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COLOMBIA

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

E. S. D.

Ref.: Expediente No. 06.099.744

Solicitud de Patente a nombre de MERZ PHARMA GMBH & CO. KGAA

Yo, DILIA MARÍA RODRÍGUEZ D' ALEMAN, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 No. 86-53, piso 6, obrando como apoderada de la sociedad MERZ PHARMA GMBH, domiciliada en Frankfurt am Main, Alemania, solicitante de la patente de la referencia, en respuesta al oficio No. 10357 notificado por fijación en lista el día 15 de agosto de 2008, me permito aclarar que la tasa cancelada para el Examen de Patentabilidad es correcta, toda vez que la presente solicitud es una solicitud Capítulo II, como consta en la información radicada junto con mi memorial del 10 de marzo de 2008, mediante el cual se pagó el respectivo examen.

Adicionalmente aprovecho la oportunidad para presentar el informe de examen preliminar, el cual como consta en el formato PCT/IPEA/416 fue emitido el 4 de junio de 2008.

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

Señor Superintendente,

DILIA MARÍA RODRÍGUEZ D' ALEMAN

C.C. 41.654.882 de Bogotá

T.P. 20824 CSJ

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
G. PATRICK SAGE
THE FIRM OF HUESCHEN AND SAGE
350 EAST MICHIGAN AVENUE
500 COLUMBIA PLAZA
KALAMAZOO, MI 49007

PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing
(day/month/year)

04 JUN 2008

Applicant's or agent's file reference

MERZ 41.PCT

IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US05/07244

03 March 2005 (03.03.2005)

03 March 2004 (03.03.2004)

Applicant

MERZ PHARMA GMBH & CO. KGAA

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Form PCT/IPEA/416 (January 2004)

Authorized officer

Sreeni Padmanabhan

Telephone No. (571) 272-0629

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US05/07244

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.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

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):*

- ☒ the international application as originally filed/furnished
- ☒ the description:
- pages 1-88 as originally filed/furnished
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☒ the claims:
- pages 89-91 as originally filed/furnished
- pages* NONE as amended (together with any statement) under Article 19
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☐ the drawings:
- pages NONE as originally filed/furnished
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☐ 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 NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/figs NONE
- ☒ the sequence listing (*specify*): NONE
- ☒ any table(s) related to the sequence listing (*specify*): NONE

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 the sequence listing (*specify*): _____

5. ☐ This report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 70.2(e)).

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

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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:

Claims 1, 4 and 8 objected to as lacking clarity under PCT Rule 66.2(a)(v) because the claims are not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because: all behavior disorders, including all of the disorder disclosed in claim 4, are not shown to be treated by all 1-aminocyclohexane compounds known in the art or that have not even been discovered yet.

Claims 1 and 8 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s): the term "1-aminocyclohexane" can apply to all types of derivatives and compounds that are currently known as well as those that have not been discovered yet.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Continuation of IPC:

A01N 33/00(2006.01); 33/02(2006.01); A61K 31/13(2006.01); 31/16(2006.01); C07C 211/00(2006.01)

V. 2. Citations and Explanations:

- (1) Claims 1 and 4 lack novelty under PCT Article 33(2) as being anticipated by Wang et al.

Wang et al. teach novel aminoadamantane derivatives that treat neurological diseases including Alzheimer's disease, depression and anxiety (see abstract), in which the compositions of the compounds are administered as a pharmaceutical composition with a suitable carrier (see column 7, lines 9-15).

Claims 1 and 4 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph.

- (2) Claims 1, 2 and 4 lack novelty under PCT Article 33(2) as being anticipated by Fogel

Fogel teaches a method of treating symptoms of tardive dyskinesia or symptoms of neuroleptic-induced tardive movement disorders in a subject comprising administering memantine, wherein the tardive dyskinesia include impaired cognitive response or irregular involuntary movements (i.e. aberrant motor activity; see claims 1-6). A pharmaceutical carrier is inherently taught being that memantine is administered to humans (see column 5 in its entirety).

