



DIRECCIÓN DE NUEVAS CREACIONES
PRESENTACIÓN DE OPOSICIÓN

1. Oposición a solicitud de:

- ☒ Patente de invención
☐ Registro de Diseño Industrial
☐ Patente de Modelo de Utilidad
☐ Esquema de Trazado de Circuitos Integrados

Número de expediente: 14.036039

Solicitante: ABBVIE DEUTSCHLAND GMBH & CO. KG

Apoderado: MARGARITA CASTELLANOS ABONDANO

Título de la Nueva Creación: FORMULACIONES BASADAS EN DISPERSIONES SOLIDAS

Gaceta: 707

2. Datos del Opositor

☐ Persona Natural ☒ Persona Jurídica
PROCAPS S.A.

Nombre o denominación /Razón social completa

WALTER TANAKA TATEKAWA

Nombre del representante legal

Documento de identificación: C.C. ☐ C.E. ☐ NIT ☒ Otro ☐ Cuál _____

Número 890106527-5 _____

Dirección: CALLE 80 78B 201 _____ Ciudad BARRANQUILLA

Teléfono 055 3719900 Fax: _____ Correo electrónico _____

☐ Autorizo expresamente a la Superintendencia de Industria y Comercio para que todas las comunicaciones sean enviadas a través de la dirección de correo electrónico

3. Datos del representante o apoderado:

MORENO BOHORQUEZ ELIANA ISaura

51.975.664

83823

Apellidos y Nombre

Documento de identificación

Tarjeta profesional

Dirección del representante		
CRA 13 119-95 OFICINA 104		
Dirección electrónica negocios@optimum-co.com	No. Fax (571)6121979	Número telefónico (571)2131213

En caso de haber presentado poder general para asuntos que se adelanten ante la Delegatura de Propiedad Industrial, sírvase indicar el número de su radicación o protocolo de poder general:

4. Fundamentos de la oposición

Causal: Art14, 16, 18,20 y 30 de la decisión 486 de la CAN 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 hecho".

Prórroga:

SI

☐

NO

☐**5. Anexos**

- ☒ Comprobante de pago de la tasa.
- ☒ Poder, si fuera el caso.
- ☒ Fundamentos de la oposición. Se anexan 6 folios (obligatorios indicar cuántos).
- ☒ Anexo de fundamentos de la oposición. Se anexan 19 folios (obligatorios indicar cuántos)
- ☒ Copias para traslado.
- ☐ Copia de la solicitud y sus anexos en formato magnético.

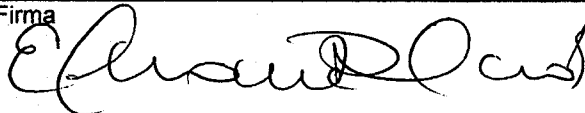
6. Firma

Nombre del Firmante

ELIANA ISaura MORENO BOHORQUEZ

CC. 51.975.664

Firma



Tarjeta Profesional: 83823

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800.176.089-2

- / -



Industria y Comercio
SUPERINTENDENCIA

RECIBO DE CAJA

No. 14 - 133903

Bogotá D.C., Diciembre 17 de 2014 - 08:53:22

RECIBIDO DE : PROCAPS S.A.

NI 890.106.527

*** Soporte del Pago ***

TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	VR PAGO
CONSIGNACION	BANCO DE BOGOTA	062754387	671879051	02/12/2014	3.015.000.00

*** Conceptos Pagados ***

CANT.	RENTISTICO	CONCEPTO	Vr. UNDITARIO	Vr. CONCEPTO
1	50005-01-04	PRESENTACION DE OBSERVACIONES A SOLICITUDES	335.000.00	335.000.00
12		OPOSICION POR CADA CLASE-MARCAS Y LEMAS COMERCIALES		335.000.00
				\$335.000.00

SON: **TRESCIENTOS TREINTA Y CINCO MIL PESOS MONEDA CORRIENTE**

Responsable: _____

Recibo de Caja Aplicado al Expediente No. _____

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Derecho de la Competencia, Propiedad
Industrial y Comercio Exterior

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

Referencia : Expediente N° 14-86039
Asunto : Oposición a la solicitud de patente de Invención titulada
"FORMULACIONES BASADAS EN DISPERSIONES
SOLIDAS"
Solicitante : ABBVIE DEUTSCHLAND GMBH & CO. KG.
Opositora : PROCAPS S.A.

Publicada en la Gaceta de la Propiedad Industrial
N° 707 del 30 de septiembre de 2014

Yo, **ELIANA ISAURA MORENO BOHÓRQUEZ**, abogada en ejercicio, identificada como aparece al pie de su firma, con tarjeta profesional No. 83823 del Consejo Superior de la Judicatura, en mi condición de apoderada de la sociedad **PROCAPS 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 "**FORMULACIONES BASADAS EN DISPERSIONES SOLIDAS**", cuyo titular **ABBVIE DEUTSCHLAND GMBH & CO. KG.**, y pido a Usted declarar fundada esta oposición y en consecuencia negar el registro de la patente solicitada.

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 legítimo 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 *Acido fenofibrico HME*. 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 23 de abril de 2014, reivindicando prioridad bajo las solicitudes EP20110182792 del 2011-09-26; y fue publicada en Colombia, en la Gaceta de la Propiedad Industrial N° 707 del 30 de septiembre de 2014, cuya publicación internacional corresponde a la WO2013045365 del 2013-04-04.
- 2.2. La solicitud colombiana 14-86039 objeto de la presente oposición se refiere a formulaciones que comprenden un producto disperso sólido compuesto por un agente activo que comprende al menos una unidad que puede operar como donante de enlaces de hidrógeno o una unidad que puede operar como donante de protones y un copolímero injertado de unidades de N-vinil lactama de polivinilo y polivinilacetato de poli(alquilenglicol) farmacéuticamente aceptable. También se refiere a métodos apropiados para preparar formulaciones como las que se han descrito.
- 2.3. 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: WO2011064111 publicada el 1 de mayo de 2003.

