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Señor Director
DIRECCION DE NUEVAS CREACIONES
Superintendencia de Industria y Comercio
E. S. D.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 11-108508- -00002-0000

Fecha: 2011-11-21 15:51:35 Dep. 2020 DIR.NUEVASCR
Tra. 11 PATENTEIYII Eve: 379 FASENACIONALI
Act. 444 RESPUESTAREQUE Folios: 16

Trámite : 011
Evento : 379
Actuación : 444

Referencia : Expediente No. 11.108.508
Asunto : Solicitud de patente para **SONDAS DE OLIGONUCLEÓTIDOS Y CEBADORES PARA LA DETECCIÓN DEL VIRUS DE LA HEPATITIS B**
Solicitante : **BIGTEC PRIVATE LIMITED**
Clase : C12Q 001/068
Fecha de Solicitud : 25 de agosto de 2011

CONTESTACION OFICIO No. 15115

1. Yo, Luz Clemencia de PAEZ, en mi condición de apoderada de la sociedad solicitante, **BIGTEC PRIVATE LIMITED**, doy contestación al requerimiento efectuado por este Despacho mediante Oficio No. **15115** notificado por fijación en lista el 23 de septiembre de 2011, para lo cual presento los siguientes documentos:

1.1. Uno (1) Documento en que consta la cesión del derecho a la patente efectuado por los tres (3) inventores en favor de la sociedad **BIGTEC PRIVATE LIMITED**.

Se presenta este documento en original, el cual fue debidamente suscrito, notariado y legalizado por Apostilla, junto con su correspondiente traducción oficial al español.

2. **IPRP**: Adicionalmente presento copia del Informe Preliminar Internacional sobre patentabilidad junto con sus anexos expedido en el trámite de la solicitud internacional No. PCT/IN2010/000048 correspondiente a la presente fase nacional.

Solicito a ese Despacho realizar el examen de patentabilidad sobre el nuevo capítulo reivindicatorio anexo al mencionado IPRP.

3. De acuerdo con lo anterior, comedidamente solicito a Usted proseguir con el trámite de este asunto y ordenar la publicación de la solicitud de la patente identificada en la referencia.

Señor Director,

Luiz Clemencia de Paéz
LUZ CLEMENCIA DE PAEZ
C.C. 35.456.344 de Usaquén
T.P.A. No. 23.555



COLO-17626-841-003-0
LLM\SCT\ID-204968\WPC17626
No. M-2011-204968\LLM

CESION

Yo, (nosotros) abajo firmado (s)

domiciliado(s) en

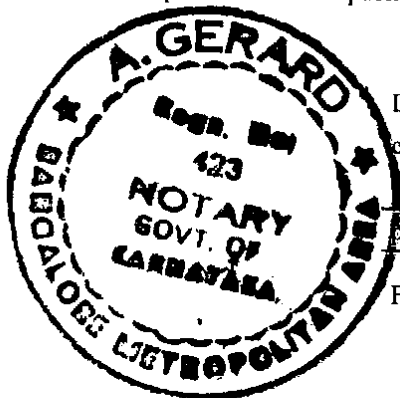
declaro(amos) bajo juramento ser único(s) y verdadero(s) inventor(es)

declaro(amos) así mismo que cedo(emos) y transfiero(erimos), sin limitación, a favor de la sociedad

constituida y existente de conformidad con las leyes de

domiciliada en

todos los derechos inherentes a dicha invención y que la citada Compañía queda facultada para solicitar en su nombre la patente de invención correspondiente en la República de Colombia.



