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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.
Petitioner,

v.

WAVEFORM TECHNOLOGIES, INC.
Patent Owner

IPR2016-01679
Patent 7,146,202

Before BRIAN P. MURPHY, JON B. TORNQUIST, and
ELIZABETH M. ROESEL, *Administrative Patent Judges*.

PATENT OWNER'S RESPONSE

**REDACTED FOR HIGHLY CONFIDENTIAL
INFORMATION**

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I. INTRODUCTION**A. Background**

Nearly twenty years ago, an Oregon company named iSense Corporation (“iSense”) was among the first to develop a minimally invasive continuous glucose monitoring (“CGM”) system.¹ A CGM system includes a tiny sensor wire that is inserted just under the surface of the skin where it continuously monitors glucose levels for an extended period.

In the 1990's, iSense obtained an exclusive license under U.S. Patent No. 5,165,407, whose lead inventor was a University of Kansas professor named George S. Wilson (“the Wilson patent”). The Wilson patent, which issued in 1992, is titled “Implantable Glucose Sensor.” In 1999, iSense discovered a serious problem with the Wilson sensor, when a sensor wire fractured inside the body of iSense employee, Ken Ward, M.D., during *in vivo* testing. The Wilson sensor had also broken in test animals.

iSense eventually determined that the platinum-iridium sensor wire used by Wilson lacked the robustness necessary to withstand the repeated flexing of the wire that occurred during *in vivo* use. iSense's inventors, Dr. Ward and Richard Sass, ultimately solved that problem by developing a sensor wire in which a

¹ iSense was the original owner of U.S. Patent No. 7,146,202 (“the '202 patent”), now assigned to Patent Owner, WaveForm Technologies, Inc.

platinum layer is plated onto a tantalum core. The platinum-clad tantalum wires are able to be repeatedly flexed for days without breaking, and are less expensive to make than platinum alloy wires.

iSense filed a provisional patent application for that invention in June 2003, which led to issuance of the '202 patent in 2006 and U.S. Patent No. 8,187,433 ("the '433 patent") in 2012.² iSense disclosed the Wilson patent to the Patent Office in its patent applications, which issued over the Wilson patent. Two key requirements of the '202 patent claims are (i) a "*structurally flexible core*"; and (ii) an electrochemically active metal "*in contact with*" the structurally flexible core.

B. Petitioner Cannot Meet Its Burden of Proving Invalidity.

Petitioner relies on three prior art references. First, Petitioner relies upon a 1992 article, published in the journal Clinical Chemistry, lead author of which was George S. Wilson ("the Wilson article"). (Ex. 1004.) The Wilson article provides an abbreviated version of the disclosure contained in the Wilson patent. Second, Petitioner relies upon unpublished Chinese patent application to Hagiwara ("Hagiwara"). (Ex. 1007.) Third, Petitioner relies upon a 1955 patent to Rosenblatt ("Rosenblatt"). (Ex. 1005.) The IPR was instituted on grounds of

² The application for the '433 patent was a division of the '202 application.

The '433 patent is the subject of co-pending IPR2016-01680.

anticipation by Hagiwara and obviousness based on the Wilson/Rosenblatt and Hagiwara/Rosenblatt combinations.

1. None of the references teach or suggest “a structurally flexible core.”

The brittle platinum alloy wire of Wilson was the problem that led to the invention of the '202 patent. The '202 patent discloses that platinum-iridium may be used as the electrochemically active plated layer, but says nothing about using it as a core material. For reasons discussed *infra*, platinum-iridium is wholly unsuited for use as a “*structurally flexible core.*”

Hagiwara discloses use of soft precious metals, like gold and platinum, for the sensor wire. While the parties agree that platinum is flexible, the '202 patent explains that platinum is a weak metal prone to breaking. Patent Owner's expert explains that gold is no more robust than platinum. Hagiwara also fails to disclose a “*structurally flexible core.*”

Finally, Rosenblatt fails to make any mention of “flexibility” and Petitioner's own expert admits that the Rosenblatt anode is inflexible. Patent Owner's expert explains that the platinum-tantalum alloy layer taught by Rosenblatt is brittle and inflexible. Rosenblatt thus fails to teach or suggest a “*structurally flexible core.*”

2. None of the references teach an electrochemically active metal “surrounding, covering, and in contact with” a structurally flexible core.

