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CARRERA 7 # 71 – 21 TORRE B – PISO 4
BOGOTÁ – COLOMBIA
TEL: (571) 744 22 00
FAX: (571) 742 22 00 – (571) 3214045
www.bc.com.co

AS: 102.493

Señores
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES
E. S. D.

RESPUESTA A OFICIO 1879 DE FEBRERO 09, 2007

REF: Expediente No. 06 121.070 - Solicitud de Patente Entrada en Fase Nacional
Corresp. a la Solicitud Internacional PCT/US2005/019641
a favor de **GENENTECH, INC.**
Titulada: MÉTODO PARA TRATAR LA ESCLEROSIS MÚLTIPLE

JUAN PABLO CADENA SARMIENTO, vecino de Bogotá, portador de la tarjeta profesional No. 57492, obrando como apoderado de la sociedad GENENTECH, INC., según lo acredita el documento de poder presentado en esa División, para dar cumplimiento al requerimiento notificado por fijación en lista el 09 de Febrero de 2007, de acuerdo con los Artículos 38 y 39 de la Decisión 486 de la Comisión de la Comunidad Andina, Artículo 27 del Tratado de Cooperación en Materia de Patentes (PCT), regla 51 bis del Reglamento y Circular Única de la SIC, me permito Allegar:

1. Documento donde consta la cesión del derecho a la Patente otorgado por el inventor al solicitante, debidamente apostillado, junto con su correspondiente traducción.
2. Reporte de Examen Preliminar Internacional sobre Patentabilidad (Formas PCT/IB/373 y PCT/ISA/237).
3. Extracto para publicación y Tarjeta de Archivo Temático.

De la señora jefe atentamente,

JUAN PABLO CADENA SARMIENTO
C.C. No. 80.410.337 de Usaquén
Cra 7 No. 16-56 Piso 9

Bogotá, 27 de febrero de 2007
CHP/MEV/hsr.

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Industria y Comercio
SUPERINTENDENCIA

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES
TARJETA ARCHIVO TEMÁTICO
PATENTE DE INVENCION _X_ PCT _X_ MODELO DE UTILIDAD ___ DISEÑO INDUSTRIAL ___

(21) N° de solicitud: 06 121.070 (22) Fecha de solicitud: 30-11-2006
(51) Clasificación Internacional :

(71) Solicitante(s) GENENTECH, INC.

(72) Inventor(es) Paul A. Frohna

(74) Agente: JUAN PABLO CADENA SARMIENTO

(30) Prioridad	(31)	No. Prioridad	(32)	Fecha	(33)	País
		60/576,993		04-06-2004		US

FIGURA CARACTERISTICA
6 x 6 cm

(85) Fecha inicio fase nacional: 04-01-2007
(86) Datos relativos a la presentación de la solic. PCT
Fecha de presentación de la solicitud: 02-06-2005
No. de solicitud PCT/US2005/019641

(87) Publicación Internacional:
Fecha: 15-12-2005
No. Publicación : WO/2005/117978 A3

(54) Título: **MÉTODO PARA TRATAR LA ESCLEROSIS MÚLTIPLE**

(57) Resumen: La presente invención se relaciona con métodos para tratar esclerosis múltiple (MS) en un sujeto utilizando regímenes y protocolos de dosificación especial, y un artículo de fabricación con instrucciones para tal uso. El artículo de fabricación que comprende:

(a) un contenedor que contiene un anticuerpo CD20; y

CONTINUA AL RESPALDO ...

(b) un inserto de paquete con instrucciones para tratar esclerosis múltiple en un sujeto, en donde las instrucciones indican que una cantidad del anticuerpo se administra al sujeto que es efectiva para suministrar una exposición al anticuerpo inicial de aproximadamente 0.5 a 4 gramos seguido por una segunda exposición de anticuerpo de aproximadamente 0.5 a 4 gramos, la segunda exposición no se administra hasta aproximadamente 16 a 60 semanas de exposición inicial y cada una de las exposiciones de anticuerpo se suministra al sujeto como una o dos dosis de anticuerpo.

