

564

AS: 103.411

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

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 07-038013- -00002-0000

Fecha: 2007-06-25 16:54:24 Dep. 2020 NUECREACIONI
Tra. 11 PATENTEIYII Eje: 378 FASENACIONALI
Act. 444 RESPUESTAREQUE Folios: 34

RESPUESTA A OFICIO 5047 DE 04 MAYO 200

REF: Expediente No. 07 038013 - Solicitud de Patente FASE NACIONAL Corresp.
a la Solicitud Internacional PCT/US2005/037471
a favor de GENENTECH, INC.
Titulada: FORMULACIÓN DE ANTICUERPO EN AMORTIGUADOR DE ACETATO
DE HISTIDINA

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 04 de mayo de 2007 y 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 anexar al presente escrito los siguientes documentos:

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

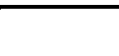
De la señora jefe atentamente,


JUAN PABLO CADENA SARMIENTO
C.C. No. 80.410.337 de Usaquén
Cra. 7 No. 71-21, Torre B, Piso 4

Bogotá, 22 de junio de 2007
CHP/MEVaac

565

 Industria y Comercio SUPERINTENDENCIA		SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO DIVISION DE NUEVAS CREACIONES TARJETA ARCHIVO TEMÁTICO PATENTE DE INVENCION ☒ PCT ☒ MODELO DE UTILIDAD ☐ DISEÑO INDUSTRIAL ☐	
(21) N° de solicitud: 07 038013		(22) Fecha de solicitud: 17-04-2007	
(51) Clasificación Internacional :		FIGURA CARACTERISTICA 6 x 6 cm	
(71) Solicitante(s) GENENTECH, INC.			
(72) Inventor(es) James D. ANDYA, Shiang C. GWEE, Jun LIU, Ye SHEN			
(74) Agente: JUAN PABLO CADENA SARMIENTO			
(30) Prioridad	(31) No. Prioridad 60/620,413		
(85) Fecha inicio fase nacional: 20-05-2007		(87) Publicación internacional:	
(86) Datos relativos a la presentación de la solíc. PCT		Fecha: 27-04-2006	
Fecha de presentación de la solicitud: 19-10-2005		No. Publicación: WO 2006/044908 A3	
No. de solicitud: PCT/US2005/037471			
(54) Título: FORMULACIÓN DE ANTICUERPO EN AMORTIGUADOR DE ACETATO DE HISTIDINA			
(57) Resumen: La invención concierne a una formulación farmacéutica estable, que comprende un anticuerpo monoclonal en amortiguador de acetato de histidina, pH 5.5 a 6.5. El anticuerpo monoclonal preferiblemente usa un antígeno seleccionado del grupo conformado por HER2, CD20, DR5, BR3, IgE, y VEGF. En otro aspecto, la invención concierne a una formulación farmacéutica que comprende: (a) un anticuerpo IgG1 de longitud total susceptible a desamidación o agregación en una cantidad desde alrededor de 10mg/mL a alrededor de 250mg/mL; (b) amortiguador de acetato de histidina, pH 5.5 a 8.5; (c) sacárido seleccionado del grupo conformado por trehalosa y sacarosa, en una cantidad desde alrededor de 80mM a alrededor de 250mM; y (d) polisorbato 20 en una cantidad desde alrededor de 0.01% a alrededor de 0.1%.			
CONTINUA AL RESPALDO ...			

 Industria y Comercio SUPERINTENDENCIA	SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO DIVISION DE NUEVAS CREACIONES EXTRACTO PARA PUBLICACIÓN SOLICITUD DE PATENTE DE INVENCION PCT
(21) N° de solicitud: 07 038013 (22) Fecha de solicitud: 17-04-2007 (30) Prioridad (31) No. Prioridad (32) Fecha (33) Pais 60/620,413 20-10-2004 US	(51) Int Cl: (71) Solicitante(s) GENENTECH, INC. (72) Inventor(es) James D. ANDYA, Shiang C. GWEE, Jun LIU, Ye SHEN (74) Agente: JUAN PABLO CADENA SARMIENTO
(85) Fecha inicio fase nacional: 20-05-2007 (86) Datos relativos a la presentación de la solicitud PCT Fecha de presentación de la solicitud: 19-10-2005 No. de solicitud: PCT/US2005/037471	(87) Publicación Internacional Fecha: 27-04-2006 N° publicación: WO 2006/044908 A3
(54) Título: FORMULACIÓN DE ANTICUERPO EN AMORTIGUADOR DE ACETATO DE HISTIDINA	

