

010507

13019 U.S. PTO

Approved for use through 01/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	BWS 06-12
First Inventor	Jin Po Lee
Title	Multiple Analyte Assay Device
Express Mail Label No.	EB 1125202.92 US

APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents.		ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450	
1. <input checked="" type="checkbox"/> Fee Transmittal Form (e.g., PTO/SB/17) <i>(Submit an original and a duplicate for fee processing)</i> 2. <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. 3. <input checked="" type="checkbox"/> Specification [Total Pages <u>23</u>] Both the claims and abstract must start on a new page <i>(For information on the preferred arrangement, see MPEP 608.01(a))</i> 4. <input checked="" type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets <u>6</u>] 5. Oath or Declaration [Total Sheets <u>29</u>] a. <input checked="" type="checkbox"/> Newly executed (original or copy) b. <input type="checkbox"/> A copy from a prior application (37 CFR 1.63(d)) <i>(for continuation/divisional with Box 18 completed)</i> i. <input type="checkbox"/> DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b). 6. <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76 7. <input type="checkbox"/> CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix) <input type="checkbox"/> Landscape Table on CD 8. Nucleotide and/or Amino Acid Sequence Submission <i>(if applicable, items a. - c. are required)</i> a. <input type="checkbox"/> Computer Readable Form (CRF) b. <input type="checkbox"/> Specification Sequence Listing on: i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or ii. <input type="checkbox"/> Paper c. <input type="checkbox"/> Statements verifying identity of above copies		ACCOMPANYING APPLICATION PARTS 9. <input type="checkbox"/> Assignment Papers (cover sheet & document(s)) Name of Assignee _____ 10. <input type="checkbox"/> 37 CFR 3.73(b) Statement <input checked="" type="checkbox"/> Power of Attorney <i>(when there is an assignee)</i> 11. <input type="checkbox"/> English Translation Document (if applicable) 12. <input checked="" type="checkbox"/> Information Disclosure Statement (PTO/SB/08 or PTO-1449) <input type="checkbox"/> Copies of citations attached 13. <input type="checkbox"/> Preliminary Amendment 14. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503) <i>(Should be specifically itemized)</i> 15. <input type="checkbox"/> Certified Copy of Priority Document(s) <i>(if foreign priority is claimed)</i> 16. <input type="checkbox"/> Nonpublication Request under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent. 17. <input type="checkbox"/> Other: _____	
18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76: <input type="checkbox"/> Continuation <input checked="" type="checkbox"/> Divisional <input type="checkbox"/> Continuation-in-part (CIP) of prior application No.: 10/-19570..... Prior application information: Examiner <u>L.A. Alexander</u> Art Unit: <u>1743</u>			
19. CORRESPONDENCE ADDRESS <input checked="" type="checkbox"/> The address associated with Customer Number: <u>46725</u> OR <input type="checkbox"/> Correspondence address below			
Name			
Address			
City	State	Zip Code	
Country	Telephone	Email	
Signature			Date <u>1-5-2007</u>
Name (Print/Type)	Bernd W. Sandt	Registration No. (Attorney/Agent)	19213

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

ALERE EX. 1002

010507



1:30:19

U.S. Patent and Trademark Office

PTO/SB/17 (07-06)

Approved for use through 01/31/2007. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). <h1 style="margin: 0;">FEE TRANSMITTAL</h1> <h2 style="margin: 0;">For FY 2006</h2>		Complete if Known	
		Application Number	
		Filing Date	
		First Named Inventor	Jin Po Lee
		Examiner Name	
		Art Unit	
		Attorney Docket No.	BWS 06-12
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27			
TOTAL AMOUNT OF PAYMENT	(\$)	500.00	

METHOD OF PAYMENT (check all that apply)

Check
 Credit Card
 Money Order
 None
 Other (please identify): _____

Deposit Account
 Deposit Account Number: 190135
 Deposit Account Name: Bernd W. Sandt

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below
 Charge fee(s) indicated below, except for the filing fee

Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17
 Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	500.00
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims 8 - 20 or HP = 0 x 0 = 0 **Multiple Dependent Claims**
 HP = highest number of total claims paid for, if greater than 20. 0 0

Indep. Claims 1 - 3 or HP = 0 x 0 = 0 **Fee Paid (\$)**
 HP = highest number of independent claims paid for, if greater than 3. 0 0

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
<u>23</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>

4. OTHER FEE(S)

Description	Fees Paid (\$)
Non-English Specification, \$130 fee (no small entity discount)	0
Other (e.g., late filing surcharge):	0

SUBMITTED BY

Signature:	Registration No. (Attorney/Agent): <u>19,213</u>	Telephone: <u>9 89 6316852</u>
Name (Print/Type): <u>Bernd W. Sandt</u>	Date: <u>01-05-2007</u>	

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

010507

13019 U.S. PTO

Approved for use through 01/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	BWS 06-12
First Inventor	Jin Po Lee
Title	Multiple Analyte Assay Device
Express Mail Label No.	EB 1125202.92 VS

APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents.	ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450
---	---

1. **Fee Transmittal Form** (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. **Applicant claims small entity status.**
See 37 CFR 1.27.
3. **Specification** [Total Pages 23]
Both the claims and abstract must start on a new page
(For information on the preferred arrangement, see MPEP 608.01(a))
4. **Drawing(s)** (35 U.S.C. 113) [Total Sheets 6]
5. **Oath or Declaration** [Total Sheets 29]
 - a. Newly executed (original or copy)
 - b. A copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 18 completed)
 - i. **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. **Application Data Sheet.** See 37 CFR 1.76
7. **CD-ROM or CD-R** in duplicate, large table or Computer Program (Appendix)
 Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission**
(if applicable, items a. - c. are required)
 - a. Computer Readable Form (CRF)
 - b. **Specification Sequence Listing on:**
 - i. CD-ROM or CD-R (2 copies); or
 - ii. Paper
 - c. Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. **Assignment Papers** (cover sheet & document(s))
Name of Assignee _____
10. **37 CFR 3.73(b) Statement** **Power of Attorney**
(when there is an assignee)
11. **English Translation Document** *(if applicable)*
12. **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
 Copies of citations attached
13. **Preliminary Amendment**
14. **Return Receipt Postcard** (MPEP 503)
(Should be specifically itemized)
15. **Certified Copy of Priority Document(s)**
(if foreign priority is claimed)
16. **Nonpublication Request** under 35 U.S.C. 122(b)(2)(B)(i).
Applicant must attach form PTO/SB/35 or equivalent.
17. **Other:** _____

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:

Continuation Divisional Continuation-in-part (CIP) of prior application No.: 10/19570.....

Prior application information: Examiner L.A. Alexander Art Unit: 1743

19. CORRESPONDENCE ADDRESS

The address associated with Customer Number: 46725 OR Correspondence address below

Name			
Address			
City	State	Zip Code	
Country	Telephone	Email	

Signature		Date	<u>1-5-2007</u>
Name (Print/Type)	Bernd W. Sandt	Registration No. (Attorney/Agent)	19213

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

112963 U.S. PTO

11/650280



010507

010507



1:30:19

U.S. Patent and Trademark Office

PTO/SB/17 (07-06)

Approved for use through 01/31/2007. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). <h1 style="margin: 0;">FEE TRANSMITTAL</h1> <h2 style="margin: 0;">For FY 2006</h2>		Complete if Known	
		Application Number	
		Filing Date	
		First Named Inventor	Jin Po Lee
		Examiner Name	
		Art Unit	
		Attorney Docket No.	BWS 06-12
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27			
TOTAL AMOUNT OF PAYMENT	(\$)	500.00	

METHOD OF PAYMENT (check all that apply)

Check
 Credit Card
 Money Order
 None
 Other (please identify): _____

Deposit Account
 Deposit Account Number: 190135
 Deposit Account Name: Bernd W. Sandt

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below
 Charge fee(s) indicated below, except for the filing fee

Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17
 Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	500.00
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims 8 - 20 or HP = 0 x 0 = 0 **Multiple Dependent Claims**
 HP = highest number of total claims paid for, if greater than 20. 0 0

Indep. Claims 1 - 3 or HP = 0 x 0 = 0 **Fee Paid (\$)**
 HP = highest number of independent claims paid for, if greater than 3. 0 0

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
<u>23</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>

4. OTHER FEE(S)

Description	Fee (\$)	Fees Paid (\$)
Non-English Specification, \$130 fee (no small entity discount)		<u>0</u>
Other (e.g., late filing surcharge):		<u>0</u>

SUBMITTED BY

Signature		Registration No. (Attorney/Agent)	19,213	Telephone	g 89 6316852
Name (Print/Type)	Bernd W. Sandt	Date	01-05-2007		

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

MULTIPLE ANALYTE ASSAY DEVICE

FIELD OF THE INVENTION

5 The present invention relates to methods and devices for assaying biological fluid samples. More particularly, the invention relates to methods and devices for detecting analytes, such as drugs, in urine. The present application is a division of copending application SN 10/0190570 filed November 8, 2001.

HISTORY OF THE RELATED ART

In their most simple form, chromatographic analyte test strips permit an assay to be
10 performed in a single step (application of an analyte sample to the device) to produce visually observable assay results (such as those indicated by colored bars on the test strip). However, a common limitation of such test strips is that they can only be used to detect a single analyte, requiring that serial assay procedures be performed to detect additional analytes (for example, to test a sample for the presence of a panel of
15 narcotics). Multiple dipping steps, such as are commonly used when multiple dipstick assays are separately performed, present not only a possible loss of sensitivity of the assay (through reagent mixing or loss of reagent solutions), but also an esthetic and hygienic problem for the analyst. Repetitive performance of assay procedures is also tedious, which increases the risk that assays will be performed improperly or the results
20 misinterpreted.

- 2 -

SUMMARY OF THE INVENTION

The present invention provides an assay device, device for separating a fluid analyte sample for use in multiple assay procedures and methods for performing multiple analyte assays. In one embodiment of the assay device, the assay device is a dipstick having
5 multiple analyte test strips, each of which includes a test zone and a control zone. The test strips are enclosed in a housing having an open side through which an end of each test strip protrudes to form a sample loading zone. A protective cap is provided to seal the protruding ends of the test strips from exposure while not in use. Each test strip is separated from the next within the housing by a raised spacer. The portion of the housing
10 which overlies the test and control zones is transparent to permit visually observable results shown in each zone to be viewed.

In cassette form, the assay device has the same structure described above, but the protruding test strips are inserted into a cap which has a sample port for application of sample to the test strips. The cap is retained on the assay device by a close fit over the
15 device housing.

Each test strip provides binders and assay reagents for detection of a different analyte in the sample fluid. In a particularly preferred embodiment of the assay device, the housing may be opened to permit substitution of different test strips to allow each device to be customized for detection of specific analytes of interest. Assay sample integrity
20 determinants consisting of test strips which allow measurement of parameters such as specific gravity and pH may also be included in each device.

The invention also provides a separator device for dividing a fluid assay sample into portions for use in multiple assays without need for contact between the assay operator and the fluid sample. This latter feature of the device increases operator safety and
25 avoids inadvertent contamination of the assay sample. The separator device may be used to separate any fluid assay sample, but is especially useful in assaying samples for the

- 3 -

presence of narcotics, where a positive result on first testing of the sample may necessarily be followed by additional testing of the sample to confirm the result and the identity of the detected narcotic. To this end, the separator device is adapted particularly well to use with the assay device of this invention.

- 5 The assay device of the invention makes specimen analysis easier because an analyte sample need only to be applied once to the assay device for testing. In addition, the replaceable nature of the analyte test strips allows the analyst to customize the array of assays to the testing situation. Because the customization can be performed before adding the test sample (*e.g.*, urine), fewer manipulations with the analyte sample are needed to
- 10 obtain the desired information. In addition, use of the separator device permits further testing of the sample to be performed without risk of adulterating the sample in a preliminary assay performed according to the invention.

The invention also provides a method for assaying one or more analytes of interest. The protruding ends of the device are dipped into a fluid analyte sample. Binding of an

15 analyte present in the sample with one or more specific ligands causes formation of specific visual pattern in the test and control zones indicative of the test result. The assay results performed according to the invention may be read visually without use of separate measuring equipment. Thus, performance of assays according to the invention requires only that the user introduce the requisite amount of test sample into the device of the

20 invention, then observe any color changes which appear shortly thereafter in a detection zone of an analyte strip. The method of the invention is especially useful for screening fluid analyte samples (*e.g.*, urine) for the presence or absence of drugs of abuse.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an exploded view of a dipstick assay device of the invention.

FIGURE 2 is a top view of a dipstick assay device of the invention.

FIGURE 3A is a top view of the upper half sample port cap of a cassette assay device of the invention, and FIGURE 3B is a top view of the lower half, base portion of the sample port cap, while FIGURE 3C is a side, cut-away view of the intact cap with test strips in place therein.

FIGURE 4 is a top view of the separator device of the invention.

FIGURE 5 is a cross-sectional view of the separator device taken along line A-A at cut-away point B-B of FIGURE 1.

FIGURE 6 is a lateral view of the separator device within a specimen collection cup.

Like numerals refer to like elements in the drawings.

DETAILED DESCRIPTION OF INVENTION

A. Definitions

For ease of understanding, the following definitions will apply throughout this description:

- 5 1. The term "antigen" as used herein refers to any analyte which is capable of binding antibodies. Antigens may comprise, without limitation, chemical compounds, polypeptides, carbohydrates, nucleic acids, lipids, and the like, including viral particles, viral subunits, bacterial and parasite surface antigens, and host proteins that may be diagnostic of the subject's condition.
- 10 2. A "binder" refers to a ligand for the analyte as in the format of a sandwich assay, or a ligand for both the analyte and the tracer as in the format of a competitive assay. A binder can be chosen from a group of molecules or compounds capable of binding the analyte, such as an antigen to the antibody analyte, or an antibody to the antigen analyte.
- 15 3. A "test zone" refers to an area in which a binder or the analyte is attached, movably or immovably, to the test strip portion of an assay device.
4. A "tracer" refers to a ligand for the analyte or the binder labeled with a detectable label, preferably a visually readable particulate label, such as colloidal gold, latex and liposomes including dye, carbon black, and the like.
- 20 5. A "sample loading zone" refers to an area of a test strip on which a fluid analyte sample is applied for migration to the test zone.

- 6 -

6. A "test strip" of the invention consists of, collectively, all of the zone supporting membranes and any filters of the assay device.

7. A "fluid analyte sample" can be any fluid suspected of containing analyte of interest for which a particular assay is specific. Test sample may represent any
5 body fluid, including urine, blood, sweat, lymph, intraperitoneal fluid, crude tissue extract or homogenate, derived from a fetus, neonate, juvenile or adult subject; a non-biological fluid such as water from some ecological niche, *e.g.*, a river or a lake; or a solution used in a laboratory.

8. A "label" is a molecule or compound which directly or indirectly
10 mediates the formation of a signal (such as a color change) which is used in assay to indicate the presence, absence or concentration range of analyte of interest in a test sample. Labels may include enzymes, fluorescers, liposomes, erythrocyte ghosts, polymer microcapsules, color polymer particles (latex), and preferably includes sols of metal-containing compounds. A wide variety of patents and patent applications provide
15 an extensive literature of different techniques for producing detectible signals in immunoassays. The following list of United States patents is merely illustrative of the type of label which can find application in this invention: U.S. Patent Nos. 3,646,346 discloses radioactive label; 3,654,090, 3,791,932, and 3,817,838 disclose enzyme labels; 3,996,345 discloses fluorescer-quencher labels; 4,062,733 discloses radioactive label;
20 4,067,959 discloses fluorescer or enzyme label; 4,104,099 discloses chemiluminescent label; and 4,160,645 discloses non-enzymatic catalyst label. U.S. Patent No. 3,966,879 discloses an electrophoretic technique employing an antibody zone and U.S. Patent No. 4,120,945 discloses a radioimmune assay (RIA) where labeled analyte is initially bound to a solid support through antibody. U.S. Patent No. 4,233,402 discloses enzyme pair
25 labels; U.S. Patent No. 4,720,450 discloses chemically induced fluorescent labels; and U.S. Patent No. 4,287,300 discloses enzyme anionic charge labels.

- 7 -

Labels can also be metal-containing sols; *i.e.*, metal or metal compounds such as metal oxides, metal hydroxides, metal salts, metals or metal-containing compounds mixed with polymers or coated onto polymer nuclei. These metal labels may include dry forms of any of the above-named metal or metal compound sols, and preferably includes
5 colloidal gold in dry form.

9. A "complex" means (depending on the context) any multimolecular complex formed by analyte and one or more ligands, or by labeled ligand and immobilized ligand. In a sandwich-type immunoassay, *e.g.*, the following complexes
10 occur: analyte/labeled ligand duplex first produced in the assay (first complex) and analyte/labeled ligand/immobilized ligand triplex formed second in the assay (second complex).

10. "Fluid communication" refers to structures which are in contact with,
15 but not necessarily affixed to, one another.

11. "Assay" refers to several different types of assay formats in which an analyte of interest can be detected using an assay test strip. For example, in a sandwich-type immunoassay, analytes of interest in the analyte sample, when present, bind a labeled tracer movably incorporated in the test strip (consisting of a porous membrane)
20 at the tracer zone to form a first complex. The tracer is a molecule which binds the analyte of interest and is conjugated to a label, preferably a metal label, and most preferably colloidal gold.

A second immobilized ligand corresponding to the analyte of interest is coupled to the test strip at the test zone. First complex and unbound labeled ligand mix
25 with the test sample and be carried along therewith by capillary action (wicking) through the test zone. Analyte sample passes through the test strip bringing the first complexes, if any, into contact with the unlabeled ligand immobilized in the test zone to form a second complex of labeled ligand-analyte-immobilized ligand. The first immobilized

- 8 -

ligand is immobilized in the test zone by means known in the art, including covalent bonding or attachment to an insoluble protein-coated surface (*see, e.g.*, U.S. Patents No. 4,200,690 and 5,075,078). When the second complex is formed, a visible color pattern appears in the test zone. Labeled ligand not bound to analyte in the test sample continue
5 migration by wicking into the control zone to contact the ligand immobilized there. The labeled ligand can bind the immobilized ligand in the control zone to form a third complex, and thus be captured in the control zone.

Within the scope of this invention, the labeled ligand forming the complex in the control zone may be the same as the tracer forming the first and second complexes,
10 or it may be a different labeled ligand. The ligand immobilized in the control zone should have specific affinity for the labeled ligand intended to form the third complex. Formation of the third complex is indicated by a visible pattern in the control zone.

Besides sandwich immunoassay method, other assay methods may be implemented in the devices of the invention. These methods may include competition
15 and inhibition assays. In a competition assay, the analyte and tracer have similar affinity properties and compete for binding with immobilized ligand. Thus, in absence of analyte, the pattern (*e.g.*, band) in the test zone is of maximum intensity. When present, the analyte binds to immobilized ligand to prevent the tracer from getting captured in the test zone. Thus, the intensity of the test band is reduced, depending on the concentration of
20 analyte in the test sample.

In an inhibition assay, the analyte and immobilized ligand in the test zone each have affinity for the tracer. In the absence of analyte in the analyte sample, the tracer is captured by immobilized ligand, and a visible pattern forms in the test zone. When present, the analyte binds the tracer, thereby preventing it from binding to the
25 immobilized ligand in the test zone. The resulting intensity of the test band is reduced depending on the concentration of analyte in the test sample.

B. Dipstick Assay Device

Turning to FIG. 1, a dipstick form of the assay device is shown in exploded view. The device consists of a housing 100, which is defined by base 101 and cover 110. Base 101 can be constructed of any sterilizable material, such as a nonporous plastic (e.g., the commercially available plastic "ABS" supplied by the Monsanto Company of St. Louis, MO.). Base 101 having a closed end 104 and an open end 106, slots 102A, 102B, 102C, 102D and 102E separated by rails 103A, 103B, 103C and 103D for insertion of test strips 105A, 105B, 105C, 105D and 105E. A particular advantage of this embodiment of the assay device is its customizability in that test strips specific for different analytes of interest to the user may be inserted into base 101 and that the number of test strips employed may vary (e.g., base 101 may have any number of slots from two upward to accommodate as many test strips as the user may desire).

Referring to FIG. 2, when inserted into slots 102A, 102B, 102C, 102D and 102E, the test strips extend out of base 101 beyond open end 106. The length to which the test strips protrude from base 101 must be sufficient to allow the test strips to contact a fluid analyte sample, preferably by immersion, and most preferably without allowing the fluid to contact housing 100. The test strips are conventional in form; therefore, because those of ordinary skill in the art will be abundantly familiar with the design of such test strips, they will not be described in detail here. However, each test strip will have a test zone 112 for binding of analyte (to indicate a positive test result for the presence of analyte in the analyte sample) and a control zone 113 for binding of tracer (to indicate correct operation of the assay). Preferably, the test zones and control zones of each test strip lie in the same location on each test strip so each can be viewed in side-by-side fashion.

Each test strip is typically constructed of a porous membrane which is substantially inert with respect to the analyte and must be porous or absorbent relative to the analyte sample to be tested, e.g., urine. The substance can be either bibulous matrices or nonbibulous matrices that are insoluble in, and maintain their structural integrity when exposed to

- 10 -

aqueous solutions or physiological fluids. Bibulous matrices that can be useful for the devices of the present invention include but are not limited to, paper, sponge materials, cellulose, hydrophilic inorganic powders, wood, synthetic resin fleeces, woven and nonwoven fabrics and like materials. Nonlimiting examples of nonbibulous matrices
5 include glass fiber, permeable polymer films and preformed or microporous membranes. The absorbent material is preferably absorbent paper. The absorbent material can be affixed by a double sided adhesive (*e.g.*, two sided adhesive tape) to a solid moisture impervious support. This support can be constructed from, for example, hydrophobic plastic, cellulose acetate, polyethylene, terephthalate, polycarbonate, or polystyrene.

- 10 The tracer is prepared according to the means known in the art. For purposes of producing a clearly visible reaction, labels of metal-containing sols are preferred, with labels of colloidal gold or selenium being most preferred. An example of a suitable product is colloidal gold available from Janssen Life Sciences Products. These colloidal metals produce distinctive visual patterns without addition of further reagents; however,
15 fluorescers (such as fluorescein) and enzymes (such as those identified in U.S. Patent No. 4,275,149), may also be used.

Selections and choices for test binders (*e.g.*, immobilized antigens, antibodies and other test and control binders), as well as suitable means for their attachment to porous test strip membranes, are well-known to those of ordinary skill in the art and will not be
20 stated in detail here. To maximize contact of test sample with the tracer and all test binders, the area occupied by each reagent on the test strip preferably extends from one side of the membrane to the other.

For further review concerning test strip construction, including selection and preparation of test reagents, the following references provide a representative sample of test strip
25 designs known in the art: US Patent No. 5,384,264 (commonly owned); US Patent No. 4,491,645; US Patent No. 4,943,522; US Patent No. 5,252,496; US Patent No. 5,714,389

- 11 -

and US Patent No. 5,602,040, the disclosures of which are incorporated for purposes of reference.

Test strips 105A, 105B, 105C, 105D and 105E may be secured within slots 102A, 102B, 102C, 102D and 102E by adhesion to the floor of each slot; however, the placement of
5 cover 110 onto base 101 is sufficient to retain the test strips within the base slots. To this end, cover 110 is conveniently constructed of an opaque tape having at least one transparent window 111 formed therein for viewing of test results along test zone 112 and control zone 113. To secure cover 110 onto base 101, as well as to secure test strips 105A, 105B, 105C, 105D and 105E within slots 102A, 102B, 102C, 102D and 102E,
10 cover 110 is pressed into place to form an adhesive attachment between cover 110 and the upper edges of rails 103A, 103B, 103C, and 103D. To provide additional surface area for adhesion of cover 110 to base 101, bar 107 separates closed end wall 104 of base 101 from rails 103A, 103B, 103C, and 103D.

15 Conveniently, cover 110 is also provided with transparent windows 115A, 115B, 115C, 115D and 115E through which labels on test strips 102A, 102B, 102C, 102D and 102E can be viewed. The labels (not shown) may be printed with information of use in performing the assay, such as the identity of analyte detectible with each test strip.

In certain instances, it may be desirable to store the assay device after test results are
20 obtained for later viewing. To that end, a five-sided cap 120 is provided for insertion over open end 106 of base 101 (with cover 110 in place) to protect the protruding ends of test strips 102A, 102B, 102C, 102D and 102E from contact with other materials, from desiccation and from contact with the assay operator. Cap 120 is easily secured onto the assay device by a close fit, such as a friction fit or snap-fit.

- 12 -

C. Cassette Assay Device

In some instances (e.g., where the analyte sample is believed to contain pathogenic organisms) it is desirable to protect the assay operator from contact with analyte sample after its application to an assay device. To this end, the dipstick assay device may be
5 conveniently modified for use in closed cassette form.

More specifically, cap 220 (FIG. 3A and 3B) is adapted to convert the dipstick assay device into a cassette. Cap 220 is similar in design to cap 120 (FIGS. 1 and 2), except that sample application slot 221 is formed therein to permit analyte sample to be applied to test strips 202A, 202B, 202C, 202D and 202E dropwise; e.g., by pipetting the sample
10 through slot 221 (in FIGURE 3C, only strip 202A is visible from the side view and the device housing is not shown). To avoid sample overflow, a reservoir 222 may be provided in the inner floor 223 of cap 220 by, for example, providing raised bar 226 on floor 223 (in FIGURES 3A and 3B, floor 223 is shown as if split from roof 225 of the cap only for the purpose of permitting reservoir 222 to be viewed in the drawing). A
15 downwardly protruding bar 224 is provided from the inner surface of roof 225 of cap 220 to depress the test strips into reservoir 222 so each test strip has equal access to the analyte sample. After performance of the assay, cap 220 remains in place on the assay device to protect the protruding ends of the test strips from contact with other materials, from dessication and from contact with the assay operator.

20 D. Separator Device for Division of Analyte Sample

If a positive result is obtained from use of the assay device of the invention, it is usually necessary to further characterize the detected compound to better enable its identification; e.g., by mass spectrometry. However, it is rarely practical to ask that more than one assay sample be obtained from a subject. As such, any assay sample which is
25 obtained must be divided into portions of sufficient volume for repeated testing, for example by pouring the original sample into separate specimen containers (at the risk of

- 13 -

operator contamination and sample loss). Even where the sample is only to be assayed once, the tendency of subjects to provide abundant urine samples poses a different problem in that too much sample can saturate a test strip and overwhelm the assay reagents. Again, division of the sample is required.

- 5 The separator device of the invention provides simple means for dividing a sample while protecting the sample from contamination and the operator from the sample. To these ends, the separator device consists of a ring which is just smaller in diameter than the inner diameter of the open end of a specimen collection cup so, when pressed inside of the open end of the cup, the ring will remain seated there. A collection chamber (for
10 example, a "V" shaped well) extends across the ring and is attached thereto so the ends of the collection chamber are closed by the inner walls of the ring.

