Industria y Comercio
SUPERINTENDENCIA

FORMULARIO UN

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
No. 08-023028- -00001-0000

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
No. 08-023028- -00001-0000

Fecha: 2008-08-28 14:12:27 Dep: 2020 NUECREACIONI
Tra: 11 PATENTEIYII Eve: 378 FASENACIONALI
Act: 400 OPOSIOBSERVTER Folios: 41

① OPOSICIÓN A :

- [x] Patente de Invención.
- [ ] Patente de Modelo de Utilidad.
- [ ] Diseño Industrial.
- [ ] Esquema de Trazado para Circuitos Integrados.
- [ ] Marcas de Productos o Servicios.
- [ ] Marca Colectiva.
- [ ] Marca de Certificación.
- [ ] Lema Comercial.

② SOLICITUD PUBLICADA

Número del expediente: **08-23028**
Solicitante: **H. LUNDBECKS A/S**
Apoderado: **EMILIO FERRERO**
Título de la nueva creación o denominación del signo: **"FORMULACIÓN SÓLIDA ESTABLE DE SERTINDOL".**
Gaceta: **592**

③ OPOSICIÓN PRESENTADA POR:

SOLICITANTE

Nombre: **GYNOPHARM S.A**
Dirección: **CALLE 80 No. 78B -201**
Nacionalidad o Domicilio:
Lugar de Constitución: **COLOMBIA BARRANQUILLA**
Teléfono: **(571)3719900** Fax: **(571)3730818**
E-mail:

IDENTIFICACIÓN
C.C. [ ] NIT [x]
C.E. [ ] Otro [ ]
Cual
Número **802.006.279-4**

REPRESENTANTE O APODERADO

Nombre: **ELIANA ISAURA MORENO BOHORQUEZ**
Dirección: **CARRERA 13 No. 119-95 104**
Teléfono: **(571) 2131213** Fax: **(571) 6121979**
E-mail: **negocios@optimum-co.com**

IDENTIFICACIÓN
C.C. [x] NIT [ ]
C.E. [ ] Otro [ ]
Cual
Numero **51`975.664** TP **83823**

④ FUNDAMENTOS DE LA OPOSICIÓN:

Causal: **Art.14, 16, 18, 20 y 30 de la Decisión 486 de la CAN**
Signo opositor: **No cumple con los requisitos de patentabilidad.**
Justificación:

La presente solicitud no cumple con los requisitos de patentabilidad dado que lo revelado, ya se encontraba en el estado de la técnica o es posible derivarlo de la misma tal y como se demostrará en el capítulo "Fundamento de Hechos".

⑤ **Comprobante de pago No.** _____ **Fecha** _____

⑥ **ANEXOS**

- [x] Comprobante de pago de la tasa.
- [x] Poderes, si fuere el caso.
- [x] Pruebas de los fundamentos de la oposición.
- [ ] Documentos que acrediten el legítimo interés, si fuere el caso.
- [x] Documento que acredita la existencia y representación legal de las partes, cuando sean personas jurídicas.

⑦

NOMBRE: **ELIANA ISAURA MORENO BOHORQUEZ**

FIRMA:

C.C. **51.975.664** **TP.** **83823**

Instrucciones para el diligenciamiento del presente formulario, ver reverso de esta página.

Optimum

Derecho de la Competencia, Propiedad
Industrial y Comercio Exterior

Señora Jefe,

DIVISIÓN DE NUEVAS CREACIONES

Superintendencia de Industria y Comercio

E. S. D.

Referencia	: Expediente N° 08 023028
Asunto	: Oposición a la solicitud de patente de Invención titulada "FORMULACIÓN SÓLIDA ESTABLE DE SERTINDOL"
Solicitante	: H. LUNDBECKS A/S.
Opositora	: GYNOPHARM S.A.

Publicada en la Gaceta de la Propiedad Industrial

N° 592 del 30 de mayo de 2008

Yo, *ELIANA ISAURA MORENO BOHORQUEZ,* abogada en ejercicio, identificada como aparece al pié de su firma, con tarjeta profesional No. 83823 del Consejo Superior de la Judicatura, en mi condición de apoderada de la sociedad *GYNOPHARM S.A.* conformada bajo las leyes de la República de Colombia y domiciliada en la ciudad de Barranquilla, Colombia, atentamente manifiesto que estando dentro del término de ley y por orden expresa de mi representada, presento oposición a la concesión del registro de la Patente de Invención titulada "FORMULACIÓN SÓLIDA ESTABLE DE SERTINDOL", cuyo titular es H. LUNDBECKS A/S, y pido a Usted declarar fundada esta oposición y en consecuencia negar el registro de la patente solicitada.

Carrera 13 N° 119-95, Of. 104 Tel. (571) 2 13 12 13 - 6 20 50 21 - Fax. (571) 6 12 19 79
E-mail: negocios@optimum-co.com - www.optimum-co.com
Bogotá Colombia

1. INTERÉS PARA ACTUAR

Conforme a lo dispuesto en el artículo 42 de la Decisión 486 de 2000 de la CAN, estando dentro del término estipulado por la ley, manifiesto el legitimo interés de nuestra representada para oponerse al registro de la patente de la referencia, atendiendo a que la solicitud pretendida no cumple con los requisitos dispuestos en la ley como se analizará más adelante y de ser concedida afectaría directamente la comercialización de algunos productos de mi representada, que contienen, en particular SERTINDOL. Por lo tanto, solicito respetuosamente a ese Despacho se sirva tener en cuenta la presente oposición dentro del trámite administrativo que se surte en esta Superintendencia.

2. FUNDAMENTOS DE HECHOS

2.1. La solicitud objeto de la presente fue presentada el 04 de marzo de 2008, reivindicando prioridad bajo la solicitud DK20050001255 del 2005-09-08; y fue publicada en Colombia, en la Gaceta de la Propiedad Industrial **Nº 592 del 30 de mayo de 2008**, cuya publicación internacional corresponde a la WO2007065448 del 2007-06-14.

2.2. La solicitud colombiana **08 023028** objeto de la presente oposición, se refiere a una composición farmacéutica que comprende sertindol y un agente protector que absorbe la radiación con una longitud de onda por debajo de 400 nm y una composición farmacéutica sólida que comprende una mezcla de sertindol y un agente protector que absorbe la radiación con una longitud de onda por debajo de 400 nm; en donde el agente protector que absorbe la radiación con una longitud de onda por debajo de 400 nm, está presente en una cantidad suficiente para

proteger el sertindol de la degradación de la luz; en donde ésta se selecciona de tabletas y cápsulas; en donde el agente protector que absorbe la radiación con longitud de onda por debajo de 400 nm se selecciona de óxido de hierro, tal como óxido de hierro amarillo, rojo, negro así como también mezclas de estos; donde el agente protector que absorbe la radiación con una longitud de onda por debajo de 400 nm se selecciona de negro de humo, índigo carmín, laca índigo carmín-aluminio, y aditivos de color permanente o provisionalmente listados sujetos de la certificación U.S en 2000 (Basada en la 21 CFR 2000) que absorbe luz de longitud de onda <400 nm, metales o mezclas de metales que absorben luz de longitud de onda <400 nm, sales de metales o mezclas de sales de metal que absorben luz de longitud de onda <400 nm; donde el agente protector que absorbe la radiación con una longitud de onda por debajo de 400 nm está presente en una cantidad de hasta 5% con relación al peso de la composición sólida; y, que comprende además un recubrimiento, tal como una capa de recubrimiento de película.

