



Industria y Comercio

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División de Nuevas Creaciones

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SOLICITUD

PATENTE DE INVENCION

05-91231

21. EXPEDIENTE No.

54. TÍTULO

COMPOSICION FARMACEUTICA COMPRENDIENDO ACIDO 5-METIL-2-(2'-CLORO-6'-
FLUOROANILINO)FENILACETICO.

51. CLASIFICACIÓN INTERNACIONAL

A61K 31/195

71. SOLICITANTE

NOVARTIS AG

DOMICILIO

BASEL, SUIZA

74. APODERADO

JIMENA ESCOBAR URIBE

22. BOGOTÁ, D. C.,

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**FORMULARIO ÚNICO DE SOLICITUD DE PATENTE
PCT
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SOLICITUD DE:

1

☒

Patente de Invención

☐

Patente de Modelo de Utilidad

☐

Capítulo I

☒

Capítulo II

2

**SOLICITANTE
(71)**

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4

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Dirección:

Nacionalidad o domicilio:

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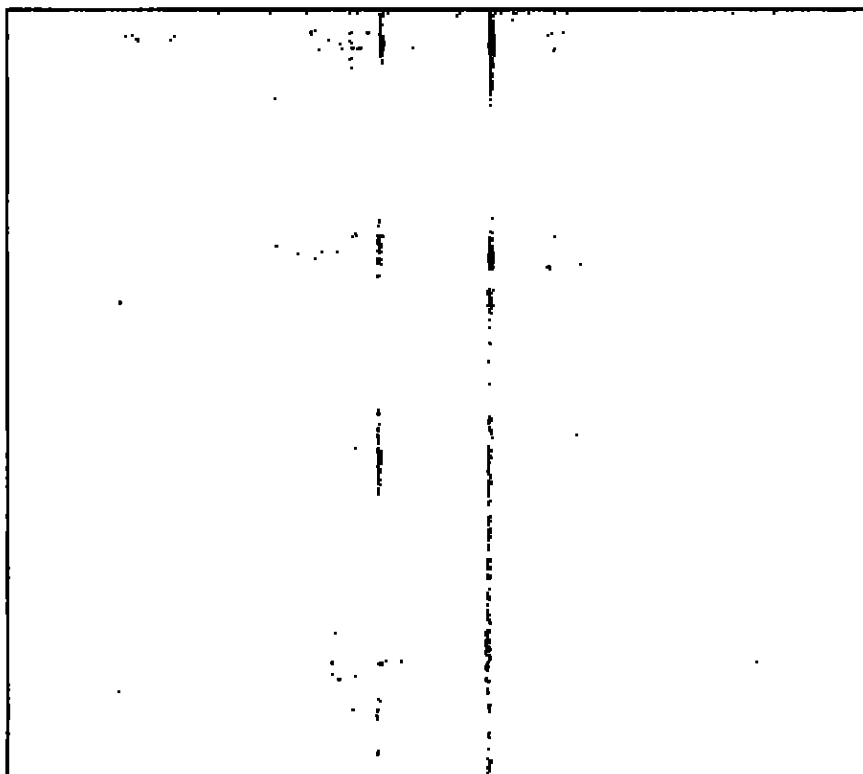
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- ☐ Comprobante de pago de la tasa de presentación de la solicitud
- ☐ Documento que acredita la existencia y representación legal cuando el solicitante sea persona
- ☐ Poderes si fuere el caso Protocolo No. 17.398
- ☐ Documento de cesión del inventor al solicitante o a su causante
- ☐ Declaraciones
- ☐ Copia de la solicitud internacional. (Resumen, descripción, reivindicaciones, dibujos)
- ☐ Traducción de la solicitud internacional al castellano. (Resumen, descripción, reivindicaciones, dibujos)
- ☐ Copia del examen preliminar internacional efectuado por la Autoridad Internacional de Examen Preliminar (IPEA).
- ☐ Traducción del examen preliminar internacional efectuado por la IPEA
- ☐ De ser el caso copia de contrato de acceso.
- ☐ De ser el caso, documento que acredite la licencia o autorización de uso de conocimientos tradicionales de las comunidades indígenas.
- ☐ De ser el caso, certificado de deposito del material biológico
- ☐ Arte final 12 X 12 .
- ☐ De ser el caso, información sobre otras solicitudes de patente o títulos obtenidos en el extranjero por el mismo titular o su causante, relacionadas parcial o totalmente con la invención de esta solicitud.
- ☐ De ser el caso, modificaciones efectuadas a la solicitud internacional
- ☐ Otros "Opinión escrita"

11 FIGURA CARACTERÍSTICA



12 Solicito la concesión de la patente

NOMBRE: JIMENA ESCOBAR URIBE

FIRMA: 

C.C. 39.779.452 DE Usaquén T.P. 68.228

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***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
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***** CONCEPTO *****

CANT. RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1 50005-01-01 SOLICITUDES	1 TRAMITES DE SOL. DE PATENTE DE IN	443,000.00
	TOTAL :	443,000.00

SON: CUATROCIENTOS CUARENTA Y TRES MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

ANEXOS

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Ψ

Solicito expresamente a nombre de la sociedad
NOVARTIS AG, sociedad constituida de conformidad
con las leyes de Suiza, domiciliada en Lichtstrasse 35,
CH-4056 Basilea, Suiza, el otorgamiento de Patente
para la invención titulada **“COMPOSICION
FARMACEUTICA COMPRENDIENDO ACIDO
5-METIL-2-(2'-CLORO-6'-FLUOROANILINO)
FENILACETICO”**.

Clase: A61K 31/195


JIMENA ESCOBAR URIBE
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T.P. 68.228

 Industria y Comercio SUPERINTENDENCIA		SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO DIVISION DE NUEVAS CREACIONES EXTRACTO PARA PUBLICACIÓN SOLICITUD DE PATENTE DE INVENCION PCT	
(21) N° de solicitud: 22) Fecha de solicitud: (30) Prioridad Estadinense (31) No. Prioridad 80/454,145 (32) Fecha 12/03/03 (33) País US		(51) Int Cl: A81K 31/195 (71) Solicitante(s) NOVARTIS AG. (72) Inventor(es) FORENZO, Patrick // KHALED, Maha, Y. // WANG, Barbara // ZIELINSKI, Joseph, Lawrence. (74) Agente: JIMENA ESCOBAR URIBE	
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(54) Título: COMPOSICION FARMACEUTICA COMPRENDIENDO ACIDO 5-METIL-2-(2'-CLORO-6'-FLUOROANILINO)FENILACETICO.			

Reivindicación(es):

1. Una formulación líquida de dosificación oral que comprende agua, ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético y un agente de suspensión, en donde el pH de dicha formulación está entre aproximadamente 4.3 y aproximadamente 5.5.

14. Un método para preparar una suspensión oral líquida que comprende ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético, que comprende:

mezclar agua, sustancia de medicamento y agente de suspensión, para producir una primera mezcla y entonces mezclar los componentes de sistema amortiguador; o

mezclar agua, agente de suspensión y componentes de sistema amortiguador para producir una primera mezcla y entonces mezclar la sustancia de medicamento.