- In use, an assay fluid is placed within the specimen collection cup to a level below the point where the separator device will be seated. The assay operator presses the separator device into place and seals the specimen collection cup with a cap. The operator inverts
15 the specimen collection cup several times so fluid pours into the collection chamber of the separator device. The balance of the fluid assay remains below the level of the separator device and is therefore protected from contact with reagents or other material placed therein. A test strip (such as the assay device of the invention) is placed into contact with the portion of the assay sample contained within the collection chamber of
20 the separator device; e.g., by dipping an end of the test strip into the collection chamber. After the assay sample is loaded from the collection chamber onto the test strip, the latter is removed and the separator device is carefully lifted from the specimen collection cup for disposal.

- Use of the separator device provides the assay operator with a volume of assay sample
25 fluid which is sufficiently limited to avoid saturation of the test strip. For example, where the assay device utilized is the device of this invention, the collection chamber is of a depth and length sufficiently limited so the maximum fluid level achievable in the

- 14 -

collection chamber is lower than the level of the assay device housing. The uncontaminated balance of the assay sample still in the specimen collection cup is available for further testing; e.g., for mass spectrometry to determine the identity of any compounds detected in the initial assay of the portion of the sample separated in the separator device. Conveniently, the separator device may be provided in the form of a kit, including the separator device, a sterilized specimen collection cup with cap and forceps for removal of the separator device from the cup after performance of the assay. Such a kit may also be provided with the assay device of the invention.

An example of a separator device is shown in Figures 4 through 6. Although the separator device shown is in the shape of a ring (to correspond to the common cup-like shape of urine collection cups), those of ordinary skill in the art will recognize that the separator device may be of any shape which conforms to a specimen collection container having at least one open end into which the separator device may be seated.

Referring to FIG. 4, a top view of separator device 400 is provided. Ring 401 has an OD of slightly less than the ID of the specimen collection cup into which the separator device is to be placed. Collection chamber 402 spans ring 401 and is defined by walls 403 and 404.

Looking through separator device 400 along line A-A from cut-away point B-B (FIG. 5), it is seen that walls 403 and 404 meet at point 405 to form a V-shaped well. Those of ordinary skill in the art will recognize that collection chamber 402 may take the form of a half-circular, squared or other shaped well, but a V-shape is a convenient well form to manufacture. Collection chamber 402 is closed at both ends of the well by inner surface 406 of ring 401. Also, it will be appreciated that separator device 400 may be provided with more than one collection chamber.

FIG. 6 shows separator device 400 in place within specimen collection cup 410. It can be seen from FIG. 6 that the height of ring 401 is restricted so neither it nor collection

- 15 -

chamber 402 extend above the level of the open mouth 411 of cup 410 (to avoid interfering with closure of cup 410 by its cap [not shown]). Assay sample fluid 412 remains below separator device 400 in cup 410.

Separator device 400 may be constructed of any sterilizable material which is acceptable
5 for use with fluid assay samples, the identity of which will be known to those of ordinary skill in the art (e.g., plastics such as polycarbonate and glass). Preferably, the material will be non-porous and hydrophobic.

E. Methods for Use of the Assay Devices

The method of the invention may be used to detect any analyte present in fluid sample.
10 The invention is especially useful for detection of monoepitopic and polypepitopic antigens and antibodies associated with pathologies, as well as physiological compounds and drugs.

The assay devices of the invention are particularly well suited for use in drug screening assays and for diagnostic testing of organisms. In the former respect, a five drug panel
15 of assay tests is recommended by the National Institute on Drug Abuse (NIDA), which includes tests for tetrahydrocannabinol and other marijuana metabolites, cocaine metabolites, opiate metabolites, phencyclidine (PCP, Angel Dust), and amphetamines. For a more extensive substance abuse testing panel, the choice of analytes tested can include marijuana metabolites; tetrahydrocannabinol and other marijuana metabolites,
20 cocaine metabolites, opiate metabolites, phencyclidine (PCP, Angel Dust), amphetamines, barbiturates, benzodiazepines, methaqualone, and propoxyphene. The analyte test strips for drug tests preferably have the sensitivity equal to the cutoffs recommended by Substance Abuse Mental Health Service Administration (SAMSHA) and NIDA, which most employers use. Binders and reagents for use in constructing test
25 strips for use in detecting drugs of abuse are well-known in the art and will not be

- 16 -

described in detail here; however, representative sources of such materials are described in the Examples below.

Subjects undergoing drug tests are often creative in their attempts to adulterate the analyte samples to evade detection of drugs of abuse likely to be present in the sample.

5 To minimize the effects of such evasion efforts on results obtainable with the assay devices of the invention, test strips may be provided in the devices which indicate the integrity and condition of the analyte sample. For example, test strips may be provided to simultaneously assay the analyte sample for for pH, osmolality (the total concentration of solutes in urine, expressed as mOsm/kg and measured as a function of fluid specific
10 gravity), or the presence of albumin.

In test strips for pH, the strip is impregnated with various dyes that respond with different color changes to a pH in the range of 5 to 9. Depending on the acid-base status, urinary pH may range from as low as 4.5 to as high as 8.0. Although this test is done routinely, it neither identifies nor excludes patients with urinary system disease. The test can,
15 however, indicate that the condition of the urine sample has deteriorated.

To test the specific gravity (which is directly proportional to urine osmolality) of an analyte test fluid, analyte test strips are available that measure specific gravity in approximations. For example, U.S. Patent 4,318,709, to Falb *et al.*, issued March 9, 1982, provides a test means for determining the ionic strength or specific gravity of an
20 aqueous test sample, the test means comprising a weakly acidic or weakly basic polyelectrolyte which is at least partially neutralized, and an indicator means capable of producing a detectable response to ion exchange between the polyelectrolyte and the sample. The test device is a carrier matrix incorporated with the test means, and the method for its use involves contacting an aqueous test sample with the device and
25 observing a detectable response. The disclosure of the '709 Patent is incorporated for reference herein.

- 17 -

Normal urine osmolality varies between 50 and 1200 mOsm/kg (specific gravity between 1.002 and 1.035). Any urine having a specific gravity over 1.035 is either contaminated, contains very high levels of glucose, or the patient may have recently received high density radiopaque dyes intravenously for radiographic studies or low molecular weight
5 dextran solutions.

Commercially available analyte test strips also permit simple and rapid testing for protein. Methods based on dye binding techniques have proven especially useful because dye binding methods are readily automated and provide reproducible and accurate results. In general, dye binding techniques use pH indicator dyes that are capable of
10 interacting with a protein, such as albumin, and that are capable of changing color upon interaction with a protein absent any change in pH. When a pH indicator dye interacts with, or binds to, a protein, the apparent pKa (acid dissociation constant) of the indicator dye is altered and the dye undergoes a color transition, producing the so-called "protein-error" phenomenon. In methods utilizing the dye binding technique, an appropriate buffer
15 maintains the pH indicator even at a constant pH to prevent a color transition of the pH indicator dye due to a substantial shift in pH. Due to the "protein-error" phenomena, upon interaction with the protein, the pH indicator dyes undergoes a color transition that is identical to the color change arising because of a change in the pH. Examples of pH indicator dyes used in the dry phase assay of proteins that are capable of interacting with
20 or binding to proteins and exhibiting "protein-error" color transitions include tetrabromophenol blue and tetrachlorophenol-3,4,5,6-tetrabromosulfophthalein. Simple, accurate and inexpensive protein detection assays have been developed for the detection or measurement of protein in urine and serum (*See, e.g.,* U.S. Patent 5,096,833 to Lau *et al.*, incorporated herein for reference).

25 The method of the invention is performed by applying analyte sample to test strips by immersion (dipstick forms of the device) or by applying the sample dropwise through slot 221 in cap 220 (FIG. 3; representing cassette forms of the device). After waiting a predetermined time, such as from about 15 seconds to about 60 seconds, test results are

- 18 -

viewed through window 111 or 211 (FIGS. 1 and 2), either visually or by an instrument. A color change in test zone 112 or 212 (FIGS. 1 and 2) indicates the presence or concentration of analyte in the sample. When no band appears in test zones, or if the control band is neither distinct nor fully formed, the assay is regarded as incompetent to
5 indicate the presence or absence of analyte in the test samples and may be performed again. In addition, the assay can be made quantitative by employing spectrophotometric or colorimetric techniques, as opposed to visual techniques, in order to more reliably and more accurately measure the degree of color transition, and therefore more accurately measure the concentration of analyte in the test sample.

10 F. Kits

The invention provides a kit useful for the detection of analytes of interest, having a carrier compartmentalized to receive one or more containers holding the multianalyte assay device of the invention or parts thereof. Preferably, the multianalyte assay device is part of a kit which may be composed of the device, instructions for its use, a sample
15 collection cup, a capillary device for measuring test sample, a pipette for introduction of sample to the device, and a desiccant packet.

Desiccant provides low humidity conditions necessary for preservation of reagents during the shelf life of the device. Alternatively, a desiccant tablet or a desiccant packet may be included in an air-tight protective pouch with the device. Instructions for use of
20 the multianalyte assay device may be printed onto the cover or onto the packaging of the multianalyte assay device or may be printed in literature to be packaged with the multianalyte assay device. The kit may additionally include an attached temperature strip, lids for the specimen cup, and the literature. Components of such a kit for use in performing an assay procedure (*e.g.*, excluding printed instructions) are preferably to be
25 sealed in one or more air-tight packages, such as foil packets.

- 19 -

The following examples are provided to illustrate a use for the invention and do not limit its scope. Unless otherwise noted, all terms and abbreviations used in the examples are standard in the art.

Example 1

5

Assay for Six Drugs of Abuse

Six chromatographic strips for detecting drugs of abuse (methamphetamine, opiates/morphine, marijuana/tetrahydrocannabinol, amphetamine, cocaine/benzoylcegonine, benzodiazepine) each of a size of 5 mm x 73 mm were placed in slots of the device of the invention as shown in FIG. 1. Each strip consisted of a
10 colloidal gold-labeled antibody (specific to the target drug) incorporated into the upstream end of the strip (tracer zone) in the middle of a 30 mm fiberglass matrix, and an antigen-BSA binder immobilized in the center (binder zone) of a 22 mm nitrocellulose membrane lying downstream of, and in fluid communication with, the fiberglass matrix (wherein the antigen is either the drug of interest or an analog thereof having the same
15 immunogenicity). Downstream to the nitrocellulose membrane was a 26 mm long filter paper. The matrix, membrane and filter paper were attached on a vinyl sheet so each was in fluid communication, by overlapping 2mm of each of their ends.

15 drops (0.7 ml each) of analyte sample (human urine) were applied to the sample port. Results were read after 10 minutes. The presence or absence of a pink-rose color band
20 in the binder zone indicated negative or positive results for the presence of each drug of interest in the analyte sample.

For comparison, additional aliquots of the analyte samples were separately tested for the presence of the same drugs of abuse by a commercial assay (Syva EMIT EIA II). The second panel of test results correlated with the results obtained according to the
25 invention.

- 20 -

Although the invention has been described with reference to the presently preferred embodiment, it should be understood that various modifications can be made without departing from the spirit of the invention. Accordingly, the invention is limited only by the following claims.

Claims

1. A device for assaying a fluid for the presence or absence of different analytes comprising:
 - (A) a base having adjacent slots therein of sufficient length for insertion of a test strip therein, wherein each slot is defined by (a) a floor, (b) raised walls depending upwardly from the floor to separate each adjacent slot from the next, and (C) at least one open end;
 - (B) a multiplicity of test strips having an upstream and a downstream end, wherein a single test strip is inserted into each slot of the base so the upstream end of each test strip protrudes out of the open end of each slot, and wherein each test strip has a test zone and a control zone therein, and each test zone contains a binder specific for a different analyte;
 - (C) a cover attached to the upwardmost surface of each raised wall of the slots of the base and extending to the open end of said base, wherein the cover retains the test strips within the slots and has a first transparent window formed therein through which the test zone and the control zone of each of the test strips can be viewed and
 - (D) a cap enclosing the protruding ends of the test strips and removably attached to the open end of said base.
2. The device according to Claim 1 further comprising a second transparent window formed within the cover through which the test strips can be viewed.
3. The device according to Claim 1 further comprising a multiplicity of test strips inserted into each slot of the base, wherein each test strip has a test zone therein and each test zone contains a binder specific for a different analyte.
4. The device according to Claim 3 wherein each binder is specific for a different drug of abuse.

5 The device according to Claim 3 wherein each test zone is visible through the first transparent window of the cover.

6. The device according claim 3 each test strip further comprises a label downstream of the test zone, which label identifies the analyte for which the binder is specific.

7. The device according to claim 6, wherein the label on the test strip is visible through the second transparent window of the cover.

8. The device according to Claim 4 wherein the drug of abuse is from the group consisting of methamphetamine, opiates/morphine, marihuana/tetrahydrocannabinol, amphetamine, cocaine/benzoylecgonine, methadone, PCP, barbituate, trichloroacetic acid and benzodaizepine.

- 23 -

ABSTRACT

The present invention relates to an assay device capable of testing for multiple analytes such as drugs using individual test strips for each analyte.

BWS 06-11

1/6

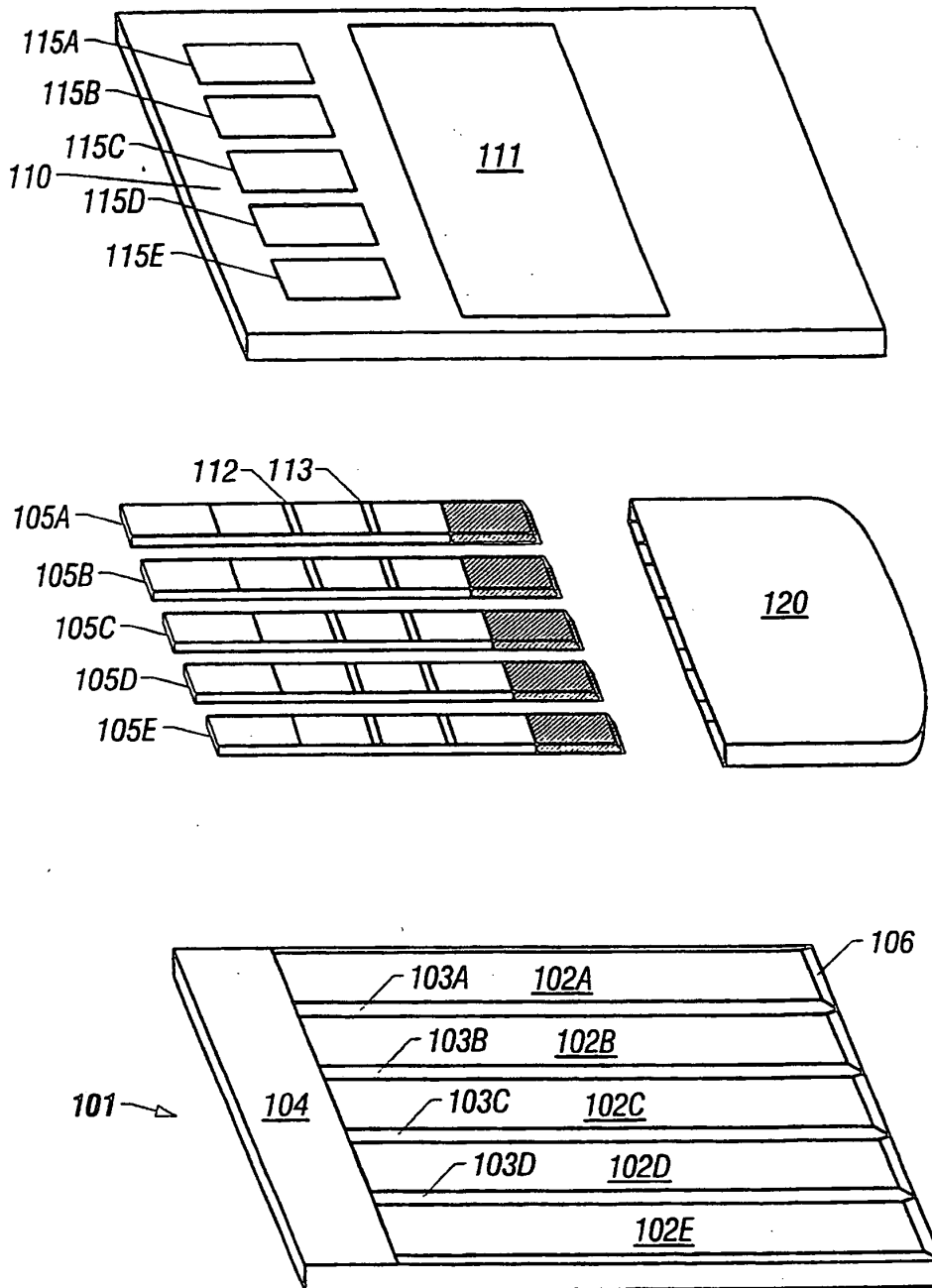


FIG. 1

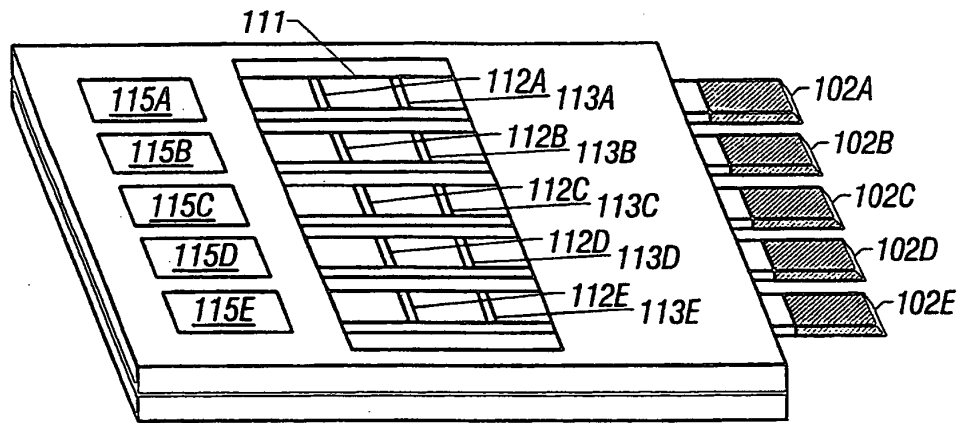


FIG. 2

3/6

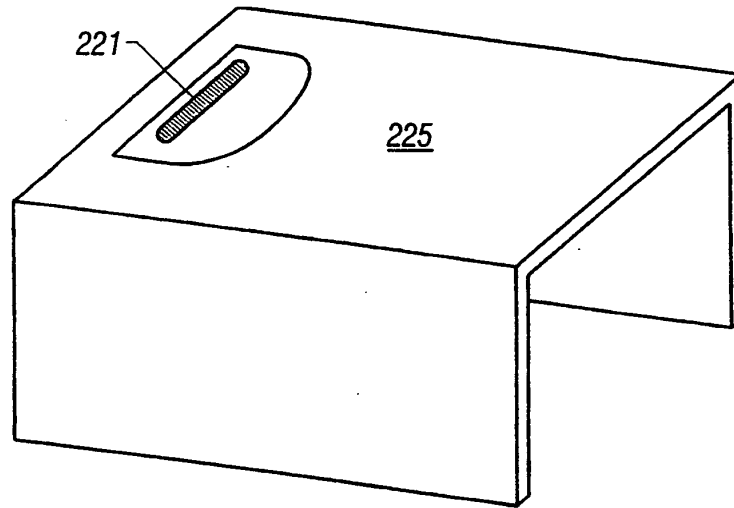


FIG. 3A

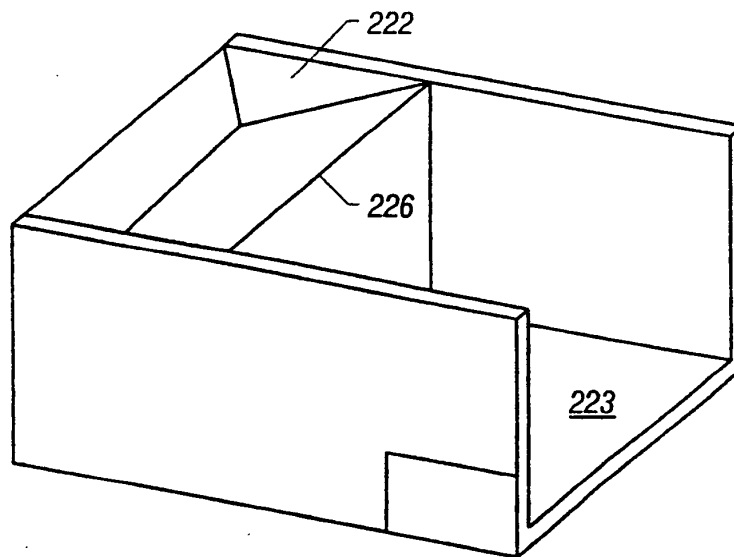


FIG. 3B

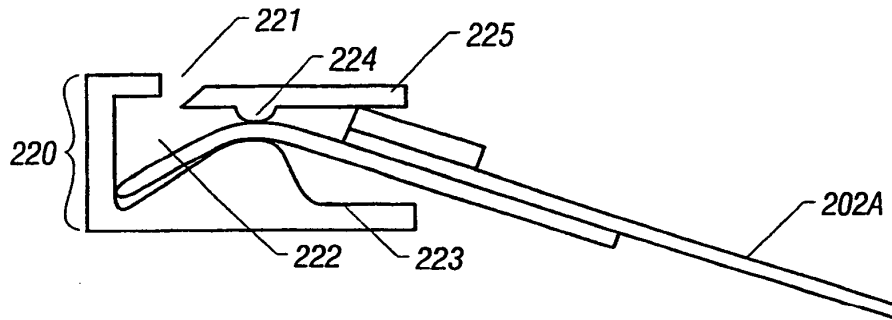


FIG. 3C

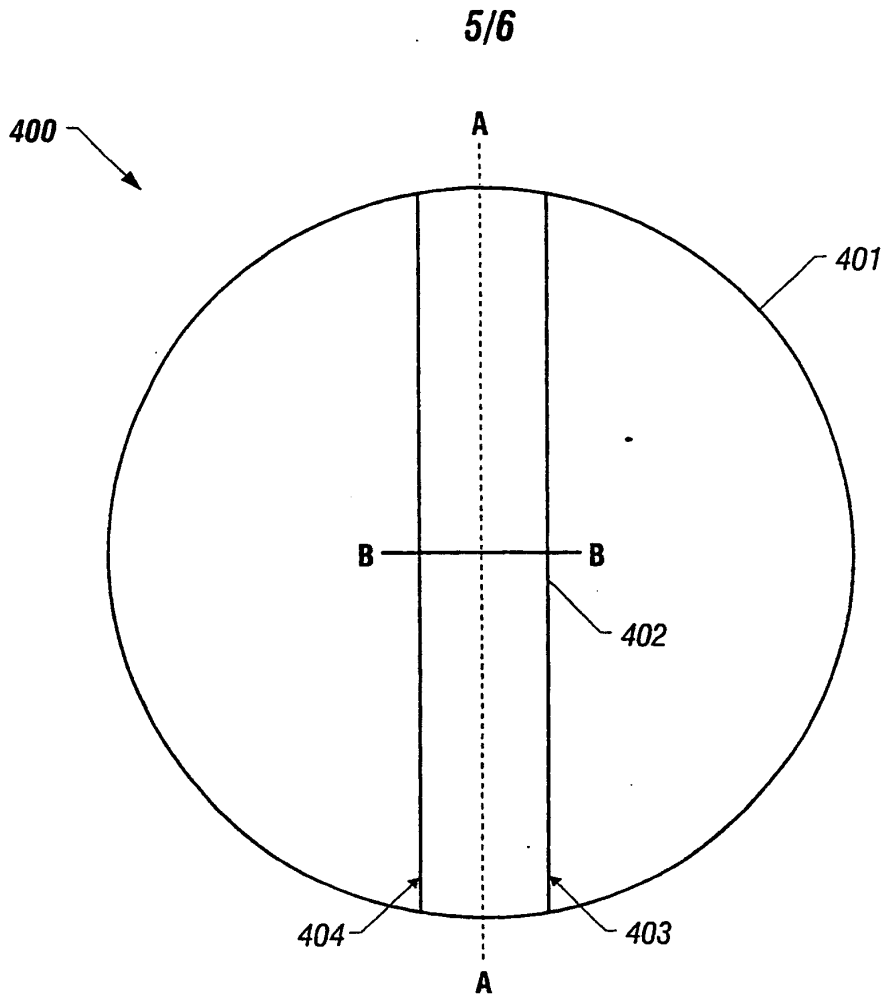


FIG. 4

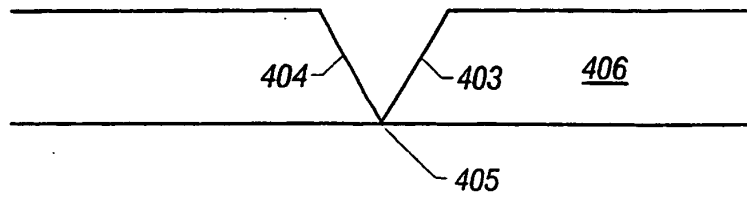


FIG. 5

6/6

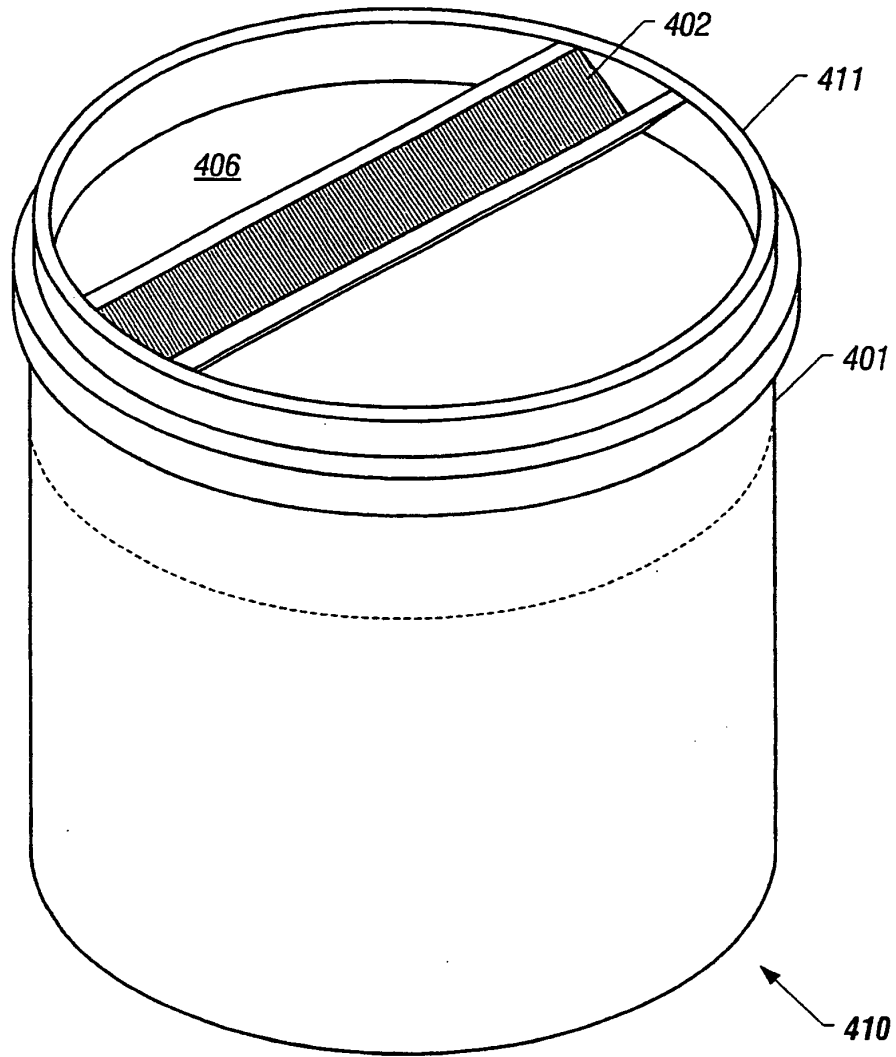


FIG. 6

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)		Attorney Docket Number	BWS 06-12
		First Named Inventor	Jin Po Lee
	<i>COMPLETE IF KNOWN</i>		
		Application Number	
		Filing Date	
		Art Unit	
		Examiner Name	

Declaration Submitted With Initial Filing **OR** Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Multiple Analyte Assay Device

(Title of the Invention)

the specification of which

is attached hereto

OR

was filed on (MM/DD/YYYY) as United States Application Number or PCT International

Application Number and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
PCT US98/15359	USA	07/22/1998	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

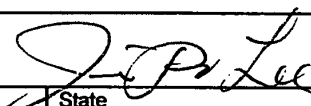
[Page 1 of 2]

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION — Utility or Design Patent Application

Direct all correspondence to:	<input checked="" type="checkbox"/> The address associated with Customer Number:	<input type="checkbox"/> OR <input type="checkbox"/> Correspondence address below
		46725
Name		
Address		
City	State	ZIP
Country	Telephone	Email
WARNING:		
<p>Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.</p>		
<p>I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p>		
NAME OF SOLE OR FIRST INVENTOR:		<input type="checkbox"/> A petition has been filed for this unsigned inventor
Given Name (first and middle [if any])		Family Name or Surname
Jin Po		Lee
Inventor's Signature		Date
		1-3-07
Residence: City	State	Country
Carlsbad	CA	USA
Mailing Address		Citizenship
3408 Escondido Omeida 7337 Melodia Ter.		USA
City	State	Zip
Carlsbad	CA	92011
		Country
		USA
<input type="checkbox"/> Additional inventors or a legal representative are being named on the _____ supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.		