Dado y firmado hoy/Given and signed this SEPTEMBER 09, 2011
en/in BANGALORE

por/by Manjula JAGANNATH

Firma/Signature

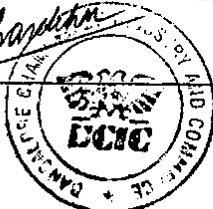
[Signature of Manjula JAGANNATH]

Dado y firmado hoy/Given and signed this SEPTEMBER 09, 2011
en/in BANGALORE

por/by Chandrasekhar NAIR

Firma/Signature

[Signature of Chandrasekhar NAIR]



ASSIGNMENT

I (we), the undersigned

1- Manjula JAGANNATH

2- Chandrasekhar NAIR

3- Pillarisetti Venkata SUBBARAO

Of

Bigtec Private Limited, II Floor, SID Entrepreneurship Building, Indian Institute of Science [IISc] Campus, Malleshwaram, Bangalore 560 012 Karnataka, India

state(s) under oath to be sole and true inventor(s) of the invention:

OLIGONUCLEOTIDE PROBES AND PRIMERS FOR DETECTION OF HEPATITIS B VIRUS

state as well, that assign, without reservations or limitations in favor of

BIGTEC PRIVATE LIMITED

a corporation constituted and existing in conformity with the laws of

India

domiciled in

II Floor, SID Entrepreneurship Building, Indian Institute of Science [IISc] Campus, Malleshwaram, Bangalore 560 012 Karnataka, India

all rights inherent to said invention and that the above mentioned company hereby is enabled to apply, in its name, for the corresponding patent invention, in the Republic of Colombia

ATTESTED
For Bangalore Chamber of Industry and Commerce

[Signature]
Deputy Secretary

संख्या 338934 दिनांक 20 SEP 2011
 No. 338934 Date 20 SEP 2011
 कागज पर मंजूर में सहायक सचिव/असिस्टेंट सचिव
 सचिव के हस्ताक्षर सत्यापित किए जाते हैं।
 The Signature of Asstt. Secretary/
 Dy. Secretary (Secretary of Chamber
 of Commerce Attested.



(सुरत सिंह)
 (SURAT SINGH)
 अनुभाग अधिकारी (ओ.आई.)
 Section Officer (O.I.)
 विदेश मंत्रालय, नई दिल्ली
 Ministry of External Affairs
 New Delhi

Dado y firmado hoy/Given and signed this SEPTEMBER 09, 2011
en/in BANGALORE

por/by Pillarisetti Venkata SUBBARAO

Firma/Signature



CERTIFICACIÓN NOTARIAL (INDIVIDUO)

A los _____ días del mes de _____
de 200 ____ Ante mí, Notario Público de _____

compareció(eron) personalmente _____

a quien(es) doy fe de conocer y me consta que es(son) la(s)
persona(s) firmante(s) del documento que precede, y quien(es)
tiene(n) capacidad legal para otorgarlo

NOTARIAL CERTIFICATION (INDIVIDUAL)

On this _____ day of _____
200 ____ before me, a Notary Public of _____

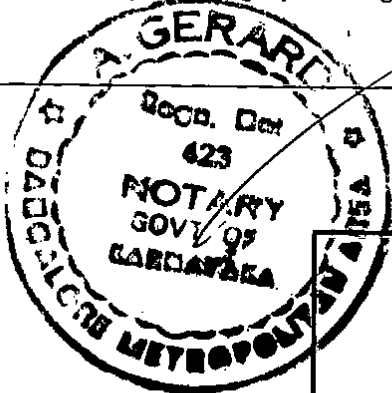
personally appeared Manjula JAGANNATH
Chandrasekhar NAIR

Pillarisetti Venkata SUBBARAO

To me known, and known to me to be the person(s) who executed
that foregoing document, and who has(have) legal capacity to
execute it.