2.3. En primera instancia, se debe advertir que la reivindicación 21 se refieren al uso y no sólo a la composición farmacológica o a un método de fabricación mediante la cual se obtenga un producto tangible y según la legislación, decisión 486 de la Comunidad Andina de Naciones, Artículo 14.- "*Los Países Miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento (...)*", los usos no están contemplados como patentables; y, Artículo 20.- "*No serán patentables (...) d) los métodos terapéuticos o quirúrgicos para el tratamiento humano o animal, así como los métodos de diagnóstico aplicados a los seres humanos o a animales*". Solo serán patentables los productos o procedimientos. Por lo tanto a luz de la norma, dicha materia referente al uso y a un método de tratamiento no seria patentable.

2.4. Ahora bien, con base en el artículo 14 de la Decisión 486 de la CAN consagra lo siguiente: "*Los países miembros otorgarán patentes para las invenciones, sean de producto o procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial*". Así las cosas, las invenciones objeto de patente deben ser nuevas y tener nivel inventivo. Bien, pues antes de la fecha de prioridad de esta solicitud se encuentran los siguientes documentos que afecta la patentabilidad de la presente solicitud:

- D1: WO9735584 publicada el 2 de octubre de 1997.

2.5. Ahora bien, el documento D1, particularmente en la descripción página 1 líneas 4 a 7 y 30 a 32 y página 4 líneas 21 a 24 así como los ejemplos 1 y 2 proporciona un método para tratar el dolor que usa un compuesto atípico antipsicótico. Esta anterioridad revela composiciones farmacéuticas sólidas que comprenden sertindol y una cubierta que comprende dióxido de titanio que puede ofrecer protección. Igualmente dicho documento anterior revela que el sertidol es un atípico antisicótico el cual es útil en el tratamiento de la esquizofrenia. Así las cosas, como lo evidencia dicho documento D1, la presente solicitud no es novedosa pues lo revelado ya se encontraba en el estado de la técnica.

2.6. Por lo tanto, este documento objeto de oposición a la luz del documento D1 carece evidentemente de NOVEDAD.

2.7. En consecuencia y de acuerdo a lo descrito anteriormente, se deriva que la solicitud colombiana **08 023028** no puede pretender un monopolio por patente toda vez que lo que pretende no cumple con dos de los tres requisitos necesarios para su protección.

2.8. Que por consiguiente, respecto a la solicitud pretendida se tiene que:

2.8.1. CARECE DE NOVEDAD: Según la decisión 486 de la Comunidad Andina de Naciones, Artículo 16.- *"Una invención se considerará nueva cuando no está comprendida en el estado de la técnica. El estado de la técnica comprenderá todo lo que haya sido accesible al público por una descripción escrita u oral, utilización, comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente o, en su caso, de la prioridad reconocida.".* A la fecha de prioridad, 8 de septiembre de 2005 ya era conocido, pues como se demostró, era parte del arte anterior con base en el documento D1, una composición farmacéutica que comprende sertindol y un agente protector, sobre el cual busca protección en el capítulo reivindicatorio.

2.8.2. CARENCIA DE APLICACIÓN INDUSTRIAL La Decisión 486 de la CAN consagra en su artículo 14 lo siguiente: *"Los países miembros otorgarán patentes para las invenciones, sean de producto o procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial"*. La presente solicitud carece de aplicación Industrial ya que como se demostró anteriormente, algunas cláusulas reclaman el método terapéutico y estos no son aplicables industrialmente porque primero no se obtiene un producto o proceso; y segundo no es reproducible o repetible a escala industrial. Por lo tanto, el objeto de la presente invención referido a los usos y métodos terapéuticos, no cumplen con el requisito de la aplicación industrial.

2.9. Dado lo anterior, es posible deducir que la solicitud y lo reivindicado no es objeto de patentabilidad pues es contrario a lo que dicta la Decisión 486 de la Comunidad Andina de Naciones, Artículo 14.- *"Los Países Miembros otorgarán*

patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial.". La solicitud pretendida no cumple con dos de los tres requisitos de patentabilidad.

2.10. Por todo lo anterior, atentamente solicito a usted que se sirva declarar fundada la presente oposición y negar el registro Patente de invención denominada "**FORMULACIÓN SÓLIDA ESTABLE DE SERTINDOL**", cuyo titular es **H. LUNDBECKS A/S,** solicitud Colombiana que apareció publicada en la Gaceta de la Propiedad Industrial **N° 592 del 30 de mayo de 2008**

3. PRUEBAS

De conformidad con lo dispuesto por las normas vigentes, solicito a usted tener como prueba en este asunto los siguientes:

- D1: WO9735584 publicada el 2 de octubre de 1997.

4. FUNDAMENTO DE DERECHO

Fundamento esta observación en las normas legales siguientes:

4.1. Numeral 1 del articulo 586 del Código de Comercio.

4.2. Artículo 42 de la Decisión 486 de la Comisión del Acuerdo de Cartagena.

4.3. En las demás normas concordantes.

5. ANEXOS

Para los efectos correspondientes anexo al presente escrito los siguientes documentos:

1. Poder para actuar en el presente.
2. Documento que acredita al representante legal de **GYNOPHARM S.A.**
3. Recibo de caja del respectivo pago de tasa.
4. Copias de los documentos:

- D1: WO9735584 publicada el 2 de octubre de 1997.

Optimum

Derecho de la Competencia, Propiedad Industrial y Comercio Exterior

6. NOTIFICACIONES

Para efectos de notificaciones que por disposición del artículo 50 del Decreto 01 de 1984 debe hacer su Despacho, informo que mi representada y la suscrita recibiremos notificaciones en la Secretaría de su Despacho o en mis oficinas situadas en la Carrera 13 Nº 119-95, Of. 104 de esta ciudad de Bogotá.

Señor Superintendente,

ELIANA ISAURA MORENO BOHÓRQUEZ
C.C. 51'975.664 de Bogotá
T.P.A. 83823 del C.S. de la J.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 08 - 68,586
FECHA : AGOSTO 28 DE 2008

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
No. 08-023028- -00001-0000
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
No. 08-023028- -00001-0000
Fecha: 2008-08-28 14:12:27 Dep: 2020 NUECREACIONI
Tra: 11 PATENTEIYII Eve: 378 FASENACIONALI
Act: 400 OPOSIOBSERVTER Folios: 41

***** C O N S I G N A C I O N *

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
GYNOPHARM S A	CONSIGNACION	BANCO DE BOGOTA	062754387	4638222	17/07/2008	1,330,000.00

***** C O N C E P T O *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-04 PRESENTACION DE OBSERVACIONES	12 MARCAS Y LEMAS COMERCIALES	266,000.00
		TOTAL : $	266,000.00

SON: DOSCIENTOS SESENTA Y SEIS MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No._____

PODER ESPECIAL

Yo, **LUIS PALACIOS ARAGÓN,** mayor de edad y vecino de la ciudad de Barranquilla (Colombia), identificado como aparece al pie de mi firma, quien en el presente documento actúa en calidad de Representante Legal de la sociedad **GYNOPHARM S.A.** sociedad legalmente constituida y domiciliada en la ciudad de Barranquilla (Colombia), por el presente documento otorgo a la doctora **ELIANA ISAURA MORENO BOHORQUEZ,** abogada en ejercicio, identificada como aparece al pie de su firma, con tarjeta profesional No. 83823 **del C.S. de la J.**, poder especial, amplio y suficiente, para formular oposiciones u observaciones a la solicitud de patente No. 08 023028, titulada "**FORMULACIÓN SÓLIDA ESTABLE DE SERTINDOL**", cuyo titular es **H. LUNDBECKS A/S,** publicada en la gaceta No. 592 del 30 de mayo de 2008.

Nuestro apoderado queda facultado, de manera expresa, para realizar todo tipo de actos necesarios para llevar a cabo el trámite de la oposición, incluyendo, sin limitación, preparar y presentar solicitudes, hacer declaraciones, pagar tasas, contribuciones e impuestos, recabar los títulos o certificados. Asimismo quedan autorizados para impugnar administrativa y judicialmente todo lo que fuere resuelto en el expediente a que se hace expresa referencia en el presente poder, con todas las facultades generales y específicas que fuera requerido para ella.

