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SUPERINTENDENCIA

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DIRECCIÓN DE NUEVAS CREACIONES
PRESENTACIÓN DE OPOSICIÓN

1. Oposición a solicitud de:

[X] Patente de invención
[ ] Registro de Diseño Industrial
[ ] Patente de Modelo de Utilidad
[ ] Esquema de Trazado de Circuitos Integrados

Número de expediente: 13-019-529.

Solicitante: QU BIOLOGICS INC.

Apoderado: LUZ CLEMENCIA SUAREZ DE PAEZ.

Título de la Nueva Creación: COMPOSICIONES INMUNOGENICAS ANTI-INFLAMATORIAS.

Gaceta: 668 de 31 de mayo de 2013, No. de publicación 627.

2. Datos del Opositor

[ ] Persona Natural [X] Persona Jurídica

TECNOQUIMICAS S.A.

Nombre o denominación /Razón social completa

Documento de identificación: C.C. [ ] C.E. [ ] NIT [X] Otro [ ] Cuál _____

Número 890 300 466-5.

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[ ] Autorizo expresamente a la Superintendencia de Industria y Comercio para que todas las comunicaciones sean enviadas a través de la dirección de correo electrónico

3. Datos del representante o apoderado:

REYES VILLAMIZAR JOSE LUIS	**79`152.473**	**44655**
Apellidos y Nombre	**Documento de identificación**	**T.P. No.**

Dirección del representante		
Cra 17 No. 88-23 Of.205		
Dirección electrónica info@reyes-abogados.com	No. Fax 621.25.42	Número telefónico 621.26.31

En caso de haber presentado poder general para asuntos que se adelanten ante la Delegatura de Propiedad Industrial, sírvase indicar el número de su radicación

6. Fundamentos de la oposición

Causal: Incumplimiento de requisitos de patentabilidad (Título II, Capítulo I, Decisión 486 de 2000)

Justificación: VER ANEXO

Prórroga: **SI** [X] **NO** [ ]

7. Anexos

- [X] Comprobante de pago de la tasa para la presentación de la solicitud No. _____ Fecha: _____
- [X] Poder, si fuera el caso con el que se acredita la representación.
- [X] Pruebas de los fundamentos de la oposición
- [X] Copias para traslado

8. Firma

JOSÉ LUIS REYES VILLAMIZAR

Nombre y apellidos

Firma

79.152.473 **C.C.**

44655 **T.P.**

REYES & REYES
A B O G A D O S

Señor
SUPERINTENDENTE DE INDUSTRIA Y COMERCIO
E. S. D.

REF:	**EXPEDIENTE 13-019-529**
TÍTULO SOLICITADO:	**"COMPOSICIONES INMUNOGÉNICAS ANTI-INFLAMATORIAS"**
PUBLICACIÓN:	**Gaceta 668 de 31 de mayo de 2013, Nº de publicación 627.**
PRIORIDAD:	**RU 2010129824 20/05/2010**
SOLICITANTE:	**QU BIOLOGICS INC.**
APODERADO:	**LUZ CLEMENCIA SUAREZ DE PAEZ**
TRÁMITE:	**PRESENTACION DE OPOSICIÓN**

JOSÉ LUIS REYES VILLAMIZAR, mayor de edad, identificado como aparece al pie de mi firma, abogado en ejercicio, titular de la tarjeta profesional número 44655 del Consejo Superior de la Judicatura, obrando en calidad de apoderado de la sociedad **TECNOQUÍMICAS S.A.,** en ejercicio de lo dispuesto por el artículo 42 de la Decisión 486 de 2000, muy respetuosamente me permito formular la siguiente

I. PETICIÓN

Sírvase negar el beneficio patentario a la solicitud contenida en el expediente **13-019-529**, por no cumplir con lo dispuesto en la Decisión 486 de 2000, con base en los fundamentos que se expondrán a continuación.

II. LEGÍTIMO INTERÉS

Asiste a **TECNOQUÍMICAS S.A.,** legítimo interés para presentar esta oposición, pues la eventual concesión de la solicitud restringiría injustificadamente el empleo de ciertas sustancias, derivados y procesos que a nuestro juicio carecen de novedad y nivel inventivo, en detrimento de sus legítimos intereses comerciales. De igual manera mis clientes están interesados, por su misma condición de industrias farmacéuticas, en evitar la concesión de privilegios de patente que incumplan los requisitos materiales de patentabilidad establecidos en las normas vigentes, y que supongan un riesgo para la libre competencia.

III. FUNDAMENTOS DE LA OPOSICIÓN

La solicitud colombiana en trámite 13-019-529, referida a métodos para formular una composición antiinflamatoria para tratar afecciones inflamatorias en un órgano o tejido específico, no cumple los requisitos materiales para otorgársele el privilegio de patente de invención, tal como puede determinarse al valorar los siguientes argumentos:

1. Carencia de claridad y concisión

La solicitud en estudio ha presentado como eje principal de sus reclamaciones, la materia consignada en la reivindicación 1 de la siguiente manera:

> *1-. Un método para formular una composición antiinflamatoria para tratar una afección caracterizada por inflamación en un órgano o tejido específico, que comprende:*
> *seleccionar al menos un patógeno que sea patógeno en el órgano o tejido específico;*
> *producir una composición antigénica que comprende determinantes antigénicos que en conjunto son específicos para el patógeno, y*
> *formular la composición antigénica para su administración como una composición antiinflamatoria que pueda producir una respuesta antiinflamatoria en el órgano o tejido específico, donde la afección caracterizada por inflamación no es un cáncer.*

De una lectura cuidadosa de lo reivindicado, se observa que las características técnicas estructurales se encuentran ausentes ya que las mismas no definen claramente el objeto a proteger. Así pues, no se observa en dicho método una estructura definida, pues no se especifica tipo patógeno seleccionado, composición antigénica o formulación que produzca la respuesta inflamatoria en un órgano o tejido específico, es decir, no se fija ninguno de los tres pasos del método de forma técnica, por lo que no existe claridad en el capítulo.

Por otro lado, observamos que en cuanto a los organismos que pueden ser seleccionables, las diferencias son altamente variables y no demuestran un concepto común en estructura y función (tal como se observa de todos los organismos que pueden incluirse en la reivindicación 1); por tanto, no se existe una muestra representativa de la amplitud reclamada en los ejemplos ni prueba de la actividad similar de los organismos o de su efecto en los distintos órganos mencionados.

Por lo anterior, me permito indicar al Despacho que la solicitud en estudio no cumple con los requisitos de claridad, concisión, soporte en la descripción o suficiencia, dado que un técnico versado en la materia no obtendría los mismos resultados descritos bajo cualquier selección de la materia reclamada en la solicitud en trámite.

De otro lado, se observa que las reivindicaciones incluyen materia dirigida a formulación para inyección subcutánea o intradérmica pero no definen las características técnicas de dicha formulación tal como se observa en las reivindicaciones 4 – 5 y 8 - 9.; lo que significa que dicha formulación se está caracterizando por resultados a alcanzar.

Otro ejemplo para demostrar que la materia revelada a lo largo del capítulo reivindicatorio de la solicitud en trámite no es concisa, se obtiene al observar la reivindicación 6, la cual se relaciona con el patógeno y el órgano a seleccionar, veamos:

> *6-. El método de cualquiera de las reivindicaciones 1-5, donde el tejido u órgano específico es X, y el patógeno se selecciona del grupo que consiste en Y, donde:*

cuando X es:	Y es uno o más de:
hematológico, piel, tejido blando, pulmón/tráquea/bronquios, peritoneo, meninges, ducto biliar, vesícula, riñón, vejiga, uréter	Achromobacter spp.
piel, tejido blando, pulmón/tráquea/bronquios, mediastino, cerebro, médula espinal, hematológico, meninges	Actinomadura spp.

(continua: ver capitulo reivindicatorio...)

El método allí reclamado no revela las características técnicas de los organismos o de los métodos para que puedan ser empleados en los órganos mencionados, en su lugar, la identificación se realiza como una selección de una larga lista de caracterizaciones con relación a un resultado a alcanzar, por lo tanto dicho método no es reclamado de forma clara y concisa.

2. Referencias a usos

Además de lo anterior, la presente solicitud reclama el uso de una composición antiinflamatoria para tratar un individuo, tal como consta a continuación:

> 16. Uso de una composición antiinflamatoria para tratar a un individuo por una afección caracterizada por inflamación en un órgano o tejido específico, donde la composición antiinflamatoria comprende determinantes antigénicos seleccionados o formulados de modo que en conjunto sean específicos para al menos un patógeno microbiano que es patógeno en el órgano o tejido específico.

Se llama la atención del Señor Examinador sobre este hecho para que tenga en cuenta que de acuerdo a la D.486, solo serán patentables los productos o procedimientos:

> *Artículo 14- Los Países Miembros otorgarán patentes para las invenciones, sean de **producto o de procedimiento**, en todos los campos de la tecnología,*

siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial.

