

P-2466

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 10-023981- -00009-0000

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Act. 523 RESPUESTA Folios: 37

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

E. S. D.

Re: Expediente No. 10.023.981
Solicitud de patente a nombre de **ONCOTHERAPY SCIENCE, INC**

Yo, DILIA MARIA RODRIGUEZ D'ALEMAN identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 No. 86-53, piso 6, obrando como apoderada de la Sociedad **ONCOTHERAPY SCIENCE, INC** domiciliada en Kawasaki-shi, Kanawa, Japón solicitante de la patente de la referencia, en respuesta al oficio No. 430 notificado por fijación en lista el 22 de enero de 2013, relacionado con concepto técnico de fondo, me permito manifestar:

1. SOLICITUD DE DIVISIONAL

Con fundamento en la facultad que confiere el artículo 36 de la Decisión 486 al solicitante para dividir en dos o más solicitudes fraccionarias, en cualquier momento del trámite, me permito presentar:

1.1 La patente divisional titulada "PEPTIDOS DE CDH3 Y AGENTE MEDICINAL QUE COMRPENDE AL MISMO" cuya memoria descriptiva corresponde a la misma de la solicitud No. 10.023.981 y con nuevo capítulo reivindicatorio que consta de 21 reivindicaciones.

Para este efecto acompañamos la siguiente documentación:

- a) La solicitud y el capítulo reivindicatorio correspondientes, junto con la memoria descriptiva que explica, ilustra y sustenta las reivindicaciones y que se encuentra en el expediente No. 10.023.981.
- b) Recibo de pago correspondiente al valor de la tasa oficial por concepto de la presentación de la solicitud divisional y la obtención de los respectivos certificados.
- c) Recibo de pago correspondiente al valor de la tasa oficial por concepto de once reivindicaciones adicionales.

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1.2 Teniendo en cuenta lo establecido en el artículo 36 de la Decisión 486, ruego a ese despacho tener en cuenta que la solicitud divisional que ahora presento, se beneficia de la fecha de presentación de la prioridad de la solicitud de la cual se deriva, es decir, de la prioridad de la solicitud japonesa 2007-213999 del 20 de agosto de 2007.

1.3 Finalmente, me permito aclarar que la solicitud divisional no involucra ampliación alguna de la divulgación contenida en la solicitud inicial.

2. SOLICITUD ORIGINAL.

2.1 MODIFICACIONES

Con fundamento en la facultad que confiere el artículo 34 de la Decisión 486 al solicitante para modificar la solicitud de patente en cualquier momento del trámite, presento junto con este memorial nuevo pliego reivindicatorio que consta de 5 reivindicaciones en donde se realizaron las siguientes modificaciones:

- La reivindicación 1 se ha modificado para limitarse en la frase final cerrada “que consiste de” en la parte A.
- La Reivindicación 1 también se ha modificado para eliminar la parte (B).
- La Reivindicación 4 se ha modificado para reescribir en la reivindicación, composición como la nueva reivindicación 2.
- Las Reivindicaciones 2, 3, 5 a 14, y 17 se han eliminado.

3. Claridad

3.1 Reivindicaciones

3.1.1 Reivindicación 1

En relación con el antiguo literal b, atentamente nos permitimos manifestar que se eliminó dicha expresión, razón por la cual la objeción en este sentido queda cabalmente superada.

3.1.2 Reivindicaciones 4 a 8

De acuerdo con el señor examinador, las reivindicaciones 4 a 8 son rechazadas en razón a que estas reivindicaciones también se refieren al resultado que se va a alcanzar “un agente que incluye inmunidad contra el cáncer”. En este sentido, se podrá corroborar que la antigua reivindicación 4 se modificó para quedar en términos de la composición y “un portador farmacéutico aceptable”.

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3.1.3 Reivindicación 15

De acuerdo con el señor examinador, la reivindicación 15 es rechazada ya que carece de las características esenciales que definen el método y sugeriría que se incluyan las etapas del método de las reivindicaciones 16 a 18 en la reivindicación 15, si es necesario.

Sin embargo, el solicitante considera que la reivindicación 15 ya contiene las características esenciales que definen el método. Consideramos que la etapa del método de “poner en contacto una célula que presenta antígeno con el péptido en la reivindicación 15 es la característica esencial.

Adicionalmente, las etapas del método de las reivindicaciones 16 a 18 no se deben incluir en la reivindicación 15, en razón a que estas etapas no se comprometen con aquellas de la reivindicación 15. En otras palabras, las etapas del método de las reivindicaciones 16 a 18 son diferentes de aquellas de la reivindicación 15. En este sentido, el solicitante pide amablemente al señor examinador retirar estas objeciones.

3.2 Descripción

El señor Examinador señala que la descripción no describe la invención en una forma completa suficiente de tal manera que el experto en la técnica pueda reducir la práctica, en razón a que no se anexa la secuencia de SEQ ID NOs: 1 y 2, y no se muestra el anticuerpo de la reivindicación 9, las células de las reivindicaciones 10- 12, el exosoma de la reivindicación 13 en la descripción.

En respuesta a estos argumentos, es deseo del solicitante señalar que se muestra la secuencia de SEQ ID NOs: 1 y 2 en la tabla 2 de la descripción. Adicionalmente, considera que la Lista de Secuencias contiene las secuencias de la SEQ ID NOs: 1 y 2 ya presentadas ante la Oficina de Patentes.