De la misma manera, además de las facultades que le confiere la naturaleza del presente mandato, se encuentran facultados para recibir, desistir, transigir, sustituir, y reasumir el presente poder, incoar acciones, interponer recursos y demás facultades conferidas por la ley.

Dado y Firmado en Barranquilla (Colombia) a los 26 días del mes de 08 de 2008.

GYNOPHARM S.A.

Cédula de Extranjería: No. 319788.
NIT: 802.006.279-4
Representante Legal

Acepto:

ELIANA ISAURA MORENO BOHORQUEZ
C.C. 51'975.664 de Bogotá
T.P.A. 83823 del C.S. de la J.

RECONOCIMIENTO DE DOCUMENTO PRIVADO

Ante mí, NIBARDO AGUSTIN FUERTES MORALES, Notario Veinticinco del Círculo de Bogotá (E), comparece Luis Palacios Arenas

identificado con cédula de ciudadanía CE. 319788 Btc.

y declara que la firma puesta en el presente instrumento privado es suya y que el contenido el mismo es cierto.

Bogotá D.C. 26 AGO.2008

FIRMA

NIBARDO AGUSTIN FUERTES MORALES
NOTARIO VEINTICINCO(E)

PRESENTACIÓN PERSONAL

El anterior escrito fue presentado ante la
NOTARIA DIECIOCHO DEL CIRCULO DE BOGOTÁ, D.C.

personalmente por Diana Marcela Bohorquez

quien exhibió la c.c. 53975664 de Bta

y Tarjeta Profesional No. 83883 C.S.J.

Fecha 28 AGO. 2008

Victoria Rafael Trujillo
NOTARIA

REPUBLICA DE COLOMBIA
NOTARIA 18 DE BOGOTA D.C.

01

72938442

CERTIFICADO NACIONAL

CAMARA DE COMERCIO DE BARRANQUILLA

Fecha : 20080814 Hora Certificado 16:59:44

Operacion : 02NJK0814067 PAGINA No. 1

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CERTIFICADO DE EXISTENCIA Y REPRESENTACION LEGAL O DE INSCRIPCION DE DOCUMENTOS.
EL SUSCRITO SECRETARIO DE LA CAMARA DE COMERCIO DE BARRANQUILLA, CON FUNDAMENTO EN LAS INSCRIPCIONES DEL REGISTRO MERCANTIL:

C E R T I F I C A

Que por Escritura P?blica No. 3,551 del 17 de Dic/bre de 1997, otorgada en la Notaria 3a. de Barranquilla, inscrito(as) en esta C?mara de Comercio, el 18 de Dic/bre de 1997 bajo el No. 72,965 del libro respectivo, fue constituida la sociedad----------
anonima denominada GYNOPHARM S.A. ----------

C E R T I F I C A

Que dicha sociedad ha sido reformada por las siguientes escrituras y/o documentos privados:

Numero	aaaa/mm/dd	Notaria	No. Insc o Reg	aaaa/mm/dd
532	1999/03/25	Notaria 3a. de Barranquilla	80,373	1999/04/13

C E R T I F I C A

Que de acuerdo con la(s) escritura(s) arriba citada(s), la sociedad se rige por las siguientes disposiciones:
DENOMINACION O RAZON SOCIAL:
GYNOPHARM S.A.----------
DOMICILIO PRINCIPAL: Barranquilla.
NIT No: 802.006.279-4.
MATRICULA MERCANTIL: 245,470.

C E R T I F I C A

Direccion para notificaciones judiciales:
CR 49 C No 80 - 125 OF 512.
De la ciudad de Barranquilla.
Correo electr?nico:

C E R T I F I C A

DURACION: El t?rmino de duraci?n de la sociedad se fij? hasta el 16 de Dic/bre de 2047.

C E R T I F I C A

OBJETO SOCIAL: a) La fabricacion de capsulas y otro productos similares a partir de materiales tales como gelatinas u otros de distinta naturaleza, que puedan ser utilizados como envases o recipientes de productos y sustancias quimicas, farmaceuticas y cosmeticas, para

*** CONTINUA ***

****

uso y consumo humano y veterinario. b) La investigacion, desarrollo y fabricacion de toda clase de productos y sustancias quimicas, farmaceuticas y cosmeticas para uso y consumo humano, animal y vegetal. c) La compra y venta de meterias primas , insumos y productos intermedios necesarios para los procesos de fabricacion de sustancias quimicas, farmaceuticas y cosmeticas, asi como la comercializacion interna y externa de los productos terminados. d) La compra, venta, importacion, exportacion y distribucion de toda clase de elementos instrumentales y equipos, medicos, quirurgicos, odontologicos y hospitalarios para la salud humana y animal. e) Actuar como representante o agente de personas naturales y juridicas nacionales y extranjeras en la realizacion de operaciones o transacciones relacionadas con la industria farmaceutica y en especial con cualesquiera de las actividades descritas en los literales a), b), c) y d) antes transcritos. f) Prestar los servicios de asesoria y consultoria en las areas administrativa, de mercadeo, analisis clinico, asistencia tecnica, investigacion, costos y produccion exportaciones, importaciones, ventas, relacionadas con iguales o similares actividades a las que constituyen el objeto de GYNOPHARM S.A., asi como los de publicidad y promocion de productos quimicos, cosmeticos y farmaceuticos para uso humano, animal o industrial. g) Adquirir, operar, administrar y explotar, a cualquier titulo,empresas o establecimientos dedicados a la investigacion, desarrollo, fabricacion o comercializacion de productos quimicos, farmaceuticos, hospitalarios o cosmeticos. En desarrollo de su objeto principal, la sociedad podra tomar interes social como accionista, socio o fundador de empresas que tengan igual o similar objeto; comprar, vender, importar y exportar maquinarias, insumos y repuestos requeridos para el desarrollo de sus actividades; tomar dinero en prestamo,financiar y garantizar las operaciones comerciales que celebre con terceros relativas a su objeto; celebrar y ejecutar todo tipo de actos y contratos necesarios para desarrollar sus operacioes; girar, aceptar, otorgar y protestar todo tipo de titulos valores e instrumentos negociables; comprar, vender y constituir gravamenes sobre bienes muebles e inmuebles; designar representantes o apoderados en el pais y en el exterior y, en general, realizar cualquier acto o negocio que sea necesario o conveniente para el desarrollo de su objeto social y para la mejor proteccion de sus intereses corporativos o lo de sus socios.----------

C E R T I F I C A

CAPITAL	Nro Acciones	Valor Acci?n
Autorizado		
$**********4,000,000,000	**********4,000,000	**********1,000
Suscrito		
$**********2,672,646,000	**********2,672,646	**********1,000
Pagado		
$**********2,672,646,000	**********2,672,646	**********1,000