NOTARIO PÚBLICO-NOTARY PUBLIC



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(Convention de La Haye du 5 octobre 1961)

1. Country:
2. This public document
3. has been signed by
4. acting in the capacity of
5. bears the seal/stamp of

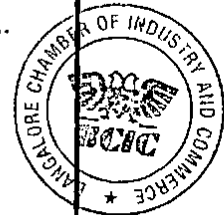
Certified

5. at
6. the
7. by
8. No.
9. Seal/stamp
10. Signature

ATTESTED

**For Bangalore Chamber of
Industry and Commerce**

Deputy Secretary



2/9/2011

A. GERARD B.Sc., LL.B.
ADVOCATE & NOTARY
No. 54 RAYAPPA ROAD
KAMMANAHALLI
BANGALORE- 560 084
MOB : 9845124378

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2

101

PAGADO IMPUESTO DE TIMBRE US\$
PAGADOS DERECHOS CONSULARES US\$

**CONSULADO DE COLOMBIA
NUEVA DELHI**

No. 1165/2011

El suscrito Cónsul de Colombia CERTIFICA
que el señor Surat Singh
que autoriza el presente documento, ejercía
legalmente en la fecha allí expresada las
funciones de Section Officer (O.I.)
Country of External Affairs, I.I.D.
y que la firma y sello que en el documento
aparecen como suyos son los que usa y
acostumbra en sus actos oficiales.

El Cónsul no asume responsabilidad alguna
por el contenido del documento.

Lino María Fajardo
LINA FAJARDO
Counsellor



1102 1308 1

MINISTERIO DE
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20 NOV - 8 P 12:38
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संख्या 338933 दिनांक 20 SEP 2011
No. 338933 Date 20 SEP 2011
यसिक् भन्दा में हस्ताक्षर तबित/उप सचिव
सचिव के हस्ताक्षर सत्यापित किए जाते हैं।
The Signature of Asstt. Secretary/
Dy. Secretary/Secretary of Chamber
of Commerce Attested.



82M
(सुरत सिंह)
(SURAT SINGH)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (O.I.)
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

Aparece documento de Cesión de 1- Manjula JAGANNATH, 2- Chandrasekhar NAIR, 3- Pillarisetti Venkata SUBBARAO de Bigtec Private Limited, II Floor, SID Entrepreneurship Building, Indian Institute of Science [IISc] Campus, Malleshwaram, Bangalore 560 012 Karnataka, India; de la invención CEBADORES Y SONDAS DE OLIGONUCLEÓTIDO PARA DETECCIÓN DEL VIRUS DE LA HEPATITIS B, de BIGTEG PRIVATE LIMITED, India con domicilio en II Floor, SID Entrepreneurship Building, Indian Institute of Science [IISc] Campus, Malleshwaram, Bangalore 560 012 Karnataka, India; Dado y firmado el 09 de septiembre, 2011 en Bangalore por Manjula JAGANNATH (aparece firma); Dado y firmado el 09 de septiembre, 2011 en Bangalore por Chandrasekhar NAIR (aparece firma);

(Aparece sello:

A. GERARD

Ilegible 423

NOTARIO

GOV. DE KARNATAKA ÁREA

METROPOLITANA DE BANGALORE)

(Aparece sello:
Cámara de Industria y
Comercio de Bangalore)

CERTIFICADO
Por Cámara de Industria y
Comercio de Bangalore
Aparece firma
Subsecretario

29 de septiembre 2011

No. 338934

La firma del Secretario Asistente/ Subsecretario/Secretario de la Cámara de Comercio es genuina

Aparece firma

SURAT SINGH

Funcionario de Sección (O.I.) Ministerio de Asuntos Exteriores

Nueva Delhi (Aparece sello)

Dado y firmado el 09 de septiembre, 2011 en Bangalore por Pillarisetti Venkata SUBBARAO (aparece firma);

(Aparece sello)

Aparece documento de Certificación Notarial de Individuo de Manjula JAGANNATH, Chandrasekhar NAIR, Pillarisetti Venkata SUBBARAO (aparece firma)

(Aparece sello:

A. GERARD

Ilegible 423 NOTARIO

GOV. DE KARNATAKA
ÁREA METROPOLITANA
DE BANGALORE)

A. GERARD B.S.C., ilegible.
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KAMMANAHALLI
BANGALORE 560-084
MOB 9845124373
9/9/2011