Petitioner's obviousness combinations fail because Rosenblatt expressly teaches away from having the active metal “*in contact with*” a core. Rosenblatt teaches that a metal alloy layer must separate the active layer and the core, *preventing* the required contact. Hagiwara also fails to teach this claim element under the broadest reasonable interpretation of relevant claim terms.

3. Objective indicia of non-obviousness weigh against obviousness.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] After learning about the '202 patent in 2008, [REDACTED]

[REDACTED]

[REDACTED] Petitioner's adoption of the patented method led to dramatic increases in its sales, market share, market capitalization, as well as to FDA approval to sell its CGM systems to children, an important new market for Petitioner. As discussed *infra*, the objective indicia weigh strongly against obviousness.

II. CLAIM CONSTRUCTION

A. “*a structurally flexible core*”

The Board has preliminarily construed “*a structurally flexible core*” to mean “*a core that is robust and able to be flexed or bent repeatedly.*” Patent Owner does not object to the Board’s proposed construction under the broadest reasonable interpretation standard. It reflects the key point that a “structurally flexible core” must be one that is sufficiently robust to withstand repeated bending and flexing. For example, while the parties agree that platinum is flexible, the ’202 patent notes that it “is a weak metal that is easily broken” (Ex. 1001 at 1:22.) So, flexibility alone is not enough; the structurally flexible core material must also be robust.

B. “*surrounding, covering, and in contact with*”

1. Patent Owner’s proposed construction

Patent Owner proposes that the term “*surrounding, covering, and in contact with*” be construed to mean: “entirely surrounding and covering, and touching.”

The “*surrounding, covering, and in contact with*” phrase appears in claim 1 of the ’202 patent, which recites in relevant part:

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;
- ...

Dependent claim 11 of the '202 patent recites a similar phrase:

11. The method of claim 1 wherein said core further comprises at least a first end, and wherein said electrochemically active metal *further surrounds, covers, and is in contact with* said at least a first end of said core.

2. Overview of claim construction analysis

The terms “surround,” “cover” and “contact” are non-technical words that have common, everyday meanings:

“**Surround**” means “envelop” or “encircle.” (Ex. 2024)

“**Cover**” means “overlay” or “envelop.” (Ex. 2025)

“**Contact**” means “touching.” (Ex. 2026)

In claim 1, the “*surround*” and “*cover*” terms address the extent to which two specified surfaces of the core (“an outer surface” and “a first end”) are surrounded and covered by the electrochemically active metal. The “*in contact with*” term deals with the proximity of the electrochemically active metal to the structurally flexible core. There is relevant prosecution history on all three terms.

The original claims of the '202 patent application recited that the electrochemically active metal was “substantially circumferentially applied to at least a portion of [the] core.” Those claims were rejected over prior art that taught circumferential coverage of a portion of a core. That claim element was amended three times before the claims were allowed.

In the final set of amendments, applicants divided the core's surface into two separate areas, an “*outer surface of the core*” that must be surrounded and covered by an electrochemically active metal, and a “*first end of the core*” that may further be surrounded and covered by the active metal. Applicants made clear in their accompanying remarks that in amended claim 35 (issued claim 1) “an outer surface of the core” must be entirely surrounded and covered by the electrochemically active metal. Applicants added dependent claim 73 (issued claim 11), reciting that the core *further* comprises a first end, that may *further* be surrounded and covered by the electrochemically active metal.³ The final set of claim amendments also added the requirement that the electrochemically active metal must be “*in contact with*” the core material. Related prosecution arguments confirm that the “*in contact with*” term is used in its ordinary sense to require that the electrochemically active metal and the core be touching.

³ Patent Owner's proposed constructions of the terms “*outer surface of the core*” and “*first end of the core*” are discussed *infra* at Section II(C).

3. The '202 patent specification

The written specification of the '202 patent does not make any relevant usage of the “*surrounding*,” “*covering*” and “*in contact with*” claim terms.

4. Relevant portions of '202 patent prosecution history

Below is a concise summary of '202 patent prosecution history events relating to the “*surrounding, covering, and in contact with*” claim term.

a. April 21, 2005 Amendment

Applicants respond to a restriction requirement by electing claims 1-12 of the original application. (Ex. 1002 at 92.) Claim 1 recites “a layer of electrochemically active metal substantially circumferentially applied to at least a portion of said core.” (*Id.* at 93.)

b. May 18, 2005 Office Action

The Examiner rejects application claim 1 over U.S. Patent No 6,501,976 to Sohrab (“Sohrab”) on grounds that Sohrab teaches a layer of electrochemically active metal circumferentially applied to the core. (*Id.* at 84-85.)