Resumen:

La invención concierne a una formulación farmacéutica estable, que comprende un anticuerpo monoclonal en amortiguador de acetato de histidina, pH 5.5 a 6.5. El anticuerpo monoclonal preferiblemente une un antígeno seleccionado del grupo conformado por HER2, CD20, DR5, BR3, IgE, y VEGF.

En otro aspecto, la invención concierne a una formulación farmacéutica que comprende: (a) un anticuerpo IgG1 de longitud total susceptible a desamidación o agregación en una cantidad desde alrededor de 10mg/mL a alrededor de 250mg/mL; (b) amortiguador de acetato de histidina, pH 5.5 a 6.5; (c) sacárido seleccionado del grupo conformado por trehalosa y sacarosa, en una cantidad desde alrededor de 60mM a alrededor de 250mM; y (d) polisorbato 20 en una cantidad desde alrededor de 0.01% a alrededor de 0.1%.

**DOCUMENT OF ASSIGNMENT OF
PATENT APPLICATION**

ASSIGNMENT

The Undersigned James D. ANDYA, Ye SHEN

acting as Inventors

of Colombian Patent Appln. No. 07 038.013

Title: ANTIBODY FORMULATION IN
HISTIDINE-ACETATE BUFFER

with domicile in 227 Richmond Drive, Apt. D,
Millbrae, CA 94030, United States of America;
386 Faxon Avenue, San Francisco, CA
94112, United States of America
(respectively)

hereby declare(s) that he (they) assign(s) all
rights of ownership as well as all rights and
privileges relating thereto without exception
over the following patent application in
Colombia:

No. 07 038.013

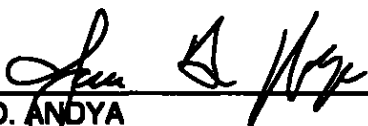
Title: ANTIBODY FORMULATION IN
HISTIDINE-ACETATE BUFFER

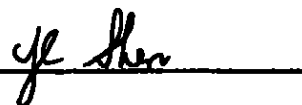
to: GENENTECH, INC.

domiciled in 1 DNA Way, South San
Francisco, CA 94080-4990, United States of
America

The assignor and the assignee sign this
document as proof of their acceptance of the
assignment.

Given and signed on the day of
of 200_
Signature of Assignor(s)


James D. ANDYA


Ye SHEN

Signature of Assignee

 EMB

Timothy R. Schwartz, Ph.D.
Associate General Counsel, Director
Genentech, Inc.
Authorized Corporate Signatory

**DOCUMENTO DE TRASPASO DE
SOLICITUD DE PATENTE**

CESION

El(los) Suscrito(s) James D. ANDYA, Ye SHEN

en calidad de Inventores

de la Sol. de patente Colombiana No. 07 038.013

Titulada: FORMULACIÓN DE ANTICUERPO
EN AMORTIGUADOR DE ACETATO DE
HISTIDINA

con domicilio en 227 Richmond Drive, Apt. D,
Millbrae, CA 94030, Estados Unidos de
América; 386 Faxon Avenue, San Francisco,
CA 94112, Estados Unidos de América
(respectivamente)

declara(n) por el presente documento que
cede(n) todos los derechos de propiedad que
le(s) correspondan, así como las prerrogativas,
sin excepción alguna, sobre la siguiente
solicitud de patente en Colombia:

No. 07 038.013

Titulada: FORMULACIÓN DE ANTICUERPO
EN AMORTIGUADOR DE ACETATO DE
HISTIDINA

a: GENENTECH, INC.

domiciliada en in 1 DNA Way, South San
Francisco, CA 94080-4990, Estados Unidos
de América

El cedente y el cesionario firman este
documento como prueba de su aceptación de
la cesión.