Claims 1, 2 and 4 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph.

- (3) Claims 1-3, 5 and 6 lack novelty under PCT Article 33(2) as being anticipated by Thomsen et al.

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Supplemental Box

Thomsen et al. teach a synergistic pharmaceutical composition for treating mild cognitive impairment or dementia comprising a therapeutically effective amount of donepezil and memantine (see claim 1). Salts of the compounds are acceptable (see page 3, lines 22-24) and the compositions can be combined with a pharmaceutically acceptable carrier (see page 5, line 17). Alzheimer's disease have the following symptoms: dementia, deficits in cognition (language, memory, motor skills), depression, insomnia, hallucinations, emotional or physical outbursts, aggression, agitation, abnormal eating, and weight loss (see page 3 last 2 lines to page 4, lines 1-9).

Claims 1-3, 5 and 6 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph.

(4) Claims 1, 2, 4 and 8 lack novelty under PCT Article 33(2) as being anticipated by Shuster et al.

Shuster et al. teach a method to treat compulsive behaviors in humans, for example, those that have been said to be a manifestation of, or related to, obsessive-compulsive disorder such as aggressive behavior such as self-directed aggression (see column 4, lines 34-35) with NMDA receptor antagonists (see abstract) such as compounds known as arylcyclohexylamines like memantine (see column 6, lines 15-39). The compositions can be combined with pharmaceutically acceptable carriers (see column 11, lines 1-37). The amount of the compound will vary depending on the size, age, body weight, general health, sex and diet of the host, and the time of administration, the biological half-life of the compounds and the particular characteristics and symptoms of the disorder to be treated. Adjustment and manipulation of established dose ranges are well within the ability of those of skill in the art, and preferably minimize side effects and toxicity (see column 11, lines 39-46).

Claims 1, 2, 4 and 8 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph.

(5) Claim 3 lack an inventive step under PCT Article 33(3) as being obvious over Fogel as applied to claims 1, 2 and 4 in view of Vogels et al.

Fogel teachings is as applied to claims 1, 2 and 4 above.

Fogel does not teach the hydrochloride salt of memantine.

Vogels et al. teach memantine hydrochloride is a noncompetitive NMDA receptor antagonist (see title and page 821, column 1, second paragraph, line 1).

To one of ordinary skill in the art it would be obvious to combine the method of Fogel and use the hydrochloride salt because the salt is also an effective NMDA receptor antagonist.

(6) Claim 10, 11 and 12 lack an inventive step under PCT Article 33(3) as being obvious over Shuster et al. as applied to claim 8 in view of Vogels et al.

Shuster et al. teachings are as applied to claim 8 above.

Shuster et al. does not teach the hydrochloride salt of memantine, nor the specific amounts of memantine as disclosed in claims 11 and 12.

Vogels et al. teach memantine hydrochloride is a noncompetitive NMDA receptor antagonist (see title and page 821, column 1, second paragraph, line 1).

To one of ordinary skill in the art it would be obvious to combine the method of Shuster et al. and to use the hydrochloride salt because the salt is also an effective NMDA receptor antagonist.

To one of ordinary skill in the art it would be obvious to combine the method of Shuster et al. and to administer the specific amounts of memantine as disclosed in claims 11 and 12 because Shuster et al. teach that the amount of the compound will vary depending on the size, age, body weight, general health, sex and diet of the host, and the time of administration, the biological half-life of the compounds and the particular characteristics and symptoms of the disorder to be treated. Shuster et al. additionally teach that adjustment and manipulation of established dose ranges are well within the ability of those of skill in the art, and preferably minimize side effects and toxicity (see column 11, lines 39-46).

(7) Claims 5 and 7 lack an inventive step under PCT Article 33(3) as being obvious over Thomsen et al. as applied to claim 1-3, 5 and 6 in view of Street et al.

Thomsen et al. teachings are as applied to claims 1-3, 5 and 6 above.

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Supplemental Box

Thomsen et al. does not teach the administration of an antipsychotic, specifically an atypical antipsychotic.

