07/2014	Iolanda Marchueta Hereu	09605.0098-00000	9175
22852 7590 02/02/2015 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413				
EXAMINER SEAMAN, D MARGARET M				
ART UNIT		PAPER NUMBER		
1625				

DATE MAILED: 02/02/2015

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

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Notice of Allowability	Application No. 14/350,108	Applicant(s) HEREU ET AL.	
	Examiner D Margaret M. SEAMAN	Art Unit 1625	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.
 ☐ A declaration(s)/affidavit(s) under 37 CFR 1.130(b) was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 1-26. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 Certified copies:
 a) ☒ All b) ☐ Some *c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
 Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892) 2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____	5. ☒ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____
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/D Margaret M SEAMAN/ Primary Examiner, Art Unit 1625	
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1. The present application is being examined under the pre-AIA first to invent provisions.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Claim 20 line 2 after "thereof" DELETE --.—

Claim 20 line 3 after "(A1)" INSERT --.—

3. The following is an examiner's statement of reasons for allowance: The above amendment was made to properly place the period at the end of claim 20. The process claimed in the instant application is different from the prior art (US 8524908) due to the protecting group on the N atom and the use of a rhodium or ruthenium-based catalyst.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Application/Control Number: 14/350,108
Art Unit: 1625

Page 3

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D Margaret M. SEAMAN whose telephone number is (571)272-0694. The examiner can normally be reached on 6am-2pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D Margaret M SEAMAN
Primary Examiner
Art Unit 1625

/D Margaret M SEAMAN/
Primary Examiner, Art Unit 1625

Notice of References Cited	Application/Control No. 14/350,108	Applicant(s)/Patent Under Reexamination HEREU ET AL.	
	Examiner D Margaret M. SEAMAN	Art Unit 1625	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-8,524,908	09-2013	Marchueta Hereu et al.	546/157
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	14/350,108
				§ 371 Date	April 7, 2014
				First Named Inventor	Iolanda Marchueta HEREU
				Art Unit	Not yet assigned
				Examiner Name	Not yet assigned
Sheet	1	of	2	Attorney Docket Number 09605.0098-00000	

U.S. PATENTS					
Examiner Initials*	Cite No.	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
	1	US 3,134,718	05-26-1964	Nobile et al.	
	2	US 4,254,129	03-03-1981	Carr et al.	
	3	US 4,254,130	03-03-1981	Carr et al.	
	4	US 5,648,370	07-15-1997	Bonnert et al.	

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials*	Cite No.	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
	5	US App. No. 14,386,424	Filed: 09-19-2014	Gemma Mestres Amat et al.	
	6	US App. No. 14,389,843	Filed: 10-01-2014	Carlos Puig Duran et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation
		Country Code Number Kind Code (if known)				
	7	DE 1 113 690	02-22-1958	Merck & Co., Inc.		Translation
	8	WO 96/35667	11-14-1996	Hoechst Marion Roussel, Inc.		
	9	WO 2005/040103	05-06-2005	Glaxo Group Ltd.		
	10	WO 2005/042514	05-12-2005	Theravance, Inc.		
	11	WO 2005/097804	10-20-2005	Hanmi Pharm. Co., Ltd.		
	12	WO 2007/106016	09-20-2007	Astrazeneca AB		
	13	WO 2007/146715	12-21-2007	Novartis AG		
	14	WO 2008/135819	11-13-2008	Pfizer Ltd.		
	15	WO 2009/026408	02-26-2009	Allergan, Inc.		
	16	WO 2009/026584	02-26-2009	Novelmed Therapeutics, Inc.		
	17	WO 2009/032764	03-12-2009	Sepracor Inc.		
	18	WO 2013/139712	09-26-2013	Almirall, S.A.		
	19	WO 2013/149959	10-10-2013	Almirall, S.A.		

Examiner Signature		Date Considered	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MS/

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				§ 371 Date	April 7, 2014
				First Named Inventor	Iolanda Marchueta HEREU
				Art Unit	Not yet assigned
				Examiner Name	Not yet assigned
Sheet	2	of	2	Attorney Docket Number	09605.0098-00000

