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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875 Effective December 8, 2004

Application or Docket Number

11783568

APPLICATION AS FILED - PART I

(Column 1)

(Column 2)

SMALL ENTITY

OR

OTHER THAN
SMALL ENTITY

FOR	NUMBER FILED	NUMBER EXTRA
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))	90 minus 20 =	70
INDEPENDENT CLAIMS (37 CFR 1.16(h))	5 minus 3 =	2
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))		

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

RATE (\$)	FEE (\$)
N/A	300.00
N/A	\$500
N/A	\$200
X\$50 =	3500
X200 =	400
+360=	
TOTAL	4900

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

APPLICATION AS AMENDED - PART II

(Column 1)

(Column 2)

(Column 3)

SMALL ENTITY

OR

OTHER THAN
SMALL ENTITY

AMENDMENT A	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))			

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

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

AMENDMENT B	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))			

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

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.

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ROCHE 1003

PATENT APPLICATION SERIAL NO. _____

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

04/11/2007 SZEWDIE1 00000032 11783568

01 FC:1011	300.00 OP
02 FC:1111	500.00 OP
03 FC:1311	200.00 OP
04 FC:1201	400.00 OP
05 FC:1202	3500.00 OP

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April 10, 2007

ATTORNEY DOCKET NO. 06882.0200-00

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

New U.S. Patent Application
Title: BIOSENSOR MANUFACTURING METHOD
Inventors: Natasha Popovich, Dennis Slomski and David Deng

Sir:

We enclose the following papers for filing in the United States Patent and Trademark Office in connection with the above patent application.

1. Application- 35 pages, including 5 independent claims and 90 claims total.
2. Drawings- 7 sheets of drawings (Figures 1-5).
3. The filing fee is calculated as follows:

Basic Utility Application Filing Fee					\$300	\$ 300.00
Search Fee					\$500	500.00
Examination Fee					\$200	200.00
	Number of Claims		Basic	Extra		
Total Claims	90	-	20	70	x \$ 50	3500.00
Independent Claims	5	-	3	2	x \$200	400.00
☐ Presentation of Multiple Dep. Claim(s)					+ \$360	0
Total Application Pages (specification, drawings, printed sequence or computer listing, and preliminary amendment)	42	If over 100 pages, add \$250 for each additional 50 pages or fraction thereof.				0
Subtotal						\$ 4900.00
Reduction by 1/2 if small entity					-	0
TOTAL APPLICATION FILING FEE						\$ 4900.00

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17712 U.S. PTO

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April 10, 2007
Page 2

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4. A check for \$4,900.00 is enclosed. The fee includes:

\$1,000.00 filing, search, and examination fees; and
\$3,900.00 additional claims fee.

Applicants claim the right to priority based on Provisional Patent Application Nos. 60/790,773, filed April 11, 2006 and 60/878,454, filed January 4, 2007.

This application will be completed in accordance with 37 C.F.R. § 1.53(f) upon receiving a Notice to File Missing Parts of Application.

Please accord this application an application number and filing date.

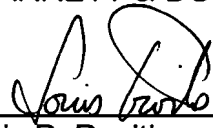
Please address all correspondence with respect to this application to:
**FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P., Customer
Number 22,852.**

The Commissioner is hereby authorized to charge any additional fees due and any other fees under 37 C.F.R. § 1.16 or § 1.17 during the pendency of this application to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By:


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EPR/JB/LAT
Enclosures

UNITED STATES PATENT APPLICATION

FOR

Biosensor Manufacturing Method

by

Natasha Popovich,

Dennis Slomski,

and

David Deng

DESCRIPTION OF THE INVENTION

- [01] This application claims priority to U.S. Provisional Application 60/790,773, filed on April 11, 2006, and U.S. Provisional Application 60/878,454 filed on January 4, 2007, both of which are herein incorporated by reference.

Technical Field

- [02] The present invention relates to electrochemical biosensors, and more particularly, to methods and systems for manufacturing biosensors.

Background

- [03] Many people require daily monitoring of their blood glucose levels. A number of available systems allow people to conveniently monitor their blood glucose levels. Such systems typically include a disposable test strip to which the user applies a blood sample, and a meter that determines the blood glucose level.
- [04] Among the various technologies available for measuring blood glucose levels, electrochemical technologies are desirable at least in part because small volumes of blood sample can be used. In electrochemical-based systems, the test strip typically includes electrodes and a sample chamber that contains chemical constituents, such as a glucose enzyme and an electron mediator. When the user applies a blood sample to the test strip, blood is drawn into the sample chamber, and chemical constituents react with the glucose present in the blood. In amperometric electrochemical systems, the instrument applies a voltage to the electrodes to cause a redox reaction. The meter initiates one or more current measurements and calculates the glucose level based on at least one of the current measurements.
- [05] There remains a continual need to develop accurate measurements of blood glucose levels, which can help maintain the long-term health of many users. Exemplary areas of development include enhanced reliability, ease-of-use, and robust tolerance of

poor user technique in the design of meters and test strips. However, as sample sizes become smaller, the dimensions of the sample chamber and electrodes in the test strip must also become smaller. This, in turn, can render the test systems more sensitive to manufacturing process and component variations, environmental factors, user technique shortcomings, damage from handling, etc. Accordingly, there is a continuing need for reliable low-volume biosensor test-strips, and also for low cost, high manufacturing volume, efficient biosensor test strip manufacturing processes.

[06] Several methods for manufacturing biosensors have been proposed. One such method is described in U.S. Patent 6,875,327 to Miyazaki et al. Miyazaki et al. describe a biosensor manufacturing process whereby a conductive layer is formed on a support. Electrodes are formed using a laser to form multiple “slits” in the conductive layer, electrically separating the working, counter and detecting electrodes. Following electrode formation, chemical reagents are selectively applied to the conductive layer.

[07] Although the electrode design described by Miyazaki et al. can provide a functional biosensor, the manufacturing process can be improved. Specifically, the manufacturing process can be inefficient, time consuming, or unsuitable to form one or more biosensors described in the present disclosure.

[08] The present disclosure is directed to a manufacturing method designed to overcome one or more of the limitations in the prior art.

Summary of the Invention

[09] The present invention includes a biosensor having a first conductive component including at least one boundary formed by a first processing technique and at least one boundary formed by a second processing technique not the same as the first processing technique. The biosensor can also have a second conductive component including at least one boundary formed by the first processing technique and at least one boundary formed by a third processing technique not the same as the first processing technique. Further, the biosensor has a third conductive component including at least one boundary

formed by the second processing technique and at least one boundary formed by the third processing technique not the same as the second processing technique.

[10] Another embodiment of the invention is directed to a method of manufacturing test strips. The method can include forming a reel containing a conductive layer and a base layer. The method includes forming a first conductive component, wherein the first conductive component includes at least one boundary formed by a first processing technique and at least one boundary formed by a second processing technique not the same as the first processing technique. A second conductive component can be formed, wherein the second conductive component includes at least one boundary formed by the first processing technique and at least one boundary formed by a third processing technique not the same as the first processing technique. The method also includes forming a third conductive component, wherein the third conductive component includes at least one boundary formed by the second processing technique and at least one boundary formed by the third processing technique not the same as the second processing technique.

[11] Another embodiment of the invention is directed to a method of manufacturing test strips. The method can include forming a reel containing a conductive layer and a base layer, and forming a first kerf in the conductive layer, wherein the first kerf can be formed using a first laser ablation process. The method can also include forming a second kerf in the conductive layer, wherein the second kerf can be formed using a second laser ablation process that is not the same as the first laser ablation process, and separating one or more test strips from the reel using a singulation process.

[12] Additional objects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

- [13] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

Brief Description of the Drawings

- [14] The following drawings form part of the present specification and are included to further demonstrate certain aspects of the present invention. The invention may be better understood by reference to one or more of these drawings in combination with the detailed description of the specific embodiments presented herein:
- [15] FIG. 1A is a top plan view of a test strip according to an illustrative embodiment of the invention.
- [16] FIG. 1B is a top plan view of a test strip according to another illustrative embodiment of the invention.
- [17] FIG. 2 is a cross-sectional view of the test strip of FIG. 1A, taken along line 2-2.
- [18] FIG. 3 is a magnified top plan view of the proximal end of a test strip according to an illustrative embodiment of the invention.
- [19] FIG. 4A is a top view of a conductive layer according to an illustrative embodiment of the invention.
- [20] FIG. 4B is a top view of a conductive layer according to another illustrative embodiment of the invention.
- [21] FIG. 5 is a top view of a dielectric layer according to an illustrative embodiment of the invention.

Detailed Description

- [22] In accordance with an illustrative embodiment, a biosensor design, manufacturing method and method for measuring a fluid constituent is described. Many industries have a commercial need to monitor the concentration of particular constituents in a fluid. Oil refining, winemaking, and dairy are examples of industries where fluid testing is routine.

In the health care field, people such as diabetics, for example, have a need to monitor a particular constituent within their bodily fluids using a biosensor. A number of systems are available that allow people to test a body fluid, such as, blood, urine, or saliva, to conveniently monitor the level of a particular fluid constituent, such as, for example, cholesterol, proteins, and glucose.

[23] A biosensor may include a test strip, which can be disposable, that may facilitate the detection of a particular constituent of a fluid. The test strip can include a proximal end, a distal end and at least one electrode. The proximal end of the test strip may include a sample chamber for receiving a fluid to be tested. The sample chamber can be dimensioned and arranged to draw-in and hold a blood sample in the sample chamber to contact the electrodes by capillary action. The distal end of the test strip may be configured to operatively connect the test strip to a meter that may determine the concentration of the fluid constituent. The test strip can have, near its distal end, a plurality of electrical contacts that provide operative connection between the electrodes and the meter. The ends of the test strip can further include improved visual and/or tactile distinguishable section, such as, for example, a taper, in order to make it easier for the user to operatively connect the test strip to the meter or apply a fluid to the sample chamber.

[24] The at least one electrode may include a working electrode, a counter electrode, and a fill-detect electrode. A diffusion barrier can be disposed between any adjacent electrodes, such as, for example, the working electrode and counter electrode. A reagent layer can be disposed in the sample chamber and may cover at least a portion of the working electrode, which can also be disposed at least partially in the sample chamber. The reagent layer can include, for example, an enzyme, such as glucose oxidase or glucose dehydrogenase, and a mediator, such as potassium ferricyanide or ruthenium hexamine, to facilitate the detection of glucose in blood. It is contemplated that other reagents and/or other mediators can be used to facilitate detection of glucose and other constituents in blood and other fluids.

Test Strip Configuration

- [25] With reference to the drawings, FIGS. 1A and 2 show a test strip 10, in accordance with an illustrative embodiment of the present invention. Test strip 10 can take the form of a substantially flat strip that extends from a proximal end 12 to a distal end 14. In one embodiment, the proximal end 12 of test strip 10 can be narrower than distal end 14 to provide facile visual recognition of distal end 14. For example, test strip 10 can include a tapered section 16, in which the full width of test strip 10 tapers down to proximal end 12, making proximal end 12 narrower than distal end 14. If, for example, a blood sample is applied to an opening in proximal end 12 of test strip 10, providing tapered section 16 and making proximal end 12 narrower than distal end 14, can, in certain embodiments, assist the user in locating the opening where the blood sample is to be applied. Further or alternatively, other visual means, such as indicia, notches, contours, textures, or the like can be used.
- [26] Test strip 10 is depicted in FIGS. 1A and 2 as including a plurality of conductive components, such as, for example, electrodes. A conductive component can include any structure configured to at least partially conduct an electrical signal. In some embodiments, a conductive component can extend substantially along the length of test strip 10 to provide an electrical contact near distal end 14 and a conductive region electrically connecting the region of the electrode near proximal end 12 to the electrical contact. In the illustrative embodiment of FIGS. 1A and 2, the plurality of electrodes includes a working electrode 22, a counter electrode 24, a fill-detect anode 28, and a fill-detect cathode 30. Correspondingly, the electrical contacts can include a working electrode contact 32, a counter electrode contact 34, a fill-detect anode contact 36, and a fill-detect cathode contact 38 positioned at distal end 14. The conductive regions can include a working electrode conductive region 40, electrically connecting the proximal end of working electrode 22 to working electrode contact 32, a counter electrode conductive region 42, electrically connecting the proximal end of counter electrode 24 to counter electrode contact 34, a fill-detect anode conductive region 44 electrically

connecting the proximal end of fill-detect anode 28 to fill-detect contact 36, and a fill-detect cathode conductive region 46 electrically connecting the proximal end of fill-detect cathode 30 to fill-detect cathode contact 38.

[27] In one embodiment, at least one electrode is partially housed within the sample chamber to allow contact with the fluid to be tested. For example, FIGS. 1A and 2 depict test strip 10 as including slot 52, forming a portion of a sample chamber 88 at proximal end 12. Slot 52 can define an exposed portion 54 of working electrode 22, an exposed portion 56 of counter electrode 24, an exposed portion 60 of fill-detect anode 28, and an exposed portion 62 of fill-detect cathode 30. Further, the illustrative embodiment is depicted including an optional auto-on conductor 48 disposed near distal end 14 to allow the meter to determine that a test strip is operatively connected to the meter.

[28] FIG. 1B is a top plan view of test strip 110 according to another illustrative embodiment of the invention. As shown, test strip 110 includes a different electrode configuration, and a plurality of encoded electrical contacts 148 disposed near a distal end 114. Test strip 110 can take the form of a substantially flat strip that extends from a proximal end 112 to distal end 114, wherein the proximal end 112 of test strip 110 can be narrower than distal end 114 to provide facile visual recognition of distal end 14. For example, test strip 110 can include a tapered section 116.

[29] Test strip 110 depicted in FIG. 1B can include a plurality of electrodes, such as, for example, a working electrode 122, a counter electrode 124, and fill-detect electrodes 128, 130. Correspondingly, the electrical contacts can include a working electrode contact 132, a counter electrode contact 134, and fill-detect electrode contacts 136, 138 positioned at distal end 114. The conductive regions can include a working electrode conductive region 140, electrically connecting the proximal end of working electrode 122 to working electrode contact 132, a counter electrode conductive region 142, electrically connecting the proximal end of counter electrode 124 to counter electrode contact 134, and fill-detect conductive regions 144, 146 electrically connecting fill-detect electrodes 128, 130 to fill-detect contacts 136, 138. Test strip 110 can also include a slot 152

configured to receive a fluid sample. In addition, test strip 110 can include one or more diffusion barriers (not shown), as described below.

[30] In some embodiments, test strip 110 can include one or more encoded electrical contacts 148 configured to encode a readable code, wherein the readable code can include test strip information, calibration information, or any other suitable data. In addition, encoded electrical contacts 148 can be resistant to scratching or abrasion. Specifically, test strip 110 can include encoded electrical contacts 148 formed of two or more layers of conductive and/or semi-conductive material (not shown). Further information relating to encoded electrical contacts 49 encoding and abrasion resistance are described in co-owned U.S. Patent Application No. 11/458,298, which is incorporated by reference herein in its entirety.

[31] FIG. 3 shows a top plan view of a test strip according to an illustrative embodiment. As shown in FIG. 3, a diffusion barrier 47 may be formed between working electrode 22 and fill-detect anode 28 and fill-detect cathode 30. Diffusion barrier 47 can electrically separate exposed portion 54 of working electrode 22 and exposed portion 60 of fill-detect anode 28 and exposed portion 62 of fill-detect cathode 30. In some embodiments, test strip 10 may also include a diffusion barrier 49 formed between working electrode 22 and counter electrode 24. Diffusion barrier 49 can electrically separate exposed portion 54 of working electrode 22 and exposed portion 56 of counter electrode 24. In other embodiments, test strip 10 may include one or more diffusion barriers positioned between any adjacent electrodes.

[32] Diffusion barriers may be configured to improve the accuracy of determining constituent concentration by reducing the migration of electrochemically active components. For example, oxidized or reduced species formed by a redox reaction in the detection of glucose may migrate between working electrode 22 and counter electrode 24. This migration may generate spurious current, reducing the accuracy of constituent concentration determination. The width of diffusion barrier 49 may provide sufficient distance to reduce the effects of migration of electrochemically active components

between exposed portion 54 of working electrode 22 and exposed portion 56 of counter electrode 24.

- [33] The equation for determining the diffusion distance of an electroactive chemical component is given by:

$$d = \sqrt{2Dt}$$

where d is the diffusion distance, D is the diffusion coefficient, and t is time. For example, the diffusion coefficient is $\sim 7.6 \times 10^{-6} \text{ cm}^2/\text{sec}$ for potassium ferricyanide and $\sim 8.8 \times 10^{-6} \text{ cm}^2/\text{sec}$ for ruthenium hexamine. During an illustrative reaction time of 5 seconds, charged potassium ferricyanide may migrate 87 micro-meters and charged ruthenium hexamine may migrate 93 micro-meters. It has been found that the current caused by migrating charged components may be reduced by separating working electrode 22 and counter electrode 24 by a distance approximately equal to or greater than the diffusion distance, such as, for example, approximately 100 micro-meters for a biosensor using potassium ferricyanide or ruthenium hexamine. According to the illustrative embodiment, diffusion barrier 49 may separate working electrode 22 and counter electrode 24 by at least approximately 100 micro-meters.

- [34] In some embodiments, the diffusion distance for a given mediator is dependent upon the reaction time. For example, shorter reaction times decrease the diffusion distance. Subsequently, the width of diffusion barrier can be decreased. Longer reaction times increase diffusion distance, and subsequently, the width of diffusion barrier can increase. It is also contemplated that the diffusion distance may vary depending upon other factors related to the design and/or function of test strip 10, such as, for example, geometry, surface energy, and environmental factors.

- [35] As shown in FIG. 2, test strip 10 can have a generally layered construction. Working upwardly from the bottom layer, test strip 10 can include a base layer 18 that can substantially extend along the entire length or define the length of test strip 10. Base layer 18 can be formed from an electrically insulating material and can have a thickness sufficient to provide structural support to test strip 10.

- [36] According to the illustrative embodiment of FIG. 2, a conductive layer 20 may be disposed on at least a portion of base layer 18. Conductive layer 20 can comprise a plurality of electrodes. In the illustrative embodiment, the plurality of electrodes includes a working electrode 22, a counter electrode 24, a fill-detect anode 28, and a fill-detect cathode 30. Further, the illustrative embodiment is depicted with conductive layer 20 including an auto-on conductor 48 disposed on base layer 18 near distal end 14. In addition, diffusion barrier 49 may be a non-conductive region formed in conductive layer 20. It is contemplated that diffusion barrier 49 may be formed by at least partially ablating conductive layer 20 between working electrode 22 and counter electrode 24.
- [37] The next layer of the illustrative test strip 10 is a dielectric spacer layer 64 disposed on conductive layer 20. Dielectric spacer layer 64 may be composed of an electrically insulating material, such as polyester. Dielectric spacer layer 64 can cover portions of working electrode 22, counter electrode 24, fill-detect anode 28, fill-detect cathode 30, and conductive regions 40-46, but in the illustrative embodiment of FIG. 2 does not cover electrical contacts 32-38, and/or auto-on conductor 48. For example, dielectric spacer layer 64 can cover a substantial portion of conductive layer 20 thereon, from a line proximal of contacts 32 and 34 to proximal end 12, except for slot 52 extending from proximal end 12.
- [38] A cover 72, having a proximal end 74 and a distal end 76, is shown in FIG. 2 as being disposed at proximal end 12 and configured to cover slot 52 and partially form sample chamber 88. Cover 72 can be attached to dielectric spacer layer 64 via an adhesive layer 78. Adhesive layer 78 can include a polyacrylic or other adhesive and can consist of sections disposed on cover 72 on opposite sides of slot 52. A break 84 in adhesive layer 78 extends from distal end 70 of slot 52 to an opening 86. Cover 72 can be disposed on spacer layer 64 such that proximal end 74 of cover 72 may be aligned with proximal end 12 and distal end 76 of cover 72 may be aligned with opening 86, thereby covering slot 52 and break 84. Further, cover 72 can be composed of an electrically insulating material, such as polyester. Cover 72 can also be transparent.

[39] Slot 52, together with base layer 18 and cover 72, can define sample chamber 88 in test strip 10 for receiving a fluid sample, such as a blood sample, for measurement in the illustrative embodiment. A proximal end 68 of slot 52 can define a first opening in sample chamber 88, through which the fluid sample is introduced. At distal end 70 of slot 52, break 84 can define a second opening in sample chamber 88, for venting sample chamber 88 as sample enters sample chamber 88. Slot 52 may be dimensioned such that a blood sample applied to its proximal end 68 is drawn into and held in sample chamber 88 by capillary action, with break 84 venting sample chamber 88 through opening 86, as the blood sample enters. In some embodiments, cover 72 can include one or more holes, or vents (not shown), configured to permit fluid flow into chamber 88. Moreover, slot 52 can be dimensioned so that the volume of blood sample that enters sample chamber 88 by capillary action is about 1 micro-liter or less.

[40] A reagent layer 90 may be disposed in sample chamber 88. In the illustrative embodiment, reagent layer 90 contacts exposed portion 54 of working electrode 22. It is also contemplated that reagent layer 90 may or may not contact diffusion barrier 49 and/or exposed portion 56 of counter electrode 24. Reagent layer 90 may include chemical components to enable the level of glucose or other analyte in the fluid, such as a blood sample, to be determined electro-chemically. For example, reagent layer 90 can include an enzyme specific for glucose, such as glucose dehydrogenase or glucose oxidase, and a mediator, such as potassium ferricyanide or ruthenium hexamine. Reagent layer 90 can also include other components, such as buffering materials (e.g., potassium phosphate), polymeric binders (e.g., hydroxypropyl-methyl-cellulose, sodium alginate, microcrystalline cellulose, polyethylene oxide, hydroxyethylcellulose, and/or polyvinyl alcohol), and surfactants (e.g., Triton X-100 or Surfynol 485).

[41] Chemical components of reagent layer 90 can react with glucose in the blood sample in the following way. The glucose oxidase initiates a reaction that oxidizes the glucose to gluconic acid and reduces the ferricyanide to ferrocyanide. When an appropriate voltage is applied to working electrode 22, relative to counter electrode 24,

the ferrocyanide is oxidized to ferricyanide, thereby generating a current that is related to the glucose concentration in the blood sample.

[42] In the determination of glucose concentration in a blood sample, diffusion barrier 49 may improve the accuracy of the determination by reducing the migration of one or more components of reagent layer 90. A component charged by oxidation or reduction, such as, for example, ruthenium hexamine, may migrate between working electrode 22 and counter electrode 24. The migration or “shuttling” of the charged components may generate spurious current, reducing the accuracy of glucose concentration determination. The width of diffusion barrier 49 is designed to provide sufficient distance to limit the migration of charged constituents between exposed portion 54 of working electrode 22 and exposed portion 56 of counter electrode 24.

[43] As depicted in FIG. 2, the position and dimensions of the layers of illustrative test strip 10 can result in test strip 10 having regions of different thicknesses. Of the layers above base layer 18, the thickness of spacer layer 64 may constitute a substantial thickness of test strip 10. Thus the distal end of spacer layer 64 may form a shoulder 92 in test strip 10. Shoulder 92 may delineate a thin section 94 of test strip 10 extending from shoulder 92 to distal end 14, and a thick section 96 of test strip 10 extending from shoulder 92 to proximal end 12. The elements of test strip 10 used to electrically connect it to the meter (not shown), namely, electrical contacts 32-38 and auto-on conductor 48, can all be located in thin section 94. Accordingly, the meter can be sized and configured to receive relatively thin section 94 but not relatively thick section 96. This may help the user to insert the correct end of test strip 10, i.e., distal end 14 of relatively thin section 94, and can prevent the user from inserting the wrong end, i.e., proximal end 12 of relatively thick section 96, into the meter.

[44] Test strip 10 can be sized for easy handling. For example, test strip 10 can measure approximately 35 mm long (i.e., from proximal end 12 to distal end 14) and about 9 mm wide. According to the illustrative embodiment, base layer 18 can be a polyester material about 0.25 mm thick and dielectric spacer layer 64 can be about 0.094

mm thick and cover portions of working electrode 22. Adhesive layer 78 can include a polyacrylic or other adhesive and have a thickness of about 0.013 mm. Cover 72 can be composed of an electrically insulating material, such as polyester, and can have a thickness of about 0.095 mm. Sample chamber 88 can be dimensioned so that the volume of fluid sample is about 1 micro-liter or less. For example, slot 52 can have a length (i.e., from proximal end 12 to distal end 70) of about 3.56 mm, a width of about 1.52 mm, and a height (which can be substantially defined by the thickness of dielectric spacer layer 64) of about 0.13 mm. The dimensions of test strip 10 for suitable use can be readily determined by one of ordinary skill in the art. For example, a meter with automated test strip handling may utilize a test strip smaller than 9 mm wide.

- [45] Although FIGS. 1A, 1B and 2 show an illustrative embodiment of test strip 10, other configurations, chemical components and electrode arrangements could be used. For example, different arrangements of working electrode, counter electrode, and/or diffusion barriers can also be used. In the configuration shown in FIGS. 1A and 2, working electrode 22, counter electrode 24 and diffusion barriers 47, 49 are separated by boundaries generally aligned in the x-axis, perpendicular to the length of test strip 10 in the y-axis. Alternatively, working electrode 22, counter electrode 24 and diffusion barrier 49 can be separated by boundaries generally aligned in the y-axis, parallel to the length of test strip 10. It is also contemplated that working electrode 22, counter electrode 24 and/or diffusion barrier 49 may be aligned at any angle relative the length of test strip 10.

Manufacturing of Test Strips

- [46] FIGs. 4A, 4B, and 5 show one test strip structure partially fabricated in order to show various steps in an illustrative method for forming the test strip. In each of FIGs. 4A, 4B, and 5, the outer shape of the test strip that would be formed in the overall manufacturing process is shown as a dotted line. Although these figures show steps for manufacturing test strip 10, as shown in FIGs. 1A, 4B, and 2, it is to be understood that

similar steps can be used to manufacture test strips having other configurations of components.

[47] Test strips 10 can be manufactured by forming a plurality of test strips 10 in an array along a reel of substrate material. The illustrative manufacturing process employs base layer 18 covered by conductive layer 20. Conductive layer 20 and base layer 18 can be in the form of a reel, such as, for example, a ribbon, web, sheet, or other similar structure. Conductive layer 20 can comprise any suitable conductive or semi-conductor material, such as gold, silver, palladium, carbon, tin oxide and others known in the art. The conductive material can be any suitable thickness and can be bonded to base layer 18 by any suitable means.

[48] Conductive layer 20 can be formed by direct writing, sputtering, screen printing, contact printing or any suitable manufacturing method. One exemplary process is direct writing of electrodes as described in commonly-assigned, copending provisional patent application No. 60/716,120 "Biosensor with Direct Written Electrode," filed September 13, 2005, the disclosure of which is hereby incorporated herein by reference in its entirety. Another exemplary process is screen printing as described in commonly-assigned, U.S. Patent No. 6,743,635 "System and methods for blood glucose sensing," filed Nov. 1, 2002, the disclosure of which is hereby incorporated herein by reference in its entirety.

[49] As depicted in the illustrative embodiment shown in FIG. 4A, 4B, test strip 10, 110 may include a plurality of electric components, such as, for example, electrodes 22, 122, 24, 124, 28, 128 and 30, 130 disposed in conductive layer 20, 120 and substantially extending from proximal end 12, 112 to distal end 14, 114. The electric components of test strip 10, 110 may be partially formed by forming a trace 80, 180. For example, trace 80 may be indicated by the solid lines on conductive layer 20 as shown in FIG. 4A. Trace 80, 180 may at least partially define one or more boundaries of one or more electric components of test strip 10, 110.

- [50] In some embodiments, the electric components of the test strip may be at least partially formed by one or more processing techniques. For example, one or more boundaries of some electric components may be at least partially formed by any process used to form the conductive layer, such as, direct writing, sputtering, screen printing and contact printing. It is also contemplated that a processing technique may be used to more precisely define the boundaries of some electric components, such as, for example, laser ablation. In other embodiments, a processing technique may include lamination, etching or a physical separation processes, such as, for example, stamping and cutting.
- [51] In some embodiments, trace 80, 180 can be formed by an ablation process, such as, for example, laser ablation where laser ablation can include any device suitable for removal of the conductive layer in appropriate time and with appropriate precision and accuracy. Various types of lasers can be used for sensor fabrication, such as, for example, solid-state lasers (e.g. Nd:YAG and titanium sapphire), copper vapor lasers, diode lasers, carbon dioxide lasers and excimer lasers. Such lasers may be capable of generating a variety of wavelengths in the ultraviolet, visible and infrared regions. For example, excimer laser provides wavelength of about 248 nm, a fundamental Nd:YAG laser gives about 1064 nm, a frequency tripled Nd:YAG wavelength is about 355 nm and a Ti:sapphire laser is at approximately 800 nm. The power output of these lasers may vary and is usually in range about 10-100 watts. Alternatively, trace 80, 180 can be formed by laser ablation process in combination with other suitable processes known in the art.
- [52] The laser ablation process can include a laser system. The laser system can include a laser source. The laser system can further include means to form trace 80, 180 such as, for example, a focused beam, projected mask or other suitable technique. The use of a focused laser beam can include a device capable of rapid and accurate controlled movement to move the focused laser beam relative to conductive layer 20, 120. For example, a scanner such as HurryScan (ScanLabs) may be used to direct the laser beam in direct write applications. The use of a mask can involve a laser beam passing through

the mask to selectively ablate specific regions of conductive layer 20, 120. A single mask can define trace 80, 180, or multiple masks may be required to form trace 80, 180. To form trace 80, 180, the laser system can move relative to conductive layer 20, 120. Specifically, the laser system, conductive layer 20, 120, or both the laser system and conductive layer 20, 120 may move to allow formation of trace 80, 180 by laser ablation. Exemplary devices available for such ablation techniques include a laser system available from LasX Industries, White Bear Lake, Minnesota and laser micro machining systems from Exitech, Ltd. (Oxford, United Kingdom).

[53] In some embodiments, trace 80, 180 may include one or more kerfs at least partially electrically isolating adjacent electric components of test strip 10, 110. A kerf may form a linear and/or curvilinear electrically-isolating region between adjacent electric components. It is also contemplated that a kerf may include a turn of any angle, such as, for example, an orthogonal angle whereby the kerf forms an “L” shape.

[54] A kerf of may partially electrically isolate adjacent electric components. In some embodiments, a kerf may partially electrically isolate adjacent electric components as the electric components may remain electrically connected following kerf formation. For example, as shown in FIG. 4A, counter electrode contact 34 and fill-detect cathode contact 38 may remain electrically connected following the formation of a kerf 57 partially separating the two electric components. Counter electrode contact 34 and fill-detect cathode contact 38 may subsequently be electrically isolated by a separation process as described below, whereby test strip 10 is separated from the laminate reel along the dashed line as shown in FIG. 4A.

[55] In some embodiments, one or more laser ablation processing techniques may be used to form a trace. For example, a first laser ablation processing technique may utilize a first laser beam of a first width and a second laser ablation processing technique may utilize a second laser beam of a second width, wherein the first and second widths may be different. The first laser beam may be used to form one or more boundaries of contiguous electric components and the second laser beam may be used to form one or

more diffusion barriers, and/or other electric components. In some embodiments, the width of the second laser beam may be at least as wide as the diffusion distance for the specific reagent used for test strip 10. For example, a second laser beam ~100 micro-meters wide may be used to form diffusion barrier 49 by at least partially removing material from conductive layer 20 between working electrode 22 and counter electrode 24. In addition, a second laser beam ~100 micro-meters wide may be used to form one or more boundaries of encoding electrical contacts 148, while a first laser beam ~20 micro-meters wide may be used to form one or more boundaries of working electrode 122, counter electrode 124, and/or fill-detect electrodes 128, 130.

[56] In some embodiments, a first laser ablation processing technique may utilize a first laser beam generated by a first type of laser and a second laser ablation processing technique may utilize a second laser beam generated by a second type of laser, wherein the first and second types of lasers may be different. As previously described, various types of lasers may be used to form various kerfs in the test strip. For example, one kerf may be formed by a laser operating in the infrared spectrum while another kerf may be formed by a laser operating in the ultraviolet spectrum. As shown in FIG. 4B, a laser operating in the infrared spectrum could be used to form a kerf 101, while a laser operating in the ultraviolet spectrum could be used to form a kerf 103. In some embodiments, kerf 101 can form a boundary of one or more conductive components at distal end 114, such as, for example, electrical contacts 132, 134, 136, 138, and/or 148. In addition, kerf 103 can form a boundary of one or more conductive components at proximal end 116, such as, for example, electrodes 122, 124, 128, and/or 130.

[57] In other embodiments, a first laser ablation processing technique may utilize a first laser beam generated at a first power and a second laser ablation processing technique may utilize a second laser beam generated a second power, wherein the first and second laser powers may be different. For example, one laser may have sufficient power to ablate material to a desired depth, while another laser may ablate material to a smaller or larger depth. Also, one laser may be of sufficient power to penetrate one or

more layers of material, while another laser may be able to penetrate fewer or greater layers of material. As previously described, test strip 10, 110 can include electrical contacts formed of two or more layers of conductive and/or semi-conductive material, as described by U.S. Patent Application No. 11/458,298.

[58] To illustrative by example, a first laser ablation process may be configured to ablate two or more layers of conductive and/or semi-conductive material to form kerf 101, while a second laser ablation process may be configured to ablate less material at a lower power to form kerf 103. For example, a TR Fiber laser manufactured by SPI (Southampton, UK) operating at suitable power may be used to form kerf 101. Such a manufacturing technique can permit formation of conductive components at proximal end 116 at appropriate resolution for the required electrochemical process and formation of conductive components at distal end 114 requiring higher power ablation to penetrate of multilayered material. Also, different laser ablation processes can be applied at different stages during a manufacturing process. For example, kerf 101 may be formed following deposition of one or more layers of conductive and/or semi-conductive material while kerf 103 may be formed prior to such a deposition process. Therefore, different processing techniques, such as lasers operating at different powers, different beam width, being of different type, etc., can be used to form one or more boundaries of one or more conductive components. For example, an AVIA-X laser manufactured by Coherent (Santa Clara, CA) can be used to form kerf 103 when operated at a first laser power, and kerf 101 when operated at a second laser power higher than the first laser power.

[59] In some embodiments, diffusion barriers may be formed by a plurality of kerfs. For example, diffusion barrier 49 may be at least partially formed by kerfs 51, 53 and 55, where kerfs 51 and 53 may be any width less than the width of diffusion barrier 49. The width and/or trajectory of the one or more kerfs used to form diffusion barrier 49 may be sufficient to form a region electrically isolating working electrode 22 and counter electrode 24. For example, the distance between kerfs 51 and 53 can define the width of

diffusion barrier 49 and thus the separation distance between working electrode 22 and counter electrode 24.

[60] Diffusion barrier 49 may be contiguous with at least one boundary of one or more electric components, such as, for example, working electrode 22 and counter electrode 24. As shown in FIG. 4A, boundaries contiguous with diffusion barrier 49, working electrode 22, and counter electrode 24 may include the boundaries formed by kerfs 51, 53, and 55. Boundaries non-contiguous with diffusion barrier 49 may include the boundaries between counter electrode conductive region 42 and fill-detect cathode conductive region 46, fill-detect cathode conductive region 46 and fill-detect anode conductive region 44, and fill-detect anode conductive region 44 and working electrode conductive region 40.

[61] Following the formation of electrical components of test strip 10, dielectric spacer layer 64 can be applied to conductive layer 20, as illustrated in FIG. 5. Spacer layer 64 can be applied to conductive layer 20 in a number of different ways. In an illustrative approach, spacer layer 64 is provided as a sheet or web large enough and appropriately shaped to cover multiple test strip traces 80. In this approach, the underside of spacer layer 64 can be coated with an adhesive to facilitate attachment to conductive layer 20. Portions of the upper surface of spacer layer 64 can also be coated with an adhesive in order to provide adhesive layer 78 in each of the test strips 10. Various slots can be cut, formed or punched out of spacer layer 64 to shape it before, during or after the application of spacer layer 64 to conductive layer 20. For example, as shown in FIG. 5, spacer layer 64 can have a pre-formed slot 98 for each test strip structure. Spacer layer 64 may then be positioned over conductive layer 20, as shown in FIG. 5, and laminated to conductive layer 20. When spacer layer 64 is appropriately positioned on conductive layer 20, exposed electrode portions 54-62 are accessible through slot 98. Similarly, spacer layer 64 leaves contacts 32-38 and auto-on conductor 48 exposed after lamination.

[62] Alternatively, spacer layer 64 could be applied in other ways. For example, spacer layer 64 can be injection molded onto base layer 18. Spacer layer 64 could also be

built up on base layer 18 by screen-printing successive layers of a dielectric material to an appropriate thickness, e.g., about 0.005 inches. An exemplary dielectric material comprises a mixture of silicone and acrylic compounds, such as the "Membrane Switch Composition 5018" available from E.I. DuPont de Nemours & Co., Wilmington, Del. Other materials could be used, however.

[63] In some embodiments, one or more kerfs may be formed following application of spacer layer 64 to base layer 18. For example, spacer layer 64 may be applied to base layer 18 such that spacer layer 64 at least partially covers one or more electrical contacts 132, 134, 136, 138, and/or 148. Following application of spacer layer 64, one or more kerfs 101 can be formed by any suitable processing technique configured to remove sufficient material from spacer layer 64 and conductive layer 120, such as, for example, laser ablation using a high-energy or infrared laser. In other embodiments, kerf 101 can be formed following application of a second conductive layer or semi-conductive layer to distal end of the test strip, as described by U.S. Patent Application No. 11/458,298. Other processing techniques may be employed, including etching.

[64] Reagent layer 90 can then be applied to each test strip structure after forming spacer layer 64. In an illustrative approach, reagent layer 90 is applied by micro-pipetting an aqueous composition onto exposed portion 54 of working electrode 22 and letting it dry to form reagent layer 90. It is also contemplated that reagent layer 90 may or may not contact diffusion barrier 49 and/or exposed portion 56 of counter electrode 24. An exemplary aqueous composition has a pH of about 6 and contains 2 weight % polyvinyl alcohol, 0.1 M potassium phosphate, 0.05 weight % Triton X-100, 0.15 M ruthenium hexamine, 0.7% hydroxyethylcellulose (such as NATROSOL®), and about 2500 units of glucose oxidase per mL. Alternatively, other methods, such as screen-printing, can be used to apply the composition used to form reagent layer 90. In other embodiments, reagent layer 90 can be applied before or concurrently with application of spacer layer 64.

- [65] Cover 72 can then be attached to space layer 64, where cover 72 is constructed to cover slot 52. Cover 72 can include adhesive layer 78 configured to adhere to spacer layer 64. Following attachment of cover 72, individual test strips 10 may be separated from the laminated reel. In an illustrative embodiment, the separation process may include stamping or “punching out” of individual test cards in a “singulation” process. For example, the singulation process could include laser ablation, stamping, cutting, or etching. In addition, one or more cover holes (not shown) can be formed in cover 72 to provide suitable venting of sample chamber 88. A cover hole could be formed by any suitable processing technique, such as, for example, laser ablation, stamping, cutting, or etching. In some embodiments, the cover hole could be formed using a carbon dioxide laser or other type of laser operated at an appropriate energy.
- [66] Various embodiments of the present invention have been described above. Those skilled in the art will understand, however, that changes and modifications may be made to these embodiments without departing from the true scope and spirit of the invention, which is defined by the claims.

Claims

What is claimed is:

1. A biosensor, comprising:
 - a first conductive component including at least one boundary formed by a first processing technique and at least one boundary formed by a second processing technique not the same as the first processing technique;
 - a second conductive component including at least one boundary formed by the first processing technique and at least one boundary formed by a third processing technique not the same as the first processing technique; and
 - a third conductive component including at least one boundary formed by the second processing technique and at least one boundary formed by the third processing technique not the same as the second processing technique.
2. The biosensor of claim 1, wherein the first processing technique includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.
3. The biosensor of claim 1, wherein the second processing technique includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.
4. The biosensor of claim 1, wherein the third processing technique includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.
5. The biosensor of claim 1, wherein the first processing technique includes laser ablation at a first ablative beam width and the second processing technique includes laser

ablation at a second ablative beam width, wherein the first beam width and the second beam width are not the same.

6. The biosensor of claim 5, wherein the first ablative beam width is at least approximately 20 micro-meters.

7. The biosensor of claim 5, wherein the second ablative beam width is at least approximately 100 micro-meters.

8. The biosensor of claim 5, wherein at least one laser ablation processing technique removes substantially all conductive material between adjacent conductive components.

9. The biosensor of claim 1, wherein the first processing technique includes laser ablation using a first type of laser and the second processing technique includes laser ablation using a second type of laser, wherein the first type of laser and the second type of laser are not the same.

10. The biosensor of claim 9, wherein the first or second type of laser is selected from the group consisting of a solid-state laser, a copper vapor laser, a diode laser, a carbon dioxide laser, and an excimer laser.

11. The biosensor of claim 9, wherein the first or second type of laser operates in a region selected from at least one of an ultraviolet, a visible, and an infrared region.

12. The biosensor of claim 1, wherein the first processing technique includes laser ablation using a first laser operating at a first power and the second processing technique includes laser ablation using a second laser operating at a second power, wherein the first power and the second power are not the same.

13. The biosensor of claim 12, wherein the first or second laser power is in the range of about 10 to about 100 watts.

14. The biosensor of claim 1, wherein the first processing technique includes forming a single kerf and the second processing technique includes forming a plurality of kerfs.

15. The biosensor of claim 1, wherein the first conductive component is contacted by at least one chemical component.

16. The biosensor of claim 15, wherein the at least one chemical component includes at least one compound selected from the group consisting of potassium ferricyanide, ruthenium hexamine, glucose oxidase and glucose dehydrogenase.

17. The biosensor of claim 1, wherein at least one of the first conductive component, the second conductive component, and the third conductive component is formed from a semi-conductive material.

18. A method of manufacturing test strips, comprising:
forming a reel containing a conductive layer and a base layer;
forming a first conductive component, wherein the first conductive component includes at least one boundary formed by a first processing technique and at least one boundary formed by a second processing technique not the same as the first processing technique;
forming a second conductive component, wherein the second conductive component includes at least one boundary formed by the first processing technique and at least one boundary formed by a third processing technique not the same as the first processing technique; and
forming a third conductive component, wherein the third conductive component includes at least one boundary formed by the second processing technique and at

least one boundary formed by the third processing technique not the same as the second processing technique.

19. The method of claim 18, wherein the first processing technique includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.

20. The method of claim 18, wherein the second processing technique includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.

21. The method of claim 18, wherein the third processing technique includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching

22. The method of claim 18, wherein the first processing technique includes using laser ablation having a first ablative beam width and the second processing technique includes using laser ablation having a second ablative beam width, wherein the first beam width and the second beam width are not the same.

23. The method of claim 22, wherein the first ablative beam width is at least approximately 20 micro-meters.

24. The method of claim 22, wherein the second ablative beam width is at least approximately 100 micro-meters.

25. The method of claim 22, wherein at least one laser ablation processing technique removes substantially all conductive material between adjacent conductive components.

26. The method of claim 18, wherein the first processing technique includes laser ablation using a first type of laser and the second processing technique includes laser ablation using a second type of laser, wherein the first type of laser and the second type of laser are not the same.

27. The method of claim 26, wherein the first or second type of laser is selected from the group consisting of a solid-state laser, a copper vapor laser, a diode laser, a carbon dioxide laser, and an excimer laser.

28. The method of claim 26, wherein the first or second type of laser operates in a region selected from at least one of an ultraviolet, a visible, and an infrared region.

29. The method of claim 18, wherein the first processing technique includes laser ablation using a first laser operating at a first power and the second processing technique includes laser ablation using a second laser operating at a second power, wherein the first power and the second power are not the same.

30. The method of claim 29, wherein the first or second laser power is in the range of about 10 to about 100 watts.

31. The method of claim 18, wherein the first processing technique includes forming a single kerf and the second processing technique includes forming a plurality of kerfs.

32. The method of claim 18, further including the step of contacting the first conductive component with at least one chemical component.

33. The method of claim 32, wherein the at least one chemical component includes at least one compound selected from the group consisting of potassium ferricyanide, ruthenium hexamine, glucose oxidase and glucose dehydrogenase.

34. The method of claim 18, wherein at least one of the first conductive component, the second conductive component, and the third conductive component is formed from a semi-conductive material.

35. A method of manufacturing test strips, comprising:
forming a reel containing a conductive layer and a base layer;
forming a first kerf in the conductive layer, wherein the first kerf is formed using a first laser ablation process;
forming a second kerf in the conductive layer, wherein the second kerf is formed using a second laser ablation process that is not the same as the first laser ablation process;
separating one or more test strips from the reel using a singulation process.

36. The method of claim 35, wherein the singulation process includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.

37. The method of claim 35, wherein the first laser ablation process includes a first laser having a first beam width and the second laser ablation process includes a second laser having a second beam width, wherein the first beam width and the second beam width are not the same.

38. The method of claim 37, wherein the first beam width is at least approximately 20 micro-meters.

39. The method of claim 37, wherein the second beam width is at least approximately 100 micro-meters.

40. The method of claim 37, wherein at least one laser ablation processing technique removes substantially all conductive material between adjacent conductive components.

41. The method of claim 35, wherein the first laser ablation process includes a first type of laser and the second laser ablation process includes a second type of laser, wherein the first type of laser and the second type of laser are not the same.

42. The method of claim 41, wherein the first or second type of laser is selected from the group consisting of a solid-state laser, a copper vapor laser, a diode laser, a carbon dioxide laser, and an excimer laser.

43. The method of claim 41, wherein the first or second type of laser operates in a region selected from at least one of an ultraviolet, a visible, and an infrared region.

44. The method of claim 35, wherein the first laser ablation process includes a first laser operating at a first power and the second laser ablation process includes a second laser operating at a second power, wherein the first power and the second power are not the same.

45. The method of claim 44, wherein the first or second laser power is in the range of about 10 to about 100 watts.

46. The method of claim 35, further including the step of contacting at least part of the conductive layer with at least one chemical component.

47. The method of claim 46, wherein the at least one chemical component includes at least one compound selected from the group consisting of potassium ferricyanide, ruthenium hexamine, glucose oxidase and glucose dehydrogenase.

48. The method of claim 35, wherein at least one of the first conductive component, the second conductive component, and the third conductive component is formed from a semi-conductive material.

49. The method of claim 35, further including application of a spacer layer to the conductive layer or the base layer.

50. The method of claim 49, wherein the second kerf is formed after application of the spacer layer.

51. The method of claim 49, further including application of a cover to the spacer layer.

52. The method of claim 35, wherein the conductive layer is formed using a technique selected from the group consisting of direct writing, sputtering, screen printing, contract printing, and lamination.

53. The method of claim 35, further including the step of applying to the conductive layer at least one of a second conductive layer and a semi-conductive layer.

54. The method of claim 53, wherein the second kerf is formed after application of at least one of the second conductive layer and the semi-conductive layer.

55. A biosensor, comprising:

a first electrode and a second electrode, wherein each said electrode includes at least one first boundary formed by a first processing technique and at least one second boundary; and

a diffusion barrier positioned between the first electrode and the second electrode and contiguous with the at least one second boundary of each said electrode, wherein the diffusion barrier is formed by a second processing technique not the same as the first processing technique.

56. The biosensor of claim 55, wherein the first processing technique includes at least one technique selected from the group consisting of direct writing, sputtering, screen printing, contact printing, lamination, laser ablation, stamping, cutting, and etching.

57. The biosensor of claim 55, wherein the second processing technique includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.

58. The biosensor of claim 55, wherein the second processing technique forms a kerf that is substantially the width of the diffusion barrier.

59. The biosensor of claim 58, wherein the width of the kerf is at least approximately 100 micro-meters.

60. The biosensor of claim 55, wherein the first processing technique includes laser ablation at a first ablative beam width and the second processing technique includes laser ablation at a second ablative beam width, wherein the first beam width and the second beam width are not the same.

61. The biosensor of claim 60, wherein the first ablative beam width is at least approximately 20 micro-meters.

62. The biosensor of claim 60, wherein the second ablative beam width is at least the diffusion distance of at least one ion generated by a redox reaction used to detect a constituent of a fluid.

63. The biosensor of claim 60, wherein the second ablative beam width is substantially the width of the diffusion barrier.

64. The biosensor of claim 60, wherein the second ablative beam width is at least approximately 100 micro-meters.

65. The biosensor of claim 55, wherein the first processing technique includes forming a single kerf and the second processing technique includes forming a plurality of kerfs.

66. The biosensor of claim 55, wherein the width of the diffusion barrier is at least the diffusion distance of at least one ion generated by a redox reaction used to detect a constituent of a fluid.

67. The biosensor of claim 55, wherein the width of the diffusion barrier is at least approximately 100 micro-meters.

68. The biosensor of claim 55, wherein the diffusion barrier is formed between a working electrode and a counter electrode.

69. The biosensor of claim 55, wherein the diffusion barrier is formed between a working electrode and a fill-detect electrode.

70. The biosensor of claim 55, wherein the diffusion barrier is formed between a fill-detect anode and a fill-detect cathode.

71. The biosensor of claim 55, wherein the first electrode is contacted by at least one chemical component.

72. The biosensor of claim 71, wherein the at least one chemical component includes at least one compound selected from the group consisting of potassium ferricyanide, ruthenium hexamine, glucose oxidase and glucose dehydrogenase.

73. A method of manufacturing a plurality of test strips, comprising:
forming a reel containing a conductive layer and a base layer;
forming a first electrode and a second electrode in the conductive layer,
wherein each said electrode includes at least one first boundary formed by a first processing technique and at least one second boundary; and
forming a diffusion barrier positioned between the first electrode and the second electrode and contiguous with the at least one second boundary of each said electrode,

wherein the diffusion barrier is formed by a second processing technique not the same as the first processing technique.

74. The method of claim 73, wherein the first processing technique includes at least one technique selected from the group consisting of direct writing, sputtering, screen printing, contact printing, lamination, laser ablation, stamping, cutting, and etching.

75. The method of claim 73, wherein the second processing technique includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.

76. The biosensor of claim 73, wherein the second processing technique forms a kerf that is substantially the width of the diffusion barrier.

77. The biosensor of claim 76, wherein the width of the kerf is at least approximately 100 micro-meters.

78. The method of claim 73, wherein the step of forming a first electrode using a first processing technique further includes using laser ablation having a first ablative beam width and wherein the step of forming a diffusion barrier using a second processing technique further includes using laser ablation having a second ablative beam width, wherein the first beam width and the second beam width are not the same.

79. The method of claim 78, wherein the first ablative beam width is at least approximately 20 micro-meters.

80. The method of claim 78, wherein the second ablative beam width is equal to at least the diffusion distance of at least one ion generated by a redox reaction used to detect a constituent of a fluid.

81. The method of claim 78, wherein the second ablative beam width is substantially the width of the diffusion barrier.

82. The method of claim 78, wherein the second ablative beam width is at least approximately 100 micro-meters.

83. The method of claim 73, wherein the first processing technique includes forming a single kerf and the second processing technique includes forming a plurality of kerfs.

84. The method of claim 73, wherein the step of forming a diffusion barrier further comprises establishing the width of the diffusion barrier to be at least equal to the diffusion distance of at least one ion generated by a redox reaction used to detect a constituent of a fluid.

85. The method of claim 73, wherein the width of the diffusion barrier is at least approximately 100 micro-meters.

86. The method of claim 73, wherein the diffusion barrier is formed between a working electrode and a counter electrode.

87. The method of claim 73, wherein the diffusion barrier is formed between a working electrode and a fill-detect electrode.

88. The method of claim 73, wherein the diffusion barrier is formed between a fill-detect anode and a fill-detect cathode.

89. The method of claim 73, further comprising the step of contacting the first electrode with at least one chemical component.

90. The method of claim 89, wherein the at least one chemical component includes at least one compound selected from the group consisting of potassium ferricyanide, ruthenium hexamine, glucose oxidase and glucose dehydrogenase.

Abstract of the Disclosure

A biosensor having a first conductive component is described, wherein the first conductive component includes at least one boundary formed by a first processing technique and at least one boundary formed by a second processing technique not the same as the first processing technique. The biosensor can also have a second conductive component including at least one boundary formed by the first processing technique and at least one boundary formed by a third processing technique not the same as the first processing technique. Further, the biosensor has a third conductive component including at least one boundary formed by the second processing technique and at least one boundary formed by the third processing technique not the same as the second processing technique.