Por esta razón, las reivindicaciones de usos tales como 16 - 19, 17, 18, 21, 22, no cumplen con los criterios de patentabilidad de la Decisión 486 de la CAN y, en consecuencia, la solicitud no puede ser patentada.

3. Las reivindicaciones están exceptuadas de patentabilidad

Se observa que, reivindicaciones como 37 - 48, 50 – 56, 73 – 86, reclaman un método de tratamiento, lo cual contraviene lo descrito en el artículo 20 literal d) de la Decisión 486:

> 37. Un método para tratar a un paciente humano por una enfermedad inflamatoria intestinal (IBD) que es sintomática en una región de un tracto gastrointestinal (GIT), que comprende administrar al paciente un medicamento que comprende una cantidad eficaz de una composición antigénica que comprende determinantes antigénicos que en conjunto son específicos para al menos un patógeno, donde el patógeno se selecciona en el entendido de que el patógeno es patógeno en la región del tracto gastrointestinal.

Así, la solicitud no puede ser patentable ya que no cumple los requisitos mínimos de claridad, concisión, soporte en la descripción, suficiencia; adicionalmente, presenta materia exceptuada de patentabilidad tal como quedó demostrado.

4. Ausencia de Novedad y Nivel Inventivo de la solicitud.

La presente solicitud 13-019-529 plantea como problema la necesidad de proveer al menos un patógeno que es patógeno en el órgano o tejido específico, producir una composición antigénica que comprende determinantes antigénicos que, en conjunto son específicos para el patógeno y formular la composición antigénica para su administración como una composición antiinflamatoria que puede producir una respuesta antiinflamatoria en el órgano o tejido específico, donde la afección caracterizada por inflamación no es un cáncer.

Aunque se ha establecido que todas estas ventajas son ofrecidas por la resolución del problema técnico en las reivindicaciones, las mismas no definen técnicamente el método para formular la composición antiinflamatoria, tal como se observó en párrafos anteriores. En ese orden de ideas, no hay razones para pensar que la multiplicidad de patógenos descritos por las reivindicaciones y en especial la indeterminación de los mismos en la reivindicación 1, presenten todos las mismas ventajas aún cuando no se tiene una estructura biológica o funcional definida por los mismos, o cuando no se ha determinado técnicamente la serie de pasos del método.

A pesar de lo anterior, se observa que la publicación internacional WO 2008/049231 de Gunn et al. titulado: *"Tissue targeted antigenic activation of the immune response to treat cancers"* y publicado el 2 de mayo de 2008, describe métodos para formular una composición inmunogénica para el tratamiento del cáncer situado en un órgano o tejido específico de un mamífero tal como un paciente humano, veamos:

> **FIELD OF THE INVENTION**
>
> **[0001]** In various aspects, the invention relates to immunological cancer therapies. In alternative embodiments, the invention provides methods of formulating antigenic microbial composition and methods of using the antigenic compositions to treat cancers.

Dicho método incluye, al igual que la solicitud en trámite, al menos un patógeno microbiano que es **naturalmente patogénico** en el órgano o tejido del mamífero dentro del cual se sitúa el cáncer; adicionalmente, la anterioridad en mención revela una composición antigénica que puede ser producida y puede incluir los determinantes antigénicos que juntos son específicos o son característicos del patógeno microbial, como consta a continuación:

> **[0004]** It has been suggested that the effectiveness of some non-specific bacterial cancer vaccines is attributable to particular bacterial components or products, such as bacterial DNA or endotoxin (LPS), or because they induce the expression of particular factors, such as tumor necrosis factor (TNF) or interleukin-12. A

Gunn et al., además describe que puede emplearse un paso adicional para identificar el tejido u órgano específico dentro del cual se sitúa el cáncer antes de producir la composición antigénica dirigida al sitio del cáncer.

En este sentido, modalidades particulares como las que se encuentran en la reivindicación 74 son plenamente anticipadas por lo descrito en la citada anterioridad, a este respecto la solicitud menciona:

> *74. Un método para controlar la eficacia de un régimen de tratamiento en un individuo que está siendo tratado por un cáncer en un órgano o tejido específico, que comprende:*
>
> *medir una característica de una respuesta inmunitaria en una muestra inmunitaria después del tratamiento, obtenida del órgano o tejido específico luego de que el individuo se ha sometido al régimen de tratamiento durante un periodo de tiempo, donde: la presencia de una característica de la respuesta inmunitaria – que es mayor en magnitud a lo esperado si el individuo no se hubiese sometido al régimen de tratamiento – indica la eficacia del régimen de tratamiento, y el régimen de tratamiento comprende administrar una preparación que comprende uno o más determinantes antigénicos de un patógeno microbiano que es patógeno en el órgano o tejido específico correspondiente en un sujeto sano.*

En cuanto a los componentes antigénicos y patógenos de las reivindicaciones como la 6 y la 45, la anterioridad en el párrafo [00246] menciona el uso de determinantes antigénicos de *Mycobacterium bobis, M vaccae, Corynebacterium parvum, Streptococcus pyogenes, Nocardia rubra, Lactobacillus case, Pseudomonas aeruginosa,* entre otros:

> **[00246]** In some embodiments, selected compositions and methods are specifically excluded from the scope of the invention. For example, the use of the following microbial pathogens in the treatment of the following cancers is excluded from some embodiments, so that the claimed invention may extend to particular embodiments with the exception of one or more of the following:
>
> a) BCG (*Mycobacterium bovis*) for the treatment of stomach cancer and colon cancer, for example by injection;
> b) *Mycobacterium w* for the treatment of lung cancer, for example by injection;
> c) *Mycobacterium vaccae* for the treatment of non-small-cell lung cancer, for example by injection;
> d) *Corynebacterium parvum* for the treatment of melanoma, for example by injection;

e) *Streptococcus pyogenes* for the treatment of stomach cancer, for example by injection;

f) *Nocardia rubra* for the treatment of lung cancer or acute myelogenous leukemia, for example by injection;

g) *Lactobacillus casei* for the treatment of cervical cancer, for example by injection;

h) *Pseudomonas aeruginosa* for the treatment of lymphoma and lung cancer, for example by injection;

i) Vaccinia for the treatment of melanoma, for example by injection;

j) Rabies virus for the treatment of melanoma, for example by injection;

k) A composition consisting of the combined antigens of the following bacterial species for the veterinary (or, alternatively, human) treatment, for example by oral administration, for primary (or, alternatively, metastatic) cancers situated in the lung: *Steptococcus pneumoniae; Neisseria catarrhalis; Streptococcus pyogenes; Haemophilus influenzae; Staphylococcus aureus; Klebsiella pneumoniae.*

l) A composition consisting of the combined antigens of the following bacterial species for the veterinary (or, alternatively, human) treatment, for example by oral administration, for primary (or, alternatively, metastatic) cancers situated in the lung: *Steptococcus pneumoniae; Neisseria catarrhalis; Streptococcus pyogenes; Haemophilus influenzae; Staphylococcus aureus; Klebsiella pneumoniae; Klebsiella ozaenae; Streptococcus viridans.*

Por lo tanto, un método para la formulación de composiciones antiinflamatorias para el tratamiento de inflamación en un órgano o tejido específico cuando un tumor esta situado en un órgano específico, tal como lo define la presente solicitud, es inherente al método formulado en la composición inmunogénica para el tratamiento del cáncer definido en el documento de Gunn et al.

En otras palabras, el documento citado como anterioridad, incluye todas las características técnicas del método definido por la solicitud en la reivindicación 1 y cualquier modalidad particular es evidente para una persona versada en la materia, quien habría llegado a los métodos reclamados al caracterizar los antígenos de cada microorganismo y su patología principal.

Como conclusión, los métodos reivindicados no son novedosos y no cumplen con el requisito de nivel inventivo, pues las características específicas incluyen aquellas que un técnico medio versado en la materia emplea rutinariamente; adicionalmente, la materia se encontraba consignada en la información divulgada por la anterioridad WO 2008/049231.

Así las cosas, y con fundamento en los argumentos expuestos a lo largo del presente escrito, respetuosamente solicito que su despacho se abstenga de conceder el privilegio de patente solicitado para la presente solicitud, y ordene en consecuencia el archivo del expediente respectivo.

IV. FUNDAMENTOS DE DERECHO

Son fundamentos de derecho el Capítulo I, (Requisitos de Patentabilidad) y el artículo 42 (Oposiciones) de la Decisión 486 de 2000.

V. SOLICITUD DE PLAZO EXTRA PARA SUSTENTAR LA OPOSICIÓN

En desarrollo de lo dispuesto por el artículo 42, inciso 2º de la Decisión 486, solicito comedidamente a su Despacho el plazo adicional de sesenta días para sustentar la presente oposición. Para los anteriores efectos, me permito anexar la constancia de pago correspondiente.

