PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,146,202

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the *Inter Partes* Review of U.S. Patent No. 7,146,202

Trial No.: Not Yet Assigned

Issued: December 5, 2006

Filed: June 16, 2004

Inventors: W. Kenneth Ward, *et al.*

Assignee: AgaMatrix, Inc.

Title: COMPOUND MATERIAL ANALYTE SENSOR

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PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100

On behalf of Dexcom, Inc. ("Dexcom" or "Petitioner") and in accordance with 35 U.S.C. § 311 and 37 C.F.R. § 42.100, *inter partes* review is respectfully requested for claims 1-3, 5, 6, and 8-11 of U.S. Patent No. 7,146,202 ("the '202 patent"), attached hereto as Exhibit 1001.

The undersigned representative of Petitioner authorizes the Patent Office to charge the $23,000 Petition Fee, along with any additional fees, to Deposit Account 501432, ref: 638143-600006. Nine claims are being reviewed, so no excess claim fees are due.

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I. Introduction

U.S. Patent No. 7,146,202 (the "'202 patent") is directed to a method of measuring the concentration of an analyte within an animal body, specifically the detection of glucose levels in blood. The '202 patent describes a simple, two layer, construction for a sensor that can be placed into the animal body to measure the concentration of glucose. Ex. 1001, Abstract and Figure 1. Independent claim 1 of the '202 patent recites a method for measuring the concentration of an analyte within an animal body with a sensor that is placed into the body. The sensor of claim 1 includes a structurally flexible core (24) and a layer of electrochemically active metal (26) covering and in contact with the core (24).

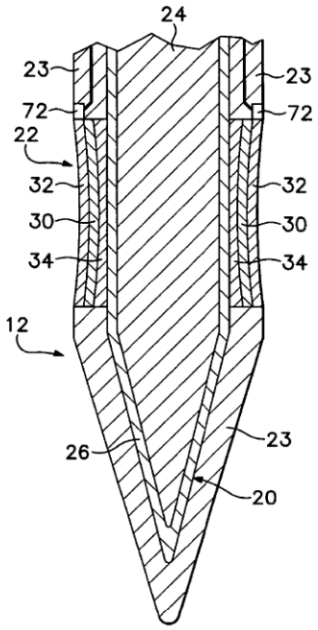


FIG.1

During prosecution, the patent applicant attempted to claim a method for measuring the concentration of an analyte using a sensor that had a core material and

a layer of electrochemically active metal applied to a portion of the core. These broad claims, and subsequent variations of these broad claims, were rejected by the Patent Office. Ultimately, the patent applicant obtained allowance of the '202 patent by focusing on minor distinctions between the prior art and the amended claims. In particular, the patent applicant indicated that the claims differed from the prior art because the claimed core was "structurally flexible" and the electrochemically active metal was in contact with the outer surface of the core. Ex. 1002, 6/13/2006 Response, p. 3, 8-9.

What the Examiner did not realize was that using plated wires in analyte sensors, such as to reduce cost, while maintaining the desired properties on the outer surface of the sensor, was well known when the '202 patent was filed. Had the Examiner been aware of the more relevant references cited herein (*see, e.g.*, Ex. 1006, Declaration of David Vachon, ¶¶ 24-42), the '202 patent would not have been allowed. This petition for *inter partes* review should therefore be granted.

II. Grounds for Standing Pursuant to 37 C.F.R. § 42.104(a)

Petitioner certifies that the '202 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging the claims on the grounds identified herein.

III. Background Information for '202 Patent

A. Overview of the '202 Patent and Prosecution History

The '202 patent was filed on June 16, 2004 and issued on December 5, 2006. The patent claims priority to U.S. Provisional Application No. 60/479,141, filed June 16, 2003. File History (Exhibit 1002) at p. 111-113, (Declaration). The patent includes a single figure illustrating a cross-sectional view of the sensor and less than 4 columns of description.

The '202 patent is entitled "Compound Materials Analyte Sensor" and describes a sensor adapted to be inserted into a mammalian body and a method for using the sensor to monitor an analyte within the mammalian body. Ex. 1001, 1:42-49. The sensor is a metal wire that is inserted into the body. According to the patent, it was well known in the art that "a typical metal used for such a wire sensor is platinum, which is electrochemically active and generally very useful in sensing applications." *Id.*, 1:19-21. An electrochemically active metal is commonly understood to include metals that facilitate current production in certain situations. As it pertains to the '202 patent, the electrochemically active metal oxidizes hydrogen peroxide produced by the chemical reaction of the analyte (*e.g.,* glucose) and oxygen. The oxidation of the hydrogen peroxide creates free electrons at the surface of the electrochemically active metal. Ex. 1006, ¶¶ 44-45.

The ’202 patent purports to address two problems associated with typical platinum sensor electrodes: (1) platinum is “a weak metal that is easily broken with only a little flexure.” Ex. 1001, 1:22-23; and (2) platinum “is very expensive.” *Id.*, 1:28-29; Ex. 1006, ¶ 46.

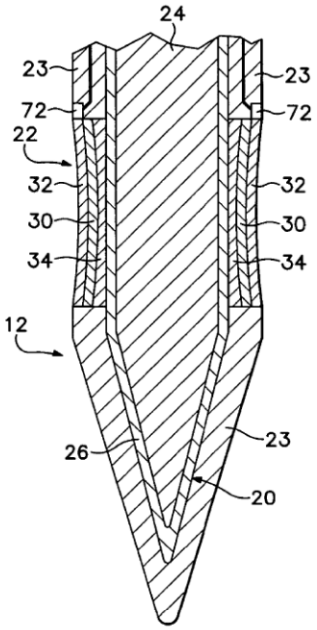


FIG.1

The ’202 patent’s proposed solution to these problems is to use a compound material sensor. A material such as tantalum, stainless steel, or nitinol is used for the wire core (24). *Id.*, 2:25-27, Fig. 1. An electrochemically active layer (26) made from a noble metal such as platinum, palladium, gold, or a combination of any of these with iridium covers the core (24). *Id.*, 2:42-44, Fig. 1. The wire sensor of the ’202 patent occupies a very small form factor. In the example provided in the specification, the core (24) is 226 microns in width with an electrochemically active layer (26) of less than 1 micron thick on top. *Id.*, 2:26-28. The compound material

sensor is manufactured by starting with the metal wire and then applying the electrochemically active layer by electroplating. *Id.*, 2:59-61; Ex. 1006, ¶ 47.

Although the claims granted in the '202 patent are method claims, prosecution of the '202 patent focused on the structure of the sensor wire. In particular, the patent applicant obtained allowance of the '202 patent by amending the claims and arguing that the claims differed from the prior art because the claimed core was "structurally flexible" and the electrochemically active metal was in contact with the outer surface of the core. Ex. 1002, 6/13/2006 Response, p. 3, 8-9.

Representative claim 1 of the '202 patent is reproduced below.

> 1. A method for measuring the concentration of an analyte within an animal body having body fluids, comprising:
>
> (a) providing a sensor having:
>
> (i) a structurally flexible core having an outer surface; and
>
> (ii) a layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core;
>
> (b) placing at least a portion of said sensor into said animal body; and
>
> (c) measuring any electric current produced by said sensor and forming a measurement of analyte concentration based on said current measurement.

IV. Identification of Challenge Pursuant to 37 C.F.R. § 42.104(b)

A. 37 C.F.R. § 42.104(b)(1): Claims for Which *Inter Partes* Review Is Requested

Inter Partes review is requested for claims 1-3, 5, 6, and 8-11 of the '202

patent.

B. 37 C.F.R. § 42.104(b)(2): The Prior Art and Specific Grounds on Which the Challenge to the Claims Is Based

Inter Partes review is requested in view of the following prior art references:

- "Progress toward the Development of an Implantable Sensor for Glucose," by George Wilson, 1992 ("Wilson") (Exhibit 1004). Wilson was published in 1992 and is prior art to the '202 patent under 35 U.S.C. § 102(b).
- U.S. Patent No. 2,719,797 to Rosenblatt ("Rosenblatt") (Ex. 1005). Rosenblatt was filed on May 23, 1950, and issued on October 4, 1955, and is prior art to the '202 patent under 35 U.S.C. § 102(b).
- Japanese Unexamined Patent Application Publication No. S57-110236 to Hagiwara ("Hagiwara") (Exhibit 1007). Hagiwara was published July 9, 1982, and is prior art to the '202 patent under 35 U.S.C § 102(b).
- U.S. Patent No. 6,275,717 to Gross ("Gross") (Exhibit 1003). Gross was filed on June 23, 1998, and issued on August 14, 2001, and is prior art to the '202 patent under 35 U.S.C. § 102(b).

The specific statutory grounds on which the challenge to the claims is based and the prior art relied upon for each ground are as follows:

a) Claims 1-3, 5, 6, and 9-11 are obvious under 35 U.S.C. § 103(a) based on Wilson in view of Rosenblatt;

b) Claims 1-3, 6, 8, and 10-11 are anticipated under 35 U.S.C. § 102(b) by Hagiwara;

c) Claim 5 is obvious under 35 U.S.C. § 103(a) based on Hagiwara in view of Rosenblatt;

d) Claims 1-3, 6, 10, and 11 are anticipated under 35 U.S.C. § 102(b) by Gross.

C. 37 C.F.R. § 42.104(b)(3): Claim Construction

Claims are to be given their "broadest reasonable construction in light of the specification" as a person of ordinary skill in the art would understand the claim terms. 37 C.F.R. § 42.100(b); *see* Ex. 1006, ¶¶ 20-23. The constructions proposed below are intended to aid in this proceeding, and should not be understood as waiving any arguments that may be raised in any litigation. Further, because the standard for claim construction at the Patent Office is different than that used during a U.S. District Court litigation, *see In re Am. Acad. Of Sci. Tech Ctr.*, 367 F.3d 1359, 1364, 1369 (Fed. Cir. 2004); MPEP § 2111, Petitioner expressly reserves the right to argue a different claim construction in litigation for any term of the '202 patent as appropriate in that proceeding.

1. "Structurally Flexible"

The term "structurally flexible" should be interpreted to mean "capable of being bent or flexed."

The ’202 patent claims the use of a structurally flexible core as the base of its sensor. The ’202 patent specification discusses materials such a tantalum, stainless steel, or nitinol as possible materials for the wire core. Ex. 1001, 2:34-37. The specification explicitly notes that tantalum and nitinol are naturally flexible but is silent as to the flexibility of stainless steel. *Id*. 2:37-39.

The dictionary definition of flexible is “[c]apable of being bent or flexed.” Ex. 1011, *Flexible*, Webster’s New College Dictionary (3rd Ed. 2008). The specification uses the term according to its plain and ordinary meaning, subject to the fact that both tantalum and nitinol fall within the patent’s definition of structurally flexible. Accordingly, “structurally flexible” should be construed for this proceeding as “capable of being bent or flexed,” where tantalum and nitinol are two examples of materials that are structurally flexible. Ex. 1006, ¶¶ 51-55 .

D. 37 C.F.R. § 42.104(b)(4): How the Construed Claims are Unpatentable

An explanation of how claims 1-3, 5, 6, and 8-11 are unpatentable, including identification of how each claim feature is found in the prior art, is set forth below in Section V.

E. 37 C.F.R. § 42.104(b)(5): Supporting Evidence

An Appendix of Exhibits supporting this Petition is attached. Included at Exhibit 1006 is a Declaration of David J. Vachon, Ph.D. under 37 C.F.R. § 1.68. In addition, the relevance of the evidence to the challenged claims, including an

identification of the specific portions of the evidence supporting the challenge, is included in Section V.

V. There Is a Reasonable Likelihood That Claims 1-3, 5, 6, and 8-11 of the '202 Patent Are Unpatentable

A. Claims 1-3, 5, 6, and 9-11 are obvious under 35 U.S.C. § 103(a) based on the Combination of Wilson and Rosenblatt

Wilson

Wilson describes the "development of an electrochemically, based implantable sensor for glucose." Ex. 1004, p. 1613. According to Wilson, "[t]he sensor is needle shaped, and an about the size of a 28-gauge needle." *Id.,* at 1613. A 28-gauge needle is 0.362 mm in diameter, which is consistent with the size of the '202 patent needles. Ex. 1006, ¶ 57. Wilson explicitly notes that the needle-shaped sensor is flexible. Ex. 1004, p. 1613.