c. July 11, 2005 Amendment

Applicants cancel claims 1-34 and add new claims 35-40. New claim 35 recites “a layer of electrochemically active metal applied to at least a portion of said core.” (*Id.* at 78.)

d. September 29, 2005 Office Action

The Examiner rejects the new claims on grounds that Sohrab teaches a layer of electrochemically active metal circumferentially applied to the core. (*Id.* at 70-71.) The Examiner also rejects claims over U.S. Patent No. 5,645,710 to Shieh (“Shieh”) and U.S. Patent No. 3,957,613 to Macur (“Macur”). (*Id.*)

e. December 19, 2005 Amendment and Response

Applicants amend independent claim 35 to recite “a layer of electrochemically active metal surrounding [applied to at least a portion of] said core.”⁴ (*Id.* at 57.) Applicants distinguish the amended claims over Shieh and Macur on grounds that Shieh teaches a core with an exposed tip and Macur teaches an exposed core. (*Id.* at 63.)

f. March 13, 2006 Office Action

The Examiner rejects application claim 35 as over U.S. Patent No. 4,805,624 to Yao (“Yao”), Macur, and U.S. Patent No. 6,915,147 to Lebel (“Lebel”) on grounds that each of those references teaches an electrochemically active metal surrounding a core. (*Id.* at 42-43.)

g. June 13, 2006 Amendment

Applicants amend claim 35 to recite, in relevant part:

⁴ Underlining indicates language added to the claim and [brackets] indicate language deleted from the claim.

35. (Currently Amended) 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;

....

(*Id.* at 28.) Applicants also add new dependent claim 73, which recites as follows:

73. (New) The method of claim [35], 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.

(*Id.* at 29.)

In their accompanying remarks, applicants argue for allowance of the amended claims over Yao, in relevant part, on grounds that:

Yao describes a core, a portion of which is wound with electrodes 8 and 10. While electrodes 8 and 10 are wound around a portion of the core, the electrodes do not form a layer, and the electrodes do not surround and cover the outer surface of the core, as provided in claim 35.

(*Id.* at 33.)

Applicants argue for allowance over Macur on the following two grounds:

First, Macur teaches a core member with exposed layers, including an exposed core. In particular, as described in column 2, lines 39-40, Macur describes a core having an uninsulated distal end tip that serves as an oxygen sensitive electrode. Thus the active layer does not surround and cover the outer surface of the core, as provided in claim 35, but rather surrounds only a portion of the core.

Second, Macur provides an electrochemically active layer 32/33 that is not in contact with the core. Macur uses an intervening insulating layer 14 that separates the core from the electrochemically active layer. Thus, the active layer is not in contact with the outer surface of the core, as provided in claim 35.

(*Id.* at 34.)

Finally, applicants distinguish the amended claims over Lebel on the following grounds:

Lebel describes a core 60, a portion of which is wrapped with conductive elements 62 in helical fashion.

Column 5 of Lebel describes the conductive elements as one or more wires that may be wrapped or wound around the core. While conductive elements may be wrapped around a portion of the core, the conductive elements do

not form a layer, and the conductive elements do not surround and cover the outer surface of the core, as provided in claim 35.

(*Id.*)

h. September 6, 2006 Notice of Allowance

The Patent Office issues a notice of allowance for pending application claims 35-39, 43-47, 73, and 74. (*Id.* at 20.) Claim 35 issues as claim 1 of the '202 patent, and application claim 73 issues as dependent claim 11.

5. Analysis of the intrinsic evidence

a. “surrounding” and “covering”

In applicants' first three successive iterations (shown below) of the claim term at issue, applicant attempted to gain allowance of the claims without specifying that any surface of the core was entirely surrounded and covered by the electrochemically active metal:

1. “a layer of electrochemically active metal substantially circumferentially applied to at least a portion of said core”
2. “a layer of electrochemically active metal applied to at least a portion of said core”
3. “a layer of electrochemically active metal surrounding said core”

In each case, the Examiner rejected the claims over prior art, such as Yao, Macur and Lebel, showing partial coverage of the core.