VI. PRUEBAS

Ruego que se tenga como tal, sin perjuicio de las que puedan presentarse al vencimiento de la prórroga solicitada, y de aquellas que el Despacho considere oficiosamente, las siguientes:

- La publicación internacional WO 2008/049231, titulado *"Tissue targeted antigenic activation of the immune response to treat cancers"* de Gunn et al., y publicado el 2 de mayo de 2008. Págs 1, 2, 3, 42, 43, 44, 92, 112, 113 – 131.

VII. ANEXOS

Para efectos del trámite correspondiente, me permito anexar al presente escrito los siguientes anexos:

1. Certificado de existencia y representación legal de TECNOQUÍMICAS S.A.
2. Poder para actuar.
3. Constancia de pago de las tasas de tramitación de oposición.

4. Constancia de pago para sustentar la solicitud de prórroga a que se refiere el artículo 42, inciso 2º de la Decisión 486.
5. Copia para correr traslado al solicitante.
6. Las mencionadas en el acápite de pruebas

VIII. NOTIFICACIONES

El suscrito recibirá notificaciones en la secretaría de su Despacho o en mi oficina localizada en la Carrera 17 No. 88-23, Oficina 205, Fax (1) 621.25.42 de esta ciudad. Tecnoquímicas S.A. las recibirá en sus oficinas localizadas en la Calle 23 N° 7-39 de Cali.

Señor Superintendente,

JOSÉ LUIS REYES VILLAMIZAR
C.C. 79.152.473 de Usaquén
T.P.A. 44.655 de C.S.J.

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Published:
— *with international search report*

(54) Title: TISSUE TARGETED ANTIGENIC ACTIVATION OF THE IMMUNE RESPONSE TO TREAT CANCERS

(57) Abstract: The invention provides in part methods of treating cancers of a specific organ or tissue by administering a composition that is antigenically specific for one or more microbes that are pathogenic in the specific organ or tissue in which the cancer is situated. The formulations of the invention thereby facilitate activation of a treatment response to a cancer in a particular tissue or organ. The compositions may for example include killed or attenuated microbial pathogens, and may be administered at sites distant from the cancer, for example the skin. In some embodiments, microbial species of endogenous flora that are known to cause infection in the relevant organ or tissue may be used in the formulation of the antigenic compositions. In alternative embodiments, exogenous microbial pathogens that are known to cause infection in the relevant organ or tissue may be used in the formulation of the antigenic compositions. The administration of the immunogenic compositions may be repeated relatively frequently over a relatively long period of time. In embodiments for intradermal or subcutaneous injection, dosages may be adjusted so that injections reproduce a consistent visible delayed inflammatory immune reaction at the successive site or sites of administration.

WO 2008/049231 A1

TISSUE TARGETED ANTIGENIC ACTIVATION OF THE IMMUNE RESPONSE TO TREAT CANCERS

FIELD OF THE INVENTION

[0001] In various aspects, the invention relates to immunological cancer therapies. In alternative embodiments, the invention provides methods of formulating antigenic microbial composition and methods of using the antigenic compositions to treat cancers.

BACKGROUND OF THE INVENTION

[0002] More than one in three people in the developed nations are diagnosed with cancer. More than one in four die from it. Therapies for cancer have primarily relied upon treatments such as surgery, chemotherapy, and radiation. These approaches however, while beneficial for some types and stages of cancer, have proved to be of limited efficacy in many common types and stages of cancers. For example, surgical treatment of a tumor requires complete removal of cancerous tissue to prevent reoccurrence. Similarly, radiation therapy requires complete destruction of cancerous cells. This is difficult since, in theory, a single malignant cell can proliferate sufficiently to cause reoccurrence of the cancer. Also, both surgical treatment and radiation therapy are directed to localized areas of cancer, and are relatively ineffective when the cancer metastasizes. Often surgery or radiation or both are used in combination with systemic approaches such as chemotherapy. Chemotherapy however has the problem of non-selectivity with the concomitant problem of deleterious side effects, as well as the possibility of the cancer cells developing resistance to the drugs.

[0003] Alternative approaches for the treatment of cancers have included therapies that involve augmentation of immune system function such as cytokine therapy (e.g., recombinant interleukin 2 and gamma interferon for kidney cancers), dendritic cell therapy, autologous tumor vaccine therapy, genetically-altered vaccine therapy, lymphocyte therapy, and microbial vaccine therapies. Microbial

vaccines have been used to vaccinate subjects against pathogens that are associated with cancer, such as the human papillomavirus. Immunostimulatory microbial vaccines that are not targeted to cancer-causing organisms, i.e. non-specific immunostimulatory vaccines, such as pyrogenic vaccines, have a long clinical history that includes reports of successes and failures in treating a variety of cancers. For example, Coley's vaccine (a combination of *Streptococcus pyogenes* and *Serratia marcescens*) has been reported to be helpful for the treatment of sarcomas, and lymphomas (Nauts HC, Fowler GAA, Bogato FH. A review of the influence of bacterial infection and of bacterial products [Coley's toxins] on malignant tumors in man. Acta Med Scand 1953; 145 [Suppl. 276]:5-103). Clinical trials have reportedly demonstrated the benefit of Coley's vaccine treatment for lymphoma and melanoma (Kempin S, Cirrincone C, Myers J et al: Combined modality therapy of advanced nodular lymphomas: the role of nonspecific immunotherapy [MBV] as an important determinant of response and survival. Proc Am Soc Clin Oncol 1983;24:56; Kolmel KF, Vehmeyer K. Treatment of advanced malignant melanoma by a pyrogenic bacterial lysate: a pilot study. Onkologie 1991;14:411-17).

[0004] It has been suggested that the effectiveness of some non-specific bacterial cancer vaccines is attributable to particular bacterial components or products, such as bacterial DNA or endotoxin (LPS), or because they induce the expression of particular factors, such as tumor necrosis factor (TNF) or interleukin-12. A correspondingly broad range of physiological mechanisms have been ascribed to such treatments, ranging from generalized effects of fever to anti-angiogenic mechanisms. In accordance with these various principles, a wide variety of microbial vaccines have been tested as general immune stimulants for the treatment of cancer, many have shown negative results, amongst those that have shown positive results are the following:

[0005] Intradermal BCG (*Mycobacterium bovis*) vaccine treatment has been reported to be effective for the treatment of stomach cancer (Ochiai T, Sato J,

Hayashi R, et al: Postoperative adjuvant immunotherapy of gastric cancer with BCG-cell wall endoskeleton. Three- to six-year follow-up of a randomized clinical trial. Cancer Immunol Immunother 1983; 14:167-171) and colon cancer (Smith RE, Colangelo L, Wieand HS, Begovic M, Wolmark N. Randomized trial of adjuvant therapy in colon carcinoma: 10-Year results of NSABP protocol C-01. J. NCI 2004;96[15]:1128-32; Uyl-de Groot CA, Vermorken JB, Hanna MG, Verboon P, Groot MT, Bonsel GJ, Meijer CJ, Pinedo HM. Immunotherapy with autologous tumor cell-BCG vaccine in patients with colon cancer: a prospective study of medical and economic benefits Vaccine 2005; 23[17-18]:2379-87).

[0006] *Mycobacterium w* vaccine therapy, in combination with chemotherapy and radiation, was found to significantly improve quality of life and response to treatment in patients with lung cancer (Sur P, Dastidar A. Role of *Mycobacterium w* as adjuvant treatment of lung cancer [non-small cell lung cancer]. J Indian Med Assoc 2003 Feb;101[2]:118-120). Similarly, Mycobacterium vaccae vaccine therapy was found to improve quality of life (O'Brien M, Anderson H, Kaukel E, et al. SRL172 [killed *Mycobacterium vaccae*] in addition to standard chemotherapy improves quality of life without affecting survival, in patients with advanced non-small-cell lung cancer: phase III results. Ann Oncol 2004 Jun;15[6];906-14) and symptom control (Harper-Wynne C, Sumpter K, Ryan C, et al. Addition of SRL 172 to standard chemotherapy in small cell lung cancer [SCLC] improves symptom control. Lung Cancer 2005 Feb;47[2]:289-90) in lung cancer patients.

[0007] *Corynebacterium parvum* vaccine was linked with a trend towards improved survival for the treatment of melanoma (Balch CM, Smalley RV, Bartolucci AA, et al. A randomized prospective trial of adjuvant *C. parvum* immunotherapy in 260 patients with clinically localized melanoma [stage I]. Cancer 1982 Mar 15;49[6]:1079-84).

[0008] Intradermal *Streptococcus pyogenes* vaccine therapy was found to be effective for the treatment of stomach cancer (Hanaue H, Kim DY, Machimura T,

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management, abdominal breath work and dietary change (such as adopting a mediterranean diet, a low glycemic diet, eating non-charred foods, including foods having omega-3 fatty acids).