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES
EXTRACTO PARA PUBLICACIÓN
SOLICITUD DE PATENTE DE INVENCIÓN PCT

(1) N° de solicitud: 06 121.070 22) Fecha de solicitud: 30-11-2006 (30) Prioridad (31) No. Prioridad 32) Fecha (33) País 60/576,993 04-06-2004 US	(51) Int Cl: (71)Solicitante(s): GENENTECH, INC. (72) Inventor(es) Paul A. Frohna (74) Agente: JUAN PABLO CADENA SARMIENTO
(85) Fecha inicio fase nacional: 04-01-2007 (86) Datos relativos a la presentación de la solicitud PCT Fecha de presentación de la solicitud: 02-06-2005 No. de solicitud PCT/US2005/019641	(87) Publicación Internacional Fecha: 15-12-2005 N° publicación: WO/2005/117978 A3
(54) Título: MÉTODO PARA TRATAR LA ESCLEROSIS MÚLTIPLE	

Resumen:

La presente invención se relaciona con métodos para tratar esclerosis múltiple (MS) en un sujeto utilizando regímenes y protocolos de dosificación especial, y un artículo de fabricación con instrucciones para tal uso. El artículo de fabricación que comprende:

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aa/102443

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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by L. Edelen

3. acting in the capacity of Certifying Officer

4. bears the seal/stamp of Patent and Trademark Office

Certified

5. at Washington, D.C.

6. the fourth of December, 2006

7. by *~~Assistant~~ Authentication Officer, United States Department of State*

8. No. 07006437-1

9. Seal/Stamp:

10. Signature:

Denitra T. Hawkins

COLUMBIA

377

A 7039839

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

November 16, 2006

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF A DOCUMENT RECORDED ON August 20, 2004.

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

L. Edelen

L. EDELEN
Certifying Officer

633235

37,878

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

RECORDATION FORM COVER SHEET
PATENTS ONLY

Atty Dkt No: PR2134

Assistant Commissioner of Patents: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

   Paul A. Prolma

   Additional name(s) of conveying party(ies) attached? _ Yes X No

2. Name and address of receiving party(ies):

   Name: GENENTECH, INC.

   Internal Address:

   Street Address: 1 DNA Way

   City: South San Francisco State: California

   ZIP: 94080-4990

   Additional name(s) & address(es) attached? _ Yes X No

3. Nature of conveyance:

   X Assignment Merger

   Security Agreement

   Change of Name

   Other:

   Execution Date: August 16, 2004

4. Application number(s) or patent number(s):

   If this document is being filed together with a new application, the execution date of the application is:

   A. Patent Application No.(s)

   60/576,993

   B. Patent No.(s)

   Additional numbers attached? _ Yes X No

5. Name and address of party to whom correspondence concerning document should be mailed:

   Wendy M. Lee
   GENENTECH, INC.
   1 DNA Way
   South San Francisco, CA 94080

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41): $ 40.00

   _ Enclosed

   X Authorized to be charged to deposit account

8. Deposit account number:
   07-0630

DO NOT USE THIS SPACE

9. Statement and signature.

   To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

   Wendy M. Lee
   Name of Person Signing
   Registration No. 40,378

   WMLee
   Signature

   August 20, 2004
   Date

Total number of pages comprising cover sheet, attachments and document: 2

Revised (10/1/02)

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Docket No. PR2134

ASSIGNMENT

WHEREAS, Paul A. Frohna, a citizen of US , residing at 3880 19th Street, San Francisco, CA 94114 (hereinafter "ASSIGNOR"), has invented a new and useful invention in

METHOD FOR TREATING MULTIPLE SCLEROSIS

for which a provisional application Serial No. 60/576,993, if received (Docket No. PR2134) has been filed by him on June 4, 2004; and

WHEREAS, GENENTECH, INC., a corporation organized and existing under and by virtue of the laws of the State of Delaware, having a place of business at 1 DNA Way, South San Francisco, California 94080-4990, is desirous of acquiring an interest in and to said invention, and in and to the Letters Patents to be obtained therefor;

NOW, THEREFORE, be it known by all whom it may concern;

That for good and valuable consideration the receipt of which is hereby acknowledged, the said ASSIGNOR have and do hereby sell, assign, transfer and set over unto the said GENENTECH, INC., its successors and assigns, the full and exclusive right, title and interest including all rights under the Paris Convention for the Protection of Industrial Property, in and to said invention, and in and to any and all Letters Patents to be granted and issued therefor or any continuation, division, renewal, or substitute thereof, and as to Letters Patents any reissue or re-examination thereof, not only for, to, and in the United States of America, its territories and possessions, but for, to and in all other countries; and it has been and is hereby authorized and requested that the appropriate government agencies issue said Letters Patents to said GENENTECH, INC., in accordance with this Assignment.