Dado y firmado a los días del mes de
de 200_

Firma del Cedente

Firma del Cesionario

568
State of California

SECRETARY OF STATE

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. *Country: United States of America*
This public document
2. *has been signed by CAROLYN C. CAIRES*
3. *acting in the capacity of Notary Public, State of California*
4. *bears the seal/stamp of CAROLYN C. CAIRES, Notary Public,*
State of California

CERTIFIED

5. *At Sacramento, California*
6. *the 16th day of May 2007*
7. *by Deputy Secretary of State, State of California*
8. *No. 391153*
9. *Seal/Stamp:*

10. *Signature*



John Bowen
Secretary of State



568
State of California

SECRETARY OF STATE

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

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10. *Signature*



Jana Bowen
Secretary of State



8 569

ACKNOWLEDGMENT

State of California
County of San Mateo

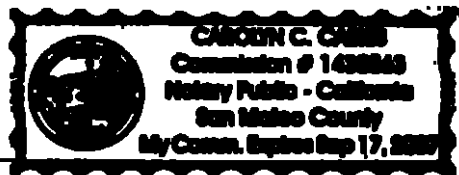
On 1 May 2007 before me, Carolyn C. Caires, Notary Public
(here insert name and title of the officer)

personally appeared James D. Andya and Ye Shen

personally known to me ~~(or proved to me on the basis of satisfactory evidence)~~ to be
the person(s) whose name(s) ~~is/are~~ subscribed to the within instrument and
acknowledged to me that ~~he/she/they~~ executed the same in ~~his/her/their~~ authorized
capacity(ies), and that by ~~his/her/their~~ signature(s) on the instrument the person(s),
or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

Signature Carolyn C. Caires
Carolyn C. Caires



(Seal)

ATE

State of California

SECRETARY OF STATE

APOSTILLE

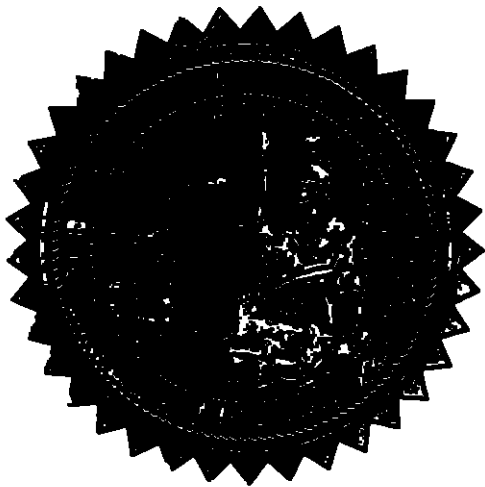
(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*
This public document
2. *has been signed by CAROLYN C. CAIRES*
3. *acting in the capacity of Notary Public, State of California*
4. *bears the seal/stamp of CAROLYN C. CAIRES, Notary Public, State of California*

CERTIFIED

5. *At Sacramento, California*
6. *the 16th day of May 2007*
7. *by Deputy Secretary of State, State of California*
8. *No. 391154*
9. *Seal/Stamp:*

10. Signature



Jana Bowen
Secretary of State



257.1

ACKNOWLEDGMENT

State of California
County of San Mateo

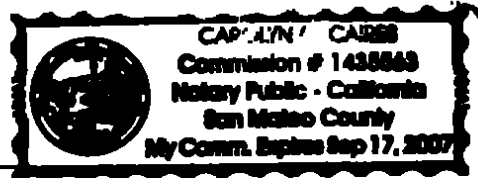
On 7 May 2007 before me, Carolyn C. Caires, Notary Public
(here insert name and title of the officer)

personally appeared Timothy R. Schwartz

personally known to me ~~(or proved to me on the basis of satisfactory evidence)~~ to be
the person(s) whose name(s) is/~~are~~ subscribed to the within instrument and
acknowledged to me that he/~~she/they~~ executed the same in his/~~her/their~~ authorized
capacity(ies), and that by his/~~her/their~~ signature(s) on the instrument the person(s),
or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

Signature Carolyn C. Caires
Carolyn C. Caires



(Seal)

CAPACITY(IES) CLAIMED BY SIGNER

Signer's Name: Timothy R. Schwartz
Corporate Officer - Title(s): Associate General Counsel - Director
Signer is representing: GENENTECH, INC.