The Wilson needle-shaped sensor is combined with a monitoring device, where the system senses an amount of glucose catalyzed by glucose oxidase and monitors glucose concentrations for as long as 10 days in rats. *Id.*

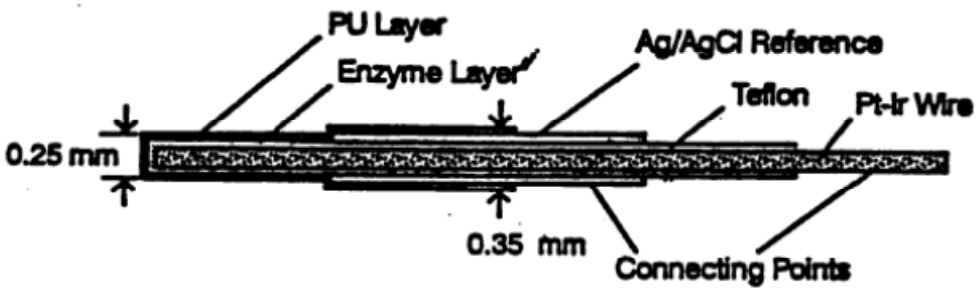


Fig. 3. Diagram of the implantable sensor
PU, polyurethane

Fig. 3 in Wilson illustrates the structure of the implantable sensor. Its overall length is 4 cm and the diameter of the sensing element is 0.25 mm. The diameter at the widest point is 0.35 mm. According to Wilson, the sensor is "extremely flexible" and can be implanted using a short stainless steel catheter which is removed after the sensor is in place. *Id.,* at 1615. In Wilson, the sensor wire is constructed of platinum-Iridium (Pt-Ir). *Id.,* Fig. 3.[1]

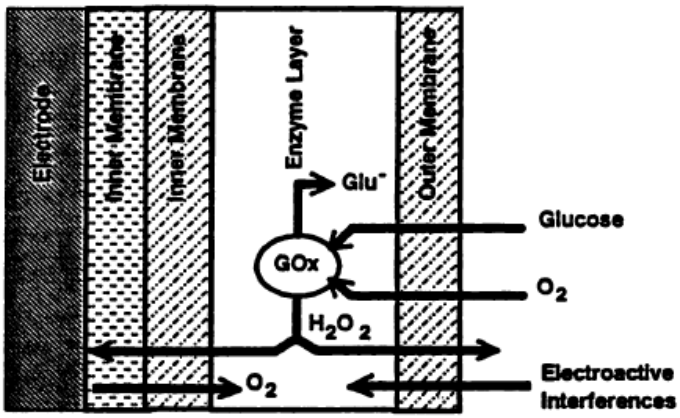


Fig. 2. Diagram of the multilayered sensing element, showing the fluxes of the various species present
GOx, glucose oxidase; glu⁻, reduced glucose

Fig. 2 of Wilson identifies a series of membrane layers that are applied to the platinum-iridium core wire. From inside to outside, the Wilson electrode includes the platinum-iridium electrode, one or more inner membranes, a glucose oxidase based enzyme layer and an outer membrane that is configured to protect the sensor

[1] Platinum iridium alloy wires are known to be of similar expense as platinum wires (*e.g.*, within 5-10% of cost of platinum wires). Ex. 1010; Ex. 1006, ¶ 58.

element and to selectively permit passage of certain molecules at certain rates. *Id.,* at 1615; Ex. 1006, ¶¶ 56-58.

Rosenblatt

Rosenblatt describes "a process for coating tantalum and like metals with metals or alloys of the platinum group." Ex. 1005, 1:15-17. In particular, Rosenblatt describes anodes manufactured using the coating process. Rosenblatt teaches that the platinum coated tantalum can be used for anodes in electrochemical processes. *Id.,* 1:17-23.

As Rosenblatt explains, if only the chemical characteristics of the material were considered in the selection of anode material, platinum (and metals of the platinum group) would be the universal choice. However, platinum is expensive. *Id.,* 1:32-38.

In the continual search for an alternative material, Rosenblatt explains that tantalum was initially thought to be a good choice because it is inert and less expensive. *Id.,* 1:60-64. But, when tantalum is used as an anode, the flow of electric current quickly stops because of the formation of an oxide layer which decreases the conductivity of the tantalum. *Id.,* 1:65-70. Accordingly, Rosenblatt explains that to prevent the formation of this film, "attempts have been made to coat a tantalum base with platinum metal" but that the attempts were not particularly successful because the platinum did not sufficiently adhere to tantalum. *Id.,* 1:72-2:6.

To achieve better adherence, the process described by Rosenblatt "involves a combination of successive treatments whereby a thin deposit of a platinum metal is made upon the surface of a tantalum body and thereafter the platinum metal is bonded to the tantalum body by heating the whole to a high temperature and under inert conditions." *Id.,* 2:40-45. One of the ways Rosenblatt proposes to deposit the platinum on the tantalum is via electroplating. *Id.,* 2:44-50; Ex. 1006, ¶¶ 59-64.

Claims 1-3, 5, 6, and 9-11 are obvious over Wilson in view of Rosenblatt, as demonstrated below.

1. Independent Claim 1

(a) Preamble – "A method for measuring the concentration of an analyte within an animal body having body fluids"

Wilson discloses the preamble of claim 1.

Wilson is entitled "Progress toward the Development of an Implantable Sensor for Glucose" and in the first sentence of the Abstract, Wilson explains that the publication describes an "electrochemically based implantable sensor for glucose." Ex. 1004, p. 1613. Glucose is an analyte. Ex. 1006 ¶¶ 74-76.

Wilson thus discloses "a method of measuring the concentration of an analyte within an animal body having body fluids."

(b) First Element – "Providing a sensor having a structurally flexible core having an outer surface;"

Wilson in view of Rosenblatt discloses the first element of claim 1.

Wilson discloses a platinum wire sensor. Ex. 1004, Fig. 3. The Wilson sensor is flexible (Ex. 1004, p. 1613), but does not have a plated flexible core like that of the '202 patent. Ex. 1006, ¶ 78.

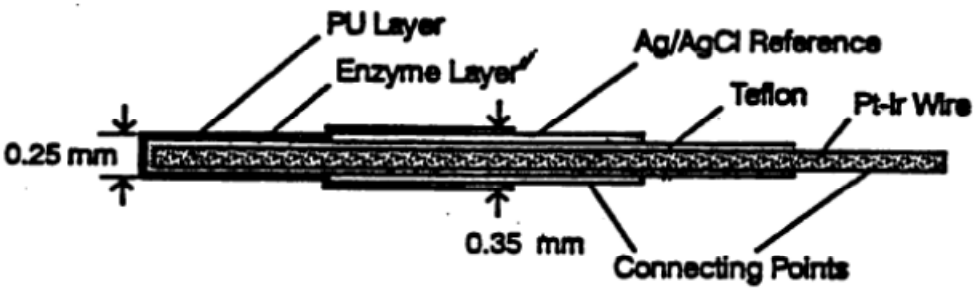


Fig. 3. Diagram of the implantable sensor
PU, polyurethane

But, Rosenblatt discloses that platinum coated tantalum can be used in electrochemical sensors as an alternative to platinum wire sensors. Ex. 1005, 1:72-2:1. As noted below in the motivation to combine section, using plated electrodes in wire-based glucose sensors was known over twenty years prior to the priority date of the '202 patent. Ex. 1007, Hagiwara, p. 7. Plated electrodes work in such instances because "only the electrode reaction surface requires noble metal properties." *Id*. Rosenblatt explains that platinum sensors suffer from being prohibitively expensive. *Id*. Wilson would benefit from modifying its platinum wire sensor to a sensor with a tantalum core and a platinum coating, as described by Rosenblatt, to save costs over the use of platinum-iridium wires in Wilson. Ex. 1006 ¶ 79.

The '202 patent explicitly states that tantalum, like the tantalum present in the

Rosenblatt electrode core, is structurally flexible. Ex. 1001, 2:36-38.[2] Thus, the tantalum core of Rosenblatt, which is plated and used as an alternative to the platinum-iridium wire in Wilson in the combination of Wilson and Rosenblatt, is structurally flexible. Ex. 1006, ¶¶ 77-81.

Wilson in view of Rosenblatt therefore discloses "providing a sensor having a structurally flexible core having an outer surface."

(c) Second Element – "a layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core;"

Wilson in view of Rosenblatt discloses the second element of claim 1.

According to Rosenblatt, the process for manufacturing the sensor with a tantalum core and platinum coating "involves a combination of successive treatments whereby a thin deposit of a platinum metal is made upon the surface of a tantalum body and thereafter the platinum metal is bonded to the tantalum body by heating the whole to a high temperature and under inert conditions." Ex. 1005, 2:40-45. The '202 patent indicates that platinum is an example of an electrochemically active metal. Ex. 1001 at 2:42-44; *see also* Ex. 1006 ¶ 84. Further, one of the ways

[2] The Rosenblatt tantalum core is of a similar form factor as that of the '202 patent, where Rosenblatt discloses at 670 micron electrode and the '202 patent describes a similarly sized 226 micron wire. Ex. 1001, 2:24-28; Ex. 1005, 5:14-20.

Rosenblatt proposes to deposit the platinum on the tantalum is via electroplating. Ex. 1005, 2:44-50. Electroplating is one of the example techniques used in the '202 patent for applying its platinum layer to its metal wire. Ex. 1001, 2:59-61.

One of ordinary skill in the art would understand that applying the Rosenblatt electroplating procedure to a tantalum core would include plating the entire tantalum core, including the distal tip. Rosenblatt describes the problems caused by incomplete platinum coverage of tantalum throughout its disclosure. Rosenblatt states that presence of any exposed tantalum in an electrode quickly results in tarnish, where the flow of electric current causes "what may be referred to as an anodic film comprising a layer of oxide which decreases the electric conductivity of the material." Ex. 1005, 1:64-70. Exposed tantalum in an electrode results in electrodes that are "corroded with a coherent tarnish layer." *Id*., 4:26-36. To avoid these problems, one of ordinary skill in the art would be motivated to electroplate the entire surface of the electrode, including the distal tip, to avoid tarnishing that could ruin function of the electrode. Covering the entire tantalum surface, including the distal tip, would avoid the undesirable oxidation process. Ex. 1006, ¶ 85. Accordingly, Rosenblatt discloses a platinum layer surrounding, covering and in contact with the outer surface of the tantalum core. Ex. 1006, ¶¶82-86.

Wilson in view of Rosenblatt therefore discloses "a layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core."

(d) Third Element – "placing at least a portion of said sensor into said animal body;"

Wilson discloses the third element of claim 1.

Fig. 3 of Wilson illustrates the structure of the implantable sensor. Its overall length is 4 cm and the diameter of the sensing element is 250 mm. The diameter at the widest point is 350 mm. According to Wilson, the sensor is "extremely flexible" and can be implanted into the body using a short stainless steel catheter which is removed after the sensor is in place. *Id.,* at 1615; *see also* Ex. 1006 ¶ 88.

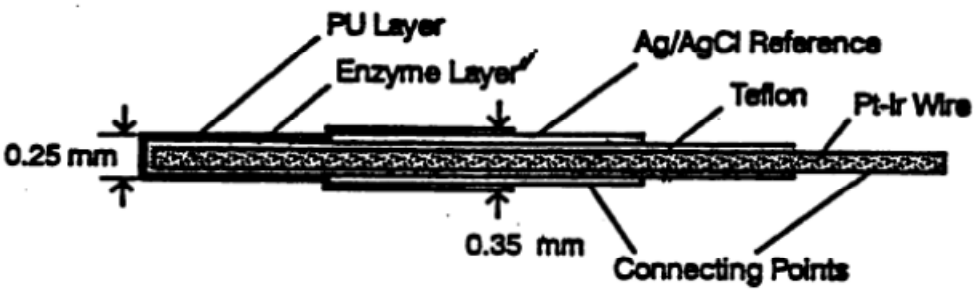


Fig. 3. Diagram of the implantable sensor
PU, polyurethane

Accordingly, at least a portion of the modified Wilson-Rosenblatt sensor can be placed into the animal body for measuring glucose. Ex. 1006, ¶¶ 87-89.

Wilson in view of Rosenblatt therefore discloses "placing at least a portion of said sensor into said animal body."

(e) Fourth Element – "measuring any electric current produced by said sensor and forming a measurement of analyte concentration based on said current measurement."

Wilson discloses the final element of claim 1.

Wilson describes the "development of an electrochemically, based implantable sensor for glucose." Ex. 1004, p. 1613. The needle is combined with a monitoring device, where the operation of the system is based on the glucose oxidase-catalyzed oxidation of glucose and can monitor glucose concentrations for as long as 10 days. *Id*. "The implementation of the continuous monitoring system requires a unit that can maintain the appropriate applied potential between the indicating and reference electrodes while measuring the resulting current. The time-dependent fluctuations of this current are stored and transformed into an estimation of the blood glucose concentration." *Id.,* at 1616; *see also* Ex. 1006 ¶¶ 90-93.