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

POWER OF ATTORNEY and CORRESPONDENCE ADDRESS INDICATION FORM	Application Number	
	Filing Date	
	First Named Inventor	Jin Po Lee
	Title	Multiple Analyte Assay Device
	Art Unit	
	Examiner Name	
	Attorney Docket Number	BWS 06-12

I hereby revoke all previous powers of attorney given in the above-identified application.

I hereby appoint:

Practitioners associated with the Customer Number: 46725

OR

Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please recognize or change the correspondence address for the above-identified application to:

The address associated with the above-mentioned Customer Number:

OR

The address associated with Customer Number: 46725

Firm or Individual Name

Address

City State Zip

Country


Telephone Email

I am the:

Applicant/Inventor.

Assignee of record of the entire interest. See 37 CFR 3.71.
 Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

Signature		Date	1-3-07
Name	Jin Po Lee	Telephone	760-683-0018 760-688-0083
Title and Company			

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

*Total of one forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

01/09/2007 HGUTEMR1 00000067 11650280

01 FC:2011	150.00 OP
02 FC:2111	250.00 OP
03 FC:2311	100.00 OP

PTO-1556
(5/87)

U.S. Government Printing Office: 2002 — 482-267/90033

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875 Effective December 8, 2004

Application or Docket Number

11650282

APPLICATION AS FILED - PART I

FOR	NUMBER FILED (Column 1)	NUMBER EXTRA (Column 2)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A
TOTAL CLAIMS (37 CFR 1.16(i))	8	minus 20 = 0
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1	minus 3 = 0
APPLICATION SIZE FEE (37 CFR 1.16(e))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).	
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))		

SMALL ENTITY	
RATE (\$)	FEE (\$)
N/A	150.00
N/A	\$250
N/A	\$100
X\$ 25	
X100	
+180=	
TOTAL	500

OTHER THAN SMALL ENTITY	
RATE (\$)	FEE (\$)
N/A	300.00
N/A	\$500
N/A	\$200
X\$50	
X200	
+360=	
TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED - PART II

AMENDMENT A	(Column 1)	(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total (37 CFR 1.16(j))	Minus	**	=
Independent (37 CFR 1.16(h))	Minus	***	=
Application Size Fee (37 CFR 1.16(s))			
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			

SMALL ENTITY	
RATE (\$)	ADDITIONAL FEE (\$)
X\$ 25	
X100	
+180=	
TOTAL ADD'L FEE	

OTHER THAN SMALL ENTITY	
RATE (\$)	ADDITIONAL FEE (\$)
X\$50	
X200	
+360=	
TOTAL ADD'L FEE	

AMENDMENT B	(Column 1)	(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total (37 CFR 1.16(i))	Minus	**	=
Independent (37 CFR 1.16(h))	Minus	***	=
Application Size Fee (37 CFR 1.16(s))			
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			

SMALL ENTITY	
RATE (\$)	ADDITIONAL FEE (\$)
X\$ 25	
X100	
+180=	
TOTAL ADD'L FEE	

OTHER THAN SMALL ENTITY	
RATE (\$)	ADDITIONAL FEE (\$)
X\$50	
X200	
+360=	
TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <h3 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h3> <p style="text-align: center;">(Use as many sheets as necessary)</p>	<p style="text-align: center;">Complete if Known</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Application Number</td> <td></td> </tr> <tr> <td>Filing Date</td> <td></td> </tr> <tr> <td>First Named Inventor</td> <td>Jin Po Lee</td> </tr> <tr> <td>Art Unit</td> <td></td> </tr> <tr> <td>Examiner Name</td> <td></td> </tr> <tr> <td>Attorney Docket Number</td> <td>BWS 06-12</td> </tr> </table>	Application Number		Filing Date		First Named Inventor	Jin Po Lee	Art Unit		Examiner Name		Attorney Docket Number	BWS 06-12
Application Number													
Filing Date													
First Named Inventor	Jin Po Lee												
Art Unit													
Examiner Name													
Attorney Docket Number	BWS 06-12												

U. S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-	Number-Kind Code ² (if known)			
	A-1	US-	5,403,557	04/04/95	Galloway et al	
	A-2	US-	5,976,895	11/02/99	Cipkowbki, Stay	
	A-3	US-	4,518,565	05/21/85	Boger et al	
	A-4	US-	4,056,359	11/11/77	Tanin, Pierre	
	A-5	US-	6,514,769	09/02/02	Lee Jin Po	
	A-6	US-	5,770,458	06/23/98	Kimtov et al	
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				

RELEVANCE

The cited references relate to assay devices involving multiple test strips.

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ²	Number ⁴	Kind Code ³ (if known)				

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
11/650,280	01/05/2007	1743	500	BWS 06-12	6	8	1

CONFIRMATION NO. 8521

46725
BERND W. SANDT
900 DEERFIELD COURT
MIDLAND, MI48640

FILING RECEIPT

Date Mailed: 02/28/2007

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Jin Po Lee, Carlsbad, CA;

Power of Attorney: The patent practitioners associated with Customer Number 46725

Domestic Priority data as claimed by applicant

This application is a DIV of 10/019,570 11/08/2001

Foreign Applications

UNITED STATES OF AMERICA PCT/US98/15359 07/14/1998

If Required, Foreign Filing License Granted: 02/27/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US11/650,280**

Projected Publication Date: 06/07/2007

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Multiple analyte assay device

Preliminary Class

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to

espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/650,280	01/05/2007	Jin Po Lee	BWS 06-12

CONFIRMATION NO. 8521

46725
BERND W. SANDT
900 DEERFIELD COURT
MIDLAND, MI48640

Title: Multiple analyte assay device

Publication No. US-2007-0128072-A1

Publication Date: 06/07/2007

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publicly available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 703-305-3028.

Pre-Grant Publication Division, 703-605-4283



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/650,280	01/05/2007	Jin Po Lee	BWS 06-12	8521
46725	7590	04/06/2009	EXAMINER	
BERND W. SANDT 900 DEERFIELD COURT MIDLAND, MI 48640			ALEXANDER, LYLE	
			ART UNIT	PAPER NUMBER
			1797	
			MAIL DATE	DELIVERY MODE
			04/06/2009	PAPER

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.

Office Action Summary	Application No. 11/650,280	Applicant(s) LEE, JIN PO	
	Examiner Lyle A. Alexander	Art Unit 1797	

-- 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 _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) 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

- 4) Claim(s) 1-8 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ 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).
- 11) 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

- 12) 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) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,347,972.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim test devices for the simultaneous detection of multiple drugs of abuse using multiple test strips with a test zone and a control zone placed into a base with a cover and a cap. Applicant has identified this application as a divisional of the above patent. However, upon consulting the originally filed claims of the above patent, the restriction requirement was made between the above multiple test strip device and a method/device for separating fluids. Therefore, the presently filed claims are directed to the elected invention in the patent and properly rejected here.

Claims 1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19; 1-15; 1-15; 1-5 of U.S. Patent No. 6,514,769; 6,730,268; 6,548,019; 6,379,620 in view of Kilmov (USP 5,770,458).

All of the patent with Mr. Lee as a common inventor teach a base for holding test strips that is indistinguishable from the claimed base by claimed a base to hold test strip.

These patents are silent to the claimed test strips having a test zone, a control zone and a second absorbent pad.

See the description of Klimov et al. below.

Kilmov et al. teach a test strip to be used in a similar device that has a test zone, a control zone and a second absorbent pad as presently claimed. It is advantageous to use a test strip with a control zone to gain the advantages of greater confidence in the test results. This greater confidence is especially important when drug testing employees because an incorrect results could result in the termination of the employee. It would have been within the skill of the art to modify U.S. Patent No. 6,514,769; 7,347,972; 6,730,268; 6,548,019; 6,379,620 in view of Kilmov (USP 5,770,458) and use the taught test strips to gain the advantages of having a control zone.

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 –

(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.

Claims 1-8 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kilmov (USP 5,770,458).

Kilmov teaches test strips in a holder device to simultaneously detect different analytes from a single sample that is indistinguishable from the instant claims. Column 10 lines 20-31 describe figures 1A –B as a device that carries three different analyte specific test strips in a plastic holder(102) and has been read on the claimed "base." Column 6 lines 5+ teach each test strip has a first and second absorbent materials that are juxtaposed to each other to facilitate fluid flow through the absorbent materials. Column 7 lines 5-15 teach the test strips are suitable for test drugs of abuse. Columns 7-8 lines 66-11 teach each strip has a control site which has been read on the claimed "control zone." Column 10 lines 32-46 describe figure 1D which teaches the test strip comprises a main membrane(101), detection site(103), control site(104), membrane(105) that is embedded with a specific binding reagent, top membrane(106) that is attached to membrane(101) by an adhesive MYLAR tape(107). The beginning end(108) is overlapped with the sample pad(109) and has been read on the claimed "upstream side" and the terminal end(112) has been read on the claimed "down stream side".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1797

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 29702825 (cited by Applicant and "DE" hereafter) in view of Klimov et al.

DE teaches a base to hold test strip and has been read on the claimed base.

DE is silent to the claimed test strips having a control zone.

See Klimov et al. supra.

Kilmov et al. teach a test strip to be used in a similar device that has a test zone, a control zone and a second absorbent pad as presently claimed. It is advantageous to use a test strip with a control zone to gain the advantages of greater confidence in the test results. This greater confidence is especially important when drug testing employees because an incorrect results could result in the termination of the employee. It would have been within the skill of the art to modify DE in view Klimov et al. and use the taught test strips to gain the advantages of having a control zone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

Lyle A Alexander
Primary Examiner
Art Unit 1797

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

Notice of References Cited	Application/Control No. 11/650,280	Applicant(s)/Patent Under Reexamination LEE, JIN PO	
	Examiner Lyle A. Alexander	Art Unit 1797	Page 1 of 1

U.S. PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-7,347,972	03-2008	Lee, Jin Po	422/58
*	B US-6,730,268	05-2004	Lee et al.	422/58
*	C US-6,548,019	04-2003	Lee et al.	422/58
*	D US-6,379,620	04-2002	Tydings et al.	422/58
	E US-			
	F US-			
	G US-			
	H US-			
	I US-			
	J US-			
	K US-			
	L US-			
	M US-			


FOREIGN PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N 29702825	05-1994	DE		
	O				
	P				
	Q				
	R				
	S				
	T				

NON-PATENT DOCUMENTS

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	
V	
W	
X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes 	Application/Control No. 11650280	Applicant(s)/Patent Under Reexamination LEE, JIN PO
	Examiner Lyle A Alexander	Art Unit 1797

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
east	4/3/09	LAA
co-pending application 11/401,193	4/3/09	LAA
parent application 10/019,570	4/3/09	LAA

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

--	--



19 BUNDESREPUBLIK
DEUTSCHLAND

12 Gebrauchsmuster
10 DE 297 02 825 U 1

51 Int. Cl. 6:
B01L 9/00
// G01N 30/80



DEUTSCHES
PATENTAMT

21	Aktenzeichen:	297 02 825.1
22	Anmeldetag:	19. 2. 97
27	Eintragungstag:	10. 4. 97
28	Bekanntmachung im Patentblatt:	22. 5. 97

Handwritten: N/A: GOIN 35100

DE 297 02 825 U 1

73 Inhaber:
The Ultimate Pharma & Health Products GmbH,
22926 Ahrensburg, DE

74 Vertreter:
Harmsen & Utescher, Rechtsanwälte,
Patentanwälte, 20087 Hamburg

113014 U.S. PTO
11/401193



5 Teststreifenhalter

DE 297 02 825 U 1

BEST AVAILABLE COPY

Teststreifenhalter

Die Erfindung betrifft einen Teststreifenhalter für Chromatographie-teststreifen.

5

Seit langem ist der Nachweis bestimmter Stoffe in Flüssigkeiten, wie z. B. in Blut oder Urin, durch das Eintauchen von präparierten Teststreifen bekannt. Solche Teststreifen bestehen üblicherweise aus einem Kunststoffträger, auf dem ein saugendes Trägermaterial aufgebracht ist, das die Flüssigkeit aufsaugt und einem Nachweisfeld zuführt. Bei positivem Ausgang des Tests, d.h. bei Vorhandensein des nachzuweisenden Stoffes in der Flüssigkeit, verfärbt sich der Nachweisbereich.

10

Solche Teststreifen werden seit langem als Schwangerschaftstest, aber auch als Diabetestest oder bei der Behandlung von Drogenabhängigen eingesetzt, die in regelmäßigen Abständen nachweisen müssen, daß sie keine Rauschmittel eingenommen haben. Beispielsweise Barbiturate und Alkaloide lassen sich innerhalb einer gewissen Zeitspanne nach der Zufuhr in den menschlichen Körper im Urin nachweisen.

15

In der Praxis hat diese Nachweismethode, insbesondere bei der Behandlung von Drogenabhängigen, jedoch einige Nachteile. Die verwendeten Teststreifen eignen sich jeweils nur für den Nachweis eines bestimmten Stoffes. Bei Personen, bei denen davon auszugehen ist, daß sie verschiedene Rauschmittel konsumieren, muß der Test also mit verschiedenen Nachweisstreifen durchgeführt werden. Die Streifen sind üblicherweise im oberen Bereich auf der Trägerrückseite markiert. Um Verwechslungen zu verhindern, muß jede Streifenserie, also jeder einzelne Streifen zusätzlich

20

25

-2-

mit dem Namen der getesteten Person beschriftet werden. Diese Arbeit erfordert eine erhebliche Zeit, die im Praxisablauf nicht immer vorhanden ist. Außerdem besteht die Gefahr, daß die Aufschrift mit der aggressiven Flüssigkeit in Verbindung kommt und verwischt.

5

Darüber hinaus bestehen für die mit der Durchführung der Tests betrauten Personen neben hygienischen Problemen auch ernstzunehmende gesundheitliche Gefahren beim Umgang mit infizierten Körperflüssigkeiten.

10 Außerdem können die offenliegenden Nachweisfelder der Teststreifen leicht bei einem Manipulationsversuch beschädigt werden. Dies ist möglicherweise nicht immer sofort offensichtlich.

Aufgabe der vorliegenden Erfindung ist es, die oben geschilderten
15 Schwierigkeiten, insbesondere beim Test mit mehr als einem Teststreifen, zu vermeiden.

Erfindungsgemäß wird ein Halter für Teststreifen vorgeschlagen, der dadurch gekennzeichnet ist, daß ein oder mehrere Teststreifen in passende
20 Aussparungen des Halters derartig einlegbar sind, daß der Teststreifen mit dem in die Probe zu tauchenden Ende aus dem Halter hervorsteht.

Dadurch wird ermöglicht, daß der Streifen auf hygienische Art und Weise in die Probe eingetaucht werden kann. Im Falle, daß eine Nachweismöglichkeit
25 für mehrere Stoffe gewünscht wird, können auch mehrere Streifen in den Halter eingelegt und dann gleichzeitig in die Probe eingetaucht werden. Mehrere Arbeitsgänge werden so zu einem Arbeitsgang zusammengefaßt.

-3-

Auf dem Halter besteht dann die Möglichkeit, in übersichtlicher Art und Weise die analysierten Stoffe, das Testergebnis und -datum sowie den Namen der untersuchten Person zu vermerken. Die Gefahr, daß die Aufschrift verwischt, kann erheblich reduziert werden.

5

In einer bevorzugten Weiterbildung der Erfindung wird das im Halter befindliche Ende, das dem in die Probe einzutauchenden Ende gegenüber liegt, gegen einen Anschlag geschoben. Dadurch ist gewährleistet, daß alle Streifen, deren Größe genormt ist, um die gleiche Länge aus dem Halter

10

Vorzugsweise wird der Halter als Kunststoffplatte mit streifenförmigen Vertiefungen ausgeführt. Diese Vertiefungen sind bevorzugt so tief, wie die Teststreifen dick sind. Die Teststreifen können dann in den Halter

15

Eine solche Klebefolie kann im Bereich der Nachweisfelder der Streifen

20

Die Klebefolie bzw. der Halter sind vorzugsweise beschriftbar. Sie können

25

4

Halter oder der Klebefolie auch die Bedeutung der Verfärbung des Nachweisfeldes erklärt sein. Zusätzlich können Halter oder Folie beschriftbar sein, um das Untersuchungsergebnis und -datum sowie den Patientennamen bzw. eine laufende Identifikationsnummer aufzubringen.

5 Bezüglich anderer bevorzugter Ausführungsformen wird auf die Unteransprüche Bezug genommen.

Die Erfindung wird im folgenden anhand der beigefügten Abbildungen an
10 einem Beispiel näher erläutert:

Fig. 1 zeigt einen erfindungsgemäßen Halter in perspektivischer Darstellung.

15 Fig. 2 zeigt eine selbstklebende Abdeckfolie zur Fixierung der Teststreifen im erfindungsgemäßen Halter.

Fig. 3 zeigt einen erfindungsgemäßen Halter mit fünf eingelegten Teststreifen.

In Fig. 1 ist der Halter 1 zu sehen, der als flache Kunststoffplatte mit fünf
20 streifenförmigen Vertiefungen ausgeführt ist. Diese Vertiefungen haben beispielsweise eine Breite von 5,8 mm, was in etwa der Breite es handelsüblichen Teststreifens entspricht. Diese Vertiefungen sind um genau das Maß vertieft, das der Dicke eines handelsüblichen Teststreifens entspricht. Die handelsüblichen Teststreifen sind etwa 75 mm lang. Die
25 Vertiefungen im Halter sind so gewählt, daß das Ende des Teststreifens, das in die Probe eingetaucht werden muß, aus dem Halter heraussteht. Es bietet sich beispielsweise eine Länge von 65 mm für die Vertiefungen an. Die

2007

-5-

Vertiefungen sind durch die Stege 3 voneinander beabstandet. Hier kann etwa ein Abstand von 2,75 mm gewählt werden. Jeder größere Abstand ist unproblematisch, hingegen sollte der Abstand der Streifen nicht zu eng gewählt werden, damit die Streifen nicht miteinander in Berührung geraten.

5

Die in Fig. 2 gezeigte selbstklebende Abdeckfolie 4 ist auf ihrer Rückseite selbstklebend. Sie wird auf den Halter 1 mit den eingelegten Teststreifen aufgeklebt und fixiert so die Streifen in ihrer Position. Die Abdeckfolie weist Klarsichtfenster 5 im Bereich der Anzeigefelder der Teststreifen auf. Die Anzeigefelder sind damit abgedeckt und gegen Manipulationen und Zerstörung gesichert. Weiterhin verfügt die Abdeckfolie über bereits vorher beschriftete oder im Einzelfall beschriftbare Felder 6, in die sich der vom Streifen nachgewiesene Stoff eintragen läßt. Darüber hinaus hat die Abdeckfolie noch Felder 7, auf denen eine Bedienungsanleitung aufgebracht oder aufbringbar ist, sowie Felder 8, auf denen die möglichen Ergebnisanzeigen dargestellt sind. Außerdem ist noch ein freies Feld vorhanden, auf dem Testdatum und Patient, oder auch Werbung aufgebracht werden kann.

10

15

20

In Fig. 3 ist ein fertig präparierter Teststreifenhalter 1 mit aufgebrachtener Abdeckfolie 4 sowie eingelegten Teststreifen 10a bis 10e dargestellt.

2007

Schutzansprüche

1. Halter für Teststreifen, dadurch gekennzeichnet, daß ein oder mehrere Teststreifen (10) in passende Aussparungen (2) des Halters (1) derart einlegbar sind, daß der Teststreifen (10) mit dem in die Probe zu tauchenden Ende aus dem Halter (1) hervorsteht.
5
2. Teststreifenhalter nach Anspruch 1, dadurch gekennzeichnet, daß das dem einzutauchenden Ende gegenüberliegende Ende des Teststreifens (10) gegen einen Anschlag (11) im Halter (1) schiebbar ist.
10
3. Teststreifenhalter nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß der Halter (1) Aussparungen (2) für zwei bis zehn, insbesondere drei bis sechs Streifen (10) aufweist.
15
4. Teststreifenhalter nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß der Halter (1) eine Kunststoffplatte mit streifenförmigen Vertiefungen (2) ist.
- 20 5. Teststreifenhalter nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Teststreifen (10) in den Halter (1) einklemmbar sind.
- 25 6. Teststreifenhalter nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Teststreifen (10) in den Halter (1) einklebbar sind.

-2-

7. Teststreifenhalter nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß der Halter (1) mit einer einseitigen Klebefolie (4) abdeckbar ist.
- 5 8. Teststreifenhalter nach Anspruch 7, dadurch gekennzeichnet, daß die Klebefolie (4) zur Fixierung der Teststreifen (10) am Halter (1) dient.
9. Teststreifenhalter nach Anspruch 7 oder 8, dadurch gekennzeichnet, daß die Klebefolie (4) wenigstens im Bereich (5) der Nachweisfelder der
10 Streifen (10) transparent ist.
10. Teststreifenhalter nach einem der Ansprüche 7 bis 9, dadurch gekennzeichnet, daß die Klebefolie (4) beschriftet oder beschriftbar ist.

15

GESAMT SEITEN 10

2007

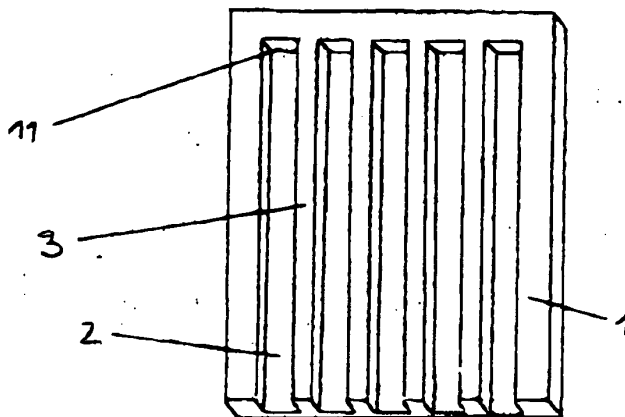


Fig. 1

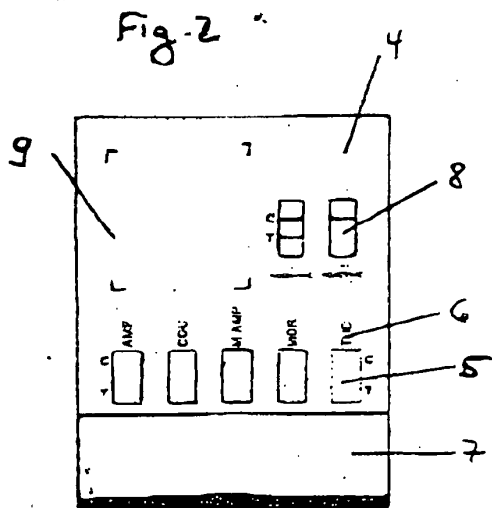


Fig. 2

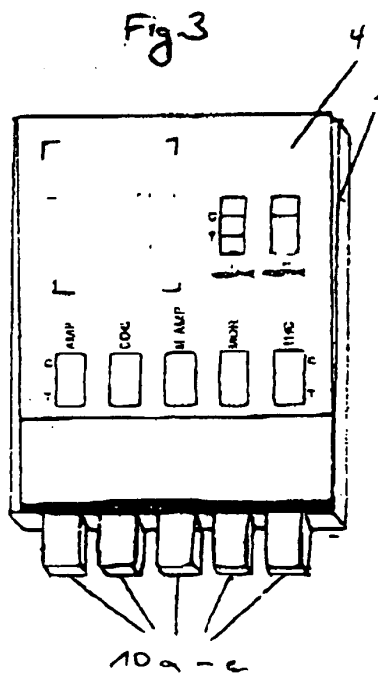


Fig. 3

THIS PAGE BLANK (USP 11)

VOSSIUS & PARTNER

Patentanwälte

PATENTANWÄLTE
EUROPEAN PATENT ATTORNEYS
EUROPEAN TRADEMARK ATTORNEYS
Dr. VOLKER VOSSIUS, Dipl.-Chem.
(bis 1992; danach in anderer Kanzlei)
5 Dr. PAUL TAUCHNER, Dipl.-Chem.
Dr. DIETER HEUNEMANN, Dipl.-Phys.
Dr. PETER A. RAUH, Dipl.-Chem.
Dr. GERHARD HERMANN, Dipl.-Phys.
JOSEF SCHMIDT, Dipl.-Ing.
Dr. HANS-RAINER JAENICHEN, Dipl.-Biol.
Dr. ALEXA VON UEXKÜLL, M.Sc.
Dr. RUDOLF WEINBERGER, Dipl.-Chem.
10 Dr. WOLFGANG BUBLAK, Dipl.-Chem.
AXEL STELLBRINK, Dipl.-Ing.
Dr. JOACHIM WACHENFELD, (Biol.)