4. Evaluación de Patentabilidad:

El señor Examinador ha argumentado que la reivindicación 4 no involucra el nivel inventivo a la luz de D1 (NAKAMURA, et al, WO 2004/031412, A2;2004-04-15) y D2 (TANIUCHI, et al., Cancer Res . 2005 Apr 15;65(8):3092-9).

Sobre este particular, respetuosamente nos permitimos indicar que estamos en desacuerdo con dichos argumentos por las siguientes razones:

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En primer lugar, D1 describe 259 secuencias de nucleótidos con regulación ascendente en células de cáncer pancreático (PNC). Entre ellas, “PNC32” corresponde a CDH3 de la presente invención. Como se señala por el Examinador; D1 describe un método para tratar o evitar PNC en un sujeto, que comprende administrar al sujeto una vacuna que contiene un polipéptido codificado por un ácido nucleico seleccionado de PNC1-259.

Sin embargo; es necesario llamar la atención del señor examinador sobre el hecho que no se puede encontrar una descripción en D1 que muestre la identificación de aquellos genes como los objetivos terapéuticos. De hecho, D1 solamente enseña la sobreexpresión de PNC1-259 en las células de cáncer pancreático. En particular; **D1 no describe específicamente la relación entre una secuencia particular y la proliferación/inhibición de células de cáncer pancreático.** Adicionalmente, D1 no dice nada sobre ninguno de los péptidos cortos específicos derivados de CDH3.

En segundo lugar, la anterioridad D2 describe que la P-cadherina (CDH3) se regula ascendentemente en el adenocarcinoma ductal pancreático (PDACs). Sin embargo; D2 solamente describe que el siRNA que objetiva CDH3 inhibe la expresión de CDH3, y el anticuerpo de bloqueo contra CDH3 suprime el motivo de la célula Panc1-CDH3 (célula que expresa CDH3) (ver página 3098, Columna derecha, el segundo párrafo y Figura 3).

Adicionalmente; es importante señalar que D2 **solo enseña que cambiar de N-cadherina a P-cadherina se asocia con tumorigenia pancreática del progreso de PDCA, especialmente en términos de motilidad de las células de cáncer** (ver página 3098, columna derecha, líneas 13 a 16). Por consiguiente, **D2 no dice nada sobre los péptidos cortos específicos de CDH3, así como D1.**

Por el contrario, la presente invención a través de su descripción, claramente detalla que los péptidos cortos específicos de la SEQ 1D NO.: 1 y 2 tienen una actividad que induce células T citotóxicas y las células T citotóxicas inducidas pueden matar específicamente las células que expresan CDH3 (ver Figuras 4 y 5). Esto es impredecible y tiene efectos notables sobre D1 y D2. De acuerdo con lo anterior, consideramos que la reivindicación 4 es inventiva sobre D1 y D2.

Aunado a lo anterior y con conocimiento de la independencia que existe entre las diferentes oficinas de propiedad intelectual en el mundo, es deseo del solicitante poner en consideración del señor examinador los siguientes documentos relacionados con la solicitud estadounidense correspondiente (12/673,451) que ya fue otorgada.

- “Acción Oficial” de la USPTO con fecha del 9 de noviembre, 2012
- La respuesta a la acción Oficial presentada el 13 de febrero, 2013 con la

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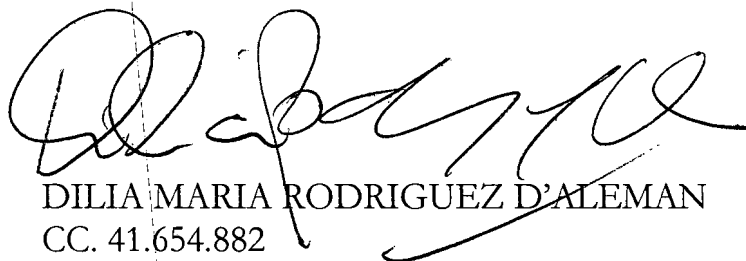
USPTO, y

- “Notificación de Asignación y tarifa debida” de USPTO con fecha del 20 de febrero, 2013.

Habiendo atendido cabalmente las objeciones presentadas por ese despacho, atentamente solicitamos se conceda el privilegio de patente de invención a la solicitud en estudio y a la solicitud divisional ahora presentada o si el señor examinador considera que subsisten razones para objetar la presente invención, rogamos expedir otro examen de fondo con los debidos motivos y razones que sustenten su objeción con el fin de que nuestro mandante tenga la posibilidad de exponer sus argumentos con base en la interpretación de los artículos 45 de la Decisión 486 -el cual otorga la facultad al examinador para emitir los exámenes de fondo-, 35 y 59 del Código Contencioso Administrativo que señala que: *“habiéndose dado oportunidad a los interesados para expresar sus opiniones, y con base en las pruebas e informes disponibles, se tomará la decisión que será motivada al menos en forma sumaria si afecta a particulares”* y *“(.) deberá proferirse la decisión definitiva. Esta se motivará en sus aspectos de hecho y de derecho, y en los de conveniencia si es el caso”*, respectivamente (El subrayado es nuestro).