Said ASSIGNOR covenants and agrees to cooperate with GENENTECH, INC., to enable said GENENTECH, INC. to enjoy to the fullest extent the right, title and interest herein conveyed in the United States and foreign countries. Such cooperation by said ASSIGNOR includes prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said GENENTECH, INC., (a) for perfecting the right, title and interest herein conveyed; (b) for prosecuting any of said applications; (c) for filing and prosecuting applications for reissuance of any of said patents; (d) for interference or other priority proceedings involving said invention; and (e) for legal proceedings involving said invention and any applications therefor and any patents granted thereon, including without limitation opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said ASSIGNOR in providing such cooperation shall be paid for by said GENENTECH, INC.

The terms and covenants of this assignment shall inure to the benefit of said GENENTECH, INC., its successors, assigns and other legal representatives, and shall be binding upon said ASSIGNOR, their respective heirs, legal representatives and assigns.

Said ASSIGNOR hereby warrants and represents that he has not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

IN WITNESS WHEREOF I undersign as follows;

South San Francisco

Dated 16 Aug 2004

Paul A. Frohna MD PhD

Paul A. Frohna

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TRADUCCION AL ESPAÑOL del Documento de Cesión a **GENENTECH, INC.** firmado por los cedentes y el cesionario.

APOSTILLA

(Convención de La Haya del 5 de octubre de 1961)

1. País: Estados Unidos de América

Este documento público

2. ha sido firmado por L. Edelen
3. actuando en capacidad de Funcionario que Certifica
4. lleva el sello/timbre de la Oficina de marcas y patentes

Certificado

5. en Washington D.C.
6. el cuatro de Diciembre de 2006
7. por el Funcionario de autenticación, Departamento de Estado de Estados Unidos
8. No. 07006437-1
9. Sello/timbre

10. Firma

(Firma)

Denitra T. Hawkins

[sello]

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LOS ESTADOS UNIDOS DE AMÉRICA
A TODO AQUEL QUE PUEDA LLEGARLE LA PRESENTE:

DEPARTAMENTO DE COMERCIO DE ESTADOS UNIDOS
Oficina de Marcas y Patentes de Estados Unidos

Noviembre 16 de 2006

ESTE ES PARA CERTIFICAR QUE EL ANEXO ES UNA COPIA VERDADERA DE LOS ARCHIVOS DE ESTA OFICINA DE UN DOCUMENTO ARCHIVADO EL 20 DE AGOSTO DE 2004.

Por autoridad del
Subsecretario de Comercio para la Propiedad Intelectual
y Director de la Oficina de Marcas y Patente de Estados Unidos

L. Edelen
Funcionario que Certifica

Hay un sello que dice:
Oficina de Marcas y Patentes de Estados Unidos
Departamento de Comercio

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HOJA DE PORTADA DEL FORMULARIO DE REGISTRO

SOLAMENTE PATENTES

Departamento de Comercio
Oficina de Marcas y Patentes
Expediente de abogado No PR2027

Comisionado Asistente para patentes: Por favor archive los documentos originales anexos o copias de los mismos

1. Nombre de la(s) parte(s) cedente(s):

Paul A. Frohna

¿Se anexa(n) nombre(s) adicional(es) de parte(s) cedente(s)? _ Si X No

2. Nombre y dirección de la(s) parte(s) receptora(s)

Nombre: GENENTECH, INC.

Dirección interna:

Dirección: 1 DNA Way

Ciudad: South San Francisco Estado: California

ZIP: 94080-4990

¿Se anexan Nombre(s) y dirección(es) adicional(es)? _ Si X No

3. Naturaleza del traspaso:

X Cesión Fusión

Acuerdo de Seguridad

Cambio de Nombre

Otro:

Fecha de Ejecución: Agosto 16, 2004

4. Numero(s) de solicitud o número(s) de patente:

Si este documento se presenta junto con una nueva solicitud, la fecha de ejecución de la solicitud es:

A Solicitud de patente No(s)

60/576,993

B Patente No(s).

¿Se anexa numeros adicionales? __ Si X No

5. Nombre y dirección de la parte a quien se le debe enviar la correspondencia:

Wendy M. Lee
GENENTECH, INC.
1DNA Way
South San Francisco, CA 94080

6. Numero total de solicitudes y patentes involucradas: 1

7. Tarifa total (37 C.F.R 3.41): $40.00

__ Adjunta
X Autorizado para cargarla a cuenta de depósito

8. Número de cuenta de Depósito:
07-0630

NO USE ESTE ESPACIO

9. Declaración y firma.
hasta donde se y creo, la información anterior es verdadera y correcta y cualquier copia anexa es una copia verdadera del documento original.