1/2
572
9

TRADUCCION AL ESPAÑOL del Documento de Cesión a **GENENTECH, INC.**
firmada por el cedente y el cesionario.

Hay un sello que dice:

Timothy R. Schwartz, Ph.D
Consejero General Asociado
Genentech, Inc.
Firmante Corporativo Autorizado

ESTADO DE CALIFORNIA
[Sello]

SECRETARIO DE ESTADO

APOSTILLA

(Convención de la Haya del 5 de Octubre 1961)

1. País: Estados Unidos de América
Este documento público
2. ha sido firmado por Carolyn C. Caires
3. actuando en capacidad de Notario Público, Estado de California
4. lleva el sello/timbre de Carolyn C. Caires, Notario Público
Estado de California

CERTIFICADO

5. En Sacramento, California
6. el 16o día de Mayo de 2007
7. por el Secretario de Estado Encargado, Estado de California
8. No. 391153
9. Sello/Timbre

Hay un sello que dice:

10. Firma

EL GRAN SELLO DE
EL ESTADO DE CALIFORNIA

(firma)
Secretario de Estado

573

RECONOCIMIENTO

Estado de California

Condado de San Mateo

El 1ro de Mayo de 2007 ante mí, Carolyn Caires, Notario Público, se
presentaron personalmente James D. Andya y Ye Shen

personalmente conocidos por mí como la(s) persona(s) cuyo(s) nombre(s) están
suscritos al presente instrumento y quienes reconocieron que ellos ejecutaron la
misma en su capacidad autorizada, y que por su(s) firma(s) en el instrumento la
persona(s) o la entidad de parte de la cual la persona(s) actuó ejecutó el
instrumento.

EN TESTIMONIO mi firma y sello oficial.

Firma (firma)
Carolyn C. Caires

Hay un sello que dice:
CAROLYN C. CAIRES
Comisión # 1435563
Notario Público – California
Condado de San Mateo
Mi Comisión Vence Sep. 17, 2007

X 574

ESTADO DE CALIFORNIA
[Sello]

SECRETARIO DE ESTADO

APOSTILLA

(Convención de la Haya del 5 de Octubre 1961)

1. País: Estados Unidos de América
Este documento público
2. ha sido firmado por Carolyn C. Caires
3. actuando en capacidad de Notario Público, Estado de California
4. lleva el sello/timbre de Carolyn C. Caires, Notario Público
Estado de California

CERTIFICADO

5. En Sacramento, California
6. el 16o día de Mayo de 2007
7. por el Secretario de Estado Encargado, Estado de California
8. No. 391154
9. Sello/Timbre

Hay un sello que dice:

10. Firma

EL GRAN SELLO DE
EL ESTADO DE CALIFORNIA

(firma)
Secretario de Estado

576
17

RECONOCIMIENTO

Estado de California

Condado de San Mateo

El 7 de Mayo de 2007 ante mí, Carolyn Caires, Notario Público, se presentó personalmente Timothy R. Schwartz

personalmente conocidos por mí como la(s) persona(s) cuyo(s) nombre(s) está suscrito al presente instrumento y quien reconoció que el ejecutó la misma en su capacidad autorizada, y que por su(s) firma(s) en el instrumento la persona(s) o la entidad de parte de la cual la persona(s) actuó ejecutó el instrumento.

EN TESTIMONIO mi firma y sello oficial.

Firma _____ (firma)
Carolyn C. Caires

Hay un sello que dice:
CAROLYN C. CAIRES
Comisión # 1435563
Notario Público – California
Condado de San Mateo
Mi Comisión Vence Sep. 17, 2007

CAPACIDAD(ES) AFIRMADAS POR EL FIRMANTE

Nombre del Firmante: Timothy R. Schwartz
Funcionario Corporativo – Título: Consejero General Asociado – Director
El firmante representa a: GENENTECH, INC.