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
	20	BERGE, S.M. et al., "Pharmaceutical salts," Journal of Pharmaceutical Sciences, 1977, 66(1), pp. 1-19.	
	21	CHOWDHURY, B.A. et al., "The risks and benefits of indacaterol - The FDA's review," New England Journal of Medicine, 2011, 365(24), pp. 2247-2249.	
	22	DAHL, R. et al., "Efficacy of a new once-daily long-acting inhaled β_2 -agonist indacaterol versus twice-daily formoterol in COPD," Thorax, 2010, 65, pp. 473-479.	
	23	Dixon A.E., "Long-acting β -agonists and asthma: The saga continues," Am. J. Resp. Criti. Care Med., 2011, 184, pp. 1220-1221.	
	24	English translation for DE1113690.	
	25	FELDMAN, G. et al., "Efficacy and safety of indacaterol 150 μ g once-daily in COPD: a double-blind, randomised, 12-week study," Bio Med Central, 2010, 10(11), pp. 1-9.	
	26	International Search Report dated June 25, 2013, for International Application No. PCT/EP2013/055488.	
	27	International Search Report dated May 13, 2013, for International Application No. PCT/EP2013/056786.	
	28	JACOBSEN, J.R. et al., "A multivalent approach to the discovery of long-acting β_2 -adrenoceptor agonists for the treatment of asthma and COPD," J. Bioorganic & Medicinal Chemistry Letters, 2012, 22, pp. 1213-1218.	
	29	KONZETT H. et al., "Versuchsanordnung zu Untersuchungen an der Bronchialmuskulatur," Arch. Exp. Path. Pharmacol. 195, 1940, pp. 71-75.	Translation
	30	KONZETT, H. et al., "Versuchsanordnung zu untersuchungen an der bronchialmuskulatur," Arch. Exp. Path. Pharmacol. 195, 1940, pp. 71-75. English Translation.	
	31	VAN NOORD, J.A. et al., "24-hour Bronchodilation following a single dose of the novel β_2 -agonist olodaterol in COPD," J. Pulmonary Pharmacology & Therapeutics, 2011, 24, pp. 666-672.	
	32	U.S. Patent Application No. 14/048,344; Office Action dated Oct. 23, 2014, Examiner Craig D. RICCI.	

Examiner Signature	/D Margaret Seaman/	Date Considered	01/28/2015
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14350108 - GAU: 1625

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete If Known	
				Application Number	Not Yet Assigned
				Filing Date	April 7, 2014
				First Named Inventor	Iolanda MARCHUETA HEREU
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	09505.0098-00000

U.S. PATENTS					
Examiner Initials ¹	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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		US-			
		US-			
		US-			
		US-			

U.S. PUBLISHED PATENT APPLICATIONS					
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		US-			
		US-			
		US-			

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		Country Code ³ Number ⁴ Kind Code ² (if known)				
		WO 2008/093186	08-07-2008	Chiesi Farmaceutici S.P.A.		
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NONPATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁵
		International Search Report for International Application No. PCT/EP2012/069475, dated October 25, 2012.	

Examiner Signature	/D Margaret Seaman/	Date Considered	01/28/2015
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	1	US 2,579,479	12-25-1951	Djerassi et al.	
	2	US 2,837,464	06-03-1958	Nobile	
	3	US 2,897,216	07-28-1959	Oliveto et al.	
	4	US 3,007,923	11-07-1961	Muller et al.	
	5	US 3,053,865	09-11-1962	Taub et al.	
	6	US 3,104,246	09-17-1963	Amiard et al.	
	7	US 3,134,719	05-26-1964	Ranchhordas et al.	
	8	US 3,678,137	07-18-1972	Pfeiffer et al.	
	9	US 3,929,768	12-30-1975	Brattsand et al.	
	10	US 3,970,677	07-20-1976	Nishimura et al.	
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	14	US 4,022,776	05-10-1977	Nakagawa et al.	
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	16	US 4,026,897	05-31-1977	Nakagawa et al.	
	17	US 4,068,076	01-10-1978	Nakagawa et al.	
	18	US 4,145,542	03-20-1979	Nakagawa et al.	
	19	US 4,753,962	06-28-1988	Ainsworth et al.	
	20	US 4,992,474	02-12-1991	Skidmore et al.	
	21	US 4,997,986	03-05-1991	Mitchell et al.	
	22	US 5,099,068	03-24-1992	Mitchell et al.	
	23	US 5,109,023	04-28-1992	Mitchell et al.	
	24	US 5,201,308	04-13-1993	Newhouse	
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	27	US 5,435,301	07-25-1995	Herold et al.	
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	29	US 5,507,281	04-16-1996	Kuhnel et al.	
	30	US 5,617,845	04-08-1997	Poss et al.	