EXAMPLE 1: Clinical Studies

Bacterial Compositions

[00137] Five killed bacterial compositions have been used to treat a wide variety of cancer types and stages in blinded studies, as follows:

1. The Bayer Corporation MRV™ "Bayer MRV" (Hollister-Steir Laboratories, Spokane, WA, U.S.A.), containing the following bacterial species:

	Organisms per ml
Staphylococcus aureus	1200 million
viridans and non-hemolytic Streptococci	200 million
Streptococcus pneumoniae	150 million
Moraxella (Neisseria) catarrhalis	150 million
Klebsiella pneumoniae	150 million
Haemophilus influenzae	150 million

[00138] This vaccine was produced for the following indications: rhinitis, infectious asthma, chronic sinusitis, nasal polyposis and chronic serous otitis media. Cancer treatment was not indicated as an intended use for this vaccine. The vaccine also included the following ingredients: 0.4% phenol, 0.9% NaCl, trace amounts of brain heart infusion (beef), peptones, yeast extract, agar, sheep blood, dextrose, and sodium phosphates.

2. Stallergenes MRV "Stallergenes MRV" (Laboratories des Stallergenes, S.A., Fresnes, France), containing the following:

	Organisms per ml
Staphylococcus aureus	600 million
Staphylococcus albus	600 million

non-hemolytic Streptococci	200 million
Streptococcus pneumoniae	150 million
Moraxella (Neisseria) catarrhalis	150 million
Klebsiella pneumoniae	150 million
Haemophilus influenzae	150 million

[00139] This vaccine was produced for the same indications as the MRV vaccine i.e., recurrent respiratory tract infections, and listed cancer as a contraindication.

[00140] As set out below, surprisingly, these MRV vaccines, which contain many common lung pathogens, were found to be effective for the treatment of lung cancer.

3. Polyvaccinum Forte (PVF; Biomed S.A., Krakow, Poland), containing the following:

	Organisms per ml
Staphylococcus aureus	500 million
Staphylococcus epidermidis	500 million
Escherichia coli	200 million
Corynebacterium pseudodiphtheriticum	200 million
Streptococcus pyogenes	100 million
Streptococcus salivarius (viridans Streptococci)	100 million
Streptococcus pneumoniae	100 million
Moraxella (Neisseria) catarrhalis	100 million
Klebsiella pneumoniae	100 million
Haemophilus influenzae	100 million

[00141] This vaccine was produced for chronic and recurrent inflammatory conditions of the upper and lower respiratory tract and genitourinary tract, including rhinopharyngitis, recurrent laryngitis, tracheitis, bronchitis, otitis media,

chronic and recurrent neuralgia of trigeminal and occipital nerve, ischialgia, brachial plexitis, intercostals neuralgia, chronic cystoureteritis, vaginitis, adnexitis, and endometrium inflammation. Cancer treatment was not indicated as an intended use for this vaccine.

[00142] Of note, although the total concentration of bacteria in PVF is identical to that of the MRVs (Bayer and Stallergenes), patients typically demonstrated a visible inflammatory response to subcutaneous injection of the PVF composition at a much smaller dose than the usual dose required to achieve a similar skin response with the MRV composition, indicating that the immune reaction was likely occurring to one of the novel components in the Polyvaccinum Forte vaccine, such as E. coli. As set out below, surprisingly, PVF, which contains *E. coli* a common pathogen of the colon, abdomen, kidney, ovaries, peritoneum, liver and pancreas, has been found to be effective in the treatment of cancers in the colon, abdominal lymph nodes, kidney, ovary, peritoneum, liver and pancreas.

4. Staphage Lysate (Delmont Laboratories Inc., Swarthmore, PA, USA), containing the following:

Staphyloccus aureus

[00143] As set out below, surprisingly, Staphage Lysate, which contains *Staphyloccocus aureus* a common pathogen of the breast and bone, was found to be effective in the treatment of cancer in the breast and bone.

<u>Administration of MRV, Staphage Lysate and PVF</u>

[00144] The bacterial compositions (vaccines) were a suspension of killed bacterial cells and therefore, the suspensions were gently shaken prior to use to ensure uniform distribution prior to withdrawing dose from vial, and administered subcutaneously three times a week on Mondays, Wednesdays, and Fridays. Patients were advised to continue treatment for at least 6 months. The dose of

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Vulva			X							X

* Bacteria have access to tissues/organs either through: Contiguous spread (X) or Bacteremic spread: (✓).

[00236] In accordance with the combined information in Tables 1 and 2, cancers located in the tissues or organs set out in column 1 of Table 2 may be treated with antigenic compositions comprising antigenic determinants of the corresponding bacterial species of Table 1, so that the column headings in Table 2 are in effect replaced with the bacterial species of Table 1.

[00237] In some embodiments, microbial pathogens for use in the invention may be exongenous bacterial pathogens. For example, the organisms listed in **Table 3** may be used as microbial pathogens to formulate antigenic compositions, or antigenic compositions having those pathogens may selected, for use to treat cancers situated in the tissues or organs listed with the relevant organism in **Table 3**. In some embodiments, antigenic determinants of both endogenous and exogenous bacterial species targeted to a specific tissue or organ may be used in combination.

Table 3 Exogenous Bacterial Human Pathogens, and their Sites of Infection

bacterial species	tissue/organ sites
Achromobacter spp.	hematological, skin, soft tissue, lung/trachea/bronchi, peritoneum, meninges, bile duct, gallbladder, kidney, bladder, ureter
Actinomadura spp.	skin, soft tissue, lung/trachea/bronchi, mediastinum, brain, spinal cord, hematological, meninges
Aerobacter spp.	small bowel, colon, hematological, peritoneum
Aerococcus spp.	hematological, heart, bone, kidney, bladder, ureter, meninges
Alcaligenes spp.	lung/trachea/bronchi
Anaplasma spp.	meninges, hematological, liver, spleen, bone, lung/trachea/bronchi
Bacillus anthracis	lung/trachea/bronchi, lymph nodes pulmonary hilum, mediastinum, meninges, skin, nasopharynx, tonsil, oral, small bowel, colon, hematological
Bacillus cereus	colon, eye, hematological

other Bacillus spp.	hematological, bone, meninges, brain, heart, lung/trachea/bronchi, mediastinum, skin, soft tissue, colon, stomach, small bowel, eye
Balneatrix spp.	lung/trachea/bronchi, meninges, hematological
Bartonella bacilliformis	skin, hematological, liver, muscle, lymph nodes
Bartonella henselae	brain, spinal cord, hematological, skin, liver, bone, pleura, lung/trachea/bronchi, mediastinum, axillary and inguinal lymph nodes, eye
Bartonella quintana	skin, hematological, liver, spleen
Bergeyella zoohelcum	skin, soft tissue, meninges, hematological, lung/trachea/bronchi
Bordetella holmesii	lung/trachea/bronchi, hematological
Bordetella parapertussis	nasopharynx, tonsil, lung/trachea/bronchi
Bordetella pertussis	nasopharynx, tonsil, lung/trachea/bronchi
Borrelia burgdorferi	meninges, brain, spinal cord, skin, eye, hematological, inguinal/axillary/cervical lymph nodes, muscle, liver, spleen, nasopharynx, lung/trachea/bronchi, testes
Borrelia recurrentis	brain, spinal cord, hematological, small bowel, liver, spleen, salivary glands, lung/trachea/bronchi, lymph nodes, eye, skin
Brevundimonas spp.	peritoneum, hematological, skin, soft tissue
Brucella spp.	lung/trachea/bronchi, lymph nodes pulmonary hilum, meninges, brain, spinal cord, lymph nodes, mediastinum, bone, eye, small bowel, colon, liver, biliary tract, kidney, ureter, bladder, hematological, skin, testes, spleen, prostate
Burkholderia gladioli	hematological, meninges, lung/trachea/bronchi
Burkholderia mallei	lung/trachea/bronchi, skin, soft tissue, liver, spleen, muscle, lymph nodes pulmonary hilum, mediastinal lymph nodes, mediastinum, head and neck lymph nodes, hematological
Burkholderia pseudomallei	lung/trachea/bronchi, skin, kidney, bladder, ureter, soft tissue, bone, brain, spinal cord, muscle, hematological, prostate, kidney, ureter, meninges
Calymmatobacterium granulomatis	skin, penis, vulva, soft tissue, vagina, cervix, bone, hematological, inguinal lymph nodes
Campylobacter coli	small bowel, colon

e) *Streptococcus pyogenes* for the treatment of stomach cancer, for example by injection;

f) *Nocardia rubra* for the treatment of lung cancer or acute myelogenous leukemia, for example by injection;

g) *Lactobacillus casei* for the treatment of cervical cancer, for example by injection;

h) *Pseudomonas aeruginosa* for the treatment of lymphoma and lung cancer, for example by injection;

i) Vaccinia for the treatment of melanoma, for example by injection;

j) Rabies virus for the treatment of melanoma, for example by injection;

k) A composition consisting of the combined antigens of the following bacterial species for the veterinary (or, alternatively, human) treatment, for example by oral administration, for primary (or, alternatively, metastatic) cancers situated in the lung: *Steptococcus pneumoniae; Neisseria catarrhalis; Streptococcus pyogenes; Haemophilus influenzae; Staphylococcus aureus; Klebsiella pneumoniae.*

l) A composition consisting of the combined antigens of the following bacterial species for the veterinary (or, alternatively, human) treatment, for example by oral administration, for primary (or, alternatively, metastatic) cancers situated in the lung: *Steptococcus pneumoniae; Neisseria catarrhalis; Streptococcus pyogenes; Haemophilus influenzae; Staphylococcus aureus; Klebsiella pneumoniae*; *Klebsiella ozaenae; Streptococcus viridans.*