As. 103411
(2/2)
577

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America

This public document

2. has been signed by M. K. Carter

3. acting in the capacity of Certifying Officer

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

Certified

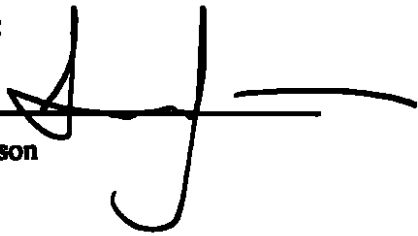
5. at Washington, D.C.

6. the twenty-third of May, 2007

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

8. No. 07023812-11

9. Seal/Stamp:

10. Signature:


Sonya N. Johnson

A 7065252



THE UNITED STATES OF AMERICA

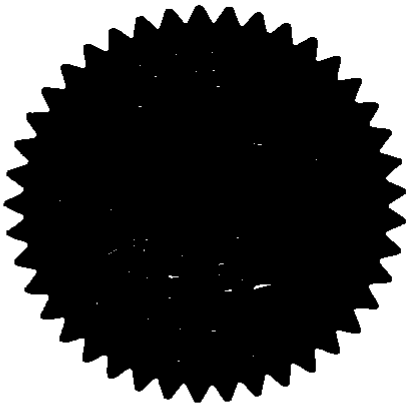
TO ALL TO WHOM THESE PRESENTS SHALL COME:

**UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office**

May 01, 2007

**THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE
RECORDS OF THIS OFFICE OF A DOCUMENT RECORDED ON
JANUARY 03, 2005.**

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




**M. K. CARTER
Certifying Officer**

**RECORDATION FORM COVER SHEET
PATENTS ONLY**

U.S. DEPARTMENT OF COMMERCE

Patent and Trademark Office

Any Dkt No: PR2104

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

1. Name of conveying party(ies):Shiang C. Gwee
Jun LiuAdditional name(s) of conveying party(ies) attached? _ Yes ☒ No**2. Name and address of receiving party(ies):**Name: GENENTECH, INC.

Internal Address:

Street Address: 1 DNA WayCity: South San Francisco State: CaliforniaZIP: 94080-4990Additional name(s) & address(es) attached? _ Yes ☒ No**3. Nature of conveyance:**☒ Assignment

Merger

Security Agreement

Change of Name

Other:

Execution Date: 12/16/04 & 12/17/04**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)

60/620,413

B. Patent No.(s)

Additional numbers attached? _ Yes ☒ 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

☒ 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

Signature

Date

Total number of pages comprising cover sheet, attachments and document: 4

4-000 (10/11/97)

ASSIGNMENT
(joint provisional appln.)

WHEREAS, Shiang C. Gwee, a citizen of the U.S.A., residing at 565 Crespi Drive, Pacifica, CA 94044, and Jun Liu, a citizen of the U.S.A., residing at 1108 Glacier Avenue, Pacifica, CA 94044, (hereinafter "ASSIGNORS"), have invented a new and useful invention in

ANTIBODY FORMULATIONS

for which a provisional application Serial No. 60/620,413 has been filed by them on October 20, 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 94080-4490, 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 ASSIGNORS 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 ASSIGNORS covenant and agree 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 ASSIGNORS 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 ASSIGNORS 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 ASSIGNORS, their respective heirs, legal representatives and assigns.

PATENT
REEL: 015616 FRAME: 0149

Handwritten: 581

Said ASSIGNORS hereby warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

IN WITNESS WHEREOF we undersign as follows;

South San Francisco
12/16/2004
Date

Shiang C. Gwee
Name: Shiang C. Gwee

South San Francisco

Date

Name: Jun Liu

Said ASSIGNORS hereby warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

IN WITNESS WHEREOF we undersign as follows;

South San Francisco

Date

Name: Shiang C. Gwee

South San Francisco

Date

Name: Jun Liu

12/17/04



RECORDED: 01/03/2005

PATENT
REEL: 015516 FRAME: 0161

27 584

**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**

Mayo 1 de 2007

**ESTE ES PARA CERTIFICAR QUE EL ANEXO ES UNA COPIA
VERDADERA DE LOS ARCHIVOS DE ESTA OFICINA DE UN
DOCUMENTO ARCHIVADO EL 3 DE ENERO DE 2005.**

