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Tra. 11 PATENTEIYII Eve: 378 FASENACIONALI
Act. 538 PETICION Folios: 2

216
216

Clarke, Modet & Cº

COLOMBIA

SEÑORES
DIVISIÓN DE NUEVAS CREACIONES
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
E. S. D.

REF: EXPEDIENTE No. 06-128.318
FECHA DE LA SOLICITUD: MARZO 28, 2006
SOLICITANTE: ID BIOMEDICAL CORPORATION
THE BRIGHAM AND WOMEN'S HOSPITAL, INC.

ASUNTO: SOLICITUD EXAMEN DE PATENTABILIDAD

DILIA RODRÍGUEZ D'ALEMAN identificada como aparece al pie de mi firma, domiciliada en Bogotá, en la Carrera 11 No. 86-53, piso 6, obrando como apoderada de la sociedad solicitante, pido a usted que se proceda a examinar si la invención, cuya patente se tramita en el expediente de la referencia, es patentable.

Adjunto al presente memorial el recibo No.08-43,853 de 4 de junio de 2008, por la suma de \$420.000.00, con lo cual queda cubierta la tasa oficial correspondiente a dicho estudio.

Señor Superintendente,

DILIA RODRIGUEZ D'ALEMAN
C.C. 41.654.882 de Bogotá
T.P. 20824 del C.S.J.

P-885 (3)

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 890176089-2

RECIBO OFICIAL DE CAJA : 08 - 43,853
FECHA : JUNIO 4 DE 2008

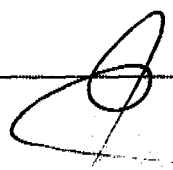
***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CLARKE MOBET Y CO. COLOMB	CONSIGNACION	BANCO DE BOGOTA	062754387	3418225	03/06/2008	39,390,000.00

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

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01	SOLICITUDES	
		85 EXAMEN DE PATENTABILIDAD DE INVEN	420,000.00
		TOTAL :	\$ 420,000.00

SON: CUATROCIENTOS VEINTE MIL PESOS

RESPONSABLE : 

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

2
P 885

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 06-128318

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCION**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **583** DE

FECHA **18 DE DICIEMBRE DE 2007** EL TÉRMINO HÁBIL SEÑALADO POR LA

LEY EXPIRA EL **14 DE MARZO DE 2008**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____

NO X

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61K 31/74, A01N 37/12, C08F 283/04, C08G 69/10, 69/48, C08L 77/00, 77/06		A1	(11) International Publication Number: WO 95/31990 (43) International Publication Date: 30 November 1995 (30.11.95)
(21) International Application Number: PCT/US95/06551 (22) International Filing Date: 23 May 1995 (23.05.95) (30) Priority Data: 08/248,037 24 May 1994 (24.05.94) US 08/344,248 23 November 1994 (23.11.94) US (71) Applicant (for all designated States except BB): YEDA RE- SEARCH AND DEVELOPMENT CO., LTD. [IL/IL]; P.O. Box 95, 76100 Rehovot (IL). (71) Applicant (for BB only): LEMMON COMPANY [US/US]; 650 Cathilli Road, Sellersville, PA 18960 (US). (72) Inventors: KONFINO, Eliezer; 14 Yosef Hagalili Street, 52416 Ramat Gan (IL). SELA, Michael; 2 Meonot Wix, Weizmann Institute of Science, 76100 Rehovot (IL). TEITELBAUM, Dvora; 5 Shkolnik Street, 76209 Rehovot (IL). ARNON, Ruth; 9 Meonot Shine, Weizmann Institute of Science, 76110 Rehovot (IL). (74) Agents: BRAINARD, Charles, R. et al.; Kenyon & Kenyon, One Broadway, New York, NY 10004 (US).		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG). Published With international search report.	
(54) Title: COPOLYMER-1 IMPROVEMENTS IN COMPOSITIONS OF COPOLYMERS			
(57) Abstract The present invention relates to an improved composition of copolymer-1 comprising copolymer-1 substantially free of species having a molecular weight of over 40 kilodaltons.			

