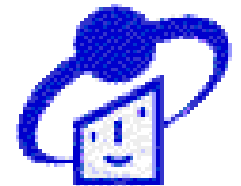


Innovations of Biotech Medicines in Developing Countries

An Overview

Hiroshi Kato

Japan Patent Office



INTRODUCTION

- **Biotech Medicines** have been developed mainly in **USA, Europe and Japan**. However, some developing countries have tried to develop some **Biotech Medicines** past several years, which can be one of the effects of **TRIPS**.
- **Some Statistic Data** are shown here to explain the recent development of **Biotech Medicines**. Moreover, **some Case Studies** are shown here to explain the development in developing countries.
- Based on these **Statistic Data** and **Case Studies**, the development of **Biotech Medicines** in **developing countries** is discussed here.

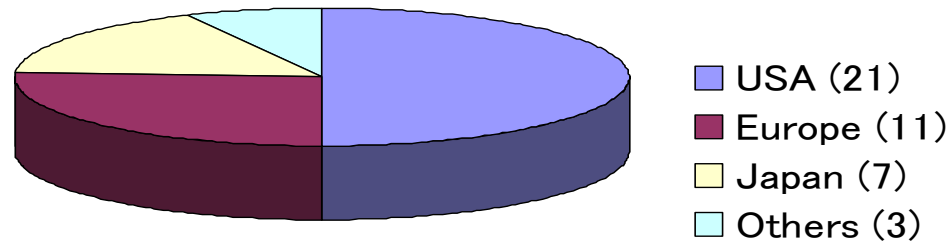
CONTENTS

- **Erythropoietin (EPO)**
- **Interferon (IFN)**
- **Tissue Plasminogen Activator (TPA)**
- **Monoclonal Antibody (MA)**

Erythropoietin (EPO)

Erythropoietin (EPO)

- Patent Applications of Erythropoietin in Japan from all over the world (published year: 2000-)



- Others: India(1), Israel(1), Korea(1)

- Total (42)

- Search: (Definition)
 - Erythropoietin /CL
 - C12N15/00 and A61K37/24

Case Study of EPO ①: India

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

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 November 2006 (30.11.2006)

PCT

(10) International Publication Number
WO 2006/126066 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/IB2006/001353

(22) International Filing Date: 24 May 2006 (24.05.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
627/CHE/2005 24 May 2005 (24.05.2005) IN

(71) Applicant (for all designated States except US):
AVESTHA GENGRAINE TECHNOLOGIES PVT LTD. [IN/IN]; "Discoverer", 9th Floor, Unit 3, International Tech Park, Whitefield Road, Bangalore 560066, Karnataka (IN).

(72) Inventor; and
(75) Inventor/Applicant (for US only): MORAWALA, Patell, Villoo [IN/IN]; Avestha Gengraine Technologies Pvt Ltd., "Discoverer" 9th Floor, Unit-3, International Tech Park, Whitefield Road, Bangalore 560066, Karnataka (IN).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,

GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

Published:

- without international search report and to be republished upon receipt of that report

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

(54) Title: A RECOMBINANT METHOD FOR PRODUCTION OF AN ERYTHROPOIESIS STIMULATING PROTEIN

WO 2006/126066, EP 1888630, JP 2009-502117,
KR 2008-26113, CA 2609473

Case Study of EPO ①: India

[Applicant] AVESTHA GENGRAINE TECHNOLOGIES PVT.LTD.

[Title] A Recombinant Method for Production of an Erythropoiesis Stimulating Protein

[Abstract]

The present invention relates to the recombinant method used for the production of a highly glycosylated form (in total five N linked glycosylations as opposed to three N linked glycosylations in the natural EPO) of erythropoietin. The added sites for glycosylation will result in greater number of carbohydrate chains, and higher sialic acid content than human EPO, which in turn would impart to the recombinant molecule a longer half-life. The invention further relates to the construction of expression cassettes comprising nucleic acid sequences encoding for the highly glycosylated form of Erythropoietin and stable expression in the host cells. The invention further relates to the optimized method for purification of the erythropoiesis stimulating protein. The recombinant EPO according to the invention, and the salts and functional derivatives thereof, may comprise the active ingredient of pharmaceutical compositions for an increase in the hematocrit for treatment of anemia and for restoration of patient well being and quality of life.