2.4. Ahora bien, el documento D1, se refiere a formas de película farmacéuticas de dosificación, que comprenden, como formadores de película, copolímeros anfífilos y una o más sustancias activas. Este documento D1 se refiere a una forma de dosificación que comprende, como formadores de película, copolímeros que se obtienen por polimerización de radicales libres de acetato de vinilo y N-vinil-lactamas en presencia de un poliéter y como formadores de película, copolímeros anfífilos que se obtienen por polimerización de radicales libres de una mezcla de i) de 30 a 80% en peso de N-vinil-lactama, ii) de 10 a 50% en peso de acetato de vinilo y iii) de 10 a 50% en peso de un poliéter, con la condición de que la suma de i), ii) y iii) es igual a 100% en peso. Igualmente D1 se refiere a que el formador de película es un copolímero de N-vinilcaprolactama, acetato de vinilo y un poliéter en cantidades de 1 a 100% en peso, basado en la cantidad total de excipientes farmacéuticos y que comprende otros polímeros, sustancias activas, plastificantes, colorantes, antioxidantes, emulsionantes, agentes tensioactivos, estabilizantes, conservantes, cargas, formadores de gel, edulcorantes, acidificantes, agentes lubricantes o aromas o mezclas de los mismos. Particularmente, D1 define ingredientes activos que comprenden restos de enlaces de hidrógeno donantes (por ejemplo, grupos amino, grupos hidroxilo, etc.) o restos donantes de protones (por ejemplo, ácidos, grupos ácidos CH), véase por ejemplo la lista de la página 7 y 8 de D1. Estas dispersiones sólidas también contienen ingredientes que modifican el pH en solución acuosa (característica (c) de la presente reivindicación 1). Igualmente, D1 revela que las películas poliméricas que contienen los ingredientes activos pueden contener adicionalmente agentes acidificantes (página 5 líneas 34 y 35). Por su parte, los ejemplos 2 y 16 de D1 revelan loperamida que tiene un grupo OH en la molécula y solubilidad en agua. El ejemplo 2 de D1 contiene docusato de sodio y el ejemplo 16 ácido tartárico, ambos de los cuales influirán en el pH. El Ejemplo 6 de D1 describe una composición que comprende naproxeno y Kollidon 30. Kollidon contiene grupos pirrolidona que tienen un nitrógeno básico y influirán en el pH. D1, por lo tanto, también contiene revelaciones específicas de la combinación reivindicada en la presente solicitud. D1 también describe los procesos de extrusión por fusión en caliente (página 4). Como se evidencia, esta anterioridad define la misma materia que

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

2.5. En consecuencia y de acuerdo a lo descrito anteriormente, se deriva que la solicitud colombiana 14-86039 no puede pretender un monopolio por patente toda vez que lo que pretende no cumple con uno de los tres requisitos necesarios para su protección.

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

2.8.1 CARENCIA 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, el 26 de septiembre de 2011, ya era conocido, pues como se demostró, era parte del arte anterior con base en los documento D1, formulaciones que comprenden un producto disperso sólido compuesto por un agente activo que comprende al menos una unidad que puede operar como donante de enlaces de hidrógeno o una unidad que puede operar como donante de protones y un copolímero injertado de unidades de N-vinil lactama de polivinilo y polivinilacetato de poli(alquilenglicol) farmacéuticamente aceptable, sobre el cual busca protección en el capítulo reivindicatorio.

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 uno de los tres requisitos de patentabilidad.

2.10 Por todo lo anterior, atentamente solicito a usted que se sirva declarar fundada **“FORMULACIONES BASADAS EN DISPERSIONES SOLIDAS”**, cuyo titular



Derecho de la Competencia, Propiedad Industrial y Comercio Exterior

ABBVIE DEUTSCHLAND GMBH & CO. KG.,, solicitud Colombiana que apareció publicada en la Gaceta de la Propiedad Industrial N° 707 del 30 de septiembre de 2014.

3. PRUEBAS

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

- D1: WO2011064111 publicada el 1 de mayo de 2003.

4. FUNDAMENTO DE DERECHO

Fundamento esta observación en las normas legales siguientes:

- 4.1. Artículo 45 de la Decisión 486 de la Comisión del Acuerdo de Cartagena.
- 4.2. 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 PROCAPS S.A.
 3. Recibo de caja del respectivo pago de tasa.
 4. Copias de los documentos:
- D1: WO2011064111 publicada el 1 de mayo de 2003.



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 N° 119-95, Of. 104 de esta ciudad de Bogotá.

Señor Superintendente,

ELIANA ISAURA MORENO BOHORQUEZ

C.C. 51'975.664 de Bogotá

T.P.A. 83823 del C.S. de la J.

ANEXO 1

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

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
3 June 2011 (03.06.2011)

PCT

(10) International Publication Number
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(30) Priority Data:

09176929.9 24 November 2009 (24.11.2009) EP
61/264,259 25 November 2009 (25.11.2009) US

(71) Applicant (for all designated States except US): BASF SE [DE/DE]; 67056 Ludwigshafen (DE).

(72) Inventors; and

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(74) Common Representative: BASF SE; 67056 Ludwigshafen (DE).

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

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: FILM-LIKE PHARMACEUTICAL DOSAGE FORMS

(57) Abstract: Film-like pharmaceutical dosage forms, comprising, as film formers, amphiphilic copolymers and one or more active substances.

WO 2011/064111 A1

Film-like pharmaceutical dosage forms

Description

- 5 The present invention relates to film-like pharmaceutical dosage forms based on amphiphilic copolymers as film formers.

The invention describes physiologically tolerated active substance-containing films for use in humans or animals.

10

The films can be used as plaster inlays and wound dressings and in particular also for oral administration.

- 15 In the case of film-like dosage forms which can be administered orally, also referred to as "oral strips", the higher permeability of the buccal mucosa in comparison with the skin can be utilized. Because of this and also because of possible circumventing of the first pass effects, it is also possible to realize higher absorption rates or higher bioavailabilities.

- 20 The major advantage of oral films in pharmacy is that they can readily be used both in pediatrics and in geriatrics. They can be readily metered and can generally be taken readily without additional liquid. Because of this, this novel drug form is particularly suitable for therapy in the case of difficulties in swallowing, nausea, attacks of dizziness and emotional disturbances.

25

Typically, polymers are used for producing films. As further additives, further polymers, active substances, plasticizers or aromas may also be added. Melt extrusion or the evaporation method are known and established as production methods according to the prior art. The following may be mentioned as examples here:

30 hydroxypropylmethylcellulose (hypromellose), hydroxypropylcellulose, starch and modified starch, pullulan, pectin, gelatin and carboxymethylcellulose (Dixit and Puthli, Journal of Controlled Release 139 (2009) 94-107).

- 35 The problem in the preparation of such film-like dosage forms consists however in the choice of a suitable base material for the films. This base material, which is intended to form the matrix of the film, must be readily processable to give films; furthermore, the active substance must be capable of being readily incorporated and, for reasons relating to drug safety, the film must have a high mechanical strength in combination with a good release profile for the active substance.