Wendy M. Lee
Nombre de la persona que firma
Registro No. 40378

(Firma)
Firma

Agosto 20, 2004
Fecha

Número total de páginas que comprenden portada, anexos y documento: 2

14 383

CESIÓN

CONSIDERANDO QUE, Paul A. Frohna, residente en 3880 19th Street, San Francisco, CA 94114 (en adelante referidos como "CEDENTE"), ha inventado una invención nueva y útil

METODO PARA EL TRATAMIENTO DE LA ESCLEROSIS MULTIPLE

para la cual se presentó la solicitud provisional No. 60/576,993 (Expediente No. PR2134) por ellos el 4 de Junio de 2004; y

CONSIDERANDO QUE, GENENTECH, INC., una corporación organizada y existente bajo y por virtud de las leyes del Estado de Delaware, que tiene oficinas en 1 DNA Way, South San Francisco, California 94080-4990, está deseosa de adquirir un interés en y para dicha invención, y en y para las patentes que se obtendrán de la misma;

AHORA, POR LO TANTO, téngase por sabido por todo aquel que le concierna:

Que por una consideración buena y valiosa el recibo de la cual se reconoce por la presente, dicho CEDENTE ha y por la presente vende, cede, transfiere y traspasa a dicha GENENTECH, INC. sus sucesores y cesionarios, el derecho, título e interés completo y exclusivo incluyendo todos los derechos bajo la Convención de Paris para la Protección de la Propiedad Industrial, en y para dicha invención, y en y para cualquiera y todas las patentes que se concedan y emitan para la misma o cualquier continuación, división, renovación, o sustitución de la misma, y en cuanto a patentes cualquier reemisión o reexaminación de las mismas, no solo para, por y en los Estados Unidos de América, sus territorios y posesiones, sin para, por y en todos los otros países; y se ha y por la presente se autoriza y solicita que las agencias gubernamentales respectivas emitan dichas patentes a GENENTECH, INC. de acuerdo con esta cesión.

Dicho CEDENTE garantiza y acuerda cooperar con GENENTECH, INC., para posibilitar a dicha GENETECH, INC., a disfrutar hasta su máxima extensión el derecho, título e interés aquí cedido en Estados Unidos y los países extranjeros. Tal cooperación por dichos CEDENTE incluye la pronta producción de hechos y documentos pertinentes, dando testimonio, ejecutando peticiones, juramentos, especificaciones, declaraciones u otros documentos, y otra ayuda todas hasta el punto considerado necesario o deseable por dichas GENETECH, INC. (a) para perfeccionar el derecho, título e interés aquí cedido; (b) para procesar cualquiera de dichas solicitudes; (c) para presentar y procesar solicitudes de reemisión de cualquiera de dichas patentes; (d) para procesos de interferencia u otros procesos de prioridad que involucran dicha invención; y (e) para procedimientos legales que involucran dicha invención y cualquier solicitud de la misma y cualquier patente concedida sobre la misma, incluyendo sin limitación procedimientos de oposición, procedimientos de cancelación, disputas de prioridad, procesos de uso público, acciones de violación y acciones de la corte; con la condición que los gastos incurridos por dicho CEDENTE al proporcionar dicha cooperación deban ser pagados por GENETECH, INC.

Los términos y garantías de esta cesión deben lastimar a benefició de dicha GENETECH, INC. sus sucesores, cesionarios y otros representantes legales, y deberá ser obligante sobre dichos CEDENTE, sus respectivos herederos, representantes legales y cesionarios.

Dicho CEDENTE por la presente garantizan y manifiestan que no ha entrado y no entrará en ninguna cesión, contrato o entendimiento en conflicto con la presente.

EN TESTIMONIO DE LO CUAL suscribimos como sigue:

South San Francisco

(Firma)
Paul A. Frohna

Fechado: 16/08/ 04

PATENTE
CERTIFICADO: 08/20/2004 **ROLLO: 015075 CUADRO 0989**

As 102493

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PATENT COOPERATION TREATY

CLC/JND/LS

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)
(PCT Rule 44bis.1(c))

RECEIVED
DEC 21 2006
GENENTECH, INC.
LEGAL DEPT.