RESUMEN

Se proporcionan composiciones que comprenden suspensiones acuosas de ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético adecuadas para administración oral. Se proporcionan métodos para hacer tales composiciones y métodos para su estabilización.

**COMPOSICION FARMACEUTICA COMPRENDIENDO ACIDO 5-METIL-2-
(2'-CLORO-6'-FLUOROANILINO)FENILACETICO**

Esta invención se refiere a composiciones para el tratamiento de
5 desórdenes y condiciones mediados por ciclooxigenasa-2, que comprenden
ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético o una sal
farmacéuticamente aceptable del mismo adecuado para administración
oral, y métodos de tratamiento de desórdenes y condiciones mediados por
ciclooxigenasa-2 mediante la administración oral de ácido 5-metil-2-(2'-
10 cloro-6'-fluoroanilino)fenilacético.

Todas las patentes, solicitudes de patente y otras publicaciones
referidas en la presente son incorporadas aquí expresamente por
referencia en su totalidad. En caso de un conflicto entre la presente
especificación y material incorporado por referencia, domina la presente
15 especificación.

La presente invención se dirige a una composición para el
tratamiento de desórdenes y condiciones mediados por ciclooxigenasa-2,
comprendiendo la composición una suspensión de ácido 5-metil-2-(2'-
cloro-6'-fluoroanilino)fenilacético. La utilidad de este compuesto y
20 métodos para su síntesis se describen en la patente estadounidense
6,291,523.

La presente invención también se dirige a métodos para tratar un
desorden o condición dependiente de ciclooxigenasa-2 comprendiendo
administrar una cantidad efectiva de las composiciones de la invención, es
25 decir, una formulación líquida de dosificación oral que comprende ácido 5-

metil-2-(2'-cloro-6'-fluoroanilino)fenilacético.

Como se discute en la patente estadounidense 6,291,523, un género de compuestos, incluyendo ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético, es útil para aliviar el dolor, fiebre e inflamación de una variedad de condiciones incluyendo fiebre reumática, síntomas asociados con influenza u otras infecciones virales, resfriado común, dolor de cuello y espalda baja, dismenorrea, dolor de cabeza, incluyendo dolor de migraña, dolor de dientes, dislocaciones y torceduras, miositis, neuralgia, sinovitis, artritis, incluyendo osteoartritis y artritis reumatoide, enfermedades degenerativas de articulaciones, gota y espondilitis anquilosante, bursitis, quemaduras y lesiones siguiendo procedimientos quirúrgicos y dentales. Algunos individuos, especialmente los niños, tienen dificultad para tragar formulaciones sólidas de dosificación oral. De esta manera, es deseable proporcionar formulaciones líquidas de dosificación oral comprendiendo ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético para el tratamiento de las condiciones antes mencionadas en individuos que tienen dificultad para tragar formulaciones sólidas de dosificación oral.

De manera sorprendente se ha encontrado que se puede preparar una formulación líquida de dosificación oral de vida de anaquel estable comprendiendo ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético. La sustancia de medicamento de ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético es relativamente insoluble en agua y también se degrada en agua, y así la capacidad para producir una formulación de vida de anaquel estable era inesperada. De manera adicional,

sorprendentemente se descubrió que la capacidad de suspensión de la
 substancia de medicamento de ácido 5-metil-2-(2'-cloro-6'-
 fluoroanilino)fenilacético puede ser altamente dependiente del orden de
 adición de los componentes de suspensión, en particular el agente de
 5 suspensión y el amortiguador.

Las formulaciones líquidas de dosificación oral comprendiendo ácido
 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético son, de preferencia,
 suspensiones de ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético. Los
 agentes de suspensión adecuados incluyen celulosa microcristalina,
 10 carboximetilcelulosa de sodio, goma guar, goma xantana, goma gelana,
 carragenina, glicolato de sodio almidón y mezclas de los mismos. Las
 concentraciones de agente de suspensión en las formulaciones de la
 invención pueden variar entre aproximadamente 0.1% hasta
 aproximadamente 3%, o entre aproximadamente 0.5% y aproximadamente
 15 2.5%, o entre aproximadamente 1% y aproximadamente 2%, o
 aproximadamente 1.5%.

Las formulaciones de la invención también pueden contener un
 agente humectante, por ejemplo, polisorbato 80, poloxámeros, incluyendo
 poloxámero 188, aceite de ricino polietoxilado y aceite de ricino
 20 hidrogenado polietoxilado y estearato de polioxilo 40. El poloxámero 188
 tiene la estructura $\text{HO}(\text{CH}_2\text{CH}_2\text{O})_a(\text{CH}(\text{CH}_3)\text{CH}_2\text{OH})_b(\text{CH}_2\text{CH}_2\text{O})_c\text{H}$, donde a
 es 75, b es 30 y c es 75, con un peso molecular promedio de
 aproximadamente 8350. El agente humectante está presente en cantidades
 normalmente entre aproximadamente 0.1% y aproximadamente 5%, o entre
 25 aproximadamente 0.18% y aproximadamente 1%, o entre aproximadamente

0.18 y aproximadamente 0.25%, o entre aproximadamente 0.18 y aproximadamente 0.22% o aproximadamente 0.2%.

El pH de la formulación puede variar entre aproximadamente 4.3 y 5.5, de preferencia entre aproximadamente 4.5 y aproximadamente 5.5 o entre aproximadamente 4.75 y aproximadamente 5.25. El pH también puede variar entre aproximadamente 4.9 y aproximadamente 5.0. Los amortiguadores adecuados incluyen, por ejemplo, amortiguadores de citrato de metal alcalino, tal como sales de citrato de metal alcalino con ácido cítrico, amortiguadores de acetato de metal alcalino, tales como sales de acetato de sodio con ácido acético y amortiguadores de succinato de metal alcalino, tales como sales de succinato de sodio con ácido succínico y mezclas de los mismos.

Las formulaciones normalmente contienen un agente antiespumante, por ejemplo, simeticona, normalmente adicionado como una emulsión, por ejemplo, una emulsión al 30%. Tal emulsión al 30% puede ser adicionada a una concentración de aproximadamente 0.1% hasta aproximadamente 0.25% en la formulación final. Pueden usarse endulzantes, tales como sacarina, sacarina de sodio, aspartame, sucralosa, acesulfame potasio, glucosa, fructosa, lactitol, maltitol, maltosa, sorbitol, sacarosa y xilitol. Los agentes saborizantes también pueden ser adicionados para mejorar la aceptación.

