

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Roche Diabetes Care, Inc.,
Petitioner,

v.

Trividia Health, Inc.,
Patent Owner.

Case No. IPR2025-00553
U.S. Patent No. 8,128,981

**DECLARATION OF DR. DAVID CUNNINGHAM REGARDING CLAIMS
1-13, 15-16, 18-30, AND 32-37 OF U.S. PATENT NO. 8,128,981**

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I, David Cunningham, Ph.D., declare as follows:

I. INTRODUCTION

1. My name is David Cunningham.

2. I am making this Declaration at the request of Roche Diabetes Care, Inc (“Petitioner”) as an independent expert in this proceeding before the United States Patent and Trademark Office and to provide testimony pertinent to Petitioner’s Petition for *Inter Partes* Review of U.S. Patent No. 8,128,981 (the “’981 patent”). I understand that Petitioner is challenging claims 1-13, 15-16, 18-30, and 32-37 of the ’981 patent (“Challenged Claims”).

II. QUALIFICATIONS AND EXPERIENCE

3. My qualifications for setting forth the conclusions in this Declaration are summarized below. My curriculum vitae, which describes *inter alia* my education, experience, professional activities, my publications, and patents, is attached as **Appendix A**.

4. I received my Bachelor of Science in Chemistry from Iowa State University (in 1977). I also received my Master of Science (in 1984), and Ph.D. (in 1987), in Analytical Chemistry, from the University of Cincinnati.

5. I have over two decades of experience designing and developing medical diagnostic devices, with a focus on electrochemical sensors and glucose

monitoring technology. From 1986-1991, I conducted contract research and was a consultant for Abbott Laboratories (“Abbott”), a medical device company that developed technologies for cardiovascular health, diabetes management, diagnostic testing, nutrition, chronic pain and more. While working at Universal Sensors and consulting for Abbott, I conducted technical studies of biosensor components. There, I integrated chemistry, material science, and engineering into manufacturable designs and demonstrated biosensor functionality on physiological samples as part of an advanced peritoneal dialysis system, resulting in three US patents. From 1991-1995, I served as a Research Investigator in the Hospital Products Division at Abbott. My work included advanced research on new formulations and drug delivery systems. From 1996-2003, I was a Research Investigator, promoted to Associate Research Fellow, in the Diagnostics Division Glucose Venture at Abbott. I managed exploratory glucose monitoring research projects, designed initial integrated systems, led human clinical studies, and coordinated research efforts with outside partners. Notably, I co-invented the Sof-Tact, a virtually painless glucose monitoring system launched in 2000. While in the Glucose Venture, I personally constructed novel configurations of glucose test strips that involved processes including reel-to-reel coating, screen printing, lamination of spacing layers, lamination of cover layers and steel-rule dye cutting operations, among others. From 2004-2011, I served as a

Program Manager and Associate Research Fellow in the Diagnostics Division Operations at Abbott. I managed multiple projects involving lean manufacturing process improvements on over 40 assays across various immunoassay systems.

6. In addition to my work in industry, I have also served as an Assistant Professor of Chemistry at Eastern Kentucky University from 2011-2018. In that capacity, I taught classes to undergraduate students and to graduate students in several courses, such as Bioanalytical Chemistry and Forensic Analytical Toxicology. Additionally, since 2018, I have been an Assistant Professor, promoted to Associate Professor in the Chemistry and Physics Department at Southeast Missouri State University, supporting chemistry and forensic science degree options. I teach undergraduate and graduate-level lecture and laboratory courses, continuing to share my expertise and passion for biosensor technology with the next generation of scientists. Since 2019, I have also been an Adjunct Assistant Professor at the University of Kentucky, College of Medicine, Department of Toxicology and Cancer Biology. I assisted with the design and launch of a Professional Masters in Forensic Toxicology & Analytical Genetics Program.

7. Since 2017, I have been the Principal at Hunter Scientific Services, providing scientific and technical consulting services to life science, diagnostics, and medical device companies. My consulting work has allowed me to leverage my

extensive experience in biosensor development and diagnostics to assist companies in advancing their technologies and improving their products.

8. I have published more than 20 peer-reviewed scientific articles and have 15 issued U.S. patents. Additionally, I have authored several books and book chapters. Notably, I have authored “Blood Glucose Monitoring” *in* “The Biomedical Engineering Handbook, Third and Fourth Editions CRC Press (2006 and 2015). I have also authored “Biosensors for Personal Diabetes Management” *in* “Commercial Biosensors: Applications to Clinical, Bioprocess and Environmental Samples, John Wiley & Sons (1998). I was a co-editor of the book: In Vivo Glucose Sensing, John Wiley & Sons (2010).

9. From 2005 to 2007 I was a member of the National Institutes of Health, Bioengineering, Technology and Surgical Sciences Study Section. From 2011 to 2016, I was on the Board of Directors of the Society for Electroanalytical Chemistry, and I am a Lifetime member.

10. Additionally, I was a grant and program reviewer on over 35 panels for the National Science Foundation and National Institutes of Health grant review panels. I have also delivered over 70 oral papers and invited lectures.

11. Throughout my career designing medical devices and diagnostics, I have routinely consulted with medical practitioners. This includes, but is not limited

to, consulting medical journals, and discussing design, performance, and treatment criteria with medical practitioners. I am being compensated for my work in this matter at my standard consulting rate of \$360 per hour. However, my conclusions are based on my own understanding of the prior art, the knowledge of a person of ordinary skill in the art, and the patent at issue. My compensation is not dependent on and in no way affects the content of my statements or conclusions in this Declaration, nor does it affect any testimony I give, nor is it dependent on the outcome of this proceeding.

12. I have no financial interest in the Petitioner. I similarly have no financial interest in the '981 patent and have had no contact with the named inventors of the '981 patent.

III. LEGAL PRINCIPLES

13. I am not an attorney. For the purposes of this Declaration, I have been informed about certain aspects of the law that are relevant to my conclusions. My understanding of the law was provided to me by Petitioner's attorneys.

A. Scope of Conclusions

14. I have been informed and understand that the petitioner in an *inter partes* review may request cancellation of claims as unpatentable only on grounds that such claims are anticipated or would have been obvious to a person of ordinary

skill in the art at the time of the purported invention, and only on the basis of prior art—i.e., art pre-dating the earliest claimed priority date of the '981 patent (April 11, 2006)—consisting of patents or printed publications. My conclusions in this matter address only such grounds.

B. Obviousness

15. I understand that a claim is unpatentable if it would have been obvious to a person of ordinary skill in the art at the time the alleged invention was made. I understand that a claim could have been obvious based on the teachings or suggestions of a single prior art reference or from a combination of two or more prior art references. I understand that an obviousness analysis requires an understanding of the scope and content of the prior art, any differences between the alleged invention and the prior art, and the level of ordinary skill in evaluating the pertinent art.

16. I further understand that a claim would have been obvious if it unites old elements with no change to their respective functions or alters prior art by mere substitution of one element for another known in the field, and that combination yields predictable results. Also, I understand that obviousness does not require physical combination/bodily incorporation, but rather consideration of what the

combined teachings would have suggested to persons of ordinary skill in the art at the time of the alleged invention.

17. In connection with obviousness, I have been informed that there must have been some reason or motivation that would have led a person of ordinary skill in the art to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have had a reasonable expectation of success in doing so.

18. While it may be helpful to identify a reason for this combination, I understand that there is no rigid requirement of finding an express teaching, suggestion, or motivation to combine within the references. If a person of ordinary skill in the art can implement a predictable variation, obviousness likely bars its patentability. For the same reason, if a technique has been used to improve one device and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique would have been obvious. I understand that a claim would have been obvious if a person of ordinary skill in the art would have had reason to combine multiple prior art references or add missing features to reproduce the alleged invention recited in the claims.

19. In sum, I understand that a determination of whether a claim would have been obvious is based upon a variety of considerations, including, among others:

- whether the teachings of the prior art references disclose known concepts combined in familiar ways, which, when combined, would yield predictable results;
- whether a person having ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;
- whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by those skilled in the art;
- whether a person having ordinary skill would have recognized a reason to combine known elements in the manner described in the claim;
- whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and
- whether the alleged invention applies a known technique that had been used to improve a similar device or method in a similar way.

20. I also understand that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered. I also understand that one of ordinary skill in the art has ordinary creativity, and is not an automaton.

21. I further understand that certain factors, commonly referred to as secondary considerations, may support or rebut the obviousness of a claim. I also understand that secondary considerations cannot be used to overcome anticipation. I understand that such secondary considerations include, among other things, commercial success of the patented invention, skepticism of those having ordinary skill in the art at the time of invention, unexpected results of the invention, any long-felt but unsolved need in the art that was satisfied by the alleged invention, the failure of others to make the alleged invention, praise of the alleged invention by those having ordinary skill in the art, and copying of the alleged invention by others in the field. I understand that there must be a nexus, that is, a connection between any such secondary considerations and the alleged invention. I also understand that contemporaneous and independent invention by others is a secondary consideration tending to show obviousness.

22. I reserve the right to respond to any allegations that may be put forth by Patent Owner in this proceeding that any secondary considerations tend to rebut the obviousness of any claim of the '981 patent discussed in this Declaration.

C. Claim Dependency

23. I understand that a patent may include two types of claims, independent claims, and dependent claims. An independent claim stands alone and includes only

the limitations it recites. A dependent claim can depend from an independent claim or another dependent claim. I understand that a dependent claim includes all the limitations that it recites in addition to all of the limitations recited in the claim or claims from which it depends.

24. The analysis in this Declaration is in accordance with the above-stated legal principles.

IV. MATERIALS CONSIDERED

25. In preparing this Declaration, I reviewed and considered the materials cited in this Declaration and in **Appendix B**, as well as any document cited in this Declaration.

V. OVERVIEW OF THE GROUNDS FOR FINDING THE CHALLENGED CLAIMS INVALID

26. It is my conclusion that the Challenged Claims are invalid on the following grounds.

- **Ground I:** The combination of Bhullar, Boogaard, and Angell makes Claims 18-30, 32-37 obvious under 35 U.S.C. §103.
- **Ground II:** The combination of Edelbrock, Boogaard, and Angell makes Claims 1-13, 15-16, 18-30, 32-34 obvious under 35 U.S.C. §103.
- **Ground III:** The combination of Edelbrock, Boogaard, Angell, and Bhullar makes claims 35-37 obvious under 35 U.S.C. §103.

27. These grounds demonstrate in detail that claims 11-13, 15-16, 18-30, and 32-37 are unpatentable as being obvious in view of the prior art. A copy of the Challenged Claims is attached as **Appendix C**.

28. I provide more explanation as to the specific grounds in Section X (Specific Grounds for Finding the Challenged Claims Invalid). Below I provide below a brief overview of the references in the grounds.

29. **Bhullar:** U.S. Publication No. 2004/0200721, entitled “Biosensor” published on October 14, 2004, to Bhullar et al. (“Bhullar”). It is directed to “[a] biosensor [that] includes a support substrate, an electrically conductive coating positioned on the support substrate, the coating being formed to define electrodes and a code pattern, wherein there is sufficient contrast between the conductive coating and the substrate such that the code pattern is discernible, and a cover cooperating with the support substrate to define a channel.” EX1007-Bhullar, Abstract. I discuss Bhullar in greater detail in Section X.A (Ground I).

30. **Edelbrock:** U.S. Publication No. 2009/0159197 entitled “Method of Forming a Multilayer Test Sensor” published on June 25, 2009, to Edelbrock (“Edelbrock”). I understand that it claims the benefit of U.S. Application No. 60/754,141 (“Edelbrock Provisional”), filed December 27, 2005. I discuss Edelbrock in greater detail in Section X.B (Ground II).

31. I understand that Edelbrock is prior art as of the December 27, 2005, date of the Edelbrock Provisional because: 1) the subject matter relied upon in the application is described in the provisional application; and 2) at least one claim in the application is supported by the provisional application.

32. As shown below, the subject matter that I rely on in Edelbrock is described in the Edelbrock Provisional.

Edelbrock (EX1032)	Edelbrock Provisional (EX1033)
[0001]	[0001]
[0008]	[0008]
[0009]	[0009]
[0028]	[0028]
[0029]	[0029]
[0030]	[0030]
[0031]	[0031]
[0032]	[0032]
[0035]	[0035]
[0036]	[0036]
[0037]	[0037]
[0038]	[0038]
[0039]	[0039]
[0040]	[0040]
[0041]	[0041]
[0042]	[0042]

Edelbrock (EX1032)	Edelbrock Provisional (EX1033)
[0043]	[0043]
[0044]	[0044]
[0045]	[0045]
[0046]	[0046]
[0047]	[0047]
[0048]	[0048]
[0049]	[0049]
[0050]	[0050]
[0051]	[0051]
[0052]	[0052]
[0056]	[0056]
[0057]	[0057]
[0075]	[0072]
FIG.2b	FIG.2b
FIG.3	FIG.3
FIG.4a	FIG.4a
FIG.4b	FIG.4b
FIG.4c	FIG.4c
FIG.4d	FIG.4d
FIG.4e	FIG.4e
FIG.6	FIG.6
FIG.8	FIG.8
Claim 1	<i>See Table below</i>

Edelbrock (EX1032)	Edelbrock Provisional (EX1033)
Claim 16	Abstract, [0008]–[0009], [0031], [0038]–[0039], [0041], [0043], [0045], [0057], [0072]

33. In addition, as shown below, at least claim 1 of Edelbrock is supported by the Edelbrock Provisional.

Edelbrock, Claim 1 (EX1032)	Edelbrock Provisional (EX1033)
A method of forming an electrochemical multilayer test sensor, the multilayer test sensor including a base, a second layer and a reactive layer, the reactive area including an enzyme, the test sensor being adapted to be used in a meter and assist in determining the concentration of an analyte, the method comprising the acts of:	Abstract, [0008], [0009], [0057], [0072]
partially defining a plurality of electrodes and their respective conductive leads on the base;	Abstract, [0008], [0009], [0045], [0057], [0072]
after partially defining the plurality of electrodes and their respective conductive leads on the base, attaching the base to a second layer to define a reaction zone in which the plurality of electrodes are fully defined; and	Abstract, [0008], [0009], [0031], [0038], [0039], [0041], [0043], [0045], [0057], [0072]

Edelbrock, Claim 1 (EX1032)	Edelbrock Provisional (EX1033)
after attaching the base to the second layer, fully defining the plurality of conductive leads on the base of the test sensor.	Abstract, [0008], [0009], [0030], [0039], [0041], [0057], [0072]

34. **Boogaard** is an article entitled “Precision laser micromachining,” published shortly after August 20, 1986, in the SPIE Vol. 611 *Laser Processing of Semiconductors and Hybrids* (“Boogaard”). EX1058-Munford-Decl. I discuss Boogaard in greater detail in Section X.A (Ground I).

35. **Angell** is an article entitled “Processing Parameters for Laser Micromachining,” published shortly after April 28, 1997, in the SPIE Vol. 2993 *Lasers as Tools for Manufacturing II*. EX1058-Munford-Decl. I discuss Angell in greater detail in Section X.A (Ground I).

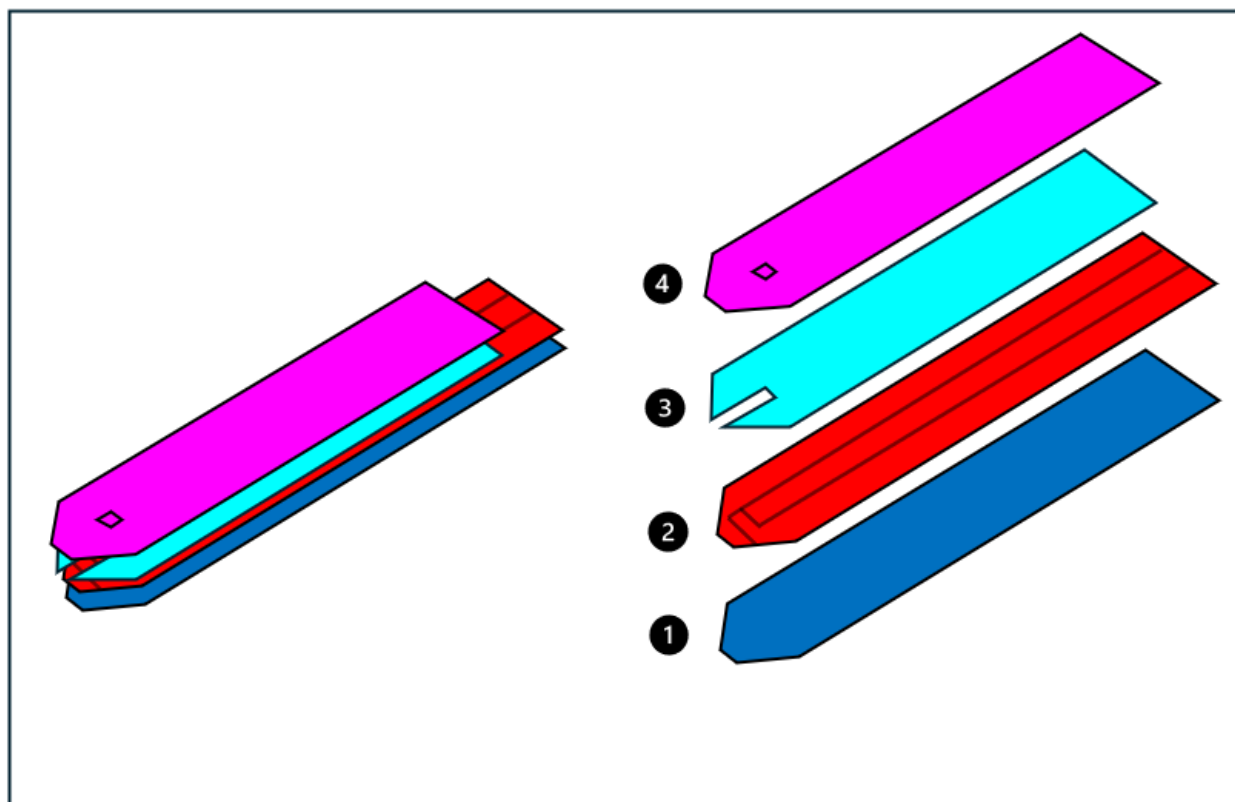
VI. OVERVIEW OF THE TECHNOLOGY

36. Glucose test strips have been ubiquitous since their introduction in the 1980s, allowing people to accurately measure the concentration of glucose in their blood. By the early 2000s, companies such as Roche, Bayer, and Abbott had developed and marketed glucose test strips that shared a common foundational design and operation. These strips were preloaded with specific chemicals that

would result in an electrochemical reaction when a drop of blood was applied. The glucose present in the blood sample would react with these chemicals, producing an electrical signal proportional to the glucose concentration. This signal was then measured and interpreted by a glucose meter, providing users with a clear and immediate reading of their blood glucose levels. The basic structure of these test strips typically included a small, disposable strip with a reaction zone containing enzymes like glucose oxidase or glucose dehydrogenase, which catalyzed the reaction. Additionally, the strips contained chemical compounds that were used to move electrons from the glucose to the electrode (i.e., electron mediators) and other reagents, to facilitate the transfer of electrons. This technology allowed for rapid, on-the-spot testing, which was crucial for effective diabetes management. EX1031-Henning-Cunningham, 20-28.

A. Overview of Glucose Test Strips

37. As shown below, a typical glucose test strip is made up of many layers of materials:



- **Base Layer (1):** As I show above labeled “1,” the foundation of the test strip is typically made from a non-conductive material such as plastic. This layer provides structural support and stability for the entire strip.
- **Conductive Layer (2):** On top of the base layer, a thin film of conductive material, such as gold, is deposited. In many cases, a laser is used to precisely “scribe” or “etch” a pattern into this conductive layer, creating multiple electrodes. These electrodes are essential for detecting the electrical signals generated during the glucose measurement process.

- **Spacer Layer (3):** The spacer layer is placed on top of the base and conductive layers. Like the base layer, this layer is also typically made from a non-conductive material. Generally, this layer features a cut-out channel that aligns with the electrodes on the conductive layer. The purpose of this channel is to create a defined pathway where the blood sample will interact with the electrodes.
 - **Chemical Reagent:** Within the channel created by the spacer layer, a chemical reagent is deposited. This chemical reagent contains chemicals that react with glucose in the blood sample. When a drop of blood is introduced into the channel, the glucose undergoes a chemical reaction with the reagent, producing electrons. These electrons generate an electrical signal that is detected by the electrodes to determine blood glucose level.
- **Cover Layer (4):** Finally, a cover layer is applied on top of the spacer layer. This cover forms the top of the channel, enclosing the reaction area and ensuring that the blood sample remains in contact with the chemical reagent and electrodes. The cover layer also helps protect the internal components of the test strip from contamination and damage.

- When a blood sample is added to the test strip, it enters the channel and interacts with the chemical reagent. The glucose in the blood reacts with the reagent, producing electrons. These electrons are detected by the electrodes, which generate an electrical signal proportional to the glucose concentration. This signal is then interpreted by the glucose meter, providing the user with an accurate measurement of their blood glucose level.

38. This basic structure of glucose test strips that I described above was well known within the art by the 1990s. For example, Winarta—issued on July 10, 2001—describes several prior art blood glucose sensors:

One type of blood glucose biosensors is an enzyme electrode combined with a mediator compound which shuttles electrons between the enzyme and the electrode resulting in a measurable current signal when glucose is present. The most commonly used mediators are potassium ferricyanide, ferrocene and its derivatives, as well as other metal-complexes. Many sensors based on this second type of electrode have been disclosed. Examples of this type of device are disclosed in the following patents.

U.S. Pat. No. 5,628,890 (1997, Carter et al.) discloses an electrode strip having an electrode support, a reference or counter electrode disposed on the support, a working electrode spaced from the reference or counter electrode on the support, a covering layer defining an enclosed space over the reference and working electrodes and having an aperture for receiving a sample into the enclosed space, and a plurality of mesh layers interposed in the enclosed

space between the covering layer and the support. The covering layer has a sample application aperture spaced from the electrodes. The working electrode includes an enzyme capable of catalyzing a reaction involving a substrate for the enzyme and a mediator capable of transferring electrons between the enzyme-catalyzed reaction and the working electrode.

This device proposes to reduce the effect of hematocrit on the sensor readings. According to the disclosure, this results from the downstream spacing of the reference electrode relative to the working electrode in combination with the thin layer of the sample solution created by the mesh layers.

U.S. Pat. No. 5,708,247 (1998, McAleer et al.) discloses a disposable glucose test strip having a substrate, a reference electrode, a working electrode, and a means for making an electrical connection. The working electrode has a conductive base layer and a coating layer disposed over the conductive base layer. The coating layer is a filler having both hydrophobic and hydrophilic surface regions which form a network, an enzyme and a mediator.

U.S. Pat. No. 5,682,884 (1997, Hill et al.) discloses a strip electrode with screen printing. The strip has an elongated support which includes a first and second conductor each extending along the support. An active electrode, positioned to contact the liquid mixture and the first conductor, has a deposit of an enzyme capable of catalyzing a reaction and an electron mediator. A reference electrode is positioned to contact the mixture and the second conductor.

U.S. Pat. No. 5,759,364 (1998, Charlton et al.) discloses an electrochemical biosensor having an insulating base plate bearing an electrode on its surface which reacts with an analyte to produce mobile electrons. The base plate is mated with a lid of deformable material which has a

concave area surrounded by a flat surface so that when mated to the base plate there is formed a capillary space into which a fluid test sample can be drawn. The side of the lid facing the base is coated with a polymeric material which serves to bond the lid to the base plate and to increase the hydrophilic nature of the capillary space.

U.S. Pat. No. 5,762,770 (1998, Pritchard et al.) discloses an electrochemical biosensor test strip that has a minimum volume blood sample requirement of about 9 microliters. The test strip has a working and counter electrodes that are substantially the same size and made of the same electrically conducting material placed on a first insulating substrate. Overlaying the electrodes is a second insulating substrate which includes a cutout portion that forms a reagent well. The cutout portion exposes a smaller area of the counter electrode than the working electrode. A reagent for analysis of an analyte substantially covers the exposed areas of the working and counter electrodes in the reagent well. Overlaying the reagent well and affixed to the second insulating substrate is a spreading mesh that is impregnated with a surfactant.

U.S. Pat. No. 5,755,953 (1998, Henning et al.) discloses a reduced-interference biosensor. The device generally comprises an electrode used to electrochemically measure the concentration of an analyte of interest in a solution. The device includes a peroxidase enzyme covalently bound to microparticle carbon and retained in a matrix in intimate contact with the electrode. According to this disclosure, it is the enzyme/microparticle carbon of the device which provides a composition which displays little sensitivity to known interfering substances.

U.S. Pat. No. 5,120,420 (1992, Nankai et al.) discloses a biosensor with a base board having an electrode system mainly made of carbon, an insulating layer, a reaction layer containing an enzyme layer thereon, a spacer and a

cover. The spacer creates a channel with an inlet and an outlet for holding a sample.

PCT Patent Application No. WO 98/35225 (1998, Heller et al.) discloses a sensor designed to determine the amount and concentration of an analyte in a sample having a volume of less than about one microliter. The sensor has facing working and reference electrodes with an optional sorbent spacer. The working electrode is coated with a reagent layer containing a non-leachable redox mediator and an enzyme. This device, which is capable of using a test sample volume of less than 1 microliter, requires the use of a sorbent material within the sample chamber in order to reduce the volume requirement and to introduce a hydrophilic character to the chamber in order for the sample to flow into such chamber.

EX1011-Winarta, 1:48-7:56.

39. Additionally, Winarta describes a similar multilayered electrochemical sensor, as shown below in Figure 2.

The preferred embodiment of the present invention is illustrated in FIGS. 1-6. FIG. 1 shows a sensor 10 of the present invention. Sensor 10 has a laminated body 100, a fluid sampling end 110, an electrical contact end 120, and a vent opening 42. Fluid sampling end 110 includes a sample fluid channel 112 between a sampling end aperture 114 and vent opening 42. Electrical contact end 120 has three discrete conductive contacts 122, 123 and 124.

EX1011-Winarta, 4:40-50.

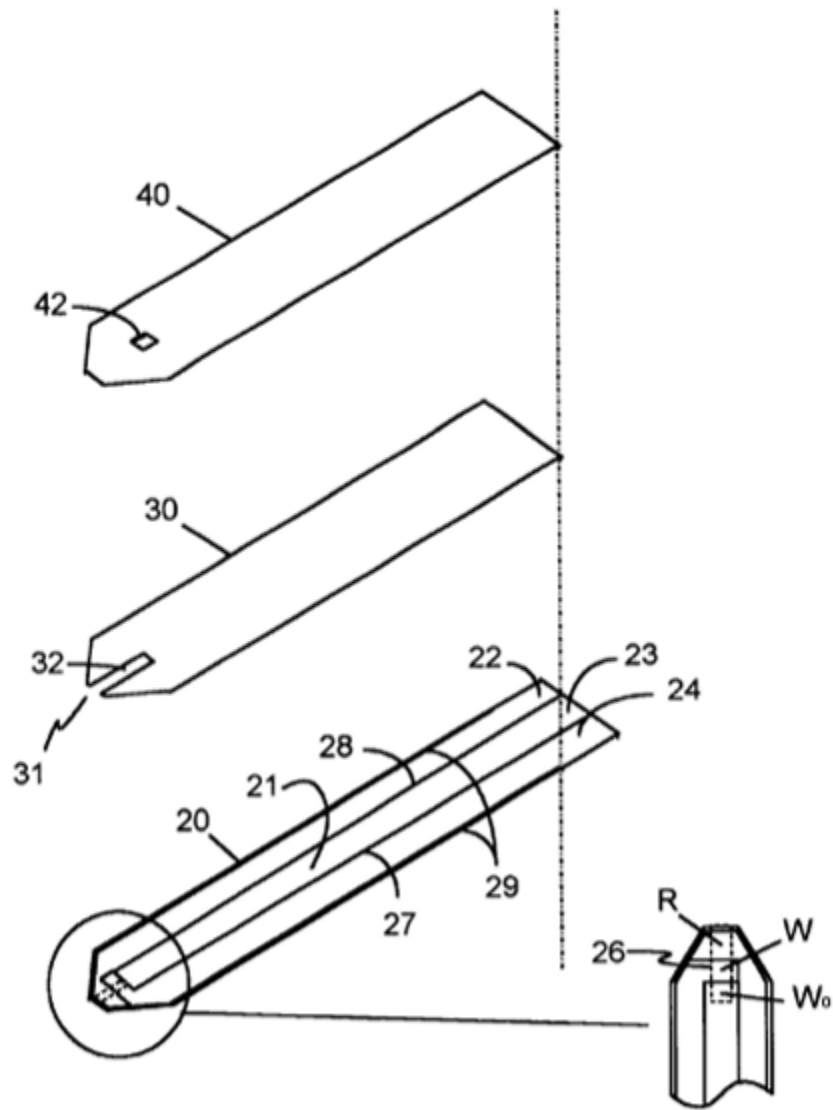


Fig. 2

EX1011-Winarta, FIG. 2.

40. I provide additional examples of known test sensors in Section X.A.1 (Overview of Bhullar) and Section X.B.1 (Overview of Edelbrock).

41. Additionally, by the early 2000s, several commercial glucose strips were widely used and known. For example, the Ascensia Breeze was a blood glucose sensor made by Bayer. As shown below, the Ascensia Breeze device is also a multi-layered test strip with the same components described above.



EX1075-Ascensia, 8.

B. Overview of Manufacturing Processes for Glucose Test Strips

42. The commercial production of glucose test strips has evolved to include various methods for mass production. One common method, known as reel-to-reel processing, involves a continuous manufacturing process that begins with a roll of base layer material wound on reels. This roll of material is then fed through a series of manufacturing stations, each performing a specific task to assemble the test strips.

43. Initially, the base layer material, typically a non-conductive plastic, is unwound from the reel and passed through a station where a conductive layer, often made of gold, is applied. Next, a laser ablation technique is used to precisely create electrodes on the conductive layer. Following the creation of the electrodes, additional layers are laminated onto the base layer. These layers include a spacer layer, which features a cut-out channel that aligns with the electrodes, and a cover layer that forms the top of the channel. Once all the layers are assembled, the continuous roll of material is cut into individual test strips. EX1007-Bhullar, [0043]-[0047]; EX1060-Atkin, 138; EX1064-Harvey, 2.

44. Chrisey explains the well-known benefits of reel-to-reel processing, such as allowing manufacturers to benefit from economies of scale:

The microelectronics industry has the vision to integrate these systems onto a reel-to-reel platform, which will enable rapid, high-volume manufacturing using flexible plastics as substrates. The compliant nature of the substrate layer(s) will enable the design and fabrication of a truly conformal electronics system. Product assembly line pulse rates will increase and will enable manufacturers to benefit from economies of scale. Furthermore, the substrate type will provide a significant reliability advantage over a nonflexible system. In particular, the strain generated by thermal expansion mismatch of the materials will be more readily dissipated in the flexible system while the strain generated in a “rigid” system will not have a mechanism by which to relax the strain.

EX1061-Chrisey, 35.

45. Additionally, Harvey describes the use of reel-to-reel processing in biomedical blood sensors. EX1064-Harvey, 2-3.

46. The manufacturing process for glucose test strips is also described in several prior art references. For example, Bhullar explains:

[0043] To manufacture biosensor 10 a roll of metallized electrode support material is fed through guide rolls into an ablation/washing and drying station. 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.

[0044] In the laser ablation station, 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, code patterns, and a recess in the film adjacent to each electrode array. To ablate electrodes 14, 16, recess 35, and code patterns 40 in 50 nm thick gold conductor 13, 90 mJ/cm² energy is applied. It is appreciated, however, that the amount 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.

[0045] Upon leaving the laser ablation station, the metallized film is fed into a reagent dispensing station.

Reagents that have been compounded are fed into a dispensing station where it is applied in a liquid form to the center of respective the array 34. Reagent application techniques are well known to one of ordinary skill in the art as described in U.S. Pat. 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.

[0046] In a separate process, a double-sided pressure-sensitive film with dual release liners is fed into a window punch unit where notches are formed. The film is then fed into a lamination & kiss-cutting station. At the same time, a roll of cover substrate material is fed over a guide roll into the lamination & kiss-cutting station, where the release liner is removed from the upper surface 44 and rewound into a roll. The upper surface 33 of the spacer substrate material is applied to the cover substrate material. Next, the film is kiss cut and a portion of the cover substrate material is removed, leaving behind the cover substrate material coupled to the spacer substrate material, extending across a portion of the notch.

[0047] The cover material/spacer substrate subassembly is fed into a sensor lamination & cut/pack station. The reagent-coated electrode-support substrate material is fed from the dispensing station into the sensor lamination & cut/pack station as well. The remaining release liner is removed from the spacer substrate and the spacer substrate is positioned on the electrode-support substrate material so that at least a portion of the electrode array 36 is aligned with the notch 52. Next, 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.

EX1007-Bhullar, [0043]-[0047].

1. Overview of Laser Ablation

47. At least by the 1990s, it was known that one or more lasers could be used to form multiple electrodes by “scribing” or “etching” away conductive materials in a controlled pattern. EX1011-Winarta, 1:48-7:56; EX1007-Bhullar, [0024]; EX1032-Edelbrock, [0041]; EX1009-Miyazaki, 6:51-54, 14:28-36, FIG. 1(b). The gaps formed by etching away material using a laser are sometimes called “**kerfs**.” *See, e.g.*, EX1035-Boogaard, 50. The general process of using a laser to remove conductive material is generally referred to as “**laser ablation**.” EX1007-Bhullar, [0019].

48. A widely used technique for laser ablation, particularly in the production of test strips, involves directing a laser beam to move or traverse across the conductive layer in a predetermined pattern, thereby forming the electrodes. This is often referred to as “**scribing**” (EX1011-Winarta, 4:30-30) or “**direct writing**” (EX1032-Edelbrock, [0041]).

49. Koo also describes scribing or direct writing techniques for laser ablation. For example, Koo explains:

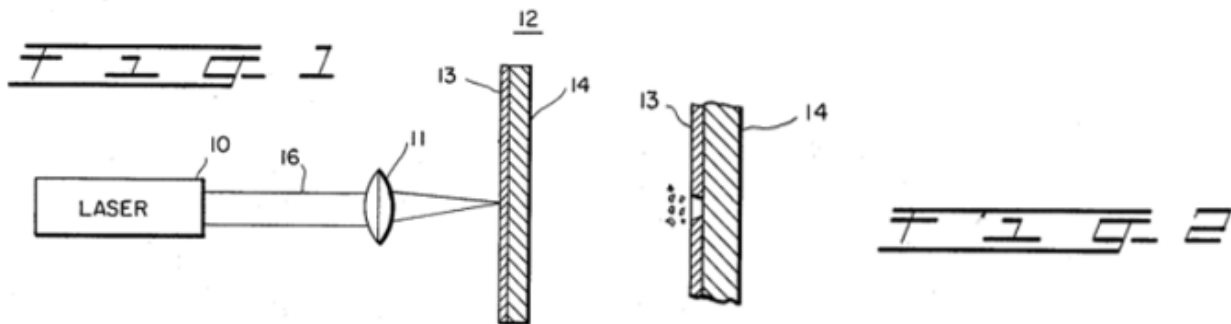
FIG. 1 depicts the apparatus used to implement the instant method. A laser 10 which provides a source of coherent light energy and focusing optics 11 are shown. A metallized substrate, generally designated by the numeral 12, comprised of a thin metal coating 13 on

a dielectric substrate 14, is spaced from the laser 10 and the optics 11. The thin metallic coating 13 has a melting temperature which is higher than the vaporization temperature of the dielectric substrate 14.

In operation, a beam 16 of light energy from the laser 10 is focused by the optics 11 onto the thin metallic coating 13 which is heated to a temperature that is below the melting point of the coating but above the vaporization temperature of the material forming a part of the dielectric substrate 14. The portions of the substrate 14 so heated will vaporize, causing a pressure buildup at the thin film 13-substrate 14 interface which is sufficient to explosively remove portions of the film from the substrate, as shown in FIG. 2. If desired, the entire thin film coating 13 may be removed from the substrate 14.

In a particular embodiment, the laser 10 was a Q-switched Nd:YAG laser having an effective wavelength of $1.06\mu\text{m}$ which was directed to an approximately 0.002 inch diameter spot on the metal coating 13. Other lasers, both pulsed and continuous, for example: CO_2 , argon, etc. may be used. The only requirement being that the laser have sufficient power to cause vaporization of the substrate material.

EX1074-Koo, 2:20-3:17.



EX1074-Koo, FIGS. 1-2.

50. By the 1990s, it was well-known that a variety of lasers were suitable for laser ablation, including for forming electrodes in electrochemical test strips. For example: (1) **carbon dioxide (CO₂) lasers**, (2) **Neodymium: Yttrium Aluminum Garnet (Nd:YAG) lasers**, and (3) **excimer lasers** were all used for laser ablation well before the '981 patent, including specifically in the context of making electrochemical test strips. EX1011-Winarta, 6:65-57; EX1034-Angell, 65; EX1038-Chryssolouris, 17. *See generally* EX1073-Allan (discussing CO₂ and Nd:YAG lasers); EX1071-Hellrung (discussing Nd:YAG lasers); EX1070-Tiffany (same); EX1066-Fisher (same); EX1052-Sercel (discussing excimer lasers).

51. It was also well-known to use two lasers for laser ablation, with each laser having different known properties. EX1073-Allan, 43; EX1060-Atkin, 139. For example, Allan describes a medical device company's use of CO₂ and Nd:YAG lasers in its manufacturing plant, as well as an automotive manufacturing company's use of two different powered CO₂ lasers in its plant. EX1073-Allan, 43. Additionally, Atkin describes the manufacturing of a filter device using both a Nd:YAG and excimer laser, compatible with web-based manufacturing. EX1060-Atkin, 139.

52. Each of Nd:YAG, CO₂, and excimer lasers have different known characteristics and properties such as wavelength, power output, and laser beam spot size. EX1035-Boogaard, 50. The specific characteristics and properties of these different lasers play an important role in the ablation process. For instance, factors such as wavelength, power output, and laser beam spot size influence how thin the kerfs (cuts) are and the depth of ablation. The ablation depth is also affected by the number and composition of the layers being ablated. These considerations and laser properties are used to achieve desired electrode patterns for electrochemical test strips. *See generally* EX1034-Angell.

53. Indeed, several references describe the differences between Nd:YAG and CO₂ lasers, indicating that Nd:YAG lasers are preferred for ablating metals and CO₂ lasers are preferred for ablating non-metals. For example, Allan explains:

Table I lists about one dozen of the most popular lasers, only two of which are used for nearly all materials-processing applications: the Nd:YAG (neodymium: yttrium-aluminum garnet) and the CO₂ (carbon-dioxide) laser. Both account for nearly 90 percent of all industrial laser material-processing uses. Figure 2 illustrates the schematic diagrams for both Nd:YAG and CO₂ lasers.

The Nd:YAG laser, which operates at a wavelength of 1.06 μm , is used principally for precision machining of thin metals and for scribing silicon semiconductor wafers and trimming resistor networks. The CO₂ laser, with a longer wavelength of 10.6 μm , is of higher output power

and is used on heavier metals. Both lasers are also used to process many other materials.

...

Metals absorb less laser-beam energy, and are generally more reflective of a laser beam than nonmetals. For some applications, like heat treating, better energy absorption is achieved by chemically treating the surfaces of metals prior to laser processing. And the energy from the 1.06 μm -wavelength Nd:YAG laser is more readily absorbed by metals than that of the 10.6 μm -wavelength CO₂ laser. However, the CO₂'s higher output power tends to compensate for this drawback.

...

Because most nonmetals absorb energy from the 10.6 μm -wavelength CO₂ laser, a host of organic and inorganic material applications has opened up—from acrylics, polyethelenes, wood, rubber, and wool to diamonds. Hole drilling in plastics and rubber materials is one of the fastest-growing applications. Both of these materials respond extremely well to CO₂ laser energy. Examples in plastics include hole drilling in aerosol valves, contact lenses, pipes, tubing, and wire insulations. Rubber examples include hole drilling in baby-bottle nipples and rubber seals. Plastic materials have been welded with CO₂ laser beams.

For both drilling and welding, medium power levels of 50 to 500 W suffice. And throughput rates can be quite high. A 250-W CO₂ laser can perforate a polyethylene plastic tubing with 0.020-inch (0.5-mm) holes spaced 6 to 24 inches (15 to 61 cm) apart, at 300 ft/min (90 m/min).

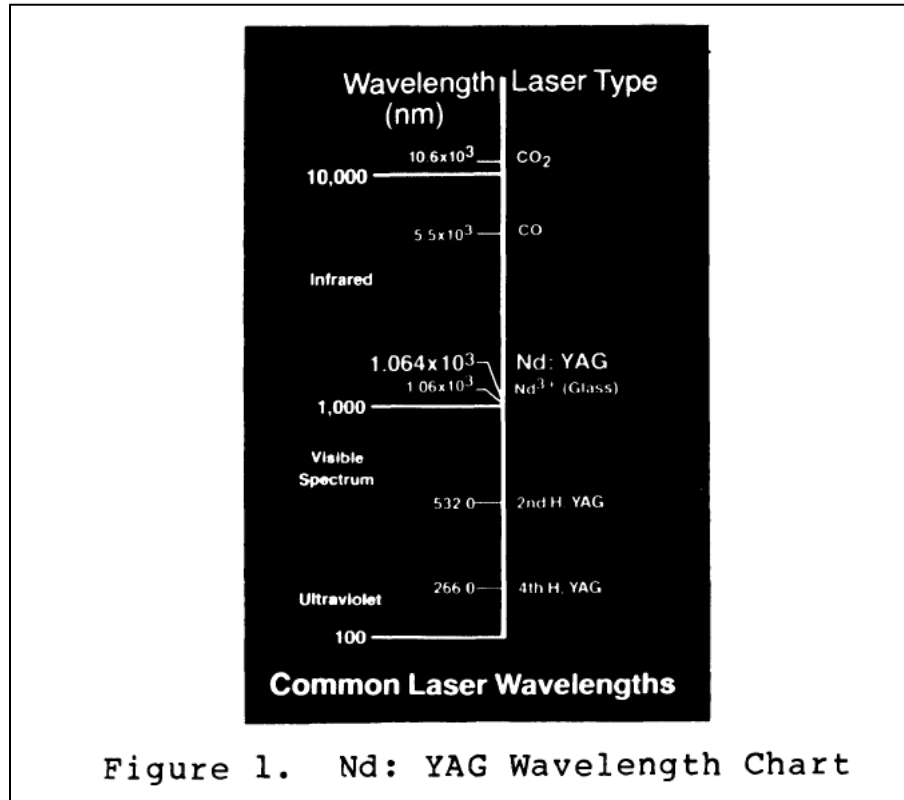
EX1073-Allan, 42-46. *See Generally* EX1066-Fisher (describing the history of the Nd:YAG laser).

54. Indeed, another reference, Tiffany, discusses the same:

Solid state Nd:YAG and Nd:Glass lasers are dominant in metal working applications, **whereas CO₂ maintains an advantage in most non-metal processing areas. This is due in large part to the fact that metals have lower reflectivities and therefore higher absorption of the shorter 1.06-micron wavelength of the solid state laser output beam than of the 10.6-microns.**

EX1070-Tiffany, 28.

55. For example, the below figure shows the different wavelengths of various lasers:



EX1035-Boogaard, 48. As shown above, CO₂ lasers have longer wavelengths in the spectrum of 10,000 nanometers (nm) and above.

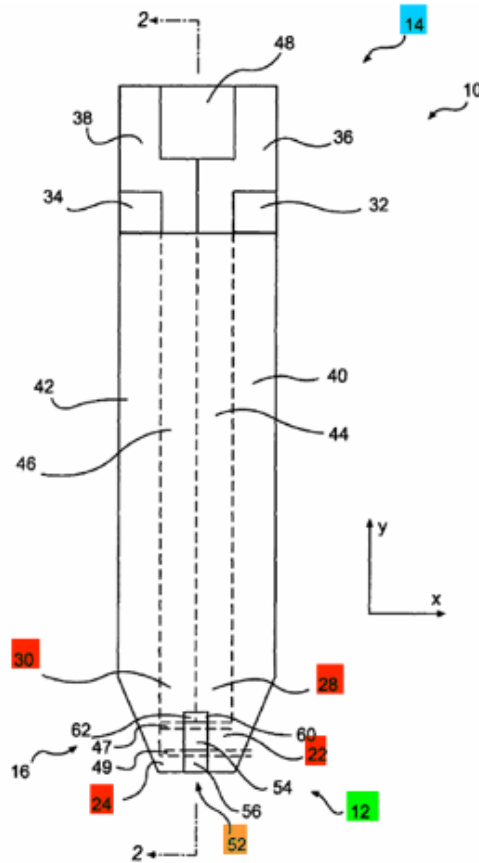
56. YAG lasers are in the “infrared” spectrum (between 1,000 and 10,000 nm). Excimer lasers (not shown in the figure) exhibit shorter wavelengths in the “ultraviolet” spectrum between 193 and 351 nanometers. EX1038-Chryssolouris, 32.

VII. OVERVIEW OF THE '981 PATENT

A. Overview of the Patent

57. The '981 patent describes a conventional glucose test strip. EX1001-'981, 1:12-2:4, FIG.1A, 4:14-51, 3:37-39, 3:63-5:11, 6:14-8:36. But the '981 patent purports to have claimed an improved method for manufacturing electrodes and other components within the test strip. EX1001-'981, 1:12-2:4.

58. As shown below, the test strip includes a **proximal end** 12 (shown in green) with a **slot** 52 (shown in orange) defining sample chamber 88 to receive a fluid sample, a **distal end** 14 (shown in blue), and **electrodes** 22, 24, 28, 30 (shown in red) near the proximal end for detection of an analyte.



EX1001-'981, FIG. 1A,¹ 4:14-51, 3:37-39, 3:63-5:11, 6:14-8:36.

59. The specification describes prior art methods to make electrodes on a test strip, including reel-to-reel processing using laser ablation to segment and isolate portions of a conductive layer to form electrodes:

¹ All color annotations and emphasis in this petition have been added unless noted otherwise.

Several methods for manufacturing biosensors have been proposed. One such method is described in U.S. Pat. No. 6,875,327 to Miyazaki et al. Miyazaki et al. describe a biosensor manufacturing process whereby a conductive layer is formed on a support.

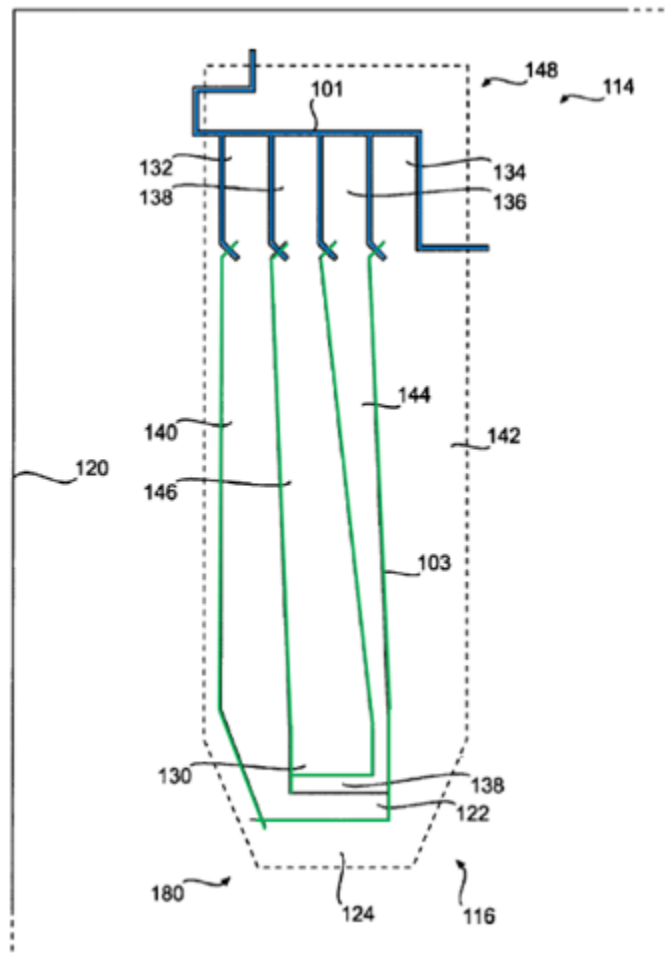
EX1001-'981, 1:53-62, 8:48-9:3, 10:8-20. *See* EX1009-Miyazaki.