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

**M. K. CARTER
Funcionario que Certifica**

585

HOJA DE PORTADA DEL FORMULARIO DE REGISTRO SOLAMENTE PATENTES		Departamento de Comercio Oficina de Marcas y Patentes Expediente de abogado No. PR2179
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): Shiang C. Gwee Jun Liu ¿Se aneja(n) nombre(s) adicional(es) de parte(s) cedente(s)? _ Si ☒ No	2. Nombre y dirección de la(s) parte(s) receptora(s) Nombre: <u>GENENTECH, INC.</u> Dirección Interna: Dirección: <u>1 DNA Way</u> Ciudad: <u>South San Francisco</u> Estado: <u>California</u> ZIP: <u>94080-4990</u> ¿Se anejan Nombre(s) y dirección(es) adicional(es)? _ Si ☒ No	
3. Naturaleza del traspaso: ☒ Cesión Fusión Acuerdo de Seguridad Cambio de Nombre Otro: Fecha de Ejecución: <u>12/16/04 & 12/17/04</u>		
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). B. Patente No(s). 60/620,413 ¿Se aneja números adicionales? _ Si ☒ 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: <u>1</u>	
	7. Tarifa total (37 C.F.R 3.41): <u>\$40.00</u> _ Adjunta ☒ Autorizado para cargarla a cuenta de depósito	
	8. Número de cuenta de Depósito: <u>97-0630</u>	
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. <u>Wendy M. Lee</u> (Firma) <u>1-3-05</u> Nombre de la persona que firma Firma Fecha Registro No. 40,378 Número total de páginas que comprenden portada, anexos y documento: <u>5</u>		

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PATENTE
ROLLO: 015516 CUADRO 0148

586

CESIÓN

CONSIDERANDO QUE, Shiang C. Gwee, un ciudadano de E.U.A., residente en 565 Crespi Drive, Pacifica, CA, 94044, y Jun Liu, un ciudadano de E.U.A., residente en 1108 Glacier Avenue, Pacifica, CA 94044 (en adelante referidos como "CEDENTE"), han inventado una invención nueva y útil

FORMULACIONES DE ANTICUERPOS

para la cual se presentaron la solicitud provisional con No. de Serie 60/620,413 el 20 de octubre 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 conclama:

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 París 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 GENENTECH, 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 GENENTECH, 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 involucren dicha invención; y (e) para procedimientos legales que involucren 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 GENENTECH, INC.

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

PATENTE

ROLLO: 015516 CUADR 0149

24 587

Dicho CEDENTE por la presente garantiza y manifiesta 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	<u>(Firma)</u>
	Shiang C. Gwee

Fechado: 12/16/ 04

South San Francisco	<u></u>
	Jun Liu

Fechado:

IX 588

Dicho CEDENTE por la presente garantiza y manifiesta 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

Shiang C. Gwee

Fechado: _____

South San Francisco

(firma)
Jun Liu

Fechado: 12/17/04

PATENT COOPERATION TREATY

PCT

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

(PCT Rule 44bis)

Applicant's or agent's file reference P2104R1	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2005/037471	International filing date (day/month/year) 19 October 2005 (18.10.2005)	Priority date (day/month/year) 20 October 2004 (20.10.2004)
International Patent Classification (8th edition unless other edition indicated) See relevant information in Form PGT/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 7 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:

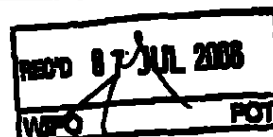
- | | |
|---|---|
| ☒ Box No. I | Basis of the report |
| ☐ Box No. II | Priority |
| ☒ Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ Box No. IV | Lack of unity of invention |
| ☒ Box No. V | Reasoned statement under Article 35(2) 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 44bis.3(c) and 93bis.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 44bis.2).