Los conservadores adecuados para suspensiones orales son conocidos para aquéllos de habilidad en la técnica e incluyen, por ejemplo, ácido benzoico, ácido sórbico, parabenos (butil, etil, metil, propil), benzoato de sodio y propionato de sodio. Un conservador, tal como

aquéllos expuestos antes, o una mezcla del mismo, pueden estar presentes en cantidades entre aproximadamente 0.01% y aproximadamente 0.3%; o entre aproximadamente 0.02% y 0.25%; o entre aproximadamente 0.1% y aproximadamente 0.2%. En una modalidad, la
5 formulación comprende aproximadamente 0.02% de propilparabeno y aproximadamente 0.18% de metilparabeno. Otras modalidades incluyen formulaciones que comprenden 0.03% de propilparabeno y 0.12% de metilparabeno, 0.148% de metilparabeno y 0.016% de propilparabeno y formulaciones comprendiendo 0.1% de metilparabeno y 0.1% de ácido
10 sórbico.

Las suspensiones de la invención pueden hacerse en equipo convencional de formulación de líquidos. En una modalidad, la suspensión de la invención es producida mediante un proceso que comprende mezclar agua, sustancia de medicamento y agente de suspensión, seguido por la
15 adición y mezcla de componentes de amortiguador. De manera alternativa, la suspensión de la invención puede ser preparada al mezclar agua, agente de suspensión y componentes de sistema amortiguador, seguido por la adición y mezcla de la sustancia de medicamento. De manera sorprendente, se ha descubierto que una suspensión no puede lograrse si
20 los componentes de amortiguador son mezclados con la sustancia de medicamento antes de la adición del agente de suspensión, cuando el agente de suspensión es una mezcla de celulosa microcristalina y carboximetilcelulosa de sodio.

Un pH de entre aproximadamente 4.3 y 5.5 proporciona una
25 suspensión con la sustancia de medicamento más estable. Las

formulaciones con un pH por abajo de 4.3 tienen un nivel incrementado de un producto de degradación cíclica, mientras que aquellas por arriba de pH 5.5 tienen niveles incrementados de un producto de degradación oxidante. Adicionalmente, aumentar el pH de formulaciones de suspensión de ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético por arriba de pH 5.5, resulta en una solubilización incrementada indeseable de la sustancia de medicamento.

Ejemplos

10 Ejemplo 1: Formulación

Tabla 1

Ingrediente	Cantidad (mg/ml)
Acido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético	10.0
Propilparabeno	1.0
Poloxámero 188	2.00
Acido sórbico	1.0
Emulsión de simeticona al 30%	1.00
Sabor	4.0
Agente de suspensión: Avicel® RC591	18.00
Propilenglicol	25.00
Solución de sorbitol al 70%	200.00
Acido cítrico anhidro	0.71
Dehidrato de citrato de sodio	1.88
Sacarina de sodio	0.50

Agua purificada, USP	q.s. a 1 ml
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El poloxámero 188 es disuelto en agua, seguido por dispersión de simeticona y sustancia de medicamento. Por separado, los metil y propilparabenos son disueltos en propilenglicol para formar una solución conservadora. El ácido cítrico, citrato de sodio y sacarina de sodio son disueltos en agua por separado. El Avicel® RC591 es dispersado entonces en la mezcla de poloxámero 188/simeticona/sustancia de medicamento y se homogeneiza. La solución conservadora es mezclada y homogeneizada entonces, seguido por la solución de sorbitol, solución de amortiguador y sabor. Alternativamente, el poloxámero 188 es disuelto en agua, seguido por la dispersión de sustancia de medicamento. Por separado, los metil y propilparabenos son disueltos en propilenglicol para formar una solución conservadora. El ácido cítrico, citrato de sodio, simeticona y sacarina de sodio son disueltos/dispersados en agua por separado. Entonces se dispersa Avicel® RC591 en la solución de sorbitol y se homogeniza. La solución conservadora es mezclada entonces, seguido por la solución de sorbitol, solución de amortiguador y sabor. La dispersión de poloxámero 188/sustancia de medicamento es mezclada entonces para formar la suspensión final.

Otras formulaciones pueden ser preparadas como se indica antes, substituyendo los otros surfactantes por poloxámero 188, con los siguientes ingredientes:

Tabla 2

Ingrediente	Cantidad (mg/ml)
Acido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético	15.0
Propilparabeno	0.20
Poloxámero 188	2.00
Metilparabeno	1.80
Emulsión de simeticona al 30%	1.00
Sabor	5.0
Agente de suspensión: Avicel® RC591	15.00
Propilenglicol	25.00
Solución de sorbitol al 70%	250.00
Acido cítrico anhidro	0.71
Dihidrato de citrato de sodio	1.88
Sacarina de sodio	0.50
Agua purificada, USP	q.s. a 1 ml

Tabla 3

Ingrediente	Cantidad (mg/ml)
Acido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético	12.5
Propilparabeno	0.20
Polisorbato 80	2.00
Metilparabeno	1.80
Emulsión de simeticona al 30%	1.00
Sabor	5.0

Agente de suspensión: Avicel® RC591	15.00
Propilenglicol	25.00
Solución de sorbitol al 70%	250.00
Acido cítrico anhidro	0.71
Dehidrato de citrato de sodio	1.88
Acido ascórbico	10
Sacarina de sodio	0.50
Agua purificada, USP	q.s. a 1 ml

Tabla 4

Ingrediente	Cantidad (mg/ml)
Acido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético	15.0
Propilparabeno	0.20
Metilparabeno	1.80
Emulsión de simeticona al 30%	1.00
Sabor	5.0
Agente de suspensión: Avicel® RC591	18.00
Propilenglicol	25.00
Solución de sorbitol al 70%	250.00
Acido cítrico anhidro	3.47
Dehidrato de citrato de sodio	9.37
Hidroxietilcelulosa	1.25
Poloxámero 188	2.0
Agua purificada, USP	q.s. a 1 ml

Tabla 5

Ingrediente	Cantidad (mg/ml)
Acido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético	15.0
Propilparabeno	0.20
Metilparabeno	1.80
Emulsión de simeticona al 30%	1.00
Sabor	5.0
Agente de suspensión: Avicel® RC591	12.00
Propilenglicol	25.00
Solución de sorbitol al 70%	250.00
Acido cítrico anhidro	3.47
Dehidrato de citrato de sodio	9.37
Carboximetilcelulosa de sodio	1.25
Poloxámero 188	2.0
Agua purificada, USP	q.s. a 1 ml

Tabla 6

Ingrediente	Cantidad (mg/ml)
Acido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético	15.0
Propilparabeno	0.16
Poloxámero 188	2.00
Metilparabeno	1.48
Emulsión de simeticona al 30%	2.00
Sabor	4.0

Agente de suspensión: Avicel® RC591	15.00
Propilenglicol	25.00
Solución de sorbitol al 70%	250.00
Acido cítrico anhidro	0.71
Dihidrato de citrato de sodio	1.88
Sacarina de sodio	0.50
Agua purificada, USP	q.s. a 1 ml

Tabla 7

Ingrediente	Cantidad (mg/ml)
Acido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético	15.0
Propilparabeno	0.16
Poloxámero 188	2.00
Metilparabeno	1.48
Emulsión de simeticona al 30%	1.00
Sabor	4.0
Agente de suspensión: Avicel® RC591	15.00
Propilenglicol	25.00
Solucion de sorbitol al 70%	250.00
Acido cítrico anhidro	0.71
Dihidrato de citrato de sodio	1.88
Sacarina de sodio	0.50
Agua purificada, USP	q.s. a 1 ml

