

Señora

Alix Carmenza Céspedes de Vergel

Jefe de División de Nuevas Creaciones

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

E. _____ S. _____ D. _____

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 08-125423- -00002-0000

Fecha: 2009-02-04 15:59:10 Dep. 2020 NUECREACIONI
Tra 11 PATENTEIYII Eve: 378 FASENACIONALI
Act. 444 RESPUESTAREQUE Folios: 27

Referencia: Expediente No. 08.125.423

Solicitud de Patente de Invención titulada: "Formulaciones novedosas que estabilizan e inhiben la precipitación de composiciones inmunogénicas"

Solicitante: Wyeth

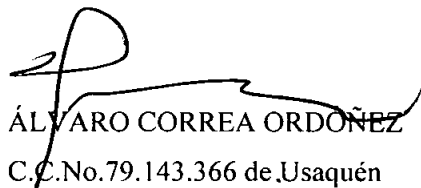
RESPUESTA AL AUTO NOTIFICADO POR FIJACIÓN EN LISTA NO. 405

DEL 12 DE DICIEMBRE DE 2008, OFICIO NO. 15764 (EXAMEN DE FORMA)

ÁLVARO CORREA ORDÓÑEZ, mayor de edad y vecino de Bogotá D.C., identificado tal como aparece al pie de mi firma, en mi carácter de apoderado de la sociedad en referencia, doy respuesta al auto emanado por ese Despacho dentro del término legal:

1. Presento copias debidamente legalizadas de los documentos en que consta la cesión del derecho a la patente a la entidad solicitante por parte de los inventores.

Atentamente,


ÁLVARO CORREA ORDÓÑEZ

C.C.No.79.143.366 de Usaquén

T.P.20.281

Anexos: Documentos de Cesión de Inventores

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Traducción oficial del ingles por Marlén Neira Castro, resolución 2117 del Ministerio de Justicia de Colombia

APOSTILLA EN CESIÓN A WYETH

APOSTILLA

(Convención De La Haya del 5 octubre de 1961)

1. País: Estados Unidos de América
2. Este documento Público ha sido firmado por Winifred A. Ventura
3. Quien ejerce funciones de notario público de Nueva Jersey
4. Lleva el sello de la corte de Winifred A. Ventura- Notario

CERTIFICADO

5. En Trenton, Nueva Jersey
6. El 23 de diciembre de 2008.
7. Por R. David Rousseau, Tesorero de Nueva Jersey
- 8 No. A 349627
9. Sello del estado de Nueva Jersey.
10. Firma ilegible

Certificado No. 11391753. verificar en línea en https://www.l.state.nj.us&Tytr_standingCert/JSP/Verify_cert.jsp

AM 102129

DECLARACIÓN JURADA

Yo, Michelle L. McGowan, por el presente certifico que la copia adjunta ha sido comparada con la Cesión Original (para U.S.S.N. 11/737.674 y todo equivalente legal de la misma en un país extranjero, para la invención titulada "formulaciones nuevas que estabilizan e inhiben la precipitación de composiciones inmunogenicas" (*Novel formulations which stabilize and inhibit precipitation of immunogenic compositions*)) fechada el 20 de junio de 2007, de Lakshmi Khandlke, Xudong Yang y Hanyoung Han, y fechada el 21 de junio de 2007 de Ronald Malone, y fechada el 22 de junio de 2007 de Jee Loon Look y Robert C. Seid, Jr.; y fechada el 11 de mayo de 2007 de Zhaowei Jin y Ying Chen a Wyeth y que dicha copia es una copia verdadera del original.

Fechada el 17 de diciembre de 2008, en Madison, Nueva Jersey, Estados Unidos de América.

Firma de Michelle L. McGowan

PARA USO EN MEJICO

RECONOCIMIENTO DE FIRMA

Estado De Nueva Jersey}

Condado de Morris] .

El 17 de diciembre de 2008, ante mi compareció personalmente *Michelle K. McGowan, International Filing Associate (asociada Internacional de presentaciones) de de Wyeth*, conocida por mi y a quien conozco como la persona descrita y quien suscribió el instrumento anterior, y ella reconoció que lo había suscrito.

Firma de Winifred A. Ventura No. 2334651

Sello de notario público de Nueva Jersey calificado en el condado de Morris. Su cargo vence el 19-9- 2010

Casillero de abogado No. 050765/326014

Marlén Neira Castro
MARLEN NEIRA CASTRO

Traductor e Intérprete

Inglés - Español

Resolución No. 2117 del 7/10/08

CESIÓN

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Por una contraprestación valiosa, cuyo recibo y suficiencia reconozco por el presente, cada uno de los inventores ha cedido, vendido, transferido y entregado y por el presente cede y vende a WYETH con sede en Five Giralda Farms – Madison, NJ 07940

Sus sucesores y cesionarios, la totalidad del título, derecho e interés en lo que se refiere a los Estados Unidos, sus territorios y posesiones y todos los países extranjeros, en y sobre la invención “Formulaciones nuevas que estabilizan e inhiben la precipitación de composiciones inmunogénicas”

Tal como establece en la solicitud de patente de los Estados Unidos

☐ suscrita concurrentemente con el presente documento

☐ suscrita en fecha

☒ solicitud no. 11/737.674, presentada el 19 de abril de 2007.

☒ La solicitud reivindica prioridad de la solicitud No. 60/ 795.261, presentada el 26 de abril de 2006, todas las solicitudes anotadas anteriormente se referirán en adelante como “la(s) solicitud(es)”;

