

Señores

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIVISIÓN DE NUEVAS CREACIONES

E. S. D.

Expediente No 06-101 799

Solicitud de Patente de Invención titulada "SISTEMA DE MEDIDOR DE ANALITOS DE FLUIDOS CORPORALES Y CARTUCHO PARA REALIZAR ENSAYOS COMBINADOS DE QUIMICA GENERAL Y DE UNION ESPECÍFICA"

Solicitante METRIKA, INC

RESPUESTA AL OFICIO N° 13903 NOTIFICADO
POR FIJACION EN LISTA No 425 DE FECHA 1 DE DICIEMBRE DE 2006,
(EXAMEN DE FORMA)

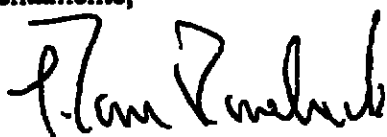
J IAN RAISBECK, mayor de edad y vecino de Bogotá, identificado tal como aparece al pie de mi firma, en mi carácter de apoderado de la sociedad solicitante, me permito manifestar lo siguiente ante el auto emanado de ese Despacho, dentro del plazo legal previsto en el artículo 39 de la Decisión 486, en los siguientes términos

1 En respuesta a la primera observación del Examinador, me permito aclarar al Despacho que la presente solicitud entra en Fase Nacional Capítulo I y no Capítulo II como inicialmente se presentó Para tal efecto, adjunto copia del Reporte Preliminar Internacional de Patentabilidad, el cual, valga aclarar, no contiene anexos

2 En respuesta a la segunda observación del Examinador, me permito aportar, junto al presente memorial, el documento de cesión debidamente legalizado, junto con su correspondiente traducción, según lo previsto en el Art. 26- k de la Decisión 486

3 En respuesta a la tercera observación del Examinador, me permito adjuntar copia auténtica del poder a mi conferido por mí representada según lo previsto en los Artículos 63 y subsiguientes del Código de Procedimiento Civil

Atentamente,



J IAN RAISBECK
C C N° 79 376 996 de Bogotá
T P 135 799 CSJ

Anexo Reporte Preliminar Internacional de Patentabilidad
Documento de Cesión
Copia auténtica del Poder

PATENT COOPERATION TREATY

PCT

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

(PCT Rule 44bis)

Applicant's or agent's file reference XMET 1035048	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2005/007278	International filing date (day/month/year) 07 March 2005 (07.03.2005)	Priority date (day/month/year) 08 March 2004 (08.03.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant METRIKA INC		

1 This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis 1(a).

2 This REPORT consists of a total of 10 sheets, including this cover sheet.

In the attached sheets any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead

3 This report contains indications relating to the following items

- | | |
|--|---|
| ☒ Box No. I | Basis of the report |
| ☐ Box No. II | Priority |
| ☐ Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ Box No. IV | Lack of unity of invention |
| ☒ Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement |
| ☐ Box No. VI | Certain documents cited |
| ☒ Box No. VII | Certain defects in the international application |
| ☒ Box No. VIII | Certain observations on the international application |

4 The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis 1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis 2)

	Date of issuance of this report 25 October 2006 (25.10.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Agnes Wittmann-Regis
Facsimile No. +41 22 338 82 70	e-mail pt06@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
Metrika, Inc.
510 Coleman Parkway
Sunnyvale, CA 94085

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis 1)

182 A

Applicant's or agent's file reference		Date of mailing (day/month/year) 18 SEP 2006
		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US05/07276	International filing date (day/month/year) 07 March 2005 (07.03.2005)	Priority date (day/month/year) 08 March 2004 (08.03.2004)
International Patent Classification (IPC) or both national classification and IPC IPC: Please See Continuation Sheet USPC: 422/55,56,57,58,61,62,1,82,05,104;435/4,7 1,287 1,287.2,287.2,288.7;436/301,66,164		
Applicant RAMEL ET AL.		

1 This opinion contains indications relating to the following items

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis 1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66 1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT Attn: ISA/US Commissioner for Patents P.O. Box 1490 Alexandria, Virginia 22313-1490 Facsimile No. (571) 273-3201	Date of completion of this opinion 15 May 2006 (15.05.2006)	Authorized officer Jacqueline DiRamio Telephone No. 571-272-1600
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Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US03/07276

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Box No. 1 Basis of this opinion

1 With regard to the language, this opinion has been established on the basis of

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23 1(b))

2 With regard to any nucleotide and/or amino acid sequences disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in electronic form.
☐ furnished subsequently to this Authority for the purposes of search

3 ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4 Additional comments:

WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43 bis 1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement

1 Statement



Novelty (N)

Claims 1-158 YES
Claims NONE NO

Inventive step (IS)

Claims NONE YES
Claims 1-158 NO

Industrial applicability (IA)

Claims 1-158 YES
Claims NONE NO

2. Citations and explanations

Please See Continuation Sheet

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted

In paragraph [0091] of the specification, reference to the "face 134" is disclosed with respect to Figure 1, however, this reference number is not found in Figure 1

In paragraph [0148] of the specification, reference to "identification tag 480" is disclosed with respect to Figures 4-6, however this reference number is not found in any of these figures.

Under the "Brief Description of the Drawings," paragraph [0060] refers to Figure "1A," however this figure does not exist, only Figure 1

In paragraph [0107] of the specification, the "distal end" is labeled as "230," however, the "distal end" was labeled in previous paragraphs and in Figures 2A and 2B as "220."