REIVINDICACIONES

1. Una formulación líquida de dosificación oral que comprende agua, ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético y un agente de suspensión,
5 en donde el pH de dicha formulación está entre aproximadamente 4.3 y aproximadamente 5.5.
2. La formulación líquida de dosificación oral de la reivindicación 1, en donde dicho agente de suspensión es un miembro seleccionado del grupo que consiste de celulosa microcristalina, carboximetilcelulosa de sodio,
10 goma guar, goma xantana, goma gelana, carragenina, glicolato de sodio almidón y mezclas de los mismos.
3. La formulación líquida de dosificación oral de la reivindicación 2, que comprende además un agente humectante.
4. La formulación líquida de dosificación oral de la reivindicación 3, en
15 donde dicho agente humectante es un miembro seleccionado del grupo que consiste de polisorbato 80, poloxámeros, aceite de ricino polietoxilado, aceite de ricino hidrogenado polietoxilado, estearato de polioxilo 40 y mezclas de los mismos.
5. La formulación líquida de dosificación oral de la reivindicación 2, en
20 donde el pH de dicha formulación está entre aproximadamente 4.5 y 5.5.
6. La formulación líquida oral de la reivindicación 6, en donde el pH de dicha formulación está entre aproximadamente 4.75 y aproximadamente 5.25.
7. La formulación líquida oral de la reivindicación 7, en donde el pH de
25 dicha formulación es aproximadamente 5.0 y dicho poloxámero es

poloxámero 188.

8. La formulación líquida oral de la reivindicación 1, en donde dicho agente de suspensión es una mezcla de celulosa microcristalina y carboximetilcelulosa de sodio.

5 9. La formulación líquida oral de la reivindicación 8, que comprende un sistema amortiguador.

10 10. La formulación líquida oral de la reivindicación 9, en donde dicho sistema amortiguador comprende un miembro seleccionado del grupo que consiste de sales de citrato de metal alcalino con ácido cítrico, sales de acetato de metal alcalino con ácido acético, sales de succinato de metal alcalino con ácido succínico y mezclas de los mismos.

11. La formulación líquida oral de la reivindicación 9, que comprende además un agente antiespumante.

15 12. La formulación líquida oral de la reivindicación 9, que comprende además un conservador.

20 13. La formulación líquida oral de la reivindicación 12, en donde dicho conservador es un miembro seleccionado del grupo que consiste de ácido benzoico, ácido sórbico, butilparabeno, etilparabeno, metilparabeno, propilparabeno, benzoato de sodio, propionato de sodio y mezclas de los mismos.

14. Un método para preparar una suspensión oral líquida que comprende ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético, que comprende:

mezclar agua, sustancia de medicamento y agente de suspensión, para producir una primera mezcla y entonces mezclar los componentes de
25 sistema amortiguador; o

mezclar agua, agente de suspensión y componentes de sistema amortiguador para producir una primera mezcla y entonces mezclar la sustancia de medicamento.

15. El método de la reivindicación 14, en donde dicho agente de suspensión es una mezcla de celulosa microcristalina y carboximetilcelulosa de sodio.

16. El método de la reivindicación 15, en donde dicha suspensión oral líquida tiene un pH de entre aproximadamente 4.3 y 5.5.

17. El método de la reivindicación 16, en donde dichos componentes de sistema amortiguador son ácido cítrico y citrato de sodio.

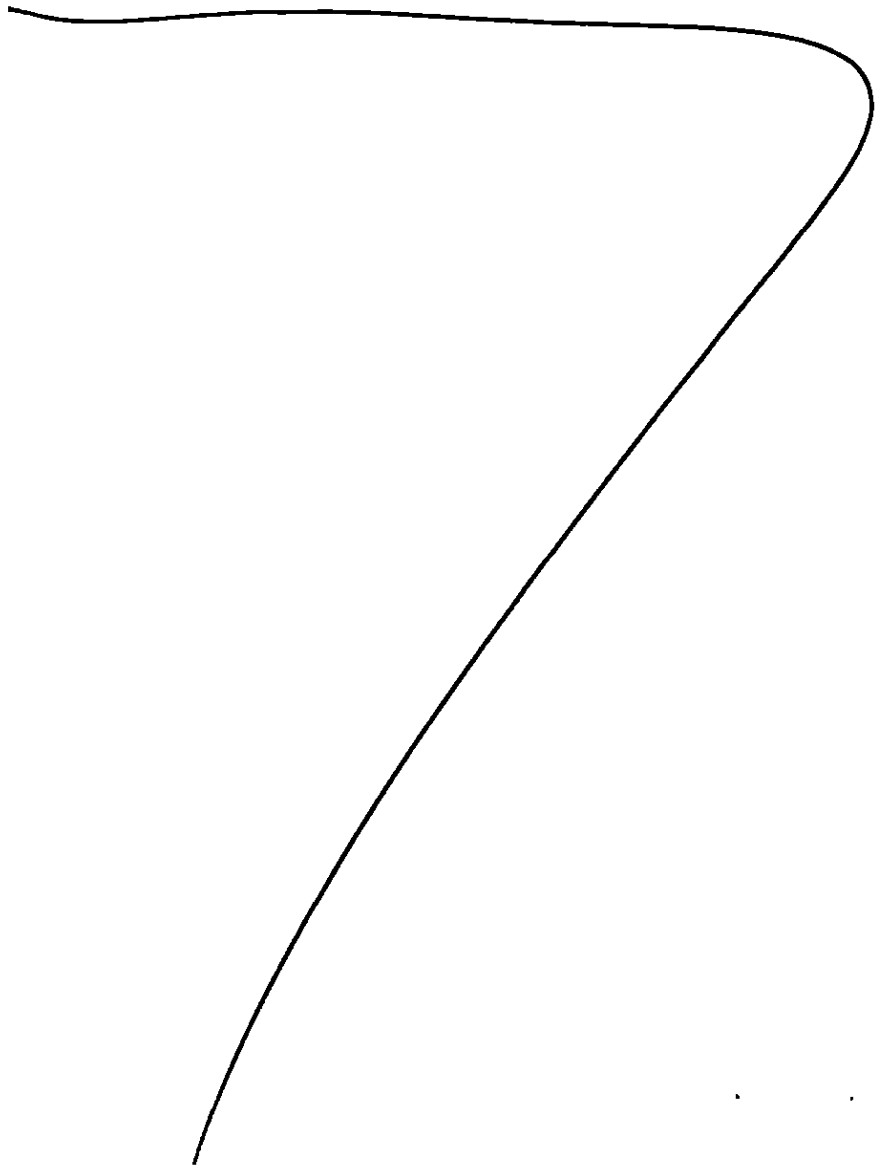
18. El método de la reivindicación 17, en donde dicha suspensión oral líquida tiene un pH de aproximadamente 5.0.