Dicha solicitud para patente de los Estados Unidos, incluyendo todas las divisiones, renovaciones, sustituciones, continuación, no provisionales, continuación en parte y solicitudes de Convención basadas total o parcialmente en dichas invenciones o sobre tales solicitudes, y todas las Patente y re-expediciones, re- exámenes, y extensiones de Patentes otorgadas para dichas invenciones o sobre tales solicitudes y cada derecho de prioridad que sea o se pueda predicar o surja de tal invención, solicitud, y dichas Patentes: dicho Cesionario queda por el presente autorizado a presentar solicitudes de patentes en uno o en todos los países o en alguna o en todas las invenciones a nombre del suscrito o a nombre de dicho Cesionario o en sentido diferente tal como lo estime aconsejable el Cesionario, bajo la Convención Internacional o de otra forma; el Comisionado de patentes y marcas comerciales de los Estados Unidos de América queda por el presente autorizado a expedir o transferir todas las Patentes mencionadas a tal Cesionario conforme al presente; esta cesión se hace bajo acuerdo, no solamente en el sentido de que el suscrito tiene poder total para hacer la misma, sino también que tales derechos cedidos no están afectados por ningún otorgamiento, licencia ni por otro derecho dado a la misma, y que el suscrito hará todos los actos razonables que sirvan para asegurar que dichas invenciones, solicitudes de patente y patentes han sido tenidas y usufructuadas por tal Cesionario tan total y completamente tal como las mismas habrían podido ser tenidas y usufructuadas por el suscrito si no se hubiera hecho tal cesión, y en particular para suscribir y entregar a tal Cesionario todos los documentos legales que incluyen peticiones, especificaciones, declaraciones juradas, cesiones, descargo de responsabilidades y declaraciones legales en forma y fondo que puedan ser requeridas por dicho Cesionario, para suministrar a tal Cesionario todos los hechos relacionados con dichas invenciones o la historia de la misma y todos y cada uno de los documentos, fotos, modelos, muestras y otros anexos físicos que pueda incorporar dicha invención, y para certificar en todo proceso referente a dichas invenciones, solicitudes de patentes y /o Patentes.

Por el presente otorgamos a un representante del Cesionario un poder de insertar en esta Cesión cualquier otra identificación que pueda ser necesaria o deseable para cumplir con las reglas de la oficina de marcas registradas y patentes de los Estados Unidos para el registro de esta cesión.

MARLEN NEIRA CASTRO
Interprete Oficial
Inglés - Español - Inglés
Resolución No. 2117 del 7 Oct 1987

Fecha: 20 junio de 2007 .

Firma de Lakshmi Khandke



Estado De Nueva York}
Condado de Rockland]

Ante mi, Janice A. White notario público de Nueva York y para tal condado certifico que compareció personalmente Lakshmi Khandke en esta fecha y quien reconoció haber suscrito tal documento. En testimonio firmo y sello el 20 de junio de 2007,

Sello oficial y firma de Janice A. White- notario de N. York No. 01-WH6052604

Sello calificado en el condado Rockland. Su cargo vence el 12-26- 2010

Fecha: 21 junio de 2007 .

Firma de Ronald Malone-

Estado De Nueva York}
Condado de Rockland]

Ronald Malone

Ante mi, Roseann D. Jastrow notario público de Nueva York y para tal condado certifico que compareció personalmente Roland Malone en esta fecha y quien reconoció haber suscrito tal documento. En testimonio firmo y sello 21 junio de 2007,

Sello oficial y firma de Roseann D. Jastrow- notario de Nueva York

No. 01- JA 6085816 Sello calificada en el condado Rockland. Su cargo vence el 1-6- 2011

Fecha: 20 junio de 2007 .

Firma de Xudong Yang-

Estado De Nueva York}
Condado de Rockland]

Xudong Yang

Ante mi, Janice A. White notario público de Nueva York y para tal condado certifico que compareció personalmente Xudong Yang en esta fecha y quien reconoció haber suscrito tal documento. En testimonio firmo y sello el 20 de junio de 2007,

Sello oficial y firma de Janice A. White- notario de N. York No. 01-WH6052604

Sello calificada en el condado Rockland. Su cargo vence el 12-26- 2010

Fecha: 20 junio de 2007 .

Firma de Hanyoung Han

Estado De Nueva York}
Condado de Rockland]

Hanyoung Han

Ante mi, Janice A. White notario público de Nueva York y para tal condado certifico que compareció personalmente Hanyoung Han en esta fecha y quien reconoció haber suscrito tal documento. En testimonio firmo y sello el 20 de junio de 2007,

Sello oficial y firma de Janice A. White- notario de N. York No. 01-WH6052604

Sello calificada en el condado Rockland. Su cargo vence el 12-26- 2010

Fecha: 22 junio de 2007 .

Firma de Jee Loon Look

Estado De Maryland}
Condado de Montgomery

Jee Loon Look

Ante mi, Mary Riggen, notario público de tal estado y condado certifico que compareció personalmente Jee Loon Look en esta fecha y quien reconoció haber suscrito tal documento. En testimonio firmo y sello el 22 de junio de 2007,

Sello oficial y firma de Mary Riggen- ilegible notario público, su cargo vence el 2-1- 2010.

MARLEN NEIRA CASTRO
Traductor e Intérprete Oficial
Inglés - Español - Inglés
Resolución No. 2117 del 7 Oct 1987

testimonio firmo y sello el 22 de junio de 2007,

Sello oficial y firma de Mary Riggen- ilegible notario público, su cargo vence el 2-1-2010.

Fecha: 11 - 5- 2007 .

Firma de Zhaowei Jin

Estado De Carolina del Norte
Condado de Wake

Zhaowei Jin

Ante mi, Edward E. Benton, notario público de tal estado y condado certifico que compareció personalmente Zhaowei Jin esta fecha y quien reconoció haber suscrito tal documento. En testimonio firmo y sello el 11 de mayo de 2007,

Sello oficial y firma de Edward E. Benton- ilegible notario público,

Condado Wake. Carolina del Norte- su cargo vence el 1-2- 2011.

Fecha: 22 junio de 2007 .

Firma de Robert C. Seid, Jr.

Estado De Maryland}
Condado de Montgomery

Robert C. Seid, Jr.

Ante mi, Mary Riggin, notario público de tal estado y condado certifico que compareció personalmente Robert C. Seid en esta fecha y quien reconoció haber suscrito tal documento. En testimonio firmo y sello el 22 de junio de 2007,

Sello oficial y firma de Mary Riggin- ilegible notario público, su cargo vence el 2-1- 2010.

--

Fecha: 11 - 5- 2007 .

Firma de Yin Chen

Estado De Carolina del Norte
Condado de Wake

Yin Chen

Ante mi, Edward E. Benton, notario público de tal estado y condado certifico que compareció personalmente YIng Chen en esta fecha y quien reconoció haber suscrito tal documento. En testimonio firmo y sello el 11 de mayo de 2007,

Sello oficial y firma de Edward E. Benton- ilegible notario público,

Condado Wake. Carolina del Norte- su cargo vence el 1-2- 2011.