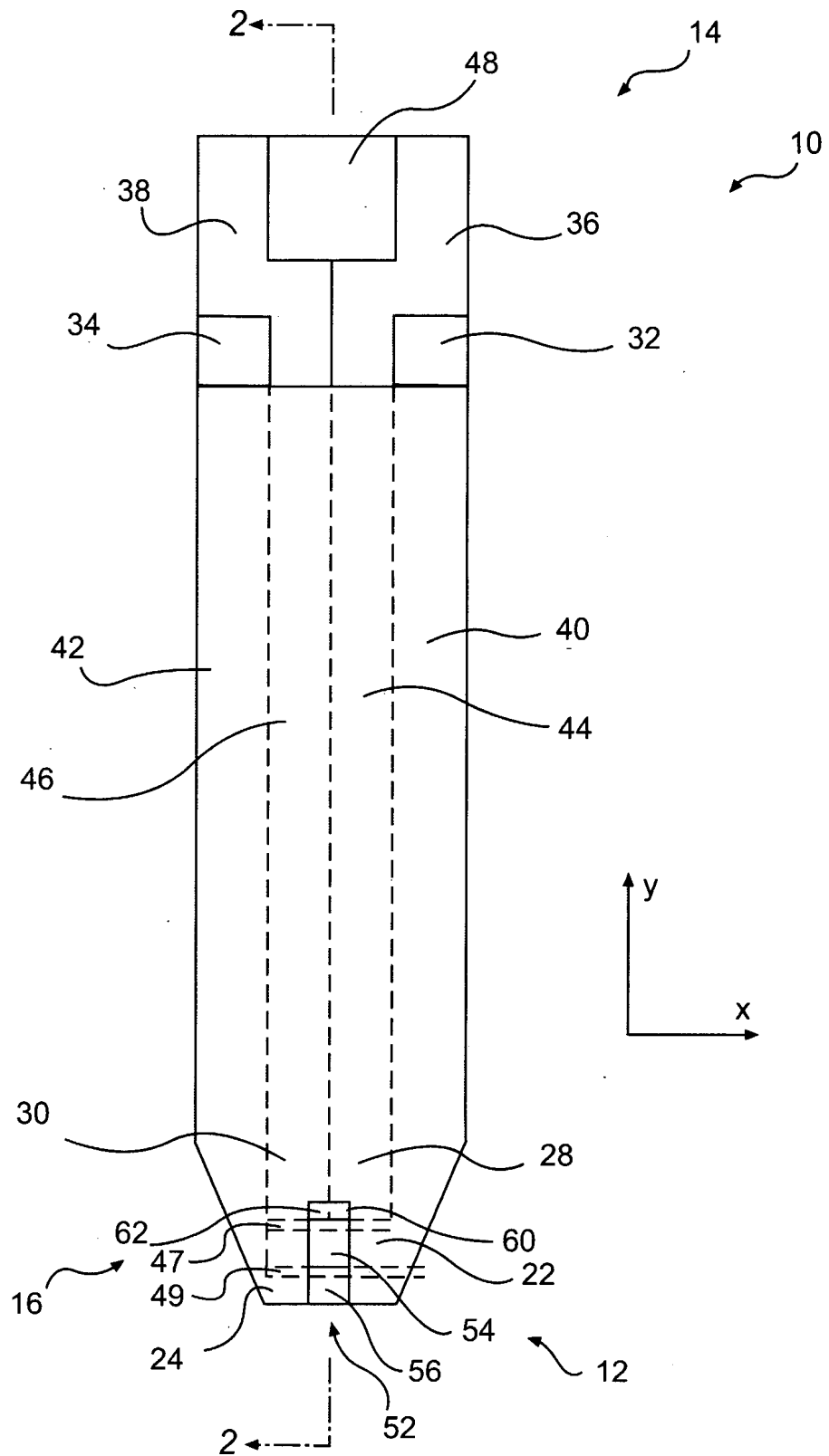


FIG. 1A



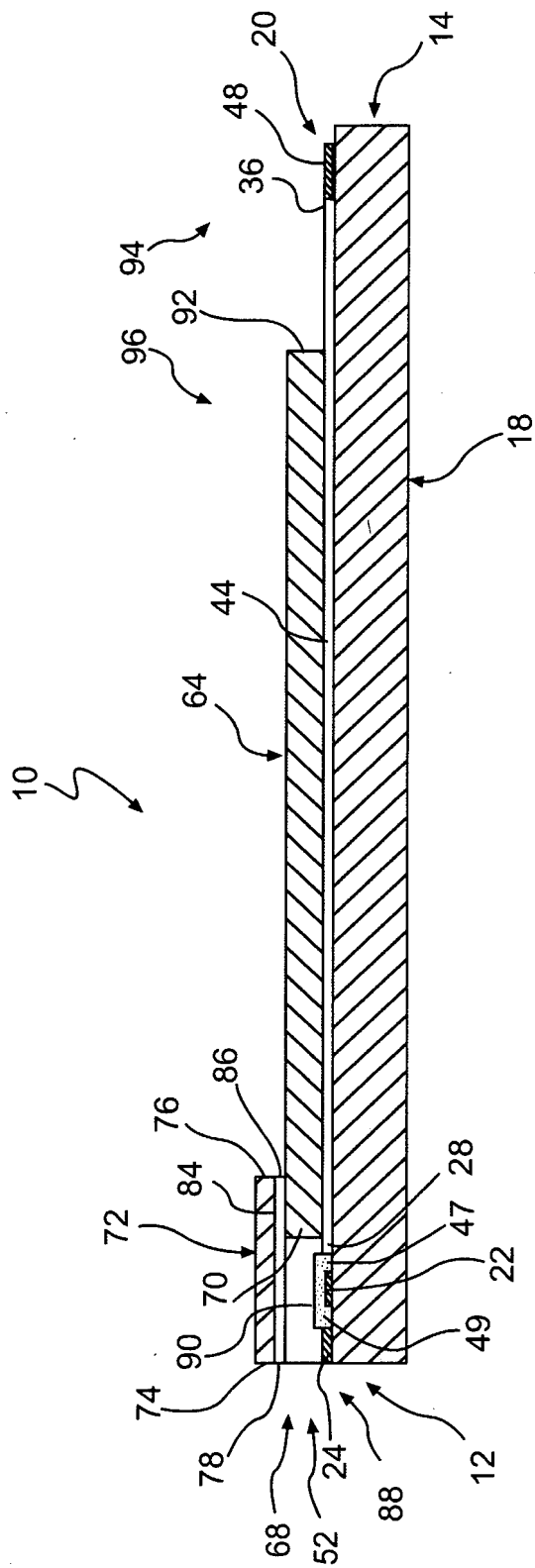


FIG. 2

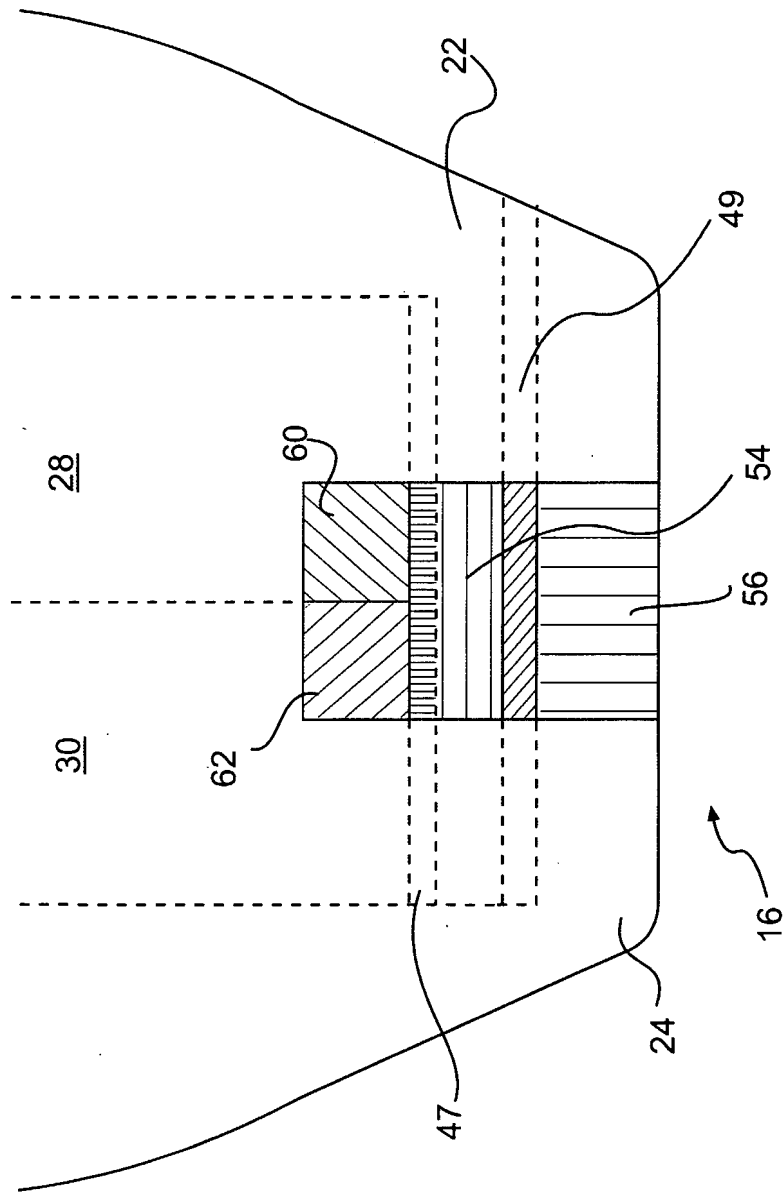


FIG. 3

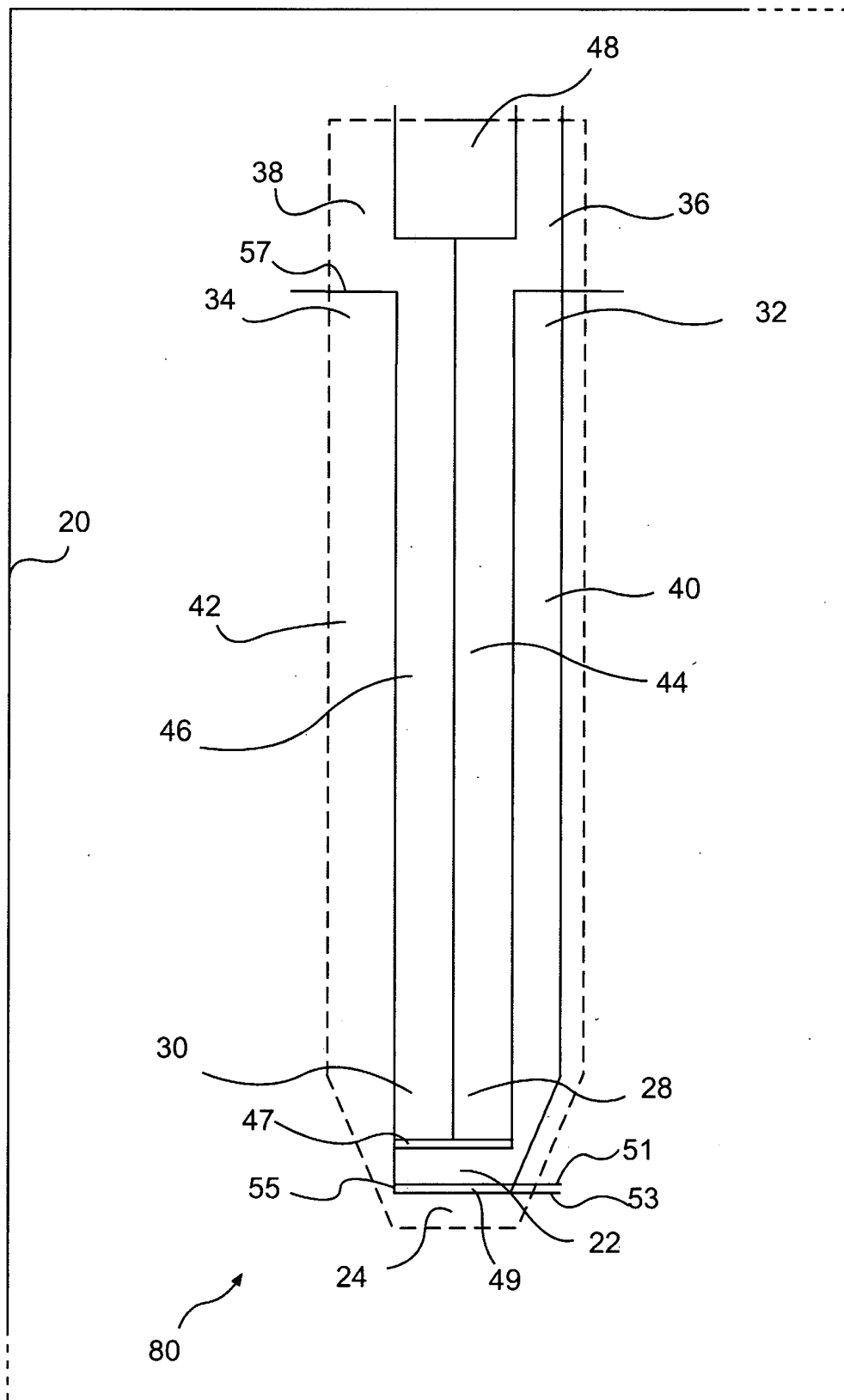


FIG. 4A

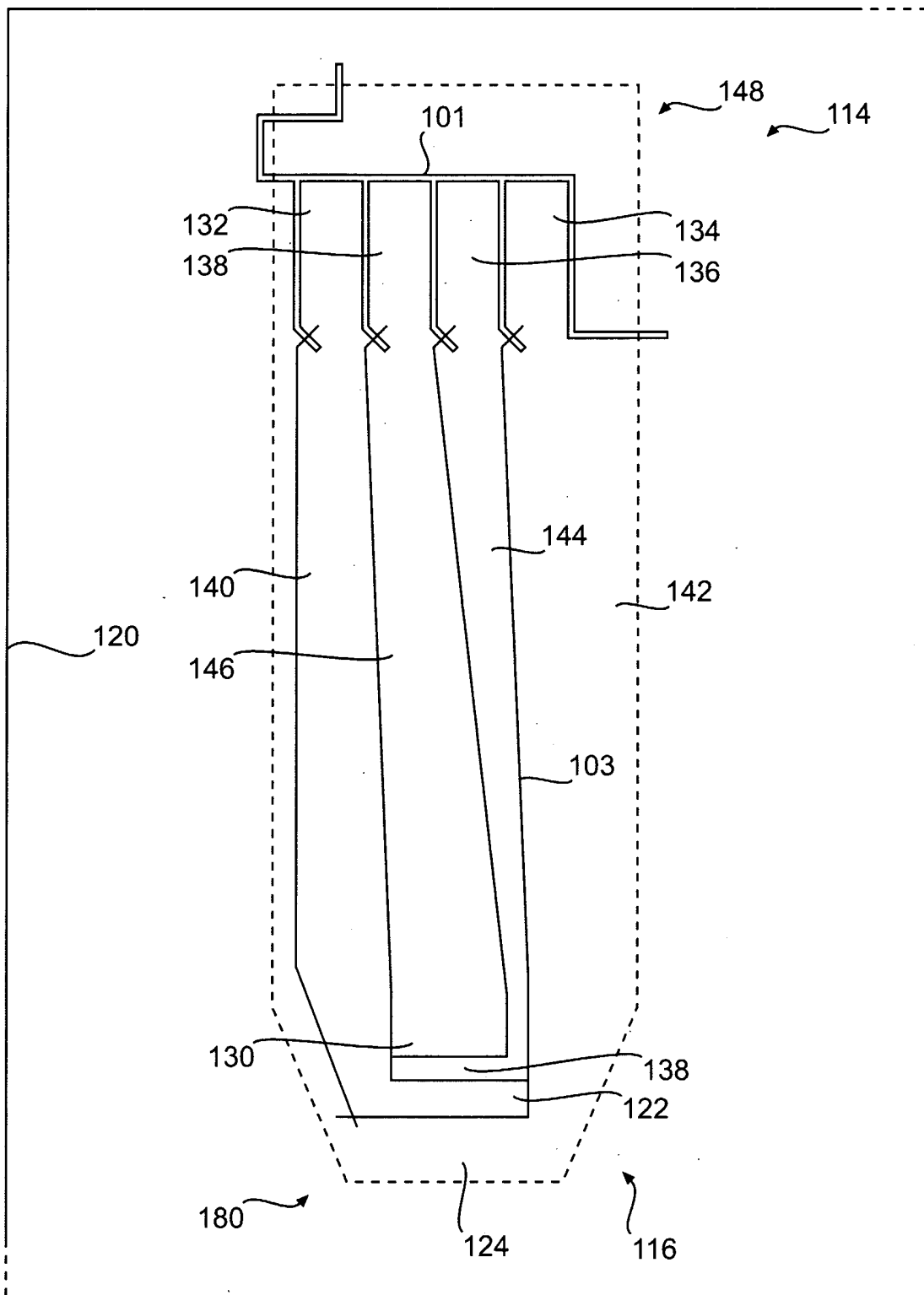


FIG. 4B

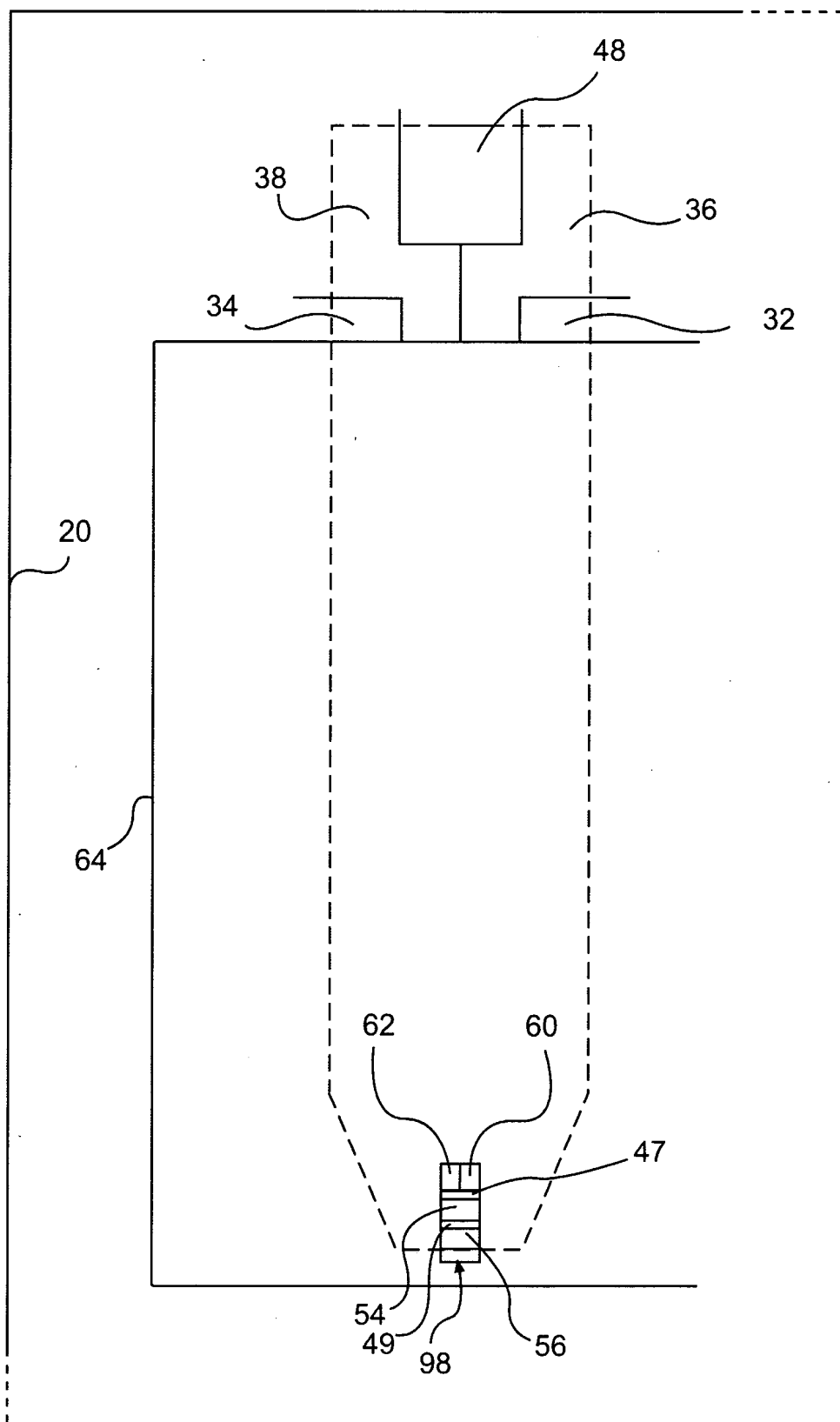


FIG. 5



901 New York Avenue, NW ■ Washington, DC 20001-4413 ■ 202.408.4000 ■ Fax 202.408.4400
www.finnegan.com

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

ERIC P. RACITI
617.452.1675
eric.raciti@finnegan.com

April 10, 2007

ATTORNEY DOCKET NO. 06882.0200-00

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

New U.S. Patent Application
Title: BIOSENSOR MANUFACTURING METHOD
Inventors: Natasha Popovich, Dennis Slomski and David Deng

Sir:

We enclose the following papers for filing in the United States Patent and Trademark Office in connection with the above patent application.

1. Application- 35 pages, including 5 independent claims and 90 claims total.
2. Drawings- 7 sheets of drawings (Figures 1-5).
3. The filing fee is calculated as follows:

Basic Utility Application Filing Fee					\$300	\$ 300.00
Search Fee					\$500	500.00
Examination Fee					\$200	200.00
	Number of Claims		Basic	Extra		
Total Claims	90	-	20	70	x \$ 50	3500.00
Independent Claims	5	-	3	2	x \$200	400.00
☐ Presentation of Multiple Dep. Claim(s)					+ \$360	0
Total Application Pages (specification, drawings, printed sequence or computer listing, and preliminary amendment)	42	If over 100 pages, add \$250 for each additional 50 pages or fraction thereof.				0
Subtotal						\$ 4900.00
Reduction by 1/2 if small entity					-	0
TOTAL APPLICATION FILING FEE						\$ 4900.00

Commissioner for Patents
April 10, 2007
Page 2

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

4. A check for \$4,900.00 is enclosed. The fee includes:

\$1,000.00 filing, search, and examination fees; and
\$3,900.00 additional claims fee.

Applicants claim the right to priority based on Provisional Patent Application Nos. 60/790,773, filed April 11, 2006 and 60/878,454, filed January 4, 2007.

This application will be completed in accordance with 37 C.F.R. § 1.53(f) upon receiving a Notice to File Missing Parts of Application.

Please accord this application an application number and filing date.

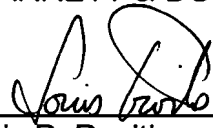
Please address all correspondence with respect to this application to:
**FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P., Customer
Number 22,852.**

The Commissioner is hereby authorized to charge any additional fees due and any other fees under 37 C.F.R. § 1.16 or § 1.17 during the pendency of this application to Deposit Account 06-0916.

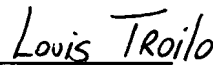
Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By:


Eric P. Raciti

Reg. No. 41,475


Louis Troilo

Reg. No. 45,284

EPR/JB/LAT
Enclosures



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	TOT CLAIMS	IND CLAIMS
11/783,568	04/10/2007	2624	4900	06882.0200-00	90	5

CONFIRMATION NO. 8766

22852
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC20001-4413

FILING RECEIPT

Date Mailed: 05/14/2007

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)

Natasha Popovich, Residence Not Provided;
Dennis Slomski, Residence Not Provided;
David Deng, Residence Not Provided;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This appln claims benefit of 60/790,773 04/11/2006
and claims benefit of 60/878,454 01/04/2007

Foreign Applications

If Required, Foreign Filing License Granted: 05/11/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is
US11/783,568

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

Title

Biosensor manufacturing method

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	ATTORNEY DOCKET NUMBER
11/783,568	04/10/2007	Natasha Popovich	06882.0200-00

CONFIRMATION NO. 8766

FORMALITIES
 LETTER

22852
 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
 LLP
 901 NEW YORK AVENUE, NW
 WASHINGTON, DC 20001-4413

Date Mailed: 05/14/2007

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

*Filing Date Granted*Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$130** for a non-small entity

- \$130 Surcharge.**

Replies should be mailed to: Mail Stop Missing Parts

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

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

FIN

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199
PART 3 - OFFICE COPY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Natasha POPOVICH et al.	)	Group Art Unit: 2624
	)	
Application No.: 11/783,568	)	Examiner: Unassigned
	)	
Filed: April 10, 2007	)	
	)	Confirmation No.: 8766
For: BIOSENSOR MANUFACTURING	)	
METHOD	)	

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

**RESPONSE TO NOTICE TO FILE
MISSING PARTS OF APPLICATION**

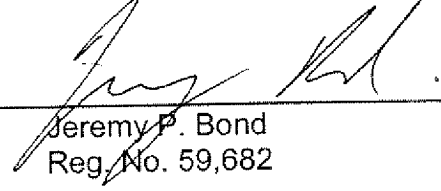
In response to the communication of May 14, 2007, Applicants submit a Declaration/Power of Attorney for filing in this application and the required fee of \$130.00.

Please associate the enclosed Declaration with the application, grant any extensions of time required to enter this response, and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: August 10, 2007

By: 
Jeremy P. Bond
Reg. No. 59,682

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first, and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: BIOSENSOR MANUFACTURING METHOD the specification of which was filed on April 10, 2007, as United States Application No. 11/783,568 and Confirmation No. 8766.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56.

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

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C.	
			☐ YES	☐ NO
			☐ YES	☐ NO

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional applications listed below:

Application Number	Date of Filing
60/790,773	April 11, 2006
60/878,454	January 4, 2007

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) or § 365(c) of any PCT International application(s) designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application(s) in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application(s) and the national or PCT International filing date of this application:

Application Number	Date of Filing	Status (Patented, Pending, Abandoned)

I hereby appoint the patent practitioners associated with **FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P., CUSTOMER NUMBER 22,852** to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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 issuing thereon.

Full Name of First Inventor Natasha Popovich	Inventor's Signature 	Date 7/17/07
Residence 471 SE 1 st Terrace, Pompano Beach, Florida 33060		Citizenship Serbia
Post Office Address Same as above		
Full Name of Second Inventor Dennis Slomski	Inventor's Signature 	Date 7/17/07
Residence 10299 Trianon Place, Wellington, Florida 33467		Citizenship USA
Post Office Address Same as above		
Full Name of Third Inventor David Deng	Inventor's Signature 	Date 7/17/07
Residence 959 Nandina Drive, Weston, Florida 33327		Citizenship USA
Post Office Address Same as above		

Electronic Patent Application Fee Transmittal

Application Number:	11783568			
Filing Date:	10-Apr-2007			
Title of Invention:	Biosensor manufacturing method			
First Named Inventor/Applicant Name:	Natasha Popovich			
Filer:	Eric Paul Raciti/Lisa Tkach			
Attorney Docket Number:	06882.0200-00			
Filed as Large Entity				
Utility Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Late filing fee for oath or declaration	1051	1	130	130
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:	Page 57 of 375			

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				130

Electronic Acknowledgement Receipt

EFS ID:	2070383
Application Number:	11783568
International Application Number:	
Confirmation Number:	8766
Title of Invention:	Biosensor manufacturing method
First Named Inventor/Applicant Name:	Natasha Popovich
Customer Number:	22852
Filer:	Eric Paul Raciti/Lisa Tkach
Filer Authorized By:	Eric Paul Raciti
Attorney Docket Number:	06882.0200-00
Receipt Date:	10-AUG-2007
Filing Date:	10-APR-2007
Time Stamp:	13:10:55
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	\$ 130
RAM confirmation Number	6567
Deposit Account	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
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1		Response-to-Missing-Parts.pdf	131878 4897b0ccae11e02868a238af4148c327e677a7a1	yes	3
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Applicant Response to Pre-Exam Formalities Notice		1	1	
	Oath or Declaration filed		2	3	
Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	8147 3424389f9ba65f48886d809f129d2aa55687ff6e	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			140025		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Roelof VAN HES, et al.	)	Group Art Unit: 1624
	)	
Application No.: 11/294,610	)	Examiner: Emily BERNHARDT
	)	
Filed: December 6, 2005	)	
	)	
For: BENZDIOXANE PIPERAZINE	)	Confirmation No.: 7048
DERIVATIVES WITH A	)	
COMBINATION OF AFFINITY	)	
FOR DOPAMINE-D ₂ RECEPTORS	)	
AND SEROTONIN REUPTAKE	)	
SITES	)	

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

Sir:

PETITION FOR EXTENSION OF TIME

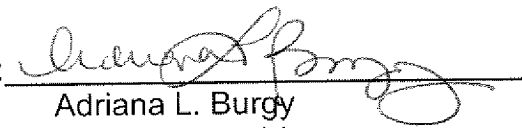
Applicants petition for a one month extension of time to file a reply to the final Office Action dated April 12, 2007, and the Advisory Acton dated July 20, 2007. A fee of \$120.00 is enclosed.

Please grant any additional extensions of time required to enter the attached reply and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: August 10, 2007

By: 
Adriana L. Burgy
Reg. No. 48,564

Electronic Patent Application Fee Transmittal

Application Number:	11783568			
Filing Date:	10-Apr-2007			
Title of Invention:	Biosensor manufacturing method			
First Named Inventor/Applicant Name:	Natasha Popovich			
Filer:	Michele C. Bosch/Lisa Tkach			
Attorney Docket Number:	06882.0200-00			
Filed as Large Entity				
Utility Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with \$0 paid	1251	1	120	120

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				120

Electronic Acknowledgement Receipt

EFS ID:	2070642
Application Number:	11783568
International Application Number:	
Confirmation Number:	8766
Title of Invention:	Biosensor manufacturing method
First Named Inventor/Applicant Name:	Natasha Popovich
Customer Number:	22852
Filer:	Michele C. Bosch/Lisa Tkach
Filer Authorized By:	Michele C. Bosch
Attorney Docket Number:	06882.0200-00
Receipt Date:	10-AUG-2007
Filing Date:	10-APR-2007
Time Stamp:	13:56:58
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	\$ 120
RAM confirmation Number	6957
Deposit Account	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
-----------------	----------------------	-----------	-------------------------------------	------------------	------------------

1	Extension of Time	Extension.pdf	29638 fabc1ecf1cb9c8efc809ec178a24d57cd 19be8ad	no	1
Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	8135 ebde15dcbe90d860f484dfb7e9183757 c5e972c7	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			37773		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					



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	TOT CLAIMS	IND CLAIMS
11/783,568	04/10/2007	2624	5030	06882.0200-00	90	5

CONFIRMATION NO. 8766

22852
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC20001-4413

UPDATED FILING RECEIPT

Date Mailed: 08/16/2007

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Power of Attorney: The patent practitioners associated with Customer Number 22852

Domestic Priority data as claimed by applicant

This appln claims benefit of 60/790,773 04/11/2006
and claims benefit of 60/878,454 01/04/2007

Foreign Applications

If Required, Foreign Filing License Granted: 05/11/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is
US11/783,568

Projected Publication Date: 11/22/2007

Non-Publication Request: No

Early Publication Request: No

Title

Preliminary Class

382

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
POPOVICH et al.	)	Group Art Unit: 2624
	)	
Application No.: 11/783,568	)	Examiner: Unassigned
	)	
Filed: April 10, 2007	)	
	)	
For: BIOSENSOR MANUFACTURING	)	Confirmation No.: 8766
METHOD	)	

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

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the listed documents on the attached PTO SB/08 Form. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed foreign and non-patent literature documents are attached.

Copies of the U.S. patent publications are not enclosed.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the

documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the U.S. Patent and Trademark Office the relevant facts and law regarding the appropriate status of such documents.

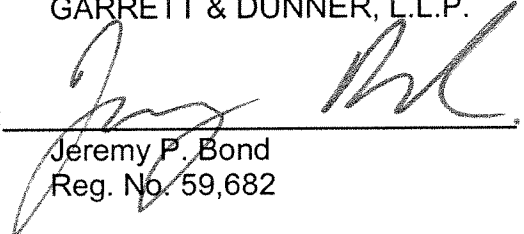
Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
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Dated: November 15, 2007

By: 
Jeremy P. Bond
Reg. No. 59,682

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	11/783,568
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				Art Unit	2624
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	06882.0200-00

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No. ¹	Document Number	Issue or 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)			
		US-2003/0116447 A1	6/26/2003	Surridge et al.	
		US-2004/0182703 A1	9/23/2004	Home Diagnostics, INC.	
		US-2005/0019953 A1	1/27/2005	Groll	
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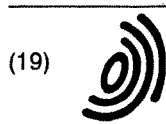
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FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		EP 1 302 545 A2	4/16/2003	Roche Diagnostics GmbH		
		WO 01/25775 A1	4/12/2001	Roche Diagnostics Corporation		
		WO 2005/066616 A2	7/21/2005	Roche Diagnostics GmbH		

NONPATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶

Examiner Signature		Date Considered	
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(54) Enzyme Biosensor

(57) A biosensor is provided in accordance with the present invention. The biosensor includes a substrate and a cover extending across at least a portion of the substrate. The cover includes a first surface facing the

substrate and a second surface. At least a portion of the first surface is removed to define a capillary channel. The capillary channel has a surface energy ranging from about 60 mN/m to about 72 mN/m.

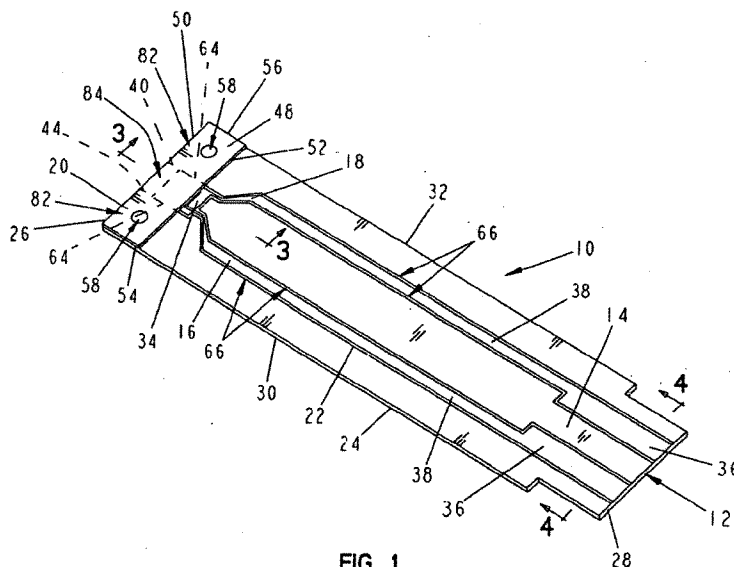


FIG. 1

EP 1 302 545 A2

Description**FIELD OF THE INVENTION**

5 [0001] The present invention is directed to physical structures and methods for controlling the flow of small volumes of liquids through a biosensor. More particularly, the present invention is directed to such physical structures that define a capillary channel and microstructures.

BACKGROUND AND SUMMARY OF THE INVENTION

10 [0002] Electrochemical biosensors are known. They have been used to determine the concentration of various analytes from biological samples, particularly from blood. Electrochemical biosensors are described in U.S. Patent Nos. 5,413,690; 5,762,770; 5,798,031; and 5,997,817 the disclosure of each of which is expressly incorporated herein by reference.

15 [0003] According to the present invention a biosensor is provided. The biosensor comprises a substrate and a cover extending across at least a portion of the substrate. The cover includes a first surface facing the substrate and a second surface. At least a portion of the first surface is removed to define a capillary channel. The capillary channel has a surface energy ranging from about 60 mN/m to about 72 mN/m.

20 [0004] According to another aspect of the invention a biosensor is provided. That biosensor comprises a capillary path defined between a substrate and a cover and at least one microstructure positioned in the capillary path. The at least one microstructure includes a fixed end coupled to either the substrate or the cover and an opposite free end, wherein the free end is metallic.

25 [0005] According to still another aspect of the present invention a biosensor is provided. The biosensor comprises a substrate, electrodes positioned on the substrate, a cover extending across at least a portion of the substrate to define a capillary path, and at least one microstructure positioned in the capillary path. The at least one microstructure includes a fixed end coupled to the cover and an opposite free end, wherein the free end is metallic.

30 [0006] According to still another aspect of the invention a method of forming biosensor is provided. The method comprises the steps of providing a substrate, a reagent for the measurement of at least one analyte, and a cover, the cover including a first surface, exposing the cover to at least one pulse of light of sufficient to ablate the first surface in a pre-determined pattern creating a channel, cleaning the first surface of the cover so that the surface energy of the channel ranges from about 60 mN/m to about 72 mN/m, and placing the first surface of the cover upon the substrate to define a capillary path and the reagent is positioned in the capillary path.

35 [0007] Additional features of the invention will become apparent to those skilled in the art upon consideration of the following detailed description of the preferred embodiment exemplifying the best mode of carrying out the invention as presently perceived.

BRIEF DESCRIPTION OF THE DRAWINGS

40 [0008] The detailed description particularly refers to the accompanying figures in which:

Fig. 1 is a perspective view of a biosensor in accordance with the present invention.

Fig. 2A is an exploded perspective view of the biosensor of Fig. 1.

45 Fig. 2B is an enlarged view of the biosensor of Fig. 2A showing the biosensor including a recess with a plurality of microstructures extending from a first surface of an electrode support substrate.

Fig. 2C is an enlarged view of the biosensor of Fig. 1 with portions broken away showing a reagent positioned on an electrode array.

50 Fig. 3 is a view taken along lines 3-3 of Fig. 1.

Fig. 4 is a view taken along lines 4-4 of Fig. 1.

55 Fig. 5 is a bottom perspective view of a cover in accordance with one aspect of the invention showing the cover including a channel and plurality of square-shaped posts formed in the channel.

Fig. 6 is a bottom perspective view of a cover in accordance with another aspect of the invention showing the cover

including a channel and plurality of round posts formed in the channel.

Fig. 7 is a bottom perspective view of a cover in accordance with another aspect of the invention showing the cover including a channel and two spaced-apart bar-shaped posts formed in the channel.

Fig. 8 is a bottom perspective view of a cover in accordance with another aspect of the invention showing the cover including a channel and plurality of bar-shaped posts formed in the channel.

Fig. 9 is a diagrammatic view of a manufacturing method in accordance with the present invention.

Fig. 10 is a perspective view of a biosensor in accordance with the present invention.

Fig. 11 is a bottom perspective view of the cover of the biosensor of Fig. 10.

DETAILED DESCRIPTION OF THE DRAWINGS

[0009] The present invention relates to a biosensor and method of manufacturing a biosensor that is formed to provide a well-controlled fluid flow and simultaneously reduce the volume of liquid sample required for testing. Biosensors can take the form of any number of diagnostic biosensors including, for example, electrochemical and photometric biosensors. Aspects of the invention are presented in Figs. 1-11, which are not drawn to scale and wherein like components in the several views are numbered alike.

[0010] A biosensor 10 for testing for biologically significant analytes of an applied biological fluid is shown in Figs. 1-5. The term analyte, as used herein, refers to the molecule or compound to be quantitatively determined. Non-limiting examples of analytes include carbohydrates, proteins, such as hormones and other secreted proteins, enzymes, and cell surface proteins; glycoproteins; peptides; small molecules; polysaccharides; antibodies (including monoclonal or polyclonal Ab); nucleic acids; drugs; toxins; viruses of virus particles; portions of a cell wall; and other compounds processing epitopes. The analyte of interest preferably comprises glucose.

[0011] Biosensor 10 has an electrode-support substrate 12, an electrical conductor 14 positioned on the substrate 12 that is disrupted to define electrodes 16, 18, and a cover substrate 20 positioned on substrate 12. Biosensor 10 is in the form of a disposable test strip. It is appreciated however, that biosensor 10 can assume any number of forms and shapes in accordance with this disclosure. Biosensor 10 is preferably produced from rolls of material however, it is understood that biosensor 10 can be constructed from individual sheets in accordance with this disclosure. Thus, when biosensors 10 are produced from rolls, the selection of materials necessitates the use of materials that are sufficiently flexible for roll processing, but which are still rigid enough to give a useful stiffness to finished biosensor 10.

[0012] Referring to Fig. 1, the electrode-support substrate 12 includes a first surface 22 and a second surface 24. In addition, substrate 12 has opposite first and second ends 26, 28 and opposite edges 30, 32 extending between the first and second ends 26, 28. Substrate 12 is generally rectangular in shape, it is appreciated however, that support 12 may be formed in a variety of shapes and sizes in accordance with this disclosure. Substrate 12 may be constructed from a wide variety of insulative materials. Non-limiting examples of insulative materials that provide desirable electrical and structural properties include glass, ceramics, vinyl polymers, polyimides, polyesters, and styrenics. Preferably, substrate 12 is a flexible polymer, such as a polyester or polyimide. A non-limiting example of a suitable material is 5 mil (125 μ m) thick KALADDEX®, a polyethylene naphthalate film commercially available from E.I. DuPont de Nemours, Wilmington, Delaware, which is coated with gold by: ROWO Coatings, Herbolzheim, Germany.

[0013] Electrodes 16, 18 are created or isolated from conductor 14 on first surface 22 of electrode-support substrate 12. Electrodes 16, 18 are isolated from conductor 14 by gaps 66. See Fig. 4. It is also appreciated that electrodes 16, 18 can be formed from multiple layers of same or different electrically conductive materials. Non-limiting examples of a suitable electrical conductor 14 include aluminum, carbon (such as graphite), cobalt, copper, gallium, gold, indium, iridium, iron, lead, magnesium, mercury (as an amalgam), nickel, niobium, osmium, palladium, platinum, rhenium, rhodium, selenium, silicon (such as highly doped polycrystalline silicon), silver, tantalum, tin, titanium, tungsten, uranium, vanadium, zinc, zirconium, mixtures thereof, and alloys, oxides, or metallic compounds of these elements. Preferably, electrical conductor 14 is selected from the following materials: gold, platinum, palladium, iridium, or alloys of these metals, since such noble metals and their alloys are unreactive in biological systems. Most preferably, electrical conductor 14 is gold.

[0014] Electrodes 16, 18 are isolated from the rest of the electrical conductor 14 by laser ablation. Techniques for forming electrodes on a surface using laser ablation are known. See, for example, U.S. Patent Application Serial No. 09/411,940 (published as WO 01/25775), titled "Laser Defined Features for Patterned Laminates and Electrodes", the disclosure of which is expressly incorporated herein by reference. Preferably, electrodes 16, 18 are created by removing the electrical conductor 14 from an area extending around the electrodes to form a gap of exposed support substrate

12. Therefore, electrodes 16, 18 are isolated from the rest of the electrically-conductive material on substrate 12 by a gap having a width of about 25 μm to about 500 μm , preferably the gap has a width of about 100 μm to about 200 μm . Alternatively, it is appreciated that electrodes 16, 18 may be created by laser ablation alone on substrate 12.

[0015] It is appreciated that while laser ablation is the preferred method for forming electrodes 16, 18 given its precision and sensitivity, other techniques such as lamination, screen-printing, photolithography, or contact printing may be used in accordance with this disclosure.

[0016] As shown in Fig. 2A, electrodes 16, 18 cooperate with one another to define an electrode array 34. In addition, electrodes 16, 18 each include a contact 36 and a lead 38 extending between the contact 34 and the array 36. It is appreciated that the leads 38 extending from the array 34 can be formed to have many lengths and extend to a variety of locations on the electrode-support substrate 12. It is appreciated that the configuration of the electrode array, the number of electrodes, as well as the spacing between the electrodes may vary in accordance with this disclosure and that a greater than one array may be formed as will be appreciated by one of skill in the art.

[0017] Referring now to Figs. 2A and 2B, a recess 40 is formed through the electrical conductor 14 and a portion of the first surface 22 of the support substrate 12 by laser ablation using techniques as described above. The recess 40 extends from end 26 of the substrate 12 to the electrode array 34. The recess 40 is defined further by walls 44. See Fig. 2B. It is appreciated that the amount of the support substrate 12 that is removed can vary in accordance with the present disclosure. It is also appreciated that substrate 12 of biosensor 10 can be formed without a recess in accordance with the present disclosure.

[0018] As best shown in Fig. 2B, the recess 40 includes a plurality of microstructures 42 extending from the first surface 22 of the support substrate 12. The microstructures 42 are spaced-apart from one another, on a nearest neighbor basis, by a first distance that is less than the distance necessary to achieve capillary flow of liquid between the microstructures. Microstructures 42 are formed as posts that extend away from the substrate through the recess 40. See Fig. 3. Each microstructure 42 includes a fixed end 78 coupled to the substrate 12 and an opposite free end 80. Free end 80 exposed in channel 40 is metallic-coated. The substrate 12 is also cleaned, removing polymeric debris and other organic material and increasing the surface energy of surfaces of both the surface of the channel 40 and the microstructures 42.

[0019] It is appreciated that the microstructures 42 can assume a variety of shapes and sizes in accordance with the present disclosure. Illustratively, the recess 40 includes six rows of sixteen microstructures 42. The number and location of microstructures 42 depend upon the size of biosensor 10. The recess 40 may in fact be formed without microstructures in accordance with the present disclosure. In addition, it is also appreciated that the microstructures 42 may be positioned in a variety of locations in the recess 40. Although not shown, at least some of the microstructures can be joined to the walls 44 (Fig. 1) of the recess 40.

[0020] The cover substrate 20 is coupled to the electrode-support substrate 12 adjacent to the first end 26. See Fig. 1. The cover substrate 20 of biosensor 10 includes a first surface 46 facing substrate 12 and an opposite second surface 48. See Fig. 3. In addition, cover substrate 20 has opposite first and second ends 50, 52 and edges 54, 56 extending between ends 50, 52. Openings 58 extend between first and second surfaces 46, 48 and through any material coating either surface 46, 48. When cover substrate 20 is coupled to the support substrate 12, openings 58 are offset from array 34. See, Fig. 1. It is appreciated, however, that any number of openings 58 can be located in a number of locations and take on a variety of shapes and sizes in accordance with this disclosure.

[0021] The cover substrate 20 is formed of a flexible polymer and preferably from a polymer such as polyester. Referring now to Fig. 3, in preferred embodiments, the first surface 46 of the cover substrate 20 is coated with a metallic material 88 and preferably with a metal such as gold, platinum, palladium, and iridium. Preferably, the cover substrate 20 is 3 mil (75 μm) Clear PEN film named KALADEX by DuPont and gold coated by: ROWO Coatings, Herbolzheim, Germany.

[0022] The cover substrate 20 is formed to include a capillary channel 60 and secondary capillary recesses 86 spaced-apart from channel 60. See Fig. 5. The capillary channel 60 is formed to provide a well-controlled fluid flow and simultaneously reduce the volume of liquid required in biosensor 10. As shown in Fig. 5, the capillary channel 60 extends between first and second ends 50, 52 and is defined by interior borders 64. The secondary capillary recesses 86 also extend between first and second ends 50, 52 and are defined by inner and outer borders 90, 92. The capillary channel 60 and secondary capillary recesses 86 are formed through at least the material 88 and preferably through a portion of the first surface 46 (Fig. 3) of the cover substrate 20 by laser ablation using techniques as described above. It is appreciated that the amount of the cover substrate 20 that is removed can vary in accordance with the present disclosure.

[0023] As shown in Fig. 5, the capillary channel 60 includes a plurality of microstructures 62. The microstructures 62 are spaced-apart from one another, on a nearest neighbor basis, by a first distance that is less than the distance necessary to achieve capillary flow of liquid between the microstructures. The capillary channel 60 illustrated in Fig. 5 includes sixteen rows of sixteen microstructures 62. The number and location of microstructures 62 depend upon the size of biosensor. Microstructures 62 shown in Fig. 5 are formed as generally square-shaped posts. It is appreciated,

however, that microstructures can have a variety of shapes and sizes, non-limiting examples of which are illustrated in Figs. 6-8 and 11, in accordance with this disclosure.

[0024] Microstructures 62 extend away from the cover substrate 20 into the capillary channel 60. See Fig. 5. Each microstructure 62 includes a fixed end 96 coupled to the cover substrate 20 and an opposite free end 98. The cover substrate 20 is also cleaned, removing polymeric debris and other organic material present and increasing the surface energy of surfaces of both the surface of the channel 60 and the microstructures 42. It is also appreciated that the microstructures 62 may be positioned in a variety of locations in the channel 60 as discussed above with reference to microstructures 42.

[0025] Once the cover substrate 20 is coupled to the support substrate 12, the channel 60 is aligned with recess 40. Channel 60 has a height of about 1 μm to about 60 μm , preferably 2 μm to about 30 μm , and most preferably about 5 μm to about 15 μm . In addition, the width of channel 60 between interior borders 64 is about 1 mm to about 4 mm, preferably 1.5 mm to about 3.0 mm, most preferably about 2.0 mm to about 2.5 mm. The channel 60 and the recess 40 cooperate to define a capillary path. It is appreciated that when the substrate 12 does not include the recess 40, the channel 60 itself will define the capillary path. Moreover, it is appreciated that while the capillary path is illustratively straight, the capillary path may be curved and/or include turns.

[0026] The cover substrate 20 is coupled to the electrode-support substrate 12 with an adhesive to create sealed portions 82 spaced apart from the array 34 and an unsealed portion 84 extending between ends 50, 52 and across at least a portion of the array 34. See Figs. 1 and 5. Referring now to Fig. 5, each sealed portion 82 has an interior border that lies in general alignment with secondary capillary recesses 86 and an exterior border. The exterior border of each sealed portion 82 lies in general alignment with a respective edge 54, 56 of the electrode-support substrate 12. Although the sealed portions 82 are not distinguishable to the user, it is appreciated that the cover substrate 20 can be at least partially transparent, exposing the recess 40 to the user when a colored fluid such as blood flows it. In addition, it is appreciated that the shape and size of the cover substrate 20 can vary in accordance with this disclosure.

[0027] The cover substrate 20 is coupled to the support substrate 12 by a liquid adhesive. A non-limiting example of such an adhesive is EPO-TEK OH100-4 commercially available from Epoxy Technology, Billerica, MA. Preferably, a heated tool is applied on the area where bonding is to take place to promote fast curing. It is appreciated that the cover substrate 20 may be coupled to the support substrate 12 using a wide variety of commercially available adhesives as well as heat sealing, or ultrasonic methods of joining the cover substrate 20 and support substrate 12 together in accordance with this disclosure.

[0028] Referring now to Fig. 2C, a reagent 68 is positioned on the array 36. When the biosensor is an electrochemical biosensor, the reagent 68 provides electrochemical probes for specific analytes. It is appreciated, however, that reagent 68 can also be formed for use in a photometric biosensor. When, however, biosensor is a photometric biosensor, other aspects of the biosensor construction will change to accommodate photometric measurements. Such a construction is well known in the art. The choice of the specific reagent 68 depends on the specific analyte or analytes to be measured, and are well known to those of ordinary skill in the art. An example of a reagent that may be used in biosensor 10 of the present invention is a reagent for measuring glucose from a whole blood sample. A non-limiting example of a reagent for measurement of glucose in a human blood sample contains 62.2 mg polyethylene oxide (mean molecular weight of 100-900 kilo Daltons), 3.3 mg NATROSOL 244M, 41.5 mg AVICEL RC-591 F, 89.4 mg monobasic potassium phosphate, 157.9 mg dibasic potassium phosphate, 437.3 mg potassium ferricyanide, 46.0 mg sodium succinate, 148.0 mg trehalose, 2.6 mg TRITON X-100 surfactant, and 2,000 to 9,000 units of enzyme activity per gram of reagent. The enzyme is prepared as an enzyme solution from 12.5 mg coenzyme PQQ and 1.21 million units of the apoenzyme of quinoprotein glucose dehydrogenase. This reagent is further described in U.S. Patent No. 5,997,817, the disclosure of which is expressly incorporated herein by reference.

[0029] Non-limiting examples of enzymes and mediators that may be used in measuring particular analytes in biosensor 10 are listed below in Table 1.

TABLE 1

Analyte	Enzymes	Mediator (Oxidized Form)	Additional Mediator
Glucose	Glucose Dehydrogenase and Diaphorase	Ferricyanide	
Glucose	Glucose-Dehydrogenase (Quinoprotein)	Ferricyanide	
Cholesterol	Cholesterol Esterase and Cholesterol Oxidase	Ferricyanide	2,6-Dimethyl-1,4-Benzoquinone

TABLE 1 (continued)

Analyte	Enzymes	Mediator	Additional Mediator
			2,5-Dichloro-1,4-Benzoquinone or Phenazine Ethosulfate
HDL Cholesterol	Cholesterol Esterase and Cholesterol Oxidase	Ferricyanide	2,6-Dimethyl-1,4-Benzoquinone 2,5-Dichloro-1,4-Benzoquinone or Phenazine Ethosulfate
Triglycerides	Lipoprotein Lipase, Glycerol Kinase, and Glycerol-3-Phosphate Oxidase	Ferricyanide or Phenazine Ethosulfate	Phenazine Methosulfate
Lactate	Lactate Oxidase	Ferricyanide	2,6-Dichloro-1,4-Benzoquinone
Lactate	Lactate Dehydrogenase and Diaphorase	Ferricyanide Phenazine Ethosulfate, or Phenazine Methosulfate	
Lactate Dehydrogenase	Diaphorase	Ferricyanide	Phenazine Ethosulfate, or Phenazine Methosulfate
Pyruvate	Pyruvate Oxidase	Ferricyanide	
Alcohol	Alcohol Oxidase	Phenylenediamine	
Bilirubin	Bilirubin Oxidase	1-Methoxy-Phenazine Methosulfate	
Uric Acid	Uricase	Ferricyanide	

[0030] In some of the examples shown in Table 1, at least one additional enzyme is used as a reaction catalyst. Also, some of the examples shown in Table 1 may utilize an additional mediator, which facilitates electron transfer to the oxidized form of the mediator. The additional mediator may be provided to the reagent in lesser amount than the oxidized form of the mediator. While the above assays are described, it is contemplated that current, charge, impedance, conductance, potential, or other electrochemically indicated property of the sample might be accurately correlated to the concentration of the analyte in the sample with biosensor 10 in accordance with this disclosure.

[0031] A plurality of biosensors 10 are typically packaged in a vial, usually with a stopper formed to seal the vial. It is appreciated, however, that biosensors 10 may be packaged individually, or biosensors can be folded upon one another, rolled in a coil, stacked in a cassette magazine, or packed in blister packaging.

[0032] Biosensor 10 is used in conjunction with the following:

1. a power source in electrical connection with contacts 36 and capable of supplying an electrical potential difference between electrodes 16, 18 sufficient to cause diffusion limited electro-oxidation of the reduced form of the mediator at the surface of the working electrode; and

2. a meter in electrical connection with contacts 36 and capable of measuring the diffusion limited current produced by oxidation of the reduced form of the mediator with the above-stated electrical potential difference is applied.

[0033] The meter will normally be adapted to apply an algorithm to the current measurement, whereby an analyte concentration is provided and visually displayed. Improvements in such power source, meter, and biosensor system are the subject of commonly assigned U.S. Pat. No. 4,963,814, issued Oct. 16, 1990; U.S. Pat. No. 4,999,632, issued

Mar. 12, 1991; U.S. Pat. No. 4,999,582, issued Mar. 12, 1991; U.S. Pat. No. 5,243,516, issued Sep. 7, 1993; U.S. Pat. No. 5,352,351, issued Oct. 4, 1994; U.S. Pat. No. 5,366,609, issued Nov. 22, 1994; White et al., U.S. Pat. No. 5,405,511, issued Apr. 11, 1995; and White et al., U.S. Pat. No. 5,438,271, issued Aug. 1, 1995, the disclosures of each of which are expressly hereby incorporated by reference.

5 **[0034]** Many fluid samples may be analyzed. For example, human body fluids such as whole blood, plasma, sera, lymph, bile, urine, semen, cerebrospinal fluid, spinal fluid, lacrimal fluid and stool specimens as well as other biological fluids readily apparent to one skilled in the art may be measured. Fluid preparations of tissues can also be assayed, along with foods, fermentation products and environmental substances, which potentially contain environmental contaminants. Preferably, whole blood is assayed with this invention.

10 **[0035]** As shown in Fig. 9, biosensor 10 is manufactured by feeding a roll of metallized electrode support material through guide rolls 70 into a first ablation station 72 as shown by arrow 74. A laser system capable of ablating support 12 is known to those of ordinary skill in the art. Non-limiting examples of which include excimer lasers, with the pattern of ablation controlled by mirrors, lenses, and masks. A non-limiting example of such a custom fit system is the LPX-300 or LPX-200 both commercially available from LPKF Laser Electronic GmbH, of Garbsen, Germany, equipped with
15 a 248 nm wavelength excimer laser. It is appreciated that higher wavelength UV lasers can, however, be used in accordance with this disclosure.

[0036] In the first laser ablation station 72, the metallic layer of the metallized film is ablated in a pre-determined pattern, to form a ribbon of isolated electrode sets on the electrode support material. To ablate electrodes 16, 18 isolated by gaps 66 in 50 nm thick gold conductor 14, 90 mJ/cm² energy is applied. It is appreciated, however, that the amount
20 of energy required may vary from material to material, metal to metal, or thickness to thickness. The ribbon is then passed through more guide rolls, with a tension loop and through an optional inspection system where both optical and electrical inspection can be made. The system is used for quality control in order to check for defects.

[0037] Next, the ribbon is fed, as shown by arrow 76 into a second laser ablation station 100. Station 100 is similar to station 72. In the second station 100, the first surface 22 of the support substrate 12 is ablated in a pre-determined
25 pattern, to form the recess 40 extending about the microstructures 42. To ablate the recess 40 in 50 nm thick gold conductor 14 and 4 micrometers into the surface 22, multi-pulses of the laser light are applied. In preferred embodiments, three to five pulses of laser light (90 mJ/cm² in each pulse) are applied. It is appreciated the depth of ablation into the surface 22 can vary. Moreover, it is appreciated that the number of pulses applied will very depending upon the polymer and the depth of ablation. For example, as the hardness of the polymer increases the number of pulses
30 will increase (a non-limiting example of which is 25 pulses) and as the hardness of polymer decreases, the number of pulses necessary to ablate the surface 22 decreases. If any seed layer or other metallic layer such as Chromium or Titanium or any other metal is used for any purpose, and then gold is put down on top of the seed layer or other metallic layer, the total thickness of all composite metals is still preferred to be 50 nm. It is appreciated, however, if the total thickness is higher, a higher energy laser will be needed.

35 **[0038]** Upon leaving the second laser ablation station 100, the ablated material that is in either roll form or that has been cut into cards is fed as shown by arrow 101 to a microwave plasma machine 111, a custom-fit equipment, which is commercially available from TePla AG, Kirchheim, Germany. The ablated material is cleaned by the microwave plasma machine to remove polymeric debris and other organic material and to increase the hydrophilicity of the channel 40 and microstructures 42. Non-limiting parameters of a plasma machine are as follows: pressure = 0.44 mbar; gas =
40 Oxygen; Microwave power= 300 watt; time = about 30 to about 60 seconds. Cleaning with the microwave plasma machine results in increased surface energy as well as the removal of loose particles, making the surfaces very hydrophilic, which helps increase the blood flow rate and fluid spreading. For example, the surface energy of recess 42 as well as the surface 14 before treatment with the plasma machine is approximately 41mN/m. The surface energy after the treatment is approximately 72 mN/m.

45 **[0039]** Upon leaving the microwave plasma machine 111, the metallized film is fed as shown by arrow 103 into a reagent dispensing station 104. Reagents that have been compounded are fed, as shown by arrow 106, into the dispensing station 104 where it is applied in a liquid form in multiple shots to the array 34. It is appreciated, however, that the reagent can be applied by multi or single dose by a custom fit precision dispensing station available from Fluiologic Systems Oy, Espoo, Finland. Reagent application techniques are well known to one of ordinary skill in the art as
50 described in U.S. Patent No. 5,762,770, the disclosure of which is expressly incorporated herein by reference. It is appreciated that reagents may be applied to the array 34 in a liquid or other form and dried or semi-dried onto the array 34 in accordance with this disclosure.

[0040] In a separate process, a roll of metallized film through guide rolls 108 into a third ablation station 110 as shown by arrow 112. The station 110 is similar to station 72. It is appreciated that although three laser ablation stations are
55 illustrated and described, that greater or fewer than three stations may be used in accordance with the disclosure. In the third station 110, the metallized film and first surface 46 of the material is ablated in a pre-determined pattern, to form the capillary channel 60 extending about microstructures 62 and secondary capillary recesses 86. To ablate channel 60 and recesses 86 in 50 nm thick gold conductor 14 and 4 micrometers into the surface 46, multi-pulses of

the laser light are applied. In preferred embodiments, three to five pulses of laser light (90 mJ/cm² in each pulse) are applied. It is appreciated that the depth of ablation into the surface 46 can vary. Moreover, it is appreciated that the number of pulses applied will vary depending upon the polymer and the depth of ablation. For example, as the hardness of the polymer increases the number of pulses will increase (a non-limiting example of which is 25 pulses) and as the hardness of polymer decreases, the number of pulses necessary to ablate the surface 46 decreases. If any seed layer or other metallic layer such as Chromium or Titanium or any other metal is used for any purpose, and then gold is put down on top of the seed layer or other metallic layer, the total thickness of all composite metals is still preferred to be 50 nm. It is appreciated, however, if the total thickness is higher, a higher energy laser will be needed.

[0041] Upon leaving the third laser ablation station 110, the ablated material that is in either roll form or that has been cut into cards is fed as shown by arrow 105 to the microwave plasma machine 111. It is appreciated, however, that a second plasma machine could also be used in accordance with this invention. Cleaning with the plasma machine 111 results in the removal of polymeric debris and other organic materials and increased surface energy, making the surfaces very hydrophilic, which helps increase the blood flow rate and fluid spreading. For example, the surface energy of the capillary channel 60 as well as the surface 46 before treatment with the plasma machine is approximately 41 mN/m. The surface energy after the treatment is approximately 72 mN/m.

[0042] Upon leaving the microwave plasma machine 111, the film is then fed as shown by arrow 114 into a sensor lamination and cut/pack station 116. At the same time, the reagent-coated film is fed, as shown by arrow 118 into the station 116. The cover support material is punched to form openings 58. The first surface 46 of the cover support material is then applied to the electrode-support substrate material over the electrode arrays 34. Next, a liquid adhesive is dispensed, as shown by arrow 120 through openings 58 of the cover substrate material in the station 116. A heated tool is applied on the area where bonding is to take place to promote fast curing of the adhesive between isolated gold surfaces 46 and 14.

[0043] The resulting assembled material is cut to form individual biosensors 10, which are sorted and packed into vials, each closed with a stopper, to give packaged biosensor strips as shown by arrow 122.

[0044] In use, for example, a user of biosensor 10 places a finger having a blood collection incision against ends 26, 50 adjacent to openings of recess 40 and channel 60. See, Fig. 3. Capillary forces pull a liquid sample flowing from the incision through the capillary channel 60 across the reagent 68 and the array 36. The liquid sample dissolves the reagent 68 and engages the array 36 where the electrochemical reaction takes place.

[0045] The user then inserts the biosensor 10 into a meter (not shown) where an electrical connection is made between the electrode contacts 36 and a meter contact (not shown) in the meter. It is appreciated that the biosensor 10 also may be inserted into the meter at any number of times including prior to the sample flowing into the opening channel 60. Once the reaction is complete, a power source (e.g., a battery) applies a potential difference between the electrodes 16, 18. When the potential difference is applied, the amount of oxidized form of the mediator at the reference electrode and the potential difference must be sufficient to cause diffusion-limited electro-oxidation of the reduced form of the mediator at the surface of the working electrode. The current measuring meter (not shown) measures the diffusion-limited current generated by the oxidation of the reduced form of the mediator at the surface of the working electrode as described above.

[0046] The measured current may be accurately correlated to the concentration of the analyte in sample when the following requirements are satisfied:

1. The rate of oxidation of the reduced form of the mediator is governed by the rate of diffusion of the reduced form of the mediator to the surface of the working electrode.
2. The current produced is limited by the oxidation of reduced form of the mediator at the surface of the working electrode.

[0047] In another aspect of the invention, a cover substrate 220 is provided in accordance with the present disclosure. Cover substrate 220 is shown in Fig. 6 and is suitable for use with the electrode-support substrate 12. The cover substrate 220 is coupled to the electrode-support substrate 12 adjacent to the first end 26. The cover substrate 220 is formed of a flexible polymer coated with a metallic material similar to cover substrate 20.

[0048] The cover substrate 220 is formed to include a capillary channel 260 and secondary capillary recesses 86 spaced-apart from channel 260. Like channel 60 in cover 20, the capillary channel 260 is also formed to provide a well controlled fluid flow and simultaneously reduce the volume of liquid required when it cooperates with support substrate 12 in a biosensor. The capillary channel 260 and secondary capillary recesses 86 are formed through at least the material 88 and preferably through a portion of the first surface 46 of the cover substrate 220 by laser ablation using techniques as described above. It is appreciated that the amount of the cover substrate 220 that is removed can vary in accordance with the present disclosure.

[0049] As shown in Fig. 6, the capillary channel 260 includes a plurality of microstructures 262. The microstructures

262 are spaced-apart from one another, on a nearest neighbor basis, by a first distance that is less than the distance necessary to achieve capillary flow of liquid between the microstructures. It is appreciated that the capillary channel 260 can include greater or fewer than the illustrated microstructures in accordance with this disclosure. Microstructures 262 are formed as generally round-shaped posts. It is appreciated, however, that microstructures can have a variety of shapes and sizes in accordance with this disclosure. In addition, the cover substrate 220 is also cleaned, as described above with reference to cover 20, increasing the surface energy of surfaces of both the surface of the channel 40 and the microstructures 42.

[0050] In another aspect of the invention, a cover substrate 320 is provided in accordance with the present disclosure. Cover substrate 320 is shown in Fig. 7 and is suitable for use with the electrode-support substrate 12. The cover substrate 320 is coupled to the electrode-support substrate 12 adjacent to the first end 26. The cover substrate 320 is formed of a flexible polymer coated with a metallic material similar to cover substrate 20.

[0051] The cover substrate 320 is formed to include a capillary channel 360 and secondary capillary recesses 86 spaced-apart from channel 360. Like channel 60 in cover 20, the capillary channel 360 is also formed to provide a well controlled fluid flow and simultaneously reduce the volume of liquid required when it cooperates with support substrate 12 in a biosensor. The capillary channel 360 and secondary capillary recesses 86 are formed through at least the material 88 and preferably through a portion of the first surface 46 of the cover substrate 320 by laser ablation using techniques as described above. It is appreciated that the amount of the cover substrate 320 that is removed can vary in accordance with the present disclosure. Further, the cover substrate 320 is also cleaned, as described above with reference to cover 20, increasing the surface energy of the surface of the channel 360.

[0052] In another aspect of the invention, a cover substrate 420 is provided in accordance with the present disclosure. Cover substrate 420 is shown in Fig. 8 and is suitable for use with the electrode-support substrate 12. The cover substrate 420 is coupled to the electrode-support substrate 12 adjacent to the first end 26. The cover substrate 420 is formed of a flexible polymer coated with a metallic material similar to cover substrate 20.

[0053] The cover substrate 420 is formed to include a capillary channel 460 and secondary capillary recesses 86 spaced-apart from channel 460. Like channel 60 in cover 20, the capillary channel 460 is also formed to provide a well controlled fluid flow and simultaneously reduce the volume of liquid required when it cooperates with support substrate 12 in a biosensor. The capillary channel 460 and secondary capillary recesses 86 are formed through at least the material 88 and preferably through a portion of the first surface 46 of the cover substrate 420 by laser ablation using techniques as described above. It is appreciated that the amount of the cover substrate 420 that is removed can vary in accordance with the present disclosure.

[0054] As shown in Fig. 8, the capillary channel 460 includes a plurality of microstructures 462. The microstructures 462 are spaced-apart from one another, on a nearest neighbor basis, by a first distance that is less than the distance necessary to achieve capillary flow of liquid between the microstructures. Illustratively, the capillary channel 460 includes five rows of microstructures 462. It is appreciated that the capillary channel 460 can include greater or fewer than the illustrated microstructures in accordance with this disclosure. Microstructures 462 are formed as generally bar-shaped posts. It is appreciated, however, that microstructures can have a variety of shapes and sizes in accordance with this disclosure. Further, the cover substrate 420 is also cleaned, as described above with reference to cover 20, increasing the surface energy of surfaces of both the surface of the channel 460 and the microstructures 462.

[0055] As shown in Fig. 10, biosensor 510 is formed to include an electrode-support substrate 512. Substrate 512 is formed in a similar manner to substrate 12, except that the electrode array 34 is spaced-apart from first end 26 and a recess 540 including microstructures 42 extends between end 26 and array 34. The recess is formed through the electrical conductor 14 and a portion of the first surface 22 of the support substrate 512 by laser ablation using techniques as described above. It is appreciated that the amount of the support substrate 512 that is removed can vary in accordance with the present disclosure. It is also appreciated that substrate 512 of biosensor 510 can be formed without a recess in accordance with the present disclosure. It is also appreciated that the microstructures 42 can assume a variety of shapes and sizes in accordance with the present disclosure.

[0056] The cover substrate 520 is coupled to the electrode-support substrate 12 adjacent to the first end 26. See Fig. 10. The cover substrate 520 is formed of materials similar to the cover substrate 20 as described above. Referring now to Fig. 11, the cover substrate 520 is formed to include a capillary channel 560 and secondary capillary recesses 86 spaced-apart from channel 560. The capillary channel 560 is formed to provide a well-controlled fluid flow and simultaneously reduce the volume of liquid required in biosensor 510. The capillary channel 560 extends between first and second ends 50, 52 and is defined by interior borders 64. The capillary channel 560 and secondary capillary recesses 86 are formed through at least the material 88 and preferably through a portion of the first surface of the cover substrate 20 by laser ablation using techniques as described above. It is appreciated that the amount of the cover substrate 520 that is removed can vary in accordance with the present invention.

[0057] As shown in Fig. 11, the capillary channel 560 includes microstructures 62 that are formed as described above with reference to biosensor 10. It is appreciated that the microstructures 62 can assume a variety of shapes and sizes the number and location of microstructures 62 depend upon the size of biosensor in accordance with the present

disclosure.

[0058] In addition, the cover substrate 520 is formed to include an inlet 522 that extends between first and second surfaces 46, 48 in the capillary channel 560. When the cover substrate 520 is coupled to the support substrate 512, the inlet 522 is offset from the array 34. See, Fig. 10. It is appreciated, however, that inlet 522 can be located in a number of locations in the channel 560 in accordance with this disclosure, a non-limiting example of which includes the inlet 522 intersecting end 50 of cover substrate 520.

[0059] Biosensor 510 is manufactured in a manner similar to biosensor 10 as described above. Recess 540 of the biosensor 510 is formed in the second laser ablation station 100 by ablating the first surface 22 in a pre-defined pattern to form the recess 540 extending between end 26 and the array 36. The hydrophilicity of the channel 540 and microstructures 42 are increased due to cleaning by a plasma machine 111 as described above with reference to biosensor 10.

[0060] Capillary channel 560 is formed in the cover substrate material in the third ablation station 110 as described above with reference to biosensor 10. The ablated material is cleaned by the plasma machine 111 to remove polymeric debris and other organic materials and increasing the hydrophilicity of the channel 560 and microstructures 62. The film is then fed into the sensor lamination and cut/pack station 116 where openings 58 and inlet 522 are punched.

[0061] As described above with reference to biosensor 10, a liquid adhesive is dispensed, through openings 58 of the cover substrate material and a heated tool is applied on the area where bonding is to take place to promote fast curing of the adhesive. The resulting assembled material is cut to form individual biosensors 510, which are sorted and packed into vials, each closed with a stopper, to give packaged biosensor strips. The biosensor 510 is used in a manner similar to biosensor 10 as described above.

[0062] Although the invention has been described in detail with reference to a preferred embodiment, variations and modifications exist within the scope and spirit of the invention, as described and defined in the following claims.

Claims

1. A biosensor comprising:

a substrate, and

a cover extending across at least a portion of the substrate, the cover including a first surface facing the substrate and a second surface, at least a portion of the first surface being removed to define a capillary channel, the capillary channel having a surface energy ranging from about 60 mN/m to about 72 mN/m.

2. The biosensor of claim 1 wherein the first surface is formed to include at least one microstructure extending into the channel.

3. The biosensor of claim 2 wherein at least one of the microstructures has a round post-like shape.

4. The biosensor of claim 2 wherein at least one of the microstructures has a generally square post-like shape.

5. The biosensor of claim 2 wherein the capillary channel includes opposite ends and at least two of the microstructures include a front side facing one end and a back side facing the opposite end and opposite inner and outer edges that extend between the front and back sides.

6. The biosensor of claim 5 wherein the front side and the back side each have a greater dimension than the inner and outer edges.

7. The biosensor of claim 1 wherein the first surface includes spaced-apart secondary capillary recesses.

8. The biosensor of claim 1 wherein at least a portion of the first surface includes a metallic coating.

9. The biosensor of claim 6 wherein the metallic coating is gold.

10. A biosensor comprising:

a capillary path defined between a substrate and a cover, and

at least one microstructure positioned in the capillary path, the at least one

microstructure including a fixed end coupled to either the substrate or the cover and an opposite free end,

wherein the free end is metallic.