(Aparece sello:
Cámara de Industria y
Comercio de Bangalore)

CERTIFICADO
Por Cámara de Industria y
Comercio de Bangalore
Aparece firma
Subsecretario

Aparece sello del Consulado de Colombia en Nueva Delhi No. 1165/2011 de Surat Singh,

Funcionario de Sección (O.I.) Ministerio de Asuntos Exteriores

(Aparece sello del Consulado de Colombia Nueva Delhi India)

Aparece firma LINA FAJARDO Cónsul

Aparece sellos del Ministerio de Relaciones Exteriores 2011 NOV 8 P 12:38, No. 104085
aparece firma

29 de septiembre 2011

No. 338933

La firma del Secretario Asistente/ Subsecretario/Secretario de la Cámara de Comercio es genuina

Aparece firma

SURAT SINGH

Funcionario de Sección (O.I.) Ministerio de Asuntos Exteriores

Nueva Delhi (Aparece sello)

Sergio Eleuterio Latorre Mendoza
Traductor e Interprete Oficial
Resol. No. 2859 Minjusticia 1991

MINISTERIO DE
RELACIONES EXTERIORES

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DEL TEXTO

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PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCT0940	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/IN2010/000048	International filing date (<i>day/month/year</i>) 27 January 2010	Priority date (<i>day/month/year</i>) 13 February 2009
International Patent Classification (IPC) or national classification and IPC Int. Cl. C12Q 1/68 (2006.01)		
Applicant BIGTEC PRIVATE LIMITED et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 6 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☒ (<i>sent to the applicant and to the International Bureau</i>) a total of 3 sheets, as follows: ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. ☐ (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see paragraph 3bis of Annex C of the Administrative Instructions).																									
4. This report contains indications relating to the following items: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">☒</td> <td style="width: 15%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td>☒</td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td>☐</td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>☐</td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td>☒</td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td>☐</td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td>☐</td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td>☐</td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>		☒	Box No. I	Basis of the report	☒	Box No. II	Priority	☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	☐	Box No. IV	Lack of unity of invention	☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement	☐	Box No. VI	Certain documents cited	☐	Box No. VII	Certain defects in the international application	☐	Box No. VIII	Certain observations on the international application
☒	Box No. I	Basis of the report																							
☒	Box No. II	Priority																							
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																							
☐	Box No. IV	Lack of unity of invention																							
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement																							
☐	Box No. VI	Certain documents cited																							
☐	Box No. VII	Certain defects in the international application																							
☐	Box No. VIII	Certain observations on the international application																							

Date of submission of the demand 28 September 2010	Date of completion of this report 11 April 2011
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized Officer GUSTAVO GUALTIERI, Ph.D. AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. +61 2 6283 2736

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/IN2010/000048

Box No. 1 Basis of the report

1. With regard to the language, this report is based on:
- ☒ The international application in the language in which it was filed
- ☐ A translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1 (b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))
2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-12 as originally filed/furnished
- pages* received by this Authority on _____ with the letter of _____
- pages* received by this Authority on _____ with the letter of _____
- ☒ the claims:
- pages as originally filed/furnished
- pages* as amended (together with any statement) under Article 19
- pages* 15-17 received by this Authority on 24 February 2011 with the letter of 24 February 2011
- pages* received by this Authority on _____ with the letter of _____
- ☒ the drawings:
- pages 1/3-3/3 as originally filed/furnished
- pages* received by this Authority on _____ with the letter of _____
- pages* received by this Authority on _____ with the letter of _____
- ☒ a sequence listing - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (e-bis)).
- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
5. ☐ This report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 70.2(e)).
6. ☐ Supplementary international search report(s) from Authority(ies) _____ have been received and taken into account in drawing up this report (Rule 45bis.8(b) and (c)).