En consecuencia, solicitamos a ese despacho pronunciarse en relación con todos los argumentos presentados en este memorial dando estricta aplicación al principio del debido proceso consagrado en el artículo 29 de la Constitución Nacional

Señor Superintendente,



DILIA MARIA RODRIGUEZ D'ALEMAN

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REIVINDICACIONES

1. Un Péptido que consiste de una secuencia de aminoácidos de la SEQ ID NO: 1 o 2;
2. Una composición que comprende uno o más péptidos de la reivindicación 1 y un portador farmacéuticamente aceptable.
3. Un método para inducir una célula que presenta antígeno que tiene actividad que induce a la célula T citotóxica (asesina), que comprende una etapa de poner en contacto una célula que presenta antígeno con el péptido de la reivindicación 1.
4. Un método para inducir una célula que presenta antígeno que tiene actividad que induce a la célula T citotóxica (asesina), que comprende una etapa de transfectar un polinucleótido que codifica el péptido de la reivindicación 1 en una célula que presenta antígeno.
5. Un método para inducir una célula T citotóxica (asesina), que comprende una etapa de cocultivar una célula que presenta antígeno en contacto con el péptido de la reivindicación 1, con una célula T CD8+.

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ANEXO 1

“Acción Oficial” de la USPTO con fecha del 9 de noviembre, 2012, respuesta a la acción Oficial presentada el 13 de febrero, 2013 con la USPTO, y “Notificación de Asignación y tarifa debida” de USPTO con fecha del 20 de febrero, 2013.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/673,451	10/22/2010	Yasuharu Nishimura	87331-782669 (022700US)	8270

20350 7590 11/09/2012
KILPATRICK TOWNSEND & STOCKTON LLP
TWO EMBARCADERO CENTER
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SAN FRANCISCO, CA 94111-3834

EXAMINER
HUFF, SHEELA JITENDRA

ART UNIT PAPER NUMBER

1643

NOTIFICATION DATE DELIVERY MODE

11/09/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipefiling@kilpatricktownsend.com
jlhice@kilpatrickfoundationip.com

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Office Action Summary	Application No. 12/673,451	Applicant(s) NISHIMURA ET AL	
	Examiner Sheela J. Huff	Art Unit 1643	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 17 October 2012.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5) ☒ Claim(s) 1-6, 8, 15 and 17-19 is/are pending in the application.

5a) ☐ Of the above claim(s) 15 and 17-19 is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-6 and 8 is/are rejected.

8) ☐ Claim(s) ____ is/are objected to.

9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

10) ☒ The specification is objected to by the Examiner.

11) ☒ The drawing(s) filed on 12 February 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some c) ☐ None of:

1) ☒ Certified copies of the priority documents have been received.

2) ☐ Certified copies of the priority documents have been received in Application No. ____.

3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: See Continuation Sheet

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____

5) ☐ Notice of Informal Patent Application

6) ☐ Other: ____

Continuation Sheet (PTOL-326)

Application No. 12/673,451

Continuation of Attachment(s) 3: Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date
:1/5/11,1/10/11,5/26/11,5/2/12,6/1/12,7/30/12,9/11/12 10/1/12

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DETAILED ACTION

Applicant's election of Group I, claims 1-6 and 8 in the reply filed on 10/17/12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

The IDS filed 1/5/11, 1/10/11, 5/26/11, 5/2/12, 6/1/12, 7/30/12, 9/11/12 and 10/1/12 have been considered and initialed copies of the PTO-1449s are enclosed.

Specification

The substitute specification filed 2/12/10 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims refer to the second amino acid and the C-terminal amino acid.

However, because of the open language to define the peptides in claim 1, the peptides are not limited to the specific SEQ ID NO.s but also read on peptides "comprising" said

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SEQ ID NO.s. Thus, the second amino acid can be the second amino acid of the specific SEQ ID NO. or of the peptide comprising said SEQ ID NO. Similar ambiguity exists with the C-terminal amino acid.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using the peptides of SEQ ID NO. 1 or 2 for inducing immunity and treating against CDH3-expressing cancers, inducing an antigen presenting cell using SEQ ID NO. 1 or 2 and for inducing a CTL using the peptides of SEQ ID NO. 1 or 2, does not reasonably provide enablement for (1) using the peptides of SEQ ID NO. 1 or 2 for inducing immunity and treating against all cancers, (2) using peptides of SEQ ID NO. 1 or 2 for the prevention of any cancer and (3) for the use of peptides of SEQ ID NO. 1 or 2 wherein one or more amino acid(s) are deleted, substituted, inserted and/or added. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant claims and discloses the peptides of SEQ ID NO. 1 or 2 and peptides of SEQ ID NO. 1 or 2 wherein one or more amino acid(s) are deleted, substituted, inserted and/or added and the use of these peptides in the induction of immunity against all cancers, treating or preventing all cancer, the induction of an antigen

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presenting cell and for inducing CTL. In support of this, applicant has provided several assays to show that the SEQ ID NO. 1 or 2 can induce immunity against CDH3-expressing cancers, can treat CDH3 expressing cancers, can induce CTL and can induce an antigen presenting cell. However, the specification, in view of the unpredictability in the state of the art, does not enable (1) the use of peptides of SEQ ID NO. 1 or 2 for inducing immunity and treating against all cancers, (2) using peptides of SEQ ID NO. 1 or 2 for the prevention of any cancer or (3) the use of peptides of SEQ ID NO. 1 or 2 wherein one or more amino acid(s) are deleted, substituted, inserted and/or added.