Street et al. teach patients with Alzheimer disease commonly exhibit psychosis and behavioral disturbances such as agitation/aggression and hallucinations according to the Neuropsychiatric Inventory clinical scale of greater than 3 with an atypical antipsychotic (see page 968, background and method; page 974, comment, paragraph 1, last 3 lines).

To one of ordinary skill in the art it would be obvious to combine the method of Thomsen et al. and to administer an atypical antipsychotic with the method of Thomsen et al. because atypical antipsychotic are effectively administered to treat psychosis exhibited by Alzheimer's disease.

(8) Claims 16-18 lack an inventive step under PCT Article 33(3) as being obvious over Shuster et al. as applied to claim 8 in view of Street et al.

Shuster et al. teachings are as applied to claim 8 above.

Shuster et al. does not teach wherein the agitation is associated with Alzheimer's disease, or that the subject is concurrently treated with an antipsychotic. Shuster et al. also does not teach wherein the subject has a score of greater than or equal to 4 according to the Neuropsychiatric Inventory clinical scale.

Street et al. teach patients with Alzheimer disease commonly exhibit psychosis and behavioral disturbances such as agitation/aggression and hallucinations according to the Neuropsychiatric Inventory clinical scale of greater than 3 with an atypical antipsychotic (see page 968, background and method; page 974, comment, paragraph 1, last 3 lines).

To one of ordinary skill in the art it would be obvious to combine the method of Shuster et al. and that the agitation is associated with Alzheimer's disease because Street et al. teach that Alzheimer disease commonly exhibit psychosis and behavioral disturbances such as agitation/aggression (see page 968, background and method).

To one of ordinary skill in the art it would be obvious to combine the method of Shuster et al. and that the subject is concurrently treated with an antipsychotic and has a score of greater than or equal to 4 according to the Neuropsychiatric Inventory clinical scale because Street et al. teach atypical antipsychotic are effectively administered to treat psychosis in patients having a score according to the Neuropsychiatric Inventory clinical scale of greater than 3 (see page 968, background and method; page 974, comment, paragraph 1, last 3 lines). Thus, one skilled in the art it would be obvious to combine the method of Shuster et al. and Street et al. in order to treat the aggression in Alzheimer's patients.

(9) Claims 13 and 15 lack an inventive step under PCT Article 33(3) as being obvious over Shuster et al. as applied to claim 8 in view of Stephens et al.

Shuster et al. teachings are as applied to claim 8 above.

Shuster et al. does not teach wherein the agitation is associated with a disorder selected from claim 13, specifically pediatric disorder disclosed in claim 15.

Stephens et al. teach aggressive behaviour has been reported as a clinical problem in attention-deficit hyperactivity disorder and obsessive compulsive disorder in children (see page 1036, background and conclusion).

To one of ordinary skill in the art it would be obvious to combine the method of Shuster et al. and wherein the agitation is associated with a disorder selected from claim 13, specifically pediatric disorder disclosed in claim 15 because Stephens et al. teach that aggression has been reported as a clinical problem in attention-deficit hyperactivity disorder and obsessive compulsive disorder in children (see page 1036, background and conclusion).

(10) Claims 13 and 14 lack an inventive step under PCT Article 33(3) as being obvious over Shuster et al. as applied to claim 8 in view of Marazziti et al.

Shuster et al. teachings are as applied to claim 8 above.

Shuster et al. does not teach wherein the agitation is associated with a disorder selected from claim 13, specifically wherein the mood disorder is schizophrenia or bipolar disorder.

Marazziti et al. teach that 20.3% of patients with obsessive-compulsive disorder have bipolar disorder and that one of the main obsessions was aggression (see page 409, column 1, paragraph 1 and 3).