60. The '981 patent states that using only one laser (which, according to the '981 patent, Miyazaki teaches) “can be inefficient, time consuming, or unsuitable...” EX1001-'981, 1:58-67. As an alleged improvement, the '981 patent proposes use of multiple lasers moved relative to the conductive layer with each laser assigned to a different set of kerfs. EX1001-'981, 9:16-10:33.

61. Per the method described in the '981 patent, a reel serves as a blank from which a series of test strips can be manufactured. EX1001-'981, 2:20-46, 8:48-58. The reel comprises a conductive layer such as gold on a base layer such as a non-conductive polymer. EX1001-'981, 8:48-58.

62. The reel is then processed using lasers to scribe a series of kerfs in the conductive layer. EX1001-'981, 10:42-61, 12:22-36. These kerfs isolate conductive segments which will serve as electrodes of the test strip. EX1001-'981, 10:1-8. For example, Figure 4B of the '981 patent depicts a representative test strip 144 under construction on reel 120 in which two groups of kerfs (also termed “traces”) are allocated to different focused laser beams with controlled movement of each laser

beam relative to the conductive layer. EX1001-'981, FIG. 4B, 9:46-52, 10:1-5. For example, kerf 101 (shown in blue below) in the '981 patent's Figure 4B (reproduced below) is formed using one focused laser while and kerf 103 (shown in green below) is formed using a different laser. EX1001-'981, 10:43-61; 11:9-34. The pattern of "traces 180" "at least partially define one or more boundaries" of the "electric components" of the test strip (EX1001-'981, 9:13-15) including multiple electrodes, such as those indicated at numerals 122 and 124. EX1001-'981, 9:7-9.



EX1001-'981, FIG. 4B.

63. Finally, individual test strips are stamped and cut from the reel at the boundaries indicated by the dashed outline in Figure 4B. EX1001-'981, 9:24-27.

64. Claim 18 is a representative claim describing the purported invention of the '981 patent. Claim 18 recites:

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.

EX1001-'981, Claim 18.

65. But as I describe below, all of the features of the challenged claims were well-known before the earliest claimed priority date.

B. Overview of the Prosecution History for the '981 Patent

66. The '981 patent issued from U.S. Application No. 11/783,568 ("568 application"), which was filed on April 10, 2007. EX1001-'981, Cover. I

understand that the '568 application claims priority to two provisional applications. The first provisional application is Application No. 60/790,773, which was filed on April 11, 2006. The second provisional application is Application No. 60/878,454, filed on January 4, 2007. EX1001-'981, Cover. I have assumed that the priority date of April 11, 2006, is correct for my analysis in this Declaration and have not analyzed whether the '981 patent is entitled to that priority date under the law.

67. When the application was filed on April 10, 2007, the Applicant claimed methods reciting multiple lasers. EX1003-'981FH, 27-38. On November 24, 2010, the Examiner rejected these claims as obvious over of U.S. Application No. 2005/0019953 ("Groll"). EX1003-'981FH, 260-68. *See Generally* EX1055-Groll. The Examiner noted that although Groll "describe[s] using a single pass of the laser to create all of the structures," ... "one of ordinary skill in the art would envisage forming the elements (or 'kerfs') in multiple steps." EX1003-'981FH, 263.

68. On May 23, 2011, the Applicant argued in response that Groll taught a particular type of laser—a "broad field laser that passes through a mask" that "does not move relative to the electrical component being formed". EX1003-'981FH, 288-89. The Applicant then amended the pending claims to require "movement" of the lasers (in issued claims 1 and 18) and a "focused laser beam" (in issued claim 18),

to allegedly distinguish them from Groll. EX1003-'981FH, 283, 288-89. I have reproduced these amendments below (amendments shown below in underlining):

[Issued Claim 1] (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.

EX1003-'981FH, 280.

[Issued Claim 18] (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.

EX1003-'981FH, 35.

69. On August 3, 2011, the Examiner allowed the amended claims based on these amendments. EX1003-'981FH, 302. However, the Examiner did not have the benefit of the references I describe below in Grounds I-III, which teach these added features.

VIII. LEVEL OF ORDINARY SKILL IN THE ART

70. It is my understanding that when considering the claims of the '981 patent and the prior art, I must do so based on the perspective of one of ordinary skill in the art at the relevant effective priority date.

71. As I detail in Section VII.B (Overview of the Prosecution History for the '981 Patent), the '981 patent was filed on April 10, 2007, and claims priority to two provisional applications filed on April 11, 2006 and January 4, 2007. Therefore, I understand the claimed priority date is April 11, 2006. I do not offer any conclusion as to whether the '981 patent is entitled to that priority date. In any event, my conclusion regarding the level of ordinary skill in the art is the same for all relevant times from April 11, 2006, to April 10, 2007.

72. I understand from Petitioner's counsel that several factors are to be considered in determining who would be a person of ordinary skill in the art. These factors include: (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the educational level of active workers in the field.

73. Based on these factors as well as my experience and expertise, a person of ordinary skill in the art as of the claimed priority date would have had a bachelor's

degree or equivalent in mechanical engineering, chemistry, physics, materials science and/or engineering, electrical engineering, chemical engineering, polymer science, or a related field, and at least three years of experience relating to biosensor research and development. Less work experience may be compensated by a higher level of education, such as a Master's degree.

74. Before April 11, 2006, which is the claimed priority date of the '981 patent, I would have qualified at least as a person of ordinary skill in the art under this standard.

75. Although my qualifications and experience exceed those of a person of ordinary skill in the art as defined above, my analysis and conclusions herein regarding the '981 patent have been based on the knowledge and perspective a person of ordinary skill in the art would have had as of the relevant time of the '981 patent.

IX. CLAIM CONSTRUCTION

76. I was informed and I understand that, in my analysis, I should give claim terms their ordinary and customary meaning, as understood by a person of skill in the art at the time of the invention. I was informed and I understand that the words of the patent's claims and the context in which the term is used in the claims are highly instructive in ascertaining the term's meaning. I further understand that

the terms of a claim are to be interpreted in the context of the entire patent, including the patent's claims, its specification, and its figures.

77. I have been further instructed that a patent's prosecution history may often provide helpful evidence about how the U.S. Patent and Trademark Office and the applicant understood the patent and its claims. Therefore, I have been instructed that claim terms should also be interpreted in light of the patent's prosecution history.

78. In addition to the claims, the specification, the figures, and the prosecution history, I have been instructed that certain "extrinsic evidence," such as scientific or technical references, may also help inform the way in which a person of ordinary skill in the art understands the claim term. I have been instructed that extrinsic evidence must always be considered in the context of the intrinsic evidence.

79. For the purposes of this Declaration, I will give the claim terms their plain and ordinary meaning, including as understood in the field of the '981 patent, and as understood by a person of ordinary skill in the art.

80. I understand that claim constructions are proposed in another proceeding involving the '981 patent—*Roche Diabetes Care, Inc. v. Trividia Health, Inc.*, Case No. 1:24-cv-00668-GBW (D. Del) ("*DDEL* litigation"). I understand that in the *DDEL* litigation, the Petitioner and the Patent Owner disagree on the construction of certain terms. *See* EX1051, 10-13 (Exhibit B). However, the prior

art makes the challenged claims obvious under either construction, so I have applied the plain and customary meaning as described above. If the Patent Owner offers a specific construction or interpretation, I reserve the right to respond to such a construction and/or propose an express construction consistent with the term's plain and ordinary meaning.

X. SPECIFIC GROUNDS FOR FINDING THE CHALLENGED CLAIMS INVALID

A. GROUND I: Claims 18-30 and 32-37 Are Obvious In View of the Combination of Bhullar, Boogaard, and Angell

1. Overview of Bhullar

81. Bhullar, published on October 14, 2004, discloses a method for manufacturing “biosensor strips” using laser ablation. EX1007-Bhullar, [0043]-[0047]. Bhullar explains:

[0043] To manufacture biosensor 10 a roll of metallized electrode support material is fed through guide rolls into an ablation/washing and drying station. 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.

[0044] In the laser ablation station, 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, code patterns, and a recess in the film adjacent to each electrode array. To ablate electrodes 14, 16, recess 35, and code patterns 40 in 50 nm thick gold conductor 13, 90 mJ/cm² energy is applied. It is appreciated, however, that the amount 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.

[0045] Upon leaving the laser ablation station, the metallized film is fed into a reagent dispensing station. Reagents that have been compounded are fed into a dispensing station where it is applied in a liquid form to the center of respective the array 34. Reagent application techniques are well known to one of ordinary skill in the art as described in U.S. Pat. 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.

[0046] In a separate process, a double-sided pressure-sensitive film with dual release liners is fed into a window punch unit where notches are formed. The film is then fed into a lamination & kiss-cutting station. At the same time, a roll of cover substrate material is fed over a guide roll into the lamination & kiss-cutting station, where the release liner is removed from the upper surface 44 and rewound into a roll. The upper surface 33 of the spacer substrate material is applied to the cover substrate material. Next, the film is kiss cut and a portion of the cover substrate material is removed, leaving behind the cover substrate material coupled to the spacer substrate material, extending across a portion of the notch.

[0047] The cover material/spacer substrate subassembly is fed into a sensor lamination & cut/pack station. The reagent-coated electrode-support substrate material is fed from the dispensing station into the sensor lamination & cut/pack station as well. The remaining release liner is removed from the spacer substrate and the spacer substrate is positioned on the electrode-support substrate material so that at least a portion of the electrode array 36 is aligned with the notch 52. Next, 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.

EX1007-Bhullar, [0043]-[0047].

82. Like the '981 patent, Bhullar's method involves "preferably produc[ing]" these biosensor strips "from rolls of material." EX1007-Bhullar, [0043], [0044], [0046], [0016].

83. Also like the '981 patent, Bhullar's biosensor is designed to test "a whole blood sample" for analytes, and indicates that "[t]he analyte of interest is preferably glucose." EX1007-Bhullar, [0032]. *See also* EX1007-Bhullar, [0033] ("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.").

84. Also like the '981 patent, the rolled material used in Bhullar's process includes a base layer and a conductive layer. EX1007-Bhullar, Abstract, [0003]-[0006], [0015]-[0017], [0019], [0020]-[0025], [0028]-[0029], [0031], [0043]-[0044],

[0047], [0057], [0060], claim 1, claim 13, claim 30, Figs. 1,4; EX1001-'981, 6:18-21.

85. For example, Bhullar teaches that:

[0016] FIGS. 1-4 illustrate an aspect of the invention in the form of a biosensor 10 having an electrode-support substrate 12, an electrical conductor 13 positioned on the substrate 12 that is disrupted to define electrodes 14, 16, a spacer substrate 18 positioned on substrate 12, and a cover substrate 20 positioned on the spacer substrate 18. Biosensor 10 is preferably rectangular in shape. It is appreciated however, that biosensor 10 can assume any number of 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, the selection of materials for the construction of biosensor 10 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.

[0017] Referring to FIG. 4, the support substrate 12 includes a first surface 22 facing the spacer substrate 18 and a second surface 24. In addition, as shown in FIG. 2, 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 may be formed in a variety of shapes and sizes in accordance with this disclosure. Substrate 12 is formed of a flexible polymer and preferably from a flexible polymer and preferably from a polymer such as a polyester or polyimide, polyethylene naphthalate (PEN). A non-limiting example of a suitable PEN is 5 mil (125 um) thick

KALADEX®, a PEN film commercially available from E.I. DuPont de Nemours, Wilmington, Del., which is coated with gold by ROWO Coating, Henbolzbelm, Germany.

[0018] Electrodes 14, 16 are created or isolated from conductor 13 on first surface 22 of substrate 12. Non-limiting examples of a suitable electrical conductor 13 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 13 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 13 is gold.

EX1007-Bhullar, Abstract, [0016]-[0018].

86. Bhullar teaches feeding a roll of metallized electrode support material through guide rolls into several stations, including an ablation station. EX1007-Bhullar, [0043]. At the ablation station, a laser system is used to ablate parts of the conductive layer to form gaps that define electrically isolated conductive components, like electrode sets, code patterns, and recesses. EX1007-Bhullar, [0019], [0043].

87. As Bhullar explains below, typical gap widths are “about 25 μm to about 500 μm ” and preferably “about 100 μm to about 200 μm :”

[0019] Electrodes 14, 16 are isolated from the rest of the electrical conductor 13 by laser ablation. See FIG. 4. Techniques for forming electrodes on a surface using laser ablation are known. See, for example, U.S. patent application Ser. No. 09/411,940, filed Oct. 4, 1999, and entitled “LASER DEFINED FEATURES FOR PATTERNED LAMINATES AND ELECTRODE”, the disclosure of which is expressly incorporated herein by reference. Preferably, electrodes 14, 16 are created by removing the electrical conductor 13 from an area extending around the electrodes to form a gap of exposed support substrate 12. Therefore, electrodes 14, 16 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 14, 16 may be created by laser ablation alone on substrate 12. It is appreciated that while laser ablation is the preferred method for forming electrodes 14, 16 given its precision and sensitivity, other techniques such as lamination, screen-printing, or photolithography may be used in accordance with this disclosure.

EX1007-Bhullar, [0019].

88. Bhullar further discloses the creation of a roll of cover substrate material, which is applied to the spacer substrate material. EX1007-Bhullar, [0046]. Bhullar further describes how the cover material/spacer substrate subassembly is fed into a sensor lamination and cut/pack station, along with the reagent-coated

electrode-support substrate material. EX1007-Bhullar, [0047]. After the materials are assembled, Bhullar discloses cutting the processed roll “to form individual biosensors, which are sorted and packed into vials, each closed with a stopper, to give packaged biosensor strips.” EX1007-Bhullar, [0047] (element numbers omitted).

89. According to Bhullar, a “laser system capable of ablating support 12 is known to those of ordinary skill in the art.” EX1007-Bhullar, [0043]-[0044]. For example, Bhullar incorporates U.S. Application No. 09/411,940 (EX1063) by reference in paragraph [0019] stating:

Techniques for forming electrodes on a surface using laser ablation are known. See, for example, U.S. patent application Ser. No. 09/411,940, filed Oct. 4, 1999, and entitled “LASER DEFINED FEATURES FOR PATTERNED LAMINATES AND ELECTRODE”, the disclosure of which is expressly incorporated herein by reference.

EX1007-Bhullar, [0019]; *see also* EX1062-BhullarFH, 6.

90. App. No. 09/411,940, in turn, incorporates U.S. Patent No. 5,593,739 (“Kickelhain”) by reference, stating:

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. Pat. Nos. 5,576,073 and **5,593,739 [Kickelhain]**, each of which is hereby incorporated by reference.

EX1063-Bhullar'940, 4.

91. Kickelhain (1997) describes the use of a focused laser beam to scribe kerfs in a multilayer material. EX1056-Kickelhain, 2:51-55, 4:51-53, Claim 1, Claim 11. For example, Kickelhain states:

In accordance with one preferred embodiment of the invention, the primer coat in the insulating channels between the later conductor strips is ablated by using a mask disposed in the path of the excimer laser beam or by means of one of the known imaging processes. Furthermore, it is possible to remove the primary coat in the insulating channels by means of patterned scanning **by a focused laser beam**. These procedures make it possible to cause the laser beam to act on the primer coat in a finely patterned manner.

EX1056-Kickelhain, 2:51-55.

92. Indeed, use of a focused laser in this manner was long known. For example, Koo (1978) teaches:

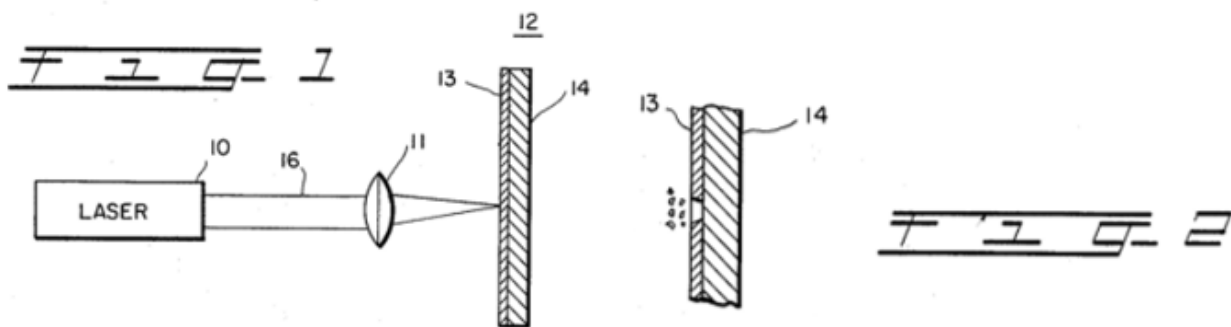
FIG. 1 depicts the apparatus used to implement the instant method. A laser 10 which provides a source of coherent light energy and focusing optics 11 are shown. A metallized substrate, generally designated by the numeral 12, comprised of a thin metal coating 13 on a dielectric substrate 14, is spaced from the laser 10 and

the optics 11. The thin metallic coating 13 has a melting temperature which is higher than the vaporization temperature of the dielectric substrate 14.

In operation, a beam 16 of light energy from the laser 10 is focused by the optics 11 onto the thin metallic coating 13 which is heated to a temperature that is below the melting point of the coating but above the vaporization temperature of the material forming a part of the dielectric substrate 14. The portions of the substrate 14 so heated will vaporize, causing a pressure buildup at the thin film 13-substrate 14 interface which is sufficient to explosively remove portions of the film from the substrate, as shown in FIG. 2. If desired, the entire thin film coating 13 may be removed from the substrate 14.

In a particular embodiment, the laser 10 was a Q-switched Nd:YAG laser having an effective wavelength of $1.06\mu\text{m}$ which was directed to an approximately 0.002 inch diameter spot on the metal coating 13. Other lasers, both pulsed and continuous, for example: CO_2 , argon, etc. may be used. The only requirement being that the laser have sufficient power to cause vaporization of the substrate material.

EX1074-Koo, 2:20-3:17



EX1074-Koo, FIGS. 1-2.

93. Shown below in Figure 1 is an example of Bhullar's test strip. Bhullar's test strip has a first end 26 with a slot 52 defining a recess 35 with notch 52 to receive a fluid sample, a second end 28, and electrodes 14, 16 near the first end 26 for detection of an analyte. Bhullar teaches that "[c]apillary forces pull a liquid blood sample flowing from the incision through the capillary channel 60 across the reagent 62 and the array 34. The liquid blood sample dissolves the reagent 62 and engages the array 34 where the electrochemical reaction takes place." EX1007-Bhullar, [0049]. Bhullar further teaches that:

In use for example, after the reaction is complete, a power source (e.g., a battery) applies a potential difference between the electrodes 14, 16 respectively. 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. A 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.

EX1007-Bhullar, [0050].

FIG. 1

2. Overview of Boogaard

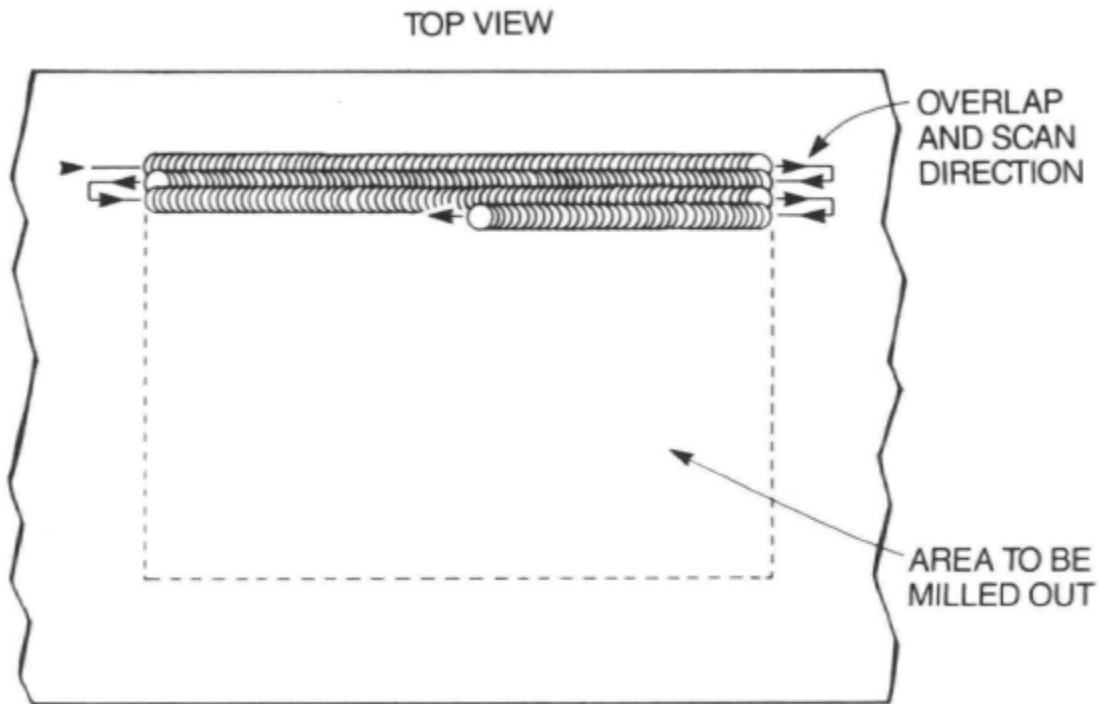
positioning systems for using the Nd:YAG laser to accomplish precision kerfs in metals. EX1035-Boogaard, 48.

95. For example, Boogaard teaches a serpentine scan method (shown in Figure 4 below), which uses a laser beam to create a series of kerfs to ablate a large area. Boogaard explains the serpentine method as follows:

A simple operation is begun by scanning the focused laser beam over the desired area back and forth making parallel cuts to form the size and shape desired. The laser is gated on and off at the beginning and end of each scan but not during the incremental movement that determines the kerf overlap. See Figure 4. The proper speed, laser q-switch rate, power and beam diameter, are set to reach the desired depth and smoothness on the bottom.

This looks quite simple and, indeed if this were done, an area could be milled away with a fair amount of precision. In actual practice however there are several conditions that are changing throughout the procedure. One of these is what is taking place as the milling process is being initiated by the laser.

EX1035-Boogaard, 50.



EX1035-Boogaard, Figure 4.

96. As shown below in Figure 7, Boogaard also teaches using a double scan method, which requires two distinct ablation processes. EX1035-Boogaard, 51. The first process begins the milling operation in the center of an area and the laser moves toward the outer wall. EX1035-Boogaard, 51. The second process also begins in the center of an area, overlapping slightly from where the first scan began and moving the laser toward the opposite outer wall. EX1035-Boogaard, 51. Boogaard explains:

A different method, but one that offers better control of the leading edge and greatly reduces this problem is to divide the area in two and begin the milling operation in the

center of the area and move toward the outer wall, or what is normally the starting point. The outside wall is then the location of the last scan and the most vertical slope will be obtained. The second part of the area is completed by overlapping slightly from where the first scan was begun and incrementing over in the opposite direction. When the second part is completed, depending on the amount of overlap used, a shallow groove or slight ridge is the only artifact that will remain and is usually not significant to the overall function of the part. See Figure 7. This groove can be kept to less than 5um in width and less than 3um in height.

EX1035-Boogaard, 51.

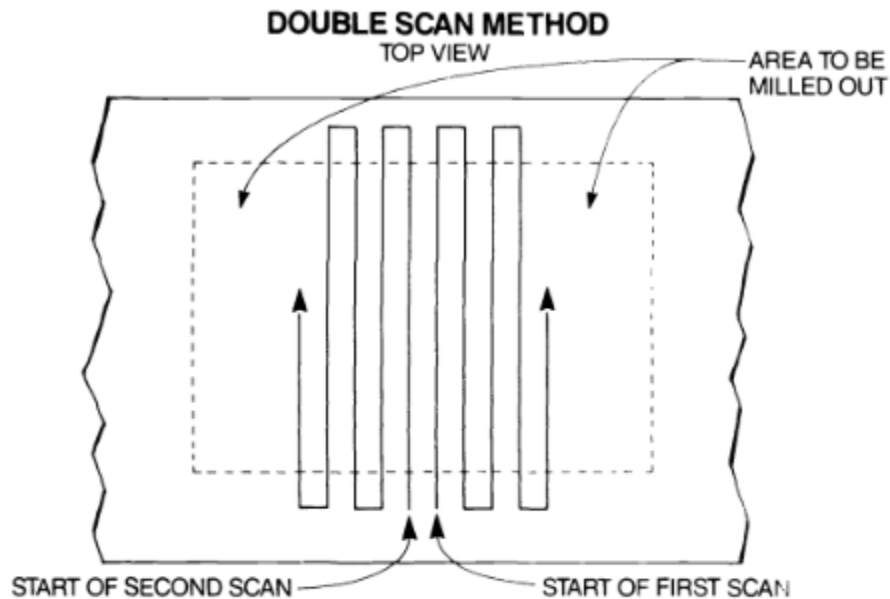


Figure 7. Double-Scan method
used to obtain vertical leading
and trailing walls

EX1035-Boogaard, Figure 7.

97. As shown below in Figures 2a and 2b, Boogaard also teaches various laser positioning systems, like the linear beam positioning system and the galvanometer beam positioning system. EX1035-Boogaard, 48. The linear beam positioning system keeps the beam at a perpendicular angle to the work surface, whereas the beam in the galvanometer beam positioning system moves along an arc or a flat field objective lens. Boogaard explains:

Even though the Nd:YAG laser has been around for many years, it continues to grow in microelectronic machining applications. For about 15 years it has been used to trim thick film and thin film resistors, on ceramic and glass substrates and silicon wafers. In these applications the beam has been moved around or positioned with either a rectilinear positioning system (**Figure 22**), driven by stepper or linear motors, or a galvanometer positioning mechanism (**Figure 26**). In the latter, the beam is scanned in an arc or scanned through a flat field objective lens where it is corrected so that the beam is perpendicular, or is close to perpendicular, to the part. With the rectilinear positioning system the beam is kept at a perpendicular angle to the work surface at all times. Both methods have their inherent advantages. The galvanometer offers greater speed because of its light weight. While the rectilinear system can achieve greater precision over a larger area. The work that is discussed in this paper has been done with a precision rectilinear positioning system.

EX1035-Boogaard, 48-49. I note that the above text's citation of Figure 22 appears to be a typo because Figure 2a, as shown below, shows a rectilinear positioning

system. I also note that the above text's citation of Figure 26 appears to be a typo because Figure 2b, as shown below, shows a galvanometer positioning system.

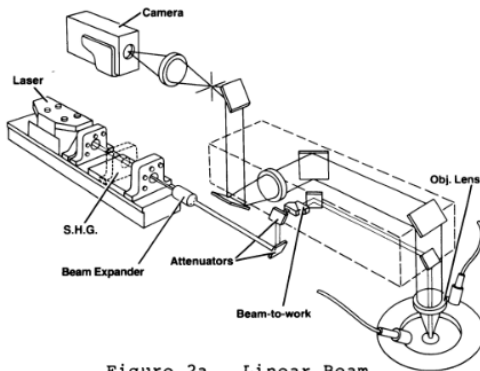


Figure 2a. Linear Beam Positioning System

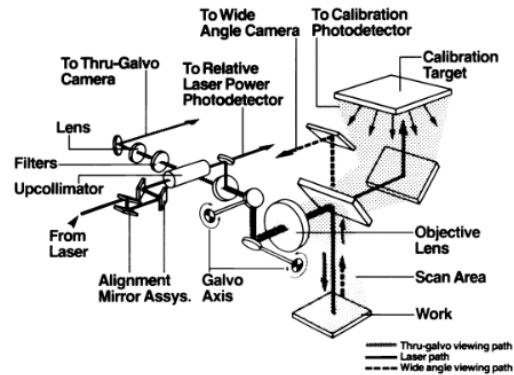


Figure 2b. Galvanometer Beam Positioning System

EX1035-Boogaard, Figures 2a-2b.

98. As shown in Figure 1 below, Boogaard also discloses that the Nd:YAG laser operates at 1.06 micrometers (μm) in the infrared spectrum.

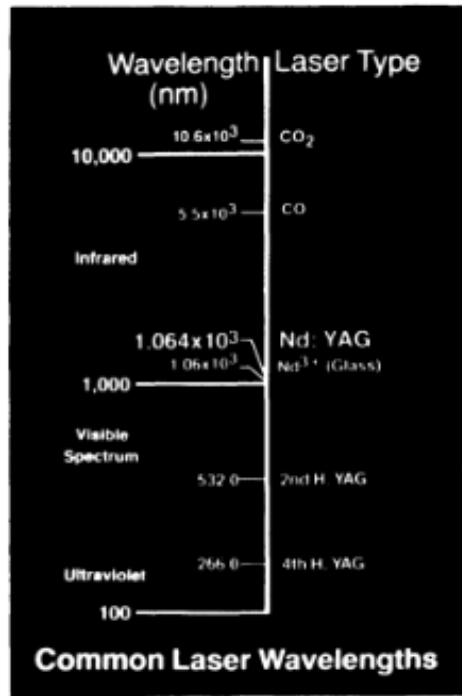


Figure 1. Nd: YAG Wavelength Chart

EX1035-Boogaard, Figure 1.

3. Overview of Angell

99. Angell, published in 1997, describes various parameters for selecting suitable lasers for laser ablation. EX1034-Angell, 66. Angell explains that it serves as a compilation of empirical information “to be used as a reference guide for those interested in laser micromachining.” EX1034-Angell, 65. Angell describes the information that it includes about several lasers such as “material type, lasers used in machining (CO₂, solid state, excimer), laser processing parameters (wavelength,

fluence, pulse width, cutting speed) and other material related information (thickness, feature sizes, etc.).” EX1034-Angell, 65.

100. Angell further explains various differences between CO₂, Nd:YAG, and excimer lasers. For example, Angell explains the CO₂ and Nd:YAG lasers operate in the infrared spectrum and have extensive industrial experience and are widely used for machining metals, plastics, ceramics, and wood. EX1034-Angell, 66. Angell further explains that excimer lasers operate in the ultraviolet spectrum and are suitable for creating smaller, higher resolution, and higher quality features compared to infrared lasers. EX1034-Angell, 66. In particular, Angell teaches that “[t]he most common industrial laser is the CO₂ laser” which “is capable of machining many different types of materials including metal, plastic, wood, and glass.” EX1034-Angell, 66. Angell also provides “[p]rocessing parameters” such as “focused spot-size” regarding the CO₂ laser. EX1034-Angell, 66.

101. Angell discloses that a CO₂ laser is appropriate for ablating plastics. EX1034-Angell, 66-67. Additionally, a person of ordinary skill in the art would have understood that a CO₂ laser was well-suited to the ablation of plastics. EX1073-Allan, 45. For example, Allan (1979) explains:

Table I lists about one dozen of the most popular lasers, only two of which are used for nearly all materials-processing applications: the Nd:YAG (neodymium:

yttrium-aluminum garnet) and the CO₂ (carbon-dioxide) laser. Both account for nearly 90 percent of all industrial laser material-processing uses. Figure 2 illustrates the schematic diagrams for both Nd:YAG and CO₂ lasers.

The Nd:YAG laser, which operates at a wavelength of 1.06 μm , is used principally for precision machining of thin metals and for scribing silicon semiconductor wafers and trimming resistor networks. The CO₂ laser, with a longer wavelength of 10.6 μm , is of higher output power and is used on heavier metals. Both lasers are also used to process many other materials.

...

Metals absorb less laser-beam energy, and are generally more reflective of a laser beam than nonmetals. For some applications, like heat treating, better energy absorption is achieved by chemically treating the surfaces of metals prior to laser processing. And the energy from the 1.06 μm -wavelength Nd:YAG laser is more readily absorbed by metals than that of the 10.6 μm -wavelength CO₂ laser. However, the CO₂'s higher output power tends to compensate for this drawback.

...

Because most nonmetals absorb energy from the 10.6 μm -wavelength CO₂ laser, a host of organic and inorganic material applications has opened up—from acrylics, polyethelenes, wood, rubber, and wool to diamonds. Hole drilling in plastics and rubber materials is one of the fastest-growing applications. Both of these materials respond extremely well to CO₂ laser energy. Examples in plastics include hole drilling in aerosol valves, contact lenses, pipes, tubing, and wire insulations. Rubber examples include hole drilling in baby-bottle nipples and rubber seals. Plastic materials have been welded with CO₂ laser beams.

For both drilling and welding, medium power levels of 50 to 500 W suffice. And throughput rates can be quite high. A 250-W CO₂ laser can perforate a polyethylene plastic tubing with 0.020-inch (0.5-mm) holes spaced 6 to 24 inches (15 to 61 cm) apart, at 300 ft/min (90 m/min).

EX1073-Allan, 42-46.

102. Indeed, another reference, Tiffany (1985), discusses the same:

Solid state Nd:YAG and Nd:Glass lasers are dominant in metal working applications, **whereas CO₂ maintains an advantage in most non-metal processing areas. This is due in large part to the fact that metals have lower reflectivities and therefore higher absorption of the shorter 1.06-micron wavelength of the solid state laser output beam than of the 10.6-microns.**

EX1070-Tiffany, 28.

4. The Bhullar, Boogaard, Angell Combination

103. As I explained in Section III.B, I have been informed by Petitioner's counsel and understand that for a claim to be obvious, a person of ordinary skill in the art must have had a reason or motivation to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have had a reasonable expectation of success in doing so. For the reasons I explain below, it is my conclusion that a person of ordinary skill in the art would have been motivated to incorporate Boogaard's teachings of a focused Nd:YAG laser beam and a laser positioning system, as well as Angell's disclosure

of a CO₂ laser suitable for ablating plastics, in Bhullar's method to manufacture biosensor strips, and would have had a reasonable expectation of success in doing so.

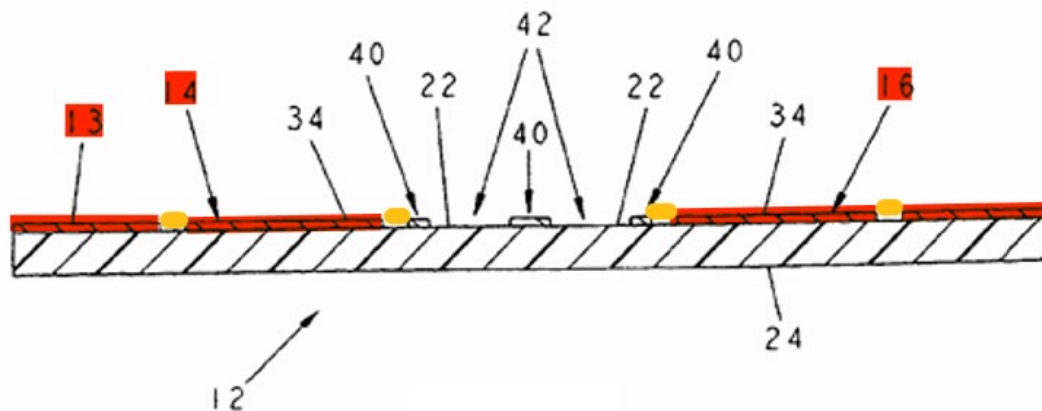
104. As I explain in **subsection (a)** below, Bhullar directs a person of ordinary skill in the art to consult the prior art for suitable lasers. Bhullar also incorporates by reference prior art that recommends use of a focused laser beam. Boogaard provides teachings of one such focused laser, a Nd:YAG laser and a positioning system for use of such a laser.

105. As I explain in **subsection (b)** below, Bhullar teaches the need for a laser to form a kerf by ablating a metal layer and a portion of a plastic layer. Angell provides teachings regarding how a CO₂ laser is one such laser that is suitable for ablating plastics.

106. As I conclude in **subsection (c)** below, based on my explanation provided herein, it is my conclusion that a person of ordinary skill in the art would have been motivated to combine Bhullar, Boogaard, and Angell and would have had a reasonable expectation of doing so.

**(a) Bhullar, Boogaard: Bhullar and Boogaard's
Teachings of a Focused Nd:YAG Laser and
Positioning System**

107. As shown in Figure 4 below, Bhullar's biosensor strip includes the ablation lines ("gaps" shown in yellow below) to separate electrodes 13, 14 and 16 (shown in red below) in Bhullar's metallized electrode support material.



EX1007-Bhullar, FIG. 4.

108. Bhullar teaches that the technology and methods for laser ablation were already established and familiar to professionals in the field, stating that "a laser system capable of ablating support 12 is known to those of ordinary skill in the art." EX1007-Bhullar, [0043]. Bhullar provides non-limiting examples of such laser systems, including excimer lasers, which are controlled by mirrors, lenses, and masks to achieve the desired ablation pattern. Bhullar also cites the LPX-300 and LPX-200 systems from LPKF Laser Electronic GmbH as commercially available

examples, further demonstrating that these laser systems were accessible and commonly known. EX1007-Bhullar, [0043]. Additionally, Bhullar describes the process of using a laser ablation station to form a pre-determined pattern on a metallic layer of the metallized film. EX1007-Bhullar, [0044]. Bhullar also mentions that “that the amount of energy required [to ablate] may vary from material to material, metal to metal, or thickness to thickness,” indicating that a person of ordinary skill in the art would know how to adapt the energy requirements (and laser selection) based on these considerations. EX1007-Bhullar, [0044].

109. To separate electrodes 13, 14 and 16 and create gaps, Bhullar leaves it up to a person of ordinary skill in the art to implement prior art laser ablation techniques. For instance, Bhullar teaches that “[t]echniques for forming electrodes on a surface using laser ablation are known.” As I explained in Section X.A.1 (Overview of Bhullar), Bhullar directs a person of ordinary skill in the art to specific examples of forming electrodes that are described in App. No. 09/411,940. EX1007-Bhullar, [0019]. App. No. 09/411,940, in turn, teaches that multiple laser ablation systems “were well known to those of ordinary skill in the art” for creating electrodes. App. No. 09/411,940 further directs a person of ordinary skill in the art to laser ablation techniques described in Kickelhain, which is also incorporated by reference. EX1063-Bhullar’940. Kickelhain teaches the use of a focused laser beam, stating

that “[i]t is possible to remove the primary coat in the insulating channels by means of patterned scanning by a focused laser beam.” EX1056-Kickelhain, 4:51-53, 2:51-55, Claim 1, Claim 11. Therefore, a person of ordinary skill in the art would have consulted the prior art, at the direction of Bhullar, for suitable laser ablation techniques, including use of a focused laser beam. As I explain below, a person of ordinary skill in the art would have recognized that Boogaard provides such techniques.

110. Like Bhullar, Boogaard teaches applications of micromachining including “removal of thin films from various substrates” “in the microelectronics area...to produce a desired electrical characteristic or geometric shape....” EX1035-Boogaard, 48. Boogaard teaches the use of a Nd:YAG focused laser beam, noting that:

A simple operation is begun by scanning the focused laser beam over the desired area back and forth making parallel cuts to form the size and shape desired. The laser is gated on and off at the beginning and end of each scan but not during the incremental movement that determines the kerf overlap. See Figure 4. The proper speed, laser q-switch rate, power and beam diameter, are set to reach the desired depth and smoothness on the bottom.

This looks quite simple and, indeed if this were done, an area could be milled away with a fair amount of precision. In actual practice however there are several conditions that are changing throughout the procedure. One of these is

what is taking place as the milling process is being initiated by the laser.

EX1035-Boogaard, 48-50.

111. As previously explained, Boogaard provides several scanning techniques for laser etching (milling) using a focused Nd:YAG laser with a positioning system, including a serpentine scan on area to be milled (shown in Figure 4 below) and a double scan method on area to be milled (shown in Figure 7 below).

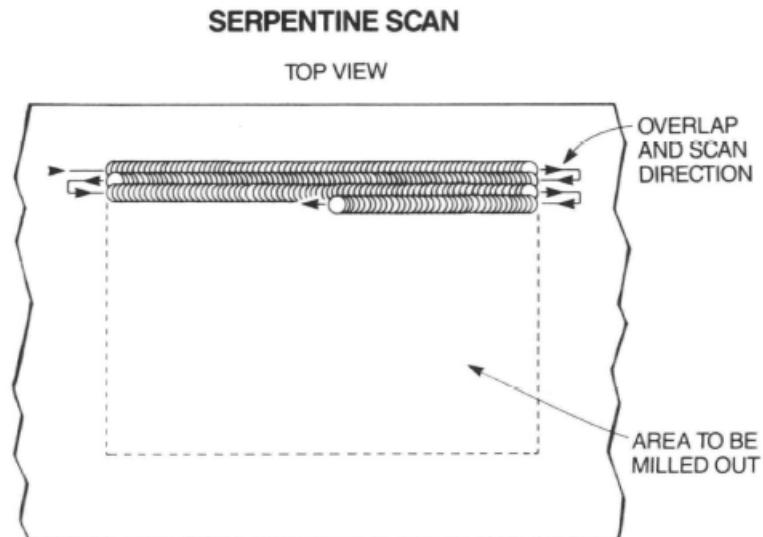


Figure 4. Serpentine scan
used in laser milling

EX1035-Boogaard, Figure 4.

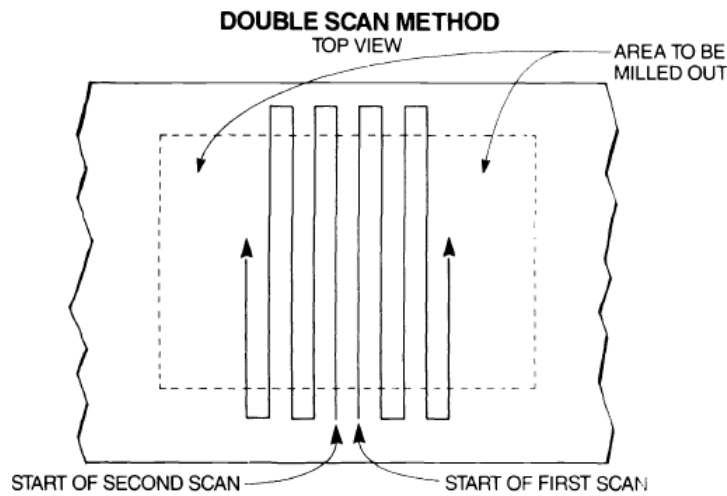


Figure 7. Double-Scan method
used to obtain vertical leading
and trailing walls

EX1035-Boogaard, Figure 7.

112. Boogaard also explains that “the ability to cut out very small holes and patterns with extremely small kerf widths brings this technology down to dimensions never before possible.” EX1035-Boogaard, 58. As shown below in Figures 13a-13b, Boogaard describes the process of laser cutting or drilling using a Nd:YAG laser to create holes of different diameters.

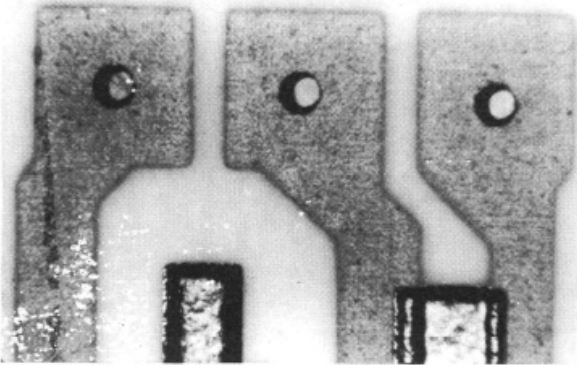


Figure 13a. Holes machined by laser through metal pads on thick film ceramic circuit allow for wire connections.

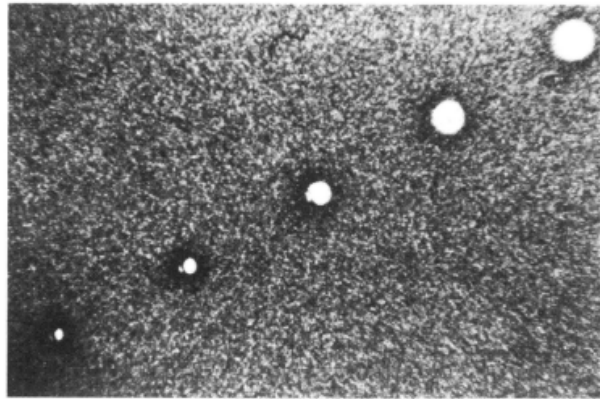


Figure 13b. Holes of different diameters "cored" through silicon. Hole diameters are from 5-25 mils, wafer thickness is 15 mils

EX1035-Boogaard, Figures 13a-13b.

113. Boogaard also teaches suitable beam widths for the ablation lines/kerfs that would be required by Bhullar's manufacturing process. According to Bhullar, typical gap widths are "about 25 μm^2 to about 500 μm , preferably the gap has a width of about 100 μm to about 200 μm ." EX1007-Bhullar, [0019]. Boogaard's Nd:YAG laser can also produce features in this range, using beam diameters of 5 microns to 38.1 microns. For example, Boogaard provides an example of a milling operation

² The terms " μm ", "microns", and "micro-meters" are used interchangeably in my Declaration.

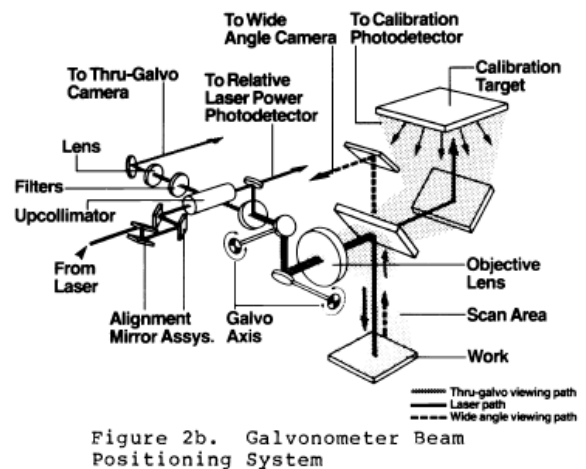
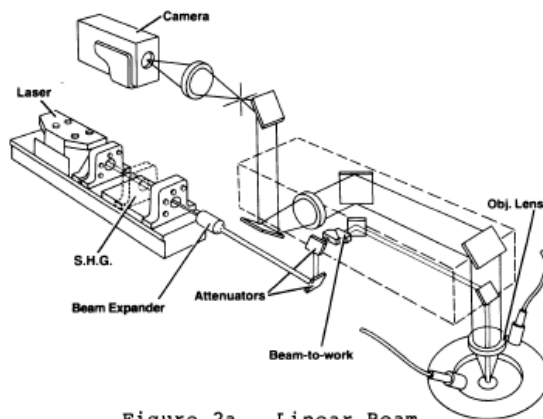
using a Nd:YAG laser and states that the “**groove can be kept to less than 5 μ m in width....**” EX1035-Boogard, 51.

114. Additionally, Boogaard explains that “hole size is then determined by the beam diameter” and provides examples of various hole sizes. EX1035-Boogaard, 54. Boogaard states that “[d]epending on the material thickness and the optics used, hole sizes can vary from 0.0005 inch [(12.7 micron)] to as large as 0.0015 inch [**38.1 micron**].” EX1035-Boogaard, 54.

115. A person of ordinary skill in the art would have recognized that Boogaard’s teachings of positioning systems, wherein a laser is moved relative to the substrate, was particularly suitable for implementation in Bhullar’s system. In Bhullar, a metallized film in the form of a reel passes through a laser ablation station, among other stations. According to Bhullar, a “roll of metallized electrode support material is fed through guide rolls into an ablation/washing and drying station.” EX1007-Bhullar, [0043]. In the laser ablation station, “the metallic layer of the metallized film is ablated in a pre-determined pattern, to form a ribbon of isolated electrode sets...” EX1007-Bhullar, [0044]. Upon leaving the laser ablation station, “the metallized film is fed into a reagent dispensing station.” EX1007-Bhullar, [0045]. Bhullar also describes processing the cover substrate as part of one of its

processing stations. EX1007-Bhullar, [0046]; *see also* EX1007-Bhullar, claims 1-30.

116. Bhullar's roll is only cut into individual sensors at the end of the process, when "cover material/spacer substrate subassembly is fed into a sensor lamination & cut/pack station." EX1007-Bhullar, [0047]. Thus, it would not have been feasible to use Bhullar's system to hold the laser in place and move the metallized film relative to the laser. A person of ordinary skill in the art would have been motivated to combine Boogaard with a reasonable expectation of success because Boogaard provided a solution to this, by teaching positioning systems that move the laser relative to the substrate with better than 1 micron positioning accuracy. EX1035-Boogaard, 48-49, Figures 2a, 2b.