In their final set of claim amendments, applicants separately claimed two distinct surface areas of the core. Claim 35 (issued claim 1) was amended to recite “the electrochemically active metal surrounding, covering, and in contact with an “*outer surface of said core.*” New claim 73 (issued claim 11) recited the method of claim 1 wherein the “*core further comprises at least a first end, and wherein said electrochemically active metal further surrounds, covers, and is in contact with said at least a first end of said core.*”

Applicants then distinguished application claim 35 over the three cited references on grounds that it requires the “outer surface” of the core to be entirely covered and surrounded by the electrochemically active metal. (*Id.* at 33-34.) Applicants argued that the cited prior art references fail to satisfy that claim requirement because, in different ways, they show only partial coverage of the core's “outer surface.”

For example, applicant argued that wound electrodes 8 and 10 of Yao fail to teach surrounding and covering the outer surface of the core with an electrochemically active metal. (*Id.* at 33.) Fig. 1 of Yao (colorized and annotated to identify exposed areas of the core's outer surface), is reproduced below (Ex. 3003; *see also* Ex. 2027 at ¶¶ 62-63):

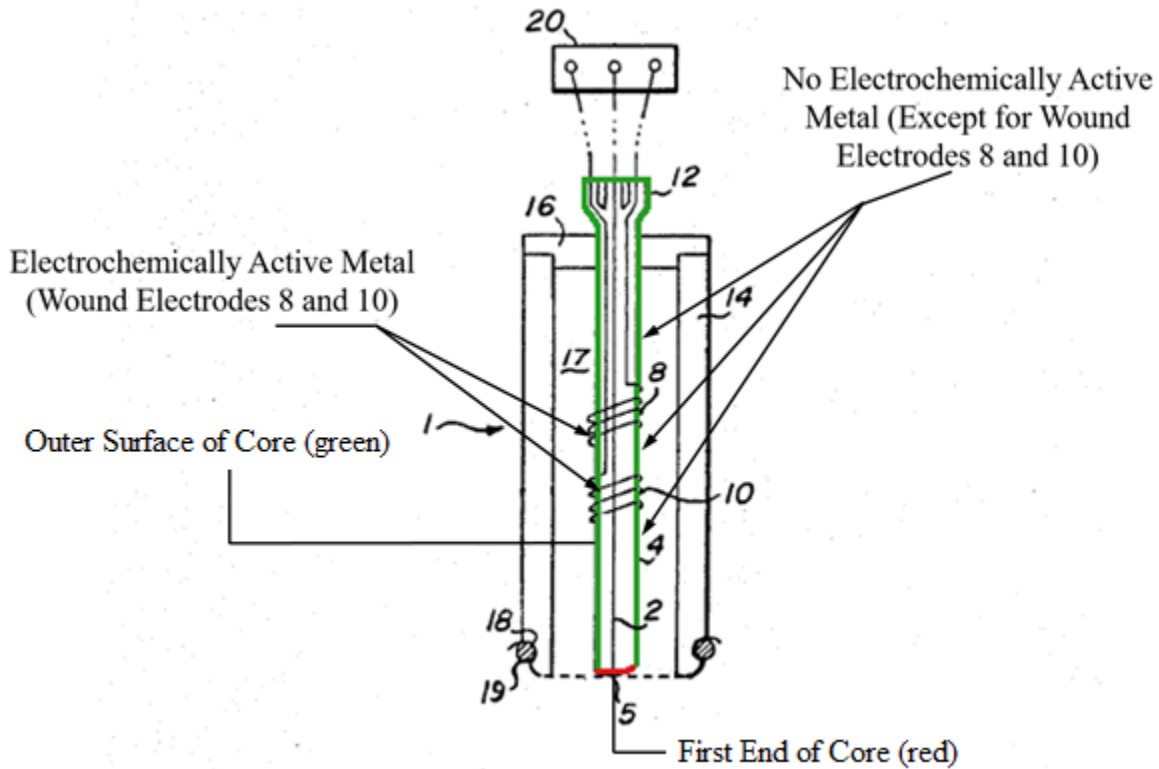
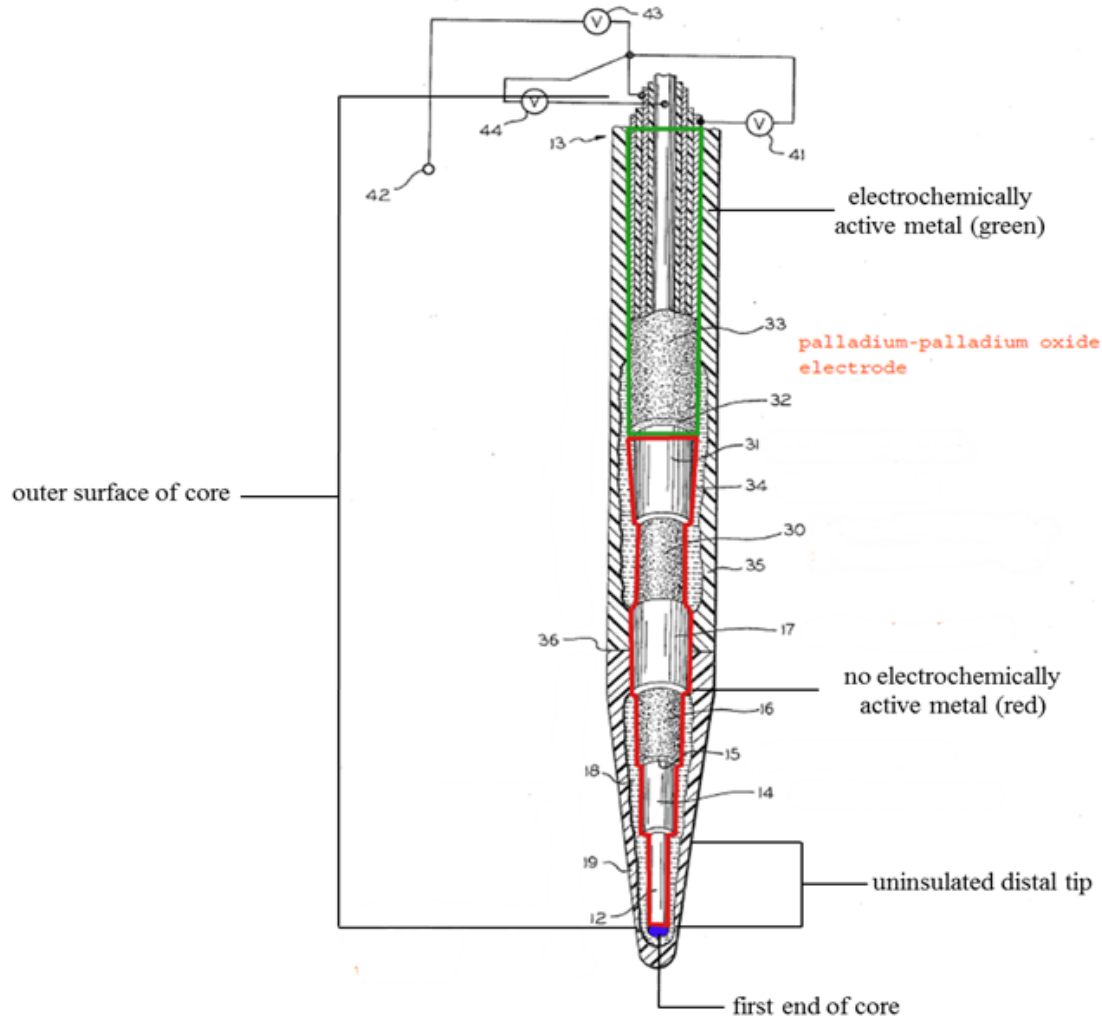
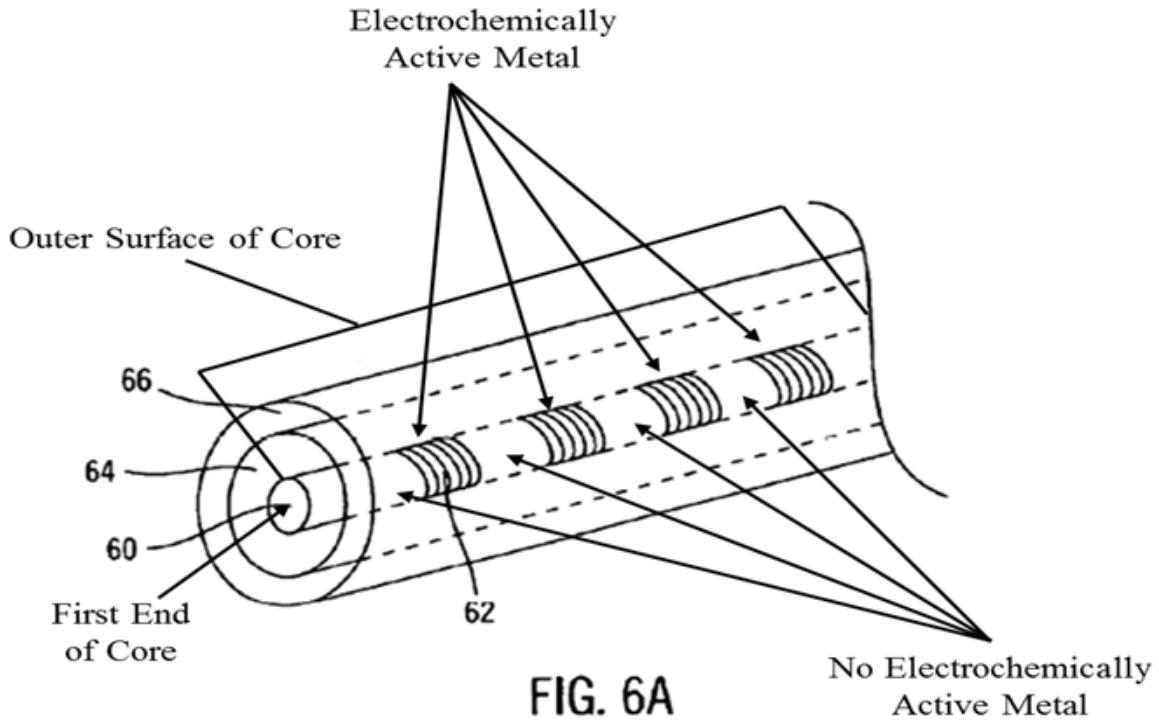