In paragraph [0110] of the specification, the "transport matrix" is labeled as "220," however, the "transport matrix" was labeled in previous paragraphs and in Figures 2A and 2B as "200."

In paragraph [0142], on page 37 of the specification, the "sample receiving aperture" is labeled as "421" for the "cartridge 430," however, this aperture was labeled in previous paragraphs and in Figures 4, 5A, and 5C as "431." Further, the "meter" is labeled as "410," however the meter was labeled in previous paragraphs and in Figures 4 and 6 as "420."

Claims 117 and 123 recite the term "the general assay zone," which is somewhat unclear and should perhaps recite "the general chemical assay zone" as recited in the preceding and subsequent claims in order to remain consistent between the recitations of this zone.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made

Claim 39 recites the term "the manufacturing lot identification information," which lacks antecedent basis.

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

Continuation of IPC

G01N 15/06(2006.01), 21/00(2006.01), 31/22(2006.01), 33/53(2006.01), 33/72(2006.01), 33/566(2006.01), B01L 3/00(2006.01), B32B 5/02(2006.01), 27/04(2006.01), C12Q 1/00(2006.01), C12M 1/34(2006.01), 3/00(2006.01)

V 2 Citations and Explanations:

Claims 1 - 8, 18, 19, 20, 23, 24, 25, 30-33, 38, 40, 42, 47 - 58, 60 - 68, 78-80, 83-85, 90-93, 96 - 107, 109 - 113, 116, 117, 124, 125, 135-137, 140-142, 147-150 and 153-158 lack an inventive step under PCT Article 32(2) as being obvious over Allen (US 5,580,794) in view of May et al. (WO 88/085434)

Allen teaches an electronic assay device (combination body fluid analyte meter and cartridge system) comprising:

- (a) a body fluid analyte meter, comprising:
 - a housing;
 - a logic circuit disposed in the housing;
 - a visual display disposed on the housing; and
 - a measurement system disposed within the housing; and

- (b) a cartridge, comprising:
 - at least one lateral flow assay test strip, the lateral flow assay test strip comprising:

- (i) a lateral flow transport matrix;
 - (ii) a specific binding assay zone on the transport matrix for receiving a fluid sample and performing a specific binding assay to produce a detectable response; or
 - (iii) a general chemical assay zone on the transport matrix for receiving the fluid sample and performing a general chemical assay to produce a detectable response;

wherein the cartridge is dimensioned to be receivable into the body fluid analyte meter such that the measurement system is positioned to detect the responses in the specific binding assay zone or the general chemical assay zone in the lateral flow assay test strip (see Figures 1-3, and column 3, lines 64-67; column 4, lines 1-51, column 6, lines 23-48, column 7, lines 1-67; column 8, lines 1-67, column 10, lines 25-36; column 13, lines 40-57; column 14, lines 5-27, and column 15, lines 18-26).

However, Allen fails to teach that the lateral flow assay test strip comprises both the specific binding assay zone and the general chemical assay zone on the same strip.

May et al. teach an analytical test device comprising a lateral flow test strip, wherein the test strip comprises a dry porous carrier, preferably comprising nitrocellulose. The test strip contains a labeled reagent that is a specific binding partner for the analyte of interest, a detection zone comprising a second specific binding partner that binds to the labeled binding partner or the analyte of interest, and a control zone (general chemical assay zone) that contains an achromatic reagent that, when moistened, produces a colour change. The control zone conveys an unrelated result to the user that the device has worked properly and that the sample has permeated the required distance through the test device (see Figures 1, 2 and 10; and p4-11).

Supplemental Box

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

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the test strip of Allen both the binding zone and the general chemical assay zone, i.e. "control" zone, on the test strip as taught by May et al. because May et al. teach the benefit of including a control zone that conducts a general chemical assay in order to convey to the user that the device has worked properly and the sample has permeated the required distance through the test device.

Claims 9, 21, 22, 26-29, 34, 36, 37, 69, 81, 82, 86-89, 94, 126, 138, 139, 143, 146 and 151 lack an inventive step under PCT Article 33(2) as being obvious over Allen (US 5,580,794) in view of May et al. (WO 88/085434), as applied above, and further in view of Messenger et al. (US 5,162,237).

The Allen and May et al. references, which were discussed above, fail to teach that the analyte is HbA1c, wherein the conjugate can bind to the HbA1c, and further a chemical indicator, which deposited upstream of the general chemical assay zone, reacts chemically in the presence of a second analyte to form a detectable response, wherein the chemical indicator can specifically convert any hemoglobin in the sample to met-hemoglobin.

Messenger et al. teach a device for performing sequential analytical assays, wherein the analytical assays can be utilized for determining hemoglobin A1c (HbA1c). In the first part of the assay procedure, hemoglobin in the whole blood sample is converted into met-hemoglobin using an oxidant (chemical indicator), which is incorporated in a dry soluble form in a first reagent zone 61 and a desiccant 70, contained in a second area 53 wherein this first reaction (general chemical assay) of the sample takes place. The conversion of hemoglobin to met-hemoglobin serves as the basis for measuring the total sample hemoglobin, wherein the total hemoglobin is measured through absorbance. In the second part of the assay procedure, the HbA1c is measured by immunoassay. A second reagent zone 62 contains an antibody particle reagent (conjugate) that forms a reaction mixture through binding to the HbA1c contained in the blood sample. This reaction mixture then binds to an agglutinator reagent 64 in a second area 55, wherein the extent of binding of the antibody particle reagent to the agglutinator reagent to form a light scattering complex is dependent on the amount of HbA1c present in the sample. By comparing the HbA1c measurement obtained through the immunoassay reaction to the total hemoglobin measurement obtained through the first chemical reaction, the correlation between these two measurements are related to the percent glycated hemoglobin in the whole blood test sample (see 5a-5g; and column 12, lines 36-68, column 13, lines 24-68, and column 14, lines 1-21).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Allen and May et al. the sequential chemical and immunoassay reactions taught by Messenger et al. because Messenger et al. teach the benefit of measuring the total hemoglobin concentration through a chemical conversion of hemoglobin in the sample to met-hemoglobin and the HbA1c concentration through an immunoassay reaction in order to correlate these two measurements because the correlation is related to and useful in determining the percent glycated hemoglobin in a whole blood test sample.