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COPOLYMER-1IMPROVEMENTS IN COMPOSITIONS OF COPOLYMERS

This application is a continuation-in-part of U.S.S.N. 08/344,248, filed November 23, 1994, which is a
5 continuation of U.S.S.N. 08/248,037, filed May 24, 1994.

Background of the Invention

Copolymer-1 is a synthetic polypeptide analog of myelin basic protein (MBP), which is a natural component of the
10 myelin sheath. It has been suggested as a potential therapeutic agent for multiple sclerosis (Eur. J. Immunol. [1971] 1:242; and J. Neurol. Sci. [1977] 31:433). All references cited herein are hereby
incorporated by reference in their entirety. Interest in
15 copolymer-1 as an immunotherapy for multiple sclerosis stems from observations first made in the 1950's that myelin components such as MBP prevent or arrest experimental autoimmune encephalomyelitis (EAE). EAE is a disease resembling multiple sclerosis that can be
20 induced in susceptible animals.

Copolymer-1 was developed by Drs. Sela, Arnon, and their co-workers at the Weizmann Institute (Rehovot, Israel). It was shown to suppress EAE (Eur. J. Immunol. [1971] 1:242; U.S. Patent No. 3,849,550). More recently,
25 copolymer-1 was shown to be beneficial for patients with the exacerbating-remitting form of multiple sclerosis (N. Engl. J. Med. [1987] 317:408). Patients treated with daily injections of copolymer-1 had fewer exacerbations
30 and smaller increases in their disability status than the control patients.

Copolymer-1 is a mixture of polypeptides composed of alanine, glutamic acid, lysine, and tyrosine in a molar

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KDa or more. More preferably, the composition contains less than 2.5% of species of copolymer-1 having a molecular weight of 40 KDa, or more.

- 5 The invention further relates to a copolymer-1 having over 75% of its molar fraction within the molecular weight range from about 2 KDa to about 20 KDa.

In addition, the invention relates to a copolymer-1
10 having an average molecular weight of about 4 to about 8.6 KDa. In particular, the invention relates to a copolymer-1 having an average molecular weight of about 4 to about 8 KDa and a copolymer-1 having an average molecular weight of about 6.25 to about 8.4 KDa.

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— Copolymer-1, according to the present invention, may be prepared by methods known in the art, for example, the process disclosed in U.S. Patent 3,849,550, wherein the N-carboxyanhydrides of tyrosine, alanine, γ -benzyl
20 glutamate and E-N-trifluoro-acetyllysine are polymerised at ambient temperature in anhydrous dioxane with diethylamine as initiator. The deblocking of the γ -carboxyl group of the glutamic acid is effected by hydrogen bromide in glacial acetic acid and is followed
25 by the removal of the trifluoroacetyl groups from the lysine residues by 1M piperidine. For the purposes of the application, the terms "ambient temperature" and "room temperature" should be understood to mean a temperature ranging from about 20 to about 26 °C.

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The copolymer-1 with the required molecular weight profile can be obtained either by methods known per se. Such methods include chromatography of copolymer-1 containing high molecular weight species and collecting
35 the fractions without the undesired species or by partial acid or enzymatic hydrolysis to remove the high molecular weight species with subsequent purification by dialysis

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222CLAIMS

1. A copolymer-1 fraction substantially free of species of copolymer-1 having a molecular weight of over 40 kilodaltons.

2. A copolymer-1 fraction, wherein said fraction contains less than 5% of species of copolymer-1 having a molecular weight of over 40 kilodaltons.

3. The copolymer-1 fraction according to claim 2, wherein the fraction contains less than 2.5% of species of copolymer-1 having a molecular weight of over 40 kilodaltons.

4. The copolymer-1 fraction according to claim 2, wherein over 75% of said fraction is within a molecular weight range from about 2 kilodaltons to about 20 kilodaltons.