Wilson in view of Rosenblatt therefore discloses "measuring any electric current produced by said sensor and forming a measurement of analyte concentration based on said current measurement."

(f) Motivation to Combine

One of ordinary skill in the art would be motivated to combine the teachings of Wilson and Rosenblatt for many reasons. First, one of ordinary skill in the art would be motivated to combine the references in part because the disclosures are in

analogous arts. Both are directed to electrodes for electrochemical electrodes. Ex. 1004, p. 1613, Ex. 1005, 1:22-23; Ex. 1006, ¶ 96.

Second, one of ordinary skill in the art would be motivated to incorporate the beneficial features of Rosenblatt with the sensor described in Wilson. In particular, Wilson discloses a platinum wire sensor for use as an implantable sensor for glucose measurement. Ex. 1004, p. 1613. Rosenblatt explains that platinum sensors suffer from being prohibitively expensive stating: "If only the chemical characteristics of a material were to be considered in the selection of a suitable [] material, the metals of the platinum group would be the universal choice because they are highly resistant to corrosion; however, the high cost of these precious metals prohibits their extended commercial use. Substitute materials have, therefore, been resorted to, whenever possible." Ex. 1005, 1:32-38. Rosenblatt discloses that platinum coated tantalum can be used in electrochemical sensors as an alternative to platinum wire sensors. Ex. 1005, 1:72-2:1; Ex. 1006, ¶ 97.

Such use of platinum coated tantalum in electrodes was in no way new at the '202 patent's priority date. For example, U.S. Patent No. 4,240,878 to Carter, issued in 1980, discloses a layer of platinum covering a tantalum core for measuring current from an electrode. The Carter specification notes corrosion resistance of its platinum clad tantalum electrode. Moreover, it also discloses using a less expensive platinum clad tantalum electrode, instead of using a platinum electrode, and states:

> The platinum metal used as an electrode in U.S. Pat. No. 3,858,114 is very expensive. It would therefore be worthwhile, if possible, to plate a tantalum core with platinum and use it as an electrode. Such an electrode would have a platinum surface and 40 tantalum core and would be *less expensive* than conventionally platinum plated electrodes.

U.S. 4,240,878, 1:36-43 (emphasis added); Ex. 1006, ¶ 98.

Further, U.S. Patent No. 3,461,058 to Haley, issued in 1969, describes a refractory (i.e., difficult to corrode) composite electrode made from a titanium or tantalum core coated with platinum. Haley further teaches that "[m]etals of the platinum group have desirable characteristics when utilized as insoluble anodes, but *because of the high cost of these metals, it is desirable to use substitute materials which are less costly*." U.S. 3,461,058, 1:41-44 (Emphasis added). One of the substitute materials described in Haley is a composite electrode made from tantalum core coated with platinum. *Id*., 3:28-38; Ex. 1006, ¶ 99.

Similarly, U.S. Patent No. 3,236,756 to Beer, issued in 1966, also describes what it considered a well known tantalum core coated with platinum anode. According to Beer:

> As is known anodes for carrying out electolyses and other electrochemical processes usually consist of a precious metal e.g. platinum. Said anodes are quite satisfactory but their high cost price constitutes a bar to their being used in the art on a large scale … In order to obviate this drawback *it is possible to use an anode consisting*

> *of a core of a less precious or base metal coated with a layer of precious metal, mostly platinum* … Thus an anode is known which consists of a core of tantalum coated with platinum while also a core of zirconium or of a zirconium alloy coated with platinum has been proposed. [Emphasis added].

U.S. 3,236,756, 1:13-30; Ex. 1006, ¶ 100.

PCT Publication No. WO 01/23033 to Bartig provides a further example of a platinum clad tantalum implantable electrode.

To summarize, as taught by Rosenblatt, and as fully corroborated by Carter, Haley, Beer, and Bartig it was not only very well known in the art at the time to use a composite electrode formed of a metal (e.g., tantalum) covered by a layer of platinum, but is was also widely known that cost saving is a strong motivation for replacing a platinum-only electrode with a composite electrode formed of a less expensive metal (e.g., tantalum) covered by a layer of platinum. Ex. 1006, ¶ 101.

Furthermore, it is well understood by persons of ordinary skill in the art that, in order to achieve the benefits of noble metals in electrodes, only the surfaces of electrodes require noble metal properties. Thus, base metal wires with precious metal coating can also be used. Ex. 1006, ¶ 102. Accordingly, the sensor design in Wilson could benefit from the alternative, platinum coated tantalum design, disclosed by Rosenblatt. This would be seen as one of ordinary skill in the art as nothing more than simple substitution of one well known material for another, where

the Rosenblatt material electrode was known over 50 years prior to the priority date of the '202 patent. Ex. 1006, ¶¶ 102. This combination of prior art elements according to known methods would yield predictable results. Ex. 1006, ¶¶ 102. Having a prototype device, like the sensor described in Wilson, one of ordinary skill in the art would seek to modify that prototype device to improve cost and manufacturability. It would be obvious to try different wire materials, seeking to improve real-world performance of the device as well as to reduce cost. A platinum-plated tantalum electrode, as disclosed in Rosenblatt would have been an obvious alternative to try. Ex. 1006, ¶ 102.

Third, the use of plated electrodes in wire-based glucose sensors was known by persons of ordinary skill in the art for over twenty years prior to the priority date of the '202 patent. Japanese Patent Application Publication No. S57-110236 to Bunji Hagiwara ("Hagiwara"), submitted herewith as Exhibit 1007, was published in July 1982 and describes wire based glucose sensors that function very similarly to the sensors described in the '202 patent and the Wilson reference. For example, Fig. 1(D) of Hagiwara discloses a polarography sensor for implementing an enzymatic reaction to detect glucose via a glucose oxidase enzyme layer 12 and a precious metal wire 1. Ex. 1007, pp. 6-7. Hagiwara discusses the known technique of using a plated electrode as a substitute for a solid precious metal wire 1, stating: "While cases were described that use precious metal wires as measuring electrode

configuring bodies in the descriptions of polarography sensor structures in FIG. 1(A) through (D) above, because only the electrode reaction surface requires noble metal properties, that is, non-variability…, base metal wires, *with precious metals vapor deposited or plated on the front ends thereof*, may also be used." *Id*., p. 7 (emphasis added). This teaching, suggestion, and motivation to combine these references was known to the person of ordinary skill in the art over twenty years prior to the priority date of the '202 patent. Ex. 1006, ¶ 103.

For at least these reasons, including that the use of plated electrodes in wire-based glucose sensors was known over twenty years prior to the priority date of the'202 patent, one of ordinary skill in the art would be motivated to combine the teachings of Wilson and Rosenblatt. Ex. 1006, ¶¶ 94-104.

Claim 1 is therefore obvious based on Wilson in view of Rosenblatt. Ex. 1006, ¶ 105.

2. Dependent Claim 2

Dependent claim 2, which depends from claim 1, adds the limitation, "wherein said electrochemically active metal comprises a noble metal."

Rosenblatt discloses that platinum coated tantalum can be used in electrochemical sensors as an alternative to platinum wire sensors. Ex. 1005, 1:72-2:1. Accordingly, the Wilson-Rosenblatt sensor has a tantalum core and an electrochemically active metal layer that is platinum. The '202 patent notes that

platinum is an electrochemically active metal and a noble metal. Ex. 1001, 2:42-46. *See also* Ex. 1006 ¶¶ 106-109.

As detailed above, Wilson in view of Rosenblatt discloses each of the elements of independent claim 1. Because Rosenblatt discloses the additional limitation recited in dependent claim 2, that claim is obvious.

3. Dependent Claim 3

Dependent claim 3, which depends from claim 2, adds the limitation, "wherein said noble metal comprises at least one of platinum, palladium, and gold."

Rosenblatt discloses that platinum coated tantalum can be used in electrochemical sensors as an alternative to platinum wire sensors. Ex. 1005, 1:72-2:1. Accordingly, the Wilson-Rosenblatt sensor has a tantalum core and an electrochemically active metal layer that is platinum. Ex. 1006, ¶¶ 110-112.

As detailed above, Wilson in view of Rosenblatt discloses each of the elements of independent claim 1 and dependent claim 2. Because Rosenblatt discloses the additional limitation recited in dependent claim 3, that claim is obvious.

4. Dependent Claim 5

Dependent claim 5, which depends from claim 1, adds the limitation, "wherein said core comprises tantalum."

Rosenblatt discloses that platinum coated tantalum can be used in electrochemical sensors as an alternative to platinum wire sensors. Ex. 1005, 1:72-2:1. Accordingly, the Wilson-Rosenblatt sensor has a tantalum core. Ex. 1006, ¶¶ 113-115.

As detailed above, Wilson in view of Rosenblatt discloses each of the elements of independent claim 1. Because Rosenblatt discloses the additional limitation recited in dependent claim 5, that claim is obvious.

5. Dependent Claim 6

Dependent claim 6, which depends from claim 1, adds the limitation, "wherein said layer of electrochemically active metal is adapted to provide at least one sensing surface."

Fig. 2 of Wilson illustrates the sensor wire acting as a sensing surface. In particular, the reaction of glucose with oxygen creates hydrogen peroxide (H_2O_2) which passes through the membranes to the electrode and reacts with the platinum electrode to generate a current . Ex. 1006, ¶¶ 117; 116-119.

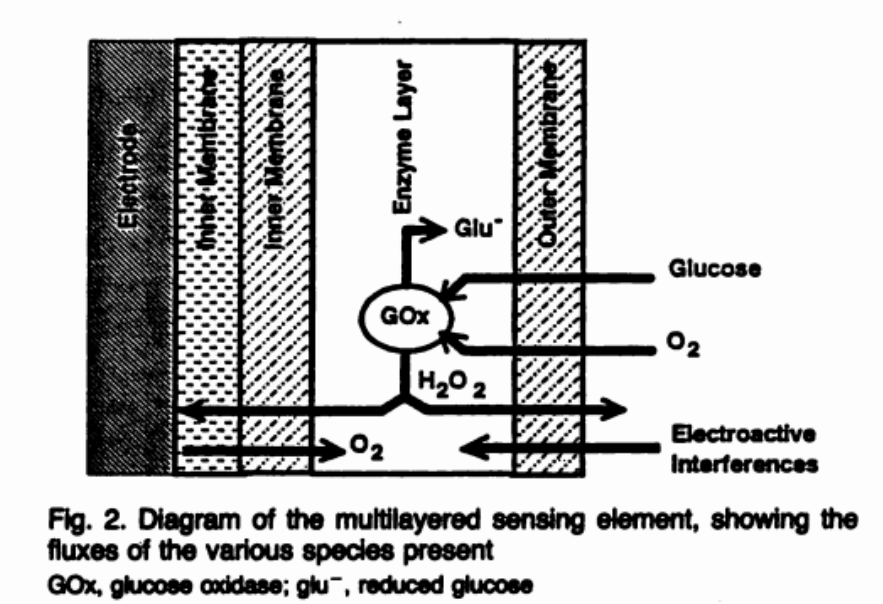


Fig. 2. Diagram of the multilayered sensing element, showing the fluxes of the various species present
GOx, glucose oxidase; glu⁻, reduced glucose

As detailed above, Wilson in view of Rosenblatt discloses each of the elements of independent claim 1. Because Wilson discloses the additional limitation recited in dependent claim 6, that claim is obvious.

6. Dependent Claim 9

Dependent claim 9, which depends from claim 1, adds the limitation, "wherein said placing at least a portion of said sensor into said animal body comprises placing said at least a portion of said sensor in said animal body for at least 24 hours."

Wilson describes the "development of an electrochemically, based implantable sensor for glucose." Ex. 1004, p. 1613. When the needle is combined with a monitoring device, the operation of the system is based on the glucose oxidase-catalyzed oxidation of glucose and can monitor glucose concentrations for

as long as 10 days in rats. Accordingly, the Wilson-Rosenblatt sensor can be placed in an animal's body for at least 24 hours. Ex. 1006, ¶¶ 120-122.

As detailed above, Wilson in view of Rosenblatt discloses each of the elements of independent claim 1. Because Wilson discloses the additional limitation recited in dependent claim 9, that claim is obvious.

7. Dependent Claim 10

Dependent claim 10, which depends from claim 1, adds the limitation, "wherein said analyte comprises glucose."