Case Study of EPO ①: India

[Claims]

1. A process for the preparation of an in vivo biologically active **Erythropoiesis Stimulating Protein**, comprising the steps of:
 - (a) Growing, under suitable nutrient conditions, host cells transformed or transfected with an isolated DNA sequence selected from the group consisting of (i) the DNA sequences set out in SEQ ID No.1 and SEQ ID No. 2, (ii) the protein coding sequence represented in SEQ ID No. 3, and (iii) DNA sequences which hybridize under stringent conditions to the DNA sequences defined in (i) and (ii) or their complementary strands; and
 - (b) Isolating said **Erythropoietin** product therefrom.

9. **A pharmaceutical composition** comprising a therapeutically effective amount of human **erythropoietin** and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture.
10. A method of raising and maintaining hematocrit in a mammal comprising administering a therapeutically effective amount of a hyperglycosylated analog of erythropoietin in a **pharmaceutical composition** of claim 9, wherein the analog is administered less frequently than an equivalent molar amount of recombinant human **erythropoietin** to obtain a comparable target hematocrit.

Case Study of EPO ②: Israel

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

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
20 November 2003 (20.11.2003)

PCT

(10) International Publication Number
WO 03/094858 A2

-
- (51) International Patent Classification⁷: **A61K**
- (21) International Application Number: PCT/US03/14995
- (22) International Filing Date: 13 May 2003 (13.05.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/380,506 13 May 2002 (13.05.2002) US
- (71) Applicant (for all designated States except US): **TECHNION ENTREPRENEURIAL INCUBATOR COMPANY LTD.** [IL/IL]; MATAM - Advanced Technology Center, Building No. 30, Haifa 31905 (IL).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **BOIME, Irving** [US/US]; 27 Oak Park Drive, St. Louis, MO 63141 (US). **FARES, Faud** [IL/IL]; 7 Michael Street, Haifa 34362 (IL).
- (74) Agents: **MURASHIGE, Kate, H.** et al.; Morrison & Foster LLP, 3811 Valley Centre Drive, Suite 500, San Diego, CA 92130-2332 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: CTP-EXTENDED ERYTHROPOIETIN

WO 2003/94858, US 2005-256035, GB 2403476, CA 2485365

Case Study of EPO ②: Israel

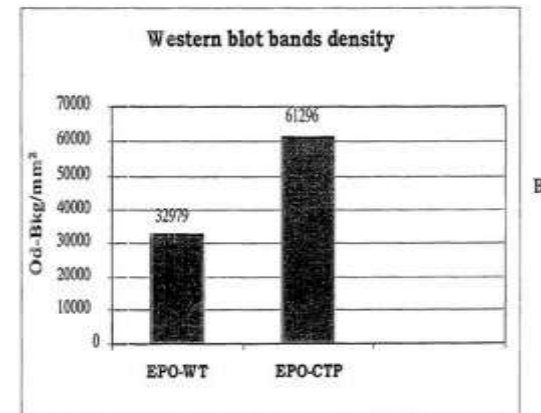
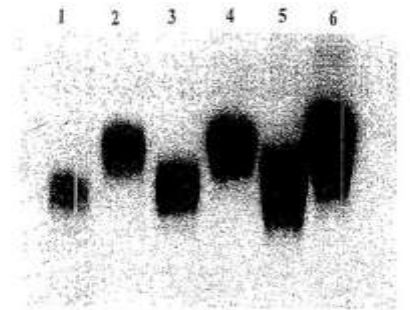
[Applicant] - MODIGENETECH LTD. (Israel)

- BOIME IRVING (USA)

[Title] CTP-Extended Erythropoietin

[Claims]