5. A copolymer-1 fraction, wherein said copolymer-1 has an average molecular weight of about 4 to about 8 kilodaltons.

6. A copolymer-1 fraction, wherein said copolymer-1 has an average molecular weight of about 6.25 to about 8.4 kilodaltons.

7. A composition for the treatment of multiple sclerosis, comprising
— a pharmaceutically effective amount of a copolymer-1 fraction, wherein said fraction contains less than 5% of species of copolymer-1 having a molecular weight of over 40 kilodaltons, and
— a pharmaceutically acceptable carrier.

8. The composition according to claim 7, wherein the

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copolymer-1 fraction contains less than 2.5% of species of copolymer-1 having a molecular weight of over 40 kilodaltons.

9. The composition according to claim 7, wherein over 75% of said copolymer-1 in said fraction is within a molecular weight range of about 2 kilodaltons to about 20 kilodaltons.

10. A composition for the treatment of multiple sclerosis, comprising

a pharmaceutically effective amount of a copolymer-1 fraction, wherein said copolymer-1 in said fraction has an average molecular weight of about 4 to about 8 kilodaltons, and

— a pharmaceutically acceptable carrier.

11. A composition for the treatment of multiple sclerosis, comprising

a pharmaceutically effective amount of a copolymer-1 fraction, wherein said copolymer-1 in said fraction has an average molecular weight of about 6.25 to about 8.4 kilodaltons, and

— a pharmaceutically acceptable carrier.

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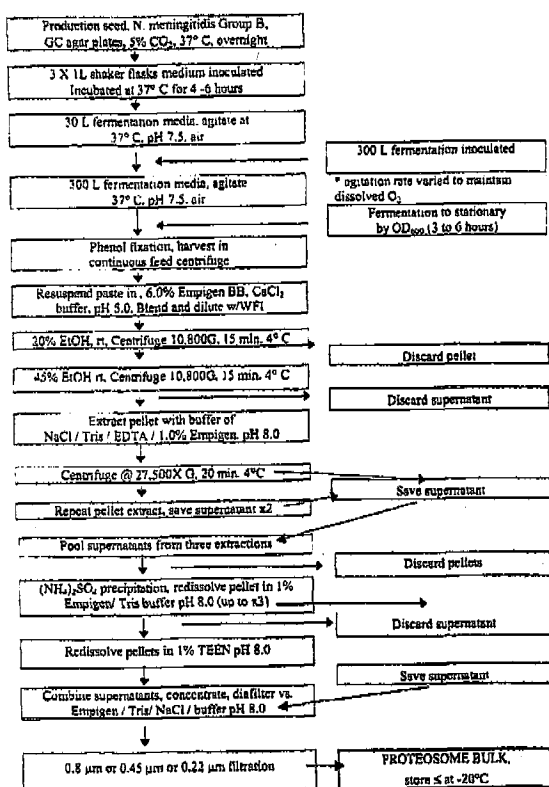
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WO 02/072012 A2

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- (21) International Application Number: PCT/US02/07108
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- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/274,232 9 March 2001 (09.03.2001) US
60/327,297 9 October 2001 (09.10.2001) US
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- (81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

[Continued on next page]

(54) Title: A NOVEL PROTEOSOME-LIPOSACCHARIDE VACCINE ADJUVANT

Manufacture of Proteosome Bulk Material: FLOW CHART 1A



(57) Abstract: An adjuvant complex composed of bacte-
rial outer membrane protein proteosomes complexed to bac-
terial liposaccharide is prepared to contain the component
parts under a variety of conditions. The complex can be for-
mulated with antigenic material to form immunogenic com-
positions, vaccines and immunotherapeutics. An induced
immune response includes protective antibodies and/or type
1 cytokines is shown for a variety of protocols.

WO 02/072012 A2

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A NOVEL PROTEOSOME-LIPOSACCHARIDE VACCINE ADJUVANT

FIELD OF INVENTION

- 5 — This invention relates to adjuvants for enhancing the immunogenicity and improvement of the immune response of antigens and to methods and compositions for preparing and using them.