Claims 10-14, 59, 70-74, 108, 118-122, and 127-131 lack an inventive step under PCT Article 33(2) as being obvious over Allen (US 5,580,794) in view of May et al. (WO 88/085434), as applied above, and further in view of Fitzpatrick (WO 93/03175).

Allen and May et al. further fail to teach the inclusion of a conjugate removal zone in between the specific binding zone and the general chemical assay zone.

Fitzpatrick teaches a test strip comprises three zones, a mobilization zone (conjugate zone), which contains a receptor specific for the analyte of interest, a trap zone, which contains an immobilized ligand that will bind to, i.e. trap, the receptor of the mobilization zone and a detection zone, which contains a receptor which binds to the receptor-analyte complex thereby providing a positive indication of the presence of analyte in the sample. The three zones can be arranged on the test strip in any order as long as movement of sample through the three zones is accomplished and the trap zone effectively binds to free receptor not bound by the analyte. Therefore, the immobilized ligand of the trap zone must be selected such that it will bind to free receptor from the mobilization zone, but not to receptor bound in the receptor-analyte complex (see Figure, p2, lines 10-35, p5, lines 6-10, and p12-15 under "The Trap Zone").

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Allen and May et al. a trap zone (conjugate removal zone) as taught by Fitzpatrick because Fitzpatrick teaches the benefit of a trap zone with an immobilized ligand that binds to free receptor in order to bind to and trap any free receptor that is not bound to analyte in a receptor-analyte complex.

Claims 15, 17, 75-77, 123 and 132, 134 lack an inventive step under PCT Article 33(2) as being obvious over Allen (US 5,580,794) in view of May et al. (WO 88/085434), as applied above, and further in view of Fleming et al. (US 6,365,417).

Allen and May et al. fail to teach that the chemical assay zone, or "control" zone, is located upstream of the specific binding zone.

Fleming et al. teach a collection device for lateral flow chromatography. The device incorporates a housing and a lateral flow test strip. The test strip contains a protruding collection member 80 that can be utilized for collection of the sample, including placing the member into the mouth to collect a saliva sample. As the body fluid sample moves into the collection member, an indicator dye 102 is solubilized and moved along collection member until it reaches an indicator window 46, which is visible to the user. The appearance of the indicator dye creates a color change of the test strip at the indicator window in order to signal to the user that a sufficient body fluid sample has been collected to perform the analytical test(s) for which the device is designed (see Figure 1, and column 9, lines 35-65).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to position the zones of the test strip of Allen and May et al. with the control zone upstream of the specific binding zone as taught by Fleming et al. because Fleming et al. teaches the benefit of utilizing an indicator dye that presents a color change on the test strip to the user prior to the reaction(s) in the later detection zone(s) in order to signal to the user that a sufficient body fluid sample has been collected to perform the analytical test(s) for which the device is designed.

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Supplemental Box

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

Claims 35, 95, and 152 lack an inventive step under PCT Article 33(2) as being obvious over Allen (US 5,580,794) in view of May et al. (WO 88/08343), as applied above, and further in view of Decastro (US 6,524,864) and Chang et al. (US 6,368,873).

Allen and May et al. fail to teach that the specific binding assay is used to detect the level of human albumin in the sample and the general chemical assay is used to detect the level of creatinine in the sample.

Decastro teaches a test strip for simultaneous detection of a plurality of analytes, wherein both creatinine and albumin can be measured on separate reaction pads through separate chemical reactions. The color produced by the analytes on the various reaction pads of the test strip can be viewed through apertures and read simultaneously with an instrument, such as a reflectance meter, in order to detect the semi-quantitative or quantitative concentration of the analytes in the sample (see Abstract; and column 6, lines 1-65).

Chang et al. teach a method and kit for identifying human urine samples, wherein the method utilizes a chromatographic medium and colloidal gold particles conjugated with antibodies specific for a human antigen, specifically human albumin. The particles bind to the antigen and then bind to a region of the chromatographic medium containing a second set of antibodies, which are also specific for the human antigen. The binding of the particles to the medium results in a positive test for the human antigen, i.e. human albumin, which positively identifies the sample as in fact a human urine sample. The use of a human antigen, such as human albumin, allows for the positive identification of a human sample over other antigens, such as creatinine, which is a normal and prevalent constituent of both human and other animal urine samples (see column 1, lines 5-56).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Allen and May et al. the detection of creatinine by the general assay zone as taught by Decastro because Decastro teaches the benefit of detecting creatinine through a chemical reaction to produce a color change because it allows for detection of the semi-quantitative or quantitative concentration of the analyte. Further, it also would have been obvious to include the detection of human albumin through the specific binding region as taught by Chang et al. because Chang et al. teach the benefit of detecting human albumin in a urine sample through a binding immunosay in order to positively identify the sample as a human urine sample because other normal and prevalent urine constituents, such as creatinine, are found in both human and animal urine samples.