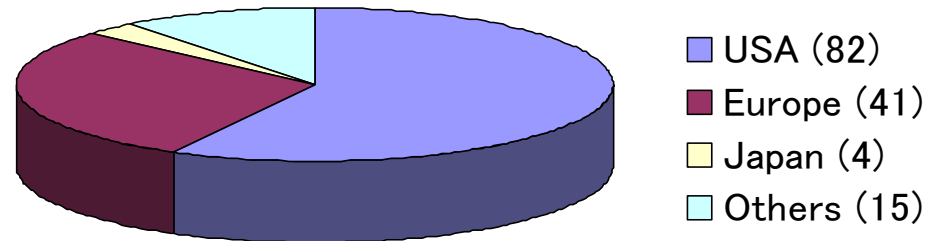
1. A human form of **erythropoietin** extended at its C-terminus by the carboxy terminal peptide derived from the β subunit of human chorionic gonadotropin, which extended protein is recombinantly produced and secreted from Chinese hamster ovary cells.
2. A pharmaceutical composition which comprises the extended **erythropoietin** of claim 1.
3. A method to enhance red blood cell production which method comprises administering to a subject in need of said red blood cell proliferation an effective amount of the **pharmaceutical composition** of claim 2.



Interferon (IFN)

Interferon (IFN)

- Patent Applications of Interferon- α in Japan from all over the world (published year: 2000-)



- Others: Israel(4), Korea(4), Australia(3), Canada(3), Cuba(1)
- Total (141)

- Search: (Definition)
 - Interferon- α /CL
 - C12N15/00 and A61K37/02

Case Study of IFN ① : Australia

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

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
6 September 2002 (06.09.2002)

PCT

(10) International Publication Number
WO 02/068470 A2

- (51) International Patent Classification: C07K 14/555
- (21) International Application Number: PCT/GB02/00830
- (22) International Filing Date: 26 February 2002 (26.02.2002)
- (23) Filing Language: English
- (24) Publication Language: English
- (30) Priority Data:
0101706.7 26 February 2001 (26.02.2001) GB
0200619.5 11 January 2002 (11.01.2002) GB
- (71) Applicant (for all designated States except US):
PHARMA PACIFIC PTY LTD (AU/AU); 103-105
Pipe Road, Laverton North, Victoria 3026 (AU).
- (72) Inventors; and
(73) Inventors/Applicants (for US only): MERIET,
Jean-François (FR/FR); 62, rue de Plepys, F 75012 Paris
(FR). DRON, Michel (FR/FR); 22, avenue des Cottages,
F-92340 Bourg la Reine (FR). TOVEY, Michael, Gerard
(GB/FR); 7, rue Lagrange, F-75005 Paris (FR).
- (74) Agents: IRVINE, Jonquil, Claire et al., J.A. Kemp & Co.,
14 South Square, Canary Wharf, London EC3R 5JJ (GB).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GR,
GM, HR, HU, ID, IL, IN, IS, JP, KB, KG, KP, KR, KZ, LC,
LK, LR, LS, LL, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MY, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,
SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ,
VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, CH, CY, DE, DK, ES, FR,
GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,
NE, SN, TD, TG).
- Published:
without international search report and to be republished
upon receipt of that report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2002/68470, EP 1368458, US 2004-175803, JP 2004-531238,
GB 200619, CA 2437898

Case Study of IFN ① : **Australia**

[Applicant] PHARMA PACIFIC PTY LTD

[Title] Interferon-alpha induced Gene

[Abstract]

The present invention relates to identification of a gene upregulated by **interferon- alpha** administration corresponding to the cDNA sequence set forth in SEQ. ID. No. 1 and SEQ. ID. No. 3. Determination of expression products of this gene is proposed as having utility in predicting responsiveness to treatment with **interferon- alpha** and other interferons which act at the Type 1 interferon receptor. Therapeutic use of the protein encoded by the same gene is also envisaged.

Case Study of IFN ① : Australia

[Claims]

1. An isolated polypeptide comprising (i) the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 4; (ii) a variant thereof having substantially similar function selected from immunomodulatory activity and/or anti-viral activity and/or anti-tumour activity; or (iii) a fragment of (i) or (ii) which retains substantially similar function selected from immunomodulatory activity and/or anti-viral activity and/or anti-tumour activity.
 -
 -
 -
11. **A pharmaceutical composition** comprising a polypeptide as claimed in claim 1 or a polynucleotide as claimed in claim 9 and a pharmaceutically acceptable carrier or diluent.