10 BACKGROUND OF THE INVENTION

- The ability of antigens to induce protective immune responses in a host can be enhanced by combining the antigen with immunostimulants or adjuvants. Alum-based adjuvants are almost exclusively used for licensed injectable human vaccines, however, while alum enhances certain types of serum antibody responses (Type 2), it is poor at
- 15 enhancing other types of antibody responses (Type 1) and is a poor activator of cellular immune responses that are important for protection against intracellular pathogens and for therapeutic vaccines for cancer and allergy. Furthermore, alum enhances allergic reactions due to production of IgE. Although numerous substances have been tested and shown to be potent adjuvants for antibody and cellular (Type 1) immune responses in animal models,
- 20 very few have proved to be suitable for use in humans due to unacceptable levels of reactogenicity and/or disappointing immuno-enhancing abilities. Furthermore, there are currently no licensed adjuvants capable of enhancing immune responses at mucosal surfaces where the majority of infectious agents enter the host. Indeed, development of the most promising nasally delivered mucosal adjuvants, the bacterial enterotoxins (e.g.
- 25 mutated cholera and heat-labile toxins), have been halted in North America due to their ability to be transported to, and cause inflammation in the olfactory bulb region of the CNS of rodents. There is a need for potent adjuvants that are safe in humans and capable of inducing protective systemic and mucosal humoral and cellular immune responses.

- 30 Lipopolysaccharides (LPS) from gram negative bacteria are potent adjuvants. LPS activates the innate immune system causing production of inflammatory cytokines such as

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5 solution (e.g. Empigen BB, Triton X-100, and/or Mega-10) and then effecting complexing of the components while removing detergent by dialysis or, preferably, by diafiltration / ultrafiltration methodologies. Mixing, co-precipitation and/or lyophilization of the two components may also be used to effect adequate complexing or association.

10 The end result of the process is the production of an adjuvant that when administered together with antigens forms an adjuvanted vaccine or immunotherapeutic that can be delivered by a mucosal route (such as nasal, oral, oropharyngeal, ocular, genitourinary mucosal including vaginal, sublingual, intrapulmonary, intratracheal or rectal) or a parenteral route (such as intramuscular, subcutaneous, intravenous, intraperitoneal, 15 submucosal, intradermal) or a transdermal, topical or transmucosal route to induce enhanced levels of serum and/or mucosal antibodies and/or type 1 cellular immune responses against the antigen compared with the antigen alone given by the same routes. In the following examples, mixtures containing proteosome-LPS (using LPS from either Shigella or Plesiomonas or Escherichia or Salmonella) and a mono or multivalent split or 20 purified recombinant influenza antigen and delivered by liquid or spray or by injection as an adjuvanted influenza vaccine induced specific anti-influenza immune responses including, for example one or more of the following: a) serum IgG antibodies or serum antibodies measured in functional assays including, but not limited to, hemagglutination inhibition (HAI) antibodies; it is noted that HAI responses are significant since their 25 induction is known to correlate with protection against influenza in humans; b) mucosal antibodies including IgA in mucosal secretions collected from the respiratory, gastrointestinal or genitourinary tracts including, but not limited to the nasopharynx, lungs and vagina and c) correlates of cell-mediated immunity (CMI) including the switch or decrease from higher or predominant type 2 responses to result in mixed, balanced, 30 increased or predominant type 1 responses, for example, as measured by the induction of cytokines such as IFN- γ without comparable increases in induction of certain type 2 cytokines such as IL-5 whose levels may, for example, be maintained, decreased, or absent. Such Type 1 responses are predictive of the induction of other CMI associated responses such as development of cytotoxic T cells (CTLs) indicative of Th1 immunity.