*** CONTINUA ***

01

72938443

CERTIFICADO NACIONAL

CAMARA DE COMERCIO DE BARRANQUILLA

Fecha : 20080814 Hora Certificado 16:59:44

Operacion : 02NJK0814067 PAGINA No. 3

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C E R T I F I C A

ADMINISTRACION: Seran funciones de la junta directiva, entre otras: Autorizar cualquier acto o contrato cuya cuantia sea superior al equivalente en pesos Colombianos a cincuenta mil dolares de los Estados Unidos de America (US$50.000.oo), liquidados a la tasa de cambio representativa del mercado vigente el dia en que se surta la aprobacion y para enajenar o gravar bienes inmuebles y demas activos fijos de la sociedad, cualquiera que sea la cuantia de la transaccion. Las demas que le sean propias y no esten atribuidas a otro organo social y las que le correspondan en virtud de la ley. la sociedad tendra un Gerente General, quien ejercera la administracion y representacion legal de la sociedad y tendra las siguientes atribuciones, entre otras: Ejercer la representacion legal de la sociedad en todos los actos y contratos que se requieran para el desarrollo del objeto social, de conformidad con lo previsto en las leyes y en los presentes estatutos. Aprobar y celebrar en nombre de la sociedad todo acto o contrato cuya cuantia sea igual o inferior al equivalente en pesos Colombianos a cincuenta mil dolares de los Estados Unidos de America (US$50.000.oo), liquidados a la tasa de cambio representativa del mercado vigente el dia en que se surta la aprobacion o celebracion del acto. Para enajenar, a cualquier titulo, bienes inmuebles de la sociedad o constituir gravamenes sobre los mismos, debera obtener la aprobacion de la junta directiva, cualquiera que sea la cuantia de la transaccion; o las demas funciones que le correspondan como representante legal por disposicion de la ley, de estos estatutos o de la junta directiva. El Gerente General tendra un suplente, designado por la junta directiva, quien lo reemplazara con identicas facultades en sus faltas temporales, absolutas o meramente acciedentales, sin que sea necesario para ello acreditar la ausencia del principal.----------

C E R T I F I C A

Que seg?n Acta No. 15 del 18 de Febrero de 2008 correspondiente a la Asamblea de Accionistas en Bogota, de la sociedad:
GYNOPHARM S.A.----------
cuya parte pertinente se inscribi? en esta C?mara de Comercio, el 25 de Febrero de 2008 bajo el No. 137,919 del libro respectivo, fueron hechos los siguientes nombramientos:

CLASE: JUNTA DIRECTIVA

Principales

1.	Llobet Poal Manuel	CC.******14,670,196
2.	Zanatta Reherman Leonardo Andres	CC.*******2,760,271
3.	Munoz Marroquin Diego	CC.*******7,688,292

*** CONTINUA ***

CERTIFICADO NACIONAL

CAMARA DE COMERCIO DE BARRANQUILLA

Fecha : 20080814 Hora Certificado 16:59:44

Operacion : 02NJK0814067 PAGINA No. 4

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Montealegre Gonzalez Andres Leonardo CC.******79,950,262

Suplentes

1 Agudelo Pelaez Luis Hernando CC.******14,238,997

2 Aroca Almanza Arleth Ayelina CC.******36,718,415

3 Penaranda Urbina Adriana Paola CC.******53,120,683

4 tovar Vasquez Ruth CC.******52,175,756

C E R T I F I C A

Que seg?n Acta No. 18 del 30 de Octubre de 2003 correspondiente a la Junta Directiva en Barranquilla, de la sociedad: GYNOPHARM S.A. cuya parte pertinente se inscribi? en esta C?mara de Comercio, el 06 de Nov/bre de 2003 bajo el No. 107,783 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre Identificaci?n

Gerente General

Palacios Aragon Luis Alberto CE.********319,788

C E R T I F I C A

Que seg?n Acta No. 49 del 03 de Marzo de 2008 correspondiente a la Junta Directiva en Barranquilla, de la sociedad: GYNOPHARM S.A. cuya parte pertinente se inscribi? en esta C?mara de Comercio, el 11 de Marzo de 2008 bajo el No. 138,342 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre Identificaci?n

Suplente del Gerente.

Mollajoli Centurion Andres Fernando CE.********351,283

C E R T I F I C A

Que seg?n Acta No. 16 del 08 de Mayo de 2008 correspondiente a la Asamblea de Accionistas en Barranquilla, de la sociedad: GYNOPHARM S.A. cuya parte pertinente se inscribi? en esta C?mara de Comercio, el 22 de Mayo de 2008 bajo el No. 140,053 del libro respectivo, fueron hechos los siguientes nombramientos:

Cargo/Nombre Identificaci?n

Revisor Fiscal

Marroquin Sepulveda Edgar CC.******17,147,542

C E R T I F I C A

Que segun Documento Privado de fecha 10 de Octubre del 2.000, inscrito en esta Camara de Comercio el 23 de Noviembre del 2.000 bajo el No. 1.872 del libro repectivo, consta que el senor RUBEN MINSKI GONTOVNIK C.C. No. 7.463.982, actuando como Presidente y representante legal de la sociedad GYNOPHARM S.A., otorga Poder Especial,

*** CONTINUA ***

01

7293844

CERTIFICADO NACIONAL

CAMARA DE COMERCIO DE BARRANQUILLA

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Operacion : 02NJK0814067 PAGINA No. 5

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Amplio y Suficienta a KAREN JENNIFER FIGUEROA GARCIA C.C. No. 32.-732.070, para que en nombre y representacion de la sociedad suscriba todas las declaraciones cambiarias a que esta obligada GYNOPHARM S.A., en el giro normal de sus negocios y operaciones sociales.-----

C E R T I F I C A

Que segun Documento Privado de fecha 10 de Octubre del 2.000, inscrito en esta Camara de Comercio el 12 de junio del 2.002, bajo el 2.164 del libro respectivo,consta que el senor JORGE CASTELLANOS MARTINEZ,identificado con C.C.No.19.460.089,actuando como representante legal de la sociedad GYNOPHARM S.A, otorga Poder Especial Amplio y Suficiente a KAREN FIGUEROA GARCIA, identificada con la cedula de ciudadania No.32.732.070 de Barranquilla, mediante documento privado de octubre 10/2000, inscrito en la Camara de Comercio de Barranquilla bajo el No.1.872 del libro respectivo, para que en representacion de GYNOFARM S.A, suscriba las declaraciones cambiarias a los que esta obligada GYNOFARM S.A. en el giro ordinario de sus negocios y operaciones sociales.----------

C E R T I F I C A

Que en esta C?mara de Comercio no aparecen inscripciones posteriores de documentos referentes a reforma, disoluci?n, liquidaci?n o nombramientos de representantes legales de la expresada sociedad.

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Que su ?ltima Renovaci?n fue el: 23 de Abril de 2008.

La informaci?n sobre embargos de establecimiento se suministra en Certificados de Matr?cula, la de contratos sujetos a registro, en Certificados Especiales.

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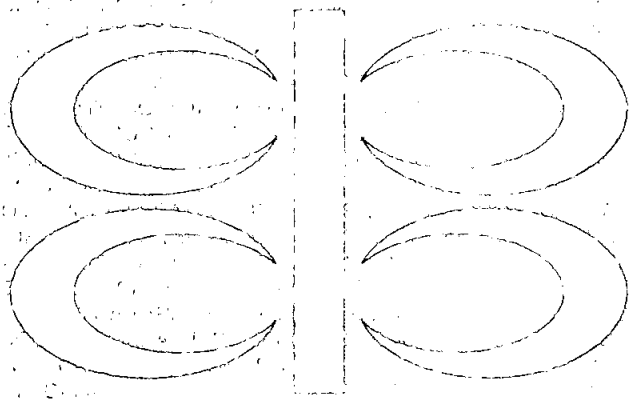

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(57) Abstract

The present invention provides a method for treating pain using an atypical antipsychotic compound.

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METHOD FOR TREATING PAIN

This invention provides a method for using an atypical antipsychotic compound selected from the group consisting of risperidone, clozapine, seroquel, sertindole, ziprasidone, and zotepine for the treatment of pain.

This invention relates to the treatment of pain using atypical antipsychotic compounds to provide analgesic activity.

Surprisingly, we have discovered that atypical antipsychotic compounds can be particular useful for treating pain. The analgesic effect may be further enhanced when used in combination with one or more another Drug Used in the Treatment of Pain compounds. More specifically, the invention provides a method of treating pain in humans using an atypical antipsychotic compound.