11. The biosensor of claim 10 wherein the capillary path has a surface energy ranging from about 60 mN/m to about 72 mN/m.
12. The biosensor of claim 10 wherein the free end is coated with a metal selected from the group consisting of gold, platinum, palladium, and iridium.
13. The biosensor of claim 12 wherein the metal is gold.
14. The biosensor of claim 10 wherein at least one of the microstructures has a round post-like shape.
15. The biosensor of claim 10 wherein at least one of the microstructures has a generally square post-like shape.
16. A biosensor comprising:
 - a substrate,
 - electrodes positioned on the substrate,
 - a cover extending across at least a portion of the substrate to define a capillary path, and
 - at least one microstructure positioned in the capillary path, the at least one microstructure including a fixed end coupled to the cover and an opposite free end, wherein the free end is metallic.
17. The biosensor of claim 16 wherein the free end formed of a metal selected from the group consisting of gold, platinum, palladium, and iridium.
18. The biosensor of claim 16 wherein the metal is gold.
19. The biosensor of claim 16 wherein the microstructures have a surface energy ranging from about 60 mN/m to about 72 mN/m.
20. A method of forming biosensor, the method comprising the steps of:
 - providing a substrate, a reagent for the measurement of at least one analyte, and a cover, the cover including a first surface,
 - exposing the cover to at least one pulse of light of sufficient to ablate the first surface in a pre-determined pattern creating a channel,
 - cleaning the first surface of the cover so that the surface energy of the channel ranges from about 60 mN/m to about 72 mN/m, and
 - placing the first surface of the cover upon the substrate to define a capillary path and the reagent is positioned in the capillary path.
21. The method of claim 20 wherein the first surface is cleaned by a microwave plasma machine.
22. The method of claim 20 wherein the first surface is ablated to create microstructures in the channel.
23. The method of claim 20 further comprising the step of forming electrodes on the substrate.
24. The method of claim 23 wherein the forming step includes exposing the substrate to at least one pulse of light sufficient to ablate a portion of the substrate about the electrodes.
25. The method of claim 23 further comprising the step of exposing the substrate to at least an additional pulse of light sufficient to ablate a portion of the substrate creating at least one microstructure extending from the substrate.
26. The method of claim 23 further comprising the step of cleaning the substrate to increase the surface energy of the substrate.
27. The method of claim 20 further comprising the steps of positioning a mask having a pre-defined pattern over the first surface and exposing the mask and the cover to at least one pulse of light sufficient to ablate the exposed

EP 1 302 545 A2

surface of the cover creating at least one microstructure extending from the cover.

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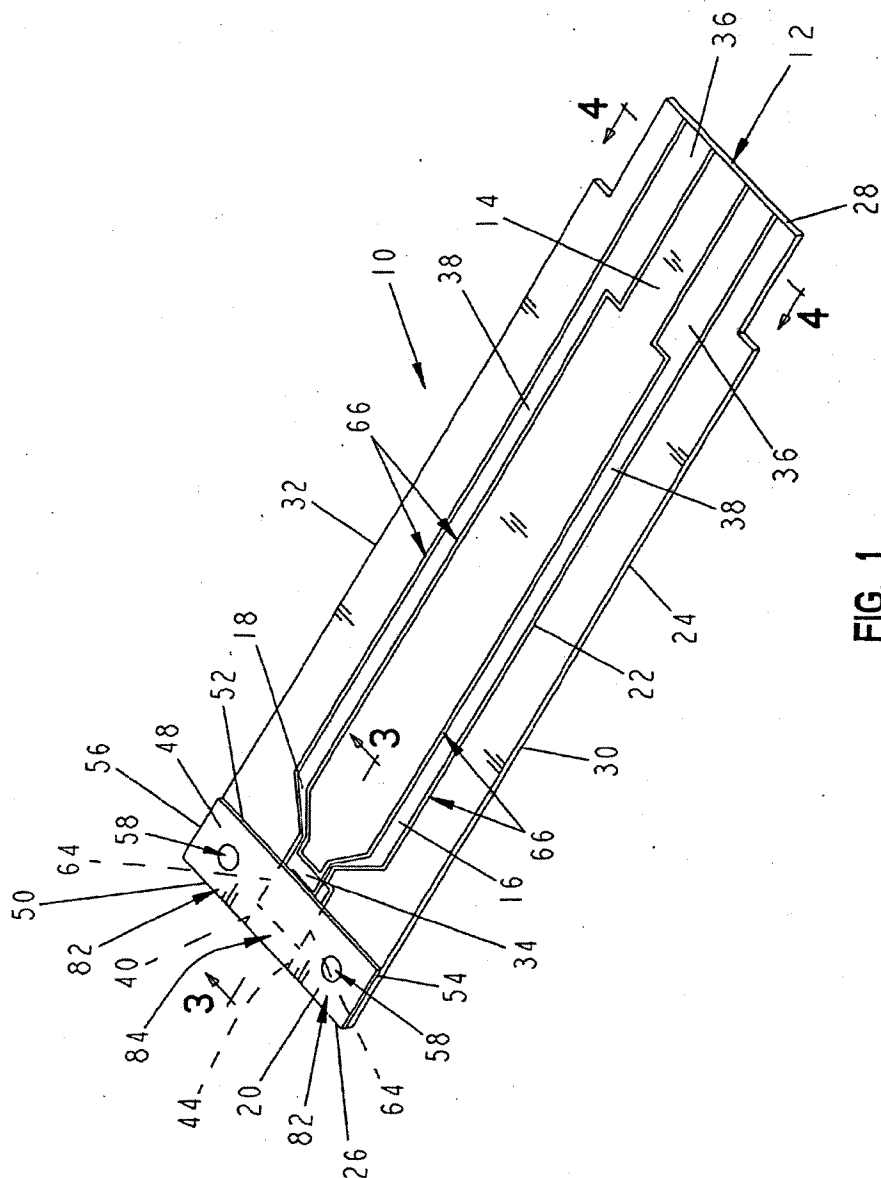
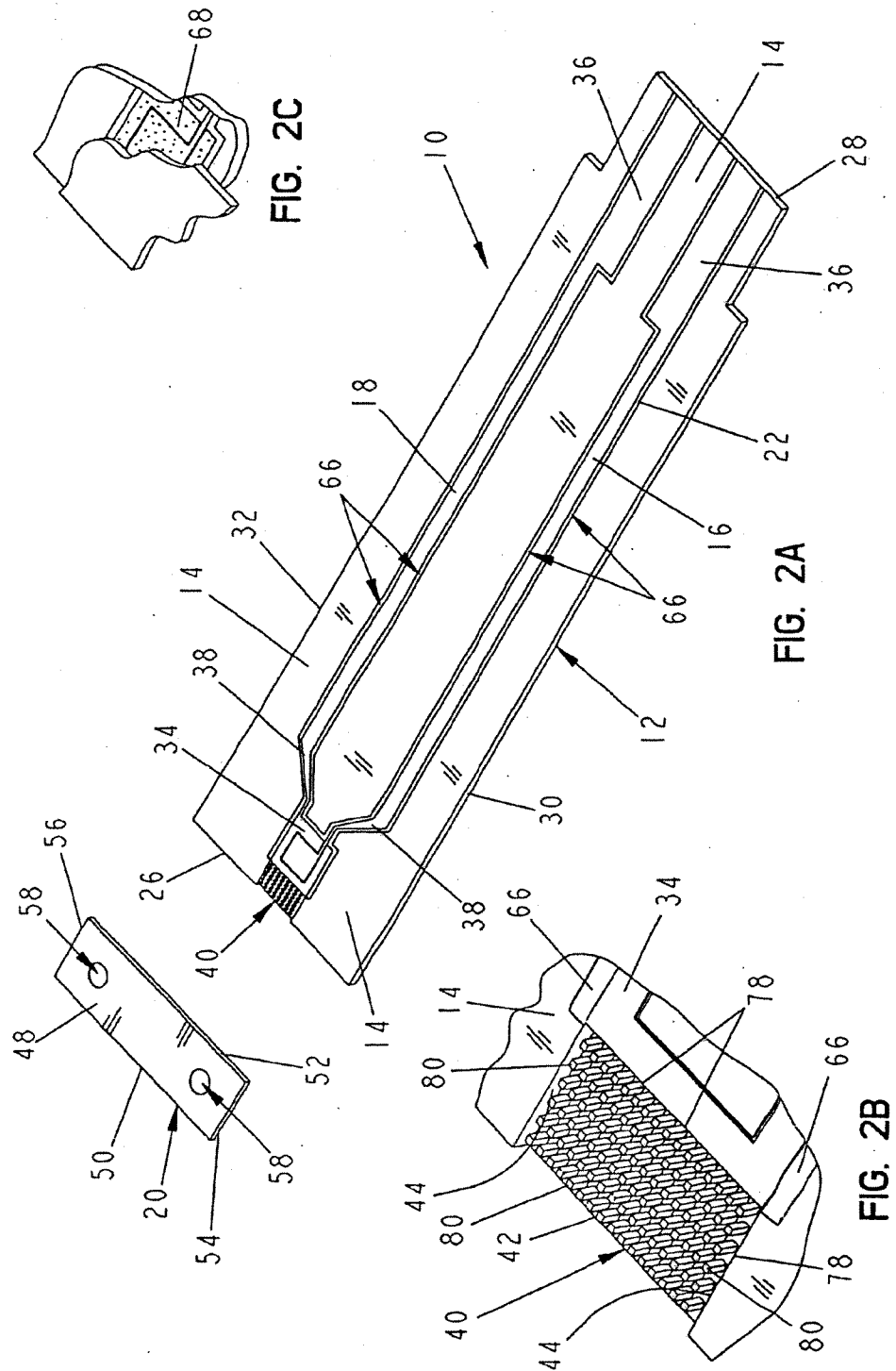


FIG. 1



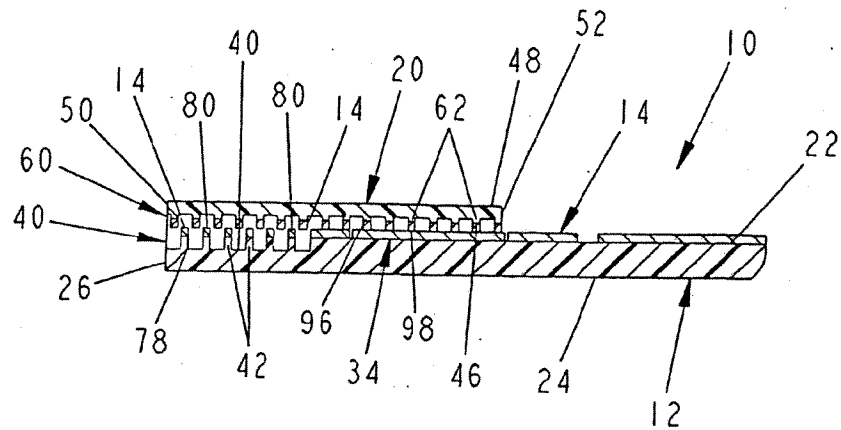


FIG. 3

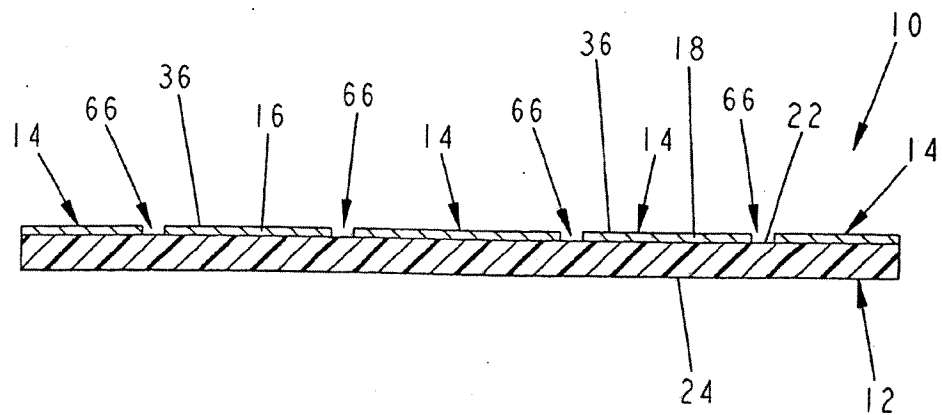
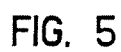


FIG. 4



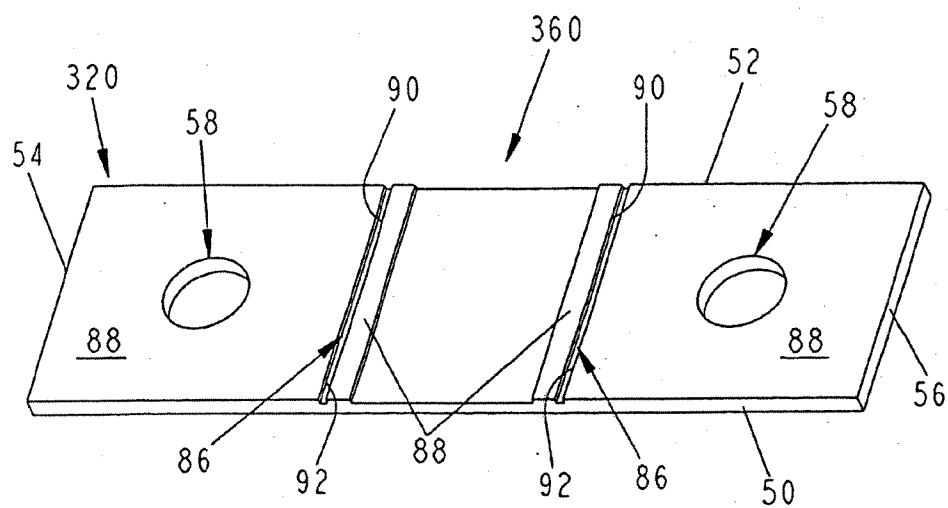


FIG. 7

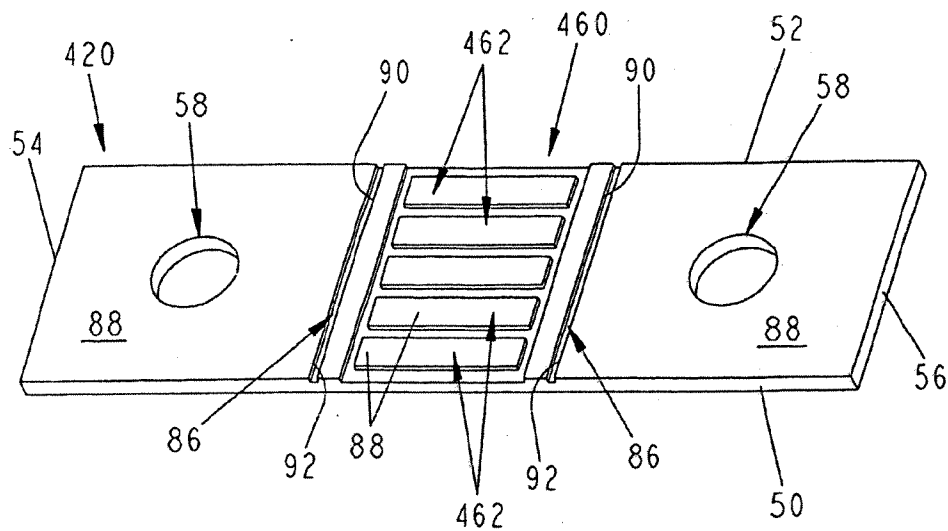


FIG. 8

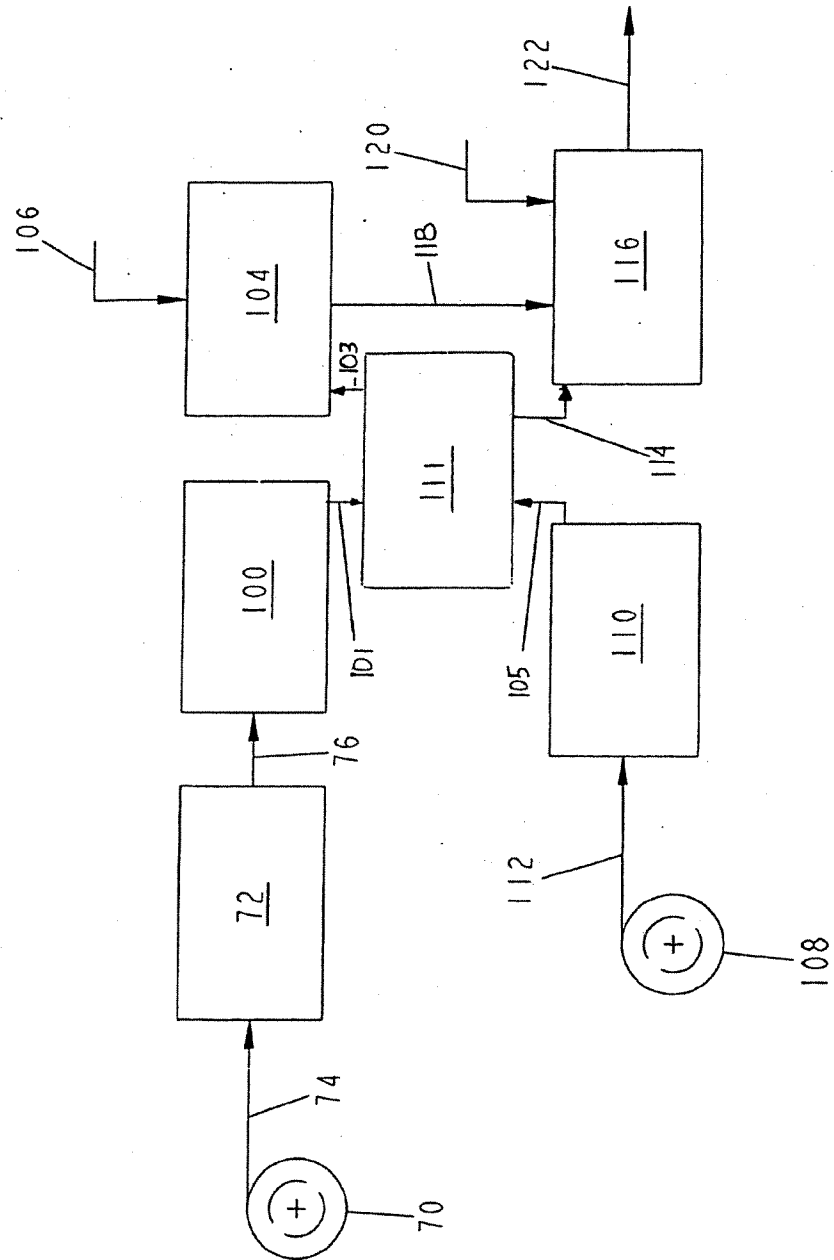


FIG. 9

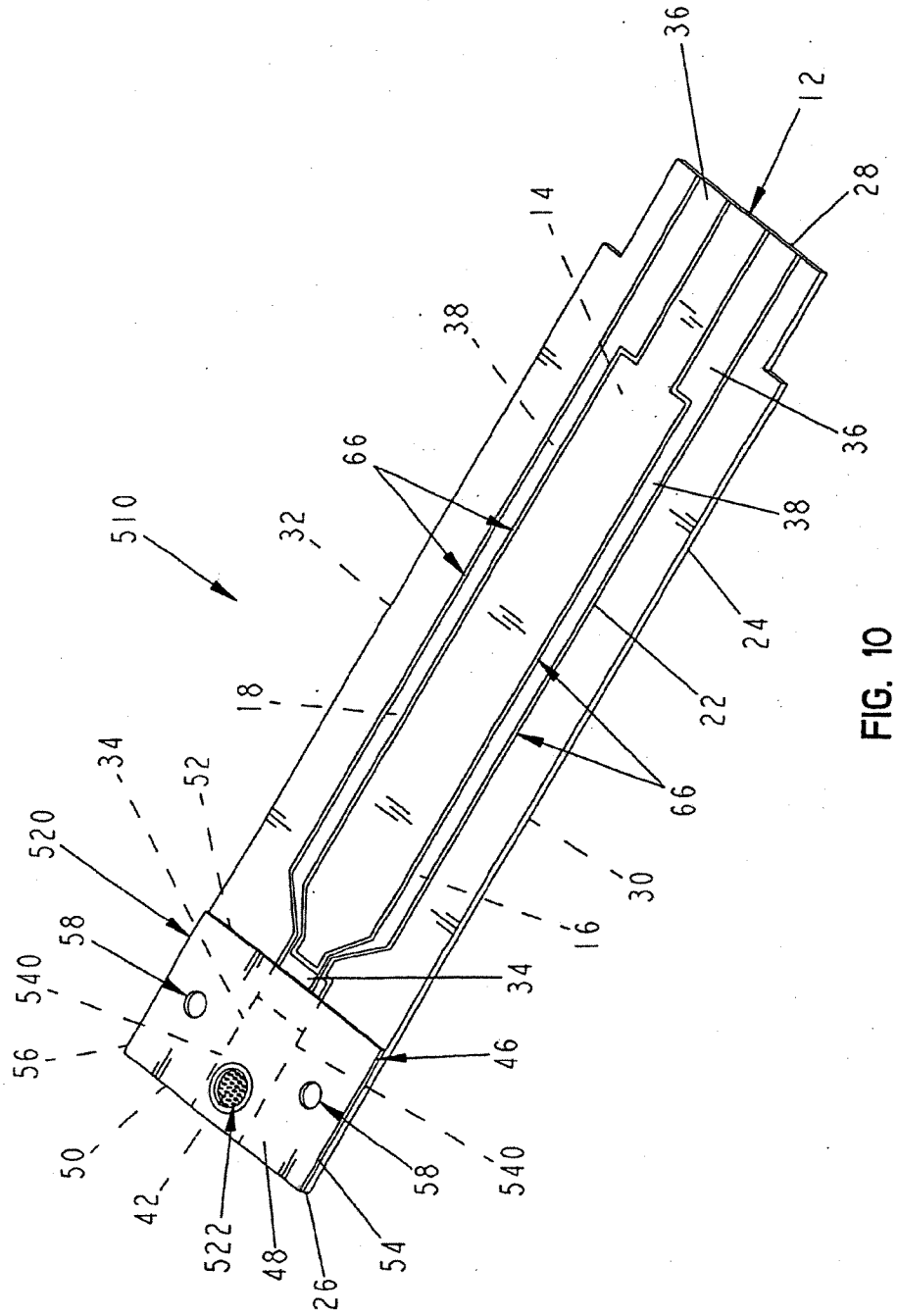


FIG. 10

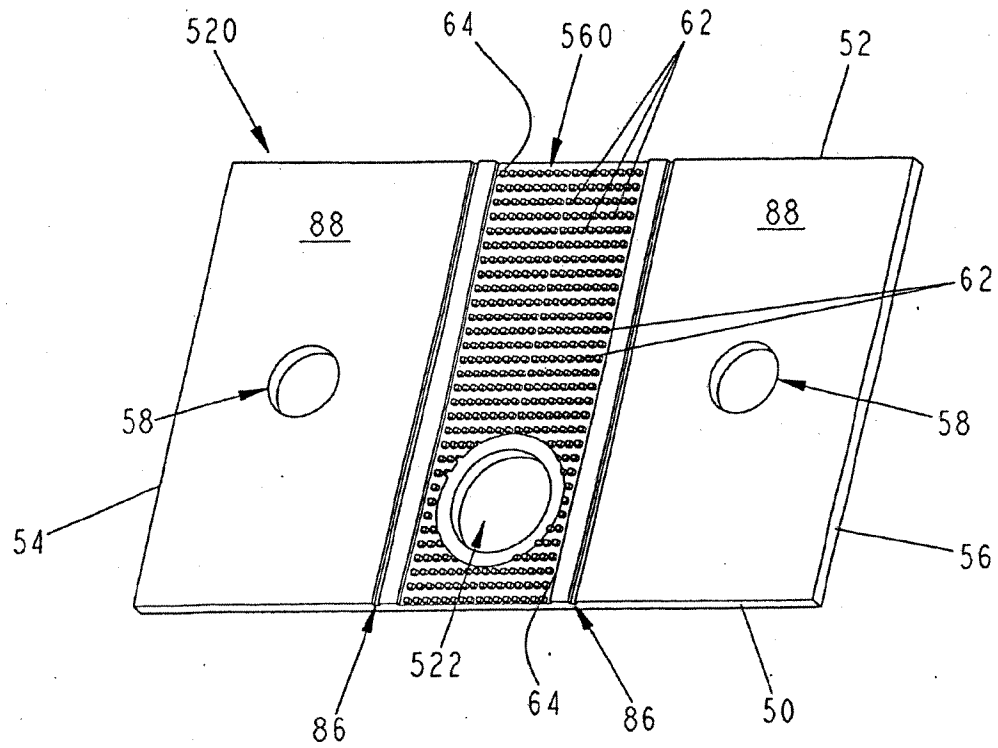
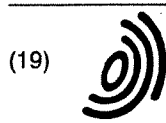


FIG. 11



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(54) **Enzyme Biosensor**

(57) A biosensor is provided in accordance with the present invention. The biosensor includes a substrate and a cover extending across at least a portion of the substrate. The cover includes a first surface facing the

substrate and a second surface. At least a portion of the first surface is removed to define a capillary channel. The capillary channel has a surface energy ranging from about 60 mN/m to about 72 mN/m.

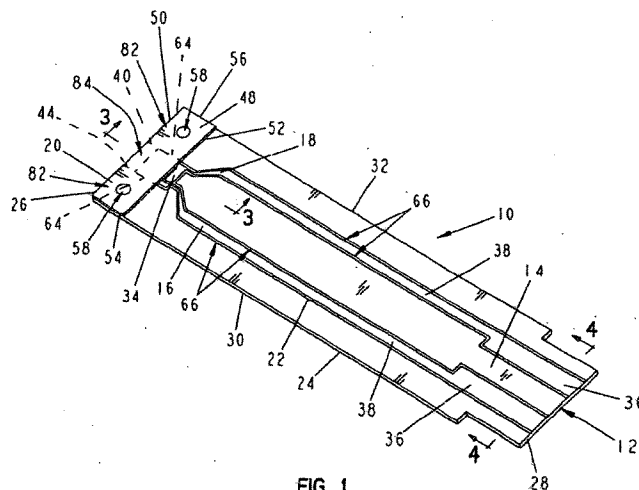


FIG. 1



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 02 02 2418

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.CI.7)
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X	EP 1 098 000 A (ROCHE DIAGNOSTICS CORP) 9 May 2001 (2001-05-09)	1,2,4, 10-13, 15-19 20-27	
Y	* the whole document *		
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Y	* claims 1-72; figures 1-16 *	20-27	
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EUROPEAN SEARCH REPORT

Application Number
EP 02 02 2418

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CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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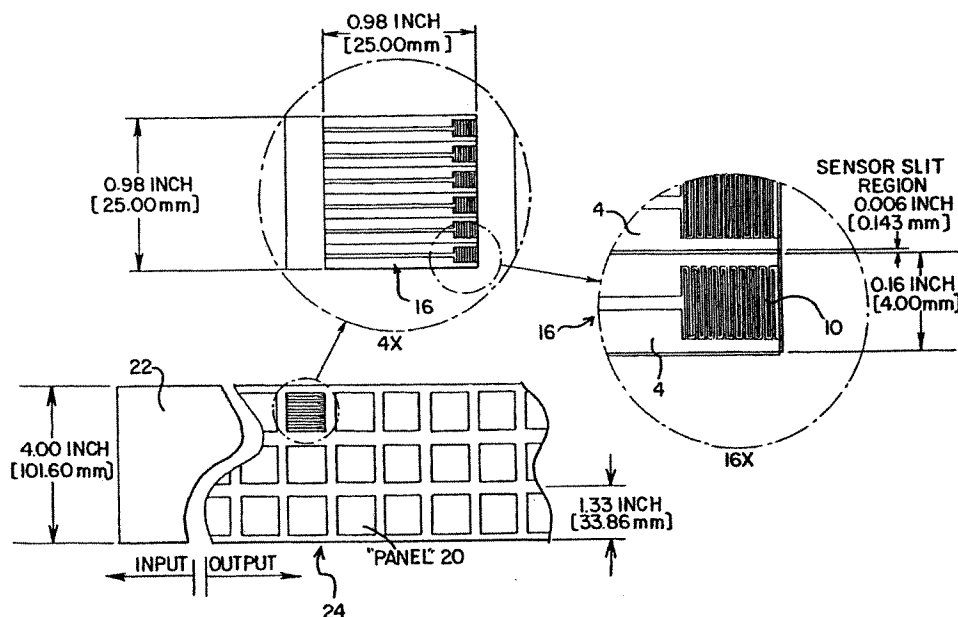
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(54) Title: PATTERNED LAMINATES AND ELECTRODES WITH LASER DEFINED FEATURES



(57) Abstract: A method of making a patterned laminate includes ablating through a portion of a metallic layer with a laser, to form a pattern in the metallic layer, where the metallic layer is on and in contact with an insulating substrate. The patterned laminate may be patterned to form electrodes, and can be formed into an electrochemical sensor strip.

PATTERNED LAMINATES AND ELECTRODES WITH LASER DEFINED FEATURES

BACKGROUND OF THE INVENTION

5 The present invention relates to laser ablation to pattern a metallic layer, as well as an electrode for an electrochemical biosensor.

 Electrochemical biosensors are well known. They have been used to determine the concentration of various analytes from biological samples, particularly from blood. Electrochemical biosensors are described in U.S. Patent Nos. 5,413,690; 5,762,770 and 5,798,031; as well as in International Publication No. WO99/13101, each of which are hereby incorporated by reference.

10 An electrochemical biosensor typically includes a sensor strip. The sensor strip includes a space that holds the sample to be analyzed, may include reagents to be released into the sample, and includes an electrode set. The electrode set normally includes an insulating substrate, electrodes that contact the sample, which have contact pads for electrically connecting the electrodes to the electronics of electrochemical biosensor.

15 It is desirable for electrochemical biosensors to be able to analyze electrolytes using as small a sample as possible, and therefore it is necessary to miniaturize the sensor strip, as well as its parts, including the electrodes, as much as possible. Usually screen printing techniques have been used to form miniaturized electrodes.

20 Electrodes formed by screen printing techniques can only be formed from composition that are both electrically conductive and which are screen printable. Furthermore, screen printing techniques only allow for the reliable formation of structures and patterns having a feature size of approximately 75 μm or greater. In addition, screen printing is a wet chemical process. It would be desirable to have a new method of forming electrodes which allows for the use of different composition, and which can form features smaller than 75 μm .

25

30

Laser ablation is a technique using a laser to cut or mold a material. This technique usually uses a high power excimer laser, such as a krypton-fluoride excimer laser with an illumination wavelength of 248 nm, to blast away surface material. This technique has been used to ablate metals, polymers and even biological material, such as the cornea of the human eye. Such systems are well known to those of ordinary skill in the art, and are described in U.S. Patent Nos. 5,576,073 and 5,593,739, each of which is hereby incorporated by reference.

SUMMARY OF THE INVENTION

In one aspect, the invention is a method of making a patterned laminate comprising ablating through a portion of a metallic layer with a laser. The metallic layer comprises at least one member of gold, platinum, palladium and iridium. Furthermore, the metallic layer is on, and in contact with, an insulating substrate, for example, a polymer.

In another aspect, the invention is a method of making a electrode set, comprising ablating through a portion of a first metallic layer with a laser, to form an electrode pattern. The first metallic layer is on an insulating substrate.

In still another aspect, the invention is a method of making an electrode set ribbon, comprising ablating through a portion of a first metallic layer with a laser, to form a plurality of electrode patterns. The first metallic layer is on an insulating substrate, for example, a polymer. The electrode set ribbon comprises a plurality of electrode sets.

In yet another aspect, the present invention is an electrode set, comprising a first metallic layer, on an insulating substrate, comprising a plurality of electrodes. The first metallic layer has a feature size of less than 75 μm .

In yet another aspect, the present invention is a patterned laminate, comprising a patterned metallic layer on, and in contact with, an insulating substrate. The metallic layer comprises at least one of gold, platinum,

palladium and iridium. Furthermore, the insulating substrate comprises a polymer, and the patterned metallic layer has a feature size of less than 75 μm .

5 An advantage of the present invention is that it allows for the possibility of small feature sizes.

As used herein, the phrase "patterned laminate" means a multilayered structure that includes an overlayer through which an underlying layer is exposed, i.e. the overlayer has gaps and does not completely cover the underlying layer. The gaps or areas of exposure form the "pattern" of the patterned laminate. Furthermore, the term "pattern" means one or more
10 intentionally formed gaps having a feature size, for example, a single linear gap having a constant width, where the smallest width is the feature size. Not included in the term "pattern" are natural, unintentional defects.

As used herein, the phrase "feature size" is the smallest dimension of a gap found in a pattern.
15

As used herein, the phrase "electrode pattern" is a pattern which when formed in a metallic layer includes at least two, for example 2 to 60, or 3 to 20, electrodes which are not electrically connected to each other, but each of which includes its own contact pad.

20 As used herein, the phrase "metallic layer" refers to a layer made of a material that is a metallic conductor of electricity, such as a pure metal or alloys.

As used herein, the phrase "electrode set" is a set of at least two electrodes, for example 2 to 60, or 3 to 20, electrodes. These electrodes may be, for example, a working electrode and a reference electrode.
25

As used herein, the phrase "ablating" means the removing of material.

Other objects, features and advantages of the present invention will become apparent from the following detailed description. It should be understood, however, that the detailed description and the specific examples, while indicating embodiments of the invention, are given by way of illustration
30 only, since various changes and modifications within the spirit and scope of

the invention will become apparent to those skilled in the art from this detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

5 The following drawings form part of the present specification and are included to further demonstrate certain aspects of the present invention. The invention may be better understood by reference to one or more of these drawings in combination with the detailed description of specific embodiments presented herein:

10 Figure 1 illustrates an electrochemical sensor strip of the present invention;

 Figure 2 illustrates an exploded view of an electrochemical sensor strip of the present invention, more clearly showing each individual part;

 Figure 3 illustrates an electrode set of the present invention;

15 Figure 4 illustrates another electrode set of the present invention;

 Figure 5 illustrates still another electrode set of the present invention;

 Figure 6 is a schematic of still another electrode set of the present invention;

20 Figure 7 is a schematic of an electrode set ribbon of the present invention;

 Figure 8 is a schematic of a device of the present invention for making an electrode set ribbon of the present invention; and

 Figure 9 is a block diagram of a process of the present invention for making a sensor strip of the present invention.

25 DETAILED DESCRIPTION OF THE INVENTION

 Figure 1 illustrates the assembled electrochemical sensor strip **12**, which includes a base **1**, the contact pads **9** and **9** that are part of the electrodes. The sensing region **10** of the electrodes is also illustrated.

30 Figure 2 illustrates an exploded view of a sensor strip **12**, which includes a base **1**, adhesive foil **2** for holding the base to the electrode

substrate **3**. The electrode set **16** is on the electrode substrate **3**, and is partially covered by a dielectric **5**. A cover **8** is attached to one end of the dielectric with adhesive tape **7**. A small gap **13** in the dielectric, and a space **14** in the adhesive tape, together with the cover and the electrodes, form a pocket inside of which may be placed reagent **6** used to aid in electrochemically detecting and quantifying an analyte. This pocket can act as a capillary, drawing the fluid to be tested onto the sensing region **10** (not shown) of the electrodes. Alternatively, the cover may be absent, exposing the sensing region of the electrodes, and the sample may be directly applied onto this region.

Figure 3 illustrates an electrode set **16**, including two electrodes **4** and **4**. The electrodes have contact pads **9** and **9**, which are electrically connected to the sensing region **10** of the electrode. Also illustrated is dielectric **5** which covers the first and second electrodes, exposing only the sensing region and the contact pads.

Figures 4 and 5 illustrate two different electrode sets **16**, which each include a substrate **1**, and first and second electrodes **4** and **4**. The electrodes are separated by a gap **18** that prevents electrical contact between the two electrodes. For purposes of illustration, the regions of the electrodes which will become the sensing region **10**, and the contact pads, **9** and **9**, are shaded. The gap **18** corresponds to the feature size of this electrode set, since it is the smallest intentional feature. Figures 4 and 5 illustrate two different electrode patterns, one having a simple straight gap (Figure 4), and the other more complex and containing a rectilinear gap, forming a region of interlacing fingers of the two electrodes (Figure 5).

Figure 6 is a schematic of an electrode set of the present invention, including two electrodes **4** and **4**. The sensing region **10** of the electrodes contains interlacing fingers of the two electrodes, again a rectilinear gap. Also shown opposite the sensing region are the contact pads **9** and **9** of each electrode. The gap between the electrodes corresponds to the feature size, and may be 1 to 100 μm , preferably less than 75 μm , more preferably 5 to 50 μm , most preferably 10 to 30 μm . The gap passes completely through the

metallic layer so that the two electrodes are not electrically connected in the electrode set. The values for the dimensions illustrated in Figure 6 are for a single specific embodiment, and these values may be selected as need for the specific use. For example, the length of the electrode set may be 2.5 to 250 mm, the width may be 0.4 to 40 mm, the gap between the contact pads may be 1 μ m to 5 mm, and the width of each contact pad may be 1 to 20 mm. The electrode pattern shown in Figure 6 (and other figures) is symmetric, however this is not required, and irregular or asymmetric patterns (or electrode shapes) are possible.

Figure 7 is a schematic of an electrode set ribbon **24**. The ribbon includes a plurality of panels **20**, each of which includes a plurality of electrode sets **16**. Also shown is the original metallic laminate ribbon **22** that is subject to laser ablation to form the electrode set ribbon **24**. The width of the ribbon is selected to accommodate the laser ablation system, and may be, for example, 40 to 0.4 inches. The ribbon may be any length, and is selected based on the desired number of electrode sets, and/or the ease of handling and transport of the ribbons. The size of each individual panel is selected to fit conveniently on the ribbon, and therefore each panel may contain 1 to 1000 electrode sets, preferably 2 to 20 electrode sets.

Figure 8 is a schematic of a device for producing electrode sets, in the form of an electrode set ribbon **24**. First a roll of metallic laminate ribbon **22** is fed through guide rolls **28** into a laser ablator **26**. In the laser ablator the metallic layer of the metallic laminate ribbon is ablated with the laser, in an electrode pattern, to form the electrode set ribbon **24**. The electrode set ribbon **24** is then passed through more guide rolls **28**, with a tension loop to adjust the tension of the ribbon, and through an optional inspection camera **30**, which may be used to check for defects. Next, optionally, the electrode set ribbon **24** may be laminated with an adhesive foil ribbon **32**, in a laminator **36**, to form a laminated electrode set ribbon **34**, which is then guided through guide rolls **28**, and rolled up.

Figure 9 is a block diagram of a process for making an electrochemical sensor strip of the present invention. As shown, in step **110** the metallic

lamine ribbon 22 is ablated by laser ablation to form an electrode set ribbon, and then laminated with adhesive foil ribbon 32 to form a laminated electrode set ribbon 34. In step 120 the laminated electrode set ribbon 34 is screen printed with a UV curable dielectric 50, which forms the dielectric 5 (not shown) of each sensor strip, forming a dielectric covered ribbon 38. In step 130 the starting reagents 40 are compounded to form reagent 6, and then in step 140 the reagent is applied onto the dielectric covered ribbon 38, the ribbon is split into reels, each one panel wide, to form reagent covered panel reels 44.

In step 150 the reagent covered panel reels 44 are covered with clear polyester roll 52 attach through double sided adhesive tape roll 54, which forms the clear cover 8 (not shown) and adhesive tape 7 (not shown) of each sensor strip. The product of step 150, clear covered panel reels 46, are then split into individual sensor reels, each one electrode set wide, and laminated with a base substrate roll 56, in step 160, which forms the base 1 (not shown) of each sensor strip, to form sensor reels 48. In step 170 the sensor reels are cut into individual sensor strips 12 (not shown) which are sorted and packed into vials 60, each closed with a stopper 58, to give packaged sensor strips 62. In steps 150 and 160, a liner is release in order to attach the base and cover.

A laser system capable of ablating the metallic layer, to form the individual electrode sets, is well known to those of ordinary skill in the art. Examples include excimer lasers, with the pattern of ablation controlled by lenses, mirrors or masks. An example of such a system is the LPX-400, or LPX-200, both from LPKF LASER ELECTRONIC, GMBH of Garbsen, Germany.

The metallic laminate is a metallic layer on the electrode substrate. The metallic layer may contain pure metals or alloys, or other materials which are metallic conductors. Examples include aluminum, carbon (such as graphite), cobalt, copper, gallium, gold, indium, iridium, iron, lead, magnesium, mercury (as an amalgam), nickel, niobium, osmium, palladium, platinum, rhenium, rhodium, selenium, silicon (such as highly doped

polycrystalline silicon), silver, tantalum, tin, titanium, tungsten, uranium, vanadium, zinc, zirconium, mixtures thereof, and alloys or metallic compounds of these elements. Preferably, the metallic layer includes gold, platinum, palladium, iridium, or alloys of these metals, since such noble metals and their alloys are unreactive in biological systems. The metallic layer may be any thickness, but preferably is 10 nm to 1 mm, more preferably, 20 nm to 100 μm , or even 25 nm to 1 μm . Figure 9 illustrates the process with a 50 nm gold film.

In the laser ablation process, the metallic layer may be ablated into an electrode pattern. Furthermore the patterned metallic layer may be coated or plated with additional metal layers. For example, the metallic layer may be copper, which is then ablated with a laser, into an electrode pattern; subsequently, the copper may be plated with a titanium/tungsten layer, and then a gold layer, to form the desired electrodes. Preferably, however, only a single layer of gold is used, which is directly in contact with the electrode substrate, since it allows for the entire elimination of wet chemical steps for the formation of the electrode sets.

The electrode substrate is formed from an insulating material, so that it will not provide an electrical connection between the electrodes of the electrode set. Examples include glass, ceramics and polymers. Preferably, the electrode substrate is a flexible polymer, such as a polyester or polyimide. An example of a suitable material would be the polyimide UPLEX from TECHNI-MET of Connecticut, which is available pre-coated with gold, palladium or platinum; or ULTEM 1000 (polyetherimide) from GE, available coated with copper.

A UV curable dielectric and which is screen printable, may be used to form the dielectric, for example the polymer composition 5018 dielectric composition from DuPont. The clear cover is a clear material that is inert to biological fluids, for example glass, polyethylene, polypropylene, polyvinylchloride, polyimide, or polyester. The clear cover may have markings. The adhesive tape is also a flexible polymer having a surfaces

covered with an adhesive; these materials are also well known to those of ordinary skill in the art.

The base is a supporting structure, and is preferably made of flexible polymer material, with a thickness sufficient to provide support to the sensor strip, for example polyester with a thickness of 6 mils. The adhesive foil may be made for the same types of compositions as the adhesive tape.

The reagent is optional, and may be used to provide electrochemical probes for specific analytes. The starting reagents are the reactants or components of the reagent, and are often compounded together in liquid form before application to the ribbons or reels. The liquid may then evaporate, leaving the reagent in solid form. The choice of specific reagent depends on the specific analyte or analytes to be measure, and are well known to those of ordinary skill in the art. For example, a reagent for measurement of glucose in a human blood sample contains 62.2 mg polyethylene oxide (mean molecular weight of 100-900 kilodaltons), 3.3 mg NATROSOL 250 M, 41.5 mg AVICEL RC-591 F, 89.4 mg monobasic potassium phosphate, 157.9 mg dibasic potassium phosphate, 437.3 mg potassium ferricyanide, 46.0 mg sodium succinate, 148.0 mg trehalose, 2.6 mg TRITON X-100 surfactant, and 2,000 to 9,000 units of enzyme activity per gram of reagent. The enzyme is prepared as an enzyme solution from 12.5 mg coenzyme PQQ and 1.21 million units of the apoenzyme of quinoprotein glucose dehydrogenase, forming a solution of quinoprotein glucose dehydrogenase. This reagent is described in WO 99/30152, pages 7-10.

The processes and products described include disposable biosensors, especially for use in diagnostic devices. However, also included are electrochemical sensors for non-diagnostic uses, such as measuring an analyte in any biological, environmental, or other, sample. Furthermore, also included is any patterned laminate, preferably a patterned laminate of a noble metal (gold, platinum, palladium, iridium, alloys thereof) in direct contact with an insulating substrate, such as a polymer. Such laminates can have a variety of electrical function, including use as electrodes, electrical wires or connectors, microwave reflectors, etc. Preferably, these patterned laminates

have a feature size of 100 μm or less, more preferably 1 to 100 μm , even more preferably 75 μm or less, including 5 to 50 μm , or even 5 to 20 μm .

CLAIMS:

1. A method of making a patterned laminate, comprising:
ablating through a portion of a metallic layer with a laser, to form
a pattern in said metallic layer;
5 wherein said metallic layer is on, and in contact with, an
insulating substrate,
said insulating substrate comprises a polymer, and
said metallic layer comprises at least one member selected from
the group consisting of gold, platinum, palladium and iridium.
- 10 2. The method of Claim 1, wherein said pattern has a feature size
of less than 75 μm .
3. The method of Claim 1, wherein said pattern has a feature size
of 1 μm to 50 μm .
- 15 4. A method of making an electrode set, comprising:
ablating through a portion of a first metallic layer with a laser, to
form an electrode pattern;
wherein said first metallic layer is on an insulating substrate.
5. The method of Claim 4, further comprising applying a second
metallic layer on said first metallic layer.
- 20 6. The method of Claim 4, wherein said first metallic layer
comprises copper.
7. The method of Claim 4, wherein said first metallic layer
comprises at least one member selected from the group consisting of gold,
platinum, palladium and iridium.
- 25 8. The method of Claim 4, wherein said insulating substrate is a
polymer.

9. The method of Claim 4, wherein said pattern has a feature size of less than 100 μm .

10. The method of Claim 4, wherein said pattern has a feature size of less than 75 μm .

5 11. The method of Claim 4, wherein said pattern has a feature size of 1 μm to 50 μm .

12. The method of Claim 8, wherein said first metallic layer is in contact with said insulating substrate.

10 13. The method of Claim 12, wherein said first metallic layer comprises at least one member selected from the group consisting of gold, platinum, palladium and iridium.

14. A method of making an electrode set ribbon, comprising:
ablating through a portion of a first metallic layer with a laser, to
form a plurality of electrode patterns;
15 wherein said first metallic layer is on an insulating substrate, and
said electrode set ribbon comprises a plurality of electrode sets.

15. The method of Claim 14, wherein said first metallic layer
comprises at least one member selected from the group consisting of gold,
platinum, palladium and iridium,
20 said insulating substrate is a polymer, and
said first metallic layer is in contact with said insulating
substrate.

16. A method of making a sensor strip, comprising:
forming an electrode set by the method of Claim 4; and
25 cutting said substrate, to form a strip.

17. The method of Claim 16, further comprising applying a dielectric
on a portion of said metallic layer.

18. The method of Claim 17, further comprising applying a reagent on a portion of said electrode set.

19. A method of making a sensor strip, comprising:
forming an electrode set ribbon by the method of Claim 14; and
cutting said ribbon into a plurality of strips;
wherein each of said strips comprises at least one of said
electrode sets.

20. The method of Claim 19, further comprising applying a dielectric on a portion of said metallic layer.

21. The method of Claim 20, further comprising applying a reagent on a portion of each of said electrode sets.

22. A patterned laminate, prepared by the method of Claim 1.

23. An electrode set, prepared by the method of Claim 4.

24. An electrode set, prepared by the method of Claim 7.

25. An electrode set, prepared by the method of Claim 13.

26. An electrode set ribbon, prepared by the method of Claim 14.

27. A sensor strip, prepared by the method of Claim 19.

28. A sensor strip, prepared by the method of Claim 21.

29. An electrode set, comprising:
a first metallic layer, on an insulating substrate, comprising a
plurality of electrodes,
wherein said first metallic layer has a feature size of less than
75 μm .

30. The electrode set of Claim 29, wherein said first metallic layer comprises at least one member selected from the group consisting of gold, platinum, palladium and iridium.

5 31. The electrode set of Claim 30, wherein said insulating substrate is a polymer.

32. The electrode set of Claim 31, wherein said first metallic layer is in contact with said insulating substrate.

10 33. A sensor strip, comprising:
the electrode set of Claim 32,
and a dielectric on a portion of said first metallic layer.

34. The sensor strip of Claim 33, further comprising reagent, on a portion of said first metallic layer.

15 35. Packaged sensor strips, comprising:
a plurality of the sensor strips of Claim 27, a vial, containing said plurality of said sensor strips, and
a stopper, sealing said vial.

20 36. Packaged sensor strips, comprising:
a plurality of the sensor strips of Claim 28, a vial, containing said plurality of said sensor strips, and
a stopper, sealing said vial.

25 37. Packaged sensor strips, comprising:
a plurality of the sensor strips of Claim 34, a vial, containing said plurality of said sensor strips, and
a stopper, sealing said vial.

38. A patterned laminate, comprising:
a patterned metallic layer on, and in contact with, an insulating substrate,

wherein said metallic layer comprises at least one member
selected from the group consisting of gold, platinum, palladium and
iridium,

said insulating substrate comprises a polymer, and

5

said patterned metallic layer has a feature size of less than

75 μm .

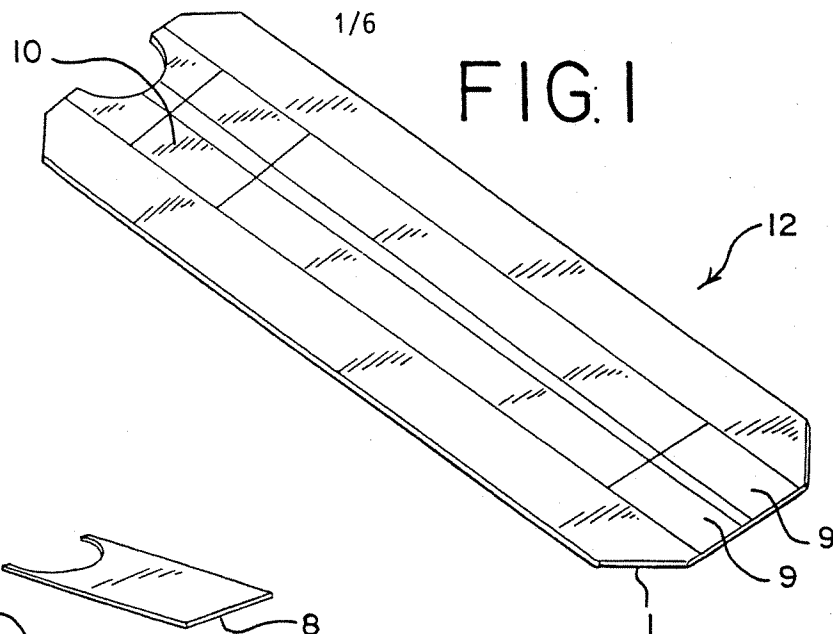


FIG. 1

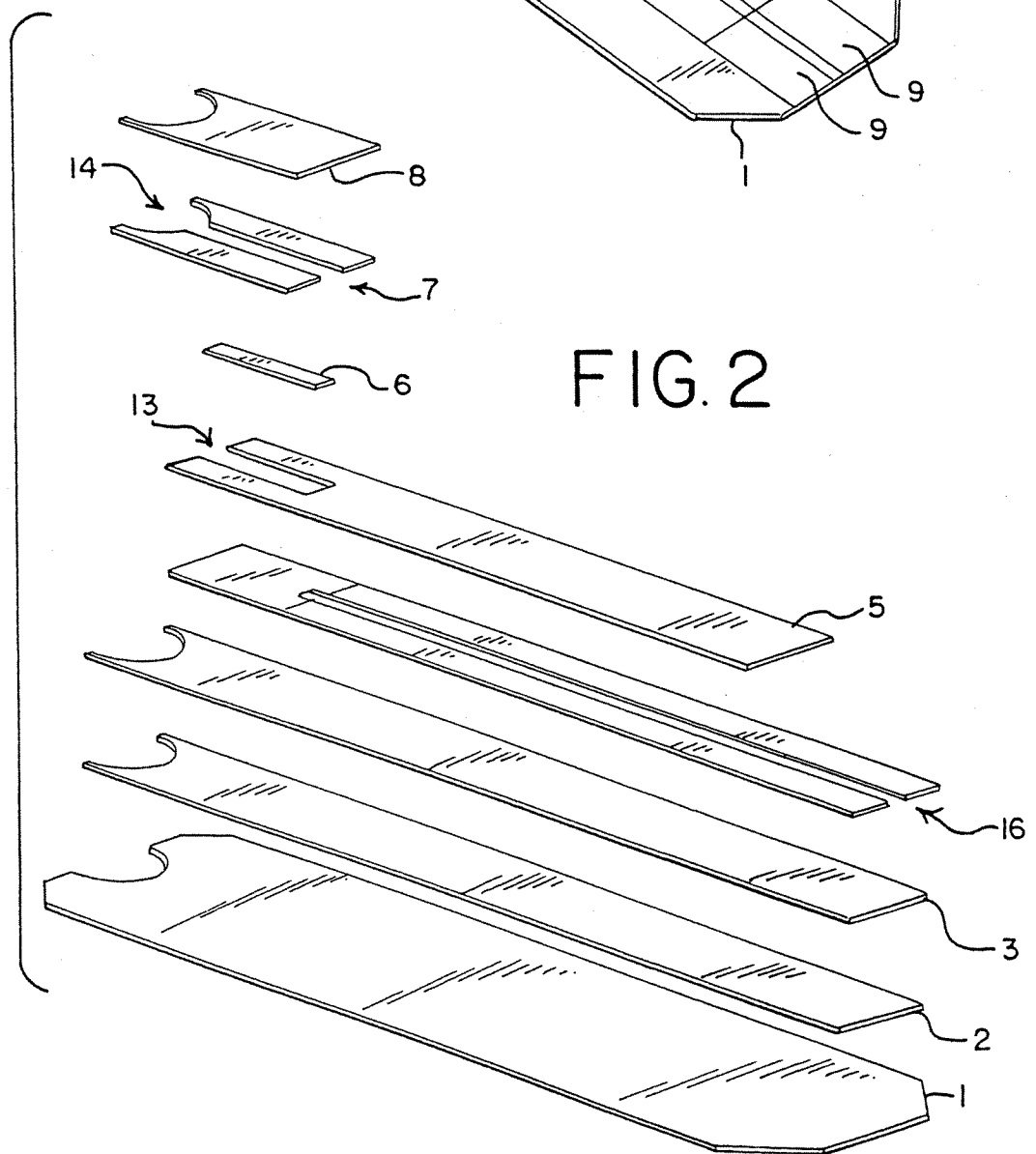
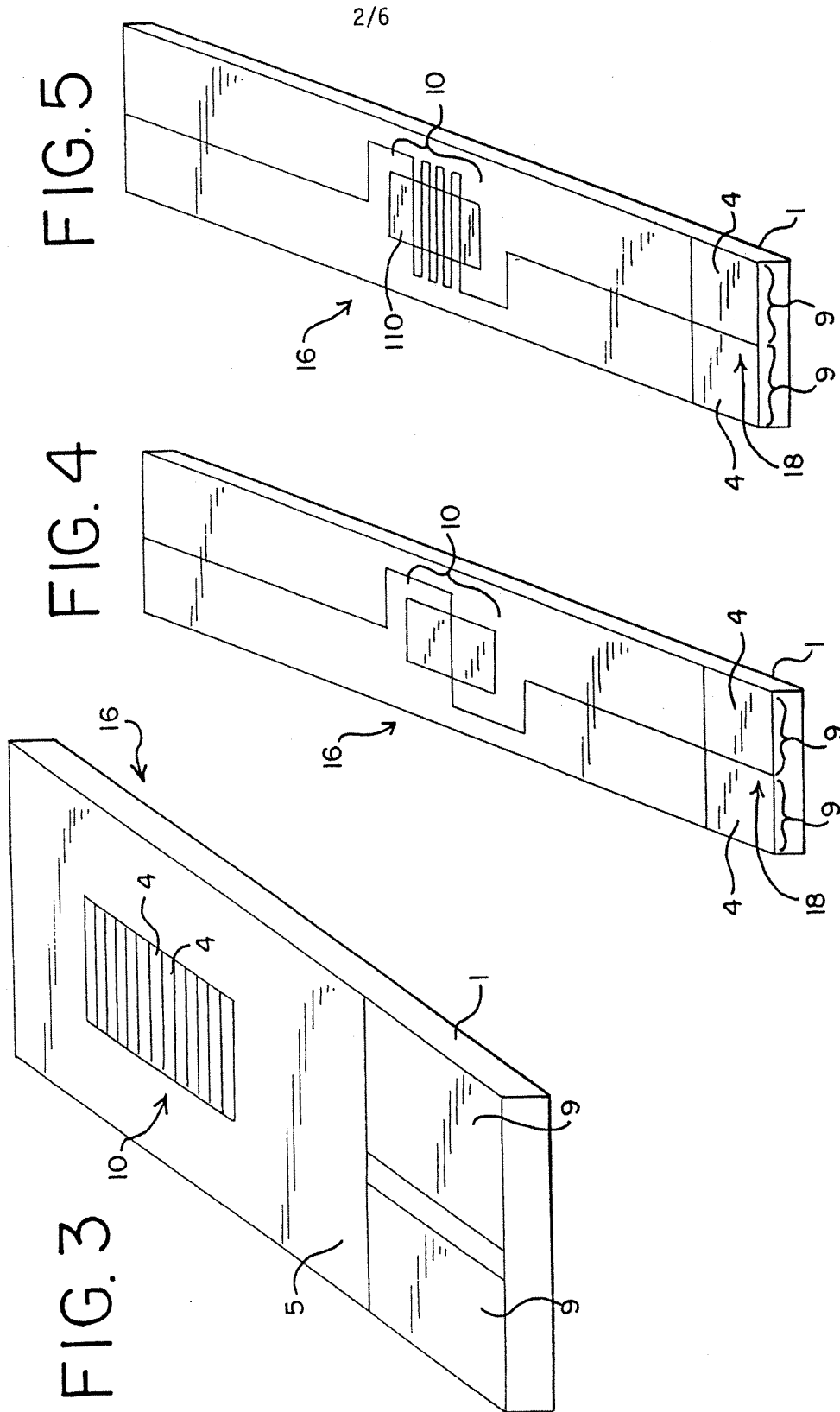
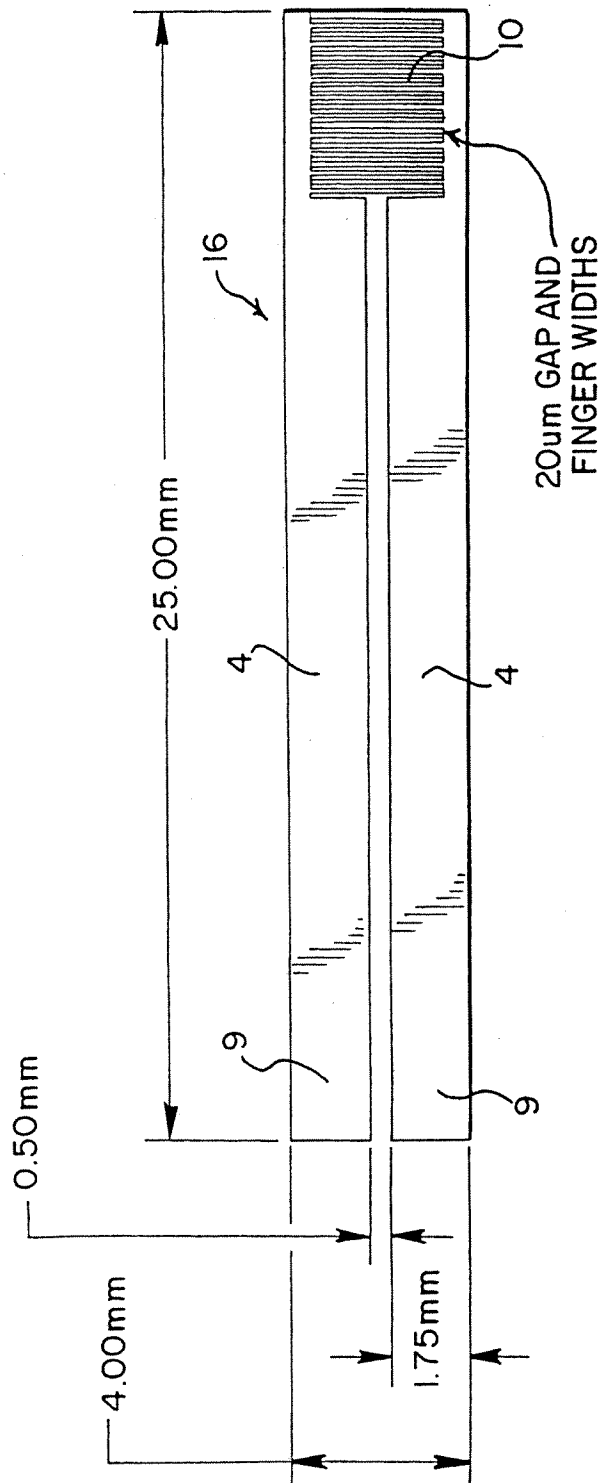


FIG. 2



3/6

FIG. 6



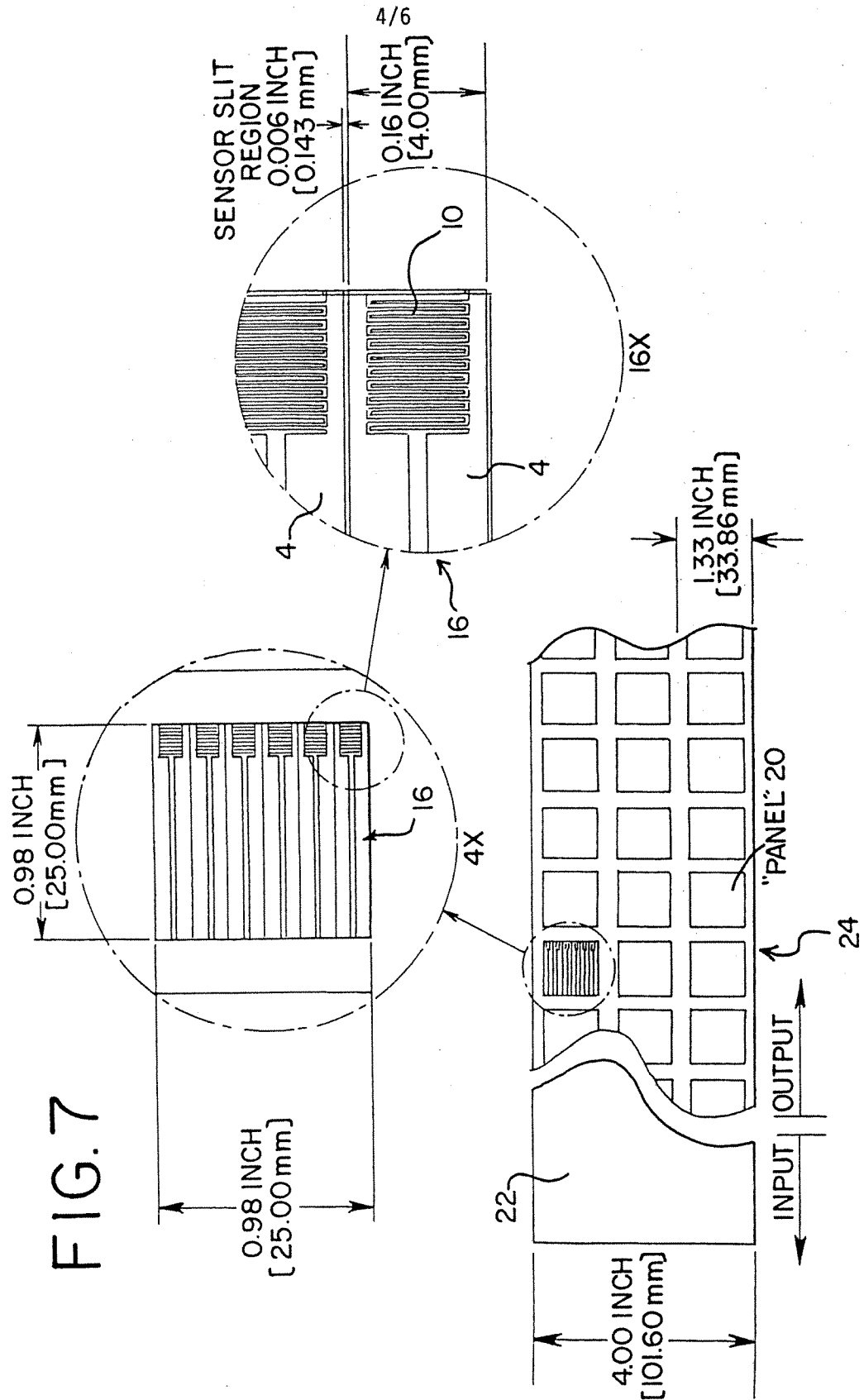
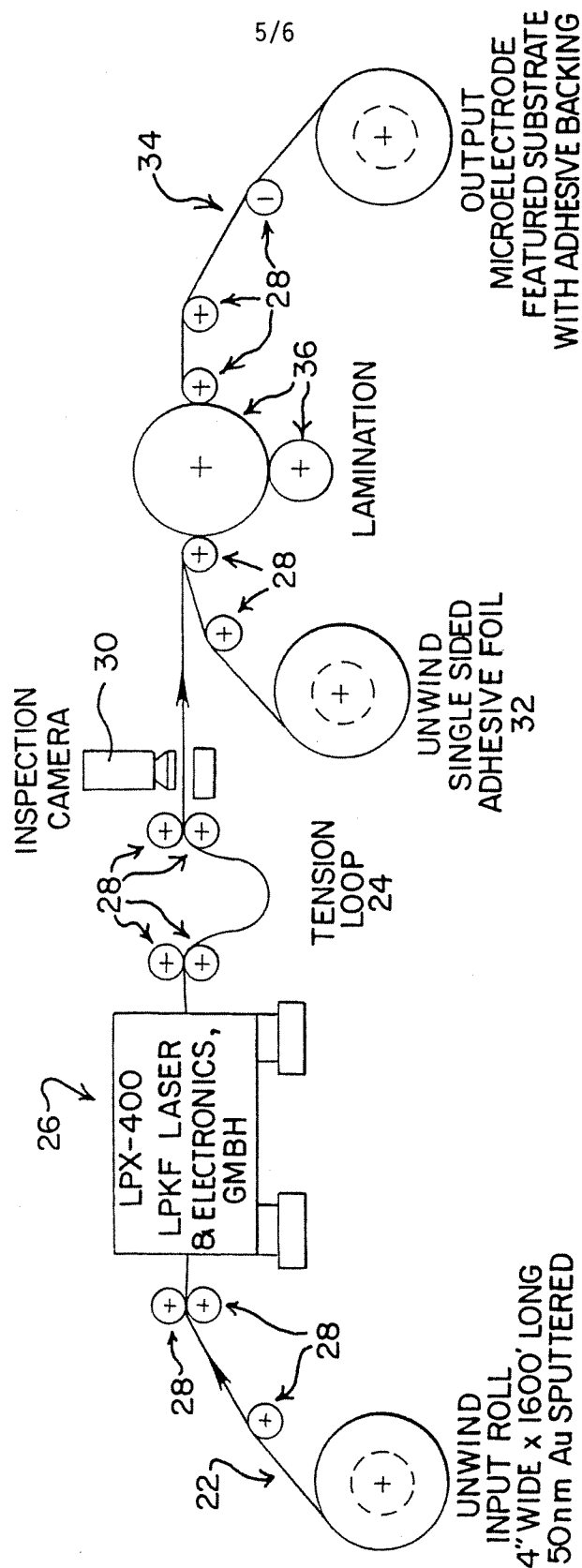
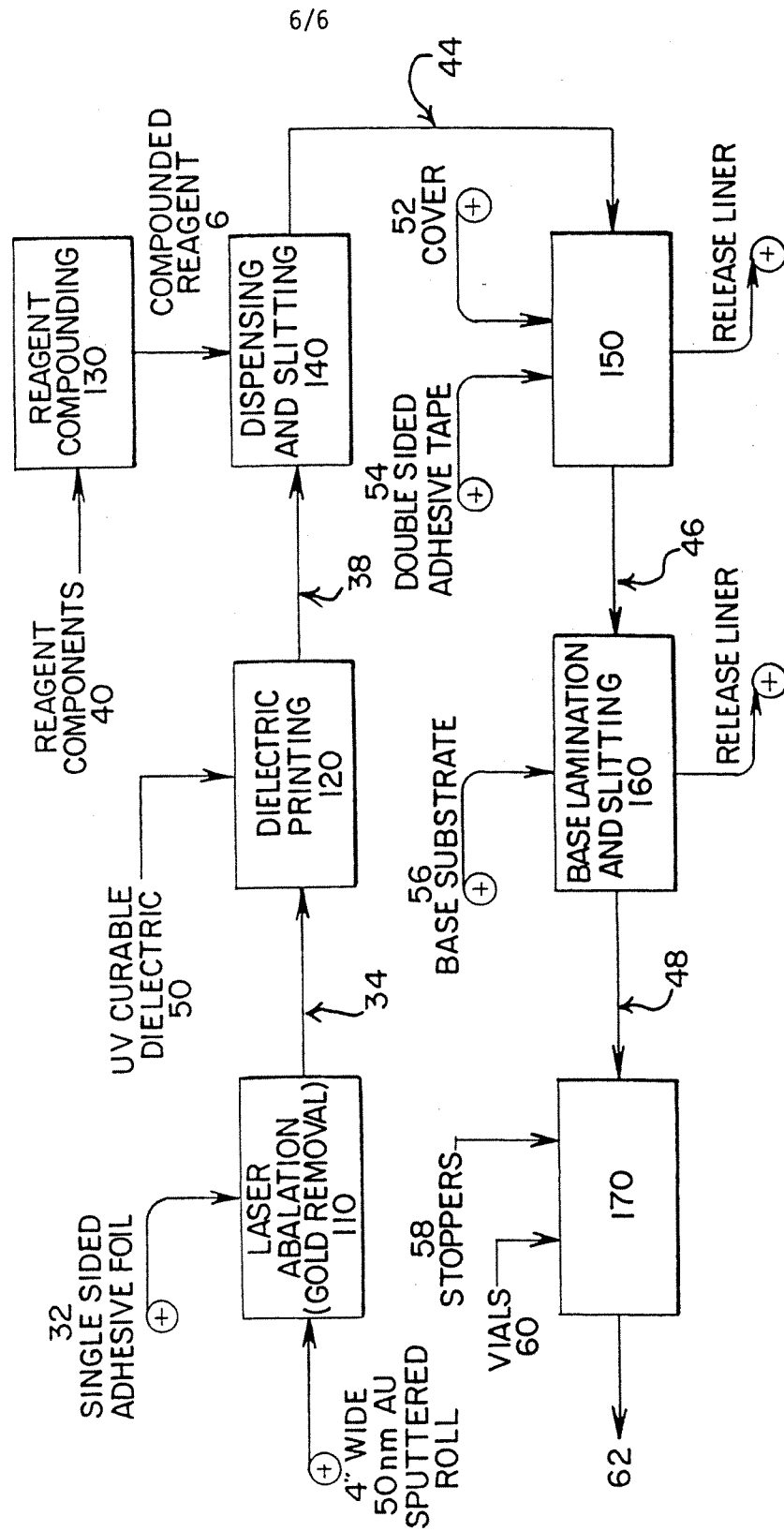


FIG. 8



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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01N27/30 G01N33/487

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N

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Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 480 703 A (GEN ELECTRIC) 15 April 1992 (1992-04-15)	1-3, 22
Y	column 5, line 28 - column 9, line 32	4-21, 23-25, 29-34, 38
Y	WO 97 22875 A (ECOLE POLYTECH ; BEATTIE PAUL DANIEL (CA); BREVET PIERRE FRANCOIS () 26 June 1997 (1997-06-26) page 3, line 23 - line 31 page 5, line 14 - line 18 page 6, line 12 - page 7, line 31 page 9, line 8 - line 30 page 10, line 18 - page 13, line 21	4-15, 23-25, 29-34, 38
Y	US 5 437 999 A (DIEBOLD ERIC R ET AL) 1 August 1995 (1995-08-01) column 3, line 17 - column 10, line 18	16-21
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☒ Further documents are listed in the continuation of box C.