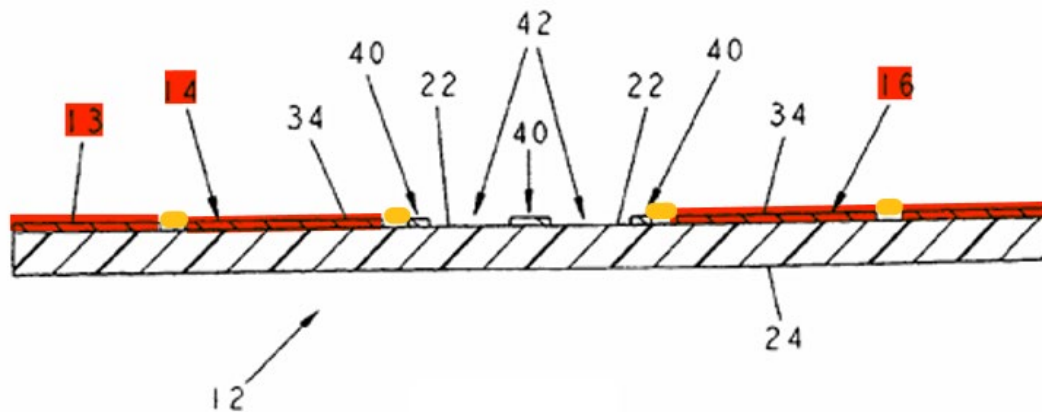
EX1035-Boogaard, Figures 2a-2b (showing example positioning systems).

117. A person of ordinary skill in the art would have been further motivated to combine the teachings of Bhullar and Boogaard because a person of ordinary skill in the art would have known that an Nd:YAG laser was a preferred laser for forming a kerf to make a glucose sensor.

118. For instance, Winarta disclosed a “method of making multiple, disposable sensors”—including those for detecting an analyte such as glucose—by laser ablation of conductive material on a base layer. EX1011-Winarta, Claim 36, Claim 1, 4:32-36. Winarta’s “preferred scribing or scoring method of the present invention is done by using a carbon dioxide (CO₂) laser, **a YAG laser** or an ex[c]imer laser.” EX1011-Winarta, 6:65-67. Similar to Boogaard, Winarta’s method involves moving the laser relative to “a base strip of an insulating material having a layer of conductive material” and “scribing in said conductive material a plurality of lines in a repetitive pattern wherein said plurality of lines contain a repetitive pattern capable of forming three conductive paths in each of said repetitive pattern...” EX1011-Winarta, Claim 1, 36, 4:32-36. Therefore, a person of ordinary skill in the art would have recognized that Boogaard’s teachings were directly applicable to the manufacturing of biosensors using laser ablation.

119. Additionally, the combination amounted to improving a known device ready for improvement using a known technique to yield predictable results by

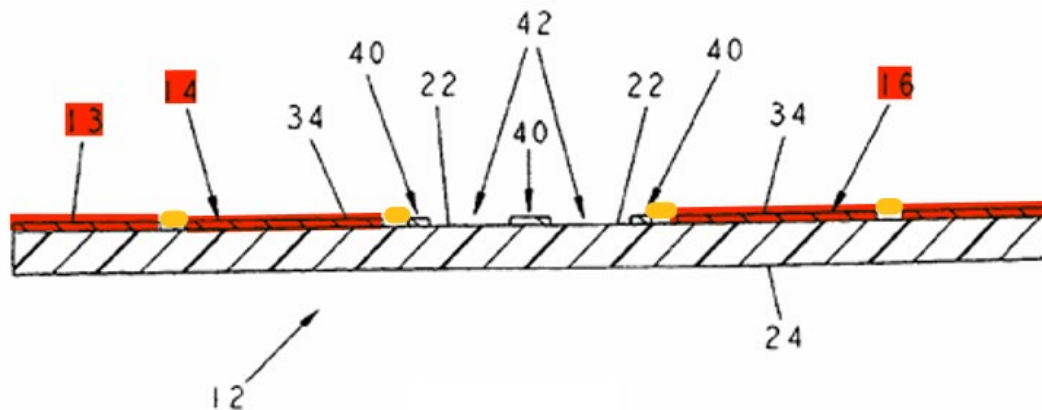
implementing Boogaard's disclosures on laser ablation to the laser ablation station in Bhullar. For example, the use of a Nd:YAG laser on a positioning system as taught by Boogaard (a known technique) would have been applied to Bhullar's laser ablation station (a known device) which was ready for improvement (because Bhullar is silent as to the implementation details regarding the Nd:YAG laser) to form the gaps shown in yellow in Figure 4 of Bhullar.



EX1007-Bhullar, FIG. 4; *see also* EX1007-Bhullar, [0043]-[0044].

120. It would have also been obvious to try implementing Boogaard's disclosures on laser ablation in the laser ablation station of Bhullar. Bhullar and the incorporated Kickelhain reference identifies only two laser ablation techniques: (1) a moving focused laser (EX1056-Kickelhain, 2:47-56, 4:49-5:5, 5:49-55); and (2) a laser with a mask (EX1007-Bhullar, [0043]). Therefore, only a small number of solutions for laser ablation were presented to a person of ordinary skill in the art and

there would have been a predictable expectation of success (as I further describe below). Moving focused laser beams and performing laser ablation, as taught by Boogaard, would have been an obvious way to form the kerfs shown in yellow in Bhullar Figure 4.



EX1007-Bhullar, FIG. 4; *see also* EX1007-Bhullar, [0043]-[0044].

121. A person of ordinary skill in the art would have also had a reasonable expectation of success, and indeed would have succeeded, using the combination of teachings of Boogaard's laser milling techniques in Bhullar's laser ablation station. Boogaard's embodiments correspond to Bhullar's use case. For example, both Boogaard and Bhullar teach using laser ablation to ablate gold with micron-scale beam widths. EX1035-Boogaard, 57; EX1007-Bhullar, [0018]. Additionally, both Kickelhain and Winarta describe the process of scanning with a focused laser beam to create patterned metallization on substrate surfaces. Winarta also demonstrated

the successful construction and testing of functional sensors for blood glucose detection using laser scribing, consistent with the methods described by Boogaard. *See* EX1011-Winarta, 8:42-9:3 (laser scribing), FIG. 2, 10:1-67, FIGS. 5-6.

122. I also note that Boogaard and Bhullar are in the same field, which includes the manufacture of microelectronic components comprising a base non-conductive layer and electrodes defined by laser ablation techniques. EX1007-Bhullar, [0018]-[0020], FIG. 2; EX1035-Boogaard, 48, 57-58.

123. It is therefore my conclusion that a person of ordinary skill in the art would have been motivated to combine the teachings of Boogaard's Nd:YAG laser and positioning system into Bhullar's laser ablation station and would have had a reasonable expectation of success in doing so.

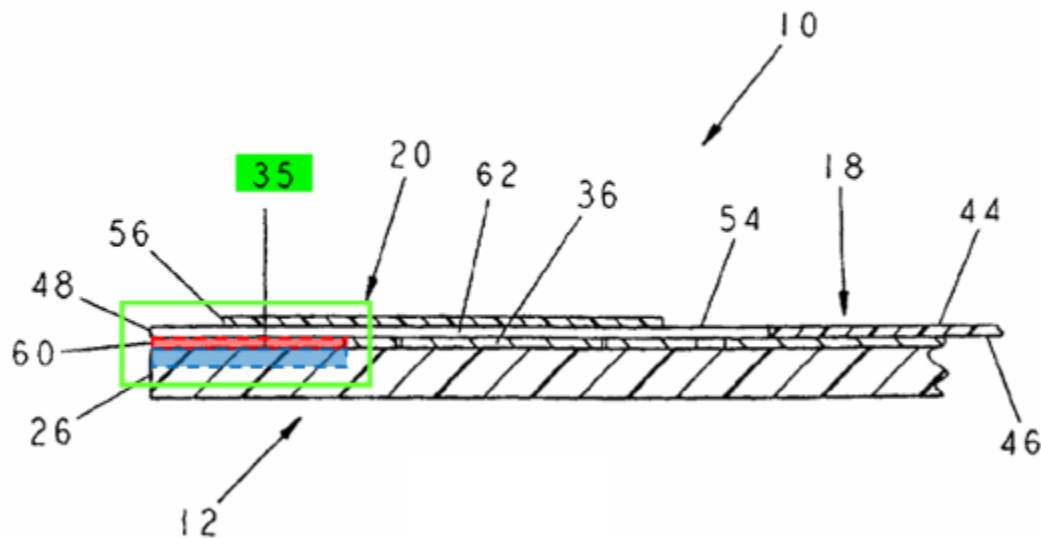
**(b) Bhullar, Boogaard, Angell: Bhullar and Boogaard
Combined With Angell's Teachings of a Focused CO₂
Laser**

124. As I explained above, it would have been obvious to use a focused Nd:YAG laser with a positioning system as taught by Boogaard to form ablation lines (gaps) in the conductive layer of Bhullar's metallized electrode support material shown in Figure 4.

125. Bhullar also teaches that:

Recess is created by removing the electrical conductor 13 to expose the first surface 22 of the support substrate 12 adjacent to the first end 26. It is appreciated that **a portion of the first surface 22 may also be removed to form the recess 35 in accordance with this disclosure.**

EX1007-Bhullar, [0021]. Therefore, Bhullar explains that recess 35 can be made through ablation of both the conductive layer and, in addition, part of the support substrate. The result would be a recess that is wider and deeper than the kerf formed by the first laser. As I show in my annotation of Figure 3 of Bhullar below, the kerf corresponding to recess 35 (light green) results from removal of **electrical conductor 13** (red) and **removed support substrate 12** (dark blue).



EX1007-Bhullar, FIG. 3. Bhullar's suggestion to ablate some of the support substrate would have indicated to a person of ordinary skill in the art to consider a

suitable additional laser for ablating plastic. This is because, for example, a person of ordinary skill in the art would have understood the electrical conductor to be a metal layer and the support substrate to be a plastic layer. Indeed, Bhullar teaches that the support substrate “is formed of a flexible polymer...such as a polyester or polyimide, polyethylene naphthalate (PEN)” and a person of ordinary skill in the art would have recognized these polymers as plastics. EX1007-Bhullar, [0017]).

126. Faced with the decision of selecting a laser that is suitable for ablating a wide area, that can also ablate both metal and some of support substrate (plastic), a person of ordinary skill in the art would have considered known suitable laser ablation techniques, including the use of a focused laser beam. As a result of that inquiry, a person of ordinary skill in the art would have easily concluded that Angell provides such techniques. Angell, like Bhullar and Boogaard, is directed to laser micromachining and teaches various considerations that one ought to determine when selecting lasers, such as the “material type, lasers used in machining (CO₂, solid state, excimer), laser processing parameters (wavelength, fluence, pulse width, cutting speed) and other material related information (thickness, feature sizes, etc.).” EX1034-Angell, 65.

127. Angell teaches that a focused CO₂ laser can ablate metal. When ablating metal, in addition to part of an electrode support substrate (like Bhullar’s),

a focused CO₂ laser would have been known to be a suitable laser beam choice. EX1034-Angell, 66, 69; *see* Section X.A.3 (Overview of Angell). First, a person of ordinary skill in the art would have recognized that CO₂ lasers were an appropriate choice when needing to form a electrodes by cutting into a gold metallic layer on a test strip substrate. EX1079-Cai, 14:60-15:9. Second, for example, Angell explains that a CO₂ laser is appropriate for ablating plastics. EX1034-Angell, 66. Additionally, a person of ordinary skill in the art would have understood that a CO₂ laser was better suited than an Nd:YAG laser to ablate plastic because a CO₂ laser operates at a longer wavelength than the Nd:YAG laser. EX1073-Allan, 45. For example, Allan (1979) explains:

Table I lists about one dozen of the most popular lasers, only two of which are used for nearly all materials-processing applications: the Nd:YAG (neodymium: yttrium-aluminum garnet) and the CO₂ (carbon-dioxide) laser. Both account for nearly 90 percent of all industrial laser material-processing uses. Figure 2 illustrates the schematic diagrams for both Nd:YAG and CO₂ lasers.

The Nd:YAG laser, which operates at a wavelength of 1.06 μm , is used principally for precision machining of thin metals and for scribing silicon semiconductor wafers and trimming resistor networks. The CO₂ laser, with a longer wavelength of 10.6 μm , is of higher output power and is used on heavier metals. Both lasers are also used to process many other materials.

...

Metals absorb less laser-beam energy, and are generally more reflective of a laser beam than nonmetals. For some applications, like heat treating, better energy absorption is achieved by chemically treating the surfaces of metals prior to laser processing. And the **energy from the 1.06 μm -wavelength Nd:YAG laser is more readily absorbed by metals than that of the 10.6 μm -wavelength CO₂ laser.** However, the CO₂'s higher output power tends to compensate for this drawback.

...

Because most nonmetals absorb energy from the 10.6 μm -wavelength CO₂ laser, a host of organic and inorganic material applications has opened up—from acrylics, polyethelenes, wood, rubber, and wool to diamonds. Hole drilling in plastics and rubber materials is one of the fastest-growing applications. Both of these materials respond extremely well to CO₂ laser energy. Examples in plastics include hole drilling in aerosol valves, contact lenses, pipes, tubing, and wire insulations. Rubber examples include hole drilling in baby-bottle nipples and rubber seals. Plastic materials have been welded with CO₂ laser beams.

For both drilling and welding, medium power levels of 50 to 500 W suffice. And throughput rates can be quite high. A 250-W CO₂ laser can perforate a polyethylene plastic tubing with 0.020-inch (0.5-mm) holes spaced 6 to 24 inches (15 to 61 cm) apart, at 300 ft/min (90 m/min).

EX1073-Allan, 42-46.

128. This means that plastic better absorbs the energy emitted from a CO₂ laser as compared to an Nd:YAG laser. EX1073-Allan, 45. Ultimately, this allows

for faster energy deposition and a lower dwell time. EX1073-Allan, 45. Indeed, another reference, Tiffany (1985), discusses the same:

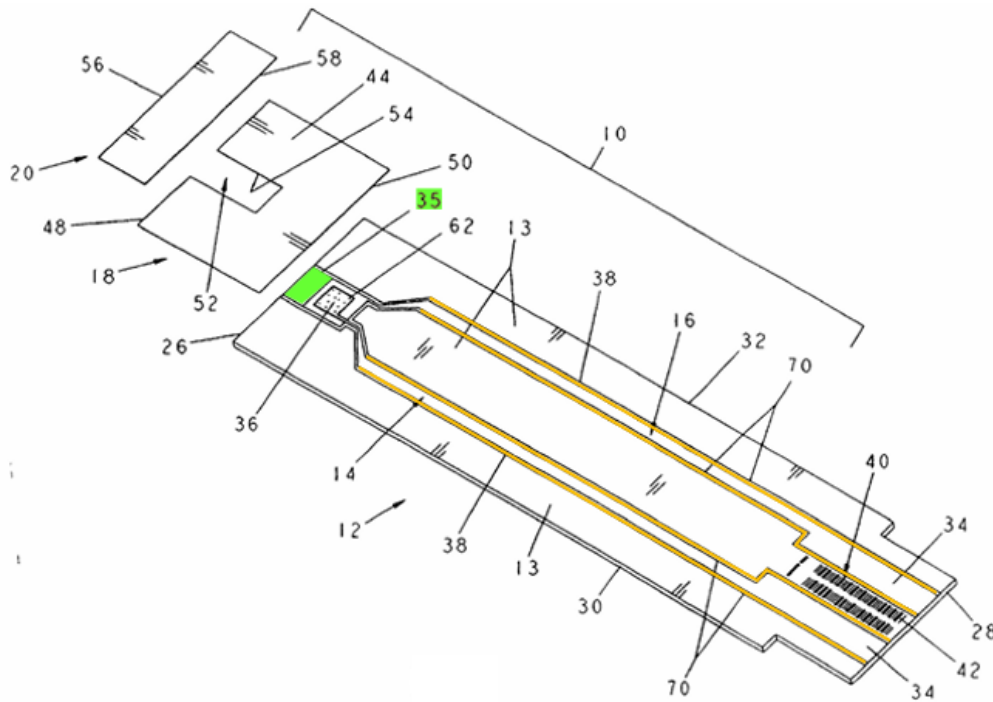
Solid state Nd:YAG and Nd:Glass lasers are dominant in metal working applications, **whereas CO₂ maintains an advantage in most non-metal processing areas. This is due in large part to the fact that metals have lower reflectivities and therefore higher absorption of the shorter 1.06-micron wavelength of the solid state laser output beam than of the 10.6-microns.**

EX1070-Tiffany, 28. Thus, in the combination of Bhullar, Boogaard, and Angell, the *second laser beam* is the CO₂ laser, which is different from the *first laser beam*, the Nd:YAG laser.

129. A person of ordinary skill in the art would have understood that using the same CO₂ laser to ablate both the plastic and metal would be more efficient than using the Nd:YAG laser to ablate the metal and then using another laser or processing method to form the recess in the plastic. Additionally, it was known to use both Nd:YAG and CO₂ lasers in medical device manufacturing plants. EX1073-Allan, 43. Therefore, a person of ordinary skill in the art would have been motivated to select a CO₂ laser as taught by Angell, as a second focused laser beam for ablating plastic to form recesses 35 as Bhullar teaches.

130. Indeed, Angell discloses suitable beam widths for the recess 35 in Bhullar. As shown in Figure 2 below, a larger ablation area (and greater overall

dimensions when depth is also considered) is required to form recess 35 (in green) compared to the ablation lines that isolate the electrodes (shown in yellow). Angell's carbon dioxide lasers provide wider beam widths than the Nd:YAG laser. For example, Angell teaches CO₂ beam widths in the range of 50.8 microns (2 mil) to 254 microns (10 mil) (EX1034-Angell, 69), whereas Boogaard teaches Nd:YAG beam widths in the range of 5 microns to 38.1 microns (EX1035-Boogaard).



EX1007-Bhullar, FIG. 2.

131. A person of ordinary skill would have also been motivated by Boogaard's teaching of a positioning system to implement Angell's teaching of a CO₂ laser, with a reasonable expectation of success. It was known that a CO₂ laser,

as taught by Angell, could be used with a positioning system, as taught by Boogaard, including scanning techniques to form large recesses. *See, e.g.*, EX1072-Martyr, 347-48.

132. In addition, the implementation of Angell's laser ablation teachings regarding the CO₂ laser in the laser ablation station (in the combination of Bhullar and Boogaard) would have amounted to applying a known technique to a known device ready for improvement to yield a predictable result. The combination of Bhullar, Boogaard, and Angell would have resulted in using Angell's CO₂ laser (a known technique) with a positioning system in Bhullar's laser ablation station (a known device ready for improvement) to form a recess in both a plastic and metal layer (a predictable result). EX1007-Bhullar, [0043]-[0044].

133. It also would have been obvious to try to implement a CO₂ laser as taught by Angell in a laser ablation station taught by the combination of Bhullar and Boogaard. Bhullar teaches the removal of both the conductive layer and the polymer base layer (e.g., plastic) to form a recess. Angell discloses four specific lasers—CO₂, Nd:YAG, Nd:YLF, and excimer lasers. Accordingly, a person of ordinary skill in the art would have been faced with only a small number of solutions for laser ablation with a predictable expectation of success (as described below). It would have been obvious to test a focused CO₂ laser as taught by Angell to perform laser

ablation that forms a kerf by removing both plastic and metal, especially given that CO₂ was well-suited for the ablation of plastic materials. *See, e.g.*, EX1070-Tiffany, 28 (“Solid state Nd:YAG and Nd:Glass lasers are dominant in metal working applications, **whereas CO₂ maintains an advantage in most non-metal processing areas.**”).

134. A person of ordinary skill in the art would have had a reasonable expectation of success, and would have succeeded, when implementing a focused CO₂ laser as taught by Angell into the combination of Bhullar and Boogaard’s laser ablation station. Angell’s embodiments closely mirror Bhullar’s use case, including using laser ablation on a micron scale to ablate metal and a polymer. EX1034-Angell, 66. Indeed, such success is even demonstrated in Winarta, which teaches using a CO₂ laser to both scribe a conductive “gold” layer to form electrodes (EX1011-Winarta, 8:43-55) and to cut a “vent hole” in a top plastic layer (EX1011-Winarta, 9:15-18; 6:48-51).

135. I also note that Angell, Boogaard, and Bhullar are in the same field of endeavor that includes the manufacture of microelectronic components comprising a base (non-conductive layer) and laser-defined electrical components. EX1007-Bhullar, [0018]-[0020], FIG. 2; EX1035-Boogaard, 48-50, Figures 2a-2b, 4; EX1034-Angell, 57-58, Figure 22, Figure 23.

136. It is therefore my conclusion that a person of ordinary skill in the art would have been motivated to combine the teachings of Bhullar and Boogaard with Angell's teaching of a CO₂ laser, with a reasonable expectation of success.

(c) Bhullar, Boogaard, Angell Combination

137. A person of ordinary skill in the art would have been motivated to make the proposed combination of Bhullar, Boogaard, and Angell with a reasonable expectation of success. The combination would have been nothing more than combining the teachings of Bhullar's manufacturing method with (1) Boogaard's teaching to use an Nd:YAG laser to form kerfs that require ablating the conductive layer of Bhullar's metallized substrate, (2) Boogaard's teaching to use a positioning system to achieve movement relative to the test sensor, and (3) Angell's teaching to use a CO₂ laser to form kerfs that require ablation of both the conductive layer and a portion of the insulating base layer of Bhullar's metallized substrate.

5. Independent Claim 18

(a) Element 18[pre]: A method of manufacturing test strips, comprising:

138. Should the preamble be found to be limiting (which I understand is a legal determination), Bhullar teaches Element 18[preamble].

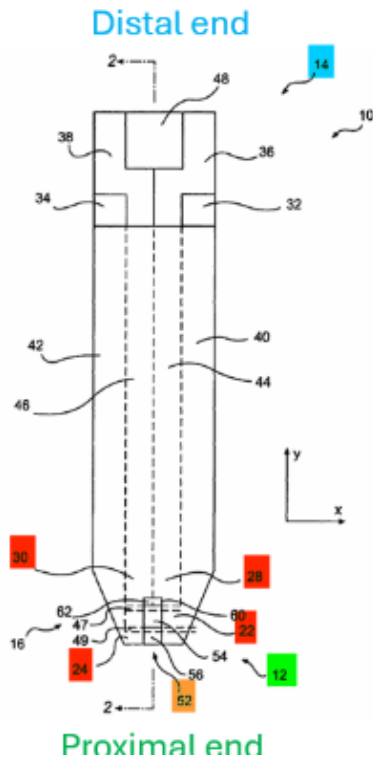
139. Bhullar discloses a method of manufacturing biosensors (*test strips*). For example, Bhullar teaches the manufacture of "packaged biosensor strips."

EX1007-Bhullar, [0047]. As I explained above, Bhullar teaches feeding a roll of metallized electrode support material through guide rolls into several stations, including an ablation station. EX1007-Bhullar, [0043]. At the ablation station, a laser system is used to ablate parts of the conductive layer to form gaps that define electrically isolated conductive components, like electrode sets, code patterns, and recesses. EX1007-Bhullar, [0043]. Bhullar further discloses the creation of a roll of cover substrate material, which is applied to the spacer substrate material. EX1007-Bhullar, [0046]. Bhullar further describes how the cover material/spacer substrate subassembly is fed into a sensor lamination and cut/pack station, along with the reagent-coated electrode-support substrate material. EX1007-Bhullar, [0047]. After the materials are assembled, Bhullar discloses cutting the processed roll “to form individual biosensors, which are sorted and packed into vials, each closed with a stopper, to give packaged biosensor strips.” EX1007-Bhullar, [0047] (element numbers omitted). *See* EX1007-Bhullar, [0015], [0005], [0019], [0025], [0043]-[0047].

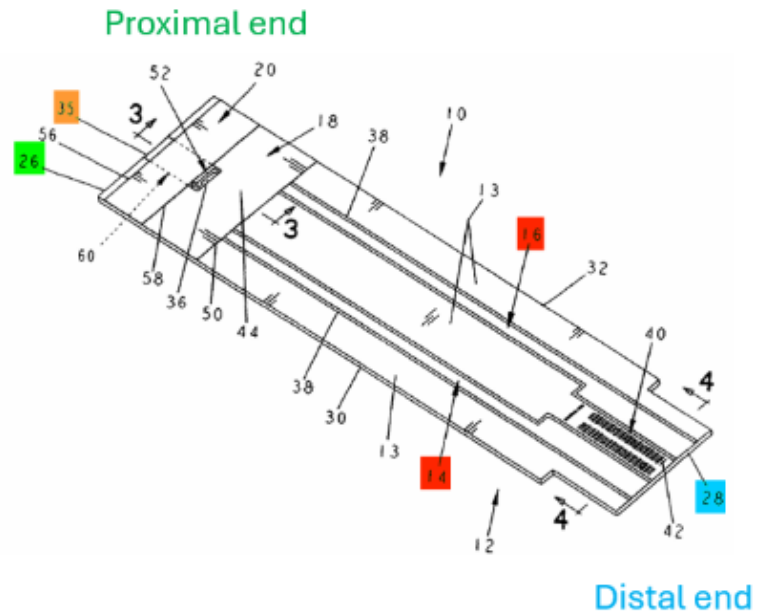
140. Like the '981 patent's test strip, Bhullar's biosensor strip is used “for measuring glucose from a whole blood sample.” EX1007-Bhullar, [0033], [0002], [0034]-[0035], [0042]. As I show below, both the '981 patent's and Bhullar's test strips are flat, generally rectangular, and comprise the same components. For

example, Figure 1A of the '981 patent has a proximal end 12 (in green) and Figure 1 of Bhullar has a first end 26 (in green). Figure 1A of the '981 patent has a slot 52 defining sample chamber 88 (in orange) and Figure 1 of Bhullar has a recess 35 with notch 52 to receive a fluid sample (in orange). Figure 1A of the '981 patent has a distal end 14 (in blue) and Figure 1 of Bhullar has a second end 289 (in blue). Figure 1A of the '981 patent has electrodes 22, 24, 28, 30 (in red) and Figure 1 of Bhullar has electrodes 14, 16 (in red), both near the proximal end of the test strip for detection of an analyte. EX1001-'981, 4:14-51, 3:37-39, 7:2-4; EX1007-Bhullar, FIG. 1, [0016], [0049].

'981 Patent, FIG. 1A



Bhullar, FIG. 1



EX1001-'981, FIG. 1A; EX1007-Bhullar, FIG. 1.

141. Additionally, Bhullar explains:

In use for example, after the reaction is complete, a power source (e.g., a battery) applies a potential difference between the electrodes 14, 16 respectively. 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. A 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.

EX1007-Bhullar, [0050]. Therefore, like the '981 patent, Bhullar uses a meter for analyte detection. EX1007-Bhullar, [0050].

(b) Element 18[a]: forming a reel containing a conductive layer and a base layer;

142. Bhullar makes Element 18[a] obvious.

143. Bhullar renders obvious forming a roll (*a reel*) containing an electrically conductive coating (*a conductive layer*) and a support substrate (*a base layer*).

144. First, the preferred method of Bhullar teaches that “a **roll** of metallized electrode support material” is “fed through guide rolls....” EX1007-Bhullar, [0043], [0044], [0046].

145. Bhullar states:

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, the selection of materials for the construction of biosensor 10 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.

EX1007-Bhullar, [0016].

146. As I show above, Bhullar states that “[b]iosensor 10 is preferably produced from rolls of material....” EX1007-Bhullar, [0016]. A person of ordinary skill in the art would have understood using a roll (*reel*) for this purpose would first require forming a reel, providing a motivation to do so. Moreover, a person of ordinary skill in the art would have had a reasonable expectation of success in doing so. For example, Bhullar left it up to a person of ordinary skill to select “materials that are sufficiently flexible for roll processing....” EX1007-Bhullar, [0016]. Moreover, it was well-known to form rolls from a sheet of metallized electrode support material. *See* EX1064-Harvey, 2-3. After the materials are assembled, Bhullar discloses cutting the processed roll “to form individual biosensors, which are sorted and packed into vials, each closed with a stopper, to give packaged biosensor strips.” EX1007-Bhullar, [0047] (element numbers omitted).

147. Second, Bhullar teaches that the roll (reel) of metallized electrode support material “contain[s] a conductive layer and a base layer.” EX1007-Bhullar, [0046]. For example, “the biosensor includes a **support substrate**, an **electrically conductive coating** positioned on the support substrate, the coating being formed to define electrodes and a code pattern, wherein there is sufficient contrast between the conductive coating and the substrate such that the code pattern is discernible, and a cover cooperating with the support substrate to define a channel.” EX1007-Bhullar,

Abstract. *See also* EX1007-Bhullar, [0003]-[0006], [0015]-[0017], [0019], [0020]-[0025], [0028]-[0029], [0031], [0043]-[0044], [0047], [0057], [0060], claim 1, claim 13, claim 30.

148. As I show below, Figures 1 and 4 of Bhullar depict “a biosensor 10 having an **electrode-support substrate 12**” (*base layer*) shown in blue and an “**electrical conductor 13**” (*conductive layer*) shown in red, where the “electrical conductor 13 [is] positioned on the substrate 12 that is disrupted to define electrodes 14, 16, a spacer substrate 18 positioned on substrate 12, and a cover substrate 20 positioned on the spacer substrate 18.” EX1007-Bhullar, [0016]. Bhullar also describes a preferred embodiment where the **electrode-support substrate 12** (*base layer*) is “a polymer” (*base layer*) that is “coated with gold” (*electrical conductor*). Bhullar teaches that “[c]apillary forces pull a liquid blood sample flowing from the incision through the capillary channel 60 across the reagent 62 and the array 34. The liquid blood sample dissolves the reagent 62 and engages the array 34 where the electrochemical reaction takes place.” EX1007-Bhullar, [0049]. Bhullar further teaches that:

In use for example, after the reaction is complete, a power source (e.g., a battery) applies a potential difference between the electrodes 14, 16 respectively. 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. A 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.

EX1007-Bhullar, [0050]. *See also* EX1007-Bhullar, [0014], [0017], [0018], [0044], claim 1, claim 3, claim 13, claim 21.

149. For example, Bhullar teaches:

[0016] FIGS. 1-4 illustrate an aspect of the invention in the form of a biosensor 10 having an electrode-support substrate 12, an electrical conductor 13 positioned on the substrate 12 that is disrupted to define electrodes 14, 16, a spacer substrate 18 positioned on substrate 12, and a cover substrate 20 positioned on the spacer substrate 18. Biosensor 10 is preferably rectangular in shape. It is appreciated however, that biosensor 10 can assume any number of 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, the selection of materials for the construction of biosensor 10 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.

[0017] Referring to FIG. 4, the support substrate 12 includes a first surface 22 facing the spacer substrate 18 and a second surface 24. In addition, as shown in FIG. 2, 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 may be formed in a variety of shapes and sizes in accordance with this disclosure. Substrate 12 is formed of a flexible polymer and preferably from a flexible polymer and preferably from a polymer such as a polyester or polyimide, polyethylene naphthalate (PEN). A non-limiting example of a suitable PEN is 5 mil (125 um) thick KALADEX®, a PEN film commercially available from E.I. DuPont de Nemours, Wilmington, Del., which is coated with gold by ROWO Coating, Henbolzbelm, Germany.

[0018] Electrodes 14, 16 are created or isolated from conductor 13 on first surface 22 of substrate 12. Non-limiting examples of a suitable electrical conductor 13 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 13 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 13 is gold.

EX1007-Bhullar, Abstract, [0016]-[0018].

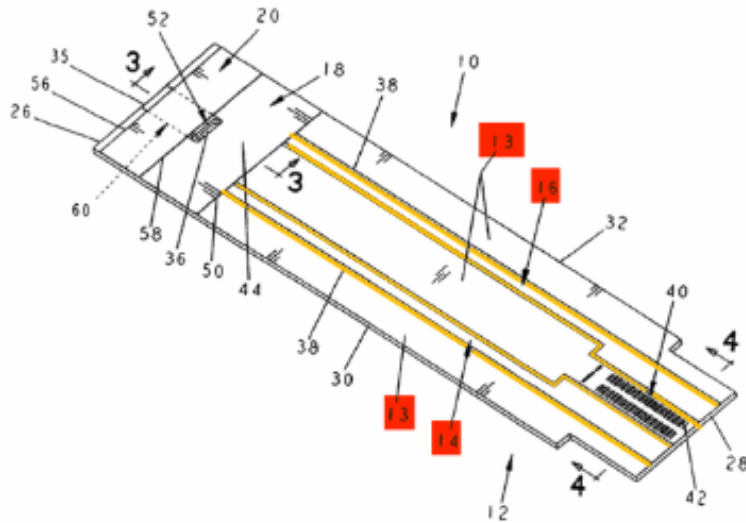
(c) Element 18[b]: forming a first kerf in the conductive layer, wherein the first kerf is formed using a first focused laser beam moved relative to the conductive layer along the first kerf;

150. The combination of Bhullar, Boogaard, and Angell makes Element 18[b] obvious.

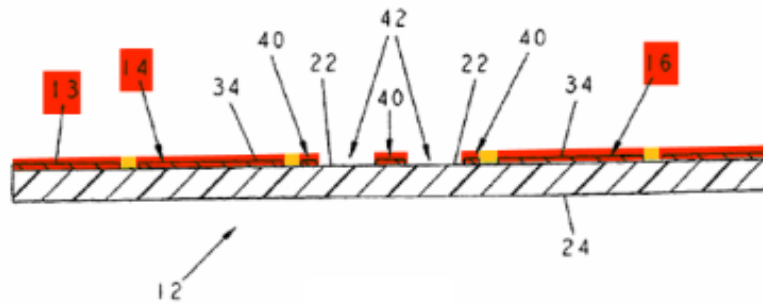
151. Bhullar teaches creating a gap (*forming a first kerf*) in the electrical conductor 13 (*conductive layer*), wherein the gap (*first kerf*) is formed using the teachings of Boogaard's Nd:YAG laser beam (*first focused laser beam*) moved relative to the conductive layer along the first kerf.

152. Bhullar teaches that “[e]lectrodes 14, 16 are created or isolated from conductor 13 on first surface 22 of substrate 12” (EX1007-Bhullar, [0018]) and further explains that “electrodes 14, 16 are created by removing the electrical conductor 13 from an area extending around the electrodes to form a gap of exposed support substrate 12.” EX1007-Bhullar, [0019]. As shown below, the electrodes 14,16 and the electrical conductor 13 are shown in red and the gap is shown in yellow. Therefore, Bhullar teaches *forming a first kerf in the conductive layer* by removing a width of *conductive layer* (electrical conductor 13) to form *the kerf* (gap).

Bhullar, FIG. 1



Bhullar, FIG. 4

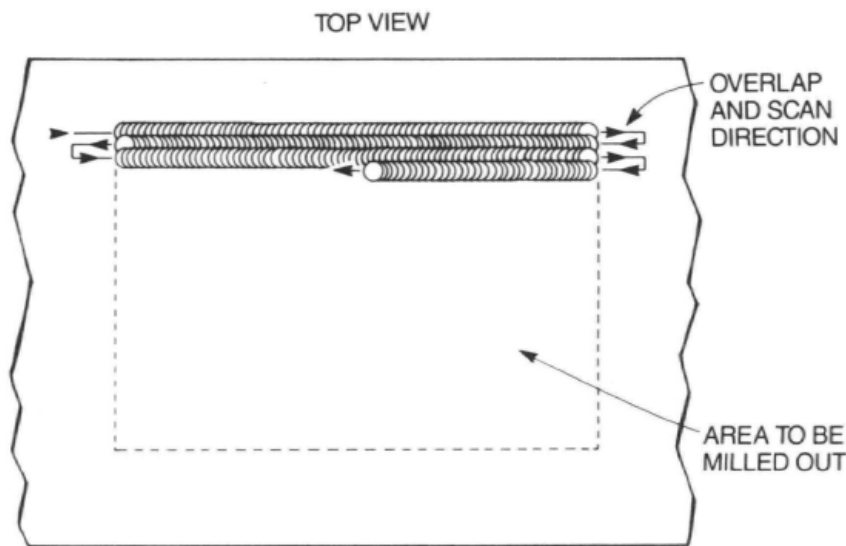


EX1007-Bhullar, FIGS. 1, 4.

153. The “base layer” 14 disclosed in the ’981 patent (shown in Figure 2 below in blue) corresponds to the “electrode-support substrate” 12 disclosed in Bhullar (shown in Figure 4 below in blue). And the “conductive layer” 20 in the ’981 patent corresponds to the “electrical conductor” 13 in Bhullar shown below (in red).

A simple operation is begun by scanning the focused laser beam over the desired area back and forth making parallel cuts to form the size and shape desired. The laser is gated on and off at the beginning and end of each scan but not during the **incremental movement that determines the kerf overlap.** See Figure 4. The proper speed, laser q-switch rate, power and beam diameter, are set to reach the desired depth and smoothness on the bottom.

EX1035-Boogaard, 50, Figure 4, 49 (focused laser diameters), Figures 2a-2b.



EX1035-Boogaard, Figure 4 (serpentine scan method); *see also* EX1035-Boogaard, Figure 7 (double scan method).

156. Boogaard's focused Nd:YAG laser beam is also *moved relative to the conductive layer along the first kerf.* For example, Boogaard teaches:

Even though the Nd:YAG laser has been around for many years, it continues to grow in microelectronic machining applications. For about 15 years it has been used to trim thick film and thin film resistors, on ceramic and glass

substrates and silicon wafers. **In these applications the beam has been moved around** or positioned with either a rectilinear positioning system (**Figure 22**), driven by stepper or linear motors, or a galvanometer positioning mechanism (**Figure 26**). In the latter, the beam is scanned in an arc or scanned through a flat field objective lens where it is corrected so that the beam is perpendicular, or is close to perpendicular, to the part. With the rectilinear positioning system the beam is kept at a perpendicular angle to the work surface at all times. Both methods have their inherent advantages. The galvanometer offers greater speed because of its light weight. While the rectilinear system can achieve greater precision over a larger area. The work that is discussed in this paper has been done with a precision rectilinear positioning system.

EX1035-Boogaard, 48-49. I note that the above text's citation of Figure 22 appears to be a typo because Figure 2a, as shown below, shows a rectilinear positioning system. I also note that the above text's citation of Figure 26 appears to be a typo because Figure 2b, as shown below, shows a galvanometer positioning system.

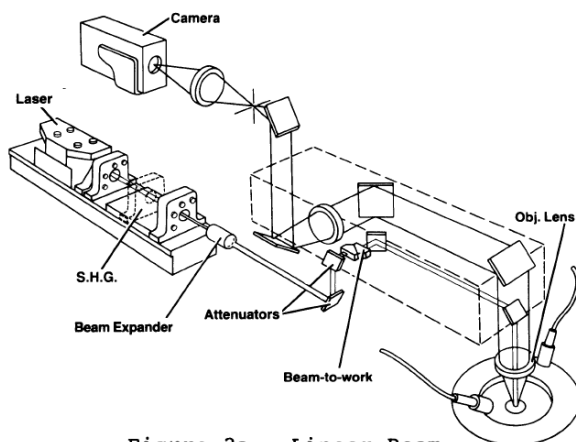


Figure 2a. Linear Beam Positioning System

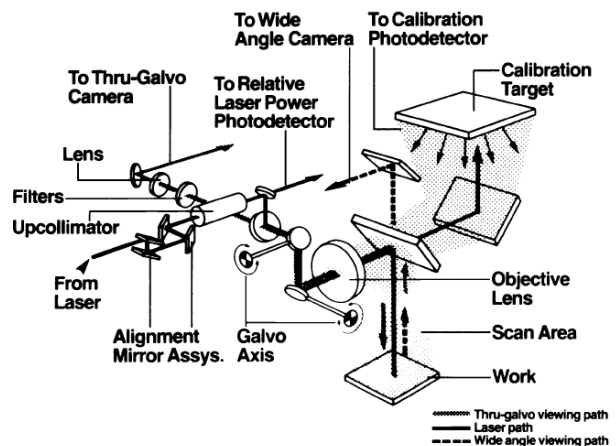


Figure 2b. Galvanometer Beam Positioning System

EX1035-Boogaard, Figures 2a, 2b.

157. This is further confirmed by Boogaard's additional description of the laser milling process, describing, for example, "the speed the laser is moving..." EX1035-Boogaard, 51-52. Boogaard also describes for the double scan method, for example, that the milling operation begins in the center of the and "move[s] toward the outer wall." EX1035-Boogaard, 52.

158. For the reasons that I explained in Section X.A.4 (The Bhullar, Boogaard, Angell Combination), it would have been obvious to incorporate Boogaard's Nd:YAG focused laser beam on a positioning system in Bhullar's manufacturing method.

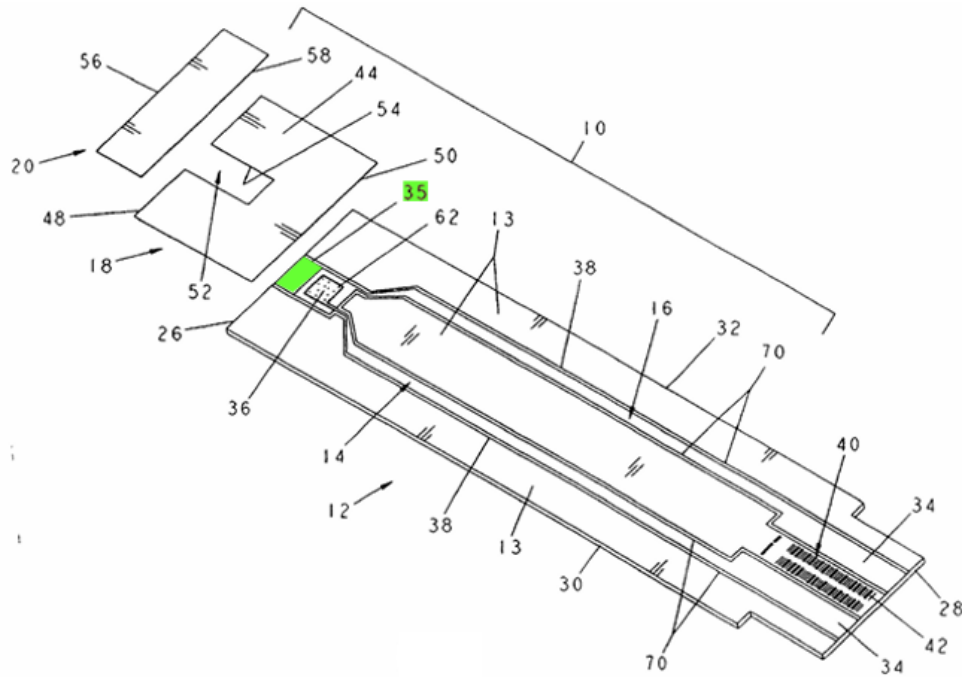
(d) Element 18[c]: forming a second kerf in the conductive layer, wherein the second kerf is formed using a second focused laser beam moved relative to the conductive layer along the second kerf, the first laser beam being different to the second laser beam;

159. The combination of Bhullar, Boogaard, and Angell makes Element 18[c] obvious.

160. Bhullar teaches forming a recess (*second kerf*) in the electrically conductive coating (*conductive layer*), wherein the recess (*second kerf*) is formed using a CO₂ laser as taught by Angell (*a second focused laser beam*) that is moved relative to the conductive layer along the first kerf as taught by Boogaard.

Boogaard's Nd:YAG laser (*first laser beam*) being different to Angell's CO₂ laser (*second laser beam*).

161. Bhullar describes forming a recess (*second kerf*) in the conductive layer. For example, Bhullar explains: “**a recess 35 is formed from the electrical conductor 13 by laser ablation using techniques** as described above. Recess is created by removing the electrical conductor 13 to expose the first surface 22 of the support substrate 12 adjacent to the first end 26.” EX1007-Bhullar, [0021]. *See also* EX1007-Bhullar, [0044]. Bhullar also notes that “[i]n use, a user of biosensor 10 places a finger having a blood collection incision against the recess 35 in the notch 52.” EX1007-Bhullar, [0049]. Therefore, as shown below, the recess 35 (*kerf* shown in green below) is the place where “a user of biosensor 10 places a finger having a blood collection incision.” EX1007-Bhullar, [0049].



EX1007-Bhullar, FIG. 2 (exploded view of the biosensor of FIG. 1).

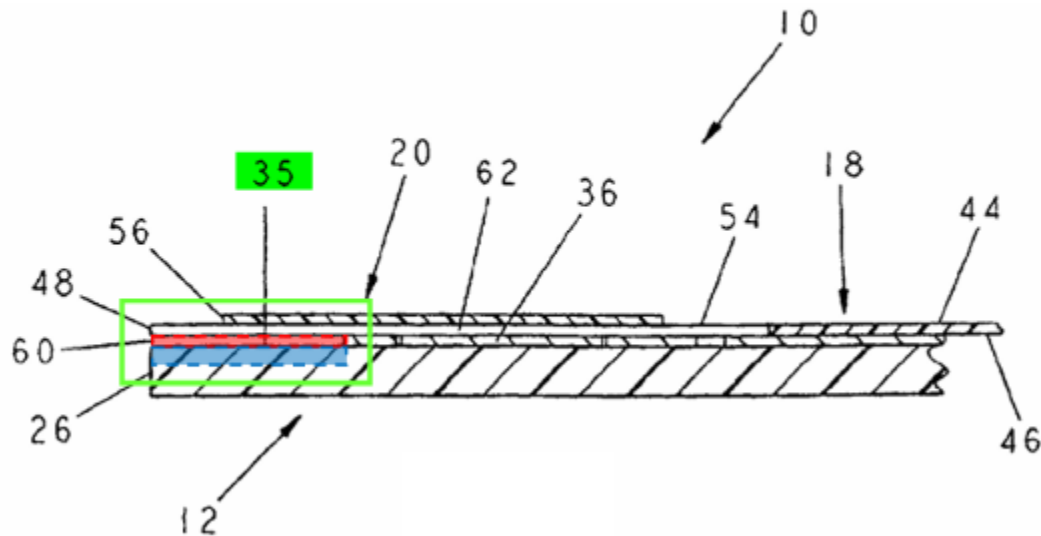
162. Additionally, the combination of Bhullar, Boogaard, and Angell teaches wherein the second kerf is formed using a second focused laser beam moved relative to the conductive layer along the second kerf. The combination of Bhullar, Boogaard, and Angell incorporates Boogaard's teaching that a kerf is formed using a focused laser with a positioning system to move the laser relative to the conducting layer. *See* Section X.A.4 (The Bhullar, Boogaard, Angell Combination). Additionally, Bhullar states that the same laser ablation techniques apply to the second kerf (recess). EX1007-Bhullar, [0021], [0019].

163. The combination of Bhullar, Boogaard, and Angell also teaches *the first laser beam being different to the second laser beam*. Bhullar teaches that one focused laser beam ablates only the conductive layer and another laser beam may be used to ablate a portion of the underlying support substrate to form a second kerf (recess) that is deeper than the first kerf. EX1007-Bhullar, [0021]. Indeed, Bhullar states:

Recess is created by removing the electrical conductor 13 to expose the first surface 22 of the support substrate 12 adjacent to the first end 26. It is appreciated that **a portion of the first surface 22 may also be removed to form the recess 35** in accordance with this disclosure.

EX1007-Bhullar, [0021].

164. As I show below in Figure 3 of Bhullar, the second kerf (Bhullar's recess 35 in light green) is formed from the removal of electrical conductor 13 (in red) and removed support substrate 12 (in blue).



EX1007-Bhullar, FIG. 3.

165. Additionally, Angell directs a person of ordinary skill in the art to select a CO₂ laser when ablating plastic. For example, Angell explains that “[t]he most common industrial laser is the CO₂ laser” which “is capable of machining many different types of materials including **metal, plastic**, wood, and glass.” EX1034-Angell, 68. Angell further provides an advantage to using the CO₂ laser, stating that “it is typically 100 to 1000 times faster [than an excimer laser]” and that “the CO₂ [laser] very effectively vaporizes plastics and there is no recast material to worry about.” EX1034-Angell, 68.