There are drugs used in the treatment of pain which known in the literature and to the skilled artisan. *see for example,* Merck Manual, 16th Ed. (1992) p. 1409.

More active analgesics are in constant demand because they offer the attractive possibility of relieving pain with reduced dosages, thereby diminishing the expected side effects and toxicity that would otherwise result from higher dosages. It would be particularly desirable to acquire a synergistic combination effect to further reduce dosages and diminish side effects. Such a composition is a subject of the present invention.

Certain compounds have been disclosed as being atypical antipsychotics which can be useful for treating schizophrenia or related psychotic conditions. Applicants have discovered that atypical antipsychotic compounds selected from the group consisting of risperidone, clozapine, seroquel, sertindole, ziprasidone, and zotepine

synergistic effect when administered with one or more other drugs used in the treatment of pain.

The present invention provides a method for treating pain, comprising administering an effective amount of an atypical antipsychotic selected from the group consisting of risperidone, clozapine, seroquel, sertindole, ziprasidone, and zotepine to a patient in need thereof.

The present invention further provides a method for treating pain comprising administering to a patient in need thereof, an analgesic composition comprising an atypical antipsychotic or a pharmaceutically acceptable salt thereof; and another Drug Used in the Treatment of Pain, in a weight ratio of one part atypical antipsychotic to from about one part to about one thousand (1,000) parts of another Drug Used in the Treatment of Pain.

A preferred composition is a weight ratio of atypical antipsychotic to another Drug Used in the Treatment of Pain of from about 1 part atypical antipsychotic to from about 1 part to about 100 parts of another Drug Used in the Treatment of Pain. An especially preferred ratio is from about 1 part atypical antipsychotic to from about 1 to about 30 parts another Drug Used in the Treatment of Pain. A further preferred ratio may be from about 1 part atypical antipsychotic to from about 1 part to about 10 parts another Drug Used in the Treatment of Pain. A final preferred ratio may be from about 1 part atypical antipsychotic to from about 1 to about 3 parts another Drug Used in the Treatment of Pain.

Preferably another Drug Used in the Treatment of Pain is one or more compounds selected from the group consisting of aspirin, acetominophen, paracetamol, indomethacin, Tylenol #3, tricyclic antidepressants (for example desipramine, imipramine, amytriptiline,

inhibitors (for example, fluoxetine, paraoxetine, sertraline), mixed serotonin-norepinephrine reuptake inhibitors (for example venlafaxine, duloxetine), serotonin receptor agonists and antagonists, cholinergic (muscarinic and nicotinic) analgesics, adrenergic agents, and neurokinin antagonists.

Particularly preferred Drug Used in the Treatment of Pain are selected from the group consisting of aspirin, acetominophen, ketorolac, allopurinol, methysergide maleate, and methotrimeprazine.

The invention further provides a composition for treating pain comprising an atypical antipsychotic or a pharmaceutically acceptable salt or solvate thereof and one or more another Drug Used in the Treatment of Pain in a weight ratio of atypical antipsychotic to another Drug Used in the Treatment of Pain of from about one (1) part atypical antipsychotic to from about 1 part to about 1000 parts Drug Used in the Treatment of Pain.

Another Drug Used in the Treatment of Pain used primarily for the symptomatic relief of pain may be divided into four major groups: 1) opiate analgesics; 2) nonopiate analgesics; 3) analgesics and antipyretics; and 4) nonsteroidal antiinflammatory drugs. Other compounds contemplated herein as "Drug Used in the Treatment of Pain" include, but are in no way limited to other drug classes which might be used with atypical antipsychotics for the treatment of pain to provide a synergistic effect, for example, acetominophen, paracetamol, indomethacin, Tylenol #3, tricyclic antidepressants (for example desipramine, imipramine, amytriptiline, nortriptile), anticonvulsants (for example, carbamazepine, valproate), and serotonin reuptake inhibitors (for example, fluoxetine, paraoxetine, sertraline), mixed serotonin-norepinephrine reuptake inhibitors (for example venlafaxine, duloxetine), serotonin receptor agonists and antagonists, cholinergic

antagonists. Some preferred another Drug Used in the Treatment of Pain s are selected from acetominphen, cholinergic analgesics, and neurokinin anatagonists. Other preferred Drug Used in the Treatment of Pain include tricyclic antidepressants, anticonvulsants, and serotonin reuptake inhibitors.

Another preferred group of Drug Used in the Treatment of Pain is nonopiate analgesics. The term "nonopiate analgesics" refer to compounds including, but not limited to Butorphanol, Propoxyphene, meperidine, alphaprodine hydrochloride, fentanyl, and tramadol.

Another preferred group of Drug Used in the Treatment of Pain is "analgesics and antipyretics" wherein the term refers to compounds such as, but not limited to, acetominophen, ketorolac, allopurinol, methysergide maleate, and methotrimeprazine.

Applicants appreciate that a new Drug Used in the Treatment of Pain may be in development, and the present invention contemplates a synergistic composition comprising such new agents with atypical antipsychotic as well.

As used herein the term "atypical antipsychotic" shall refer to a compound selected from the group consisting of risperidone, clozapine, seroquel, sertindole, ziprasidone, and zotepine.

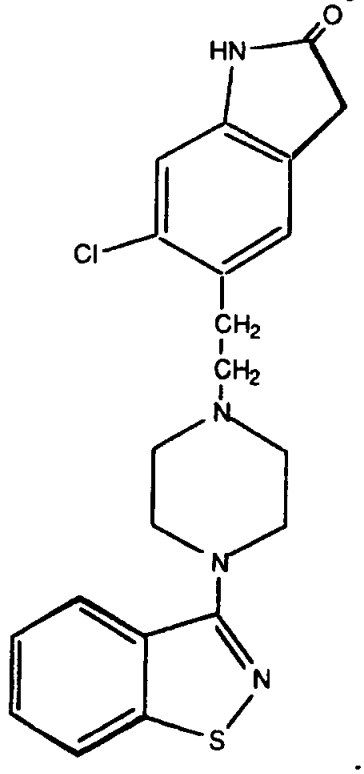
Risperidone is a known antipsychotic compound currently marketed by Janssen and claimed by U.S. Patent No. 5,246,935 which is hereby incorporated by reference in its entirety.

Clozapine is a well known atypical antipsychotic compound currently marketed by Sandoz.

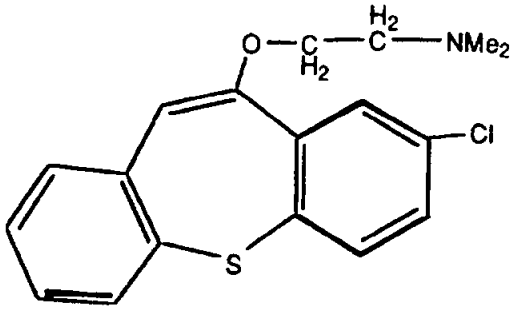
Seroquel is a known compound claimed by U.S. Patent 4,879,288 which is hereby incorporated by reference in its entirety.

Sertindole is a known compound and is claimed by U.S. Patent Nos. 5,112,838 and 5,2238,945 each of which is

Ziprasidone is a known compound and is claimed in EP281309-A which is readily available to the skilled artisan. Ziprasidone has the following structure:



Zotepine is a known compound claimed in U.S. Patent No. 3,704,245 which is hereby incorporated by reference in its entirety. Zotepine has the following structure:



As used herein, the term "mammal" shall refer to the Mammalia class of higher vertebrates. The term "mammal" includes, but is not limited to, a human. The term "treating" as used herein includes prophylaxis of the named

condition or amelioration or elimination of the condition once it has been established.