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCION DE NUEVAS CREACIONES2020
Bogotá, D.C.,Abogado
DILIA RODRIGUEZ D'ALEMAN

ASUNTO

Radicación 06-099744
Trámite 002
Evento 001
Actuación 430
Oficio 009073
Folios 6Patente de Invención ☒ Patente de Modelo de Utilidad ☐Vía Nacional ☐Vía PCT (fase nacional) ☒ Cap. I ☐ Cap. II ☒

No. Sol. Internacional PCT/US2005/007244

Fecha de Presentación Internal. Marzo 03 de 2005

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. Documentos estudiados

- 1.1. Descripción: Folios: 96 a 198 como se radicó inicialmente
- 1.2. Reivindicaciones: Folios: 199 a 201 como se radicó inicialmente
Folios: 378 a 379 modificadas
- 1.3. Prioridad: US No. 60/550,171 del 03 de Marzo de 2004
- 1.4. Oposición: Gynopharm S.A. Folios: 268 a 298
Lafrancol S.A. Folios: 300 a 360
Respuesta a Oposiciones Folios: 369 a 380

2. Modificaciones no aceptadas (artículo 34 D.486)

Modificación en el Capítulo Reivindicatorio: no se acepta el capítulo reivindicatorio modificado, ya que las reivindicaciones se están refiriendo a una composición farmacéutica y éstas presentan falta de sustento en el capítulo descriptivo.

Por lo tanto y en conclusión las modificaciones realizadas sobre dicho capítulo reivindicatorio original, no se permiten, ya que modifican el objeto inicial de protección.

Con base a lo anterior, no se acepta el nuevo capítulo Reivindicatorio; el estudio de patentabilidad se realizará al primer capítulo reivindicatorio presentado por el solicitante.

Exp 2006 099744

3. Objeto de la invención

Título:

"COMPOSICIONES FARMACEUTICAS QUE COMPRENDEN DERIVADOS DEL AMINO CICLOHEXANO Y UN INHIBIDOR DE ACETILCOLINESTERASA PARA EL TRATAMIENTO DE LOS TRASTORNOS DE CONDUCTA ASOCIADAS CON LA ENFERMEDAD DE ALZHEIMER". Modificado folio 369.

El objeto de la presente solicitud de patente de invención consiste en:

- Reivindicaciones 1 a 20: Método de tratamiento

El problema planteado en esta solicitud es la necesidad de presentar métodos de tratamiento de los trastornos de conducta asociados con los trastornos del sistema nervioso central, especialmente la enfermedad de Alzheimer.

Para solucionar este problema técnico la solicitud en estudio presenta un novedoso método para tratar, prevenir, detener, retardar el comienzo y/o reducir el riesgo de desarrollar, o revertir trastornos de la conducta asociados con un trastorno del sistema nervioso central.

El objeto de la invención definido anteriormente se clasifico de acuerdo con la IPC: A61K 31/13 y A61K 31/445

4. Análisis de la Oposición: (artículo 43 D. 486):

4.1 OPOSICION DE GYNOPHARM S.A. (Folios 268 a 298; del 28-03-2008):

El opositor argumenta que a la presente solicitud se debería negar el beneficio patentario; ya que incumple los requisitos de patentabilidad establecidos por la Decisión 486 de 2000 de la Comisión de la Comunidad Andina.

FUNDAMENTOS DE HECHO:

El opositor dice, que la solicitud en referencia refiere a un método para tratar un trastorno de conducta en un sujeto que lo necesite, que comprende administrar una cantidad efectiva de un 1-amino ciclohexano (clorhidrato de memantina) en un vehículo adecuado para su uso farmacéutico.

Se debe advertir que las reivindicaciones se refieren a un método de tratamiento; y de acuerdo a la normatividad vigente los métodos de tratamiento no son patentables.

Ahora bien, el opositor dice que aunque el objeto reivindicado no es objeto de protección, la composición farmacéutica que comprende un 1-amino ciclohexano en un vehículo; antes de la fecha de prioridad de esta solicitud, se encuentra el siguiente documento que afecta la patentabilidad de la presente invención; este es:

1. D1= WO 03/101458 del 11 de Diciembre de 2003, revela:

Una composición que comprende una cantidad eficaz de un inhibidor de acetilcolinesterasa y una cantidad eficaz de NMDA-antagonista (Pág. 3 línea

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31 a pág. 6 línea 26). Por lo tanto esto verifica que no es novedoso el método de tratamiento ni la composición farmacéutica y la solicitud en general crece de Aplicación Industrial.