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/IN2010/000048

Box No. II Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

☐ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

The priority date has been assessed and is found to be valid.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IN2010/000048**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-22	YES
	Claims NONE	NO
Inventive step (IS)	Claims 1-22	YES
	Claims NONE	NO
Industrial applicability (IA)	Claims 1-22	YES
	Claims NONE	NO

2. Citations and explanations (Rule 70.7)

The following documents cited in the International Search Report (ISR) were used for the purpose of this report:

D1: WO 2003/031934 A2 (CHIRON CORPORATION), 17 April 2003

D2: WO 2007/033444 A2 (K.U. LEUVEN RESEARCH AND DEVELOPMENT), 29 March 2007

D3: Abe A. et al. Journal of Clinical Microbiology, 1999, vol. 37, no. 9, pp. 2899-2903

D4: WO 2009/122422 A1 (BIGTEC PRIVATE LIMITED), 8 October 2009. This citation was considered P, X by in the ISR/ISO; however, it is no longer considered relevant.

The present invention is directed to a method of detecting Hepatitis B Virus (HBV) in a test sample such as blood, serum, or plasma, comprising a PCR amplification reaction (e.g. as in the TaqMan technique) comprising probe SEQ ID NO: 1 designated for the surface gene of HBV in combination with primers SEQ ID Nos: 3 and 4, or probe SEQ ID NO: 2 designated for the X-gene region of HBV in combination with SEQ ID Nos: 5 and 6; wherein said probes comprise a fluorophore (e.g. FAM) at the 5' end and a quencher (e.g. TAMRA) in an internal region or at the 3' end; and the invention is also directed to said probes and primers as well as to a kit for the detection of HBV.

D1 discloses a method of detecting HVB in a test sample such as blood, serum, or plasma, comprising a PCR amplification reaction such as in the TaqMan technique, wherein said reaction can comprise the 22 nucleotide-long primer SEQ ID NO: 7 which reverse complement comprises 18 nucleotides 100% identical to present 18 nucleotide-long primer SEQ ID NO: 6 used to amplify the X-gene (see p.14 l.15-27, p.16 l.3-18, p.25 l.1-25).

D2 discloses a method of detecting HVB in a culture supernatant, comprising a real time quantitative PCR (Q-PCR) amplification reaction such as in the TaqMan technique, wherein said reaction comprises a forward and a reverse primer pair in combination with a 26 nucleotide long Taqman probe (SEQ ID NO: 3) comprising a 5' FAM fluorophore and a 3' TAMRA quencher (see p. 41 l.30-p. 42 l.8). It is noted that said *probe* comprises 18 continuous nucleotides that are 100% identical to preset *primer* SEQ ID NO: 6 used to amplify the X-gene.

D3 discloses a method of detecting HVB in serum samples, comprising a real time quantitative PCR based on the Taq Man chemistry, wherein said reaction comprises a forward and a reverse primer pair for amplification of segments of the HBV surface gene or the X gene, in combination with corresponding Taqman probes, wherein a reporter dye (6-carboxy-fluorescein) is attached to the 5' end of said probe whereas a quencher dye (6-carboxy-tetramethyl-rhodamine) is attached to the 3' end of said probe (see Abstract, section Material and Methods Oligonucleotides Primers and Probes).

Continued in Supplemental Box I

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IN2010/000048

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of a sequence listing filed or furnished:
 - a. (means)
 - ☒ on paper
 - ☐ in electronic form
 - b. (time)
 - ☒ in the international application as filed
 - ☐ together with the international application in electronic form
 - ☐ subsequently to this Authority for the purposes of search and/or examination
 - ☐ to this Authority as an amendment* on
2. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

The PCT request indicates that an electronic copy of the sequence listing was filed with the receiving office; however, this copy was not provided to the International Search Authority. An electronic sequence listing accompanied the Demand on 28 September 2010, but was not used for the purpose of this report.

* If item 4 in Box No. I applies, the sequence listing, which forms part of the basis of the report, may be marked "superseded."