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A major disadvantage of the films known to date is that they have too low a dissolving power for active substances and the active substance is therefore present in crystalline

form, with the result that it has poor bioavailability. Moreover, a grainy sensation in the mouth may be produced thereby. Two-phase systems generally entail the problem of homogeneity and of uniformity of content. The flexibility, too, is frequently low, with the result that they can easily break or tear. The polymers known to date tend to be hydrophilic and, owing to their high glass transition temperature and high viscosity, are scarcely extrudable, extrudable only at high temperature or difficult to produce from solutions by knife coating. In the knife coating process, inhomogeneities and air inclusions frequently occur.

Amphiphilic copolymers, such as graft polymers, obtained by free radical polymerization of vinyl acetate and N-vinyl lactams in the presence of a polyether, are known per se.

WO 2007/051743 discloses the use of water-soluble or water-dispersible copolymers of N-vinyl lactam, vinyl acetate and polyethers, as solubilizers for pharmaceutical, cosmetic, food, agrotechnical or other technical applications. It is stated very generally therein that the corresponding graft polymers can also be processed in the melt with the active substances.

WO 2009/013202 discloses that such graft polymers of N-vinyl lactam, vinyl acetate and polyethers are melted in an extruder and mixed with pulverulent or liquid active substances and can be processed to give tablets.

It was an object of the present invention to provide improved film-like dosage forms which have advantages over the prior art with respect to production and handling of the films, mechanical strength and release behavior.

Accordingly, film-like dosage forms comprising, as a film former, an amphiphilic copolymer and one or more active substances and, if appropriate, further pharmaceutical excipients were found.

The film-like dosage forms may comprise the amphiphilic copolymers in amounts of from 1 to 100% by weight, preferably from 10 to 90% by weight, particularly preferably from 40 to 70% by weight, based on the total amount of pharmaceutical excipients.

The content of active substance depends on its effective dose per dosage form.

Suitable amphiphilic copolymers are in particular copolymers of polyethers, N-vinyl monomers and further vinyl monomers.

Copolymers which are obtained by free radical polymerization of vinyl acetate and N-vinyl lactams in the presence of a polyether are preferred.

Corresponding copolymers are obtained by free radical polymerization of a mixture of

- i) from 30 to 80% by weight of N-vinyl lactam,
- ii) from 10 to 50% by weight of vinyl acetate and
- 5 iii) from 10 to 50% by weight of a polyether,

with the proviso that the sum of i), ii) and iii) is equal to 100% by weight.

According to an embodiment of the invention, preferred copolymers, obtainable from:

10

- i) from 30 to 70% by weight of N-vinyl lactam
- ii) from 15 to 35% by weight of vinyl acetate and
- iii) from 10 to 35% by weight of a polyether, are used.

15 Particularly preferably used copolymers are obtainable from:

- i) from 40 to 60% by weight of N-vinyl lactam
- ii) from 15 to 35% by weight of vinyl acetate and
- iii) from 10 to 30% by weight of a polyether.

20

Very particularly preferably used copolymers are obtainable from

- i) from 50 to 60% by weight of N-vinyl lactam
- ii) from 25 to 35% by weight of vinyl acetate and
- 25 iii) from 10 to 20% by weight of a polyether.

The proviso that the sum of the components i), ii) and iii) is equal to 100% by weight is also true for the preferred and particularly preferred compositions.

30 N-vinyl caprolactam or N-vinyl pyrrolidone or mixtures thereof are suitable as the N-vinyl lactam. N-vinyl caprolactam is preferably used.

Accordingly, an amphiphilic copolymer of N-vinyl caprolactam, vinyl acetate and polyether is particularly preferred.

35

Polyethers serve as the grafting base. Suitable polyethers are preferably polyalkylene glycols. The polyalkylene glycols may have molecular weights of from 1000 to 100 000 Da [Dalton], preferably from 1500 to 35 000 Da, particularly preferably from 1500 to 10 000 Da. The molecular weights are determined starting from the OH

40 number measured according to DIN 53240.

Particularly preferred polyalkylene glycols are polyethylene glycols. Furthermore,

polypropylene glycols, polytetrahydrofurans or polybutylene glycols, which are obtained from 2-ethyloxirane or 2,3-dimethyloxirane, are also suitable.

5 Suitable polyethers are also random or block copolymers of polyalkylene glycols obtained from ethylene oxide, propylene oxide and butylene oxides, such as, for example, polyethylene glycol-polypropylene glycol block copolymers. The block copolymers may be of the AB or of ABA type.

10 The preferred polyalkylene glycols also include those which are alkylated at one terminal OH group or at both terminal OH groups. Suitable alkyl radicals are branched or straight-chain C₁- to C₂₂-alkyl radicals, preferably C₁-C₁₈-alkyl radicals, for example methyl, ethyl, n-butyl, isobutyl, pentyl, hexyl, octyl, nonyl, decyl, dodecyl, tridecyl or octadecyl radicals.

15 General processes for the preparation of the copolymers used according to the invention are known per se. The preparation is effected by free radical polymerization, preferably in solution, in nonaqueous, organic solvents or in mixed nonaqueous/aqueous solvents. Suitable preparation processes are described, for example, in WO 2007/051743 and WO 2009/013202, the disclosure of which with
20 regard to the preparation process is hereby incorporated by reference.

According to an embodiment of the invention, the film-like dosage forms are obtained by melt extrusion. In the melt extrusion, all of the ingredients (active substance, polymer, additives) are melted together with the aid of a melt extruder and extruded via
25 a slot die. After cooling, the resulting film can be cut into the suitable final size. A particular embodiment of the melt extrusion is designed so that extrusion is effected by means of a round or slot die and a calender having at least two rolls is loaded with the resulting extrudate. A homogeneous film leaves the calender. Usually, oral films are from 20 to 1000 µm, preferably 50-500 µm, thick. The active substance is present
30 either finely suspended in crystalline or amorphous form or dissolved in the final film, the suspension representing by far the most frequent case.

According to a further embodiment of the invention, a suitable production method is evaporation. Here, the film-forming polymer, active substance and further additives are
35 dissolved in a common solvent. Possible solvents are water or organic solvents, for example alcohols, such as ethanol, n-propanol, isopropanol, ketones, such as acetone, esters, such as ethyl acetate, butyl acetate, hydrocarbons, amides, such as dimethylacetamide, dimethylformamide. These solvents can be mixed with one another or with water in weight ratios which can be chosen according to requirements.