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5 specific serum IgG compared with the allergen alone, and a reduction in Bet v 1a-specific serum IgE compared with allergen administered with aluminum phosphate, a depot and Type 2 adjuvant known to sensitize mice for allergic responses against an allergen. Importantly, the increase in the type 1 cytokine, IFN γ was also observed following the immunization of allergic mice with the same allergen given with IVX-908. The pre-
10 allergic state of the mice mimics the situation in allergic humans, suggesting that IVX-908/allergen formulations may be candidates for therapeutic allergy vaccines.

It is noted that the instant invention can readily adjuvant vaccines containing single, monovalent or multi-component antigens such as peptides, proteins, toxoids,
15 glycoproteins, glycolipids, carbohydrates and/or polysaccharides, isolated from biologic organisms of the animal or plant kingdom that may be infectious organisms, such as parasites, viruses and bacteria, or may be extracts or purified or chemically modified extracts of allergens derived from unicellular or multicellular organisms or may be chemical material. It is also envisioned that whole or disrupted microorganisms including
20 viruses, bacteria or parasites, attenuated or inactivated could be used as antigen. These materials may also be produced by synthetic or recombinant molecular procedures to induce immunity to and protect against several strains of a particular organism or multiple organisms or disease-causing agents or against allergies, cancer or auto-immune diseases. The utility in human and veterinary fields is proposed. Furthermore, the invention can be
25 used to enhance immunity when given together with the antigen as an adjuvanted vaccine or immunotherapeutic as priming or boosting immunizations prior to or subsequent to administering the antigen (by mucosal or parenteral routes) without the instant invention.

For parenteral, nasal, oral or suppository use, the adjuvant may be given together
30 with amounts of a variety of excipients or other adjuvants including oils, emulsions, nano-emulsions, fats, waxes, buffers, or sugars, as diluents or vehicles customary in the art to provide stable delivery of the product in the desired delivery format.

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Results show the following activities of IVX-908 adjuvant when mixed with ovalbumin (OVA), a known poor immunogen and given by the nasal or injectable route.

1. Enhances OVA-specific serum IgG titers by greater than 60- and 75-fold via the nasal and injectable routes respectively compared with antigen alone,
2. Enhances the secretion of OVA-specific IFN- γ and IL-5 from re-stimulated splenocytes compared with antigen alone resulting in a balanced type of immune response.

15 EXAMPLES

Example 1: Production of proteosomes

Two examples of outer membrane protein proteosome preparations are shown. These preparations were purified from type 2 *Neisseria meningitidis* by extraction of phenol-killed bacterial paste with a solution of 6% Empigen BB (EBB) (Albright and Wilson, 20 Whithaven, UK) in 1 M calcium chloride followed by precipitation with ethanol, solubilization in 1% EBB-Tris/EDTA-saline and then precipitation with ammonium sulphate. The precipitates were re-solubilized in the 1% EBB buffer, diafiltered and stored in an EBB buffer at -70°C. A flow chart of this process, which resulted in proteosomes 25 having a liposaccharide content of between 0.5% and 5%, is shown in Flowchart 1A (Figure 1A) on the following pages. Proteosomes may also be prepared by omitting the ammonium sulphate precipitation step to shorten the process as desired with resultant proteosomes having a liposaccharide content of between 12% and 25%, and may, depending upon the materials, be between 15% and 20% as shown in Flowchart 1B 30 (Figure 1B).

Example 2: Production of liposaccharides

The example in Flowchart 2 (Figure 2) shows the process for the isolation and purification