EUROPEAN PATENT ATTORNEY
Dr. RENATE BARTH, Dipl.-Chem.

RECHTSANWÄLTE
HELGA TREMMEL
15 BARBARA GUGGENMOS, Dipl.-Chem.

SIEBERTSTRASSE 4
81676 MÜNCHEN

POB 880767
81634 MÜNCHEN
GERMANY

TELEFON: +49-89-4 13 04-0
FAX G3: +49-89-4 13 04-111
FAX G4: +49-89-4 13 04-101

20 Potential Opposition
German Utility Model DE 297 02 825 U1
Our Ref.: PA-1332/24

hg

25 **English translation of German Utility Model DE 297 02 825 U1**

30 Test strip holder

The invention is directed to a test strip holder for chromatography test strips.

35 It has long been known to prove the presence of certain substances in liquids, such as blood or urine, by dipping prepared test strips into them. Such test strips are usually made of a plastic carrier onto which an absorbing substrate material is coated; the substrate material absorbs the liquid and shows it to a test display. If the result of the
40 test is positive, i.e. if the substance to be detected is

present in the liquid, the test display shows a change in color.

Such test strips have long been used as pregnancy tests, diabetes tests or in the treatment of drug addicts, who have to show at regular intervals that they do not have taken any drugs. Barbiturates and alkaloids, for instance, may be detected in urine within a certain time after having been fed to the human body.

10

The test method, however, has some drawbacks, in particular when used in the treatment of drug addicts. The test strips may be employed for detecting only one certain substance. On persons who are supposed to have consumed several drugs, the test has to be carried out with different test strips. The strips are usually marked in the upper portion on the carrier back. Each series of strips, i.e. every single strip, needs to be inscribed with the name of the tested person in order to avoid mixing up of the strips. This task requires considerable time which is not always available in the surgery. There is also the danger that the inscription gets in contact with the aggressive liquid and is blurred.

20

Furthermore, the persons in charge of carrying out the tests are faced with hygienic problems as well as serious health risks when handling infected body liquids.

25

Also, the open displays of the test strips may easily be damaged in a manipulation attempt. This may not always be discovered at once.

30

It is the object of the present invention to avoid the difficulties discussed above, in particular with more than one test strip.

5 The invention proposes a holder for test strips which is characterized in that one or more test strips can be inserted into corresponding recesses of the holder such that the test strip protrudes with the end to be dipped into the sample.

10

Thus the strip may be dipped into the sample in a hygienic manner. If the presence of several substances is to be tested, several strips may be inserted into the holder and then simultaneously dipped into the sample. Several method
15 steps are thus summarized into one single step.

The holder offers the possibility of clearly inscribing the analyzed substances, the test result and date as well as the names of the persons tested. The danger of blurred
20 inscriptions is reduced considerably.

In a preferred embodiment of the invention, the end in the holder which is opposite the end to be dipped into the sample is pushed against a stop. This ensures that all
25 strips of a standard size protrude by the same length.

The holder is preferably designed as a plastic plate with strip-like indentations. These indentations preferably are as deep as the test strips are thick. The test strips may
30 then be clamped into the holder. Another alternative is to fix a film over the holder and strips which is adhesive on one side and holds the test strips in their position.

Such an adhesive film may comprise transparent recesses where the test displays of the strips are located, which can then be viewed. The test displays are thus secure against manipulations and destruction.

5

Preferably, the adhesive film and the holder may be written upon. They may be industrially produced, prefabricated test sets with, e.g., two to ten, in particular with three to six, test strips and inscribed with the names of the analyzed substances. The holder or the adhesive film may also comprise an explanation of what the change in color of the test display means. The holder and the film may also be inscribable in order to show the test result, date and the name of the patient or a serial identification number.

15

As regards other preferred embodiments, reference is made to the subclaims.

20

One example of the invention will be discussed now in more detail with respect to the attached drawings.

Fig. 1 is a perspective view of a holder according to the invention.

25

Fig. 2 shows a self-adhesive cover film for fixing the test strips in the holder according to the invention.

30

Fig. 3 shows a holder according to the invention with five inserted test strips.

Fig. 1 shows the holder 1 as a flat plastic plate with five strip-like indentations. These indentations have, e.g.,

a width of 5.8 mm, which corresponds approximately to the width of conventional test strips. The size of the indentations corresponds to the thickness of a conventional test strip. Conventional test strips are about 75 mm long.

5 The length of the indentations in the holder is chosen such that the end of the test strip to be dipped into the sample protrudes from the holder. The indentations may, e.g., have a length of 65 mm and are separated from each other by the webs 3. The distance may be about 2.75 mm but even a larger

10 distance may be chosen; however, the distance of the strips should not be too narrow so that the strips do not contact each other.

The cover film 4 shown in Fig. 2 is self-adhesive on its back. It is glued on the holder 1 with the inserted test strips and thus fixes the strips in their position. The cover film comprises transparent windows 5 over the test displays of the test strips. The test displays fields are thus covered and secured against manipulations and

15 destruction. The cover film further has displays 6 already inscribed or inscribable, if desired, where the substance detected by the strip may be written upon. The cover film also has displays 7, where instructions may be attached or

20 are attachable, as well as displays 8, where the possibly indicated results are shown. Furthermore, there is a free display for showing the test date and patient or advertisements.

Fig. 3 shows a readily prepared test strip holder 1 with the

30 attached cover film 4 and inserted test strips 10a to 10e.

Claims

1. A holder for test strips, characterized in that one or several test strips (10) are insertable into corresponding recesses (2) of the holder (1) such that the test strip (10) protrudes from the holder with its end to be dipped into the sample.
2. The test strip holder according to claim 1, characterized in that the end of the test strip (10) opposite the end to be dipped into the sample is slideable against a stop (11) in the holder (1).
3. The test strip holder according to claims 1 or 2, characterized in that the holder (1) comprises recesses (2) for two to ten, in particular three to six strips (10).
4. The test strip holder according to any one of claims 1 to 3, characterized in that the holder (1) is a plastic plate with strip-like xxx (2).
5. The test strip holder according to any one of claims 1 to 4, characterized in that the test strips (10) are clampable into the holder (1).
6. The test strip holder according to any one of claims 1 to 4, characterized in that the test strips (10) are gluable into the holder (1).
7. The test strip holder according to any one of claims 1 to 6, characterized in that the holder (1) is coverable with a one-side adhesive film (4).

8. The test strip holder according to claim 7, characterized in that the adhesive film (4) serves for fixing the test strip (10) on the holder (1).
9. The test strip holder according to claim 7 or 8, characterized in that the adhesive film (4) is transparent at least in the area (5) of the detection fields of the strip (10).
10. The test strip holder according to any one of claims 7 to 9, characterized in that the adhesive film (4) is inscribed or inscribable.

8

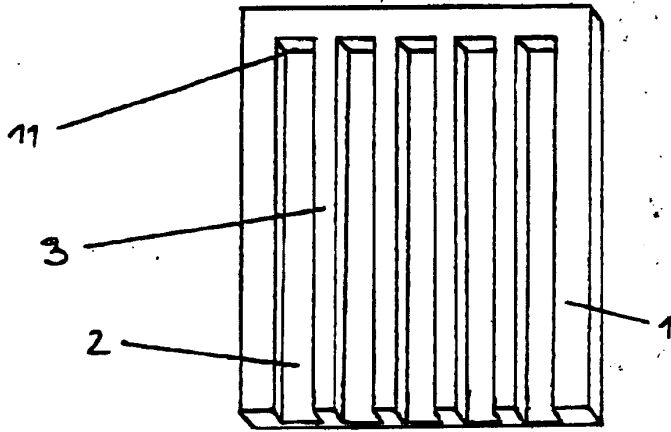


Fig. 1

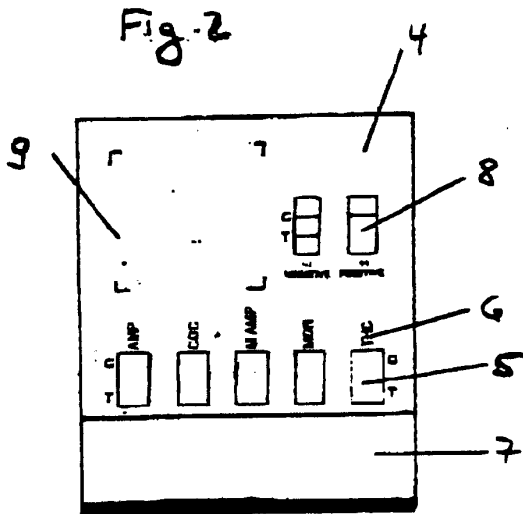


Fig. 2

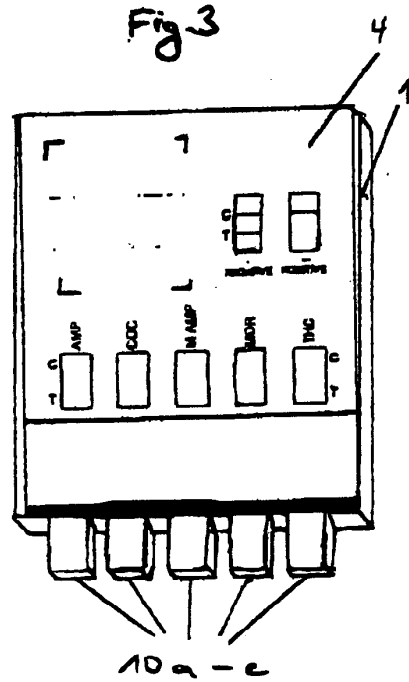


Fig. 3

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER: _____**

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO <h2 style="text-align: center; margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center; margin: 0;">(Use as many sheets as necessary)</p>	Complete if Known												
Sheet <input type="text" value="1"/> of <input type="text" value="1"/>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">Application Number</td><td style="width: 50%;"></td></tr> <tr><td>Filing Date</td><td></td></tr> <tr><td>First Named Inventor</td><td>Jin Po Lee</td></tr> <tr><td>Art Unit</td><td></td></tr> <tr><td>Examiner Name</td><td></td></tr> <tr><td>Attorney Docket Number</td><td>BWS 06-12</td></tr> </table>	Application Number		Filing Date		First Named Inventor	Jin Po Lee	Art Unit		Examiner Name		Attorney Docket Number	BWS 06-12
Application Number													
Filing Date													
First Named Inventor	Jin Po Lee												
Art Unit													
Examiner Name													
Attorney Docket Number	BWS 06-12												

U. S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-	Number-Kind Code ² (if known)			
LAI ↓ ↓ ↓ ↓ ↓ ↓	A-1	US-	6,403,557	04/04/95	Galloway et al	
	A-2	US-	5,976,895	11/02/99	Cipkowsky, Stay	
	A-3	US-	4,518,565	05/21/85	Boger et al	
	A-4	US-	4,056,359	11/11/77	Tanin, Pierre	
	A-5	US-	6,514,769	09/02/02	Lee Jin Po	
	A-6	US-	5,770,458	06/23/98	Kimtov et al	
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				

RELEVANCE

The cited references relate to assay devices involving multiple test strips.

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ²	Number ⁴ Kind Code ⁵ (if known)				

Examiner Signature	/Lyle Alexander/	Date Considered	04/02/2009
--------------------	------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	14	"5403551".pn. or "5976895". pn. or "4518565".pn. or "4056359". pn. or "6514769".pn. or "5770458". pn.	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/04/03 10:02
L2	456265	lee.in.	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/04/03 10:03
L3	27	tydings.in.	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/04/03 10:09
L4	2	"7347972".pn.	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/04/03 10:35

4/ 3/ 09 10:56:25 AM

C:\ Documents and Settings\ LAlexander\ My Documents\ EAST\ Workspaces\ Default
EAST Workspace 1600x1200.wsp

(E-mail: billandt@chartermi.net)

RECEIVED
CENTRAL FAX CENTER

APR 22 2009

Fax

Date	04-22-2009	From:	B.W. Sandt
To:	Mr. Lyle Alexander US Patent & Trademark Office	Phone	(989) 631-6852
cc		Fax	(989) 835-6030
Fax:	1-571-273-8300 1-571-273-1254	Pages:	10
Phone:		Re:	SN 11/650/280

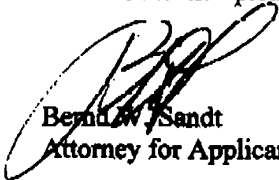
Urgent For Review Please Comment Please Reply Please Recycle

Unless otherwise indicated, or obvious from the nature of this transmittal, the information contained in this fax is **Confidential**, intended for the use of only the person or entity named above. If the reader of this message is not the intended recipient, he is hereby notified that any dissemination, distribution or copying of this message is strictly prohibited. If this message has been received in error, please immediately notify the sender and delete all copies received from the original copy to the sender at sender's expense.

Message

Applicant: Jin Po Lee
Serial No: 11/650,280
Filed: 01-05-2007
From: Multinational Development & Patent Services

Attached please find applicant's response to the Office Action dated 04-06-2009.


Bernard W. Sandt
Attorney for Applicant

PAGE 1/1 * RCVD AT 4/22/2009 2:06:21 PM [Eastern Daylight Time] * SVR:USPTO-EFAX-4/12 * DNIS:2738300 * CSID:9898356030 * DURATION (mm-ss):02-14

BEST AVAILABLE COPY

RECEIVED
CENTRAL FAX CENTER

APR 22 2009

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Jin Po Lee
Serial No: 11/650,280
Filed: 01/05/2007
For: Multiple Analyte Assay Device
Group Art Unit: 1797 **Examiner:** L. A. Alexander

Commissioner for Patents
P.O Box 1450
Alexandria, VA 22313-1450

RESPONSE A

In response to the Office Action dated 04/06/2009 please amend the claims as set forth in the attached listing of claims.

In response to the double patenting rejection of applicant's claims over US Patent No. 7,347,972 applicant submits that the attached terminal disclaimer.

Applicant's claims have also been rejected on the ground of non-statutory obviousness double patenting as being unpatentable over the claims of US Patent No. 6,514,769, 6,730,268, 6,548,019 and 6,379,620 in view of Klimov US 5,770,458. Applicant's terminal disclaimer is effective to disclaim any extension of any patent resulting from this application beyond the expiration date of applicant's '972 patent. By virtue of this disclaimer any patent resulting from this application will expire either at the same time or before the expiration dates of the patents listed. Although applicant is not adverse to limiting the term of any patent resulting from this application to the expiration dates of the listed patents, additional disclaimers are believed to be redundant and unnecessary. The double patenting rejection is furthermore traversed with respect to US Patents 6,514,769, 6,548,019 and 6,379,620.

- 1 -

SN11/650,280
BWS 06-12

The patents claim a device involving a container fully enclosing any test strips. The test strips do not protrude from the container with the protruding ends freestanding and do not allow for direct contact of the sample with the sample pad of each test strip.

Applicant's claims have been rejected under 35 USC 102 (b) as being anticipated by Klimov et al, US patent No. 5,770,458 (hereafter Klimov). Klimov relates to an assay in which the assay strips are totally encased in the assay housing and in which all strips contained in the assay housing are fed the analyte solution to be analyzed by a single pad stretching across all assay strips. Thus Klimov fails to disclose or suggest the concept of a freestanding, protruding test strip end containing an sample addition pad that can be immersed into a sample solution. Furthermore even though the assay strips appear to be maintained in the housing without contacting each other, it is not clear that if excess sample exudes from a test strip in the housing, cross contamination of the adjacent assay strips is prevented. Such contamination could have a radical effect on the reliability of the test results. It appears that in order to actually supply samples to the assay strips in Klimov, pressure has to be applied to the sample pad by means of squeezing a flexible rubber cover in order to get the assay sample to flow into the assay strip.

In applicant's assay device on the other hand each assay strip protrudes out of the housing and maintains its integrity not only in the housing but also above the housing. By having the assay strips protrude out of the housing and being free standing each test strip will acquire its own sample for analysis by directly absorbing a sample amount from the sample through capillary action from the sample addition pad in the free standing portion of the test strip. Similarly within the housing each strip is maintained in its separate compartment to prevent cross contamination of the analyses being conducted. In applicant's assay strip furthermore capillary action is the sole means necessary to transport the sample through the strip to obtain the test results. No additional pressure is necessary as is the case in Klimov. Furthermore such additional pressure could cause the sample to exude from the strip and cause cross contamination.

- 2 -

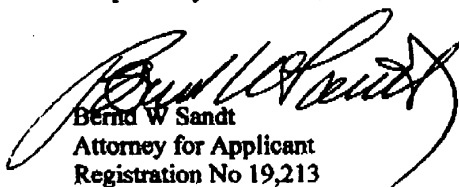
SN11/650,280
BWS 06-12

It is clear that the advantage of applicant's device is the ease with which it can be used while still providing integrity to the assay results. Thus the sample does not have to be placed in a special vessel before the analysis can be performed. In applicant's device all that needs to be done is to remove the cap and for the protruding ends of the test strips to be dipped into the sample for a time sufficient for the strips to absorb sufficient of the analyte solution to conduct the assay. The protruding parts of the assay strips are further protected from physical damage as well as contamination by the cap over the freestanding parts of the assay strips none of which is disclosed in Klimov.

It is believed well-established law that in order to anticipate the reference must show every element of the claimed invention (see decisions cited in MPEP 2131). Klimov fails to disclose or suggest the protruding freestanding assay strips of applicant's claims, fails to suggest a removable cap to protect the protruding portions of the assay strips, and fails to suggest the integrity of the analysis in each assay strip by failing to disclose or suggest separate compartments for each assay strip. Applicant's claims are deemed to be patentable over Klimov.

Applicant's claims have also been rejected under 35 USC 103a as unpatentable over DE 29702825 (DE) in view of Klimov et al. The combination fails to suggest a removable cap over the freestanding portion of the test strips protruding over the housing to protect the test strips from damage and contamination.

Respectfully submitted,



Bernd W Sandt
Attorney for Applicant
Registration No 19,213

- 3 -

SN11/650,280
BWS 06-12

Claim Status

Claims 1-8 cancelled.

9. (New) A device for assaying a fluid for the presence or absence of different analytes comprising:

(A) a base having adjacent slots therein of sufficient length for insertion of part of a test strip therein, wherein each slot is defined by (a) a floor, (b) raised walls depending upwardly from the floor to separate each adjacent slot from the next, and (C) at least one open end,

(B) a multiplicity of test strips having an upstream and a downstream end, wherein a single test strip is inserted into each slot of the base so the upstream end of each test strip protrudes out of the open end of each slot, and wherein each test strip has a test zone and a control zone therein, and each test zone contains a binder specific for a different analyte; the protruding freestanding end of each test strip containing a sample addition pad for direct contact with the fluid to be analyzed;

(C) a cover attached to the upwardmost surface of each raised wall of the slots of the base and extending to the open end of said base, wherein the cover retains the test strips within the slots and has a first transparent window formed therein through which the test zone and the control zone of each of the test strips can be viewed and

(D) a cap enclosing the protruding ends of the test strips and removably attached to the open end of said base.

10. (New) The device according to Claim 9 further comprising a second transparent window formed within the cover through which the test strips can be viewed.

11. (New) The device according to Claim 9 further comprising a multiplicity of test strips inserted into each slot of the base, wherein each test strip has a test zone therein and each test zone contains a binder specific for a different analyte.

12. (New) The device according to Claim 11 wherein each binder is specific for a different drug of abuse.

- 1 -

BWS 06-12
SN 11/650,280

13. (New) The device according to Claim 11 wherein each test zone is visible through the first transparent window of the cover.

14. (New) The device according claim 11 each test strip further comprises a label downstream of the test zone, which label identifies the analyte for which the binder is specific.

15. (New) The device according to claim 14, wherein the label on the test strip is visible through the second transparent window of the cover.

16. (New) The device according to Claim 12 wherein the drug of abuse is from the group consisting of methamphetamine, opiates/morphine, marihuana/tetrahydrocannabinol, amphetamine, cocaine/benzoylcegonine, methadone, PCP, barbituate, trichloroacetic acid and benzodaizepine.

17. (New) A method for detecting a multiplicity of analytes which comprises removing the cap from the device of claim 9 and inserting the protruding ends of the test strips into a sample to be analyzed and observing the effect of the sample on the test and control zones of the test strips contained in the device..

- 2 -

BWS 06-12
SN 11/650,280

APR 22 2009

PTO/SB/28 (03-06)

Approved for use through 04/30/2009. OMB 0661-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
a collection of information unless it displays a valid OMB control number.

**TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING
REJECTION OVER A "PRIOR" PATENT**

Docket Number (Optional)
BWS06-12

In re Application of: Jin Po Lee

Application No.: 11/650,280

Filed: 01/05/2007

For: Multiple Analyte Assay Device

The owner, Jin Po Lee of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term prior patent No. 7,347,972 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
 expires for failure to pay a maintenance fee;
 is held unenforceable;
 is found invalid by a court of competent jurisdiction;
 is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
 has all claims canceled by a reexamination certificate;
 is released; or
 is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

- 1. For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

- 2. The undersigned is an attorney or agent of record. Reg. No. 19,213

Bernd W. Sandt Signature 04/22/09 Date
Bernd W. Sandt
Typed or printed name

869 631 6652
Telephone Number

- Terminal disclaimer fee under 37 CFR 1.20(d) included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1480, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1480, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

04/23/2009 HHARZ12 00000003 190135 11650280

01 FC:2814 70.00 DA

APR 22 2009

PTO/SB/17 (10-08)

Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 1/30/2004. Fees pursuant to the Consolidated Appropriations Act, 2008 (H.R. 4818). FEE TRANSMITTAL For FY 2009		Complete if Known	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Application Number: SN 11/850,280	Filing Date: 01-04-2007
TOTAL AMOUNT OF PAYMENT (\$) 70.00		First Named Inventor: Lin Po Lee	Examiner Name: L. A. Alexander
		Art Unit: 1797	Attorney Docket No.: BWS 08-12

METHOD OF PAYMENT (check all that apply)

Check
 Credit Card
 Money Order
 None
 Other (please identify): _____

Deposit Account
 Deposit Account Number: 190135
 Deposit Account Name: Bernd W. Sandt

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below
 Charge fee(s) indicated below, except for the filing fee

Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.18 and 1.17
 Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-8588.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	330	165	540	270	220	110	
Design	220	110	100	50	140	70	
Plant	220	110	330	165	170	85	
Reissue	330	165	540	270	650	325	
Provisional	220	110	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	52	26
Each independent claim over 3 (including Reissues)	220	110
Multiple dependent claims	390	195

Total Claims **Extra Claims** **Fee (\$)** **Fees Paid (\$)** **Multiple Dependent Claims**

- 20 or MP = _____ x _____ = _____ **Fee (\$)** **Fees Paid (\$)**

HP = Highest number of total claims paid for, if greater than 20.

Indep. Claims **Extra Claims** **Fee (\$)** **Fees Paid (\$)**

- 3 or HP = _____ x _____ = _____

MP = Highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$270 (\$135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets **Extra Sheets** **Number of each additional 50 or fraction thereof** **Fee (\$)** **Fees Paid (\$)**

- 100 = _____ / 50 = _____ (round up to a whole number) x _____ = _____

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount) **Fees Paid (\$)**

Other (e.g., late filing surcharge): Terminal Disclaimer **Fees Paid (\$)** 70.00

SUBMITTED BY

Signature: <i>Bernd W. Sandt</i>	Registration No. (Attorney/Agent): 19213	Telephone per 831 6852
Name (Print/Type): Bernd W. Sandt		Date: 04-22-2009

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1460.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

RECEIVED
CENTRAL FAX CENTER

APR 22 2009

Sandt & Associates
 900 Deerfield Court
 Midland, MI 48640
 (E-mail: billsandt@chartermi.net)

Fax

Date	04-22-2009		
To:	Mr. Lyle Alexander US Patent & Trademark Office	From:	B.W. Sandt
cc		Phone	(989) 631-6852
Fax:	1-571-273-8300 1-571-273-1254	Fax	(989) 835-6030
Phone:		Pages:	10
Re:	SN 11/650/280		

Urgent For Review Please Comment Please Reply Please Recycle

Unless otherwise indicated, or obvious from the nature of this transmittal, the information contained in this Fax is **Confidential**, intended for the use of only the person or entity named above. If the reader of this message is not the intended recipient, he is hereby notified that any dissemination, distribution or copying of this message is strictly prohibited. If this message has been received in error, please immediately notify sender and destroy all copies and return the original copy to the sender at sender's expense.

Message

Applicant: Jin Po Lee
 Serial No: 11/650,280
 Filed: 01-05-2007
 For: Multiple Analyte Assay Device
 Group Art Unit: 97 Examiner: Lyle. A. Alexander

Attached please find applicant's response to the Office Action dated 04-06-2009.



 Bernd W. Sandt
 Attorney for Applicant

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/650,280		Filing Date 01/05/2007		<input type="checkbox"/> To be Mailed		
APPLICATION AS FILED – PART I											
(Column 1)			(Column 2)		SMALL ENTITY <input checked="" type="checkbox"/> OR			OTHER THAN SMALL ENTITY			
FOR		NUMBER FILED	NUMBER EXTRA		RATE (\$)	FEE (\$)	OR		RATE (\$)	FEE (\$)	
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>		N/A	N/A		N/A		OR		N/A		
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>		N/A	N/A		N/A		OR		N/A		
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>		N/A	N/A		N/A		OR		N/A		
TOTAL CLAIMS <small>(37 CFR 1.16(j))</small>		minus 20 =	*		X \$ =		OR		X \$ =		
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>		minus 3 =	*		X \$ =		OR		X \$ =		
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>											
					TOTAL		OR		TOTAL		
* If the difference in column 1 is less than zero, enter "0" in column 2.											
APPLICATION AS AMENDED – PART II											
(Column 1)			(Column 2)		SMALL ENTITY OR			OTHER THAN SMALL ENTITY			
AMENDMENT	04/22/2009	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR		RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(i))</small>	* 9	Minus	** 20	= 0	X \$26 =	0	OR		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>	* 1	Minus	***3	= 0	X \$110 =	0	OR		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>										
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>										
					TOTAL ADD'L FEE	0	OR		TOTAL ADD'L FEE		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR		RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(i))</small>	*	Minus	**	=	X \$ =		OR		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>	*	Minus	***	=	X \$ =		OR		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>										
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>										
					TOTAL ADD'L FEE		OR		TOTAL ADD'L FEE		
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.											
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".											
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".											
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.											
						Legal Instrument Examiner: /KIM WATSON SAUNDERS/					

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Application Number 	Application/Control No. 11/650,280	Applicant(s)/Patent under Reexamination LEE, JIN PO	

Document Code - DISQ	Internal Document – DO NOT MAIL
-----------------------------	--

TERMINAL DISCLAIMER	<input checked="" type="checkbox"/> APPROVED	<input type="checkbox"/> DISAPPROVED
Date Filed : April 22, 2009	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
Henry D. Jefferson

U.S. Patent and Trademark Office



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/650,280	01/05/2007	Jin Po Lee	BWS 06-12	8521
46725	7590	06/26/2009	EXAMINER	
BERND W. SANDT 900 DEERFIELD COURT MIDLAND, MI 48640			ALEXANDER, LYLE	
			ART UNIT	PAPER NUMBER
			1797	
			MAIL DATE	DELIVERY MODE
			06/26/2009	PAPER

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.