19. Un método para minimizar la disolución y degradación de una suspensión acuosa de ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético, que comprende proporcionar una suspensión acuosa de ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético y ajustar el pH de dicha suspensión hasta entre aproximadamente 4.3 y aproximadamente 5.5.

20. El método de la reivindicación 19, en donde dicho pH es ajustado hasta aproximadamente 5.0.

21. Un método para tratar un desorden o condición dependiente de ciclooxigenasa-2, que comprende administrar una cantidad efectiva de una formulación líquida de dosificación oral comprendiendo ácido 5-metil-2-(2'-cloro-6'-fluoroanilino)fenilacético, en donde el pH de dicha formulación está entre aproximadamente 4.3 y 5.5.

22. El método de la reivindicación 22, en donde el pH de dicha formulación es aproximadamente 5.0.



PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

PCT/EP200 4 / 0 0 2 5 2 8.
International Application No.(11 03 2004)
International Filing Date

11 MAR 2004

EUROPEAN PATENT OFFICE
PCT INTERNATIONAL APPLICATION

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum) 4 -32907A/USN

Box No. I TITLE OF INVENTION PHARMACEUTICAL COMPOSITION	
Box No. II APPLICANT ☐ This person is also inventor	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) Novartis AG Lichtstrasse 35 4056 Basel CH	
Telephone No. +41 61 324 11 11	
Facsimile No. +41 61 322 75 32	
Teleprinter No.	
Applicant's registration No. with the Office	
State (that is, country) of nationality: CH	State (that is, country) of residence: CH
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☒ the States indicated in the Supplemental Box	
Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) Novartis Pharma GmbH Brunner Strasse 59 1230 Vienna AT	
This person is: ☒ applicant only ☐ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.)	
Applicant's registration No. with the Office	
State (that is, country) of nationality: AT	State (that is, country) of residence: AT
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☒ the States indicated in the Supplemental Box	
☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.	
Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) GRUBB, Philip Novartis AG Corporate Intellectual Property 4002 Basel CH	
Telephone No. +41 61 324 11 11	
Facsimile No. +41 61 322 75 32	
Teleprinter No.	
Agent's registration No. with the Office	
☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.	

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
<i>If none of the following sub-boxes is used, this sheet should not be included in the request.</i>	
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence (if no State of residence is indicated below.)</i> FORENZO, Patrick 337 Newport Road Glen Gardner, NJ 08826 US	This person is: ☐ applicant only ☒ applicant and inventor ☐ inventor only <i>(If this check-box is marked, do not fill in below.)</i> Applicant's registration No. with the Office
State <i>(that is, country)</i> of nationality: US	State <i>(that is, country)</i> of residence: US
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence (if no State of residence is indicated below.)</i> KHALED, Maha Y. 27 Pebble Beach Drive Livingston, NJ 07039 US	This person is: ☐ applicant only ☒ applicant and inventor ☐ inventor only <i>(If this check-box is marked, do not fill in below.)</i> Applicant's registration No. with the Office
State <i>(that is, country)</i> of nationality: US	State <i>(that is, country)</i> of residence: US
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence (if no State of residence is indicated below.)</i> WANG, Barbara 19 Baldwin Drive Berkeley Heights, NJ 07922 US	This person is: ☐ applicant only ☒ applicant and inventor ☐ inventor only <i>(If this check-box is marked, do not fill in below.)</i> Applicant's registration No. with the Office
State <i>(that is, country)</i> of nationality: US	State <i>(that is, country)</i> of residence: US
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this box is the applicant's State (that is, country) of residence (if no State of residence is indicated below.)</i> ZIELINSKI, Joseph Lawrence 53 Beechwood Road Florham Park, NJ 07932 US	This person is: ☐ applicant only ☒ applicant and inventor ☐ inventor only <i>(If this check-box is marked, do not fill in below.)</i> Applicant's registration No. with the Office
State <i>(that is, country)</i> of nationality: US	State <i>(that is, country)</i> of residence: US
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box	
☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.	

Supplemental Box
If the Supplemental Box is not used, this sheet should not be included in the request.

1. *If, in any of the Boxes, except Boxes Nos. VIII(f) to (v) for which a special continuation box is provided, the space is insufficient to furnish all the information: in such case, write "Continuation of Box No." (Indicate the number of the Box) and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:*
 - (i) *if more than two persons are to be indicated as applicants and/or inventors and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below;* Continuation of Box No. II
Novartis AG is applicant for all designated States with the exception of: AT (Austria) and US (USA)
 - (ii) *if, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;* Continuation of Box No. III
Novartis Pharma GmbH is applicant for AT (Austria) only.
 - (iii) *if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;*
 - (iv) *if, in addition to the agent(s) indicated in Box No. IV, there are further agents: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;*
 - (v) *if, in Box No. VI, there are more than three earlier applications whose priority is claimed: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.*
2. *If the applicant intends to make an indication of the wish that the international application be treated, in certain designated States, as an application for a patent of addition, certificate of addition, inventor's certificate of addition or utility certificate of addition: in such a case, write the name or two-letter code of each designated State concerned and the indication "patent of addition," "certificate of addition," "inventor's certificate of addition" or "utility certificate of addition," the number of the parent application or parent patent or other parent grant and the date of grant of the parent patent or other patent grant or the date of filing of the parent application (Rules 4.11(a)(iii) and 49bis.1(a) or (b)).*
3. *If the applicant intends to make an indication of the wish that the international application be treated, in the United States of America, as a continuation or continuation-in-part of an earlier application: in such a case, write "United States of America" or "US" and the indication "continuation" or "continuation-in-part" and the number and the filing date of the parent application (Rules 4.11(a)(iv) and 49bis.1(d)).*

Box No. V DESIGNATIONS

The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.

However,

- ☐ DE Germany is not designated for any kind of national protection
- ☐ KR Republic of Korea is not designated for any kind of national protection
- ☐ RU Russian Federation is not designated for any kind of national protection

(The check-boxes above may be used to exclude (irrevocably) the designations concerned in order to avoid the ceasing of the effect, under the national law, of an earlier national application from which priority is claimed. See the Notes to Box No. V as to the consequences of such national law provisions in these and certain other States.)

Box No. VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country or Member of WTO	regional application:* regional Office	international application: receiving Office
item (1) 12 March 2003 (12.03.03)	60/454,145	US		
item (2)				
item (3)				

☐ Further priority claims are indicated in the Supplemental Box.