Wilson describes the "development of an electrochemically, based implantable sensor for glucose." Ex. 1004, p. 1613. Accordingly, the Wilson-Rosenblatt sensor measures the concentration of the glucose analyte. Ex. 1006, ¶¶ 123-125.

As detailed above, Wilson in view of Rosenblatt discloses each of the elements of independent claim 1. Because Wilson discloses the additional limitation recited in dependent claim 10, that claim is obvious.

8. Dependent Claim 11

Dependent claim 11, which depends from claim 1, adds the limitation, "wherein said core further comprises at least a first end, and wherein said electrochemically active layer further surrounds, covers, and is in contact with said at least a first end of said core."

Rosenblatt describes an electroplating process where a treated tantalum electrode core is placed in a plating bath – "[a]fter the tantalum base has been roughened as by etching in a manner as explained above, it is placed in the cathode position in a plating bath." Ex. 1005, 3:42-44.

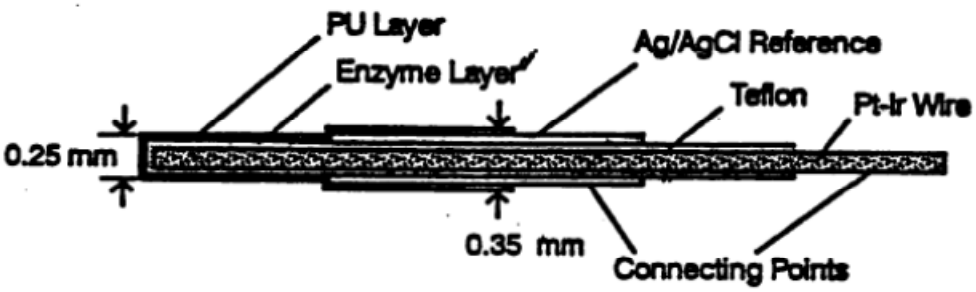


Fig. 3. Diagram of the implantable sensor
PU, polyurethane

Placing the Wilson-Rosenblatt tantalum wire in a plating bath to create an electrode with a platinum coating would necessarily result in the platinum plating covering at least one end of the tantalum core. Ex. 1006, ¶ 129. One of ordinary skill in the art would understand that applying the Rosenblatt electroplating procedure to a tantalum core would include plating the entire tantalum core, including the distal tip. Rosenblatt describes the problems caused by incomplete platinum coverage of tantalum throughout its disclosure. Rosenblatt states that presence of exposed tantalum in an electrode quickly results in tarnish, where the flow of electric current causes "what may be referred to as an anodic film comprising a layer of oxide which decreases the electric conductivity of the material." Ex. 1005, 1:64-70. Exposed tantalum in an electrode results in electrodes

that are "corroded with a coherent tarnish layer." *Id*., 4:26-36. To avoid these problems, one of ordinary skill in the art would be motivated to electroplate the entire surface of the electrode, including the distal tip, to avoid tarnishing that could ruin function of the electrode. Covering the entire tantalum surface, including the distal tip, would further improve sensor performance including potential noise reductions and sensor-to-sensor variability due to differences in electroactive surface areas. Ex. 1006, ¶ 130. Accordingly, Rosenblatt discloses a platinum layer surrounding, covering and in contact with the outer surface of the tantalum core. Ex. 1006, ¶¶ 126-131.

As detailed above, Wilson in view of Rosenblatt discloses each of the elements of independent claim 1. Because Rosenblatt discloses the additional limitation recited in dependent claim 11, that claim is obvious.

B. Claims 1-3, 6, 8, and 10-11 are anticipated under 35 U.S.C. § 102(b) by Hagiwara

Hagiwara

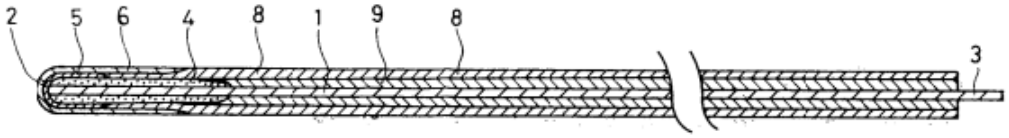
Hagiwara describes "a polarography sensor used by being inserted into a tissue (*e.g.*, a blood vessel), and, in particular, to a technique for inhibiting a blood coagulation reaction from occurring when the sensor is inserted into a blood vessel." Ex. 1007, Hagiwara, pp. 2-3. Hagiwara teaches that "[i]n general, the concentration of an oxidizing substance or a reducing substance contained in an aqueous solution can be measured through polarography using a measuring electrode (working

electrode) made of a precious metal such as platinum." *Id*., p. 3. Example analytes that can be detected by Hagiwara sensors include O_2, H_2, glucose, uric acid, l-ascobyl acid, and noradrenaline. *Id*.

Hagiwara describes electrodes that can be "used as intravenous polarography sensors to be inserted into blood vessels." *Id*. at 4. "[T]his would enable extremely important observations for clinical and research purposes because doing so would allow continuous measurement and recording of the concentrations of all types of intravascular components." *Id*.

Fig. 1(B) of Hagiwara discloses a polarography sensor that forms a flexible separation type measuring electrode. Ex. 1007, p. 6. "[M]ost of this polarography sensor is flexible and can thus be inserted deep (for example to the heart) along the inside of a vein." *Id*. The Fig. 1(B) sensor includes a precious metal wire 1 that is covered by a number of layers of membrane and other materials that enable it to sense the chemical makeup (*e.g.*, oxygen content) of the blood into which the sensor is inserted (*i.e.*, an analyte). *Id*., p. 7, Ex. 1006, ¶ 68. The sensor of Fig. 1(B) includes "an insulating coating 9 made of a flexible resin" that runs the length of most of the sensor. Ex. 1007, p. 6. That flexible resin layer 9 is further covered by "a flexible tube 8 made of Teflon, silicon, or the like." *Id*.

FIG. 1 (B)



At a sensing end portion, the precious metal wire is covered by a small, hard insulating coating 4, which protects the sensitive end portion. *Id*. That insulating coating 4 has an opening at the tip of the sensor that provides the precious metal wire 1 access to the bloodstream into which the sensor is inserted via two membrane layers 5, 6. Ex. 1007, p. 6. Specifically, the end portion includes a contamination inhibiting coating 5, and a blood coagulation inhibiting coating 6. *Id*.

While Fig. 1(B) is described using a precious metal wire 1 at its core (*e.g.*, platinum, gold), Hagiwara describes alternatives that can be used in actual manufacturing practice. *Id*., p. 3. Specifically, Hagiwara states that "[w]hile cases were described that use precious metal wires as measuring electrode configuring bodies in the descriptions of polarography sensor structures in FIG. 1(A) through (D) above, because only the electrode reaction surface requires noble metal properties, that is, non-variability, base metal wires… with precious metals vapor deposited or plated on the front ends thereof may also be used." *Id*., p. 7; Ex. 1006, ¶¶ 65-70.

1. Independent Claim 1

(a) Preamble – "A method for measuring the concentration of an analyte within an animal body having body fluids"

Hagiwara discloses the preamble of claim 1.

Hagiwara describes "a polarography sensor used by being inserted into a

tissue (*e.g.*, a blood vessel), and, in particular, to a technique for inhibiting a blood coagulation reaction from occurring when the sensor is inserted into a blood vessel." Ex. 1007, pp. 2-3. Example analytes that can be detected by Hagiwara sensors include O_2, H_2, glucose, uric acid, l-ascobyl acid, and noradrenaline. *Id.;* Ex. 1006 ¶¶ 132-134.

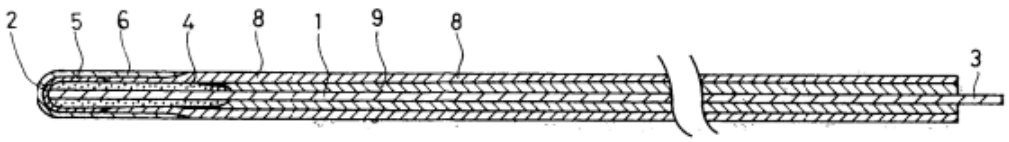
Hagiwara thus discloses "a method of measuring the concentration of an analyte within an animal body having body fluids."

(b) First Element – "Providing a sensor having a structurally flexible core having an outer surface;"

Hagiwara discloses the first element of claim 1.

Fig. 1(B) of Hagiwara discloses a polarography sensor that forms a flexible separation type measuring electrode. Ex. 1007, p. 6. "[M]ost of this polarography sensor is flexible and can thus be inserted deep (for example to the heart) along the inside of a vein." *Id*. The Fig. 1(B) sensor includes a precious metal wire 1 that is covered by a number of layers of membrane and other materials that enable it to sense the chemical makeup (*e.g.*, oxygen content) of the blood into which the sensor is inserted. *Id*., p. 7, Ex. 1006, ¶ 136.

FIG. 1 (B)



In order for the sensor of Fig. 1(B) to be flexible, such that it can be safely inserted into blood vessels near the heart, the precious metal wire 1 at its core must also be flexible. Ex. 1006, ¶ 137. Otherwise sensitive tissue could be damaged in traumatic ways. Ex. 1006, ¶ 137. Hagiwara further discloses the use of plated electrodes in the Fig. 1(B) sensor instead of a pure precious metal wire. Ex. 1007, p. 7. Specifically, Hagiwara states that "[w]hile cases were described that use precious metal wires as measuring electrode configuring bodies in the descriptions of polarography sensor structures in FIG. 1(A) through (D) above, because only the electrode reaction surface requires noble metal properties, that is, non-variability, base metal wires… with precious metals vapor deposited or plated on the front ends thereof may also be used." *Id.*, p. 7. Hagiwara further discloses the option of using compound material sensors for sensing analyte concentrations in its chemistry discussion at page 3, where Hagiwara states:

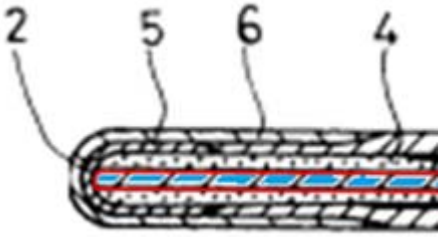
> Furthermore, in a case where H_2, which is a reducing substance, is measured; high voltage (0.1 to 0.4 V) is applied to a *measuring electrode (anode) made of Pt, Au, and the like, to which Pt or Pt-black has adhered*, and to an Ag/AgCl standard reference electrode (cathode). An oxidation reaction expressed by:
>
> $$H_2 \rightarrow 2H^+ + 2e^-$$
>
> occurs in the measuring electrode, and a reducing reaction expressed by:
>
> $$2AgCl + 2e^- \rightarrow 2Ag + 2Cl^-$$

> occurs in the standard reference electrode, and thus electric current flows between the two electrodes.

Ex. 1007, p. 3 (emphasis added); Ex. 1006 ¶ 138.

Using a plated wire in place of the Fig. 1(B) precious metal wire 1, as explicitly described at page 7 of Hagiwara (*e.g.*, using the plating bath of Rosenblatt), would produce the following, where a base wire material is illustrated in blue and a noble metal electroplated coating on its front end is shown in red. Such a coating is identical to the coating disclosed in the '202 patent, where the sensing element has its electrochemically active layer coating 26 present around its end where its sensing window resides. Ex. 1006, ¶ 139.

FIG. 1 (B)



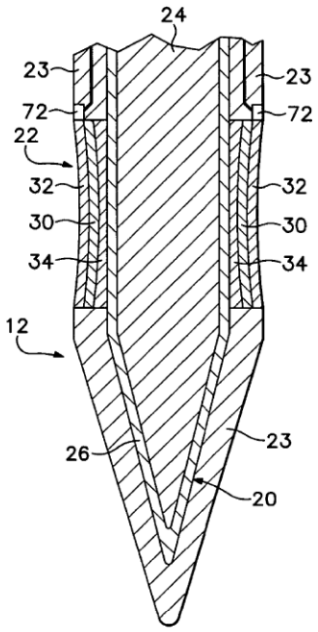


FIG.1

Because the sensor of Fig. 1(B) is required to be flexible, so that it can be inserted into sensitive blood vessels near the heart, that blue-highlighted, wire core material must also be flexible. Ex. 1006, ¶ 140. The geometry of that core necessitates that it also have an outer surface (*i.e.*, the surface that is plated by the red-highlighted noble metal). Ex. 1006, ¶¶ 135-141.

Hagiwara therefore discloses "providing a sensor having a structurally flexible core having an outer surface."

(c) Second Element – "a layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core;"

Hagiwara discloses the second element of claim 1.