Office Action Summary	Application No. 11/650,280	Applicant(s) LEE, JIN PO
	Examiner Lyle A. Alexander	Art Unit 1797

-- **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 22 April 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) 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

- 4) Claim(s) 9-17 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 9-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ 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).
- 11) 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

- 12) 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) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19; 1-15; 1-15; 1-5 of U.S. Patent No. 6,514,769; 6,730,268; 6,548,019; 6,379,620 in view of Kilmov (USP 5,770,458).

All of the patent with Mr. Lee as a common inventor teach a base for holding test strips that is indistinguishable from the claimed base by claimed a base to hold test strip.

These patents are silent to the claimed test strips having a test zone, a control zone and a second absorbent pad.

See the description of Klimov et al. below.

Kilmov et al. teach a test strip to be used in a similar device that has a test zone, a control zone and a second absorbent pad as presently claimed. It is advantageous to

use a test strip with a control zone to gain the advantages of greater confidence in the test results. This greater confidence is especially important when drug testing employees because an incorrect results could result in the termination of the employee. It would have been within the skill of the art to modify U.S. Patent No. 6,514,769; 7,347,972; 6,730,268; 6,548,019; 6,379,620 in view of Kilmov (USP 5,770,458) and use the taught test strips to gain the advantages of having a control zone.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 29702825 (cited by Applicant and "DE" hereafter) in view of Klimov et al.

DE teaches a base to hold test strip and has been read on the claimed base.

DE is silent to the claimed test strips having a control zone.

See Klimov et al. supra.

Kilmov et al. teach a test strip to be used in a similar device that has a test zone, a control zone and a second absorbent pad as presently claimed. It is advantageous to use a test strip with a control zone to gain the advantages of greater confidence in the test results. This greater confidence is especially important when drug testing employees because an incorrect results could result in the termination of the employee. It would have been within the skill of the art to modify DE in view Klimov et al. and use the taught test strips to gain the advantages of having a control zone.

Response to Arguments

Applicant's arguments filed 4/22/09 have been fully considered but they are not persuasive.

Applicant's 4/22/09 terminal disclaimer obviated the obviousness type of double patenting rejections over USP 7,347,972.

Applicant's amendments have obviated the 35 USC 102(b) rejections over Kilmov et al.

No other grounds of rejection were traversed. The Office maintains all of the rejections of record are proper.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

Lyle A Alexander
Primary Examiner
Art Unit 1797

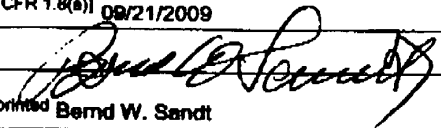
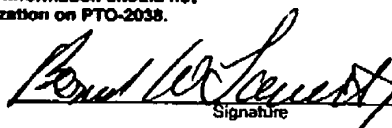
/Lyle A Alexander/
Primary Examiner, Art Unit 1797

RECEIVED
CENTRAL FAX CENTER
SEP 21 2009

PTO/SB/31 (07-09)

Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

NOTICE OF APPEAL FROM THE EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES		Docket Number (Optional) BWS 6-12	
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>09/21/2009</u>		In re Application of Jin Po Lee	
Signature  Typed or printed name Bernd W. Sandt		Application Number 11/650280	Filed 01/05/2007
		For Multiple Analyte Assay Device	
		Art Unit 1797	Examiner Alexander, Lyle
Applicant hereby appeals to the Board of Patent Appeals and Interferences from the last decision of the examiner.			
The fee for this Notice of Appeal is (37 CFR 41.20(b)(1))		\$ <u>540.00</u>	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is:		\$ <u>270.00</u>	
<input type="checkbox"/> A check in the amount of the fee is enclosed.			
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.			
<input type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account.			
<input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. <u>190135</u>			
<input type="checkbox"/> A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.			
WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.			
I am the			
<input type="checkbox"/> applicant/inventor.		Signature	
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)		Typed or printed name Bernd W. Sandt	
<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>19213</u>		Telephone number 989 631 6852	
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____		Date 09/21/2009	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.			
<input type="checkbox"/> *Total of _____ forms are submitted.			

This collection of information is required by 37 CFR 41.31. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1460.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

09/22/2009 HMARZ11 00000004 190135 11650280

01 FC:2401 270.00 DA

RECEIVED
CENTRAL FAX CENTER
SEP 21 2009

Sandt & Associates
900 Deerfield Court
Midland, MI 48640
(E-mail: billsandt@chartermi.net)

Fax

Date	09-21-2009		
To:	Mr. Lyle Alexander US Patent & Trademark Office	From:	B.W. Sandt
cc		Phone	(989) 631-6852
Fax:	1-571-273-8300 1-571-273-1254	Fax	(989) 835-6030
Phone:		Pages:	2
Re:	SN 11/850/280		

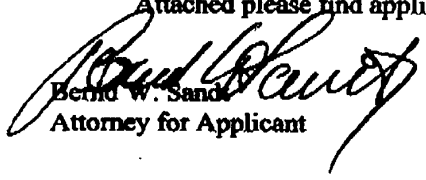
Urgent For Review Please Comment Please Reply Please Recycle

Unless otherwise indicated, or obvious from the nature of this transmittal, the information contained in this Fax is **Confidential**, intended for the use of only the person or entity named above. If the reader of this message is not the intended recipient, he is hereby notified that any dissemination, distribution or copying of this message is strictly prohibited. If this message has been received in error, please immediately notify sender and destroy all copies and return the original copy to the sender at sender's expense.

Message

Applicant: Jin Po Lee
Serial No: 11/650,280
Filed: 01-05-2007
For: Multiple Analyte Assay Device
Group Art Unit: 1797 Examiner: Lyle. A. Alexander

Attached please find applicant's notice of appeal to the Board


Bernd W. Sandt
Attorney for Applicant



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Jin Po Lee
Serial No: 11/650,280
5 Filed: 01/05/2007
For: Multiple Analyte Assay Device
Group Art Unit:1797 Examiner: L.A. Alexander

10 Hon. Commissioner for Patents
& Trademarks,
Washington, D.C. 20231

RECEIVED
NOV 20 2009
TC 1700

15

Appeal Brief under 37 CFR 1.191

Appellant files this brief in support of its appeal in the subject application:

20 Real party

The real party in interest is the named inventor, Jin Po Lee.

Related matters

Appellant issued US patent No. 6,514,769 and 7,347,942 from the same
25 PCT parent application PCT/US98/15,369 as is the case in this
application. A terminal disclaimer has been filed for US Patent No.
7347,942, which contains a terminal container for US Patent No.
6,514,769.

- 1 -

Appeal SN 11/650,280
BWS 06-12

11/16/2009 EFLORES 0000015 11650280
01 FC:2432 270.00 OP

Jurisdictional Statement

This is an appeal from the final rejection of the Examiner to the Board of Patent Appeals and Interferences as provided by 35 USC 134 (a).

5

Grounds of Rejection to be Reviewed

The appealed claims 9-17 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over US Patent Nos. 6,514,679, 6,730,268, 6,548,019 and 6,679,620 in view of Klimov et al US Patent No. 5,770,458.

10

The appealed claims 9-17 have been further rejected as unpatentable under 35 USC 103(a) over DE 29702825 in view of Klimov et al US Patent No. 5,770,458.

15 Status of Amendments

No amendments or changes were filed following the final rejection.

	<u>Table of Contents</u>	Page
	Real party	1
20	Related Matters	1
	Jurisdictional Statement	2
	Grounds of rejection to be reviewed	2
	Status of Amendments	2
	Table of Authorities	3
25	Statement of Fact	3
	Argument	7
	Claim Support and Drawings	5
	Means or step plus function	9

Table of Authorities

KSR International Co. v. Teleflex Inc., 550 US ___, 82 USPQ1385 (2207)

5 Cited at page ____

In re Kahn, 441 F.3d 977, 78 USPQ 2d 1329 (Fed. Cir. 2006)

Cited at Page ____

Status of the Amendments,

10 No amendments or changes were filed following the final rejection of the claims.

Statement of Fact

15 (1) The device of the appealed claims comprises a housing for multiple analyte assay test strips in which the test strips containing a sample addition pad extend beyond the housing and a removable cap over the exposed, free standing portions of the test strips {Fig. 1, 2 and pages 9-11}.

20 (3) This application is a division of US Patent No. 7,347,972 (the '972 patent) and is owned by the same entity. Appellant filed a terminal disclaimer removing the double patenting rejection over the '972 patent. The '972 patent contains a terminal disclaimer over US Patent No. 6,514,769 (the '769 patent). The claims of the '972 patent relate to the same device as claimed here, except that the claims of the '972 patent are
25 limited to a cap having an opening in communication with the test strips of the device {Claim 1, column 12, lines 6-15 Figs.4A, 4B}.

(4) US Patent No. 6,514,769 owned by the same entity as the current application on appeal is derived from the same parent application and

claims a multiple analyte assay device of generally the same construction except that the device contains a sample integrity monitoring system {Claim 1, column 14, lines 12 to 21} comprising a test strip inserted in conjunction with the analyte test strip in the same channel.

5 (5) US patents Nos. 6,548,019 (the '019 patent) and US patent No. 6,730,268 (the '268 patent) are owned by the same entity as the application on appeal. The '019 patent claim a multiple analyte detection device in which analyte detection test strips are totally encased in multiple flow channels except for an opening for the sample to contact
10 each test strip. {Claim 1, column 8, lines 49-54} The encased flow channel is disposed inside in a container such that the opening is at the bottom of the container {Claim 1, column 8, lines 55-58}. The '268 patent claims exactly the same device as the 019 patent, except that the opening to the encased flow channels containing the test strips is at the
15 top of the container, such that the container would have to be inverted for the sample to reach the test strips {Claim 1, column 9, lines 1-4}.

(6) US Patent No. 6,379,620 (the '620 patent) claims multiple analyte assay device in which the test strips are inserted in flow channels formed against a backing wall and extend out of the channel and are attached to
20 the back of the wall back of the wall {Claim 1, column 8, lines 31-36, Fig.1}. The back of the wall contains wicking means whereby the sample is wicked to the test strips attached to the back of the wall. The assembly is placed inside a container similar to the container in the '019 patent.

(7) US Patent No. 5,770,458 to Klimov et al (Klimov) also shows a
25 multiple analyte assay device in which the test strips are totally encased in the channels within the container {Fig. 1A, and Fig. 1B, column 10 lines 21-46}. The examiner relies on this reference as disclosing the particular construction of the test strips {Fig. 1D} used in appellant's

device. Appellant admits that the construction of the test strip itself is not novel.

(8) DE 297 02 825 is a German utility model patent which discloses a multiple analyte assay device in which the assay test strips extend beyond the housing for the test strips which are contained in channels in the housing {Fig 3, page 4 of translation lines 29-30}. The patent does not disclose any kind of cap or cover for the exposed parts of the test strips

Claim Support and Drawing Analysis (Summary of Invention).

10 The present invention provides a biological assay device for simultaneously but separately analyzing for multiple analytes in a fluid sample. The device comprises {page 9, lines 2-12; Fig. 1} a generally flat housing base {Fig 1, 101} containing a number of parallel slots {Fig 1, 102 A-E}, each separated by a wall or rail {Fig. 1, 103 A-D}, allowing
15 different test strips to be placed between the walls in the slots {Fig. 1, 102 A-E}. The test strips {Fig. 1, 105 A-E} contain different binders, antibodies and labels to allow for the visual testing of different analytes {page 9, lines 18-22; Fig1, 112, 113}. The strips extend beyond the housing so as to allow contact of a sample with the sample absorption pad
20 of the strips {page 9, lines 13-22, Fig. 2, 102 A-E}. To protect the integrity of each assay test the housing is equipped with a cover {page 11, lines 5-14, Fig. 1, 110}, and containing windows {Fig. 1, 111} to allow for the viewing of the results in the test and control zones of the analytical assay strip {page 9 lines 19-23; Fig. 2, 112, 113} inserted in the housing.
25 In addition the device contains a further removable cap {page 11, lines 19-24; Fig. 1, 120}, which encloses the protruding ends of the test strips.

The key feature of the claimed invention is that it minimizes any contamination of and damage to the various assay strips. With the cap

on, the exposed strips are protected during transport and any contact between the operator of the test and the sample is further reduced. As applied to the independent claims the reference to the specification and drawings is as follows:

- 5 9. A device for assaying a fluid for the presence or absence of different analytes {page 9 lines 2-18, Fig. 1, 2} comprising:
- (A) a base having adjacent slots therein of sufficient length for insertion of part of a test strip therein {Fig 1, **101**}, wherein each slot is defined by (a) a floor, (b) raised walls {Fig. 1 **103 A-D**} depending
- 10 upwardly from the floor to separate each adjacent slot from the next {Fig. 1 **102 A-E**}, and at least one open end {Fig. 1 **106**},
- (B) a multiplicity of test strips {Fig. 1, **105 A-E**} having an upstream and a downstream end, wherein a single test strip is inserted into each slot of the base so the upstream end of each test strip protrudes out of the
- 15 open end of each slot {Fig 2. **102 A-E**}, and wherein each test strip has a test zone and a control zone therein, and each test zone contains a binder specific for a different analyte Fig. 1 **112, 113**}; the protruding freestanding end of each test strip containing a sample addition pad for direct contact with the fluid to be analyzed {page 9, line 18 to page 10,
- 20 line 9}
- (C) a cover attached to the upward most surface of each raised wall of the slots of the base and extending to the open end of said base {page 11.lines 3-14, Fig 1, **110**} wherein the cover retains the test strips within the slots and has a first transparent window formed therein through which
- 25 the test zone and the control zone of each of the test strips can be viewed {Fig.1, **111**} and
- (D) a cap enclosing the protruding ends of the test strips and removably attached to the open end of said base {page 11 lines 19-25, Fig. 1, **120**}

17. A method for detecting a multiplicity of analytes which comprises removing the cap from the device of claim 9 {page 11, lines 19-24} and inserting the protruding ends of the test strips into a sample to be analyzed and observing the effect of the sample on the test and control
5 zones of the test strips contained in the device {page 9, lines 13-18}.

Argument

The Examiner has rejected appellant's claims 9-17 on the basis of obviousness double patenting over US Patent No. 6,514,769 (the '769
10 patent) in view of Klimov et al US Patent No. 5,770,458 (Klimov). Appellants filed a terminal disclaimer to overcome a double patenting rejection with respect to US Patent No. 7,347,972, (the '972 patent), of which US 6,514,769 (the '769 patent) is a continuation-in-part. Thus both patents terminate on the same date as based on their relationship
15 and thus there is no extension in the term of these two patents. Further the '972 patent is subject to a terminal disclaimer with respect to the '769 patent. Thus since the '972 patent has terminal disclaimer over '769 patent and the present application contains a terminal disclaimer over the '972 patent, any patent issuing from this application would also be
20 terminally disclaimed over the '769 patent.

The Examiner has further rejected appellant's claims on the basis of double patenting over US Patents Nos. 6,730,268 (the '268 patent), 6,548,019 (the '019 patent), and 6,739,620 (the '620 patent) in view of Klimov. The examiner argued that these patents are properly cited
25 because they teach a base for holding the test strips, as do the appealed claims. However the examiner ignored the substantially different construction of the test bases involved in the cited patents and as defined by the appealed claims. Thus in both the '268 and the '019 patent the test

strips are enclosed in a channel and a backing (Fig. 5) which is inserted into a container (Fig. 6), whereas in the appealed claim the test strips are freestanding extending beyond the housing (Fig. 2). Thus the housings for the test strips are significantly different and the examiner has cited no evidence that persons skilled in the art would modify the housing for the test strips claimed in the '268 and in the '019 patent so that the test strips extend beyond the housing in these patents. It is clear that the devices shown in the '268 and the '019 patent cannot be used in the same way as the device defined by the appealed claims. In the appealed claims the free ends of the device can be inserted directly into any sample whereas in the devices claimed in the '268 and '019 patent the sample must be inserted into the container in order for the strips to have contact with the sample. The '620 patent differs from the '268 and '019 patent in that the test strips extend over the back wall of the channels for the test strips (Fig. 3). The extended part is then attached to the back wall, and again the entire assembly is inserted into a container. No freestanding test strip sections are disclosed and there is no reason for suggesting such. Hence the double patenting rejection should be reversed.

Klimov is cited by the examiner for the design of the test strip only. Appellant does not rely on the design of the test strip to support the argument that the double patenting rejection should be reversed.

Appellants claims 9-17 have been rejected as being unpatentable over DE 29702825 ("DE") in view of Klimov et al US Patent No 5,770,458, above identified as Klimov.

Klimov is cited by the examiner as disclosing the type of test strip with a control zone as is employed in the assay device claimed by appellant. As already indicated, appellant does not rely on the construction of the test strip to support the patentability of the appealed claims. The examiner

stated that DE teaches a base to hold the test strips, which is argued to read on the claimed base. The statement is not correct since the claimed base includes a removable cap over the freestanding test strips protruding out of the base. In the absence of any argument to the contrary this modification must be deemed to be patentable. If in fact it would be obvious to supply such a cap it would have been disclosed in the reference. The inclusion of such a cap is only obvious on hindsight. Furthermore a mere conclusory statement that it would be obvious does not meet the burden to demonstrate such. As the Supreme Court stated in *KSR International Co. v. Teleflex Inc* 550 US at ___, 82 USPQ2d 1385 at 1396, citing *In re Kahn*, 441 F3d 977, at 988, 78 USPQ2d 1329, at 1336, (Fed. Cir. 2006)

“Rejections on obviousness can not be sustained by mere conclusory statement; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”

It is submitted that the final rejection of the Examiner of claims 9-17 fails to meet this test of the Supreme Court, nor do the references cited provide the required rational underpinning to support a rejection of appellant’s claims on the basis of obviousness.

Means or step plus function analysis

There are no means or step plus function claims involved in this appeal.

Conclusion

It is submitted that the references fails to disclose or suggest all of the elements of the claimed device and its use and thus make obvious the

claimed subject matter. A reversal of the final rejection and an allowance of the appealed claims is therefore requested.

Respectfully submitted,

5



Bernd W Sandt

Attorney for Appellant
Registration No 19,213

10

900 Deerfield Court,
Midland, MI 48640
Tel: (989) 631-6852
Fax: (989) 835 6030

15

Certificate under 37 CFR 1.8

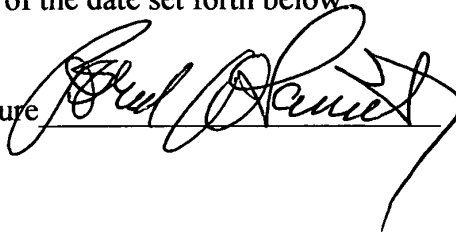
I hereby certify that a copy of the foregoing brief being deposited with the United States Postal Service by Express Mail addressed Mail Stop: ~~Appeal Brief - Patents~~ ^{SPB}Patents, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, as of the date set forth below.

20

Date:

11/13/2009

Signature



Claim Appendix
Claims on Appeal

9. A device for assaying a fluid for the presence or absence of
5 different analytes comprising:
- (A) a base having adjacent slots therein of sufficient length for
insertion of part of a test strip therein, wherein each slot is defined by (a)
a floor, (b) raised walls depending upwardly from the floor to separate
each adjacent slot from the next, and (C) at least one open end,
- 10 (B) a multiplicity of test strips having an upstream and a downstream
end, wherein a single test strip is inserted into each slot of the base so the
upstream end of each test strip protrudes out of the open end of each slot,
and wherein each test strip has a test zone and a control zone therein, and
each test zone contains a binder specific for a different analyte; the
15 protruding freestanding end of each test strip containing a sample
addition pad for direct contact with the fluid to be analyzed;
- (C) a cover attached to the upward most surface of each raised wall of
the slots of the base and extending to the open end of said base, wherein
the cover retains the test strips within the slots and has a first transparent
20 window formed therein through which the test zone and the control zone
of each of the test strips can be viewed and
- (D) a cap enclosing the protruding ends of the test strips and removably
attached to the open end of said base.
- 25 10. The -device according to Claim 9 further comprising a second
transparent window formed within the cover through which the test strips
can be viewed.

11. The device according to Claim 9 further comprising a multiplicity of test strips inserted into each slot of the base, wherein each test strip has a test zone therein and each test zone contains a binder specific for a different analyte.
- 5
12. The device according to Claim 11 wherein each binder is specific for a different drug of abuse.
13. The device according to Claim 11 wherein each test zone is visible
10 through the first transparent window of the cover.
14. The device according claim 3 each test strip further comprises a label downstream of the test zone, which label identifies the analyte for which the binder is specific.
- 15
15. The device according to claim 14, wherein the label on the test strip is visible through the second transparent window of the cover.
16. The device according to Claim 12 wherein the drug of abuse is
20 from the group consisting of methamphetamine, opiates/morphine, marihuana/tetrahydrocannabinol, amphetamine, cocaine/benzoylecgonine, methadone, PCP, barbituate, trichloroacetic acid and benzodaizepine.
- 25 17. A method for detecting a multiplicity of analytes which comprises removing the cap from the device of claim 9 and inserting the protruding ends of the test strips into a sample to be analyzed and observing the

effect of the sample on the test and control zones of the test strips contained in the device.

Evidence Appendix

- 5 1. US. Patent No. 5,770,458 to Klimov al cited by Examiner in the initial office action dated 11-26-2005. (Part of prosecution history file)
2. US Patent No 7347,972 issued Jin Po Lee originally cited in the initial action of Examiner. (Part of prosecution history file)
- 10 3. US Patent No. 6,514,769 issued to Jim Po lee originally cited in the initial office action of the Examiner. (Part of prosecution history file)
- 15 4. Us Patent No. 6,730,268 assigned to Jin Po Lee originally cited by the Examiner in the initial office action. (Part of prosecution history file)
- 20 5. US Patent No. 6,548,019 assigned to Jin Po Lee, originally cited by the Examiner in the initial office action. (Part of prosecution history file)
- 25 6. US Patent No. 6,379,620 jointly owned by Jin Po Lee, originally cited by the Examiner in the initial action. (Part of prosecution history file)
7. Terminal disclaimer over US Patent No. 7,347,972. (Part of prosecution history file)
- 30 8. Terminal disclaimer over US Patent No. 6,514,769. (Attached)
9. German utility model DE29702825 and translation cited by appellant. (Part of prosecution history file)



PTO/BB/26 (09-04)

Approved for use through 07/31/2008. OMB 0951-0031 U.S. Patent and Trademark Office U.S. DEPARTMENT OF COMMERCE

TERMINAL DISCLAIMER TO OBTAIN A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION

Doclet Number (Optional)
BWS 05-01

In re Application of: Jin Po Lee

Application No.: 10/019,670

Filed: 11/9/2001

For: Multiple Analyte Assay Device

The owner, Jin Po Lee, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number 09/314,277 filed on 7/27/1999, as such term is defined in 35 U.S.C. 154 and 173, and as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is renewed, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Check either box 1 or 2 below, if appropriate.

- For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements made or made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

- The undersigned is an attorney or agent of record. Reg. No. 19,213

[Signature]
Signature

NOV 20 2005
TC 1700
2-14-2005
Date

Bernad W. Sandt
Typed or printed name

689 831 6952
Telephone Number

- Terminal disclaimer fee under 37 CFR 1.20(f) is included.
charge to: Account 190 135

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2033.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/BB/08 may be used for making this statement. See MPEP § 304.

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the form and/or suggestions for reducing this burden. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9100 and select option 2.

BEST AVAILABLE COPY



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/650,280	01/05/2007	Jin Po Lee	BWS 06-12	8521
46725	7590	07/21/2010	EXAMINER	
BERND W. SANDT			ALEXANDER, LYLE	
900 DEERFIELD COURT			ART UNIT	PAPER NUMBER
MIDLAND, MI 48640			1797	
			MAIL DATE	DELIVERY MODE
			07/21/2010	PAPER

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.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 11/650,280
Filing Date: January 05, 2007
Appellant(s): LEE, JIN PO

Mr. Bernd Sandt
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/13/09 appealing from the Office action mailed 6/26/09.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

9-17

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,730,268	Lee et al.	5-2004
6,548,019	Lee et al.	4-2003
5,770,458	Klimov et al.	6-1998
6,514,769	Lee	2-2003
6,379,620	Tydings et al.	4-2002

DE 29702825, 5-1997

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19; 1-15; 1-15; 1-5 of U.S. Patent No. 6,514,769; 6,730,268; 6,548,019; 6,379,620 in view of Klimov (USP 5,770,458).

The primary patents all have Mr. Lee as a common inventor and each teaches a device for holding test strips that is indistinguishable from the claimed device to hold test strips. However, these patents are silent to the test strips within the device having a control zone.

Klimov et al. teach a test strip used in a similar device that has a test zone, a control zone and a second absorbent pad as presently claimed. It is advantageous to use a test strip with a control zone to gain the advantages of greater confidence in the test results. This greater confidence is especially important when drug testing employees because an incorrect results could result in the termination of the employee. It would have been within the skill of the art to modify U.S. Patent No. 6,514,769; 6,730,268; 6,548,019; 6,379,620 in view of Klimov (USP 5,770,458) and use the taught test strips to gain the advantages of having a control zone.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 29702825 (cited by Applicant and "DE" hereafter) in view of Klimov et al.

DE teaches on page 3 lines 5+ a holder to support multiple different test strips for drug testing. Each test strip is inserted into a corresponding recess of the holder such that each test strip protrudes from the end of the holder. Figure 1 show the holder(1). Figure 2 shows the cover(4) with an area for instructions(7), transparent windows(5) that permit viewing of the test strip results and an additional display window(8). Figure 3 shows the test device(1) with the protruding test strips(10a-c). The claimed "base" has been read on the taught **--base(1)--**, the claimed "multiplicity of test strips ..." has been read on the taught **--test strip(10a-c)--** and the claimed "cover" has been read on the taught **--cover(4)--**. However, DE is silent to the claimed test strips having a control zone and a cover over the ends of the test strips.