40 Ethanol/water are preferred as a solvent.

The concentration of the solutions can be chosen freely within wide ranges and depends on the solubility of the components. In order to achieve sufficient film

formation, however, preferably at least 1 to 40% by weight of film formers should be present.

5 The solution is usually mixed for a sufficient time and introduced into film molds (special rubber mats). In the next step, the solvent is removed. This is typically effected in a vacuum drying oven. The resulting films can then be removed from the molds and already have their final shape. This method of processing frequently manages without an additional cutting step.

10 The films can be also be drawn on Teflon sheets with a similar effort. However, the evaporation method can also be used in a continuous process. For this purpose, the polymer solution is applied to drying drums in a thin layer, dried by means of the energy of the drum and/or additional drying air and detached directly from the drum. This film must subsequently be cut into appropriate pieces. Instead of drum drying, the
15 polymer solution can also be applied in a thin layer to a substrate sheet, which then passes through a heating tunnel for drying. Thereafter, the film with or without substrate sheet is cut into pieces.

In a particular embodiment, the films may be designed with a plurality of layers. As a result, incompatible components can be separated from one another and different
20 active substance releases, higher adhesive power or different sensations of flavor can be achieved.

The films are usually packed either in multidose containers with up to 100 films or individual packaging.

25 The use of the amphiphilic polymers for film production has substantial advantages over conventional film-forming polymers, owing to the ability to form solid solutions. Surprisingly, the amphiphilic polymer is completely neutral in taste and therefore also ideally suitable for aroma-free films.

30 The following additives can be added as further pharmaceutical excipients to the film in order to achieve certain properties:

Further polymers, active substances, plasticizers, colorants, antioxidants, emulsifiers, surfactants, stabilizers, preservatives, fillers, gel formers, sweeteners, acidifying
35 agents, lubricants or aromas or mixtures thereof.

The use of microcrystalline cellulose can increase the decomposition rate. Further additives which can shorten the decomposition time are polyvinylpyrrolidones or vinylpyrrolidone copolymers, such as copovidone.
40

Further polymers which can be used are polyvinyl alcohols, polyvinyl alcohol-polyethylene glycol graft copolymer (commercially available as Kollicoat® IR, from

BASF), polyethylene glycols, poloxamers, pullulan, starch and also modified starches, gelatin, hydroxyalkylated cellulose derivatives, carboxyalkylated cellulose derivatives or acrylic acid-methacrylic acid copolymers.

- 5 It is also possible to use mixtures of these polymers.

Furthermore, the films may also comprise disintegrants, such as crospovidone, croscarmellose, hydroxypropylcellulose having a low degree of substitution or crosslinked sodium carboxymethyl starch.

10

Mucoadhesive films, i.e. films which are intended for a relatively long residence time in the mouth, can likewise be produced. For this purpose, further polymers which have mucoadhesive properties are additionally incorporated. In particular, polycarbophil, polyacrylic acid, carrageenan, guar gum, alginates, xanthane, pectin, galactomannans, 15 chitosan and also cellulose ethers are suitable here. These additional polymers can be used in amounts of from 1 to 95% by weight, preferably from 2 to 70% by weight.

20

For prolonging the duration of action, the incorporation of retard polymers may also be advisable. Ethylcellulose, ethyl acrylate-methyl methacrylate copolymer, ethyl acrylate-methyl methacrylate-trimethylammoniummethyl methacrylate copolymer, polyvinyl acetate, and ethylene-vinyl acetate copolymers are particularly suitable for this purpose.

25

In order to improve the organoleptic properties of the oral films, it is possible, as already mentioned, to add flavor improvers in the form of aromas or other sweeteners.

30

Additives such as cyclodextrins or resins, which can be added to the polymers, are also flavor-masking. Surprisingly, in some cases the polymer alone is also sufficient for masking an unpleasant flavor of the active substance. This is possibly caused by the incorporation of the active substance in micelles of the amphiphilic polymer.

35

Saliva-influencing substances which are simultaneously also flavor-influencing can likewise be added, for example citric acid, tartaric acid, glucose, fructose, sucrose, mannitol, sorbitol, erythritol, isomalt, aspartame and saccharine. Typical concentrations are in the range of 1-20% by weight.

40

The addition of plasticizers (0-20% by weight) can improve the texture of the films, so that they are more readily extrudable or disintegrate more rapidly. Suitable additives here are in particular short- and medium-chain polyethylene glycols. It is also possible to use higher molecular polyethylene glycols. Furthermore, propylene glycols, glycerol and other polyols may be used. Surfactants too have particularly plasticizing properties with respect to polymers. The following may be mentioned in particular here: TPGS,

polysorbate 20, 40, 60, 80, Span 20, stearic acid or salts thereof, glyceryl monostearate, sorbitan laurate, sodium laurylsulfate, docusate sodium, poloxamers, ethoxylated castor oil, hydrogenated ethoxylated castor oil, macrogol fatty alcohol ethers, macrogol fatty acid esters, macrogol sorbitan fatty alcohol ethers, macrogol sorbitan fatty acid esters, lecithin.

The abovementioned amounts in % by weight of additional pharmaceutical excipients are based on the total formulation.

Color-imparting agents or in particular pigments can likewise be added in order to impart a corresponding color to the film.

One or more active substances may be incorporated. Usually 1-50% by weight, preferably 2-30% by weight, of active substance are incorporated into the formulation, it also being possible for the amounts to differ therefrom, depending on the activity of the active substance. The film-like dosage forms according to the invention can in principle be used for all active substances. Particularly readily water-soluble as well as very sparingly water-soluble active substances can be used.

According to the invention, in particular active substances which are suitable for applications in transdermal dosage forms, such as, for example, hormones or opioid analgesics, or which are particularly frequently used in geriatrics or pediatrics are processed.

Benzodiazepines, antihypertensives, vitamins, cytostatics - in particular taxol, anesthetics, neuroleptics, antidepressants, antiviral agents, such as, for example, anti-HIV agents, antibiotics, antimycotics, antidementives, fungicides, chemotherapeutics, urologicals, platelet aggregation inhibitors, sulfonamides, spasmolytics, hormones, immunoglobulins, sera, thyroid therapeutics, psychopharmaceuticals, anti-Parkinson agents and other antihyperkinetics, ophthalmologicals, neuropathy preparations, calcium metabolism regulators, muscle relaxants, lipid-lowering agents, liver therapeutics, coronary agents, cardiac agents, immunotherapeutics, regulatory peptides and their inhibitors, hypnotics, sedatives, gynecologicals, anti-gout agents, fibrinolytics, enzyme preparations and transport proteins, enzyme inhibitors, emetics, perfusion promoters, diuretics, diagnostics, corticoids, cholinergics, biliary therapeutics, antiasthmatics, bronchospasmolytics, beta-receptor blockers, calcium antagonists, ACE inhibitors, arteriosclerosis agents, anti-inflammatory agents, anticoagulants, antihypotensives, antihypoglycemics, antihypertensives, antifibrinolytics, antiepileptics, antiemetics, antidotes, antidiabetics, antiarrhythmics, antianemics, antiallergics, anthelmintics, analgesics, analeptics, aldosterone antagonists, weight-reducing agents may be mentioned as examples here.