Fig. 1

Applicants argued for allowance over Macur on grounds that the electrochemically active metal layer (palladium-palladium oxide 32/33) does not fully surround and cover the outer surface of the core. (Ex. 1002 at 34.) The Macur figure (colorized and annotated to identify exposed areas of the core's outer surface), is reproduced below (Ex. 3002; *see also* Ex. 2027 at ¶¶ 66-68):



Finally, applicants distinguished Lebel on grounds that the helically wrapped conductive elements (62) do not surround and cover the outer surface of the core, as required by claim 35. (Ex. 1002 at 34.) Fig. 6A of Lebel (annotated to identify exposed portions of the core's outer surface), is reproduced below (Ex. 3004; *see also* Ex. 2027 at ¶¶ 64-65):

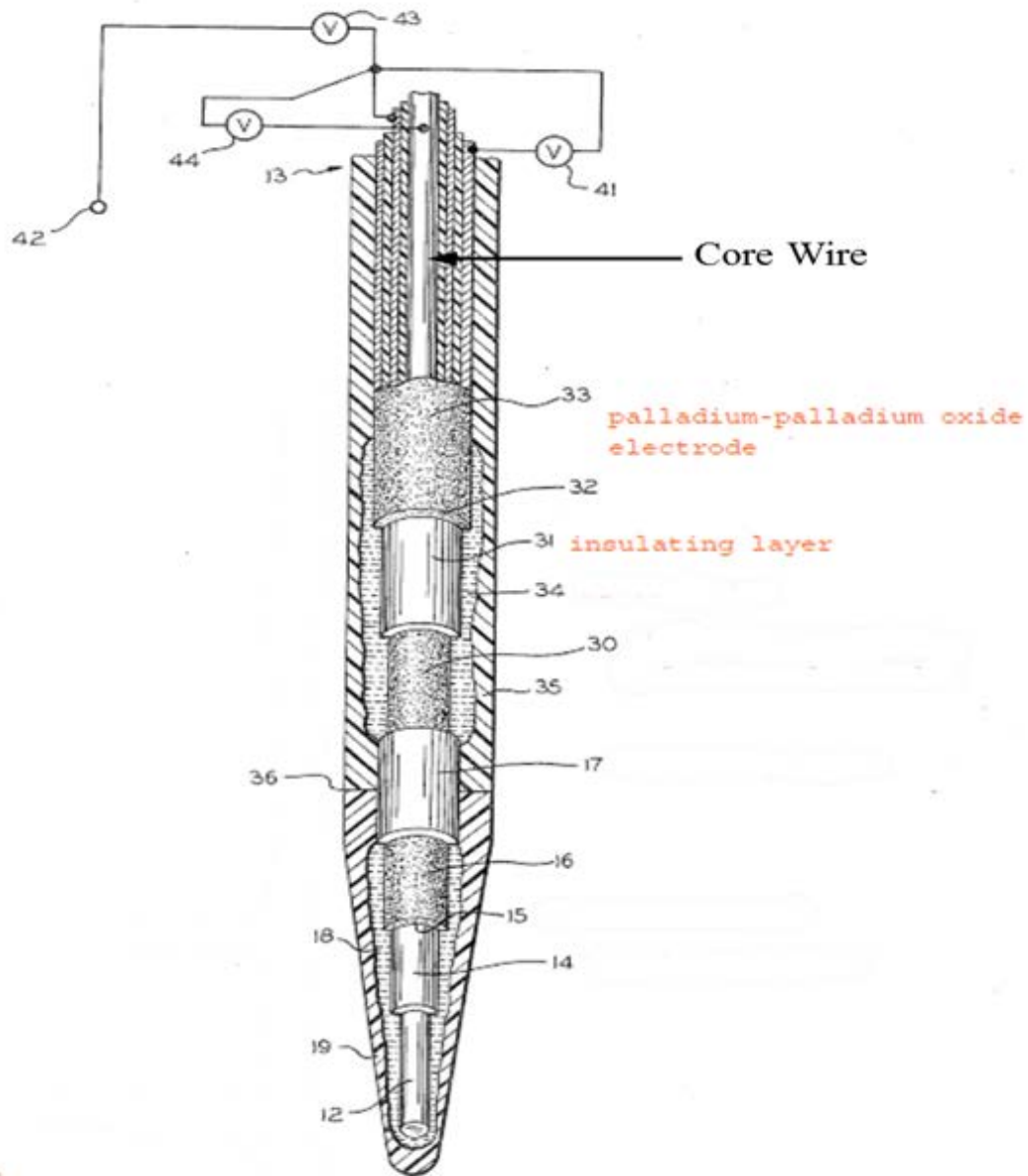


To the extent the “*surrounding*” and “*covering*” terms could be construed to allow incomplete coverage of the core’s “*outer surface*,” that broader scope was clearly and unmistakably disclaimed by these arguments made to secure allowance of applicants’ amended claims. *See, e.g., N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1345 (Fed. Cir. 2005); *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304 (Fed. Cir. 1997). The claims of the ’202 patent therefore must be construed to require the electrochemically active metal to entirely surround and cover the “*outer surface of the core*.”

b. “in contact with”

The “*in contact with*” limitation also was added in the final set of claim amendments in the '202 patent prosecution. (Ex. 1002 at 28.) It requires the electrochemically active metal to be “*in contact with*” an outer surface of the core. The dictionary definition of “contact” is “touching.” (Ex. 2026.)

The intrinsic evidence confirms that the '202 patent claims use the “*in contact with*” term in this ordinary sense to require that the electrochemically active metal be touching the outer surface of the core. Specifically, in its final amendment and response, Patent Owner argued for allowance over Macur on grounds that in Macur an intervening insulating layer (14) separates the outer surface of the core (12) from the electrochemically active layer (32/33). This is shown in the annotated Macur figure reproduced below (Ex. 3002; *see also* Ex. 2027 at ¶¶ 69-70):