Klimov teaches test strips in a holder device to simultaneously detect different analytes from a single sample that is similar to the instant claims. Column 10 lines 20-

31 describe figures 1A –B as a device that carries three different analyte specific test strips in a plastic holder(102). Column 6 lines 5+ teach each test strip has a first and second absorbent materials that are juxtaposed to each other to facilitate fluid flow through the absorbent materials. Column 7 lines 5-15 teach the test strips are suitable for test drugs of abuse. Columns 7-8 lines 66-11 teach each strip has a control site. Column 10 lines 32-56 teach seal(110) covers and the sample pad(109) and the sealing or covering of the test strips(101) is advantageous to prevent leakage of the sample.

It is advantageous to use a test strip with a control zone to gain the advantages of greater confidence in the test results. This greater confidence is especially important when drug testing employees because an incorrect results could result in the termination of the employee. Additionally, sealing or covering the sample pads is advantageous to keep potential contaminants away from the test pads and prevent leakage that could adversely influence the results.

It would have been within the skill of the art to modify DE in view Klimov et al. and use the taught test having a control zone and a cover to gain the above advantages of confidence in the integrity of the test results.

(10) Response to Argument

Appellant traverses the obviousness type double patenting rejections over USP 6,514,769 in view of Klimov et al. on the basis a terminal disclaimer for USP 7,347,972 has been filed and both the 6,514,769 and 7,347,972 patent terms terminate on the same date. Therefore, the double patenting rejection over 6,514,769 should be vacated because there would not be any extension term of the 6,514,769 in light of the terminal

disclaimer of 7,347,972. These remarks are not convincing because each patent must be terminally disclaimed to overcome the double patenting rejections.

Appellant traverses the obviousness type double patenting rejections of 6,730,268; 6,548,019 or 6,379,620 in view of Klimov et al. based upon structural differences. Specifically, Appellant states the '268 and '019 patents teach inserting the test strip holding device into a container whereas the instant claims are directed to a "freestanding" housing. The instant claim language is open (e.g. comprising) and does not exclude additional elements, such as the additional containers, that are taught by the '268 and '019 patents. The Office maintains the instant claim language is sufficiently broad to have been properly read on the '268 and '019 patents.

Appellant states the '620 patent differs from the instant claims in that the test strips extend over the back wall of the channel. Again, the Office notes the instant claim language is open (e.g. comprising) and does not exclude the test strips extending over the back wall of the channel. The Office maintains the obviousness type double patenting rejections of 6,514,769; 6,730,268; 6,548,019 or 6,379,620 in view of Klimov et al. are all proper and should be maintained.

In the last paragraph on page 8 Appellant characterizes Klimov et al. "as disclosing the type of test strip with a control zone as is employed in the assay device claimed by Appellant ... Appellant does not rely on the construction of the test strip to support the patentability of the appealed claims." The Office has interpreted these statements as Appellant acknowledging the test strip taught by Klimov et al. is indistinguishable from the presently claimed test strips with a test zone and a control

zone. Appellant states in the same paragraph that continues on page 9 the 35 USC 103 rejection of DE in view of Klimov et al. is untenable because DE fails to teach a cap to cover the protruding test strips are presently claimed. Appellant state there is not motivation of record to include a cap. The Office maintains Klimov et al. teaches sealing the ends of the test strips "to prevent leakage" which has constructively been read on a cap. Additionally notes that caps or covers are notoriously well known in the analytical test art to keep contaminants away from a test strip that could compromise the results.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1797

Conferees:

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

/PATRICK RYAN/
Supervisory Patent Examiner, Art Unit 1795

Sandt & Associates
900 Deerfield Court
Midland, MI 48640
(E-mail: bw.sandt@sandt-associates.com)

Fax

Date	09-01-2010		
To:	Board of Patent Appeals and Interferences US Patent & Trademark Office	From:	B.W. Sandt
cc		Phone	(989) 631-6852
Fax:	1-571-273-0053	Fax	(989) 835-6030
Phone:		Pages:	5
Re:	SN 11/650/280- Reply Brief		


Urgent For Review Please Comment Please Reply Please Recycle

Unless otherwise indicated, or obvious from the nature of this transmittal, the information contained in this Fax is **Confidential**, intended for the use of only the person or entity named above. If the reader of this message is not the intended recipient, he is hereby notified that any dissemination, distribution or copying of this message is strictly prohibited. If this message has been received in error, please immediately notify sender and destroy all copies and return the original copy to the sender at sender's expense.

Message

Applicant: Jin Po Lee
Serial No: 11/650,280
Filed: 01-05-2007
For: Multiple Analyte Assay Device
Group Art Unit: 1797 Examiner: Lyle. A. Alexander

Attached please find appellant's reply brief.


Brent W. Sandt
Attorney for Appellant

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Jin Po Lee

Serial No: 11/650,280

5 **Filed:** 01/05/2007

For: Multiple Analyte Assay Device

Group Art Unit: 1797

Examiner: L.A. Alexander

10

Hon. Commissioner for Patents

Washington, D.C. 20231

15

Reply Brief under 37 CFR 41.41

Appellant files this reply brief in response to the Examiner's Answer.

20 **The Double Patenting Rejection**

The Examiner has rejected appellant's claims on the basis of obviousness double patenting over US Patent No. 6,514,769 (hereafter the '769 patent) in view of Klimov et al US Patent No .5,770,458 (hereafter Klimov). Appellant has filed a terminal disclaimer over US Patent No. 25 7,347,972. US Patent No. 7,347,972 contains a terminal disclaimer over the '769 patent. If any part of the term of the '769 patent is disclaimed such disclaimer would disclaim that part of the term of the '972 patent which in turn would disclaim the same part of the term here. It is

**Reply brief
Appeal of SN 11/650,280
BWS 06-12**

therefore impossible for the term of a patent issued from the current application to extend beyond the term of the '769 patent.

The Examiner has cited no rule that requires redundant terminal disclaimers and has elevated form over substance.

- 5 The Examiner has also maintained his double patenting rejection of appellant's claims over US Patents Nos. 6,730,268, 6,548,019 and 6,379,620 in view of Klimov. Thus it is argued that each of these patents "teaches" a device for holding the test strips that is indistinguishable from the claimed device. However the standard in double patenting is not what
- 10 a patent teaches but what the patent claims. In that connection the Examiner argues that the instant claims are directed to a "freestanding housing". No such element exists in appellant's claims, which involve a free standing test strip extending beyond the housing. None of the commonly owned patents listed disclose, let alone claim, a freestanding
- 15 test strip extending beyond the housing, the claims of which are limited to test strips contained within the housing of the device. It should be noted that the same double patenting rejection would have been applicable to the claims of the '972 patent but was never raised. The Examiner argues that the instant claim language is open to include additional elements.
- 20 However appellant submits that there is no ambiguity of the wording in the claims in limiting the claims to devices containing free standing test strips extending beyond the housing of the base and that such language can not be extended to cover test strips fully contained with in a test strip container.
- 25 The secondary reference cited by the Examiner, Klimov, is cited for the existence in the prior art of a control zone on a test strip. The patentability of the appellant's claims does not reside in the use of a control zone, as disclosed in Klimov, but in the overall construction of the

device as claimed. Therefore the citation of Klimov does not provide an additional basis for the rejection.

Claim Rejection under 35 USC 103

- 5 The Examiner has maintained his rejection of the appealed claims as being unpatentable under 35 USC 103 over DE 29702825 (DE) in view of Klimov.

It is apparent that the devices disclosed in DE and in Klimov are very different. In DE the test strips extend beyond the housing whereas in
10 Klimov the test strips are contained in a sample cup. Because of the significantly different construction of the two devices, the combination is not justified.

The examiner argues that the sealing of the cup is advantageous to prevent leakage of the sample and to keep potential contaminants away.
15 Although the leakage problem is disclosed in the cited sections of the reference, the latter assertion of the examiner is not supported by the reference. Nothing in Klimov suggests that the sample needs to be protected from contamination that sealing a test strip would provide. The reference clearly teaches that the integrity of the results is obtained by
20 using a control zone and not by sealing the test strip. Therefore there is no suggestion for the need of a cap in Klimov. It is to be noted that both references have the same inventor and yet DE fails to suggest a cap over the exposed freestanding ends of the test strips.

The examiner has equilibrated the sealing of the test strips to prevent
25 leakage in Klimov with the cap in applicant's claims. However the examiner has ignored the limitation in the claims that the cap must be removable. In Klimov the seal is maintained as an integral part of the device and cannot be removed without destroying the functionality of the

Reply brief
Appeal of SN 11/650,280
BWS 06-12

- 3 -

device. The examiner argues that caps are notoriously well known in the analytical test art. If that were the case the Examiner should have been able to cite art showing the use of a cap instead of just asserting such without a reference. His failure to do so further supports the patentability
5 of the claims.

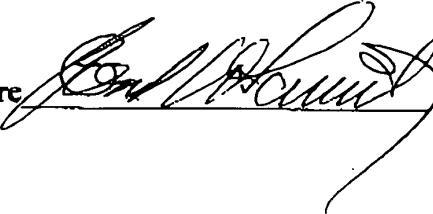
Respectfully submitted,

10 
Bernd W Sandt

Attorney for Appellant
Registration No 19,213
900 Doerfield Court,
Midland, MI 48640
15 Tel: (989) 631-6852
Fax: (989) 835 6030

Certificate under 37 CFR 1.8

20 I hereby certify that a copy of the foregoing reply brief was sent by facsimile to 571-273-0053, the number listed for the Board of Patent Appeals and Interferences on the date indicated below.

Date: 09-01-2010 Signature: 
25



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/650,280	01/05/2007	Jin Po Lee	BWS 06-12	8521
46725	7590	12/09/2010	EXAMINER	
BERND W. SANDT			ALEXANDER, LYLE	
900 DEERFIELD COURT			ART UNIT	PAPER NUMBER
MIDLAND, MI 48640			1773	
			MAIL DATE	DELIVERY MODE
			12/09/2010	PAPER

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.



UNITED STATES DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
11650280	1/5/07	LEE, JIN PO	BWS 06-12

BERND W. SANDT
900 DEERFIELD COURT
MIDLAND, MI 48640

EXAMINER

LYLE A. ALEXANDER

ART UNIT	PAPER
1773	20101207

DATE MAILED:

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

Commissioner for Patents

- The reply brief filed 9/1/10 has been entered and considered. The application has been forwarded to the Board of Patent Appeals and Interferences for decision on the appeal.

/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1773



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Table with columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
Row 1: 11/650,280, 01/05/2007, Jin Po Lee, BWS 06-12, 8521
Row 2: 46725, 7590, 12/22/2010, (Empty), (Empty)
Row 3: BERND W. SANDT, 900 DEERFIELD COURT, MIDLAND, MI 48640, (Empty), (Empty)
Row 4: (Empty), (Empty), (Empty), EXAMINER, (Empty)
Row 5: (Empty), (Empty), (Empty), ALEXANDER, LYLE, (Empty)
Row 6: (Empty), (Empty), (Empty), ART UNIT, PAPER NUMBER
Row 7: (Empty), (Empty), (Empty), 1773, (Empty)
Row 8: (Empty), (Empty), (Empty), MAIL DATE, DELIVERY MODE
Row 9: (Empty), (Empty), (Empty), 12/22/2010, PAPER

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.



United States Patent and Trademark Office

**Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office**
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BERND W. SANDT
900 DEERFIELD COURT
MIDLAND, MI 48640

Appeal No: 2011-003339
Application: 11/650,280
Appellant: Jin Po Lee

**Board of Patent Appeals and Interferences
Docketing Notice**

Application 11/650,280 was received from the Technology Center at the Board on December 13, 2010 and has been assigned Appeal No: 2011-003339.

In all future communications regarding this appeal, please include both the application number and the appeal number.

The mailing address for the Board is:

BOARD OF PATENT APPEALS AND INTERFERENCES
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VIRGINIA 22313-1450

The facsimile number of the Board is 571-273-0052. Because of the heightened security in the Washington D.C. area, facsimile communications are recommended. Telephone inquiries can be made by calling 571-272-9797 and referencing the appeal number listed above.

By order of the Board of Patent Appeals and Interferences.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
Row 1: 11/650,280, 01/05/2007, Jin Po Lee, BWS 06-12, 8521
Row 2: 46725, 7590, 08/10/2012, [EXAMINER], [ALEXANDER, LYLE]
Row 3: [ART UNIT], [PAPER NUMBER], [1773]
Row 4: [MAIL DATE], [DELIVERY MODE], [08/10/2012], [PAPER]

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.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JIN PO LEE

Appeal 2011-003339
Application 11/650,280
Technology Center 1700

Before BRADLEY R. GARRIS, TERRY J. OWENS, and
KAREN M. HASTINGS, *Administrative Patent Judges*.

OWENS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

The Appellant appeals under 35 U.S.C. § 134(a) from the Examiner's rejection of claims 9-17, which are all of the pending claims. We have jurisdiction under 35 U.S.C. § 6(b).

The Invention

The Appellant claims an assaying device and a method for using the device to detect analytes. Claim 9 is illustrative:

9. A device for assaying a fluid for the presence or absence of different analytes comprising:

(A) a base having adjacent slots therein of sufficient length for insertion of part of a test strip therein, wherein each slot is defined by (a) a floor, (b) raised walls depending upwardly from the floor to separate each adjacent slot from the next, and (C) [sic, (c)] at least one open end,

(B) a multiplicity of test strips having an upstream and a downstream end, wherein a single test strip is inserted into each slot of the base so the upstream end of each test strip protrudes out of the open end of each slot, and wherein each test strip has a test zone and a control zone therein, and each test zone contains a binder specific for a different analyte; the protruding freestanding end of each test strip containing a sample addition pad for direct contact with the fluid to be analyzed;

(C) a cover attached to the upward most surface of each raised wall of the slots of the base and extending to the open end of said base, wherein the cover retains the test strips within the slots and has a first transparent window formed therein through which the test zone and the control zone of each of the test strips can be viewed and

(D) a cap enclosing the protruding ends of the test strips and removably attached to the open end of said base.

The References

Klimov	US 5,770,458	Jun. 23, 1998
Tydings	US 6,379,620 B1	Apr. 30, 2002
Lee (Lee '769)	US 6,514,769 B2	Feb. 4, 2003
Lee (Lee '019)	US 6,548,019 B1	Apr. 15, 2003
Lee (Lee '268)	US 6,730,268 B2	May 4, 2004
DE '825	DE 297 02 825 U 1	May 22, 1997

The Rejections

Claims 9-17 stand rejected under 35 U.S.C. § 103 over DE '825 in view of Klimov and stand rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-19 of Lee '769 in view of Klimov, claims 1-15 of Lee '268 in view of Klimov, claims 1-15 of Lee '019 in view of Klimov, and claims 1-5 of Tydings in view of Klimov.

OPINION

We affirm the obviousness-type double patenting rejection over claims 1-19 of Lee '769 in view of Klimov and reverse the other rejections.

Rejection under 35 U.S.C. § 103

The Appellant's independent claims (9 and 17) require a cap enclosing protruding ends of test strips. To meet that claim requirement the Examiner relies upon Klimov's soft rubber seal (110) (Ans. 5-6).

Klimov's soft rubber seal (110) sits on top of a sample pad (109) inside a chromatographic assay device to prevent sample leakage when chromatographic membranes are installed vertically and the sample migrates in a downward direction (col. 10, ll. 41-49; Figs. 1A, 1B).

The Appellant argues that the Appellant's claims require a removable cap, whereas Klimov's soft rubber seal (110) is an integral part of the device

and cannot be removed without destroying the functionality of the device (Br. 9; Reply Br. 3-4).

The Examiner does not explain how Klimov would have rendered a removable cap prima facie obvious to one of ordinary skill in the art (Ans. 5-6, 8). Hence, we reverse the rejection under 35 U.S.C. § 103.

Obviousness-type double patenting rejections

The Appellant argues that the present application includes a terminal disclaimer over US 7,347,972 and that US 7,347,972 includes a terminal disclaimer over Lee ‘769 (Br. 7; Reply Br. 1). Thus, the Appellant argues, “since the ‘972 patent has [a] terminal disclaimer over [the] ‘769 patent and the present application contains a terminal disclaimer over the ‘972 patent, any patent issuing from this application would also be terminally disclaimed over the ‘769 patent” (Br. 7).

As indicated by the terminal disclaimer of the present application over US 7,347,972, a terminal disclaimer also requires that “[t]he owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned.” To acknowledge that agreement with respect to Lee ‘769, the Appellant must file a terminal disclaimer over that patent.

Hence, we affirm the obviousness-type double patenting rejection over claims 1-19 of Lee ‘769 in view of Klimov.

As for the other obviousness-type double patenting rejections, the Appellant argue that no claim in Lee ‘268, Lee ‘019 or Tydings recites a free standing test strip extending beyond a housing (Br. 7-8; Reply Br. 2).

The Examiner does not point out where any claim in Lee ‘268, Lee ‘019 or Tydings recites or would have suggested a free standing test

strip extending beyond a housing (Ans. 4, 7).¹ Accordingly, we reverse the obviousness-type double patenting rejections over claims 1-15 of Lee '268 in view of Klimov, claims 1-15 of Lee '019 in view of Klimov, and claims 1-5 of Tydings in view of Klimov.

DECISION/ORDER

The rejection of claims 9-17 under 35 U.S.C. § 103 over DE '825 in view of Klimov is reversed. The obviousness-type double patenting rejection of claims 9-17 over claims 1-19 of Lee '769 in view of Klimov is affirmed. The obviousness-type double patenting rejections of claims 9-17 over claims 1-15 of Lee '268 in view of Klimov, claims 1-15 of Lee '019 in view of Klimov, and claims 1-5 of Tydings in view of Klimov are reversed.

It is ordered that the Examiner's decision is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

tc/sld

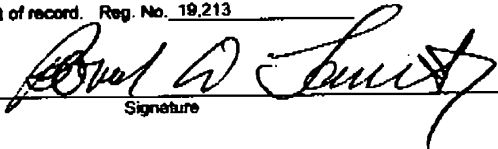
¹ The Examiner relies upon Klimov only for a disclosure of a test strip control zone (Ans. 4).

RECEIVED
CENTRAL FAX CENTER
AUG 20 2012

PTO/SB/26 (03-09)

Approved for use through 04/30/2009. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) BWS 06-12
In re Application of: <u>Jin Po Lee</u>	
Application No.: <u>11/650,280</u>	
Filed: <u>01/05/2007</u>	
For: <u>Multiple Analytic Assay Device</u>	
<p>The owner, <u>Jin Po Lee</u>, of <u>100</u> percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term prior patent No. <u>6,514,769</u> as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.</p>	
<p>In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer." In the event that said prior patent later:</p> <ul style="list-style-type: none"> expires for failure to pay a maintenance fee; is held unenforceable; is found invalid by a court of competent jurisdiction; is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; has all claims canceled by a reexamination certificate; is reissued; or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. 	
Check either box 1 or 2 below, if appropriate.	
<p>1. <input type="checkbox"/> For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.</p>	
<p>I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p>	
<p>2. <input checked="" type="checkbox"/> The undersigned is an attorney or agent of record. Reg. No. <u>19,213</u></p>	
 Signature	<u>8-20-2012</u> Date
<u>Bernd W. Sandt</u> Typed or printed name	
<u>989486-8454</u> Telephone Number	
<p><input checked="" type="checkbox"/> Terminal disclaimer fee under 37 CFR 1.20(d) included.</p>	
<p>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p>	
<p>*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP § 324.</p>	

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1460.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

RECEIVED
CENTRAL FAX CENTER
AUG 20 2012

Sandt & Associates
900 Deerfield Court
Midland, MI 48840
(E-mail: bwandt@sandt-associates.com)

Fax

Date	08-01-2010	From:	B.W. Sandt
To:	Board of Patent Appeals and Interferences US Patent & Trademark Office	Phone	(889) 631-6852
cc		Fax	(989) 835-6030
Fax:	1-571-273-0053 1-571-273-8300	Pages:	5
Phone:		Re:	SN 11/650/280- Request for Rehearing

Urgent For Review Please Comment Please Reply Please Recycle

Unless otherwise indicated, or obvious from the nature of this transmittal, the information contained in this Fax is ~~Confidential~~, intended for the use of only the person or entity named above. If the reader of this message is not the intended recipient, he is hereby notified that any dissemination, distribution or copying of this message is strictly prohibited. If this message has been received in error, please immediately notify sender and destroy all copies and return the original copy to the sender at sender's expense.

Message

Applicant: Jin Po Lee
Serial No: 11/650,280
Filed: 01-05-2007
For: Multiple Analyte Assay Device
Group Art Unit: 1797 Examiner: Lyle. A. Alexander

Attached please find appellant's request for Rehearing.


Bernd W. Sandt
Attorney for Appellant

RECEIVED
CENTRAL FAX CENTER
AUG 20 2012

IN THE UNITED STATES PATENT & TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND
INTERFERENCES

Applicant: Jin Po Lee
5 Serial No: 11/650,280
Filed: 01/05/2007
For: Multiple Analyte Assay Device
Group Art Unit:1797 Examiner: L.A. Alexander

10

Request for Rehearing under 37 CFR § 41.52

15

The decision of the Board of patent Appeals and Interferences
In the subject application affirms the Examiner in the rejection of the
appealed claims on the basis of the obviousness double patenting
20 rejection over claims 1-19 of Lee US Patent No. 6,514,769 in view of
Klimov.


It is respectfully requested that the Board reconsider its decision or
in the alternative remand the case to the examiner to consider the attached
terminal disclaimer, which should resolve the outstanding issue of the
25 appeal. Such resolution it is submitted does not require any substantive
consideration, but is merely a matter of form since the filing of the
terminal disclaimer removes the stated rejection of the appealed claims.

Request for Rehearing
Appeal of SN 11/650,280
BWS 06-12

- 1 -

RECEIVED
CENTRAL FAX CENTER
AUG 20 2012

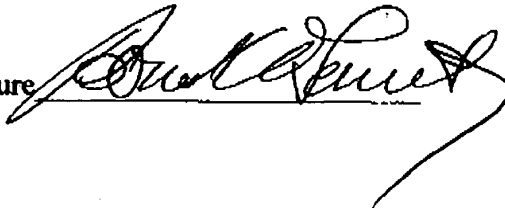
Respectfully submitted,

5 
Bernd W Sandt

Attorney for Appellant
Registration No 19,213
900 Deerfield Court,
Midland, MI 48640
10 Tel: (989) 486-8454
Fax: (989) 835 6030

Certificate under 37 CFR 1.8

15 I hereby certify that a copy of the foregoing REQUEST FOR
REHEARING was sent by facsimile to 571-273-0053, and to Patent
Office facsimile number the number listed for the Board of Patent
Appeals and Interferences on the date indicated below.

20 Date: 8-20-2012 Signature 

Request for Rehearing
Appeal of SN 11/650,280
BWS 06-12

Sandt & Associates
900 Deerfield Court
Midland, MI 48640
(E-mail: bw sandt@sandt-associates.com)

Fax

Date	09-01-2010		
To:	Board of Patent Appeals and Interferences US Patent & Trademark Office	From:	B.W. Sandt
cc		Phone	(989) 631-6852
Fax:	1-571-273-0053 1-571-273-8300	Fax	(989) 835-6030
Phone:		Pages:	5
Re:	SN 11/650/280- Request for Rehearing		

Urgent For Review Please Comment Please Reply Please Recycle

Unless otherwise indicated, or obvious from the nature of this transmittal, the information contained in this Fax is **Confidential**, intended for the use of only the person or entity named above. If the reader of this message is not the intended recipient, he is hereby notified that any dissemination, distribution or copying of this message is strictly prohibited. If this message has been received in error, please immediately notify sender and destroy all copies and return the original copy to the sender at sender's expense.

Message

Applicant: Jin Po Lee
Serial No: 11/650,280
Filed: 01-05-2007
For: Multiple Analyte Assay Device
Group Art Unit: 1797 Examiner: Lyle. A. Alexander

Attached please find appellant's request for Rehearing.


Bernd W. Sandt
Attorney for Appellant

IN THE UNITED STATES PATENT & TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND
INTERFERENCES

Applicant: Jin Po Lee

5 Serial No: 11/650,280

Filed: 01/05/2007

For: Multiple Analyte Assay Device

Group Art Unit: 1797

Examiner: L.A. Alexander

10

Request for Rehearing under 37 CFR § 41.52

15

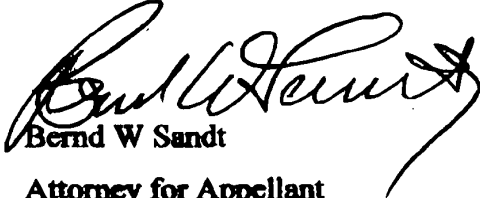
The decision of the Board of patent Appeals and Interferences
In the subject application affirms the Examiner in the rejection of the
appealed claims on the basis of the obviousness double patenting
20 rejection over claims 1-19 of Lee US Patent No. 6,514,769 in view of
Klimov.

It is respectfully requested that the Board reconsider its decision or
in the alternative remand the case to the examiner to consider the attached
terminal disclaimer, which should resolve the outstanding issue of the
25 appeal. Such resolution it is submitted does not require any substantive
consideration, but is merely a matter of form since the filing of the
terminal disclaimer removes the stated rejection of the appealed claims.

Request for Rehearing
Appeal of SN 11/650,280
BWS 06-12

- 1 -

Respectfully submitted,

5 

6 Bernd W Sandt
 7 Attorney for Appellant
 8 Registration No 19,213
 9 900 Deerfield Court,
 10 Midland, MI 48640

11 Tel: (989) 486-8454
 12 Fax: (989) 835 6030

Certificate under 37 CFR 1.8

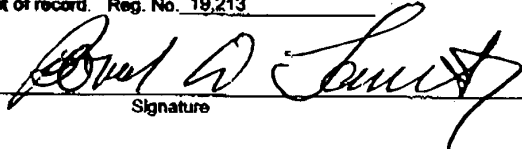
13 I hereby certify that a copy of the foregoing REQUEST FOR
 14 REHEARING was sent by facsimile to 571-273-0053, and to Patent
 15 Office facsimile number the number listed for the Board of Patent
 16 Appeals and Interferences on the date indicated below.