Hagiwara discloses the use of a noble metal-plated wire in place of precious metal wire 1 in the flexible Fig. 1(B) configuration. Ex. 1007, p. 7. Hagiwara

includes noble metal plating because "the electrode reaction surface requires noble metal properties." *Id*. Hagiwara thus discloses plating the electrode with "precious metals vapor deposited or plated." *Id*. Ex. 1006, ¶ 143.

This disclosure is identical to the disclosure of the '202 patent. In the '202 patent, an electrochemically active layer (26) made from a noble metal covers the core (24). Ex. 1001, 2:42-44, Fig. 1. The compound material sensor is manufactured by starting with the metal wire and then applying the electrochemically active layer by electroplating. *Id.*, 2:59-61; Ex. 1006, ¶ 144. One of ordinary skill in the art would understand such electroplating (*e.g.*, using an electroplating bath) as providing complete coverage of the base material with the noble metal, where incomplete coverage would result in suboptimal performance of the electrode. *See*, Ex. 1005, Rosenblatt, 3:42-44; 4:26-36. Such has been well known in the art for fifty years prior to the filing of the '202 patent, as evidenced by Rosenblatt. Ex. 1006, ¶¶ 142-145.

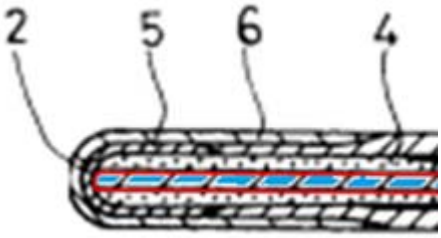
Because Hagiwara discloses using a base wire electroplated with a noble metal in its flexible sensor of Fig. 1(B), Hagiwara discloses "a layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core."

(d) Third Element – "placing at least a portion of said sensor into said animal body;"

Hagiwara discloses the third element of claim 1.

Fig. 1(B) of Hagiwara discloses a polarography sensor that forms a flexible separation type measuring electrode. Ex. 1007, p. 6. "[M]ost of this polarography sensor is flexible and can thus be inserted deep (for example to the heart) along the inside of a vein." *Id.*; Ex. 1006, ¶¶ 146-148.

FIG. 1 (B)



Hagiwara therefore discloses "placing at least a portion of said sensor into said animal body."

(e) Fourth Element – "measuring any electric current produced by said sensor and forming a measurement of analyte concentration based on said current measurement."

Hagiwara discloses the final element of claim 1.

Hagiwara describes "a polarography sensor used by being inserted into a tissue (*e.g.*, a blood vessel), and, in particular, to a technique for inhibiting a blood coagulation reaction from occurring when the sensor is inserted into a blood vessel." Ex. 1007, pp. 2-3. Hagiwara teaches that "[i]n general, the concentration of an oxidizing substance or a reducing substance contained in an aqueous solution can be measured through polarography using a measuring electrode (working electrode) made of a precious metal such as platinum." *Id.*, p. 3. Example analytes that can be

detected by Hagiwara sensors include O_2, H_2, glucose, uric acid, l-ascobyl acid, and noradrenaline. *Id*. Ex. 1006, ¶ 150.

Hagiwara discloses its process for measuring electric current, and therefore analyte concentration on page 3, stating:

> In general, the concentration of an oxidizing substance or a reducing substance contained in an aqueous solution can be measured through polarography using a measuring electrode (working electrode) made of a precious metal such as platinum, gold, and the like. In a case where O_2, which is an oxidizing (reducing) molecule, is measured; low voltage of 0.5 to 0.7 V is applied to a measuring electrode (cathode) made of Pt, Au, Ag, and the like, and to an Ag/AgCl standard reference electrode (anode). A reduction reaction expressed by:
>
> $$O_2 + 2H_2O + 4e^- \rightarrow 4OH^-$$
>
> occurs in the measuring electrode, and an oxidation reaction expressed by:
>
> $$4Ag + 4Cl^- \rightarrow 4AgCl + 4e^-$$
>
> occurs in the standard reference electrode, and thus electric current flows between the two electrodes. Furthermore, in a case where H_2, which is a reducing substance, is measured; high voltage (0.1 to 0.4 V) is applied to a measuring electrode (anode) made of Pt, Au, and the like, to which Pt or Pt-black has adhered, and to an Ag/AgCl standard reference electrode (cathode). An oxidation reaction expressed by:

$$H_2 \rightarrow 2H^+ + 2e^-$$

> occurs in the measuring electrode, and a reducing reaction expressed by:
>
> $$2AgCl + 2e^- \rightarrow 2Ag + 2Cl^-$$
>
> occurs in the standard reference electrode, and thus electric current flows between the two electrodes. Because the electric currents are proportional to the concentrations (partial pressures) of the O_2 or the H_2 under appropriate conditions, the concentrations of the O_2 or the H_2 can be measured based on the electric current values. This type of measuring method can also be applied to oxidizing substances and reducing substances other than O_2 and H_2.

Ex. 1007, p. 3. Thus, Hagiwara discloses that electric current is measured and used as a proxy for calculating concentrations of a variety of analytes in blood. Ex. 1006, ¶¶ 149-153.

Hagiwara therefore discloses "measuring any electric current produced by said sensor and forming a measurement of analyte concentration based on said current measurement."

For these reasons, Hagiwara anticipates claim 1.

2. Dependent Claim 2

Dependent claim 2, which depends from claim 1, adds the limitation, "wherein said electrochemically active metal comprises a noble metal."

Hagiwara discloses the use of a noble metal-plated wire in place of precious metal wire 1 in the flexible Fig. 1(B) configuration. Ex. 1007, p. 7. Hagiwara includes noble metal plating because "the electrode reaction surface requires noble metal properties." *Id*. Hagiwara thus discloses plating the electrode with "precious metals vapor deposited or plated." *Id.*; Ex. 1006, ¶ 155.

This disclosure is identical to the disclosure of the '202 patent. In the '202 patent, an electrochemically active layer (26) made from a noble metal covers the core (24). *Id.*, 2:42-44, Fig. 1. The compound material sensor is manufactured by starting with the metal wire and then applying the electrochemically active layer by electroplating. *Id.*, 2:59-61; Ex. 1006, ¶¶ 154-157.

As detailed above, Hagiwara discloses each of the elements of independent claim 1. Because Hagiwara discloses the additional limitation recited in dependent claim 2, that claim is anticipated.

3. Dependent Claim 3

Dependent claim 3, which depends from claim 2, adds the limitation, "wherein said noble metal comprises at least one of platinum, palladium, and gold."

Hagiwara discloses the use of a noble metal-plated wire in place of precious metal wire 1 in the flexible Fig. 1(B) configuration. Ex. 1007, p. 7. Hagiwara discloses that noble metal electrode can be made of "a precious metal such as platinum, gold, and the like." *Id*., p. 3. Accordingly, Hagiwara discloses a noble

metal-plated electrode that utilizes a platinum, palladium, or gold plating. Ex. 1006, ¶¶ 158-160.

As detailed above, Hagiwara discloses each of the elements of independent claim 1 and dependent claim 2. Because Hagiwara discloses the additional limitation recited in dependent claim 3, that claim is anticipated.

4. Dependent Claim 6

Dependent claim 6, which depends from claim 1, adds the limitation, "wherein said layer of electrochemically active metal is adapted to provide at least one sensing surface."

Hagiwara discloses the use of a noble metal-plated wire in place of precious metal wire 1 in the flexible Fig. 1(B) configuration. Ex. 1007, p. 7. Hagiwara includes noble metal plating because "the electrode reaction surface requires noble metal properties." *Id*. Throughout its disclosure, Hagiwara similarly describes the outer surface of the precious metal wire as the "reaction surface," where electrons freed by the reactions described at page 3 of Hagiwara are acquired to form a current which is used to sense the level of analytes present in the bloodstream in which the Hagiwara sensors are placed. *See*, *Id*. p. 6 (describing surface 2 of the Fig 1(B) embodiment as the reaction surface). That noble metal-plated reaction surface 2 is thus a sensing surface. Ex. 1006, ¶¶ 161-163.

As detailed above, Hagiwara discloses each of the elements of independent

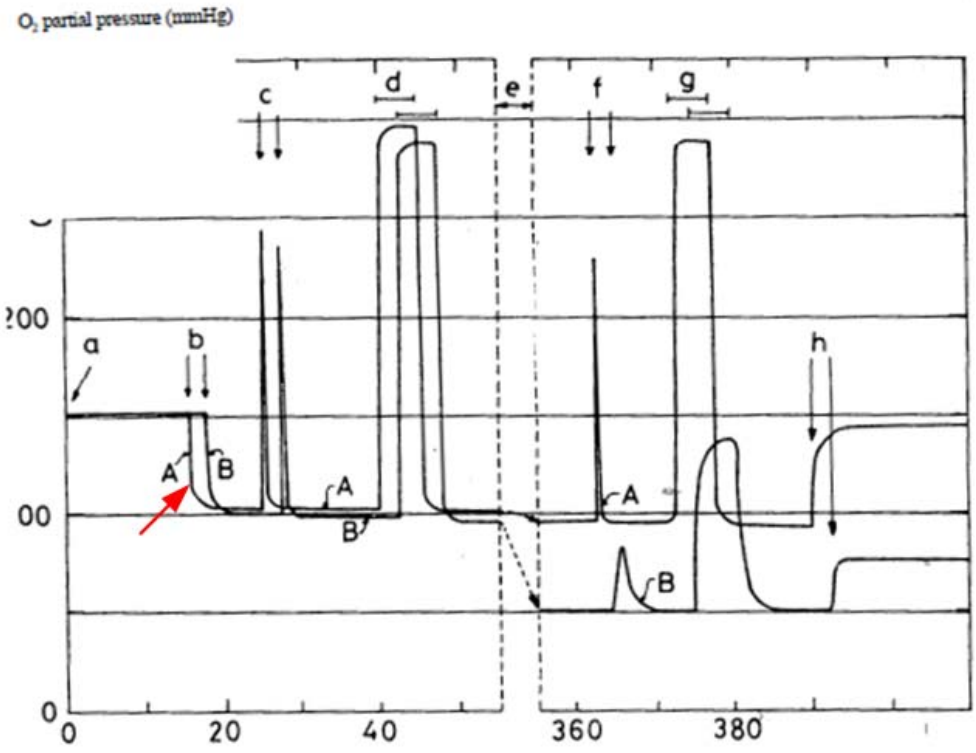
claim 1. Because Hagiwara discloses the additional limitation recited in dependent claim 6, that claim is anticipated.

5. Dependent Claim 8

Dependent claim 8, which depends from claim 1, adds the limitation, "wherein said placing at least a portion of said sensor into said animal body comprises placing said at least a portion of said sensor in said animal body for less than 3 minutes."

Fig. 3 of Hagiwara discloses a graph of oxygen levels detected by the flexible sensor of Fig. 1(B) and a traditional analyte sensor when implanted into a dog. Ex. 1007, pp. 7-8.

FIG. 3



The line marked A, noted by the red arrow, identifies oxygen levels detected by the Fig. 1(B) sensor. *Id*., p. 8. The point labeled b is the point where the sensor was exposed to blood. *Id*. Within two minutes, the plot of sensed oxygen settles to its baseline point, where it remains until the dog is placed on oxygen for 10 seconds, resulting in the spike shown at c. *Id*. Because oxygen levels are sensed in under three minutes, one of ordinary skill in the art would understand that the sensor could be removed after the ~ 2 minute settling time (*i.e.*, between two and three minutes), and an accurate blood oxygen level would be detected. In many applications, prompt removal would be preferred, because sensor introduction to a blood vessel is intrusive. Ex. 1006, ¶ 166. Hagiwara thus discloses a sensor that could accurately sense an analyte, even when being removed from the body in under 3 minutes. Ex. 1006, ¶¶ 164-167.

As detailed above, Hagiwara discloses each of the elements of independent claim 1. Because Hagiwara discloses the additional limitation recited in dependent claim 8, that claim is anticipated.

6. Dependent Claim 10

Dependent claim 10, which depends from claim 1, adds the limitation, "wherein said analyte comprises glucose."

Hagiwara describes "a polarography sensor used by being inserted into a tissue (*e.g.*, a blood vessel), and, in particular, to a technique for inhibiting a blood

coagulation reaction from occurring when the sensor is inserted into a blood vessel." Ex. 1007, pp. 2-3. Hagiwara teaches that "[i]n general, the concentration of an oxidizing substance or a reducing substance contained in an aqueous solution can be measured through polarography using a measuring electrode (working electrode) made of a precious metal such as platinum." *Id*., p. 3. Example analytes that can be detected by Hagiwara sensors include O_2, H_2, glucose, uric acid, l-ascobyl acid, and noradrenaline, where glucose, uric acid, l-ascobyl acid, and noradrenaline through the incorporation of an enzyme layer into the described sensors. *Id.*; Ex. 1006, ¶¶ 168-170.