Supplemental Box I

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box No. V

NOVELTY (N)

Claims 1-22 meet the requirements of PCT Article 33(2) with regard to novelty because the cited art does not disclose a method of detecting Hepatitis B Virus (HVB) comprising a PCR amplification reaction comprising the instant probe SEQ ID NO: 1 in combination with the instant primers SEQ ID Nos: 3 and 4, or the instant probe SEQ ID NO: 2 in combination with the instant primers SEQ ID NOs: 5 and 6; and does not disclose the instant probe and/or primer sequences, and kits thereof, of the present invention.

INVENTIVE STEP (IS)

Claims 1-22 meet the requirements of PCT Article 33(3) with regard to inventive step because considering the cited art, alone or in combination, it would not be obvious to a person skilled in the art (PSA), a method of detecting Hepatitis B Virus (HVB) comprising a PCR amplification reaction comprising the instant probe SEQ ID NO: 1 in combination with the instant primers SEQ ID Nos: 3 and 4, or the instant probe SEQ ID NO: 2 in combination with the instant primers SEQ ID NOs: 5 and 6; and it would also not be obvious to a PSA the instant probe and/or primer sequences, and kits thereof, of the present invention.

INDUSTRIAL APPLICABILITY (IA)

The invention defined in **claims 1-22** is considered to meet the requirement of PCT Article 33(4) with regards to industrial applicability, because it can be made by, or used in, industry.

We claim:

- 1) Oligonucleotide probes as set forth in SEQ ID No. 1 or SEQ ID No. 2.
- 2) The probes as claimed in claim 1, wherein said probes are dual labeled probes.
- 5 3) The probes as claimed in claim 1, wherein said probes detect Hepatitis B Virus.
- 4) The probes as claimed in claim 1, wherein said probes are conjugated with detectable labels having fluorophore at 5' end and a quencher in an internal region or at 3' end.
- 10 5) The probes as claimed in claim 1, wherein the SEQ ID No. 1 is designated for surface gene of Hepatitis B virus and SEQ ID No. 2 is designated for X-gene region of Hepatitis B virus.
- 6) Primers as set forth in SEQ ID Nos. 3, 4, 5 or 6.
- 7) The primers as claimed in claim 6, wherein said primers of SEQ ID No.3 and SEQ ID No.5 are sense and SEQ ID No.4 and SEQ ID No.6 are anti sense primers
15 respectively.
- 8) The primers as claimed in claim 6, wherein said primers of SEQ ID No.3 and SEQ ID No.4 are for dual labeled probe of SEQ ID No. 1 and primers of SEQ ID No.5 and SEQ ID No.6 are for dual labeled probe of SEQ ID No. 2.
- 20 9) A PCR reaction mixture for detection of Hepatitis B Virus, said mixture comprising nucleic acid amplification reagents, dual labeled probes as set forth in SEQ ID No. 1 or SEQ ID No.2, corresponding primers as set forth in SEQ ID Nos. 3 and 4 or SEQ ID Nos. 5 and 6 respectively, and test sample.
- 10) The PCR reaction mixture as claimed in claim 9, wherein said sample is selected from a group comprising blood, serum and plasma.
- 25 11) The PCR reaction mixture as claimed in claim 10, wherein said mixture is used in real time PCR.
- 12) A method of detecting Hepatitis B Virus, said method comprising steps of:
 - (a) forming a reaction mixture comprising nucleic acid amplification reagents, oligonucleotide probe as set forth in SEQ ID No. 1 or SEQ ID No.2 with
30 corresponding primers as set forth in SEQ ID Nos. 3 and 4 or SEQ ID Nos. 5 and 6 respectively, a test sample; and

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(b) subjecting the reaction mixture to PCR to obtain copies of the target sequence followed by measuring the increase in fluorescence signal for detecting the Hepatitis B Virus.