166. A person of ordinary skill in the art would have understood that a CO₂ laser was better suited than an Nd:YAG laser to ablate plastic because a CO₂ laser

operates at a longer wavelength than the Nd:YAG laser. EX1073-Allan, 45. For example, Allan (1979) explains:

Table I lists about one dozen of the most popular lasers, only two of which are used for nearly all materials-processing applications: the Nd:YAG (neodymium: yttrium-aluminum garnet) and the CO₂ (carbon-dioxide) laser. Both account for nearly 90 percent of all industrial laser material-processing uses. Figure 2 illustrates the schematic diagrams for both Nd:YAG and CO₂ lasers.

The Nd:YAG laser, which operates at a wavelength of 1.06 μm , is used principally for precision machining of thin metals and for scribing silicon semiconductor wafers and trimming resistor networks. The CO₂ laser, with a longer wavelength of 10.6 μm , is of higher output power and is used on heavier metals. Both lasers are also used to process many other materials.

...

Metals absorb less laser-beam energy, and are generally more reflective of a laser beam than nonmetals. For some applications, like heat treating, better energy absorption is achieved by chemically treating the surfaces of metals prior to laser processing. And the **energy from the 1.06 μm -wavelength Nd:YAG laser is more readily absorbed by metals than that of the 10.6 μm -wavelength CO₂ laser.** However, the CO₂'s higher output power tends to compensate for this drawback.

...

Because most nonmetals absorb energy from the 10.6 μm -wavelength CO₂ laser, a host of organic and inorganic material applications has opened up—from acrylics, polyethelenes, wood, rubber, and wool to diamonds. Hole drilling in plastics and rubber

materials is one of the fastest-growing applications. Both of these materials respond extremely well to CO₂ laser energy. Examples in plastics include hole drilling in aerosol valves, contact lenses, pipes, tubing, and wire insulations. Rubber examples include hole drilling in baby-bottle nipples and rubber seals. Plastic materials have been welded with CO₂ laser beams.

For both drilling and welding, medium power levels of 50 to 500 W suffice. And throughput rates can be quite high. A 250-W CO₂ laser can perforate a polyethylene plastic tubing with 0.020-inch (0.5-mm) holes spaced 6 to 24 inches (15 to 61 cm) apart, at 300 ft/min (90 m/min).

EX1073-Allan, 42-46.

167. This means that plastic better absorbs the energy emitted from a CO₂ laser as compared to an Nd:YAG laser. EX1073-Allan, 45. Ultimately, this allows for faster energy deposition and a lower dwell time. EX1073-Allan, 45. Indeed, another reference, Tiffany (1985), discusses the same:

Solid state Nd:YAG and Nd:Glass lasers are dominant in metal working applications, **whereas CO₂ maintains an advantage in most non-metal processing areas. This is due in large part to the fact that metals have lower reflectivities and therefore higher absorption of the shorter 1.06-micron wavelength of the solid state laser output beam than of the 10.6-microns.**

EX1070-Tiffany, 28.

168. Thus, in the combination of Bhullar, Boogaard, and Angell, the *second laser beam* is the CO₂ laser, which is different from the *first laser beam*, the Nd:YAG

laser. Therefore, the CO₂ laser beam (second laser beam) is different from the Nd:YAG laser beam (first laser beam).

169. For the reasons that I explained in Section X.A.4 (The Bhullar, Boogaard, Angell Combination), it would have been obvious to incorporate Angell's teaching to use a focused CO₂ laser beam with Boogaard's teaching of a positioning system in Bhullar's manufacturing method.

(e) Element 18[d]: separating one or more test strips from the reel using a singulation process.

170. Bhullar teaches Element 18[d].

171. Bhullar's method to "manufacture biosensor 10" from a "roll of metallized electrode support material" (EX1007-Bhullar, [0043]) includes cutting (*separating*) "the resulting assembled material...to form individual biosensors 10" (*single test strips*). EX1007-Bhullar, [0047]. Additionally, Bhullar's cutting is a *singulation process* because the '981 patent teaches that "the singulation process could include...**cutting**...." EX1001-'981, 12:59-67, claim 18, claim 19.

6. **Dependent Claim 19**

- (a) **The method of claim 18, wherein the singulation process includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.**

172. Claim 19 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

173. Bhullar teaches the additional requirement of Claim 19. Bhullar teaches that “assembled material is **cut** to form individual biosensors.” EX1007-Bhullar, [0046]-[0047]. As I explained in Section X.A.5.(e) (Element 18[d]), *cutting* is a *singulation process*.

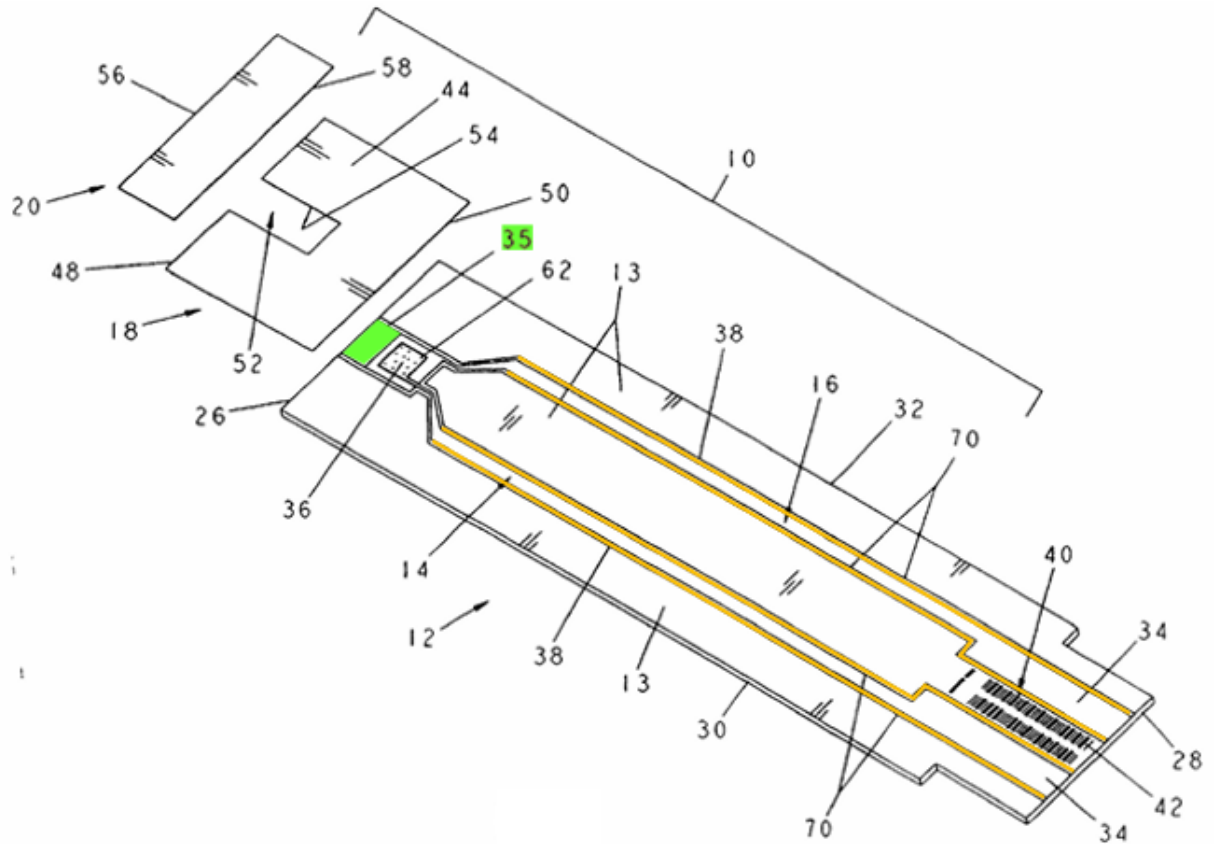
7. **Dependent Claim 20**

- (a) **The method of claim 18, 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.**

174. Claim 20 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

175. The combination of Bhullar, Boogaard, and Angell makes the additional requirements of Claim 20 obvious. The CO₂ laser beam (*second laser beam*) would have created a second kerf (recess 35 shown in green) that is wider

(*not the same*) than the first kerf (shown in yellow) created by the Nd:YAG laser (*first laser beam*).



EX1007-Bhullar, FIG. 2.

176. A person of ordinary skill in the art would have been motivated to select a wider beam for the CO₂ laser, which is used to make the second kerf, for the reasons given above in Section X.A.4 (The Bhullar, Boogaard, Angell Combination). Indeed, since Bhullar teaches that the first kerf preferably has a width of 100-200 microns, the recess 35 would have been much wider than 200 microns. EX1007-

Bhullar, [0019]. As seen in Figure 2 above, recess 35 is shown as wider cut-out area than gap between conducting elements 13, 14, and 16. For this reason, a person of ordinary skill in the art would have been motivated to select a beam width for the CO₂ laser greater than 200 microns while limiting an Nd:YAG laser to a beam width of 200 microns or less in order to select laser beam widths that best match the area to be ablated. Angell and Boogaard illustrate that these selections were achievable. For example, Angell teaches that the CO₂ laser has a beam width of 10 mil (254 microns). EX1034-Angell, 69. Additionally, Boogaard teaches that the Nd:YAG laser has a beam width of 1.5 mil (38.1 microns). EX1035-Boogaard, 54.

8. Dependent Claim 21

(a) The method of claim 20, wherein the first beam width is at least approximately 20 micro-meters.

177. Claim 21 depends from claim 20. Therefore, I incorporate by reference my discussion of claim 20.

178. Boogaard teaches the additional requirements of Claim 21.

179. The Nd:YAG laser is the *first laser beam*. See Section X.A.5.(c) (Element 18[b]). Boogaard teaches Nd:YAG beam widths “at least approximately 20 micro-meters.” Boogaard teaches that the Nd:YAG laser has a beam width of 1.5 mil (38.1 microns). EX1035-Boogaard, 54.

180. As I explained above in Section X.A.7 (Claim 20), Bhullar's preferred kerf width is between 100 microns and 200 microns. Therefore, a person of ordinary skill in the art would have selected a first laser beam with a beam width greater than 20 microns to better match the size of the kerf being formed. EX1007-Bhullar, [0019].

9. Dependent Claim 22

(a) The method of claim 20, wherein the second beam width is at least approximately 100 micro-meters.

181. Claim 22 depends from claim 20. Therefore, I incorporate by reference my discussion of claim 20.

182. Angell teaches the additional requirements of Claim 22.

183. The CO₂ laser is the *second laser beam*. See Section X.A.5.(d) (Element 18[c]). Angell discloses a CO₂ laser beam with a width 10 mil (254 microns), which is greater than a beam width of at least 100 micro-meters. EX1034-Angell, 69. As I explained above in Section X.A.7 (Claim 20), Bhullar's recess is larger than 200 microns. Therefore, a person of ordinary skill in the art would have selected a first laser beam with a beam width greater than 100 microns to better match the size of the kerf being formed and reduce processing time.

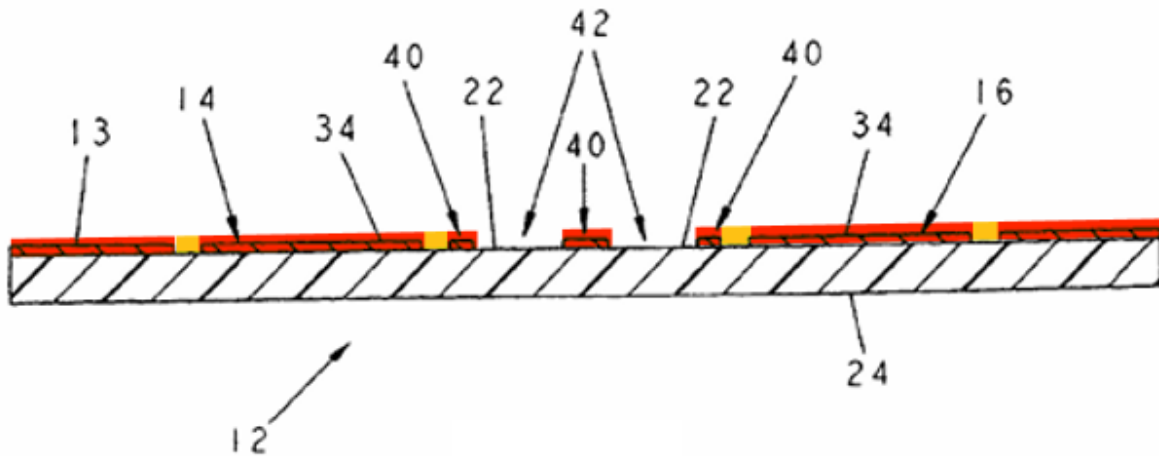
10. Dependent Claim 23

- (a) The method of claim 18, wherein at least one laser beam removes substantially all conductive material between adjacent conductive components.**

184. Claim 23 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

185. Bhullar teaches the additional requirements of Claim 23. Bhullar teaches the use of at least one laser to form adjacent conductive components (two electrodes) by “removing the electrical conductor 13 from an area extending around the electrodes to form a gap of exposed support substrate 12.” EX1007-Bhullar, [0019], FIGs. 2, 4. Bhullar therefore discloses *wherein at least one laser beam removes substantially all conductive material between adjacent conductive components*. The fact that “*substantially all*” of the electrical conductor is removed is confirmed by Bhullar’s use of “the” (and not a portion of) electrical conductor is removed to form a “gap.” EX1007-Bhullar, [0019]. In addition, Bhullar states that the two electrodes (electrodes 14, 16) are “isolated from the rest of the electrically-conductive material on substrate 12 by a gap.... EX1007-Bhullar, [0019]. As shown below, Figure 4, which corresponds to Bhullar’s disclosure in paragraph [0019], confirms that *substantially all* of the electrical conductor is removed between

adjacent conductive components (shown in red) including in the gaps (shown in yellow) between the adjacent conductive components, as required by claim 23.



EX1007-Bhullar, [0019], FIG. 4.

11. Dependent Claim 24

- (a) **The method of claim 18, 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.**

186. Claim 24 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

187. The combination of Bhullar, Boogaard, and Angell teaches the additional requirements of Claim 24. The Nd:YAG laser (*first laser*) emits a first laser beam and is a different type of laser than the CO₂ laser (*second laser*), which

emits a second laser beam, as claimed. *See* Section X.A.4 (The Bhullar, Boogaard, Angell Combination); Section X.A.5.(c) (Element 18[b]), Section X.A.5.(d) (Element 18[c]).

12. Dependent Claim 25

- (a) The method of claim 24, 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.**

188. Claim 25 depends from claim 24. Therefore, I incorporate by reference my discussion of claim 24.

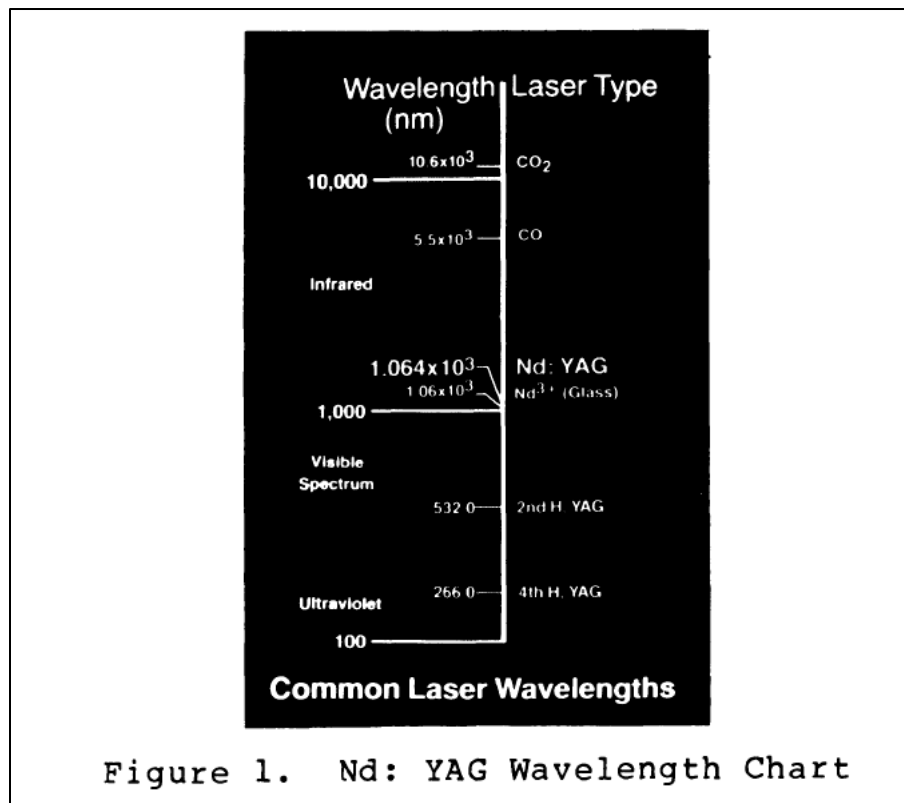
189. The combination of Bhullar, Boogaard, and Angell teaches the additional requirements of Claim 25. The Nd:YAG laser (*first laser*) is a solid-state laser. EX1070-Tiffany, 28 (describing the Nd:YAG as a solid-state laser product). The CO₂ laser (*second laser*) is a CO₂ (carbon dioxide) laser. *See* Section X.A.4 (The Bhullar, Boogaard, Angell Combination); Section X.A.5.(d) (Element 18[c]).

13. Dependent Claim 26

- (a) The method of claim 24, 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.**

190. Claim 26 depends from claim 24. Therefore, I incorporate by reference my discussion of claim 24.

191. The combination of Bhullar, Boogaard, and Angell teaches the additional requirements of Claim 24. The Nd:YAG laser is the *first laser*. See Section X.A.4 (The Bhullar, Boogaard, Angell Combination); Section X.A.5.(c) (Element 18[b]). An Nd:YAG laser operates in the *infrared region* (1000-10,000 nm). EX1035-Boogaard, 48.



EX1035-Boogaard, 48

14. Dependent Claim 27

- (a) The method of claim 18, 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.**

192. Claim 27 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

193. The combination of Bhullar, Boogaard, and Angell teaches the additional requirements of Claim 27, or at least make it obvious. The Nd:YAG laser is the *first laser* and the CO₂ laser is the *second laser*. See Section X.A.4 (The Bhullar, Boogaard, Angell Combination). A Nd:YAG laser is intended to be operated at a lower power level than a CO₂ laser, indicating that the power levels of the two lasers are not the same. Indeed, Boogaard teaches that the Nd:YAG is a medium-powered laser and provides an example of the laser operating at 800mWatts (0.8 Watts). EX1035-Boogaard, 48. Angell, on the other hand, states that the CO₂ beam has a “maximum average power output of...50 to 250 Watts.” EX1034-Angell, 66.

15. Dependent Claim 28

- (a) The method of claim 27, wherein the first or second laser power is in the range of about 10 to about 100 watts.**

194. Claim 28 depends from claim 27. Therefore, I incorporate by reference my discussion of claim 27.

195. The combination of Bhullar, Boogaard, and Angell makes the additional requirements of Claim 28 obvious. Angell teaches that a CO₂ carbon dioxide laser is a *second laser beam*, which operates at a “maximum average power output of...50 to 250 Watts.” EX1034-Angell, 66. I have been instructed that, under the law, an overlapping range in the prior art can make a claimed range obvious where there is nothing critical about the claimed range. In its discussion of Nd:YAG and carbon dioxide lasers (among others), the '981 patent states that “[t]he power output of these lasers may vary and is usually in range about 10-100 watts.” EX1001-'981, 9:32-43. It is my opinion that the '981 patent does not teach anything critical about using a laser in the range of 10 to 100 watts. Because Angell teaches a range of 50 to 250 Watts, it makes this limitation—claiming a range of about 10 to about 100 Watts—obvious. Angell therefore teaches that the *second laser power is in the range of about 10 to about 100 watts*.

16. Dependent Claim 29

- (a) The method of claim 18, further including the step of contacting at least part of the conductive layer with at least one chemical component.**

196. Claim 29 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

197. Bhullar teaches the additional requirements of Claim 29. Bhullar teaches contacting at least part of the electrode array 36 (*conductive layer*) with at least one electrochemical reagent 62 (*chemical component*). EX1007-Bhullar, [0032]. For example, Bhullar's electrochemical reagent "provides **electrochemical probes for specific analytes**" (EX1007-Bhullar, [0032]) such as **glucose** (EX1007-Bhullar, [0033], Table 1). Moreover, the electrode array 36 is part of electrical conductor 13 (the conductive layer). EX1007-Bhullar, [0016], [0020]. Thus, Bhullar's teaching corresponds exactly to the '981 patent's chemical component, which is described as "enabl[ing] the level of **glucose** or other analyte in the fluid, such as a blood sample, to be determined **electro-chemically**." EX1001-'981, 7:16-18, 7:18-35.

17. **Dependent Claim 30**

- (a) **The method of claim 29, 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.**

198. Claim 30 depends from claim 29. Therefore, I incorporate by reference my discussion of claim 29.

199. Bhullar teaches the additional requirements of Claim 30. Bhullar teaches that its electrochemical reagent 62 (*chemical component*) includes potassium ferricyanide. EX1007-Bhullar, [0033]. Bhullar states:

The choice of the specific reagent 62 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. Pat. No. 5,997,817, the disclosure of which is expressly incorporated herein by reference.

EX1007-Bhullar, [0033]. Moreover, the electrode array 36 is part of electrical conductor 13 (the conductive layer).

18. Dependent Claim 32

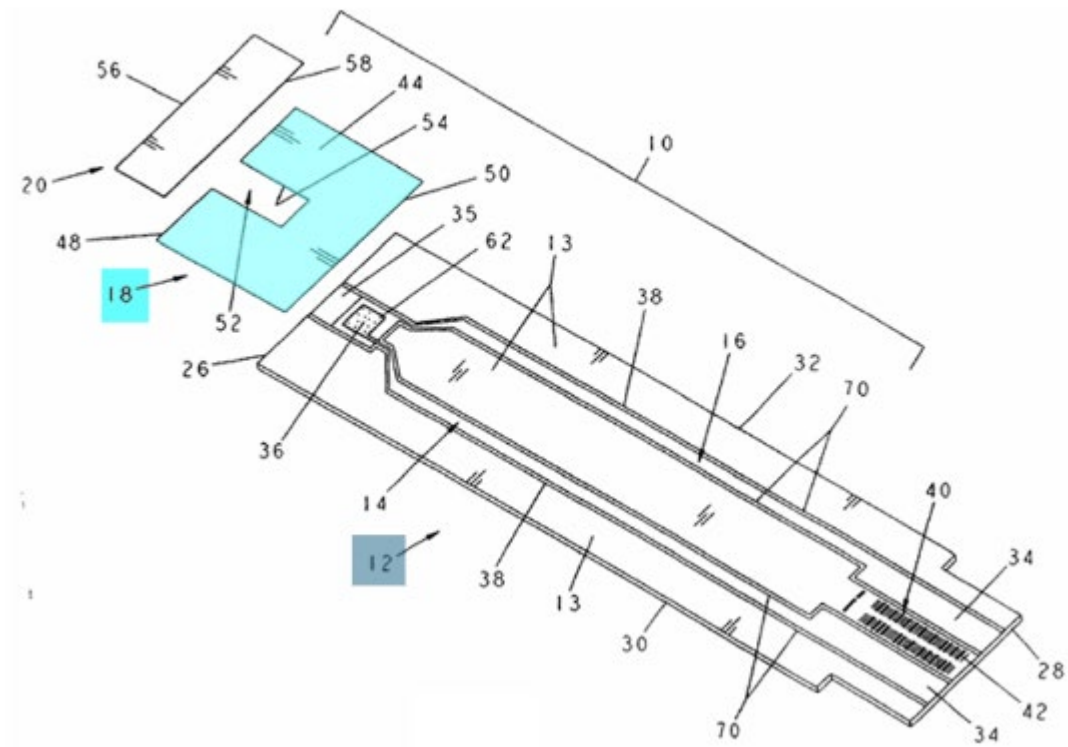
(a) The method of claim 18, further including application of a spacer layer to the conductive layer or the base layer.

200. Claim 32 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

201. Bhullar teaches the additional requirements of Claim 32. Bhullar teaches that its biosensor has a spacer substrate 18 (*spacer layer* shown in light blue) positioned on electrode-support substrate 12 (*base layer* reference numeral shown in dark blue). EX1007-Bhullar, [0016]; *see also* EX1007-Bhullar, [0027], [0028], [0046], [0047].

spacer substrate 18 (*spacer layer*) is applied, but it would have been obvious to try this. As shown in Figure 2 below, Bhullar's spacer layer (in blue) has a notch so that it does not cover recess 35. Therefore, there is no barrier to accessing the portion of the substrate from which recess 35 (*second kerf*) is formed using the second laser beam, nor will application of the second laser beam interfere with the spacer layer. Because the spacer layer's notch defines the area where recess 35 should be formed, forming recess 35 *after* applying the spacer layer with notch would help ensure that the recess 35 is aligned with the notch. Therefore, a person of ordinary skill in the art would have found it obvious to try forming recess 35 (*second kerf*) after application of the spacer substrate 18 (*spacer layer*). In particular, a person of ordinary skill in the art would have chosen from only two predictable options: (1) forming the recess *before* the application of the spacer layer or (2) forming the recess *after* the application of the spacer layer. Either would yield the predictable solution of forming the recess because the spacer layer would not obstruct the ability to the laser to form the recess. Thus, a person of ordinary skill in the art would have enjoyed a reasonable expectation of success for the same reasons given in Section X.A.4 (The Bhullar, Boogaard, Angell Combination).

Bhullar, FIG. 2



EX1007-Bhullar, FIG. 2.

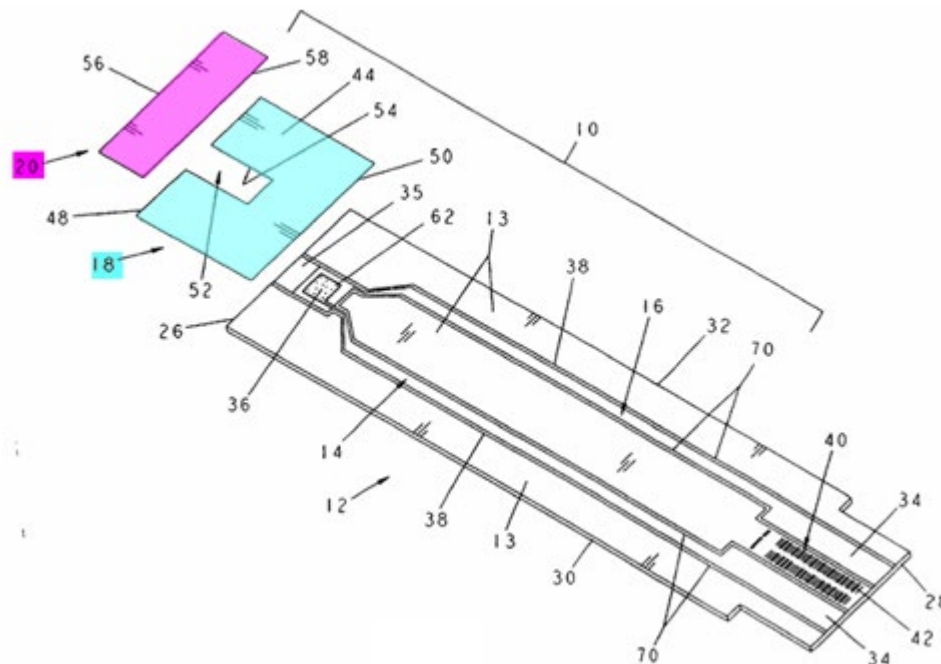
20. Dependent Claim 34

- (a) The method of claim 32, further including application of a cover to the spacer layer.**

204. Claim 34 depends from claim 32. Therefore, I incorporate by reference my discussion of claim 32.

205. Bhullar teaches the additional requirements of Claim 34. As shown below in Figure 2, Bhullar teaches that its biosensor 10 has a cover substrate 20 (*a*

cover shown in pink) positioned on top of the spacer substrate 18 (*spacer layer* shown in blue). EX1007-Bhullar, [0016]. Indeed, Bhullar states that “the cover substrate 20 is coupled to the upper surface 44 of the spacer substrate 18”). EX1007-Bhullar, [0029]; *see also* EX1007-Bhullar, [0030], [0031], [0046].



EX1007-Bhullar, FIG. 2.

21. Dependent Claim 35

- (a) The method of claim 18, wherein the conductive layer is formed using a technique selected from the group consisting of direct writing, sputtering, screen printing, contract printing, and lamination.

206. Claim 35 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

207. Bhullar teaches the additional requirements of Claim 35. For example, App. No. 09/411,940, which is incorporated by reference in Bhullar,³ discloses screen printing for forming large conductive layers. EX1063-Bhullar'940, 1:23-31; *see also* EX1067-Vitriol, 215-220.

22. Dependent Claim 36

- (a) The method of claim 18, further including the step of applying to the conductive layer at least one of a second conductive layer and a semi-conductive layer.**

208. Claim 36 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

209. Bhullar teaches the additional requirements of Claim 36. Bhullar teaches applying to the electrical conductor 13 (*conductive layer*) a conductive material (*second conductive layer*) in order to create a discernible code pattern that has contrasting structures to ensure readability of the code. EX1007-Bhullar, [0023]. For example, Bhullar explains the process of implementing a code pattern and its advantages in manufacturing:

[0022] In addition, as shown in FIGS. 1, 2, and 4, the discernible code pattern 40 is formed from the electrical conductor 13 by laser ablation using techniques as described above with reference

³ EX1007-Bhullar, [0019] (incorporating App. No. 09/411,940 by reference).

to electrodes 14, 16. Specifically, the code pattern 40 is created by removing the electrical conductor 13 in a pre-defined pattern to expose the first surface 22 of the support substrate 12. While pattern 40 is illustratively a barcode type pattern, it is appreciated that the pattern 40 can take on any number of shapes and patterns, non-limiting examples of which are shown in FIGS. 5 and 6.

[0023] It is also appreciated that the pattern 40 can be provided in a human readable, optical readable, or electrical readable form in accordance with this disclosure. The structures could show contrast in their optical reflectivity, their electrical conductivity, or their resistivity respectively. To aid in contrasting the electrical conductivity of the code pattern 40, the electrical conductor 13 of the pattern 40 may be coated with a second conductive material (not shown) that is different from the electrical conductor 13. Non-limiting examples of the second conductive material include carbon and silver. It is appreciated, however, that a wide variety of materials may be coated on the electrical conductor 13 to change the electrical property of the code pattern 40.

[0024] It is also appreciated; electrodes 14, 16 could be formed from layers of electrically conductive materials having different colors, reflectivity, conductance, etc. Thus, the code pattern can be formed by removing a portion of the electrical conductor layers, leaving behind areas of high reflectivity surrounded by low reflectivity areas or vice versa, areas of high electrical conductivity surrounded by areas of low conductivity or vice versa. It is also possible to laser etch a code pattern that has a known resistance and this area can be read electrochemically to identify or recognize the code pattern. Moreover, it is appreciated that the code pattern can be a combination of any of the above readable forms in accordance with the present invention.

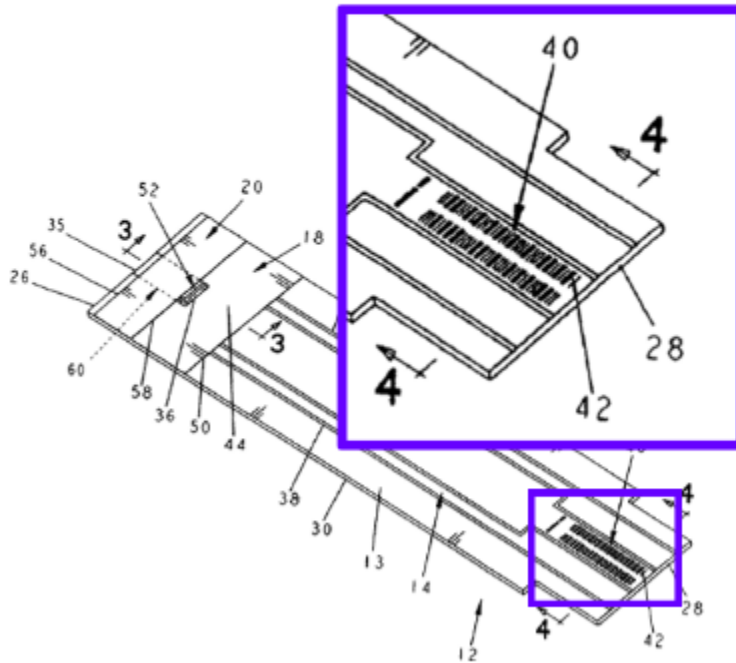
[0025] As shown in FIG. 4, the code pattern 40 is isolated from the rest of the electrically conductive material 13 on substrate 12 by gaps 42. Gaps 42 can have a wide variety of widths in accordance with this disclosure depending upon the specific use of the code pattern 40. Non-limiting examples of widths of the gaps include from about 1 μm to about 1000 μm . Alternatively, it is appreciated that the code pattern 40 may be created by laser ablation alone on substrate 12. It is appreciated that while laser ablation is the preferred method for forming the code pattern 40 given its precision and sensitivity, other techniques such as lamination, screen-printing, or photolithography may be used in accordance with this disclosure.

[0026] **The manufacturer of biosensor 10 may maintain a central database containing a set of code patterns, each of which uniquely identifies an individual biosensor, or batch of biosensors.** There may also be associated with each code pattern a set of calibration data for the biosensor 10. It is appreciated that the code patterns may be associated with any number of identification or data sets in accordance with the present invention.

EX1007-Bhullar, [0022]-[0026].

210. An example of Bhullar's code pattern is seen in Figure 1 below:

Bhullar, FIG. 1



EX1007-Bhullar, FIG. 1.

211. As I show above, Bhullar states that “[t]o aid in contrasting the electrical conductivity of the code pattern 40, the electrical conductor 13 of the pattern 40 may be coated **with a second conductive material** (not shown) **that is different from the electrical conductor 13.**” EX1007-Bhullar, [0023]; *see also* EX1007-Bhullar, [0015].

212. A person of ordinary skill in the art would have incorporated this teaching of Bhullar specifically for purposes of implementing Bhullar’s code pattern

because it was “known to include a code on a test strip that identifies the manufacturing batch of the strip.” EX1007-Bhullar, [0002]. And Bhullar explains that its “code pattern is beneficially formed from the same electrically conductive material and in the same manner as the electrodes of the biosensor, which reduces steps in the manufacturing process.” EX1007-Bhullar, [0015]. Therefore, a person of ordinary skill in the art would have been motivated to include a code pattern to identify manufacturing batches, which would have been a predictable feature, and also would have looked to Bhullar’s teachings of implementing a code pattern in the same manner as the electrodes, which would have been a desired feature in order to reduce steps in the manufacturing process.

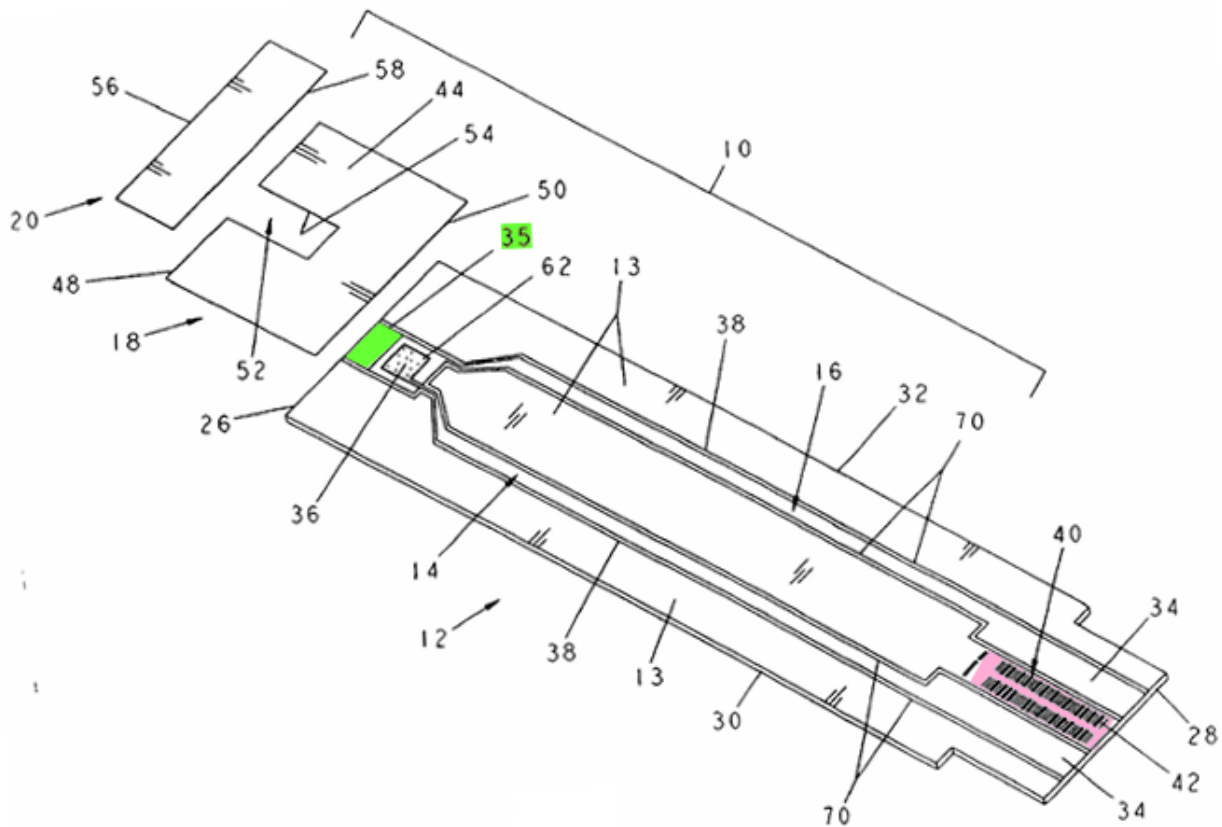
23. Dependent Claim 37

- (a) The method of claim 36, wherein the second kerf is formed after application of at least one of the second conductive layer and the semi-conductive layer.**

213. Claim 37 depends from claim 36. Therefore, I incorporate by reference my discussion of claim 36.

214. Bhullar makes the additional requirements of Claim 37 obvious. Bhullar does not expressly disclose forming the recess 35 (*second kerf*) after application of the *second conductive layer*, but it would have been obvious to try this. As shown in Figure 2, Bhullar’s *second conductive material* (in pink) is placed

at the opposite end of the test strip from the recess (*second kerf*). Therefore, using the second laser beam to form the recess (*second kerf*) has no effect on the second conductive material; nor does application of the second conductive material affect the recess or the area of the substrate from which it is formed.



EX1007-Bhullar, FIG. 2.

215. Therefore, a person of ordinary skill in the art would have found it obvious to try forming recess 35 (*second kerf*) after application of the *second conductive layer*. In particular, a person of ordinary skill in the art would have

chosen from only two predictable options: (1) forming the recess *before* the application of the second conductive layer or (2) forming the recess *after* the application of the second conductive layer. Either would yield the predictable solution of forming the recess because second conductive layer would not obstruct the ability to the laser to form the recess. Thus, a person of ordinary skill in the art would have enjoyed a reasonable expectation of success for the same reasons given in Section X.A.4 (The Bhullar, Boogaard, Angell Combination).

B. GROUND II: Claims 1-13, 15-16, 18-30, and 32 Are Obvious In View of the Combination of Edelbrock, Boogaard, and Angell.

1. Overview of Edelbrock

216. Edelbrock published on June 25, 2009, and claims the benefit to a provisional filed December 27, 2005. See Section V (Overview of the Grounds for Finding the Challenged Claims Invalid). Edelbrock teaches “a method of forming a multilayer test sensor that is adapted to assist in determining a concentration of an analyte.” EX1032-Edelbrock, [0001]. Like the ’981 patent, Edelbrock’s test sensor is used to test for analytes (*e.g.*, “glucose”) in a fluid sample (*e.g.*, “whole blood sample”). EX1032-Edelbrock, [0029]. For example, Edelbrock teaches:

[0028] The present invention is directed to an improved method of forming a multilayer test sensor by eliminating or reducing problems between the conductive leads or traces and the contacts of the instrument caused by

misregistering the base and the lid in the attachment (e.g., lamination) act. By eliminating or reducing such problems, erroneous readings of an analyte concentration are reduced, as well as no readings of an analyte concentration are reduced.

[0029] In one embodiment, a test sensor is adapted to receive a fluid sample and is analyzed using an instrument or meter. The test sensor assists in determining the concentrations of analytes. Analytes that may be measured include glucose, lipid profiles (e.g., cholesterol, triglycerides, LDL and HDL), microalbumin, hemoglobin A1C, fructose, lactate, or bilirubin. It is contemplated that other analyte concentrations may be determined. The analytes may be in, for example, a whole blood sample, a blood serum sample, a blood plasma sample, other body fluids like ISF (interstitial fluid) and urine, and non-body fluids.

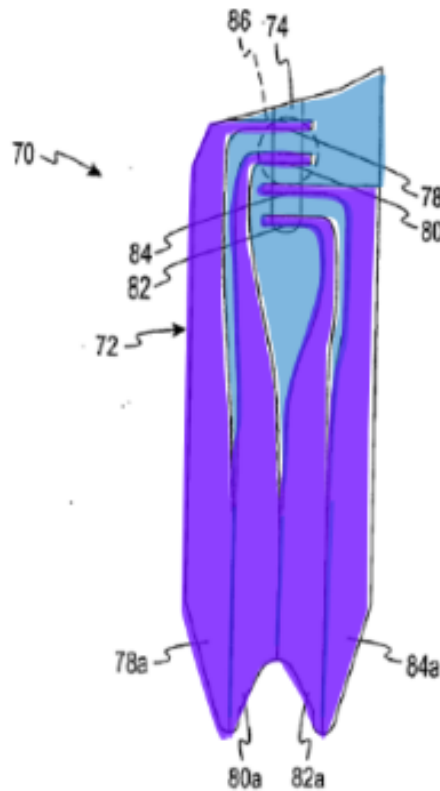
[0030] The multilayer test sensors to be made using the inventive process include at least a base and a second layer such as a lid. The multilayer test sensors are electrochemical test sensors. The base and lid may be made from a variety of materials such as polymeric materials. Non-limiting examples of polymeric materials that may be used to form the base and lid include polycarbonate, polyethylene terephthalate (PET), polystyrene, polyimide, and combinations thereof. As will be discussed below, the multilayer test sensors may include additional layers such as a spacer. For example, a base, spacer and lid may form the multilayer test sensor in another embodiment.

EX1032-Edelbrock, [0028]-[0030].

217. Edelbrock's test sensor is formed from a "base-ribbon strip" using a "web process." EX1032-Edelbrock, [0036]. A "web process" refers to "reel-to-reel

processing” in which electronic devices are created on a roll of flexible plastic, metal foil, and the like. Edelbrock’s base-ribbon strip includes a base layer and a conductive layer. EX1032-Edelbrock, [0030], [0035], [0039], [0045]-[0048], FIGS. 4a-4e.; EX1001-’981, 6:18-21. Edelbrock’s base-ribbon strip is shown in Figure 2b, which includes (1) electrodes (shown in purple), which are formed of a conductive material such as gold, and (2) gaps between the electrodes (shown in blue):

Edelbrock, FIG. 2b



EX1032-Edelbrock, FIG. 2b, [0031]-[0035].

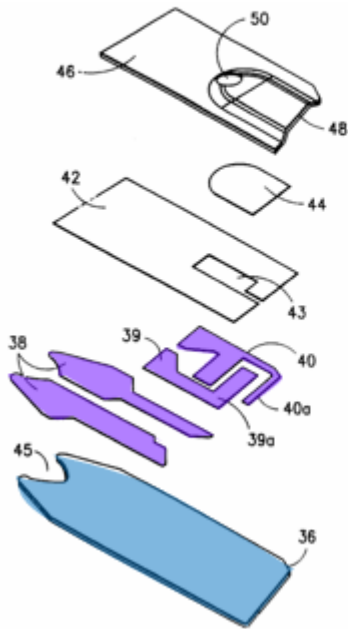
218. Edelbrock teaches that the electrodes can be defined by “direct writing” with a laser, “printing (e.g., screen-printing), coating (e.g., reverse roll), vapor deposition, sputtering and electrochemical deposition.” EX1032-Edelbrock, [0041]-[0042].

219. Edelbrock also states that components of its test sensors are disclosed in U.S. Patent No. 6,531,040 (“Musho”)(EX1049):

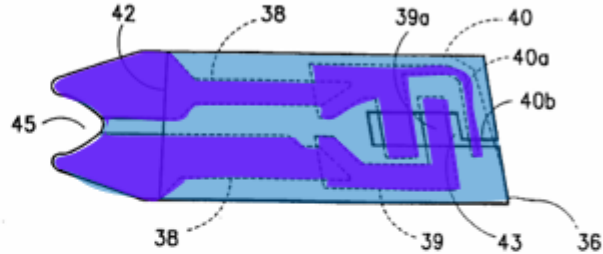
The electrodes are formed of conductive materials such as, for example, metallic materials (e.g., gold, platinum, palladium, rhodium, ruthenium, or combinations thereof) or carbon. **Examples of components of electrochemical test sensors, including their operation, may be found at, for example, U.S. Pat. No. 6,531,040.** It is contemplated that other components of electrochemical test sensors may be used other than that disclosed in, for example, U.S. Pat. No. 6,531,040.

EX1032-Edelbrock, [0035]. Musho (2003) shows an electrochemical test sensor that is similar to Edelbrock’s where the gaps between conducting components (“electrical conductor pattern 38, an[d] electrode pattern[s] (39 and 40)” shown in purple below in Figures 1 and 2) are an “insulating base” 36 (shown in blue below in Figures 1 and 2) which can be made of various polymers or polymer blends. EX1049-Musho, 4:34-39, 3:1-5.

Musho, FIG. 1

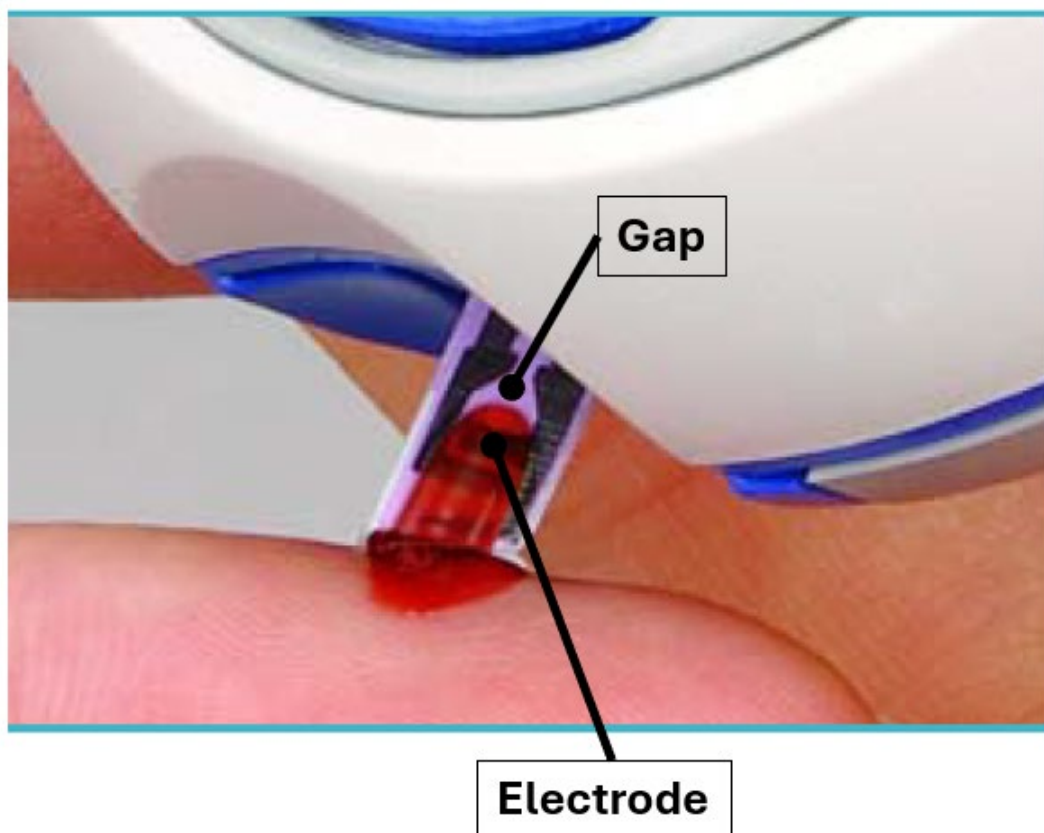


Musho, FIG. 2



EX1049-Musho, FIGS.1-2, 3:1-4:34.