As detailed above, Hagiwara discloses each of the elements of independent claim 1. Because Hagiwara discloses the additional limitation recited in dependent claim 10, that claim is anticipated.

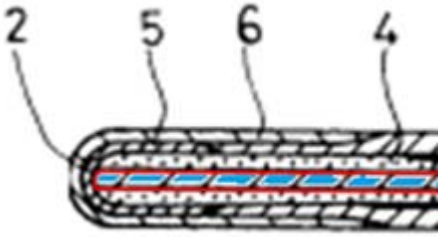
7. Dependent Claim 11

Dependent claim 11, which depends from claim 1, adds the limitation, "wherein said core further comprises at least a first end, and wherein said electrochemically active layer further surrounds, covers, and is in contact with said at least a first end of said core."

Hagiwara discloses the use of a noble metal-plated wire in place of precious metal wire 1 in the flexible Fig. 1(B) configuration. Ex. 1007, p. 7. Hagiwara includes noble metal plating because "the electrode reaction surface requires noble

metal properties, that is, non-variability." *Id*. Hagiwara thus discloses covering the electrode with "precious metals vapor deposited or plated." *Id*. Ex. 1006, ¶ 172.

FIG. 1 (B)



This disclosure is identical to the disclosure of the '202 patent. In the '202 patent, an electrochemically active layer (26) made from a noble metal covers the core (24). *Id.*, 2:42-44, Fig. 1. The compound material sensor is manufactured by starting with the metal wire and then applying the electrochemically active layer by electroplating. *Id.*, 2:59-61; Ex. 1006, ¶ 173. One of ordinary skill in the art would understand such electroplating (*e.g.*, using a Rosenblatt electroplating bath) to provide complete coverage of the base material with the noble metal. *See*, Ex. 1005, Rosenblatt, 3:42-44; 4:26-36. Such has been well known in the art for fifty years prior to the filing of the '202 patent, as evidenced by Rosenblatt. Ex. 1006, ¶ 173.

Because Hagiwara discloses using a base wire electroplated with a noble metal in its flexible sensor of Fig. 1(B), it discloses a core whose electroplating surrounds, covers, and is in contact with said at least a first end of said core. Ex. 1006, ¶¶ 171-175.

As detailed above, Hagiwara discloses each of the elements of independent claim 1. Because Hagiwara discloses the additional limitation recited in dependent

claim 11, that claim is anticipated.

C. Claim 5 is obvious under 35 U.S.C. § 103(a) by Hagiwara in view of Rosenblatt

1. Dependent Claim 5

Dependent claim 5, which depends from claim 1, adds the limitation, "wherein said core comprises tantalum."

Rosenblatt discloses that platinum coated tantalum can be used in electrochemical sensors as an alternative to platinum wire sensors. Ex. 1005, 1:72-2:1. Hagiwara describes a flexible core plated with a noble metal in its Fig. 1(B) embodiment that presents a sensor electrode designed to traverse blood vessels to near the heart. Ex. 1007, pp. 6, 7. Tantalum coated with platinum fits both of those needs expressly noted in Hagiwara. The '202 patent admits both that platinum is a noble metal and that tantalum is flexible. Ex. 1001, 2:41-44; 2:36-38. Accordingly, a Hagiwara-Rosenblatt sensor has a tantalum core. Ex. 1006 ¶¶ 176-177

2. Motivation to Combine

One of ordinary skill in the art would be motivated to combine the teachings of Hagiwara and Rosenblatt for many reasons. First, one of ordinary skill in the art would be motivated to combine the references in part because the disclosures are in analogous arts. Both are directed to electrodes for electrochemical electrodes. Ex. 1007, p. 2-3, Ex. 1005, 1:22-23; Ex. 1006 ¶ 178.

Second, Hagiwara contains an express teaching, suggestion, and motivation to combine its disclosure with a disclosure describing a noble metal plated-core electrode. Hagiwara discusses the known technique of using a plated electrode as a substitute for a solid precious metal wire 1, stating: "While cases were described that use precious metal wires as measuring electrode configuring bodies in the descriptions of polarography sensor structures in FIG. 1(A) through (D) above, because only the electrode reaction surface requires noble metal properties, that is, non-variability…, base metal wires, *with precious metals vapor deposited or plated on the front ends thereof*, may also be used." Ex. 1007, p. 7 (emphasis added). This teaching, suggestion, and motivation to combine Hagiwara with a noble metal plated-electrode reference was known to the person of ordinary skill in the art over twenty years prior to the priority date of the '202 patent. Ex. 1006 ¶ 179.

Third, one of ordinary skill in the art would be motivated to incorporate the beneficial features of Rosenblatt with the sensor described in Hagiwara. In particular, Hagiwara discloses a precious metal wire sensor for use as an implantable sensor for glucose measurement. Ex. 1007, p. 6. Rosenblatt explains that precious metal sensors, such as platinum sensors, suffer from being prohibitively expensive stating: "If only the chemical characteristics of a material were to be considered in the selection of a suitable [] material, the metals of the platinum group would be the universal choice because they are highly resistant to corrosion; however, the high

cost of these precious metals prohibits their extended commercial use. Substitute materials have, therefore, been resorted to, whenever possible." Ex. 1005, 1:32-38. Rosenblatt discloses that platinum coated tantalum can be used in electrochemical electrodes as an alternative to platinum wire sensors. Ex. 1005, 1:72-2:1; Ex. 1006 ¶ 180.

Such use of platinum coated tantalum in electrodes was in no way new at the '202 patent's priority date. For example, U.S. Patent No. 4,240,878 to Carter, issued in 1980, discloses a layer of platinum covering a tantalum core for measuring current from an electrode. The Carter specification notes the reduced cost and corrosion resistance of its platinum clad tantalum electrode. Further, U.S. Patent No. 3,461,058 to Haley, issued in 1969, describes a refractory (i.e., difficult to corrode) composite electrode made from a titanium or tantalum core coated with platinum. Similarly, U.S. Patent No. 3,236,756 to Beer, issued in 1966, describes what it considered a well known tantalum core coated with platinum anode. Ex. 1006 ¶¶ 176-182.

As detailed above, Hagiwara discloses each of the elements of independent claim 1. Because Rosenblatt discloses the additional limitation recited in dependent claim 5, that claim is obvious.

D. Claims 1-3, 6, 10, and 11 are anticipated under 35 U.S.C. § 102(b) by Gross

Gross

Gross describes "devices and methods for measuring an analyte in vivo, and in particular to sensors for use in such devices and methods." Ex. 1003, 1:6-8. In relevant part, Gross describes that a monitor device 10 includes a "sensor needle 15 [that] penetrates the skin of the subject and enters the subcutaneous region where it is in contact with subcutaneous tissue" to provide a ". . . measure of the glucose concentration in the bloodstream." *Id.*, 11:2-4, 12:21-22. Glucose is an example of one such analyte. *E.g., id.*, 1:14.

In operation, when a voltage is applied to the working electrode (sensor needle) 15, the microprocessor 18 measures the current flowing through the circuit of which the working electrode 15 and a counter electrode 16 form a part thereof. The magnitude of the current flowing through the circuit provides a measure of the number of free electrons in the vicinity of the working electrode 15. This current arises from the free electrons which are generated by the breakdown of hydrogen peroxide at the platinum (or platinum-iridium) needle surface. *Id.*, 11:48-57.

Gross further explains that "[t]he measured current is integrated by the microprocessor 18 to provide a measure of the total charge giving rise to the measured current." *Id.*, 12:13-19. "[B]y integrating the current over the duration of

the applied voltage, an uncalibrated measure of the glucose concentration in the bloodstream is provided." *Id.*, 12:19-23.

Gross describes the structure of a sensor needle that can be used to measure glucose in Fig. 14. As Gross explains, "FIG. 14 shows an alternative construction of a sensor needle, indicated generally at 110, in which the platinum-iridium needle of FIG. 3 is replaced by a stainless steel needle shaft 111 on which a coating of platinum black 112 (otherwise referred to as colloidal platinum) is provided, with glucose oxidase enzyme embedded in the platinum black coating 112." *Id.*, 19:19-25.

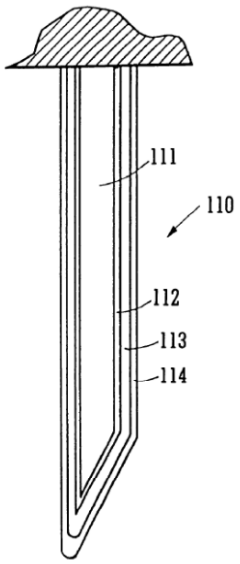


FIG. 14

As shown in Fig. 14, the platinum black layer 112 is in direct contact with the outer surface of the stainless steel core 111, including the lower portion of the sensor needle 110. Ex. 1006, ¶¶ 71-73.

Claims 1-3, 6, 10, and 11 are anticipated by Gross, as demonstrated below.

1. Independent Claim 1

(a) Preamble – "A method for measuring the concentration of an analyte within an animal body having body fluids"

Gross discloses the preamble of claim 1.

Gross is entitled "Device and method of calibrating and testing a sensor for in vivo measurement of an analyte." Gross explains that according to the disclosed method, a "sensor needle 15 penetrates the skin of the subject and enters the subcutaneous region where it is in contact with subcutaneous tissue" and that a "measure of the glucose concentration in the bloodstream is provided." *Id.*, 11:2-4, 12:21-22. Gross further explains that glucose is an analyte. *E.g.*, *id.*, 1:14. Ex. 1006 ¶¶ 183-186.

Gross thus discloses a method of measuring the concentration of an analyte within an animal body having body fluids.

(b) First Element – "Providing a sensor having a structurally flexible core having an outer surface;"

Gross discloses the first element of claim 1.

Gross discloses a "sensor needle" at Figure 14 (annotation added; *see* Ex. 1006 ¶ 187):

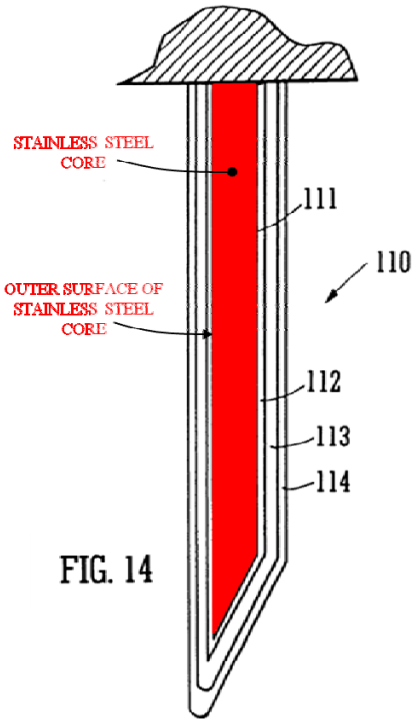


FIG. 14

Gross explains that "FIG. 14 shows an alternative construction of a sensor needle, indicated generally at 110, in which the platinum-iridium needle of FIG. 3 is replaced by a stainless steel needle shaft 111 on which a coating of platinum black 112 (otherwise referred to as colloidal platinum) is provided, with glucose oxidase enzyme embedded in the platinum black coating 112." Ex. 1003, 19:19-25. By virtue of its geometry, the stainless steel core 111 (colored in red above) has an outer surface. Ex. 1006 ¶ 189.

The '202 patent explains that the core may be made of stainless steel. Ex. 1001, 2:34-36. As discussed above, the term "structurally flexible" means "capable of being bent or flexed" where tantalum and nitinol are examples of flexible materials.

Stainless steel is also structurally flexible in the context of the ’202 patent. Although metals and alloys are, in some contexts, not considered to be flexible, the wire sensors described in the ’202 patent have extremely small diameters of less than 300 microns. The wire sensors of Gross are on a similar size-scale, where “[s]uitable dimensions are a [sensor] needle length 26 of 5 mm and a needle diameter 27 of 0.3 mm [300 microns].” Ex. 1003, 10:56-57. With such a small diameter, even some materials that might initially be thought of as rigid materials exhibit flexibility. Ex. 1006, ¶ 189.