In particular, the dosage forms according to the invention are suitable for the following

active substances:

- Nicotine, nitroglycerine and derivatives thereof, loperamide (antidiarrheal agent), flurazepam (anxiolytic agent), famotidine (antacid), dicyclomine (muscle relaxant),
 5 ketoprofen (cox inhibitor).

Antimicrobial substances, such as chlorhexidine gluconate, PVP-iodine, cetylpyridinium chloride, benzalkonium chloride, antibiotics.

Cortisones, such as hydrocortisone, betamethasone, dexamethasone.

- 10 Antihistamine agents, such as loratadine, desloratadine, cetirizine, acrivastine, diphenhydramine, diphenhydramine hydrochloride, azatidine maleate, chlorpherinamine, chlorpherinamine maleate, tirolidine hydrochloride

- Prazoles such as omeprazole, pantoprazole, lansoprazole. Triptans, such as
 15 zolmitriptan, sumatriptan succinate, almotriptan, eletriptan. Opioids, such as oxycodone.

- The films obtained according to the invention can, as mentioned, be used as oral forms, in particular as forms rapidly decomposing in the oral cavity or in the pharynx, or
 20 as transdermal forms. Transdermal systems can be designed as matrix- or membrane-controlled forms. Here, the matrix systems may have a one-layer or multilayer structure, it being necessary for the layer resting on the skin to be tacky. This tack can be achieved by the use of known tacky polymers, such as polyisobutylene, acrylate-methacrylate polymers or silicone adhesives having very low glass transitions
 25 temperatures (less than 10°C) or by the use of relatively large amounts of plasticizer. Transdermal systems usually have a backing layer and a release liner. The release liner is peeled off prior to application to the skin, and the backing layer forms the sealing layer of the system and ensures that the back is not tacky but has an attractive appearance and is occlusive.

- 30 The amphiphilic copolymers have substantial advantages over the prior art for these intended uses.

- In the melt extrusion process, this class of compounds has advantages owing to their
 35 outstanding extrudibility because of their comparatively low glass transition temperature < 100°C. Conventional polymers for film formation have glass transition temperature of > 100°C (for example hydroxypropylmethylcellulose/HPMC or hydroxypropylcellulose/HPC, alginates, carrageenan). Because even particularly sparingly soluble active substances can be dissolved in the molecular state in the polymer, this
 40 invention permits access to a completely novel dosage form for many active substances.

In the evaporation process, also referred to as "film casting", the amphiphilic polymer shows further strengths. Because even particularly sparingly soluble active substances are dissolved in the polymer, it is also not possible for sedimentation to occur during the drying phase in the polymer. Thus, active substance films comprising the
5 amphiphilic polymer are distinguished in that they show particularly good content uniformity. With the use of conventional hydrophilic polymers for the evaporation method, the suspended active substance particles separate out so that inhomogeneous active substance distributions in the film result.

10 Oral films can be formulated in such a way that they disintegrate rapidly after being taken into the oral cavity. However, the films can also be formulated by means of special additives so that they are mucoadhesive and remain for a relatively long time in the oral cavity and release the active substance. In this way, sustained release of the active substance can be ensured.

15

Examples

Films were produced by means of either melt extrusion or evaporation.

20 The melt extrusion was effected in a two-screw extruder, screw diameter 16 mm, a length-to-diameter ratio of 40, and at 200 rpm screw speed. Extrusion was effected by means of a slot die having the dimensions 3 cm × 0.5 mm. The film thickness can be adjusted by stretching the still soft film on a rotating belt or by 2 calender rolls which have an appropriate spacing.

25 A polyvinylcaprolactam-polyvinyl acetate-polyethylene glycol graft polymer commercially available under the name Soluplus® (from BASF) and having an average molecular weight M_w (determined by gel permeation chromatography) of from 90 000 to 140 000 g/mol, referred to below as "polymer", was used as the film-forming amphiphilic copolymer.

30

General method for the production of the films

35 The products of the evaporation were produced using sufficient solvent (1:1 ethanol/water mixtures). The pulverulent substances were completely dissolved in the solvent with stirring. The liquid was poured into special rubber mats. Drying was effected in a vacuum drying oven for 5 h at 30°C. The resulting film was suitably cut.

For dissolution of the film, USP (US Pharmacopoeia) apparatus 2 (paddle method), 37°C, 900 ml of 0.08 N-HCl, 75 rpm (BTWS 600, Pharmatest) was used.

40 For this purpose, the film was clamped in a slide frame (35 × 23 mm) and immersed in a release apparatus by means of a special apparatus. The orientation of the slide frame was radial and the distance to the liquid surface was 3 cm.

The time which was required until the film had the first hole (initial dissolution time) or had completely dissolved (complete dissolution time) was measured.

5 The film thickness was determined by means of a layer thickness measuring apparatus (Minitest 600BFN2). The elongation at break of the films was measured according to DIN 53504. The films were stored for 24 hours at 25°C and 54% relative humidity before the measurement.

Abbreviation: DE water = demineralized water

10

Example 1

1200 g of polymer and 300 g of famotidine (melting point 163°C) were weighed into a Turbula mixing container and mixed for 10 minutes in the T10B Turbula mixer.

15

The mixture was extruded under the following conditions:

- zone temperature of 1st cylinder: 20°C; 2nd cylinder: 40°C
- zone temperature from 3rd cylinder onward: 160°C
- 20 • screw speed 200 rpm
- throughput: 300 g/h

The resulting film had a thickness of 80 µm and exhibited an elongation at break of 26%. The initial dissolution time in DE water was 20 seconds. The elongation at break is the percentage increase in length on tearing of film defined in the DIN standard.

25

Example 2

1200 g of polymer, 10 g of docusate sodium and 300 g of loperamide (melting point 222°C) were weighed into a Turbula mixing container and mixed for 10 minutes in the T10B Turbula mixer.