- 13) The method as claimed in claim 12, wherein said probes are conjugated with detectable labels having fluorophore at 5' end and a quencher in an internal region or at 3' end.
- 14) The method as claimed in claim 12, wherein said primers of SEQ ID No.3 and SEQ ID No.5 are sense and SEQ ID No.4 and SEQ ID No.6 are anti sense primers respectively.
- 15) The method as claimed in claim 12, wherein said test sample is selected from a group comprising blood, serum and plasma.
- 16) The method as claimed in claim 12, wherein said amplification reagents include magnesium chloride, Taq polymerase and buffer for amplification.
- 17) The method as claimed in claim 12, wherein said detection is qualitative or quantitative in nature.
- 18) The method as claimed in claim 13, wherein said fluorophore is selected from a group comprising fluorescein and fluorescein derivatives FAM, VIC, JOE, 5-(2'-aminoethyl)aminonaphthalene-1-sulphonic acid, coumarin and coumarin derivatives, lucifer yellow, texas red, tetramethylrhodamine, 6-Carboxy Fluorescein, tetrachloro-6-carboxyfluorescein, 5-carboxyrhodamine and cyanine dyes.
- 19) The method as claimed in claim 13, wherein said quencher is selected from a group comprising Tetra Methyl Rhodamine [TAMRA], 4'-(4-dimethylaminophenylazo)benzoic acid, 4-dimethylaminophenylazophenyl-4'-maleimide, tetramethylrhodamine, carboxytetramethylrhodamine and BHQ dyes.
- 20) The method as claimed in claims 18 and 19, wherein said fluorophore is preferably 6-Carboxy Fluorescein at 5' end and said quencher is preferably tetra methyl rhodamine at 3' end or Black hole quencher 1 [BHQ1] in the internal region or at the 3' end.
- 21) A kit for detection of Hepatitis B Virus, said kit comprising dual labeled probes as set forth in SEQ ID No. 1 and SEQ ID No. 2, individually or in combination;

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corresponding pair of primers as set forth in SEQ ID Nos. 3, 4, and 5, 6, individually or in combination and amplification reagents.

22) The kit as claimed in claim 21, wherein said amplification reagents include magnesium chloride, Taq polymerase and buffer for amplification.

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REIVINDICACIONES

Reivindicamos

- 1) Sondas de oligonucleótido como se establece en la SEQ ID No. 1 o SEQ ID No. 2.
- 2) Las sondas como se reivindica en la reivindicación 1, en donde dichas sondas son sondas etiquetadas duales.
- 3) Las sondas como se reivindica en la reivindicación 1, en donde dichas sondas detectan Virus de Hepatitis B.
- 4) Las sondas como se reivindica en la reivindicación 1, en donde dichas sondas se conjugan con etiquetas detectables que tienen fluoróforo en el extremo 5' y un inhibidor en una región interna o en el extremo 3'.
- 5) Las sondas como se reivindica en la reivindicación 1, en donde la SEQ ID No. 1 se designa para el gen de superficie del virus de Hepatitis B y la SEQ ID No. 2 se designa para la región de gen X del virus de la Hepatitis B.
- 6) Cebadores como se establece en las SEQ ID Nos. 3,4, 5 o 6.
- 7) Los cebadores como se reivindica en la reivindicación 6, en donde dichos cebadores de la SEQ ID No.3 y SEQ ID No.5 son cebadores codificantes y de la SEQ ID No.4 y SEQ ID No.6 son cebadores anticodificantes, respectivamente.
- 8) Los cebadores como se reivindica en la reivindicación 6, en donde dichos cebadores de la SEQ ID No.3 y la SEQ ID No.4 son para sonda etiquetada dual de la SEQ ID No. 1 y los cebadores de la SEQ ID No.5 y SEQ ID No.6 son para la sonda etiquetada dual de la SEQ ID No. 2.
- 9) Una mezcla de reacción PCR para detección del virus de Hepatitis B, dicha mezcla comprende reactivos de amplificación de ácido nucleico, sondas etiquetadas duales como se establece en la SEQ ID No. 1 o SEQ ID No.2, a los cebadores correspondientes como se establece en la SEQ ID Nos. 3 y 4 o SEQ ID Nos. 5 y 6 respectivamente, y la muestra de prueba.
- 10) La mezcla de reacción PCR como se reivindica en la reivindicación 9, en donde dicha muestra de prueba se selecciona de un grupo que comprende sangre, suero y plasma.
- 11) La mezcla de reacción PCR como se reivindica en la reivindicación 10, en donde dicha mezcla se utiliza en PCR en tiempo real.
- 12) Un método para detectar el virus de Hepatitis B, dicho método comprende las etapas de:
 - (a) formar una mezcla de reacción que comprende reactivos de amplificación de ácido nucleico, sonda de oligonucleótido como se establece en la SEQ ID No, 1 o SEQ ID No. 2 con los cebadores correspondientes como se establece en las SEQ ID Nos. 3 y 4 o SEQ ID Nos. 5 y 6, respectivamente, una muestra de prueba; y
 - (b) someter la mezcla de reacción a PCR para obtener copias de la secuencia objetivo al medir el aumento en la señal de fluorescencia para detectar el Virus de la Hepatitis B.