Claims 39, 41, 43, 44, and 114 lack an inventive step under PCT Article 33(2) as being obvious over Allen (US 5,580,794) in view of May et al. (WO 88/08343), as applied above, and further in view of Douglas et al. (US 6,106,780).

Allen and May et al. fail to teach that the logic circuit is configured to read manufacturing lot information to confirm a proper match to the pre-stored calibration information, that the housing and cartridge contain a V-shaped stop and notch for centering and aligning the housing and cartridge, or that the device further includes a sample preparation device.

Douglas et al. teach an analyte testing system comprising a multi-use testing instrument and single use test strips. A particular set of test strips are distributed with a calibration chip, wherein the calibration chip contains calibration information uniquely specific to the reagent provided with the particular set of test strips. In this way, lot differences in the reagent can be compensated for using the required information, while at the same time obviating the need for the user to enter or contribute this information, which minimizes error and greatly facilitates use and accuracy of the testing instrument. The housing of the testing instrument and the test strip are constructed in such a way as to insure proper alignment of the test strip within the testing instrument, thereby sealing the optics area, which serves to minimize ambient light corruption and blood contamination. Additionally, the system of Douglas et al. can include a sampler or sampling device (sample preparation device) in order to draw a sample of capillary blood that can then be applied to the instrument for analyte testing (see column 3, lines 35-67, column 4, lines 1-21, column 5, lines 33-53, column 7, lines 3-15, column 8, lines 39-67, column 9, lines 1-8, and column 10, lines 19-29).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Allen and May et al. the configuring of the device to read manufacturing lot information as taught by Douglas et al. because Douglas et al. teach the benefit of using a calibration chip, which contains calibration information uniquely specific to the reagent provided with the particular set of test strips, in order to compensate for lot differences in the reagent and obviate the need for the user to enter or contribute this information, which minimizes error and greatly facilitates use and accuracy of the testing instrument. It also would have been obvious to construct the housing and test strip to insure proper alignment as taught by Douglas et al. in order to seal the optics area within the testing instrument, which serves to minimize ambient light corruption and blood contamination. Also, it would have been obvious to include a sample preparation device as taught by Douglas et al. in order to draw a sample of capillary blood that can then be applied to the instrument for analyte testing.

Claims 45 and 46 lack an inventive step under PCT Article 33(2) as being obvious over Allen (US 5,580,794) in view of May et al. (WO 88/08343) and Douglas et al. (US 6,106,780), as applied to claim 43 above, and further in view of Bautista et al. (US 2003/0129767).

Allen, May et al., and Douglas et al. fail to teach that the sample preparation device comprises a diluent, surfactant or buffer. Bautista et al. teach a test device and method for detecting an analyte in a sample. The device includes a sample receiving chamber which receives the sample of interest. The sample receiving chamber allows for sample preparation prior to introducing the sample to the test platform containing a test strip(s). The sample preparation can include mixing the sample with one or more reagents, including diluents, buffering agents, stabilizers, detergents, enzymes or cofactors. Therefore, the sample can comprise a multitude of biological materials, which can be prepared for analyte detection through the use of the sample receiving chamber (see Figures and paragraphs [0039] and [0048]-[0052]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Allen, May et al. and Douglas et al. the use of a diluent, surfactant or buffer with the sample preparation device, as taught by Bautista et al. because Bautista et al. teaches the benefit of a sample receiving chamber to receive the sample prior to introduction of the sample into a test platform in order to allow for a multitude of biological materials to be utilized for the analyte detection, because the

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Supplemental Box

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

various samples can be prepared for analyte detection through the mixing of the sample with various reagents, such as diluents, buffering agents, stabilizers, detergents, enzymes or cofactors in the sample receiving chamber

Claim 115 lacks an inventive step under PCT Article 33(2) as being obvious over Allen (US 5,580,794) in view of May et al (WO 88/085434) and Douglas et al. (US 6,106,780), as applied to claim 114 above, and further in view of Krishnaswamy et al. (US 2002/0060247).

Allen, May et al and Douglas et al. fail to teach that the identification tag that is read by the meter for calibration information is an optically scanned barcode.

Krishnaswamy et al. teach an analyte test instrument system comprising a handheld instrument 20, which contains a housing 22, and a test strip 40, which is inserted in the instrument for determining the level of an analyte in a blood sample. The test strip is inserted in the housing of the test instrument and a sample is applied to a sample area. The test strip further includes a barcode or strip identifier code, which is read by a barcode reader contained within the test instrument. The barcode reader allows for non-contact reading of the barcode contained on the test strip, which obviates the need of the user to manually enter information necessary for the analyte testing, as well as validating the barcode to insure the test strip has not expired and can utilized by the test system for accurate analyte measurement (see Figures; and paragraphs [0032], [0033], and [0036]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to create the identification tag of the test strip of Allen, May et al and Douglas et al as an optically scanned barcode as taught by Krishnaswamy et al. because Krishnaswamy et al. teach the benefit of including a barcode on the test strip and a barcode reader in the test instrument in order to allow for non-contact reading of the test strip, which obviates the need of the user to manually enter information necessary for the analyte testing, as well as validating the barcode to insure the test strip has not expired and can utilized by the test system for accurate analyte measurement.