220. At the time Edelbrock was published, it was assigned to Bayer Corp., a known manufacturer of medical devices, including glucose monitors. *See* EX1032-Edelbrock, Cover. At the time Musho issued, it was also assigned to Bayer Corp. EX1049-Musho, Cover. As I show below, the Ascensia Breeze was a blood glucose sensor made by Bayer Corp. and seems to be a commercial embodiment of the electrochemical sensor shown in Edelbrock and Musho. As shown below, from the June 15, 2004, User Manual (EX1058-Munford-Decl.), the Ascensia Breeze device also shows insulating gaps between electrodes:



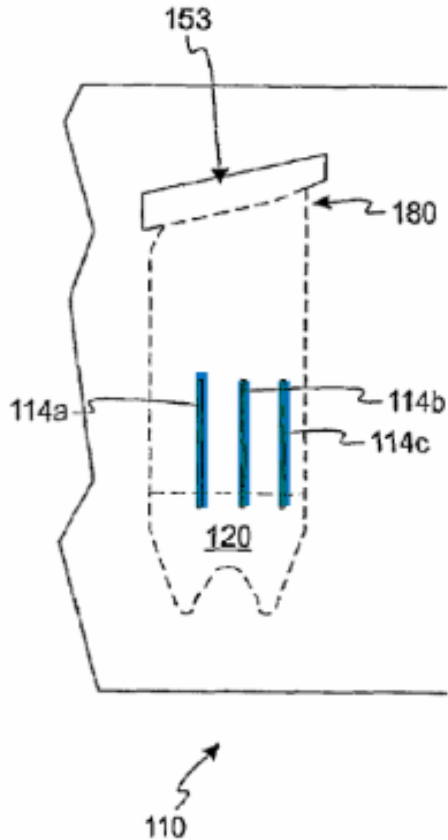
EX1075-Ascensia, 8.

221. A person of ordinary skill in the art would have understood that Edelbrock, and particularly Figure 2b in Edelbrock, to teach electrodes formed of a conductive material such as gold with insulating gaps between the electrodes.

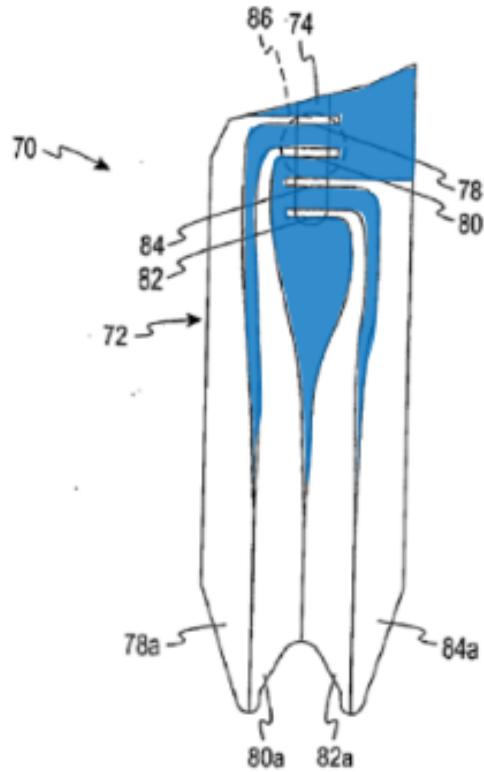
222. Edelbrock's method uses laser beams to make "a plurality of laser cuts" in the conductive layer to define electrically isolated conductive components, including electrodes. EX1032-Edelbrock, [0039]-[0041], [0046], FIGs. 2b, 3, 4d (reproduced below). Edelbrock's method requires two distinct sets of cuts. A **first**

series of cuts (shown in blue in the left image below as elements 114a-c) defines boundaries between conductive areas 120. EX1032-Edelbrock, [0039]-[0041]. Edelbrock states that cuts 114a-c show just the initial laser cuts and that additional cuts are made in to complete the gaps between conductive areas, resulting in the pattern of unablated areas (shown in blue) shown in Edelbrock's Figure 3 (reproduced below). EX1032-Edelbrock, [0039]-[0041] Specifically, Edelbrock states that "a plurality of laser cuts 114 a-c begins the process of defining the plurality of conductive leads in the conductive area 120. In this process, the plurality of electrodes has been partially defined but as discussed above, are not shown in FIG. 3." EX1032-Edelbrock, [0039].

Edelbrock, FIG. 3
Exemplary laser cuts 114a-c
into conductive layer



Edelbrock, FIG. 2b
Complete set of cuts defining gaps
between conductive areas



[L]aser cuts 170 a-c [including laser cuts 174a-c] and the laser cuts 114 a-c **are performed at distinct times and are considered to be separate acts.** The laser used in forming the laser cuts 170 a-c, however, may be the same laser used in the separate act of forming the laser cuts 114 a-c. **It is contemplated that the laser used in forming the laser cuts 170 a-c and 114 a-c may be different.**

EX1032-Edelbrock, [0046].

225. After the steps described above are completed, the test sensors are separated from the sensor ribbon strip using a “mechanical punch that excises the test sensors from the sensor-ribbon strip.” EX1032-Edelbrock, [0052].

2. Overview of Boogaard and Angell

226. Boogaard is summarized in Section X.A.2 (Overview of Boogaard). Angell is summarized in Section X.A.3 (Overview of Angell).

3. The Edelbrock, Boogaard, Angell Combination

227. As I explained in Section III.B, I have been informed by Petitioner’s counsel and understand that for a claim to be obvious, a person of ordinary skill in the art must have had a reason or motivation to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and must have had a reasonable expectation of success in doing so. For the reasons I explain below, it is my conclusion that a person of ordinary skill in the art would have been motivated to use Edelbrock’s method to manufacture test sensors and incorporate Boogaard’s

teaching to use an Nd:YAG laser to form fine boundaries (kerfs) between conductive components with Boogaard's teaching to use a positioning system to implement Edelbrock's movement relative to the test sensor, and Angell's teaching to use a CO₂ laser to ablate larger surface areas of conductive material, and would have had a reasonable expectation of success in doing so.

228. As I explain in **subsection (a)** below, Edelbrock discloses use of yttrium aluminum garnet (YAG) lasers for "direct writing" of ablation lines by moving a laser relative to a substrate. EX1032-Edelbrock, [0041]. Additionally, Boogaard provides implementation details for YAG lasers including use of an Nd:YAG laser, particular beam widths, and a positioning system, as described below. Given these features, and for the reasons explained below, a person of ordinary skill in the art would have found it obvious to select Boogaard's Nd:YAG laser to form laser cuts for the narrow boundaries (elements 174a-c) in Edelbrock's test sensor.

229. As I explain in **subsection (b)** below, a person of ordinary skill in the art also would have been motivated to combine, with a reasonable expectation of success, Angell's teaching of a CO₂ laser suitable for ablating wide areas of a conductive layer with Edelbrock's method to manufacture test sensors because, among other reasons, Edelbrock teaches the use of CO₂ lasers for "direct writing" of ablation lines. EX1032-Edelbrock, [0041]. Angell provides the implementation

details for CO₂ lasers, including the use of a CO₂ laser and beam widths suitable for large surface areas that require ablation on Edelbrock's conductive substrate. Given these features, and for the reasons explained below, a person of ordinary skill in the art would have found it obvious to select Edelbrock's CO₂ laser to form the laser cuts for larger ablation areas (including elements 114a-c) in Edelbrock's test sensor.

230. As I conclude in **subsection (c)** below, based on my explanation provided herein, it is my conclusion that a person of ordinary skill in the art would have been motivated to combine Edelbrock, Boogaard, and Angell and would have had a reasonable expectation of success in doing so.

(a) Edelbrock, Boogaard: Edelbrock and Boogaard's Teachings of a Focused Nd:YAG Laser and Positioning System

231. Edelbrock discloses the use of a YAG laser for direct writing (ablation of a conductive layer), but it lacks specific implementation details such as beam width, the particular type of YAG laser, the positioning system to use, and which specific laser cuts are best suited for the YAG laser. EX1032-Edelbrock ("Non-limiting examples of such lasers are carbon dioxide-based lasers and **yttrium-based lasers such as yttrium aluminum garnet (YAG) lasers.**"). Consequently, a person of ordinary skill in the art would have referred to existing literature for these details and would have readily recognized that Boogaard provides such information.

232. Indeed, Boogaard, like Edelbrock, is directed to applications of micromachining including “removal of thin films from various substrates” “in the microelectronics area...to produce a desired electrical characteristic or geometric shape....” EX1035-Boogaard, 48. Boogaard teaches that a focused Nd:YAG laser is suitable for milling micron scale features on a substrate by scanning techniques. EX1035-Boogaard, 50. Boogaard teaches the use of a Nd:YAG focused laser beam, noting that “[a] simple operation is begun by scanning the focused laser beam over the desired area back and forth making parallel cuts to form the size and shape desired.” EX1035-Boogaard, 50.

233. As previously explained, Boogaard provides several scanning techniques for laser etching (milling) using a focused Nd:YAG laser with a positioning system, including a serpentine scan on area to be milled (shown in Figure 4 below) and a double scan method on area to be milled (shown in Figure 7 below).

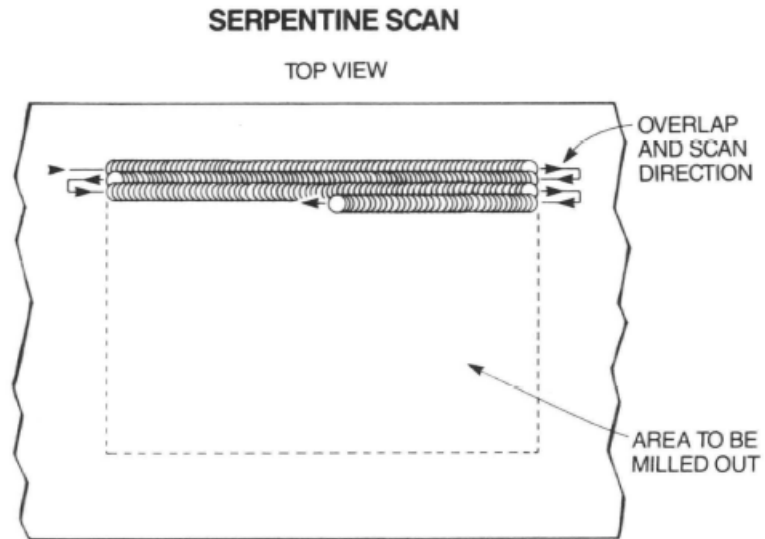


Figure 4. Serpentine scan
used in laser milling

EX1035-Boogaard, Figure 4.

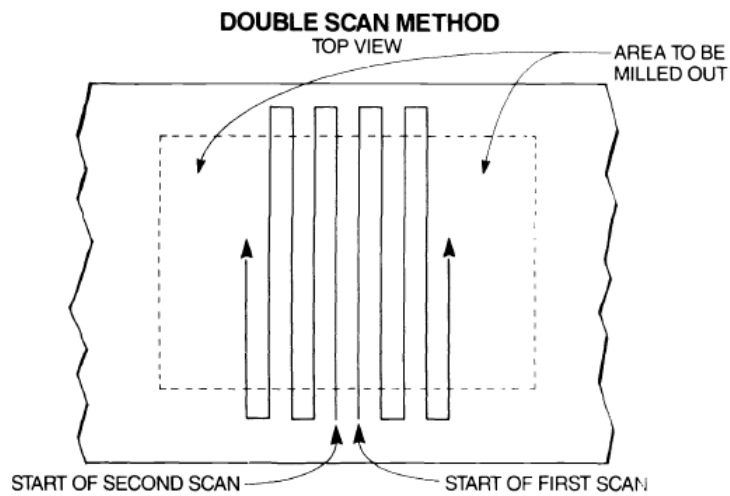


Figure 7. Double-Scan method
used to obtain vertical leading
and trailing walls

EX1035-Boogaard, Figure 7.

234. Boogaard also explains that “the ability to cut out very small holes and patterns with extremely small kerf widths brings this technology down to dimensions never before possible.” EX1035-Boogaard, 58. As shown below in Figures 13a-13b, Boogaard describes the process of laser cutting or drilling using a Nd:YAG laser to create holes of different diameters.

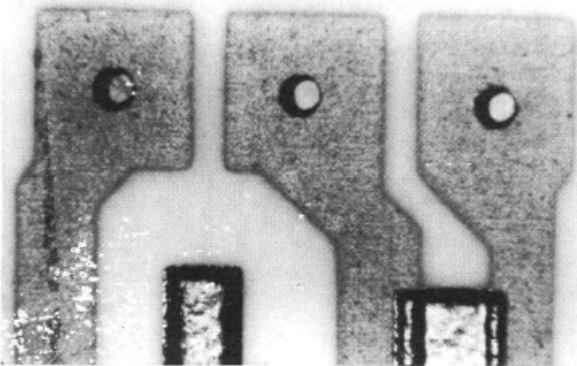


Figure 13a. Holes machined by laser through metal pads on thick film ceramic circuit allow for wire connections.

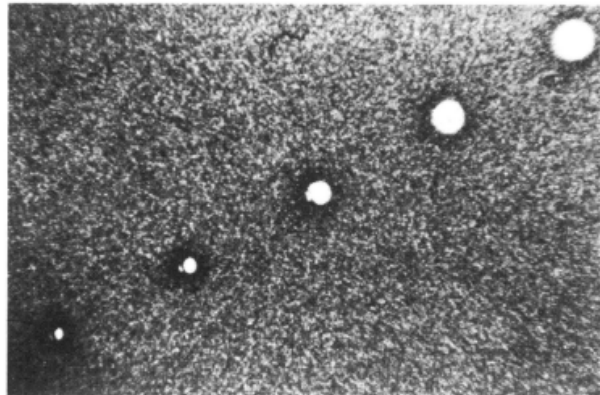


Figure 13b. Holes of different diameters "cored" through silicon. Hole diameters are from 5-25 mils, wafer thickness is 15 mils

EX1035-Boogaard, Figures 13a-13b.

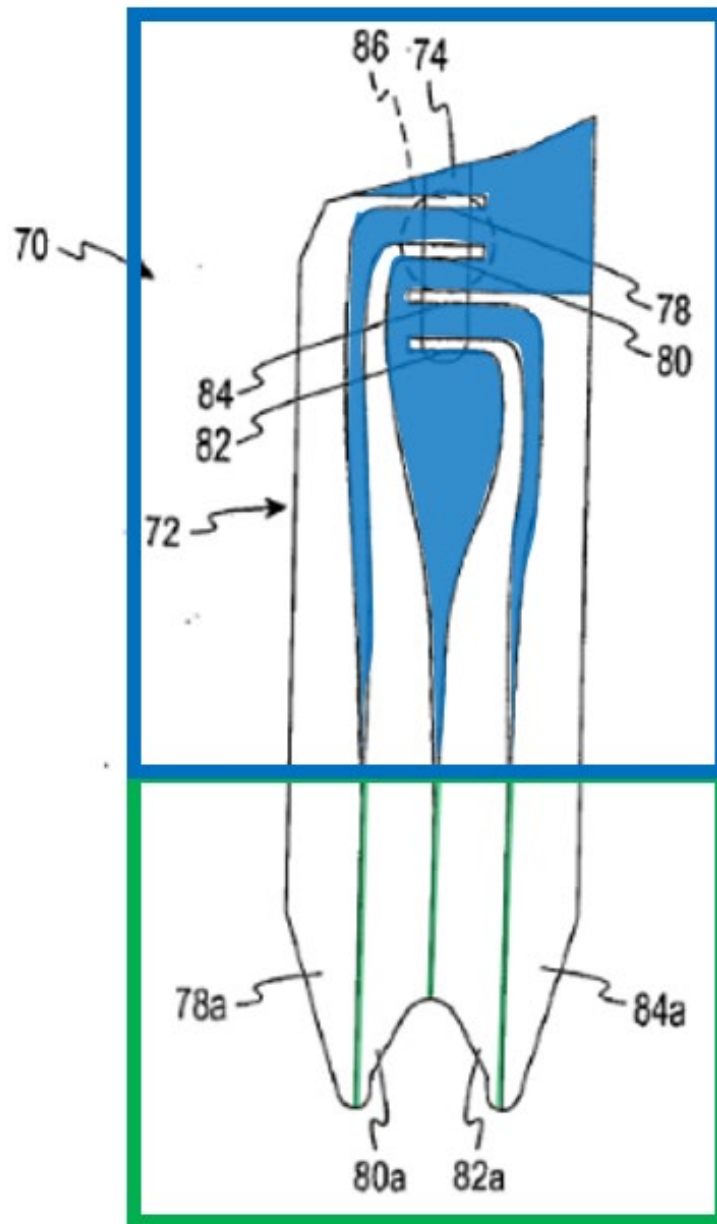
235. Edelbrock discloses kerfs defining fine boundaries (shown in green below) and the need for precise manufacturing tolerances. EX1032-Edelbrock, [0048]. For example, Edelbrock states that “[l]aser-cutting is desirable because of the ability to maintain low manufacturing tolerances (typically less than 0.005 in.

[127 microns]) when using mechanical or optical guides.” EX1032-Edelbrock, [0048].

236. Boogaard specifically discloses suitable beam widths for the fine boundaries depicted in Edelbrock, such as elements 174a-c in Figure 4d. Boogaard’s Nd:YAG laser can produce cuts corresponding to beam widths in the range of 5 microns to 38.1 microns. For example, Boogaard provides an example of a milling operation using a Nd:YAG laser and states that the “**groove can be kept to less than 5 μ m in width....**” EX1035-Boogaard, 51.

237. Additionally, Boogaard explains that “hole size is then determined by the beam diameter” and provides examples of various hole sizes. EX1035-Boogaard, 54. Boogaard states that “[d]epending on the material thickness and the optics used, hole sizes can vary from 0.0005 inch [(12.7 micron)] to as large as 0.0015 inch [**38.1 micron**].” EX1035-Boogaard, 54.

238. As such, Boogaard teaches beam widths in the range of **5 microns to 38.1 microns**. These beam widths are suited to forming fine boundaries (shown in green below) between conductive components in Edelbrock’s test sensor (Figure 2b).



Edebrock-1032, FIG. 2b.

239. A person of ordinary skill in the art would have recognized that Boogaard's positioning system, wherein the laser is moved relative to the substrate, was particularly suitable for implementing Edelbrock's YAG laser, which performs

“direct writing of the lines” in which “a laser beam of light is moved so as to partially define the plurality of electrodes.” EX1032-Edelbrock, [0041]. Boogaard provided a solution to this action of moving the laser via a positioning system with better than 1 micron positioning accuracy relative to the substrate. EX1035-Boogaard, 48-49, Figures 2a, 2b.

240. In addition, implementing Boogaard’s laser ablation teachings in Edelbrock’s method would have amounted to [a]pplying a known technique to a known device ready for improvement to yield predictable results. Boogaard’s Nd:YAG laser on a positioning system would be employed by Edelbrock to form fine boundaries as I explained above. EX1032-Edelbrock, FIG. 2b, FIG. 4d (elements 174a-c), [0048].

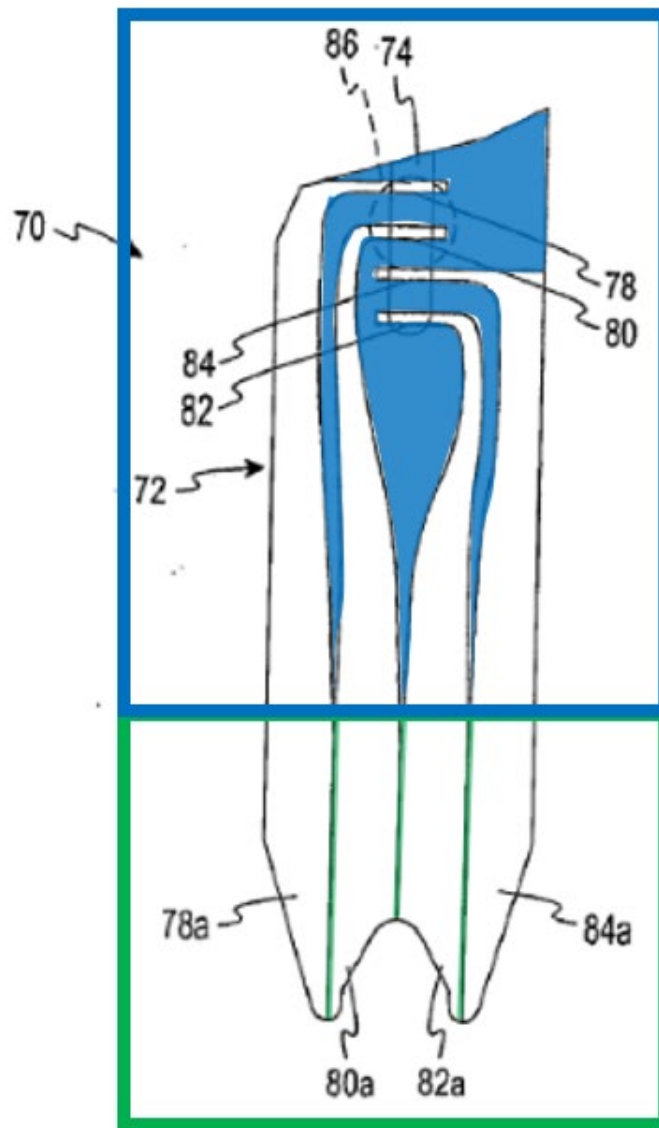
241. A person of ordinary skill in the art would have had a reasonable expectation of success, and would have succeeded, implementing Edelbrock’s laser ablation step using Boogaard’s laser milling techniques. Both Boogaard and Edelbrock use laser ablation on the same materials on a micron scale. For example, both teach the use of gold as an ablative material. Boogaard teaches the use of the Nd:YAG laser to ablate gold (EX1035-Boogaard, 57) and Edelbrock teaches that “[t]he electrodes are formed of conductive materials such as, for example, metallic materials (e.g., **gold**).” EX1032-Edelbrock, [0035].

242. Also, I note that Boogaard and Edelbrock are in the same field of endeavor that includes the manufacture of microelectronic components comprising a base (non-conductive layer) and laser-defined electrodes. EX1035-Boogaard, 48, 57-58.

243. It is therefore my conclusion that a person of ordinary skill in the art would have been motivated to combine the teachings of Boogaard and Edelbrock to incorporate into Edelbrock's method for manufacturing a test sensor Boogaard's Nd:YAG laser and positioning system, with a reasonable expectation of success.

(b) Edelbrock, Boogaard, Angell: Edelbrock and Boogaard Combined With Angell's Teachings of a Focused CO₂ Laser

244. As I explained in Section X.B.3.(a) (Edelbrock, Boogaard), it would have been obvious to use a focused Nd:YAG laser to form ablation lines in the range of 5 microns to 38.1 microns suitable for defining fine boundaries (shown in green) between Edelbrock's conductive/reactive area. However, a significant portion of Edelbrock's test sensor requires ablation of large areas of material to form insulating gaps between electrodes (*see* blue areas in Figure 2b). *See also* Section X.B.1 (where I provide an overview of Edelbrock).



EX1032-Edelbrock, FIG. 2b.

245. A person of ordinary skill in the art would have looked to prior art to identify a second laser suitable for removing larger areas. This is because Edelbrock expressly teaches using two different lasers. Edelbrock also provides examples of potential lasers, including the YAG laser and carbon-dioxide based lasers.

246. Edelbrock discloses the use of a carbon dioxide-based laser for direct writing (ablation of a conductive layer), but it lacks specific implementation details such as beam width, the particular type of carbon dioxide laser, the positioning system to use, and which specific laser cuts are best suited for the carbon dioxide laser. EX1032-Edelbrock (“Non-limiting examples of such lasers are **carbon dioxide-based lasers** and yttrium-based lasers such as yttrium aluminum garnet (YAG) lasers.”). Consequently, a person of ordinary skill in the art would have referred to existing literature for these details and would have readily recognized that Angell provides such information.

247. Similar to Edelbrock and Boogaard, Angell focuses on laser micromachining and details the selection of lasers based on “material type, lasers used in machining (CO₂, solid state, excimer), laser processing parameters (wavelength, fluence, pulse width, cutting speed) and other material related information (thickness, feature sizes, etc.).” EX1034-Angell, 65.

248. Angell provides a focused laser at suitable beam widths that would assist in the creation of wider kerfs required by Edelbrock. EX1034-Angell, 66. For example, Angell teaches that the “beam can, with the appropriate lens, **be focused** to about a 50micron spot....” EX1034-Angell, 66. Angell further teaches that “CO₂...lasers are used in focal point machining where usually a single element lens

is used to **focus** the beam....” EX1034-Angell, 69. Angell also teaches CO₂ laser beam widths of 2 mil (50.8 microns) to 10 mil (254 microns). EX1034-Angell, 69. Moreover, like Boogaard’s Nd:YAG laser, it was well-known that Angell’s CO₂ laser could be moved with a positioning system and used with scanning techniques to ablate areas larger than the beam width. *See, e.g.*, EX1071-Hellrung, 267; EX1035-Boogaard, 4.

249. A person of ordinary skill in the art would have been motivated by Boogaard’s teaching of a positioning system to incorporate Angell’s CO₂ laser into the method of the Edelbrock and Boogaard combination, using a positioning system with a reasonable expectation of success. It was well-known that Angell’s CO₂ laser, similar to Boogaard’s Nd:YAG laser, could be maneuvered with a positioning system relative to an ablation target. *See, e.g.*, EX1071-Hellrung, 267; EX1035-Boogaard, 49.

250. A person of ordinary skill in the art would have reasonably expected to succeed in adding a CO₂ laser as taught by Angell, as a second laser for implementing the combination of Edelbrock’s and Boogaard’s teachings. Angell, Boogaard, and Edelbrock all use laser ablation on metals at a micron scale. EX1034-Angell, 66.

251. Furthermore, as previously noted, Angell, Boogaard, and Edelbrock operate within the same field of endeavor, which includes the manufacture of microelectronic components consisting of a base (non-conductive layer) and laser-defined electrical components. EX1034-Angell, 57-58, EX1035-Boogaard, Figures 22 and 23.

252. Consequently, a person of ordinary skill in the art would have been motivated to combine the teachings of Angell with the combination of Edelbrock and Boogaard method to incorporate Angell's CO₂ laser, with a reasonable expectation of success.

(c) Edelbrock, Boogaard, Angell Combination

253. A person of ordinary skill in the art would have been motivated to make the proposed combination of Edelbrock, Boogaard, and Angell with a reasonable expectation of success. The combination would have simply involved integrating the teachings of (1) Boogaard's use of an Nd:YAG laser to create fine boundaries (kerfs) between conductive components; (2) Boogaard's use of a positioning system to facilitate Edelbrock's movement relative to the test sensor; and (3) Angell's use of a CO₂ laser to ablate larger surface areas of conductive material, in Edelbrock's manufacturing process.

4. **Independent Claim 1**

(a) **Element 1[pre]: A method of manufacturing test strips, comprising:”**

254. Should the preamble be found to be limiting (which I understand is a legal determination), Edelbrock teaches Element 1[preamble].

255. Edelbrock teaches a method of manufacturing test sensors (*test strips*).

For example, Edelbrock states:

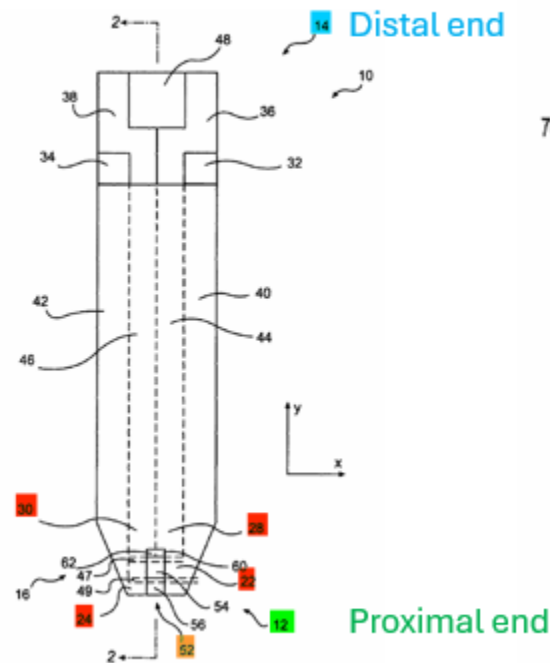
The present invention generally relates to a method of forming a test sensor. More specifically, the present invention generally relates to **a method of forming a multilayer test sensor** that is adapted to assist in determining a concentration of an analyte.

EX1032-Edelbrock, [0001]. Like the '981 patent's test strip, Edelbrock's test sensor is used to test “a whole blood sample, a blood serum sample, a blood plasma sample, other body fluids like ISF (interstitial fluid) and urine, and non-body fluids” for analytes such as glucose. EX1032-Edelbrock, [0029].

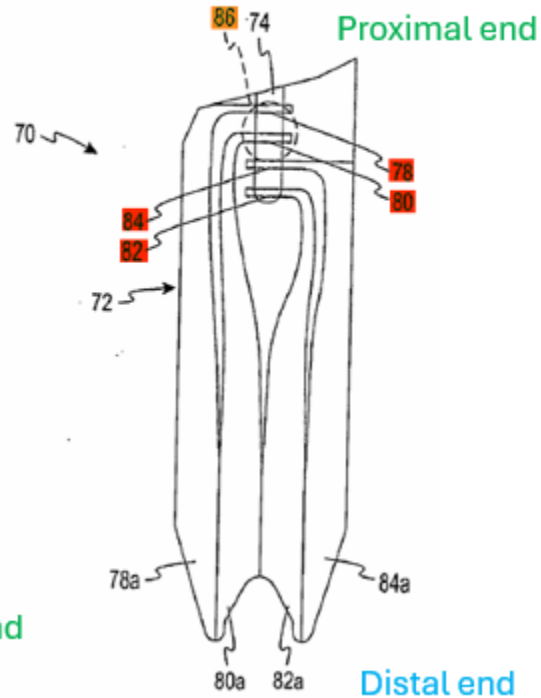
256. Below, I compare FIG. 1A of the '981 patent with FIG. 1 of Edelbrock. Both test strips are flat, elongated, and comprise the same components. For example, Edelbrock has a proximal end shown in green, which corresponds to '981 patent's element 12. Edelbrock has a fluid receiving area 86 (in orange) which corresponds to the '981 patent's slot 52 (in orange) to receive a fluid sample. Edelbrock has a distal end (in below) which corresponds to the '981 patent's element 14. Finally,

Edelbrock has electrodes 78, 80, 82, 84 (in red) and which corresponds to the '981 patent's electrodes 22, 24, 28, 30 (in red) used for detection of an analyte.

'981 Patent, FIG. 1A



Edelbrock, FIG. 2b



EX1032-Edelbrock, FIG. 2b; EX1001-'981, FIG. 1A.

257. In addition, Edelbrock's test strip facilitates analyte detection using a meter. EX1032-Edelbrock, [0008]. For example, Edelbrock states that "[t]he test sensor is adapted to be used in a meter and assist in determining the concentration of an analyte." *See also* EX1032-Edelbrock, [0009], [0029], [0038], [0045], [0057], [0075], Claim 1, Claim 16. Accordingly, Edelbrock teaches Element 18

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, if
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 limiting.

(b) Element 1[a]: forming a reel containing a conductive layer and a base layer;

258. Edelbrock teaches Element 1[a].

259. Edelbrock's states that:

The present invention is directed to an inventive process for forming a test sensor and, more specifically, an electrochemical test sensor. In one method, the electrochemical multilayer test sensors may be formed from a test-sensor ribbon. The ribbon is made from processes such as a multiple sheet process or a web process.

EX1032-Edelbrock, [0036]. As described above, Edelbrock's uses "a web process" to form "an electrochemical test...from a test-sensor ribbon," which involves formation of *a reel*. EX1032-Edelbrock, [0036].

260. Indeed, a "web process" refers to "reel-to-reel processing" in which electronic devices are created on a roll of flexible plastic, metal foil, and the like. Chrisey (2002) explains the well-known benefits of reel-to-reel processing, such as allowing manufacturers to benefit from economies of scale:

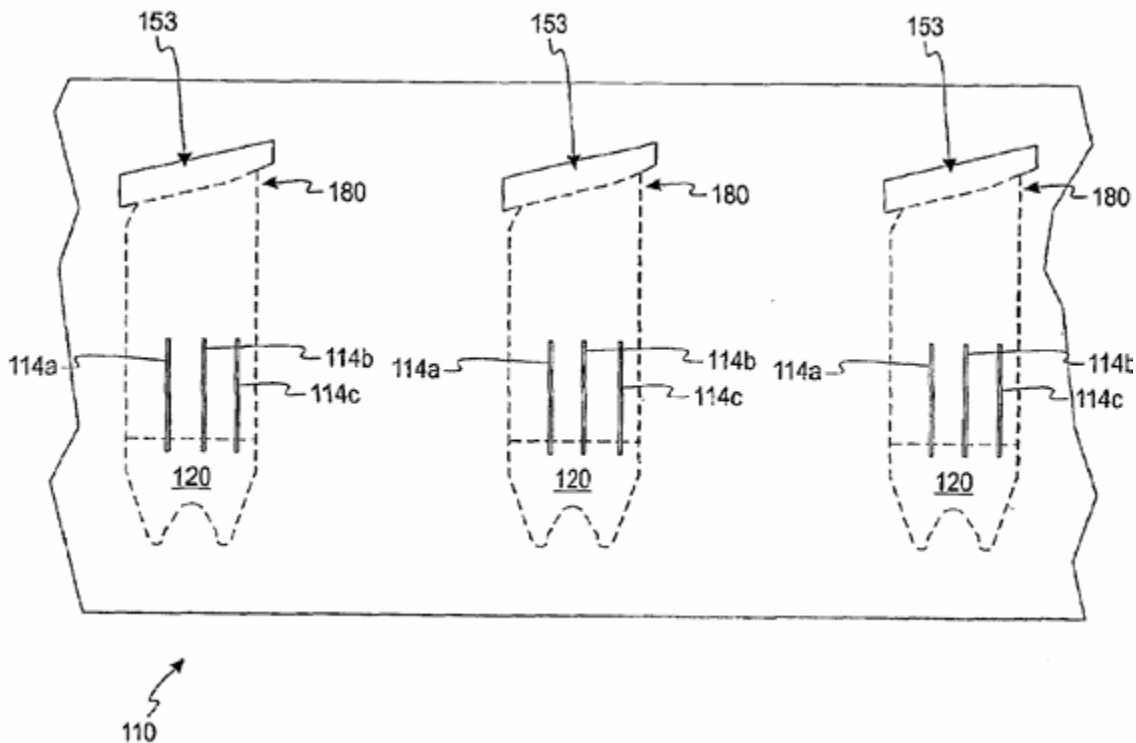
The microelectronics industry has the vision to integrate these systems onto a reel-to-reel platform, which will enable rapid, high-volume manufacturing using flexible plastics as substrates. The compliant nature of the substrate layer(s) will enable the design and fabrication of a truly conformal electronics system. Product assembly line pulse rates will increase and will enable manufacturers to benefit from economies of scale. Furthermore, the substrate type will provide a significant

reliability advantage over a nonflexible system. In particular, the strain generated by thermal expansion mismatch of the materials will be more readily dissipated in the flexible system while the strain generated in a “rigid” system will not have a mechanism by which to relax the strain.

EX1061-Chrisey, 35.

261. Additionally, Harvey (1995) describes the use of reel-to-reel processing in biomedical blood sensors. EX1064-Harvey, 2-3.

262. According to this process, the “base-ribbon strip 110” shown in Figure 3 of Edelbrock (below) is provided in the form of a reel and processed to form “test sensors 180.” EX1032-Edelbrock, [0037], [0038]-[0056].



EX1032-Edelbrock, FIG. 3, [0037].

263. Edelbrock explains that:

The multilayer test sensors to be made using the inventive process include at least a base and a second layer such as a lid. The multilayer test sensors are electrochemical test sensors. **The base and lid may be made from a variety of materials such as polymeric materials.** Non-limiting examples of polymeric materials that may be used to form the base and lid include polycarbonate, **polyethylene terephthalate (PET)**, polystyrene, polyimide, and combinations thereof. As will be discussed below, the multilayer test sensors may include additional layers such as a spacer. For example, a base, spacer and lid may form the multilayer test sensor in another embodiment.

EX1032-Edelbrock, [0030].

264. Thus, Edelbrock's base-ribbon strip (*a reel*) includes a polymer *base layer*. It was known that polyester is electrically insulating. EX1057-Goosey, 9-11. And the '981 patent states that the base layer can be a polyester, and PET is a type of polyester. EX1001-'981, 8:4-7.

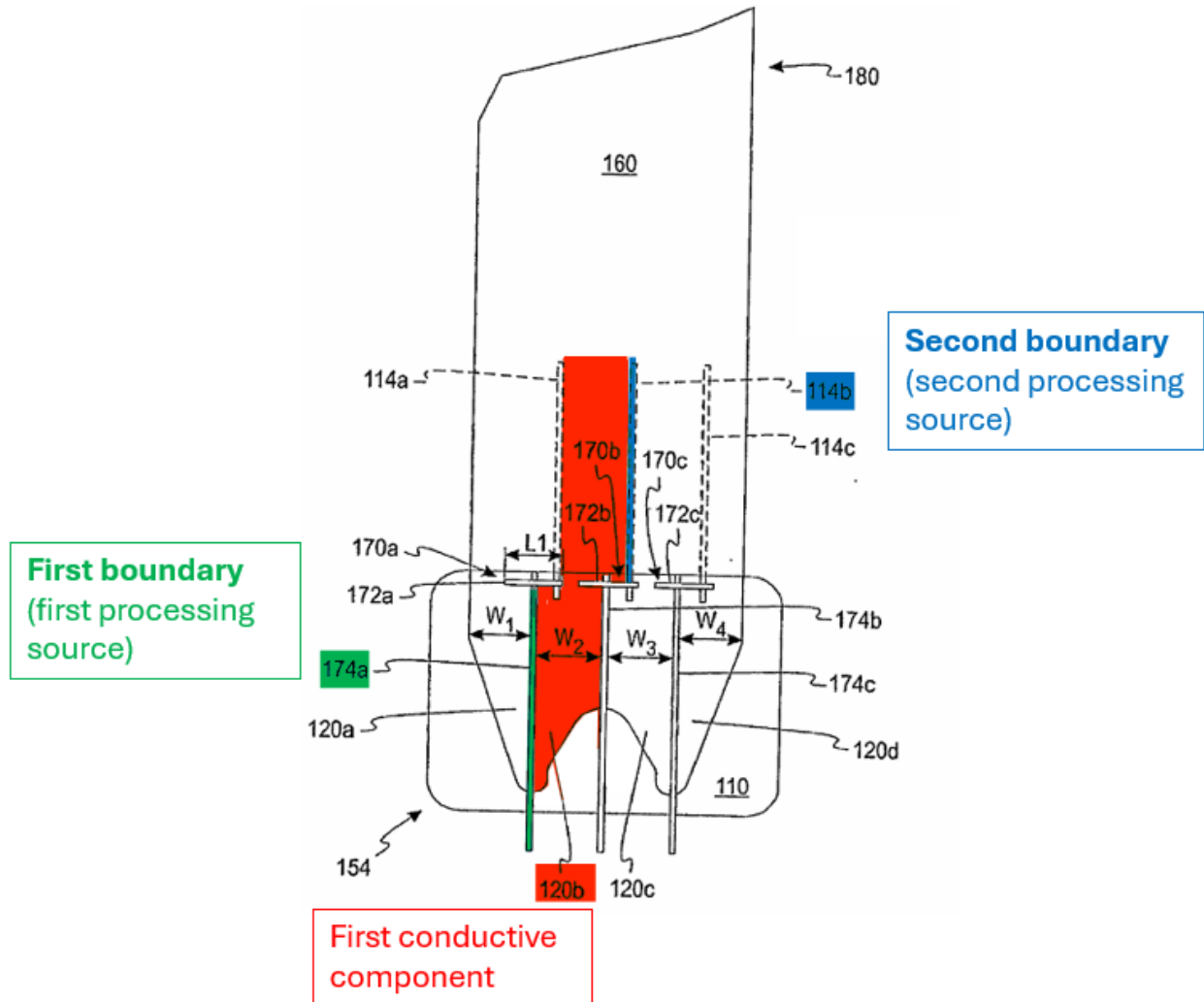
265. Edelbrock's base-ribbon strip (*reel*) also includes a conductive/reactive area (*conductive layer*) which is seen above in Figure 3 as element 120. EX1032-Edelbrock, FIG. 3. Edelbrock further explains that "[t]he base-ribbon strip 110 includes a **conductive/reactive area 120**, which will eventually form a plurality of conductive leads that is adapted to contact a meter or instrument." EX1032-

Edelbrock, [0038]; *see also* EX1032-Edelbrock, [0035], [0039], FIGS. 4a-e, [0045]-[0048].

- (c) **Element 1[b]: 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;**

266. The combination of Edelbrock, Boogaard, and Angell teaches Element 1[b].

267. Edelbrock teaches forming a first conductive area 120b (*first conductive component* in red) that includes element 174a (*first boundary* in green) and a different element 114b (*second boundary* in blue).



EX1032-Edelbrock, FIG. 4d, [0046]-[0052].

268. In Edelbrock's method, element 174a (in green) is *at least one first boundary* of the first conductive component 120b (*first conductive component* in red) because it is a boundary between *first conductive component* 120b and third conductive component 120a (*see* Element 1[d]). EX1032-Edelbrock, [0039], FIG.

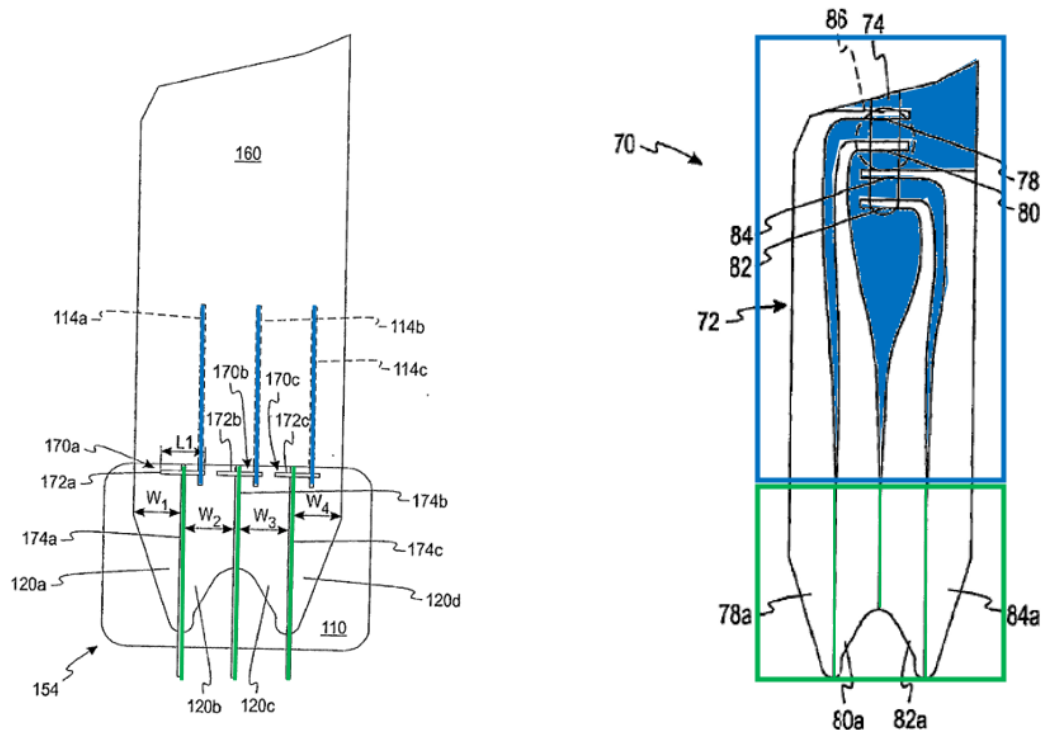
4d. Additionally, element 114b (in blue) is *at least one second boundary* of the *first conductive component* because it is a boundary between *first conductive component* 120b (in red) and second conductive component 120c (*see* Element 1[c]). EX1032-Edelbrock, [0046], [0049], FIG. 4d.

269. Edelbrock explains that “the plurality of electrodes on the base-ribbon strip 110 is partially formed with a laser using direct writing of the lines” where “a laser beam of light is moved so as to partially define the plurality of electrodes. Lasers that produce a beam of energy capable of removing a layer and that can be moved to form a pattern may be used in this method.” EX1032-Edelbrock, [0041]. In this way, laser cuts 114b and 174a ablate conductive material between adjacent portions of conductive area 120 which creates boundaries that “define[] a plurality of electrodes.” EX1032-Edelbrock, [0041].

270. In the combination of Edelbrock, Boogaard, and Angell, element 174a (in green) is the *first boundary* which is formed by Boogaard’s Nd:YAG laser (*first processing source*) and element 114b (in blue) is the *second boundary* which is formed by a different laser, namely Angell’s CO₂ laser (*second processing source*).

271. For element 174a (*first boundary*), a person of ordinary skill in the art would have been motivated to use Boogaard’s Nd:YAG laser. Section X.B.3 (The Edelbrock, Boogaard, Angell Combination). In particular, element 174a (in green)

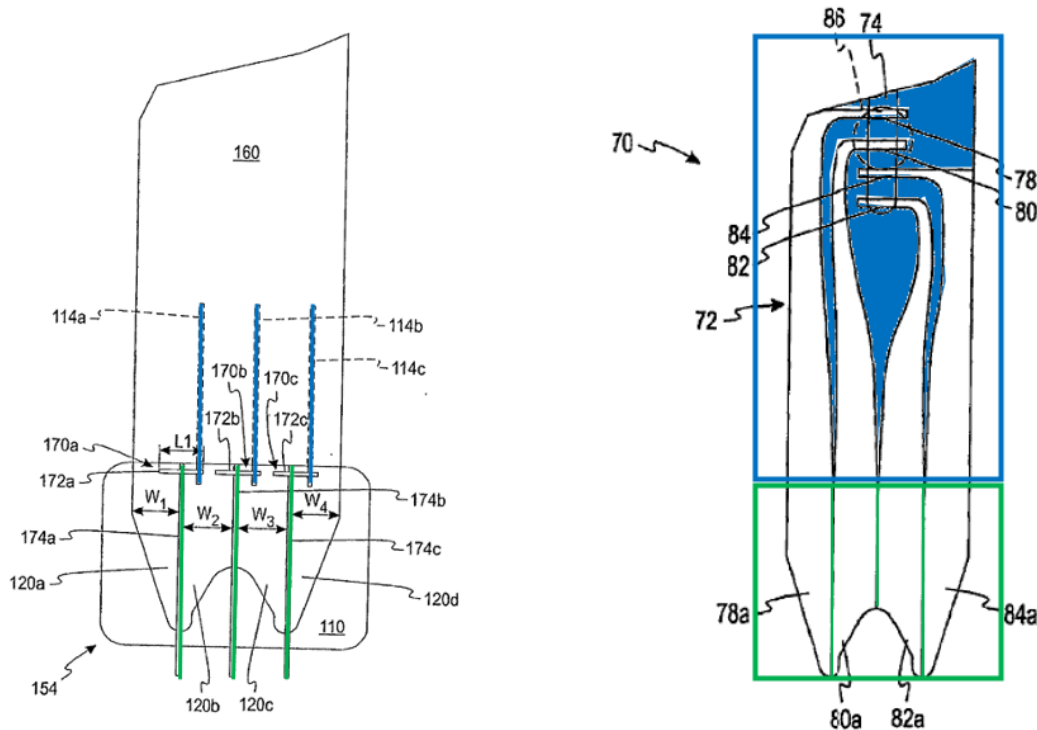
defines a relatively narrow gap, indicating that a person of ordinary skill in the art would select Boogaard's Nd:YAG laser instead of Angell's CO₂ laser because Boogaard's Nd:YAG laser has a narrower beam than the CO₂ laser.