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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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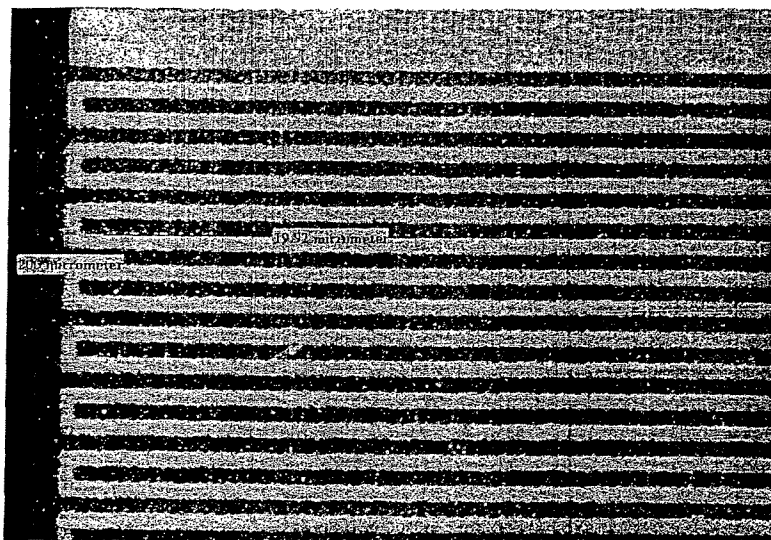
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(54) Title: BIOSENSOR AND METHOD OF MAKING CROSS-REFERENCE TO RELATED APPLICATIONS



(57) Abstract: An electrochemical biosensor with electrode elements that possess smooth, highquality edges. These smooth edges define gaps between electrodes, electrode traces and contact pads. Due to the remarkable edge smoothness achieved with the present invention, the gaps can be quite small, which provides marked advantages in terms of test accuracy, speed and the number of different functionalities that can be packed into a single biosensor. Further, the present invention provides a novel biosensor production method in which entire electrode patterns for the inventive biosensors can be formed all at one, in nanoseconds -- without regard to the complexity of the electrode patterns or the amount of conductive material that must be ablated to form them.

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BIOSENSOR AND METHOD OF MAKING
CROSS-REFERENCE TO RELATED APPLICATIONS

5

The present application is a Continuation in Part of U.S. Patent Application Serial No. 09/840,843, filed April 24, 2001; a Continuation in Part of U.S. Application Serial No. 10/264,891, filed October 4, 2002; a Continuation-in-Part of U.S. Application Serial No. 10/601,144, filed June 20, 2003; and claims priority to U.S. Patent Application Serial No. 60/480,397, filed June 20, 2003, each of which is hereby incorporated by reference in its entirety.

10

FIELD OF THE INVENTION

The present invention relates to a method of making a biosensor, more specifically a biosensor having electrode sets formed by laser ablation.

15

BACKGROUND

Electrochemical biosensors are well known and have been used to determine the concentration of various analytes from biological samples, particularly from blood. Examples of such electrochemical biosensors are described in U.S. Patent Nos.: 5,413,690; 5,762,770 and 5,798,031; and 6,129,823 each of which is hereby incorporated by reference.

20

It is desirable for electrochemical biosensors to be able to analyze analytes using as small a sample as possible, and it is therefore necessary to minimize the size of their parts, including the electrodes, as much as possible. As discussed below, screen-printing, laser scribing, and photolithography techniques have been used to form miniaturized electrodes.

25

Electrodes formed by screen-printing techniques are formed from compositions that are both electrically conductive and screen-printable. Furthermore, screen printing is a wet chemical technique that generally allows reliable formation of structures and patterns having a gap width or feature size of approximately 75 μm or greater. Such techniques are well known to those of ordinary skill in the art.

Laser scribing is a technique that usually uses a high power excimer laser, such as a krypton-fluoride excimer laser with an illumination wavelength of 248 nm, to etch or scribe individual lines in the conductive surface material and to provide insulating gaps between residual conductive material which forms electrodes and other desired components. This scribing is accomplished by moving the laser beam across the surface to be ablated. The scribing beam generally has a relatively small, focused size and shape, which is smaller than the features desired for the product, and the formation of the product therefore requires rastering techniques. Such a technique can be rather time consuming if a complex electrode pattern is to be formed on the surface. Further, the precision of the resulting edge is rather limited. This scribing technique has been used to ablate metals, polymers, and biological material. Such systems are well known to those of ordinary skill in the art, and are described in U.S. Patent Nos. 5,287,451, 6,004,441, 6,258,229, 6,309,526, WO 00/73785, WO 00/73788, WO 01/36953, WO 01/75438, and EP 1 152 239 each of which is hereby incorporated by reference. It would be desirable to have a new method of forming electrodes which allows precise electrode edges, a variety of feature sizes, and which can be formed in a high speed / throughput fashion without the use of rastering.

SUMMARY OF THE INVENTION

The present invention provides an electrochemical biosensor with electrode elements that possess smooth, high-quality edges. These smooth edges define gaps
5 between electrodes, electrode traces and contact pads. Due to the remarkable edge smoothness achieved with the present invention, the gaps can be quite small, the advantages of which are described below. Further, the present invention provides a novel biosensor production method in which entire electrode patterns for the inventive biosensors can be formed all at one, in nanoseconds -- irrespective of the
10 complexity of the electrode patterns or the amount of conductive material that must be ablated to form them.

In one form thereof, the present invention provides a biosensor comprising a base substrate having first and second electrode elements formed thereon. The first and
15 second electrode elements have first and second respective edges defining a gap therebetween. The gap has a width and a length. The first edge is spaced by a first distance from a first "theoretical line" that corresponds to the desired or ideal shape and location of the first edge. This first distance varies along the length of the gap because the edge actually produced is not as smooth or perfect as the desired
20 theoretical line. The standard deviation of the first distance is less than about $6\mu\text{m}$ over the entire length of the gap. The biosensor also includes a reagent at least partially covering the base substrate and one or more layers overlying and adhered to the base substrate. The one or more layers cooperate to form a sample-receiving chamber and a cover for the biosensor, and at least a portion of both the reagent
25 and an electrode are positioned in the chamber.

In a related form of the inventive biosensor described above, the *actual* or *real* deviation of the edge from the theoretical line is no more than about $6\mu\text{m}$ along the entire length of the gap. Stated another way, the distance between the edge
30 actually produced and the theoretical line (if the edge were perfect) is less than $6\mu\text{m}$ no matter where along the gap the distance is measured. More preferably, the real deviation is less than about $4\mu\text{m}$, most preferably less than about $2\mu\text{m}$. In this

most preferred form, it is possible to space the electrodes as close as about 5 μm without having the electrical components touch and thus short. Similarly, the width of the electrical feature such as electrodes can be as small as about 10 μm . As discussed in detail below, the close spacing of electrode components allowed
5 by the present invention in turn allows a greater number of electrode elements and thus greater functionality in a smaller area.

The smoothness or quality of the edges is most important in areas of the biosensor where adjacent edges are positioned close to one another, e.g., the gap between two
10 electrodes. In a preferred aspect of the present invention, like the first edge discussed above, the second edge is spaced from a second theoretical line by a second distance that varies along the length of the gap. The first and the second theoretical lines thus define a "theoretical gap" therebetween. If the production process were perfect, and if the edges were intended to be straight and parallel to
15 one another, the theoretical gap width would be constant along its length. In practice, however, the actual gap width varies from the theoretical one along the length of the gap. Deviations from theoretical of the first and second edges can be compounded to produce larger variations in the actual gap width than are produced in either edge alone. In a preferred form of the invention, the standard deviation of
20 the second distance is less than about 6 μm over the entire length of the gap. More preferably, the standard deviation of both the first and second distances is less than about 2 μm , even more preferably, less than about 1 μm .

In another preferred form of the invention, the method comprises removing at least
25 10% of the conductive material, more preferably at least 50% of the conductive material, and most preferably at least 90% of the conductive material. The conductive material is preferably removed by broad field laser ablation, which allows relatively large percentages of the conductive layer to be removed from the base substrate very quickly to form electrode patterns. For example, in preferred
30 forms, the entire electrode pattern for a biosensor is formed by broad field laser ablation in less than about 0.25 seconds, more preferably in less than about 50 nanoseconds, and most preferably in less than about 25 nanoseconds.

As noted above, the inventive method also allows for the placement of two or more electrode sets having different feature sizes in the same biosensor. Furthermore, as noted above, the feature sizes can be quite small and spaced close together.

5 In another form, the present invention provides an efficient and fast method for mass producing biosensors having electrode patterns with the highly desirable smooth edges discussed above. In this method, a web of base substrate material having a metal conductive layer formed thereon is provided. An image of an electrode pattern is projected onto the metal conductive layer with a laser apparatus
10 such that an electrode pattern that corresponds to the image is formed by laser ablation on the web of base substrate material. Either the laser apparatus or the web of base substrate material (or both) is moved and this process is repeated to produce many electrode patterns at spaced intervals along the web of base substrate material. A reagent is deposited on the web of base substrate material
15 and at least partially covers each electrode pattern of the plurality of electrode patterns. At least one web of a covering layer or a spacing layer is laminated over the web of base substrate material, thereby forming a cover and a sample-receiving cavity for each biosensor. The resulting laminated web of layers is then cut into individual biosensors.

20 In a preferred form, the image projected by the laser apparatus is of the complete electrode pattern for one of the biosensors, such that the complete electrode pattern for each biosensor is formed in a single step with a single laser image. In another preferred form, more than one entire electrode pattern is formed all at once; i.e.,
25 the image includes patterns for two or more biosensors.

In another preferred form, the electrode pattern includes at least two electrode sets having different feature sizes. Examples of this may include one set of electrodes for measuring analyte concentration and another set for detecting whether and
30 when the biosensor has received an adequate dose of sample fluid. The inventive biosensor may also include electrode elements providing other features, such as

biosensor identification, calibration or other information associated with the biosensor.

One advantage of this inventive mass production process is that it is much faster
5 than prior art processes that require forming electrode patterns by screen printing, lithography, rastering and the like. With the laser ablation process employed by the present invention, the entire electrode pattern for a biosensor can be formed all at once, in a single step, in only nanoseconds. This allows a continuous web of material from which the individual biosensors will ultimately be cut to be
10 processed at speeds of 60 meters per minute or greater.

Not only is the inventive process much faster than prior art processes, it provides biosensors with electrode patterns whose edges have much better edge quality than prior art biosensors. Edge quality becomes increasingly important as electrode
15 spacing becomes closer. Close electrode spacing is desirable because it generally increases the accuracy of the test result, reduces sample size, and yields a quicker test. Additionally, it allows a greater quantity of electrode elements and associated functionalities to be packed into a single biosensor.

20 Yet another advantage of the inventive production method is that it allows a large percentage of the electrically conductive layer to be removed from the base substrate all at once. By contrast, prior art rastering processes use a collimated laser beam that slowly scribes and removes only a thin line of conductive material, which is a much longer and less versatile process in comparison with the present
25 invention.

Another advantage related to the one just noted is that the manufacturing process of the present invention provides great freedom in the shape and variation in the electrode pattern produced in the inventive biosensors. Asymmetric or anisotropic
30 electrode patterns do not present a problem with the manufacturing process of the present invention. Further, since the electrode pattern is preferably projected on the base substrate by a laser image formed by a mask, limitations as to size, shape,

number of electrode patterns, gap width, etc. that are encountered with prior art processes are reduced. By comparison, rastering processes are typically limited to movement of a focused laser beam along axes that are oriented 90 degrees relative to one another. The resulting patterns typically are limited to thin lines of the same width oriented parallel or perpendicular to one another. In addition, separate but adjacent conductive metal planes used to carry separate signals in a device can capacitively couple when the separation distance between the planes becomes very small resulting in signal degradation and interference between the planes. A method that allows removal of more conductive material between isolated traces therefore can be advantageous in minimizing such interference.

The following definitions are used throughout the specification and claims:

As used herein, the phrase "electrically conductive material" refers to a layer made of a material that is a conductor of electricity, non-limiting examples of which include a pure metal or alloys.

As used herein, the phrase "electrically insulative material" refers to a material that is a nonconductor of electricity.

As used herein, the term "electrode" means a conductor that collects or emits electric charge and controls the movement of electrons. An electrode may include one or more elements attached to a common electrical trace and/or contact pad.

As used herein, the term "electrical component" means a constituent part of the biosensor that has electrical functionality.

As used herein, the phrase "electrode system" refers to an electrical component including at least one electrode, electrical traces and contacts that connect the element with a measuring instrument.

As used herein, the term “electrode element” refers to a constituent part of an electrode system. Specific non-limiting examples of electrode elements include electrodes, contact pads and electrode traces.

- 5 As used herein, the phrase “electrode set” is a grouping of at least two electrodes that cooperate with one another to measure the biosensor response.

As used herein, the term “pattern” means a design of one or more intentionally formed gaps, a non-limiting example of which is a single linear gap having a
10 constant width. Not included in the term “pattern” are natural, unintentional defects.

As used herein, the phrase “insulative pattern” means a design of one or more intentionally formed gaps positioned within or between electrically insulative
15 material(s). It is appreciated that electrically conductive material may form the one or more gaps.

As used herein, the phrase “conductive pattern” means a design of one or more intentionally formed gaps positioned within or between electrically conductive
20 material(s). It is appreciated that exposed electrically insulative material may form the one or more gaps.

As used herein, the phrase “microelectrode array” means a group of microelectrodes having a predominantly spherical diffusional characteristic.
25

As used herein, the phrase “macroelectrode array” means a group of macroelectrodes having a predominantly radial diffusional characteristic.

As used herein, the phrase “electrode pattern” means the relative configuration of
30 the intentionally formed gaps situated between the elements of electrodes in an electrode set specifically or biosensor generally. Non-limiting examples of

“electrode patterns” include any configuration of microelectrode arrays, macroelectrode arrays or combinations thereof that are used to measure biosensor response. “Electrode pattern” may also refer to the shape and configuration of all electrical components that are formed on the biosensor.

5

As used herein, the phrase “feature size” is the smallest dimension of gaps or spaces found in a pattern. For example, in an insulative pattern, the feature size is the smallest dimension of electrically conductive gaps found within or between the electrically insulative material(s). When, however, the pattern is a conductive

10 pattern, the feature size is the smallest dimension of electrically insulative gaps found within or between the electrically conductive material(s). Therefore, in a conductive pattern the feature size represents the shortest distance between the corresponding edges of adjacent elements.

15 As used herein, the term “interlaced” means an electrode pattern wherein the elements of the electrodes are interwoven relative to one another. In a particular embodiment, interlaced electrode patterns include electrodes having elements, which are interdigitated with one another. In the simplest form, interlaced elements include a first electrode having a pair of elements and a second electrode

20 having a single element received within the pair of elements of the first electrode.

As used herein, the term “ablating” means the removing of material. The term “ablating” is not intended to encompass and is distinguished from loosening, weakening or partially removing the material.

25

As used herein, the phrase “broad field laser ablation” means the removal of material from a substrate using a laser having a laser beam with a dimension that is greater than the feature size of the formed pattern. Broad field ablation includes the use of a mask, pattern or other device intermediate a laser source and a

30 substrate. The laser is projected through the mask, the latter of which forms an image of an electrode pattern which is projected onto and impinges on the substrate to create all or part of the electrode patterns on the substrate. Broad field laser

ablation simultaneously creates the pattern over a significant area of the substrate. The use of broad field laser ablation avoids the need for rastering or other similar techniques that scribe or otherwise define the pattern by continuous movement of a relatively focused laser beam relative to the substrate. A non-limiting example of a process for broad field laser ablation is described below with reference to biosensor 210.

As used herein, the term "line" means a geometric figure formed by a point moving in a first direction along a pre-determined linear or curved path and in a reverse direction along the same path. In the present context, an electrode pattern includes various elements having edges that are defined by lines forming the perimeters of the conductive material. Such lines demarcating the edges have desired shapes, and it is a feature of the present invention that the smoothness of these edges is very high compared to the desired shape.

"Theoretical line" as used herein refers to the desired or ideal shape and location of an edge of an electrode element that would be obtained if the manufacturing process were perfect. In most cases, if the edge is straight, the theoretical line will coincide with the average location of the edge.

As used herein, the term "point" means a dimensionless geometric object having no properties except location.

The smoothness or quality of the edge of an electrode element can be defined by the distance that the placement of the edge differs from the theoretical line that represents the perfect or ideal edge. That is, the edge will be spaced from the theoretical line by a distance that varies along the length of the edge. This distance will range from zero to a maximum value. One useful way to define the quality or smoothness of an edge is to simply specify the maximum distance that the edge is spaced from the theoretical line over a specified length of the edge.

The smoothness or quality of an edge can also be specified in terms of the “standard deviation” of the distance between the edge and the theoretical line over a specified length of the edge. To calculate the standard deviation, the distance must be measured at discrete intervals along the length, as described in further detail herein. If the varying distance is denoted “d” and the number of data points is denoted n, then the standard deviation of the distance is calculated as $\{\sum(d_i)^2/(n-1)\}^{1/2}$. So that the equation just noted accurately approximates the integral equation from which it is derived, the intervals at which data points are taken should be spaced closely together. All standard deviations expressed herein are measured by taking data points that are spaced by no more than about 20 μ m, preferably closer.

As used herein, the term “smoothness standard deviation,” when referring to an edge of an electrode element, refers to the standard deviation of the distance that the edge is spaced from a theoretical line over a specified length of the edge. The quality of a gap between electrode elements can be expressed in terms of the individual deviations or standard deviations of the two edges forming the gap from the theoretical lines corresponding to the two edges.

As used herein, the phrase “biological fluid” includes any bodily fluid in which the analyte can be measured, for example, interstitial fluid, dermal fluid, sweat, tears, urine, amniotic fluid, spinal fluid and blood.

As used herein, the term “blood” includes whole blood and its cell-free components, namely plasma and serum.

As used herein, the term “working electrode” is an electrode at which analyte, or product, is electrooxidized or electroreduced with or without the agency of a redox mediator.

As used herein, the term "counter electrode" refers to an electrode that is paired with the working electrode and through which passes an electrochemical current equal in magnitude and opposite in sign to the current passed through the working electrode. The term "counter electrode" is meant to include counter electrodes, which also function as reference electrodes (i.e., a counter/reference or auxiliary electrode).

As used herein, the term "electrochemical biosensor" means a device configured to detect the presence and/or measure the concentration of an analyte by way of electrochemical oxidation and reduction reactions within the biosensor. These reactions are transduced to an electrical signal that can be correlated to an amount or concentration of the analyte.

Additional features of the invention will become apparent to those skilled in the art upon consideration of the following detailed description of the preferred embodiment exemplifying the best mode known for carrying out the invention. It should be understood, however, that the detailed description and the specific examples, while indicating embodiments of the invention, are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

5 The following drawings form part of the present specification and are included to further demonstrate certain aspects of the present invention. The invention may be better understood by reference to one or more of these drawings in combination with the detailed description of specific embodiments presented herein:

10 Figure 1 is a perspective view of a biosensor of the present invention;

Figure 2 is an exploded assembly view of the biosensor of Figure 1;

Figure 3 is an enlarged plan view of the biosensor of Figure 1 showing a macroelectrode array and a microelectrode array;

15

Figure 4 is a diagram of the deviation of an edge of an electrode element from a theoretical or ideal line representing the desired shape and placement of the edge;

20 Figure 5 is a diagram of the deviation in gap width and placement resulting from the deviations in the two individual edges forming the gap;

Figure 6 is an enlarged section of the microelectrode array of Figure 3;

25 Figure 7 is a diagram of the deviation of an edge of an electrode element from a theoretical or ideal line representing the desired shape and placement of the edge;

Figure 8 illustrates a cross-section taken along lines 8-8 of Figure 1;

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Figure 9 illustrates a cross-section taken along lines 9-9 of Figure 1;

Figure 10 is a graph showing the deviation from mean or theoretical of an electrode edge of the microelectrode array of Figure 3;

Figure 11 is an exploded assembly view of a biosensor in accordance with another embodiment of the invention;

- 5 Figure 12 is an exploded assembly view of a biosensor in accordance with another embodiment of the invention;

Figure 13 is an exploded assembly view of a biosensor in accordance with another embodiment of the invention;

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Figure 14 is an exploded assembly view of a biosensor in accordance with another embodiment of the invention;

- 15 Figure 15 is an exploded assembly view of a biosensor in accordance with another embodiment of the invention;

Figure 16 is an enlarged perspective view of a biosensor in accordance with another embodiment of the invention;

- 20 Figure 17 is a view of an ablation apparatus suitable for use with the present invention;

Figure 18 is a view of the laser ablation apparatus of Figure 17 showing a second mask;

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Figure 19 is a view of an ablation apparatus suitable for use with the present invention;

Figure 20 is a schematic of an electrode set ribbon of the present invention;

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Figure 21 is a photograph illustrating a biosensor substrate initially coated with a gold conductive layer from which approximately 10% of the conductive material has been removed;

- 5 Figure 22 is a photograph illustrating a biosensor substrate having an electrical pattern with a gap width of approximately 20 μ m and where approximately 20% of the conductive material initially covering the substrate has been removed to form the electrical pattern;
- 10 Figure 23 is a photograph illustrating a biosensor substrate having an electrical pattern with a gap width of approximately 20 μ m and where approximately 50% of a conductive material initially covering the substrate has been removed to form the electrical pattern; and
- 15 Figure 24 is a photograph illustrating a biosensor substrate having an electrical pattern with a gap width of approximately 250 μ m and where approximately 90% of the conductive material initially covering the substrate has been removed to form the electrical pattern.

DETAILED DESCRIPTION OF THE INVENTION

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings, and
5 specific language will be used to describe the embodiments. It will nevertheless be understood that no limitation of the scope of the invention is intended. Alterations and modifications in the illustrated devices, and further applications of the principles of the invention as illustrated therein, as would normally occur to one skilled in the art to which the invention relates are contemplated, are desired to be
10 protected.

A biosensor in accordance with the present invention provides a surface with electrode patterns formed thereon, the electrode patterns preferably having a smooth edge quality. It is a particular aspect of the present invention that precise
15 quality is obtained for the edges of the electrical components located on the biosensor. Having a smooth or high edge quality of the elements can contribute to greater precision, accuracy, and reproducibility of test results. Further, a smooth or high edge quality also allows for a great number of electrode arrays to be formed on a defined surface area of the biosensor. By increasing the edge quality of the
20 elements, it is possible to increase the number of electrode elements and thus increase the achievable functionality in the defined surface area. These functions may include, for example: multiple measurement electrode pairs for simultaneous measurement of the same or different analytes, including by alternative means; electrodes used to provide correction factors for the basic measurement electrodes;
25 electrodes for detecting dose application or sample sufficiency; multiple electrode traces to monitor electrode functioning or to provide detection or correction of defective traces; and multiple contact pads for coupling to the foregoing functionalities, or for providing additional features such as identification, calibration, or other information pertaining to the biosensor. Further, the selected
30 functionalities for a given biosensor can be provided in a smaller space when the high edge quality allows closer placement of the electrical components. It is a

feature of the present invention to enable all of this, and more, in a manner that is relatively fast, reliable and cost effective.

Specifically, a biosensor of the present invention has electrical components with edges that are smooth and are precisely located. The precise locating of the smooth edge is important, particularly relative to a corresponding edge of another electrical component, and especially with respect to a paired element. The importance and the degree of quality of a component's edge quality and placement will vary with the nature of the component.

For macroelectrodes, the edge smoothness and placement are important for the quality of the electrochemical results obtained by use of the macroelectrodes. One factor in the accuracy of such a test is the reproducibility of the area of each macroelectrode. Obtaining precise edge smoothness and placement will yield an area which is highly accurate. Another factor in the use of macroelectrodes is the placement of one of the electrodes relative to the other, e.g., the position of the counter element(s) in relationship to the position of the working element(s). Moreover, since biosensors are generally operated based on calibration methods that rely on the reproducibility of the sizes and locations of the measuring electrodes, the ability to consistently produce lots of such tests trips can enhance the results achieved with the tests.

Similarly, the edge smoothness and placement contribute to the results obtained from microelectrodes. For microelectrodes, the issues can be magnified because of the number and relatively close placement of the numerous microelements. Poor edge quality can greatly affect the operating characteristics of microelectrodes, and the present invention helps to overcome this potential problem. Moreover, an advantage of placing microelements in close proximity is the rapid establishment of steady-state operation. High edge quality and precise edge placement enables closer placement of the elements and in turn faster achievement of steady-state operation. In addition, such closer placement allows for a greater number of microelements to be placed in a given space.

In a first aspect, the present invention provides a high quality edge for the various electrical components on a biosensor. The quality of the edge relates to the smoothness or uniformity of the edge relative to a theoretical profile of the edge.

- 5 Non-limiting examples of such "smooth" edges formed in accordance with the present invention are shown in Figs. 21-24.

In one respect, the smoothness relates simply to the deviation of the edge surface relative to the theoretical line defining the desired shape of the edge. It will be appreciated that any electrical component on a biosensor has an intended location and shape that will not be exactly duplicated by the physical embodiment. The extent to which the actual edge of the component varies from the theoretical one is a measure of the smoothness of the edge. As discussed above, this smoothness or quality of the edge can be expressed in terms of the varying distance that the edge is spaced from a theoretical line over a specified length. This distance can be measured at closely spaced intervals, as discussed in detail below, and the standard deviation of the distance can be calculated. Further, the maximum value the distance achieves over a specified length is also a meaningful parameter. For example, in a design where electrodes are to form a gap having a desired width of, e.g., 10 μ m, the manufacturing process must be capable of producing edges that will vary by less (preferably much less) than 5 μ m over the length of the gap. Otherwise, the electrodes may touch and thus short circuit.

As relates to the various electrical components, the extent to which a given portion of the component is "smooth" may vary. Referring in particular to the measuring electrodes, it will be appreciated that certain edges of the elements are more critical than others. For example, certain edges of the counter and working electrodes are adjacent one another and spaced closely together, while others are not. Also, certain edges are located within the sample-receiving chamber, and others are not.

30 In a first aspect, the present invention relates to providing smooth edges for all of the edges of the measuring electrodes. In another aspect, the invention provides smooth edges particularly for the edges of the measuring electrodes located within

the sample-receiving chamber, and more particularly for the edges of the measuring elements that are adjacent to one another. "Adjacent edges" in this context refers to the fact that an edge of a counter element is closest to, i.e., adjacent to, an edge of an element of a working electrode with which the counter
5 electrode is paired.

As indicated previously, the present invention relates in one aspect to providing macroelectrodes having a closely determined area. The desired accuracy of the provided area can vary based on the absolute size of the macroelectrode, as
10 determined by the quality of the edges defining the electrode. Thus, as the smoothness of the edges improves, the difference between the area actually occupied by the electrode and the desired area decreases.

The spacing of macroelectrodes also can benefit from the present invention. For
15 example, for macroelectrodes that are spaced apart by 250 μm , the edges forming the gap preferably have a smoothness standard deviation of less than about 4 μm over the entire length of the edges; for elements spaced apart by 100 μm , the standard deviation is preferably less than about 2 μm .

20 For microelectrodes, the desired smoothness can differ. For example, for microelements that are spaced apart by 50 μm , the adjacent edges have a smoothness standard deviation of less than about 6 μm , preferably less than about 2 μm , and most preferably less than about 1 μm . If the microelements are spaced apart by about 10 μm , then the smoothness standard deviation is preferably less
25 than about 1 μm , more preferably less than about 0.5 μm . In general, the smoothness standard deviation for microelectrodes is preferably less than about 5% of the width of the gap between adjacent microelements (i.e., feature size), more preferably less than about 2% of the feature size.

30 It is also an aspect of the present invention that the other electrical components can be provided with smooth edges to facilitate close placement of such components.

Such other components preferably have a smoothness standard deviation that is less than about 6 μm , and more preferably less than about 2 μm .

5 The present invention also provides for the accurate placement of the electrical components relative to one another and to the overall biosensor. The relative placement of components is achieved, at least in part, by the use of broad field laser ablation that is performed through a mask or other device that has a precise pattern for the electrical components. The relative placement of the components therefore does not depend on the controlled movement of a rastering laser or of the
10 substrate relative to the rastering laser. Moreover, this accurate positioning of adjacent edges is further enhanced by the close tolerances for the smoothness of the edges.

Therefore, in a further aspect the invention provides electrical components that
15 have gaps or features that are precisely controlled. More specifically, the electrical components will have designed, theoretical configurations for the gaps between adjacent edges, whereas the physical embodiments will have variations and irregularities. The present invention provides gaps between adjacent edges that are highly uniform. Specifically, the present invention provides a "uniform gap,"
20 which is defined as a gap for which the smoothness standard deviation for each edge defining the gap is less than about 6 μm . Preferably, the smoothness standard deviation of both edges defining the gap is less than about 2 μm , more preferably less than about 1 μm .

25 It is appreciated that the biosensor of the present invention is suitable for use in a system for assessing an analyte in a sample fluid. In addition to the biosensor, the system includes a meter (not shown) and provides methods for evaluating the sample fluid for the target analyte. The evaluation may range from detecting the presence of the analyte to determining the concentration of the analyte. The
30 analyte and the sample fluid may be any for which the test system is appropriate. For purposes of explanation only, a preferred embodiment is described in which

the analyte is glucose and the sample fluid is blood or interstitial fluid. However, the present invention clearly is not so limited in scope.

Non-limiting examples of meters suitable for use with the biosensor of the present invention for determination of the analyte in the sample fluid are disclosed in U.S. Patent Nos. 4,963,814; 4,999,632; 4,999,582; 5,243,516; 5,352,351; 5,366,609; 5,405,511; and 5,438,271, the disclosures of each being incorporated herein by reference. The suitable meter (not shown) will include a connection with electrodes of the biosensor, and circuitry to evaluate an electrochemical signal corresponding to the concentration of the analyte. The meter may also include electrical components that determine whether the sample fluid has been received by the biosensor and whether the amount of sample fluid is sufficient for testing. The meter typically will store and display the results of the analysis, or may alternatively provide the data to a separate device.

The biosensor of the present invention forming part of the system can provide either a qualitative or quantitative indication for the analyte. In one embodiment, the biosensor cooperates with the meter to indicate simply the presence of the analyte in the sample fluid. The biosensor and meter may also provide a reading of the quantity or concentration of the analyte in the sample fluid. In a preferred embodiment, it is a feature of the present invention that a highly accurate and precise reading of the analyte concentration is obtained.

The biosensor is useful for the determination of a wide variety of analytes. The biosensor, for example, is readily adapted for use with any suitable chemistry that can be used to assess the presence of the analyte. Most preferably, the biosensor is configured and used for the testing of an analyte in a biological fluid. Commensurate modifications to the system will be apparent to those skilled in the art. For purposes of explanation, and in a particularly preferred embodiment, the system is described with respect to the detection of glucose in a biological fluid.

The biosensor is also useful with a wide variety of sample fluids, and is preferably used for the detection of analytes in a biological fluid. In addition, the biosensor is useful in connection with reference fluids that are used in conventional fashion to verify the integrity of the system for testing.

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In a preferred embodiment, the biosensor is employed for the testing of glucose. The sample fluid in this instance may specifically include, for example, fresh capillary blood obtained from the finger tip or approved alternate sites (e.g., forearm, palm, upper arm, calf and thigh), fresh venous blood, and control

10 solutions supplied with or for the system. The fluid may be acquired and delivered to the biosensor in any fashion. For example, a blood sample may be obtained in conventional fashion by incising the skin, such as with a lancet, and then contacting the biosensor with fluid that appears at the skin surface. It is an aspect of the present invention that the biosensor is useful with very small fluid samples.
15 It is therefore a desirable feature that only a slight incising of the skin is necessary to produce the volume of fluid required for the test, and the pain and other concerns with such method can be minimized or eliminated.

Biosensor 210 in accordance with an embodiment of the present invention has two
20 electrode patterns having different feature sizes on a common planar surface and thus permits the accurate measurement of an analyte in a fluid. As shown in Figure 1, biosensor 210 comprises a base or base substrate 212, conductive material 216 positioned on the base 212, a spacer 214, and a cover 218. The cover 218 and spacer 214 cooperate with the base 212 to define a sample-receiving
25 chamber 220 (Figure 9) having a sample inlet opening 221 for the sample fluid, and a reagent 264 for producing an electrochemical signal in the presence of a test analyte. The biosensor 210 is formed as a test strip, particularly one having a laminar construction providing an edge or surface opening to the sample-receiving chamber 220. The reagent 264, as shown in Figures 2 and 9, is exposed by the
30 sample-receiving chamber 220 to provide the electrochemical signal to a working electrode also positioned within the chamber 220. In appropriate circumstances,

such as for glucose detection, the reagent may contain an enzyme and optionally a mediator.

5 The base 212 of biosensor 210 includes edges 222 that define opposite ends 224, 226 and sides 228, 230 extending between the ends 224, 226. Base 212 also has a top surface 232 supporting the conductive material 216 and an opposite bottom surface 234 (Figures 8 and 9). Illustratively, base 212 has a length of 40 mm and a width of 10 mm. It is appreciated, however that these values are merely illustrative and that the dimensions of the base 212 may vary in accordance with the present
10 disclosure.

The base 212 is a substrate that is formed from an insulating material, so that it will not provide an electrical connection between electrodes formed from the conductive material 216. Non-limiting examples of suitable insulating materials
15 include glass, ceramics and polymers. Preferably, the base is a flexible polymer and has a strong absorbance in the UV. Non-limiting examples of suitable materials include polyethylene terephthalate (PET), polyethylene naphthalate (PEN), and polyimide films. The suitable films are commercially available as MELINEX[®], KALADEX[®] and KAPTON[®], respectively from E.I. duPont de
20 Nemours, Wilmington, Delaware, USA ("duPont") and UPILEX[®], a polyimide film from UBE Industries Ltd, Japan. Preferred materials are selected from 10 mil thick MELINEX[®] 329 or KAPTON[®], which are coated with 50 ± 4 nm gold within-lot C.V. of $< 5\%$ by: Techni-Met Advanced Depositions, Inc., Windsor, Connecticut, USA. It is appreciated that the base 212 may be either purchased pre-
25 coated with conductive material 216 or may be coated by sputtering or vapor deposition, in accordance with this disclosure. It is further appreciated that the thickness of the conductive material can vary in accordance with this disclosure.

Spacer 214 is illustratively positioned on the top surface 232 of the base 212
30 adjacent to end 224. Spacer 214 has an upper surface 236 and a lower surface 238 (Figure 9) facing the base 212. Referring now to Figure 2, the spacer 214 has edges 240, 242, 244, 246. Illustratively, spacer 214 has a length of about 6 mm, a

width of about 10 mm and a height of about 4 mil. It is appreciated, however that these values are merely illustrative and that the biosensor may be formed without a spacer and that the dimensions of the spacer 214 may vary in accordance with the present disclosure.

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Spacer 214 is formed from an insulating material, so that it will not provide an electrical connection between electrodes formed from the conductive material 216. Non-limiting examples of suitable insulating materials include glass, ceramics, polymers, photoimageable coverlay materials, and photoresists - non-limiting
10 examples of which are disclosed in U.S. Patent Application Serial No. Serial No. 10/264,891, filed October 4, 2002, the disclosure of which is incorporated herein by reference. Illustratively, spacer 214 is formed of 4 mil MELINEX[®] polyester film, which is preferred for use with whole blood samples. It is appreciated, however, that when the sample is plasma or serum, 1-2 mil film may be preferred
15 for use in accordance with this disclosure. It is appreciated, however that these values are merely illustrative and that the composition and dimension of the spacer 214 may vary in accordance with the desired height of the sample-receiving chamber.

20 A slit or void 248 is formed in the spacer 214 and extends from the edge 240 toward the edge 242. The slit 248 defines at least the length and width of the sample-receiving chamber 220 and is defined by edges 249. Illustratively, the slit 248 has a length of 5 mm, a width of 1 mm, and a height of 0.1 mm, but may have a variety of lengths and widths in accordance with the present disclosure. It is
25 further appreciated that the edges 249 of the slit may also be curved or angular in accordance with this disclosure.

As shown in Figure 1, the cover 218 is positioned on the upper surface 236 of spacer 214. Cover 218 has a first surface 250 and a second surface 252 (Figure 9)
30 facing the base 212. Further, the cover 218 has edges 254, 256, 258, 260. As shown in Figure 1, the cover 218 has a length that is less than the length of the slit 248. Illustratively, cover 218 has a length of about 4 mm, a width of about 10 mm

and a height of about 0.1 mm. It is appreciated, however that these values are merely illustrative and that the biosensor may be formed without a cover and that the dimensions of the cover 218 may vary in accordance with the present disclosure.

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The cover 218 is illustratively formed of a clear material having a hydrophilic adhesive layer in proximity to the spacer. Non-limiting examples of materials suitable for cover 218 include polyethylene, polypropylene, polyvinylchloride, polyimide, glass, or polyester. A preferred material for cover 218 is 100 μ m polyester. A preferred adhesive is ARCare 8586 having a MA-55 hydrophilic coating, commercially available from Adhesives Research Inc., Glen Rock, PA. Further, it is appreciated that the cover may have markings in accordance with this disclosure.

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15 The slit 248 in the spacer 214, together with the cover 218, and the base 212, form the sample-receiving chamber 220 (Figure 9), which acts to expose reagent 264 to a fluid to be tested from a user of biosensor 210. This sample-receiving chamber 220 can act as a capillary channel, drawing the fluid to be tested from the opening 221 onto a sensing region of the conductive material 216 and toward a vent 262. It is appreciated that the biosensor may be formed without a spacer in accordance with this disclosure and that in addition to or instead of the spacer and the cover, a variety of dielectric materials may cover the base 212 exposing only selected portions of the conductive material in accordance with this disclosure. Moreover, it is appreciated that when present, the dimensions of the channel 220 may vary in accordance with this disclosure.

20

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Figure 2 illustrates the conductive material 216 defining electrode systems comprising a first electrode set 266 and a second electrode set 268, and corresponding traces 279, 277 and contact pads 278, 282, respectively. The conductive material 216 may contain pure metals or alloys, or other materials, which are metallic conductors. Preferably, the conductive material is transparent at the wavelength of the laser used to form the electrodes and of a thickness amenable

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to rapid and precise processing. Non-limiting examples include aluminum, carbon, copper, chromium, gold, indium tin oxide (ITO), palladium, platinum, silver, tin oxide/gold, titanium, mixtures thereof, and alloys or metallic compounds of these elements. Preferably, the conductive material includes noble metals or alloys or
5 their oxides. Most preferably, the conductive material includes gold, palladium, aluminum, titanium, platinum, ITO and chromium. The conductive material ranges in thickness from about 10 nm to 80 nm, more preferably, 30 nm to 70 nm. Figures 1-3, 6, and 8-9 illustrate the biosensor 210 with a 50 nm gold film. It is appreciated that the thickness of the conductive material depends upon the
10 transmissive property of the material and other factors relating to use of the biosensor.

Illustratively, the conductive material 216 is ablated into two electrode systems that comprise sets 266, 268. In forming these systems, the conductive material 216
15 is removed from at least about 5% of the surface area of the base 212, more preferably at least about 50% of the surface area of the base 212, and most preferably at least about 90% of the surface area of the base 212. As shown in Figure 2, the only conductive material 216 remaining on the base 212 forms at least a portion of an electrode system.

20 While not illustrated, it is appreciated that the resulting patterned conductive material can be coated or plated with additional metal layers. For example, the conductive material may be copper, which is then ablated with a laser, into an electrode pattern; subsequently, the copper may be plated with a titanium/tungsten
25 layer, and then a gold layer, to form the desired electrodes. Preferably, a single layer of conductive material is used, which lies on the base 212. Although not generally necessary, it is possible to enhance adhesion of the conductive material to the base, as is well known in the art, by using seed or ancillary layers such as chromium nickel or titanium. In preferred embodiments, biosensor 210 has a
30 single layer of gold, palladium, platinum or ITO.

As shown in Figures 2 and 9, the biosensor 210 includes an electrode system comprising at least a working electrode and a counter electrode within the sample-receiving chamber 220. The sample-receiving chamber 220 is configured such that sample fluid entering the chamber is placed in electrolytic contact with both the working electrode and the counter electrode. This allows electrical current to flow between the electrodes to effect the electrooxidation or electroreduction of the analyte or its products.

Referring now to Figure 3, the first electrode set 266 of the electrode system includes two electrodes 270, 272. Illustratively, electrode 270 is a working electrode and electrode 272 is a counter electrode. The electrodes 270, 272 each have a single element or finger 280 that is in communication with a contact pad 278 via a connecting trace 279 (shown in Figure 2). The electrode fingers 280 of the electrodes 270, 272 cooperate to define an electrode pattern formed as a macroelectrode array. It is appreciated, as will be discussed hereafter, that the electrodes 270, 272 can include more than one finger each in accordance with this disclosure. It is further appreciated that the shape, size and relative configuration of the electrodes or electrode fingers may vary in accordance with the present disclosure.

As shown in Figure 2, the second electrode set 268 includes two electrodes 274, 276. Illustratively, electrode 274 is a working electrode and electrode 276 is a counter electrode. Further, the electrodes 274, 276 each have five electrode elements or fingers 284 that are in communication with a contact pad 282 via a connecting trace 277. Referring now to Figure 3, the electrode fingers 284 cooperate to define an electrode pattern formed as an interlaced microelectrode array. While five electrode fingers 284 are illustrated, it is appreciated that the elements of electrodes 274, 276 can each be formed with greater or fewer than five electrode fingers in accordance with this disclosure. It is further appreciated that the shape, size and relative configuration of the electrodes may vary in accordance with the present disclosure.

It is appreciated that the values for the dimensions of the electrode sets 266, 268 as illustrated in Figure 2 are for a single specific embodiment, and these values may be selected as needed for the specific use. For example, the length of the electrode sets may be any length up to the length of the base, depending upon the orientation of the electrode sets on the base. Further, it is appreciated that the width of the conducting traces in communication with the electrode sets may vary, a non-limiting example of which is from about 0.4 mm to about 5 mm. It is further appreciated that the width of each contact pad may vary, a non-limiting example of which is from about 1 mm to about 5 mm. The electrode patterns shown in Figure 2 are symmetric, however this is not required, and irregular or asymmetric patterns (or electrode shapes) are possible in accordance with this disclosure. Further, the number of electrode sets on the base 212 may vary, and therefore each base 212 can contain, for example 1 to 1000 electrode sets, preferably 2 to 20 electrode sets, more preferably 2 to 3 electrode sets.

Referring again to the first electrode set 266 of Figure 3, each electrode finger 280 is defined by an inner edge 281, an outer edge 283, and opposite third and fourth edges 285, 287. Each edge 218, 283, 285, 287 has a smooth edge quality. As discussed earlier, the edge quality of the electrodes 270, 272 is defined by the edge's deviation from a theoretical line extending between first and second points. The following description of deviations can apply to each edge of electrodes 270, 272 of biosensor 210. For clarity purposes, however, only the edge 281 of electrode 270 will be discussed hereafter.

As shown in Figure 3, the edge 281 of electrode 270 extends between points 289, 291 located on the base 212. Points 289, 291 are located at opposite ends of the inner edge 281, which represents the entire length of the gap 286 between electrodes 280. It is appreciated that the points 289, 291 may be positioned at a variety of locations and at a variety of distances relative to one another depending upon the length of the desired edge in accordance with this disclosure. However, the length of interest will typically be the entire length over which a gap extends,

since the smoothness of the adjacent edges is normally most important over this entire length.

Figure 4 illustrates the theoretical line 293 that extends exactly between points 289, 291. That is, line 293 represents the ideal or desired edge that would be obtained if the process of forming the electrodes were perfect. However, at any given point along the length of line 293, the edge 281 will be spaced in either direction from theoretical line 293 by a distance " d_i ." The distance d_i varies from zero to a maximum value depending upon where it happens to be measured, as shown, e.g., with reference to distances d_1 , d_2 , d_3 and d_4 in Figure 4. A standard deviation of this distance over the length of line 293 is less than about 6 μm in accordance with this disclosure, creating an edge with a smooth edge quality. In preferred embodiments, the standard deviation of the edge 281 from theoretical line 293 is less than 2 μm , and most preferably less than 1.0 μm . An example of this deviation from mean or theoretical is illustrated in Figure 10.

The edge quality illustrated in Figure 10 was measured using Micro-Measure system commercially available from LPKF Laser Electronic GmbH, of Garbsen, Germany with Metric 6.21 software. The Metric software allows the display and measuring of video images on a PC. Measurements were made by capturing the image and then allowing the software to place a 10 μm grid over the image. The grid was aligned with the edge by moving the electrode structure under the measurement objective. (By physically manipulating the image, the edge can be vertically aligned to be parallel with the grid.) Using the software, measurements from the grid line to the electrode edge were then made at 10 μm intervals along the length of a line 250 μm long using a point-to-point process. The effective video magnification to video screen was 575X. (Using objective Q750). Video magnification = Actual measured "Scale length" on the video screen (μm) / Scale value (μm). For example, 115000 μm / 200 μm = 575X.

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In one analysis of an electrical pattern formed using the principles of the present invention, the deviation from mean of the edges was measured using a QVH-606

PRO Vision Measuring System (computer-controlled non-contact measurement system), commercially available from Mitutoyo America Corporation, Aurora, IL with an effective magnification to video screen = 470X. Standard deviations were calculated from measurements made at an average interval of $0.69\text{ }\mu\text{m}$ for a length of at least $250\text{ }\mu\text{m}$. Other settings: Ring lighting (Intensity 89, Position 60), Edge Detection (Edge Slope = Falling, Edge Detection TH=169, THS = 18.5, THR =0.5 Scan Interval =1). The standard deviation from the mean value was less than about $2\text{ }\mu\text{m}$.

- 10 Referring again to Figure 4, the line 293 is illustratively a straight line. It is appreciated, however, that the shape of the line 293 may be curved or angular, so long as the standard deviation of the distance of edge 281 from that line 293 over the length of the edge is less than about $6\text{ }\mu\text{m}$.
- 15 The electrode fingers 280, as shown in Figure 3, are separated from one another by an electrode gap 286, which corresponds to the feature size of the electrode pattern of the electrode set 266. The electrode gap 286 shown in Fig. 3 is shown as formed by two straight edges 281. However, as just noted, the placement of edges 281 varies from theoretical value 293 (Fig. 4) by a distance that varies along the
- 20 length of the edge. Illustratively, in biosensor 210, the electrically insulative material of the top surface 232 is exposed between the electrode fingers 280 along a length 290. It is appreciated, however, that rather than top surface 232 being exposed, the base can be coated with materials, or recesses can be formed between the electrodes as disclosed in U.S. Patent Application Serial No. 09/704,145, filed
- 25 on November 1, 2000, now U.S. Patent No. 6,540,890, the disclosure of which is incorporated herein by reference.

As shown in Figures 3 and 5, the inner edges 281 of electrode fingers 280 have an equal length, illustrated by the numeral 290 and are separated from one another by

30 the electrode gap 286, whose length is also represented by length 290. Because the two edges 281 defining gap 286 are not perfect, gap 286 will in fact vary in width and placement over its length, as shown with reference to gaps 292a-292d in

Figure 5. When the deviations of the two edges defining gap 286 are in the same direction, they tend to cancel each other as to width deviation, at least in part, and cause a net shift in placement of the gap, as illustrated with respect to reference numerals 292c and 292d of Fig. 5. A theoretical gap can be defined by two
5 theoretical lines 293 associated with edges 281. The quality of the gap or its deviation from the theoretical gap can be specified in terms of the quality of the two individual edges defining it. Preferably, the smoothness standard deviation of both edges defining gap 286 is less 6 μm , preferably less than 2.0 μm , and most preferably less than 1 μm .

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The electrode fingers 284, which define the elements of electrodes 274, 276 are illustrated in Figures 3 and 6. For clarity purposes, however, only three of these electrode fingers 284 will be discussed hereafter as they are illustrated in Figure 6. Each electrode finger 284 is defined by a first edge 296 and a second edge 297.
15 Further, adjacent fingers 284 have spaced-apart third and fourth edges 298, 299 respectively. These edges 296, 297, 298, 299 of fingers 284 can also have a smooth edge quality. As previously described with reference to electrodes 270, 272, the edge quality of the electrodes 274, 276 is defined by the respective edge's deviation from a line extending between first and second points. The following
20 description of deviations will apply to each edge of electrode fingers 284 of biosensor 210. For clarity purposes, however, only one edge 296 of electrode finger 284 will be discussed hereafter.

The edge 296 of electrode finger 284 extends between first and second points 301, 302 located on the base 212. As shown in Figure 7, a theoretical line 300 extends
25 exactly between points 301, 302, which is typically the length of the gap formed by edge 296 and 297. A standard deviation of the varying distance of edge 296 from line 300 is less than about 6 μm , in accordance with this disclosure, creating an edge with a smooth edge quality. In preferred embodiments, the standard
30 deviation of the edge 296 from theoretical line 300 is less than 2 μm , and most preferably less than 1.0 μm . Illustratively, the line 300 is a straight line. It is appreciated, however, that the shape of the line 300 may be curved or angular. It is

also appreciated that the specific positions of first and second locations 300, 301 on the surface 232 may vary in accordance with the disclosure, although the lengths of most importance are typically the entire length of the gaps between these closely spaced electrode fingers.

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Referring again to Figure 3, the electrode fingers 284 are separated from one another by an electrode gap 288, which corresponds to the feature size of the electrode pattern of the electrode set 268. The electrode gap 288 relates to the width between adjacent edges 296, 297 of fingers 284. Because the two edges
10 defining gap 288 are not perfect, gap 288 will in fact vary in position and placement over its length. Illustratively, in biosensor 210, the electrically insulative material of the base 212 is exposed between the electrode fingers 284 along a length 303. It is appreciated, however, that rather than top surface 232 being exposed, the base can be coated with materials, or recesses can be formed
15 between the electrodes as disclosed in U.S. Patent Application Serial No. 09/704,145, filed on November 1, 2000, now U.S. Patent No. 6,540,890, entitled "Biosensor", the disclosure of which is incorporated herein by reference.

20 The electrode gap 288, which corresponds to the feature size of the electrode pattern of the electrode set 268 is different than the feature size of the electrode pattern of the electrode set 266. Illustratively, the feature size, or gap 288 between the electrode fingers 284 has a width of about 100 μm or less, including about 1 μm to about 100 μm , even more preferably 75 μm or less, including about 17 μm
25 to about 50 μm . It is appreciated that the electrode gap for a microelectrode array can vary. For example, it is understood that the electrode gap can be less than 1 μm in accordance with the present disclosure. The size of the achievable gap is dependent upon the quality of the optics, the wavelength of the laser, and the window size of a mask field.

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As illustrated in Figure 3, the gap 288 has a width along a length 303 of the opposing edges 296, 297 of the electrode fingers 284. Like gap 286, the quality of

gap 286 or its deviation from a theoretical gap can be specified in terms of the quality of the two individual edges defining it. Preferably, the smoothness standard deviation of both edges defining gap 286 is less 6 μm , preferably less than 2.0 μm , and most preferably less than 1 μm .

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Referring now to Figure 9, the electrode fingers 284 are covered with the reagent 264 and may be used to provide electrochemical probes for specific analytes. The starting reagents are the reactants or components of the reagent, and are often compounded together in liquid form before application to the ribbons or reels, or in
10 capillary channels on sheets of electrodes. The liquid may then evaporate, leaving the reagent in solid form. The choice of a specific reagent depends on the specific analyte or analytes to be measured, and is not critical to the present invention. Various reagent compositions are well known to those of ordinary skill in the art. It is also appreciated that the placement choice for the reagent on the base may
15 vary and depends on the intended use of the biosensor. Further, it is appreciated that the techniques for applying the reagent onto the base may vary. For example, it is within the scope of the present disclosure to have the reagent screen-printed onto the fingers.

20 A non-limiting example of a dispensable reagent for measurement of glucose in a human blood sample contains 62.2 mg polyethylene oxide (mean molecular weight of 100-900 kilodaltons), 3.3 mg NATROSOL 250 M, 41.5 mg AVICEL RC-591 F, 89.4 mg monobasic potassium phosphate, 157.9 mg dibasic potassium phosphate, 437.3 mg potassium ferricyanide, 46.0 mg sodium succinate, 148.0 mg trehalose,
25 2.6 mg TRITON X-100 surfactant, and 2,000 to 9,000 units of enzyme activity per gram of reagent. The enzyme is prepared as an enzyme solution from 12.5 mg coenzyme PQQ and 1.21 million units of the apoenzyme of quinoprotein glucose dehydrogenase, forming a solution of quinoprotein glucose dehydrogenase. This reagent is further described in U.S. Patent No. 5,997,817, the disclosure of which is
30 expressly incorporated herein by reference.

A non-limiting example of a dispensable reagent for measurement of hematocrit in a sample contains oxidized and reduced forms of a reversible electroactive compound (potassium hexacyanoferrate (III) ("ferricyanide") and potassium hexacyanoferrate (II) ("ferrocyanide"), respectively), an electrolyte (potassium phosphate buffer), and a microcrystalline material (Avicel RC-591F - a blend of 88% microcrystalline cellulose and 12% sodium carboxymethyl -cellulose, available from FMC Corp.). Concentrations of the components within the reagent before drying are as follows: 400 millimolar (mM) ferricyanide, 55 mM ferrocyanide, 400 mM potassium phosphate, and 2.0% (weight: volume) Avicel. A further description of the reagent for a hematocrit assay is found in U.S. Patent No. 5,385,846, the disclosure of which is expressly incorporated herein by reference.

Non-limiting examples of enzymes and mediators that may be used in measuring particular analytes in biosensors of the present invention are listed below in Table 1.

TABLE 1

Analyte	Enzymes	Mediator (Oxidized Form)	Additional Mediator
Glucose	Glucose Dehydrogenase and Diaphorase	Ferricyanide Osmium complexes, nitrosoaniline complexes	
Glucose	Glucose-Dehydrogenase (Quinoprotein)	Ferricyanide	
Cholesterol	Cholesterol Esterase and Cholesterol Oxidase	Ferricyanide	2,6-Dimethyl-1,4-Benzoquinone 2,5-Dichloro-1,4-Benzoquinone or Phenazine Ethosulfate
HDL Cholesterol	Cholesterol Esterase and Cholesterol Oxidase	Ferricyanide	2,6-Dimethyl-1,4-Benzoquinone 2,5-Dichloro-1,4-Benzoquinone or Phenazine Ethosulfate

Triglycerides	Lipoprotein Lipase, Glycerol Kinase, and Glycerol-3-Phosphate Oxidase	Ferricyanide or Phenazine Ethosulfate	Phenazine Methosulfate
Lactate	Lactate Oxidase	Ferricyanide	2,6-Dichloro-1,4- Benzoquinone
Lactate	Lactate Dehydrogenase and Diaphorase	Ferricyanide Phenazine Ethosulfate, or Phenazine Methosulfate	
Lactate Dehydrogenase	Diaphorase	Ferricyanide	Phenazine Ethosulfate, or Phenazine Methosulfate
Pyruvate	Pyruvate Oxidase	Ferricyanide	
Alcohol	Alcohol Oxidase	Phenylenediamine	
Bilirubin	Bilirubin Oxidase	1-Methoxy- Phenazine Methosulfate	
Uric Acid	Uricase	Ferricyanide	

In some of the examples shown in Table 1, at least one additional enzyme is used as a reaction catalyst. Also, some of the examples shown in Table 1 may utilize an additional mediator, which facilitates electron transfer to the oxidized form of the mediator. The additional mediator may be provided to the reagent in lesser amount than the oxidized form of the mediator. While the above assays are described, it is contemplated that current, charge, impedance, conductance, potential, or other electrochemically indicated property of the sample might be accurately correlated to the concentration of the analyte in the sample with biosensors in accordance with this disclosure.