APOSTILLA

(Convención de La Haya del 5 de octubre de 1961)

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8 Bajo el número 07010057-4

9 Aparece sello del Departamento de Estados Unidos de
América

10 Firmado por Sonya N Johnson

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Departamento de Comercio de los Estados Unidos

Oficina de Marcas y Patentes

27 de diciembre de 2006

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198

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1 Nombre de las partes que otorgan la cesión

URS A RAMEL
DILLAN TAY
CAROLE R STIVERS
JOEL M BLATT
BENJAMIN R IRVIN

Nombres de cedentes adicionales? [no]

2 Nombre y dirección de la parte beneficiaria de la cesion

Nombre METRIKA, INC

Dirección 510 Oakmead Parkway

Sunnyvale, CA 94085-4022

Se adjuntan nombres o direcciones adicionales? [no]

3 Naturaleza del Traspaso [x] Cesión

Fecha de ejecución 2 de mayo de 2005 y 4 de mayo de 2005

4 Número de solicitud de patente o número de patente

A Solicitud de Patente No 11/038 213

B Patente No (s)

Se adjuntan números adicionales? [no]

5 Nombre y dirección de la parte a quien se debe dirigir la correspondencia en relación con el documento

Nombre David R Heckadon, Esq

Dirección Interna Embarcadero Center West Suite 2000

Ciudad San Francisco Estado California Zip 94111

Número telefónico (415) 875-3266

Numero de Fax (415) 986-8054

e-mail dheckadon@gordonrees co,

6 Total de Solicitudes y Patentes [1]

7 Total derechos pagados (37CFR 3 41) US\$40 oo (8021)

Se autoriza cargo a la cuenta de depósito? [si]

8 Número de la Cuenta donde se hace el cargo 50-1990

9 Declaración y firma

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(Fdo) David R Heckadon, Fecha 19 de diciembre de 2006

No Total de páginas incluyendo hoja introductoria [6]

Registro de Patente No 018609 Marco 0949

17
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**CESION DEL INVENTORES
(CONJUNTA)**

Este documento de cesión, por Urs A Ramel, Dillan Tay, Carole R Stivers, Joel M Blatt, Benjamin R Irvin, domiciliados en 1331 Los Arboles Avenue, Sunnyvale, California 97087, 1537 Shumaker Way, San Jose, California 95131, 2732 Ross Road, Palo Alto, California 94303, 2149 Junction Avenue, Unit 7, Mountain View, California 94043, 21881 Hermosa Avenue, Cupertino, California 95014, (de aquí en adelante llamados "los cedentes"), respectivamente, testificamos que los cedentes hemos realizado un invento y mejora útil en **COMBINACION TERAPEUTICA PARA TRATAMIENTO DE LA ENFERMEDAD DE ALHEIMER** manifestamos que la solicitud de patente de los Estados Unidos es una

- (1) ☐ solicitud provisional
 - (a) ☐ solicitud No _____, y presentada el _____,
 - (b) ☐ será presentada con, ó
- (2) ☒ ninguna solicitud provisional
 - (a) ☒ solicitud No 11/038 213, y presentada el 21 de enero de 2005,
 - (b) teniendo una declaración ejecutada en cualquier evento anterior a la presentación de la solicitud,
 - (c) teniendo una declaración ejecutada en una fecha diferente a esta cesión, y

CONSIDERANDO QUE, Metrika Inc, una sociedad legalmente organizada y constituida bajo las leyes de California, Estados Unidos de América, cuya oficina comercial es 510 Oakmead Parkway, Sunnyvale, California 94085-4022, (de aquí en adelante denominado como "el cesionario"), desea adquirir la totalidad del derecho, título e interés en y a dicha invención, el derecho a presentar solicitudes en dicha invención y en todos los derechos, títulos e

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POR CONSIGUIENTE, en contraprestación onerosa y suficiente,
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vendido, cedido y transferido y por el presente vende, cede
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países extranjeros, puede concederse por consiguiente y
sobre, y en y a cualquiera y todas las solicitudes que
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Y, por la misma consideración, los Cedentes pactan por la presente y están de acuerdo a y con el Cesionario, sus sucesores, los representantes legales, y las cesiones, que en el momento de ejecución y entrega del presente, los Cedentes son los únicos y legales dueños de la totalidad del derecho, título e interés en y a las invenciones en adelante en las aplicaciones y dichas aplicaciones, mientras incluyendo las aplicaciones provisionales, antedicho, y que el mismo es saneado, y que los Cedentes tienen derecho total y pleno de la autoridad legal para vender y llevar el mismo de la manera aquí dentro pactada

Y, por la misma consideración, los Cedentes por la presente y están de acuerdo a y con el Cesionario, sus sucesores, los representantes legales, y las cesiones que los cedentes quieran, siempre y cuando lo aconseje el cesionario o los consejos de sus sucesores, los representantes legales y cesiones, deben informar que cualquier procedimiento con respecto a dicha invención o a dicha solicitud de patente, o patentes, o cualquier procedimiento con respecto a patente o patentes de dicha invención en cualquier país, incluyendo intervención de procedimientos, de ser legal y requerido, o que cualquier solicitud que reivindique prioridad para dicha, solicitud, división, continuación o parte de una continuación, de cualquier solicitud de patente o patentes o cualquier republicaciones o extensión de cualquier solicitud de patente o patentes que sea concedida de ahora en adelante, de ser legal y requerido, firmar todos los papeles y documentos, aceptar todos las declaraciones juramentadas legales, y hacer todo lo necesario o requerido para hacer su obtención, sostenimiento, aplicación, y defensa de la patente o patentes de dicha invención, sin cargos para el cesionario, sus sucesores y representantes legales y cesiones, excepto

los costos y gastos del cesionario sus sucesores y
representantes legales y cesiones