EX1032-Edelbrock, FIGs. 4d, 2b.

272. For element 114b (*second boundary*) a person of ordinary skill in the art would have been motivated to use CO₂ laser for element 114b because its wider beam could ablate more material where required compared to Boogaard's Nd:YAG laser. Section X.B.3 (The Edelbrock, Boogaard, Angell Combination). Element

114b is one of several cuts made to form relatively large gaps (shown below in blue) between conductive areas in the boxed region of Edelbrock's Figure below.



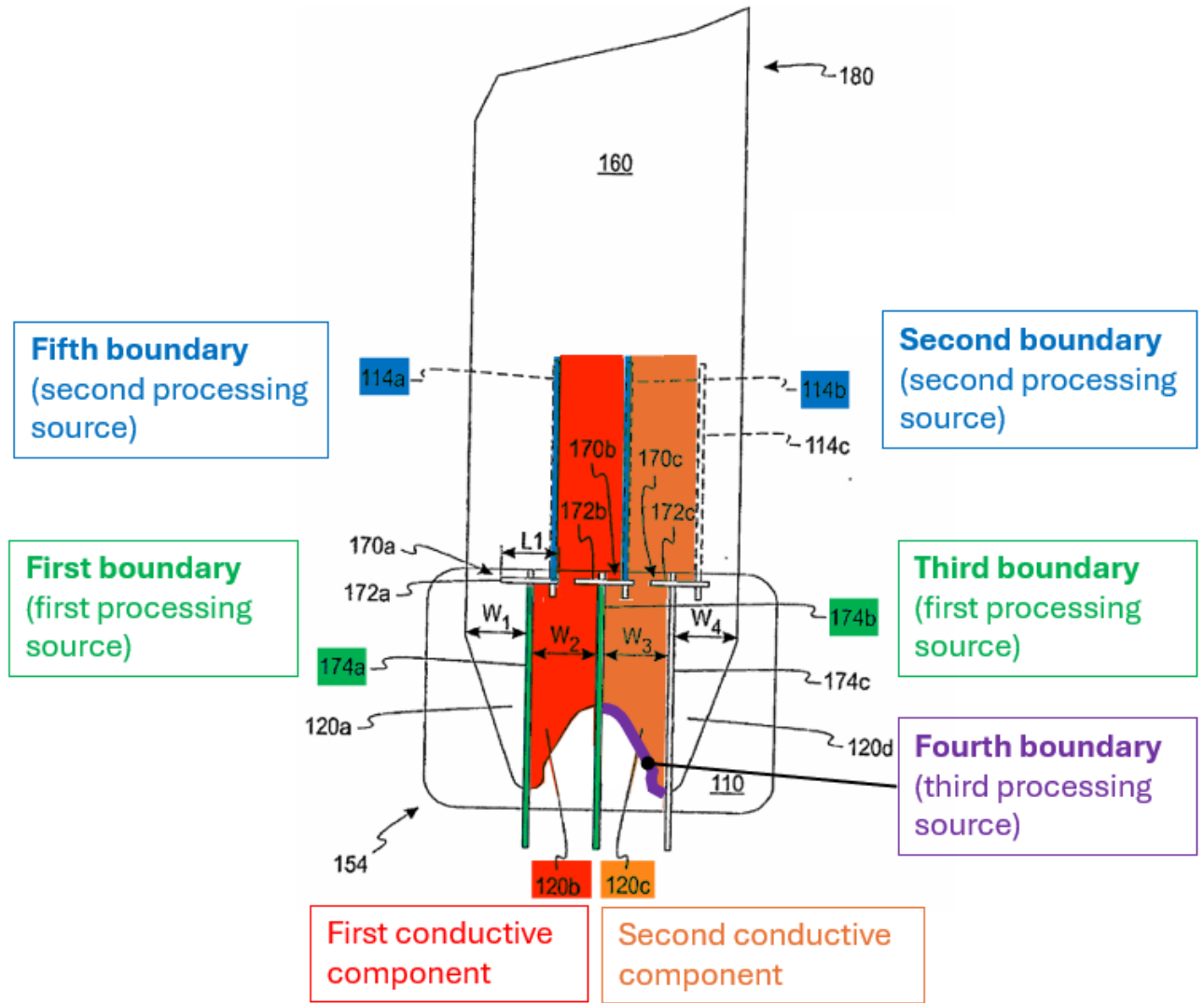
EX1032-Edelbrock, FIG. 4d (excerpted), FIG. 2d (excerpted); Section X.B.1 (Overview of Edelbrock).

273. Lastly, element 174b (*first boundary*) (green) is formed by movement of the Nd:YAG laser (*first processing source*), along the *first boundary* Section X.B.3 (The Edelbrock, Boogaard, Angell Combination). Similarly, Edelbrock's element 114b (*second boundary*) is formed by movement of the CO₂ laser (*second processing source*), along the second boundary. EX1032-Edelbrock, [0041].

- (d) Element 1[c]: 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**

274. The combination of Edelbrock, Boogaard, and Angell teaches Element 1[c].

275. As I show below, Edelbrock forms a second conductive area 120c (*second conductive component* in orange) that includes element 174b (*third boundary* in green) between the *first conductive component* (in red) 120b and the *second conductive component* (in orange) 120c.



EX1032-Edelbrock, FIG. 4d. *See also* EX1032-Edelbrock, [0046]-[0052].

276. Element 174b (*third boundary* in green) is a boundary of the *second conductive component* 120c (in orange) for the same reasons I provided above regarding Element 1[b], specifically as it relates to Edelbrock's element 174a's (first

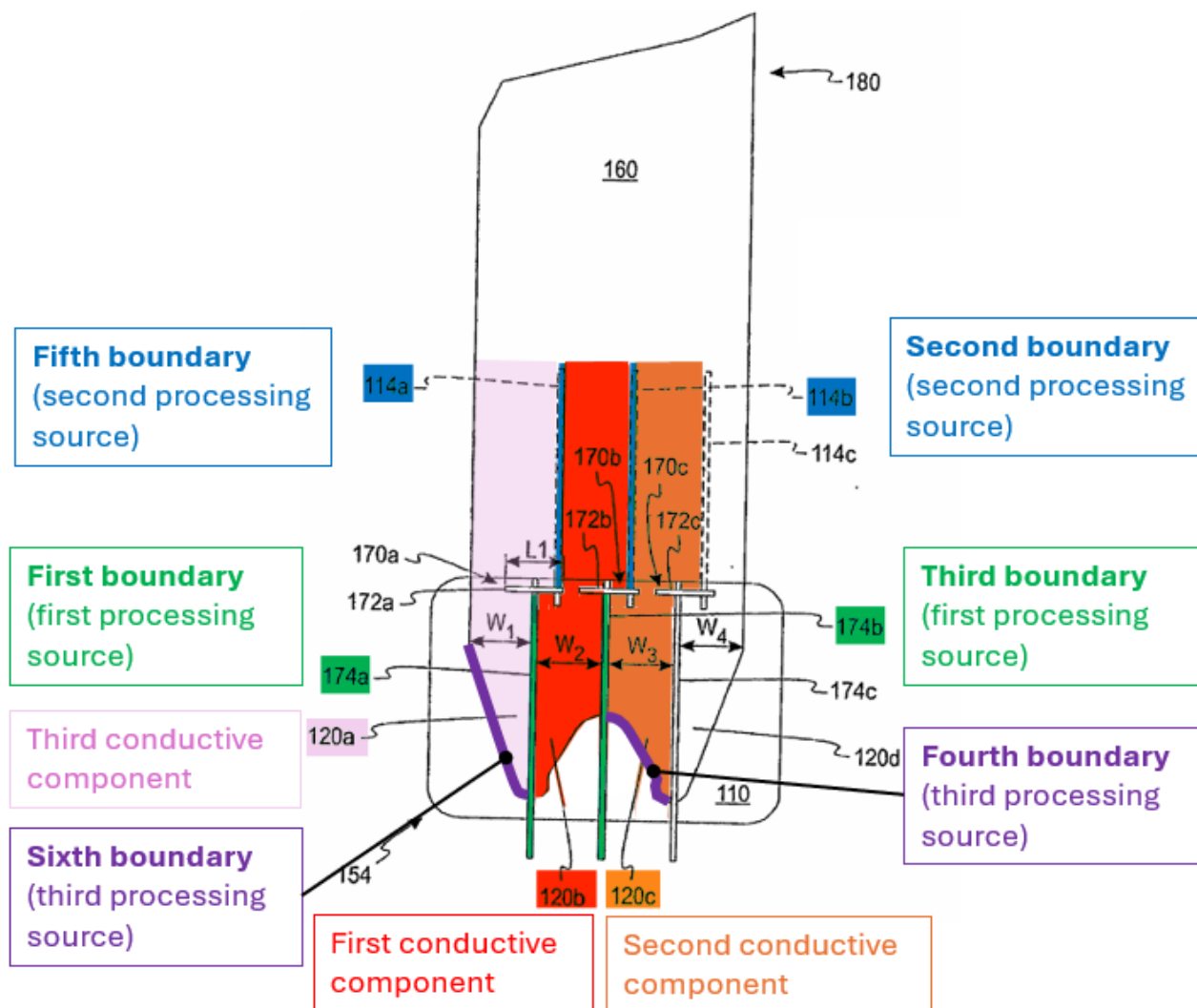
boundary) relationship to the first conductive component 120b. *See* Section X.B.4.(c) (Element 1[b]). Additionally, element 174b (*third boundary* in green) is formed by Boogaard's Nd:YAG laser (*first processing source*) for the same reasons given above with respect to element 174a (*first boundary* in green). Element 174b (*third boundary* in green) is formed by movement of the Nd:YAG laser (*first processing source*) along the third boundary for the same reasons given above with respect to element 174a (*first boundary*).

277. Edelbrock further describes a distinct *fourth boundary* (in purple) that is not the same as element 174b (*third boundary* in green). EX1032-Edelbrock, FIG. 4d, [0046]-[0052], FIG. 3, [0037]-[0044]. This *fourth boundary* is a free edge of the test sensor, which Edelbrock explains is stamped out using a mechanical punch—not a laser: “[A] mechanical punch is used to excise a plurality of test sensors in the sensor-ribbon strip.” EX1032-Edelbrock, [0052]. Therefore, Edelbrock's mechanical punch (*third processing source*) that is used to form the *fourth boundary* (in purple) is not the same as the laser beam (*first processing source*). *See* Section X.B.4.(c) (Element 1[b]).

- (e) **Element 1[d]: 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.**

278. The combination of Edelbrock, Boogaard, and Angell teaches Element 1[d].

279. Edelbrock teaches forming a third conductive area 120a (*third conductive component* in pink) that includes element 114a (*fifth boundary* in blue) between the first conductive component 120b (in red) and *the third conductive component* 120a (in pink).



EX1032-Edelbrock, FIG. 4d, [0046]-[0052].

280. Element 114a (*fifth boundary* in blue) is a boundary of *the third conductive component* 120a (in pink) for the same reasons given above regarding Element 1[b] with respect to Edelbrock's element 114b's (*second boundary* in blue)

relationship to the *second conductive component* 120c (in orange). See Section X.B.4.(c) (Element 1[b]). Additionally, element 114a (*fifth boundary* in blue) is formed by Angell's CO₂ laser (*second processing source*) for the same reasons given above with respect to element 114b (*second boundary* in blue). In addition, element 114a element (*fifth boundary* in blue) is formed by movement of the second processing source (CO₂ laser) along the *fifth boundary* for the same reasons given above with respect to element 114b (*second boundary*).

281. Lastly, Edelbrock describes a distinct sixth boundary (in purple) that is not the same as the element 114a (*fifth boundary* in blue). EX1032-Edelbrock, FIG. 4d, [0046]-[0052], FIG. 3, [0037]-[0044]. This *sixth boundary* is a free edge of the test sensor, which Edelbrock explains is stamped out using a mechanical punch—not a laser: “[A] mechanical punch is used to excise a plurality of test sensors in the sensor-ribbon strip.” EX1032-Edelbrock, [0052]. EX1032-Edelbrock, [0052]. Therefore, Edelbrock's mechanical punch (*third processing source*) that is used to form the *sixth boundary* is not the same as the laser beam (*second processing source*). See Section X.B.4.(d) (Element 1[c]).

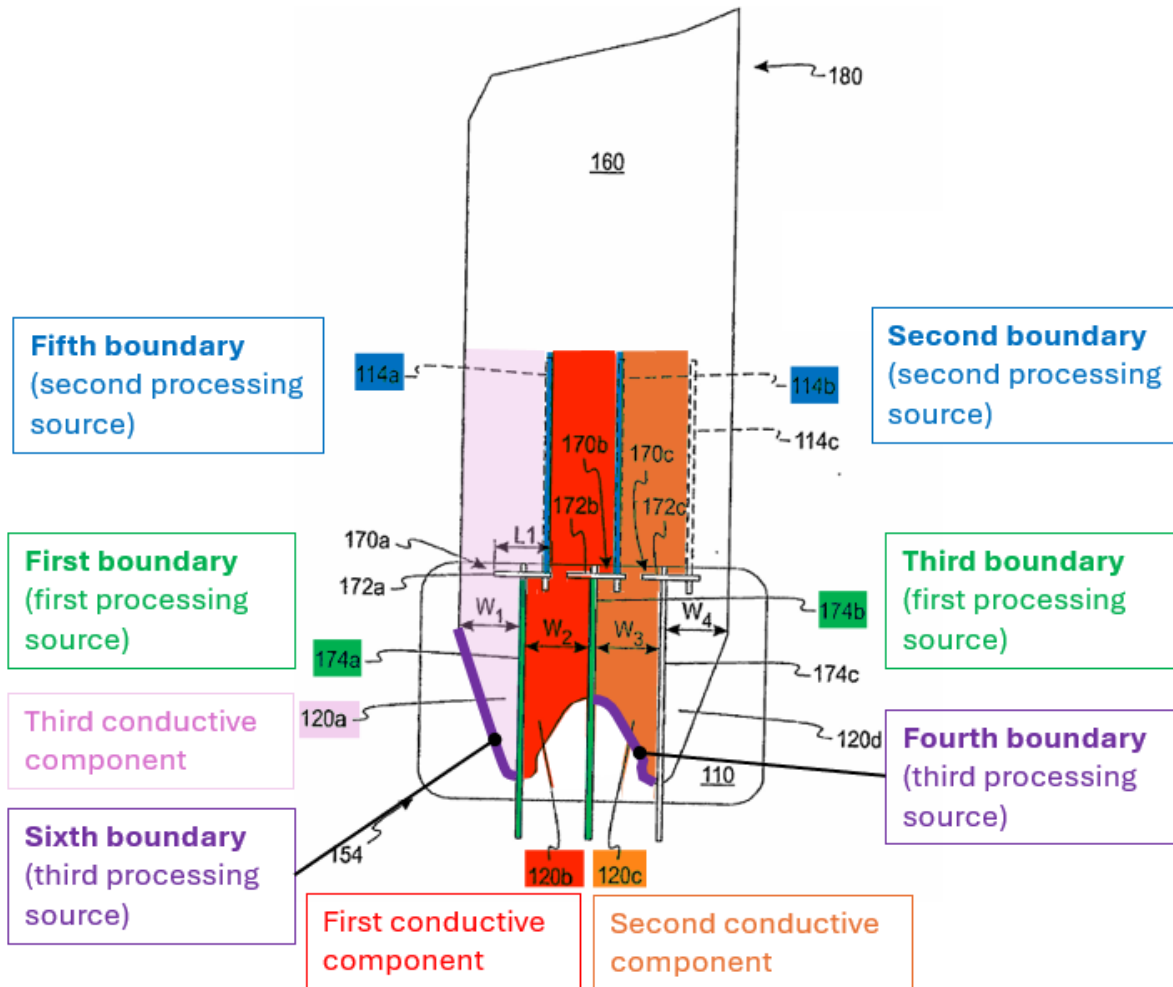
5. Dependent Claims 2 and 3

- (a) Claim 2: The method of claim 1, 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.**
- (b) Claim 3: The method of claim 1, 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.**

282. Claim 2 depends from claim 1. Claim 3 also depends from claim 1.

Therefore, I incorporate by reference my discussion of claim 1.

283. Edelbrock teaches the additional requirements of claims 2 and 3. EX1032-Edelbrock, [0041], [0046]. As I explained above in Section X.B.4.(c) (Element 1[b]), Boogaard's Nd:YAG laser (*first processing source*) performs *laser ablation*. Additionally, Angell's CO₂ laser (*second processing source*) performs *laser ablation*.



EX1032-Edelbrock, FIG. 4d, [0046]-[0052].

6. Dependent Claim 4

- (a) “The method of claim 1, 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.”

284. Claim 4 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

285. Edelbrock teaches the additional requirement of claim 4. As I explained in Section X.B.4.(d) (Element 1[c]), Edelbrock explains that after the manufacturing steps described above are completed, “a mechanical punch is used to excise a plurality of test sensors in the sensor-ribbon strip.” EX1032-Edelbrock, [0052]. Therefore, Edelbrock’s mechanical punch is the *third processing source*. A “mechanical punch” is a known form of *stamping*.

7. **Dependent Claim 5**

- (a) **“The method of claim 1, 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.”**

286. Claim 4 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

287. The combination of Edelbrock, Boogaard, and Angell teaches the additional requirement of claim 5. As I explained in Sections X.B.4.(c)–X.B.4.(e) (Elements 1[b]–[d]), the *first processing source* is an Nd:YAG laser and the *second processing source* is a CO₂ laser.

288. As I explained in Section X.B.3 (The Edelbrock, Boogaard, Angell Combination), the Nd:YAG laser is configured with a first ablative beam width in

the range of 5 microns to 38.1 microns (EX1035-Boogaard, 54) and the CO₂ laser is configured with a second ablative beam width in the range of 50.8 microns to 254 microns (EX1034-Angell, 69).

8. Dependent Claim 6

- (a) “The method of claim 5, wherein the first ablative beam width is at least approximately 20 micro-meters.”**

289. Claim 6 depends from claim 5. Therefore, I incorporate by reference my discussion of claim 5.

290. The combination of Edelbrock, Boogaard, and Angell teaches the additional requirement of claim 6. As I explained in Sections X.B.4.(c)–X.B.4.(e) (Elements 1[b]–[d]), Section X.B.3 (The Edelbrock, Boogaard, Angell Combination), and Section X.B.7 (Claim 5), the first processing source is an Nd:YAG laser and the *first ablative beam width* is 38.1 microns, which is at least *approximately 20 micro-meters*.

9. Dependent Claim 7

- (a) “The method of claim 5, wherein the second ablative beam width is at least approximately 100 micro-meters.”**

291. Claim 7 depends from claim 5. Therefore, I incorporate by reference my discussion of claim 5.

292. The combination of Edelbrock, Boogaard, and Angell teaches the additional requirement of claim 7. As I explained in Sections X.B.4.(c)–X.B.4.(e) (Elements 1[b]–[d]), Section X.B.3 (The Edelbrock, Boogaard, Angell Combination), and Section X.B.7 (Claim 5), the second processing source is a CO₂ laser and the *second ablative beam* width is 254 microns, which is at least *approximately 100 micron-meters*.

10. Dependent Claim 8

- (a) **“The method of claim 5, 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.”**

293. Claim 8 depends from claim 5. Therefore, I incorporate by reference my discussion of claim 5.

294. The combination of Edelbrock, Boogaard, and Angell teaches (*see* paragraphs 295–296 below) and makes obvious (*see* paragraph 297 below) the additional requirements of claim 8.

295. Edelbrock teaches that “substantially all of the conductive material between adjacent conductive components is removed” because Edelbrock’s lasers

“produce a beam of energy **capable of removing a layer....**” EX1032-Edelbrock, [0041]. According to Edelbrock:

According to another method, the plurality of electrodes on the base-ribbon strip 110 is partially formed with a laser using **direct writing of the lines**. As discussed above, the plurality of electrodes is not fully defined until the base-ribbon strip is attached to a second layer so as to define a reaction zone. In a method using a laser with direct writing of the lines, a laser beam of light is moved so as to partially define the plurality of electrodes. Lasers that produce a beam of energy **capable of removing a layer** and that can be moved to form a pattern may be used in this method. Non-limiting examples of such lasers are carbon dioxide-based lasers and yttrium-based lasers such as yttrium aluminum garnet (YAG) lasers.

EX1032-Edelbrock, [0041].

296. Forming Edelbrock’s electrodes by “removing a layer” therefore teaches removing the layer removed by the directly written lines (*substantially all conductive material*) between the electrodes (*between adjacent conductive components*) because, if not all conductive material were removed, adjacent electrodes could short circuit.

297. The combination of Edelbrock, Boogaard, and Angell additionally makes it obvious that 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. For example, element 174a (*first boundary*) is formed by

Boogaard's Nd:YAG laser having a beam width in the range of between 5 microns to 38.1 microns. *See* Section X.B.7 (Claim 5). A person of ordinary skill in the art would have understood that a beam width of 38.1 microns was a sufficient distance between Edelbrock's element 120b (the *first conductive component*) and Edelbrock's element 120a (the third conductive component). For example, Bhullar explains that typical gap widths are "about **25 μm to about 500 μm**" EX1007-Bhullar, [0019]. It would have been obvious to a person of ordinary skill in the art to select Boogaard's Nd:YAG laser having a beam width of 38.1 microns to form a gap with a width of 38.1 microns, especially considering that a person of ordinary skill in the art had the knowledge that this width was suitable and even "typical."

298. In addition, a person of ordinary skill in the art would have been motivated to make this combination because adjusting the beam width to match the distance of the first boundary means only one cut is necessary. This approach saves laser energy and reduces manufacturing time by eliminating the need for multiple kerfs (laser scans) to create the initial boundary. Additionally, a person of ordinary skill in the art would have had a reasonable expectation of success in making this combination, and would have succeeded, because implementing this approach amounts to simply operating Boogaard's Nd:YAG laser to form a single cut for the first boundary.

11. Dependent Claim 9

- (a) **“The method of claim 1, 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.”**

299. Claim 9 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

300. The combination of Edelbrock, Boogaard, and Angell teaches the additional requirement of claim 1. The combination of Edelbrock, Boogaard, and Angell combination teaches that a Nd:YAG laser is a *first processing source*, which is different type of laser than the CO₂ laser employed by *the second processing source*. See Section X.B.3 (The Edelbrock, Boogaard, Angell Combination); Sections X.B.4.(c)–X.B.4.(e) (Elements 1[b]–[d]).

12. Dependent Claim 10

- (a) **“The method 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.”**

301. Claim 10 depends from claim 9. Therefore, I incorporate by reference my discussion of claim 9.

302. The combination of Edelbrock, Boogaard, and Angell teaches the additional requirement of claim 10. The combination of Edelbrock, Boogaard, and

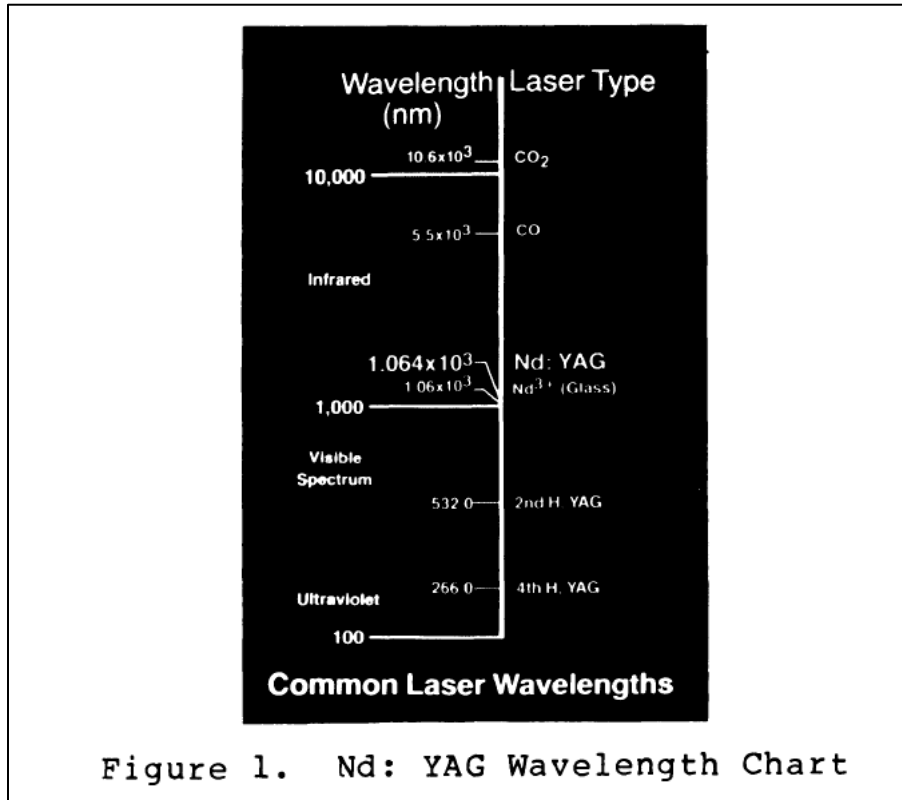
Angell teaches that a Nd:YAG laser is a *first type of laser*, which is a solid-state laser. EX1070-Tiffany, 28. The combination of Edelbrock, Boogaard, and Angell teaches that a CO₂ carbon dioxide laser is a *second type of laser*. See Section X.B.3 (The Edelbrock, Boogaard, Angell Combination); Section X.B.4.(c)–X.B.4.(e) (Elements 1[b]–[d]); Section X.11 (Claim 9).

13. Dependent Claim 11

- (a) “The method 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.”**

303. Claim 11 depends from claim 9. Therefore, I incorporate by reference my discussion of claim 9.

304. The combination of Edelbrock, Boogaard, and Angell teaches the additional requirement of claim 11. The combination of Edelbrock, Boogaard, and Angell combination teaches that a Nd:YAG laser is a *first type of laser*. See X.B.11 (Claim 9). An Nd:YAG laser operates in the *infrared region* (1000-10,000 nm). EX1035-Boogaard, 48.



EX1035-Boogaard, 48.

14. Dependent Claim 12

- (a) “The method of claim 1, 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.”

305. Claim 12 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

306. The combination of Edelbrock, Boogaard, and Angell teaches the additional requirement of claim 12, or at least makes it obvious. The combination

of Edelbrock, Boogaard, and Angell teaches that a Nd:YAG laser is a *first laser beam*, which is operated at 0.8 watts. EX1035-Boogaard, 48. The combination of Edelbrock, Boogaard, and Angell teaches that a CO₂ carbon dioxide laser is a *second laser beam*, which operates at a “maximum average power output of...50 to 250 Watts.” EX1034-Angell, 66; *see* Section X.B.3 (The Edelbrock, Boogaard, Angell Combination); Sections X.B.4.(c)–X.B.4.(e) (Elements 1[b]–[d]). Therefore, the combination of Edelbrock, Boogaard, and Angell teaches that *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*, or at least makes this limitation obvious.

15. Dependent Claim 13

- (a) “The method of claim 12, wherein the first or second laser power is in the range of about 10 to about 100 watts.”**

307. Claim 13 depends from claim 12. Therefore, I incorporate by reference my discussion of claim 12.

308. The combination of Edelbrock, Boogaard, and Angell teaches the additional requirement of claim 13. The combination of Edelbrock, Boogaard, and Angell teaches that a CO₂ carbon dioxide laser is a *second laser beam*, which operates at a “maximum average power output of...50 to 250 Watts.” EX1034-

Angell, 66. I have been instructed that, under the law, an overlapping range in the prior art can make a claimed range obvious where there is nothing critical about the claimed range. In its discussion of Nd:YAG and carbon dioxide lasers (among others), the '981 patent states that “[t]he power output of these lasers may vary and is usually in range about 10-100 watts.” EX1001-'981, 9:32-43. It is my opinion that the '981 patent does not teach anything critical about using a laser in the range of 10 to 100 watts. Because Angell teaches a range of 50 to 250 Watts, it makes this limitation—claiming a range of about 10 to about 100 Watts—obvious. Angell therefore teaches that the *second laser power is in the range of about 10 to about 100 watts*. Angell therefore teaches that the *second laser power is in the range of about 10 to about 100 watts*.

16. Dependent Claim 15

- (a) “The method of claim 1, further including the step of contacting the first conductive component with at least one chemical component.”**

309. Claim 15 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

310. Edelbrock teaches the additional requirement of claim 15. Edelbrock forms a reactive layer 86 (shown in orange below) containing an enzyme and electron acceptor (*e.g.*, a ferricyanide salt) (*a chemical component*) that contacts the

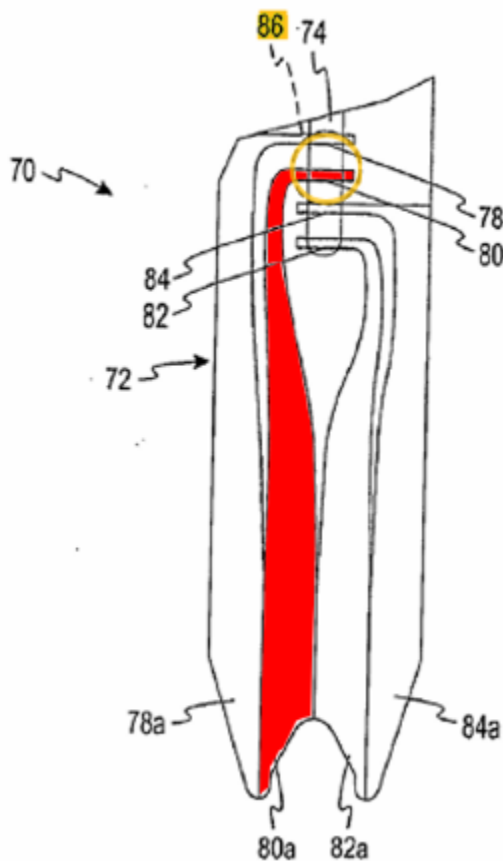
first conductive component (shown in red below). I addressed the *first conductive component* in Section X.B.4.(c) (Element 1[b]).

311. Edelbrock further explains that:

As shown in FIG. 2 b, **the test sensor 70 (without the lid 76) includes a reactive or fluid-receiving area 86 that contains an enzyme.** The enzyme is selected to react with the desired analyte or analytes to be tested so as to assist in determining an analyte concentration of a fluid sample. The reactive area 86 includes a reagent for converting an analyte of interest (e.g., glucose) in a fluid test sample (e.g., blood) into a chemical species that is electrochemically measurable, in terms of the electrical current it produces, by the components of the electrode pattern. **The reagent typically contains an enzyme (e.g., glucose oxidase), which reacts with the analyte (e.g., glucose) and with an electron acceptor (e.g., a ferricyanide salt) to produce an electrochemically measurable species that can be detected by the electrodes.** The reactive area 86 may comprise a polymer, an enzyme, and an electron acceptor. The reactive area 86 also may include additional ingredients such as a buffer and a surfactant in some embodiments of the present invention. It is contemplated that other enzymes may be used to react with glucose such as glucose dehydrogenase. If the concentration of another analyte is to be determined, an appropriate enzyme is selected to react with the analyte.

EX1032-Edelbrock, [0032]; *see also* EX1032-Edelbrock, Claim 1, Claim 16.

312. As shown below in Figure 2b of Edelbrock, the reactive layer (86) in orange is the *chemical component* that contacts the *first conductive component* shown in red.



EX1032-Edelbrock, FIG.2b.

17. Dependent Claim 16

- (a) “The method 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.”

313. Claim 16 depends from claim 15. Therefore, I incorporate by reference my discussion of claim 15.

314. Edelbrock makes the additional requirement of claim 16 obvious. Edelbrock's reagent layer (*chemical component*) includes a "ferricyanide salt." EX1032-Edelbrock, [0032]. Potassium ferricyanide is a well-known ferricyanide salt, as O'Leary teaches. EX1069-O'Leary, 175-179. Therefore, it would have been obvious to select a *potassium ferricyanide* as the *chemical component*.

18. Independent Claim 18

(a) Element 18[pre]: A method of manufacturing test strips, comprising:

315. Should the preamble be found to be limiting (which I understand is a legal determination), Edelbrock teaches Element 18[preamble]. Element 18[pre] is identical to Element 1[pre] and is taught by Edelbrock for the reasons I explained in Element 1[pre].

(b) Element 18[a]: forming a reel containing a conductive layer and a base layer;

316. Element 18[a] is identical to Element 1[a] and is taught by Edelbrock for the reasons I explained in Element 1[a].

(c) Element 18[b]: "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;"

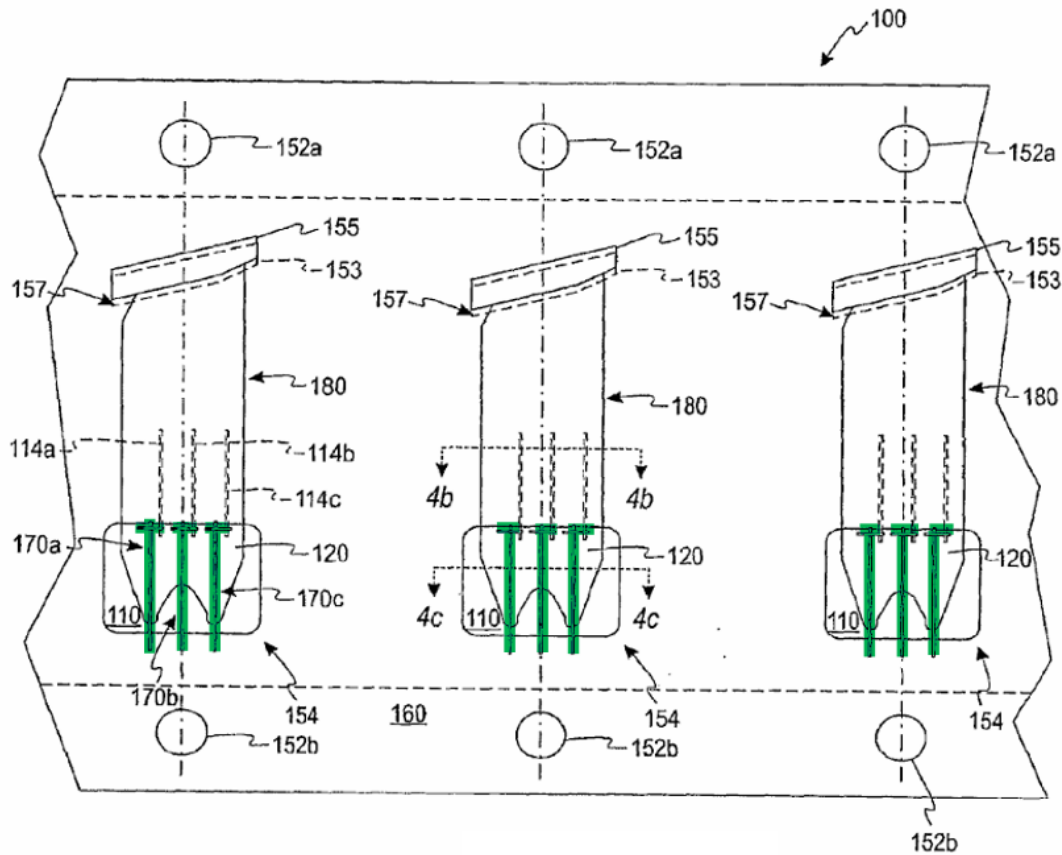
317. The combination of Edelbrock, Boogaard, and Angell teaches this limitation.

318. There are two ways to map the *first kerf* in Edelbrock: (1) laser cuts 170a-c, or (2) laser cuts 114a-c. Element 18[b]’s *first kerf* and *first focused laser beam* are interchangeable with Element 18[c]’s *second kerf* and *second focused laser beam* without any change in the scope of the claims. Accordingly, both mappings meet the requirements of Element 18[b] *wherein the first kerf is formed using a first focused laser beam moved relative to the conductive layer along the first kerf*.

319. For dependent claims 19-30 and 35-37, I have mapped the first kerf to element 170a. For dependent claims 32-34, I have mapped the first kerf to element 114a.

Claims	“first kerf” mapping
Claims 19-30, 35-37	Element 170a
Claims 32-34	Element 114a

320. **Regarding the first mapping** for example, Edelbrock’s Figure 3 (shown below) teaches a distinct step of making a “plurality of laser cuts” 170a-c in the conductive layer. EX1032-Edelbrock, [0046]. The first kerf is one of the laser cuts 170a-c, for example, element 170a (*first kerf*) shown below in green. EX1032-Edelbrock, [0046]. Edelbrock therefore teaches *forming a first kerf in the conductive layer*.



EX1032-Edelbrock, FIG. 3.

321. The combination of Edelbrock, Boogaard, and Angell also teaches *wherein the first kerf is formed using a first focused laser beam moved relative to the conductive layer along the first kerf*. For example, Edelbrock teaches that “[t]he conductive leads 120 a-d may be formed by the processes discussed above in connection with the plurality of electrodes, including laser processes.” EX1032-Edelbrock, [0046]. Edelbrock also states that:

According to another method, the plurality of electrodes on the base-ribbon strip 110 is partially formed with a laser

using **direct writing of the lines**. As discussed above, the plurality of electrodes is not fully defined until the base-ribbon strip is attached to a second layer so as to define a reaction zone. In a method using a laser with direct writing of the lines, **a laser beam of light is moved so as to partially define the plurality of electrodes**. Lasers that produce a beam of energy capable of removing a layer and that can be moved to form a pattern may be used in this method. Non-limiting examples of such lasers are carbon dioxide-based lasers and yttrium-based lasers such as **yttrium aluminum garnet (YAG) lasers**.

EX1032-Edelbrock, [0041].

322. Therefore, Edelbrock teaches that a YAG laser may be used to form the *first kerf*. Additionally, Boogaard's Nd:YAG laser is a *focused laser beam* that is used to form Edelbrock's first kerfs 170a-c because Boogaard teaches that the laser produces a focused beam. EX1007-Boogaard, 49.

323. **Regarding the second mapping**, for example, the *first kerf* may be selected as one of a plurality of laser cuts 114a-c. EX1032-Edelbrock, [0039]. As I explained, Element 18[b]'s *first kerf* and *first focused laser beam* are interchangeable with Element 18[c]'s *second kerf* and *second focused laser beam* without any change in the scope of the claims. Accordingly, selecting one of cuts 114a-c, which are formed by a CO₂ laser as taught by Angell (Section X.B.18.(d) (Element 18[c])) also meets the requirements of Element 18[b] *wherein the first kerf is formed using a first focused laser beam moved relative to the conductive layer along the first kerf*.

324. As I explained, for dependent claims 19-30 and 35-37, I have mapped the first kerf to element 170a. For dependent claims 32-34, I have mapped the first kerf to element 114a.

(d) Element 18[c]: “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;”

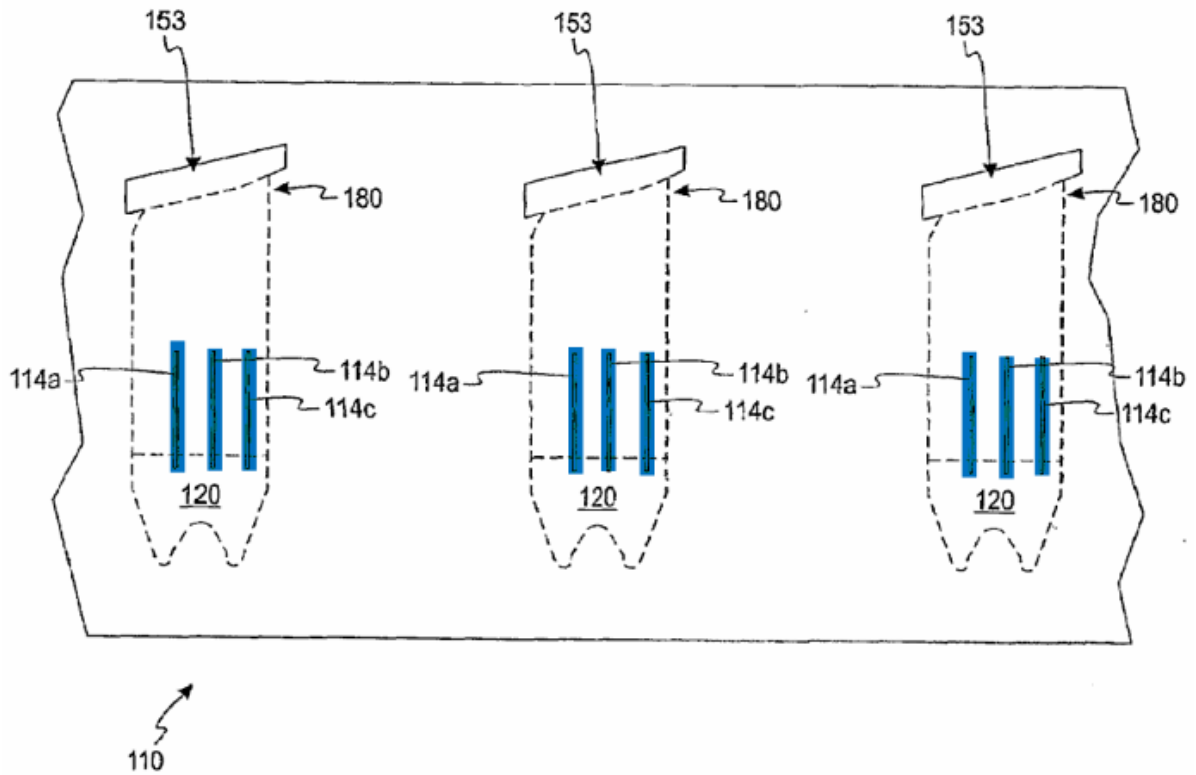
325. The combination of Edelbrock, Boogaard, and Angell teaches this limitation.

326. There are two ways to map the *second kerf* in Edelbrock: (1) laser cuts 114a-c, or (2) laser cuts 170a-c. Element 18[b]’s *first kerf* and *first focused laser beam* are interchangeable with Element 18[c]’s *second kerf* and *second focused laser beam* without any change in the scope of the claims. Accordingly, both mappings meet the requirements of Element 18[c] *wherein the second kerf is formed using a second focused laser beam moved relative to the conductive layer along the second kerf*.

327. For dependent claims 19-30 and 35-37, I have mapped the second kerf to element 114a. For dependent claims 32-34, I have mapped the second kerf to element 170a.

	“first kerf”	“second kerf”
Claims 19-30, 35-37	Element 170a	Element 114a
Claims 32-34	Element 114a	Element 170a

328. **Regarding the first mapping** for example, Edelbrock teaches making a plurality of laser cuts 114 a-c (*forming a second kerf* shown in blue in Figure 3 below) to begin “the process of defining the plurality of conductive leads in the conductive area 120” indicating that the second kerfs are formed in the *conductive layer*. EX1032-Edelbrock, [0039].



EX1032-Edelbrock, FIG. 3.

329. Edelbrock also teaches that the cuts 114a-c are made in the conductive layer using “direct writing of the lines.” EX1032-Edelbrock, [0041]. Edelbrock explains that:

According to another method, the plurality of electrodes on the base-ribbon strip 110 is partially formed with a laser using **direct writing of the lines**. As discussed above, the plurality of electrodes is not fully defined until the base-ribbon strip is attached to a second layer so as to define a reaction zone. In a method using a laser with direct writing of the lines, **a laser beam of light is moved so as to partially define the plurality of electrodes**. Lasers that produce a beam of energy capable of removing a layer and

that can be moved to form a pattern may be used in this method. Non-limiting examples of such lasers are **carbon dioxide-based lasers** and yttrium-based lasers such as yttrium aluminum garnet (YAG) lasers.

EX1032-Edelbrock, [0041].

330. Angell's CO₂ laser is used to form Edelbrock's second kerfs 114a-c is a *focused laser beam* because Angell teaches that the laser produces a focused "spot size," which a person of ordinary skill in the art would understand to be a focused laser beam. EX1034-Angell, 66. Therefore, the combination of Edelbrock, Boogaard, and Angell teaches *wherein the second kerf is formed using a second focused laser beam moved relative to the conductive layer along the second kerf*.

331. Lastly, Edelbrock teaches that "the laser used in forming the laser cuts 170 a-c and 114 a-c **may be different**." EX1032-Edelbrock, [0046]. And the combination of Edelbrock, Boogaard, and Angell includes the use of different lasers—the first laser is Boogaard's Nd:YAG laser and the second laser is Angell's CO₂ laser. Section X.B.3 (The Edelbrock, Boogaard, Angell Combination). Therefore, the combination of Edelbrock, Boogaard, and Angell teaches *the first laser beam being different to the second laser beam*.

332. **Regarding the second mapping** for example, the second kerf may be selected as one of laser cuts 170a-c, and the first kerf may be selected as one of laser

cuts 114a-c. EX1032-Edelbrock, [0039]. As I explained, Element 18[b]’s *first kerf* and *first focused laser beam* are interchangeable with Element 18[c]’s *second kerf* and *second focused laser beam* without any change in the scope of the claims. Accordingly, selecting one of cuts 114a-c, which are formed by a CO₂ laser as taught by Angell (described in Section X.B.18.(c) (Element 18[b])) also meets the requirements of Element 18[c] *wherein the second kerf is formed using a second focused laser beam moved relative to the conductive layer along the second kerf*.

(e) Element 18[d]: “separating one or more test strips from the reel using a singulation process.”

333. Edelbrock teaches this limitation. For example, Edelbrock’s method explains that after the manufacturing steps described above are completed, “a mechanical punch is used to excise a plurality of test sensors in the sensor-ribbon strip....” EX1032-Edelbrock, [0052]. Edelbrock’s use of a mechanical punch is a “singulation process;” in fact, the ’981 patent teaches that “the separation process may include stamping or ‘punching out’ of individual test cards in a ‘singulation’ process.” EX1001-’981, 12:59-61.

19. Dependent Claim 19

- (a) “The method of claim 18, wherein the singulation process includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.”**

334. Claim 19 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

335. Edelbrock teaches the additional requirement of Claim 19. For example, Edelbrock’s method explains that after the manufacturing steps described above are completed, “a mechanical punch is used to excise a plurality of test sensors in the sensor-ribbon strip....” EX1032-Edelbrock, [0052]. Edelbrock’s use of a mechanical punch is a form of stamping.

20. Dependent Claim 20

- (a) “The method of claim 18, 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.”**

336. Claim 20 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

337. As I show below, following the preamble, the remainder of Claim 20 is substantively the same as Claim 5:

Claim 20	Claim 5
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first laser beam has a first beam width	first processing source includes a first laser configured to emit a first ablative beam width
second laser beam has a second beam width	second processing source includes a second laser configured to emit a second ablative beam width

338. Therefore, it is my conclusion that the combination of Edelbrock, Boogaard, and Angell makes Claim 20 obvious for the same reasons I explained with respect to Claim 5. *See* Section X.B.7 (claim 5).

21. Dependent Claim 21

(a) “The method of claim 20, wherein the first beam width is at least approximately 20 micro-meters.”

339. Claim 21 depends from claim 20. Therefore, I incorporate by reference my discussion of claim 20.

340. As I show below, following the preamble, the remainder of Claim 21 is substantively the same as Claim 6:

Claim 21	Claim 6
first beam width	first ablative beam width

341. Therefore, it is my conclusion that the combination of Edelbrock, Boogaard, and Angell makes Claim 21 obvious for the same reasons I explained with respect to Claim 6. *See* Section X.B.8 (Claim 6).

22. Dependent Claim 22

(a) “The method of claim 20, wherein the second beam width is at least approximately 100 micro-meters.”

342. Claim 22 depends from claim 20. Therefore, I incorporate by reference my discussion of claim 20.

343. As I show below, following the preamble, the remainder of Claim 22 is substantively the same as Claim 7:

Claim 22	Claim 7
second beam width	second ablative beam width

344. Therefore, it is my conclusion that the combination of Edelbrock, Boogaard, and Angell makes Claim 22 obvious for the same reasons I explained with respect to Claim 7. *See* Section X.B.9 (Claim 7).

23. Dependent Claim 23

- (a) “The method of claim 18, wherein at least one laser beam removes substantially all conductive material between adjacent conductive components.”**

345. Claim 23 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

346. As I show below, following the preamble, the remainder of Claim 23 is substantively the same as Claim 8:

Claim 23	Claim 8
at least one laser beam removes substantially all conductive material between adjacent conductive components	wherein substantially all of the conductive material between adjacent conductive components is removed

347. Therefore, it is my conclusion that the combination of Edelbrock, Boogaard, and Angell makes Claim 23 obvious for the same reasons I explained with respect to Claim 8. *See* Section X.B.10 (Claim 8).