Applicants distinguished Macur on grounds that this separation meant that the electrochemically active metal of Macur is not “*in contact with*” the outer surface of the core, and the claims were then allowed to issue. (Ex. 1002 at 34.) This argument is consistent with the plain meaning of “contact,” which requires elements “in contact with” one another to be touching. Moreover, because

applicants disavowed any broader meaning of “in contact with,” any such broader construction would be unreasonable and impermissible. *See, e.g., N. Am.*

Container, supra, 415 F.3d at 1345; *Ekchian, supra*, 104 F.3d at 1304.

- i. The three-layer embodiment disclosed in the '202 patent is not encompassed by claim 1.

In its institution decision, the Board cited to a three-layer embodiment disclosed in the '202 patent specification. (Paper 10 at 10-13.) In this alternative embodiment, a stainless steel core is first coated with an intermediate layer that may be gold or nickel, and a platinum or palladium layer is then coated on top of the intermediate layer. (Ex. 1001 at 2:60-3:3.)

Notably, this disclosure in the '202 patent does not state that the top layer of platinum or palladium is “*in contact with*” the stainless steel core. That is because they are not touching. Instead, the electrochemically active platinum (or palladium) layer is separated from the outer surface of the core by the intermediate gold/nickel layer. Petitioner's expert, David Vachon, agrees that in this embodiment, the outer platinum layer is not “*in contact with*” the stainless steel core. (Ex. 2036 at 184:10-17.)

Additional evidence supporting this interpretation is found in claim 16 of the '433 patent, which is the only claim in either of the two related patents that is directed to the alternative three-layer embodiment.