OTHER EMBODIMENTS

[00247] Although various embodiments of the invention are disclosed herein, many adaptations and modifications may be made within the scope of the invention in accordance with the common general knowledge of those skilled in this art. Such modifications include the substitution of known equivalents for any aspect of the invention in order to achieve the same result in substantially the same way. Numeric ranges are inclusive of the numbers defining the range. In

the specification, the word "comprising" is used as an open-ended term, substantially equivalent to the phrase "including, but not limited to", and the word "comprises" has a corresponding meaning. Citation of references herein shall not be construed as an admission that such references are prior art to the present invention. All publications are incorporated herein by reference as if each individual publication were specifically and individually indicated to be incorporated by reference herein and as though fully set forth herein. The invention includes all embodiments and variations substantially as hereinbefore described and with reference to the examples and drawings.

WHAT IS CLAIMED IS:

1. A method for formulating an immunogenic composition for treating a cancer situated in a specific organ or tissue in a human patient, comprising:

selecting at least one microbial pathogen that is pathogenic in the specific organ or tissue of the patient within which the cancer is situated;

producing an antigenic composition comprising antigenic determinants that together are specific for the microbial pathogen; and,

formulating the antigenic composition for administration as an immunogenic composition capable of illiciting an immune reaction to treat the cancer in the patient.

2. The method of claim 1, wherein the antigenic composition is formulated for subcutaneous injection, intradermal injection or oral administration.

3. The method of claim 1 or 2, further comprising a diagnostic step of identifying the specific organ or tissue within which the cancer is situated prior to producing the antigenic composition.

4. The method of claim 1, 2 or 3, wherein the antigenic composition is formulated for injection to produce a localized skin immune response at a site of administration.

5. The method of claim 4, wherein the skin immune response is an inflammatory immune response.

6. The method of any one of claims 1 to 5, wherein the organ or tissue is selected from the group consisting of skin, soft tissue, breast, head and neck lymph nodes, axillae/arm lymph nodes, mediastinal lymph nodes, pulmonary hilar lymph nodes, intra-abdominal lymph nodes, inguinal/leg lymph nodes,

hematological, bone, meninges, brain, spinal cord, eye/orbit, salivary glands, oral, tonsil, sinus, nasopharynx, thyroid, larynx, trachea, bronchi, lung, pleura, mediastinum, heart, esophagus, stomach, small bowel, colon/rectum, anus, perineum, liver, gallbladder, biliary tract, pancreas, spleen, adrenal gland, kidney, ureter, bladder, peritoneum, retroperitoneal area, prostate, testicle, penis, ovary/adnexae, uterus, cervix, vagina, vulva.

7. The method of any one of claims 1 to 6, wherein the cancer is a metastatic cancer having a site of metastasis, and the organ or tissue is a site of metastsis.

8. The method of any one of claims 1 to 6, wherein the cancer is a primary cancer in the organ or tissue.

9. The method of any one of claims 1 to 8, wherein the antigenic composition is formulated for repeated subcutaneous or intradermal administration.

10. The method of any one of claims 1 to 9, wherein the antigenic composition is formulated for administration in an organ or tissue that is not the organ or tissue within which the cancer is situated.

11. The method of any one of claims 1 to 10, wherein the microbial pathogen is a bacteria.

12. The method of claim 11, further comprising killing the bacteria to formulate the antigenic composition.

13. The method of claim 11 or 12, wherein the bacteria is a member of an endogenous human flora of the specific organ or tissue.

14. The method of claim 13, wherein the bacteria is endogenous to flora of the respiratory system, mouth, stomach, duodenum, jejunum, ileum, colon, genitourinary (GU) system, vagina or skin.

15. The method of any one of claims 1 to 14, wherein the antigenic composition is capable of eliciting an immune response in the patient specific to the microbial pathogen.

16. The method of any one of claims 1 to 12 or 15, wherein the microbial pathogen is an exogenous bacterial species.

17. The method of any one of claims 1 to 10, or 15 wherein the microbial pathogen is a virus.

18. The method of claim 13, wherein the organ or tissue is x, and the bacteria is endogenous to flora of the y of the patient, and:

when x is skin, y is skin or mouth;
when x is soft tissue, y is skin;
when x is breast, y is skin or mouth;
when x is lymph nodes of the head and neck, y is skin, respiratory system or mouth;
when x is lymph nodes of the axillae/arm, y is skin, mouth or colon;
when x is lymph nodes of the mediastinum, y is respiratory system, mouth or colon;
when x is lymph nodes of the pulmonary hilum, y is respiratory system;
when x is intra-abdominal lymph nodes, y is GU system, mouth, duodenum/jejunum, ileum or colon;
when x is inguinal/let lymph nodes, y is skin, genital, mouth or colon;
when x is hematological, y is skin, mouth or colon;
when x is bone, y is skin, mouth or colon;
when x is meninges, y is respiratory system or mouth;

when x is brain, y is skin, mouth or colon;
when x is spinal cord, y is skin, mouth or colon;
when x is eye/orbit, y is skin, respiratory system, genital or mouth;
when x is salivary glands, y is mouth;
when x is oral, y is mouth;
when x is tonsil, y is respiratory system or mouth;
when x is nasopharynx/sinus, y is respiratory system or mouth;
when x is thyroid, y is skin, mouth or colon;
when x is larynx, y is respiratory system or mouth;
when x is lung/bronchi/trachea, y is respiratory system;
when x is pleura, y is skin, respiratory system, mouth or colon;
when x is mediastinum, y is respiratory system;
when x is heart, y is skin, mouth or colon;
when x is esophagus, y is stomach;
when x is stomach, y is stomach
when x is small bowel, y is duodenum/jejunum or ileum;
when x is colon/rectum, y is colon;
when x is anus, y is skin or colon;
when x is perineum, y is skin or colon;
when x is liver, y is skin, mouth or colon;
when x is gallbladder, y is duodenum/jejunum;
when x is biliary tract, y is duodenum/jejunum;
when x is pancreas, y is duodenum/jejunum;
when x is spleen, y is skin, mouth or colon;
when x is adrenal gland, y is skin, mouth or colon;
when x is kidney, y is skin, GU system, mouth or colon;
when x is ureter, y is GU system;
when x is bladder, y is skin, genital or GU system;
when x is peritoneum, y is stomach, duodenum/jejunum, ileum or colon;
when x is retroperitoneal area, y is stomach, duodenum/jejunum, ileum or colon;

when x is prostate, y is gential or GU system ;
when x is testicle, y is gential or GU system;
when x is penis, y is skin, genital or GU system;
when x is ovary/adnexae, y is genital, GU system or colon;
when x is uterus, y is genital, GU system or colon;
when x is cervix, y is genital, GU system or colon;
when x is vagina, y is genital or colon;
when x is vulva, y is genital or colon.

19. The method of any one of claims 1 to 18, further comprising formulating the antigenic composition for administration with an anti-inflammatory.