-Es traducción conforme con copia para confrontar-. Bogotá, enero 14, 2009


MARLEN NEIRA CASTRO
Traductor e Intérprete Oficial
Inglés - Español - Inglés
Resolución No. 2117 del 7 Oct 1987

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APOSTILLE

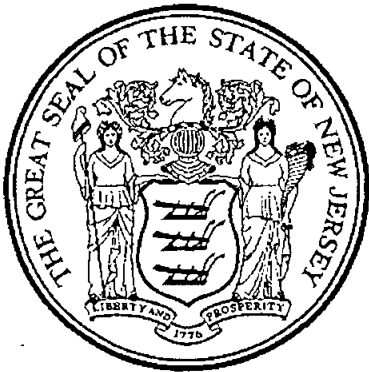
(CONVENTION DE LA HAYE DU 5 OCTOBRE 1961)

1. COUNTRY: UNITED STATES OF AMERICA
2. THIS PUBLIC DOCUMENT HAS BEEN SIGNED BY:
WINIFRED A VENTURA
3. ACTING IN THE CAPACITY OF:
NOTARY PUBLIC OF NEW JERSEY
4. BEARS THE SEAL/STAMP OF:
WINIFRED A VENTURA, NOTARY

CERTIFIED

5. AT TRENTON, NEW JERSEY
6. THE 23RD DAY OF DECEMBER 2008
7. BY: R. David Rousseau, NEW JERSEY TREASURER
8. NO. A349627
9. SEAL/STAMP:

10. SIGNATURE



A handwritten signature, likely of R. David Rousseau, is written over a horizontal line.

Certificate Number: 113291753

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/ISP/Verify_Cert.jsp

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AM102129

AFFIDAVIT

I, Michelle L. McGowan, International Filing Associate, Wyeth, do hereby certify that the attached copy has been compared with the original Assignment (for U.S.S.N. 11/737,674, and any legal equivalent thereof in a foreign country, for the invention entitled: "NOVEL FORMULATIONS WHICH STABILIZE AND INHIBIT PRECIPITATION OF IMMUNOGENIC COMPOSITIONS") dated June 20, 2007 from Lakshmi Khandke, Xudong Yang and Hanyoung Han; and dated June 21, 2007 from Ronald Malone; and dated June 22, 2007 from Jee Loon Look and Robert C. Seid, Jr.; and dated May 11, 2007 from Zhaowei Jin and Ying Chen to Wyeth and that the said copy is a true copy of the original.

Dated this 17th day of December, 2008, at Madison, New Jersey, United States of America.

Wyeth

Michelle L. McGowan
Michelle L. McGowan
International Filing Associate

TO BE USED IN COLOMBIA

ACKNOWLEDGMENT

State of New Jersey)
)
County of Morris)

On this 17th day of December, 2008, before me personally appeared Michelle L. McGowan, International Filing Associate of Wyeth, to me known and known to me to be the individual described in and who executed the foregoing instrument, and she acknowledged to me that she executed the same.

Winifred A. Ventura
Notary Public

WINIFRED A. VENTURA
NOTARY PUBLIC, State of New Jersey
No. 2334651
Qualified in Morris County
Commission Expires September 19, 2010

ASSIGNMENT - WORLDWIDE

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each undersigned inventor has sold and assigned, and by these presents hereby sells and assigns, unto

Wyeth
Five Giralda Farms
Madison, NJ 07940

its successors and assigns, the entire right, title and interest, so far as concerns the United States and the Territories and Possessions thereof and all foreign countries in and to the invention in **"NOVEL FORMULATIONS WHICH STABILIZE AND INHIBIT PRECIPITATION OF IMMUNOGENIC COMPOSITIONS"**

as set forth in this United States Patent Application

- ☐ executed concurrently herewith
- ☐ executed on
- ☒ Application No. 11/737,674; filed April 19, 2007
- ☒ Application claims priority from Application No. 60/795,261, filed April 26, 2006, all applications listed above being hereinafter referred to as the "application(s)";

said application for United States Letters Patent, including all divisional, renewal, substitute, continuation, nonprovisionals, continuation-in-parts, and Convention applications based in whole or in part upon said inventions or upon said applications, and any and all Letters Patent and reissues, reexaminations, and extensions of Letters Patent granted for said inventions or upon said applications and every priority right that is or may be predicated upon or arise from said inventions, said applications, and said Letters Patent; said Assignee being hereby authorized to file patent applications in any or all countries on any or all said inventions in the name of the undersigned or in the name of said Assignee or otherwise as said Assignee may deem advisable, under the International Convention or otherwise; the Commissioner of Patents and Trademarks of the United States of America being hereby authorized to issue or transfer all said Letters Patent to said Assignee in accordance herewith; this assignment being under covenant, not only that full power to make the same is had by the undersigned, but also that such assigned right is not encumbered by any grant, license, or other right theretofore given, and that the undersigned will do all acts reasonably serving to ensure that the said inventions, patent applications and Letters Patent shall be held and enjoyed by said Assignee as fully and entirely as the same could have been held and enjoyed by the undersigned if this assignment had not been made, and particularly to execute and deliver to said Assignee all lawful documents including petitions, specifications, oaths, assignments, invention disclaimers, declarations, and lawful affidavits in form and substance which may be requested by said Assignee, to furnish said Assignee with all facts relating to said inventions or the history thereof and any and all documents, photographs, models, samples or other physical exhibits which may embody said inventions, and to testify in any proceedings relating to said inventions, patent applications, and/or Letters Patent.

The undersigned hereby grant(s) an authorized representative of Assignee the power to insert in this Assignment any further identification that may be necessary or desirable to comply with the rules of the U.S. Patent and Trademark Office for recordation of this Assignment.

June 20, 2007
Date

Lakshmi Khandke
Lakshmi Khandke

State of New York
County of Rockland

I, JANICE A. WHITE, a Notary Public for said County and State, do hereby certify that Lakshmi Khandke personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the 20 day of June, 2007.

(Official Seal)

My commission expires 12-26-2010

Janice A. White
Notary Public

JANICE A. WHITE
Notary Public - State of New York
No. 01-WH6052604
Qualified in Rockland County
My Commission Expires 12-26-2010

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21-June-2007

Date

Ronald Malone

Ronald Malone

State of New York

County of Rockland

I, RoseAnn D. JASTROW, a Notary Public for said County and State, do hereby certify that Ronald Malone personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the 21st day of June, 2007.