Another non-limiting example of a suitable dispensable reagent for use with biosensors of the present invention is nitrosoaniline reagent, which includes a PQQ-GDH and para-Nitroso-Aniline mediator. A protocol for the preparation of the nitrosoaniline reagent is the same in all respects as disclosed in U.S. Patent Application Serial No. 10/688,312, entitled "System And Method For Analyte Measurement Using AC Phase Angle Measurement", filed October 17, 2003, the

disclosure of which is incorporated herein by reference. The reagent mass composition - prior to dispensing and drying is as set forth in Table 2.

Table 2

	Component	% w/w	Mass for 1 kg
solid	Polyethylene oxide (300KDa)	0.8054%	8.0539g
solid	NATROSOL [®] 250 M	0.0470%	0.4698g
solid	AVICEL [®] RC-591F	0.5410%	5.4104g
solid	Monobasic potassium phosphate (anhydrous)	1.1437%	11.4371g
solid	Dibasic potassium phosphate (anhydrous)	1.5437%	15.4367g
solid	Sodium Succinate hexahydrate	0.5876%	5.8761g
solid	Potassium Hydroxide	0.3358%	3.3579g
solid	Quinoprotein glucose dehydrogenase (EncC#: 1.1.99.17)	0.1646%	1.6464g
solid	PQQ	0.0042%	0.0423g
solid	Trehalose	1.8875%	18.8746g
solid	Mediator BM 31.1144	0.6636%	6.6363g
solid	TRITON [®] X-100	0.0327%	0.3274 g
solvent	Water	92.2389%	922.3888g

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% Solids	0.1352687
Target pH	6.8
Specific Enzyme Activity Used (U/mg	689 DCIP
Dispense Volume per Biosensor	4.6 mg

A coatable reagent suitable for use with the present disclosure is as follows in Table 3.

Table 3

Component	% w/w	Mass for 1 kg
Keltrol F, xanthan gum	0.2136 %	2.1358 g
Sodium Carboxymethylcellulose (CMC)	0.5613 %	5.6129 g
Polyvinylpyrrolidone, (PVP K25)	1.8952 %	18.9524 g
PROPIOFAN [®] ,	2.8566 %	28.5657 g
GlucDOR	0.3310 %	3.3098 g
PQQ	0.0092 %	0.0922 g
Sipernat 320 DS	2.0039 %	20.0394 g
Na-Succinat x 6H ₂ O	0.4803 %	4.8027 g
Trehalose	0.4808 %	4.8081 g
KH ₂ PO ₄	0.4814 %	4.8136 g
K ₂ HPO ₄	1.1166 %	11.1658 g
Mediator 31.1144	0.6924 %	6.9242 g
Mega 8	0.2806 %	2.8065 g
Geropon T 77	0.0298 %	0.2980 g
KOH	0.1428 %	1.4276 g
Water	88.4245 %	884.2453 g

% Solids	11.5755
Target pH	7.0
Specific Enzyme Activity Used (U/mg	2.23 DCIP
Coat Weight	55 g/m ²

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Biosensor 210 is illustratively manufactured using two apparatuses 10, 10', shown in Figures 17-18 and 19, respectively. It is appreciated that unless otherwise described, the apparatuses 10, 10' operate in a similar manner. Referring first to Figure 17, biosensor 210 is manufactured by feeding a roll of ribbon or web 20 having an 80 nm gold laminate, which is about 40 mm in width, into a custom fit broad field laser ablation apparatus 10. The apparatus 10 comprises a laser source

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11 producing a beam of laser light 12, a chromium-plated quartz mask 14, and optics 16. It is appreciated that while the illustrated optics 16 is a single lens, optics 16 is preferably a variety of lenses that cooperate to make the light 12 in a pre-determined shape or image that is then projected onto the web of base substrate 20.

A non-limiting example of a suitable ablation apparatus 10 (Figures 17-18) is a customized MicrolineLaser 200-4 laser system commercially available from LPKF Laser Electronic GmbH, of Garbsen, Germany, which incorporates an LPX-400, LPX-300 or LPX-200 laser system commercially available from Lambda Physik AG, Göttingen, Germany and a chromium-plated quartz mask commercially available from International Phototool Company, Colorado Springs, Co.

For the MicrolineLaser 200-4 laser system (Figures 17-18), the laser source 11 is a LPX-200 KrF-UV-laser. It is appreciated, however, that higher wavelength UV lasers can be used in accordance with this disclosure. The laser source 11 works at 248nm, with a pulse energy of 600mJ, and a pulse repeat frequency of 50 Hz. The intensity of the laser beam 12 can be infinitely adjusted between 3% and 92% by a dielectric beam attenuator (not shown). The beam profile is $27 \times 15 \text{ mm}^2$ (0.62 sq. inch) and the pulse duration 25ns. The layout on the mask 14 is homogeneously projected by an optical elements beam expander, homogenizer, and field lens (not shown). The performance of the homogenizer has been determined by measuring the energy profile. The imaging optics 16 transfer the structures of the mask 14 onto the ribbon 20. The imaging ratio is 2:1 to allow a large area to be removed on the one hand, but to keep the energy density below the ablation point of the applied chromium mask on the other hand. While an imaging of 2:1 is illustrated, it is appreciated that the any number of alternative ratios are possible in accordance with this disclosure depending upon the desired design requirements. The ribbon 20 moves as shown by arrow 25 to allow a number of layout segments to be ablated in succession.

The positioning of the mask 14, movement of the ribbon 20, and laser energy are computer controlled. As shown in Figure 17, the laser beam 12 is projected onto the ribbon 20 to be ablated. Light 12 passing through the clear areas or windows 18 of the mask 14 ablates the metal from the ribbon 20. Chromium coated areas 24
5 of the mask 14 blocks the laser light 12 and prevent ablation in those areas, resulting in a metallized structure on the ribbon 20 surface. Referring now to Figure 18, a complete structure of electrical components may require additional ablation steps through a second mask 14'. It is appreciated that depending upon the optics and the size of the electrical component to be ablated, that only a single
10 ablation step or greater than two ablation steps may be necessary in accordance with this disclosure. Further, it is appreciated that instead of multiple masks, that multiple fields may be formed on the same mask in accordance with this disclosure.

15 Specifically, a second non-limiting example of a suitable ablation apparatus 10' (Figure 19) is a customized laser system commercially available from LPKF Laser Electronic GmbH, of Garbsen, Germany, which incorporates a Lambda STEEL (Stable energy excimer laser) laser system commercially available from Lambda Physik AG, Göttingen, Germany and a chromium-plated quartz mask
20 commercially available from International Phototool Company, Colorado Springs, Co. The laser system features up to 1000 mJ pulse energy at a wavelength of 308 nm. Further, the laser system has a frequency of 100 Hz. The apparatus 10' may be formed to produce biosensors with two passes as shown in Figures 17 and 18, but preferably its optics permit the formation of a 10x40 mm pattern in a 25 ns
25 single pass.

While not wishing to be bound to a specific theory, it is believed that the laser pulse or beam 12 that passes through the mask 14, 14', 14'' is absorbed within less than 1 μ m of the surface 232 on the ribbon 20. The photons of the beam 12 have
30 an energy sufficient to cause photo-dissociation and the rapid breaking of chemical bonds at the metal/polymer interface. It is believed that this rapid chemical bond breaking causes a sudden pressure increase within the absorption region and forces

material (metal film 216) to be ejected from the polymer base surface. Since typical pulse durations are around 20-25 nanoseconds, the interaction with the material occurs very rapidly and thermal damage to edges of the conductive material 216 and surrounding structures is minimized. The resulting edges of the electrical components have high edge quality and accurate placement as contemplated by the present invention.

Fluence energies used to remove or ablate metals from the ribbon 20 are dependent upon the material from which the ribbon 20 is formed, adhesion of the metal film to the base material, the thickness of the metal film, and possibly the process used to place the film on the base material, i.e. supporting and vapor deposition. Fluence levels for gold on KALADEX[®] range from about 50 to about 90 mJ/cm², on polyimide about 100 to about 120 mJ/cm², and on MELINEX[®] about 60 to about 120 mJ/cm². It is understood that fluence levels less than or greater than the above mentioned can be appropriate for other base materials in accordance with the disclosure.

Patterning of areas of the ribbon 20 is achieved by using the masks 14, 14'. Each mask 14, 14' illustratively includes a mask field 22 containing a precise two-dimensional illustration of a pre-determined portion of the electrode component patterns to be formed. Figure 17 illustrates the mask field 22 including contact pads and a portion of traces. As shown in Figure 18, the second mask 14' contains a second corresponding portion of the traces and the electrode patterns containing fingers. As previously described, it is appreciated that depending upon the size of the area to be ablated, the mask 14 can contain a complete illustration of the entire electrode pattern for each biosensor (Figure 19), or partial patterns different from those illustrated in Figures 17 and 18 in accordance with this disclosure.

Preferably, it is contemplated that in one aspect of the present invention, the entire pattern of the electrical components on the test strip are laser ablated at one time, i.e., the broad field encompasses the entire size of the test strip (Figure 19), or even encompasses the entire size of two or more test strips (not shown). In the

alternative, and as illustrated in Figures 17 and 18, portions of the entire biosensor are done successively.

While mask 14 will be discussed hereafter, it is appreciated that unless indicated
5 otherwise, the discussion will apply to masks 14', 14'' as well. Referring to Figure 17, areas 24 of the mask field 22 protected by the chrome will block the projection of the laser beam 12 to the ribbon 20. Clear areas or windows 18 in the mask field 22 allow the laser beam 12 to pass through the mask 14 and to impact
predetermined areas of the ribbon 20. As shown in Figure 17, the clear area 18 of
10 the mask field 22 corresponds to the areas of the ribbon 20 from which the conductive material 216 is to be removed.

Further, the mask field 22 has a length shown by line 30 and a width as shown by
line 32. Given the imaging ratio of 2:1 of the LPX-200, it is appreciated that the
15 length 30 of the mask is two times the length of a length 34 of the resulting pattern and the width 32 of the mask is two times the width of a width 36 of the resulting pattern on ribbon 20. The optics 16 reduces the size of laser beam 12 that strikes the ribbon 20. It is appreciated that the relative dimensions of the mask field 22 and the resulting pattern can vary in accordance with this disclosure. Mask 14'
20 (Figure 18) is used to complete the two-dimensional illustration of the electrical components.

Continuing to refer to Figure 17, in the laser ablation apparatus 10 the excimer
laser source 11 emits beam 12, which passes through the chrome-on-quartz mask
25 14. The mask field 22 causes parts of the laser beam 12 to be reflected while allowing other parts of the beam to pass through in the form of an image of part or all of an electrode pattern. The image or part of laser beam 12 that passes through mask 14 in turn creates a pattern on the gold film where impacted by the laser beam 12. It is appreciated that ribbon or web 20 can be stationary relative to
30 apparatus 10 or move continuously on a roll through apparatus 10. Accordingly, non-limiting rates of movement of the ribbon 20 can be from about 0 m/min to about 100 m/min, more preferably about 30 m/min to about 60 m/min. It is

appreciated that the rate of movement of the ribbon 20 is limited only by the apparatus 10 selected and may well exceed 100 m/min depending upon the pulse duration of the laser source 11 in accordance with the present disclosure.

5 Once the pattern of the mask 14 is created on the ribbon 20, the ribbon is rewound and fed through the apparatus 10 again, with mask 14' (Figure 18). It is appreciated that laser apparatus 10 could, alternatively, be positioned in series in accordance with this disclosure. A detailed description of the step and repeat process is found in U.S. Application Serial Number 60/480,397, filed June 20,
10 2003, entitled "Devices And Methods Relating To Analyte Sensors", the disclosure of which is incorporated herein by reference. Thus, by using masks 14, 14', large areas of the web or ribbon 20 can be patterned using step-and-repeat processes involving multiple mask fields 22 in the same mask area to enable the economical creation of intricate electrode patterns and other electrical components on a
15 substrate of the base, the precise edges of the electrode components, and the removal of greater amounts of the metallic film from the base material.

Figure 20 is a non-limiting schematic of an electrode set ribbon 124 formed in accordance with the present disclosure, although having an electrode pattern
20 different from that illustrated in Figures 17 and 18. The ribbon 124 includes a plurality of panels 120, each of which includes a plurality of electrode systems 116. Each system includes two electrodes, both labeled 104 and having a sensing region 110. Also shown is the original metallic laminate ribbon 122 that is subject to laser ablation to form the electrode set ribbon 124. The width of the
25 ribbon 122 is selected to accommodate the laser ablation system 10, 10', and may be, for example, 40 to 0.4 inches (1.2 m to 10.25 mm). The ribbon may be any length, and is selected based on the desired number of electrode sets, and/or the ease of handling and transport of the ribbons. The size of each individual panel is selected to fit conveniently on the ribbon, and therefore each panel may contain 1
30 to 1000 electrode sets, preferably 2 to 20 electrode sets.

Once the complete electrode patterns are created, it is appreciated that the ribbon 20 may be coupled to a spacer and a cover using any number of well-known commercially available methods. A non-limiting example of a suitable method of manufacture, is described in detail in U.S. Application Serial Number 60/480,397, filed June 20, 2003, entitled "Devices And Methods Relating To Analyte Sensors", the disclosure of which is incorporated herein by reference. In summary, however, it is appreciated that a reagent film is placed upon the ribbon and dried conventionally with an in-line drying system. The rate of processing is nominally 30-38 meters per minute and depends upon the rheology of the reagent. Reagents suitable for the biosensor 210 are given above, but a preferable reagent is set out in Table 2.

The materials are processed in continuous reels such that the electrode pattern is orthogonal to the length of the reel, in the case of the base. Once the base has been coated, the spacer material is laminated onto the coated ribbon 20. Prior to laminating the spacer material, however, a portion of the spacer material is removed, thereby forming a slit. A punching process is used to remove the unneeded portion of the spacer. The die set governs the shape of the slit. The resulting slit-spacer is placed in a reel-to-reel process onto the base. A cover is then laminated onto the spacer using a reel-to-reel process. The biosensors can then be produced from the resulting reels of material by means of slitting and cutting.

The slit in the spacer preferably forms a capillary fill space between the base and the cover. A hydrophobic adhesive on the spacer prevents the test sample from flowing into the reagent under the spacer and therefore the fill space defines the test chamber volume. It is appreciated that the chamber volume can vary in accordance with this disclosure depending upon the application of the biosensor. A non-limiting detailed description of suitable fill volumes is found in U.S. Application Serial No. 60/480,397, noted above.

As discussed above, biosensor 210 has two electrode patterns having different feature sizes on a common planar surface and thus achieves multiple functionalities on that surface. Preferably, electrode set 266 has an electrode pattern formed as a macro electrode array with a first pre-defined feature size. A non-limiting example of a suitable functionality of the macroelectrode array is hematocrit level correction, which is described in U.S. Patent Application Serial No. 10/688,312, entitled "System And Method For Analyte Measurement Using AC Phase Angle Measurement", filed October 17, 2003, the disclosure of which is incorporated herein by reference.

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Further, it is appreciated that during use, a test meter (not shown) applies a voltage to one electrode and measures the current response at the other electrode to obtain a signal as described in U. S. Patent Application Serial No. 10/688,312 just noted.

15

Electrode set 268 has an electrode pattern formed as an interlaced microelectrode array with a second pre-defined feature size. A non-limiting example of a suitable functionality of the microelectrode array is glucose estimation, which is also described in U.S. Patent Application Serial No. 10/688,312. Further, it is appreciated that during use, a test meter (not shown) applies a voltage to one electrode and measures the current response at the other electrode to obtain a signal as described in U. S. Patent Application Serial No. 10/688,312.

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In operation, a user places his or her lanced finger at opening 221 of biosensor 210. A liquid sample (whole blood) flows from the finger into the opening 221. The liquid sample is transported via capillary action through the sample-receiving chamber 220 and across the fingers 280 of the element of the electrode set 266. Subsequently, the liquid sample flows through the sample-receiving chamber 220 toward vent 262 and into engagement with the reagent 264 situated upon the fingers 284 of the element of the electrode set 268. As discussed above, hematocrit correction values are determined from the interaction of the liquid sample with the fingers 280 and a glucose determination from the interaction of the liquid sample/reagent mixture with the fingers 284. While hematocrit and glucose

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determination functionalities are described with reference to biosensor 210, it is appreciated that the electrode patterns, may be used for a variety of functionalities in accordance with the present disclosure.

5 The processes and products described include disposable biosensors, especially for use in diagnostic devices. However, also included are electrochemical biosensors for non-diagnostic uses, such as measuring an analyte in any biological, environmental, or other, sample. In addition, it is appreciated that various uses and available functions of the biosensor may stand alone or be combined with one
10 another in accordance with this disclosure.

As discussed below with reference to Figures 11-16, each of the disclosed biosensors operates from the standpoint of a user in a manner similar to that described above with reference from 210. In addition, like components of the
15 biosensors are numbered alike.

Referring now to Figure 11, a biosensor 310 is formed and manufactured in a manner similar to biosensor 210 except for the pattern of the conductive material 216 positioned on the base 212. The conductive material 216 of biosensor 310
20 defines a first electrode system 366 and a second electrode system 368. The electrode systems 366, 368 are similar to the systems of biosensor 210 except for the resulting pattern of the connecting traces 377, 379 and contact pads 378, 383 on the base 212. It is submitted that the traces 377, 379 and pads 378, 383 may take on a variety of shapes and sizes in accordance with this disclosure.

25 As shown in Figure 12, a biosensor 510 is formed in a manner similar to biosensor 210 except for the pattern of the conductive material 216 positioned on the base 212. In addition to electrode set 268, the conductive material 216 of biosensor 510 defines a first electrode set 566. The electrode set 566 is similar to set 366 except
30 for the configuration of the interlacing electrode pattern formed by the elements of the electrodes.

Specifically, the first electrode set 566 includes a working electrode having an element with one electrode finger 581 and a counter electrode having an element with two electrode fingers 580. The fingers 580, 581 cooperate with one another to create an interlaced electrode pattern configured as a macroelectrode array having a feature size or gap width of about 250 μm . The electrodes 580, 581 each have an electrode width of about 250 μm . As discussed above with set 266, the electrode and gap widths may vary in accordance with this disclosure.

As described above with reference to biosensor 210, the first and second electrode sets 566, 268 have different feature sizes and are used to create different functionalities on biosensor 510. A non-limiting example of a suitable functionality of the first electrode set 566 is for determining correction factors for hematocrit levels. The measurement methods are as discussed above with reference to biosensor 210.

Referring now to Figure 13, a biosensor 610 is formed in a manner similar to biosensor 210 except for the pattern of the conductive material 216 positioned on the base 212. In addition to the first electrode set 566 as discussed above, the conductive material 216 of biosensor 610 defines a second electrode set 668 spaced-apart from set 566.

The electrode set 668 is similar to set 268 except for the pattern of interlacing electrode pattern in the element of the electrodes. Specifically, the second electrode set 668 includes a working electrode and a counter electrode, each having an element with three electrode fingers 661. The fingers 661 cooperate with one another to define an interlaced electrode pattern configured as a microelectrode array having a feature size or gap width of about 50 μm , which is less than the feature size of the electrode pattern of the set 566. The electrodes 661 each have an electrode width of about 50 μm . As discussed above with set 268, the electrode and gap widths may vary in accordance with this disclosure.

In addition, biosensor 610 includes a reagent 664. Reagent 664 is similar to reagent 264, and only differs in its width as it is applied onto the base 212. Specifically, the reagent 664 extends across electrode fingers 661. A non-limiting example of a suitable functionality of the second electrode set 668 is a glucose determination functionality. The measurement methods are as discussed above with reference to biosensor 210.

As shown in Figure 14, a biosensor 710 is formed in a manner similar to biosensor 210 except for the pattern of the conductive material 216 positioned on the base 212. The conductive material 216 of biosensor 710 defines the first electrode set 366 as discussed above and a second electrode set 768. The electrode set 768 is similar to set 268 except for the pattern of an interlacing electrode pattern formed by the element of the electrodes. Specifically, the second electrode set 768 includes a working electrode and a counter electrode, each having element with five electrode fingers 770. The fingers 770 cooperate with one another to define an interlaced electrode pattern configured as a microelectrode array having a feature size or gap width of about 30 μm , which is less than the feature size of electrode pattern of set 366. The electrode fingers 770 each have an electrode width of about 50 μm . As discussed above with set 266, the electrode and gap widths may vary in accordance with this disclosure. A non-limiting example of a suitable functionality of the second electrode set 668 is a glucose determination functionality. The measurement methods are as discussed above with reference to biosensor 210.

In addition, biosensor 710 includes a reagent 364 that is dispensed upon the fingers 770 by any of a variety of dispensing methods that are well known to those skilled in the art. Reagent 364 is preferably the reagent set forth in Table 3. Moreover, it is appreciated that a variety of reagents, non-limiting examples of which have been discussed above, may be used in accordance with this disclosure.

Figure 15 illustrates a biosensor 1310 in accordance with this disclosure. Biosensor 1310 is formed in a manner similar to biosensor 210 except for the configuration of the conductive material 216 positioned on the base 212, the cover

1118, and the spacer 1114. The cover 1118 and spacer 1114 are similar to cover 218 and spacer 214 except for their dimensions relative to the base 212 as shown in Figure 15. The conductive material 216 of biosensor 1310 defines a first electrode set 1366 and a second electrode set 1368. The first electrode set 1366 includes a
5 working electrode and a counter electrode, each having five electrode fingers 1370. The fingers 1370 cooperate with one another to define an interlaced electrode pattern formed as a microelectrode array having a feature size or gap width of about 17 μm . The electrode fingers 1370 each have an electrode width of about 20 μm .

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The second electrode set 1368 includes a working electrode and a counter electrode, each having three electrode fingers 1371. The electrode fingers 1371 cooperate with one another to define an interlaced electrode pattern formed as a microelectrode array having a feature size or gap width of about 10 μm . The
15 electrode fingers 1371 each have an electrode width of about 20 μm . As discussed above with set 266, the electrode and gap widths of fingers 1370 and 1371 may vary in accordance with this disclosure.

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The reagent 264 extends across the electrode fingers 1371 of the electrode set 1368. A non-limiting example of a suitable functionality of the first electrode set 1366 includes hematocrit correction as described above with reference to biosensor 210. Likewise, a non-limiting example of a suitable functionality of the second electrode set 1368 is used for determining a glucose estimate as described above with reference to biosensor 210. The method of measurement for the electrode
25 sets, 1366 and 1368 is also as described above with reference to biosensor 210

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Figure 16 illustrates biosensor 1510. Biosensor 1510 is identical to biosensor 210, except for the reagent 1564. Reagent 364 is dispensed onto the electrode fingers 284 as discussed above with reference to biosensor 710 of Figure 14.

Figs. 21-24 are photographs of electrical patterns formed using the principles of the present invention. Fig. 21 is a photograph of a base substrate having an electrical

pattern formed thereon by removing 10% of the conductive material initially covering the base substrate. In this embodiment the conductive material is gold. The pattern was formed with a single pulse of a laser.

5 Fig. 22 is a photograph of a base substrate having an electrical pattern formed thereon by removing 20% of the conductive material initially covering the base substrate. In this embodiment the conductive material is gold and the gap widths are approximately 20 μm as indicated. The pattern was formed with a single pulse of a laser.

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Fig. 23 is a photograph of a base substrate having an electrical pattern formed thereon by removing 50% of the conductive material initially covering the base substrate. In this embodiment the conductive material is gold and the gap widths are approximately 20 μm as indicated. The pattern was formed with a single pulse of a laser.

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Fig. 24 is a photograph of a base substrate having an electrical pattern formed thereon by removing 90% of the conductive material initially covering the base substrate. In this embodiment the conductive material is gold and the gap widths are approximately 250 μm as indicated. The pattern was formed with a single pulse of a laser.

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Several production runs were made which demonstrate the very fast speed in which the electrical patterns of the biosensors in accordance with the present invention can be produced. Many of the runs included electrode patterns with two different feature sizes, as indicated in Table 4. Figs. 21-24 are photos taken of selected ones of the electrode structures, as also indicated in Table 4. The masks used to make the patterns included both "Structure 1" and "Structure 2" listed in Table 4. A single laser pulse of about 25 nanoseconds was used to form the patterns. As indicated, long webs (about 450 m or more) of material were passed under the laser ablation apparatus at a controlled speed as the electrical patterns were formed.

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Table 4

Run #	Structure 1 Finger/Gap (μm)	Structure 2 Finger/Gap (μm)	Run time (min)	Patterns per min.	Figure	Roll Length (m)
1	20/20	250/200	20	2585		466
2	250/50	---	40	1256		453
3	20/250	250/20	13	3873	24 (Structure 1)	454
4	20/20	250/20	22	2284	Fig. 21 (Structure 2)	453
5	50/50	100/100	22	2289		454
6	100/50	---	20	2518		454
7	20/20	100/20	23	2363	Fig. 23 - Structure 1; Fig. 22 - Structure 2	490
8	50/100	---	19	2755		472
9	20/20	50/20	19	2860		490

As can be seen from the above table 4, the method embodied by the present
 5 invention is well suited to fast mass production.

Although the invention has been described in detail with reference to a preferred
 embodiment, variations and modifications exist within the scope and spirit of the
 invention, on as described and defined in the following claims.

WHAT IS CLAIMED IS:

1. A biosensor, comprising:
a base substrate having first and second electrode elements formed thereon;
the first and second electrode elements having first and second respective
5 edges defining a gap therebetween, the gap having a width and a length;
the first edge being spaced from a first theoretical line by a first distance
that varies along the length of the gap, the first theoretical line defining a desired
shape and placement of the first edge, wherein the standard deviation of the first
distance is less than about $6\mu\text{m}$ over the entire length of the gap;
10 a reagent at least partially covering the base substrate; and
one or more layers overlying and adhered to the base substrate, the one or
more layers cooperating to form a sample-receiving chamber and a cover for the
biosensor, at least a portion of the reagent and an electrode being positioned in the
chamber.
15
2. The biosensor of claim 1, wherein the standard deviation of the first
distance is less than about $2\mu\text{m}$.
3. The biosensor of claim 1, wherein the standard deviation of the first
20 distance is less than about $1\mu\text{m}$.
4. The biosensor of claim 1, wherein the second edge is spaced from a
second theoretical line by a second distance that varies along the length of the gap,
the second theoretical line defining a desired shape and placement of the second
25 edge, wherein the standard deviation of the second distance is less than about $6\mu\text{m}$
over the entire length of the gap.
5. The biosensor of claim 4, wherein the standard deviation of both the
first distance and the second distance is less than about $2\mu\text{m}$.
30
6. The biosensor of claim 4, wherein the standard deviation of both the
first distance and the second distance is less than about $1\mu\text{m}$.

7. The biosensor of claim 1, wherein the gap width is about 250 μ m or less.
8. The biosensor of claim 1, wherein the gap width is less than about
5 50 μ m.
9. The biosensor of claim 1, wherein the gap width is less than about 20 μ m.
- 10 10. The biosensor of claim 1, wherein the electrode elements are formed by broad field laser ablation.
11. The biosensor of claim 1, wherein the first and second electrode elements comprise a first electrode set, one of the electrodes of the set being the
15 electrode positioned in the sample receiving chamber.
12. The biosensor of claim 11, further comprising a second electrode set formed on the base substrate, the second electrode set having a different feature size than the first electrode set.
- 20 13. The biosensor of claim 1, wherein the first and second electrode elements comprise first and second electrode traces.
14. The biosensor of claim 1, wherein the first and second electrode
25 elements comprise first and second contact pads.
15. The biosensor of claim 1, wherein the length of the gap is at least 0.1 mm.
- 30 16. The biosensor of claim 1, wherein the length of the gap is at least 1 mm.

17. The biosensor of claim 1, wherein the length of the gap is at least 1 cm.

18. The biosensor of claim 1, wherein the length of the gap is at least one third the length of the biosensor.

19. The biosensor of claim 1, wherein the length of the gap is at least one half the length of the biosensor.

20. The biosensor of claim 1, wherein the gap is positioned within the sample receiving chamber.

21. The biosensor of claim 1, wherein the electrode elements comprise contact pads and the gap extends between the contact pads.

22. The biosensor of claim 1, wherein the electrode elements comprise electrode traces and the gap extends between the electrode traces.

23. The biosensor of claim 1, wherein the electrode elements comprise a working electrode and a counter electrode and the gap extends between the working electrode and the counter electrode.

24. The biosensor of claim 23, wherein the gap extends across the sample receiving chamber.

25. A biosensor, comprising:
a base substrate having first and second electrode elements formed thereon;
the first and second electrode elements having first and second respective edges defining a gap therebetween, the gap having a width and a length;
the first edge being spaced from a first theoretical line by a first distance that varies along the length of the gap, the first theoretical line defining a desired

shape and placement of the first edge, wherein the first distance is less than about $6\mu\text{m}$ over the entire length of the gap;

a reagent at least partially covering the base substrate; and

one or more layers overlying and adhered to the base substrate, the one or
5 more layers cooperating to form a sample-receiving chamber and a cover for the
biosensor, at least a portion of the reagent layer and an electrode being positioned
in the chamber.

26. The biosensor of claim 25, wherein the first distance is less than
10 about $2\mu\text{m}$.

27. The biosensor of claim 25, wherein the first distance is less than
about $1\mu\text{m}$.

15 28. The biosensor of claim 25, wherein the second edge is spaced from
a second theoretical line by a second distance that varies along the length of the
gap, the second theoretical line defining a desired shape and placement of the
second edge, wherein the second distance is less than about $6\mu\text{m}$ over the entire
length of the gap.

20 29. The biosensor of claim 28, wherein the first distance and the second
distance are both less than about $4\mu\text{m}$.

30. The biosensor of claim 28, wherein the first distance and the second
25 distance are both less than about $2\mu\text{m}$.

31. The biosensor of claim 25, wherein the electrode elements are
formed by broad field laser ablation.

30 32. The biosensor of claim 25, wherein the first and second electrode
elements comprise an electrode set, one of the electrodes of the set being the
electrode positioned in the sample receiving chamber.

33. The biosensor of claim 32, further comprising a second electrode set formed on the base substrate, the second electrode set having a different feature size than the first electrode set.

5 34. The biosensor of claim 25, wherein the first and second electrode elements comprise first and second electrode traces.

35. The biosensor of claim 25, wherein the first and second electrode elements comprise first and second contact pads.

10

36. A method of making a biosensor comprising the following steps:
providing a base substrate having a layer of electrically conductive material thereon;

removing a portion of the conductive material to form first and second
15 electrode elements on the base substrate having first and second respective edges
defining a gap therebetween, the gap having a width and a length;

the first edge being spaced from a first theoretical line by a first distance that varies along the length of the gap, the first theoretical line defining a desired shape and placement of the first edge, wherein the standard deviation of the first
20 distance is less than about 6 μ m over the entire length of the gap;

providing a reagent at least partially covering the base; and

adhering one or more layers to the base, the one or more layers cooperating to form a sample-receiving chamber and a cover for the biosensor, at least a portion of the reagent and an electrode being positioned within the chamber.

25

37. The method of claim 36, further comprising removing at least 10% of the conductive material.

38. The method of claim 36, further comprising removing at least 50%
30 of the conductive material.

39. The method of claim 36, further comprising removing at least 90% of the conductive material.

40. The method of claim 36, wherein the electrically conductive material is removed by broad field laser ablation.

41. The method of claim 36, wherein the first and second electrode elements comprise a first electrode set.

42. The method of claim 41, further comprising forming a second electrode set on the base substrate having a feature size different from the first electrode set, one of the electrodes of the first electrode set being the electrode positioned within the sample receiving chamber and one of the electrodes of the second electrode set being positioned in the sample receiving chamber.

43. The method of claim 36, wherein the standard deviation is less than about 2 μ m.

44. The method of claim 36, wherein the standard deviation is less than about 1 μ m.

45. The method of claim 36, further comprising forming the electrode elements in less than about 0.25 seconds.

46. The method of claim 36, further comprising forming the electrode elements in less than about 50 nanoseconds.

47. The method of claim 36, further comprising forming the electrode elements in less than about 25 nanoseconds.

48. The method of claim 36, wherein the step of adhering the one or more layers to the base comprises laminating a spacing layer having a void that

defines the perimeter of the sample receiving chamber over the base substrate and laminating a covering layer over the spacing layer.

49. The method of claim 48, further comprising forming a vent opening
5 in the covering layer that communicates with the sample receiving chamber.

50. A method of forming a biosensor used to measure presence or concentration of an analyte in a fluid sample, comprising:

- (a) providing an electrically conductive material on a base;
- 10 (b) removing a portion of the electrically conductive material by broad field laser ablation to form an electrode set on the base;
- (c) providing a reagent at least partially covering the base; and
- (d) adhering one or more layers to the base, the one or more layers cooperating to form a sample-receiving chamber and a cover for the biosensor, at
15 least a portion of both the reagent layer and the electrode set being positioned in the chamber.

51. The method of claim 50, wherein the electrode set comprises first and second electrodes having first and second respective edges defining a gap
20 therebetween, the gap having a width and a length, the first edge being spaced from a first theoretical line by a first distance that varies along the length of the gap, the first theoretical line defining a desired shape and placement of the first edge, wherein the standard deviation of the first distance is less than about 6 μ m over the entire length of the gap.

25

52. The method of claim 51, wherein the standard deviation of the first distance is less than about 2 μ m.

53. The method of claim 51, wherein the standard deviation of the first
30 distance is less than about 1 μ m.

58

54. The method of claim 51, wherein the electrode set comprises at least two electrode sets having different feature sizes.

55. The method of claim 50, wherein the electrode set comprises at least two electrode sets having different feature sizes.

56. The method of claim 50, wherein step (c) comprises at least partially covering the electrode set with the reagent.

57. The method of claim 50, further comprising removing at least 10% of the conductive material.

58. The method of claim 50, further comprising removing at least 50% of the conductive material.

59. The method of claim 50, further comprising removing at least 90% of the conductive material.

60. A method of forming a biosensor used to measure concentration of an analyte in a fluid sample, comprising:

- (a) providing an electrically conductive material on a base;
- (b) removing at least 10% of the electrically conductive material to form at least two electrode sets on the base, the electrode sets having different feature sizes;
- (c) providing a reagent at least partially covering the base; and
- (d) adhering one or more layers to the base, the one or more layers cooperating to form a sample-receiving chamber, at least a portion of one of the electrode sets being positioned in the chamber.

61. The method of claim 60, further comprising removing at least 50% of the conductive material.

62. The method of claim 60, further comprising removing at least 90% of the conductive material.

63. The method of claim 60, wherein the electrically conductive material is removed by broad field laser ablation.

64. The method of claim 60, wherein one of the electrode sets comprises first and second electrodes having first and second respective edges defining a gap therebetween, the gap having a width and a length, the first edge being spaced from a first theoretical line by a first distance that varies along the length of the gap, the first theoretical line defining a desired shape and placement of the first edge, wherein the standard deviation of the first distance is less than about 6 μ m over the entire length of the gap.

65. The method of claim 64, wherein the standard deviation of the first distance is less than about 2 μ m.

66. The method of claim 64, wherein the standard deviation of the first distance is less than about 1 μ m.

67. The method of claim 60, wherein step (c) comprises at least partially covering the electrode set with the reagent.

68. A method of manufacturing a plurality of biosensors, comprising:

(a) providing a web of base substrate material having a metal conductive layer formed thereon;

(b) projecting an image of an electrode pattern onto the metal conductive layer with a laser apparatus, wherein an electrode pattern that corresponds to the image is formed by laser ablation on the web of base substrate material;

60

(c) moving one of the laser apparatus and the web of base substrate material and repeating step (b) a plurality of times to produce a plurality of the electrode patterns at spaced intervals along the web of base substrate material;

(d) depositing a reagent on the web of base substrate material and at
5 least partially covering each electrode pattern of the plurality of electrode patterns with the reagent;

(e) laminating at least one web of a covering layer or a spacing layer over the web of base substrate material, thereby forming a cover and a sample-receiving chamber for each biosensor; and

10 (f) cutting through the at least one web of a covering layer or a spacing layer and the web of base substrate material to form the plurality of biosensors.

69. The method of claim 68, wherein the electrode pattern formed in step (b) comprises a complete electrode pattern for one of the biosensors, whereby
15 the complete electrode pattern for each biosensor is formed in a single step.

70. The method of claim 68, wherein the electrode pattern formed in step (b) comprises a partial electrode pattern, the image comprises a plurality of the same or different images, and steps (b) and (c) are repeated until the plurality of
20 electrode patterns comprises a plurality of complete electrode patterns, whereby each complete electrode pattern is formed in multiple steps.

71. The method of claim 68, wherein step (c) comprises continuously moving the web of base substrate material.
25

72. The method of claim 68, wherein step (c) comprises moving the web of base substrate material in discrete increments.

73. The method of claim 68, wherein step (c) comprises moving the
30 web of base substrate material at a rate of at least 60 meters per minute.

74. The method of claim 68, wherein the electrode pattern includes at least two electrode sets having different feature sizes.

75. The method of claim 68, wherein the electrode pattern comprises
5 first and second electrodes having first and second respective edges defining a gap therebetween, the gap having a width and a length, the first edge being spaced from a first theoretical line by a first distance that varies along the length of the gap, the first theoretical line defining a desired shape and placement of the first edge, wherein the standard deviation of the first distance is less than about 6 μ m
10 over the entire length of the gap.

76. The method of claim 75, wherein the standard deviation is less than about 2 μ m.

15 77. The method of claim 75, wherein the standard deviation is less than about 1 μ m.

78. The method of claim 68, wherein the metal conductive layer comprises at least one member selected from the group consisting of gold,
20 platinum, palladium and iridium.

79. The method of claim 68, wherein step (e) comprises:
laminating the spacing layer over the base substrate material, the spacing layer having a void that defines the perimeter of the chamber; and
25 laminating the covering layer over the spacing layer.

80. The method of claim 68, wherein each electrode pattern formed in step (b) is formed in less than 1 second.

30 81. The method of claim 68, wherein each electrode pattern formed in step (b) is formed in less than 0.25 second.

62

82. The method of claim 68, wherein each electrode pattern formed in step (b) is formed all at once.

83. The method of claim 68, wherein each electrode pattern formed in step (b) comprises the entire electrode pattern for one of the biosensors and each entire electrode pattern is formed all at once.

84. The method of claim 68, wherein the reagent is applied in a substantially continuous stripe.

85. The method of claim 68, wherein the electrode pattern is anisotropic.

86. The method of claim 68, wherein the electrode pattern is asymmetric.

87. The method of claim 68, wherein the electrode pattern formed in step (b) comprises a complete electrode pattern for one of the biosensors, whereby the complete electrode pattern for each biosensor is formed in a single step, the method further comprising forming the complete electrical patterns at a rate of at least 500 per minute.

88. The method of claim 87, wherein forming the electrode patterns comprises removing at least 20% of the metal conductive layer.

89. The method of claim 87, wherein forming the electrode patterns comprises removing at least 50% of the metal conductive layer.

90. The method of claim 87, wherein forming the electrode patterns comprises removing at least 90% of the metal conductive layer.

91. The method of claim 68, wherein the electrode pattern formed in step (b) comprises a complete electrode pattern for one of the biosensors, whereby the complete electrode pattern for each biosensor is formed in a single step, the method further comprising forming the complete electrical patterns at a rate of at least 1000 per minute.

92. The method of claim 91, wherein forming the electrode patterns comprises removing at least 20% of the metal conductive layer.

93. The method of claim 91, wherein forming the electrode patterns comprises removing at least 50% of the metal conductive layer.

94. The method of claim 91, wherein forming the electrode patterns comprises removing at least 90% of the metal conductive layer.

95. The method of claim 68, wherein the electrode pattern formed in step (b) comprises a complete electrode pattern for one of the biosensors, whereby the complete electrode pattern for each biosensor is formed in a single step, the method further comprising forming the complete electrical patterns at a rate of at least 2000 per minute.

96. The method of claim 95, wherein forming the electrode patterns comprises removing at least 20% of the metal conductive layer.

97. The method of claim 95, wherein forming the electrode patterns comprises removing at least 50% of the metal conductive layer.

98. The method of claim 95, wherein forming the electrode patterns comprises removing at least 90% of the metal conductive layer.

99. The method of claim 68, wherein the electrode pattern formed in step (b) comprises a complete electrode pattern for one of the biosensors, whereby

the complete electrode pattern for each biosensor is formed in a single step, the method further comprising forming the complete electrical patterns at a rate of at least 3000 per minute.

5 100. The method of claim 99, wherein forming the electrode patterns comprises removing at least 20% of the metal conductive layer.

 101. The method of claim 99, wherein forming the electrode patterns comprises removing at least 50% of the metal conductive layer.

10

 102. The method of claim 99, wherein forming the electrode patterns comprises removing at least 90% of the metal conductive layer.

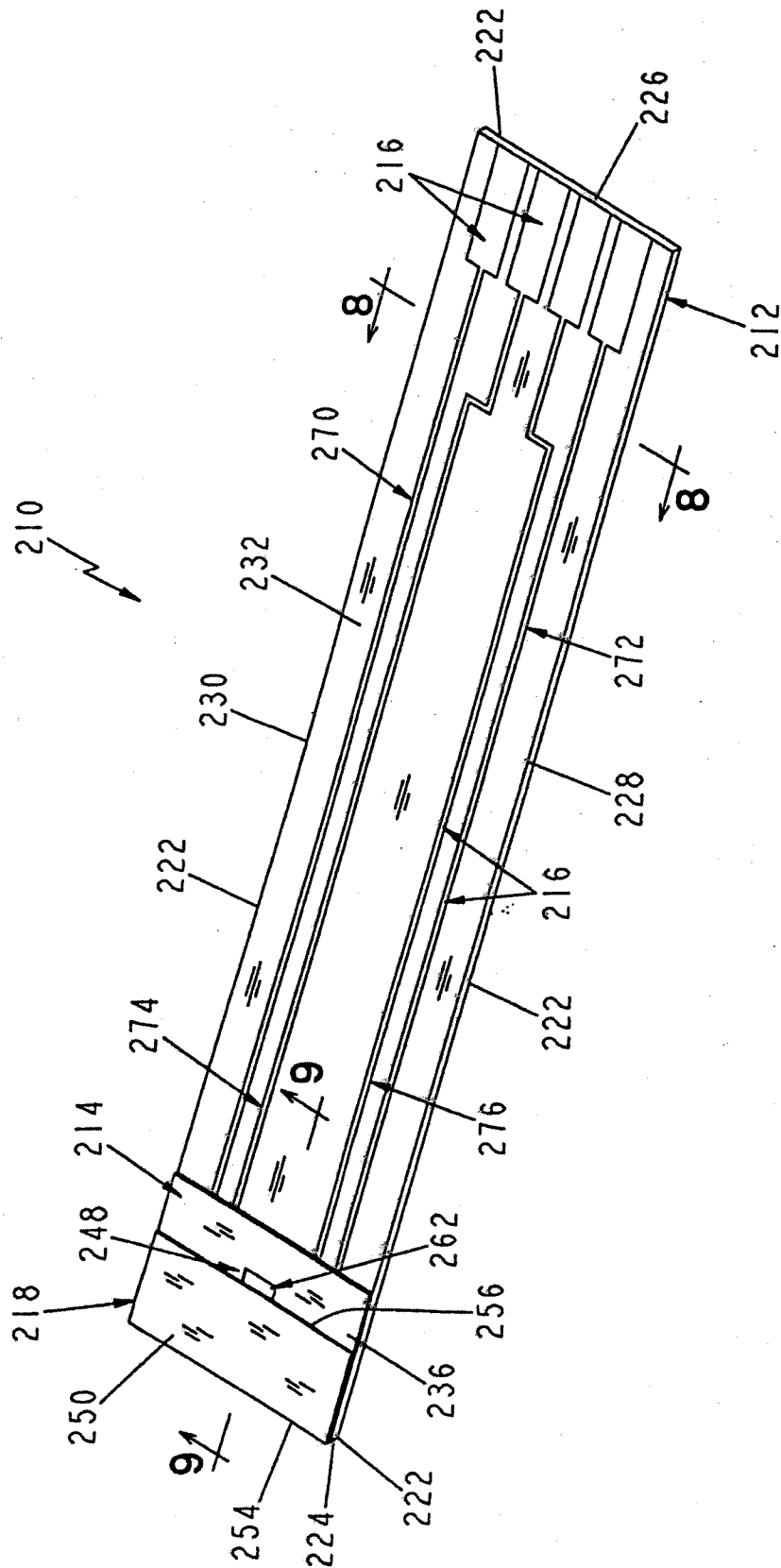


FIG. 1

2/20

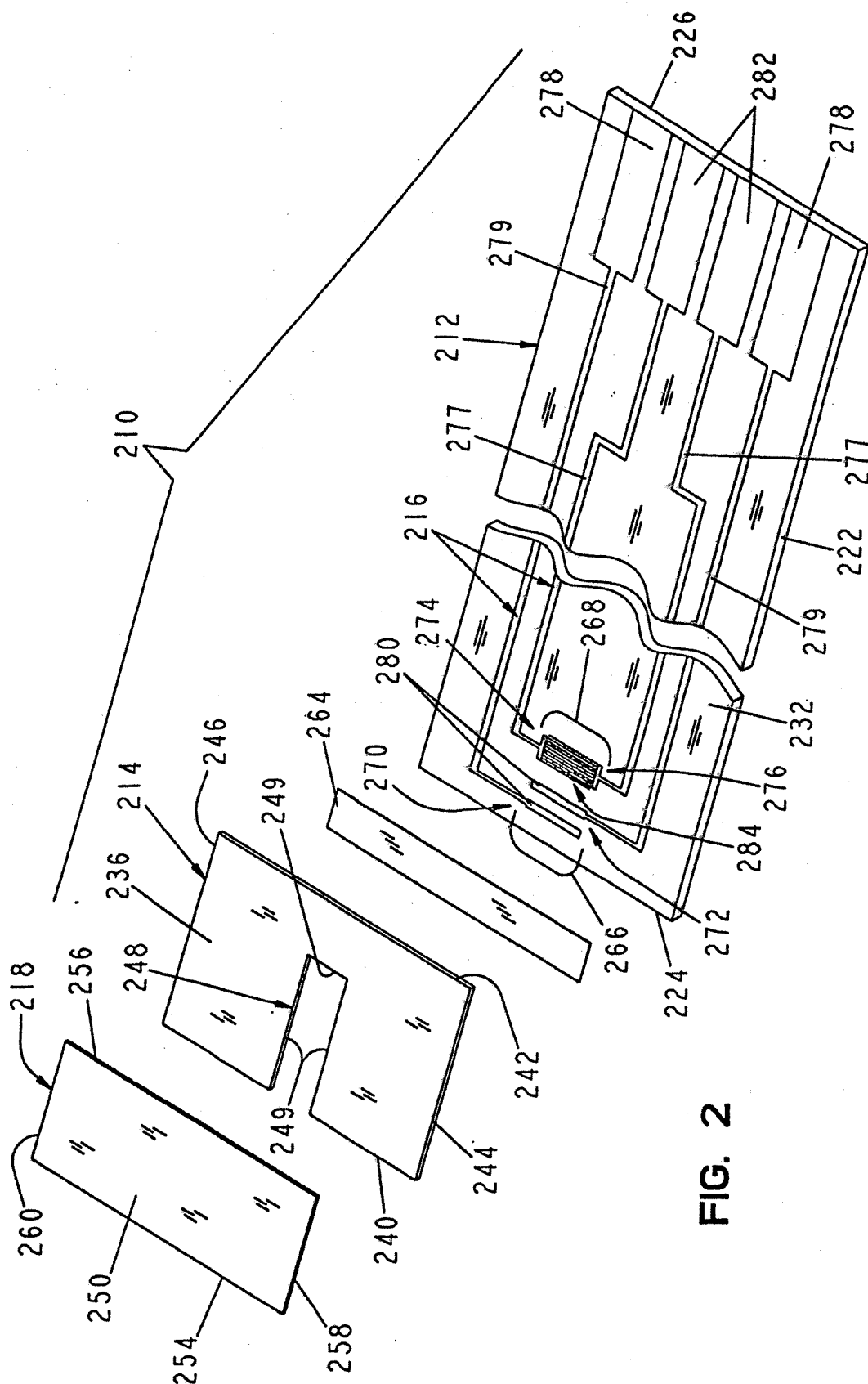
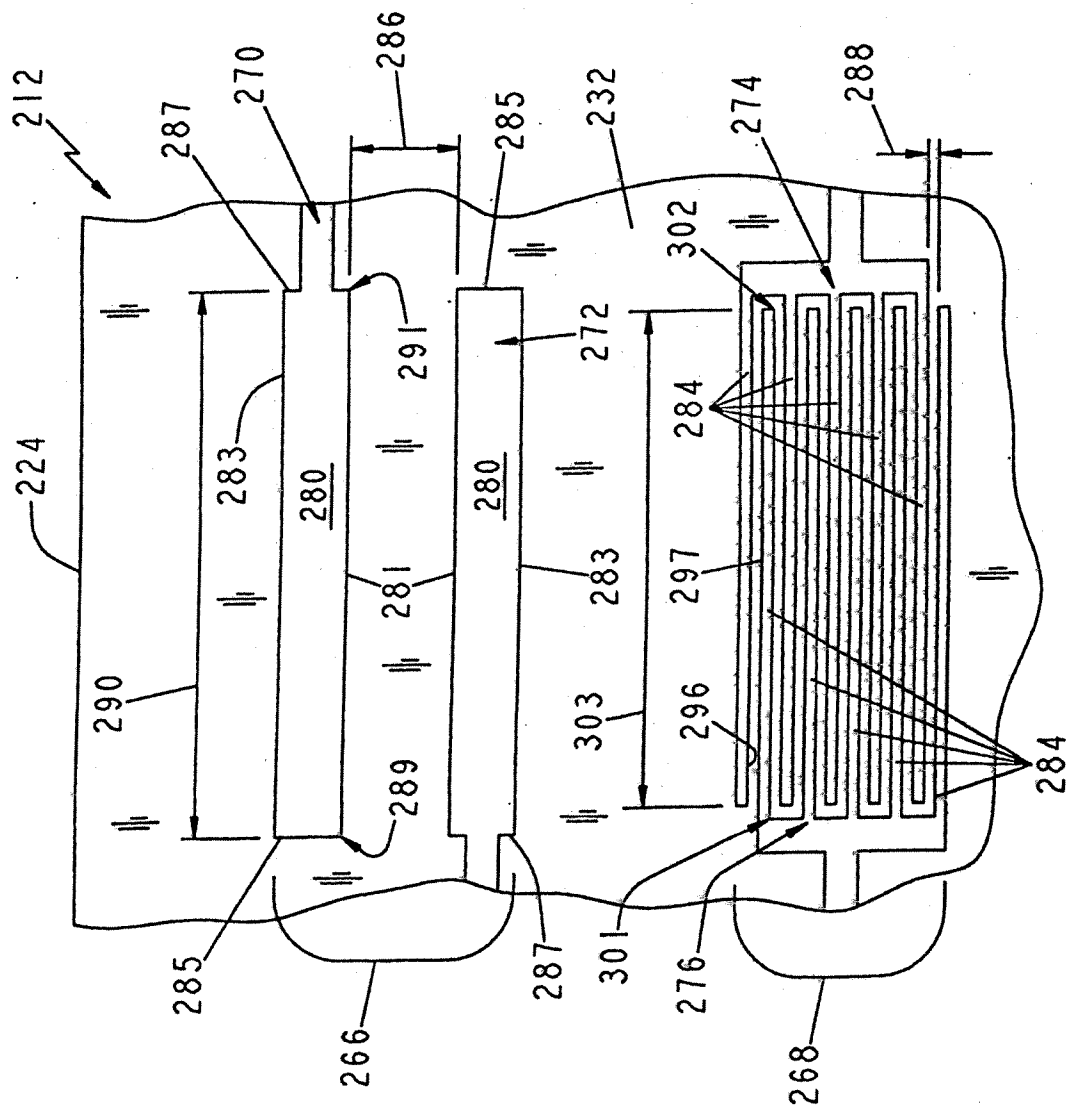


FIG. 2

FIG. 3



4/20

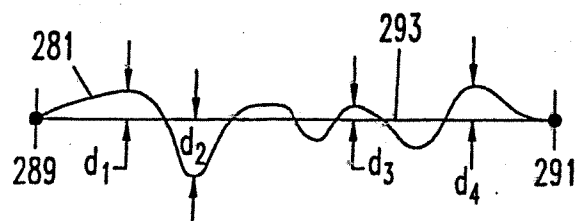


FIG. 4

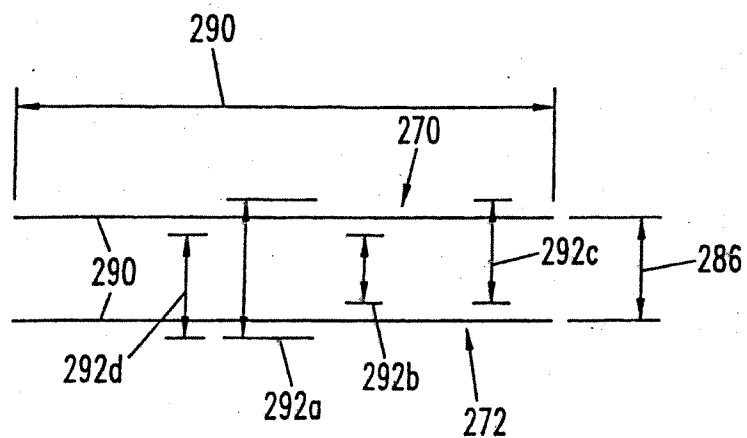


FIG. 5

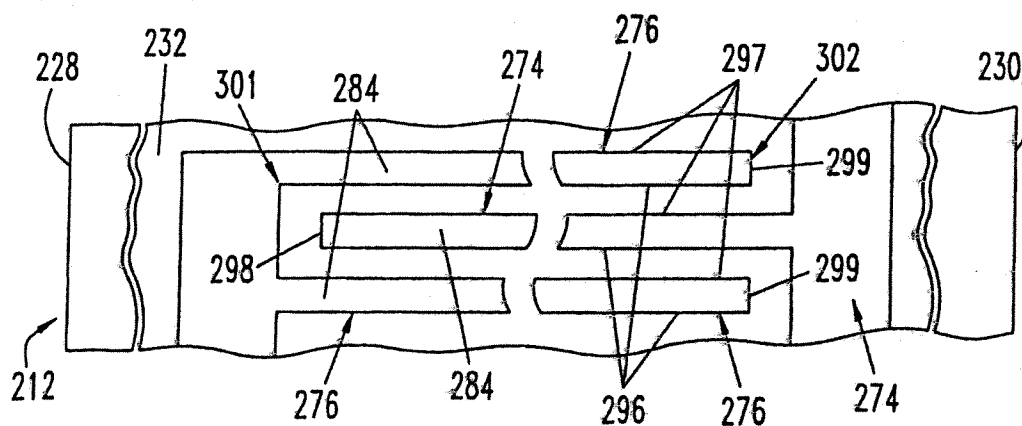


FIG. 6

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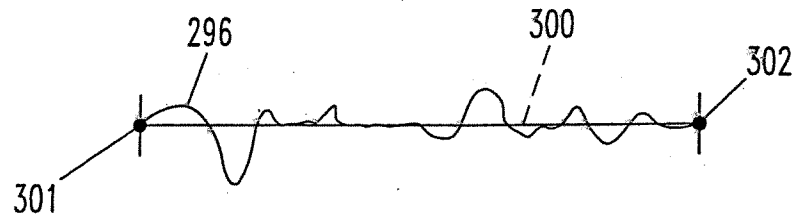