24. Dependent Claim 24

- (a) **“The method of claim 18, 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.”**

348. Claim 24 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

349. The combination of Edelbrock, Boogaard, and Angell teaches the additional requirements of Claim 24. The Nd:YAG laser (*first laser*) emits a first laser beam and is a different type of laser than the CO₂ laser (*second laser*), which emits a second laser beam, as claimed. *See* Section X.B.3 (The Edelbrock, Boogaard, Angell Combination); Section X.B.18.(c) (Element 18[b]), Section X.B.18.(d) (Element 18[c]).

25. Dependent Claim 25

- (a) **“The method of claim 24, 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.”**

350. Claim 25 depends from claim 24. Therefore, I incorporate by reference my discussion of claim 24.

351. The combination of Edelbrock, Boogaard, and Angell teaches the additional requirements of Claim 25. The Nd:YAG laser (*first laser*) is a solid-state

laser. EX1070-Tiffany, 28 (describing the Nd:YAG as a solid-state laser product). The CO₂ laser (*second laser*) is a carbon dioxide laser and is therefore a different type of laser than the first laser. See Section X.B.3 (The Edelbrock, Boogaard, Angell Combination); Section X.B.18.(d) (Element 18[c]).

352. Additionally, following the preamble, the remainder of Claim 25 is identical to Claim 10. Therefore, the combination of Edelbrock, Boogaard, and Angell makes Claim 25 obvious by for the reasons I explained for Claim 10.

26. Dependent Claim 26

- (a) “The method of claim 24, 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.”**

353. Claim 26 depends from claim 24. Therefore, I incorporate by reference my discussion of claim 24.

354. The combination of Edelbrock, Boogaard, and Angell teaches the additional requirements of Claim 24. The Nd:YAG laser is the *first laser*. See Section X.B.3 (The Edelbrock, Boogaard, Angell Combination); Section X.B.18.(c) (Element 18[b]). An Nd:YAG laser operates in the *infrared region* (1000-10,000 nm). EX1035-Boogaard, 48.

355. Additionally, following the preamble, the remainder of Claim 26 is identical to Claim 11. Therefore, the combination of Edelbrock, Boogaard, and Angell makes Claim 26 obvious by for the reasons I explained for Claim 11.

27. Dependent Claim 27

- (a) **“The method of claim 18, 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.”**

356. Claim 27 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

357. The combination of Edelbrock, Boogaard, and Angell makes the additional requirements of Claim 27 obvious. The Nd:YAG laser is the *first laser* and the CO₂ laser is the *second laser*. See Section X.B.3 (The Edelbrock, Boogaard, Angell Combination). A Nd:YAG laser is intended to be operated at a lower power level than a CO₂ laser, indicating that the power levels of the two lasers are not the same. Indeed, Boogaard teaches that the Nd:YAG is a medium-powered laser and provides an example of the laser operating at 800mWatts (0.8 Watts). EX1035-Boogaard, 48. Angell, on the other hand, states that the CO₂ beam has a “maximum average power output of...50 to 250 Watts.” EX1034-Angell, 66.

358. Additionally, following the preamble, the remainder of Claim 27 is substantively the same as Claim 12:

Claim 27	Claim 12
first laser beam is emitted from a first laser	first processing source includes a first laser
second laser beam is emitted from a second laser	second processing source includes a second laser

359. Therefore, it is my conclusion that the combination of Edelbrock, Boogaard, and Angell makes Claim 27 obvious for the same reasons I explained with respect to Claim 12. *See* Section X.B.14 (Claim 12).

28. Dependent Claim 28

- (a) **“The method of claim 27, wherein the first or second laser power is in the range of about 10 to about 100 watts.”**

360. Claim 28 depends from claim 27. Therefore, I incorporate by reference my discussion of claim 27.

361. The combination of Edelbrock, Boogaard, and Angell makes the additional requirements of Claim 28 obvious. The *second laser beam* in the

combination of Edelbrock, Boogaard, and Angell is the CO₂ laser, which is configured to operate with power (50 Watts) that is in the range of about 10 to about 100 watts, rendering Claim 28 obvious. EX1034-Angell, 66 (CO₂ beam has a “maximum average power output of...**50 to 250 Watts**”). The '981 patent admits that the laser power of a CO₂ laser is “usually in range about 10-100 watts.” EX1001-'981, 9:32-43.

362. Additionally, following the preamble, the remainder of Claim 28 is identical to Claim 13. Therefore, it is my conclusion that the combination of Edelbrock, Boogaard, and Angell renders Claim 28 for the reasons explained for Claim 13. *See* Section X.B.15 (Claim 13).

29. Dependent Claim 29

(a) “The method of claim 18, further including the step of contacting at least part of the conductive layer with at least one chemical component.”

363. Claim 29 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

364. Following the preamble, the remainder of Claim 29 is substantively the same as Claim 15:

Claim 29	Claim 15
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at least part of the conductive layer	the first conductive component
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365. Therefore, it is my conclusion that the combination of Edelbrock, Boogaard, and Angell makes Claim 29 obvious for the same reasons I explained with respect to Claim 15. *See* Section X.B.16 (Claim 15).

30. Dependent Claim 30

- (a) **“The method of claim 29, 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.”**

366. Claim 30 depends from claim 29. Therefore, I incorporate by reference my discussion of claim 29.

367. Following the preamble, the remainder of Claim 30 is identical to Claim 16. Therefore, the combination of Edelbrock, Boogaard, and Angell makes Claim 30 obvious for the reasons explained for Claim 16.

31. Dependent Claim 32

- (a) **“The method of claim 18, further including application of a spacer layer to the conductive layer or the base layer.”**

368. Claim 32 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18.

369. Edelbrock teaches the additional requirements of Claim 32. As I explained earlier, for dependent claims 32-34, I have mapped the first kerf to element 114a and the second kerf to element 170a.

Claims	“first kerf” mapping
Claims 19-30, 35-37	Element 170a
Claims 32-34	Element 114a

370. Edelbrock teaches the application of a spacer (*spacer layer*) to a base (*base layer*). For example, Edelbrock’s method includes **“attaching the base to a second layer”** (EX1032-Edelbrock, Claim 1, Claim 16) **“wherein the second layer is a spacer.”** EX1032-Edelbrock, Claim 8, Claim 18, [0043] (“second layer may be a spacer-ribbon strip such as shown in FIGS. 7-9”), [0054]-[0056], [0030], FIGS. 7a-b, 8, 9a-b, [0065], [0066], [0081], [0082].

371. For example, Edelbrock describes an “Alternative Process A”:

[0057] A method of forming an electrochemical multilayer test sensor, the multilayer test sensor including a base, a second layer and a reactive layer, the reactive area including an enzyme, the test sensor being adapted to be used in a meter and assist in determining the concentration of an analyte, the method comprising the acts of:

[0058] partially defining a plurality of electrodes and their respective conductive leads on the base;

[0059] after partially defining the plurality of electrodes and their respective conductive leads on the base, attaching the base to a second layer to define a reaction zone in which the plurality of electrodes are fully defined; and

[0060] **after attaching the base to the second layer**, fully defining the plurality of conductive leads on the base of the test sensor.

372. Edelbrock also explains regarding the second layer:

After partially defining the plurality of electrodes, the base-ribbon strip 110 is attached to a second layer. In one embodiment, the base-ribbon strip 110 is attached to a lid-ribbon strip 160 to form a sensor-ribbon strip 100 such as shown in FIG. 4 a. After attachment of the base-ribbon strip 110 and the lid-ribbon strip 160 so as to define a reaction zone, the plurality of electrodes is fully defined. It is contemplated that the second layer may be a spacer-ribbon strip such as shown in FIGS. 7-9. According to another embodiment, the second layer may be a spacer-lid ribbon strip combination in which the spacer-ribbon strip and lid-ribbon strip have been previously attached before the spacer-lid ribbon strip combination is later attached to the base-ribbon strip.

32. Dependent Claim 33

(a) “The method of claim 32, wherein the second kerf is formed after application of the spacer layer.”

373. Claim 33 depends from claim 32. Therefore, I incorporate by reference my discussion of claim 32.

374. Edelbrock teaches the additional requirements of Claim 33. As I explained earlier, for dependent claims 32-34, I have mapped the first kerf to element 114a and the second kerf to element 170a.

Claims	“first kerf” mapping
Claims 19-30, 35-37	Element 170a
Claims 32-34	Element 114a

375. Therefore, the *second kerf* is mapped to element 170a for purposes of claim 33 (and claim 32, from which claim 33 depends). Edelbrock’s second set of “cuts 170 a-c are formed **after** the lid-ribbon strip 160, **the spacer-ribbon strip 305** and the base-ribbon strip 175 **are attached**.” EX1032-Edelbrock, [0056]. Therefore, Edelbrock teaches that the element 170a used to form test sensors (*second kerf*) is formed after the spacer-ribbon strip 305 (*spacer layer*) is attached. EX1032-Edelbrock, [0037]; [0046]; FIGs. 4, 6, 8, Claim 1.

33. Dependent Claim 34

(a) “The method of claim 32, further including application of a cover to the spacer layer.”

376. Claim 34 depends from claim 32. Therefore, I incorporate by reference my discussion of claim 32.

377. Edelbrock teaches the additional requirements of Claim 34. As I explained earlier, for dependent claims 32-34, I have mapped the first kerf to element 114a and the second kerf to element 170a.

Claims	“first kerf” mapping
Claims 19-30, 35-37	Element 170a
Claims 32-34	Element 114a

378. Edelbrock discloses the application of a lid (*cover*) to a spacer ribbon strip (*spacer layer*) to form a spacer-lid ribbon strip that is then attached to the base. For example, Edelbrock states that “the second layer may be a **spacer-lid ribbon strip combination** in which the spacer-ribbon strip and lid-ribbon strip have been **previously attached** [application] before the spacer-lid ribbon strip combination is later attached to the base-ribbon strip.” EX1032-Edelbrock, [0043]; *see also* EX1032-Edelbrock, [0044]. Edelbrock’s lid-ribbon strip is a “cover to the spacer

layer” because Edelbrock’s spacer-ribbon strip is sandwiched between the base-ribbon strip and the lid-ribbon strip. Indeed, Edelbrock states that “only a small portion of the spacer-ribbon strip 305 is visible through the aperture 155 of the lid-ribbon strip 160.” EX1032-Edelbrock, [0056].

C. GROUND III: Claims 35-37 Are Obvious In View of the Combination of Edelbrock, Boogaard, Angell, and Bhullar

1. Overview of Edelbrock, Boogaard, Angell, and Bhullar

379. I summarized Edelbrock in Section X.B.1 (Overview of Edelbrock).

380. I summarized Boogaard in Section X.A.2 (Overview of Boogaard).

381. I summarized Angell in Section X.A.3 (Overview of Angell).

382. I summarized Bhullar in Section X.A.1 (Overview of Bhullar).

2. The Edelbrock, Boogaard, Angell, and Bhullar Combination

383. A person of ordinary skill in the art would have been motivated, with a reasonable expectation of success, to combine Edelbrock, Boogaard, and Angell for the reasons I explained in Section X.B.3 (The Edelbrock, Boogaard, Angell Combination). Additionally, a person of ordinary skill in the art would have been further motivated to incorporate teachings from Bhullar, with a reasonable expectation of success, to form the combination of Edelbrock, Boogaard, Angell, and Bhullar.

384. As I previously explained, Edelbrock and Bhullar are from the same field of endeavor (manufacturing glucose test strips using micromachining). Indeed, Edelbrock, Boogaard, Angell, and Bhullar are all directed to techniques for micromachining using laser ablation. *See* Section X.B.1 (Overview of Edelbrock); Section X.A.2 (Overview of Boogaard); Section X.A.3 (Overview of Angell); Section X.A.1 (Overview of Bhullar). Furthermore, a person of ordinary skill in the art would have considered Boogaard and Angell to be pertinent prior art to teach laser ablation techniques that were applicable to the methods of Edelbrock and Bhullar. *See* Section X.A.2 (Overview of Boogaard); Section X.A.3 (Overview of Angell).

385. In addition, a person of ordinary skill in the art would have been motivated to incorporate Bhullar's teaching of creating a code on the test strip. Bhullar explains that it was well-known to include a code on a test strip so that the manufacturer can identify the manufacturing batch and cites background art for this teaching. EX1007-Bhullar, [0002]. For example, Bhullar cites Heinonen (WO 99/22236) (EX1007-Bhullar, [0002]) which describes a "system for measuring the blood glucose level in a sample of a patient's blood" where the "test strips (5) are provided with a code (7) which identifies the manufacturing batch of the strip (5)."

EX1078-Heinonen, Abstract. Heinonen explains the need to identify test strips correctly to make sure that the strip is calibrated with the measurement device:

It will be appreciated that in the case of a blood glucose meter, **where a patient determines an insulin treatment regime on the basis of blood glucose measurements, the accuracy of the meter is critical. This requires very precise calibration of the meter.** Initial calibration of the meter is normally carried out during and immediately following manufacturing, with certain calibration data being stored in permanent memory of the meter. However, calibration of the meter at this stage cannot easily account for changes and variations in the properties of the consumable reagents themselves, variations which might arise due to slight changes in the manufacturing process of the reagent and the test strip, environmental factors such as temperature and humidity, and changes in the property of the reagent over time.

It is known to provide blood glucose test strips, or rather a pack of such test strips, with a machine readable memory in which calibration data is stored. When a new pack of test strips is opened, the machine readable memory is read by the meter and calibration data downloaded into the memory of the blood glucose meter. In this way it is possible to take account of reagent manufacturing variations in the calibration of the meter. However, it will be appreciated that providing a machine readable memory with each packet of test strips is relatively expensive both in terms of the hardware required and in terms of the additional time required to program the memory during the manufacturing process. In addition, it remains difficult to account for changes in the properties of a reagent over time. At best, only a poor estimate can be made based upon some predetermined criteria and only then if the age of the reagent is known. As such, manufacturers of blood

glucose test strips tend to supply test strips in very limited numbers and make tight specifications for storage and lifetime to ensure that the properties of the reagents remain within desired limits. These specifications tend to work against economies of scale in the manufacturing and distribution of test strips.

EX1078-Heinonen, 1:7-2:7. Heinonen offered the solution to this problem by including an “identification code” which “may be contained in a bar-code or in a solid state memory.” EX1078-2:20-23.

386. Bhullar further explains the process of implementing a code pattern and its advantages in manufacturing:

[0022] In addition, as shown in FIGS. 1, 2, and 4, the discernible code pattern 40 is formed from the electrical conductor 13 by laser ablation using techniques as described above with reference to electrodes 14, 16. Specifically, the code pattern 40 is created by removing the electrical conductor 13 in a pre-defined pattern to expose the first surface 22 of the support substrate 12. While pattern 40 is illustratively a barcode type pattern, it is appreciated that the pattern 40 can take on any number of shapes and patterns, non-limiting examples of which are shown in FIGS. 5 and 6.

[0023] It is also appreciated that the pattern 40 can be provided in a human readable, optical readable, or electrical readable form in accordance with this disclosure. The structures could show contrast in their optical reflectivity, their electrical conductivity, or their resistivity respectively. To aid in contrasting the electrical conductivity of the code pattern 40, the electrical conductor 13 of the pattern 40 may be coated with a

second conductive material (not shown) that is different from the electrical conductor 13. Non-limiting examples of the second conductive material include carbon and silver. It is appreciated, however, that a wide variety of materials may be coated on the electrical conductor 13 to change the electrical property of the code pattern 40.

[0024] It is also appreciated; electrodes 14, 16 could be formed from layers of electrically conductive materials having different colors, reflectivity, conductance, etc. Thus, the code pattern can be formed by removing a portion of the electrical conductor layers, leaving behind areas of high reflectivity surrounded by low reflectivity areas or vice versa, areas of high electrical conductivity surrounded by areas of low conductivity or vice versa. It is also possible to laser etch a code pattern that has a known resistance and this area can be read electrochemically to identify or recognize the code pattern. Moreover, it is appreciated that the code pattern can be a combination of any of the above readable forms in accordance with the present invention.

[0025] As shown in FIG. 4, the code pattern 40 is isolated from the rest of the electrically conductive material 13 on substrate 12 by gaps 42. Gaps 42 can have a wide variety of widths in accordance with this disclosure depending upon the specific use of the code pattern 40. Non-limiting examples of widths of the gaps include from about 1 μm to about 1000 μm . Alternatively, it is appreciated that the code pattern 40 may be created by laser ablation alone on substrate 12. It is appreciated that while laser ablation is the preferred method for forming the code pattern 40 given its precision and sensitivity, other techniques such as lamination, screen-printing, or photolithography may be used in accordance with this disclosure.

[0026] The manufacturer of biosensor 10 may maintain a central database containing a set of code

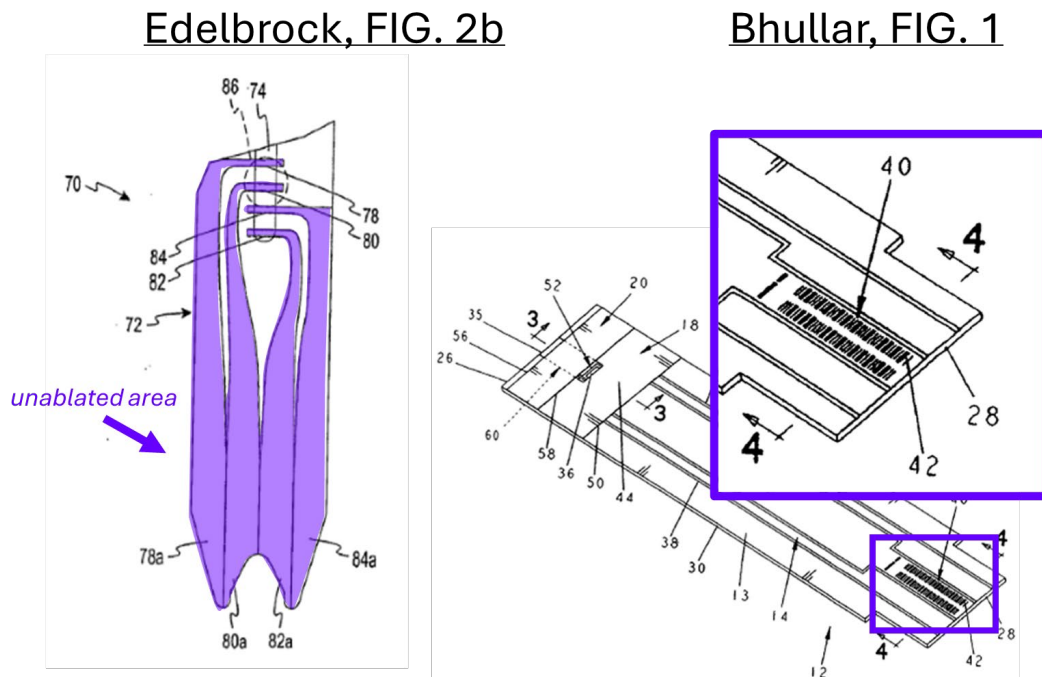
patterns, each of which uniquely identifies an individual biosensor, or batch of biosensors. There may also be associated with each code pattern a set of calibration data for the biosensor **10**. It is appreciated that the code patterns may be associated with any number of identification or data sets in accordance with the present invention.

EX1007-Bhullar, [0022]-[0026].

387. Therefore, although Edelbrock does not explicitly call for the addition of a code to its test sensor, a person of ordinary skill in the art would have been motivated to incorporate such a technique in order to track manufacturing batches of the test sensors, and would have looked to relevant teachings in the art. Bhullar provides extensive teachings regarding various laser ablation techniques to create a code in a biosensor which are consistent with the manufacturing techniques employed by Edelbrock. EX1007-Bhullar, [0016], [0018]-[0021], [0043]-[0047].

388. In addition, a person of ordinary skill in the art looking to implement Bhullar's code would have recognized that Edelbrock's test strip has a large unablated area that would be available to be used to form Bhullar's code. Therefore, implementing the teaching of Bhullar's code on Edelbrock's test sensor would have merely amounted to applying a known technique to a known method ready for improvement to yield predictable results.

389. Additionally, a person of ordinary skill in the art would have had a reasonable expectation of success and would have succeeded in manufacturing Bhullar's teaching of a code feature in Edelbrock's test sensor. As I explained previously, both Edelbrock and Bhullar utilize laser ablation techniques that can be implemented using Boogaard's and Angell's lasers. In addition, Edelbrock's unutilized areas (shown below in purple) provided enough unused space to manufacture a code pattern as taught by Bhullar's (e.g., code pattern 40 shown below in purple).



EX1032-Edelbrock, FIG. 2b; EX1007-Bhullar, FIG. 1

390. Bhullar also discusses the use of a meter that can read the etched code. EX1007-Bhullar, [0040]-[0041].

391. It therefore would have been obvious for a person of ordinary skill in the art to combine the teachings of Bhullar in the combination of Edelbrock, Boogaard, and Angell to include a code for a test sensor code.

3. Claim 35

- (a) The method of claim 18, wherein the conductive layer is formed using a technique selected from the group consisting of direct writing, sputtering, screen printing, contract printing, and lamination.**

392. Claim 35 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18 in Ground II.

393. Bhullar teaches the additional requirements of Claim 35. For example, App. No. 09/411,940, which is incorporated by reference in Bhullar,⁴ discloses screen printing for forming large conductive layers. EX1063-Bhullar'940, 1:23-31; *see also* EX1067-Vitriol, 215-220. *See also* Section X.C.2 (The Edelbrock, Boogaard, Angell, Bhullar Combination).

⁴ EX1007-Bhullar, [0019] (incorporating App. No. 09/411,940 by reference).

4. Claim 36

- (a) The method of claim 18, further including the step of applying to the conductive layer at least one of a second conductive layer and a semi-conductive layer.**

394. Claim 36 depends from claim 18. Therefore, I incorporate by reference my discussion of claim 18 in Ground II.

395. Bhullar teaches the additional requirements of Claim 36. Bhullar teaches applying to the electrical conductor 13 (*conductive layer*) a conductive material (*second conductive layer*) in order to create a discernible code pattern that has contrasting structures to ensure readability of the code. EX1007-Bhullar, [0023]. For example, Bhullar states that “[t]o aid in contrasting the electrical conductivity of the code pattern 40, the electrical conductor 13 of the pattern 40 may be coated **with a second conductive material** (not shown) **that is different from the electrical conductor 13.**” EX1007-Bhullar, [0023]; see also EX1007-Bhullar, [0015].

396. A person of ordinary skill in the art would have incorporated this teaching of Bhullar specifically for purposes of implementing Bhullar’s code pattern, which would have been a predictable and desired feature for the same reasons given in Section X.C.2 (The Edelbrock, Boogaard, Angell, Bhullar Combination).

5. Claim 37

- (a) The method of claim 36, wherein the second kerf is formed after application of at least one of the second conductive layer and the semi-conductive layer.**

397. Claim 37 depends from claim 36. Therefore, I incorporate by reference my discussion of claim 36.

398. Bhullar makes the additional requirements of Claim 37 obvious. Bhullar does not expressly disclose forming the recess 35 (*second kerf*) after application of the second conductive material (*second conductive layer*), but it would have been obvious to try this. As I explained above, Edelbrock's test strip has a large unablated area where adding a code would not interfere with adding the second kerf. Therefore, there is unobstructed access to the substrate area for forming the second kerf with the second laser beam. Additionally, the application of the second laser beam would not interfere with Bhullar's code (the second conductive material).

399. Therefore, a person of ordinary skill in the art would have found it obvious to try forming recess 35 (*second kerf*) after application of the *second conductive layer*. In particular, a person of ordinary skill in the art would have chosen from only two predictable options: (1) forming the recess ***before*** the application of the second conductive layer or (2) forming the recess ***after*** the application of the second conductive layer. Either would yield the predictable

solution of forming both Bhullar's code and defining the other conductive components on Edelbrock's test sensor because the second conductive layer would not obstruct the ability of the laser to form the recess. Thus, a person of ordinary skill in the art would have enjoyed a reasonable expectation of success for the same reasons given in Section X.C.2 (The Edelbrock, Boogaard, Angell, Bhullar Combination).

XI. AVAILABILITY FOR CROSS-EXAMINATION

400. In signing this Declaration, I recognize that the Declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

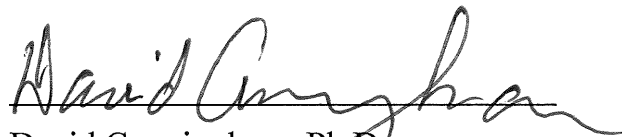
XII. RIGHT TO SUPPLEMENT

401. I reserve the right to supplement my opinions and conclusions to respond to any arguments that the Patent Owner raises, and to take into account new information as it becomes available to me.

XIII. JURAT

402. I 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.

Dated: March 6, 2025


David Cunningham, Ph.D.

APPENDIX A

DAVID D. CUNNINGHAM, Ph.D.

30 Meadow Lake Drive
Lancaster, KY 40444
224-321-3812

EXPERIENCE

SOUTHEAST MISSOURI STATE UNIVERSITY 2018-present

Associate Professor, Department of Chemistry and Physics

Supporting chemistry and forensic science degree options. Teaching undergraduate and graduate level lecture and laboratory courses.

UNIVERSITY OF KENTUCKY 2019-present

Adjunct Assistant Professor, College of Medicine, Department of Toxicology and Cancer Biology

Assisting with the design and launch of a Professional Master in Forensic Toxicology & Analytical Genetics Program.

HUNTER SCIENTIFIC SERVICES 2017-present

Principal

Providing scientific and technical consulting services to Life Science, Diagnostics and Medical Device companies.

EASTERN KENTUCKY UNIVERSITY, 2011-2018

Assistant Professor, Department of Chemistry

Supporting ACS and FEPAC accredited degree programs and member of the Graduate School Faculty. Teaching lecture and laboratory courses. Led numerous hands-on STEM-H activities for visiting students. Initiated research programs for undergraduate and Master's degree students.

- Developed upper level undergraduate and Master's degree courses including Bioanalytical Chemistry, Forensic Analytical Toxicology, Forensic Capstone and Drugs and Toxicology Lab. Designed new laboratory experiments for immunoassay, solid and liquid phase extraction, HPLC, GCMS and DART methods on solid dosage forms of drugs, plant material, blood, urine, saliva and gastric fluid. Teaching load varied between 9 and 12 hours each semester.
- Mentored 18 students during their first research experience. Projects included enzyme immobilization, enhancement of latent fingerprints and analysis of trace drugs by mass spectrometry.

ABBOTT LABORATORIES, ABBOTT PARK, ILLINOIS, 1989-2011

A diversified healthcare company

Program Manager and Associate Research Fellow, Diagnostics Division Operations, 2004-2011

Managed multiple, simultaneous projects in a matrixed environment involving trouble-shooting and lean manufacturing process improvements on 40+ assays across multiple hardware platforms (IMx, AxSYM, PRISM, Architect immunoassay systems and PlexID for nucleic acids). Provided leadership in the areas of purification and analysis of proteins, conjugation, microparticle coating, scale-up for manufacturing, and reagent-system integration. Minimized supply chain disruptions and back-orders while adhering to stringent operating and inspection requirements mandated by Abbott's 1999 Consent Decree with the FDA.

- Purified a human virus in a biosafety level 3 manufacturing facility using two chromatographic modalities to compare yields and demonstrate feasibility at the 50-L scale.
- Established a correlation between microparticle synthetic conditions, physical-chemical properties and immunoassay performance, facilitating the launch of the PRISM system in 2005.
- Utilized instrumental and wet methods, including chromatographic techniques (HPLC, GPC, IEX, HIC), protein analysis, carbohydrate analysis, flow cytometry, light scattering, zeta potential and ELISA, to measure protein properties and trace level contaminants affecting immunoassay performance.
- Identified the causes of batch failures and implemented corrective actions (generally multiple batch failures of >\$25,000/batch, three to seven investigations/year).
- Scaled-down several unit process operations using engineering principles to reduce reagent usage and achieve the department budget (\$13 million / \$3 million operating expenses).

- Collaborated with product quality, medical affairs, and regulatory teams to address customer complaints.
- Directed an intense effort to complete over two man-years of work in two months to maintain inventory of Center for Biologics Evaluation and Research (CEBR) licensed hepatitis and retrovirus ELISA products.

Associate Research Fellow, Diagnostics Division Glucose Venture, 1996-2003

Managed exploratory glucose monitoring research projects with run rates up to \$150,000/mo. Designed initial integrated systems, led human clinical studies, and coordinated research efforts with outside partners. 15 US patents, Abbott Chairman's Award 1998, elected to Abbott's Volwiler Society 1998.

- Co-invented a virtually painless glucose monitoring system (Sof-Tact™) launched in 2000.
- Collected blood and interstitial fluid samples with innovative prototype devices in human clinical studies. Pioneered the field of transdermal microfluidics and characterized the role of skin anatomy and physiology on the volume of fluid extracted and wound healing.
- Designed a novel capillary fill glucose test strip, formulated stable dry reagents, and developed reagent coating methodologies. Transferred the design, reagents and coating procedure from a discreet format to a reel-to-reel system with a capacity in excess of one million strips per day.
- Completed technical assessments involving freedom to operate, patent mapping, review of scientific literature, and competitor tracking for 15 strategic initiatives and licensing opportunities.

Research Investigator, Hospital Products Division, 1991-1995

Developed and characterized wet and instrumental analytical methods for injectable drug products while supervising technicians. Selected drug vendors, developed product configurations, completed stability studies, wrote regulatory submission reports, and answered deficiency letters in collaboration with pharmacists. Conducted advanced research on new formulations and drug delivery systems. Three Abbott Chairman's Awards and Outstanding Researcher of the Year 1995.

- Started project and completed all analytical work for ten product configurations of cimetidine small and large volume parenterals, allowing product launch upon innovator patent expiration in 1994.
- Updated the biological heparin assay method and established formulation and manufacturing conditions for ten product configurations of Heparin in Dextrose in flexible containers launched in 1994.
- Developed and set up trace level analysis of degradation products of a volatile anesthesia agent in hospital clinics worldwide to address a key toxicity issue for the New Drug Application (Ultane™ / Sevoflurane, 2006 sales \$800 million).
- Utilized many HPLC separation techniques and detectors for method development and manufacturing equipment cleaning validations, including suppressed ion conductivity, triple detection (RI/light scattering/viscosity) for polymer analysis, amperometric detection, and electrospray-mass spec detection.
- Identified degradation products involved in two marketed product recalls and crafted appropriate responses.
- Discovered and implemented a lower cost manufacturing option for a small volume parenteral (maintained as a trade secret).
- Synthesized novel polymers and fabricated iontophoresis drug delivery electrodes.

Consultant, Abbott Laboratories, 1989-1991

Conducted technical studies of biosensor components. Integrated chemistry, material science and engineering into manufacturable designs. Showed biosensor functionality on physiological samples as part of an advanced peritoneal dialysis system. 3 US patents.

Senior Research Scientist, Universal Sensors, Inc., New Orleans, 1986-1989

Devised protein immobilization methods for enzyme- and antibody-based electrochemical sensors. Obtained external funding through major government research grants to grow a small company.

EDUCATION

Ph.D. Analytical Chemistry, University of Cincinnati
M.S. Analytical Chemistry, University of Cincinnati
B.S. Chemistry, Iowa State University

PROFESSIONAL AFFILIATIONS

Society for Electroanalytical Chemistry (Lifetime member); Board of Directors (2011-2016)
American Chemical Society 1982 – present
American Academy of Forensic Sciences 2014-2024
American Association of University Professors 2019-2022
Council of Forensic Science Educators 2013-2021
Kentucky Academy of Sciences 2011-2018
Electrochemical Society 1984 - 2013
Biomedical Engineering Society 2005 - 2007
American Association for Clinical Chemistry 1998-2004

SERVICE

University of Kentucky College of Medicine
External Advisory Board for the Forensic Toxicology and Analytical Genetics Master's degree program
(2021-present)

American Association of University Professors
Local Chapter Secretary-Treasurer 2019-2022

Southeast Missouri State University
University Committees
Johnson Faculty Center Governing Committee (2022-present)
College Committees
Graduate Programs (2018-2019)
Department Committees
Forensic Programs Committee (2018-present)
Safety Committee (2018-2024)
Scholarship and Awards Committee (2018-present; Chair 2020-present)
Geophysicist Search ad-hoc Committee (2019-2020)
Program Prioritization ad-hoc Committee (2020-2021)

Eastern Kentucky University
University Graduate Council 2012-2018
Faculty Senate 2016-2017
University Safety Committee –2016-2017
University Policy Drafting Committee – 2015-2016

American Chemical Society – Lexington Local Section President Elect - 2018

National Science Foundation Grant Review Panels and Program Reviews

- Engineering Research Center Site Review Feb 20, 27-28, March 1, 2023
- Engineering Research Center Site Review March 2 and 5-8, 2022
- Engineering Research Center Site Review March 2-4, 2021
- Engineering Research Center Site Review March 2-4, 2020
- Engineering Research Center Site Review May 14-17, 2018
- Industry/University Cooperative Research Center Reviews April 14, 2017
- Engineering Research Center Site Review May 15-17, 2017
- NanoBioSensing Panel A - Photonics and Bioelectronics January 5-6, 2015
- NanoBioSensing Panel B - Molecular Interface and Nanopores January 7-8 2015
- Optical Biosensing Panel November 14-15 2011
- Electrochemical Biosensing Panel November 28-29 2011
- Engineering Research Center Program on Nanosystems - December 2011
- Biosensing and Bioengineering Review Panel December 2010
- Generation 3 Engineering Research Center Panel, October 2009
- Biosensing and Bioengineering Review Panel, May 2009

National Institutes of Health Grant Review Panels in Bethesda MA (22 panels)

- National Institutes of Health, Bioengineering, Technology and Surgical Sciences Study Section, Temporary Member, 2004-2005, 2009, Member 2005-2007 (total of 12 two-day panels)
- National Institutes of Health, Surgery and Bioengineering Study Section, Temporary Member, 2002 -2003 (total of 6 two-day panels)
- National Institutes of Health, Islet Cell Biology Special Emphasis Panel, 2007
- National Institutes of Health, Insulin Release and Action Special Emphasis Panel, 2007
- National Institutes of Health, Endocrinology, Metabolism and Reproductive Sciences, Special Reviews Study Section, 2005
- National Institutes of Health, National Center for Complementary & Alternative Medicine, Special Emphasis Panel, 2005

Small Business Innovation Research (SBIR) program, ad hoc reviewer of grant applications.

Symposia / Workshops Organized (6)

- Biennial Conference on Chemical Education 2024. Co-organizer of a symposium "*Integrating Forensic Science Courses Into the Curriculum and Growing Forensic Science Programs*" Lexington KY.
- American Academy of Forensic Sciences 2014. Co-organizer of a workshop "*Effective Curricular Design and Improvement for Forensic Science Educational Programs*", Seattle WA.
- PittCon 2006, organizer of a symposium "*Nanohybrid Bioanalytical Systems*" Orlando, FL
- PittCon 2005, co-organizer of a symposium "*In Vivo Analytical Chemistry: From Glucose to 'Omics*" Orlando, FL.
- American Chemical Society 221st National Meeting 2001, co-organizer of a full day symposium "*Recent Advances in Microfluidics*" San Diego, CA.
- Electrochemical Society 197th Meeting 2000, co-organizer of a 2 day symposium "*Advances in Sensors for Diabetes Monitoring*" Toronto, Canada.

Editorial Advisory Board of the journal *Sensor Letters* 2003 - 2010

Scientific journals, ad hoc reviewer of manuscripts: *Forensic Chemistry*; *Science and Justice: Rapid Communications in Mass Spectrometry*; *Analytica Chimica Acta*; *Analytical Letters*; *Clinical Chemistry*;

Clinical Chemistry and Laboratory Medicine; Diabetes, Technology and Therapeutics; Journal of the Electrochemical Society; Sensor Letters; Talanta; Journal of Biomaterials Science; Cells, Tissues and Organs; and Lab on a Chip.

Kentucky Science and Engineering Fair Judge (2012-2018); Science Fair judge at middle and high schools

Career Day presentations on chemistry/forensic science at elementary, middle and high schools

Abbott Laboratories

Abbott Diagnostics New Technology Expert Panel 2009-2011

Abbott Global Engineering Forum, 1st Operating Chairman 2004-2005

Abbott Drug Delivery Exchange Committee 2000-2006

Abbott Diagnostics Division Technical Advisory Board 1997-1999

Abbott Corporate Technology Exchange Abstract Review Chairman 1997

Abbott Corporate Technology Exchange Abstract Review Chairman 1995

AWARDS

Provost's Award for Teaching Excellent in Teaching General Education, Southeast Missouri State University 2020

Teaching Award Nominations at Eastern Kentucky University

Critical Thinking Teachers of the Year 2013

Distinguished Educational Leader Award 2017

Abbott Diagnostics Division President's Award 2004

Inducted into the Volwiler Society, Associate Research Fellow 1998

Abbott Chairman's Award 1998

Abbott Chairman's Award 1996

Hospital Products Division: Outstanding Researcher of the Year 1995 (inaugural award)

Abbott Chairman's Award 1994

Abbott Chairman's Award 1993

PRINCIPAL INVESTIGATOR TRAINING

Abbott Laboratories Principal Investigator Training, April 30, 2001 (Qualifications to Lead Human Clinical Trials with Institutional Review Board Approval)

PUBLICATIONS

1. M. Friedel, I.A.P. Thompson, G. Kasting, R. Polsky, **D. Cunningham**, H.T. Soh, and J. Heikenfeld "Opportunities and challenges in the diagnostic utility of dermal interstitial fluid", *Nature Biomedical Engineering*, 2023, 7 1541-1555.
2. **D. Cunningham**, 2018, "Analysis of Trace Drugs of Abuse by Direct Analysis in Real Time (DART) Mass Spectrometry", In: *"Analysis of Drugs of Abuse"*, R. Musah, Springer.
3. C. Smith, M. Clements and **D. Cunningham** "Examining the Potential Interference of Lime for Distance Determinations", *Association of Firearms and Toolmark Examiners Journal*, 2016, **48** 7-14.
4. **D. Cunningham** and J. Jenkins, 2016, "Facilitating Self Reflection as a Metacognitive Tool", In: *It Works for Me, Metacognitively: Shared Tips for Effective Teaching*, H. Blythe, C. Sweet, R. Carpenter, New Forums Press, 74-77. ISBN: 1-58107-293-7

5. **D. Cunningham**, 2015, "Blood Glucose Monitoring" In: *"The Biomedical Engineering Handbook, Fourth Edition: Medical Devices and Human Engineering"*, J. Bronzino and D. Peterson, CRC Press, 23-1 to 23-13.
6. **D. Cunningham**, 2013, "Human Body to Device Biofluid Transfer", In: *Encyclopedia of Microfluidics and Nanofluidic*, D. Li, Springer, 1-12, DOI 10.1007/978-3-642-27758-0_1775-1
7. **D. Cunningham**, 2010, "Transdermal Microfluidic Continuous Monitoring", In: *In Vivo Glucose Sensing*, D. Cunningham and J. Stenken, John Wiley & Sons, 191-216.
8. T. Henning, W. King and **D. Cunningham**, 2006, "Technology Assessment of Medical Devices" In: *Wiley Encyclopedia of Biomedical Engineering*, M. Akay, John Wiley & Sons, 1-15, DOI: 10.1002/9780471740360.ebs1175
9. **D. Cunningham**, 2006, "Blood Glucose Monitoring" In: *"The Biomedical Engineering Handbook, Third Edition: Medical Devices and Systems"*, J. Bronzino, CRC Press, 66-1 to 66-10.
10. **D. Cunningham** "Construction of a Potentiometric Biosensor for Monitoring Urea During Peritoneal Dialysis", *Sensor Letters*, 2004, **2** 1-4.
11. **D. Cunningham** and M. Lowery "Moisture Vapor Transport Channels for the Improved Attachment of Medical Devices to the Human Body", *Biomedical Microdevices*, 2004, **6** 149-154.
12. **D. Cunningham** and D. Young "Measurements of Glucose on the Skin Surface, in Stratum Corneum and in Transcutaneous Extracts: Implications for Physiological Sampling", *Clinical Chemistry and Laboratory Medicine*, 2003, **41** 1224-1228.
13. **D. Cunningham** "Integration of Compressed and Composite Immobilized Enzyme Membranes into an Injection Molded Pin Format by Ultrasonic Welding", *Sensors and Actuators B*, 2002, **87** 371-378.
14. **D. Cunningham**, T. Henning, E. Shain, J. Hanning, E. Barua and R. Lee "Blood Extraction from Lancing Wounds Using Vacuum Combined with Skin Stretching", *Journal of Applied Physiology*, 2002, **92** 1089-1096.
15. **D. Cunningham** "Fluidics and Sample Handling in Clinical Chemical Analysis", *Analytica Chimica Acta*, 2001, **429** 1-18.
16. **D. Cunningham**, T. Henning, E. Shain, D. Young, T. Elstrom, E. Taylor, S. Schroder, P. Gatcomb, and W. Tamborlane "Vacuum-Assisted Lancing of the Forearm: An effective and less painful approach to blood glucose monitoring". *Diabetes Technology & Therapeutics*, 2000, **2** 541-548.
17. **D. Cunningham**, T. Henning, D. Young, and E. Berardesca "Wound Healing After Lancing the Skin", *Wounds: A Compendium of Clinical and Research Practice*, 2000, **12** 131-137.
18. **D. Cunningham** and T. Henning 1998 "Biosensors for Personal Diabetes Management" In: *Commercial Biosensors: Applications to Clinical, Bioprocess and Environmental Samples*, G. Ramsay, ef, 3-46.
19. H. Schmidt, H. Hofmann, U. Schindler, Z. Shutenko, **D. Cunningham**, and M. Feelisch "No Nitric Oxide from Nitric Oxide Synthase", *Proceedings of the National Academy of Sciences*, 1996, **93** 14492-14497.
20. **D. Cunningham**, S. Huang, J. Webster, J. Mayoral and R.W. Grabenkort "Sevoflurane Degradation to Compound A in Anesthesia Breathing Systems", *British Journal of Anaesthesia*, 1996, **77** 537-543.
21. **D. Cunningham**, J. Webster, D. Nelson, and B. Williamson "Analysis of Sevoflurane Degradation Products in Vapor-Phase Samples", *Journal of Chromatography B: Biomedical Applications*, 1995, **668** 41-52.
22. **D. Cunningham**, and D. Stephens "Analysis of the Enantiomeric Purity of Lactate with an Enzyme Electrode", *Analytical Letters*, 1992, **25** 1813-1821.
23. R. Villarta, **D. Cunningham**, and G. Guilbault "Immobilized Enzyme Electrodes for the Determination of Glutamate", *Talanta*, 1990, **38** 49-55.
24. C. Pham, A. Burkhardt, R. Shabana, **D. Cunningham**, H. Mark and H. Zimmer. "A Convenient Synthesis of 2,5-Thienylene Oligomers: Some of their Spectroscopic and Electrochemical Properties", *Phosphorous, Sulfur, and Silicon*, 1989, **46** 153-168.
25. H. Zimmer, and H. Mark "The Spectroelectrochemical Determination of 'Formal Potentials and n-values' of Some Electrochemically-Formed Conducting Polyheterolene Films", *Journal of the Electrochemical Society*, 1988, **135** 2750-2754.
26. **D. Cunningham**, L. Laguren-Davidson, H. Mark, C. Pham, and H. Zimmer "Synthesis of Oligomeric 2,5-Thienylenes; Their UV-Spectra and Oxidation Potentials", *Journal of the Chemical Society Chemical Communication*, 1021-1023 (1987).
27. A. Czerwinski, **D. Cunningham**, H. Zimmer, A. Amer, C. Pham, H. Mark and B. Pons. "The Electrochemical Behavior in Aqueous Media of Conducting Polymers (II): The Insoluble Fractions Obtained on the Cu(II) Catalyzed Polymerization of 2,5-Dibromo-3-"group IV"-Substituted Thiophenes; Substituent Effects", *Journal of the Electrochemical Society*, 1987, **134** 1158-1164.

28. A. Czerwinski, C. Pham, **D. Cunningham**, L. Laguren-Davidson, H. Zimmer, and H. Mark "The Charge-Discharge Properties of a Cu(II)-Poly(thienylene) Cell in Aqueous Media", *Journal of the Electrochemical Society*, 1986, **133** 576-578.
29. Ph.D. Dissertation: "Conducting Polymers: Electrochemical Studies of Polysulfur Nitride, o-Diaminobenzene, Thiophenes, and Polyheterolenes" University of Cincinnati (1987).

PAPERS and INVITED LECTURES

1. "Challenges and Opportunities Facing a Forensic Science Program at a Regional University" **D. Cunningham** and J. McGill, Biennial Conference on Chemical Education Lexington KY, July 2024.
2. "Forensic Projects: Rapid Measurement of Drugs and Enhancement of Latent Fingerprints" **D. Cunningham**, University of Arkansas Fort Smith, May 20, 2018.
3. "Lab Quality Testing Outside the Lab" **D. Cunningham**, University of Arkansas, May 19, 2018.
4. "Rapid and Reliable Testing" **D. Cunningham**, Southeast Missouri State University, May 12, 2018.
5. "Test Anywhere: Measurement of Glucose, Cocaine, Fingerprints and the Shirt off your Back" **D. Cunningham**, University of Northern Colorado, February 23, 2018.
6. "Direct Analysis in Real-Time (DART) Mass Spectrometry and Analysis of Controlled Substances" **D. Cunningham** and S. Josselyn, 46th Midwestern Association of Forensic Scientists, Cincinnati, September 22, 2017.
7. "Recent Advances in the Commercialization of Biosensors" **D. Cunningham**, Department of Electrical and Computer Engineering, Florida International University, September 1, 2017.
8. "Research Efforts on Fingerprints, Trace Drug Analysis and Wearable Biosensors" **D. Cunningham**, Department of Chemistry, Western Carolina University, March 24, 2017.
9. "Progress towards Enhancement of Latent Fingerprints on Metal Surfaces such as Cartridge Casings" **D. Cunningham**, 101st International Education Conference, International Association of Identification, Cincinnati, August 12, 2016.
10. "Recent Progress on Ion Selective Electrodes" **D. Cunningham**, June 15, 2016, Eccrine Systems, Inc. Cincinnati.
11. "Glimmers of New Point-of-Care Products through the Patent Thicket" **D. Cunningham**, C. Smith and C. Miller, 229th Electrochemical Society Meeting, San Diego, May 30, 2016, M02-2010 (Keynote Lecture).
12. "Commercial Sensors and Skin Studies", **D. Cunningham**, Department of Electrical Engineering, University of Cincinnati, March 18, 2016.
13. "When the Rubber Meets the Skin: Real Devices, **D. Cunningham**, National Science Foundation Workshop on Skin for Engineers, Florida International University, January 19, 2016 (featured speaker).
14. "Collection of Drug Traces from Fabric for DART Analysis" A. Hartman, R. Masek and **D. Cunningham**, Kentucky Academy of Sciences, Northern Kentucky University, KY, Nov. 2015, 3:45 pm oral.
15. "Opening the Doors of Learning using Forensic Science Activities", **D. Cunningham**, 2015 Pedagogicon, EKU, Richmond KY, May 22, 2015, Session I.
16. "Tales of Scientific Innovation and Fingerprint Enhancement", **D. Cunningham**, Department of Chemistry, Berea College, Berea KY, March 12, 2015.
17. "Practical Applications of Electrochemical Polymerization for Latent Fingerprint Development on Varying Metal Surfaces, C. Miller, T. Baldwin and **D. Cunningham**, Kentucky Academy of Sciences, Lexington, KY, Nov. 2014, 1 pm oral.
18. "Hands-on Inquiry-Based Forensic Science Activities: From blood spatter to drug analysis", **D. Cunningham**, 2014 Southeastern Regional Meeting American Chemical Society, Nashville, TN, Oct. 18, 2014 Abstract 581.
19. "Enhancement of Latent Fingerprints on Steel Surfaces", **D. Cunningham**, T. Baldwin, C. Miller and C. Smith, 2014 Southeastern Regional Meeting American Chemical Society, Nashville, TN, Oct. 19, 2014 Abstract 802.
20. "Improving Practitioner Relations", **D. Cunningham** and P. Staton, American Academy of Forensic Science, Seattle WA, April 2014, Workshop "Effective Curricular Design and Improvement for Forensic Science Educational Programs".
21. "Enhancement of Latent Fingerprints through Electrochemical Polymerization", **D. Cunningham**, Eastern Kentucky University, Richmond KY, September 2013.
22. "Chemical-Physical Design of Superior Materials for Electrochemical Sensors" **D. Cunningham** Eastern Kentucky University, Richmond KY, September 2012.