With respect to the use of SEQ ID NO. 1 or 2 to induce immunity or treat all types of cancers, the Johnson et al; Cancer Treatment Reviews vol. 2 p.17 (1975) (see Table 2) clearly shows that one agent cannot treat all types of cancers. In view of this, one of skill in the art would find it hard to believe that the peptides of SEQ ID NO. 1 or 2 can treat all types of cancers.

With respect to the use of SEQ ID NO. 1 or 2 for the prevention of cancer, the specification provides no exemplification of or guidance on how to use the claimed prevention formulation. Essell (J. NIH Res. 1995 7:46) states that no one is very optimistic that a single peptide will trigger an immune response strong enough to eradicate tumors or even to prevent the later growth of micrometastases among patients whose tumors have been surgically removed or killed by radiation or chemotherapy (p.48, para 6). Furthermore, Boon (Adv. Can. Res. 1992 58:177-210) teaches that for active immunization in human patients we have to stimulate immune

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defenses of organisms that have often carried a large tumor burden. Establishment of immune tolerance may therefore have occurred and it may prevent immunization and several lines of evidence suggest that large tumor burdens can tolerate or at least depress the capability to respond against the tumor (p. 206, para 2).

With respect to the use of peptides of SEQ ID NO. 1 or 2 wherein one or more amino acid(s) are deleted, substituted, inserted and/or added, those of skill in the art readily recognize that even a single amino acid substitution can drastically alter the function of a peptide. For example, the replacement of a single lysine at position 118 of the acidic fibroblast growth factor by a glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (see Burgess et al, Journal of Cell Biology Vol 111 November 1990 2129-2138). In transforming growth factor alpha, replacement of aspartic acid at position 47 with asparagine, did not affect biological activity while the replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen (see Lazar et al Molecular and Cellular Biology Mar 1988 Vol 8 No 3 1247-1252). The specification provides no guidance as to which amino acid(s) of the nonapeptides SEQ ID NO. 1 or 2 can be changed without loss of function.

Additionally, in the absence of any such guidance, undue experimentation would be required by one of skill in the art to determine which residues can and cannot be altered.

Thus, in view of the above, it is the Examiner's position that applicant is claiming too broadly and that undue experimentation would be required by one of skill in the art to practice the claimed invention.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States;

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Due to numerous references that contain peptides that read on the claimed invention, only a few of the references have been cited below.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Mintz et al US 7745391 (priority to 9/13/02).

This reference discloses SEQ ID NO. 764220 (length is 263aa) of which aa 89-97 read on peptides comprising applicant's SEQ ID NO.1. Also, aa 191-199 of this same sequence reads on peptides comprising applicant's SEQ ID NO. 2.

This reference discloses SEQ ID NO. 764219 (length is 595 aa) of which aa 421-429 read on peptides comprising applicant's SEQ ID NO.1. Also, aa 523-531 of this same sequence reads on peptides comprising applicant's SEQ ID NO. 2.

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This reference discloses SEQ ID NO. 764222 (length is 712 aa) of which aa 655-663 read on peptides comprising applicant's SEQ ID NO.1.

This reference discloses SEQ ID NO. 812578 (length is 206 aa) of which aa 184-192 read on peptides comprising applicant's SEQ ID NO.1 with 2 substitutions.

This reference discloses SEQ ID NO. 757975 (length is 132 aa) of which aa 16-22 read on peptides comprising applicant's SEQ ID NO.1 with 2 deletions.

This reference discloses SEQ ID NO. 874188 (length is 144 aa) of which aa 90-98 read on peptides comprising applicant's SEQ ID NO.1 with 2 substitutions.

This reference also discloses SEQ ID NO. 764225 (length 829) of which aa 757-765 read on applicant's SEQ ID NO. 2.

This reference also discloses SEQ ID NO. 825528 (length 134) of which aa 62-70 read on applicant's SEQ ID NO. 2 with 1 substitution.

This reference also discloses SEQ ID NO. 825499 (length 375) of which aa 303-311 read on applicant's SEQ ID NO. 2 with 1 substitution.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

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Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Nackman et al US 7033832.

This reference discloses SEQ ID NO. 1 (length is 829 aa) of which aa 655-663 read on peptides comprising applicant's SEQ ID NO.1. Also, aa 757-765 of this same sequence reads on peptides comprising applicant's SEQ ID NO. 2.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoo et al US 5891432.

This reference discloses SEQ ID NO. 1 (length is 25 aa) of which aa 1-9 read on peptides comprising applicant's SEQ ID NO.1 with one substitution.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are intended use and a recitation of the intended use of the claimed invention must result in

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a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovalic et al US 7214786.

This reference discloses SEQ ID NO. 205971 (length is 89 aa) of which aa 42-50 read on peptides comprising applicant's SEQ ID NO.1 with 3 substitutions.

This reference discloses SEQ ID NO. 197265 (length is 141 aa) of which aa 37-45 read on peptides comprising applicant's SEQ ID NO.1 with 3 substitutions.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

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Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Cao et al US 7314974 (priority to 2/21/02).