20. The method of claim 19, wherein the anti-inflammatory is an NSAID.

21. The method of any one of claims 1 to 20, wherein the antigenic composition is produced so that at least 70% of the antigenic determinants in the antigenic composition are specific for microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

22. The method of any one of claims 1 to 20, wherein the antigenic composition is produced so that at least 90% of the antigenic determinants in the antigenic composition are specific for microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

23. The method of any one of claims 1 to 20, wherein the antigenic composition is produced so that 100% of the antigenic determinants in the antigenic composition are specific for microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

24. The method of any one of claims 1 to 20, wherein the antigenic composition is produced so that at least 70% of the antigenic determinants in the

antigenic composition are specific for a microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

25. The method of any one of claims 1 to 20, wherein the antigenic composition is produced so that at least 90% of the antigenic determinants in the antigenic composition are specific for a microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

26. The method of any one of claims 1 to 20, wherein the antigenic composition is produced so that 100% of the antigenic determinants in the antigenic composition are specific for a microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

27. The method of any one of claims 1 to 20, wherein the antigenic composition is produced so that, of the total number of microbial pathogens in the antigenic composition, at least 70% are microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

28. The method of any one of claims 1 to 20, wherein the antigenic composition is produced so that, of the total number of microbial pathogens in the antigenic composition, at least 90% are microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

29. The method of any one of claims 1 to 20, wherein the antigenic composition is produced so that, of the total number of microbial pathogens in the antigenic composition, at least 70% are microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

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30. The method of any one of claims 1 to 20, wherein the antigenic composition is produced so that, of the total number of microbial pathogens in the antigenic composition, at least 90% are microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

31. The method of any one of claims 1 to 20, wherein the antigenic composition is produced so that, of the total number of microbial pathogens in the antigenic composition, 100% are microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

32. The method of any one of claims 1 to 20, wherein the antigenic composition comprises antigenic determinants of a single microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

33. The method of any one of claims 1 to 20, wherein at least 70% of the antigenic determinants in the antigenic composition are antigenic determinants of a single microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

34. The method of any one of claims 1 to 20, wherein at least 90% of the antigenic determinants in the antigenic composition are antigenic determinants of a single microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

35. The method of any one of claims 1 to 20, wherein 100% of the antigenic determinants in the antigenic composition are antigenic determinants of a single

microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

36. The method of any one of claims 1 to 20, wherein the antigenic composition is produced so that the antigenic composistion consists essentially of antigenic determinants of one or more microbial pathogens that are each pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

37. The use of an antigenic composition for formulating a medicament for treating a human patient for a cancer situated in a tissue or an organ, the antigenic composition comprising antigenic determinants that together are specific for at least one microbial pathogen, the microbial pathogen being pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

38. The use according to claim 37, wherein the medicament is formulated for administration at an administration site in successive doses given at a dosage interval of between one hour and one month, over a dosage duration of at least two weeks.

39. The use according to claim 38, wherein the medicament is formulated so that each dose is effective to cause a visible localized inflammatory immune response at the administration site.

40. The use according to claim 37, 38 or 39, wherein the medicament is formulated for intradermal or subcutaneously administration.

41. The use according to claim 37, wherein the medicament is formulated for oral administration.

42. The use according to claim 37, 38 or 40, wherein the medicament is formulated so that visible localized inflammation at the administration site occurs within 1 to 48 hours.

43. The use according to any one of claims 37 to 42, further comprising the use of an anti-inflammatory to treat the patient.

44. The use according to claim 43, wherein the anti-inflammatory is an NSAID.

45. The use according to any one of claims 37 to 44, wherein the tissue or organ is X, and the microbial pathogen is selected from the group consisting of Y, wherein:

when X is:	Y is one or more of:
Skin	*Staphylococcus aureus*, Beta hemolytic streptococci group A, B, C and G, *Corynebacterium diptheriae, Corynebacterium ulcerans, Pseudomonas aeruginosa*
	rubeola, rubella, varicella-zoster, echoviruses, coxsackieviruses, adenovirus, vaccinia, herpes simplex, parvo B19;
Soft tissue (i.e. fat and muscle) (e.g., sarcoma)	*Streptococcus pyogenes, Staphylococcus aureus, Clostridium perfringens,* other *Clostridium spp.*
	influenza, coxsackieviruses;
Breast	*Staphylococcus aureus, Streptococcus pyogenes;*
Lymph nodes: head and neck	*Staphylococcus aureus, Streptococcus pyogenes*
	Epstein-Barr, cytomegalovirus, adenovirus, measles, rubella, herpes simplex, coxsackieviruses, varicella-zoster;
Lymph nodes: axillae/arm	*Staphylococcus aureus, Streptococcus pyogenes*
	measles, rubella, Epstein-Barr, cytomegalovirus, adenovirus, varicella-zoster;
Lymph nodes: mediastinal	viridans streptococci, P*eptococcus spp., Peptostreptococcus spp., Bacteroides spp., Fusobacterium spp., Mycobacterium tuberculosis*
	measles, rubella, Epstein-Barr, cytomegalovirus, varicella-zoster, adenovirus;
Lymph nodes: pulmonary hilum	*Streptococcus pneumoniae, Moraxella catarrhalis, Mycoplasma pneumoniae, Klebsiella pneumoniae, Haemophilus influenza, Chlamydophila pneumoniae, Bordetella pertussis, Mycobacterium tuberculosis*

	influenza, adenovirus, rhinovirus, coronavirus, parainfluenza, respiratory syncytial virus, human metapneumovirus, coxsackievirus
Lymph nodes: intra-abdominal	*Yersinia enterocolitica, Yersinia pseudotuberculosis, Salmonella spp., Streptococcus pyogenes, Escherichia coli, Staphylococcus aureus, Mycobacterium tuberculosis*
	measles, rubella, Epstein-Barr, cytomegalovirus, varicella-zoster, adenovirus, influenza, coxsackieviruses;
Lymph nodes: inguinal/leg	*Staphylococcus aureus, Streptococcus pyogenes*
	measles, rubella, Epstein-Barr, cytomegalovirus, herpes simplex;
Hematological (e.g. leukemias, multiple myeloma)	*Staphylococcus aureus, Streptococcus pyogenes,* coagulase-negative staphylococci, *Enterococcus spp., Escherichia coli, Klebsiella spp., Enterobacter spp., Proteus spp., Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus pneumoniae,* group B streptococci
	rubeola, rubella, varicella-zoster, echoviruses, coxsackieviruses, adenovirus, Epstein-Barr, cytomegalovirus, herpes simplex;
Bone	*Staphylococcus aureus,* coagulase-negative staphylococci, *Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus agalactiae,* other streptococci spp., *Escherichia coli, Pseudomonas spp., Enterobacter spp., Proteus spp., Serratia spp.*
	parvovirus B19, rubella, hepatitis ;B
Meninges	*Haemophilus influenzae, Neisseria meningitidis, Streptococcus pneumoniae, Streptococcus agalactiae, Listeria monocytogenes*
	echoviruses, coxsackieviruses, other enteroviruses, mumps;
Brain	*Streptococcus spp.* (including *S. anginosus, S. constellatus, S. intermedius*), *Staphylococcus aureus, Bacteroides spp., Prevotella spp., Proteus spp., Escherichia coli, Klebsiella spp., Pseudomonas spp., Enterobacter spp., Borrelia burgdorferi*
	coxsackieviruses, echoviruses, poliovirus, other enteroviruses, mumps, herpes simplex, varicella-zoster, flaviviruses, bunyaviruses;
Spinal cord	*Haemophilus influenzae, Neisseria meningitidis, Streptococcus pneumoniae, Streptococcus agalactiae, Listeria monocytogenes, Borrelia burgdorferi*
	coxsackieviruses, echoviruses, poliovirus, other enteroviruses, mumps, herpes simplex, varicella-zoster, flaviviruses, bunyaviruses;

Eye/Orbit	*Staphylococcus aureus, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus milleri, Escherichia coli, Bacillus cereus, Chlamydia trachomatis, Haemophilus influenza, Pseudomonas spp., Klebsiella spp., Treponema pallidum*
	adenoviruses, herpes simplex, varicella-zoster, cytomegalovirus;
Salivary glands	*Staphylococcus aureus,* viridans streptococci (*e.g., Streptococcus salivarius, Streptococcus sanguis, Streptococcus mutans), Peptostreptococcus spp., Bacteroides spp., and other oral anaerobes*
	mumps, influenza, enteroviruses, rabies;
Oral	*Prevotella melaninogenicus,* anaerobic streptococci, viridans streptococci, *Actinomyces spp., Peptostreptococcus spp., Bacteroides spp.,* and other oral anaerobes
	herpes simplex, coxsackieviruses, Epstein-Barr;
Tonsil	*Streptococcus pyogenes,* Group C and G B-hemolytic streptococci
	rhinoviruses, influenza, coronavirus, adenovirus, parainfluenza, respiratory syncytial virus, herpes simplex;
Sinus	*Streptococcus pneumoniae, Haemophilus influenza, Moraxella catarrhalis,* α-streptococci, anaerobic bacteria (e.g., *Prevotella), Staphylococcus aureus*
	rhinoviruses, influenza, adenovirus, parainfluenza;
Nasopharynx	*Streptococcus pyogenes,* Group C and G B-hemolytic streptococci
	rhinoviruses, influenza, coronavirus, adenovirus, parainfluenza, respiratory syncytial virus, herpes simplex;
Thyroid	*Staphylococcus aureus, Streptococcus pyogenes, Streptococcus pneumoniae*
	mumps, influenza;
Larynx	*Mycoplasma pneumoniae, Chlamydophila pneumoniae, Streptococcus pyogenes*
	rhinovirus, influenza, parainfluenza, adenovirus, corona virus, human metapneumovirus;
Trachea	*Mycoplasma pneumoniae*
	parainfluenza, influenza, respiratory syncytial virus, adenovirus;
Bronchi	*Mycoplasma pneumoniae, Chlamydophila pneumoniae, Bordetella pertussis, Streptococcus pneumoniae, Haemophilus influenzae*
	influenza, adenovirus, rhinovirus, coronavirus, parainfluenza, respiratory syncytial virus, human metapneumovirus, coxsackievirus;