(Official Seal)

RoseAnn D. JASTROW

Notary Public

My commission expires 01-06-2011

ROSEANN D. JASTROW
NO. 01JA6085816
QUALIFIED IN ROCKLAND COUNTY
MY COMMISSION EXPIRES 01-06-2011

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Date 06/20/2007

Xudong Yang
Xudong Yang

State of New York

County of Rockland

I, JANICE A. WHITE, a Notary Public for said County and State, do hereby certify that Xudong Yang personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the 20 day of JUNE, 2007.

(Official Seal)

My commission expires 12-26-2010

Janice A. White
Notary Public

JANICE A. WHITE
Notary Public - State of New York
No. 01-WH6052604
Qualified in Rockland County
My Commission Expires 12-26-2010

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Date 6/20/2007

[Signature]
Hanyoung Han

State of New York)
County of Rockland)

I, JANICE A. WHITE, a Notary Public for said County and State, do hereby certify that Hanyoung Han personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the 20 day of June, 2007.

(Official Seal)

My commission expires 12-26-2010

[Signature]
Notary Public

JANICE A. WHITE
Notary Public - State of New York
No. 01-WH6052604
Qualified in Rockland County
My Commission Expires 12-26-2010

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June 22, 2007
Date

Jee Look
Jee Loon Look

State of Maryland
County of Montgomery

I, Mary Riggan, a Notary Public for said County and State, do hereby certify that Jee Loon Look personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the 22nd day of June, 2007.

(Official Seal)

Mary Riggan
Notary Public

My commission expires 2/1/2010

142
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05/11/2007

Zhaowei Jin

Date

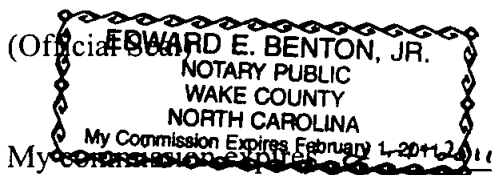
Zhaowei Jin

State of North Carolina

County of Wake

I, Edward E. Benton Jr, a Notary Public for said County and State, do hereby certify that Zhaowei Jin personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the 11th day of May, 2007.



Edward E. Benton Jr
Notary Public

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22 Jun 07
Date

Robert C. Seid, Jr.
Robert C. Seid, Jr.

State of Maryland
County of Montgomery

I, Mary Riggins, a Notary Public for said County and State, do hereby certify that Robert C. Seid, Jr. personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the 22nd day of June, 2007.

(Official Seal)

Mary Riggins
Notary Public

My commission expires 2/1/2010

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May 11, 2007
Date

Ying Chen
Ying Chen

State of North Carolina)

County of Wake)

I, Edward E Benton Jr, a Notary Public for said County and State, do hereby certify that Ying Chen personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the 11th day of May, 2007.

(Official Seal)
EDWARD E. BENTON, JR.
NOTARY PUBLIC
WAKE COUNTY
NORTH CAROLINA
My Commission Expires February 1, 2011
My commission expires 2-1-2011

Edward E Benton Jr
Notary Public

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TRADUCCIÓN OFICIAL No. 716/08 de un documento escrito en inglés, el cual para su identificación se sella con el sello del Traductor. Esta es una Traducción Oficial efectuada el día 18 de diciembre de 2008 por la Sra. María Teresa Lara, c.c. 41.568.055 de Bogotá, Traductora Oficial según Resolución No. 01016 del 2 de octubre de 1998, expedida por el Ministerio de Justicia.

=====

Cesión a WYETH del invento titulado "FORMULACIONES NOVEDOSAS QUE ESTABILIZAN E INHIBEN LA PRECIPITACIÓN DE COMPOSICIONES INMUNOGÉNICAS". Certificación notarial suscrita por Barbara A. Kiely, Notario Público del estado de Nueva Jersey, y legalizaciones subsiguientes.

AM102129

MARIA TERESA LARA R.
TRADUCTORA OFICIAL
RESOLUCION No. 01016
DE MINISTERIO DE JUSTICIA

DECLARACIÓN JURAMENTADA

La suscrita, Michelle L. McGowan, Asociada para Registros Internacionales de Wyeth, certifico por la presente que la copia adjunta ha sido comparada con la Cesión original (para la U.S.S.N. 60/795,261, y cualquier equivalente legal de la misma en un país extranjero, para el invento titulado: "FORMULACIONES NOVEDOSAS QUE ESTABILIZAN E INHIBEN LA PRECIPITACIÓN DE COMPOSICIONES INMUNOGÉNICAS"), fechada el 3 de mayo de 2006 de Jee Loon Look y Ying Chen a Wyeth y que la citada copia es fiel copia del original.

Dado a los 9 días del mes de octubre de 2008, en Madison, Nueva Jersey, Estados Unidos de América.

Wyeth

(Fdo.) Michelle L. McGowan
Michelle L. McGowan
Asociada para Registros Internacionales

PARA USO EN COLOMBIA

Estado de Nueva Jersey)
)
 Condado de Morris)

MARIA TERESA LARA R.
TRADUCTORA OFICIAL
RESOLUCION N.º 282
DE MINISTRIA

(2) Nombre Completo del Inventor: Ying CHEN
Residencia: 1005 Edinburgh Downs Lane, Apex, NC 27502
Ciudadanía: República Popular China

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200

por la presente vende, cede y traspasa a la CESIONARIA:

Wyeth
Five Giralda Farms
Madison, Nueva Jersey 07940

y a los sucesores, cesionarios y representantes legales de la CESIONARIA, todo derecho, título e interés para los Estados Unidos y sus posesiones territoriales y en todos los países extranjeros, incluidos todos los derechos a reclamar prioridad, en y sobre el invento titulado:

FORMULACIONES NOVEDOSAS QUE ESTABILIZAN E INHIBEN LA PRECIPITACIÓN DE COMPOSICIONES INMUNOGÉNICAS

e inventado por el CEDENTE y los siguientes inventores adicionales, en caso de haberlos:

y el cual se encuentra en la Solicitud Provisional de los E.U. No. 60/795261 presentada el: 26 de abril de 2006

[X] Yo/nosotros, el suscrito CEDENTE, por la presente autorizo y solicito la inserción anterior del número de solicitud y la fecha de presentación, una vez se conozcan,

[marcar también si se están cediendo solicitud(es) extranjera(s)]

[X] y cualquier equivalente legal de las mismas en un país extranjero,

incluyendo el derecho a reclamar prioridad, incluidas todas y cada una de las mejoras allí divulgadas, y en y sobre todas las Patentes que hayan de obtenerse para dicho invento en virtud de la solicitud anterior o cualquier solicitud provisional, no provisional, de continuación, divisional, de renovación o sustituta de la misma posteriormente presentada, y respecto de Patentes, cualquier reemisión o reexamen de las mismas.