This reference discloses SEQ ID NO. 15155 (length is 522 aa) of which aa 13-21 read on peptides comprising applicant's SEQ ID NO.1 with 4 substitutions.

This reference discloses SEQ ID NO. 11579 (length is 606 aa) of which aa 92-100 read on peptides comprising applicant's SEQ ID NO.1 with 4 substitutions.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubenfield et al US 6551795.

This reference discloses SEQ ID NO. 22916 (length is 158 aa) of which aa 82-89 read on peptides comprising applicant's SEQ ID NO.1 with 2 substitutions and 1 deletion.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are

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intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsunoda et al WO 08/102557.

This reference discloses SEQ ID NO. 344 (length is 10 aa) of which aa 1-9 read on peptides comprising applicant's SEQ ID NO.1.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsunoda et al US 20100040641 (priority to 2/21/07).

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This reference discloses SEQ ID NO. 344 (length is 10 aa) of which aa 1-9 read on peptides comprising applicant's SEQ ID NO.1.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinstock et al US 6747137.

This reference discloses SEQ ID NO. 25601 (length is 72 aa) of which aa 46-54 read on peptides comprising applicant's SEQ ID NO.2 with 2 substitutions.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's

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position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Boukharov et al US 8088976 (priority to 2/24/05).

This reference discloses SEQ ID NO. 165317 (length is 119 aa) of which aa 97-104 read on peptides comprising applicant's SEQ ID NO.2 with 3 substitutions and 1 deletion.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Agriculture Victoria Services WO 07/009181 (priority to 7/19/06).

This reference discloses SEQ ID NO. 53 (length is 147 aa) of which aa 81-89 read on peptides comprising applicant's SEQ ID NO.2 with 4 substitutions.

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The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Eisenreich et al US 7:122331.

This reference discloses SEQ ID NO. 111 (length is 165 aa) of which aa 116-123 read on peptides comprising applicant's SEQ ID NO. 2 with 2 substitutions and 1 deletion.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

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Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Doucette-Stamm et al US 6699703.

This reference discloses SEQ ID NO. 5232 (length is 85 aa) of which aa 24-30 read on peptides comprising applicant's SEQ ID NO.2 with 1 substitutions and 2 deletions.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of claims 4-6 and 8.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 08/47473 (priority to 10/17/06).

This reference discloses SEQ ID NO. 34 (length is 9 aa) (page 34) of which aa 3-7 read on peptides comprising applicant's SEQ ID NO.2 with 1 substitutions and 4 deletions.

The limitations in claims 4-6 and 8 for inducing immunity against cancer, treating/preventing cancer, inducing an antigen presenting cell and inducing a CTL are

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intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art structure is capable of performing the intended use limitation of

claims 4-6 and 8.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7960608—see SEQ ID NO. 53 and claims

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (571) 272-0834. The examiner can normally be reached on Monday-Wednesday 7am to 3pm and Thursday 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sheela J. Huff

Primary Examiner

Art Unit 1643

Sjh

/Sheela J. Huff/

Primary Examiner, Art Unit 1643

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J. J. J.

TECHNICAL
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I hereby certify that this correspondence is being filed via
EFS-Web with the United States Patent and Trademark Office
on Feb 13 2013

KILPATRICK TOWNSEND & STOCKTON LLP

By: [Signature]

PATENT
Attorney Docket No.: 87331-782669-022700US
Client Ref. No.: ONC-A0711P-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Yasuharu Nishimura et al.

Application No.: 12/673,451

Filed: June 5, 2008

For: CDH3 PEPTIDE AND MEDICINAL
AGENT COMPRISING THE SAME

Customer No.: 20350

Confirmation No.: 8270

Examiner: Sheela Jitendra Huff

Technology Center/Art Unit: 1643

SUPPLEMENTAL AMENDMENT

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Commissioner:

In response to the Office Action mailed November 9, 2012, and further to the
Amendment as filed on February 8, 2013, please enter the following supplemental amendments
and remarks:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this
paper.

Remarks/Arguments begin on page 4 of this paper.

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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Currently Amended) An isolated peptide of the following (A) or (B):
(A) a peptide ~~comprising an~~ consisting of the amino acid sequence of SEQ ID NO: 1 or 2;
(B) a peptide ~~comprising an~~ consisting of the amino acid sequence of SEQ ID NO: 1 or 2, wherein one, two, or several in which one or two amino acid(s) are substituted, deleted, inserted and/or added, and wherein the peptide has an activity to induce a cytotoxic (killer) T cell.
2. (Currently Amended) The peptide of claim 1, wherein the second amino acid from the N-terminus of the amino acid sequence of SEQ ID NO: 1 or 2 is substituted with leucine or methionine.
3. (Currently Amended) The peptide of claim 1, wherein the C-terminal amino acid of the amino acid sequence of SEQ ID NO: 1 or 2 is substituted with valine or leucine.
4. (Currently Amended) An agent for inducing immunity against cancer expressing CDH3, comprising one or more peptide(s) of claim 1 as an active ingredient.
5. (Currently Amended) An agent for treating and/or preventing cancer expressing CDH3, comprising one or more peptide(s) of claim 1 as an active ingredient.
6. (Original) An agent for inducing an antigen presenting cell having cytotoxic (killer) T cell-inducing activity, comprising one or more peptide(s) of claim 1 as an active ingredient.
7. (Cancelled)

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8. (Original) An agent for inducing a cytotoxic (killer) T cell, comprising one or more peptide(s) of claim 1 as an active ingredient.