FIG. 7

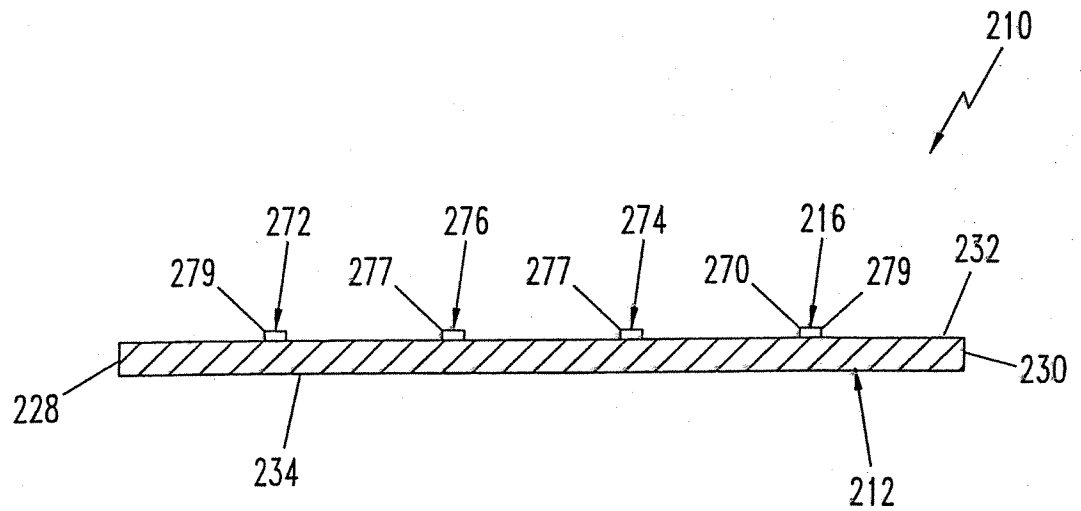


FIG. 8

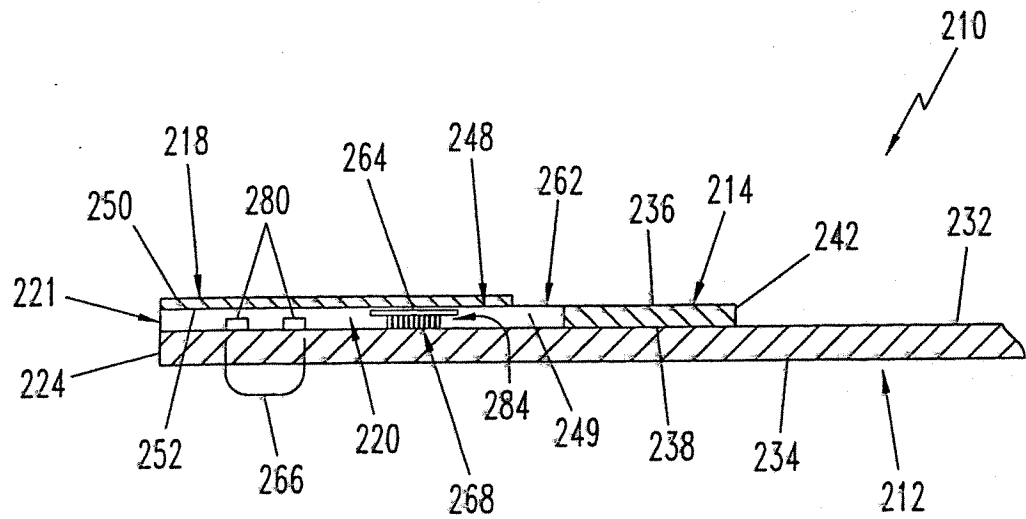


FIG. 9

6/20

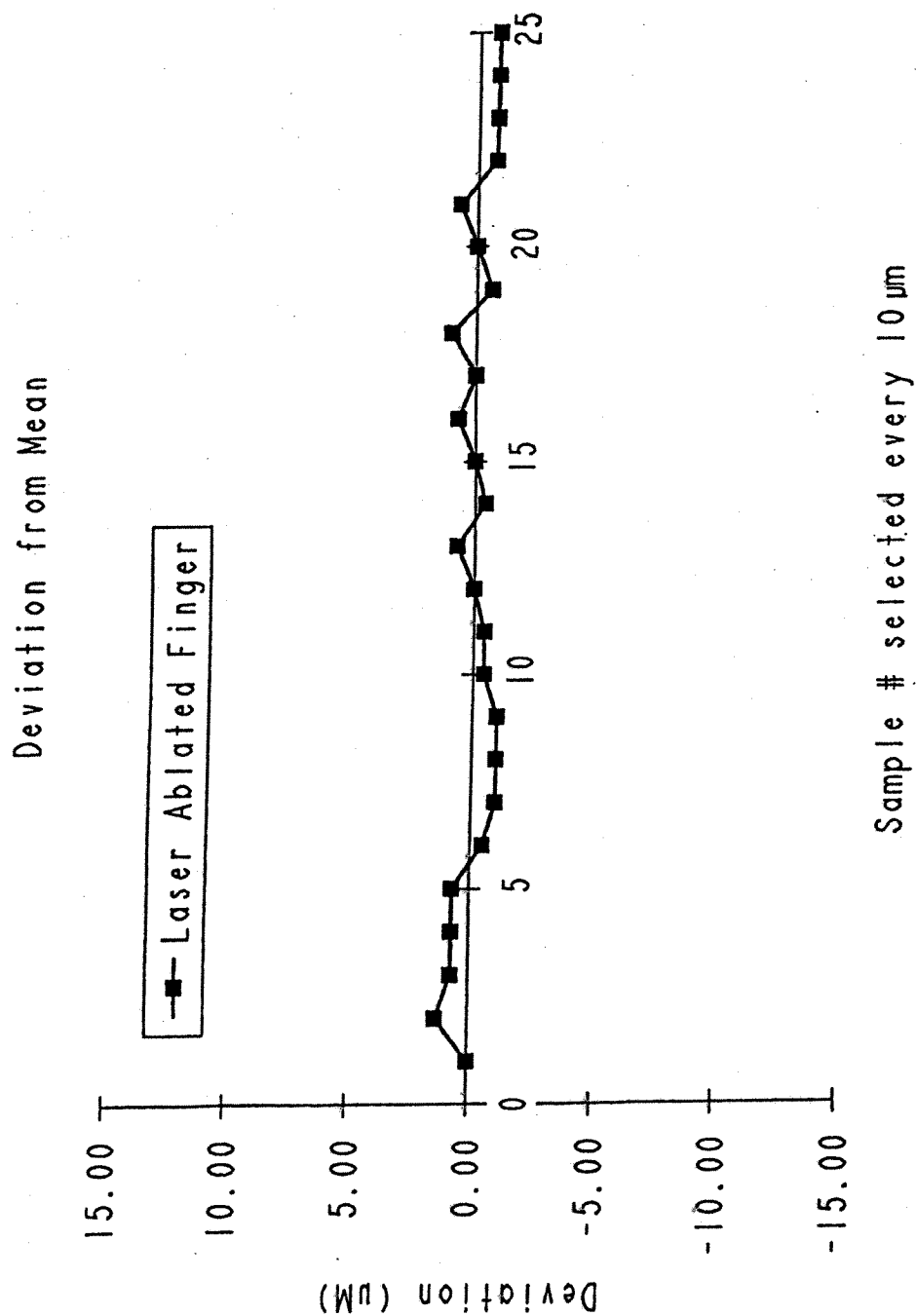


FIG. 10

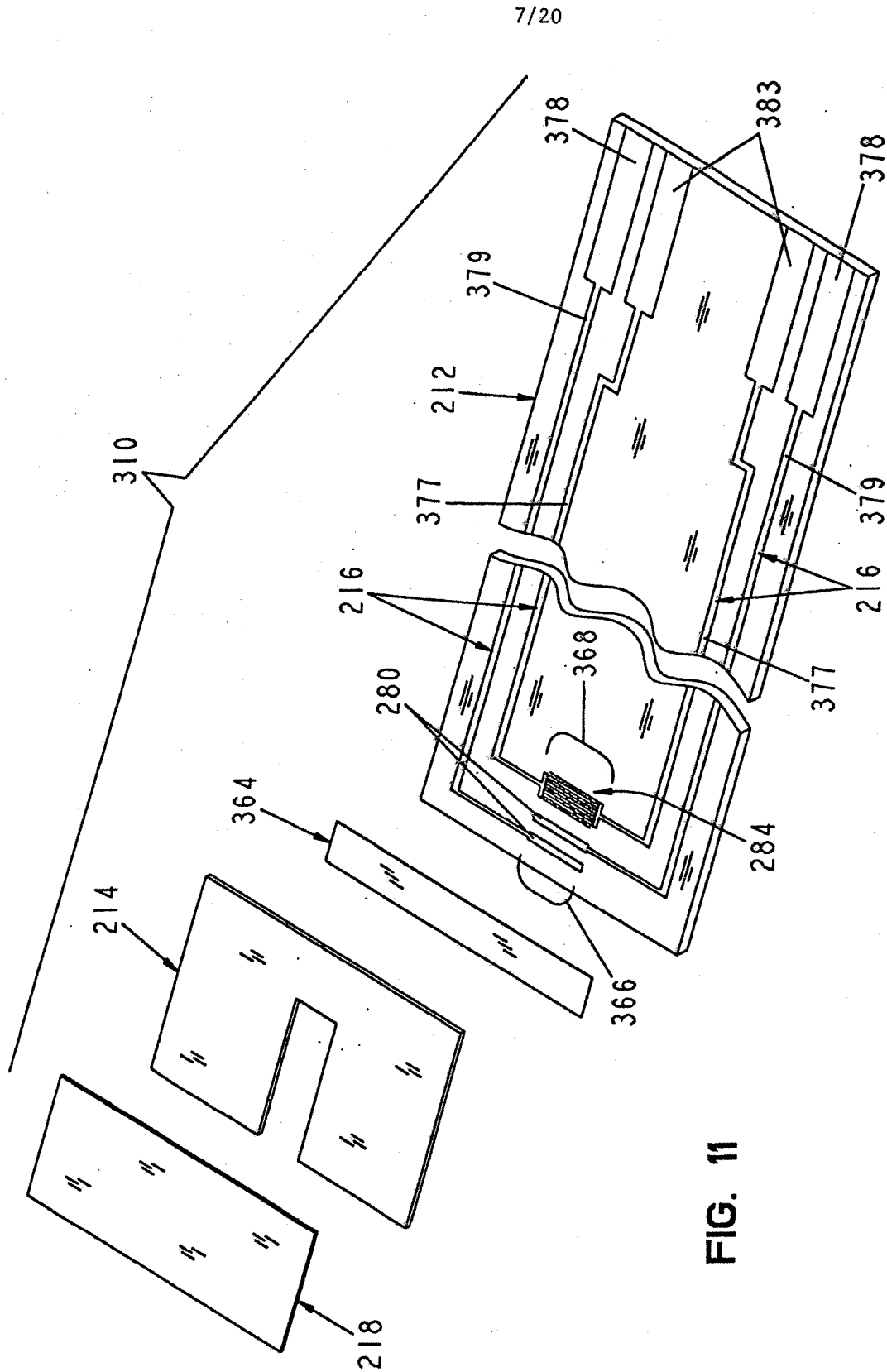


FIG. 11

8/20

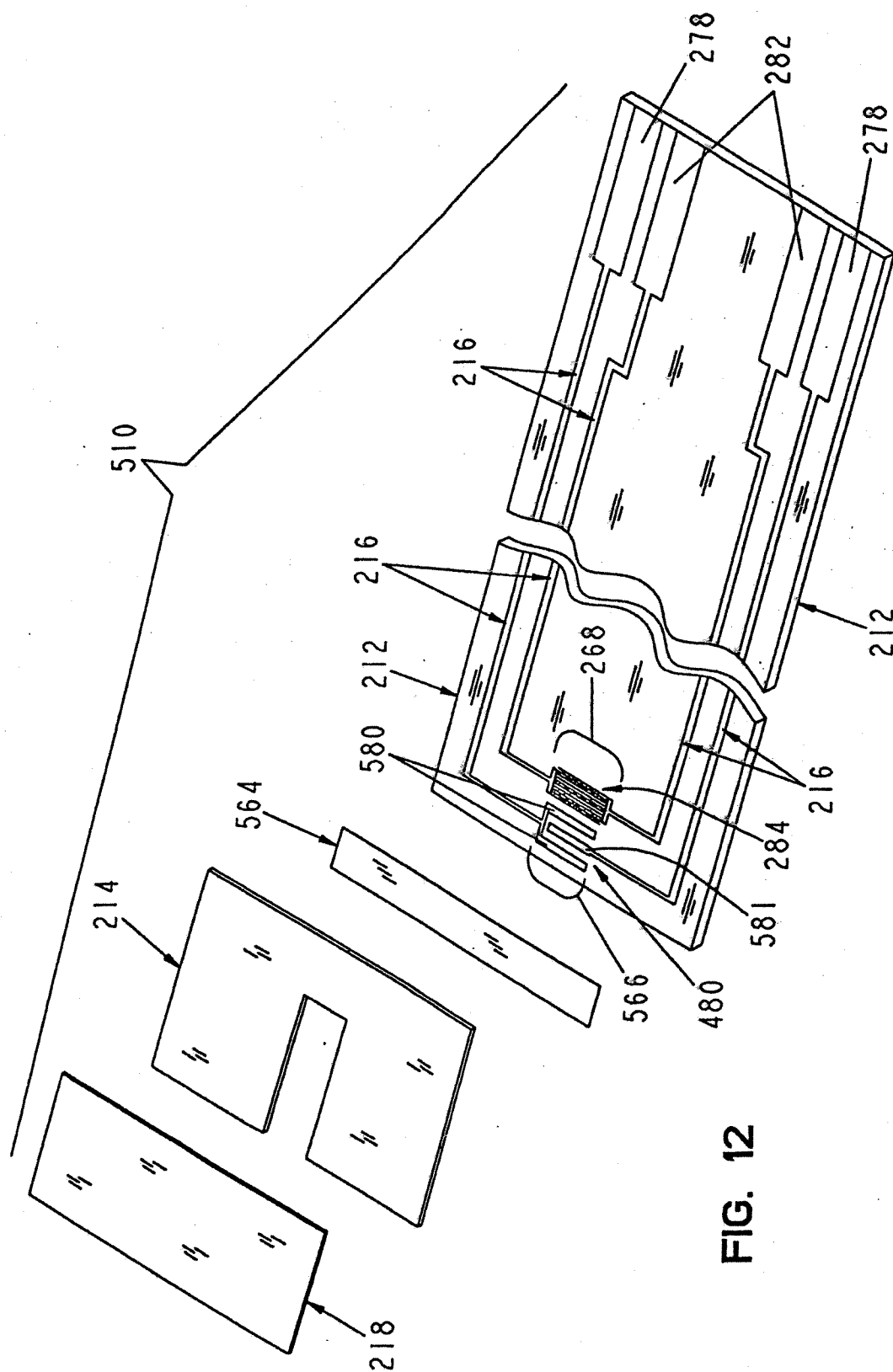


FIG. 12

9/20

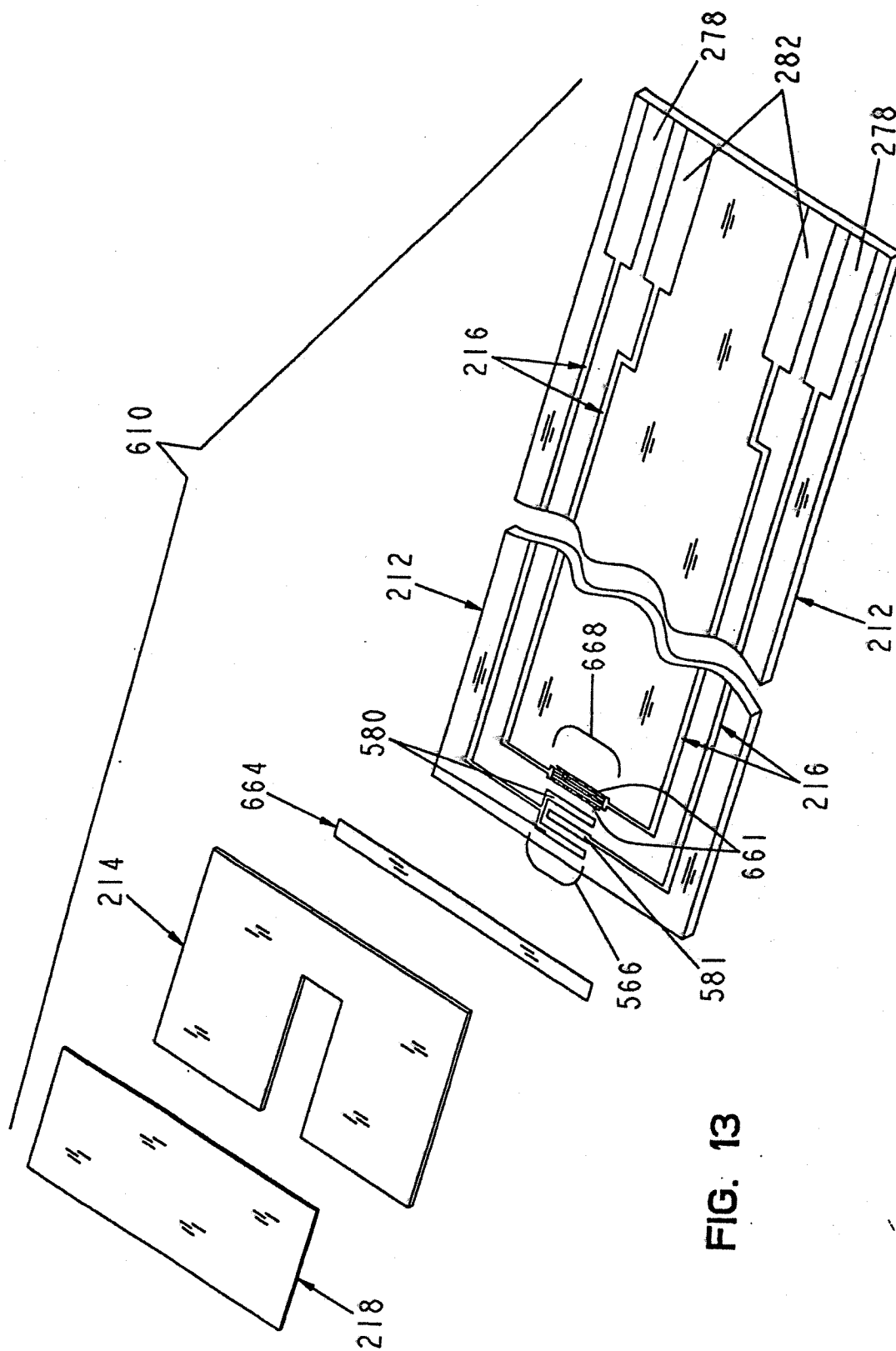


FIG. 13

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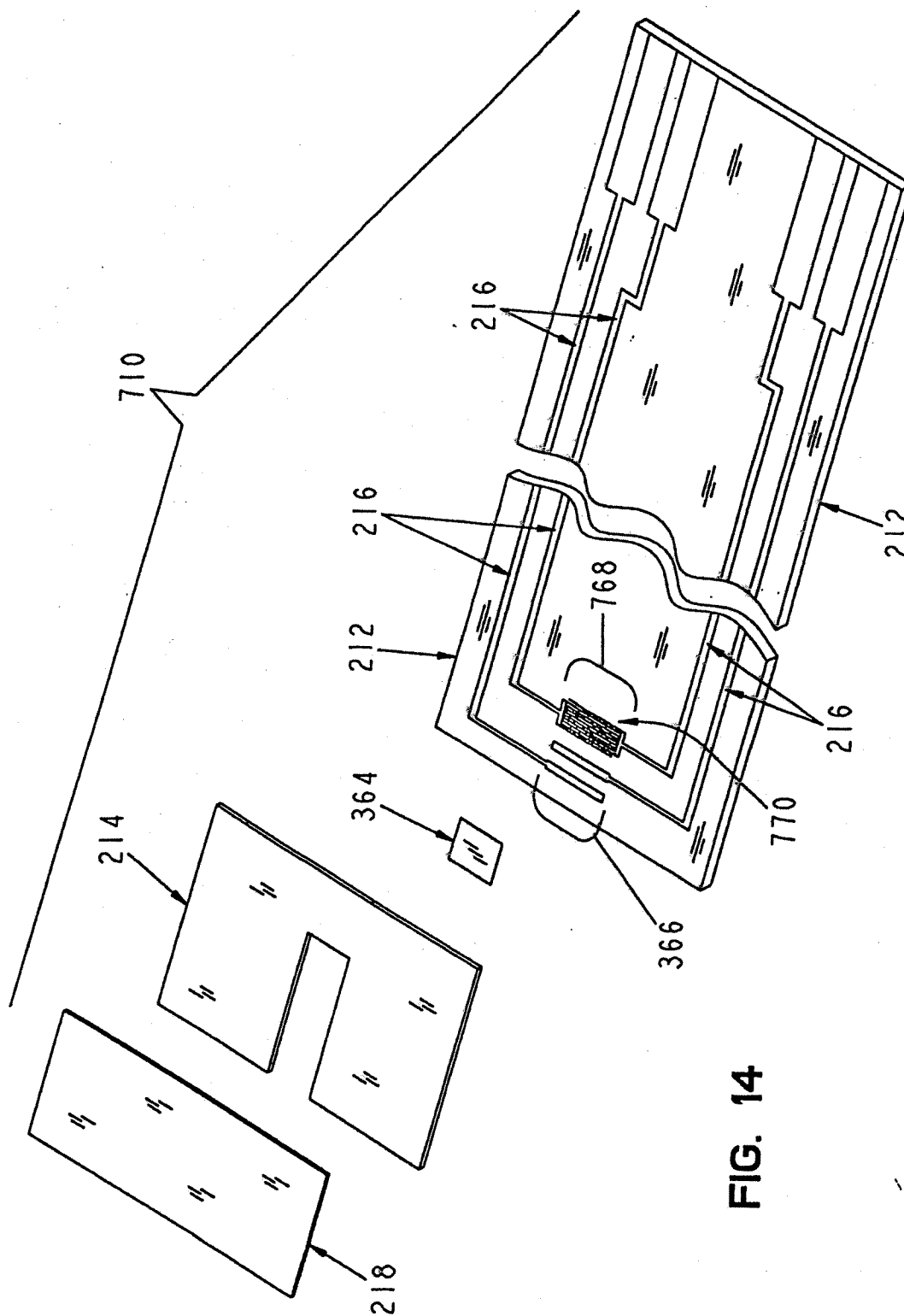


FIG. 14

11/20

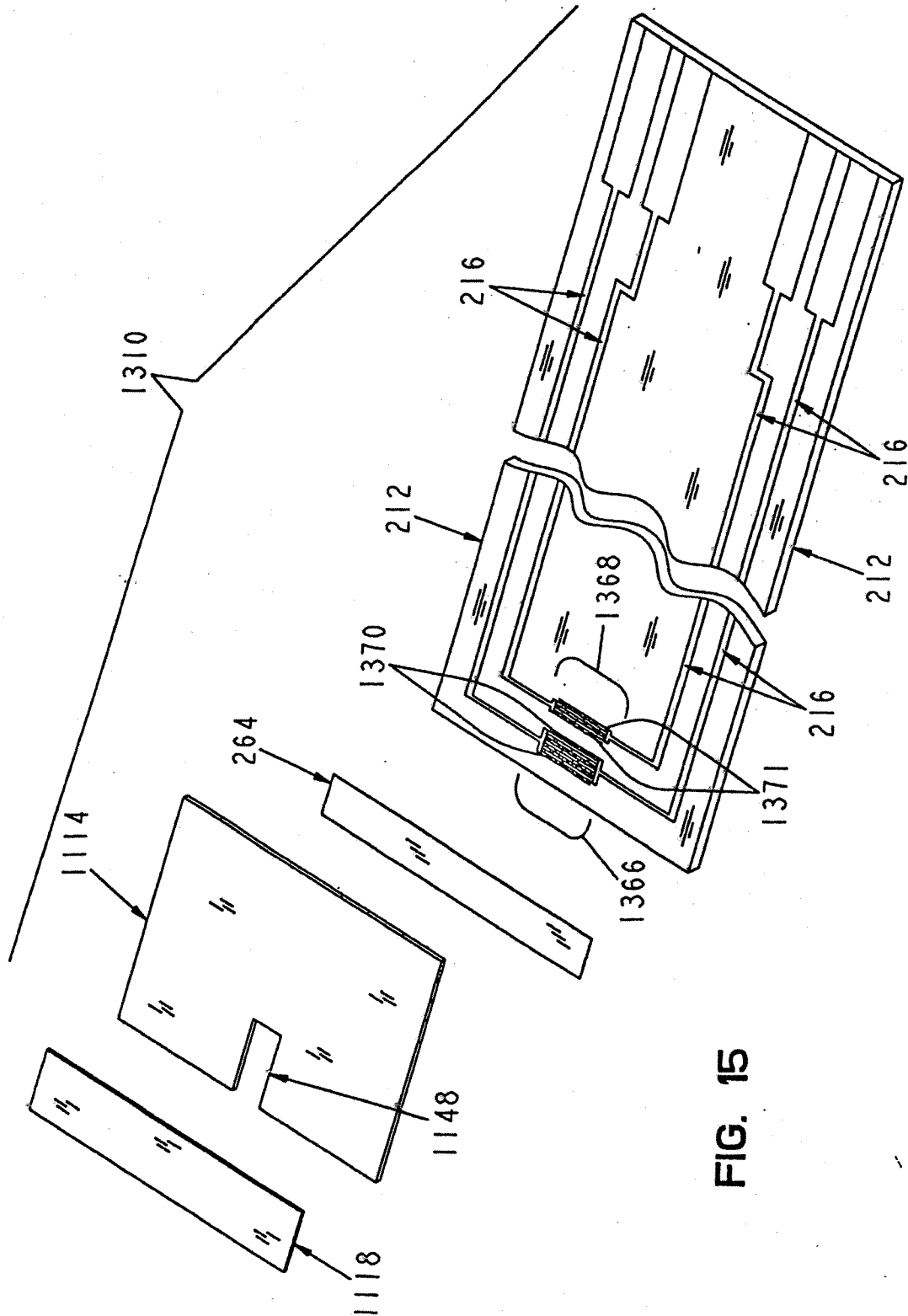


FIG. 15

12/20

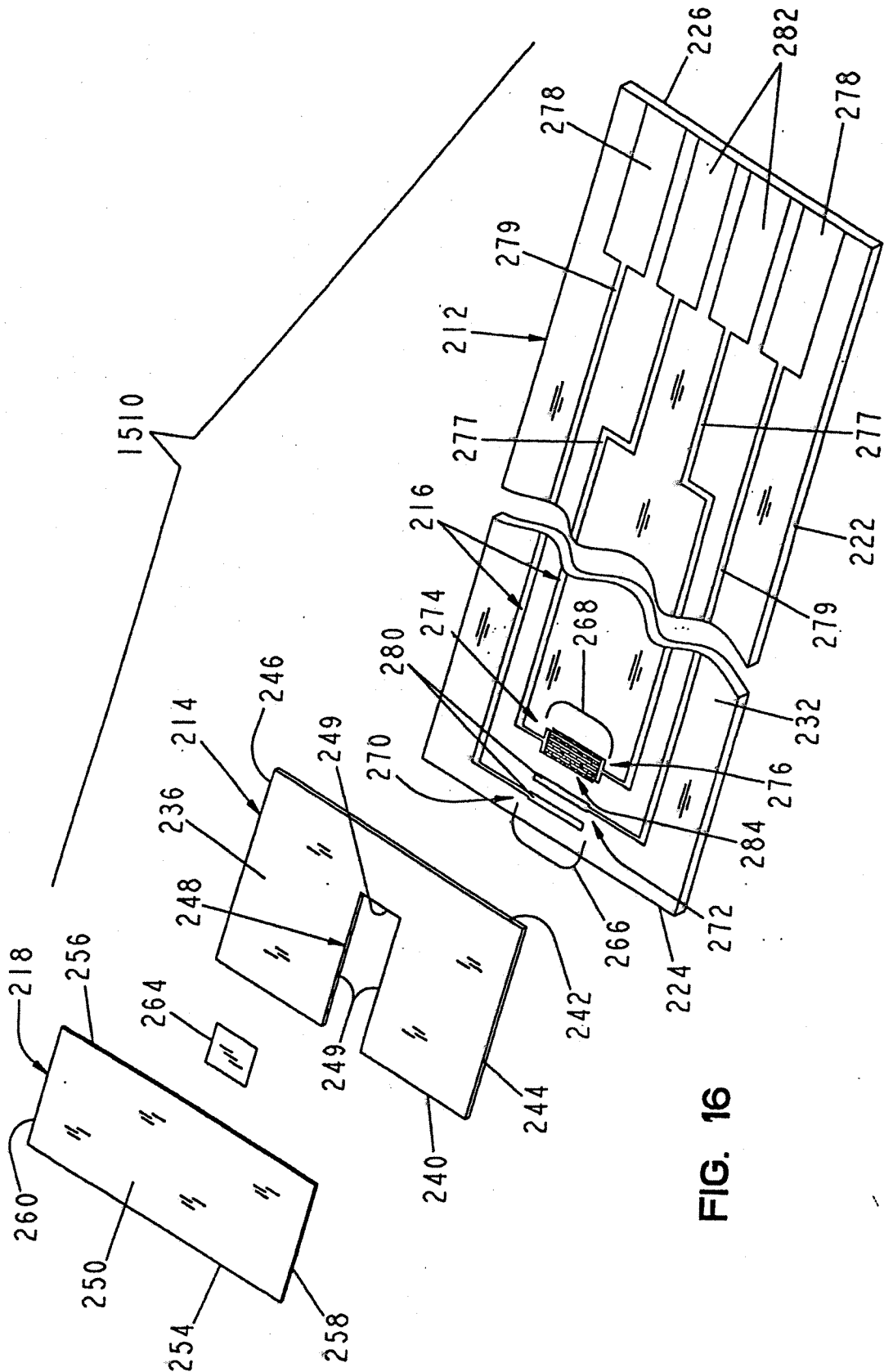
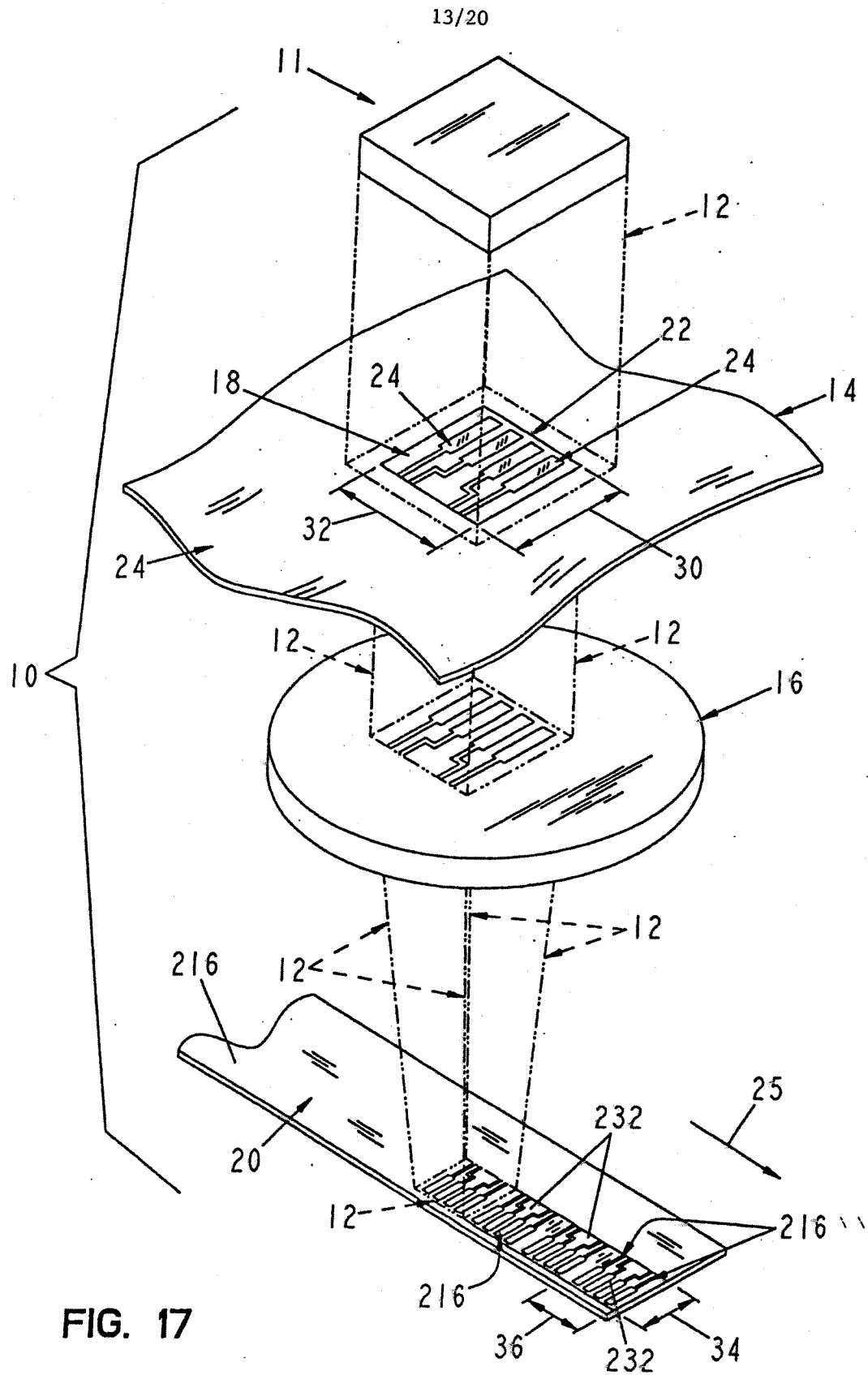
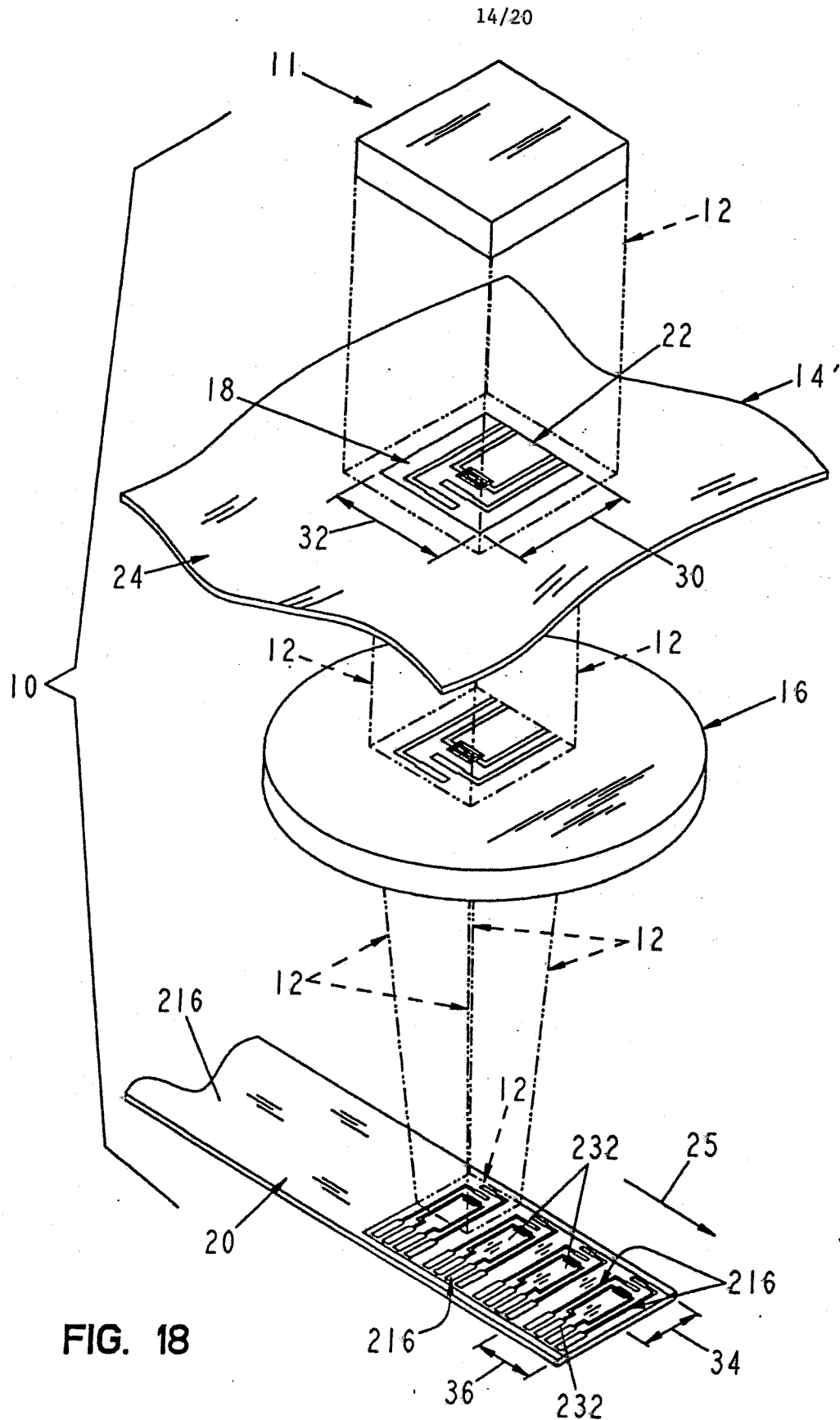


FIG. 16





15/20

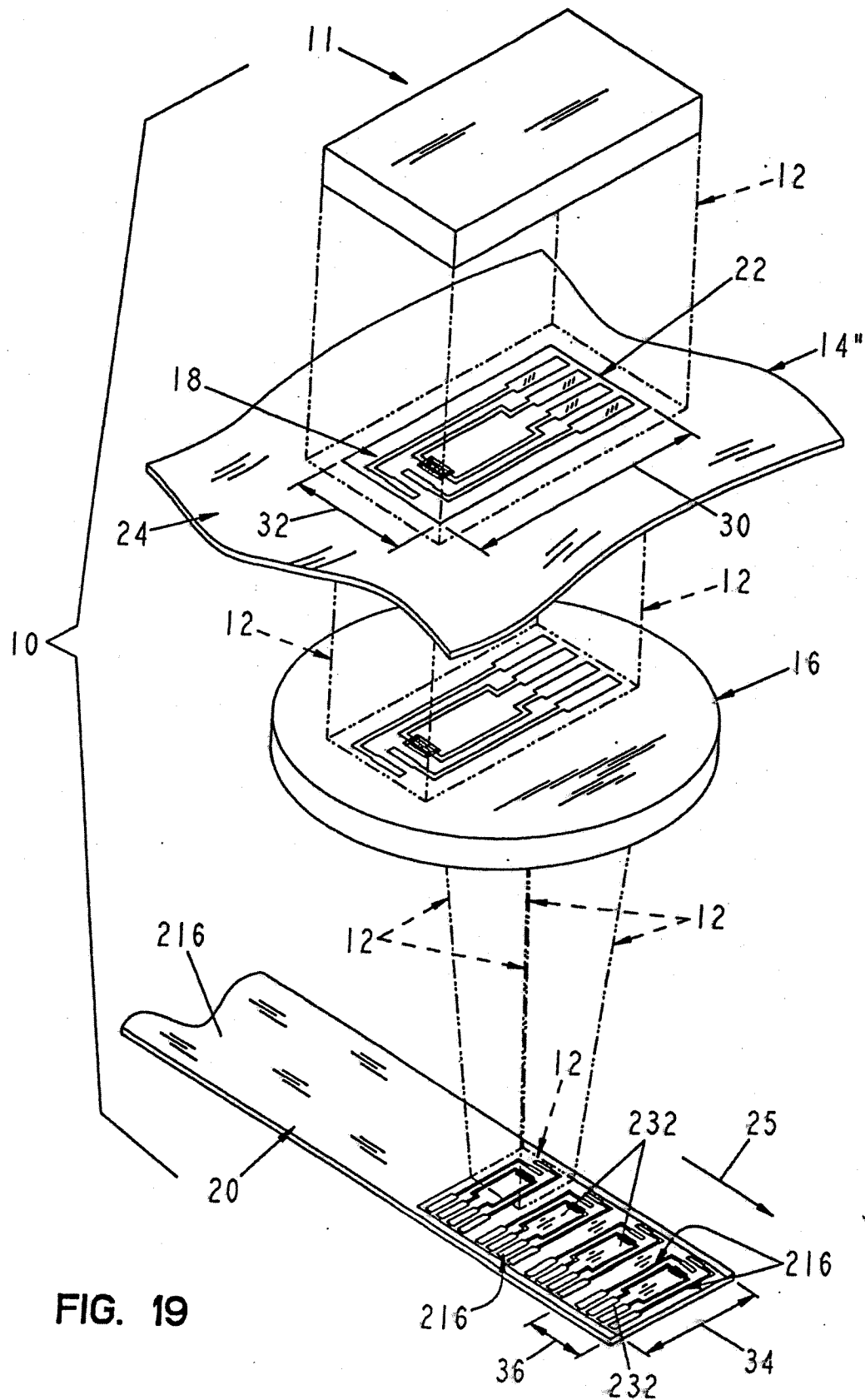
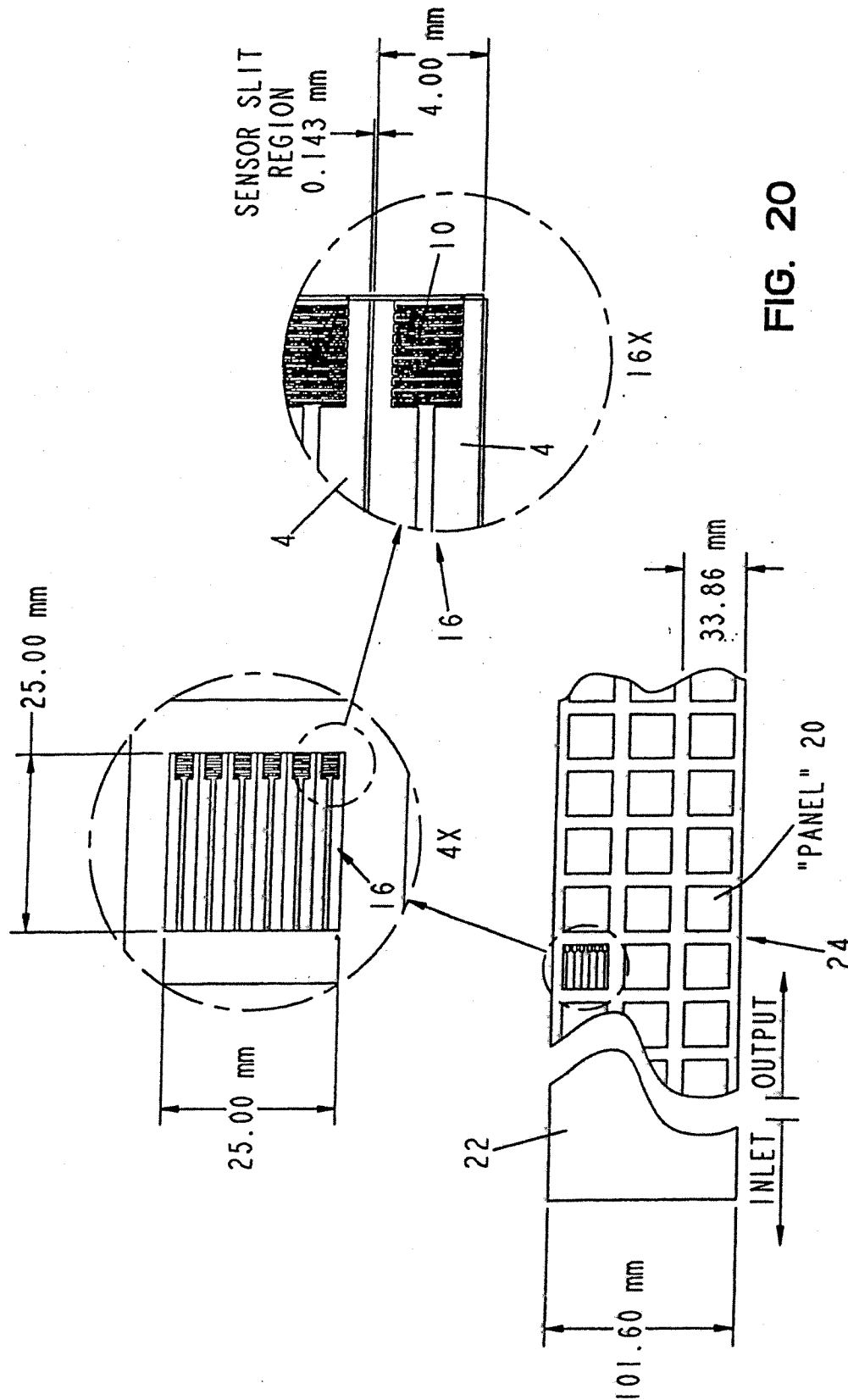


FIG. 19

16/20



17/20

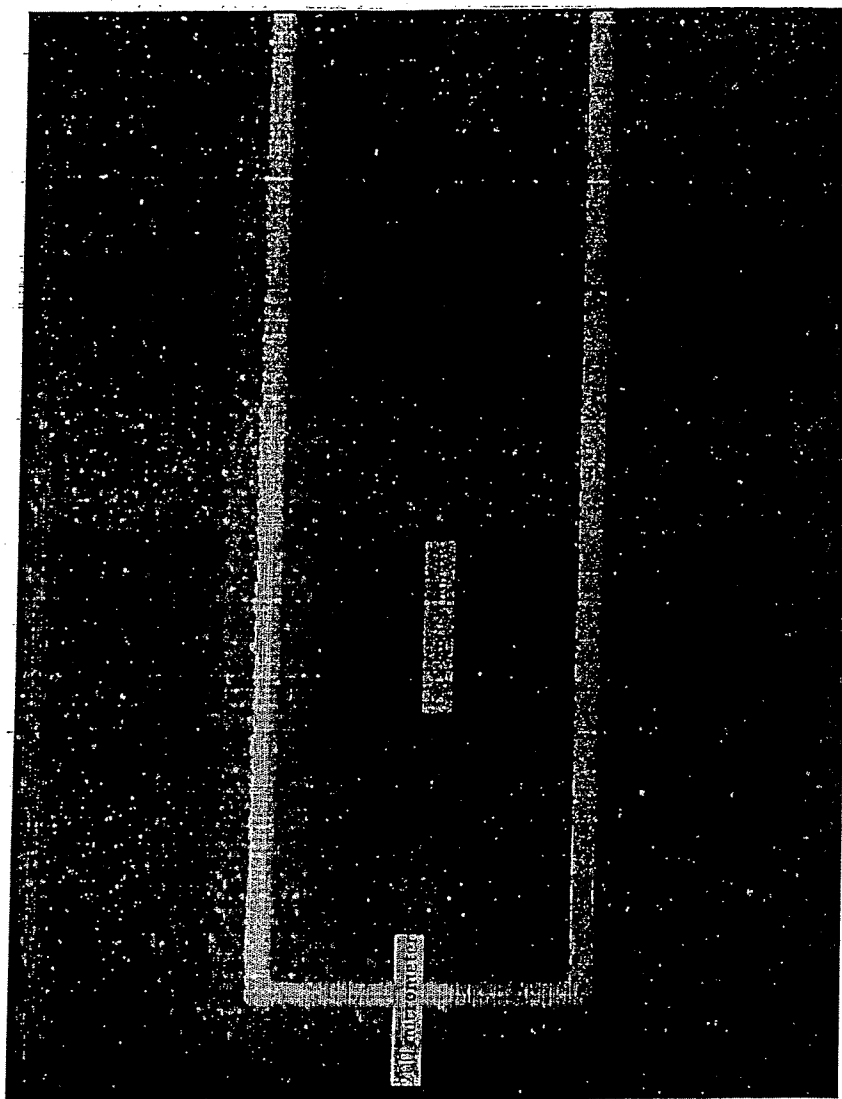


FIG. 21

18/20

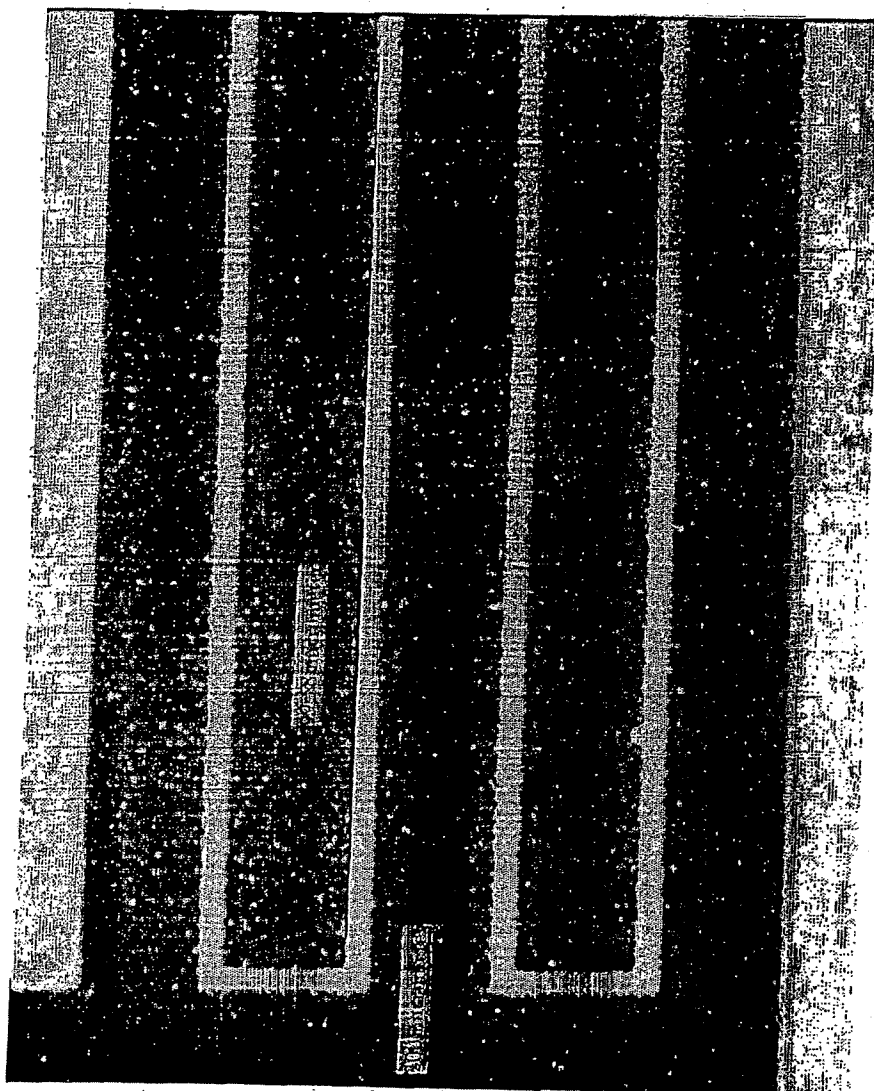


FIG. 22

19/20

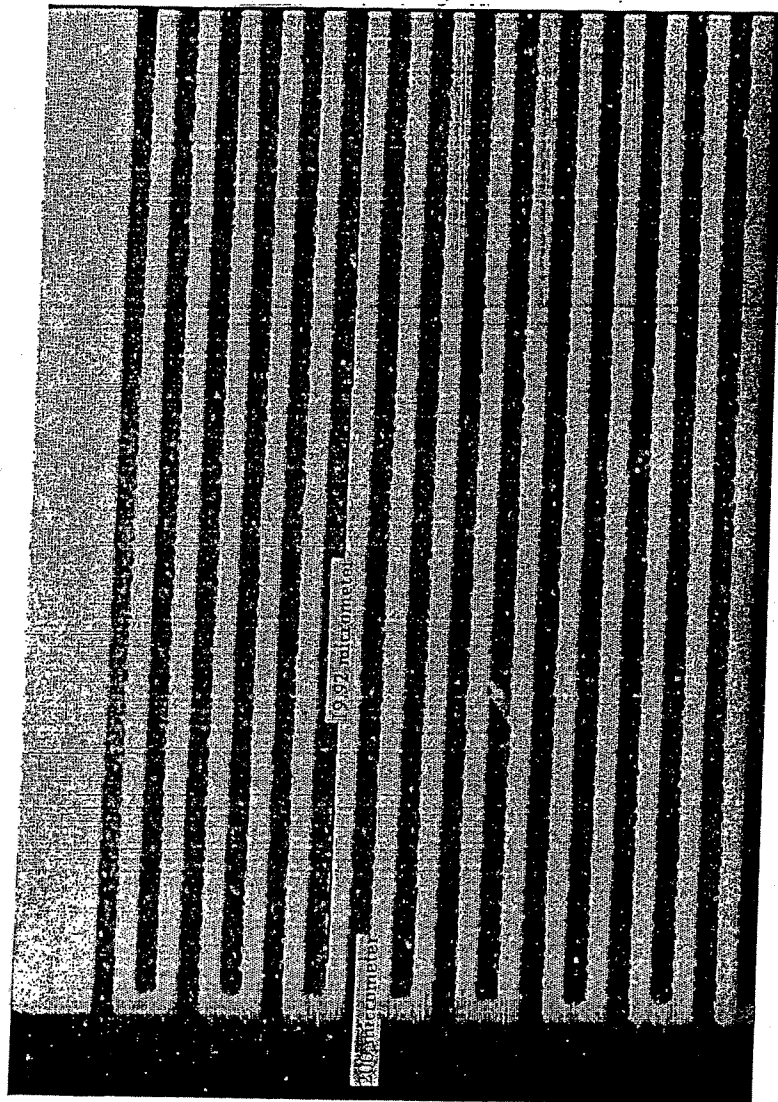


FIG. 23

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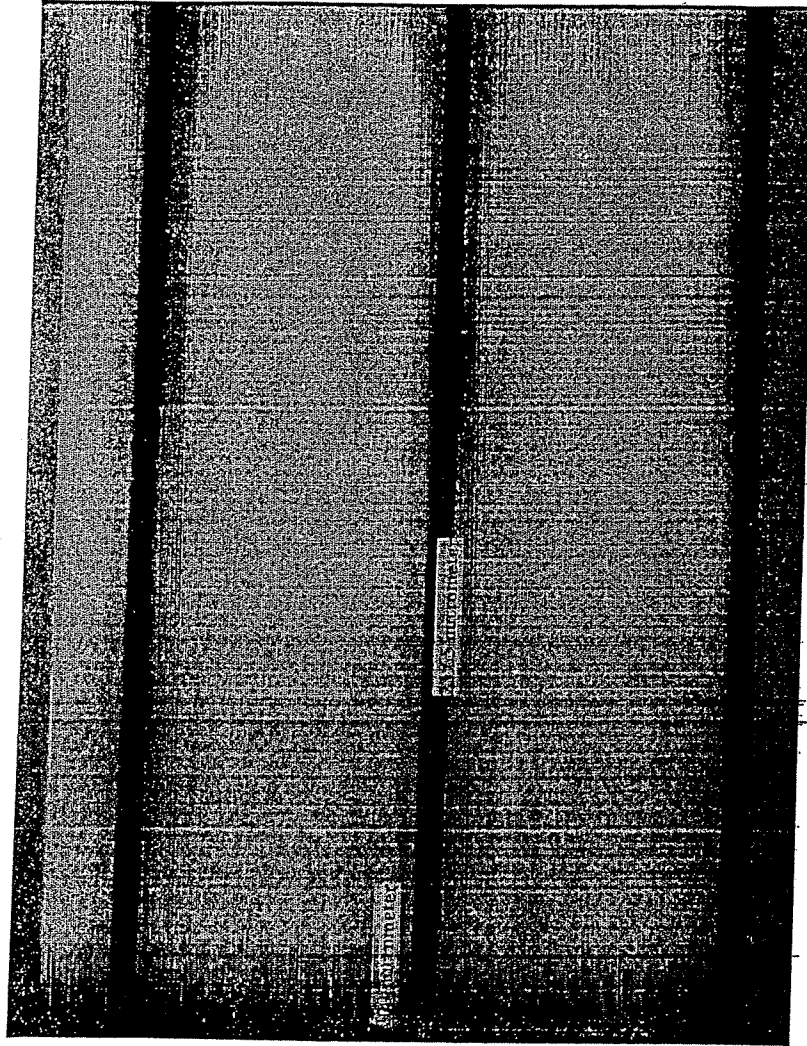


FIG. 24

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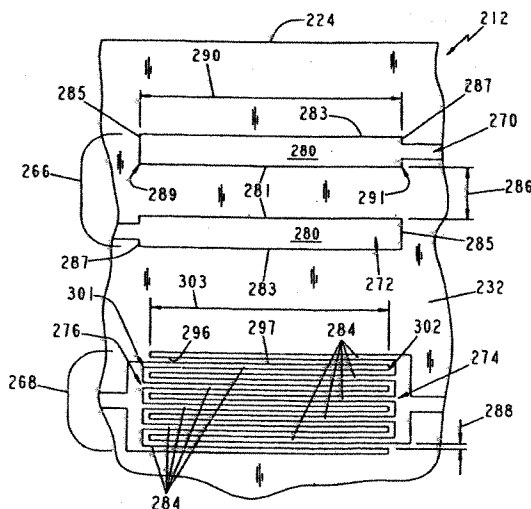
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FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI,

[Continued on next page]

(54) Title: **BIOSENSOR AND METHOD OF MAKING CROSS-REFERENCE TO RELATED APPLICATIONS**



(57) Abstract: An electrochemical biosensor (210) with electrode elements (274, 276) that possess smooth, high-quality edges (281, 283, 285, 287) with an edge definition better than 6µm. These smooth edges define gaps between electrodes, electrode traces and contact pads. Due to the remarkable edge smoothness achieved, the gaps can be quite small, which provides marked advantages in terms of test accuracy, speed and the number of different functionalities that can be packed into a single biosensor. Further, the present application provides a biosensor production method in which entire electrode patterns for the inventive biosensors can be formed all at one, in nanoseconds - without regard to the complexity of the electrode patterns or the amount of conductive material that must be ablated to form them.

WO 2005/066616 A3



SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:

10 November 2005

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/019553

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G01N27/30 C12Q1/00 B23K26/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N C12Q B23K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/25775 A (ROCHE DIAGNOSTICS CORPORATION) 12 April 2001 (2001-04-12)	1-11, 13-32, 34-41, 43,44, 48-54, 56-59, 68-72, 75-79, 82-86
Y		45-47, 73,80, 81, 87-102
A	page 4, line 26 - page 10, line 2; figures ----- -/-	12,33, 42,55, 60-67,74

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

16 August 2005

Date of mailing of the international search report

06/09/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Authorized officer

Johnson, K

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/019553

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	MEIER D J ET AL: "Laser structuring of fine lines" CIRCUITREE, vol. 13, September 2000 (2000-09), pages 36-42, XP009051440 ISSN 1059-843X	45-47, 73,80, 81, 87-102
A	the whole document	1-10, 15-17, 25-31, 36-40, 43,44, 50-53, 57-66, 68-72
X	EP 1 260 589 A (ROCHE DIAGNOSTICS GMBH; F.HOFFMANN-LA ROCHE AG) 27 November 2002 (2002-11-27)	50
Y		1-11, 13-32, 34-41, 43-54, 56-59, 68-73, 75-102
A	paragraph '0028! - paragraph '0035!; figures 1,5	12,33, 42,55, 60-67,79
Y	MEIER D J ET AL: "Laser direct patterning mass-produces microstructures" EUROPHOTONICS, vol. 6, no. 6, November 2001 (2001-11), pages 25-27, XP009051439	1-11, 13-32, 34-41, 43-54, 56-59, 68-73, 75-102
A	the whole document	60-66
X	EP 1 098 000 A (ROCHE DIAGNOSTICS CORPORATION) 9 May 2001 (2001-05-09)	1,2,4,5, 7-9,11, 13-26, 28-30, 32,34,35
A	paragraph '0038! - paragraph '0046!; figures 13-15	3,6,10, 12,27, 31,33
	----- -/-	

International Application No
PCT/US2004/019553

PCT/US2004/019553

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>DE 199 51 721 A1 (LPKF LASER & ELECTRONICS AG) 15 June 2000 (2000-06-15)</p> <p>column 1, line 52 - column 4, line 64; figures</p>	<p>1-10, 25-31, 36-40, 43, 44, 50-53, 60-66, 68, 75-78, 88-90, 92-94, 96-98, 100-102</p>
E	<p>WO 2004/113914 A (ROCHE DIAGNOSTICS GMBH) 29 December 2004 (2004-12-29) page 18, line 1 - page 23, line 20 page 13, line 16 - page 14, line 26 figures 4-7</p>	<p>1-102</p>

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/019553

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0125775	A	12-04-2001	US 6662439 B1	16-12-2003
			AU 7748300 A	10-05-2001
			CA 2386172 A1	12-04-2001
			EP 1218732 A1	03-07-2002
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EP 1260589	A	27-11-2002	US 2002192115 A1	19-12-2002
			CA 2387283 A1	25-11-2002
			EP 1260589 A2	27-11-2002
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EP 1098000	A	09-05-2001	US 2002139668 A1	03-10-2002
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			JP 2001189546 A	10-07-2001
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			US 2005161345 A1	28-07-2005
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			US 2005016846 A1	27-01-2005
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			WO 2004113909 A1	29-12-2004
			WO 2004113911 A1	29-12-2004
			WO 2005003751 A1	13-01-2005
			WO 2004113914 A1	29-12-2004
			WO 2004113915 A1	29-12-2004

Electronic Acknowledgement Receipt

EFS ID:	2472080
Application Number:	11783568
International Application Number:	
Confirmation Number:	8766
Title of Invention:	Biosensor manufacturing method
First Named Inventor/Applicant Name:	Natasha Popovich
Customer Number:	22852
Filer:	Eric Paul Raciti/Lisa Tkach
Filer Authorized By:	Eric Paul Raciti
Attorney Docket Number:	06882.0200-00
Receipt Date:	15-NOV-2007
Filing Date:	10-APR-2007
Time Stamp:	14:42:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		IDS.pdf	218172	yes	3
			ee24fdb294c2f6e7fdb3f2069bd244527c5db137		

	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Information Disclosure Statement Letter		1	2	
	Information Disclosure Statement (IDS) Filed		3	3	
Warnings:					
Information:					
2	Foreign Reference	EP1302545A2.pdf	1608426	no	25
			0a27f99754f2855a7ca189f2e7cd008a4f6f802b		
Warnings:					
Information:					
3	Foreign Reference	WO01-25775A1.pdf	1170188	no	25
			a166fa9a3a91e24062ae51a046671f370fdbf789		
Warnings:					
Information:					
4	Foreign Reference	WO2005-066616A2.pdf	5332783	no	92
			935dff588a5d9017c5e5d2560112bbd4430b144		
Warnings:					
Information:					
Total Files Size (in bytes):			8329569		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					



APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/783,568	04/10/2007	Natasha Popovich	06882.0200-00

CONFIRMATION NO. 8766

22852
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC20001-4413

Title: Biosensor manufacturing method

Publication No. US-2007-0286772-A1

Publication Date: 12/13/2007

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 1-866-217-9197.

Pre-Grant Publication Division, 703-605-4283



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/783,568

04/10/2007

Natasha Popovich

06882.0200-00

8766

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7590

04/15/2010

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

BOWMAN, ANDREW J

ART UNIT

PAPER NUMBER

1711

MAIL DATE

DELIVERY MODE

04/15/2010

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.

Office Action Summary	Application No. 11/783,568	Applicant(s) POPOVICH ET AL.	
	Examiner ANDREW BOWMAN	Art Unit 1711	

-- 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 1 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 15 November 2007.
- 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) 1-90 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) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-90 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) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17 and 55-72, drawn to a biosensor classified in class 204, subclass 403.01.
 - II. Claims 18-54 and 73-90 drawn to a method of manufacturing test strips classified in class 427, subclass 2.11.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a process that does not require producing a reel.

3.

4. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. This application contains claims directed to the following patentably distinct species. The applicant is required to make one election from each category listed below.

- i. The applicant is required to elect a specific first processing technique (as in claim(s) 2)
- ii. The applicant is required to elect a specific second processing technique (as in claim(s) 3)
- iii. The applicant is required to elect a specific third processing technique (as in claim(s) 4)
- iv. The applicant is required to elect a specific chemical component (as in claim(s) 16, 72, 90).
- v. The applicant is required to elect the first processing technique (as in claim(s) 19).

- vi. The applicant is required to elect the second processing technique (as in claim(s) 20).
- vii. The applicant is required to elect the third processing technique (as in claim(s) 21).
- viii. The applicant is required to elect a specific chemical component (as in claim(s) 33 and 47).
- ix. The applicant is required to elect a conductive layer forming technique (as in claim(s) 52).
- x. The applicant is required to elect the position of where the diffusion barrier is formed (as in claim(s) 68-70).
- xi. The applicant is required to elect the position of where the diffusion barrier is formed (as in claim(s) 86-88).

6. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would

Art Unit: 1711

not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

7. A telephone call was made to Eric Raciti on 4/12/2010 to request an oral election to the above restriction requirement, but did not result in an election being made.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

Art Unit: 1711

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW BOWMAN whose telephone number is (571)270-5342. The examiner can normally be reached on Monday through Friday (7:30 to 5:00)EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Barr can be reached on 571-272-1414. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1711

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.

/Michael Barr/
Supervisory Patent Examiner, Art Unit 1711

Andrew J Bowman
Examiner
Art Unit 1711

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Natasha POPOVICH et al.) Group Art Unit: 1711
)
Application No.: 11/783,568) Examiner: BOWMAN, Andrew J.
)
Filed: April 10, 2007)
) Confirmation No.: 8766
For: BIOSENSOR MANUFACTURING)
METHOD)

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

Sir:

**RESPONSE TO RESTRICTION REQUIREMENT AND
REQUIREMENT FOR ELECTION OF SPECIES**

In an Office Action dated April 15, 2010 (hereinafter, "Office Action"), the
Examiner requires restriction under 35 U.S.C. § 121 between:

- I. Claims 1-17 and 55-72, drawn to a biosensor; and
- II. Claims 18-54 and 73-90 drawn to a method of manufacturing test strips.

Office Action, p. 2.

In reply to the Office Action, the period for response having been extended by two months to July 15, 2010, by the Petition for Extension of Time and fee submitted concurrently herewith, Applicant elects to prosecute Group II, drawn to a method of manufacturing test strips, **without traverse**. Claims 18-54 and 73-90 read on the elected method.

The Examiner also requires an election of species from each category listed below:

- i. The applicant is required to elect a specific first processing technique (as in claim(s) 2);
- ii. The applicant is required to elect a specific second processing technique (as in claim(s) 3);
- iii. The applicant is required to elect a specific third processing technique (as in claim(s) 4);
- iv. The applicant is required to elect a specific chemical component (as in claim(s) 16, 72, 90);
- v. The applicant is required to elect the first processing technique (as in claim(s) 19);
- vi. The applicant is required to elect the second processing technique (as in claim(s) 20);
- vii. The applicant is required to elect the third processing technique (as in claim(s) 21);
- viii. The applicant is required to elect a specific chemical component (as in claim(s) 33 and 47);
- ix. The applicant is required to elect a conductive layer forming technique (as in claim(s) 52);
- x. The applicant is required to elect the position of where the diffusion barrier is formed (as in claim(s) 68-70); and

- xi. The applicant is required to elect the position of where the diffusion barrier is formed (as in claim(s) 86-88).

Id. at pp. 4, 5.

Given that the Applicant has elected Group II (claims 18-54 and 73-90), it is respectfully submitted that only election categories iv-ix and xi apply in the instant matter.

I. Election with Traverse

Applicant respectfully traverses the requirement for election of species for at least the reasons set forth below. In particular, Applicant traverses the requirement because: i) it does not identify a generic claim or indicate that no claims are generic; ii) it improperly breaks up the Markush groups recited in claims 19-21, 33, 47, 52, and 90; iii) a search of all species recited in the claims 86-88 may be made without serious burden.

To be fully responsive, however, Applicant elects, **with traverse**, to prosecute the alleged species of the following election categories:

- iv. "ruthenium hexamine" as a chemical component (claim 90);
- v. "laser ablation" as the first processing technique (claim 19);
- vi. "laser ablation" as the second processing technique (claim 20);
- vii. "laser ablation" as the third processing technique (claim 21);
- viii. "ruthenium hexamine" as a chemical component (claims 33 and 47);
- ix. "screen printing" as a conductive layer forming technique (claim 52), and;
- xi. forming the diffusion barrier between a working electrode and a counter electrode (claim 86).

a. The Requirement for Election of Species is Improper Because It Does Not Identify a Generic Claim or Indicate That No Claims Are Generic

Applicant traverses the requirement for election of species on the grounds that the Office Action fails to identify a generic claim or indicate that no claims are generic.

Where restriction between species is appropriate Action as follows should be taken:

(A) Identify generic claims or indicate that no generic claims are present. See M.P.E.P. § 806.04(d) for definition of a generic claim...

M.P.E.P. 809.02(a).

The Examiner has failed to identify whether or not any of the pending claims are generic to the identified species. As a result, Applicant is at a loss as to how to respond to the Office Action, as it is incomplete. Applicant believes that the identification of such claims as generic would advance prosecution, and respectfully request that the Examiner reconsider his position on this issue.

Applicant submits that claims 18-22, 26, 29, 31-37, 41, 44, 46-54, 73-78, and 83-90 should be considered generic since they meet the definition of a generic claim set forth in M.P.E.P. 806.04(d), e.g., they require no material element additional to those required by the dependant (species) claims.

b. The Requirement for Election of Species Improperly Breaks Up the Alternative Groups Recited in Claims 19-21, 33, 47, 52, and 90

Applicant further traverses the requirement for election of species because it breaks up the alternative groups recited in claims 19-21, 33, 47, 52, and 90. Dependent claims 19, 20, and 21 are Markush claims that each recite four processing techniques. See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). Dependent claims 33, 47,

and 90 are also Markush claims that each recite four chemical compounds. *Id.*

Dependent claim 52 is another Markush claim that recites five conductive layer forming techniques. *Id.* The election requirement contravenes the whole purpose of groups reciting alternative elements, which deems such groups proper if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. *Id.*

The M.P.E.P. states that “[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions.” M.P.E.P. 803.02.