As used herein the term "Drug Used in the Treatment of Pain" refers to compounds known to be clinically useful as analgesics. The term refers to one or more such compounds. Thus, the term Drug Used in the Treatment of Pain can refer to one known analgesic or a combination comprising from two to three known analgesic compounds. Drug Used in the Treatment of Pain are most preferably selected from the compounds named herein.

In the composition of this invention an atypical antipsychotic or a pharmaceutically acceptable salt thereof and one or more Drug Used in the Treatment of Pain are combined in a weight ratio of atypical antipsychotic to Drug Used in the Treatment of Pain of from about one part atypical antipsychotic to from about 1 to about 1000 parts Drug Used in the Treatment of Pain.

A preferred composition is a weight ratio of atypical antipsychotic to another Drug Used in the Treatment of Pain is from about 1 part atypical antipsychotic to from about 1 part Drug Used in the Treatment of Pain to about 100 parts Drug Used in the Treatment of Pain. An especially preferred ratio is from about 1 to about 30. A further preferred ratio may be from about 1 to about 10. A final preferred ratio may be from about 1 to about 3.

Atypical antipsychotics are effective over a wide dosage range; however, it is desirable to administer a dosage that is as low as possible. The amount of Drug Used in the Treatment of Pain present in the composition is adjusted as described above in ratio to the atypical antipsychotic dosage. For example, dosages per day of the atypical antipsychotic will normally fall within the range of about 0.5 mg to about 300 mg per day and the Drug Used in the Treatment of Pain in the composition would be from 3 to 1000 times this amount. However, it will be understood that

circumstances including the condition to be treated, the choice of compound to be administered, the age, weight, and response of the individual patient, the severity of the patient's symptoms, and the chosen route of administration, and therefore the above dosage ranges are not intended to limit the scope of the invention in any way. While the present compounds are preferably administered orally to humans susceptible to or suffering from pain, the compounds may also be administered by a variety of other routes such as the transdermal, parenterally, subcutaneous, intranasal, intramuscular and intravenous routes. Such formulations may be designed to provide delayed or controlled release using formulation techniques which are known in the art.

As used herein the term "treating" includes prophylaxis of a physical and/or mental condition or amelioration or elimination of the developed physical and/or mental condition once it has been established or alleviation of the characteristic symptoms of such condition.

As used herein the term "pain" shall refer to all types of pain. Preferredly, the term shall refer to chronic pains, such as neuropathic pain, and post-operative pain, chronic lower back pain, cluster headaches, herpes neuralgia, phantom limb pain, central pain, dental pain, neuropathic pain, another Drug Used in the Treatment of Pain -resistant pain, visceral pain, surgical pain, bone injury pain, pain during labor and delivery, pain resulting from burns, including sunburn, post partum pain, migraine, angina pain, and genitourinary tract-related pain including cystitis, the term shall also preferredly refer to nociceptive pain or nociception.

The dosage administered will, of course, vary depending on known factors such as the pharmacodynamic characteristics of the particular agent, and its mode and route of administration; age, health, and weight of the recipient; nature and extent of the symptoms, kind of concurrent treatment, frequency of

that the active ingredient is administered at a daily dosage of from about 0.2 mg to about 50 mg atypical antipsychotic and from about 0.6 to about 500 mg of another Drug Used in the Treatment of Pain s.

Compositions suitable for internal administration contain from about one half (0.5) milligrams to about 600 milligrams of active ingredient per unit. In these pharmaceutical compositions, the active ingredient will ordinarily be present in an amount of from about 0.5% to about 95% by weight based on the total weight of the composition.

Typical compositions include atypical antipsychtoic or a pharmaceutically acceptable acid addition salt thereof and one or more another Drug Used in the Treatment of Pain s, associated with a pharmaceutically acceptable excipient which may be a carrier, or a diluent or be diluted by a carrier, or enclosed within a carrier which can be in the form of a capsule, sachet, paper, or other container. In making the compositions, conventional techniques for the preparation of pharmaceutical compositions may be used. For example, the active compound will usually be mixed with a carrier, or diluted by a carrier, or enclosed within a carrier which may be in the form of a ampoule, capsule, sachet, paper, or other container. When the carrier serves as a diluent, it may be solid, semi-solid, or liquid material which acts as a vehicle, excipient, or medium for the active compound. The active compound can be adsorbed on a granular solid container for example in a sachet. Some examples of suitable carriers are water, salt solutions, alcohols, polyethylene glycols, polyhydroxyethoxylated castor oil, gelatine, lactose, amylose, magnesium stearate, talc, silicic acid, fatty acid monoglycerides and diglycerides, pentaerythritol fatty acid esters, hydroxymethylcellulose and

preserving agents, sweetening agents, or flavoring agents. The formulations of the invention may be formulated so as to provide quick, sustained, or delayed release of the active ingredient after administration to the patient by employing procedures well known in the art.

The pharmaceutical preparations can be sterilized and mixed, if desired, with auxiliary agents, emulsifiers, salt for influencing osmotic pressure, buffers and/or coloring substances and the like, which do not deleteriously react with the active compounds.

For parenteral application, particularly suitable are injectable solutions or suspensions, preferably aqueous solutions with the active compound dissolved in polyhydroxylated castor oil.

Tablets, dragees, or capsules having talc and/or a carbohydrate carrier or binder or the like are particularly suitable for oral application. Preferable carriers for tablets, dragees, or capsules include lactose, corn starch, and/or potato starch. A syrup or elixir can be used in cases where a sweetened vehicle can be employed.

The compositions of this invention may be suitable for administration to an animal. Such animals include both domestic animals, for example livestock, laboratory animals, and household pets, and non-domestic animals such as wildlife. More preferredly, the animal is a vertebrate. Most preferredly, a compound of this invention shall be administered to a mammal. It is especially preferred that the animal is a domestic mammal or a human. The most preferred mammal is a human. For such purposes, a compound of this invention may be administered as a feed additive.

Utility Test Methods

intially conducted on mice. Mice weighing from about 18-25 grams at the time of testing are used for the following studies. All mice are dosed by the oral route with a Drug Used in the Treatment of Pain and/or an atypical antipsychotic.

Mouse Writhing Test

An accepted standard for detecting and comparing the analgesic activity of different classes of analgesic compounds for which there is a good correlation with human analgesic activity is the prevention of acetic acid induced writhing in mice. [R. Koster et al. Acetic acid for analgesic screening. Fed. Proc. **18**:412, 1959].

Mice, treated with various doses of atypical antipsychotic, another Drug Used in the Treatment of Pain, an atypical antipsychotic:Drug Used in the Treatment of Pain composition, or vehicle are injected intraperitoneally with a standard challenge dose of acetic acid 5 minutes prior to a designated observation period. The acetic acid is prepared as a 0.55% solution and injected at a volume of 0.1 ml/10 grams of body weight. For scoring purposes a "writhe" is indicated by whole body stretching or contracting of the abdomen during an observation period beginning about five minutes after the administration of acetic acid.

Sciatic Nerve Ligation Model

An accepted model for assessment of neuropathic pain analgesia is the sciatic nerve ligation model [Bennett, G.J. and Xie, Y.-K. A peripheral mononeuropathy in rat that produces disorders of pain sensation like those seen in man. Pain 33 (1988) 87-107; Lee, Y.-W., Chaplan, S.R. and Yaksh, T.L.: Systemic and supraspinal, but not spinal, opiates suppress allodynia in a rat neuropathic pain model. Neuroci Lett 186 (1995) 111-114]. Rats are anesthetized and a nerve

exposed and 4 ligatures tied loosely around it with about 1 mm spacing. One day to 10 weeks after surgery, the nociceptive testing is performed. Responses to noxious heat are determined by placing the rats in a chamber with a clear glass floor and aiming at the plantar surface of the affected foot a radiant heat source from beneath the floor. Increased latency to withdraw the hindpaw is demonstrative of analgesic activity. Responses to normally innocuous mechanical stimuli is determined by placing the rats in a chamber with a screen floor and stimulating the plantar surface of the hind paw with graduated von Frey hairs which are calibrated by the grams of force required to bend them. Rats with sciatic nerve ligation respond to lower grams of mechanical stimulation by reflexive withdrawal of the foot than unoperated rats. This response to stimuli which are normally innocuous is termed allodynia. Increases in the grams of mechanical force required to produce foot withdrawal is demonstrative of antiallodynic activity.