9-14. (Cancelled)

15. (Withdrawn) A method for inducing an antigen presenting cell having cytotoxic (killer) T cell-inducing activity, comprising a step of contacting an antigen presenting cell with the peptide of claim 1.

16. (Cancelled)

17. (Withdrawn) A method for inducing a cytotoxic (killer) T cell, comprising a step of contacting a T cell with the peptide of claim 1.

18. (Withdrawn-Currently Amended) A method for inducing immunity against cancer expressing CDH3, comprising a step of administering the peptide of claim 1 to a subject.

19. (Withdrawn-Currently Amended) A method for treating and/or preventing cancer expressing CDH3, comprising a step of administering the peptide of claim 1 to a subject.

20-23. (Canceled)

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REMARKS/ARGUMENTS

Claims 1-6 and 8 are pending in the present application. Claims 15 and 17-19 are withdrawn, but have been amended, as appropriate, to preserve applicants right to rejoinder.

The instant Supplemental Response is made to correct typographic errors in Appendix B. No changes have been made to the Amendment and Remarks and no new matter has been added.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 2 and 3 stand rejected for using open language to define the claimed peptides so that the position of the second and C-terminal amino acids is allegedly indefinite. To expedite prosecution, the claims have been amended to explicitly recite that the 2nd amino acid from the N terminus and the C-terminal amino acid are those of a peptide *consisting of* the amino acid sequence of SEQ ID NO: 1 or 2. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 4 and 5 stand rejected for allegedly lacking enablement. According to the Examiner, the present application lacks enablement to the extent the claims encompass use of peptides of SEQ ID NO: 1 or 2 for treatment of cancers that do not express CDH3, use of the peptides for prevention of any cancer, and use of peptides of SEQ ID NO: 1 or 2 in which one or more residues are deleted, substituted, inserted and/or added.

In the interest of expediting prosecution, Applicants have amended claim 1 to

1. define the claimed amino acid sequence with "consisting of";
2. restrict the number of amino acid modifications to one or two; and
3. limit the type of amino acid modification to substitutions.

Support for these claim amendments can be found throughout the specification and in particular at paragraph [0036] and [0037].

With respect to peptides having 1 or 2 substitutions and those in which the second amino acid from the N-terminus or the C terminal residue is substituted (claims 2 and 3), it is noted that the claimed peptides epitopes are restricted to HLA-A02. In humans, it was known at the time of the invention that HLA-A Class I molecules, such as HLA-A02, recognize peptides of a specific length (nine or ten amino acids) that carry specific anchor residues. In addition, it was well

known that HLA-A2 binding affinity of epitope peptides can be maintained or enhanced after replacement of anchor residues at position 2 or at the C-terminal position (*see, e.g.* Rammensee *et al. Immunogenetics*, 1995, 41: 178-228;¹ Kubo *et al. J Immunol.*, 1994, 152:3913-3924;² Falk *et al. Nature* 1991, 351: 290-296;³ and page 7, lines 14-17 of the specification).

In addition, Zaremba *et al. Cancer Res.* 1997, 57:4570-4577⁴ demonstrated that the CTL inducibility of an epitope peptide can be maintained or enhanced by the replacement of an amino acid residue at anyone of positions 5-7 in the original epitope peptide. Further, it was known that epitope peptides can maintain CTL inducibility after substitution of amino acid residue at various other positions⁵

Considering the above evidence, Applicants respectfully submit that, in view of the knowledge of anchor residues in T cell epitope peptides, one of skill could prepare peptides recited in claim 1 and in particular the substitutions at the anchor positions recited in claims 2 and 3. One of skill would have further recognized that such substituted peptides would be capable of inducing cytotoxic T cells specific for tumors expressing the CDH3 antigen. Thus, the skilled person in the art could readily have made and used the claimed peptides without undue experimentation at the time of the present invention.

In the Office Action, Examiner specifically questions whether the claimed peptides with amino acid sequence modifications are enabled for cancer therapy for cancers that do not express CDH3. The Examiner acknowledges, however, that the specification provides enablement for treating cancer expressing CDH3 (page 4, 1st. paragraph of the Action).

As confirmed by the results of the present application, CTLs induced by the claimed peptides induce a cytotoxic effect *in vitro* against cancer cells expressing CDH3 (Fig. 4 and [0135]). Further, cancer regression has been confirmed *in vivo* in mice administered with the peptides and CTLs (Fig. 5 and [0139]). Such data show that the information provided in the

¹ See, for example, page 193, Table 2B. Cited in IDS submitted October 31, 2012.

² See, for example, page 3915, right column, lines 6-12 from the bottom. Cited in IDS filed with application.

³ See, for example, page 293, lines 6-7 and Table 4. Cited in IDS submitted October 31, 2012.

⁴ See, for example, left column of page 4572, lines 4-10 and left column of page 4572, line 21 to right column, line 1. Cited in IDS filed with application.