30

The mixture was extruded under the following conditions:

- 35 • zone temperature of 1st cylinder: 20°C; 2nd cylinder: 40°C
- zone temperature from 3rd cylinder onward: 180°C
- screw speed 200 rpm
- throughput: 200 g/h

40 The resulting film had a thickness of 88 µm and exhibited an elongation at break of 22%. The initial dissolution time in DE water was 23 seconds.

Example 3

1200 g of polymer and 300 g of cetirizine (melting point 115°C) were weighed into a
5 Turbula mixing container and mixed for 10 minutes in the T10B Turbula mixer.

The mixture was extruded under the following conditions:

- zone temperature of 1st cylinder: 20°C; 2nd cylinder: 40°C
- 10 • zone temperature from 3rd cylinder onward: 110°C
- screw speed 200 rpm
- throughput: 400 g/h

The resulting film had a thickness of 79 µm and exhibited an elongation at break of
15 57%. The initial dissolution time in DE water was 21 seconds.

Example 4

1000 g of polymer and 250 g of ketoprofen (melting point 94°C) were weighed into a
20 Turbula mixing container and mixed for 10 minutes in the T10B Turbula mixer.

The mixture was extruded under the following conditions:

- zone temperature of 1st cylinder: 20°C; 2nd cylinder: 40°C
- 25 • zone temperature from 3rd cylinder onward: 100°C
- screw speed 200 rpm
- throughput: 600 g/h

The resulting film had a thickness of 119 µm and exhibited an elongation at break of
30 53%. The initial dissolution time in DE water was 34 seconds.

Example 5

1100 g of polymer, 400 g of Kollidon VA 64, 100 g of PEG 1500 and 200 g of
35 itraconazole (melting point 166°C) were weighed into a Turbula mixing container and
mixed for 10 minutes in the T10B Turbula mixer.

The mixture was extruded under the following conditions:

- 40 • zone temperature of 1st cylinder: 20°C; 2nd cylinder: 40°C

- zone temperature from 3rd cylinder onward: 130°C
- screw speed 200 rpm
- throughput: 300 g/h

- 5 The resulting film had a thickness of 94 µm and exhibited an elongation at break of 31%. The initial dissolution time in DE water was 120 seconds.

Example 6

- 10 1000 g of polymer, 200 g of Kollidon 30, 100 g of polyethylene glycol 1500 and 200 g of naproxen (melting point 157°C) were weighed into a Turbula mixing container and mixed for 10 minutes in the T10B Turbula mixer.

The mixture was extruded under the following conditions:

15

- zone temperature of 1st cylinder: 20°C; 2nd cylinder: 40°C
- zone temperature from 3rd cylinder onward: 160°C
- screw speed 200 rpm
- throughput: 600 g/h

20

The resulting film had a thickness of 140 µm and exhibited an elongation at break of 24%. The initial dissolution time in DE water was 48 seconds.

- 25 Example 7

1000 g of polymer, 100 g of Kollidon CL-M and 300 g of cinnarizine (melting point 122°C) were weighed into a Turbula mixing container and mixed for 10 minutes in the T10B Turbula mixer.

30

The mixture was extruded under the following conditions:

- zone temperature of 1st cylinder: 20°C; 2nd cylinder: 40°C
- zone temperature from 3rd cylinder onward: 130°C
- 35 • screw speed 200 rpm
- throughput: 600 g/h

The resulting film had a thickness of 170 µm and exhibited an elongation at break of 25%. The initial dissolution time in DE water was 50 seconds.

40

Example 8

1000 g of polymer and 10 g of cetylpyridinium chloride were extruded to give a film having a film thickness of 53 μm .

5

The mixture was extruded under the following conditions:

- zone temperature of 1st cylinder: 20°C; 2nd cylinder: 40°C
- zone temperature from 3rd cylinder onward: 130°C
- 10 • screw speed 200 rpm
- throughput: 600g/h

The resulting film exhibited an elongation at break of 50%. The initial dissolution time in DE water was 15 seconds. 138 seconds were required for complete dissolution of the film.

15

Example 9

1000 g of polymer and 50g of desloratadine were extruded without further additions to give a film having a film thickness of 170 μm .

20

The mixture was extruded under the following conditions:

- zone temperature of 1st cylinder: 20°C; 2nd cylinder: 40°C
- 25 • zone temperature from 3rd cylinder onward: 130°C
- screw speed 200 rpm
- throughput: 600g/h

The resulting film exhibited an elongation at break of 43%. The initial dissolution time in DE water was 140 seconds. 990 seconds were required for complete dissolution of the film.

30

Example 10

35 5 g of polymer and 2 g of felodipine were dissolved in 40 ml of ethanol and drawn to give a film. After drying, a thin film having a film thickness of 37 μm was obtained.

The measured elongation at break of the film was 49%. The initial dissolution time in DE water was 10 seconds. 65 seconds were required for complete dissolution of the film.

40

Example 11

4 g of polymer, 1.5 g of famotidine and 0.1 g of saccharine sodium were dissolved in 30 ml of ethanol and drawn to give a film. After drying, a thin film having a film thickness of 40 μm was obtained.

The measured elongation at break of the film was 46%. The initial dissolution time in DE water was 12 seconds. 69 seconds were required for complete dissolution of the film.

10

Example 12

6 g of polymer and 2.2 g of cinnarizine were dissolved in 30 ml of isopropanol and drawn to give a film. After drying, a thin film having a film thickness of 52 μm was obtained.

The measured elongation at break of the film was 47%. The initial dissolution time in DE water was 11 seconds. 62 seconds were required for complete dissolution of the film.

20 Example 13

6 g of polymer, 2 g of PEG 400 and 1.2 g of felodipine were dissolved in 30 ml of ethanol and drawn. After drying, a thin film having a film thickness of 57 μm was obtained.

The measured elongation at break of the film was 64%. The complete dissolution time in DE water was 10 seconds.

Example 14

5 g of polymer, 1.5 g of PEG 1500, 0.1 g of aspartame and 1.0 g of loratadine were dissolved in 20 ml of isopropanol and 10 ml of dimethylacetamide and drawn. After drying, under reduced pressure a thin film having a film thickness of 44 μm was obtained.

The measured elongation at break of the film was 51%. The initial dissolution time in DE water was 10 seconds. 71 seconds were required for complete dissolution of the film.

Example 15

3 g of polymer, 2 g of HPMC, 1.0 g of triethyl citrate, 0.1 g of riboflavin and 2.2 g of famotidine were dissolved in 30 ml of ethanol and drawn to give a film. After drying, a thin film having a film thickness of 48 μm was obtained.