TERESA LARA R.
TRADUCTORA JURADA
RESOLUCION No. 61810
DE MINISTERIO DE JUSTICIA

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El CEDENTE pacta por el presente que no se ha hecho ni se hará ni se realizará ninguna cesión, venta, acuerdo o gravamen que pudiese entrar en conflicto con esta cesión.

El CEDENTE autoriza a la CESIONARIA a presentar solicitudes y recibir Patentes para dicho invento en cualquiera de dichos países en su propio nombre, o en nombre del CEDENTE, a su elección.

El CEDENTE pacta y acuerda suscribir u obtener cualquier garantía adicional necesaria del título sobre dicho invento y cualquier Patente que pueda expedirse para el mismo y, en cualquier momento, a solicitud y por cuenta de la CESIONARIA, entregar cualquier testimonio en cualquier interferencia, litigio o proceso relacionado con el mismo y otorgar todos los documentos que puedan ser necesarios o convenientes para perfeccionar el título sobre dicho invento o cualquier Patente que pueda otorgarse para el mismo a la CESIONARIA, sus sucesores, cesionarios u otros representantes legales y, en cualquier momento, a solicitud y por cuenta de la CESIONARIA, suscribir cualquier continuación, continuación en parte, solicitud divisional, de renovación o sustituta de la misma, y en cuanto a Patentes y reemisión o reexamen de las mismas, o cualquier otra solicitud adicional de Patente para dicho invento o cualquier parte del mismo, todas las cuales solicitudes y cualesquiera Patentes que se expidan sobre las mismas son por la presente cedidas a la CESIONARIA; y hará todos los juramentos o declaraciones lícitos, y realizará todo los actos lícitos requeridos para adquirir las mismas, sin otra compensación, pero por cuenta de la CESIONARIA, sus sucesores, cesionarios u otros representantes legales.

El CEDENTE autoriza y solicita al Comisionado de Patentes expedir todas y cada una de las Patentes de los Estados Unidos para dicho invento, resultantes de cualquiera de las anteriores solicitudes a su CESIONARIA.

MARIA TERESA LARA R.
TRADUCTORA OFICIAL
RESOLUCION 28-01518
DE MINISTERIO

24
202

(Fdo.) Jee Loon Look
Jee Loon LOOK

3 de mayo de 2006
Fecha

RECONOCIMIENTO

Estado de Carolina del Norte }
ss:
Condado de Wake }

A los 3 días del mes de mayo de 2006, compareció personalmente ante mí Jee Loon LOOK, a quien conozco como la misma persona descrita en el instrumento anterior y quien lo otorgó, y reconoció haber otorgado el mismo, por su propia voluntad y para los propósitos allí señalados.

(Fdo.) John U. Mellish
Notario Público

[Sello]

JOHN U. MELLISH
NOTARIO PÚBLICO
CONDADO DE WAKE, N.C.
Mi comisión expira el 13 de diciembre de 2009

MARIA TERESA LARA R.
TRADUCTORA OFICIAL
RESOLUCION DE CHEN
DE MINISTROS

(Fdo.) Ying Chen
Ying CHEN

3 de mayo de 2006
Fecha

RECONOCIMIENTO

Estado de Carolina del Norte }
ss:
Condado de Wake }

A los 3 días del mes de mayo de 2006, compareció personalmente ante mí Ying CHEN, a quien conozco como la misma persona descrita en el instrumento anterior y quien lo otorgó, y reconoció haber otorgado el mismo, por su propia voluntad y para los propósitos allí señalados.

(Fdo.) John U. Mellish
Notario Público

22
203

[Sello] JOHN U. MELLISH
 NOTARIO PÚBLICO
 CONDADO DE WAKE, N.C.
 Mi comisión expira el 13 de diciembre de 2009

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

- 1. País: Estados Unidos de América
- 2. Este documento público ha sido firmado por: Barbara A. Kiely
- 3. actuando en calidad de: Notario Público de Nueva Jersey
- 4. lleva el sello/timbre de: Barbara A. Kiely, Notario

CERTIFICADO

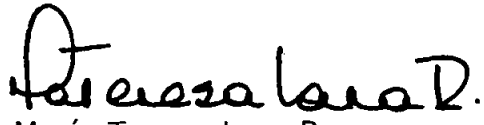
- 5. en Trenton, Nueva Jersey
- 6. el día 14 de octubre de 2008
- 7. por R. David Rousseau, TESORERO DE NUEVA JERSEY
- 8. No. A342902
- 9. Sello/Timbre:
- 10. Firma

(El Gran Sello del Estado de Nueva Jersey) (Fdo.) R. David Rousseau

Número del Certificado : 112794440
Verificar este certificado en línea en
https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

=====

La anterior es traducción fiel y completa del documento en referencia, de la cual se deja copia en este archivo para su confrontación.


María Teresa Lara R.
c.c. 41.568.055 de Bogotá
Traductora Oficial según
Resolución No. 01016 del
2 de octubre de 1998, del
Ministerio de Justicia

MARIA TERESA LARA R.
TRADUCTORA OFICIAL
RESOLUCION No. 01016
DE OCTUBRE DE 1998

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204

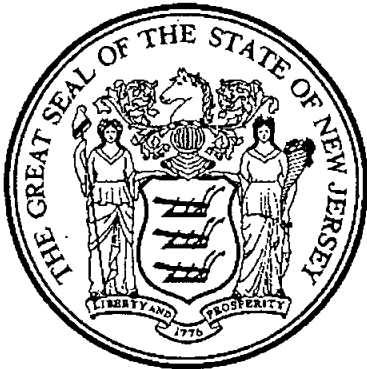
APOSTILLE

(CONVENTION DE LA HAYE DU 5 OCTOBRE 1961)