23. "Electrochemical Sensors: A Look Towards Forensic Applications", **D. Cunningham** Eastern Kentucky University, Richmond KY, September 2011.
24. "Opportunities in Forensic Analytical Chemistry" **D. Cunningham** Department of Chemistry, Eastern Kentucky University, Richmond KY, April 2011.
25. "HPLC Analysis of Carboxylic Acids after Derivatization with Aryldiazoalkanes" **D. Cunningham**, PittCon, Atlanta GA, March 2011,
26. "Blood, Sweat and HTLV" **D. Cunningham** Abbott Point of Care, Nepean Ontario, Canada, March 2011.
27. "Challenges in Sample Acquisition and Analytical Chemistry", **D. Cunningham** Department of Chemistry, West Virginia Wesleyan College, Buckhannon WV, March 2011.
28. "Diagnostic Blockbusters and Promising Scientific Innovations" **D. Cunningham**, National Science Foundation-Chinese National Science Foundation Workshop on Advanced Sensors and Bio-inspired Technologies, Shanghai China, Nov. 2010,
29. "Biomedical Engineering Careers at Abbott Laboratories", **D. Cunningham** Department of Biomedical Engineering, University of Illinois Chicago IL, November 2007.
30. "Turning Science into Caring: From Clinical Immunoassay Systems to Whole Blood Glucose Testing", **D. Cunningham** Department of Chemistry, Georgetown University, Washington DC, February 2007.
31. "The Road to Improved Immunoassay Systems" **D. Cunningham** and J. Russell, Biomedical Engineering Society Meeting, Chicago, October 2006.
32. "Scaling-up Nanotechnology for Clinical Immunoassay Systems" **D. Cunningham** and J. Russell, PittCon, Orlando, March 2006,
33. "Biosensor Research, Development and Product Support in a Large Company" **D. Cunningham** Graduate Research Seminar, Gordon Research Conference on Bioanalytical Sensors, Ventura, CA, February 2006.
34. "Bringing It All Together: Fluidics, Biochemistry and Engineering of Commercial Clinical Diagnostics Devices", **D. Cunningham** Department of Chemical Engineering, University of California, Santa Barbara, February 2006.
35. "Bringing Biosensor Technology to Market, Painlessly" **D. Cunningham** Department of Chemistry, University of Iowa, Iowa City, IA, November 2005.
36. "On-demand and Continuous Glucose Monitoring Systems "NOT" At Your Fingertips" **D. Cunningham**, Biomedical Engineering Society Meeting, Boston, October 2005.
37. "Shaping the Future: From Science to Patient Care", **D. Cunningham** Great Lakes Chinese American Chemical Society, Abbott Park, IL, June 2005.
38. Design and Optimization of Glucose Monitoring Systems for the Control of Diabetes" **D. Cunningham**, American Institute of Chemical Engineers Chicago Section Symposium, Chicago, April 2005.
39. "Transdermal and Subcutaneous Approaches to Glucose Monitoring" **D. Cunningham**, B. Feldman and T. Henning, PittCon, March 2005.
40. "Industrial Analytical Chemistry and the Great Divide: Analysts and Instrument Builders", **D. Cunningham** Department of Chemistry, Colorado State University, Fort Collins CO, August 2004.
41. "Microfluidics: Translation of Physical Principles into Commercial Products", **D. Cunningham** Department of Chemical and Biochemical Engineering, Northwestern University, Evanston IL, February 2004.
42. "Glucose Testing at Alternative Sites: Giving the Finger to the Finger", **D. Cunningham** Department of Bioengineering and School of Medicine, George Washington University, Washington DC, June 2003.
43. "Clinical Chemistry and Fluidics Applications in Biotechnology", **D. Cunningham** Department of Chemical Engineering, Northwestern University, Evanston IL, April 2003.
44. "Fluidics and Sample Handling in Diagnostics Products: Glucose Testing "NOT" at your Fingertips", **D. Cunningham** Department of Chemistry, University of Wisconsin, Madison WI, January 2003.
45. "Physiology, Fluid Extraction and Glucose Monitoring", **D. Cunningham** 2nd La Jolla Conference: Glucose Monitoring and Control, La Jolla, CA February 2003.
46. "Micro-Volume Glucose Testing "NOT" at your Fingertips" **D. Cunningham**, T. Henning, E. Shain, D. Young, and M. Lowery, American Chemical Society National Meeting, August 2002.
47. "How to Make a Painless Glucose Monitoring System (Sof-Tact™)", **D. Cunningham** iCOM, Engineering Forum, September 2001.
48. "Automated Collection of Micro-Volumes of Whole Blood for Glucose Monitoring and Other Diagnostic Product Fluidic Systems" **D. Cunningham**, T. Henning, E. Shain and D. Young, American Chemical Society National Meeting, May 2001.
49. "Conducting Polymer Electrodes for Iontophoresis Drug Delivery" **D. Cunningham**, Electrochemical Society National Meeting, Toronto, CA, April 2001.

50. "Fluidics Control of Whole Blood in Point-of-Care Diagnostic Products", **D. Cunningham** Materials Research Center, University of Chicago, Chicago IL, April 2001.
51. "Fluidic Sample Handling in Biosensor Systems" **D. Cunningham**, Sixth World Congress on Biosensors, San Diego, May 2000.
52. "Commercial Biosensors in Clinical Settings", **D. Cunningham** Department of Chemistry, University of Kentucky, Lexington KY, July 1999.
53. "Nonspecific Binding or Bad Things in Real Samples", **D. Cunningham** Gordon Research Conference on Bioanalytical Sensors, Ventura CA, January 1999.
54. "Biosensor Technology: What's Out There and What's Coming", **D. Cunningham** Clinical Ligand Assay Society and National Academy of Clinical Biochemistry joint meeting, Rye Brook NY, May 1998.
55. "ICH and FDA Guidelines for HPLC Method Validation", **D. Cunningham** Technical Training/Seminar, Abbott Laboratories, May 1995.
56. "Iontophoresis Drug Delivery", **D. Cunningham** Hospital Products Division Roundtable, Abbott Laboratories, April 1995.
57. "Enzyme Electrodes", **D. Cunningham** Analytical Discussion Group, HPD, Abbott Laboratories, June 1993.
58. "Ion Selective Electrodes", **D. Cunningham** Analytical Discussion Group, HPD, Abbott Laboratories, May 1992.
59. "Biosensors and Bioelectronics", **D. Cunningham** Boehringer Mannheim, Indianapolis, IN, March 1991.
60. "Biosensors and Electrically Conducting Polymers", **D. Cunningham** Becton Dickinson, Research Triangle Park, NC, February 1991.
61. "Enzyme Electrodes for the Determination of Branched-Chain Amino Acids and Aromatic Amino Acids", **D. Cunningham**, Pittsburgh Conference, Chicago, March 1991.
62. "Bioelectronics -- A Chemist's Involvement in Recent Advances in Conducting Polymers and Biosensors", **D. Cunningham** Hospital Products Division, Abbott Laboratories, Abbott Park, IL, August 1990.
63. "Recent Advances in the Electrochemistry of Conducting Polymers and Biosensors", **D. Cunningham** Yellow Springs Instrument Company, Yellow Springs, OH, May 1989.
64. "Immobilized Enzyme Electrodes and the Determination of Amino Acids", **D. Cunningham** Diagnostic Systems Group, Beckman Instruments, Brea, CA, October 1988.
65. "Conducting Polymers: Electrochemical Studies of Polysulfur Nitride, o-Diaminobenzene, Thiophenes and Polyheterolenes", **D. Cunningham** Department of Chemistry, University of Cincinnati, January 1987.
66. "Surface Enhanced Raman Spectroscopy and Other New Types of Spectroelectrochemistry", **D. Cunningham** Division of Analytical Chemistry, University of Cincinnati, February 1984.
67. "Small Fiber Probes for 'In Vivo' Monitoring of NAD(P)+", **D. Cunningham** Division of Analytical Chemistry, University of Cincinnati, May 1983.
68. "Spectroelectrochemical Analysis of Some Polyheterolenes", **D. Cunningham**, O. Ataman, A. Galal, L. Laguren-Davidson, E. Lewis, C. Pham, A. Burkhardt, H. Zimmer and H. Mark, Pittsburgh Conference, February 1988.
69. "A Spectroelectrochemical Method for the Determination of the 'Formal Potentials and n-Value' of Conducting Poly-thienylene Films", H. Mark, **D. Cunningham**, H. Zimmer, C.V. Pham, T. Lewis, A. Nkansah, T.-L. Chang, N. Klaus, and L. Laguren-Davidson, Electrochemical Society National Meeting, October 1987.
70. "Electrochemical Studies of Thiophene Derivatives: Spectroelectrochemical Determination of Half-Wave Potentials and n-Values for Polyheterolenes", H. Mark, H. Zimmer, **D. Cunningham**, C. Pham, E. Lewis, A. Nkansah, T.-L. Chang, N. Klaus, and L. Laguren-Davidson, American Chemical Society National Meeting, September 1987.
71. "Steric Effects on the Electrooxidation of 3-substituted Thiophenes and the Properties of the Resulting Polymer Films", H. Mark, H. Zimmer, C.V. Pham, L. Laguren-Davidson, **D. Cunningham** and A. Nkansah, American Chemical Society National Meeting, September 1986.
72. "Reduction of Acetylene at Molybdenum Modified Poly-Sulfur Nitride Electrodes", H. Mark, Jr., J. Robinson, **D. Cunningham**, T.M. Davidson, T.D. Behymer, L. Laguren, and B.S. Pons, Fifth Biennial Carl S. Marvel Symposium, Tuscon, Arizona, March 1983.

POSTERS

1. "The Use of Flawed Solid Phase Extraction and a Broken High-Pressure Liquid Chromograph to find the Concentration of Sudan IV" T. Flescher, A. Jones and **D. Cunningham**. Student Research Conference, SEMO April 2022
2. "Continuous Biochemical Monitoring with Minimally Invasive Microneedle Technology and Affinity-Based Aptamer Biosensors" M. Friedel, **D. Cunningham** and J. Heikenfeld. Chemical and Biological Defense Science & Technology (CBD S&T) Conference, Cincinnati OH. November 2019
3. "High Performance Liquid Chromatographic Detection of Counterfeit Antibiotics" D. Mayes, M. Mumma, S. Haney, E. Delaney and **D. Cunningham**. Midwestern Association of Forensic Scientists Annual Meeting, Louisville KY October 2019,
4. "High Performance Liquid Chromatography for Counterfeit Drugs" D. Mayes, M. Mumma and **D. Cunningham** Student Research Conference, SEMO April 2019,
5. "Sub Potent and Ineffective Antibiotic Analysis" S. Haney, E. Delaney and **D. Cunningham** Student Research Conference, SEMO April 2019
6. "Determining Isobaric Internal Standards Suitable for Use in DART Analysis of Trace Drugs" S. Josselyn and **D. Cunningham** University Presentation (UP) Showcase, ECU April 2018,
7. "Analysis of Trace Drugs by Direct Analysis in Real Time (DART) Mass Spectrometry, **D. Cunningham** and S. Josselyn, PittCon Orlando FL February 2018
8. "Electrochemical Oxidation of Heterolenes for Enhancement of Latent Fingerprints" **D. Cunningham** and C. Smith PittCon Orlando FL February 2018
9. "Latent Fingerprint Enhancement on a Brass Metal Surfaces using Paint Electrodeposition", R. Haskell and **D. Cunningham** University Presentation (UP) Showcase, ECU, April 2017,
10. "Characterization of Trace Drug Recovery from Various Fabrics for DART Analysis" S. Josselyn, N. Lindsey, K. Ruiter and **D. Cunningham** University Presentation (UP) Showcase, ECU April 2017,
11. "Semi-Quantitation of Trace Drug Residues on Fabric by Direct Analysis in Real-Time (DART)" S. Josselyn and **D. Cunningham**, American Academy of Forensic Science, New Orleans, February 2017.
12. "Formulation of Printable Analyte Limiting and Enzyme Loaded Films", **D. Cunningham** and C. Miller, Bioanalytical Sensors Gordon Research Conference, Salve Regina University, Rhode Island, June 2016.
13. "Building the Road from a Research Project to a Core Curricular Laboratory Experiment", **D. Cunningham**, A. Hartman and S. Josselyn, Pedagogicon 2016, ECU, May 2016.
14. "Sample Introduction Studies for Direct Analysis in Real-Time (DART) Systems", R. Masek, A. Hartman and **D. Cunningham**, American Academy of Forensic Science, Las Vegas, NV, February 2016.
15. "Forensic Analysis of Drug Traces from Cotton Fabrics", A. Hartman, S. Josselyn and **D. Cunningham** University Presentation (UP) Showcase, ECU April 2016,
16. "Developing an Undergraduate Lab to Find Trace Drugs using Mass Spectrometry" University Presentation (UP) Showcase, ECU April 2016, S. Josselyn, A. Hartman, R. Masek and **D. Cunningham**
17. "Forensic Analysis of Drug Traces from Fabric", A. Hartman, R. Masek and **D. Cunningham**, Posters at the Capital, Frankfort KY, February 2016.
18. "Assessment of Trace Methamphetamine Levels on Various Fabrics by DART-MS, R. Masek, A. Hartman and **D. Cunningham**, Kentucky Academy of Sciences, Northern Kentucky University, KY, Nov. 2015,
19. "Exploration of the Electrochemical Enhancement of Latent Fingerprints", **D. Cunningham**, C. Smith, C. Miller and T. Baldwin, American Academy of Forensic Science Scientific Meeting, Orlando FL, Feb. 2015.
20. "Field Deployable Electrochemical Cell for Enhancement of Latent Fingerprints on Metal Surfaces" ", T. Baldwin, C. Miller and **D. Cunningham**, Kentucky Academy of Sciences, Lexington, KY, Nov. 2014, poster 85.
21. "Enhancement of Latent Fingerprints Via Polymer Coating", C. Smith and **D. Cunningham**, National Collegiate Honors Council Conference, Denver CO, Nov. 8, 2014,.
22. "Exploring Coating Methods for Protein Containing Sensors", C. Smith and **D. Cunningham**, Undergraduate Presentation (UP) Showcase, ECU April 2014,
23. "Exploring Methods of Fingerprint Enhancement For Forensic Applications", C. Smith, A. Pennington and **D. Cunningham**, National Conference On Undergraduate Research, Lexington, KY, April 2014.
24. "Formulation and Long-term Stability of Enzyme Layers for Biosensors", D. Perraut, C. Smith, K. Elmer and **D. Cunningham**, National Conference on Undergraduate Research, Lexington, KY, April 2014.
25. "Electrochemistry and the Enhancement of Latent Fingerprints", **D. Cunningham** Junior Faculty Summer Research Awards Presentations, Eastern Kentucky University, Nov. 2013.

26. "Electrochemistry and the Enhancement of Latent Fingerprints", A. Pennington, C. Smith and **D. Cunningham** Kentucky Academy of Sciences, Morehead State University, Nov. 2013.
27. "Enhancement of Latent Fingerprints via Polymer Coating" C. Smith and **D. Cunningham**, Midwest Association of Forensic Scientists, Dayton OH, October 2013.
28. "Characterization of Enzyme Formulations for Electrochemical Sensors", C. Smith, M. Sterling and **D. Cunningham**, Posters at the Capital, Frankfort KY, February, 2013.
29. "Photopatterning of Hydrogels with a Photoinitiator", C. Smith and **D. Cunningham**, Undergraduate Presentation (UP) Showcase, ECU April 2013.
30. "Photopatterning of Ethylene Glycol Diacrylate and Evaluation by Scanning Electron Microscopy" C.T. Smith, K.A. Francis and **D. Cunningham**, Kentucky Academy of Sciences, Oct. 2012.
31. "Illumination Sources for Polymerization of Hydrogels" K.A. Francis and **D. Cunningham**, Regional Poster Competition, Undergraduate Research in Chemistry, University of Kentucky, April 2012.
32. "Illumination Sources for Polymerization of Hydrogels: Light-emitting Diodes, Blacklights, Organic Reactors, and a Fingernail-Curing Lamp" K.A. Francis and **D. Cunningham**, Undergraduate Presentation (UP) Showcase, ECU, April 2012.
33. "Analytical Characterization of Biotinylated Viral Antigens for Automated Clinical Immunoassays" **D. Cunningham**, T. Rae and G. Burgos, PittCon, March 2010,
34. "Membrane-Based Centrifugal Separations for Development of Rapid Analytical Methods" **D. Cunningham** PittCon, March 2009,
35. "Folate Capture Reagent Improvements and Assay of Folate Binding Protein" **D. Cunningham**, M. Knight, N. Gast, M. Struck, A. Lach, Abbott Diagnostics Division Technology Exchange, Abbott Park IL, October 2008.
36. "AxSYM Folate Reagent Optimization with Commercial Folate Binding Protein" N. Gast, **D. Cunningham**, M. Knight, M. Struck, A. Lach Abbott Diagnostics Division Technology Exchange, Abbott Park IL, October 2008.
37. "Molecular Structure and Performance Characteristics of Competitive Ion-capture Immunoassay Reagents, Revisited" American Chemical Society National Meeting, August 2008, **D. Cunningham**
38. "Flow Cytometry and Characterization of Fine Particles for Immunoassays" **D. Cunningham** and A. Schwartz, PittCon, February 2007,
39. "Cleaning of Purchased Microparticles with Mixed-Bed Ion Exchange Resin and Separation with Polypropylene Mesh" **D. Cunningham**, D. Stein Abbott Diagnostics Division Technology Exchange, Abbott Park IL, October 2006.
40. "PRISM HIV-1 Microparticle Concentrate MF 84111: Process Characterization, Improvement, and Scale-up" E. Kim, **D. Cunningham**, P. Johnson, C. Tomas Abbott Diagnostics Division Technology Exchange, Abbott Park IL, October 2006.
41. "Commercial Biosensor Technology Through The Years" **D. Cunningham**, Gordon Research Conference, Ventura, CA, February 2006,
42. "Microparticle Lot Investigation for PRISM HBsAg Immunoassay" E. Kim, **D. Cunningham**, P. Johnson, B. Peterson, J. Patrick, O. Khalil, C. Lueck, A. Vogt, N. Robbins, D. Schisla Abbott Corporate Technology Exchange, Abbott Park IL, September 2005.
43. "Increased Activity of Microparticles for Immunoassays" **D. Cunningham** and J. Schulz Abbott Corporate Technology Exchange, Abbott Park IL, September 2005.
44. "Characterization and Scale-up of a Peptide Biotinylation Reaction and Dialysis Clean-up" **D. Cunningham** and M. Hutton, American Institute of Chemical Engineers Chicago Section Symposium, Chicago, April 2005.
45. "Inhibition of Microparticle Antibody Coating at Low EDAC Levels by Azide" **D. Cunningham**, J. Bodner and C. Peterson. Abbott Diagnostics Division Technology Exchange, Abbott Park IL, October 2004.
46. "Root Cause Identification of the PRISM HCV Assay Conjugate Failures", T. Pena, C. Tomas, **D. Cunningham**, A. Hoffman, J. Pennoyer, D. Shah, C. Bryant and K. Callear Abbott Diagnostics Division Technology Exchange, Abbott Park IL, October 2004.
47. "Variation Identification of Anti-Biotin Conjugation Process Used in PRISM", C. Tomas, T. Pena, **D. Cunningham** and J. Pennoyer Abbott Diagnostics Division Technology Exchange, Abbott Park IL, October 2004.
48. "Integration of Immobilized Enzyme Membranes into Plastic Potentiometric Sensor Systems" **D. Cunningham**, PittCon, March 2004.
49. "Fluidics, Physiology and Continuous Glucose Monitoring" **D. Cunningham** and T. Henning Vowiler Day Session on Diabetes and Metabolic Disease, Lake Forest, IL October 2003.

50. "Transdermal Sampling with Microneedles: From Patent Mapping to Human Clinical Trials" **D. Cunningham**, T. Henning and Y. Wang Abbott Corporate Technology Exchange, Abbott Park IL, October 2003.
51. "Transdermal Sampling with Ultrasound" **D. Cunningham**, T. Henning, B. Calfin, D. McNeill, T. Doan and L. Balen, Abbott Corporate Technology Exchange, Abbott Park IL, October 2003.
52. "Detection of Magnetic Particles for Quantitative Immunoassays", **D. Cunningham**, M. Pope and E. Shain Abbott Diagnostics Division Technology Exchange, Abbott Park IL, June 2002.
53. "Combination of Technologies for the Commercialization of Biosensors: Examples from Ultrasonics and Skin Physiology" **D. Cunningham**, T. Henning, E. Shain, D. Young, M. Lowery, and T. Schapira, Gordon Conference on Bioanalytical Sensors, Ventura CA, March 2002.
54. "Clinical Research Subsystems, Prototypes and the Sof-Tact™ Meter", **D. Cunningham**, T. Henning, J. Forsyth, N. Loomis, M. Lowery, L. Semple, E. Shain, G. Winter and D. Young, iCOM, North Chicago, IL September 2001.
55. "Attachment of a Device to the Human Body" **D. Cunningham** and M. Lowery Abbott Corporate Technology Exchange, Abbott Park IL, June 2001.
56. "Less Painful and Effective Approach to Blood Glucose Monitoring Using a Vacuum-Pump and Skin Stretching" **D. Cunningham**, T. Henning, D. Young, P. Gatcomb, and W. Tamborlane, 17th International Diabetes Federation Congress, Mexico City, Mexico November 2000.
57. "Glucose Content of the Skin: Implications for "on-vivo" Monitoring" **D. Cunningham** and D. Young, Abbott Corporate Technology Exchange, Abbott Park IL, June 1999.
58. "Minimally Invasive Sampling of Blood" T. Henning, **D. Cunningham**, E. Shain, and D. Young, Oak Ridge Conference, Chapel Hill, NC April 1999.
59. "Measurement of Glucose in Physiological Samples by HPLC-PAD" **D. Cunningham**, D. Young and M. Pope, PittCon, March 1999.
60. "Pneumatic Lancing Device" E. Shain, M. Lowery, H. Schwartz, T. Henning, **D. Cunningham** and D. Young. Abbott Diagnostics Division Technology Exchange, Abbott Park IL, June 1998.
61. "Access to Interstitial Fluid for Glucose Monitoring in Diabetes Management" M. Pope, J. Grace, P. Bojan, D. Schmidt, S. Wong, T. Huang, G. Hiltbran, M. Lowery, B. Tarkowski, T. Schapira, **D. Cunningham** and J. Babb. Abbott Diagnostics Division Technology Exchange, Abbott Park IL, June 1998.
62. "Multi-Center Evaluation of a Less Painful Glucose Testing Method" **D. Cunningham**, T. Henning, T. Elstrom, D. Young, E. Shain, G. Winter, M. Lowery, W. Tamborlane, and K. Cousineau. Abbott Diagnostics Division Technology Exchange, Abbott Park IL, June 1998.
63. "Minimally Invasive Glucose Analysis Using Novel Technology" T. Schapira, **D. Cunningham**, E. Shain, T. Elstrom, J. Babb, S. Mitragotri, J. Kost, and R. Langer. Abbott Diagnostics Division Technology Exchange, Abbott Park IL, June 1996.
64. "Low Level Glucose Quantitation by HPLC" D. Young, M. Pope and **D. Cunningham**. Abbott Diagnostics Division Technology Exchange, Abbott Park IL, June 1996.
65. "Minimally Invasive Sampling: Modeling of Key Parameters" **D. Cunningham**, E. Shain, S. Mitragotri, T. Elstrom and M. Lowery. Abbott Diagnostics Division Technology Exchange, Abbott Park IL, June 1996.
66. "Iontophoresis Drug Delivery", **D. Cunningham** Abbott Corporate Technology Exchange, Abbott Park IL, June 1995.
67. "Formation of Compound A from Sevoflurane", **D. Cunningham**, S. Huang, B. Williamson and J. Webster. Abbott Corporate Technology Exchange, Abbott Park IL, June 1995.
68. "No Nitric Oxide from Nitric Oxide Synthase", H. Schmidt, H. Hofmann, **D. Cunningham**, A. Shutenko, and M. Feelisch, Biology of Nitric Oxide Conference, August 1995.
69. "Development of a Liquid Drug Formulation", **D. Cunningham** Abbott Corporate Technology Exchange, Abbott Park IL, June 1993.
70. "Development of a Thermostable Drug Formulation", **D. Cunningham**, C. Mahon and J. Webster Abbott Corporate Technology Exchange, Abbott Park IL, June 1993.
71. "Naloxone Hydrochloride: Investigation of a Late-Eluting Peak", D. Stephens, **D. Cunningham**, M. Burchett, P. Moy, R. Raghavan, J. Webster and B. Williamson. Abbott Corporate Technology Exchange, Abbott Park IL, June 1993.
72. "Trace Analysis of Isoproterenol by HPLC/EC", **D. Cunningham** Abbott Corporate Technology Exchange, Abbott Park IL, June 1991.
73. "Immobilized Enzyme Electrodes for the Determination of Glutamate", **D. Cunningham**, G. Guilbault and R. Villarta, Pittsburgh Conference, New Orleans, March 1990

74. "Immobilized Enzyme Electrodes for the Determination of Tryptophan", **D. Cunningham**, G. Lubrano, R. Phillips, and G. Guilbault, American Chemical Society National Meeting, September 1988.
75. "Effect of Supporting Electrolyte on the Properties of Conducting Polyheterolene Films", A. Galal, **D. Cunningham**, O. Ataman, E. Lewis, L. Laguren-Davidson, C. Pham, A. Burkhardt, H. Zimmer, and H. Mark, Pittsburgh Conference, February 1988.

PATENTS and PATENT APPLICATIONS

1. J. Bhogal, S. A. Karinka, T. P. Henning, **D. Cunningham**, U. Hoss, A. H. Naegeli, and J. LaTour. 2012, "Methods of Collecting and Analyzing Samples" Published 4/17/14 under the Patent Cooperation Treaty as WO 2012149410 A3.
2. J. Bhogal, S. A. Karinka, T. P. Henning, **D. Cunningham**, U. Hoss, A. H. Naegeli, and J. LaTour. 2012, "Methods of Collecting and Analyzing Samples" Published 11/22/12 as United States Patent Application Serial No. 2012/0296189 A1.
3. J. Bhogal, S. A. Karinka, T. P. Henning, **D. Cunningham**, U. Hoss, A. H. Naegeli, and J. LaTour. 2012, "Methods of Collecting and Analyzing Samples" Published 11/1/12 under the Patent Cooperation Treaty as WO 2012149410 A2.
4. J. Bhogal, S. A. Karinka, T. P. Henning, **D. Cunningham**, U. Hoss, A. H. Naegeli, and J. LaTour. 2012, "Methods of Collecting and Analyzing Samples" Published 11/22/12 as United States Patent Application Serial No. 2012/0296189 A1.
5. **D. Cunningham**, T. Henning, E. Shain, D. Young, A. Muetterties, T. Schapira, G. Chambers, G. Hughes, J. Watkin, G. Prokop, and J. Goldfarb. 2005 "Method and Apparatus for Obtaining Blood for Diagnostic Tests", Issued 1/4/05 as United States Patent 6,837,858.
6. J. Grace, N. Loomis, T. Schapira, S. Wong, K. Noonan, M. Lowery, P. Bojan, D. Schmidt, T. Huang, R. Hiltibran, M. Pope, J. Kotlarik, B. Tarkowski and **D. Cunningham**. 2004 "Apparatus and Method for the Collection of Interstitial Fluids", Issued 9/7/04 as United States Patent 6,786,874.
7. **D. Cunningham**, T. Henning, E. Shain and D. Young. 2002 "Method and Apparatus for Obtaining Blood for Diagnostic Tests", 2002, Published 11/14/02 as United States Patent Application Serial No. 2002/0169393 A1
8. J. Grace, N. Loomis, T. Schapira, S. Wong, M. Lowery, P. Bojan, T. Huang, R. Hiltibran, M. Pope, J. Kotlarik, B. Tarkowski, K. Noonan D. Schmidt, and **D. Cunningham**. 2002 "Apparatus and Method for the Collection of Interstitial Fluids", Issued 10/22/02 as United States Patent 6,468,229.
9. **D. Cunningham**, T. Henning, D. Young, E. Shain, T. Schapira, A. Muetterties, G. Chambers, J. Watkin, G. Hughes, G. Prokop, and J. Goldfarb. 2001 "Method and Apparatus for Obtaining Blood for Diagnostic Tests", Issued 10/23/01 as United States Patent 6,306,104.
10. **D. Cunningham**, T. Henning, E. Shain and D. Young. 2001 "Method and Apparatus for Obtaining Blood for Diagnostic Tests", Published 10/18/01 as United States Patent Application Serial No. 2001/0031931 A1
11. **D. Cunningham**, T. Henning, D. Young and E. Shain. 2001 "Method and Apparatus for Obtaining Blood for Diagnostic Tests", Issued 9/4/01 as United States Patent 6,283,926.
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13. T. Henning, R. Hiltibran, **D. Cunningham**, E. Shain, B. Tarkowski and D. Young, 2000, "Method and Apparatus for Obtaining Interstitial Fluid for Diagnostic Tests", Issued 12/2/00 as United States Patent 6,155,992
14. **D. Cunningham**, T. Henning, D. Young, E. Shain, T. Schapira, A. Muetterties, G. Chambers, J. Watkin, G. Hughes, G. Prokop, and J. Goldfarb, 2000, "Method and Apparatus for Extracting Blood for Diagnostic Tests", Issued 7/25/00 as United States Patent 6,093,156
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16. **D. Cunningham**, T. Henning, E. Shain, D. Young, M. Lowery, and H. Graham. 2000 "Method and Apparatus for Extracting Blood for Diagnostic Tests", Issued 6/6/00 as United States Patent 6,071,249
17. **D. Cunningham**, T. Henning, D. Young and E. Shain. 2000, "Method and Apparatus for Extracting Blood for Diagnostic Tests", Issued 5/16/00 as United States Patent 6,063,039

18. E. Shain, M. Lowery, **D. Cunningham**, T. Henning, and D. Young, 2000, "Method and Apparatus for Extracting Blood for Diagnostic Tests", Issued 2/22/00 as United States Patent 6,027,459
19. K. Capel, **D. Cunningham**, J. Gordon, T. Henning, and S. Stroupe, 1999, "Telemedicine", Published 1/28/99 as World Patent Application WO 99/04043.
20. **D. Cunningham**, 1994, "Composite Membrane". Issued 7/5/94 as US 5,326,449
21. **D. Cunningham**, N. Sleszynski, S. Brontman, T. Henning, H. Helgren, J. Geist, L. Morici, T. Schapira and K. Johnson, 1994, "Biosensor with a Membrane Containing Biologically Active Material" Issued 5/10/94 as United States Patent 5,310,469
22. **D. Cunningham** and K. Johnson 1994, "Membrane Containing Biologically Active Material" Issued 2/1/94 as United States Patent 5,283,186

Foreign equivalents of US patents prior to 2011 are not included.

PATENTS (INTERNATIONAL BASE PATENT WITHOUT UNITED STATES COUNTERPART)

1. "Telemedicine", K. Capel, **D. Cunningham**, J. Gordon, T. Henning, and S. Stroupe. Published 1/28/99 as WO 99/04043.

FUNDED GRANT PROPOSALS

1. "United States Pharmacopeia National Formulary (USP-NF) purchase, **D. Cunningham**, Carrie Woodburn Johnson Endowment, Kent Library, \$850, April 2019.
2. "Coating Research, **D. Cunningham**, Abbott Point-of-Care Canada Limited, \$25,000, July 2014 – August 2015.
3. "Coating Research" **D. Cunningham**, Abbott Point-of-Care Canada Limited, \$24,000, June 2013 – June 2014.
4. "Visualization of Latent Fingerprints on Forensic Evidence by Electrochemical Polymerization of Heterolenes", **D. Cunningham**, ECU College of Arts and Sciences, \$4,500, May-July 2013,
5. "Drug Delivery Proposal", **D. Cunningham**, Hospital Products Division, Abbott Laboratories, non-public, January 1994-January 1995.
6. "Microelectrodes for the Determination of Neuroregulators", **D. Cunningham**, National Institutes of Health, \$48,265, January 1990-July 1990.
7. "Electrode Probes for the Rapid Assay of Seafood Toxicants", **D. Cunningham** (Co-PI's G. Lubrano, G. Ramsay), U.S. Department of Defense, \$49,847, July 1989-December 1989.
8. "Electrode Probes for the Rapid Assay of Toxins in Feed Products" **D. Cunningham** (Co-PI G. Lubrano), U.S. Department of Agriculture, \$49,675, July 1989-December 1989.

NON-FUNDED GRANT PROPOSALS

1. "Rapid Method to Determine Synthetic Organic Dyes used to Adulterate Foodstuffs", **D. Cunningham**, Forensic Science Foundation, \$1300, submitted May 2022.
2. "Enhancement of Fingermarks on Brass and Brass Cartridge Casings", **D. Cunningham**, Forensic Science Foundation, \$1000, submitted October 2016.
3. "In-situ measurements of nanomechanical forces in free-standing fibrous thin-film substrates to understand cell attachment, growth and proliferation" **D. Cunningham** (Co-PI's A. Lakhtakia and F. Sciammarella), National Science Foundation, \$247,248 ECU budget, total budget \$831,899, submitted October 2013.
4. "NanoMechanical properties of 1D/2D/3D free-standing fibrous thin-film substrates of parylene-C for cell adhesion, growth, and proliferation" **D. Cunningham** (Co-PI's A. Lakhtakia and F. Sciammarella), National Science Foundation, \$238,993 ECU budget, total budget \$759,500, submitted October 2012.
5. "Enhancement of Latent Fingerprints on Metallic Surfaces" **D. Cunningham**, Oak Ridge Associated Universities, \$10,000, submitted January 2013.

ONLINE COURSE DEVELOPMENT AND TEACHING CERTIFICATE

Completed a program by the Office of e-Campus Learning at Eastern Kentucky University, July 2015

UNDERGRADUATE AND GRADUATE STUDENTS SUPERVISED

1. Tyler Flescher, January 2022 – May 2022
2. Alex Jones, January 2022 – May 2022
3. Allison Kester, January 2021 – May 2021
4. Tej Gottapu (grad), August 2019-January 2021
5. Destiny Mayes, February 2019-May 2020
6. Erin Delaney, February 2019-May 2019
7. Madison Mumma, February 2019-May 2019
8. Stephanie Haney, February 2019-May 2019
9. Samantha Josselyn, August 2015- May 2018
10. Marshall Heath, January 2018-May 2018
11. Mary Lewis, January 2018-May 2018
12. Maura (Delany) Stovall, August 2017-December 2017
13. Nichole Lindsey (undergrad/grad), August 2015-May 2017
14. Karla Ruiters, August 2016-May 2017
15. Reika Haskell (grad), May 2016-May 2017
16. Rachel Masek (grad), August 2015-August 2016
17. Rachel Bracker, January 2016-May 2016
18. Amelia Hartman, May 2015-May 2016
19. Courtney Miller, May 2014-May 2015
20. Taylor Baldwin, May 2014-August 2014
21. Armanda Pennington, August 2013-December 2013
22. Kevin Elmer, August 2013-December 2013
23. Dylan Perraut, August 2013-May 2014
24. Mellissa Sterling, August 2012-December 2012
25. Connor Smith, August 2012-May 2015
26. Kyle Francis, January 2012-May 2012

TEACHING (Southeast Missouri State University)

Course Prefix and Number	Title	Times Taught
CH085	General Chemistry Lab	1 (F18)
CH675	Topics in Analytical Chemistry: Chromatography	2 (F18, F19)
CH181	Basic Principles of Chemistry	13 (S19-F24)
CH081	Basic Principles of Chemistry Lab	13(S19-F24)
CH001	Basic Principles of Chemistry Recitation	13 (S19-F24)
CH187	Inorganic Chemistry and Qualitative Analysis Lab	7 (S19, F19, F20-S22)
CH184	General Chemistry I Laboratory	3 (F22,S24, F24)
CH020	Forensic Chemistry Laboratory	3 (F22, F23, F24)
CH450	Environmental Chemistry	2 (S23, S24)

TEACHING (Eastern Kentucky University)

Course Prefix and Number	Title	Times Taught
CHE 101	Introductory Chemistry	8 (F12, S19, F13, S14, F14, S15, F15, F17, S18)
CHE 101L	Introductory Chemistry Laboratory	5 (S13, F16, S17, F17, S18)
CHE 105L	Health Science Chemistry Lab	1 (S12)
CHE 111	General Chemistry	2 (F11, S12)
CHE 111L	General Chemistry Laboratory	4 (F11, S12, S13, F17)
CHE 200	Volunteering in Chemistry	8 (F12, Summer 14, S15, F15, S16, F16, S17, S18)
CHE 495	Chemistry Laboratory Independent Research	3 (F13, S14, S15)
CHE 501/802	Topics in Analytical Chemistry - Bioanalytical Chemistry	1 (F12)
CHE 811	Chemistry Practicum	1 (F15)
CHE 899	Thesis (Chemistry MS)	5 (F15, S16, Summer 16, F16, S17)
HON 420	Thesis Project and Seminar Honors)	4 (F14, S15, S16, F16)
EMS 858	Practicum for Gifted and Talented Education (CSI Summer Camp)	3 (Summers 13, 14, 15)
FOR 349	Applied Learning in Forensic Science (Internship)	1 (S15)
FOR 411L	Forensic Instrumental Lab	6 (F11, F12, F13, F14, F15, F16)
CHE 425 / FOR 411	Instrumental Analysis	2 (F11, F12)
FOR 430/442	Forensic Analytical Toxicology	4 (S15, S16, S17, S18)
FOR 442L	Drugs and Toxicology Lab	6 (S12, S13, S14, S15, S16, S17)
FOR 490	Introduction to Research (Forensic Independent Research)	11 (S12, F12, S13, F13, S14, Summer 14, F14, F15, S16, F17)
FOR 499	Forensic Science Capstone	4 (S15, F15, F16, F17)

APPENDIX B

Appendix B: Materials Considered

Exhibit No.	Description
1001	U.S. Patent No. 8,128,981 (“’981 patent”)
1003	File History for U.S. Patent No. 8,128,981
1007	U.S. Pub. No. 2004/0200721 (“Bhullar”)
1009	U.S. Patent No. 6,875,327 (“Miyazaki”)
1011	U.S. Patent No. 6,258,229 (“Winarta”)
1031	Timothy P. Henning & David D. Cunningham, <i>Biosensors for Personal Diabetes Management</i> , in COMMERCIAL BIOSENSORS: APPLICATIONS TO CLINICAL, BIOPROCESS AND ENVIRONMENTAL SAMPLES 3–46, (John Wiley & Sons, 1998) (“Henning-Cunningham”)
1032	U.S. Pub. No. 2009/0159197 (“Edelbrock”)
1033	U.S. App. No. 60/754,141 (“Edelbrock-Prov”)
1034	James Angell et al., <i>Processing Parameters for Laser Micromachining</i> , in SPIE VOL. 2993 LASERS AS TOOLS FOR MANUFACTURING 65–74 (1997) (“Angell”)
1035	Jerry Boogaard, <i>Precision Laser Micromachining</i> , in SPIE Vol. 611 LASER PROCESSING OF SEMICONDUCTORS AND HYBRIDS 48–59 (1986) (“Boogaard”)
1038	George Chryssolouris, <i>Lasers for Machining</i> , in LASER MACHINING THEORY AND PRACTICE 17–46 (Springer Science+Business Media, 1991) (“Chryssolouris”)
1049	U.S. Patent No. 6,531,040 (“Musho”)
1051	Claim Construction Chart, Dkt. 61, <i>Roche Diabetes Care, Inc. v. Trividia Health, Inc.</i> , Case No. 1:24-cv-00668 (DDE), Feb. 6, 2025
1052	J. Sercel, et al, <i>Industrial microprocessing applications of excimer lasers</i> , in SPIE VOL. 998 EXCIMER BEAM APPLICATIONS 76–83 (1988) (“Sercel”)
1055	U.S. Pub. No. 2005/0019953 (“Groll”)
1056	U.S. Patent No. 5,593,739 (“Kickelhain”)
1057	Martin Goosey, <i>Introduction to Polymers and their Important Properties for Electronic Applications</i> , in PLASTICS FOR ELECTRONICS (2nd ed. 1999) (“Goosey”)
1058	Declaration of June A. Munford (“Munford-Decl.”)

Cunningham Declaration: Appendix B (Materials Considered)

Exhibit No.	Description
1060	Micah Atkin et al., <i>A Microfabricated Polymer Filter Device for Bio-Applications</i> , in SPIE VOL. 5345 MICROFLUIDICS, BIOMEMS, AND MEDICAL MICROSYSTEMS II 138–146 (2004) (“Atkin”)
1061	Douglas B. Chrisey & Alberto Piqué, <i>Introduction to Direct-Write Technologies for Rapid Prototyping Applications</i> & Jie Zhang, et al., <i>Role of Direct-Write Tools and Technologies for Microelectronic Manufacturing</i> , in DIRECT-WRITE TECHNOLOGIES FOR RAPID PROTOTYPING APPLICATIONS: SENSORS, ELECTRONICS, AND INTEGRATED POWER SOURCES 1–13, 33–54 (Academic Press 2002) (“Chrisey”)
1062	File History for U.S. Pub. No. 2004/0200721 (“BhullarFH”)
1063	File History for USAN 09/411,940 (“Bhullar’940”)
1064	E. Harvey, <i>Microsensors for Minimally Invasive Diagnostics</i> , THE INSTITUTION OF ELECTRICAL ENGINEERS (1995) (“Harvey”)
1066	John C. Fisher, <i>A Brief History of the Nd:YAG Laser</i> , in ADVANCES IN ND:YAG LASER SURGERY 7–9 (S. N. Joffee et al. ed. 1988) (“Fisher”)
1067	William A. Vitriol, <i>Thick Film and Ceramic Technologies for Hybrid Multichip Modules</i> , in MULTICHIP MODULE TECHNOLOGIES AND ALTERNATIVES: THE BASICS 215–254 (D. A. Doane et al. ed. 1993) (“Vitriol”)
1069	Niall O’Leary, et al., <i>A robust procedure for the automated measurement of total serum bilirubin using potassium ferricyanide</i> , 30:2 ANN. CLIN. BIOCHEM. (1993) (“O’Leary”)
1070	William B. Tiffany, <i>Drilling, marking and other applications for industrial Nd:YAG lasers</i> , in SPIE VOL. 527 APPLICATIONS OF HIGH POWER LASERS 28–36 (1985) (“Tiffany”)
1071	D. Hellrung et. al., <i>Laser beam removal of micro-structures with Nd:YAG-Lasers</i> , in SPIE Vol. 3097 LASERS IN MATERIAL PROCESSING 266–273 (1997) (“Hellrung”)
1072	D. R. Martyr & T. Holt, <i>High Power Laser Processing of Materials</i> , in SPIE VOL. 801 HIGH POWER LASERS 344–353 (1987) (“Martyr”)
1073	Roger Allan, <i>Lasers in the factory: Nd: YAG and CO2 lasers are growing in popularity for cutting, drilling, welding, scribing, and</i>

Cunningham Declaration: Appendix B (Materials Considered)

Exhibit No.	Description
	<i>heat-treating a host of metals and nonmetals</i> , 16:5 IEEE SPECTRUM (May 1979) (“Allan”)
1074	U.S. Patent No. 4,081,653 (“Koo”)
1075	Bayer HealthCare Ascensia Breeze User Manual (2003) (“Ascensia”)
1078	WO Pub. No. 1999022236 (“Heinonen”)
1079	U.S. Patent No. 7,547,383 (“Cai”)

APPENDIX C

Appendix C (Challenged Claims)

Ground	35 U.S.C. Section	Claims	References
I	103	18-30, 32-37	<u>Bhullar</u> + <u>Boogaard</u> + <u>Angell</u>
II	103	1-13, 15-16, 18-30, 32	<u>Edelbrock</u> + <u>Boogaard</u> + <u>Angell</u>
III	103	35-37	<u>Edelbrock</u> + <u>Boogaard</u> + <u>Angell</u> + <u>Bhullar</u>

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
1[pre]	A method of manufacturing test strips, comprising:	<u>Ground II</u>
1[a]	forming a reel containing a conductive layer and a base layer;	
1[b]	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;	
1[c]	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	

Cunningham Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
	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	
1[d]	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.	
2	The method of claim 1, 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.	<u>Ground II</u>
3	The method of claim 1, 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.	<u>Ground II</u>
4	The method of claim 1, 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.	<u>Ground II</u>
5	The method of claim 1, wherein the first processing source includes a first laser	<u>Ground II</u>

Cunningham Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
	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.	
6	The method of claim 5, wherein the first ablative beam width is at least approximately 20 micro-meters.	<u>Ground II</u>
7	The method of claim 5, wherein the second ablative beam width is at least approximately 100 micro-meters.	<u>Ground II</u>
8	The method of claim 5, 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.	<u>Ground II</u>
9	The method of claim 1, 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.	<u>Ground II</u>

Cunningham Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
10	The method 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.	<u>Ground II</u>
11	The method 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.	<u>Ground II</u>
12	The method of claim 1, 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.	<u>Ground II</u>
13	The method of claim 12, wherein the first or second laser power is in the range of about 10 to about 100 watts.	<u>Ground II</u>
15	The method of claim 1, further including the step of contacting the first conductive component with at least one chemical component.	<u>Ground II</u>
16	The method 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.	<u>Ground II</u>

Cunningham Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
18[pre]	A method of manufacturing test strips, comprising:	Ground I Ground II
18[a]	forming a reel containing a conductive layer and a base layer;	
18[b]	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;	
18[c]	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;	
18[d]	separating one or more test strips from the reel using a singulation process.	
19	The method of claim 18, wherein the singulation process includes at least one technique selected from the group consisting of laser ablation, stamping, cutting, and etching.	Ground I Ground II
20	The method of claim 18, 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.	Ground I Ground II
21	The method of claim 20, wherein the first beam width is at least approximately 20 micro-meters.	Ground I Ground II

Cunningham Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
22	The method of claim 20, wherein the second beam width is at least approximately 100 micro-meters.	<u>Ground I</u> <u>Ground II</u>
23	The method of claim 18, wherein at least one laser beam removes substantially all conductive material between adjacent conductive components.	<u>Ground I</u> <u>Ground II</u>
24	The method of claim 18, 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.	<u>Ground I</u> <u>Ground II</u>
25	The method of claim 24, 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.	<u>Ground I</u> <u>Ground II</u>
26	The method of claim 24, 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.	<u>Ground I</u> <u>Ground II</u>
27	The method of claim 18, 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.	<u>Ground I</u> <u>Ground II</u>

Cunningham Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
28	The method of claim 27, wherein the first or second laser power is in the range of about 10 to about 100 watts.	<u>Ground I</u> <u>Ground II</u>
29	The method of claim 18, further including the step of contacting at least part of the conductive layer with at least one chemical component.	<u>Ground I</u> <u>Ground II</u>
30	The method of claim 29, 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.	<u>Ground I</u> <u>Ground II</u>
32	The method of claim 18, further including application of a spacer layer to the conductive layer or the base layer.	<u>Ground I</u> <u>Ground II</u>
33	The method of claim 32, wherein the second kerf is formed after application of the spacer layer.	<u>Ground I</u>
34	The method of claim 32, further including application of a cover to the spacer layer.	<u>Ground I</u>
35	The method of claim 18, wherein the conductive layer is formed using a technique selected from the group consisting of direct writing, sputtering, screen printing, contract printing, and lamination.	<u>Ground I</u> <u>Ground III</u>

Cunningham Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
36	The method of claim 18, further including the step of applying to the conductive layer at least one of a second conductive layer and a semi-conductive layer.	<u>Ground I</u> <u>Ground III</u>
37	The method of claim 36, wherein the second kerf is formed after application of at least one of the second conductive layer and the semi-conductive layer.	<u>Ground I</u> <u>Ground III</u>