Lung	*Streptococcus pneumoniae, Moraxella catarrhalis, Mycoplasma pneumoniae, Klebsiella pneumoniae, Haemophilus influenza*
	influenza, adenovirus, respiratory syncytial virus, parainfluenza;
Pleura	*Staphylococcus aureus, Streptococcus pyogenes, Streptococcus pneumoniae, Haemophilus influenzae, Bacteroides fragilis, Prevotella spp., Fusobacterium nucleatum, peptostreptococcus, Mycobacterium tuberculosis*
	influenza, adenovirus, respiratory syncytial virus, parainfluenza;
Mediastinum	viridans streptococci, *Peptococcus spp., Peptostreptococcus spp., Bacteroides spp., Fusobacterium spp., Mycobacterium tuberculosis*
	measles, rubella, Epstein-Barr, cytomegalovirus;
Heart	*Streptococcus spp.* (including *S. mitior, S. bovis, S. sanguis, S. mutans, S. anginosus), Enterococcus spp., Staphylococcus spp., Corynebacterium diptheriae, Clostridium perfringens, Neisseria meningitidis, Salmonella spp.*
	enteroviruses, coxsackieviruses, echoviruses, poliovirus, adenovirus, mumps, rubeola, influenza;
Esophagus	*Actinomyces spp., Mycobacterium avium, Mycobacterium tuberculosis, Streptococcus spp.*
	cytomegalovirus, herpes simplex, varicella-zoster;
Stomach	*Streptococcus pyogenes, Helicobacter pylori*
	cytomegalovirus, herpes simplex, Epstein-Barr, rotaviruses, noroviruses, adenoviruses;
Small bowel	*Escherichia coli, Clostridium difficile, Bacteroides fragilis, Bacteroides vulgatus, Bacteroides thetaiotaomicron, Clostridium perfringens, Salmonella enteriditis, Yersinia enterocolitica, Shigella flexneri*
	adenoviruses, astroviruses, caliciviruses, noroviruses, rotaviruses, cytomegalovirus;
Colon/Rectum	*Escherichia coli, Clostridium difficile, Bacteroides fragilis, Bacteroides vulgatus, Bacteroides thetaiotaomicron, Clostridium perfringens, Salmonella enteriditis, Yersinia enterocolitica, Shigella flexneri*
	adenoviruses, astroviruses, caliciviruses, noroviruses, rotaviruses, cytomegalovirus;
Anus	*Streptococcus pyogenes, Bacteroides spp., Fusobacterium spp.*, anaerobic streptococci, *Clostridium spp., E. coli, Enterobacter spp., Pseudomonas aeruginosa, Treponema pallidum*
	herpes simplex;

Perineum	*Escherichia coli, Klebsiella spp., Enterococcus spp., Bacteroides spp., Fusobacterium spp., Clostridium spp., Pseudomonas aeruginosa, anaerobic streptococci, Clostridium spp., E. coli, Enterobacter spp.,*
	herpes simplex;
Liver	*Escherichia coli, Klebsiella spp., Streptococcus (anginosus* group*), Enterococcus, spp. o*ther viridans streptococci, *Bacteroides spp.*
	hepatitis A, Epstein-Barr, herpes simplex, mumps, rubella, rubeola, varicella-zoster, coxsackieviruses, adenovirus;
Gallbladder	*Escherichia coli, Klebsiella spp., Enterobacter spp., enterococci, Bacteroides spp., Fusobacterium spp., Clostridium spp., Salmonella enteriditis, Yersinia enterocolitica, Shigella flexneri;*
Biliary tract	*Escherichia coli, Klebsiella spp., Enterobacter spp., enterococci, Bacteroides spp., Fusobacterium spp., Clostridium spp., Salmonella enteriditis, Yersinia enterocolitica, Shigella flexneri*
	hepatitis A, Epstein-Barr, herpes simplex, mumps, rubella, rubeola, varicella-zoster, cocsackieviruses, adenovirus;
Pancreas	*Escherichia coli, Klebsiella spp., Enterococcus spp., Pseudomonas spp., Staphylococcal spp., Mycoplasma, Salmonella typhi, Leptospirosis spp., Legionella*
	mumps, coxsackievirus, hepatitis B, cytomegalovirus, herpes simplex 2, varicella-zoster ;
Spleen	*Streptococcus spp., Staphylococcus spp., Salmonella spp., Pseudomonas spp., Escherichia coli, Enterococcus spp.*
	Epstein-Barr, cytomegalovirus, adenovirus, measles, rubella, coxsackieviruses, varicella-zoster;
Adrenal gland	*Streptococcus spp., Staphylococcus spp., Salmonella spp., Pseudomonas spp., Escherichia coli, Enterococcus spp.*
	varicella-zoster;
Kidney	*Escherichia coli, Proteus mirabilis, Proteus vulgatus, Providentia spp., Morganella spp., Enterococcus faecalis, Pseudomonas aeruginosa*
	BK virus, mumps;
Ureter	*Escherichia coli, Proteus mirabilis, Proteus vulgatus, Providentia spp., Morganella spp., Enterococcus spp.;*

Bladder	*Escherichia coli, Proteus mirabilis, Proteus vulgatus, Providentia spp., Morganella spp., Enterococcus faecalis, Corynebacterium jekeum*
	adenovirus, cytomegalovirus;
Peritoneum	*Staphylococcus aureus, Streptococcus pyogenes, Streptococcus pneumonia, Escherichia coli, Klebsiella spp., Proteus spp.*, enterococci, *Bacteroides fragilis, Prevotella melaninogenica, Peptococcus spp., Peptostreptococcus spp., Fusobacterium, Clostridium spp.;*
Retroperitoneal area	*Escherichia coli, Staphylococcus aureus;*
Prostate	*Escherichia coli, Klebsiella spp., Enterobacter spp., Proteus mirabilis*, enterococci, *Pseudomonas spp., Corynebacterium spp., Neisseria gonorrhoeae*
	herpes simplex;
Testicle	*Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Staphylococcus spp., Streptococcus spp., Salmonella enteriditis*
	mumps, coxsackievirus, lymphocytic choriomeningitis virus;
Penis	*Staphylococcus aureus, Streptococcus pyogenes, Neisseria gonorrhoeae, Treponema pallidum*
	herpes simplex, human papillomavirus;
Ovary/Adnexae	*Neisseria gonorrhoeae, Chlamydia trachomatis, Gardenerella vaginalis, Prevotella spp., Bacteroides spp., Peptococcus spp. Streptococcus spp., Escherichia coli;*
Uterus	*Neisseria gonorrhoeae, Chlamydia trachomatis, Gardenerella vaginalis, Prevotella spp., Bacteroides spp., Peptococcus spp., Streptococcus spp., Escherichia coli;*
Cervix	*Neisseria gonorrhoeae, Chlamydia trachomatis, Treponema pallidum*
	herpes simplex;
Vagina	*Gardenerella vaginalis, Prevotella spp., Bacteroides spp., peptococci spp., Escherichia coli, Neisseria gonorrhoeae, Chlamydia Trachomatis, Treponema pallidum,*
	herpes simplex;
Vulva	*Staphylococcus aureus, Streptococcus pyogenes, Treponema pallidum*
	herpes simplex.

46. The use according to any one of claims 37 to 45, wherein the use is not the use of:

a) antigenic determinants of BCG (*Mycobacterium bovis*) for the treatment of stomach cancer or colon cancer by injection;

b) antigenic determinants of *Mycobacterium w* for the treatment of lung cancer by injection;

c) antigenic determinants of *Mycobacterium vaccae* for the treatment of non-small-cell lung cancer by injection;

d) antigenic determinants of *Corynebacterium parvum* for the treatment of melanoma by injection;

e) antigenic determinants of *Streptococcus pyogenes* for the treatment of stomach cancer by injection;

f) antigenic determinants of *Nocardia rubra* for the treatment of lung cancer or acute myelogenous leukemia by injection;

g) antigenic determinants of *Lactobacillus casei* for the treatment of cervical cancer by injection;

h) antigenic determinants of *Pseudomonas aeruginosa* for the treatment of lymphoma and lung cancer by injection;

i) antigenic determinants of Vaccinia for the treatment of melanoma by injection;

j) antigenic determinants of Rabies virus for the treatment of melanoma by injection;

k) a composition consisting of the combined antigens of the following bacterial species for the veterinary or human treatment by oral administration of metastatic cancers situated in the lung: *Steptococcus pneumoniae; Neisseria catarrhalis; Streptococcus pyogenes; Haemophilus influenzae; Staphylococcus aureus; Klebsiella pneumoniae.*

l) a composition consisting of the combined antigens of the following bacterial species for the veterinary (or, alternatively, human) treatment, for example by oral administratoin, for metastatic cancers situated in the lung: *Steptococcus pneumoniae; Neisseria catarrhalis; Streptococcus pyogenes;*

Haemophilus influenzae; Staphylococcus aureus; Klebsiella pneumoniae; Klebsiella ozaenae; Streptococcus viridans.