- El Cedente por el presente otorga a la firma BURNS, DOANE,
SWECKER & MATHIS, L L P la facultad y autoridad para
insertar en los espacios el título de la invención, fecha
de presentación, solicitud, número, y referencia de abogado
para dicha solicitud cuando esta sea conocida

El Cedente por medio de la presente solicita al Comisionado
de Patentes la concesión de todas las patentes en los
Estados Unidos a favor del cesionario de dicha invención,
las patentes a ser publicadas deben ser únicamente para el
uso y en nombre del cesionario, sucesores y representantes
legales y cesiones

Fecha 5/2/2005 (Fdo) Urs A Ramel

Fecha 5/2/2005 (Fdo) Dillan Tay

Fecha 5/2/2005 (Fdo) Benjamin R Irvin,

El Cedente por medio de la presente solicita al Comisionado
de Patentes la concesión de todas las patentes en los
Estados Unidos a favor del cesionario de dicha invención,
las patentes a ser publicadas deben ser únicamente para el
uso y en nombre del cesionario, sucesores y representantes
legales y cesiones

Fecha 5/2/2005 (Fdo) Carole R Stivers

El Cedente por medio de la presente solicita al Comisionado
de Patentes la concesión de todas las patentes en los
Estados Unidos a favor del cesionario de dicha invención,
las patentes a ser publicadas deben ser únicamente para el

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198

uso y en nombre del cesionario, sucesores y representantes
legales y cesiones

Fecha 4/5/2005 (Fdo) Joel M Blatt,

21
199

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

260

1 Country United States of America

This public document

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3 acting in the capacity of Certifying Officer

4 bears the seal/stamp of Patent and Trademark Office

Certified

5 at Washington, D C

6 the sixteenth of January, 2007

7 by Assistant Authentication Officer, United States Department of State

8 No 07010057-4

9 Seal/Stamp

10 Signature

Sonya N Johnson

23
201

A 1555809

THE UNITED STATES OF AMERICA

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December 27, 2006

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T. Lawrence

T. LAWRENCE
Certifying Officer

Form PTO-1035 (Rev. 05/05)
OMB No. 0551-0027 (exp. 6/30/2009)Attorney's Docket No. XMET-1035044
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Urs A. Ramel
Dillon Tay
Carole R. Stivers
Joel M. Blatt
Benjamin R. IrvinAdditional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

2 Name and address of receiving party(ies)

Name: METRIKA INC

Internal Address: _____

3 Nature of conveyance/Execution Date(s)

Execution Date(s) May 2, 2008 and May 4, 2008☒ Assignment☐ Merger☐ Security Agreement☐ Change of Name☐ Joint Research Agreement☐ Government Interest Assignment☐ Executive Order 9424, Confirmatory License☐ OtherStreet Address: 510 Oakmead ParkwayCity: SunnyvaleState: CACountry: U.S.A. Zip: 94085-4022Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application or patent number(s)

☐ This document is being filed together with a new application

A. Patent Application No.(s)

11/038,213

B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

5. Name and address to whom correspondence concerning document should be mailed

Name: David R. Heckadon, EsqInternal Address: Embarcadero Center WestSuite 2000Street Address: 275 Battery StreetCity: San FranciscoState: CA Zip: 94111Phone Number (415) 875-3285Fax Number (415) 885-8054Email Address dheckadon@gordonreese.com6. Total number of applications and patents involved One (1)7 Total fee (37 CFR 1.21(h) & 3.41) \$ 40.00☐ Authorized to be charged by credit card☒ Authorized to be charged to deposit account☐ Enclosed☐ None required (government interest not affecting fee)

8. Payment Information

a. Credit Card Last 4 Numbers _____

Expiration Date _____

b. Deposit Account Number 50-1980Authorized User Name David R. Heckadon

9. Signature

David Heckadon
SignatureDecember 8, 2008

Date

David R. Heckadon

Name of Person Signing

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PATENT

REEL 018609 FRAME 0949

700300629

Application No. 71458173
Attorney Serial No. 00000000

(hereinafter referred to as "the Assignor"), is a citizen of the United States, who, and interest in and to said invention, the right to the applications on said invention and the entire right, title and interest in and to any applications, including provisional applications for Letters Patent of the United States or other countries claiming priority to said application, and in and to any Letters Patent or Patents, United States or foreign, to be obtained thereon and thereon.

NOW, THEREFORE, for good and sufficient consideration, the receipt of which is hereby acknowledged, the Assignor has sold, assigned, transferred, and set over, and by these presents does sell, assign, transfer, and set over unto the Assignee, its successors, legal representatives, and assigns the entire right, title, and interest in and to the above-mentioned invention, the right to the applications on said invention and the entire right, title and interest in and to any applications for Letters Patent of the United States or other countries claiming priority to said application, and any and all Letters Patent or Patents of the United States or foreign and all foreign countries that may be granted therefor and interest, and in and to any and all applications claiming priority to said application, divisions, continuations, and amendments-in-part of said applications, and renewals and extensions of said Letters Patent or Patents, and all rights under the International Convention for the Protection of Industrial Property, the same to be sold and assigned by the Assignor, for its own use and behalf if at the "end" and behalf of its successors, legal representatives, and assigns, on the full and entire of the term or terms for which Letters Patent or Patents may be granted or fully and jointly on the terms which have been sold and assigned by the Assignor and this said and assignment and each other.