Different materials exhibit different degrees of flexibility. Young’s modulus is one measure that provides an indication of the intrinsic flexibility of solid materials. *Id.*, ¶ 190. Tantalum has a Young’s modulus of 186 GPa; nitinol has a Young’s modulus of 83 GPa; and stainless steel can have a Young’s modulus from 189-210 GPa. Ex. 1013; Ex. 1006, ¶¶ 191-192. Thus, stainless steel has a flexibility that is similar to that of tantalum, a materially explicitly noted by the ’202 patent as being flexible.

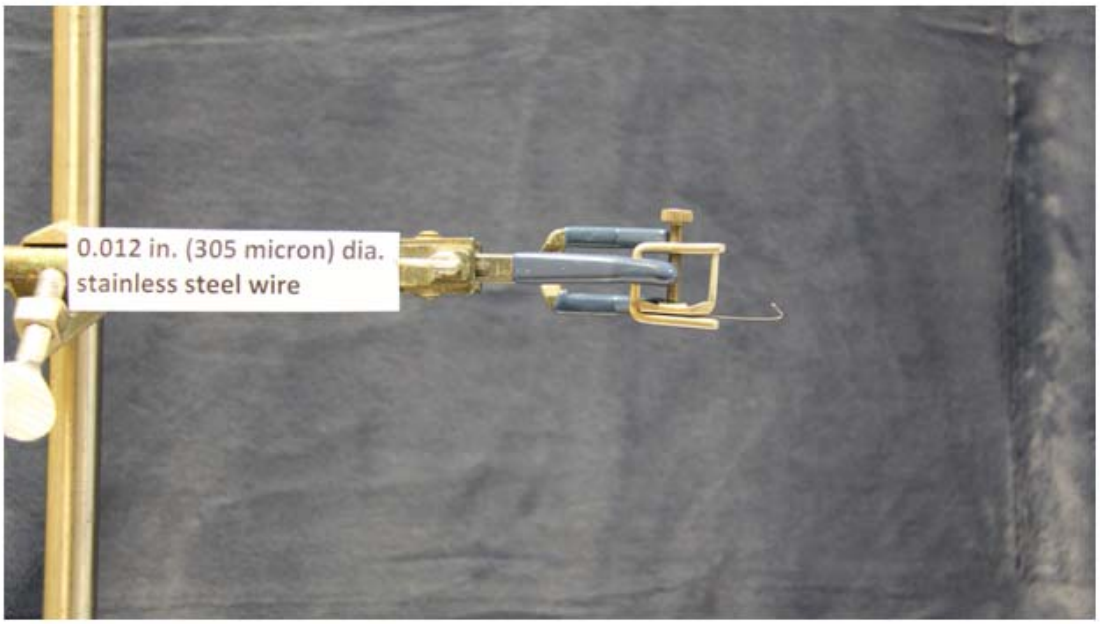
Shape and size also affect the flexibility of a structure. For example, a steel I-beam used for constructing a sky scraper will have a different flexibility than a portion of fishing line from the same material. Exhibit 1008 is an advertisement for Surflon Micro Supreme fishing wire. Exhibit 1008 notes that: “Surflon Micro Ultra 19 strand stainless steel wire is more flexible than regular 7 strand Surflon. Smooth

nylon coating adds kink resistance. Attach to your line using common fishing knots such as the Albright Knot, Clinch Knot and Nail Knot to name a few." A later write-up on the Surflon Micro Supreme 49 strand wire notes, "Micro Supreme is so flexible, you can secure it using your favorite knots or with leader sleeves." The stainless steel strands of the Surflon leader wire are comparable in size to the wire sensors of Gross. In Gross "[s]uitable dimensions are a needle length 26 of 5 mm and a needle diameter 27 of 0.3 mm," while the Surflon Micro Ultra 19 leader wire is 0.33 mm in diameter. Ex. 1006 ¶ 193. There is no question that stainless steel sized similarly to the Surflon leader wire (which can be tied in knots and is advertised as "extremely flexible") would be structurally flexible. *Id*.

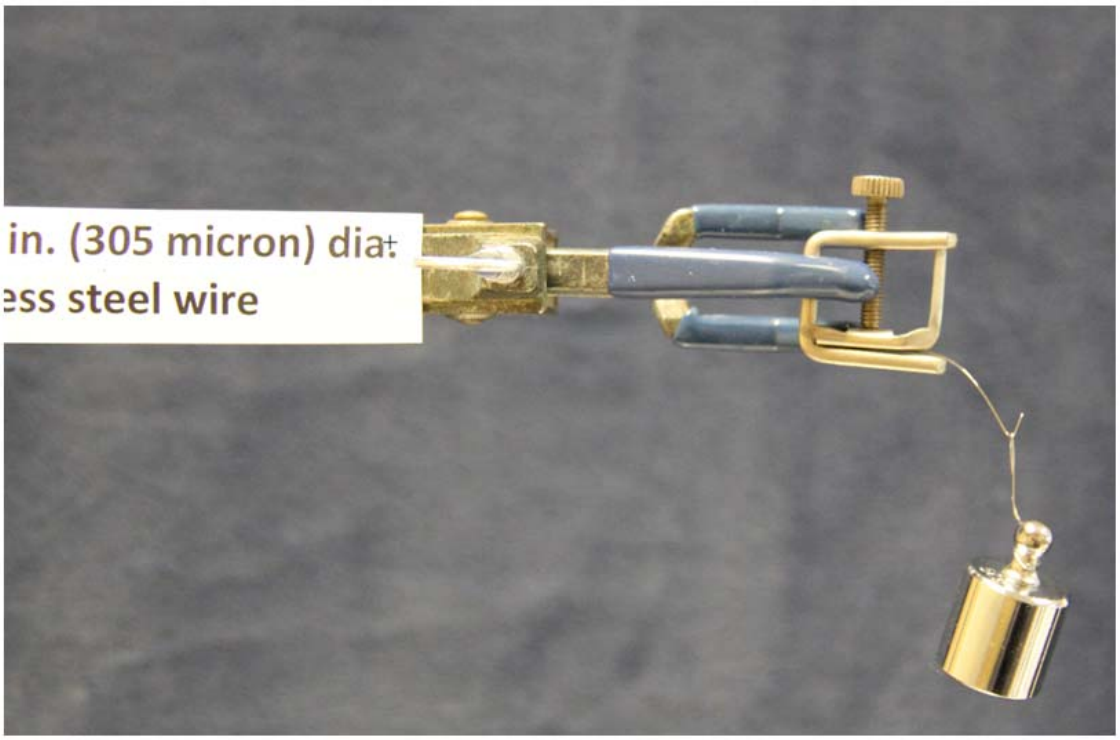
To confirm the flexibility of stainless steel at the diameters at issue in the present matter, an experiment was performed by Dr. David Vachon, as detailed at paragraphs 194-199. In this experiment, Dr. Vachon demonstrated that stainless steel wire of 305 micron diameter and short length (~25 mm) can undergo reversible flexure by the addition of a controlled mass to the stationary fixed wires.

Specifically, a portion of the wire (~ 25 mm length) was fixed into a small clamp and the clamp fixed onto a ring stand holding the wire approximately perpendicular to a ring stand. Once fixed into place, the wire end was kinked to provide a hook-like portion to allow the placement and retention of a calibrated

weight of 50 grams. The following figure depicts a 305 micron diameter stainless steel wire gripped by the clamp prior to flexure. Ex. 1006 ¶ 196.



The next figure shows that same 305 micron diameter wire supporting the 50 gram calibration weight and demonstrating significant flexure. Ex. 1006 ¶ 197.



When the weight was removed, the wire returned to its original, relaxed state, as shown in the following figure. Ex. 1006 ¶ 198.

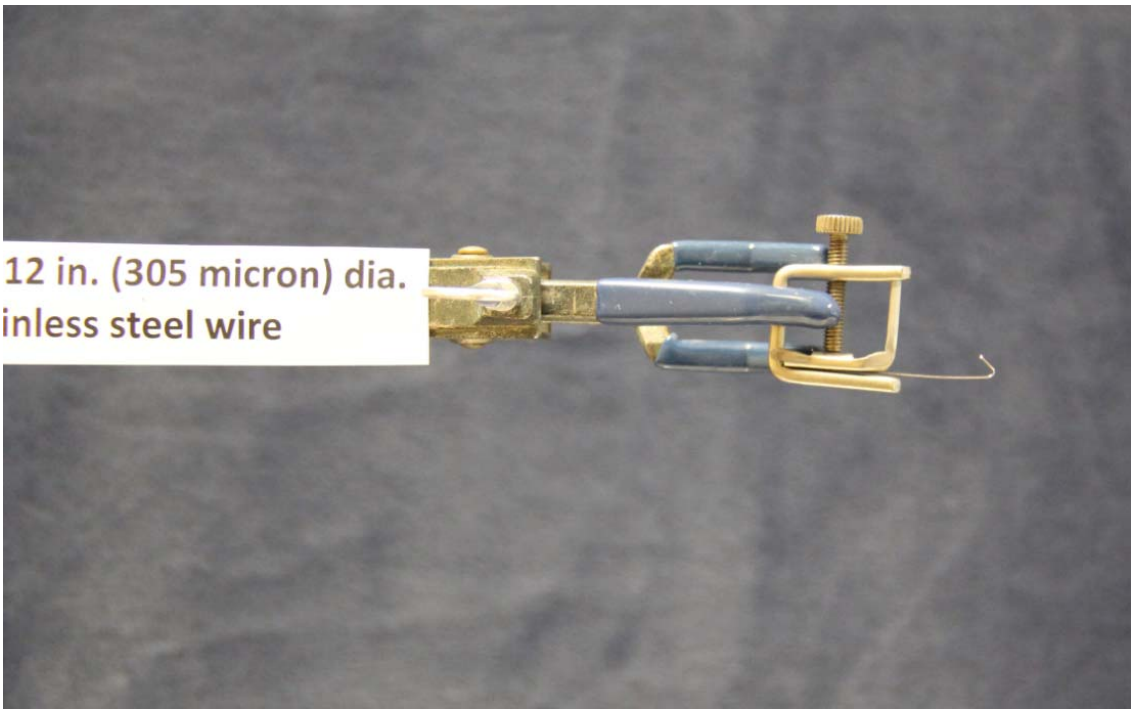


Exhibit 1012 is a video of the experiment from which the three images above were captured. Ex. 1006 ¶ 199.

Thus, stainless steel is an example of a material that, like nitinol and tantalum, is also structurally flexible. The stainless steel core disclosed in Gross is structurally flexible because it is capable of bending without permanently being deformed in the form factors relevant to the patent at issue here. Gross explains that a suitable dimension for the sensor needle is 0.3 mm (300 microns). Ex. 1003, 10: 56-57. At a diameter this small, a person of ordinary skill in the art would understand that stainless steel is flexible as illustrated in the testing performed by Dr. Vachon. Ex. 1006, ¶¶ 187-200.

Because of the similarity of flexibility measurement parameters of tantalum and stainless steel and the Vachon illustration of stainless steel flexibility in the form factor of the wire sensor disclosed by Gross, Gross discloses "providing a sensor having a structurally flexible core having an outer surface."

(c) Second Element – "a layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core;"

Gross discloses the second element of claim 1.

Gross explains that "FIG. 14 shows an alternative construction of a sensor needle, indicated generally at 110, in which the platinum-iridium needle of FIG. 3 is replaced by a stainless steel needle shaft 111 on which a coating of platinum black

112 (otherwise referred to as colloidal platinum) is provided, with glucose oxidase enzyme embedded in the platinum black coating 112." Ex. 1003, 19:19-25. As shown in Figure 14, the Gross platinum black layer 112 (colored in blue below) is surrounding, covering, and in contact with the outer surface of the stainless steel core. Ex. 1006 ¶ 203.

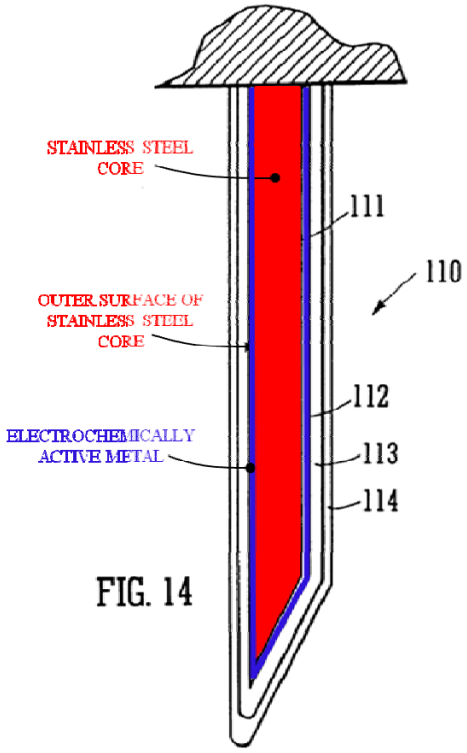


FIG. 14

This coating 112 surrounding the stainless steel core disclosed by Gross is made of an electrochemically active platinum black layer, and the '202 patent indicates that platinum is an example of an electrochemically active metal. Ex. 1001 at 2:42-44; *see also* Ex. 1006 ¶¶ 201-204.