- 13) El método como se reivindica en la reivindicación 12, en donde dichas sondas se conjugan con etiquetas detectables que tienen fluoróforo en el extremo 5' y un inhibidor en una región interna o en el extremo 3'.
- 14) El método como se reivindica en la reivindicación 12, en donde dichos cebadores de la SEQ ID No.3 y SEQ ID No.5 son cebadores codificantes y de la SEQ ID No.4 y SEQ ID No.6 son cebadores anticodificantes, respectivamente
- 15) El método como se reivindica en la reivindicación 12, en donde dicha muestra de prueba se selecciona de un grupo que comprende sangre, suero y plasma.
- 16) El método como se reivindica en la reivindicación 12, en donde dichos reactivos de amplificación incluyen cloruro de magnesio, polimerasa Taq y regulador para amplificación.
- 17) El método como se reivindica en la reivindicación 12, en donde dicha detección tiene una naturaleza cualitativa o cuantitativa.
- 18) El método como se reivindica en la reivindicación 13, en donde dicho fluoróforo se selecciona de un grupo que comprende fluoresceína y derivados de fluoresceína, FAM, VIC, JOE, ácido 5-(2'-aminoetil) aminonaftaleno-1-sulfónico, coumarina, y derivados de coumarina, amarillo lucifer, rojo texas, tetrametilrodamina, 6-Carboxi Fluoresceína, tetracloro-6-carboxifluoresceína, 5-carboxirodamina, y tintes de cianina .
- 19) El método como se reivindica en la reivindicación 13, en donde dicho inhibidor se selecciona del grupo que comprende Tetra Metil Rodamina [TAMRA], ácido 4'-(4- dimetilaminofenilazo) benzoico, 4-dimetilaminofenilazofenil-4'- maleimida, tetrametilrodamina, carboxitetrametilrodamina y tintes de BHQ.
- 20) El método como se reivindica en la reivindicaciones 18 y 19, en donde el fluoróforo es preferiblemente 6-Carboxi Fluoresceína en el extremo 5' y dicho inhibidor es preferiblemente tetra metil rodamina en el extremo 3' o inhibidor de agujero Negro 1 [BHQ1] en la región interna o en el extremo 3'.
- 21) Un equipo para detección del Virus de Hepatitis B, dicho equipo comprende sondas etiquetadas duales como se establece en la SEQ ID No. 1 y SEQ ID No. 2, individualmente o en combinación; pares correspondientes de cebadores como se establece en las SEQ ID No. 3, 4, y 5, 6, individualmente o en combinación y reactivos de amplificación.
- 22) El equipo como se reivindica en la reivindicación 21, en donde dichos reactivos de amplificación incluyen cloruro de magnesio, polimerasa Taq y regulador para amplificación.