The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office) identified above as:

- ☐ all items ☐ item (1) ☐ item (2) ☐ item (3) ☐ other, see Supplemental Box

* Where the earlier application is an ARIPO application, indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.10(b)(ii)):

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) (if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):

ISA /

Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):

Date (day/month/year) Number Country (or regional Office)

Box No. VIII DECLARATIONS

The following declarations are contained in Boxes Nos. VIII (i) to (v) (mark the applicable check-boxes below and indicate in the right column the number of each type of declaration):

		Number of declarations
☐ Box No. VIII (i)	Declaration as to the identity of the inventor	:
☐ Box No. VIII (ii)	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	:
☐ Box No. VIII (iii)	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	:
☐ Box No. VIII (iv)	Declaration of inventorship (only for the purposes of the designation of the United States of America)	:
☐ Box No. VIII (v)	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	:

Box No. IX CHECK LIST; LANGUAGE OF FILING																																																							
This international application contains: (a) in paper form, the following number of sheets: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">request (including declaration sheets)</td> <td style="width: 20%; text-align: right;">5</td> </tr> <tr> <td>description (excluding sequence listing and/or tables related thereto)</td> <td style="text-align: right;">7</td> </tr> <tr> <td>claims</td> <td style="text-align: right;">3</td> </tr> <tr> <td>abstract</td> <td style="text-align: right;">1</td> </tr> <tr> <td>drawings</td> <td style="text-align: right;">1</td> </tr> <tr> <td>Sub-total number of sheets</td> <td style="text-align: right;">16</td> </tr> <tr> <td>sequence listing</td> <td></td> </tr> <tr> <td>tables related thereto</td> <td></td> </tr> <tr> <td colspan="2"><i>(for both, actual number of sheets if filed in paper form, whether or not also filed in computer readable form; see (c) below)</i></td> </tr> <tr> <td>Total number of sheets</td> <td style="text-align: right;">16</td> </tr> </table> (b) ☐ only in computer readable form (Section 801(a)(i)) (i) ☐ sequence listing (ii) ☐ tables related thereto (c) ☐ also in computer readable form (Section 801(a)(ii)) (i) ☐ sequence listing (ii) ☐ tables related thereto Type and number of carriers (diskette, CD-ROM, CD-R or other) on which are contained the ☐ sequence listing: ☐ tables related thereto: <i>(additional copies to be indicated under items 9(ii) and/or 10(ii), in right column)</i>	request (including declaration sheets)	5	description (excluding sequence listing and/or tables related thereto)	7	claims	3	abstract	1	drawings	1	Sub-total number of sheets	16	sequence listing		tables related thereto		<i>(for both, actual number of sheets if filed in paper form, whether or not also filed in computer readable form; see (c) below)</i>		Total number of sheets	16	This international application is accompanied by the following item(s) (mark the applicable check-boxes below and indicate in right column the number of each item): <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">1. ☒ fee calculation sheet</td> <td style="width: 20%; text-align: right;">1</td> </tr> <tr> <td>2. ☐ original separate power of attorney</td> <td style="text-align: right;"></td> </tr> <tr> <td>3. ☐ original general power of attorney</td> <td style="text-align: right;"></td> </tr> <tr> <td>4. ☒ copy of general power of attorney; reference number, if any: AV.36671.+ A6171</td> <td style="text-align: right;">2</td> </tr> <tr> <td>5. ☐ statement explaining lack of signature</td> <td style="text-align: right;"></td> </tr> <tr> <td>6. ☒ priority document(s) identified in Box No. VI as item(s): (1)</td> <td style="text-align: right;">1</td> </tr> <tr> <td>7. ☐ translation of international application into (language):</td> <td style="text-align: right;"></td> </tr> <tr> <td>8. ☐ separate indications concerning deposited microorganism or other biological material</td> <td style="text-align: right;"></td> </tr> <tr> <td>9. ☐ sequence listing in computer readable form (indicate type and number of carriers)</td> <td style="text-align: right;"></td> </tr> <tr> <td style="margin-left: 20px;">(i) ☐ copy submitted for the purposes of international search under Rule 13ter only (and not as part of the international application)</td> <td style="text-align: right;"></td> </tr> <tr> <td style="margin-left: 20px;">(ii) ☐ (only where check-box (b)(i) or (c)(i) is marked in left column) additional copies including, where applicable, the copy for the purposes of international search under Rule 13ter</td> <td style="text-align: right;"></td> </tr> <tr> <td style="margin-left: 20px;">(iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listing mentioned in left column</td> <td style="text-align: right;"></td> </tr> <tr> <td>10. ☐ tables in computer readable form related to sequence listing (indicate type and number of carriers)</td> <td style="text-align: right;"></td> </tr> <tr> <td style="margin-left: 20px;">(i) ☐ copy submitted for the purposes of international search under Section 802(b-quater) only (and not as part of the international application)</td> <td style="text-align: right;"></td> </tr> <tr> <td style="margin-left: 20px;">(ii) ☐ (only where check-box (b)(ii) or (c)(ii) is marked in left column) additional copies including, where applicable, the copy for the purposes of international search under Section 802(b-quater)</td> <td style="text-align: right;"></td> </tr> <tr> <td style="margin-left: 20px;">(iii) ☐ together with relevant statement as to the identity of the copy or copies with the tables mentioned in left column</td> <td style="text-align: right;"></td> </tr> <tr> <td>11. ☐ other (specify):</td> <td style="text-align: right;"></td> </tr> </table>	1. ☒ fee calculation sheet	1	2. ☐ original separate power of attorney		3. ☐ original general power of attorney		4. ☒ copy of general power of attorney; 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11. ☐ other (specify):																																																							
Figure of the drawings which should accompany the abstract:	Language of filing of the international application: English																																																						
Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE <i>Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).</i> In the name of the applicants, the representative GRUBB, Philip AV 36671 + 46171																																																							

For receiving Office use only		
1. Date of actual receipt of the purported international application:	11.03.04	11 MAR 2004
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:		
4. Date of timely receipt of the required corrections under PCT Article 11(2):		
5. International Searching Authority (if two or more are competent): ISA /	6. ☐ Transmittal of search copy delayed until search fee is paid	2. Drawings: ☐ received: ☐ not received:

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Date of receipt of the record copy by the International Bureau:

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



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PCT

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(71) Applicant (for all designated States except AT, US): NO-VARTIS AG [CH/CH]; Lichtstrasse 35, CH-4056 Basel (CH).

(71) Applicant (for AT only): NOVARTIS PHARMA GMBH [AT/AT]; Brunner Strasse 59, A-1230 Vienna (AT).

(72) Inventors; and

(75) Inventors/Applicants (for US only): FORENZO, Patrick [US/US]; 337 Newport Road, Glen Gardner, NJ 08826 (US). KHALED, Maha, Y. [US/US]; 27 Pebble Beach Drive, Livingston, NJ 07039 (US). WANG, Barbara [US/US]; 19 Baldwin Drive, Berkeley Heights, NJ 07922 (US). ZIELINSKI, Joseph, Lawrence [US/US]; 53 Beechwood Road, Florham Park, NJ 07932 (US).
- (74) Agent: GRUBB, Philip; Novartis AG, Corporate Intellectual Property, CH-4002 Basel (CH).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

 - with international search report
 - before the expiration of the time limits for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

- (54) Title: PHARMACEUTICAL COMPOSITION COMPRISING 5-METHYL-2-2'-(CHLORO-6'-FLUOROANILINO) PHENYLACETIC ACID
- (57) Abstract: Provided are compositions comprising aqueous suspensions of 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid suitable for oral administration. Methods for making such compositions and methods for their stabilization are provided.