Therefore, Gross discloses "a layer of electrochemically active metal [112] surrounding, covering, and in contact with said outer surface of said core [111]."

(d) Third Element – "placing at least a portion of said sensor into said animal body;"

Gross discloses the third element of claim 1.

With reference to Fig. 1A, Gross explains that the figure is "a schematic illustration of an analyte monitor device for the in vivo measurement of an analyte according to the invention." Ex. 1003, 9:45-47. Gross further explains that the monitor device 10 "is applied to a subject by removing a release liner (not shown) which protects adhesive lower surface 14 and sensor needle 15 before use, and then pressing the lower surface 14 against the skin of a subject so that sensor needle 15 penetrates the skin of the subject and enters the subcutaneous region where it is in contact with subcutaneous tissue." *Id.*, 10:62-11:4.

Although this description in Gross refers to the sensor needle disclosed in Fig. 3, Gross explains that the platinum-coated, stainless steel core sensor needle disclosed in Figure 14 is an "alternate construction" of the sensor needle described in Fig. 3, and that "[t]he operation of the sensor needle 110 is essentially identical to that of the sensor needle 15 of FIG. 3 . . ." *Id.*, 19:19-29; *see also*, Ex. 1006 ¶¶ 205-207.

Gross therefore discloses "placing at least a portion of said sensor into said animal body."

(e) Fourth Element – "measuring any electric current produced by said sensor and forming a measurement of analyte concentration based on said current measurement."

Gross discloses the final element of claim 1.

Gross explains that current flows through the sensor in the presence of hydrogen peroxide (a byproduct of the chemical reaction between glucose and oxygen):

> Thus, when a voltage is applied to the working electrode 15, the microprocessor 18 measures the current flowing through the circuit of which the working electrode 15 and the counter electrode 16 form a part thereof. Since this current can only flow if free charge carriers are present, the current provides a measure of the number of charge carrying species in the vicinity of the working electrode 15. The majority of the current arises from the free electrons which are generated by the breakdown of hydrogen peroxide at the platinum (or platinum-iridium) needle surface.

Id., 11:48-57. After obtaining the current measurement, "[t]he measured current is integrated by the microprocessor 18 to provide a measure of the total charge giving rise to the measured current . . . [t]hus, by integrating the current over the duration of the applied voltage, an uncalibrated measure of the glucose concentration in the bloodstream is provided." *Id.,* 12:13-28.

Although the portion of Gross cited above refers to the sensor needle disclosed in Fig. 3, Gross explains that the platinum-coated, stainless steel core

sensor needle disclosed in Fig. 14 is an "alternate construction" of the sensor needle in Fig. 3, and that "[t]he operation of the sensor needle 110 is essentially identical to that of the sensor needle 15 of FIG. 3. *Id.,* 19:27-33; *see also*, Ex. 1006 ¶¶ 208-211.

Gross therefore discloses "measuring any electric current produced by said sensor and forming a measurement of analyte concentration based on said current measurement."

For all of the reasons above, Gross anticipates claim 1 of the '202 Patent. Ex. 1006 ¶ 212.

2. Dependent Claim 2

Dependent claim 2, which depends from claim 1, adds the limitation, "wherein said electrochemically active metal comprises a noble metal."

Gross explains that Fig. 14 shows a construction of a sensor needle 110 with a stainless steel needle shaft 111 on which a coating of platinum black 112 (otherwise referred to as colloidal platinum) is provided. Ex. 1003, 19:19-25. The '202 patent notes that platinum is an electrochemically active metal and a noble metal. Ex. 1001, 2:42-46. Thus, the platinum black layer 112 is made of a material that the '202 patent explicitly notes is a noble metal. Ex. 1006 ¶¶ 213-216.

As detailed above, Gross discloses each of the elements of independent claim 1. Because Gross discloses the additional limitation recited in dependent claim 2, that claim is anticipated.

3. Dependent Claim 3

Dependent claim 3, which depends from claim 1, adds the limitation, "wherein said noble metal comprises at least one of platinum, palladium, and gold."

Gross explains that Fig. 14 shows a construction of a sensor needle 110 with a stainless steel needle shaft 111 on which a coating of platinum black 112 (otherwise referred to as colloidal platinum) is provided. Ex. 1003, 19:19-25. Because Gross describes a platinum coating on a structurally flexible core, Gross discloses this limitation. Ex. 1006, ¶¶ 217-219.

As detailed above, Gross discloses each of the elements of independent claim 1. Because Gross discloses the additional limitation recited in dependent claim 3, that claim is anticipated.

4. Dependent Claim 6

Dependent claim 6, which depends from claim 1, adds the limitation, "wherein said layer of electrochemically active metal is adapted to provide at least one sensing surface."

Gross discloses that the platinum needle surface is adapted to provide a sensing surface. According to Gross, "when a voltage is applied to the working electrode 15, the microprocessor 18 measures the current flowing through the circuit of which the working electrode 15 and the counter electrode 16 form a part thereof." The current "provides a measure of the number of charge carrying species in the

vicinity of the working electrode 15 [and] [t]he majority of the current arises from the free electrons which are generated by the breakdown of hydrogen peroxide at the platinum (or platinum-iridium) needle surface." Ex. 1003, 11:48-57. *See also* Ex. 1006, ¶ 221. Thus, Gross is explicit that the electrochemically active platinum surface provides the surface at which electrons are accessed for sensing glucose levels in the surrounding tissue. Ex. 1006, ¶¶ 220-222.

As detailed above, Gross discloses each of the elements of independent claim 1. Because the additional limitation recited in dependent claim 6 is disclosed by Gross, that claim is anticipated.

5. Dependent Claims 10

Dependent claim 10, which depends from claim 1, adds the limitation, "wherein said analyte comprises glucose."

Gross explains that during operation of the senor needle 110, ". . . glucose reacts with oxygen and water in the presence of the enzyme embedded in the platinum black coating 112, thereby producing hydrogen peroxide which is catalyzed by the colloidal platinum to provide free electrons." Ex. 1003, 19:19-27. *See also* Ex. 1006, ¶ 224. Thus, Gross explicitly states that it is configured for measuring the concentration of glucose analyte in a body. Ex. 1006, ¶¶ 223-225.

As detailed above, Gross discloses each of the elements of independent claim 1. Because the additional limitation recited in dependent claim 10 is disclosed by Gross, claim 10 is anticipated by Gross.

6. Dependent Claims 11

Dependent claim 11, which depends from claim 1, adds the limitation, "wherein said core further comprises at least a first end, and wherein said electrochemically active layer further surrounds, covers, and is in contact with said at least a first end of said core."

In Fig. 14, Gross discloses a sensor needle 110 having a platinum black electrochemically active layer 112 surrounding a stainless steel core 111. The first end of the stainless steel core 111 is the lower tip of the stainless steel core 111. As shown in Fig. 14, the electrochemically active platinum layer 112 surrounds, covers, and is in contact with said at least a first end of the stainless steel core 111. Thus, Gross discloses the limitation of claim 11. Ex. 1006 ¶¶ 226-228.

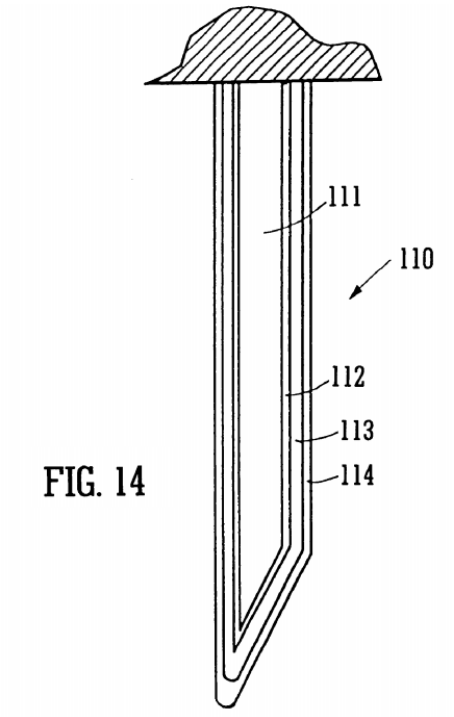


FIG. 14

As detailed above, Gross discloses each of the elements of independent claim 1. Because the additional limitation recited in dependent claim 10 is disclosed by Gross, that claim is anticipated.

VI. Mandatory Notices Pursuant to 37 C.F.R. § 42.8(a)(1)

Pursuant to 37 C.F.R. § 42.8(a)(1), the mandatory notices identified in 37 C.F.R. § 42.8(b) are provided below as part of this Petition.

A. C.F.R. § 42.8(b)(1): Real Party-In-Interest

Dexcom, Inc. is the real party-in-interest for Petitioner.

B. C.F.R. § 42.8(b)(2): Related Matters

The '202 patent is currently the subject of a patent infringement lawsuit brought by AgaMatrix against Dexcom, styled as:

- *AgaMatrix, Inc. v. Dexcom, Inc.*, U.S. District Court for the District of Oregon, Civil Action No. 3:16-cv-536-JE.

C. C.F.R. § 42.8(b)(3) and (4): Lead and Back-up Counsel and Service Information

Dexcom provides the following designation of counsel:

Lead Counsel	Back-up Counsel	Back-up Counsel
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Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this Petition. Please address all correspondence to lead and back-up counsel at the Cleveland, Ohio address above. Dexcom also consents to electronic service by email at the email addresses listed above.

VII. Conclusion

For the reasons set forth above, Petitioner has established a reasonable likelihood of prevailing with respect to claims 1-3, 5, 6, and 8-11 of the '202 patent. Petitioner therefore requests that the Patent Office order an *Inter Partes Review* trial and then proceed to cancel claims 1-3, 5, 6, and 8-11.

Respectfully submitted,

Date: _August 25, 2016____ By:__/Matthew W. Johnson/_____

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 7,146,202, including all Exhibits and the Power of Attorney, was served on August 25, 2016 via Express Mail delivery directed to the attorney of record for the patent at the following address:

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PACWEST CENTER, SUITE 1900
1211 SW FIFTH AVENUE
PORTLAND OR 97204

Date: _August 25, 2016__ _/Matthew W. Johnson/_____
Matthew W. Johnson

CERTIFICATE OF WORD COUNT UNDER 37 C.F.R. § 42.24(a)

I, the undersigned, do hereby certify that the attached Petition, including footnotes, contain 12,439 words, as measured by the Word Count function of Word 2007. This is less than the limit of 14,000 words as specified by 37 C.F.R. § 42.24(a)(i).

Date: August 25, 2016 By: /Matthew W. Johnson/

APPENDIX OF EXHIBITS

EXHIBIT NO.	TITLE
1001	U.S. Patent No. 7,146,202, filed June 16, 2004, Issued December 5, 2006 (‘202 Patent).
1002	File History of ’202 Patent.
1003	U.S. Patent No. 5,920,490, Filed June 23, 1998, Issued August 14, 2001 (Gross).
1004	Wilson, George et al., “Progress toward the Development of an Implantable Sensor for Glucose,” Clinical Chemistry, Vol. 38, No. 9, 1613-1617, 1992 (Wilson).
1005	U.S. Patent No. 2,719,797, filed May 23, 1950, Issued October 4, 1955 (Rosenblatt).
1006	Declaration of David J. Vachon, Ph.D.
1007	Japanese Patent Application Publication No. S57-110236 to Bunji Hagiwara published on July 9, 1982 (Hagiwara).
1008	Jann’s Netcraft Advertisement for Stainless Steel Fishing Wire, accessed July 10, 2016, available at: http://www.jannsnetcraft.com/afw-leader-wire/
1009	Declaration of Morris Jackson regarding status of Ex. 1004 as a publication.

1010	Price quote for Platinum and Platinum-Iridium wire.
1011	Definition of "Flexible," Webster's II New College Dictionary (1995).
1012	Video of experiment confirming flexibility of 305 micron stainless steel wire.
1013	Materials Data Book, 2003 Edition, Cambridge University, Engineering Department, p. 11 (http://www-mdp.eng.cam.ac.uk/web/library/enginfo/cueddatabooks/materials.pdf)