	Date of issuance of this report 24 April 2007 (24.04.2007)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Ellen Moyse
Facsimile No. +41 22 338 81 70	e-mail: p05.pat@wipo.int

Form PCT/IB/373 (January 2004)

PATENT CO PERATION TREATY



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From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCTISA220

705

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

Date of mailing
(day/month/year) see form PCTISA210 (second sheet)

Applicant's or agent's file reference
see form PCTISA220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2005/037471

International filing date (day/month/year)
19.10.2005

Priority date (day/month/year)
20.10.2004

International Patent Classification (IPC) or both national classification and IPC
INV. A61K39/085 A61K47/18

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 43bis.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") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 62.1bis(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 3 months from the date of mailing of Form PCTISA220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCTISA220.

3. For further details, see notes to Form PCTISA220.

Name and mailing address of the ISA:



European Patent Office
D-50538 Munich
Tel. +49 89 3593 - 0 Fax: 023636 opau d
Pac +49 89 3593 - 4466

Date of completion of
this opinion

see form
PCTISA210

Authorized Officer

Wagner, R

Telephone No. +49 89 2363-7337



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/J82005/037471

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
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purpose of international search (Rules 12.3(a) 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:
 - ☒ on paper
 - ☒ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☒ furnished subsequently to this Authority for the purpose 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:

see separate sheet

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2005/037471

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. 45,61,62,76-79

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (specify):

☐ 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 (specify):

☒ no international search report has been established for the whole application or for said claims Nos. 45,61,62,76-79 (regarding industrial applicability)

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

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

☐ See Supplemental Box for further details

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/037471

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

1. Statement

Novelty (N)	Yes: Claims	25-27, 40-56, 57-62, 64-79
	No: Claims	1-24, 28-48
Inventive step (IS)	Yes: Claims	
	No: Claims	1-79
Industrial applicability (IA)	Yes: Claims	1-44, 46-60, 63-73
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

27-594
International application No.

PCT/US2005/037471

Re Item I

Base of the report

The sequence listing filed with the letter dated 02.05.06 does not form part of the application as originally filed

Re Item III

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

Claims 45, 61, 62, 76-79 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 with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: WO03/105894

D2: WO03/106844

2. Claim 1 is directed to a pharmaceutical composition comprising a monoclonal antibody and a histidine acetate buffer at a pH between 5.5 and 6.5.

The prior art document D1 discloses an antibody formulation at the same pH range (page 21, lines 2-3) in a histidine buffer. The histidine salt used can be acetate (page 20, line 30). Therefore D1 anticipates the subject-matter of independent claim 1. The additional features of dependent claims 2-18 are also disclosed on pages 20 and 21 of D1. The characteristics of the antibody used to limit dependent claims 19-23 are inherent to the antibody used in D1 (see page 4). The additional features of

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2005/037471

dependent claims 24, 28-44 are either formulated as a result to be achieved or are inherent to the formulation, or are not considered to be characterising the formulation of claim 1 (vials, tanks etc). Therefore the subject-matter of said claims is not considered to be novel (Article 33(2) PCT).

Claims 25-27 are novel (Article 33(2) PCT) because D1 does not disclose a composition with the precise antibodies of said claims. But the subject-matter of claims 25-27 does not involve an inventive step because it refers to randomly chosen, commercially interesting antibodies and no technical effect can be related to the said choice. Therefore the subject-matter of claims 25-27 does not involve an inventive step (Article 33(3) PCT).

The method of treatment of claim 45 is not new (Article 33(2) PCT) because the antibodies of D1 are also intended for treating a disease.

The combination of features of claim 46 is also disclosed on pages 20 and 21 of D1 and therefore the subject-matter of claim 46 is not novel (Article 33(2) PCT).

In example 1 of D1 (page 57) the physical aggregation of the formulation was measured, with the aim to reduce aggregation. Therefore claims 47, 48, 63 are not new (Article 33(2) PCT).

The pharmaceutical compositions and their medical use of claims 49-56, 57-62, 64-79 differ from the disclosure of D1 only by the random choice of a precise therapeutic antibody. Therefore the subject-matter of said claim is considered to be novel (Article 33(2) PCT) but does not involve an inventive step (Article 33(3) PCT).

Document D2, is a patent application filed by the same applicant as D1 and discloses the same subject-matter relating to the formulation of the antibodies.