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5 of LPS from *S. flexneri* or *P. shigelloides* bacteria. This process can similarly be used for preparing LPS from other gram-negative bacteria including, but not restricted to *Shigella*, *Plesiomonas*, *Escherichia* and *Salmonella* species. Following growth of the bacteria by fermentation, the cell paste was re-hydrated with 3 mL 0.9M NaCl, 0.005 M EDTA/g paste. Ten mg lysozyme /g paste was also added. Lysozyme digestion was allowed to
10 proceed for 1 hour at room temperature. Fifty U/mL Benzonase (DNase) was then added with 0.025M MgCl₂. DNase digestion was allowed for 30 minutes to proceed at room temperature. The suspension was then cracked by passage through a microfluidizer at 14,000 to 19,000 psi. Fresh DNase (50 U/mL) was added and the suspension was digested for a further 30 min at room temperature. The digested cell suspension was heated to 68°C
15 in a water bath. An equal volume of 90% phenol (at the same temperature) was added and the mixture was incubated with shaking at 68°C for 30 min. The mixture was centrifuged at 4°C to separate the aqueous and organic phases. The aqueous phase was harvested and the organic phase was re-extracted with WFI (water for injection) at 68°C for 30 min. The mixture was centrifuged at 4°C to separate the aqueous and organic phases and the
20 aqueous phases were combined. Twenty percent ethanol and 10 mM CaCl₂ were added to the combined aqueous phase to precipitate nucleic acids. The mixture was stirred at 4°C overnight. Precipitated nucleic acids were then pelleted by centrifugation at 10,000XG for 30 minutes and the supernatant was collected.

25 The supernatant was concentrated and diafiltered using a 30,000 MW hollow fiber cartridge into 0.15M NaCl, 0.05M Tris, 0.01M EDTA and 0.1% Empigen BB, pH 8.0. Finally, the LPS was sterile-filtered using a 0.22 um Millipak 60 filter unit aliquoted into sterile storage containers and frozen at -80°C.

30 Example 3: Preparation and characterisation of a proteosome-liposaccharide adjuvant complex

The adjuvant is manufactured by non-covalently complexing Proteosomes to LPS. The LPS can be derived from any of a number of gram negative bacteria including, but not

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCION DE NUEVAS CREACIONES

2020
Bogotá, D.C.

Abogado
DILIA MARIA RODRIGUEZ D'ALEMAN

ASUNTO	Radicación	06128318
	Trámite	011
	Evento	378
	Actuación	411 4006
	Oficio	
	Folios	015

Patente de Invención ☒ Patente de Modelo de Utilidad ☐

Vía Nacional ☐

Vía PCT (fase nacional) ☒ Cap. I ☐ Cap. II ☒

No. Sol. Internacional PCT/US2005/022922

Fecha de Presentación Internal. Junio 27 de 2005.

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

1. Documentos estudiados

- 1.1. Descripción: Folios: 38 a 116 como se radicó inicialmente
- 1.2. Reivindicaciones: Folios: 117 a 120 como se radicó inicialmente
- 1.3. Prioridad: Junio 25 de 2004; US; 60/582,999

2. Objeto de la invención

Título de la invención: COMPOSICIONES Y MÉTODOS PARA EL TRATAMIENTO DE TRASTORNOS NEUROLÓGICOS.

Problema Técnico Planteado: Necesidad de una composición para tratar trastornos neurológicos.

Solución: Una Composición de acuerdo a la reivindicación 21 (folio 120, pg83

IPC: A61k/3174.

3. Unidad de invención (artículo 25 D 486)

La reivindicación 22, se refiere a dos composiciones diferentes:

- Una que contiene el acetato de Glatiramer y
- otra que contiene una composición basada en proteosomas.

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

Las reivindicaciones 1-20 y 23, se refieren a métodos de tratamiento.

5. Determinación del Estado de la Técnica

La fecha que se ha tenido en cuenta para determinar el Estado de la Técnica es:

Fecha de presentación de la solicitud prioritaria: Junio 25 de 2004.

Teniendo en cuenta la fecha indicada se realizó la búsqueda en el estado de la técnica de documentos relacionados con la solicitud encontrándose los siguientes documentos más relevantes:

Nº	Documento	Título	Fecha de publicación*
D1	WO9531990	Copolymer-1 improvements in compositions of copolymers	Noviembre 30 de 1995
D2	WO02072012	A novel proteosome-liposaccharide vaccine adjuvant	Septiembre 19 de 2002

D1 (Folios: 219-221); D2 (Folios: 224-229)

6. Análisis de patentabilidad (artículo 14 D486)

6.1 Novedad (artículo 16 D486)

La reivindicación 22, se refiere a:

- Una composición que contiene acetato de Glatiramer y
- Una composición basada en proteosomas.