1. COUNTRY: UNITED STATES OF AMERICA
2. THIS PUBLIC DOCUMENT HAS BEEN SIGNED BY:
BARBARA A KIELY
3. ACTING IN THE CAPACITY OF:
NOTARY PUBLIC OF NEW JERSEY
4. BEARS THE SEAL/STAMP OF:
BARBARA A KIELY, NOTARY

CERTIFIED

5. AT TRENTON, NEW JERSEY
6. THE 14TH DAY OF OCTOBER 2008
7. BY: R. David Rousseau, NEW JERSEY TREASURER
8. NO. A342902
9. SEAL/STAMP:
10. SIGNATURE



Certificate Number: 112794440

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

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AFFIDAVIT

I, Michelle L. McGowan, International Filing Associate, Wyeth, do hereby certify that the attached copy has been compared with the original Assignment (for U.S.S.N. 60/795,261, and any legal equivalent thereof in a foreign country, for the invention entitled: "NOVEL FORMULATIONS WHICH STABILIZE AND INHIBIT PRECIPITATION OF IMMUNOGENIC COMPOSITIONS") dated May 3, 2006 from Jee Loon Look and Ying Chen to Wyeth and that the said copy is a true copy of the original.

Dated this 9th day of October, 2008 at Madison, New Jersey, United States of America.

Wyeth

Michelle L. McGowan
Michelle L. McGowan
International Filing Associate

TO BE USED IN COLOMBIA

ACKNOWLEDGMENT

State of New Jersey)
)
County of Morris)

On this 9th day of October, 2008 before me personally appeared Michelle L. McGowan, International Filing Associate of Wyeth, to me known and known to me to be the individual described in and who executed the foregoing instrument, and she acknowledged to me that she executed the same.

Barbara A. Kiely
Notary Public

Barbara A. Kiely ID. 33893
Notary Public of New Jersey
My Commission Expires June 20, 2009

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Assignment of Invention

In consideration of the payment by ASSIGNEE to ASSIGNOR of good and valuable consideration, the receipt of which is hereby acknowledged,
ASSIGNOR:

(1) Full Name of Inventor: Jee Loon LOOK
Residence: 102 Cockleshell Court, Cary, NC 27513
Citizenship: United States of America

(2) Full Name of Inventor: Ying CHEN
Residence: 1005 Edinburgh Downs Lane, Apex, NC 27502
Citizenship: People's Republic of China

hereby sells, assigns and transfers to ASSIGNEE:

Wyeth
Five Giralda Farms
Madison, New Jersey 07940

and the successors, assigns and legal representatives of the ASSIGNEE the entire right, title and interest for the United States and its territorial possessions and in all foreign countries, including all rights to claim priority, in and to the invention entitled:

**NOVEL FORMULATIONS WHICH STABILIZE AND INHIBIT PRECIPITATION OF
IMMUNOGENIC COMPOSITIONS**

and invented by ASSIGNOR and the following additional inventors, if any:

and which is found in U.S. Provisional Application No. 60/795261 filed on: April 26, 2006

☒ I/we the ASSIGNOR signing below, hereby authorize and request insertion above of the application number and filing date, when they become known,

[also check if foreign application(s) is(are) also being assigned]

☒ and any legal equivalent thereof in a foreign country,

including the right to claim priority, including any and all improvements disclosed therein, and in and to all Letters Patent to be obtained for said invention by the above application or any subsequently filed provisional, nonprovisional, continuation, divisional, renewal, or substitute thereof, and as to Letters Patent any reissue or re-examination thereof.

ASSIGNOR hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

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ASSIGNOR authorizes ASSIGNEE to make applications for and to receive Letters patent for said invention in any of said countries in its own name, or in ASSIGNOR's name, at its election.

ASSIGNOR covenants and agrees to execute or procure any further necessary assurance of the title to said invention and any Letters Patent which may issue therefore and to, at any time, upon the request and at the expense of ASSIGNEE deliver any testimony in any interference, litigation or proceeding related thereto and execute all papers that may be necessary or desirable to perfect the title to said invention or any Letters Patent which may be granted therefore in ASSIGNEE, its successors, assigns or other legal representatives, and that to, at any time, upon the request and at the expense of ASSIGNEE execute any continuation, continuation-in-part, divisional, renewal or substitute thereof, and as to Letters Patent and reissue or re-examination thereof, or any other additional applications of Letters Patent for said invention or any part thereof, all of which applications and any Letters Patent issuing thereon are hereby assigned to ASSIGNEE, and will make all rightful oaths or declarations, and do all lawful acts requisite for procuring the same therein, without further compensation, but at the expense of ASSIGNEE, its successors, assigns or other legal representatives.

ASSIGNOR authorizes and requests the Commissioner of Patents to issue any and all Letters Patent of the United States for said invention, resulting from any of the aforesaid applications to its ASSIGNEE.

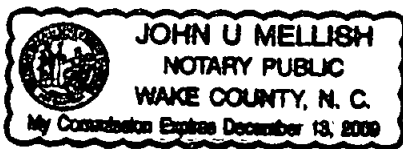
Jee Look
Jee Loon LOOK

May 3, 2006
Date

ACKNOWLEDGMENT

State of North Carolina }
County of Wake } ss:

On the 3rd day of May 2006, Jee Loon LOOK personally appeared before me, known by me to be the same person described in and who executed the foregoing instrument, and acknowledged that he/she executed the same, of his/her own free will and for the purposes set forth.



[Signature]
Notary Public

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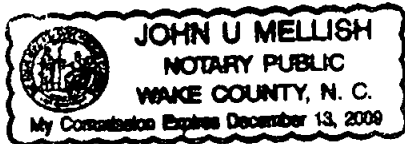
Ying Chen
Ying CHEN

May 3, 2006
Date

ACKNOWLEDGMENT

State of North Carolina }
County of Wake } ss:

On the 3rd day of May 2006, Ying CHEN personally appeared before me, known by me to be the same person described in and who executed the foregoing instrument, and acknowledged that he/she executed the same, of his/her own free will and for the purposes set forth.