AND for the same consideration, the Assignor hereby warrants and agrees in and with the Assignee, its successors, legal representatives, and assigns, that, at the time of execution and delivery of these presents, the Assignor was the sole and lawful owner of the entire right, title, and interest in and to the invention and claim in said application and said applications, including provisional applications, above-mentioned, and that the same are unencumbered, and that the Assignor has given over all right and lawful authority to sell and convey the same in the manner herein set forth.

AND for the same consideration, the Assignor hereby warrants and agrees in and with the Assignee, its successors, legal representatives, and assigns that the Assignor will, through counsel of the Assignee, or the counsel of its successors, legal representatives, and assigns, shall obtain and pay processing in connection with said invention or said applications for Letters Patent or Patents, or any processing in connection with Letters Patent or Patents for said invention in any country, including international proceedings, is made and made, or that any application claiming priority to said application, division, continuation, or continuation-in-part of any applications for Letters Patent or Patents, or any renewal or extension of any Letters Patent or Patents to be obtained thereon, is made and made, sign all papers and documents, take all lawful steps, and do all else necessary or required to be done for the prosecution, maintenance, continuance, and defense of Letters Patent or Patents for said invention, without charge to the Assignee, its successors, legal representatives, and assigns, but at the cost and expense of the Assignor, its successors, legal representatives, and assigns.

AND the Assignor hereby warrants and represents the ownership of Barry, Dancy, Gaudin & Mahan, L.L.P. as listed in the space provided above the title of the invention, the title, application number, and attorney serial number of said application when known.

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Page 6 of 3

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PATENT
REEL 018609 FRAME 0951

205

Application No. 11028178
 Attorney Docket No. 018609-000

And this Assignor hereby requests the Director of the United States Patent and Trademark Office to issue any and all such Letters Patent of the United States to the Assignor or the Assignee of said Inventions, the Letters Patent to be issued for the said inventions and behalf of the Assignor, its successors, legal representatives, and assigns.

Date: <u>5/2/2005</u>	Signature of Assignor: <u>[Signature]</u> Lin A. Pearl
Date: <u>5-2-05</u>	Signature of Assignor: <u>[Signature]</u> Ellen Toy
Date: _____	Signature of Assignor: _____ Curtis R. Shivers
Date: _____	Signature of Assignor: _____ Jack H. Stein
Date: <u>May 2, 2005</u>	Signature of Assignor: <u>[Signature]</u> Garth R. Ingh
Date: _____	Signature of Assignor: _____
Date: _____	Signature of Assignor: _____
Date: _____	Signature of Assignor: _____
Date: _____	Signature of Assignor: _____
Date: _____	Signature of Assignor: _____

PLAQUE CHAIRS
 10/10/2005

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Page 3 of 3

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PATENT
 REEL 018609 FRAME 0962

28
206

Application No. 114387.872
Priority Patent No. 038518-882

AND the Assignors hereby request the Director of the United States Patent and Trademark Office to issue any and all said Letters Patent of the United States to the Assignee as the Assignee of said inventions, the Letters Patent to be issued for the sole use and benefit of the Assignee, its successors, legal representatives, and assigns.

Date: _____ Signature of Assignor W. A. Kenna

Date: _____ Signature of Assignor Oliver Toy

Date: 2/25/05 Signature of Assignor Carol R. Stoen

Date: _____ Signature of Assignor John H. Stoen

Date: _____ Signature of Assignor Benjamin R. Stoen

Date: _____ Signature of Assignor _____

Date: _____ Signature of Assignor _____

Date: _____ Signature of Assignor _____

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Page 2 of 2

PATENT
REEL 018609 FRAME 0953

Application No. 11,025,212
 Agency Patent No. 095279-000

AND the Assignors hereby request the Director of the United States Patent and Trademark Office to issue any and all said Letters Patent to the Assignee or the Assignee of said Inventions, the Letters Patent to be issued for the sole use and benefit of the Assignee, its successors, legal representatives, and assigns.

Date: _____ Signature of Assignor LEE A. PEARL

Date: _____ Signature of Assignor DEAN TOR

Date: _____ Signature of Assignor CAROL R. GILLES

Date: May 4, 2001 Signature of Assignor JAMES M. BELL
JAMES M. BELL

Date: _____ Signature of Assignor BARBARA H. IRWIN

Date: _____ Signature of Assignor _____

Date: _____ Signature of Assignor _____

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ELI LILLY JOSEPH ARROWOOD Page 2 of 3

PATENT
REEL 018609 FRAME. 0954

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DIRECT DIAL (415) 985-3268

ATTORNEYS AT LAW
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275 BATTERY STREET, SUITE 2000
SAN FRANCISCO, CA 94111
PHONE: (415) 985-3900
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For BODY FLUID ANALYTE METER & CARTRIDGE SYSTEM FOR
PERFORMING COMBINED GENERAL CHEMICAL & SPECIFIC BINDING ASSAY
Filed January 21, 2005
Our Ref No XMET-1035044

Papers Attached.