17 Date: 8-20-2012 Signature 

PTO/SB/26 (03-09)

Approved for use through 04/30/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT		Docket Number (Optional) BWS 06-12
In re Application of: <u>Jin Po Lee</u>		
Application No.: <u>11/660,260</u>		
Filed: <u>01/05/2007</u>		
For: <u>Multiple Analyte Assay Device</u>		
<p>The owner, <u>Jin Po Lee</u>, of <u>100</u> percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term prior patent No. <u>6,514,769</u> as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.</p> <p>In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:</p> <ul style="list-style-type: none"> expires for failure to pay a maintenance fee; is held unenforceable; is found invalid by a court of competent jurisdiction; is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; has all claims canceled by a reexamination certificate; is reissued; or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. <p>Check either box 1 or 2 below, if appropriate.</p> <p>1. <input type="checkbox"/> For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.</p> <p>I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p> <p>2. <input checked="" type="checkbox"/> The undersigned is an attorney or agent of record. Reg. No. <u>19,213</u></p> <p style="text-align: center;">  Signature <u>8-20-2012</u> Date </p> <p style="text-align: center;"> <u>Bernd W. Sandt</u> Typed or printed name </p> <p style="text-align: right;"> <u>989486-8454</u> Telephone Number </p> <p><input checked="" type="checkbox"/> Terminal disclaimer fee under 37 CFR 1.20(d) included.</p> <p style="text-align: center;">WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/06 may be used for making this certification. See MPEP § 324.</p>		

This collection of information is required by 37 CFR 1.521. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1480, Alexandria, VA 22313-1480.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes details for application 11/650,280 filed 01/05/2007 by Jin Po Lee, attorney BWS 06-12, examiner ALEXANDER, LYLE, art unit 1773, and mail date 09/12/2012.

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.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JIN PO LIN

Appeal 2011-003339
Application 11/650,280
Technology Center 1700

Before BRADLEY R. GARRIS, TERRY J. OWENS, and
KAREN M. HASTINGS, *Administrative Patent Judges*.

OWENS, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

Appeal 2011-003339
Application 11/650,280

The Appellant requests rehearing of our decision to affirm the obviousness-type double patenting rejection of claims 9-17 over claims 1-19 of Lee '769 in view of Klimov (Request 1).

The Appellant requests that we reconsider our decision in view of a newly-submitted terminal disclaimer (filed August 20, 2012) (Request 1).¹ The Appellant, however, does not show error in our decision. Accordingly, the request for hearing is denied.

DENIED

cam

¹ See *Manual of Patent Examining Procedure* § 1490 IV (8th ed., rev. 7, July 2008) for the processing procedure for a terminal disclaimer filed in an application pending in a Technology Center.

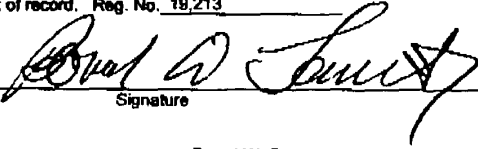
RECEIVED
CENTRAL FAX CENTER
SEP 19 2012

PTO/SB/26 (03-09)

Approved for use through 04/30/2009. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT		Docket Number (Optional) BWS 06-12
In re Application of: Jin Po Lee		
Application No.: 11/660,260	09/28/2012 APEREZAM 00000003 190135	11550280
Filed: 01/06/2007	02 FC:2814	00.00 DA
For: Multiple Analyte Assay Device		
<p>The owner, <u>Jin Po Lee</u>, of <u>100</u> percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term prior patent No. <u>6,514,769</u> as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.</p> <p>In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:</p> <ul style="list-style-type: none"> expires for failure to pay a maintenance fee; is held unenforceable; is found invalid by a court of competent jurisdiction; is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; has all claims cancelled by a reexamination certificate; is reissued; or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. <p>Check either box 1 or 2 below, if appropriate.</p> <p>1. <input type="checkbox"/> For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.</p> <p>I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p> <p>2. <input checked="" type="checkbox"/> The undersigned is an attorney or agent of record. Reg. No. <u>19,213</u></p> <p style="text-align: center;">  Signature 8-20-2012 Date Bernd W. Sandt Typed or printed name </p> <p style="text-align: right;">989486-8454 Telephone Number</p> <p><input checked="" type="checkbox"/> Terminal disclaimer fee under 37 CFR 1.20(d) included.</p> <p>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/06 may be used for making this certification. See MPEP § 324.</p>		

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1460.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

RECEIVED
CENTRAL FAX CENTER
SEP 19 2012

Sandt & Associates
900 Deerfield Court
Midland, MI 48640
(E-mail: billsandt@chartermi.net)

Fax

Date	09-18-2012		
To:	Mr. Lyle Alexander US Patent & Trademark Office	From:	B.W. Sandt
cc		Phone	(989) 486 8454
Fax:	1-571-273-8300 1-571-273-1254	Fax	(989) 835-6030
Phone:		Pages:	4
Re:	SN 11/650/280		


Urgent For Review Please Comment Please Reply Please Recycle

Unless otherwise indicated, or obvious from the nature of this transmittal, the information contained in this Fax is ~~Confidential~~ intended for the use of only the person or entity named above. If the reader of this message is not the intended recipient, he is hereby notified that any dissemination, distribution or copying of this message is strictly prohibited. If this message has been received in error, please immediately notify sender and destroy all copies and return the original copy to the sender at sender's expense.

Message

Applicant: Jin Po Lee
Serial No: 11/650,280
Filed: 01-05-2007
For: Multiple Analyte Assay Device
Group Art Unit: 1773 Examiner: Lyle. A. Alexander

Attached please find applicant's request for continued examination


Bernd W. Sandt
Attorney for Applicant

RECEIVED
CENTRAL FAX CENTER
SEP 19 2012

PTO/SB/30 (07-09)
Approved for use through 07/31/2012. OMB 0851-0031
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no person should be required to respond to a collection of information unless it carries a valid OMB control number.

Request for Continued Examination (RCE) Transmittal Address to: Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number	S.N. 11/650,260
	Filing Date	01/05/2007
	First Named Inventor	Lin Po Lee
	Art Unit	1773
	Examiner Name	Alexander, Lyle
	Attorney Docket Number	BWS06-12

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application. Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

a. Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

i. Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

ii. Other _____

b. Enclosed

i. Amendment/Reply

ii. Affidavit(s)/ Declaration(s)

iii. Information Disclosure Statement (IDS)

iv. Other Terminal Disclaimer _____

2. **Miscellaneous**

a. Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

b. Other _____

3. **Fees** The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed. The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 190136

a. RCE fee required under 37 CFR 1.17(e)

b. Extension of time fee (37 CFR 1.136 and 1.17)

iii. Other _____

b. Check in the amount of \$ _____ enclosed 01 FC:2801 465.00 DA

c. Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-5038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	<i>Berg W. Sandt</i>	Date	9-18-2012
Name (Print/Type)	Berg W. Sandt	Registration No.	19213

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage so first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature	<i>Berg W. Sandt</i>	Date	09-19-2012
Name (Print/Type)	Berg W. Sandt		

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

BEST AVAILABLE COPY

RECEIVED
CENTRAL FAX CENTER
SEP 19 2012

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: JIn Po Lee
Serial No: 11/650,280
Filed: 01/05/2007
For: Multiple Analyte Assay Device
Group Art Unit: 1797 **Examiner:** L. A. Alexander

Commissioner for Patents
P.O Box 1450
Alexandria, VA 22313-1450

Request for Continued Examination

In response to the decision of the Board of Appeals and Interferences, applicant files this request for continued examination.

In its decision the Board reversed the rejection of applicant's claims 9-17 over DE '825, in view of Klimov, the rejection of claims 9-17 on the grounds of double patenting over the claims of the Lee '268 patent in view of Klimov and claims 1-19 of the Lee '019 patent in view of Klimov and claims 1-5 of the Tyding patent in view of Klimov. The Board affirmed the Examiner's double patenting rejection of rejection of applicant's claims 9-17 over the Lee '769 patent in view of Klimov.

Applicant argued during the prosecution and on appeal that he had provided a *de facto* terminal disclaimer for US Patent No. 6,514,769 (the '769 patent) by filing a disclaimer in US Patent No. 7,347,972, which contained a disclaimer over the '769 patent. However the Board did not consider that argument and rejected the claims.

- 1 -

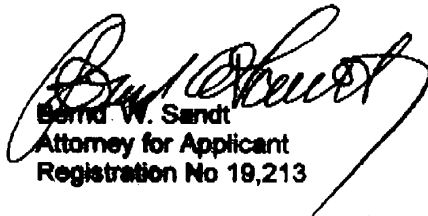
SN11/650,280
BWS 06-12

This double patenting rejection is the only outstanding issue barring an allowance of the application and resulted only from a misunderstanding of the scope of a terminal disclaimer, which applicant's counsel thought would apply to the '769, patent. Applicant is submitting herewith a terminal disclaimer over the '769 patent which thus should resolve the remaining rejection.

The filing of the attached disclaimer overcomes the rejection left standing by the Board on a basis which is not require any further searches on the part of the examiner. It would be inequitable for the applicant to have to refile the application with the time delay involved to obtain an allowance because of a misinterpretation of a formal requirement by counsel, particularly given the long prosecution time, the application was filed in January of 2007, and the short time remaining for the issued patent, the expiration date being 2018.

Allowance is requested.


Respectfully submitted,



Bernd W. Sandt
Attorney for Applicant
Registration No 19,213

- 2 -

SN11/650,280
BWS 06-12

Application Number 	Application/Control No. 11/650,280	Applicant(s)/Patent under Reexamination LEE, JIN PO	

Document Code - DISQ	Internal Document – DO NOT MAIL
-----------------------------	--

TERMINAL DISCLAIMER	<input checked="" type="checkbox"/> APPROVED	<input type="checkbox"/> DISAPPROVED
Date Filed : 19 SEPT 2012	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

JAB

RECEIVED
CENTRAL FAX CENTER

JUL 11 2013

PTO/SB/26 (03-09)

Approved for use through 04/30/2009. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no actions are required to respond to a collection of information unless it displays a valid OMB control number.

TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT		Docket Number (Optional) BWS 06-12
In re Application of: <u>Jin Po Lee</u>		
Application No.: <u>11/000,200</u>	<u>07/12/2013 STANN1</u>	<u>00000006 190135</u>
Filed: <u>01/06/2007</u>	<u>01 FC:1814</u>	<u>160.00 DA</u>
For: <u>Multiple Analytic Assay Device</u>		
<p>The owner, <u>Jin Po Lee</u>, of <u>100</u> percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term prior patent No. <u>8,202,457</u> as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.</p> <p>In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:</p> <ul style="list-style-type: none"> expires for failure to pay a maintenance fee; is held unenforceable; is found invalid by a court of competent jurisdiction; is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; has all claims canceled by a reexamination certificate; is reissued; or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. <p>Check either box 1 or 2 below, if appropriate.</p> <p>1. <input type="checkbox"/> For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.</p> <p>I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p> <p>2. <input checked="" type="checkbox"/> The undersigned is an attorney or agent of record. Reg. No. <u>18,213</u></p> <p style="text-align: center;"><u><i>Bernd W. Sandt</i></u> Signature</p> <p style="text-align: right;"><u>07-11-2013</u> Date</p> <p style="text-align: center;"><u>Bernd W. Sandt</u> Typed or printed name</p> <p style="text-align: right;"><u>989 8486 8454</u> Telephone Number</p> <p><input checked="" type="checkbox"/> Terminal disclaimer fee under 37 CFR 1.20(d) included.</p> <p>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>*Statement under 37 CFR 3.75(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/06 may be used for making this certification. See MPEP § 324.</p>		

11650200

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1480, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1480, Alexandria, VA 22313-1480.

If you need assistance in completing the form, call 1-800-PTO-0199 and select option 2.

RECEIVED
CENTRAL FAX CENTER

JUL 11 2013

Sandt & Associates
900 Deerfield Court
Midland, MI 48640
(E-mail: bill@sandt@chartermi.net)

Fax

Date	07-11-2013		
To:	Mr. Lyle Alexander US Patent & Trademark Office	From:	B.W. Sandt
cc		Phone	(989) 486 8454
Fax:	1-571-273-8300 1-571-273-1254	Fax	(989) 835-6030
Phone:		Pages:	4
Re:	BN 11/650/280		

Urgent For Review Please Comment Please Reply Please Recycle

Unless otherwise indicated, or obvious from the nature of this transmittal, the information contained in this Fax is ~~Confidential~~, intended for the use of only the person or entity named above. If the reader of this message is not the intended recipient, he is hereby notified that any dissemination, distribution or copying of this message is strictly prohibited. If this message has been received in error, please immediately notify sender and destroy all copies and return the original copy to the sender at sender's expense.

Message

Applicant: Jin Po Lee
Serial No: 11/650,280
Filed: 01-05-2007
For: Multiple Analyte Assay Device
Group Art Unit: 1773 Examiner: Lyle. A. Alexander

The applicant thanks the Examiner for advising on the status of the subject application. In line with that advice applicant is submitting a terminal disclaimer over US Patent No. 8,202,487, the terminal disclaimer fee of \$160 to be debited to my account. An additional copy will be mailed via US Postal Service.


Bernd W. Sandt
Attorney for Applicant

JUL 11 2013

PTO/SB/17 (03-13)

Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995 no charge is required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL		Complete if known	
		Application Number	11/650,280
<input checked="" type="checkbox"/> Applicant asserts small entity status. See 37 CFR 1.27.		Filing Date	01/05/2007
<input type="checkbox"/> Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.		First Named Inventor	Jin Po Liu
TOTAL AMOUNT OF PAYMENT (\$) 160.00		Examiner Name	Lyle Alexander
		Art Unit	1773
		Practitioner Docket No.	BWS 06 12

METHOD OF PAYMENT (check all that apply)

Check Credit Card Money Order None Other (please identify): _____

Deposit Account Deposit Account Number: **190135** Deposit Account Name: **Bernd W. Sandt**

For the above-identified deposit account, the Director is hereby authorized to (check all that apply):

Charge fee(s) indicated below Charge fee(s) indicated below, except for the filing fee

Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 Credit any overpayment of fee(s)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES (U = undiscounted fee; S = small entity fee; M = micro entity fee)

Application Type	FILING FEES			SEARCH FEES			EXAMINATION FEES			Fees Paid (\$)
	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	
Utility	280	140*	70	600	300	150	720	360	180	
Design	180	90	45	120	60	30	460	230	115	
Plant	180	90	45	380	190	95	580	290	145	
Reissue	280	140	70	600	300	150	2,160	1,080	540	
Provisional	260	130	65	0	0	0	0	0	0	

* The \$140 small entity status filing fee for a utility application is further reduced to \$70 for a small entity status applicant who files the application via EFS-Web.

2. EXCESS CLAIM FEES

Fee Description	Undiscounted Fee (\$)	Small Entity Fee (\$)	Micro Entity Fee (\$)
Each claim over 20 (including Reissues)	90	40	20
Each independent claim over 3 (including Reissues)	420	210	105
Multiple dependent claims	780	390	195
Total Claims			
-20 or HP =	Extra Claims	Fee (\$)	Fee Paid (\$)
HP = Highest number of total claims paid for, if greater than 20.			Multiple Dependent Claims
Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
-3 or HP =			Fee (\$)
HP = Highest number of independent claims paid for, if greater than 3.			Fee Paid (\$)

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$400 (\$200 for small entity) (\$100 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
-100 =	/50 =	(round up to a whole number)		

4. OTHER FEES

Non-English specification, \$136 fee (no small or micro entity discount)

Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, \$400 fee (\$200 small or micro entity)

Other (e.g., late filing surcharge): **Terminal disclaimer fee under 37 CFR 120(d)** 160.00

SUBMITTED BY

Signature	<i>Bernd W. Sandt</i>	Registration No. (Attorney/Agent)	19213	Telephone	989 4868454
Name (Print/Type)	Bernd W. Sandt	Date	7-11-2013		

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

BEST AVAILABLE COPY



AW

TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT

Docket Number (Optional)
BWS 06-12

In re Application of: Jin Po Lee
Application No.: 11/650,280
Filed: 01/05/2007
For: Multiple Analyte Assay Device

The owner*, Jin Po Lee, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term prior patent No. 8,202,487 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

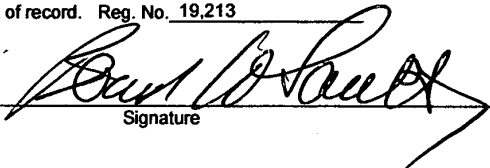
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. The undersigned is an attorney or agent of record. Reg. No. 19,213


Signature

07-11-2013
Date

Bernd W. Sandt
Typed or printed name

989 6486 8454
Telephone Number

- Terminal disclaimer fee under 37 CFR 1.20(d) included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

07/15/2013 ZJU HAR1 00000016 190135 11650280
01 FC 1014 160 00 00

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

FEE TRANSMITTAL		Complete if known	
		Application Number	11/650,280
		Filing Date	01/05/2007
<input checked="" type="checkbox"/> Applicant asserts small entity status. See 37 CFR 1.27.		First Named Inventor	Jin Po Lee
<input type="checkbox"/> Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.		Examiner Name	Lyle Alexander
		Art Unit	1773
TOTAL AMOUNT OF PAYMENT	(\$) 160.00	Practitioner Docket No.	BWS 06-12

METHOD OF PAYMENT (check all that apply)

Check Credit Card Money Order None Other (please identify): _____

Deposit Account Deposit Account Number: 190135 Deposit Account Name: Bernd W. Sandt

For the above-identified deposit account, the Director is hereby authorized to (check all that apply):

Charge fee(s) indicated below Charge fee(s) indicated below, except for the filing fee

Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 Credit any overpayment of fee(s)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES (U = undiscounted fee; S = small entity fee; M = micro entity fee)

Application Type	FILING FEES			SEARCH FEES			EXAMINATION FEES			Fees Paid (\$)
	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	
Utility	280	140*	70	600	300	150	720	360	180	
Design	180	90	45	120	60	30	460	230	115	
Plant	180	90	45	380	190	95	580	290	145	
Reissue	280	140	70	600	300	150	2,160	1,080	540	
Provisional	260	130	65	0	0	0	0	0	0	

* The \$140 small entity status filing fee for a utility application is further reduced to \$70 for a small entity status applicant who files the application via EFS-Web.

2. EXCESS CLAIM FEES

Fee Description	Undiscounted Fee (\$)	Small Entity Fee (\$)	Micro Entity Fee (\$)
Each claim over 20 (including Reissues)	80	40	20
Each independent claim over 3 (including Reissues)	420	210	105
Multiple dependent claims	780	390	195

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims	Fee (\$)	Fee Paid (\$)
_____ - 20 or HP = _____	_____ x _____	_____ = _____	_____	_____	_____	_____
HP = highest number of total claims paid for, if greater than 20.						
_____ Indep. Claims	_____ Extra Claims	_____ Fee (\$)	_____ Fee Paid (\$)	_____	_____	_____
_____ - 3 or HP = _____	_____ x _____	_____ = _____	_____	_____	_____	_____
HP = highest number of independent claims paid for, if greater than 3.						

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$400 (\$200 for small entity) (\$100 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
_____ - 100 = _____	_____ / 50 = _____	_____ (round up to a whole number)	_____ x _____ = _____	_____

4. OTHER FEE(S)

Non-English specification, \$130 fee (no small or micro entity discount)	_____	_____
Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, \$400 fee (\$200 small or micro entity)	_____	_____
Other (e.g., late filing surcharge): Terminal disclaimer fee under 37 CFR 120 (d)	_____	160.00
		Fees Paid (\$)

SUBMITTED BY		
Signature		Registration No. (Attorney/Agent) 19213 Telephone 989 4868454
Name (Print/Type)	Bernd W. Sandt	Date 7-11-2013

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Best Available Copy

PTO/SB/17 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

FEE TRANSMITTAL		Complete if known	
		Application Number	11/650,280
<input checked="" type="checkbox"/> Applicant asserts small entity status. See 37 CFR 1.27.		Filing Date	01/05/2007
<input type="checkbox"/> Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.		First Named Inventor	Jin Po Lee
TOTAL AMOUNT OF PAYMENT (\$)		Examiner Name	Lyle Alexander
		Art Unit	1773
(\$)		Practitioner Docket No.	BWS 06-12

METHOD OF PAYMENT (check all that apply)

Check Credit Card Money Order None Other (please identify): _____

Deposit Account Deposit Account Number: 190135 Deposit Account Name: Bernd W. Sandt

For the above-identified deposit account, the Director is hereby authorized to (check all that apply):

Charge fee(s) indicated below Charge fee(s) indicated below, except for the filing fee

Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 Credit any overpayment of fee(s)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES (U = undiscounted fee; S = small entity fee; M = micro entity fee)

Application Type	FILING FEES			SEARCH FEES			EXAMINATION FEES			Fees Paid (\$)
	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	
Utility	280	140*	70	600	300	150	720	360	180	
Design	180	90	45	120	60	30	460	230	115	
Plant	180	90	45	380	190	95	580	290	145	
Reissue	280	140	70	600	300	150	2,160	1,080	540	
Provisional	260	130	65	0	0	0	0	0	0	

* The \$140 small entity status filing fee for a utility application is further reduced to \$70 for a small entity status applicant who files the application via EFS-Web.

2. EXCESS CLAIM FEES

Fee Description	Undiscounted Fee (\$)	Small Entity Fee (\$)	Micro Entity Fee (\$)
Each claim over 20 (including Reissues)	80	40	20
Each independent claim over 3 (including Reissues)	420	210	105
Multiple dependent claims	780	390	195

Total Claims - 20 or HP = _____ x _____ = _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims - 3 or HP = _____ x _____ = _____

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$400 (\$200 for small entity) (\$100 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
_____ - 100 = _____	_____ / 50 = _____	_____ (round up to a whole number)	x _____ = _____	_____

4. OTHER FEE(S)

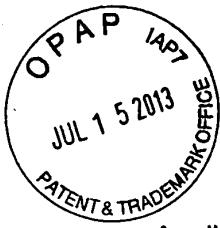
Description	Fee (\$)	Fees Paid (\$)
Non-English specification, \$130 fee (no small or micro entity discount)	_____	_____
Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, \$400 fee (\$200 small or micro entity)	_____	_____
Other (e.g., late filing surcharge): Terminal disclaimer fee under 37 CFR 120(d)	160.00	160.00

SUBMITTED BY

Signature	<i>Bernd W. Sandt</i>	Registration No. (Attorney/Agent)	19213	Telephone	989 4868454
Name (Print/Type)	Bernd W. Sandt	Date	7-11-2013		

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Jin Po Lee

Serial No: 11/650,280

Filed: 01/05/2007

For: Multiple Analyte Assay Device

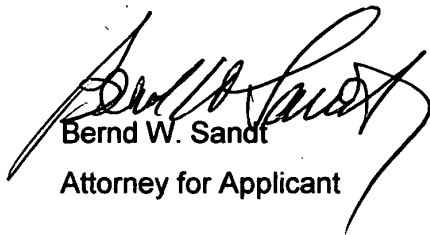
Group Art Unit: 1797

Examiner: L. A. Alexander

Commissioner for Patents
P.O Box 1450
Alexandria, VA 22313-1450

Terminal Disclaimer

The attached terminal disclaimer and transmittal fee form were filed by facsimile on July 11, 2013. At the request of the Examiner this copy is forwarded by the US Postal Service



Bernd W. Sandt
Attorney for Applicant



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/650,280	01/05/2007	Jin Po Lee	BWS 06-12	8521
46725	7590	07/16/2013	EXAMINER	
BERND W. SANDT			ALEXANDER, LYLE	
900 DEERFIELD COURT			ART UNIT	PAPER NUMBER
MIDLAND, MI 48640			1773	
			MAIL DATE	DELIVERY MODE
			07/16/2013	PAPER

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.

Office Action Summary	Application No. 11/650,280	Applicant(s) LEE, JIN PO	
	Examiner LYLE ALEXANDER	Art Unit 1773	AIA (First Inventor to File) Status No

-- 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 19 September 2012.
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 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) 9-17 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 9-17 is/are rejected.
- 8) Claim(s) _____ is/are objected to.
- 9) Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on _____ 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).

Priority under 35 U.S.C. § 119

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

Certified copies:

- a) All b) Some * c) None of the:
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) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 3) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 4) Other: _____.

The 8/10/12 decision by the BPAI reversed all of the rejections of record except for an obviousness double patenting rejection over Lee (US 6,514,769) in view of Klimov. Applicant has filed a proper terminal disclaimer over Lee (US 6,514,769) and the rejections previously of record have been overcome based upon the 8/10/12 decision by the BPAI. However, upon updating the search, US 8,202,487 was found. US 8,202,487 issued on 6/19/12 after the 7/21/10 Examiner's answer was filed and raises obviousness type of double patenting issues. If Applicant files a proper and timely terminal disclaimer over US 8,202,487 all of the art of record will be overcome.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*,

686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 9-17 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 8,202,487. Although the claims at issue are not identical, they are not patentably distinct from each other because the patent claims a device for holding test strips that is indistinguishable from the claimed device and include a control zone.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE ALEXANDER whose telephone number is (571)272-1254. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/Lyle Alexander/
Primary Examiner, Art Unit 1773

Notice of References Cited	Application/Control No. 11/650,280	Applicant(s)/Patent Under Reexamination LEE, JIN PO	
	Examiner LYLE ALEXANDER	Art Unit 1773	Page 1 of 1

U.S. PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-8,202,487	06-2012	Lee, Jin Po	422/401
	B US-			
	C US-			
	D US-			
	E US-			
	F US-			
	G US-			
	H US-			
	I US-			
	J US-			
	K US-			
	L US-			
	M US-			


FOREIGN PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N				
	O				
	P				
	Q				
	R				
	S				
	T				

NON-PATENT DOCUMENTS

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	
V	
W	
X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.


Application Number 	Application/Control No. 11/650,280	Applicant(s)/Patent under Reexamination LEE, JIN PO	

Document Code - DISQ	Internal Document – DO NOT MAIL
-----------------------------	--

TERMINAL DISCLAIMER	<input checked="" type="checkbox"/> APPROVED	<input type="checkbox"/> DISAPPROVED
Date Filed : 7/11/13	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

Felicia D. Roberts The TD is unreadable/unclear.

Application Number 	Application/Control No. 11/650,280	Applicant(s)/Patent under Reexamination LEE, JIN PO	

Document Code - DISQ	Internal Document – DO NOT MAIL
-----------------------------	--

TERMINAL DISCLAIMER	<input checked="" type="checkbox"/> APPROVED	<input type="checkbox"/> DISAPPROVED
Date Filed : 7/15/13	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

Felicia D. Roberts 8,202,487

Applicant-Initiated Interview Summary	Application No. 11/650,280	Applicant(s) LEE, JIN PO	
	Examiner LYLE ALEXANDER	Art Unit 1773	

All participants (applicant, applicant's representative, PTO personnel):

(1) LYLE ALEXANDER. (3) _____.

(2) Mr. Sandt. (4) _____.

Date of Interview: 07 August 2013.

Type: Telephonic Video Conference
 Personal [copy given to: applicant applicant's representative]

Exhibit shown or demonstration conducted: Yes No.
If Yes, brief description: _____.

Issues Discussed 101 112 102 103 Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: all.

Identification of prior art discussed: Lee (US 8202487).