Case Study of IFN ② : Cuba

(12) SOLICITUD INTERNACIONAL PUBLICADA EN VIRTUD DEL TRATADO DE COOPERACIÓN EN MATERIA DE PATENTES (PCT)

(19) Organización Mundial de la Propiedad Intelectual
Oficina Internacional



(43) Fecha de publicación Internacional
20 de Noviembre de 2003 (20.11.2003)

PCT

(10) Número de Publicación Internacional
WO 03/095488 A1

- (51) Clasificación Internacional de Patentes:
C07K 14/715, 14/55.
A61K 39/21, A61P 29/00, C12N 15/62
- (21) Número de la solicitud internacional: PCT/WT103/00006
- (22) Fecha de presentación internacional:
8 de Mayo de 2003 (08.05.2003)
- (25) Idioma de presentación: español
- (26) Idioma de publicación: español
- (30) Datos relativos a la prioridad:
CU2002/0095 10 de Mayo de 2002 (10.05.2002) CU
- (71) Solicitante (para todos los Estados designados salvo US):
CENTRO DE INGENIERIA GENETICA Y BIOTECNOLOGIA [CU/CU]; Ave. 31 de 158 y 190 Cabañacán, Playa., 10600 Ciudad de la Habana (CU).
- (72) Inventores: e
- (75) Inventores/solicitantes (para US solamente): BELLO RIVERO, Iraldo [CU/CU]; Calle 184 No. 5112 de 31 y 33, Apto 30, Playa., 12100 La Habana (CU). TORRES RUIZ, Yeny [CU/CU]; Edif. C11 Apto 3 Zona 10, Alamar, Habana del Este., 10600 La Habana (CU). BLANCO GARCÉS, Elizabeth [CU/CU]; Gral Lee # 251 de Juan Delgado, y Distrampes, Santo Suárez, Vibora., 10600 La Habana (CU). PENTÓN ROLL, Giselle [CU/CU]; Calle 110 No. 539 de 5ta F y 7ma, Playa., 10600 La Habana (CU). LÓPEZ SAURA, Pedro [CU/CU]; Ave. 19 No 6810 de 68 y 70., Playa., 12100 La Habana (CU).
- (74) Mandatario: POVEDA MARCHECO, Argia; Ave. 21 de 158 y 190, Cabañacán, Playa., 10600 La Habana (CU).
- (81) Estados designados (nacional): AE, AG, AI, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GH, GI, GN, GR, HU, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Estados designados (regional): patente ARIPO (GH, GM, KI, LS, MW, MZ, SD, SI, SZ, TZ, UG, ZM, ZW), patente europea (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), patente OAPI (BF, BJ, CI, CG, CL, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, UG).
- Publicada:
— con informe de búsqueda internacional
antes de la expiración del plazo para modificar las reivindicaciones y para ser republicada si se reciben modificaciones
- Para códigos de dos letras y otras abreviaturas, véase la sección "Guidance Notes on Codes and Abbreviations" que aparece al principio de cada número regular de la Gaceta del PCT.

WO 2003/95488, EP 1550672, US 2007-160575, JP 2006-506958,
CN 1662555, CA 2485439, BR 304827, RU 2322455

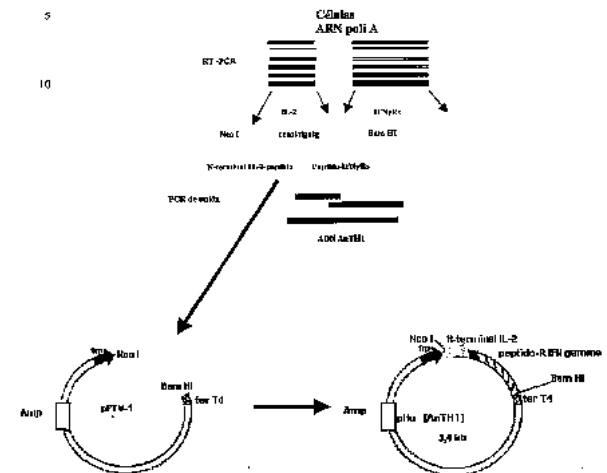
Case Study of IFN ② : Cuba

[Applicant] CT INGENIERIA GENETICA BIOTECH

[Title] Chimeric Antagonist ANTHI

[Abstract]