John U. Mellish
Notary Public

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 08-125423- -00003-0000

Fecha: 2009-02-23 16:12:46 Dep. 2020 NUECREACION
Tra. 11 PATENTEIYII Eve: 378 FASENACIONALI
Act. 329 CTOINFORMACION Folios: 13

Señora

Alix Carmenza Céspedes de Vergel

Jefe de División de Nuevas Creaciones

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

E. S. D.

Referencia: Expediente No. 08.125.423

Solicitud de Patente de Invención titulada: "formulaciones novedosas que estabilizan e inhiben la precipitación de composiciones inmunogénicas"

Solicitante: Wyeth

MEMORIAL DE COMPLEMENTACIÓN

ÁLVARO CORREA ORDÓÑEZ, mayor de edad y vecino de Bogotá D.C., identificado según aparece al pie de mi firma, en mi condición de apoderado de la sociedad en referencia, manifiesto lo siguiente:

1. El día 25 de noviembre de 2008, bajo el número de radicación 08.125.423, presenté la solicitud de patente de invención de la referencia, para la cual adjunto informe preliminar internacional sobre patentabilidad y opinión escrita de la solicitud de la referencia.

Atentamente,

ÁLVARO CORREA ORDÓÑEZ

C.C.No.79.143.366 de Usaquén

T.P.20.281

Anexo: IPER

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DT

PATENT COOPERATION TREATY

PCT/US2007/066959

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))

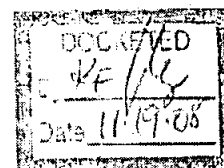
To:

CASH, David, E.
Alston & Bird LLP
Bank Of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
ETATS-UNIS D'AMERIQUE

NOV 19 2008

Date of mailing (day/month/year) 06 November 2008 (06.11.2008)		
Applicant's or agent's file reference AM102129(326169)		IMPORTANT NOTICE
International application No. PCT/US2007/066959	International filing date (day/month/year) 19 April 2007 (19.04.2007)	Priority date (day/month/year) 26 April 2006 (26.04.2006)
Applicant WYETH et al		

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



The International Bureau of WIPO 34, chemin des Coloinbettes 1211 Geneva 20, Switzerland	Authorized officer Masashi Honda ALSTON & BIRD JLS RTA 11/20/08
Facsimile No. +41 22 338 82 70	e-mail: pt08.pct@wipo.int

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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 AM102129(326169)	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2007/066959	International filing date (day/month/year) 19 April 2007 (19.04.2007)	Priority date (day/month/year) 26 April 2006 (26.04.2006)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant WYETH			

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 11 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 28 October 2008 (28.10.2008)	
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Masashi Honda e-mail: pt08.pct@wipo.int

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.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.
PCT/US2007/066959

International filing date (day/month/year)
19.04.2007

Priority date (day/month/year)
26.04.2006

International Patent Classification (IPC) or both national classification and IPC
INV. A61K47/12 A61K47/48

Applicant
WYETH

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 66.1bis(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 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 - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Date of completion of
this opinion

See form
PCT/ISA/210

Authorized Officer

Boulois, Denis

Telephone No. +31 70 340-3878



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/066959

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 purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. 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 purposes of search.
4. ☐ 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.
5. Additional comments:

for
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2007/066959

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. 14-40

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. 14-40

☐ 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/US2007/066959

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-13

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

1. Statement

Novelty (N)	Yes: Claims	<u>3,4,10,11,13</u>
	No: Claims	<u>1,2,5-9,12</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-13</u>
Industrial applicability (IA)	Yes: Claims	<u>1-13</u>
	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/US2007/066959

Re Item IV

Lack of unity of invention

This Authority considers that there are 6 inventions covered by the claims indicated as follows:

Subject 1): a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) a surfactant (iii) a polysaccharide-protein conjugate (claims 1-13)

Subject 2): a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 6.5 (ii) a surfactant (iii) a streptococcal C5a peptidase (claims 14-23)

Subject 3): a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) an aluminium salt (iii) a polysaccharide-protein conjugate (claims 24-30)

Subject 4): a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 6.5 (ii) an aluminium salt (iii) a streptococcal C5a peptidase (claims 31-36)

Subject 5): a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) a surfactant (iii) a N. meningitidis 2086 protein (claims 37-39)

Subject 6): a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) an aluminium salt (iii) a N. meningitidis 2086 protein (claim 40)

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

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

International application No.

PCT/US2007/066959

1. The problem to be solved by the present application is to provide a formulation which stabilizes and inhibits precipitation of immunogenic compositions.

2. The solutions proposed by the Applicant in its broader form are:

- a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) a surfactant (iii) a polysaccharide-protein conjugate (claim 1)

- a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 6.5 (ii) a surfactant (iii) a streptococcal C5a peptidase (claim 14)

- a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) an aluminium salt (iii) a polysaccharide-protein conjugate (claim 24)

- a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) an aluminium salt (iii) a streptococcal C5a peptidase (claim 31)

- a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) a surfactant (iii) a N. meningitidis 2086 protein (claim 37)

- a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) an aluminium salt (iii) a N. meningitidis 2086 protein (claim 40)

3. The use of a buffer with a Pka of 3.5 to 7.5 with a surfactant to stabilize a composition against aggregation is further known from the following documents:

- WO0141800 is directed to the same problem than the present application, namely the stabilisation of a composition against aggregation; the active agent may be a conjugate polypeptide-polysaccharide (see p. 4, l 8-11 ; p. 7, l. 31-p. 8, l. 6; p. 9. l. 18-27 ; examples and claims). One stabilizing composition used comprises a surfactant such as Tween and a buffer such as a Histidine buffer. These compounds are among the preferred

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

International application No.

PCT/US2007/066959

compounds of present application (see Table 3 of WO0141800).

- WO03039485 shows the stabilizing effect on proteins of a composition comprising succinate or histidine buffer with polysorbate as surfactant (see p. 1, l. 12-17; p. 2, l. 1-31; p. 3, l. 5-18; p. 11, l. 8-29 , examples and claims)
- WO200539620 also discloses the stabilisation against aggregation of a protein by a surfactant like polysorbate with a buffer combination, such as a succinate buffer (see p. 8, l. 15-26; p. 9, l. 26 - p. 10, l. 7).

Moreover a composition comprising a conjugate polysaccharide-protein, a surfactant, and a buffer with a Pka of 3.5 to 7.5 is also known from following documents:

- US2004/0047882 discloses compositions comprising polysorbate, a citrate buffer and a conjugate (see claims 1 and 5,6; see par. [013])
- EP-A-941738 shows a composition comprising a conjugate of lipopolysaccharide with a surfactant, namely QS21 and a phosphate buffer system (par. [053]).
- US6224880 discloses a vaccine made from a conjugate, combined with a surfactant (tween) with a phosphate buffer (see example and claims)

The use of an Aluminium salt with a buffer such as a phosphate buffer to stabilize a protein composition against aggregation is known from WO0205846 (see p. 2, l. 14-20; p. 3, l. 13-20; p. 4, l. 6-13 p. 13, l. 14, examples and claims).