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant informed the Office that a proper terminal disclaimer had been filed to overcome the obviousness type of double patenting rejection over Lee. The Office updated the search and no new art was found. The application is in condition for allowance in light of the 8/10/12 Decision by the PTAB and overcoming the only remaining rejection over Lee.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Attachment

/Lyle Alexander/ Primary Examiner, Art Unit 1773	
---	--

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

46725 7590 08/19/2013
BERND W. SANDT
900 DEERFIELD COURT
MIDLAND, MI 48640

EXAMINER

ALEXANDER, LYLE

ART UNIT PAPER NUMBER

1773

DATE MAILED: 08/19/2013

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.

11/650,280 01/05/2007 Jin Po Lee BWS 06-12 8521

TITLE OF INVENTION: Multiple analyte assay device

Table with 7 columns: APPLN. TYPE, ENTITY STATUS, ISSUE FEE DUE, PUBLICATION FEE DUE, PREV. PAID ISSUE FEE, TOTAL FEE(S) DUE, DATE DUE

nonprovisional SMALL \$890 \$300 \$0 \$1190 11/19/2013

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

46725 7590 08/19/2013
BERND W. SANDT
 900 DEERFIELD COURT
 MIDLAND, MI 48640

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

_____ (Depositor's name)
_____ (Signature)
_____ (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/650,280	01/05/2007	Jin Po Lee	BWS 06-12	8521

TITLE OF INVENTION: Multiple analyte assay device

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$890	\$300	\$0	\$1190	11/19/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
ALEXANDER, LYLE	1773	422-401000

<p>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</p> <p><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p><input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.</p>	<p>2. For printing on the patent front page, list</p> <p>(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____</p> <p>(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____</p> <p>3 _____</p>
---	---

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE _____ (B) RESIDENCE: (CITY and STATE OR COUNTRY) _____

Please check the appropriate assignee category or categories (will not be printed on the patent): Individual Corporation or other private group entity Government

<p>4a. The following fee(s) are submitted:</p> <p><input type="checkbox"/> Issue Fee</p> <p><input type="checkbox"/> Publication Fee (No small entity discount permitted)</p> <p><input type="checkbox"/> Advance Order - # of Copies _____</p>	<p>4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)</p> <p><input type="checkbox"/> A check is enclosed.</p> <p><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input type="checkbox"/> The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).</p>
---	--

5. **Change in Entity Status** (from status indicated above)

- Applicant certifying micro entity status. See 37 CFR 1.29
- Applicant asserting small entity status. See 37 CFR 1.27
- Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.

46725 7590 08/19/2013
BERND W. SANDT
900 DEERFIELD COURT
MIDLAND, MI 48640

EXAMINER

ALEXANDER, LYLE

ART UNIT PAPER NUMBER

1773

DATE MAILED: 08/19/2013

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 1456 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 1456 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 11/650,280	Applicant(s) LEE, JIN PO	
	Examiner LYLE ALEXANDER	Art Unit 1773	AIA (First Inventor to File) Status No

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to the 7/15/13 terminal disclaimer and 8/7/13 interview summary.
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. 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.
3. The allowed claim(s) is/are 9-17 renumbered as 1-9 respectively. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) All b) Some *c) None of the:
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)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material 4. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>8/7/13</u> . | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____. |
|--|---|

/Lyle Alexander/
Primary Examiner, Art Unit 1773




UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 8521


SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO. BWS 06-12		
11/650,280	01/05/2007	422	1773			
APPLICANTS Jin Po Lee, Carlsbad, CA;						
** CONTINUING DATA ***** This application is a DIV of 10/019,570 11/08/2001 PAT 7347972						
** FOREIGN APPLICATIONS ***** UNITED STATES OF AMERICA PCT/US98/15359 07/14/1998						
** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** ** SMALL ENTITY ** 02/27/2007						
Foreign Priority claimed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input type="checkbox"/> No			CA	6	8	1
Verified and Acknowledged <u>/LYLE ALEXANDER/</u> Examiner's Signature		Initials				
ADDRESS BERND W. SANDT 900 DEERFIELD COURT MIDLAND, MI 48640 UNITED STATES						
TITLE Multiple analyte assay device						
FILING FEE RECEIVED 500	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:			<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit		

Issue Classification 	Application/Control No. 11650280	Applicant(s)/Patent Under Reexamination LEE, JIN PO	
	Examiner LYLE ALEXANDER	Art Unit 1773	

CPC			Type	Version
Symbol				


CPC Combination Sets				
Symbol	Type	Set	Ranking	Version

NONE		Total Claims Allowed:	
		9	
(Assistant Examiner)	(Date)	O.G. Print Claim(s)	O.G. Print Figure
/LYLE ALEXANDER/ Primary Examiner. Art Unit 1773	08/09/2013	1	2
(Primary Examiner)	(Date)		

Issue Classification 	Application/Control No. 11650280	Applicant(s)/Patent Under Reexamination LEE, JIN PO
	Examiner LYLE ALEXANDER	Art Unit 1773


US ORIGINAL CLASSIFICATION					INTERNATIONAL CLASSIFICATION								
CLASS		SUBCLASS			CLAIMED				NON-CLAIMED				
422		401			G	0	1	N	33 / 48 (2006.01.01)				
CROSS REFERENCE(S)													
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)												
422	420	430											
436	164	165											

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	9	
/LYLE ALEXANDER/ Primary Examiner. Art Unit 1773	08/09/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	2

Issue Classification 	Application/Control No. 11650280	Applicant(s)/Patent Under Reexamination LEE, JIN PO
	Examiner LYLE ALEXANDER	Art Unit 1773

<input checked="" type="checkbox"/> Claims renumbered in the same order as presented by applicant																<input type="checkbox"/> CPA		<input checked="" type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47	
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original						

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	9	
/LYLE ALEXANDER/ Primary Examiner. Art Unit 1773	08/09/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	2

<i>Index of Claims</i> 	Application/Control No. 11650280	Applicant(s)/Patent Under Reexamination LEE, JIN PO
	Examiner LYLE ALEXANDER	Art Unit 1773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected


Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

CLAIM		DATE							
Final	Original	07/10/2013	08/09/2013						
	1	-	-						
	2	-	-						
	3	-	-						
	4	-	-						
	5	-	-						
	6	-	-						
	7	-	-						
	8	-	-						
	9	✓	=						
	10	✓	=						
	11	✓	=						
	12	✓	=						
	13	✓	=						
	14	✓	=						
	15	✓	=						
	16	✓	=						
	17	✓	=						

EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	12	"8202487".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/09 12:53
L2	144839	lee-j\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/09 13:27
L3	7003	test near3 (strip or device) and control and analyte and (cover or slot or cap or protrud\$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/09 13:29
L4	35	2 and 3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/09 13:30
L5	126	((test near3 (strip or device)) same control same analyte same (cover or slot or cap or protrud\$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/09 13:53
L6	101	((test near3 (strip or device)) and control and analyte and (cover or slot or cap or protrud\$4)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/09 13:59

8/ 9/ 2013 2:04:57 PM**C:\Users\lalexander\Documents\EAST\Workspaces\13172048.wsp**

Search Notes 	Application/Control No. 11650280	Applicant(s)/Patent Under Reexamination LEE, JIN PO
	Examiner Lyle A Alexander	Art Unit 1797

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
422	401,420,430	8/9/13	LAA
436	164,165	8/9/13	LAA

SEARCH NOTES		
Search Notes	Date	Examiner
east	4/3/09	LAA
co-pending application 11/401,193	4/3/09	LAA
parent application 10/019,570	4/3/09	LAA
east	7/10/13	LAA
east	8/9/13	LAA

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	see the 7/10/13 and 8/9/13 east searches	8/9/13	LAA

--	--



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

11/650,280	01/05/2007	Jin Po Lee	BWS 06-12	8521
------------	------------	------------	-----------	------

46725 7590 11/11/2013
 BERND W. SANDT
 900 DEERFIELD COURT
 MIDLAND, MI 48640

EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
----------	--------------

1773

MAIL DATE	DELIVERY MODE
-----------	---------------

11/11/2013	PAPER PAPER
------------	-------------

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.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 11650280
Applicant : Lee
Filing Date : 01/05/2007
Date Mailed : 11/11/2013

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given 1 month from the mail date of this Notice, or the time remaining from the Notice of Allowance and Fee(s) Due, whichever is longer, within which to respond.

The application is not in compliance with 37 CFR 1.78, as indicated in the attachment. The consequences of failure to respond within the above-identified time period are set forth in the attachment.

Even if the Office has recognized a benefit claim and has entered it into the Office's database and included it on applicant's filing receipt, the benefit claim is not a proper benefit claim unless the reference in compliance with 37 CFR 1.78 is included, depending upon the application's filing date and as indicated in the attachment, in an application data sheet or in the first sentence(s) of the specification and all other requirements are met.

This period for reply is NOT extendable under 37 CFR 1.136(a).

See attachment.

*A copy of this notice **MUST** be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".*

/Joanna Black/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 11650280

**APPLICATION FILED PRIOR TO SEPTEMBER 16, 2012,
NOT IN COMPLIANCE WITH 37 CFR 1.78**

- The 37 CFR 1.78(a)(2) reference on the application data sheet or in the first sentence(s) of the specification does not indicate the relationship (continuation, division, continuation-in-part) to the prior U.S. nonprovisional application or international application designating the U.S. See document coded dated , listing application number(s) .
- The 37 CFR 1.78(a)(2) reference on the application data sheet or in the first sentence(s) of the specification following the title does not provide the U.S. nonprovisional application number (series code and serial number) or, with respect to an international PCT application designating the U.S., it provides the international application number or international filing date but not both. See document coded dated , in which the following is missing: .
- The 37 CFR 1.78(a)(2) reference on the application data sheet or in the first sentence(s) of the specification following the title shows an incorrect, incomplete, or illegible U.S. nonprovisional application number, international PCT application number, or international PCT filing date. See document coded SPEC dated 01/05/2007, in which the following error was made: 100190570 should be 10019570.
- The 37 CFR 1.78(a)(2) reference to the prior U.S. nonprovisional application or international application designating the U.S. is not present on an application data sheet or in the first sentence(s) of the specification following the title, thus removing the validating link under 35 U.S.C. 119(a)-(d) to a prior foreign application or under 35 U.S.C. 119(e) to a prior U.S. provisional application.
- The 37 CFR 1.78(a)(2) reference to the prior U.S. nonprovisional application or international application designating the U.S. is not present on an application data sheet or in the first sentence(s) of the specification following the title.
- The 37 CFR 1.78(a)(5) reference to the prior U.S. provisional application is not present on an application data sheet or in first sentence(s) of the specification following the title.
- The 37 CFR 1.78(a)(5) reference to the prior U.S. provisional application on an application data sheet or in first sentence(s) of the specification following the title does not provide the provisional application number (series code and serial number). See document coded dated , in which the following is missing: .
- The 37 CFR 1.78(a)(5) reference to the prior U.S. provisional application on an application data sheet or in first sentence(s) of the specification following the title shows an incorrect, incomplete, or illegible U.S. provisional application number. See document coded dated , in which the following error was made: .
- Other: .

HOW TO RESPOND

A proper response to this notice would include any one of: (1) a supplemental Application Data Sheet (ADS) pursuant to 37 CFR 1.76(c) which provides benefit information that complies with 37 CFR 1.78(a)(2) or 37 CFR 1.78(a)(5); (2) an amendment to the first sentence(s) of the specification which provides benefit information that complies with 37 CFR 1.78(a)(2) or 37 CFR 1.78(a)(5); or (3) a petition filed pursuant to the provisions of 37 CFR 1.78(a)(3) or 37 CFR 1.78(a)(6) if the benefit information from the document identified above by code and date does not accurately reflect the benefits under 35 U.S.C. 119(e), 120, 121 or 365(c) as claimed by applicant (a grantable petition would include either a supplemental ADS or an amendment to the first sentence(s) of the specification as required by 37 CFR 1.78(a)(3)(i) or 37 CFR 1.78(a)(6)(i)). Such amendments to the specification or supplemental ADS submission may be filed after payment of the issue fee if limited to informalities noted herein. See Waiver of 37 CFR 1.312 for Document Required by Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004).

WARNING: If Applicant fails to timely submit a proper response, the benefit information will be deleted and the patent will be printed without the benefit information present.

PART B - FEE(S) TRANSMITTAL

11-18-13

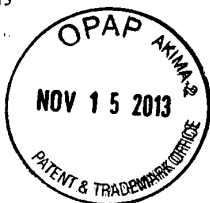
1 fw

Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 or **Fax** (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

46725 7590 08/19/2013
 BERND W. SANDT
 900 DEERFIELD COURT
 MIDLAND, MI 48640



Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
 I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

BERND W SANDT	(Depositor's name)
<i>BAS</i>	(Signature)
11-15-2013	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/650,280	01/05/2007	Jin Po Lee	BWS 06-12	8521

TITLE OF INVENTION: Multiple analyte assay device

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$890	\$300	\$0	\$1190	11/19/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
ALEXANDER, LYLE	1773	422-401000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
 Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
 "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list
 (1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
 (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1. BERND W SANDT
 2. _____
 3. _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)
 PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.
 (A) NAME OF ASSIGNEE
 (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): Individual Corporation or other private group entity Government

4a. The following fee(s) are submitted:
 Issue Fee
 Publication Fee (No small entity discount permitted)
 Advance Order - # of Copies 5

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)
 A check is enclosed.
 Payment by credit card. Form PTO-2038 is attached.
 The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 110155 (enclose an extra copy of this form).

11/18/2013 EEKUBAY2 00000035 11650280

01 FC:2501 890.00 OP
 02 FC:1504 300.00 OP
 03 FC:8001 15.00 OP

5. Change in Entity Status (from status indicated above)

- Applicant certifying micro entity status. See 37 CFR 1.29
- Applicant asserting small entity status. See 37 CFR 1.27
- Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 or **Fax** (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

46725 7590 08/19/2013
BERND W. SANDT
 900 DEERFIELD COURT
 MIDLAND, MI 48640



Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

<u>BERND W SANDT</u>	(Depositor's name)
<u>[Signature]</u>	(Signature)
<u>11-15-2013</u>	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/650,280	01/05/2007	Jin Po Lee	BWS 06-12	8521

TITLE OF INVENTION: Multiple analyte assay device

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$890	\$300	\$0	\$1190	11/19/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
ALEXANDER, LYLE	1773	422-401000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
 Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
 "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list
 (1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
 (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1. BERND W. SANDT
 2. _____
 3. _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): Individual Corporation or other private group entity Government

4a. The following fee(s) are submitted:

Issue Fee
 Publication Fee (No small entity discount permitted)
 Advance Order - # of Copies 5

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

A check is enclosed.
 Payment by credit card. Form PTO-2038 is attached.
 The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 988-51 (enclose an extra copy of this form).
190135

5. Change in Entity Status (from status indicated above)

- Applicant certifying micro entity status. See 37 CFR 1.29
- Applicant asserting small entity status. See 37 CFR 1.27
- Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PART B - FEE(S) TRANSMITTAL

11-18-13

1/2

Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 or **Fax** (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

46725 7590 08/19/2013
 BERND W. SANDT
 900 DEERFIELD COURT
 MIDLAND, MI 48640



Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
 I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

BERND W SANDT	(Depositor's name)
<i>[Signature]</i>	(Signature)
11-15-2013	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/650,280	01/05/2007	Jin Po Lee	BWS 06-12	8521

TITLE OF INVENTION: Multiple analytic assay device

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$890	\$300	\$0	\$1190	11/19/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
ALEXANDER, LYLE	1773	422-401000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

"Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1. BERND W SANDT

2. _____

3. _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): Individual Corporation or other private group entity Government

4a. The following fee(s) are submitted:

- Issue Fee
- Publication Fee (No small entity discount permitted)
- Advance Order - # of Copies 5

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- A check is enclosed.
- Payment by credit card. Form PTO-2038 is attached.
- The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 191135 (enclose an extra copy of this form).

11/18/2013 EEKUBAY2 00000035 11650280

01 FC:2501 890.00 OP
 02 FC:1504 300.00 OP
 03 FC:8001 15.00 OP

5. Change in Entity Status (from status indicated above)

- Applicant certifying micro entity status. See 37 CFR 1.29
- Applicant asserting small entity status. See 37 CFR 1.27
- Applicant changing to regular undiscouraged fee status.

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature [Signature]

Date 12-04-2013

Typed or printed name BERND W SANDT

Registration No. 19213

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

RECEIVED
CENTRAL FAX CENTER

NOV 21 2013



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 11650280
Applicant : Lee
Filing Date : 01/05/2007
Date Mailed : 11/11/2013

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given 1 month from the mail date of this Notice, or the time remaining from the Notice of Allowance and Fee(s) Due, whichever is longer, within which to respond.

The application is not in compliance with 37 CFR 1.78, as indicated in the attachment. The consequences of failure to respond within the above-identified time period are set forth in the attachment.

Even if the Office has recognized a benefit claim and has entered it into the Office's database and included it on applicant's filing receipt, the benefit claim is not a proper benefit claim unless the reference in compliance with 37 CFR 1.78 is included, depending upon the application's filing date and as indicated in the attachment, in an application data sheet or in the first sentence(s) of the specification and all other requirements are met.

This period for reply is NOT extendable under 37 CFR 1.136(a).

See attachment.

*A copy of this notice **MUST** be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".*

/Joanna Black/
Publication Branch
Office of Data Management
(571) 272-4200

RECEIVED
CENTRAL FAX CENTER

NOV 21 2013

MULTIPLE ANALYTE ASSAY DEVICE**BACKGROUND**

This application is a continuation-in-part of SN 10/019,570 filed 11/08/2001 now US Patent No. 7,347,972, which is based on PCT application US98/15369 filed 07/22/1998.

FIELD OF THE INVENTION

The present invention relates to methods and devices for assaying biological fluid samples. More particularly the invention relates to methods and devices for detecting analytes, such as drugs, in urine.

HISTORY OF THE RELATED ART

In their most simple form, chromatographic analyte devices permit an assay to be performed in a single step(application of an analyte sample to the device) to produce visually observable assay results (such as those indicated by colored bars on the test strip). However a common limitation of such devices is that they can only be used to detect a single analyte, requiring that serial assay procedures be performed to detect additional analytes (for example to test a sample for the presence of a panel of narcotics). Multiple dipping steps such as are commonly used when multiple dipstick assays are separately performed, present not only possible loss of sensitivity of the assay (through reagent mixing or possible loss reagent solutions) but also an esthetic and hygienic problem for the analyst. Repetitive performance of assay procedures is also tedious, which increases the risk that assays will be performed improperly or the results misinterpreted.

RECEIVED
CENTRAL FAX CENTER

NOV 21 2013

Sandt & Associates
 900 Deerfield Court
 Midland, MI 48640
 (E-mail: bw.sandt@sandt-associates.com)

Fax

Date	11-20-2013		
To:	Mail Stop Issue Fee US Patent & Trademark Office	From:	B.W. Sandt
cc		Phone	(989) 486 8454
Fax:	1-571-273-8300	Fax	(989) 835-6030
Phone		Pages:	4
Re:	SN 11/650/280		

Urgent For Review Please Comment Please Reply Please Recycle

Unless otherwise indicated, or obvious from the nature of this transmittal, the information contained in this Fax is **Confidential**, intended for the use of only the person or entity named above. If the reader of this message is not the intended recipient, he is hereby notified that any dissemination, distribution or copying of this message is strictly prohibited. If this message has been received in error, please immediately notify sender and destroy all copies and return the original copy to the sender at sender's expense.

Message

Applicant: Jin Po Lee
 Serial No: 11/650,280
 Filed: 01-05-2007
 For: Multiple Analyte Assay Device
 Group Art Unit: 1773 Examiner: Lyle. A. Alexander

In response to the office action of 11/11/1013 attached please find a corrected version of page 1 of the specification showing the relation back to the corresponding PCT application as a first sentence under a new heading of "Background. No new matter is involved.

Bernd W. Sandt
 Attorney for Applicant



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Table with 7 columns: APPLICATION NUMBER, FILING or 371(c) DATE, GRP ART UNIT, FIL FEE REC'D, ATTY DOCKET NO, TOT CLAIMS, IND CLAIMS. Row 1: 11/650,280, 01/05/2007, 1773, 800, BWS 06-12, 8, 1

CONFIRMATION NO. 8521

CORRECTED FILING RECEIPT



46725
BERND W. SANDT
900 DEERFIELD COURT
MIDLAND, MI 48640

Date Mailed: 11/27/2013

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections

Inventor(s) Jin Po Lee, Carlsbad, CA;
Applicant(s) Jin Po Lee, Carlsbad, CA;

Power of Attorney: The patent practitioners associated with Customer Number 46725

Domestic Priority data as claimed by applicant
This application is a CIP of 10/019,570 11/08/2001 PAT 7347972
which is a 371 of PCT/US98/15359 07/14/1998 ABN

Foreign Applications for which priority is claimed (You may be eligible to benefit from the Patent Prosecution Highway program at the USPTO. Please see http://www.uspto.gov for more information.) - None. Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

If Required, Foreign Filing License Granted: 02/27/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US 11/650,280

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Multiple analyte assay device

Preliminary Class

422

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications:**PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/650,280	01/05/2007	Jin Po Lee	BWS 06-12	8521
46725	7590	12/02/2013	EXAMINER	
BERND W. SANDT 900 DEERFIELD COURT MIDLAND, MI 48640			ALEXANDER, LYLE	
			ART UNIT	PAPER NUMBER
			1773	
			MAIL DATE	DELIVERY MODE
			12/02/2013	PAPER

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.

Response to Rule 312 Communication	Application No.	Applicant(s)
	11/650,280	
	Examiner	Art Unit

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

1. The amendment filed on 21 November 2013 under 37 CFR 1.312 has been considered, and has been:
- a) entered.
 - b) entered as directed to matters of form not affecting the scope of the invention.
 - c) disapproved because the amendment was filed after the payment of the issue fee.
Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.
 - d) disapproved. See explanation below.
 - e) entered in part. See explanation below.

L.HILL

Publishing Division

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Complete if Known Application Number _____ Filing Date _____ First Named Inventor Jin Po Lee Art Unit _____ Examiner Name _____ Attorney Docket Number BWS 06-12
Sheet _____ of _____	

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
Change(s) applied to document, N.W.S. 12/3/2013	A-1	US	6,403,557	04/04/95	Galloway et al	
	A-2	US	5,976,895	11/02/99	Cipkowsky, Shay	
	A-3	US	4,518,565	05/21/85	Boger et al	
	A-4	US	4,056,359	11/11/77	Tanin, Pierre	
	A-5	US	6,514,769	04/02/02	Lee Jin Po	February 4, 2003
	A-6	US	5,770,458	06/23/98	Klimov et al	Klimov., et al.
		US				
		US				
		US				
		US				
		US				
		US				
		US				
		US				
		US				
		US				
		US				
		US				
		US				
		US				
		US				

RELEVANCE

The cited references relate to assay devices involving multiple test strips.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ²	Number ⁴ Kind Code ³ (if known)				

Examiner Signature /Lyle Alexander/	Date Considered 04/02/2009
--	-----------------------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Table with 5 columns: APPLICATION NO., ISSUE DATE, PATENT NO., ATTORNEY DOCKET NO., CONFIRMATION NO.

11/650,280 01/07/2014 8623291 BWS 06-12 8521

46725 7590 12/18/2013
BERND W. SANDT
900 DEERFIELD COURT
MIDLAND, MI 48640

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 1444 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Jin Po Lee, Carlsbad, CA;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
 Stylesheet Version v1.2

EPAS ID: PAT3530085

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	ASSIGNMENT
CONVEYING PARTY DATA	
Name	Execution Date
MR JIN PO LEE	09/16/2015
RECEIVING PARTY DATA	
Name:	ASSURANCE BIOTECH LLC
Street Address:	7337 MELODIA TER
City:	CARLSBAD
State/Country:	CALIFORNIA
Postal Code:	92011
PROPERTY NUMBERS Total: 1	
Property Type	Number
Patent Number:	8623291
CORRESPONDENCE DATA	
Fax Number:	(415)461-2726
<i>Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.</i>	
Phone:	4152728210
Email:	Steve@NielsenPatents.com
Correspondent Name:	STEVEN A NIELSEN
Address Line 1:	100 LARKSPUR LANDING CIR #216
Address Line 4:	LARKSPUR, CALIFORNIA 94939
ATTORNEY DOCKET NUMBER:	ASSURANCE101N
NAME OF SUBMITTER:	STEVEN A NIELSEN
SIGNATURE:	/Steven A. Nielsen, Reg. 54,699/
DATE SIGNED:	09/17/2015
	This document serves as an Oath/Declaration (37 CFR 1.63).
Total Attachments: 2	
source=assignment of patent#page1.tif	
source=assignment of patent#page2.tif	

ASSIGNMENT OF PATENT Application Number 11/650,280 Patent Number 8,623,291	Docket Number: BWS 06-12 Page 1 of 1
--	---

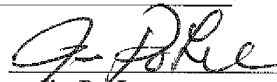
Whereas, Jin Po Lee of Carlsbad California, hereafter referred to as "assignor" is the sole inventor and current owner of U.S. Patent 8,623,291 "Multiple analyte assay device" and is now desirous of assigning the patent to the assignee as described below;

Whereas, Assurance Biotech LLC of Carlsbad California, herein referred to as "assignee" whose mailing address is 7337 Melodia Ter, Carlsbad CA 92011 is desirous of acquiring the entire right, title, and interest in said patent;

Now, therefore, for good and valuable consideration, the receipt of which is hereby acknowledged, the assignor by these presents does sell, assign and transfer unto said assignee ownership and the full and exclusive right to the said patent.

Executed this 16 day of 09, 2015,

at Carlsbad


Jin Po Lee 9/16/2015

Notary Seal:

PLEASE SEE ATTACHED
CALIFORNIA ALL PURPOSE ACKNOWLEDGEMENT

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

CIVIL CODE § 1189

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California)
County of SAN DIEGO)

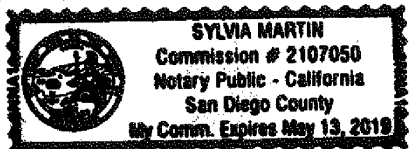
On 9/10/15 before me, SYLVIA MARTIN, NOTARY PUBLIC
Date Here Insert Name and Title of the Officer

personally appeared JIN PO LEE
Name(s) of Signer(s)

who 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.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.



Signature [Handwritten Signature]
Signature of Notary Public

Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: ASSIGNMENT OF PATENT Document Date: 9/10/15
Number of Pages: 1 Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: _____ Signer's Name: _____
 Corporate Officer — Title(s): PRESIDENT Corporate Officer — Title(s): _____
 Partner — Limited General Partner — Limited General
 Individual Attorney in Fact Individual Attorney in Fact
 Trustee Guardian or Conservator Trustee Guardian or Conservator
 Other: _____ Other: _____
Signer Is Representing: _____ Signer Is Representing: _____