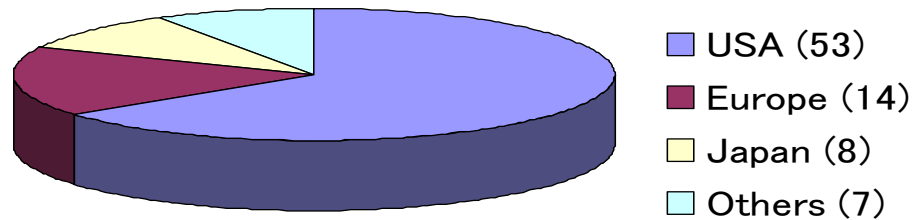
The invention relates to a recombinant chimeric protein comprising a fragment of 60 amino acids from the N-terminal region of the human interleukin 2 (IL-2) fused to the N-terminal of the extracellular region of the alpha chain of the receptor for IFN gamma (IFN gamma). Said in vitro protein exhibits T cell growth-stimulating activity, inhibits IL-2 growth-stimulating activity in T cells, inhibits the induction of HLA-DR by IFN gamma and inhibits the antiproliferative activity of IFN gamma. The invention is suitable for use in medicine for the treatment of various pathologies, such as autoimmune diseases, transplantation rejections, chronic inflammations, sepsis, ischemia and reperfusion syndrome and atherosclerosis.



Tissue Plasminogen Activator (TPA)

Tissue Plasminogen Activator (TPA)



- Patent Applications of TPA in Japan from all over the world (published year: 2000-)



- Others: Israel(2), China(2), Australia(1), Canada(1), Mexico(1)
- Total (82)

- Search: (Definition)
 - Tissue Plasminogen Activator or TPA
 - C12N15/00 and A61K37/54

Case Study of TPA ① : China

(19)	 Europäisches Patentamt European Patent Office Office européen des brevets	 (11) EP 1 323 826 A1
(12)	EUROPEAN PATENT APPLICATION published in accordance with Art. 158(3) EPC	
(43)	Date of publication: 02.07.2003 Bulletin 2003/27	(51) Int. Cl.7: C12N 15/57, C07K 14/745
(21)	Application number: 01907318.8	(86) International application number: PCT/CN01/00127
(22)	Date of filing: 16.02.2001	(87) International publication number: WO 02/022832 (21.03.2002 Gazette 2002/12)
(84)	Designated Contracting States: AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR Designated Extension States: AL LT LV MK RO SI	(72) Inventor: Xia, Jiahui Changsha, Hunan Province 410078 (CN)
(30)	Priority: 04.05.2000 WOPCT/CN00/00260	(74) Representative: Grünecker, Kinkeldey, Stockmair & Schwanhäusser Anwaltssozietät Maximilianstrasse 58 80538 München (DE)
(71)	Applicant: Xia, Jiahui Changsha, Hunan Province 410078 (CN)	
(54)	A CELL LINE EXPRESSING MUTATED HUMAN TISSUE - TYPE PLASMINOGEN ACTIVATOR, THE CONSTRUCTING STRATEGY THEREOF AND METHOD OF PREPARING EXPRESSED PROTEIN	

WO 2002/20802, EP 1323826, US 2004-77042, JP 2004-508066,
CN 21468310, AU 3532001

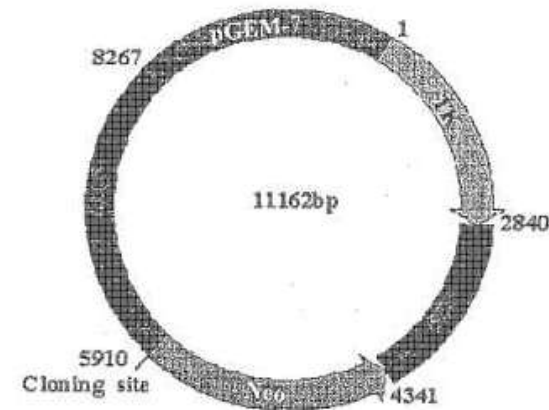
Case Study of TPA ① : China

[Applicant] XIA JIAHUI

[Title] A Cell Line Expressing Mutated Human Tissue - Type Plasminogen Activator

[Abstract]

The invention involves a cell line which can express human mutated tissue-type plasminogen activator (TNK-TPA), and its preparation methods. The collection No. of cell line in this invention is CCTCC C200006. We firstly use a DNA fragment from the short arms of human D, G group chromosomes or its homologous to construct a recombinant human source gene vector-TNK-TPA (collection number is CCTC m200032); TNK-TPA gene is then transferred into the target site of nucleolus organizing region (NOR) of human D, G group chromosomes in host cell HT1080 by the recombinant and the cell line is attained after screening, which can be used for manufacturing protein.