4.2 OPOSICION DE LAFRANCOL S.A. (Folios 300 a 360; del 31-03-2008):

El opositor argumenta que a la presente solicitud se debería negar el beneficio patentario; ya que incumple los requisitos de patentabilidad establecidos por la Decisión 486 de 2000 de la Comisión de la Comunidad Andina.

FUNDAMENTOS DE LA OPOSICION:

El opositor dice, que la solicitud en referencia refiere a un método para tratar un trastorno de conducta asociado a la enfermedad de Alzheimer, que comprende administrar una cantidad efectiva de un 1-aminociclohexano (memantina o neramexano) en combinación con una cantidad efectiva de un inhibidor de acetilcolinesterasa (Donepezil) o un antipsicótico atípico. El opositor solicita, se niegue el privilegio de patente; tal como se demuestra con los siguientes argumentos:

1. El capítulo reivindicatorio (en sus 20 reivindicaciones), incurre claramente en una improcedencia de patentabilidad, ya que refiere específicamente a un método de tratamiento.

2. Existen diversos documentos que pueden desvirtuar tanto la novedad como el nivel inventivo. Los documentos son:

(a) WO 03/101458 del 11 de Diciembre de 2003, la cual revela un tratamiento para el deterioro cognitivo leve o (MCI) y para diferentes tipos de demencia como el tipo Alzheimer. Un grupo de los medicamentos allí mencionados son los inhibidores de acetilcolinesterasa entre los que se encuentra el Donepezil y otro grupo son los antagonistas de NMDA, de los cuales la memantina es la más representativa. Así que la combinación de la solicitud colombiana ya había sido sugerida.

De esta manera, e irrefutablemente, puede afirmarse que la solicitud colombiana en trámite carece totalmente de Novedad, puesto que toda la información y las características del método terapéutico que se reivindica, se encuentran absolutamente contenidas y descritas en el estado de la técnica.

(b) La publicación científica (Abstrac) "No Interaction of Memantine with Acetylcholinesterase Inhibitors Approved for Clinical use" (Febrero 11 de 2000); revela (ver folio 305).

(c) La publicación científica (Abstrac) "Tolerability of Memantine in combination with Cholinesterase in Dementia therapy" (Marzo de 2003); revela (ver folio 306).

(d) La publicación científica (Abstrac) "Memantine for the treatment of Dementia" (Agosto de 2003); revela (ver folios 306 y 307).

Como se puede observar en las tres publicaciones científicas (b, c y d), contienen argumentos que sustentan la combinación farmacológica entre la

Memantina e inhibidores de la acetilcolinesterasa (Donepezil); lo cual desvirtúa el Nivel Inventivo del contenido del capítulo reivindicatorio (reivindicaciones 1 a 3, 5 y 6).

- (e) US 5,334,618 del 02 de Agosto de 1994; revela: el uso de la Memantina y antagonistas NMDA, para tratar enfermedades degenerativas neuronales como la enfermedad de Alzheimer.
- (f) WO 03/040084 del 15 de Mayo de 2003; revela: el uso de derivados de 1-aminoalquilciclohexano en el tratamiento de desordenes de la ansiedad y la enfermedad de Alzheimer.
- (g) WO 01/98253 del 27 de Diciembre de 2001; revela: el uso de derivados de 1-aminoalquilciclohexano en el tratamiento de la ansiedad, desordenes del apetito y depresión la enfermedad de Alzheimer
- (h) US 2003/207881 de Noviembre 06 de 2003; revela: compuestos tipo adamantaminas útiles en el tratamiento de la enfermedad de Alzheimer, depresión, desorden bipolar y esquizofrenia.
- (i) WO 03/039468 del 15 de Mayo de 2003; revela: entre otros compuestos la Memantina para el tratamiento de desorden bipolar, depresión, esquizofrenia, desordenes de ansiedad.