Formalin Test

The formalin test is a well accepted model of inflammatory pain [Malmberg, A.B. and Yaksh, T.L.: Antinociceptive actions of spinal nonsteroidal anti-inflammatory agents on the formalin test in the rat. The Journal of Pharmacology and Experimental Therapeutics 263 (1992) 136-146]. Rats are anesthetized and when there is a loss of spontaneous movement they are injected subcutaneously in the dorsal surface of the hindpaw with 50 µl of 5% formalin solution using a 30 gauge needle. Rats are then individually placed in an open Plexiglas chamber for observation, and within a maximum interval of 1 to 2 min, the animals display recovery from anesthesia with spontaneous activity and normal motor function. Pain behavior is quantified by periodically counting the

paw. The flinches are counted for 1-min periods at 1- to 2-, 5- to 6- and 5min intervals during the interval from 10 to 60 min. Inhibition of the pain behavior is demonstrative of an analgesic activity.

All ED_{50} values and their standard errors of the mean (S.E.M.) are determined using accepted numerical methods. For example, see R. E. Kirk (1982) Experimental Design: Procedures for the behavioral sciences, 2nd ed. Belmont, CA: Brooks/Cole Publishing Co. The interaction of the dosages on analgesia is demonstrated graphically by the Loewe isobologram (S. Loewe, Pharm. Rev. 9:237-242, 1957).

The interaction of an atypical antipsychotic and another compound used in the treatment of pain on analgesia is demonstrated by Loewe isobologram analysis. In the isobolographic analysis, the analgesic effects of an atypical antipsychotic are presented on the X-axis and of the other compound used in the treatment of pain on the Y-axis. The line connecting the ED_{50} dosages of an atypical antipsychotic alone and another compound used in the treatment of pain alone represents the "ED50 addition line" which indicates the expected location of the ED_{50} values for an atypical antipsychotic and another compound used in the treatment of pain combinations if simple additivity were to describe their combined effects. According to Loewe's isobolographic theory, if the analgesic effects of an atypical antipsychotic and an another compound used in the treatment of pain were simply additive to one another, the expected location of the ED_{50} values of the an atypical antipsychotic and another compound used in the treatment of pain components of each fixed dosage ratio would lie on the addition line. Combination ED_{50} values located significantly below the ED_{50} addition line would represent unexpectedly enhanced analgesic activity and combination

ED_{50} values located above the line would represent unexpected diminished analgesic effect.

One method to establish the significance of such unexpected enhanced or diminished activity is to calculate the SEM values for each ED_{50}. If the SEM values do not overlap the line of addition, then the ED_{50} values are significantly different from the line of addition.

Surprisingly, such experiments demonstrate that compositions comprised of an atypical antipsychotic and another compound used in the treatment of pain show a statistically significant synergistic analgesic effect.

It will be apparent that the instant specifications and examples are set forth by way of illustration and not limitation, and that various modifications and changes may be made without departing from the spirit and scope of the present invention.

Such experiments support that atypical antipsychotics and atypical antipsychotic:another Drug Used in the Treatment of Pain compositions can provide an analgesic effect. Such compositions can provide a statistically significant synergistic analgesic effect.

Clinical observations.

A double-blind multicenter clinical trial is designed to assess the safety and efficacy of the atypical antipsychotic. Patients are randomized to atypical antipsychotic, atypical antipsychotic: another Drug Used in the Treatment of Pain composition of this invention, another Drug Used in the Treatment of Pain alone, or placebo. Patients are monitored for perception of pain using standard methods.

The materials for the present invention can be

to those of ordinary skill in the art. The atypical antipsychotic compounds are either commercially avialable or can be prepared using methods described in the patents incorporated herein by reference or as described in widely available publications.

The following examples are provided for purposes of illustration and are not to be construed as limiting the scope of the claimed invention.

EXAMPLE 1

A portion of the hydroxypropyl cellulose was dissolved in purified water to form a solution for granulation. The remaining hydroxypropyl cellulose (total of 4.0% w/w final tablet weight), which was an extra fine grade, was combined with the atypical antipsychtic (1.18% w/w), another Drug Used in the Treatment of Pain (3 % w/w), lactose (79.32% w/w) and a portion of the crospovidone (5% w/w) in a high shear granulator. All ingredients were security sieved prior to addition and dry blended in the granulator. This mixture was then granulated with the hydroxypropyl cellulose solution in the high shear granulator. The granulation was wet sized using standard methods. The wet granulation was then dried in a fluidized bed dryer and sized. The material was then added to a tumble bin mixer.

The running powders consisting of microcrystalline cellulose (granular) (10% w/w), magnesium stearate (0.5% w/w), and the remainder of the crospovidone were added to the sized granulation. The mixture was blended and compressed with the appropriate tooling on tablet compression equipment.

Subcoating:

divided into approximately equal sections and spray coated with the hydroxypropyl methylcellulose solution . The operation was performed in a perforated coating pan.

Coating of Core Tablets:

Color Mixture White (hydroxypropyl methylcellulose, polyethylene glycol, polysorbate 80, and titanium dioxide) was mixed with purified water to form the coating suspension. Subcoated tablets were divided into approximately equal sections and spray coated with the coating suspension described above. The operation was performed in a perforated coating pan.

The coated tablets were lightly dusted with carnauba wax and imprinted with appropriate identification.

EXAMPLE 2

A portion of the hydroxypropyl cellulose was dissolved in purified water to form a solution for granulation. The remaining hydroxypropyl cellulose (total of 4.0% w/w final tablet weight), which was an extra fine grade, was combined with the atypical antipsychtic (1.18% w/w), lactose (79.32% w/w) and a portion of the crospovidone (5% w/w) in a high shear granulator. All ingredients were security sieved prior to addition and dry blended in the granulator. This mixture was then granulated with the hydroxypropyl cellulose solution in the high shear granulator. The granulation was wet sized using standard methods. The wet granulation was then dried in a fluidized bed dryer and sized. The material was then added to a tumble bin mixer.

The running powders consisting of microcrystalline cellulose (granular) (10% w/w

granulation. The mixture was blended and compressed with the appropriate tooling on tablet compression equipment.

Subcoating:

Hydroxypropyl methylcellulose (10% w/w) was mixed with purified water to form a solution. Core tablets were divided into approximately equal sections and spray coated with the hydroxypropyl methylcellulose solution . The operation was performed in a perforated coating pan.

Coating of Core Tablets:

Color Mixture White (hydroxypropyl methylcellulose, polyethylene glycol, polysorbate 80, and titanium dioxide) was mixed with purified water to form the coating suspension. Subcoated tablets were divided into approximately equal sections and spray coated with the coating suspension described above. The operation was performed in a perforated coating pan.

The coated tablets were lightly dusted with carnauba wax and imprinted with appropriate identification.

Claims

1. A composition for treating pain comprising an analgesic dose of an atypical antipsychotic selected from the group consisting of risperidone, clozapine, seroquel, sertindole, ziprasidone, and zotepine or a pharmaceutically acceptable salt or solvate thereof; and one or more Drug Used in the Treatment of Pain in a weight ratio of atypical antipsychotic to another Drug Used in the Treatment of Pain from about one part atypical antipsychotic to from about one (1) to about one thousand (1000) parts Drug Used in the Treatment of Pain.