Case Study of TPA ① : China

[Claims]

1. A cell lines that express human mutated **tissue-type plasminogen activator (TNK-TPA)**, its Collection NO. is CCTCC C200006.
2. A construction strategy of the cell lines said in claim 1, includes the following steps: (1) Using a DNA sequence from the short arms of human D,G group chromosomes, or its homologous sequence as leading sequence for gene targeting to construct a human source gene vector, in which no important physiological function gene is found. (2)The target gene **TNK-TPA** is ligated into the human source vector above with routine method, and the recombinant of the vector and **TNK-TPA** is obtained. (3)**TNK-TPA** gene is targeted to nucleolus organizing region of human D,G group chromosomes in host cell HT1080 by the above recombinant and the cell line attained by screening.
3. The construction strategy of the cell lines according to claim 2 wherein the vector has the DNA sequence as shown in the SEQ No. 1.
4. The method of preparing mutated human tissue-type plasminogen activator is that the cell lines mentioned in Claim 1 are used as engineering cell line to express and manufacture **TNK-TPA** protein.

Case Study of TPA ② : Mexico

(12) SOLICITUD INTERNACIONAL PUBLICADA EN VIRTUD DEL TRATADO DE COOPERACIÓN
EN MATERIA DE PATENTES (PCT)

(19) Organización Mundial de la Propiedad
Intelectual
Oficina internacional



(43) Fecha de publicación internacional
29 de Marzo de 2001 (29.03.2001)

PCT

(10) Número de Publicación Internacional
WO 01/21761 A2

- | | | |
|----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (51) Clasificación Internacional de Patentes: | C12N | (72) Inventores: e |
| (21) Número de la solicitud internacional: | PCT/MX00/00035 | (75) Inventores/Solicitantes (para US solamente): ARMEN-
DARIZ BORRINDA, Juan [MX/MX]; Prolongación
División del Norte No. 4280, Col. Prado Coapa, México,
D.F. 14200 (MX). AGUILAR CORDOVA, Estuardo
[MX/MX]; Prolongación División del Norte No. 4280,
Col. Prado Coapa, México, D.F. 14300 (MX). |
| (22) Fecha de presentación internacional: | 14 de Septiembre de 2000 (14.09.2000) | (74) Mandatarios: HINOJOSA CUELLAR, José, Fran-
cisco etc.; Paseo de los Tamarindos 400-A 9o. Piso, Col.
Bosques de la Lomas, México, D.F. 05120 (MX). |
| (35) Idioma de presentación: | español | (81) Estados designados (nacional): AE, AI, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE,
DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID,
IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LI,
LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PT,
PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ,
UA, UG, US, UZ, VN, YU, ZA, ZW. |
| (36) Idioma de publicación: | español | |
| (30) Datos relativos a la prioridad: | 998515 17 de Septiembre de 1999 (17.09.1999) MX | |
| (71) Solicitante (para todos los Estados designados salvo US): | TGT LABORATORIES, S.A. DE C.V. [MX/MX]; Pro-
longación División del Norte No. 4280, Col. Prado Coapa,
México, D.F. 14300 (MX). | |

[Continúa en la página siguiente]

(54) Title: RECOMBINANT ADENOVIRAL VECTORS AND THEIR UTILIZATION IN THE TREATMENT OF VARIOUS
TYPES OF HEPATIC, RENAL AND PULMONARY FIBROSIS AND HYPERTROPHIC SCARS