Examiner Signature		Date Considered	
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	32	US 6,541,669	04-01-2003	Moran et al.	
	33	US 7,498,321	03-03-2009	Biggadike et al.	
	34	US 7,964,615	06-21-2011	Puig Duran et al.	
	35	US 8,178,679	05-15-2012	Matassa et al.	
	36	US 8,242,177	08-14-2012	Puig Duran et al.	
	37	US 8,283,342	10-09-2012	Puig Duran et al.	
	38	US 8,420,669	04-16-2013	Puig Duran et al.	
	39	US 8,524,908	09-03-2013	Marchueta Hereu et al.	
	40	US 8,563,731	10-12-2013	Carrera et al.	
	41	US 2002/0055651 A1	05-09-2002	Moran et al.	
	42	US 2003/0136405 A1	07-24-2003	Goede et al.	
	43	US 2003/0153597 A1	08-14-2003	Moran et al.	
	44	US 2004/0059116 A1	03-25-2004	Moran et al.	
	45	US 2004/0167167 A1	08-26-2004	Mammen et al.	
	46	US 2005/0043337 A1	02-24-2005	Rito et al.	
	47	US 2005/0159448 A1	07-21-2005	McKinnell et al.	
	48	US 2005/0192316 A1	09-01-2005	Moran et al.	
	49	US 2005/0215590 A1	09-29-2005	Brown et al.	
	50	US 2005/0272769 A1	12-08-2005	Linsell	
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	52	US 2006/0035931 A1	02-16-2006	Chao et al.	
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	57	US 2009/0042933 A1	02-12-2009	Duran et al.	
	58	US 2009/0082378 A1	03-26-2009	Puig Duran et al.	
	59	US 2010/0093681 A1	04-15-2010	Puig Duran et al.	
	60	US 2010/0168161 A1	07-01-2010	Taña et al.	

Examiner Signature		Date Considered	
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Sheet	3	of	11	Attorney Docket Number	09605.0098-00000

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		Number-Kind Code (if known)			
	61	US 2010/0324000 A1	12-23-2010	Giulio Matassa et al.	
	62	US 2011/0028442 A1	02-03-2011	Puig Duran et al.	
	63	US 2011/0251165 A1	10-13-2011	Puig Duran et al.	
	64	US 2011/0251166 A1	10-13-2011	Puig Duran et al.	
	65	US 2011/0251234 A1	10-13-2011	Carrera Carrera et al.	
	66	US 2012/0004414	01-05-2012	Marchueta Hereu et al.	
	67	US 2012/0029014	02-02-2012	Ruf et al.	
	68	US 2012/0040941	02-16-2012	Ruf et al.	
	69	US 2014/0038928	02-06-14	Ruf et al.	
	70	US App. No. 11/920,561	Filed: 02-11-2008	Puig Duran et al.	
	71	US App. No. 12/298,131	Filed: 11-10-2008	Puig Duran et al.	
	72	US App. No. 12/444,935	Filed: 05-14-2009	Bach Tafia et al.	
	73	US App. No. 12/526,090	Filed: 10-08-2009	Puig Duran et al.	
	74	US App. No. 12/745,195	Filed: 05-27-2010	Giulio Matassa et al.	
	75	US App. No. 12/919,134	Filed: 10-07-2010	Puig Duran et al.	
	76	US App. No. 13/141,156	Filed: 06-21-2011	Carrera Carrera et al.	
	77	US App. No. 13/094,163	Filed: 04-26-2011	Puig Duran et al.	
	78	US App. No. 13/141,156	Filed: 06-21-2011	Carrera Carrera et al.	
	79	US App. No. 13/202,020	Filed: 10-18-2011	Ruf et al.	
	80	US App. No. 13/202,025	Filed: 10-14-2011	Ruf et al.	
	81	US App. No. 13/255,621	Filed: 09-19-11	Marchueta Hereu et al.	
	82	US App. No. 13/428,450	Filed: 03-23-2012	Giulio Matassa et al.	
	83	US App. No. 13/538,117	Filed: 06-29-12	Bach Tafia et al.	
	84	US App. No. 14/048,344	Filed: 10-08-2013	Thorsten Ruf et al.	

Examiner Signature		Date Considered	
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28

14350108 - GAU: 1625

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	14/350,108
				Filing Date	April 7, 2014
				First Named Inventor	Iolanda MARCHUETA HEREU et al.
				Art Unit	Not yet assigned
				Examiner Name	Not yet assigned
Sheet	4	of	11	Attorney Docket Number	09605.0098-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials*	Cite No.	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
	85	US App. No. 14/225,849	Filed: 03-28-2014	Thorsten Ruf et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

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		Country Code Number Kind Code (if known)				
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	87	DE 2 323 215	11-29-1973	AB Bofors		English counterpart
	88	DE 2 310 140	09-12-1974	BASF AG		Abstract
	89	DE 24 61 861	08-07-1975	Otsuka Pharmaceutical Co. Ltd.		English counterpart
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		Country Code Number Kind Code (if known)				
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	14/350,108
				Filing Date	April 7, 2014
				First Named Inventor	Iolanda MARCHUETA HEREU et al.
				Art Unit	Not yet assigned
				Examiner Name	Not yet assigned
Sheet	11	of	11	Attorney Docket Number	09605.0098-00000