2. A composition of **Claim 1** wherein the another Drug Used in the Treatment of Pain is selected from the group consisting aspirin, ibuprophen, acetaminophen, indomethacin, Tylenol #3, tricyclic antidepressants (for example desipramine, imipramine, amytriptiline, nortriptile), anticonvulsants (for example, carbamazepine, valproate), and serotonin reuptake inhibitors (for example, fluoxetine, paraoxetine, sertraline), mixed serotonin-norepinephrine reuptake inhibitors (for example venlafaxine, duloxetine), serotonin receptor agonists and antagonists, cholinergic (muscarinic and nicotinic) analgesics, adrenergic agents, and neurokinin antagonists.

3. A composition of **Claim 1** wherein the atypical antipsychotic is risperidone.

4. A composition of **Claim 2** wherein the Drug Used in the Treatment of Pain is selected from the group consisting of acetaminophen, cholinergic analgesics, and neurokinin anatagonists.

5. A composition of **Claim 1** wherein the weight ratio of atypical antipsychotic to another Drug Used in the Treatment of Pain is from about one part atypical antipsychotic to from about one (1) part to from about one hundred (100) parts Drug Used in the Treatment of Pain.

6. A composition of **Claim 5** wherein the Drug used in the Treatment of Pain is selected from the group consisting of acetaminophen, meperidine, alphaprodine hydrochloride, fentanyl, tramadol, ketorolac, allopurinol, methysergide maleate, methotrimeprazine, and indomethacin.

7. A composition of **Claim 5** wherein the weight ratio of atypical antipsychotic to another Drug Used in the Treatment of Pain is from about one part atypical antipsychotic to from about one (1) part to from about ten (10) parts Drug Used in the Treatment of Pain.

8. A composition of **Claim 7** wherein the weight ratio of atypical antipsychotic to another Drug Used in the Treatment of Pain is from about one part atypical antipsychotic to from about one (1) part to from about three (3) parts Drug Used in the Treatment of Pain.

9. A composition of **Claim 8** wherein the Drug Used in the Treatment of Pain is acetaminophen.

10. A composition of **Claim 1** wherein the atypical antipsychotic is clozapine.

11. A composition of **Claim 1** wherein the atypical antipsychotic is seroquel.

12. A composition of **Claim 1** wherein the atypical antipsychotic is sertindole.

13. A composition of **Claim 1** wherein the atypical antipsychotic is ziprasidone.

14. A composition of **Claim 1** wherein the atypical antipsychotic is zotepine.

15. A method for treating pain comprising administering an analgesic dose of a composition comprising an atypical antipsychotic selected from the group consisting of risperidone, clozapine, seroquel, sertindole, ziprasidone, and zotepine or a pharmaceutically acceptable salt or solvate thereof; and one or more Drug Used in the Treatment of Pain in a weight ratio of atypical antispychotic to Drug Used in the Treatment of Pain of from about one (1) part atypical antipsychotic to from about one (1) part to about one thousand (1000) parts Drug Used in the Treatment of Pain.

16. A method of **Claim 15** wherein the Drug Used in the Treatment of Pain is selected from the group consisting of group consisting of acetominophen, indomethacin, Tylenol #3, tricyclic antidepressants (for example desipramine, imipramine, amytriptiline, nortriptile), anticonvulsants (for example, carbamazepine, valproate), and serotonin reuptake inhibitors (for example, fluoxetine, paraoxetine, sertraline), mixed serotonin-norepinephrine reuptake inhibitors (for example venlafaxine, duloxetine), serotonin receptor agonists and antagonists, cholinergic (muscarinic and nicotinic) analgesics, adrenergic agents, and neurokinin antagonists.

17. A method of **Claim 16** wherein Drug Used in the Treatment of Pain is selected from the group consisting of acetaminophen, meperidine, alphaprodine hydrochloride, fentanyl, tramadol, ketorolac, allopurinol, methysergide maleate, methotrimeprazine, and indomethacin.

18. A method for treating pain in a mammal comprising administering an analgesic dose an atypical antipsychotic selected from the group consisting of risperidone, clozapine, seroquel, sertindole, ziprasidone, and zotepine or a pharmaceutically acceptable salt or solvate thereof; to a mammal in need of such treatment.

19. A method of **Claim 18** wherein the atypical antipsychotic is Clozapine.

20. A method of **Claim 18** wherein the atypical antipsychotic is risperidone.

21. A method of **Claim 18** wherein the atypical antipsychotic is seroquel.

22. A method of **Claim 18** wherein the atypical antipsychotic is sertindole.

23. A method of **Claim 18** wherein the atypical antipsychotic is ziprasidone.

24. A method of **Claim 18** wherein the atypical antipsychotic is zotepine.

25. A method of **Claim 18** wherein pain is neuropathic pain.

26. A method of **Claim 18** wherein pain is nociceptive pain.

27. An atypical antipsychotic selected from the group consisting of risperidone, clozapine, seroquel, sertindole, ziprasidone, and zotepine or a pharmaceutically acceptable salt or solvate thereof; for use in the treatment of pain.

28. An atypical antipsychotic selected from the group consisting of risperidone, clozapine, seroquel, sertindole, ziprasidone, and zotepine or a pharmaceutically acceptable salt or solvate thereof; for use an analgesic.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/04699

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61K 31/55, 31/495, 31/445, 31/16
US CL :514/211, 253, 254, 255, 323, 629

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)

U.S. : 514/211, 253, 254, 255, 323, 629

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

none

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

cas-online, aps

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3,704,245 A (UMIO et al.) 28 November 1972, see the entire document.	1, 5, 7,8, 14, 15, 18, and 24-28
Y	US 4,879,288 (WARAWA et al.) 07 November 1989, see the entire document.	1, 5, 7, 8, 11, 15, 18, 21 and 25-28
Y	US 5,045,539 A (HELSLEY et al.) 03 September 1991, see the entire document.	1, 5, 7, 8, 10, 15, 18, 19 and 25-28
Y	US 5,112,838 A (PERREGAARD et al.) 12 May 1992, see the entire document.	1, 5, 7, 8, 12, 15, 18, 22 and 25-28

[X] Further documents are listed in the continuation of Box C. [ ] See patent family 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 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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
04 JUNE 1997	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/04699

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,246,935 A (JEPPESEN et al.) 21 September 1993, see the entire document.	1, 3, 5, 7, 8, 15, 18, 20 and 25-28
Y	DAHLIN et al., "THE MERCK INDEX, AN ENCYCLOPEDIA OF CHEMICALS , DRUGS, AND BIOLOGICALS" published 1983 by Merck & Co., Inc. (N.J.), see page 7, abstract No. 39.	2, 4, 6, 9 and 16

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Industria y Comercio
SUPERINTENDENCIA

2020
Bogotá, D.C.,

Doctor:
Emilio Ferrero
Apoderado

Oficio N°: №14513

ASUNTO:

Radicación PCT Nº	08-23028
Trámite	011
Evento	378
Actuación	440
Folios	009

Con fundamento en lo previsto por el artículo 43 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica que la oposición presentada por la doctora Eliana Isaura Moreno Bohórquez, en su calidad de apoderada de Gynopharm S.A., reúne los requisitos formales exigidos por la ley al momento de su presentación.

En cumplimiento de lo dispuesto en la citada norma, se le concede el término de sesenta (60) días hábiles siguientes a la fecha de notificación del presente oficio, para que haga valer sus argumentaciones y presente pruebas.

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

ALIX CARMENZA CESPEDES DE VERGEL
Jefe de la División de Nuevas Creaciones.

El anterior oficio fue notificado por fijación en lista de fecha, 14 NOV. 2008.

202021

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