The measured elongation at break of the film was 37%. The initial dissolution time in DE water was 11 seconds. The complete dissolution in DE water took place after 70 seconds.

5 Example 16

3 g of polymer, 2 g of HPC, 0.1 g of tartaric acid and 2 g of loperamide were dissolved in 20 ml of ethanol and 10 ml of dimethylformamide and drawn to give a film. After drying, a thin film having a film thickness in the range of 42 μm was obtained.

- 10 The measured elongation at break of the film was 39%. The initial dissolution time in DE water was 10 seconds. The complete dissolution in DE water took place after 69 seconds.

Example 17

15

2 g of polymer, 2 g of polyvinyl alcohol-polyethylene glycol graft copolymer (Kollicoat IR) and 0.5 g of chlorhexidine gluconate were dissolved in 20 ml of water and drawn to give a film. After drying, a thin film having a film thickness of 45 μm was obtained.

- 20 The measured elongation at break of the film was 71%. The initial dissolution time in DE water was 9 seconds. The complete dissolution in DE water took place after 51 seconds.

We claim:

- 5 1. A film-like pharmaceutical dosage form comprising, as film formers, amphiphilic copolymers and one or more active substances.
2. The dosage form according to claim 1, comprising, as film formers, amphiphilic copolymers of polyethers, N-vinyl monomers and further vinyl monomers.
- 10 3. The dosage form according to claim 1 or 2, comprising, as film formers, copolymers which are obtained by free radical polymerization of vinyl acetate and N-vinyl lactams in the presence of a polyether.
- 15 4. The dosage form according to any of claims 1 to 3, comprising, as film formers, amphiphilic copolymers which are obtained by free radical polymerization of a mixture of i) from 30 to 80% by weight of N-vinyl lactam, ii) from 10 to 50% by weight of vinyl acetate and iii) from 10 to 50% by weight of a polyether, with the proviso that the sum of i), ii) and iii) is equal to 100% by weight.
- 20 5. The dosage form according to any of claims 1 to 4, comprising, as a film former, a copolymer of N-vinyl caprolactam, vinyl acetate and a polyether.
6. The dosage form according to any of claims 1 to 5, comprising, as film formers, amphiphilic copolymers in amounts of from 1 to 100% by weight, based on the
25 total amount of pharmaceutical excipients.
7. The dosage form according to any of claims 1 to 6, comprising, as film formers, amphiphilic copolymers in amounts of from 10 to 90% by weight, based on the
30 total amount of pharmaceutical excipients.
8. The dosage form according to any of claims 1 to 7, comprising, as film formers, amphiphilic copolymers in amounts of from 40 to 70% by weight, based on the
total amount of pharmaceutical excipients.
- 35 9. The dosage form according to any of claims 1 to 8, comprising, as further pharmaceutical excipients, further polymers, active substances, plasticizers, colorants, antioxidants, emulsifiers, surfactants, stabilizers, preservatives, fillers, gel formers, sweeteners, acidifying agents, lubricants or aromas or mixtures thereof.
- 40 10. The dosage form according to any of claims 1 to 9, comprising, as further polymers, povidone, copovidone, polyvinyl alcohols, polyvinyl alcohol-

24.08.2010 Gd/Ya

polyethylene glycol graft copolymers, polyethylene glycols, poloxamers, pullulan, starch, modified starches, gelatin, hydroxyalkylated cellulose derivatives, carboxyalkylated cellulose derivatives, acrylic acid-methacrylic acid copolymers or mixtures thereof.

5

11. The dosage form according to any of claims 1 to 10, comprising disintegrants.

10

12. The dosage form according to any of claims 1 to 11, comprising mucoadhesive polymers from the group consisting of polycarbophil, polyacrylic acid, carrageenan, guar gum, alginates, galactomannans, pectins, chitosan and cellulose ethers.

15

13. The dosage form according to any of claims 1 to 12, comprising from 0.1 to 50% by weight, based on the total formulation, of active substance.

14. A process for the preparation of film-like dosage forms according to any of claims 1 to 13, wherein film formers, active substances and, if appropriate, further excipients are mixed and the mixture is shaped into a film.

20

15. The process according to claim 14, wherein the shaping is effected by melt extrusion.

25

16. The process according to claim 14, wherein film formers, active substances and, if appropriate, further excipients are mixed in solution, the solution is drawn to give a film and a film forms as a result of evaporation of the solvent.

17. The process according to claim 16, wherein water, alcohols, ketones, esters, hydrocarbons, amides or mixtures thereof are used as the solvent.



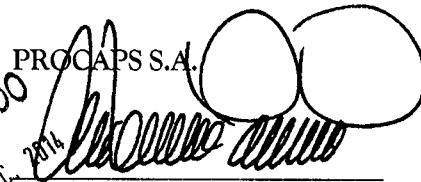
PODER ESPECIAL

Yo, **WALTER TANAKA TATEKAWA**, 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 **PROCAPS 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. 14.086.039, titulada "FORMULACIONES BASADAS EN DISPERSIONES SOLIDAS", cuyo titular es **ABBVIE DEUTSCHLAND GMBH & CO. KG.** publicada en la gaceta No. 707 del 30 de septiembre de 2014.

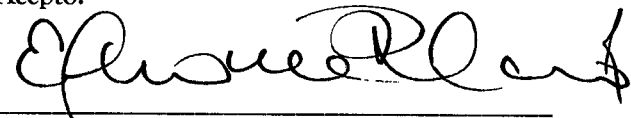
Nuestro apoderado queda facultado, de manera expresa, para realizar todo tipo de actos necesarios para llevar a cabo el trámite de la oposición, incluyendo, sin limitación, preparar y presentar solicitudes, hacer declaraciones, pagar tasas, contribuciones e impuestos, recabar los títulos o certificados. Asimismo quedan autorizados para impugnar administrativamente 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 2 días del mes de Diciembre de 2014.


PROCAPS S.A.
APROBADO
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C.C. 16'251.923
NIT: 890.106.527-5
Representante Legal

Acepto:


ELIANA ISAURA MORENO BOHÓRQUEZ
C.C. 51.975.664
T.P. 83823 del C.S.J

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

Referencia : Expediente N° 14-86039
 Asunto : Oposición a la solicitud de patente de Invención titulada
 "FORMULACIONES BASADAS EN DISPERSIONES SOLIDAS"
 Solicitante : ABBVIE DEUTSCHLAND GMBH & CO. KG.
 Opositora : PROCAPS S.A.