To:

LEE, Wendy, M.
Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080-4990
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)	
14 December 2006 (14.12.2006)	
Applicant's or agent's file reference: P2134R1	IMPORTANT NOTICE

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/US2005/019641	02 June 2005 (02.06.2005)	04 June 2004 (04.06.2004)

Applicant: GENENTECH, INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

Calendared/LRS
Forward IPRP to Assocs ID
15 JAN 07
Due Date

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Nora Lindner
Facsimile No. +41 22 338 82 70	e-mail: pt02@wipo.int

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference P2134R1	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2005/019641	International filing date *(day/month/year)* 02 June 2005 (02.06.2005)	Priority date *(day/month/year)* 04 June 2004 (04.06.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant GENENTECH, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

   - [X] Box No. I — Basis of the report
   - [ ] Box No. II — Priority
   - [X] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV — Lack of unity of invention
   - [X] Box No. V — Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI — Certain documents cited
   - [ ] Box No. VII — Certain defects in the international application
   - [ ] Box No. VIII — Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 04 December 2006 (04.12.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Nora Lindner
Facsimile No. +41 22 338 82 70	e-mail: pt02@wipo.int

Form PCT/IB/373 (January 2004)

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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 01 MAY 2006
WIPO PCT

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2005/019641	02.06.2005	04.06.2004

International Patent Classification (IPC) or both national classification and IPC
INV. A61K39/395 A61P25/00

Applicant
GENENTECH, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Perez, F

Telephone No. +49 89 2399-7338

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2005/019641

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☒ in written format

   ☒ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☒ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2005/019841

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-35

because:

☒ the said international application, or the said claims Nos. 1-35 (industrial applicability) relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the whole application or for said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2005/019641

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-35
	No:	Claims	36-38
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-38
Industrial applicability (IA)	Yes:	Claims	36-38
	No:	Claims	

2. Citations and explanations

see separate sheet

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No.
PCT/US2005/019641

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 1-35 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO 2004/035607 A (GENMAB A/S; MEDAREX, INC; TEELING, JESSICA; RUULS, SIGRID; GLENNIE, MA) 29 April 2004
D2: WO 02/22212 A (IDEC PHARMACEUTICALS CORPORATION) 21 March 2002
D3: WO 01/13945 A (BIOCRYSTAL LTD) 1 March 2001
D4: WO 03/068821 A (IMMUNOMEDICS, INC; MCCALL, JOHN, DOUGLAS) 21 August 2003
D5: COLES A J ET AL: "Pulsed monoclonal antibody treatment and autoimmune thyroid disease in multiple sclerosis" LANCET THE, LANCET LIMITED. LONDON, GB, vol. 354, no. 9191, 13 November 1999 (1999-11-13), pages 1691-1695
D6: COLES A J ET AL: "MONOCLONAL ANTIBODY TREATMENT EXPOSES THREE MECHANISMS UNDERLYING THE CLINICAL COURSE OF MULTIPLE SCLEROSIS" ANNALS OF NEUROLOGY, BOSTON, US, vol. 46, no. 3, September 1999 (1999-09), pages 296-304
D7: US 2004/072749 A1 (ZOCHOER MARCEL ET AL) 15 April 2004

Novelty (Articles 33.1 and 33.2 PCT)

Claim 1 relates to a method of treating multiple sclerosis comprising administering CD20 antibody in two exposures separated by 16-60 weeks.

Whereas D1-D2 disclose the use of CD20 antibody for treating multiple sclerosis, none disclose the dosage regimen covered by claim 1. Claims 1-35 are therefore novel.

Claims 36-38 cover articles of manufactures. Instructions of use are not considered as a technical feature susceptible to differentiate a compound. The articles of manufactures are therefore characterised as a container comprising a CD20 antibody, and optionally a second container containing a second medicament.

CD20 antibody is a well known product in the prior art which thus is packaged into a container and CD20 antibodies are commonly associated with other medicaments. Claims 36-38 therefore lack novelty.

Inventive Step (Articles 33.1 and 33.3 PCT)

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses the use of CD20 antibody for treating multiple sclerosis using a single exposure of the antibody.

The subject-matter of claim 1 therefore differs from this known treatment in that a second injection is performed 16-50 week after the first injection.

The problem to be solved by the present invention may therefore be regarded as providing a different dosage regimen for the treatment of multiple sclerosis with CD20 antibody.

The application nevertheless fails to show any technical advantage which is new and surprising, and that could convincingly be related to a second administration. The application can therefore be construed as an arbitrary modification of the treatments of multiple sclerosis known from the prior art.

Consequently, the present application cannot be considered as involving an inventive step (Article 33(3) PCT).

Industrial applicability (Articles 33.1 and 33.4 PCT)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No.
PCT/US2005/019841

For the assessment of the present claims 1-35 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Further remarks

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D6 is not mentioned in the description, nor are these documents identified therein.

It should be noted that upon entry within the regional phase, the allowability of claim 1 would be reconsidered in the light of Article 52(4) EPC.