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REEL 018609 FRAME 0955

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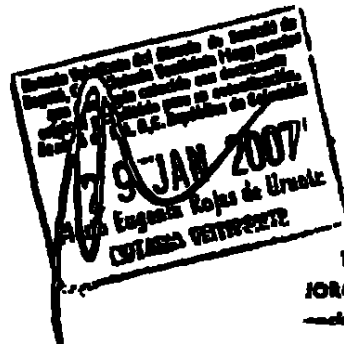
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El dia 16 de Octubre de 2006, ante mi, Pavneet Singh, Notario Publico,
se presento personalmente Andrew Galligan, a quien conozco
personalmente (o comprobo su identidad ante mi satisfactoriamente)
como a persona cuyo nombre está suscrito al documento y reconoció
ante mi que ejecuto el mismo en su calidad autorizada y que por su
firma en el instrumento, la persona o la entidad en cuyo nombre actuo,
ejecuto el instrumento

En constancia firmo y pongo mi sello oficial (Firmado)

Sello Pavneet Singh, comision No 1596611 - Notario Publico de
California, Condado de Santa Clara Mi comisión vence el 20 de Agosto
de 2009

Apostilla adjunta



Traductor Oficial
JORGE L. SIERRA REYES
Cred. 376 1993 Minjusticia

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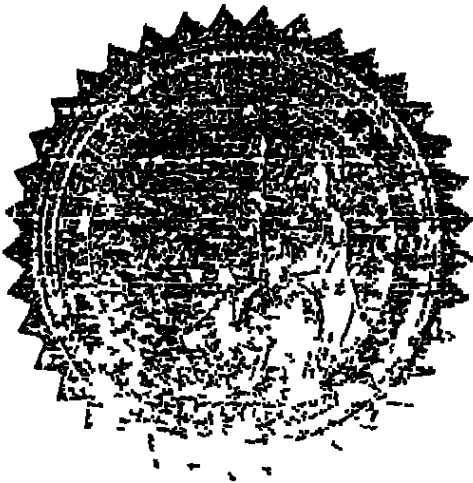
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- 5 At Sacramento, California
- 6 the 19th day of October 2006
- 7 by Deputy Secretary of State, State of California
- 8 No 316917
- 9 Seal/Stamp

10 Signature



Pavneet Singh

Secretary of State

Jayne Wink



Power of Attorney

Poder

The undersigned,

El suscrito,

METRIKA, INC

domiciled in

domiciliado en

510 Oakmead Parkway, Sunnyvale, California 94085-4022, U.S.A.

by means of these presents hereby grants to Carlos R. Olarte and/or J. Ian Raisbeck and/or Ana María Frieri and/or Juan Guillermo Moure and/or Natalia Castro full and sufficient Power of Attorney to file, prosecute, obtain, defend and enforce any and all of the company's Patents for Inventions, Utility Models, Layout-Designs (topographies) of Integrated Circuits, Industrial Designs, Trademarks, Advertising Slogans, Trade Names, Commercial Emblems, Geographical Indications, Protection of Trade Secrets, Obtainer's Certificates, Copyrights, Registration of Domain Names, Health Registrations, or any other intellectual property right in the Republic of Colombia, to which end it empowers them to take all steps necessary before any administrative or judicial authority of any class for the objects stated, to file petitions, recourses, replies and oppositions, pay taxes and annuities, request testimonies, receive documents and securities, abandon applications, collect refunds, desist, settle, conciliate or negotiate. Sufficient power is hereby granted to receive notifications on behalf of the Company, to confer powers on those who are to represent the company judicially and extrajudicially, to answer in court in the matter of all claims and demands that may be presented in connection with the objects stated, giving them likewise power to substitute these presents and revoke such substitutions

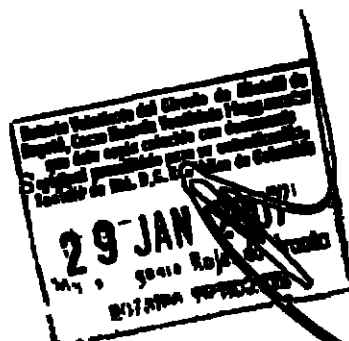
por medio del presente otorga a Carlos R. Olarte y/o J. Ian Raisbeck y/o Ana María Frieri y/o Juan Guillermo Moure y/o Natalia Castro poder especial, amplio y suficiente para presentar, tramitar, obtener, defender y hacer respetar todas y cualquiera de las Patentes de Invención, Modelos de Utilidad, Esquemas de Trazados de Circuitos Integrados, Diseños Industriales, Marcas, Lemas Comerciales, Nombres Comerciales, Enseñas Comerciales, Denominaciones de Origen, Protección de Secretos Empresariales, Certificados de Obtentor, Derechos de Autor, Registro de Nombres de Dominio, Registros Sanitarios, o cualquier otro bien de propiedad intelectual de la compañía en la República de Colombia, a cuyo efecto los faculta para dar todos los pasos necesarios ante cualquier autoridad administrativa o judicial de cualquier jerarquía para cumplir con lo encomendado, elevar solicitudes, recursos, respuestas y oposiciones, pagar impuestos y anualidades, solicitar testimonios, recibir documentos y valores, desistir, transigir, y percibir. Se concede poder bastante para recibir notificaciones a nombre de la compañía, otorgar poderes a quienes vayan a representar a la compañía judicial y extrajudicialmente, responder en juicio a todas las reclamaciones o demandas que por motivo de lo encomendado se presentaren, dándoles asimismo facultad para sustituir el presente y revocar dichas sustituciones

(s1g)

Signature/Firma. Andrew Galligan

VP Finance & CFO Metrika, Inc
Date/Fecha 16 October, 2006

City/Country/Ciudad,País Sunnyvale, California, U



ACKNOWLEDGMENT

State of California
County of Santa Clara

On 10/16/2006 before me, PAVNEET SINGH (Notary Public)
(here insert name and title of the officer)

personally appeared Andrew Bralligan

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

WITNESS my hand and official seal

Signature

Pavneet Singh



(Seal)