⁵ Hoffmann *et al. J Immunol.* 2002 Feb 1; 168(3): 1338-47. (*see, for example, page 1344, 2nd paragraph of Discussion. Cited in IDS submitted October 31, 2012*); Dionne *et al. Cancer Immunol Immunother.* 2003, 52: 199-206 (*see, for example, right column of page 204, 3rd and 4th paragraphs. Cited in IDS submitted October 31, 2012*); and Dionne *et al. Cancer Immunol Immunother* 2004, 53, 307-314 (*see, for example, right column, 1st and 2nd paragraph. Cited in IDS submitted October 31, 2012*).

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present specification is sufficient and enabling for skilled artisans to arrive at the cytotoxic effect of the specified peptides against CDH3-expressing cells.

In the interest of expediting prosecution, claims 4, 5, 18 and 19 have been amended to specify that the cancer being treated expressed CDH3. Support for these amendments is found, for example, in paragraph [0060] and [0135]. Finally, reference to prevention of cancer has been removed from the claims.

In view of the above comments and amendments, applicants respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. § 102

Claims 1, 4-6 and 8 stand rejected as allegedly lacking novelty over several cited prior art references which disclose amino acid sequences that have partial identity to the sequences of SEQ ID NO: 1-2. As noted above, the pending claims are directed to peptides "consisting of" the recited sequences and are limited to amino acid sequences comprising of 1 or 2 substitutions.

Comparison of the amino acid sequences disclosed in the prior art references and the presently claimed amino acid sequences are summarized in Appendix B. As shown there, no sequence identity exists between the claimed amino acid sequences and the prior art amino acid sequences. As noted above, all of the claims are directed to peptides consisting of 9 amino acids (the length of SEQ ID NOs: 1 and 2). Appendix B shows that all of the sequences cited by the Examiner are longer than 9 amino acids. In this regard, however, Applicants cannot find a significant sequence similarity between SEQ ID NO: 825528 disclosed in sequence listing of Mintz et. al. and presently claimed SEQ ID NO: 2. Accordingly, Applicants respectfully request the Examiner to identify which sequence disclosed in the sequence listing of Mintz et. al. show sequence similarity with the presently claimed SEQ ID NO: 2, if the Examiner still has any concerns about the novelty over other amino acid sequence disclosed in Mintz et al., as well as Hoo et al. and Cao et al. (see footnote of the Appendix B).

Moreover, the rejections under 35 U.S.C. § 102 (e) over Tsunoda et al (WO2008/102557 and US20100040641⁶) are improper. The pending claims are entitled to the benefit of the Japanese priority application filed August 20, 2007. SEQ ID NO: 344, which is cited by the Examiner as the basis for the present rejections, was not disclosed in the priority application of

⁶ US20100040641 is a CIP of WO2008/102557

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the Tsunoda publications (US Provisional Application No. 60/902,949, filed February 21, 2007) as stated in the Office Action, but was first disclosed in International Application PCT/JP2008/000290, filed February 21, 2008 (which published as WO 2008/102557). In the absence of evidence that SEQ ID NO: 344 was disclosed in the February 21, 2007 priority application, the rejection is improper and should be withdrawn.

In view of the above, Applicants respectfully submit that the rejections under 35 U.S.C. §102 should be withdrawn.

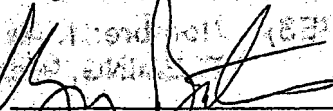
CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Further, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account No. 20-1430.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,



Kevin L. Bastian

Registration No. 34,774

KILPATRICK TOWNSEND & STOCKTON LLP

Two Embarcadero Center, Eighth Floor

San Francisco, California 94111-3834

Tel: 415 576 0200

Fax: 415 576 0300

Attachments

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Appendix B

Cited references	§102	Cited sequence /length	claimed sequences	number of differences
Mintz et al US7745391	(e)	SEQ ID NO:764220 /263aa	1,2	-
		SEQ ID NO:764219 /595aa	1,2	
		SEQ ID NO:764222 /712aa	1	-
		SEQ ID NO:812578 /206aa	1	2
		SEQ ID NO:757975 /132aa	1	-2 ¹
		² SEQ ID NO:874188 /114aa	1	2
		SEQ ID NO:764225 /829aa	2	
		³ SEQ ID NO:825528 /134aa	2	1
		SEQ ID NO:825499 /375aa	2	1
Nackman et al US 7033832	(b)	SEQ ID NO:1 /829aa	1,2	-
Hoo et al US 5891432	(b)	⁴ SEQ ID NO: 4 /25aa	1	1
Kovalic et al US 7214786	(b)	SEQ ID NO:205971 /89aa	1	3
		SEQ ID NO:197265 /141aa		

¹ “-” means deletion(s) of amino acid(s) in cited amino acid sequence.

² According to the Action, the sequence of SEQ ID NO:874188 disclosed in Mintz et al. has 144 residues; however, the sequence of SEQ ID NO: 874188 disclosed in the sequence listing of Mintz et. al. has 114 residues.

³ In the Action, amino acids 62-70 of SEQ ID NO: 825528 (length 134) disclosed in Mintz et. al. is asserted to be identical to the presently claimed sequence of SEQ ID NO: 2 with 1 substitution. However, the sequence of SEQ ID NO: 825528 disclosed in the sequence listing of Mintz et. al. has 206 residues, and has no identity to the claimed sequence of SEQ ID NO: 2.