The idea to use a composition comprising "i). a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 or from 3.5 to 6.5 with (ii) a surfactant or an aluminium salt " as stabilizing composition is therefore not novel, because it is already known from the cited prior art documents.

All these documents disclose compositions from which the presently claimed compositions differ in the nature of the immunogenic substance in the case of claims 1, 14, 24, 31, 37, and 40.

The technical contribution to the known prior art is therefore the nature of the immunogenic substance. All these technical contributions are different (polysaccharide-protein conjugate in claims 1 and 24, streptococcal C5s peptidase in claims 14 and 31, N. meningitidis 2086 protein in claims 37 and 40).

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In the present application, no further technical feature can be distinguished that can be regarded as a "special technical feature" involved in the technical relationship among the different inventions. Each of the invention listed below is a distinct invention, characterized by its own technical feature, defining the contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Consequently, there is lack of unity a posteriori and the different inventions not belonging to a common inventive concept are formulated as the different subjects on the communication pursuant to Rule 13 PCT.

Furthermore, searching this plurality of different inventions would have caused "major additional searching efforts".

The application has to be divided into the following subjects:

Subject 1): a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) a surfactant (iii) a polysaccharide-protein conjugate (claims 1-13)

Subject 2): a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 6.5 (ii) a surfactant (iii) a streptococcal C5a peptidase (claims 14-23)

Subject 3): a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) an aluminium salt (iii) a polysaccharide-protein conjugate (claims 24-30)

Subject 4): a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 6.5 (ii) an aluminium salt (iii) a streptococcal C5a peptidase (claims 31-36)

Subject 5): a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) a surfactant (iii) a N. meningitidis 2086 protein (claims 37-39)

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Subject 6): a formulation comprising (i) a pH buffered saline solution wherein the buffer has a pKa of about 3.5 to about 7.5 (ii) an aluminium salt (iii) a N. meningitidis 2086 protein (claim 40)

Only the first subject was searched.

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 following documents:

D1: US 2004/047882 A1 (BROEGER MICHAEL [DE]) 11 March 2004 (2004-03-11)

D2: EP-A-0 941 738 (AMERICAN CYANAMID CO [US] WYETH CORP [US]) 15 September 1999 (1999-09-15)

D3: US-B1-6 224 880 (CHAN CHRISTINA Y [US] ET AL) 1 May 2001 (2001-05-01)

D4: WO 02/05846 A (GREEN CROSS VACCINE CO LTD [KR]; BAE CHEON SOON [KR]; LIM GWAN YEUL [K]) 24 January 2002 (2002-01-24)

D5: WO 01/41800 A (CHIRON CORP [US]; ESIKOVA IRINA [US]; WOLFE SIDNEY [US]; THOMSON JAMES) 14 June 2001 (2001-06-14)

D6: WO 2005/039620 A (HEXAL BIOTECH FORSCHUNGS GMBH [DE]; SKUFCA PETER [DE]; SEIBERT FABIAN) 6 May 2005 (2005-05-06)

D7: WO 03/039485 A (PROTEIN DESIGN LABS [US]; KAISHEVA ELIZABET A [US]; GUPTA SUPRIYA [US]) 15 May 2003 (2003-05-15)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1,2,5-9,12 is not new in the sense of Article 33(2) PCT.

D1 discloses compositions comprising polysorbate, a citrate buffer and a conjugate (see claims 1 and 5,6; see par. [013]) and is relevant for the novelty of claims 1,2,5-9 and 12.

D2 shows a composition comprising a conjugate of lipopolysaccharide with a surfactant,

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namely QS21 and a phosphate buffer system (par. [053]).

D3 discloses a vaccine made from a conjugate, combined with a surfactant (tween) with a phosphate buffer (see example and claims) . Consequently, claims 1,2 are not novel over D2 or D3.

3. Even if novelty could be established, the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 3,4, 10,11,13 does not involve an inventive step in the sense of Article 33(3) PCT.

The problem addressed by the present application is to provide a compositions stable against aggregation.

The solution is the use of a composition of a surfactant and a buffer.

The document D1 appear to be of particular relevance as far as inventive step is concerned (Article 33(3) PCT). This document solves indeed the same problem, so that, as far as novel subject-matter is concerned, the present application does apparently not fulfill the requirements of Article 33(3) PCT over these prior art documents.

The choice of a particular surfactant, buffer or antigen is a normal design routine for the skilled person.

Dependent claims 3,4,10,11,13 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step as said features are disclosed in the cited prior art or also fall within the knowledge and ability of the skilled person.

Therefore, as no unexpected effect for the present composition (as far as novel) over the prior art compositions has been demonstrated, this composition does apparently not fulfill the requirements of Article 33(3) PCT.

The present drafting of the claims does not recite any features which appear to either provide novelty or which could form a basis for the recognition of an inventive step. The cited documents merely represent those considered most relevant to the claims as presently on file. Further documents may become relevant if amended claims are filed.



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Bogotá D.C.,

Director(a)
ORREA ORDOÑEZ ALVARO
poderado(a) y/o Representante de
YETH

REFERENCIA	Radicación No.	8 125423
	Solicitud internacional	PCT/US2007/066959
	Fecha inicio fase nacional	26/11/2008
	Trámite	11
	Evento	378
	Actuación	416
	Oficio No.	9544
	Folios	1

Entendiendo en cuenta que la solicitud de privilegio de patente que se tramita bajo el expediente indicado en la referencia, reúne los requisitos de forma establecidos en la Decisión 486 de la Comisión de la Comunidad Andina, el Tratado de Cooperación en Materia de Patentes (PCT), el Reglamento y la Circular Única de la Superintendencia de Industria y Comercio, se envía el extracto de la solicitud a la Oficina de Comunicaciones para efecto de su publicación en la Gaceta de Propiedad Industrial.

Úmplase
Bogotá DC,

07 DIC. 2009


LIX CARMENZA CESPEDES DE VERGEL
Directora de Nuevas Creaciones (c)

dpall