WO 2004/080451 A1

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 4 -32907A/USM	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, Item 5 below.	
International application No. PCT/EP2004/002528	International filing date (day/month/year) 11/03/2004	(Earliest) Priority Date (day/month/year) 12/03/2003
Applicant NOVARTIS AG		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (See Box II).

3. ☐ Unity of invention is lacking (see Box III).

4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

**PHARMACEUTICAL COMPOSITION COMPRISING 5-METHYL-2-2' - (CHLORO-6' -FLUOROANILINO) PHE
NYLACETIC ACID**

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K31/195 A61K9/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, MEDLINE, EMBASE, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/061932 A1 (GIMONA ALBERTO ET AL) 23 May 2002 (2002-05-23) page 4 - page 5; example 1	1,2,5,6, 8,21,22
A	US 6 291 523 B1 (XU DAQIANG ET AL) 18 September 2001 (2001-09-18) cited in the application column 16, line 12 - column 17, line 47; example 1 column 25, line 12 - column 26, line 37; example 10 column 26, line 39 - line 51; example 11 claims 17,23,26,33,36	1-22



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"A" document member of the same patent family

Date of the actual completion of the international search

22 July 2004

Date of mailing of the international search report

09/08/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 apo nl,
Fax (+31-70) 340-3016

Authorized officer

Muller, S

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2004/002528

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Box II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 21,22 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the formulation.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2004/002528

31

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002061932 A1	23-05-2002	AU 1390002 A	22-03-2002
		BR 0113809 A	29-07-2003
		CA 2416771 A1	14-03-2002
		CN 1455691 T	12-11-2003
		CZ 20030673 A3	18-06-2003
		WO 0220090 A2	14-03-2002
		EP 1331972 A2	06-08-2003
		HU 0301128 A2	28-10-2003
		NO 20031095 A	10-03-2003
		SK 2902003 A3	07-10-2003
US 6291523 B1	18-09-2001	US 2002183391 A1	05-12-2002
		US 6310099 B1	30-10-2001
		US 2004122254 A1	24-06-2004
		US 2002013369 A1	31-01-2002
		AT 237580 T	15-05-2003
		AU 743371 B2	24-01-2002
		AU 9534098 A	22-03-1999
		BR 9812010 A	12-12-2000
		CA 2298033 A1	11-03-1999
		CN 1140500 C	03-03-2004
		DE 69813570 D1	22-05-2003
		DE 69813570 T2	12-02-2004
		DK 1007505 T3	21-07-2003
		WO 9911605 A1	11-03-1999
		EP 1007505 A1	14-06-2000
		ES 2197508 T3	01-01-2004
		ID 23953 A	08-06-2000
		JP 2001514244 T	11-09-2001
		NO 20000943 A	25-02-2000
		NZ 502669 A	01-02-2002
		PL 338357 A1	23-10-2000
		PT 1007505 T	29-08-2003
		RU 2186762 C2	10-08-2002
		SI 1007505 T1	31-10-2003
		SK 2472000 A3	12-09-2000
		TR 200000447 T2	21-07-2000
		ZA 9807785 A	01-03-1999
		HU 0002514 A2	28-12-2000

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/EP2004/002528

International filing date (day/month/year)
11.03.2004

Priority date (day/month/year)
12.03.2003

International Patent Classification (IPC) or both national classification and IPC
A61K31/195, A61K9/08

Applicant
NOVARTIS AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, 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 three 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 - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Muller, S

Telephone No. +31 70 340-2060



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2004/002528

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, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/002528

Box No. II Priority

1. ☒ The following document has not been furnished:

- ☒ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/002528

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 21,22, with respect to industrial applicability

because:

- ☒ the said international application, or the said claims Nos. 21,22, with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 21,22, with respect to industrial applicability
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form
 - ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form
 - ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/002528

**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	3,4,7,9-20
	No: Claims	1,2,5,6,8,21,22
Inventive step (IS)	Yes: Claims	3,4,7,9-20
	No: Claims	1,2,5,6,8,21,22
Industrial applicability (IA)	Yes: Claims	1-20
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

For the assessment of the present claims 21 and 22 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item V**1. Cited Document**

The following document is referred to in this communication:

D1 : US-A-2002/0061932

2. Novelty

D1 discloses (see example 1 on pages 4 and 5) tablets which are prepared by wet-granulating a drug mixture comprising the drug 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid and the suspending agents MCC and CMC Na with an aqueous suspension. It is believed that the resulting mixture is in the form of a suspension and has a pH of between 4,75 and 5,25. The subject-matter of claims 1,2,5,6,8,21,22 is therefore not new (Article 33(2) PCT).

3. Inventive Step

Should the applicant overcome the abovementioned novelty objection, he should note that the present application appears to be inventive over the prior art (Article 33(3) PCT).

4. Industrial applicability

Claims 21 and 22 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1 (iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Claims 1-20 satisfy the criterion of industrial applicability set forth in Article 33(4) PCT.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PA4-32907A/usn	FOR FURTHER ACTION See Form PCT/PEA416	
International application No. PCT/EP2004/002528	International filing date (day/month/year) 11.03.2004	Priority date (day/month/year) 12.03.2003
International Patent Classification (IPC) or national classification and IPC A61K31/195, A61K9/08		
Applicant NOVARTIS AG		
1. This report is the International preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 6 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☐ sent to the applicant and to the International Bureau a total of sheets, as follows: ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 807 of the Administrative Instructions). ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in Item 4 of Box No. I and the Supplemental Box. b. ☐ (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).		
4. This report 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 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		
Date of submission of the demand 24.09.2004	Date of completion of this report 08.03.2005	
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tlx 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Muller, S Telephone No. +31 70 340-2080 	

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/002528

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements* of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-7 as originally filed

Claims, Numbers

1-22 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify)*:
- ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify)*:
- ☐ any table(s) related to sequence listing *(specify)*:

* If item 4 applies, some or all of these sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/002528

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 21,22, with respect to industrial applicability
because:
 - ☒ the said international application, or the said claims Nos. 21,22, with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (specify):
see separate sheet
 - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - ☒ no international search report has been established for the said claims Nos. 21,22, with respect to industrial applicability
 - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
 - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
 - ☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/002528

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3,4,7,9-20
	No: Claims	1,2,5,6,8,21,22
Inventive step (IS)	Yes: Claims	3,4,7,9-20
	No: Claims	1,2,5,6,8,21,22
Industrial applicability (IA)	Yes: Claims	1-20
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/EP2004/002528

Re Item III

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

For the assessment of the present claims 21 and 22 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item V

1. Cited Document

The following document is referred to in this communication:

D1 : US-A-2002/0061932

2. Novelty

D1 discloses (see example 1 on pages 4 and 5) tablets which are prepared by wet-granulating a drug mixture comprising the drug 5-methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid and the suspending agents MCC and CMC Na with an aqueous suspension. It is believed that the resulting mixture is in the form of a suspension and has a pH of between 4,75 and 5,25. The subject-matter of claims 1,2,5,6,8,21,22 is therefore not new (Article 33(2) PCT).