Dependent claims 19, 20, 21, 33, 47, and 90 include only four members in each Markush group, and claim 52 includes five members. For claims 19, 20, and 21, all members are methods for removing part of a conductive layer, and are therefore related. Likewise, all members of claims 33, 47, and 90 are related chemical compounds, and the members of claim 52 are related techniques used for forming a conductive layer. Because the members of the Markush groups in claims 19, 20, 21, 33, 47, 52, and 90 are few in number and related, a search and examination of these claims can be made without a serious burden. As such, Applicant respectfully requests withdrawal of the requirement for election of species for election categories iv-ix.

c. The Requirements for Election of Species is Improper Because Search of All Species Recited in the Claims 86-88 May be Made Without Serious Burden

Applicants further traverse the requirement for election of species because all of the species recited in the present claims 86-88 may be made without serious burden. In election category xi, the Examiner requires election between three positions of a diffusion barrier relative to various electrodes, as recited in claims 86-88. See Office Action, p. 5. However, Applicant suggests that the three recited positions will likely require search and consideration of the same classes and keywords.

The M.P.E.P. explains that in order to assert that a search of all the species is a serious burden, the Examiner must show by appropriate explanation one of the following: (a) a separate classification thereof; (b) a separate status in the art when they are classifiable together; or (c) a different field of search. M.P.E.P. 808.02. Where the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions. *Id.*

Here, the Examiner cannot establish that examination of the three recited positions together would constitute an undue burden. Indeed, Applicant submits that a proper search of a diffusion barrier position relative to an electrode would necessarily encompass the other recited positions. Accordingly, Applicant respectfully requests that the full scope of the claimed invention as encompassed by claims 86-88 be examined without a requirement for election of species.

II. Conclusion

Applicant asks the Examiner to withdraw the applied requirement for election of species in favor of a more reasonable requirement. If the Examiner chooses to maintain the election requirement, however, Applicant expects that the Examiner will, if the elected species is found allowable, continue to examine the full scope of the subject matter to the extent necessary to determine the patentability thereof, *i.e.*, extending the search to a reasonable number of the non-elected species as required by M.P.E.P. 803.02 and 35 U.S.C. § 121.

In view of the foregoing remarks, Applicants respectfully submit that the election of species requirement is in error and should be withdrawn.

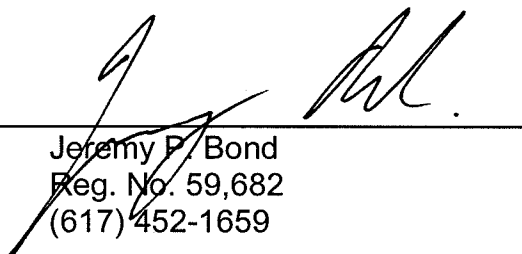
Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: July 15, 2010

By: _____


Jeremy P. Bond
Reg. No. 59,682
(617) 452-1659

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Natasha POPOVICH et al.	)	Group Art Unit: 1711
	)	
Application No.: 11/783,568	)	Examiner: BOWMAN, Andrew J.
	)	
Filed: April 10, 2007	)	
	)	Confirmation No.: 8766
For: BIOSENSOR MANUFACTURING	)	
METHOD	)	

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

Sir:

PETITION FOR EXTENSION OF TIME

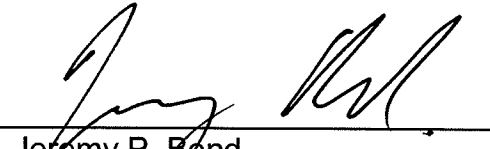
Applicant petitions for a two-month extension of time to file a reply to the Office
Action of April 15, 2010. A fee of \$490.00 is enclosed.

Please grant any additional extensions of time required to enter the attached
reply and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: July 15, 2010

By: 
Jeremy P. Bond
Reg. No. 50,682
(617) 452-1659

Electronic Patent Application Fee Transmittal

Application Number:	11783568			
Filing Date:	10-Apr-2007			
Title of Invention:	Biosensor manufacturing method			
First Named Inventor/Applicant Name:	Natasha Popovich			
Filer:	Nicole Valtz/marijke abbes			
Attorney Docket Number:	06882.0200-00			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Page 235 of 375				
Extension - 2 months with \$0 paid	1252	1	490	490

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				490

Electronic Acknowledgement Receipt

EFS ID:	8019820
Application Number:	11783568
International Application Number:	
Confirmation Number:	8766
Title of Invention:	Biosensor manufacturing method
First Named Inventor/Applicant Name:	Natasha Popovich
Customer Number:	22852
Filer:	Nicole Valtz/marijke abbes
Filer Authorized By:	Nicole Valtz
Attorney Docket Number:	06882.0200-00
Receipt Date:	15-JUL-2010
Filing Date:	10-APR-2007
Time Stamp:	10:00:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$490
RAM confirmation Number	9072
Deposit Account	
Authorized User	

File Listing:

Page 237 of 375

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Response to Election / Restriction Filed	Response.pdf	257016 e29b8ae7c7b70a79eee2e4aea26622198497cbe7	no	7
Warnings:					
Information:					
2	Extension of Time	EOT.pdf	29313 8a3b6969020ca3f773e9ad0878745c0a8a29ea73	no	1
Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	30328 45aa95f339723794e4ef134c3d3f4f77ae94f12c	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			316657		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					



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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/783,568

04/10/2007

Natasha Popovich

06882.0200-00

8766

22852

7590

09/15/2010

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

BOWMAN, ANDREW J

ART UNIT

PAPER NUMBER

1711

MAIL DATE

DELIVERY MODE

09/15/2010

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.

Office Action Summary	Application No. 11/783,568	Applicant(s) POPOVICH ET AL.	
	Examiner ANDREW BOWMAN	Art Unit 1711	

-- 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 1 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 15 July 2010.
- 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) 1-90 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) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-90 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) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Upon examination of the elected species, the examiner has determined that with regards to claims 19-21, the elected species (laser ablation for all) is not congruent with the claim language of claim 1, wherein the processes are different from one another. As such, the initial restriction requirement is done away with and the current restriction requirements are pending. The applicant is advised to either elect species that make the examination of claim 18 possible or to call the examiner at the number listed below. Otherwise, claim 18 will be rejected based on a 101-type rejection.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17 and 55-72, drawn to a biosensor classified in class 204, subclass 403.01.
 - II. Claims 18-54 and 73-90 drawn to a method of manufacturing test strips classified in class 427, subclass 2.11.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a process that does not require producing a reel.
3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a

Art Unit: 1711

serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species.

The applicant is required to make one election from each category listed below.

- i. The applicant is required to elect a specific first processing technique (as in claim(s) 2)
- ii. The applicant is required to elect a specific second processing technique (as in claim(s) 3)
- iii. The applicant is required to elect a specific third processing technique (as in claim(s) 4)
- iv. The applicant is required to elect a specific chemical component (as in claim(s) 16, 72, 90).
- v. The applicant is required to elect the first processing technique (as in claim(s) 19).
- vi. The applicant is required to elect the second processing technique (as in claim(s) 20).

- vii. The applicant is required to elect the third processing technique (as in claim(s) 21).
- viii. The applicant is required to elect a specific chemical component (as in claim(s) 33 and 47).
- ix. The applicant is required to elect a conductive layer forming technique (as in claim(s) 52).
- x. The applicant is required to elect the position of where the diffusion barrier is formed (as in claim(s) 68-70).
- xi. The applicant is required to elect the position of where the diffusion barrier is formed (as in claim(s) 86-88).

5. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are considered to be generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. A telephone call was made to Eric Raciti on 4/12/2010 to request an oral election to the above restriction requirement, but did not result in an election being made.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

Art Unit: 1711

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW BOWMAN whose telephone number is (571)270-5342. The examiner can normally be reached on Monday through Friday (7:30 to 5:00)EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Barr can be reached on 571-272-1414. 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.

/Michael Barr/
Supervisory Patent Examiner, Art Unit 1711

Andrew J Bowman
Examiner
Art Unit 1711

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Natasha POPOVICH et al.	)	Group Art Unit: 1711
	)	
Application No.: 11/783,568	)	Examiner: BOWMAN, Andrew J.
	)	
Filed: April 10, 2007	)	Confirmation No.: 8766
	)	
For: BIOSENSOR MANUFACTURING	)	<i>Via EFS Web</i>
METHOD	)	

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

Sir:

**RESPONSE TO RESTRICTION REQUIREMENT AND
REQUIREMENT FOR ELECTION OF SPECIES**

In an Office Action dated September 15, 2010 (hereinafter, "Office Action"), the Examiner alleges that, with regards to claims 19-21, the species previously elected by the Applicant (in a Response to Restriction Requirement mailed July 15, 2010) is not congruent with the language of claim 1. Office Action, p. 2. Applicant respectfully disagrees. As provided in the as-filed specification, the first, second, and third processing techniques can include laser ablation. For example, Fig. 4B of the as-filed specification shows a test strip having a kerf 101 that can be formed by a laser ablation process and a kerf 103 that can be formed by a different laser ablation process. Singulating the test strip can include a third laser ablation process.

The Examiner also requires restriction under 35 U.S.C. § 121 between:

- I. Claims 1-17 and 55-72, drawn to a biosensor; and

- II. Claims 18-54 and 73-90 drawn to a method of manufacturing test strips.

Id.

In reply to the Office Action, the period for response having been extended by one month to November 15, 2010, by the Petition for Extension of Time and fee submitted concurrently herewith, Applicant elects to prosecute Group II, drawn to a method of manufacturing test strips, **without traverse**. Claims 18-54 and 73-90 read on the elected method.

The Examiner also requires an election of species from each category listed below:

- i. The applicant is required to elect a specific first processing technique (as in claim(s) 2);
- ii. The applicant is required to elect a specific second processing technique (as in claim(s) 3);
- iii. The applicant is required to elect a specific third processing technique (as in claim(s) 4);
- iv. The applicant is required to elect a specific chemical component (as in claim(s) 16, 72, 90);
- v. The applicant is required to elect the first processing technique (as in claim(s) 19);
- vi. The applicant is required to elect the second processing technique (as in claim(s) 20);

- vii. The applicant is required to elect the third processing technique (as in claim(s) 21);
- viii. The applicant is required to elect a specific chemical component (as in claim(s) 33 and 47);
- ix. The applicant is required to elect a conductive layer forming technique (as in claim(s) 52);
- x. The applicant is required to elect the position of where the diffusion barrier is formed (as in claim(s) 68-70); and
- xi. The applicant is required to elect the position of where the diffusion barrier is formed (as in claim(s) 86-88).

Id. at pp. 4, 5.

Given that the Applicant has elected Group II (claims 18-54 and 73-90), it is respectfully submitted that only election categories iv-ix and xi apply in the instant matter.

I. Election with Traverse

Applicant respectfully traverses the requirement for election of species for at least the reasons set forth below. In particular, Applicant traverses the requirement because: i) it does not identify a generic claim or indicate that no claims are generic; ii) it improperly breaks up the Markush groups recited in claims 19-21, 33, 47, 52, and 90; iii) a search of all species recited in the claims 86-88 may be made without serious burden.

To be fully responsive, however, Applicant elects, **with traverse**, to prosecute the alleged species of the following election categories:

- iv. "ruthenium hexamine" as a chemical component (claim 90);
- v. "laser ablation" as the first processing technique (claim 19);

- vi. "laser ablation" as the second processing technique (claim 20);
- vii. "laser ablation" as the third processing technique (claim 21);
- viii. "ruthenium hexamine" as a chemical component (claims 33 and 47);
- ix. "screen printing" as a conductive layer forming technique (claim 52), and;
- xi. forming the diffusion barrier between a working electrode and a counter electrode (claim 86).

a. The Requirement for Election of Species is Improper Because It Does Not Identify a Generic Claim or Indicate That No Claims Are Generic

Applicant traverses the requirement for election of species on the grounds that the Office Action fails to identify a generic claim or indicate that no claims are generic.

Where restriction between species is appropriate Action as follows should be taken:

(A) Identify generic claims or indicate that no generic claims are present. See M.P.E.P. § 806.04(d) for definition of a generic claim...

M.P.E.P. 809.02(a).

The Examiner has failed to identify whether or not any of the pending claims are generic to the identified species. As a result, Applicant is at a loss as to how to respond to the Office Action, as it is incomplete. Applicant believes that the identification of such claims as generic would advance prosecution, and respectfully request that the Examiner reconsider his position on this issue.

Applicant submits that claims 18-22, 26, 29, 31-37, 41, 44, 46-54, 73-78, and 83-90 should be considered generic since they meet the definition of a generic claim set

forth in M.P.E.P. 806.04(d), e.g., they require no material element additional to those required by the dependant (species) claims.

b. The Requirement for Election of Species Improperly Breaks Up the Alternative Groups Recited in Claims 19-21, 33, 47, 52, and 90

Applicant further traverses the requirement for election of species because it breaks up the alternative groups recited in claims 19-21, 33, 47, 52, and 90. Dependent claims 19, 20, and 21 are Markush claims that each recite four processing techniques. See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). Dependent claims 33, 47, and 90 are also Markush claims that each recite four chemical compounds. *Id.* Dependent claim 52 is another Markush claim that recites five conductive layer forming techniques. *Id.* The election requirement contravenes the whole purpose of groups reciting alternative elements, which deems such groups proper if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. *Id.*

The M.P.E.P. states that “[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions.” M.P.E.P. 803.02.

Dependent claims 19, 20, 21, 33, 47, and 90 include only four members in each Markush group, and claim 52 includes five members. For claims 19, 20, and 21, all members are methods for removing part of a conductive layer, and are therefore related. Likewise, all members of claims 33, 47, and 90 are related chemical

compounds, and the members of claim 52 are related techniques used for forming a conductive layer. Because the members of the Markush groups in claims 19, 20, 21, 33, 47, 52, and 90 are few in number and related, a search and examination of these claims can be made without a serious burden. As such, Applicant respectfully requests withdrawal of the requirement for election of species for election categories iv-ix.

c. The Requirements for Election of Species is Improper Because Search of All Species Recited in the Claims 86-88 May be Made Without Serious Burden

Applicants further traverse the requirement for election of species because all of the species recited in the present claims 86-88 may be made without serious burden. In election category xi, the Examiner requires election between three positions of a diffusion barrier relative to various electrodes, as recited in claims 86-88. See Office Action, p. 5. However, Applicant suggests that the three recited positions will likely require search and consideration of the same classes and keywords.

The M.P.E.P. explains that in order to assert that a search of all the species is a serious burden, the Examiner must show by appropriate explanation one of the following: (a) a separate classification thereof; (b) a separate status in the art when they are classifiable together; or (c) a different field of search. M.P.E.P. 808.02. Where the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions. *Id.*

Here, the Examiner cannot establish that examination of the three recited positions together would constitute an undue burden. Indeed, Applicant submits that a proper search of a diffusion barrier position relative to an electrode would necessarily

encompass the other recited positions. Accordingly, Applicant respectfully requests that the full scope of the claimed invention as encompassed by claims 86-88 be examined without a requirement for election of species.

II. Conclusion

Applicant asks the Examiner to withdraw the applied requirement for election of species in favor of a more reasonable requirement. If the Examiner chooses to maintain the election requirement, however, Applicant expects that the Examiner will, if the elected species is found allowable, continue to examine the full scope of the subject matter to the extent necessary to determine the patentability thereof, *i.e.*, extending the search to a reasonable number of the non-elected species as required by M.P.E.P. 803.02 and 35 U.S.C. § 121.

In view of the foregoing remarks, Applicants respectfully submit that the election of species requirement is in error and should be withdrawn.

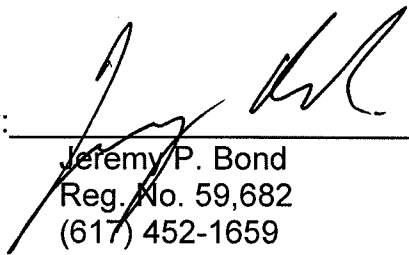
Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: November 11, 2010

By: _____


Jeremy P. Bond
Reg. No. 59,682
(617) 452-1659

Electronic Patent Application Fee Transmittal				
Application Number:		11783568		
Filing Date:		10-Apr-2007		
Title of Invention:		Biosensor manufacturing method		
First Named Inventor/Applicant Name:		Natasha Popovich		
Filer:		Jeremy Peter Bond		
Attorney Docket Number:		06882.0200-00		
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with \$0 paid	Page 255 of 375	1	130	130

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				130

Electronic Acknowledgement Receipt

EFS ID:	8817087
Application Number:	11783568
International Application Number:	
Confirmation Number:	8766
Title of Invention:	Biosensor manufacturing method
First Named Inventor/Applicant Name:	Natasha Popovich
Customer Number:	22852
Filer:	Jeremy Peter Bond
Filer Authorized By:	
Attorney Docket Number:	06882.0200-00
Receipt Date:	11-NOV-2010
Filing Date:	10-APR-2007
Time Stamp:	14:58:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 130
RAM confirmation Number	11887
Deposit Account	
Authorized User	

File Listing:

Page 257 of 375

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1		ResponseEOT.pdf	309968 684dbb51c1effc9191cc4530fce0ddd174c115c0	yes	8
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Extension of Time		1	1	
	Response to Election / Restriction Filed		2	8	
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	29629 d5fa5b80aedddd71f492c4f8effbfa89fed22f1e	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			339597		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Natasha POPOVICH et al.	)	Group Art Unit: 1711
	)	
Application No.: 11/783,568	)	Examiner: BOWMAN, Andrew J.
	)	
Filed: April 10, 2007	)	Confirmation No.: 8766
	)	
For: BIOSENSOR MANUFACTURING	)	<i>Via EFS Web</i>
METHOD	)	

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

Sir:

PETITION FOR EXTENSION OF TIME

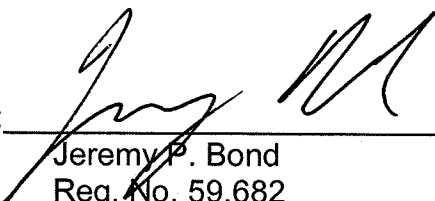
Applicant petitions for a one-month extension of time to file a reply to the Office
Action of September 15, 2010. A fee of \$130.00 is enclosed.

Please grant any additional extensions of time required to enter the attached
reply and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: November 11, 2010

By: 

Jeremy P. Bond
Reg. No. 59,682
(617) 452-1659



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/783,568

04/10/2007

Natasha Popovich

06882.0200-00

8766

22852

7590

11/24/2010

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

BOWMAN, ANDREW J

ART UNIT

PAPER NUMBER

1711

MAIL DATE

DELIVERY MODE

11/24/2010

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.

Office Action Summary	Application No. 11/783,568	Applicant(s) POPOVICH ET AL.	
	Examiner ANDREW BOWMAN	Art Unit 1711	

-- 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 11 November 2010.
- 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) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 and 55-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-54 and 73-90 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) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/15/07</u> . | 6) ☐ Other: _____ |

DETAILED ACTION

All election of species requirements with regards to this application have been withdrawn. However, the restriction requirement remains in place. As such, claims 1-90 remain pending in the current application, with claims 1-17 and 55-72 being withdrawn.

Claim Rejections - 35 USC § 103

1. 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.

2. 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.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1711

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 18-29, 31, 34-44, 48-54, and 73-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (USPGPub 2005/0019953).

a. Regarding claims 18-21, 31 Groll teaches forming a reel of a base material with a conductive coating [0035][0037] and using said reel to create test strips by laser ablating areas between regions on the strip that will be the resultant electrodes [0052]. The primary disclosure of Groll is to describe using a single pass of the laser to create all of the structures. Groll does not expressly state forming the three individual elements in three separate steps. However, 1) Groll does teach multiple ablation steps may be necessary to create multiple elements [0052] and 2) in general the separation of steps (i.e., the separation of one pass into multiple passes wherein the result is the same) has been determined by the court to be unpatentable over the original step. Therefore it is the position of the examiner that in a case where the separation of steps of the current application might be held to be patentable over the prior art, is the position of the examiner that although it is not implicitly stated, one of ordinary skill in the art would envisage forming the elements (or "kerfs") in multiple steps from reading the disclosure of Groll. Additionally, Groll teaches forming multiple conductive layers on top of the conductive pattern described above that would also meet the limitations of the current claim [0048].

Art Unit: 1711

b. Regarding claim 22, 25 it is the position of the examiner that the beam shining through the mask would be different widths in different areas.

Additionally the widths of the beams when using successive masking techniques would be different (as the same pattern being used two times in a row would serve no purpose). Additionally the widths of the beams used for the additional conductive layers as discussed above, would be different widths, as they would be patterning on top of the existing conductive pattern.

c. Regarding claims 23 and 24, the overall beam width of Groll appears to be at least 5mm (Fig.1). Further, none of the patterned areas of Fig.1 appear to be less than 100 micrometers in width, which implies that for the item of Fig.1, beams of less than 100 micrometers were not used.

d. Regarding claim 26-28, the teachings of Groll are as shown above. Groll teaches the use of two laser passes to create one patterned device through the use of two masks [0052]. Groll fails to teach the use of two different lasers. However, one of ordinary skill in the art would be motivated to use two separate lasers so that time would not have to be spent changing the masks out for one another, wherein one laser ablates through one mask and a second laser through a second mask, which could be done in-line. Further, Groll teaches the use of both excimer and UV lasers for the ablation [0051][0053]. One would be motivated to use any of the lasers shown be Groll for either one of the lasers associated with an individual mask because Groll shows them as suitable for

Art Unit: 1711

such purposes. Per the description of Groll, the use of two different types would have to be considered at least obvious to try.

e. Regarding claim 29, the teachings of Groll are as shown above. Groll fails to teach wherein the power of the two lasers applied is different. However, it is the position of the examiner that because the lasers can be of different types as above, it would be implied (based on the idea that different types of lasers require different amounts of energy to attain a minimal particle excitation necessary for the laser to work) that the lasers of different types would be set to use different amounts of power in the absence of a teaching that the same power was provided to two different types of lasers for some reason, which Groll does not teach. Therefore if the lasers weren't inherently provided with different power amounts, one would be motivated to provide them with different power amounts in order to optimize the outputs of each laser, independently.

f. Regarding claim 34, Groll additionally teaches that the electrodes may be made from ITO [0047].

g. Regarding claim 35-44, 48, 53, and 54, Groll additionally teaches cutting the finished roll into individual test strips [0037].

h. Regarding claims 49-51, Groll additionally teaches the use of a layer that could be considered a "spacer layer" that is used to enhance the bond between the base and conductive layer [0048], wherein if applied to the base, the conductive layer would be a cover layer.

Art Unit: 1711

- i. Regarding claim 52, Groll teaches applying the conductive layer by sputter coating [0035].
 - j. Regarding claim 73-79, 81-83, and 85, it is the position of the examiner that the kerfs themselves would function as diffusion barriers between the electrodes.
 - k. Regarding claim 80 and 84 although the diffusion distance is not numerically defined by the current claim, it is the position of the examiner that because the prior art uses kerf dimensions that are larger than those claimed by the current application, the prior art would inherently meet the limitations of this claim.
 - l. Regarding claim 86-88, it is the position of the examiner that one reading Groll would envisage the scenario of the current claim due to the fact that Groll teaches creating counter and working electrodes [0035], which in a two electrode system correspond to anode and cathode. Additionally, it should be noted that the "fill-detect electrode" of the current application is the functional equivalent of the "dose sufficiency" electrode of the prior art.
5. Claims 30 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (USPGPub 2005/0019953) in view of See et al. (US6764914).
- m. Regarding claims 30 and 45, the teachings of Groll are as shown above. Groll fails to teach the power requirements of the current claims. However, Sees teaches that the normal power requirements for the ablation of metals by an excimer laser are about 10 watts (column 3, lines 9-11). Therefore one of

Art Unit: 1711

ordinary skill in the art would be motivated to use the power of the excimer laser of Sees for the power of the excimer laser of Groll because Sees shows that his power is suitable for excimer metal ablation processes.

6. Claims 32, 33, 46, 47, 89, and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (USPGPub 2005/0019953) in view of Winarta et al.

(US6287451)

n. Regarding claims 32, 33, 46, 47, 89, and 90, the teachings of Groll are as shown above. Groll fails to teach the use of the chemical components of the current claims. However, Winarta teaches that the common chemical used for the detection of blood glucose levels using electrode test strips is glucose oxidase (claim 2). Therefore, one of ordinary skill in the art would be motivated to apply the glucose oxidase of Winarta to the test strips of Groll because Winarta shows that it is the desirable chemical to be used for the intended purpose of Groll.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW BOWMAN whose telephone number is (571)270-5342. The examiner can normally be reached on Monday through Friday (7:30 to 5:00)EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Barr can be reached on 571-272-1414. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1711

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.

/Michael Barr/
Supervisory Patent Examiner, Art Unit 1711

Andrew J Bowman
Examiner
Art Unit 1711

Notice of References Cited	Application/Control No. 11/783,568		Applicant(s)/Patent Under Reexamination POPOVICH ET AL.	
	Examiner ANDREW BOWMAN		Art Unit 1711	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,764,914	07-2004	See et al.	438/393
*	B	US-2005/0019953	01-2005	Groll, Henning	436/514
*	C	US-6,287,451	09-2001	Winarta et al.	205/777.5
	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.

Search Notes 	Application/Control No. 11783568	Applicant(s)/Patent Under Reexamination POPOVICH ET AL.
	Examiner ANDREW BOWMAN	Art Unit 1711

SEARCHED			
Class	Subclass	Date	Examiner
436	514	11/22/2010	ajb
438	393	11/22/2010	ajb
205	777.5	11/22/2010	ajb

SEARCH NOTES		
Search Notes	Date	Examiner
EAST history included	11/22/2010	ajb
invnetor search	11/22/2010	ajb
searched google for glucose dehydrogenase, glucose oxidase, working electrodes, counter electrodes, references electrodes, lasers	11/22/2010	ajb

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/ANDREW BOWMAN/ Examiner.Art Unit 1711	
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<i>Index of Claims</i> 	Application/Control No. 11783568	Applicant(s)/Patent Under Reexamination POPOVICH ET AL.
	Examiner ANDREW BOWMAN	Art Unit 1711

✓	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	11/22/2010									
	1	N									
	2	N									
	3	N									
	4	N									
	5	N									
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	35	✓									
	36	✓									

<i>Index of Claims</i> 	Application/Control No. 11783568	Applicant(s)/Patent Under Reexamination POPOVICH ET AL.
	Examiner ANDREW BOWMAN	Art Unit 1711

✓	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	11/22/2010									
	37	✓									
	38	✓									
	39	✓									
	40	✓									
	41	✓									
	42	✓									
	43	✓									
	44	✓									
	45	✓									
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	56	N									
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	61	N									
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	63	N									
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	65	N									
	66	N									
	67	N									
	68	N									
	69	N									
	70	N									
	71	N									
	72	N									

<i>Index of Claims</i> 	Application/Control No. 11783568	Applicant(s)/Patent Under Reexamination POPOVICH ET AL.
	Examiner ANDREW BOWMAN	Art Unit 1711

✓	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	11/22/2010							
	73	✓							
	74	✓							
	75	✓							
	76	✓							
	77	✓							
	78	✓							
	79	✓							
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	86	✓							
	87	✓							
	88	✓							
	89	✓							
	90	✓							



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BIB DATA SHEET

CONFIRMATION NO. 8766

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.		
11/783,568	04/10/2007	382	1711	06882.0200-00		
RULE						
APPLICANTS Natasha Popovich, Pompano Beach, FL; Dennis Slomski, Wellington, FL; David Deng, Weston, FL;						
** CONTINUING DATA ***** This appln claims benefit of 60/790,773 04/11/2006 and claims benefit of 60/878,454 01/04/2007						
** FOREIGN APPLICATIONS *****						
** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 05/11/2007						
Foreign Priority claimed ☐ Yes ☒ No 35 USC 119(a-d) conditions met ☐ Yes ☒ No Verified and /BRUCE F BELL/ Acknowledged Examiner's Signature		☐ Met after Allowance Initials	STATE OR COUNTRY FL	SHEETS DRAWINGS 7	TOTAL CLAIMS 90	INDEPENDENT CLAIMS 5
ADDRESS FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 UNITED STATES						
TITLE Biosensor manufacturing method						
FILING FEE RECEIVED 5030	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:			☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit		

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	6	("20030116447" "20040182703" "20050019953").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 18:50
L2	2	I1 and (reel or roll)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 18:51
L3	1	(US-20050019953-\$). did.	US-PGPUB	ADJ	ON	2010/11/21 19:53
L4	0	I3 and (ablation with separate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 19:53
L5	1	I3 and ablation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 19:53
L6	0	I5 and watt	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:08
L7	0	I5 and power	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:08

L8	0	l3 and (power or watts)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:09
L9	7288	ablation and watts	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:15
L10	1	l1 and ablation and (power or watts)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:16
L11	588	watts with ablation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:16
L12	0	watts with ablation with excimer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:17
L13	3	watts with ablation with excimer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:17
L14	0	watts with ablation with (UV or ultraviolet)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:18
L15	0	l3 and semiconduct\$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:26

L16	0	I3 and semi conduct\$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:27
L17	1	I3 and (cut\$4 or singulat \$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:34
L18	0	I3 and diffusion	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:44
L19	1	I3 and electrode	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:49
L20	55	fill-detect electrode	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:52
L21	0	I3 and (anode or cathode)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:53

EAST Search History (I nterference)

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11/ 21/ 2010 8:57:38 PM**C:\ Documents and Settings\ abowman2\ My Documents\ EAST\ Workspaces\ 11783568.wsp**

IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	11/783,568
				Filing Date	April 10, 2007
				First Named Inventor	Popovich et al.
				Art Unit	2624
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	06882.0200-00

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No. ¹	Document Number	Issue or 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)			
		US-2003/0116447 A1	6/26/2003	Surridge et al.	
		US-2004/0182703 A1	9/23/2004	Home Diagnostics, INC.	
		US-2005/0019953 A1	1/27/2005	Groll	
		US-			
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Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

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	Translation ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		EP 1 302 545 A2	4/16/2003	Roche Diagnostics GmbH		
		WO 01/25775 A1	4/12/2001	Roche Diagnostics Corporation		
		WO 2005/066616 A2	7/21/2005	Roche Diagnostics GmbH		

NONPATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶

Examiner Signature	/Andrew Bowman/	Date Considered	11/22/2010
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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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Natasha POPOVICH et al.	)	Group Art Unit: 1711
	)	
Application No.: 11/783,568	)	Examiner: BOWMAN, Andrew J.
	)	
Filed: April 10, 2007	)	Confirmation No.: 8766
	)	
For: BIOSENSOR MANUFACTURING	)	<i>Via EFS Web</i>
METHOD	)	

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

Sir:

REPLY TO OFFICE ACTION

In reply to the Office Action mailed November 24, 2010, the period for response having been extended to May 24, 2011 by a request for extension of six months and fee payment filed concurrently herewith, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims in this paper.

Remarks/Arguments follow the amendment sections of this paper.

AMENDMENTS TO THE CLAIMS:

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

1-17. (Cancelled)

18. (Currently Amended) A method of manufacturing test strips, comprising:
forming a reel containing a conductive layer and a base layer;
forming a first conductive component, wherein the first conductive component includes at least one first boundary formed by the movement of a first processing technique source along the at least one first boundary and at least one second boundary formed by the movement of a second processing technique source along the at least one second boundary, the second processing source is not the same as the first processing technique source, and the at least one first boundary is not the same as the at least one second boundary;
forming a second conductive component, wherein the second conductive component includes at least one third boundary formed by the movement of the first processing technique source along the at least one third boundary and at least one fourth boundary formed by a third processing technique source not the same as the first processing technique source, and the at least one third boundary is not the same as the at least one fourth boundary; and
forming a third conductive component, wherein the third conductive component includes at least one fifth boundary formed by the movement of the second processing technique source along the at least one fifth boundary and at least one sixth boundary formed by the third processing technique source not the same as the second processing technique source, and the at least one fifth boundary is not the same as the at least one sixth boundary.

19. (Currently Amended) The method of claim 18, wherein the first processing source is configured to perform technique~~includes~~ at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.

20. (Currently Amended) The method of claim 18, wherein the second processing source is configured to perform technique~~includes~~ at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.

21. (Currently Amended) The method of claim 18, wherein the third processing source is configured to perform technique~~includes~~ at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching

22. (Currently Amended) The method of claim 18, wherein the first processing ~~technique~~ source includes a first laser configured to emit using laser ablation having a first ablative beam width and the second processing ~~technique~~ source includes a second laser configured to emit using laser ablation having a second ablative beam width, wherein the first ablative beam width and the second ablative beam width are not the same.

23. (Original) The method of claim 22, wherein the first ablative beam width is at least approximately 20 micro-meters.

24. (Original) The method of claim 22, wherein the second ablative beam width is at least approximately 100 micro-meters.

25. (Currently Amended) The method of claim 22, wherein ~~at least one laser-ablation processing technique removes substantially all of the~~ conductive material between adjacent conductive components is removed and a distance between the adjacent conductive components is substantially equal to at least one of the first ablative beam width and the second ablative beam width.

26. (Currently Amended) The method of claim 18, wherein the first processing source technique ~~includes laser ablation using a first type of laser and the~~

second processing source technique includes laser ablation using a second type of laser, wherein the first type of laser and the second type of laser are not the same.

27. (Original) The method of claim 26, wherein the first or second type of laser is selected from the group consisting of a solid-state laser, a copper vapor laser, a diode laser, a carbon dioxide laser, and an excimer laser.

28. (Original) The method of claim 26, wherein the first or second type of laser operates in a region selected from at least one of an ultraviolet, a visible, and an infrared region.

29. (Currently Amended) The method of claim 18, wherein the first processing source technique includes laser ablation using a first laser operating at a first power and the second processing source technique includes laser ablation using a second laser operating at a second power, wherein the first power and the second power are not the same.

30. (Original) The method of claim 29, wherein the first or second laser power is in the range of about 10 to about 100 watts.

31. (Currently Amended) The method of claim 18, wherein the first processing source forms technique includes forming a single kerf and the second processing source forms technique includes forming a plurality of kerfs that does not include the single kerf.

32. (Original) The method of claim 18, further including the step of contacting the first conductive component with at least one chemical component.

33. (Original) The method of claim 32, wherein the at least one chemical component includes at least one compound selected from the group consisting of potassium ferricyanide, ruthenium hexamine, glucose oxidase and glucose dehydrogenase.

34. (Original) The method of claim 18, wherein at least one of the first conductive component, the second conductive component, and the third conductive component is formed from a semi-conductive material.

35. (Currently Amended) A method of manufacturing test strips, comprising:
forming a reel containing a conductive layer and a base layer;
forming a first kerf in the conductive layer, wherein the first kerf is formed using a first focused laser ablation process beam moved relative to the conductive layer along the first kerf;

forming a second kerf in the conductive layer, wherein the second kerf is formed using a second focused laser ablation process beam moved relative to the conductive layer along the second kerf, the first laser beam being different to the second laser beam that is not the same as the first laser ablation process;

separating one or more test strips from the reel using a singulation process.

36. (Original) The method of claim 35, wherein the singulation process includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.

37. (Currently Amended) The method of claim 35, wherein the first laser beam has ~~ablation process includes a first laser having a first beam width and the second laser~~ beam has ~~ablation process includes a second laser having a second beam width, wherein the first beam width and the second beam width are not the same.~~

38. (Original) The method of claim 37, wherein the first beam width is at least approximately 20 micro-meters.

39. (Original) The method of claim 37, wherein the second beam width is at least approximately 100 micro-meters.

40. (Currently Amended) The method of claim 35 ~~[[37]]~~, wherein at least one laser beam ~~ablation processing technique~~ removes substantially all conductive material between adjacent conductive components.

41. (Currently Amended) The method of claim 35, wherein the first laser beam is emitted from ~~ablation process includes~~ a first type of laser and the second laser beam is emitted from ~~ablation process includes~~ a second type of laser, wherein the first type of laser and the second type of laser are not the same.

42. (Original) The method of claim 41, wherein the first or second type of laser is selected from the group consisting of a solid-state laser, a copper vapor laser, a diode laser, a carbon dioxide laser, and an excimer laser.

43. (Original) The method of claim 41, wherein the first or second type of laser operates in a region selected from at least one of an ultraviolet, a visible, and an infrared region.

44. (Currently Amended) The method of claim 35, wherein the first laser beam is emitted from ~~ablation process includes~~ a first laser operating at a first power and the second laser beam is emitted from ~~ablation process includes~~ a second laser operating at a second power, wherein the first power and the second power are not the same.

45. (Original) The method of claim 44, wherein the first or second laser power is in the range of about 10 to about 100 watts.

46. (Original) The method of claim 35, further including the step of contacting at least part of the conductive layer with at least one chemical component.

47. (Original) The method of claim 46, wherein the at least one chemical component includes at least one compound selected from the group consisting of potassium ferricyanide, ruthenium hexamine, glucose oxidase and glucose dehydrogenase.

48. (Original) The method of claim 35, wherein at least one of the first conductive component, the second conductive component, and the third conductive component is formed from a semi-conductive material.

49. (Original) The method of claim 35, further including application of a spacer layer to the conductive layer or the base layer.

50. (Original) The method of claim 49, wherein the second kerf is formed after application of the spacer layer.

51. (Original) The method of claim 49, further including application of a cover to the spacer layer.

52. (Original) The method of claim 35, wherein the conductive layer is formed using a technique selected from the group consisting of direct writing, sputtering, screen printing, contract printing, and lamination.

53. (Original) The method of claim 35, further including the step of applying to the conductive layer at least one of a second conductive layer and a semi-conductive layer.

54. (Original) The method of claim 53, wherein the second kerf is formed after application of at least one of the second conductive layer and the semi-conductive layer.

55-72. (Cancelled)

73. (Currently Amended) A method of manufacturing a plurality of test strips, comprising:

forming a reel containing a conductive layer and a base layer;

forming a first electrode and a second electrode in the conductive layer, wherein each said electrode includes at least one first boundary formed by a first processing technique and at least one second boundary; and

forming a diffusion barrier positioned between the first electrode and the second electrode and contiguous with the at least one second boundary of each said

electrode, wherein the diffusion barrier has a width about equal to the diffusion distance of at least one ion generated by a redox reaction used to detect a constituent of a fluid and is formed by a second processing technique not the same as the first processing technique.

74. (Original) The method of claim 73, wherein the first processing technique includes at least one technique selected from the group consisting of direct writing, sputtering, screen printing, contact printing, lamination, laser ablation, stamping, cutting, and etching.

75. (Original) The method of claim 73, wherein the second processing technique includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.

76. (Original) The biosensor of claim 73, wherein the second processing technique forms a kerf that is substantially the width of the diffusion barrier.

77. (Original) The biosensor of claim 76, wherein the width of the kerf is at least approximately 100 micro-meters.

78. (Original) The method of claim 73, wherein the step of forming a first electrode using a first processing technique further includes using laser ablation having a first ablative beam width and wherein the step of forming a diffusion barrier using a second processing technique further includes using laser ablation having a second ablative beam width, wherein the first beam width and the second beam width are not the same.

79. (Original) The method of claim 78, wherein the first ablative beam width is at least approximately 20 micro-meters.

80. (Cancelled)

81. (Original) The method of claim 78, wherein the second ablative beam width is substantially the width of the diffusion barrier.

82. (Original) The method of claim 78, wherein the second ablative beam width is at least approximately 100 micro-meters.

83. (Original) The method of claim 73, wherein the first processing technique includes forming a single kerf and the second processing technique includes forming a plurality of kerfs.

84. (Cancelled)

85. (Original) The method of claim 73, wherein the width of the diffusion barrier is at least approximately 100 micro-meters.

86. (Original) The method of claim 73, wherein the diffusion barrier is formed between a working electrode and a counter electrode.

87. (Original) The method of claim 73, wherein the diffusion barrier is formed between a working electrode and a fill-detect electrode.

88. (Original) The method of claim 73, wherein the diffusion barrier is formed between a fill-detect anode and a fill-detect cathode.

89. (Original) The method of claim 73, further comprising the step of contacting the first electrode with at least one chemical component.

90. (Original) The method of claim 89, wherein the at least one chemical component includes at least one compound selected from the group consisting of potassium ferricyanide, ruthenium hexamine, glucose oxidase and glucose dehydrogenase.

REMARKS

In a non-final Office Action mailed November 24, 2010 (hereinafter, "Office Action"), claims 1-17 and 55-72 were withdrawn pursuant to a restriction requirement and claims 18-54 and 73-90 were rejected. See Office Action, pp. 2-7.

By this Amendment, Applicant has cancelled claims 1-17, 55-72, 80 and 84, and amended claims 18-22, 25, 26, 29, 31, 35, 37, 40, 41, 44, and 73. Claims 18-54, 73-79, 81-83, and 85-90 remain pending for examination.

35 U.S.C. § 103(a) Rejections

Under 35 U.S.C. § 103(a), claims 18-29, 31, 34-44, 48-54, and 73-88 stand rejected as being unpatentable over U.S. Patent Application Publication No. 2005/0019953 to Groll ("Groll"), claims 30 and 45 as being unpatentable over Groll in view of U.S. Patent No. 6,764,914 to See et al. ("See"), and claims 32, 33, 46, 47, 89, and 90 stand rejected as being unpatentable over Groll in view of U.S. Patent No. 6,287,451 to Winarta et al. ("Winarta"). *Id.* at pp. 3-7. Applicant respectfully traverses these rejections for at least the following reasons.

Independent claim 18 has been amended to recite forming at least two boundaries of three conductive components using the movement of two different processing sources along each boundary. Independent claim 35 has been amended to recite forming two kerfs using two different focused laser beams. In contrast, Groll forms electrical components using a broad field laser that passes through a mask. See *id.* at para. [0035], [0046], [0049]-[0060]. The broad field laser is required to achieve the

close tolerances and high densities of electrical components necessary for Groll's invention. See *id.* at para. [0080], [0085].

During ablation, a broad field laser does not move relative to the electrical component being formed. Rather, laser source 411 produces laser beam 412 that passes through mask 414 and imaging optics 416 to selectively ablate ribbon 420. See Groll, Figs. 4-7, para. [0049]-[0060]. Either an electrical component is formed using a single pass of a high-energy excimer laser (see *id.* at Fig. 7, para. [0053], [0056]) or using multiple passes of a low-energy UV laser with different masks (414, 414') (see *id.* at Figs. 5, 6, para. [0050]-[0052], [0060]).

Because a broad field laser system uses no moving parts during ablation, Groll fails to disclose or suggest the movement of processing sources recited by claim 18. Groll also fails to disclose or suggest the focused laser beams recited by claim 35 because Groll's invention only works with a broad field laser.

Independent claim 73 has been amended to recite a diffusion barrier having "a width about equal to the diffusion distance of at least one ion generated by a redox reaction used to detect a constituent of a fluid." Nowhere does Groll contain any mention of a diffusion barrier. For at least this reason, Groll fails to disclose or suggest the method recited by claim 73.

See and Wintara, alone or in combination, fail to cure the deficiencies of Groll. Therefore, Applicant respectfully requests that the rejections of claims 18, 35, and 73, and claims 19-34, 36-54, 74-79, 81-83, and 85-90 that depend therefrom, be withdrawn. Claims 80 and 84 have been cancelled, rendering the rejection of these claims moot.

CONCLUSION

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

In discussing the claims in this Amendment, it is to be understood that Applicant in no way intends to limit the scope of the claims to any exemplary embodiments described in the specification or abstract, or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

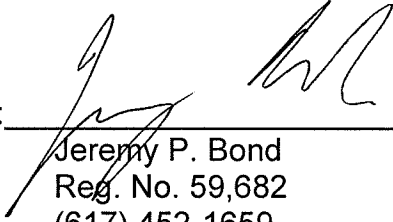
In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 23, 2011

By: 

Jeremy P. Bond
Reg. No. 59,682
(617) 452-1659

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Natasha POPOVICH et al.	)	Group Art Unit: 1711
	)	
Application No.: 11/783,568	)	Examiner: BOWMAN, Andrew J.
	)	
Filed: April 10, 2007	)	Confirmation No.: 8766
	)	
For: BIOSENSOR MANUFACTURING	)	<i>Via EFS Web</i>
METHOD	)	

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

Sir:

PETITION FOR EXTENSION OF TIME

Applicant petitions for a three-month extension of time to file a reply to the Office
Action of November 24, 2010. A fee of \$1,110.00 is enclosed.

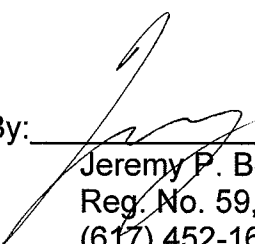
Please grant any additional extensions of time required to enter the attached
reply and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 23, 2011

By: _____


Jeremy P. Bond
Reg. No. 59,682
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Electronic Patent Application Fee Transmittal

Application Number:	11783568			
Filing Date:	10-Apr-2007			
Title of Invention:	Biosensor manufacturing method			
First Named Inventor/Applicant Name:	Natasha Popovich			
Filer:	Jeremy Peter Bond/marijke abbes			
Attorney Docket Number:	06882.0200-00			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Page 292 of 375				
Extension - 3 months with \$0 paid	1253	1	1110	1110

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				1110

Electronic Acknowledgement Receipt

EFS ID:	10147609
Application Number:	11783568
International Application Number:	
Confirmation Number:	8766
Title of Invention:	Biosensor manufacturing method
First Named Inventor/Applicant Name:	Natasha Popovich
Customer Number:	22852
Filer:	Jeremy Peter Bond/marijke abbes
Filer Authorized By:	Jeremy Peter Bond
Attorney Docket Number:	06882.0200-00
Receipt Date:	23-MAY-2011
Filing Date:	10-APR-2007
Time Stamp:	16:12:19
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1110
RAM confirmation Number	3089
Deposit Account	
Authorized User	

File Listing:

Page 294 of 375

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1		Reply.pdf	519878 cd6a2f3329aebb11ccb1f6ed13f7f8459e321741	yes	12
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	9	
	Applicant Arguments/Remarks Made in an Amendment		10	12	
Warnings:					
Information:					
2	Extension of Time	EOT.pdf	31375 41c0364060c22e26723ed41b46b05402f7ca801e	no	1
Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	29894 2dd684bfeedbc0a79f44d5d514a8ed452330a4f0	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			581147		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

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 11/783,568		Filing Date 04/10/2007		☐ To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY ☐ OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(j))	minus 20 =	*	X \$	=	OR	X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=		X \$	=			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	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))										
			TOTAL			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	05/23/2011	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 53	Minus	** 90	= 0	X \$	=	OR	X \$52=	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***5	= 0	X \$	=	OR	X \$220=	0
☐ Application Size Fee (37 CFR 1.16(s))										
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR			
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0	
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$	=	OR	X \$	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$	=	OR	X \$	=
☐ Application Size Fee (37 CFR 1.16(s))										
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR			
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE		
<p>* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.</p> <p>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".</p> <p>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".</p> <p>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.</p>										

Legal Instrument Examiner:
/DALE A. HALL/

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.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/783,568	04/10/2007	Natasha Popovich	06882.0200-00	8766

22852 7590 08/03/2011
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

BOWMAN, ANDREW J

ART UNIT	PAPER NUMBER
----------	--------------

1717

MAIL DATE	DELIVERY MODE
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08/03/2011

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. 11/783,568	Applicant(s) POPOVICH ET AL.	
	Examiner ANDREW BOWMAN	Art Unit 1717	

-- 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 23 May 2011.
- 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) 18-54, 73-79, 81-83 and 85-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-54 is/are allowed.
- 6) ☒ Claim(s) 73-79, 81-83 and 85-90 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) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

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

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

2. Claims 73-79, 81-83, and 85-90 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the actual step of performing the redox reaction. The applicant in no way defines this redox reaction, making it impossible for the examiner to even guess about what distance may occur over.

Claim Rejections - 35 USC § 103

1. 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.

2. 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.

Art Unit: 1717

3. Claims 73-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (USPGPub 2005/0019953).

Regarding claims 73-79, 81-83, and 85, Groll teaches forming a reel of a base material with a conductive coating [0035][0037] and using said reel to create test strips by laser ablating areas between regions on the strip that will be the resultant electrodes [0052]. The primary disclosure of Groll is to describe using a single pass of the laser to create all of the structures. Groll does not expressly state forming the three individual elements in three separate steps. However, 1) Groll does teach multiple ablation steps may be necessary to create multiple elements [0052] and 2) in general the separation of steps (i.e., the separation of one pass into multiple passes wherein the result is the same) has been determined by the court to be unpatentable over the original step. Therefore it is the position of the examiner that in a case where the separation of steps of the current application might be held to be patentable over the prior art, is the position of the examiner that although it is not implicitly stated, one of ordinary skill in the art would envisage forming the elements (or “kerfs”) in multiple steps from reading the disclosure of Groll. Additionally, Groll teaches forming multiple conductive layers on top of the conductive pattern described above that would also meet the limitations of the current claim [0048]. Although Groll does not expressly teach forming each part with a different laser source, the Court has determined that in the absence of an unexpected result stemming from the duplication of parts (i.e., the use of multiple lasers instead of one), the mere duplication of parts that serve the same function as one part is considered to be unpatentable over the use of said one part. Two other points should

Art Unit: 1717

be made. Further it is the position of the examiner that the kerfs themselves would function as diffusion barriers between the electrodes.

Regarding claim 80 and 84 although the diffusion distance is not numerically defined by the current claim, it is the position of the examiner that because the prior art uses kerf dimensions that are larger than those claimed by the current application, the prior art would inherently meet the limitations of this claim.

Regarding claim 86-88, it is the position of the examiner that one reading Groll would envisage the scenario of the current claim due to the fact that Groll teaches creating counter and working electrodes [0035], which in a two electrode system correspond to anode and cathode. Additionally, it should be noted that the “fill-detect electrode” of the current application is the functional equivalent of the “dose sufficiency” electrode of the prior art.

4. Claims 89 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (USPGPub 2005/0019953) in view of Winarta et al. (US6287451)

Regarding claims 89 and 90, the teachings of Groll are as shown above. Groll fails to teach the use of the chemical components of the current claims. However, Winarta teaches that the common chemical used for the detection of blood glucose levels using electrode test strips is glucose oxidase (claim 2). Therefore, one of ordinary skill in the art would be motivated to apply the glucose oxidase of Winarta to the test strips of Groll because Winarta shows that it is the desirable chemical to be used for the intended purpose of Groll.

Allowable Subject Matter

5. Claims 18-54 are allowed.
6. The following is an examiner's statement of reasons for allowance:

It is the position of the examiner that it is not known in the prior art to move a laser over a reel containing a conductive/base layered material to ablate conductive elements, each with its own corresponding laser source.

The most pertinent prior art (USPGPub 2005/0019953) teaches that it is known to use a wide laser to ablate patterns in a conductive reel using a mask to define the pattern at one time but fails to teach cutting individual elements by moving a laser along the edges of the kerfs that define the elements.

Another prior art teaches wherein test strips function by using the enzyme glucose oxidase but is otherwise generally unrelated.

Another prior art teaches that common ablation laser include excimer laser and YAG laser.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

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

Art Unit: 1717

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 ANDREW BOWMAN whose telephone number is (571)270-5342. The examiner can normally be reached on Monday through Friday (7:30 to 5:00)EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dah-Wei Yuan can be reached on 571-272-1295. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1717

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.

Andrew J Bowman
Examiner
Art Unit 1717

/Dah-Wei D. Yuan/
Supervisory Patent Examiner, Art Unit 1717

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	917	kerf with laser	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2011/07/30 21:32
L2	1	kerf with laser and test strip	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2011/07/30 21:32
S1	6	("20030116447" "20040182703" "20050019953").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 18:50
S2	2	S1 and (reel or roll)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 18:51
S3	1	(US-20050019953-\$). did.	US-PGPUB	ADJ	ON	2010/11/21 19:53
S4	0	S3 and (ablation with separate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 19:53
S5	1	S3 and ablation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 19:53

S6	0	S5 and watt	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:08
S7	0	S5 and power	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:08
S8	0	S3 and (power or watts)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:09
S9	7288	ablation and watts	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:15
S10	1	S1 and ablation and (power or watts)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:16
S11	588	watts with ablation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:16
S12	0	watts with ablation with excimer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:17
S13	3	watts with ablation with excimer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:17

S14	0	watts with ablation with (UV or ultraviolet)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:18
S15	0	S3 and semiconduct\$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:26
S16	0	S3 and semi conduct\$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:27
S17	1	S3 and (cut\$4 or singulat\$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:34
S18	0	S3 and diffusion	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:44
S19	1	S3 and electrode	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:49
S20	55	fill-detect electrode	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:52
S21	0	S3 and (anode or cathode)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:53

EAST Search History (I nterference)

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7/ 30/ 2011 9:33:15 PM

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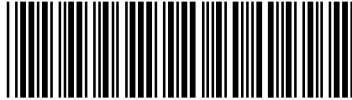
Search Notes 	Application/Control No. 11783568	Applicant(s)/Patent Under Reexamination POPOVICH ET AL.
	Examiner ANDREW BOWMAN	Art Unit 1711

SEARCHED			
Class	Subclass	Date	Examiner
436	514	11/22/2010	ajb
438	393	11/22/2010	ajb
205	777.5	11/22/2010	ajb

SEARCH NOTES		
Search Notes	Date	Examiner
EAST history included	11/22/2010	ajb
invnetor search	11/22/2010	ajb
searched google for glucose dehydrogenase, glucose oxidase, working electrodes, counter electrodes, references electrodes, lasers	11/22/2010	ajb
EAST history updated	7/30/2011	ajb

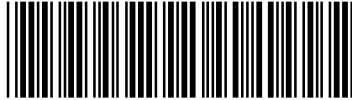
INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/ANDREW BOWMAN/ Examiner.Art Unit 1717	
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<i>Index of Claims</i> 	Application/Control No. 11783568	Applicant(s)/Patent Under Reexamination POPOVICH ET AL.
	Examiner ANDREW BOWMAN	Art Unit 1711

✓	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	11/22/2010	07/30/2011												
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	2	N	-												
	3	N	-												
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	33	✓	=												
	34	✓	=												
	35	✓	=												
	36	✓	=												

<i>Index of Claims</i> 	Application/Control No. 11783568	Applicant(s)/Patent Under Reexamination POPOVICH ET AL.
	Examiner ANDREW BOWMAN	Art Unit 1711

✓	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	11/22/2010	07/30/2011						
	37	✓	=						
	38	✓	=						
	39	✓	=						
	40	✓	=						
	41	✓	=						
	42	✓	=						
	43	✓	=						
	44	✓	=						
	45	✓	=						
	46	✓	=						
	47	✓	=						
	48	✓	=						
	49	✓	=						
	50	✓	=						
	51	✓	=						
	52	✓	=						
	53	✓	=						
	54	✓	=						
	55	N	-						
	56	N	-						
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	59	N	-						
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	62	N	-						
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	64	N	-						
	65	N	-						
	66	N	-						
	67	N	-						
	68	N	-						
	69	N	-						
	70	N	-						
	71	N	-						
	72	N	-						

<i>Index of Claims</i> 	Application/Control No. 11783568	Applicant(s)/Patent Under Reexamination POPOVICH ET AL.
	Examiner ANDREW BOWMAN	Art Unit 1711

✓	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	11/22/2010	07/30/2011						
	73	✓	✓						
	74	✓	✓						
	75	✓	✓						
	76	✓	✓						
	77	✓	✓						
	78	✓	✓						
	79	✓	✓						
	80	✓	-						
	81	✓	✓						
	82	✓	✓						
	83	✓	✓						
	84	✓	-						
	85	✓	✓						
	86	✓	✓						
	87	✓	✓						
	88	✓	✓						
	89	✓	✓						
	90	✓	✓						

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Natasha POPOVICH et al.	)	Group Art Unit: 1717
	)	
Application No.: 11/783,568	)	Examiner: BOWMAN, Andrew J.
	)	
Filed: April 10, 2007	)	Confirmation No.: 8766
	)	
For: BIOSENSOR MANUFACTURING	)	<i>Via EFS Web</i>
METHOD	)	

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

Sir:

AMENDMENT AFTER FINAL

In reply to the Final Office Action mailed August 3, 2011, and pursuant to
37 C.F.R. § 1.116, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims in this paper.

Remarks/Arguments follow the amendment sections of this paper.

AMENDMENTS TO THE CLAIMS:

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

1-17. (Cancelled)

18. (Previously Presented) A method of manufacturing test strips, comprising:
- forming a reel containing a conductive layer and a base layer;
 - forming a first conductive component, wherein the first conductive component includes at least one first boundary formed by the movement of a first processing source along the at least one first boundary and at least one second boundary formed by the movement of a second processing source along the at least one second boundary, the second processing source is not the same as the first processing source, and the at least one first boundary is not the same as the at least one second boundary;
 - forming a second conductive component, wherein the second conductive component includes at least one third boundary formed by the movement of the first processing source along the at least one third boundary and at least one fourth boundary formed by a third processing source not the same as the first processing source, and the at least one third boundary is not the same as the at least one fourth boundary; and
 - forming a third conductive component, wherein the third conductive component includes at least one fifth boundary formed by the movement of the second processing source along the at least one fifth boundary and at least one sixth boundary formed by the third processing source not the same as the second processing source, and the at least one fifth boundary is not the same as the at least one sixth boundary.
19. (Previously Presented) The method of claim 18, wherein the first processing source is configured to perform at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.

20. (Previously Presented) The method of claim 18, wherein the second processing source is configured to perform at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.

21. (Previously Presented) The method of claim 18, wherein the third processing source is configured to perform at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching

22. (Previously Presented) The method of claim 18, wherein the first processing source includes a first laser configured to emit a first ablative beam width and the second processing source includes a second laser configured to emit a second ablative beam width, wherein the first ablative beam width and the second ablative beam width are not the same.

23. (Original) The method of claim 22, wherein the first ablative beam width is at least approximately 20 micro-meters.

24. (Original) The method of claim 22, wherein the second ablative beam width is at least approximately 100 micro-meters.

25. (Previously Presented) The method of claim 22, wherein substantially all of the conductive material between adjacent conductive components is removed and a distance between the adjacent conductive components is substantially equal to at least one of the first ablative beam width and the second ablative beam width.

26. (Previously Presented) The method of claim 18, wherein the first processing source includes a first type of laser and the second processing source includes a second type of laser, wherein the first type of laser and the second type of laser are not the same.

27. (Original) The method of claim 26, wherein the first or second type of laser is selected from the group consisting of a solid-state laser, a copper vapor laser, a diode laser, a carbon dioxide laser, and an excimer laser.

28. (Original) The method of claim 26, wherein the first or second type of laser operates in a region selected from at least one of an ultraviolet, a visible, and an infrared region.

29. (Previously Presented) The method of claim 18, wherein the first processing source includes a first laser operating at a first power and the second processing source includes a second laser operating at a second power, wherein the first power and the second power are not the same.

30. (Original) The method of claim 29, wherein the first or second laser power is in the range of about 10 to about 100 watts.

31. (Previously Presented) The method of claim 18, wherein the first processing source forms a single kerf and the second processing source forms a plurality of kerfs that does not include the single kerf.

32. (Original) The method of claim 18, further including the step of contacting the first conductive component with at least one chemical component.

33. (Original) The method of claim 32, wherein the at least one chemical component includes at least one compound selected from the group consisting of potassium ferricyanide, ruthenium hexamine, glucose oxidase and glucose dehydrogenase.

34. (Original) The method of claim 18, wherein at least one of the first conductive component, the second conductive component, and the third conductive component is formed from a semi-conductive material.

35. (Previously Presented) A method of manufacturing test strips, comprising:
forming a reel containing a conductive layer and a base layer;
forming a first kerf in the conductive layer, wherein the first kerf is formed using a first focused laser beam moved relative to the conductive layer along the first kerf;
forming a second kerf in the conductive layer, wherein the second kerf is

formed using a second focused laser beam moved relative to the conductive layer along the second kerf, the first laser beam being different to the second laser beam;

separating one or more test strips from the reel using a singulation process.

36. (Original) The method of claim 35, wherein the singulation process includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.

37. (Previously Presented) The method of claim 35, wherein the first laser beam has a first beam width and the second laser beam has a second beam width, wherein the first beam width and the second beam width are not the same.

38. (Original) The method of claim 37, wherein the first beam width is at least approximately 20 micro-meters.

39. (Original) The method of claim 37, wherein the second beam width is at least approximately 100 micro-meters.

40. (Previously Presented) The method of claim 35, wherein at least one laser beam removes substantially all conductive material between adjacent conductive components.

41. (Previously Presented) The method of claim 35, wherein the first laser beam is emitted from a first type of laser and the second laser beam is emitted from a second type of laser, wherein the first type of laser and the second type of laser are not the same.

42. (Original) The method of claim 41, wherein the first or second type of laser is selected from the group consisting of a solid-state laser, a copper vapor laser, a diode laser, a carbon dioxide laser, and an excimer laser.

43. (Original) The method of claim 41, wherein the first or second type of laser operates in a region selected from at least one of an ultraviolet, a visible, and an infrared region.

44. (Previously Presented) The method of claim 35, wherein the first laser beam is emitted from a first laser operating at a first power and the second laser beam is emitted from a second laser operating at a second power, wherein the first power and the second power are not the same.

45. (Original) The method of claim 44, wherein the first or second laser power is in the range of about 10 to about 100 watts.

46. (Original) The method of claim 35, further including the step of contacting at least part of the conductive layer with at least one chemical component.

47. (Original) The method of claim 46, wherein the at least one chemical component includes at least one compound selected from the group consisting of potassium ferricyanide, ruthenium hexamine, glucose oxidase and glucose dehydrogenase.

48. (Original) The method of claim 35, wherein at least one of the first conductive component, the second conductive component, and the third conductive component is formed from a semi-conductive material.

49. (Original) The method of claim 35, further including application of a spacer layer to the conductive layer or the base layer.

50. (Original) The method of claim 49, wherein the second kerf is formed after application of the spacer layer.

51. (Original) The method of claim 49, further including application of a cover to the spacer layer.

52. (Original) The method of claim 35, wherein the conductive layer is formed using a technique selected from the group consisting of direct writing, sputtering, screen printing, contract printing, and lamination.

53. (Original) The method of claim 35, further including the step of applying to the conductive layer at least one of a second conductive layer and a semi-conductive layer.

54. (Original) The method of claim 53, wherein the second kerf is formed after application of at least one of the second conductive layer and the semi-conductive layer.

55-90. (Cancelled)

REMARKS

Claims 1-17, 55-72, 80, and 84 were previously cancelled. In a final Office Action mailed August 3, 2011 (hereinafter, "Office Action"), claims 18-54 were allowed, and claims 73-79, 81-83, and 85-90 were rejected. See Office Action, pp. 2-5.

By this Amendment, Applicant has cancelled the rejected claims 73-79, 81-83, and 85-90 in order to expedite issuance of a Notice of Allowance for the present application.

CONCLUSION

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 18-54 in condition for allowance.