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation	
	244	U.S. Patent Application No. 13/094,163: Office Action dated August 20, 2012, Examiner Taylor OH.		
	245	U.S. Patent Application No. 13/094,163: Notice of Allowance dated December 12, 2012, Examiner Taylor OH.		
	246	U.S. Patent Application No. 12/745,195: Interview Summary dated February 22, 2012, Examiner Timothy ROZOF.		
	247	U.S. Patent Application No. 12/745,195: Notice of Allowance dated February 24, 2012, Examiner Timothy ROZOF.		
	248	U.S. Patent Application No. 12/526,090: Restriction Requirement dated July 20, 2011, Examiner U. RAMACHANDRAN.		
	249	U.S. Patent Application No. 12/526,090: Office Action dated October 14, 2011, Examiner U. RAMACHANDRAN.		
	250	U.S. Patent Application No. 12/526,090: Office Action dated April 24, 2012, Examiner U. RAMACHANDRAN.		
	251	U.S. Patent Application No. 12/526,090: Interview Summary dated June 26, 2012, Examiner Taylor RAMACHANDRAN.		
	252	U.S. Patent Application No. 12/526,090: Notice of Allowance dated June 26, 2012, Examiner Taylor RAMACHANDRAN.		
	253	U.S. Patent Application No. 13/141,156 Notice of Allowance dated June 21, 2013, Examiner D. Margaret M. SEAMAN.		
	254	U.S. Patent Application No. 13/202,020: Restriction Requirement dated October 2, 2012, Examiner Craig D. RICCI.		
	255	U.S. Patent Application No. 13/202,020: Office Action dated April 8, 2013, Examiner Craig D. RICCI.		
	256	U.S. Patent Application No. 14/048,344: Restriction Requirement dated Feb. 27, 2014, Examiner Craig D. RICCI.		
	257	U.S. Patent Application No. 13/202,025: Restriction Requirement dated October 4, 2012, Examiner Craig D. RICCI.		
	258	U.S. Patent Application No. 13/202,025: Office Action dated April 17, 2013, Examiner Craig D. RICCI.		
	259	U.S. Patent Application No. 13/202,025: Office Action dated October 1, 2013, Examiner Craig D. RICCI.		
	260	U.S. Patent Application No. 13/202,025: Interview Summary dated March 10, 2014, Examiner Craig D. RICCI.		
	261	U.S. Patent Application No. 13/255,621: Notice of Allowance dated May 10, 2013, Examiner D. Margaret M. SEAMAN.		

Examiner Signature	/D Margaret Seaman/	Date Considered	01/28/2015
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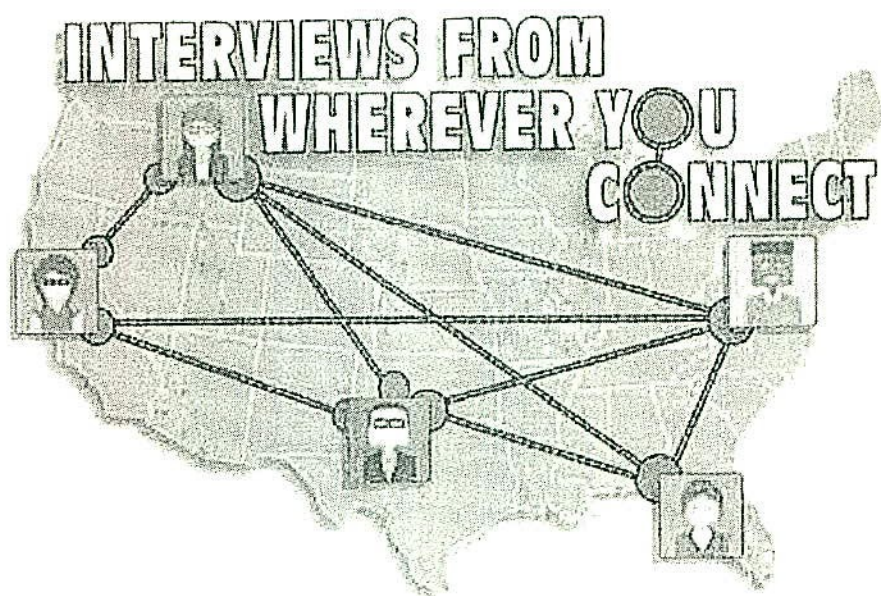
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