3. Inventive Step

Should the applicant overcome the abovementioned novelty objection, he should note that the present application appears to be inventive over the prior art (Article 33(3) PCT).

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/EP2004/002528

4. Industrial applicability

Claims 21 and 22 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Claims 1-20 satisfy the criterion of industrial applicability set forth in Article 33(4) PCT.

International Patent Application (PCT) with International filing date on or after 01.01.04
Activities in connection with entry into the national phase according to PCT

45

Case:

Instructions to Filing/Formalities Group

A Entry into the national phase according to PCT

The Filing/Formalities Group is instructed to initiate national action in good time

- ☐ In the countries listed in variant _____
- ☐ amendments to the variant as follows (please also state extension states if applicable) _____

The following documents are to form the basis of the national phase at the selected Office

- ☐ The original wording of the international application (description, claims and drawings);
- ☐ If amendments were made in the course of the international phase, the version of the application prevailing after conclusion of international examination.
- ☐ A copy of all replacement pages filed in the course of the international phase.
- ☐ Any claims and/or shortened descriptions which should be filed in specially designated countries (please define precisely!) for further procedures.
- ☐ Request for examination in Japan/South-Korea to be made at the same time as entry into national phase. Early request required for NCE's, see CRM 03/01, please identify the claims selected for request for examination. (The PRA deadlines will nevertheless be generated automatically and can be ignored by the PS or deleted - they will automatically disappear 25 months after the international filing date).
Request examination for the following claims: _____
- ☐ No request for early examination has to be made.
- ☐ Filing in India as follows:
 - ☐ Regular Application for Process Inventions
 - ☐ Black Box Application for other Inventions
- ☐ A copy of the application for the national phase may be found on the g:Drive under "Filing Texts".

B Non-entry into the national phase according to PCT

- ☐ B1 The above-mentioned PCT application is to be abandoned through inactivity (Filing/Formalities Group by settlement of PCT 30 deadline)
- ☐ B2 All priority applications are to be actively withdrawn by Patent Attorney (Mail/Data Input Group: for PCT record store "PRIO. WITHDRAWN" and change identifying code to "AO", and
Filing/Formalities Group: extend PCT deadlines (calculate from application date))
By withdrawing the earliest priority claim(s), 12 months time is gained until the final abandonment, since the 30-month term is calculated from the filing date of the PCT application.

If the application falls under the German law of employees' invention rights:

- ☐ The waiver of the inventor(s) is enclosed (Instructions to abandon may only be given if the inventor(s) has (have) waived the same.)

Enclosures

by Patent Attorney to Filing/Formalities Group after receipt of the International Preliminary Examination Report, at latest by x + 28 (PCT28)

- PCT country file
- Description, claims (if amended, old claims as originally filed and new amended claims) as well as any declaration made according to Article 19 PCT
- Upon entry into the national phase: optional receipt(s) of deposited microorganism(s) and viability statement(s)
- Optional shortened list of claims and/or description for specially designated countries

Date:

Signature:

Visum Section Head or Group Head:

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INFORME DE PROTOCOLO

Expediente 05 - 91231

Fecha: 08 DE NOVIEMBRE DE 2005

Se certifica que:

Desde fecha 16 de abril de 1997,
del folio 90.643 al folio 90.650 del
libro de Protocolo N° 311, obra el poder
N° 17.398 conferido por NOVARTIS AG
(NOVARTISSA) (NOVARTIS INC.)
domiciliado(a) en Basilea - Suiza
al doctor JIMENA ESCOBAR URIBE y/o IGNACIO
ESCOBAR URIBE.
Representante en Santafé de Bogotá D.C. Los
mismos.

Facultad para desistir y sustituir SI.

Revisado 202027.

48
47

INDUSTRIA Y COMERCIO
Radicacion : USP51231 00000000
Fecha (AMD) : 2005-09-09 15:29:07
Tramite : 011 PCT-PATENT 379 FASE NACI 411 PRESENTAC
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

REQUISITOS NECESARIOS PARA PRESENTACION Y AGILIZACION DEL TRAMITE

	USUARIO	RADICADOR
PATENTE DE INVENCION	()	()
MODELO DE UTILIDAD	()	()
- Indicación de que se solicita la concesión de una patente.	()	()
- Datos de identificación del solicitante o de la persona que presenta la solicitud.	()	()
- Descripción de la invención.	()	()
- Dibujos de ser estos pertinentes.	()	()
- Comprobante de Pago de las tasas establecidas.	()	()

COMPLETA () **INCOMPLETA** ()

DISEÑO INDUSTRIAL ()

- Indicación de que se solicita el registro de Diseño Industrial	()	()
- Datos de identificación del solicitante o de la persona que presenta la solicitud.	()	()
- Representación gráfica o fotográfica del Diseño Industrial o muestra del Material que incorpora el diseño.	()	()
- Comprobante de pago de las tasas establecidas	()	()

COMPLETA () **INCOMPLETA** ()

ESQUEMA DE TRAZADO ()

- Indicación de que solicita el registro de un Esquema de trazado.	()	()
- Datos de identificación del solicitante o de la persona que presenta la solicitud.	()	()
- Representación gráfica del Esquema de Trazado	()	()
- Comprobante de pago de las tasas establecidas.	()	()

COMPLETA () **INCOMPLETA** ()

Firma Responsable:

Fecha:

2005-09-09 de 2005

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REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCI

Bogotá,
2020

Doctor(a)
ESCOBAR URIBE JIMENA
Apoderado(a) y/o Representante de
NOVARTIS AG

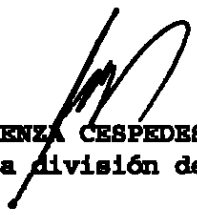
REFERENCIA	Radicación No.	5 91231
	Solicitud internacional	PCT/EP2004/002528
	Fecha inicio fase nacional	12/10/2005
	Trámite	11
	Evento	379
	Actuación	430
	Oficio No.	10663

Como resultado del examen de forma, realizado con fundamento en el artículo 38 de la Decisión 486 de la Comisión de la Comunidad Andina, artículo 27 del Tratado de Cooperación en Materia de Patentes (PCT), regla 51 bis del Reglamento y Circular Única de la Superintendencia de Industria y Comercio, se le comunica que:

1. La solicitud no contiene la copia del documento en que consta la cesión del derecho a la patente del inventor al solicitante o a su causante. (Art. 26-k) Decisión 486.

En cumplimiento de lo dispuesto por el artículo 39 de la Decisión 486, se le requiere para que dentro del término de dos meses siguientes a la fecha de notificación del presente oficio, complete los requisitos anteriormente enunciados. En caso de no dar cumplimiento al presente requerimiento, la solicitud se considerará abandonada y perderá su prelación.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Unica No.10 de 2001.


ALIX CARMONA CESPEDES DE VERGEL
Jefe de la división de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista de
fecha 11 NOV 2005
adpal