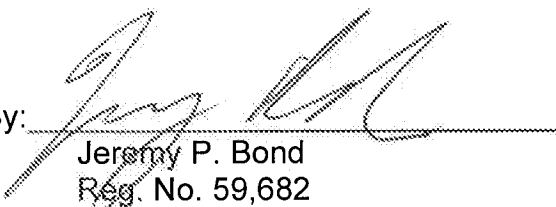
In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Amendment and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: 10/5/2011

By: 

Jeremy P. Bond
Reg. No. 59,682
(617) 452-1659

Electronic Acknowledgement Receipt

EFS ID:	11115914
Application Number:	11783568
International Application Number:	
Confirmation Number:	8766
Title of Invention:	Biosensor manufacturing method
First Named Inventor/Applicant Name:	Natasha Popovich
Customer Number:	22852
Filer:	Jeremy Peter Bond
Filer Authorized By:	
Attorney Docket Number:	06882.0200-00
Receipt Date:	05-OCT-2011
Filing Date:	10-APR-2007
Time Stamp:	14:40:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Amendment.pdf	669587 30bccc1cad47f9c1b6229742238d33f752a06f8	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Amendment After Final	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	8
Warnings:			
Information:			
Total Files Size (in bytes):		669587	
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>			

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/783,568		Filing Date 04/10/2007		☐ To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY ☐ OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)			
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	300			
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
☒ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	200			
TOTAL CLAIMS (37 CFR 1.16(j))	minus 20 =	*	X \$	=		X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=		X \$	=			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	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))										
			TOTAL			TOTAL	500			
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	10/05/2011	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 37	Minus	** 90	= 0	X \$	=	OR	X \$60=	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***5	= 0	X \$	=	OR	X \$250=	0
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0	
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$	=	OR	X \$	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$	=	OR	X \$	=
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE		
<p>* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.</p> <p>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".</p> <p>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".</p> <p>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.</p>										

Legal Instrument Examiner:
/ANGELA JONES/

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.**

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NOTICE OF ALLOWANCE AND FEE(S) DUE

22852 7590 10/27/2011
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

BOWMAN, ANDREW J

ART UNIT

PAPER NUMBER

1717

DATE MAILED: 10/27/2011

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/783,568

04/10/2007

Natasha Popovich

06882.0200-00

8766

TITLE OF INVENTION: BIOSENSOR MANUFACTURING METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1740	\$300	\$0	\$2040	01/27/2012

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 SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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.

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Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE
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Alexandria, Virginia 22313-1450
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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.

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22852 7590 10/27/2011
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

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.
-----------------	-------------	----------------------	---------------------	------------------

11/783,568 04/10/2007 Natasha Popovich 06882.0200-00 8766

TITLE OF INVENTION: BIOSENSOR MANUFACTURING METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional NO \$1740 \$300 \$0 \$2040 01/27/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
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BOWMAN, ANDREW J 1717 427-002110

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, 1 _____
(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 _____
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 _____

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 _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

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.

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/783,568	04/10/2007	Natasha Popovich	06882.0200-00	8766

22852 7590 10/27/2011
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

BOWMAN, ANDREW J

ART UNIT PAPER NUMBER

1717

DATE MAILED: 10/27/2011

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 586 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 586 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.

11/783,568

Applicant(s)

POPOVICH ET AL.

Examiner

Art Unit

ANDREW BOWMAN

1717

-- 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 10/5/2011.
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 18-54.
4. ☐ 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 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. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ 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).**
7. ☐ 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)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date ____.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____.

/Andrew J Bowman/
Examiner, Art Unit 1717

REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance:

It is the position of the examiner that it is not known in the prior art to move a laser over a reel containing a conductive/base layered material to ablate conductive elements, each with its own corresponding laser source.

The most pertinent prior art (USPGPub 2005/0019953) teaches that it is known to use a wide laser to ablate patterns in a conductive reel using a mask to define the pattern at one time but fails to teach cutting individual elements by moving a laser along the edges of the kerfs that define the elements.

Another prior art teaches wherein test strips function by using the enzyme glucose oxidase but is otherwise generally unrelated.

Another prior art teaches that common ablation laser include excimer laser and YAG laser.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW BOWMAN whose telephone number is

Art Unit: 1717

(571)270-5342. The examiner can normally be reached on Monday through Friday (7:30 to 5:00)EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dah-Wei Yuan can be reached on 571-272-1295. 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.

/Andrew J Bowman/
Examiner
Art Unit 1717

/Dah-Wei D. Yuan/
Supervisory Patent Examiner, Art Unit 1717

Search Notes 	Application/Control No. 11783568	Applicant(s)/Patent Under Reexamination POPOVICH ET AL.
	Examiner ANDREW BOWMAN	Art Unit 1711

SEARCHED			
Class	Subclass	Date	Examiner
436	514	11/22/2010	ajb
438	393	11/22/2010	ajb
205	777.5	11/22/2010	ajb
427	2.11	10/17/2011	ajb

SEARCH NOTES		
Search Notes	Date	Examiner
EAST history included	11/22/2010	ajb
invnetor search	11/22/2010	ajb
searched google for glucose dehydrogenase, glucose oxidase, working electrodes, counter electrodes, references electrodes, lasers	11/22/2010	ajb
EAST history updated	7/30/2011	ajb

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
427	2.11	10/17/2011	ajb

/ANDREW BOWMAN/ Examiner.Art Unit 1717	
---	--

OK TO ENTER: /A.B./

RESPONSE UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE REQUESTED
EXAMINING GROUP 1717
PATENT
Customer No. 22,852
Attorney Docket No. 06882.0200-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Natasha POPOVICH et al.	)	Group Art Unit: 1717
	)	
Application No.: 11/783,568	)	Examiner: BOWMAN, Andrew J.
	)	
Filed: April 10, 2007	)	Confirmation No.: 8766
	)	
For: BIOSENSOR MANUFACTURING	)	<i>Via EFS Web</i>
METHOD	)	

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

Sir:

AMENDMENT AFTER FINAL

In reply to the Final Office Action mailed August 3, 2011, and pursuant to
37 C.F.R. § 1.116, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims in this paper.

Remarks/Arguments follow the amendment sections of this paper. OK TO ENTER: /A.B./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	6	("20030116447" "20040182703" "20050019953").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 18:50
S2	2	S1 and (reel or roll)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 18:51
S3	1	(US-20050019953-\$). did.	US-PGPUB	ADJ	ON	2010/11/21 19:53
S4	0	S3 and (ablation with separate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 19:53
S5	1	S3 and ablation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 19:53
S6	0	S5 and watt	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:08
S7	0	S5 and power	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:08

S8	0	S3 and (power or watts)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:09
S9	7288	ablation and watts	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:15
S10	1	S1 and ablation and (power or watts)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:16
S11	588	watts with ablation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:16
S12	0	watts with ablation with excimer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:17
S13	3	watts with ablation with excimer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:17
S14	0	watts with ablation with (UV or ultraviolet)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:18
S15	0	S3 and semiconduct\$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:26

S16	0	S3 and semi conduct\$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:27
S17	1	S3 and (cut\$4 or singulat\$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:34
S18	0	S3 and diffusion	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:44
S19	1	S3 and electrode	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:49
S20	55	fill-detect electrode	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:52
S21	0	S3 and (anode or cathode)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2010/11/21 20:53

EAST Search History (I nterference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3166	427/1-4.ccls.	USPAT; UPAD	ADJ	ON	2011/10/17 11:35
L2	0	sixth boundary.clm. and l1	USPAT; UPAD	ADJ	ON	2011/10/17 11:35

10/ 17/ 2011 11:35:38 AM**C:\ Documents and Settings\ abowman2\ My Documents\ EAST\ Workspaces\ 11783568.wsp**

Issue Classification 	Application/Control No. 11783568	Applicant(s)/Patent Under Reexamination POPOVICH ET AL.
	Examiner ANDREW BOWMAN	Art Unit 1717

ORIGINAL						INTERNATIONAL CLASSIFICATION												
CLASS		SUBCLASS				CLAIMED					NON-CLAIMED							
427		2.11				G	0	1	N	1 / 28 (2006.0)								
CROSS REFERENCE(S)																		
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																	
436	514																	
438	494																	
205	777.5																	
427	58	96.1	289	292														

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17	16	33	32	49		65		81				
	2	1	18	17	34	33	50		66		82				
	3	2	19	18	35	34	51		67		83				
	4	3	20	19	36	35	52		68		84				
	5	4	21	20	37	36	53		69		85				
	6	5	22	21	38	37	54		70		86				
	7	6	23	22	39		55		71		87				
	8	7	24	23	40		56		72		88				
	9	8	25	24	41		57		73		89				
	10	9	26	25	42		58		74		90				
	11	10	27	26	43		59		75						
	12	11	28	27	44		60		76						
	13	12	29	28	45		61		77						
	14	13	30	29	46		62		78						
	15	14	31	30	47		63		79						
	16	15	32	31	48		64		80						

/ANDREW BOWMAN/ Examiner.Art Unit 1717 (Assistant Examiner)	10/10/2011 (Date)	Total Claims Allowed: 37	
/DAH-WEI YUAN/ Supervisory Patent Examiner.Art Unit 1717 (Primary Examiner)	10/19/2011 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Natasha POPOVICH et al.) Group Art Unit: 1717
)
Application No.: 11/783,568) Examiner: BOWMAN, Andrew J.
)
Filed: April 10, 2007) Confirmation No.: 8766
)
For: BIOSENSOR MANUFACTURING) ***Via EFS Web***
METHOD)

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

Sir:

FEE ADDRESS FOR MAINTENANCE FEE PURPOSES
IN ACCORDANCE WITH 37 C.F.R. 1.363

In accordance with the provisions of 37 C.F.R. 1.363, the fee address set forth below is being supplied for purposes of receiving notices, receipts, and other correspondence relating to the payment of maintenance fees:

Computer Packages Annuity Service, Inc.
Phone: 301-517-5501
Fax: 301-763-8663
www.computerpackages.com

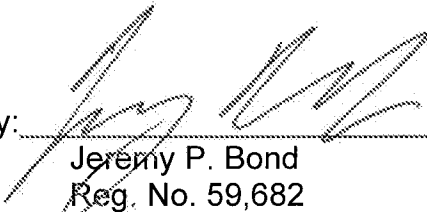
Payor Number: 00204

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: January 26, 2012

By: _____


Jeremy P. Bond
Reg. No. 59,682
(617) 452-1600

Electronic Patent Application Fee Transmittal				
Application Number:		11783568		
Filing Date:		10-Apr-2007		
Title of Invention:		BIOSENSOR MANUFACTURING METHOD		
First Named Inventor/Applicant Name:		Natasha Popovich		
Filer:		Jeremy Peter Bond/marijke abbes		
Attorney Docket Number:		06882.0200-00		
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	1501	1	1740	1740
Publ. Fee- early, voluntary, or normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				2040

Electronic Acknowledgement Receipt

EFS ID:	11928887
Application Number:	11783568
International Application Number:	
Confirmation Number:	8766
Title of Invention:	BIOSENSOR MANUFACTURING METHOD
First Named Inventor/Applicant Name:	Natasha Popovich
Customer Number:	22852
Filer:	Jeremy Peter Bond
Filer Authorized By:	
Attorney Docket Number:	06882.0200-00
Receipt Date:	26-JAN-2012
Filing Date:	10-APR-2007
Time Stamp:	15:25:58
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 2040
RAM confirmation Number	2103
Deposit Account	
Authorized User	

File Listing:

Page 340 of 375

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
-----------------	----------------------	-----------	-------------------------------------	------------------	------------------

1		filing.pdf	254771 64619a20cea1a75fc81c28892643ca9f7437fb69	yes	2
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Issue Fee Payment (PTO-85B)		1	1	
	Change of Address		2	2	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32073 93cd3c52f18c190cc671c153f54aa20101f1a29a	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			286844		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

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)

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.

22852 7590 10/27/2011
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

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.
11/783,568	04/10/2007	Natasha Popovich	06882.0200-00	8766

TITLE OF INVENTION: BIOSENSOR MANUFACTURING METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1740	\$300	\$0	\$2040	01/27/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
BOWMAN, ANDREW J	1717	427-002110

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 Finnegan, Henderson,
 2 Farabow, Garrett
 3 & Dunner, LLP

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

NIPRO DIAGNOSTICS, INC.

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

FORT LAUDERDALE, FLORIDA

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 _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☒ Payment by credit card. ~~XXXXXXXXXXXX~~
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 06-0916 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

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 January 26, 2012

Typed or printed name Jeremy P. Bond

Registration No. 59,682

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.

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	11/783,568
				Filing Date	April 10, 2007
				First Named Inventor	Popovich et al.
				Art Unit	2624
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	06882.0200-00

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No. ¹	Document Number	Issue or 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)			
		US-2003/0116447 A1	6/26/2003	Surridge et al.	
		US-2004/0182703 A1	9/23/2004	Home Diagnostics, Inc. Bell et al.	
		US-2005/0019953 A1	1/27/2005	Groll	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

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	Translation ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		EP 1 302 545 A2	4/16/2003	Roche Diagnostics GmbH		
		WO 01/25775 A1	4/12/2001	Roche Diagnostics Corporation		
		WO 2005/066616 A2	7/21/2005	Roche Diagnostics GmbH		

NONPATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶

Examiner Signature	/Andrew Bowman/	Date Considered	11/22/2010
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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.



UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/783,568	03/06/2012	8128981	06882.0200-00	8766

22852 7590 02/15/2012

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

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 1277 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):

Natasha Popovich, Pompano Beach, FL;
Dennis Slomski, Wellington, FL;
David Deng, Weston, FL;

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
 Stylesheet Version v1.2

EPAS ID: PAT2603113

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	SECURITY AGREEMENT

CONVEYING PARTY DATA

Name	Execution Date
NIPRO DIAGNOSTICS, INC.	11/01/2013

RECEIVING PARTY DATA

Name:	WELLS FARGO BANK, NATIONAL ASSOCIATION, AS ADMINISTRATIVE AGENT
Street Address:	2450 COLORADO AVENUE
Internal Address:	SUITE 3000 WEST
City:	SANTA MONICA
State/Country:	CALIFORNIA
Postal Code:	90404

PROPERTY NUMBERS Total: 58

Property Type	Number
Application Number:	07287883
Application Number:	07862733
Application Number:	08872088
Application Number:	09059082
Application Number:	09263975
Application Number:	09379130
Application Number:	09448711
Application Number:	09794037
Application Number:	09794044
Application Number:	09794045
Application Number:	09984948
Application Number:	10208878
Application Number:	10286648
Application Number:	10378797

Application Number:	10420995
Application Number:	10706161
Application Number:	10706634
Application Number:	10706663
Application Number:	10764972
Application Number:	10764974
Application Number:	10857917
Application Number:	10967901
Application Number:	11084007
Application Number:	11118494
Application Number:	11181778
Application Number:	11254881
Application Number:	11352209
Application Number:	11373284
Application Number:	11417225
Application Number:	11434063
Application Number:	11458298
Application Number:	11476702
Application Number:	11590854
Application Number:	11594753
Application Number:	11764471
Application Number:	11783568
Application Number:	11930862
Application Number:	12017496
Application Number:	12115770
Application Number:	12179853
Application Number:	12410048
Application Number:	12724280
Application Number:	13331346
Application Number:	13403318
Application Number:	29171117
Application Number:	29182200
Application Number:	29183323
Application Number:	29191862
Application Number:	29206525

	29206526
Application Number:	29222351
Application Number:	29255167
Application Number:	29259436
Application Number:	29302659
Application Number:	12102218
Patent Number:	6284550
Application Number:	13025203
Application Number:	11711621

CORRESPONDENCE DATA

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Correspondence will be sent via US Mail when the email attempt is unsuccessful.
 Correspondent Name: LASHANA C. JIMMAR
 Address Line 1: GREENBERG TRAUIG, LLP
 Address Line 2: 3333 PIEDMONT ROAD, NE, SUITE 2500
 Address Line 4: ATLANTA, GEORGIA 30305

ATTORNEY DOCKET NUMBER:	148294.010100
NAME OF SUBMITTER:	LASHANA C. JIMMAR
Signature:	/LaShana C. Jimmar/
Date:	11/04/2013
	This document serves as an Oath/Declaration (37 CFR 1.63).

Total Attachments: 10

source=Wells_Nipro- Patent Security Agreement#page1.tif
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 source=Wells_Nipro- Patent Security Agreement#page10.tif

PATENT SECURITY AGREEMENT

This PATENT SECURITY AGREEMENT (this “Patent Security Agreement”) is made this 1st day of November, 2013, by and among the Grantors listed on the signature pages hereof (each a “Grantor” and collectively, “Grantors”), and **WELLS FARGO BANK, NATIONAL ASSOCIATION**, a national banking association (“Wells Fargo”), in its capacity as agent for each member of the Lender Group and the Bank Product Providers (in such capacity, together with its successors and assigns in such capacity, “Agent”).

W I T N E S S E T H:

WHEREAS, pursuant to that certain Amended and Restated Credit Agreement, dated of even date herewith (as amended, modified, supplemented, renewed, refinanced, restructured, restated or replaced from time to time, the “Credit Agreement”), by and among the lenders identified on the signature pages thereof (each of such lenders, together with its successors and permitted assigns, a “Lender”), **Wells Fargo**, as administrative agent for each member of the Lender Group and the Bank Product Providers (in such capacity, together with its successors and assigns in such capacity, “Agent”), **Wells Fargo**, as sole lead arranger and sole book runner, the Grantors and certain of their Affiliates and/or Subsidiaries, the Lender Group has agreed to make certain financial accommodations available to **Nipro Diagnostics, Inc.**, a Delaware corporation (“NDI” and together with those additional Persons that are parties to the Credit Agreement as a borrower, each a “Borrower” and collectively, the “Borrowers”), from time to time pursuant to the terms and conditions thereof; and

WHEREAS, the members of the Lender Group and the Bank Product Providers are willing to make the financial accommodations to the Borrowers as provided for in the Credit Agreement, the other Loan Documents, and the Bank Product Agreements, but only upon the condition, among others, that the Grantors shall have executed and delivered to Agent, for the benefit of the Lender Group and the Bank Product Providers, that certain Amended and Restated Guaranty and Security Agreement, dated of even date herewith (including all annexes, exhibits or schedules thereto, as from time to time amended, modified, supplemented, renewed, restated or replaced, the “Guaranty and Security Agreement”); and

WHEREAS, pursuant to the Guaranty and Security Agreement, Grantors are required to execute and deliver to Agent, for the benefit of the Lender Group and the Bank Product Providers, this Patent Security Agreement;

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each Grantor hereby agrees as follows:

1. DEFINED TERMS. All initially capitalized terms used but not otherwise defined herein have the meanings given to them in the Guaranty and Security Agreement or, if not defined therein, in the Credit Agreement, and this Patent Security Agreement shall be subject to the rules of construction set forth in Section 1(b) of the Guaranty and Security Agreement, which rules of construction are incorporated herein by this reference, *mutatis mutandis*.

2. GRANTS OF SECURITY INTEREST IN PATENT COLLATERAL. Each Grantor hereby unconditionally grants, assigns, and pledges to Agent, for the benefit each member of the Lender Group and each of the Bank Product Providers, to secure the Secured Obligations, a continuing security interest (referred to in this Patent Security Agreement as the “Security Interest”) in all of such Grantor’s right, title and interest in and to the following, whether now owned or hereafter acquired or arising (collectively, the “Patent Collateral”):

(a) all of its Patents and Patent Intellectual Property Licenses to which it is a party including those referred to on Schedule I;

(b) all divisionals, continuations, continuations-in-part, reissues, reexaminations or extensions of the foregoing; and

(c) all products and proceeds of the foregoing, including any claim by such Grantor against third parties for past, present or future infringement of any Patent or any Patent exclusively licensed under any Intellectual Property License, including the right to receive damages, or right to receive license fees, royalties, and other compensation under any Patent Intellectual Property License.

3. SECURITY FOR SECURED OBLIGATIONS. This Patent Security Agreement and the Security Interest created hereby secures the payment and performance of the Secured Obligations, whether now existing or arising hereafter. Without limiting the generality of the foregoing, this Patent Security Agreement secures the payment of all amounts which constitute part of the Secured Obligations and would be owed by Grantors or any of them, to Agent, the other members of the Lender Group, the Bank Product Providers or any of them, whether or not they are unenforceable or not allowable due to the existence of an Insolvency Proceeding involving any Grantor.

4. SECURITY AGREEMENT. The Security Interest granted pursuant to this Patent Security Agreement is granted in conjunction with the security interests granted to Agent, for the benefit of the Lender Group and the Bank Product Providers, pursuant to the Guaranty and Security Agreement. Each Grantor hereby acknowledges and affirms that the rights and remedies of Agent with respect to the Security Interest in the Patent Collateral made and granted hereby are more fully set forth in the Guaranty and Security Agreement, the terms and provisions of which are incorporated by reference herein as if fully set forth herein. To the extent there is any inconsistency between this Patent Security Agreement and the Guaranty and Security Agreement, the Guaranty and Security Agreement shall control.

5. AUTHORIZATION TO SUPPLEMENT. If any Grantor shall obtain rights to any new Patent application or issued Patent or become entitled to the benefit of any Patent application or Patent for any divisional, continuation, continuation-in-part, reissue or reexamination of any existing Patent or Patent application, the provisions of this Patent Security Agreement shall automatically apply thereto. Grantors shall give prompt notice in writing to Agent with respect to any such new Patent rights. Without limiting Grantors' obligations under this Section, Grantors hereby authorize Agent unilaterally to modify this Patent Security Agreement by amending Schedule I to include any such new Patent rights of each Grantor. Notwithstanding the foregoing, no failure to so modify this Patent Security Agreement or amend Schedule I shall in any way affect, invalidate or detract from Agent's continuing security interest in all Collateral, whether or not listed on Schedule I.

6. COUNTERPARTS. This Patent Security Agreement is a Loan Document. This Patent Security Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Patent Security Agreement. Delivery of an executed counterpart of this Patent Security Agreement by telefacsimile or other electronic method of transmission shall be equally as effective as delivery of an original executed counterpart of this Patent Security Agreement. Any party delivering an executed counterpart of this Patent Security Agreement by telefacsimile or other electronic method of transmission also shall deliver an original executed counterpart of this Patent Security Agreement but the failure to deliver an original executed counterpart shall not affect the validity, enforceability, and binding effect of this Patent Security Agreement.

7. CHOICE OF LAW AND VENUE, JURY TRIAL WAIVER, AND JUDICIAL REFERENCE PROVISION. THIS PATENT SECURITY AGREEMENT SHALL BE SUBJECT TO

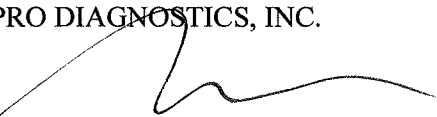
THE PROVISIONS REGARDING CHOICE OF LAW AND VENUE, JURY TRIAL WAIVER, AND JUDICIAL REFERENCE SET FORTH IN SECTION 25 OF THE GUARANTY AND SECURITY AGREEMENT, AND SUCH PROVISIONS ARE INCORPORATED HEREIN BY THIS REFERENCE, *MUTATIS MUTANDIS*.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have caused this Patent Security Agreement to be executed and delivered as of the day and year first above written.

GRANTORS:

NIPRO DIAGNOSTICS, INC.

By: 

Name: Scott Verner

Title: President and Chief Executive Officer

AGENT:

ACCEPTED AND ACKNOWLEDGED BY:

WELLS FARGO BANK, NATIONAL
ASSOCIATION, as Agent

By: _____

Name: Kathy R. Plisko

Title: Authorized Signatory

IN WITNESS WHEREOF, the parties hereto have caused this Patent Security Agreement to be executed and delivered as of the day and year first above written.

GRANTORS:

NIPRO DIAGNOSTICS, INC.

By: _____
Name: Scott Verner
Title: President and Chief Executive Officer

AGENT:

ACCEPTED AND ACKNOWLEDGED BY:

WELLS FARGO BANK, NATIONAL
ASSOCIATION, as Agent

By: Kathy R. Plisko
Name: Kathy R. Plisko
Title: Authorized Signatory

SCHEDULE 1
to
PATENT SECURITY AGREEMENT
PATENT APPLICATIONS AND PATENT NUMBERS

Patent Applications and Patent Numbers:

OWNER	APPLICATION NUMBER	PATENT NUMBER	PATENT
NIPRO DIAGNOSTICS, INC.	07287883	4889131	PORTABLE BELT MONITOR OF PHYSIOLOGICAL FUNCTIONS AND SENSORS
NIPRO DIAGNOSTICS, INC.	07862733	5296192	DIAGNOSTIC TEST STRIP
NIPRO DIAGNOSTICS, INC.	08872088	6040195	DIAGNOSTIC SANITARY TEST STRIP
NIPRO DIAGNOSTICS, INC.	09059082	5995236	BLOOD FLUID CHARACTERISTICS ANALYSIS INSTRUMENT
NIPRO DIAGNOSTICS, INC.	09263975	6248550	ASSAYS FOR PROTEIN KINASES USING FLUORESCENT PROTEIN SUBSTRATES
NIPRO DIAGNOSTICS, INC.	09379130	6201607	BLOOD FLUID CHARACTERISTICS ANALYSIS INSTRUMENT
NIPRO DIAGNOSTICS, INC.	09448711	6458326	PROTECTIVE TEST STRIP PLATFORM
NIPRO DIAGNOSTICS, INC.	09794037	6525330	METHOD OF STRIP INSERTION DETECTION
NIPRO DIAGNOSTICS, INC.	09794044	6562625	DISTINGUISHING TEST TYPES THROUGH SPECTRAL ANALYSIS
NIPRO DIAGNOSTICS, INC.	09794045	6541266	METHOD FOR DETERMINING CONCENTRATION OF AN ANALYTE IN A TEST STRIP
NIPRO DIAGNOSTICS, INC.	09984948	6991940	DIAGNOSTIC SANITARY TEST STRIP

OWNER	APPLICATION NUMBER	PATENT NUMBER	PATENT
NIPRO DIAGNOSTICS, INC.	10208878	6979571	METHOD OF USING A PROTECTIVE TEST STRIP PLATFORM FOR OPTICAL METER APPARATUS
NIPRO DIAGNOSTICS, INC.	10286648	6743635	SYSTEM AND METHODS FOR BLOOD GLUCOSE SENSING
NIPRO DIAGNOSTICS, INC.	10378797	7390665	DISTINGUISHING TEST TYPES THROUGH SPECTRAL ANALYSIS
NIPRO DIAGNOSTICS, INC.	10420995	6946299	SYSTEMS AND METHODS FOR BLOOD GLUCOSE SENSING
NIPRO DIAGNOSTICS, INC.	10706161	6953693	SYSTEMS AND METHODS FOR BLOOD GLUCOSE SENSING
NIPRO DIAGNOSTICS, INC.	10706634	7160251	SYSTEMS AND METHODS FOR BLOOD GLUCOSE SENSING
NIPRO DIAGNOSTICS, INC.	10706663	6959247	SYSTEMS AND METHODS FOR BLOOD GLUCOSE SENSING
NIPRO DIAGNOSTICS, INC.	10764972	6964871	SYSTEMS AND METHODS FOR BLOOD GLUCOSE SENSING
NIPRO DIAGNOSTICS, INC.	10764974		MEDICAL DIAGNOSTIC TESTING DEVICE WITH VOICE MESSAGE CAPABILITY
NIPRO DIAGNOSTICS, INC.	10857917	8147426	INTEGRATED DIAGNOSTIC TEST SYSTEM
NIPRO DIAGNOSTICS, INC.	10967901	7025226	DRIVE SYSTEM FOR AN INFUSION PUMP
NIPRO DIAGNOSTICS, INC.	11084007	7049130	DIAGNOSTIC SANITARY TEST STRIP
NIPRO DIAGNOSTICS, INC.	11118494	7467065	COMPUTER INTERFACE FOR DIAGNOSTIC METER

OWNER	APPLICATION NUMBER	PATENT NUMBER	PATENT
NIPRO DIAGNOSTICS, INC.	11181778		DIAGNOSTIC STRIP CODING SYSTEM AND RELATED METHODS OF USE
NIPRO DIAGNOSTICS, INC.	11254881	8394337	TEST STRIP CONTAINER WITH INTEGRATED METER
NIPRO DIAGNOSTICS, INC.	11352209	8394328	TEST STRIP CONTAINER WITH INTEGRATED METER HAVING STRIP CODING CAPABILITY
NIPRO DIAGNOSTICS, INC.	11373284	8388905	METHOD AND APPARATUS FOR CODING DIAGNOSTIC METERS
NIPRO DIAGNOSTICS, INC.	11417225	7909983	SYSTEM AND METHODS FOR AUTOMATICALLY RECOGNIZING A CONTROL SOLUTION
NIPRO DIAGNOSTICS, INC.	11434063	7560288	DIAGNOSTIC SANITARY TEST STRIP
NIPRO DIAGNOSTICS, INC.	11458298		DIAGNOSTIC STRIP CODING SYSTEM WITH CONDUCTIVE LAYERS
NIPRO DIAGNOSTICS, INC.	11476702	7465597	METHOD OF MANUFACTURING A DIAGNOSTIC TEST STRIP
NIPRO DIAGNOSTICS, INC.	11590854	7819161	SYSTEMS AND METHODS FOR BLOOD GLUCOSE SENSING
NIPRO DIAGNOSTICS, INC.	11594753	7955856	METHOD OF MAKING A DIAGNOSTIC TEST STRIP HAVING A CODING SYSTEM
NIPRO DIAGNOSTICS, INC.	11764471	7972866	BIOSENSOR AND ULTRASONIC METHOD OF MAKING A BIOSENSOR
NIPRO DIAGNOSTICS, INC.	11783568	8128981	BIOSENSOR MANUFACTURING METHOD

OWNER	APPLICATION NUMBER	PATENT NUMBER	PATENT
NIPRO DIAGNOSTICS, INC.	11930862	8388906	APPARATUS FOR DISPENSING TEST STRIPS
NIPRO DIAGNOSTICS, INC.	12017496	7678250	REAGENT COMPOSITIONS FOR USE IN ELECTROCHEMICAL DETECTION
NIPRO DIAGNOSTICS, INC.	12115770		EMBEDDED STRIP LOT AUTOCALIBRATION
NIPRO DIAGNOSTICS, INC.	12179853	8088272	SYSTEM AND METHODS FOR DETERMINATION OF ANALYTE CONCENTRATION USING TIME RESOLVED AMPEROMETRY
NIPRO DIAGNOSTICS, INC.	12410048	8101062	SYSTEM AND METHODS FOR DETERMINATION OF ANALYTE CONCENTRATION USING TIME RESOLVED AMPEROMETRY
NIPRO DIAGNOSTICS, INC.	12724280	8062490	REAGENT COMPOSITIONS FOR USE IN ELECTROCHEMICAL DETECTION
NIPRO DIAGNOSTICS, INC.	13331346		SYSTEM AND METHODS FOR DETERMINATION OF ANALYTE CONCENTRATION USING TIME RESOLVED AMPEROMETRY
NIPRO DIAGNOSTICS, INC.	13403318	8529741	SYSTEM AND METHODS FOR DETERMINING AN ANALYTE CONCENTRATION INCORPORATING A HEMATOCRIT CORRECTION
NIPRO DIAGNOSTICS, INC.	29171117	D496461	BLOOD GLUCOSE METER
NIPRO DIAGNOSTICS, INC.	29182200	D512512	BLOOD GLUCOSE TEST STRIP

OWNER	APPLICATION NUMBER	PATENT NUMBER	PATENT
NIPRO DIAGNOSTICS, INC.	29183323	D499100	REMOVABLE MEMORY MODULE FOR A METER
NIPRO DIAGNOSTICS, INC.	29191862	D495418	BLOOD GLUCOSE METER
NIPRO DIAGNOSTICS, INC.	29206525	D506832	METER FOR AN INTEGRATED DIAGNOSTIC TEST SYSTEM
NIPRO DIAGNOSTICS, INC.	29206526	D507657	METER FOR AN INTEGRATED DIAGNOSTIC TEST SYSTEM
NIPRO DIAGNOSTICS, INC.	29222351	D561904	METER FOR AN INTEGRATED DIAGNOSTIC TEST SYSTEM
NIPRO DIAGNOSTICS, INC.	29255167	D555021	DIAGNOSTIC METER
NIPRO DIAGNOSTICS, INC.	29259436	D547216	DIAGNOSTIC METER
NIPRO DIAGNOSTICS, INC.	29302659	D600811	DIAGNOSTIC TEST SYSTEM
NIPRO DIAGNOSTICS, INC.	12102218	8460524	SYSTEM AND METHODS FOR CHEMISTRY PATTERNING IN A MULTIPLE SAMPLE WELL BIOSENSOR
NIPRO DIAGNOSTICS, INC.	08872088	6284550	DIAGNOSTIC SANITARY TEST STRIP
NIPRO DIAGNOSTICS, INC.	13025203		SYSTEM AND METHODS FOR AUTOMATICALLY RECOGNIZING A CONTROL SOLUTION
NIPRO DIAGNOSTICS, INC.	11711621		TEST STRIP WITH INTEGRATED LANCET

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
Stylesheet Version v1.2

EPAS ID: PAT2604081

SUBMISSION TYPE:

NEW ASSIGNMENT

NATURE OF CONVEYANCE:

RELEASE BY SECURED PARTY

CONVEYING PARTY DATA

Name	Execution Date
REGIONS BANK	11/01/2013

RECEIVING PARTY DATA

Name:	NIPRO DIAGNOSTICS, INC.
Street Address:	2400 NW 55TH COURT
City:	FORT LAUDERDALE
State/Country:	FLORIDA
Postal Code:	33309

PROPERTY NUMBERS Total: 57

Property Type	Number
Patent Number:	D315210
Application Number:	07287883
Application Number:	07862733
Application Number:	08872088
Application Number:	09059082
Application Number:	09263975
Application Number:	09379130
Application Number:	09448711
Application Number:	09794037
Application Number:	09794044
Application Number:	09794045
Application Number:	09984948
Application Number:	10208878
Application Number:	10286648
Application Number:	10378797

Application Number:	10420995
Application Number:	10706161
Application Number:	10706634
Application Number:	10706663
Application Number:	10764972
Application Number:	10764974
Application Number:	10857917
Application Number:	10967901
Application Number:	11084007
Application Number:	11118494
Application Number:	11181778
Application Number:	11254881
Application Number:	11352209
Application Number:	11373284
Application Number:	11417225
Application Number:	11434063
Application Number:	11458298
Application Number:	11476702
Application Number:	11590854
Application Number:	11594753
Application Number:	11764471
Application Number:	11783568
Application Number:	11930862
Application Number:	11934004
Application Number:	12017496
Application Number:	12115770
Application Number:	12179853
Application Number:	12247563
Application Number:	12410048
Application Number:	12724280
Application Number:	13331346
Application Number:	13403318
Application Number:	29171117
Application Number:	29182200
Application Number:	29183323

	29191862
Application Number:	29206525
Application Number:	29206526
Application Number:	29222351
Application Number:	29255167
Application Number:	29259436
Application Number:	29302659

CORRESPONDENCE DATA

Fax Number: (678)553-2602
 Phone: 6785532601
 Email: jimmarl@gtlaw.com
Correspondence will be sent via US Mail when the email attempt is unsuccessful.
 Correspondent Name: LASHANA C. JIMMAR
 Address Line 1: GREENBERG TRAUIG, LLP
 Address Line 2: 3333 PIEDMONT ROAD, NE, SUITE 2500
 Address Line 4: ATLANTA, GEORGIA 30305

ATTORNEY DOCKET NUMBER:	148294.010100
NAME OF SUBMITTER:	LASHANA C. JIMMAR
Signature:	/LaShana C. Jimmar/
Date:	11/05/2013
	This document serves as an Oath/Declaration (37 CFR 1.63).

Total Attachments: 7

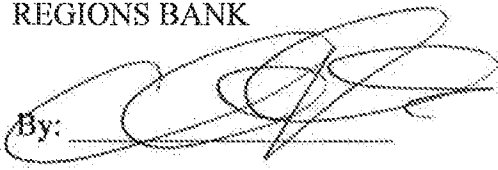
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 source=Regions-NIPRO Release of Security Interest in Patents#page6.tif
 source=Regions-NIPRO Release of Security Interest in Patents#page7.tif

Release of Security Interest

KNOW ALL MEN BY THESE PRESENTS that REGIONS BANK, an Alabama banking corporation having a place of business at 100 SE 3rd Avenue, 17th Floor, Fort Lauderdale, FL 33394, for One Dollar and other good and valuable consideration, does hereby release and discharge the security interests in the **patents** shown in Schedule A attached hereto, and incorporated in this Release by reference, granted to it by NIPRO DIAGNOSTICS, INC., a Delaware corporation having a principal place of business at 2400 NW 55th Court, Fort Lauderdale, FL 33309, Tax I.D. # 22-2594383, which security interest is dated August 22, 2012, and which was recorded on August 24, 2012 at **Reel 028840, Frame 0948**, in the U.S. Patent and Trademark Office, to which reference may be had.

IN WITNESS WHEREOF, said REGIONS BANK has hereunto caused its corporate name to be subscribed and seal affixed by Amish Patel, its _____ Vice President, thereby duly authorized, as of this Nov. 1 day of October, 2013.

REGIONS BANK

By: 

Name: Amish S Patel

Its: Vice President

STATE OF FLORIDA

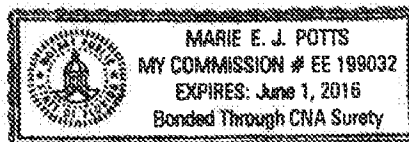
ss:

COUNTY OF Palm Bch

Before me, personally appeared Amish Patel Vice President of said REGIONS BANK, the signer and sealer of the foregoing instrument, who acknowledged the same to be the free act and deed of said REGIONS BANK.


Notary Public

My Commission Expires: 6/1/16



SCHEDULE A



UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

AUGUST 27, 2012

PTAS

GARY M. KRASNA
1900 NW CORPORATE BLVD
SUITE 301W
BOCA RATON, FL 33431

502036782

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT RECORDATION BRANCH OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE ASSIGNMENT RECORDATION BRANCH AT 571-272-3350. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, MAIL STOP: ASSIGNMENT RECORDATION BRANCH, P.O. BOX 1450, ALEXANDRIA, VA 22313.

RECORDATION DATE: 08/24/2012

REEL/FRAME: 028840/0948
NUMBER OF PAGES: 17

BRIEF: SECURITY AGREEMENT

ASSIGNOR:

NIPRO DIAGNOSTICS, INC.

DOC DATE: 08/22/2012

ASSIGNEE:

REGIONS BANK
100 SE THIRD AVENUE
17TH FLOOR
FORT LAUDERDALE, FLORIDA 33394

APPLICATION NUMBER: 07128475

FILING DATE: 12/03/1987

PATENT NUMBER: D315210

ISSUE DATE: 03/05/1991

TITLE: COMBINED PORTABLE CARDIAC AND RESPIRATORY MONITOR

APPLICATION NUMBER: 07287883

FILING DATE: 12/20/1988

PATENT NUMBER: 4889131

ISSUE DATE: 12/26/1989

TITLE: PORTABLE BELT MONITOR OF PHYSIOLOGICAL FUNCTIONS AND SENSORS THEREFOR

APPLICATION NUMBER: 07862733

FILING DATE: 04/03/1992

PATENT NUMBER: 5296192

ISSUE DATE: 03/22/1994

TITLE: DIAGNOSTIC TEST STRIP

APPLICATION NUMBER: 08872088	FILING DATE: 06/10/1997
PATENT NUMBER: 6040195	ISSUE DATE: 03/21/2000
TITLE: DIAGNOSTIC SANITARY TEST STRIP	
APPLICATION NUMBER: 09059082	FILING DATE: 04/13/1998
PATENT NUMBER: 5995236	ISSUE DATE: 11/30/1999
TITLE: BLOOD FLUID CHARACTERISTICS ANALYSIS INSTRUMENT	
APPLICATION NUMBER: 09263975	FILING DATE: 03/05/1999
PATENT NUMBER: 6248550	ISSUE DATE: 06/19/2001
TITLE: ASSAYS FOR PROTEIN KINASES USING FLUORESCENT PROTEIN SUBSTRATES	
APPLICATION NUMBER: 09379130	FILING DATE: 08/20/1999
PATENT NUMBER: 6201607	ISSUE DATE: 03/13/2001
TITLE: BLOOD FLUID CHARACTERISTICS ANALYSIS INSTRUMENT	
APPLICATION NUMBER: 09448711	FILING DATE: 11/24/1999
PATENT NUMBER: 6458326	ISSUE DATE: 10/01/2002
TITLE: PROTECTIVE TEST STRIP PLATFORM	
APPLICATION NUMBER: 09794037	FILING DATE: 02/28/2001
PATENT NUMBER: 6525330	ISSUE DATE: 02/25/2003
TITLE: METHOD OF STRIP INSERTION DETECTION	
APPLICATION NUMBER: 09794044	FILING DATE: 02/28/2001
PATENT NUMBER: 6562625	ISSUE DATE: 05/13/2003
TITLE: DISTINGUISHING TEST TYPES THROUGH SPECTRAL ANALYSIS	
APPLICATION NUMBER: 09794045	FILING DATE: 02/28/2001
PATENT NUMBER: 6541266	ISSUE DATE: 04/01/2003
TITLE: METHOD FOR DETERMINING CONCENTRATION OF AN ANALYTE IN A TEST STRIP	
APPLICATION NUMBER: 09984948	FILING DATE: 10/31/2001
PATENT NUMBER: 6991940	ISSUE DATE: 01/31/2006
TITLE: DIAGNOSTIC SANITARY TEST STRIP	
APPLICATION NUMBER: 10208878	FILING DATE: 08/01/2002
PATENT NUMBER: 6979571	ISSUE DATE: 12/27/2005
TITLE: PROTECTIVE TEST STRIP PLATFORM FOR OPTICAL METER APPARATUS	
APPLICATION NUMBER: 10286648	FILING DATE: 11/01/2002
PATENT NUMBER: 6743635	ISSUE DATE: 06/01/2004
TITLE: SYSTEM AND METHODS FOR BLOOD GLUCOSE SENSING	
APPLICATION NUMBER: 10378797	FILING DATE: 03/04/2003
PATENT NUMBER: 7390665	ISSUE DATE: 06/24/2008
TITLE: DISTINGUISHING TEST TYPES THROUGH SPECTRAL ANALYSIS	
APPLICATION NUMBER: 10420995	FILING DATE: 04/21/2003
PATENT NUMBER: 6946299	ISSUE DATE: 09/20/2005
TITLE: SYSTEMS AND METHODS FOR BLOOD GLUCOSE SENSING	
APPLICATION NUMBER: 10706161	FILING DATE: 11/12/2003
PATENT NUMBER: 6953693	ISSUE DATE: 10/11/2005
TITLE: SYSTEMS AND METHODS FOR BLOOD GLUCOSE SENSING	

APPLICATION NUMBER: 10706634	FILING DATE: 11/12/2003
PATENT NUMBER: 7160251	ISSUE DATE: 01/09/2007
TITLE: SYSTEMS AND METHODS FOR BLOOD GLUCOSE SENSING	
APPLICATION NUMBER: 10706663	FILING DATE: 11/12/2003
PATENT NUMBER: 6959247	ISSUE DATE: 10/25/2005
TITLE: SYSTEMS AND METHODS FOR BLOOD GLUCOSE SENSING	
APPLICATION NUMBER: 10764972	FILING DATE: 01/26/2004
PATENT NUMBER: 6964871	ISSUE DATE: 11/15/2005
TITLE: SYSTEMS AND METHODS FOR BLOOD GLUCOSE SENSING	
APPLICATION NUMBER: 10764974	FILING DATE: 01/26/2004
PATENT NUMBER:	ISSUE DATE:
TITLE: MEDICAL DIAGNOSTIC TESTING DEVICE WITH VOICE MESSAGE CAPABILITY	
APPLICATION NUMBER: 10857917	FILING DATE: 06/02/2004
PATENT NUMBER: 8147426	ISSUE DATE: 04/03/2012
TITLE: INTEGRATED DIAGNOSTIC TEST SYSTEM	
APPLICATION NUMBER: 10967901	FILING DATE: 10/18/2004
PATENT NUMBER: 7025226	ISSUE DATE: 04/11/2006
TITLE: DRIVE SYSTEM FOR AN INFUSION PUMP	
APPLICATION NUMBER: 11084007	FILING DATE: 03/21/2005
PATENT NUMBER: 7049130	ISSUE DATE: 05/23/2006
TITLE: DIAGNOSTIC SANITARY TEST STRIP	
APPLICATION NUMBER: 11118494	FILING DATE: 05/02/2005
PATENT NUMBER: 7467065	ISSUE DATE: 12/16/2008
TITLE: COMPUTER INTERFACE FOR DIAGNOSTIC METER	
APPLICATION NUMBER: 11181778	FILING DATE: 07/15/2005
PATENT NUMBER:	ISSUE DATE:
TITLE: DIAGNOSTIC STRIP CODING SYSTEM AND RELATED METHODS OF USE	
APPLICATION NUMBER: 11254881	FILING DATE: 10/21/2005
PATENT NUMBER:	ISSUE DATE:
TITLE: TEST STRIP CONTAINER WITH INTEGRATED METER	
APPLICATION NUMBER: 11352209	FILING DATE: 02/13/2006
PATENT NUMBER:	ISSUE DATE:
TITLE: TEST STRIP CONTAINER WITH INTEGRATED METER HAVING STRIP CODING CAPABILITY	
APPLICATION NUMBER: 11373284	FILING DATE: 03/13/2006
PATENT NUMBER:	ISSUE DATE:
TITLE: METHOD AND APPARATUS FOR CODING DIAGNOSTIC METERS	
APPLICATION NUMBER: 11417225	FILING DATE: 05/04/2006
PATENT NUMBER: 7909983	ISSUE DATE: 03/22/2011
TITLE: SYSTEM AND METHODS FOR AUTOMATICALLY RECOGNIZING A CONTROL SOLUTION	
APPLICATION NUMBER: 11434063	FILING DATE: 05/16/2006
PATENT NUMBER: 7560288	ISSUE DATE: 07/14/2009
TITLE: DIAGNOSTIC SANITARY TEST STRIP	

APPLICATION NUMBER: 11458298	FILING DATE: 07/18/2006
PATENT NUMBER:	ISSUE DATE:
TITLE: DIAGNOSTIC STRIP CODING SYSTEM WITH CONDUCTIVE LAYERS	
APPLICATION NUMBER: 11476702	FILING DATE: 06/29/2006
PATENT NUMBER: 7465597	ISSUE DATE: 12/16/2008
TITLE: METHOD OF MANUFACTURING A DIAGNOSTIC TEST STRIP	
APPLICATION NUMBER: 11590854	FILING DATE: 11/01/2006
PATENT NUMBER: 7819161	ISSUE DATE: 10/26/2010
TITLE: SYSTEMS AND METHODS FOR BLOOD GLUCOSE SENSING	
APPLICATION NUMBER: 11594753	FILING DATE: 11/09/2006
PATENT NUMBER: 7955856	ISSUE DATE: 06/07/2011
TITLE: METHOD OF MAKING A DIAGNOSTIC TEST STRIP HAVING A CODING SYSTEM	
APPLICATION NUMBER: 11764471	FILING DATE: 06/18/2007
PATENT NUMBER: 7972866	ISSUE DATE: 07/05/2011
TITLE: BIOSENSOR AND ULTRASONIC METHOD OF MAKING A BIOSENSOR	
APPLICATION NUMBER: 11783568	FILING DATE: 04/10/2007
PATENT NUMBER: 8128981	ISSUE DATE: 03/06/2012
TITLE: BIOSENSOR MANUFACTURING METHOD	
APPLICATION NUMBER: 11930862	FILING DATE: 10/31/2007
PATENT NUMBER:	ISSUE DATE:
TITLE: APPARATUS FOR DISPENSING TEST STRIPS	
APPLICATION NUMBER: 11934004	FILING DATE: 11/01/2007
PATENT NUMBER:	ISSUE DATE:
TITLE: METHOD AND APPARATUS FOR CODING DIAGNOSTIC METERS	
APPLICATION NUMBER: 12017496	FILING DATE: 01/22/2008
PATENT NUMBER: 7678250	ISSUE DATE: 03/16/2010
TITLE: REAGENT COMPOSITIONS FOR USE IN ELECTROCHEMICAL DETECTION	
APPLICATION NUMBER: 12115770	FILING DATE: 05/06/2008
PATENT NUMBER:	ISSUE DATE:
TITLE: EMBEDDED STRIP LOT AUTOCALIBRATION	
APPLICATION NUMBER: 12179853	FILING DATE: 07/25/2008
PATENT NUMBER: 8088272	ISSUE DATE: 01/03/2012
TITLE: SYSTEM AND METHODS FOR DETERMINATION OF ANALYTE CONCENTRATION USING TIME RESOLVED AMPEROMETRY	
APPLICATION NUMBER: 12247563	FILING DATE: 10/08/2008
PATENT NUMBER:	ISSUE DATE:
TITLE: DUAL FREQUENCY IMPEDANCE MEASUREMENT OF HEMATOCRIT IN STRIPS	
APPLICATION NUMBER: 12410048	FILING DATE: 03/24/2009
PATENT NUMBER: 8101062	ISSUE DATE: 01/24/2012
TITLE: SYSTEM AND METHODS FOR DETERMINATION OF ANALYTE CONCENTRATION USING TIME RESOLVED AMPEROMETRY	
APPLICATION NUMBER: 12724280	FILING DATE: 03/15/2010
PATENT NUMBER: 8062490	ISSUE DATE: 11/22/2011
TITLE: REAGENT COMPOSITIONS FOR USE IN ELECTROCHEMICAL DETECTION	

APPLICATION NUMBER: 13331346 FILING DATE: 12/20/2011
PATENT NUMBER: ISSUE DATE:
TITLE: SYSTEM AND METHODS FOR DETERMINATION OF ANALYTE CONCENTRATION
USING TIME RESOLVED AMPEROMETRY

APPLICATION NUMBER: 13403318 FILING DATE: 02/23/2012
PATENT NUMBER: ISSUE DATE:
TITLE: SYSTEM AND METHODS FOR DETERMINING AN ANALYTE CONCENTRATION
INCORPORATING A HEMATOCRIT CORRECTION

APPLICATION NUMBER: 29171117 FILING DATE: 11/15/2002
PATENT NUMBER: D496461 ISSUE DATE: 09/21/2004
TITLE: BLOOD GLUCOSE METER

APPLICATION NUMBER: 29182200 FILING DATE: 05/21/2003
PATENT NUMBER: D512512 ISSUE DATE: 12/06/2005
TITLE: BLOOD GLUCOSE TEST STRIP

APPLICATION NUMBER: 29183323 FILING DATE: 06/10/2003
PATENT NUMBER: D499100 ISSUE DATE: 11/30/2004
TITLE: REMOVABLE MEMORY MODULE FOR A METER

APPLICATION NUMBER: 29191862 FILING DATE: 10/14/2003
PATENT NUMBER: D495418 ISSUE DATE: 08/31/2004
TITLE: BLOOD GLUCOSE METER

APPLICATION NUMBER: 29206525 FILING DATE: 06/02/2004
PATENT NUMBER: D506832 ISSUE DATE: 06/28/2005
TITLE: METER FOR AN INTEGRATED DIAGNOSTIC TEST SYSTEM

APPLICATION NUMBER: 29206526 FILING DATE: 06/02/2004
PATENT NUMBER: D507657 ISSUE DATE: 07/19/2005
TITLE: METER FOR AN INTEGRATED DIAGNOSTIC TEST SYSTEM

APPLICATION NUMBER: 29222351 FILING DATE: 01/31/2005
PATENT NUMBER: D561904 ISSUE DATE: 02/12/2008
TITLE: METER FOR AN INTEGRATED DIAGNOSTIC TEST SYSTEM

APPLICATION NUMBER: 29255167 FILING DATE: 03/07/2006
PATENT NUMBER: D555021 ISSUE DATE: 11/13/2007
TITLE: DIAGNOSTIC METER

APPLICATION NUMBER: 29259436 FILING DATE: 05/08/2006
PATENT NUMBER: D547216 ISSUE DATE: 07/24/2007
TITLE: DIAGNOSTIC METER

APPLICATION NUMBER: 29302659 FILING DATE: 01/22/2008
PATENT NUMBER: D600811 ISSUE DATE: 09/22/2009
TITLE: DIAGNOSTIC TEST SYSTEM

ASSIGNMENT RECORDATION BRANCH
PUBLIC RECORDS DIVISION

**REVOCATION OF POWER OF ATTORNEY WITH NEW POWER
OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS**

#	Application No.	Filing Date	First Named Inventor	Art Unit	Examiner
1	09/448,711	24-Nov-1999	Brent Modzelewski	1743	Alexander, Lyle
2	29/183,323	10-Jun-2003	Gary T. Neel	2911	Tung, Melanie H.
3	29/182,200	21-May-2003	Douglas E. Bell	2914	Simmons, Ian
4	11/254,881	21-Oct-2005	Gary T. Neel	1773	Hammond, Charles
5	29/206,525	02-Jun-2004	Gary T. Neel	2914	Pellegrini, Melanie Sue
6	29/222,351	31-Jan-2005	Gary T. Neel	2914	Doan, Anhdao
7	11/181,778	15-Jul-2005	Gary T. Neel	1797	Fritchman, Rebecca M.
8	12/115,770	06-May-2008	Gary T. Neel	1759	Dieterle, Jennifer M.
9	11/373,284	13-Mar-2006	Gary T. Neel	1773	Merkling, Sally Anne
10	11/934,004	01-Nov-2007	Gary T. Neel	1773	Turk, Neil N.
11	11/395,266	03-Apr-2006	Gary T. Neel	3736	Foreman, Jonathan M.
12	29/259,436	08-May-2006	George R. Rounds	2915	Davis, Antoine D.
13	11/458,298	18-Jul-2006	Natasha Popovich	1731	Olsen, Kaj K.
14	11/711,621	28-Feb-2007	Gary Neel	3736	Stout, Michael C.
15	13/403,318	23-Feb-2012	Gary T. Neel	1759	Dieterle, Jennifer M.
16	29/302,659	22-Jan-2008	George R. Rounds	2914	Doan, Anhdao
17	13/331,346	20-Dec-2011	David Deng	1759	Bell, Bruce F.
18	12/179,870	25-Jul-2008	Ferhan Kayihan	2862	Nghiem, Michael P.
19	10/764,974	26-Jan-2004	Gary T. Neel	3686	Woods, Teresa S.
20	11/734,473	12-Apr-2007	Brent E. Modzelewski	1773	Alexander, Lyle
21	11/764,471	18-Jun-2007	Steven B. Gilmour	1772	Jarrett, Lore Ramillano
22	11/783,568	10-Apr-2007	Natasha Popovich	1717	Bowman, Andrew J.
23	11/845,860	28-Aug-2007	Gary T. Neel	1759	Dieterle, Jennifer M.
24	12/102,218	14-Apr-2008	Natasha Popovich	1759	Dieterle, Jennifer M.
25	13/025,203	11-Feb-2011	Natasha Popovich	1759	Ball, John C.

I hereby revoke all previous powers of attorney given in the above-identified patent applications and patents.

☐

A Power of Attorney is submitted herewith.

Or

☒

I hereby appoint the practitioners associated with the Customer Number: **35893**

☒

Please change the correspondence address for the above-identified applications/patents to
 x The address associated with Customer Number: **35893**

I am the:

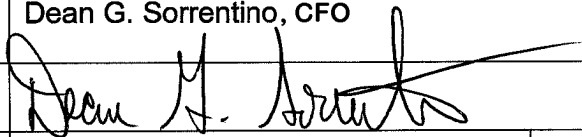
 x Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed.

SIGNATURE of Applicant or Assignee of Record

Name

Dean G. Sorrentino, CFO

Signature



Date

April 21, 2014

Telephone

(954) 677-4522

STATEMENT UNDER 37 CFR 3.73(b)

#	APPLICANT/ PATENT OWNER	APPLICATION No	FILING DATE	ENTITLED	NAME OF ASSIGNEE	ASSIGNMENT RECORDED AT REEL/FRAE NO.
1	NIPRO DIAGNOSTICS, INC.	09/448,711	24-Nov-1999	PROTECTIVE TEST STRIP PLATFORM	NIPRO DIAGNOSTICS, INC.	024678/0455
2	NIPRO DIAGNOSTICS, INC	29/183,323	10-Jun-2003	REMOVABLE MEMORY MODULE FOR A METER	NIPRO DIAGNOSTICS, INC.	024678/0455
3	NIPRO DIAGNOSTICS, INC	29/182,200	21-May-2003	BLOOD GLUCOSE TEST STRIP	NIPRO DIAGNOSTICS, INC.	024678/0455
4	NIPRO DIAGNOSTICS, INC	11/254,881	21-Oct-2005	TEST STRIP CONTAINER WITH INTEGRATED METER	NIPRO DIAGNOSTICS, INC.	024678/0455
5	NIPRO DIAGNOSTICS, INC	29/206,525	02-Jun-2004	METER FOR AN INTEGRATED DIAGNOSTIC TEST SYSTEM	NIPRO DIAGNOSTICS, INC.	024678/0455
6	NIPRO DIAGNOSTICS, INC	29/222,351	31-Jan-2005	METER FOR AN INTEGRATED DIAGNOSTIC TEST SYSTEM	NIPRO DIAGNOSTICS, INC.	024678/0455
7	Neel et al.	11/181,778	15-Jul-2005	DIAGNOSTIC STRIP CODING SYSTEM AND RELATED METHODS OF USE	NIPRO DIAGNOSTICS, INC.	024678/0455
8	Neel et al.	12/115,770	06-May-2008	EMBEDDED STRIP LOT AUTOCALIBRATION	NIPRO DIAGNOSTICS, INC.	024678/0455
9	NIPRO DIAGNOSTICS, INC	11/373,284	13-Mar-2006	METHOD AND APPARATUS FOR CODING DIAGNOSTIC METERS	NIPRO DIAGNOSTICS, INC.	024678/0455
10	Neel et al.	11/934,004	01-Nov-2007	METHOD AND APPARATUS FOR CODING DIAGNOSTIC METERS	NIPRO DIAGNOSTICS, INC.	024678/0455
11	NIPRO DIAGNOSTICS, INC	11/395,266	03-Apr-2006	DIAGNOSTIC METER	NIPRO DIAGNOSTICS, INC.	024678/0455
12	NIPRO DIAGNOSTICS, INC	29/259,436	08-May-2006	DIAGNOSTIC METER	NIPRO DIAGNOSTICS, INC.	024678/0455
13	Popovich et al.	11/458,298	18-Jul-2006	DIAGNOSTIC STRIP CODING SYSTEM WITH CONDUCTIVE LAYERS	NIPRO DIAGNOSTICS, INC.	024678/0455
14	NIPRO DIAGNOSTICS, INC	11/711,621	28-Feb-2007	TEST STRIP WITH INTEGRATED LANCET	NIPRO DIAGNOSTICS, INC.	024678/0455
15	NIPRO DIAGNOSTICS, INC	13/403,318	23-Feb-2012	SYSTEM AND METHODS FOR DETERMINING AN ANALYTE CONCENTRATION INCORPORATING A HEMATOCRIT CORRECTION	NIPRO DIAGNOSTICS, INC.	024678/0455
16	NIPRO DIAGNOSTICS, INC	29/302,659	22-Jan-2008	DIAGNOSTIC TEST SYSTEM	NIPRO DIAGNOSTICS, INC.	024678/0455
17	NIPRO DIAGNOSTICS, INC	13/331,346	20-Dec-2011	SYSTEM AND METHODS FOR DETERMINATION OF ANALYTE CONCENTRATION USING TIME RESOLVED AMPEROMETRY	NIPRO DIAGNOSTICS, INC.	024678/0455
18	Kayihan et al.	12/179,870	25-Jul-2008	SYSTEM AND METHODS FOR DETERMINATION OF ANALYTE CONCENTRATION USING TIME RESOLVED AMPEROMETRY	NIPRO DIAGNOSTICS, INC.	024678/0455
19	Neel et al.	10/764,974	26-Jan-2004	MEDICAL DIAGNOSTIC TESTING DEVICE WITH VOICE MESSAGE CAPABILITY	NIPRO DIAGNOSTICS, INC.	024678/0455
20	. Modzelewski et al.	11/734,473	12-Apr-2007	ERROR DETECTION AND REJECTION FOR A DIAGNOSTIC TESTING SYSTEM	NIPRO DIAGNOSTICS, INC.	024678/0455
21	NIPRO DIAGNOSTICS, INC	11/764,471	18-Jun-2007	BIOSENSOR AND ULTRASONIC METHOD OF MAKING A BIOSENSOR	NIPRO DIAGNOSTICS, INC.	024678/0455
22	NIPRO DIAGNOSTICS, INC	11/783,568	10-Apr-2007	BIOSENSOR MANUFACTURING METHOD	NIPRO DIAGNOSTICS, INC.	024678/0455

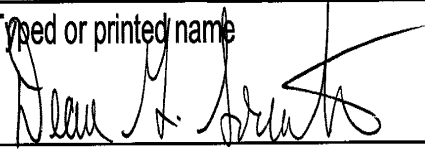
#	APPLICANT/ PATENT OWNER	APPLICATION No	FILING DATE	ENTITLED	NAME OF ASSIGNEE	ASSIGNMENT RECORDED AT REEL/FRAME NO.
23	Neel et al.	11/845,860	28-Aug-2007	SYSTEM AND METHODS FOR DETERMINING AN ANALYTE CONCENTRATION INCORPORATING A HEMATOCRIT CORRECTION	NIPRO DIAGNOSTICS, INC.	024678/0455
24	NIPRO DIAGNOSTICS, INC	12/102,218	14-Apr-2008	SYSTEM AND METHODS OF CHEMISTRY PATTERNING FOR A MULTIPLE WELL BIOSENSOR	NIPRO DIAGNOSTICS, INC.	024678/0455
25	NIPRO DIAGNOSTICS, INC	13/025,203	11-Feb-2011	SYSTEM AND METHODS FOR AUTOMATICALLY RECOGNIZING A CONTROL SOLUTION	NIPRO DIAGNOSTICS, INC	024678/0455

Patent owner states that it is the Assignee of the entire right, title, and interest of the above-listed patent applications and patents and that Assignments were recorded at the United States Patent and Trademark Office at the reel and frame numbers listed above.

The undersigned (whose title is supplied below) is authorized to act on behalf of Assignee.

April 21, 2014
Date

(954) 677-4522
Telephone number

Dean G. Sorrentino
Typed or printed name

Signature

Chief Financial Officer
Title

CHI 64679087v1

Electronic Acknowledgement Receipt

EFS ID:	18828921
Application Number:	11783568
International Application Number:	
Confirmation Number:	8766
Title of Invention:	BIOSENSOR MANUFACTURING METHOD
First Named Inventor/Applicant Name:	Natasha Popovich
Customer Number:	22852
Filer:	David Jack Dykeman/Juliann Raymond
Filer Authorized By:	David Jack Dykeman
Attorney Docket Number:	06882.0200-00
Receipt Date:	22-APR-2014
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Time Stamp:	16:10:54
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	POAandChangeofAddress.pdf	710232 58aa3670b450752269cfaac92a0c66ea719b21b2	no	2

Warnings:

Information:

2	Assignee showing of ownership per 37 CFR 3.73.	Statement.pdf	345141 303382d5053c1376696707594ba873a75e079ccd	no	2
Warnings:					
Information:					
Total Files Size (in bytes):				1055373	
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/783,568	04/10/2007	Natasha Popovich	

35893
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ONE INTERNATIONAL PLACE, 20th FL
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BOSTON, MA 02110

CONFIRMATION NO. 8766
POA ACCEPTANCE LETTER



Date Mailed: 05/06/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/22/2014.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/jtfitzhugh sr/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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11/783,568	04/10/2007	Natasha Popovich	06882.0200-00

CONFIRMATION NO. 8766

POWER OF ATTORNEY NOTICE



OC000000068245187

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Date Mailed: 05/06/2014

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/22/2014.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/jtfitzhugh sr/

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