Publicada en la Gaceta de la Propiedad Industrial
 N° 707 del 30 de septiembre de 2014

Yo, *ELIANA ISAURA MORENO BOHÓRQUEZ*, abogada en ejercicio, identificada como aparece al pie de su firma, con tarjeta profesional No. 83823 del Consejo Superior de la Judicatura, en mi condición de apoderada de la sociedad **PROCAPS 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 *"FORMULACIONES BASADAS EN DISPERSIONES SOLIDAS"*, cuyo titular **ABBVIE DEUTSCHLAND GMBH & CO. KG.**, y pido a Usted declarar fundada esta oposición y en consecuencia negar el registro de la patente solicitada.

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 legítimo 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 *Acido fenofibrico HME*. 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 23 de abril de 2014, reivindicando prioridad bajo las solicitudes EP20110182792 del 2011-09-26; y fue publicada en Colombia, en la Gaceta de la Propiedad Industrial N° 707 del 30 de septiembre de 2014, cuya publicación internacional corresponde a la WO2013045365 del 2013-04-04.

2.2. La solicitud colombiana 14-86039 objeto de la presente oposición se refiere a formulaciones que comprenden un producto disperso sólido compuesto por un agente activo que comprende al menos una unidad que puede operar como donante de enlaces de hidrógeno o una unidad que puede operar como donante de protones y un copolímero injertado de unidades de N-vinil lactama de polivinilo y polivinilacetato de poli(alquilenglicol) farmacéuticamente aceptable. También se refiere a métodos apropiados para preparar formulaciones como las que se han descrito.

2.3. 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: WO2011064111 publicada el 1 de mayo de 2003.

2.4. Ahora bien, el documento D1, se refiere a formas de película farmacéuticas de dosificación, que comprenden, como formadores de película, copolímeros anfífilos y una o más sustancias activas. Este documento D1 se refiere a una forma

de dosificación que comprende, como formadores de película, copolímeros que se obtienen por polimerización de radicales libres de acetato de vinilo y N-vinil-lactamas en presencia de un poliéter y como formadores de película, copolímeros anfífilos que se obtienen por polimerización de radicales libres de una mezcla de i) de 30 a 80% en peso de N-vinil-lactama, ii) de 10 a 50% en peso de acetato de vinilo y iii) de 10 a 50% en peso de un poliéter, con la condición de que la suma de i), ii) y iii) es igual a 100% en peso. Igualmente D1 se refiere a que el formador de película es un copolímero de N-vinilcaprolactama, acetato de vinilo y un poliéter en cantidades de 1 a 100% en peso, basado en la cantidad total de excipientes farmacéuticos y que comprende otros polímeros, sustancias activas, plastificantes, colorantes, antioxidantes, emulsionantes, agentes tensioactivos, estabilizantes, conservantes, cargas, formadores de gel, edulcorantes, acidificantes, agentes lubricantes o aromas o mezclas de los mismos. Particularmente, D1 define ingredientes activos que comprenden restos de enlaces de hidrógeno donantes (por ejemplo, grupos amino, grupos hidroxilo, etc.) o restos donantes de protones (por ejemplo, ácidos, grupos ácidos CH), véase por ejemplo la lista de la página 7 y 8 de D1. Estas dispersiones sólidas también contienen ingredientes que modifican el pH en solución acuosa (característica (c) de la presente reivindicación 1). Igualmente, D1 revela que las películas poliméricas que contienen los ingredientes activos pueden contener adicionalmente agentes acidificantes (página 5 líneas 34 y 35). Por su parte, los ejemplos 2 y 16 de D1 revelan loperamida que tiene un grupo OH en la molécula y solubilidad en agua. El ejemplo 2 de D1 contiene docusato de sodio y el ejemplo 16 ácido tartárico, ambos de los cuales influirán en el pH. El Ejemplo 6 de D1 describe una composición que comprende naproxeno y Kollidon 30. Kollidon contiene grupos pirrolidona que tienen un nitrógeno básico y influirán en el pH. D1, por lo tanto, también contiene revelaciones específicas de la combinación reivindicada en la presente solicitud. D1 también describe los procesos de extrusión por fusión en caliente (página 4). Como se evidencia, esta anterioridad define la misma materia que comprende la presente solicitud. Por lo tanto, este documento objeto de oposición a la luz del documento D1 carece evidentemente de NOVEDAD.

2.5. En consecuencia y de acuerdo a lo descrito anteriormente, se deriva que la solicitud colombiana 14-86039 no puede pretender un monopolio por patente toda vez que

lo que pretende no cumple con uno de los tres requisitos necesarios para su protección.

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

2.8.1 CARENCIA 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, el 26 de septiembre de 2011, ya era conocido, pues como se demostró, era parte del arte anterior con base en los documento D1, formulaciones que comprenden un producto disperso sólido compuesto por un agente activo que comprende al menos una unidad que puede operar como donante de enlaces de hidrógeno o una unidad que puede operar como donante de protones y un copolímero injertado de unidades de N-vinil lactama de polivinilo y polivinilacetato de poli(alquilenglicol) farmacéuticamente aceptable, sobre el cual busca protección en el capítulo reivindicatorio.

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 uno de los tres requisitos de patentabilidad.

2.10 Por todo lo anterior, atentamente solicito a usted que se sirva declarar fundada ***“FORMULACIONES BASADAS EN DISPERSIONES SOLIDAS”***, cuyo titular **ABBVIE DEUTSCHLAND GMBH & CO. KG.,,** solicitud Colombiana que apareció publicada en la Gaceta de la Propiedad Industrial N° 707 del 30 de septiembre de 2014.

3. PRUEBAS

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

- D1: WO2011064111 publicada el 1 de mayo de 2003.

4. FUNDAMENTO DE DERECHO

Fundamento esta observación en las normas legales siguientes:

- 4.1. Artículo 45 de la Decisión 486 de la Comisión del Acuerdo de Cartagena.
- 4.2. 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 PROCAPS S.A.
 3. Recibo de caja del respectivo pago de tasa.
 4. Copias de los documentos:
- D1: WO2011064111 publicada el 1 de mayo de 2003.

6. NOTIFICACIONES

Para efectos de notificaciones que 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 N° 119-95, Of. 104 de esta ciudad de Bogotá.

Señor director,

ELIANA ISAURA MORENO BOHÓRQUEZ

C.C. 51'975.664 de Bogotá

T.P.A. 83823 del C.S. de la J.