WO 2001/21761, EP 1221490, US 2005-201984, JP 2004-500040,
DE 1221490, ES 2183752, CA 2385538, AU 7322600

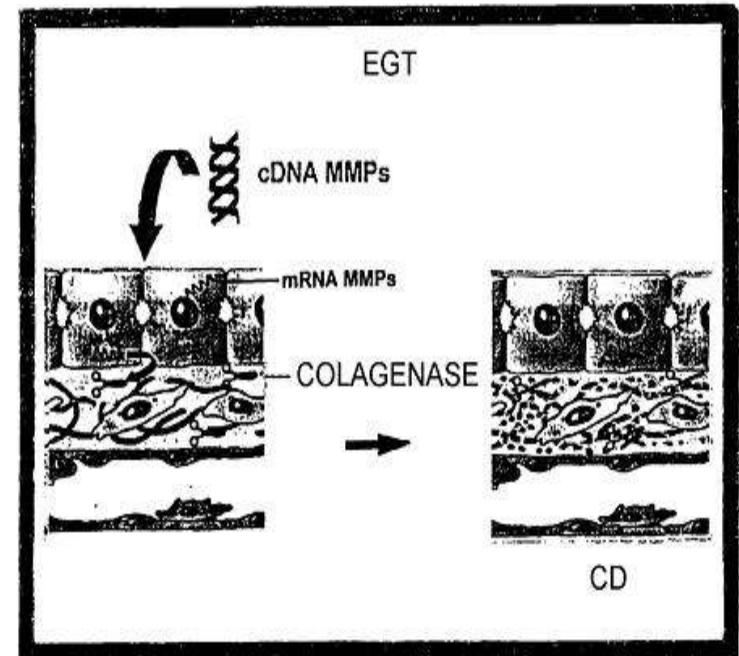
Case Study of TPA ② : Mexico

[Applicant] TGT LAB S A DE C V

[Title] Recombinant Adenoviral Vectors and their Utilization in the Treatment of Various Types of Hepatic, Renal and Pulmonary Fibrosis and Hypertrophic SCARS

[Abstract]

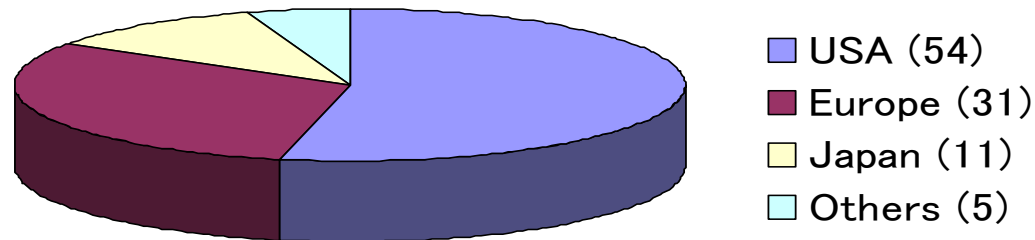
The invention relates to the utilization of genic therapy in the treatment of various fibrosis in humans. The invention aims at using therapeutic genes specifically directed to target organs with the purpose of reverting and/or preventing the evolution of the process associated with fibrosis.



Monoclonal Antibody (MA)

Monoclonal Antibody (MA) and HIV


- Patent Applications of Monoclonal Antibody and HIV in Japan from all over the world (published year: 2006-)



- Others: Canada(3), Australia(1), Thailand(1)
- Total (101)

- Search: (Definition)
 - HIV + AIDS /CL
 - C12N15/00 × A61K39/00

Case Study of MA (HIV) ① : Taiwan

	<p>Europäisches Patentamt European Patent Office Office européen des brevets</p>	
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(84)	Designated Contracting States: AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LU MC NL PL PT RO SE SI SK TR Designated Extension States: AL HR LT LV MK	(71) Applicant: CCL Holdings Co., Ltd. Taipei (TW)
(30)	Priority: 16.07.2003 US 822003	
(54)	Preparation of fully human antibodies	
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EP 1498426, US 2005-14230, JP 2005-34154, CN 1626669

Case Study of MA (HIV) ① : Taiwan

[Applicant] CCL HOLDINGS CO LTD

[Title] Methods for the Preparation of Fully Human Antibodies

[Abstract]

The present invention provides a method of preparing fully human **antibodies** that recognize a pre-determined antigen without relying on human donors that have already been exposed to the antigen. To this end, lymphocytes from naive human donors are immunized in vitro with the antigen of interest, and cells that produce antibodies against the antigen are identified. Since the lymphocytes are immunized in vitro rather than in vivo, it is possible to control which antigen, or which part of the antigen, would be recognized by the antibody. A preferred antigen is gp120 of **HIV**, particularly the co-receptor binding region of gp120.