⁴ The sequence of SEQ ID NO:1 by Hoo et al. is referred to in the Action. However, the sequence of SEQ ID NO: 1 disclosed in the sequence listing of Hoo et. al is a cDNA sequence, not an amino acid sequence. Applicants note that the sequence of SEQ ID NO:4 disclosed in the sequence listing of Hoo et. al. has 25 residues, and amino acids 1-9 in the sequence of SEQ ID NO:4 differ from the presently claimed sequence of SEQ ID NO:1 by one residue.

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REMOVAL OF THE SEQUENCE LISTING FROM THE PATENT

Cao et al US 7314974	(e)	SEQ ID NO:15155 /522aa	1	4
		5SEQ ID NO:14674 /606aa		
Rubenfield et al US 6551795	(b)	SEQ ID NO: 22916 /158aa	1	2, -1
Tsunoda et al WO08/102557	(e)	SEQ ID NO:344 /10aa	1	-
Tsunoda et al US 20100040641	(e)	SEQ ID NO:344 /10aa	1	-
Weinstock et al US 6747137	(b)	SEQ ID NO:25601 /72aa	2	2, -1
Boukharov et al US 8088976	(e)	SEQ ID NO:165317 /119aa	2	3, -1
Mouradov et al WO07/009181	(e)	SEQ ID NO:53 /147aa	2	4
Eisenreich et al US 7122331	(b)	SEQ ID NO:111 /165aa	2	2, -1
Doucette-Stamm US 6699703	(b)	SEQ ID NO:5232 /85aa	2	1, -2
Nakamura et al WO08/47473	(e)	SEQ ID NO:34 /9aa	2	1, -4

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5 In the Action, amino acids 92:100 of the sequence of SEQ ID NO: 11579 (length is 606 residues) disclosed in Cao et. al. is asserted to be identical to the presently claimed sequence of SEQ ID NO: 1 with 4 substitutions. However, the sequence of SEQ ID NO: 11579 disclosed in the sequence listing of Cao et. al. has 258 residues, and no identity to the claimed sequence of SEQ ID NO: 1. On the other hand, Applicants noticed that the presently claimed sequence of SEQ ID NO:1 differs by four residues from the sequence of SEQ ID NO:14674 (at amino acids 92-100 in its full-length sequence of 606 aa) in Cao's sequence listing.

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DIRECCIÓN DE NUEVAS CREACIONES
CONVERSIÓN, DIVISIÓN Y FUSIÓN DE SOLICITUDES

1. Identificación del Trámite

- ☐ Conversión ☒ División ☐ Fusión
- ☒ Patente de Invención
☐ Patente de Modelo de Utilidad
☐ Registro de Diseño Industrial
☐ Esquema de Trazado de Circuitos Integrados

2. Datos del solicitante

Persona Natural ☐ Persona Jurídica ☒

ONCOTHERAPY SCIENCE, INC.

Nombre o denominación / Nombre o razón social

Nombre del representante legal _____

Tipo de empresa Micro ☐ Pequeña ☐ Mediana ☐ Otra ☐

Documento de identificación: ☐ C.C. ☐ C.E. ☐ NIT ☐ Otro Número _____

Nacionalidad/País de constitución	Dirección del titular	Ciudad
Japón	2-1, Sakado 3-chome, Takatsu-ku, Kawasaki-shi,	Kanagawa 2130012,
Dirección electrónica	No. Fax	Número telefónico

☐ 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 apoderado:

RODRÍGUEZ D'ALEMAN DILIA MARÍA

Apellidos y Nombre

C.C. 41.654.882

Documento de identificación

20824 CSJ

Tarjeta profesional

Dirección y domicilio		Ciudad
Carrera 11 No. 86-53, Piso 6, Bogotá D.C., Colombia		Bogotá D.C.
Dirección electrónica	No. Fax	Número telefónico
clarkemodet@clarkemodet.com.co	6350824	6181088

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 o protocolo de poder general _____

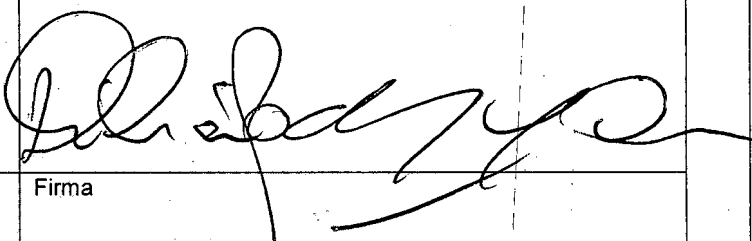
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4. Datos del trámite		
CONVERSION Expediente _____ _____ _____ De: _____ A: _____	DIVISION Expediente <u>10-023.981A</u> De: _____ A: _____	FUSION Expediente _____ _____ _____ De: _____ A: _____

5. Comprobante de Pago No.	Fecha
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6. Anexos	
☐	Comprobante de pago de la tasa para la presentación de la corrección y/o modificación
☐	Poder, si fuere el caso con el que se acredita la representación
☐	Número de documento que ordena la comisión o fusión o división
☐	Documento que contiene la conversión, división o fusión de la solicitud
☐	Copia de la solicitud y sus anexos en formato magnético

7. Firma	
DILIA MARÍA RODRÍGUEZ D'ALEMAN Nombre y apellidos	 Firma
C.C. 41.654.882	Tarjeta Profesional 20824 CSJ

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