D1, WO9531990, que da a conocer un polipéptido sintético, que es el copolímero 1 ó acetato de glatiramer y sus composiciones (folio 220, página 1, líneas 8, 34; folios: 222 y 223 reivindicaciones 7-11.

D2, WO02072012, describe una composición adyuvante, basada en proteosomas (folios 228-229, págs 12-13, ejemplo 1)

Las características esenciales de la reivindicación 22 es decir: Una composición que contiene acetato de Glatiramer y Una composición basada en proteosomas, habían sido divulgadas previamente en D1 y D2. Por lo tanto dicha reivindicación no se considera nueva.

6.2 Nivel inventivo (artículo 18 D486)

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La reivindicación 21, consiste en:

Una composición farmacéutica que comprende: Acetato de glatiramer en una emulsión en submicras o nanoemulsión.

El Estado de la Técnica más cercano es D1 (WO9531990) que da a conocer un polipéptido sintético, que es el copolímero 1 ó acetato de glatiramer: que contiene alanina, ácido glutámico, lisina y tirisina y sus composiciones (folio 220, página 1, líneas 8, 34; folios: 222 y 223 reivindicaciones 7-11).

La composición objeto de esta solicitud se diferencia de las composiciones de D1, en que esta menciona como vehículo farmacéuticamente aceptable: una emulsión en submicras o nanoemulsión.

El hecho de incluir una emulsión en submicras o nanoemulsión, en las composiciones que se daban a conocer en D1, causa que la composición reclamada, tenga una mejor respuesta inmune, útil en el tratamiento de trastornos neurológicos como la esclerosis múltiple (folio 45, pg 8).

El Problema Técnico Objetivo era "cómo obtener composiciones de acetato de glatiramer tenga una mejor respuesta inmune, útil en el tratamiento de trastornos neurológicos como la esclerosis múltiple".

D2 (WO02072012) describe una manera de solucionar el problema técnico, mediante una composición adyuvante, para aumentar la inmunogenicidad y mejorar la respuesta inmune de la respuesta de antígenos, que contiene excipientes como nanoemulsiones (folio 225, pág 1, líneas 1-5 y folio 227, pg6, líneas 30-31).

Por tanto, la solicitud, tal como se reivindica, es obvia, porque el Experto en la Materia enfrentado al problema de "cómo obtener composiciones de acetato de glatiramer tenga una mejor respuesta inmune, útil en el tratamiento de trastornos neurológicos como la esclerosis múltiple", incluiría una composición adyuvante, para aumentar la inmunogenicidad y mejorar la respuesta inmune de la respuesta de antígenos, que contiene excipientes como nanoemulsiones (folio 225, pág 1, líneas 1-5 y folio 227, pg6, líneas 30-31), dentro de las composiciones que se enseñan en D1, logrando de esta forma la composición objeto de esta solicitud.

Por lo tanto la reivindicación 21 no es inventiva.

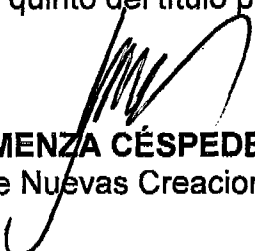
7. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

Nº	Documento Nº	Reivindicaciones afectadas	Requisito que afecta
D1	WO9531990	21 22	Nivel Inventivo Novedad
D2	WO02072012	21 22	Nivel Inventivo Novedad

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

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 N° 10 de 2001.


ALIX CARMENZA CÉSPEDES DE VERGEL
Directora de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por fijación en lista, de fecha
19 MAR. 2010

CONCEPTO TÉCNICO No. 267	EXAMINADOR TÉCNICO Código No.202078
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