Case Study of MA (HIV) ① : Taiwan

[Claims]

1. A method of preparing a fully human **antibody** recognizing an antigen, comprising: (a) providing a group of lymphocytes from a naïve human donor; (b) immunizing said lymphocytes with the antigen in vitro; (c) fusing the immunized lymphocytes with a heteromyeloma cell line to form trioma cells; (d) identifying trioma cells that produce an antibody that recognizes the antigen; and (e) collecting the antibody produced by the trioma cells identified in step (d).
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21. A composition comprising the antibody or fragment of any of claims 15-20.
22. The composition of claim 21 further comprising a pharmaceutically acceptable carrier or excipient.

Case Study of MA (HIV) ② : Thailand

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NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK,

(Continued on next page)

(54) Title: A METHOD OF PRIME-BOOST VACCINATION

WO 2006/057454, JP 2006-149234, CN 1107359

Case Study of MA (HIV) ② : Thailand

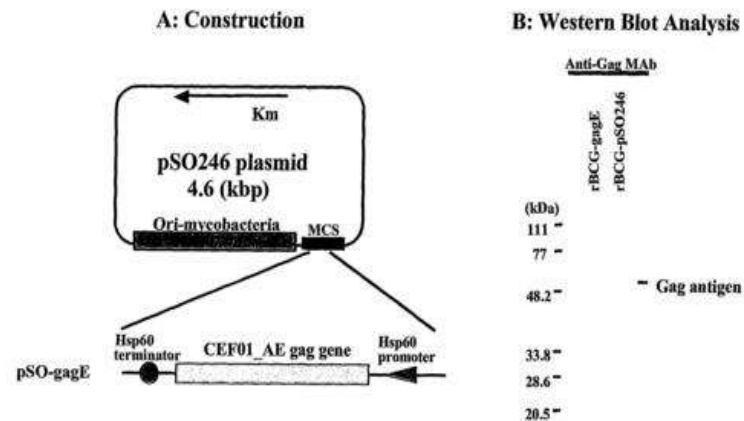
[Applicant]

- DEPARTMENT OF MEDICAL SCIENCES, MINISTRY OF PUBLIC HEALTH (Thailand)
- JAPAN SCIENCE AND TECHNOLOGY AGENCY (Japan)

[Title] A Method of Prime-Boost Vaccination

[Abstract]

As a novel means for effective prevention from HIV-1 CEF01_AE infection, the present invention provide a method of prime-boost vaccination comprising a priming step by a recombinant BCG vaccine and one or more boosting steps by a recombinant vaccine, wherein both of the recombinant BCG vaccine for priming step and the recombinant vaccine for boosting steps have at least one gene of HIV- 1 CRFO 1_AE strain.



Case Study of MA (HIV) ② : Thailand

[Claims]

1. A method of prime-boost **vaccination** comprising a priming step by a recombinant BCG vaccine and one or more boosting steps by a recombinant vaccine, wherein both of the recombinant BCG vaccine for priming step and the recombinant vaccine for boosting steps have at least one gene of **HIV-I** CRFO 1_AE strain.
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9. gag gene of HIV-I CRF01_AE strain having the nucleotide sequence of SEQ ID NO: 1.
10. A recombinant BCG vaccine having the gag gene of claim 9.
11. Gag protein of HIV-I CRF01_AE strain, which is an expression product of the gag gene of claim 9.
12. **An antibody** specifically recognizing the Gag protein of claim 11.

DISCUSSION

- **Biotech Medicines** have been developed mainly in **USA, Europe and Japan**. Patents of **Biotech Medicines** have been also applied **mainly from USA, Europe and Japan**.
- However, **some developing countries** have tried to apply some patents of **Biotech Medicines** past several years, which can be one of the effects of **TRIPS**.
- **Intellectual Property** is thought to be effective for innovation and economic growth. **Developing countries should develop new Biotech Medicines and advance economic growth**.
- **Collaboration with developed countries** is one of the superior ways to develop new **Biotech Medicines**, as shown in case studies (**EPO, MA**) here.

Thank you