En conclusión, la solicitud colombiana incurre en una directa improcedencia de patentabilidad al reivindicar un método de tratamiento, para trastornos del tipo Alzheimer. Careciendo totalmente de Novedad y Nivel Inventivo las composiciones reveladas.

FUNDAMENTOS DE DERECHO:

Son fundamentos de derecho el Capítulo I, artículos 14, 16, 18 y 20 literal d) (Requisitos de Patentabilidad) y el artículo 42 (Oposiciones) de la decisión 486 del 2000.

PRUEBAS:

Se anexan las publicaciones anteriormente descritas.

4.3 RESPUESTA DEL SOLICITANTE MERZ PHARMA GMBH & CO. KGAA., A LOS OPOSITORES GYNOPHARM S.A. Y LAFRANCOL S.A. (Folios 369 a 380; del 23-07-2008):

El solicitante se permite manifestar:

1. Presenta un nuevo capítulo reivindicatorio modificado, dirigido a una Composición farmacéutica, que comprende un derivado de 1-amino ciclohexano con un vehículo farmacéuticamente aceptable.
2. Realiza el cambio del título de la solicitud, quedando ahora: "COMPOSICIONES FARMACEUTICAS QUE COMPRENDEN DERIVADOS DEL AMINO CICLOHEXANO Y UN INHIBIDOR DE ACETILCOLINESTERASA PARA EL TRATAMIENTO DE LOS TRASTORNOS DE CONDUCTA ASOCIADAS CON LA ENFERMEDAD DE ALZHEIMER"

PRETENCIONES DE LAS OPOSICIONES:

El solicitante se opone a los escritos de las Oposiciones, ya que el solicitante considera que su solicitud si cumple con los requisitos de patentabilidad. Y responde a los argumentos de cada uno de los opositores:

1. Argumentos presentados por el Opositor 1 GYNOPHARM S.A.; el solicitante se permite decir:

- Con el nuevo capítulo reivindicatorio, quedan subsanadas la mayoría de las objeciones planteadas en cuanto a la materia patentable, toda vez que la solicitud esta ahora en términos de una composición.
- La falta de Novedad por el documento D1= WO 03/101458, queda subsanada, ya que la composición de la solicitud no había sido revelada en el mismo; y frente a la aplicabilidad industrial, al cancelar las reivindicaciones de método de tratamiento la invención cubre un producto (composiciones) que son susceptibles a ser producidas a nivel industrial.

2. A los argumentos presentados por el Opositor 2 LAFRANCOL S.A.; el solicitante se permite decir:

- Con el nuevo capítulo reivindicatorio, queda subsanada la supuesta improcedencia de patentabilidad; ya que ahora se encuentra dirigida a una composición farmacéutica.
- La supuesta falta de Novedad por el documento D1= WO 03/101458, queda subsanada, ya que la composición de la solicitud no había sido revelada en el mismo.
- El opositor además, menciona otros artículos y documentos que afectan la patentabilidad (folios 320 a 353); y de los mismos dice que con el nuevo capítulo reivindicatorio se cumple cabalmente con los requisitos de patentabilidad; ya que se cancelaron las reivindicaciones de método y además porque la composición de la solicitud no había sido revelada o anticipada por ninguno de los documentos anteriores.

4.3 RESPUESTA DEL EXAMINADOR TECNICO A OPOSICIONES DE GYNOPHARM S.A., PROCAPS S.A. Y AL SOLICITANTE:

Esta oficina considera que las Oposiciones presentadas por GYNOPHARM S.A., PROCAPS S.A. y PROCAPS S.A., tienen fundamento y que para una posible evaluación de patentabilidad se tendrán en cuenta los documentos por los opositores presentados.

5. Excepción a la patentabilidad (artículo 20 D486 literal d)

Las Reivindicaciones 1 a 20, reclaman método de tratamiento, y de acuerdo con la legislación Colombiana, los métodos de tratamiento no se consideran para protección por patente.