47. The use according to any one of claims 37 to 46, wherein at least 70% of the antigenic determinants in the antigenic composition are specific for microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

48. The use according to any one of claims 37 to 46, wherein at least 90% of the antigenic determinants in the antigenic composition are specific for microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

49. The use according to any one of claims 37 to 46, wherein 100% of the antigenic determinants in the antigenic composition are specific for microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

50. The use according to any one of claims 37 to 46, wherein at least 70% of the antigenic determinants in the antigenic composition are specific for a microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

51. The use according to any one of claims 37 to 46, wherein at least 90% of the antigenic determinants in the antigenic composition are specific for a microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

52. The use according to any one of claims 37 to 46, wherein 100% of the antigenic determinants in the antigenic composition are specific for a microbial

pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

53. The use according to any one of claims 37 to 46, wherein, of the total number of microbial pathogens in the antigenic composition, at least 70% are microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

54. The use according to any one of claims 37 to 46, wherein, of the total number of microbial pathogens in the antigenic composition, at least 90% are microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

55. The use according to any one of claims 37 to 46, wherein, of the total number of microbial pathogens in the antigenic composition, 100% are microbial pathogens that are pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

56. The use according to any one of claims 37 to 46, wherein at least 70% of the antigenic determinants in the antigenic composition are antigenic determinants of a single microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

57. The use according to any one of claims 37 to 46, wherein at least 90% of the antigenic determinants in the antigenic composition are antigenic determinants of a single microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

58. The use according to any one of claims 37 to 46, wherein 100% of the antigenic determinants in the antigenic composition are antigenic determinants of

a single microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

59. The use according to any one of claims 37 to 46, wherein the antigenic composition comprises antigenic determinants of a single microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

60. The use according to any one of claims 37 to 46, wherein the antigenic composition consists essentially of antigenic determinants of one or more microbial pathogens that are each pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

61. The use according to any one of claims 37 to 46, wherein the antigenic composition consists essentially of antigenic determinants of the microbial pathogen that is the most commonly pathogenic in the specific organ or tissue of the patient within which the cancer is situated.

ESCRITURA NUMERO CUATRO MIL QUINIENTOS - TREINTA Y NUEVE (No.4.539) -------------- En la ciudad de Cali, Capital del Departamento del Valle del Cauca, República de Colombia, a los VEINTITRES (23) días - del mes de OCTUBRE del año DOS MIL UNO -- (2.001), ante mí, JORGE ENRIQUE CAICEDO ZAMORANO, Notario T E R C E R O (3o.) del Círculo de Cali, -

compareció JUAN MANUEL BARBERI OSPINA mayor de edad, vecino de Cali, identificado con la cédula de ciudadanía número 14.949.561 de Cali, y dijo: ----.

PRIMERO.- Que obra en su carácter de Representante Legal de en nombre y representación de TECNOQUIMICAS S.A. sociedad comercial organizada y existente conforme a las leyes colombianas, con domicilio y sede principal en Cali constituida mediante escritura pública número 2670 de la Notaría Segunda de Cali de fecha 12 de junio de 1957, reformada en distintas oportunidades, según consta en el certificado expedido por la Cámara de Comercio de Cali --

SEGUNDO: Que en tal carácter, por este público instrumento, concede Poder Especial pero amplio y suficiente a JOSE LUIS REYES VILLAMIZAR, mayor de edad, vecino de Bogotá, identificado con C.C. # 79.152.473 de Usaquén, abogado en ejercicio, portador de la T.P 44655 del C.S.de la J., domiciliado en Bogotá, D.C., República de Colombia con dirección carrera 7 No. 88.23 oficina 205, de la misma ciudad, como su representante con poder especial, amplio y suficiente, para obtener la protección de nuestra propiedad industrial y contra la competencia desleal, a cuyo efecto lo autorizo, para que nos represente ante cualesquiera entidad o persona, ejerzan o no jurisdicción, especialmente ante las del orden administrativo, contencioso-administrativo y judicial, en todo lo concerniente a los siguientes asuntos: a) Obtención, formulación de observaciones y oposición a patentes de invención, modelos y dibujos industriales y el registro de licencias de uso de esos derechos; b) Las acciones de oposición, cancelación, nulidad, medidas cautelares, concesión de licencias y en general los procesos civiles, penales, administrativos o contencioso-administrativos relacionados con estos derechos u otros de diferente naturaleza; acciones y procesos que promovamos o se nos promuevan; y c) para

que en todos los asuntos arriba determinados, , tanto en los términos señalados por los artículos 42 y complementarios de la Decisión 486 de la Comunidad Andina como del artículo 70 del C.P.C pueda sustituir este mandato, transigir, conciliar, admitir los hechos del proceso, desistir, cancelar, recibir, renunciar, y ratificar los actos de agentes oficiosos y ceder a titulo gratuito y/o oneroso, licenciar, inscribir contratos de cesión y de licencia, inscripción de prendas, levantamiento de prendas, inscribir derechos de retención y en general todos los asuntos que se deban tramitar ante la Superintendencia de Industria y Comercio.----------

Leído el presente instrumento al otorgante, lo aprobó y en constancia firma conmigo el Notario de todo lo cual doy fe.----------

Se agregan comprobantes. Derechos $30.000.oo Decreto 1681 de Septiembre 16 de 1996. Reformado mediante Resolución No.5839 de Diciembre 27 del año 2.000 y Decreto 1326 de Julio 06 del año 2.001. Se corrió en la hoja número AA 3286877. ENMENDADO "OCTUBRE" VALE.

Como Notario Veintitres de este Circulo hago constar que esta fotocopia coincide con su fotocopia auténtica que he tenido a la vista.
13 AGO 2007
WILLY VÁLEK MORA
NOTARIO VEINTITRES
Bogotá D.C., Colombia

JUAN MANUEL BARBERI OSPINA

En rep. de TECNOQUIMICAS S.A.

REPUBLICA DE COLOMBIA
NOTARIA TERCERO
JORGE CAICEDO

El Notario Tercero de Cali

Dr. JORGE ENRIQUE CAICEDO ZAMORANO

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
NIT : 800.176.089-2
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Industria y Comercio
SUPERINTENDENCIA

RECIBO DE CAJA

No. 13 - 0087165

Bogotá D.C., Agosto 30 de 2013 - 16:16:35

RECIBIDO DE : REYES Y REYES ABOGADOS NI 900.048.328

*** Soporte del Pago ***

TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	VR.PAGO
CONSIGNACION	BANCO DE BOGOTA	062754387	598294001	30/08/2013	856.000.00

*** Conceptos Pagados ***

CANT.	RENTISTICO	CONCEPTO	Vr.UNDITARIO	Vr.CONCEPTO
1	50005-01-04 PRESENTACION DE OBSERVACIONES A SOLICITUDES	12 OPOSICION POR CADA CLASE-MARCAS Y LEMAS COMERCIALES	325.000.00	325.000.00
				$325.000.00

SON: **TRESCIENTOS VEINTICINCO MIL PESOS MONEDA CORRIENTE***

Responsable: _____
-*******-

Recibo de Caja Aplicado al Expediente No. _____

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
No. 13-019529- -00004-0000
Fecha: 2013-08-30 16:28:00 Dep. 2020 DIR.NUEVASCR
Tra. 11 PATENTEIYII Eve: 378 FASENACIONALI
Act. 400 OPOSIOBSERVTER Folios: 44

44

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
NIT : 800.176.089-2
- / -

Industria y Comercio
SUPERINTENDENCIA

RECIBO DE CAJA

No. 13 - 0087168

Bogotá D.C., Agosto 30 de 2013 - 16:16:35

RECIBIDO DE : REYES Y REYES ABOGADOS NI 900.048.328

*** Soporte del Pago ***

TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	VR.PAGO
CONSIGNACION	BANCO DE BOGOTA	062754387	598294001	30/08/2013	856.000.00

*** Conceptos Pagados ***

CANT.	RENTISTICO	CONCEPTO	Vr.UNDITARIO	Vr.CONCEPTO
1	50005-01-08 PRORROGA DE TERMINOS	1608 N.CREACION PRORROGA DE TERMINOS O PLAZO ADICIONAL	103.000.00	103.000.00
				$103.000.00

SON: **CIENTO TRES MIL PESOS MONEDA CORRIENTE***

Responsable: _____

Recibo de Caja Aplicado al Expediente No. _____

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
No. 13-019529- -00004-0000
Fecha: 2013-08-30 16:28:00 Dep. 2020 DIR.NUEVASCR
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