Claim 16 of the '433 patent recites as follows:

16. An analyte sensing element, comprising:

a wire core of stainless steel having an outer surface;

a continuous *layer of gold* surrounding, covering, and *in contact with* said *outer surface of said core*, wherein the layer of gold prevents body fluid from contacting said core; and

a *layer of platinum* surrounding, covering, and *in contact with* said *layer of gold*, wherein said layer of platinum is at least partially surrounded by a membrane system.

(Ex. 2028 at 6:19-27) (emphases added.)

Claim 16 uses the “*in contact with*” phrase consistent with the ordinary meaning of the term to require that materials “in contact with” one another are touching. Specifically, claim 16 of the ’433 patent recites that the top platinum layer is “in contact with” the intermediate gold layer, and that the intermediate gold layer, in turn, is “in contact with” the stainless steel core. In short, claim 16 uses “in contact with” to mean that two materials are touching one another. This usage of the term “in contact with” in the ’433 patent claims is relevant to construction of the same term in the ’202 patent. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1333 (Fed. Cir. 2010); *Microsoft Corp. v. Multi-Tech Sys.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004).

Given this intrinsic evidence, the “*in contact with*” term in claim 1 of the '202 patent should be read to require that the electrochemically active metal and the structurally flexible core are touching.

Accordingly, claim 1 of the '202 patent does not encompass the alternative three-layer embodiment because, in that embodiment, the electrochemically active platinum layer is separated from the stainless steel core by an intervening layer of gold or nickel. The plain language of claim 1, as confirmed by the relevant prosecution history, does not permit an intervening structure to separate the electrochemically active metal and the structurally flexible core. *See TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008) (“[T]he claims... need not encompass all disclosed embodiments. ... [T]he mere fact that there is an alternative embodiment... that is not encompassed by [the]... claim construction does not outweigh the language of the claim, especially when the... construction is supported by the intrinsic evidence.”) (collecting cases); *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008) (excluding disclosed embodiments “does not mean that these embodiments are all excluded from the scope of the invention, but rather that they are excluded from the scope of these particular claims”).

- ii. The disclosure of an oxide film is consistent with the Patent Owner's construction.

The Board also called attention to the passivated oxide surface disclosed in the '202 patent specification. (Paper 10 at 11.) The '202 patent discloses that tantalum may be passivated to produce an oxide surface. (*Id.* at 3:17-19.) The patent describes this passivated oxide surface as potentially beneficial because it can electrically insulate the core if there is a pinhole in the platinum layer. (*Id.* at 3:24-30.)

Tantalum oxide, chemical formula Ta_2O_5 , readily forms when tantalum is exposed to ambient air. (Ex. 2029 at ¶ 96.) It is a tenacious surface film that reforms immediately on exposure to air or vapor after any cleaning treatment. (*Id.*) The oxide film is highly adherent and stable against attack by many solvents and acids. (*Id.*) The Rosenblatt reference relied upon by Petitioner describes the oxidation of an exposed tantalum surface, and complex procedures used to strip off the oxide and prevent its regeneration. (Ex. 1005 at 1:64-2:1, 2:71-3:26, 5:37-57; *see also* Ex. 2029 at ¶¶ 141-145.) Indeed, metals such as tantalum and nitinol are rarely, if ever, encountered in an un-passivated state in nature. (Ex. 2029 at ¶ 96.) It is well-known that this natural oxide layer contributes to tantalum's corrosion-resistance. (*Id.*)

A person of ordinary skill in the art ("POSA") reading the '202 patent would have understood and expected that certain structurally flexible core metals, such as

tantalum or nitinol, would naturally have a passivated oxide surface, and would have interpreted the claims consistent with that expectation. (*Id.* at ¶ 96 n. 15.) *SAS Inst., Inc. v. ComplementSoft, LLC*, 825 F.3d 1341, 1348 (Fed. Cir. 2016) (“[E]ven under the broadest reasonable interpretation, the Board’s construction... must be consistent with the one that those skilled in the art would reach.”).

This conclusion is reinforced by other intrinsic evidence. For example, claim 7 of the ’433 patent recites:

7. The analyte sensing element of claim 1, wherein said ***outer surface of said core comprises a passivated oxide surface.***

(Ex. 2028 at 5:7-9 (emphasis added).)

This claim clearly communicates applicants’ understanding that the “*outer surface*” of the core includes any passivated oxide surface. *See, e.g., Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003) (“[W]e presume, unless otherwise compelled, that the same claim term in ... related patents carries the same construed meaning.”). Because the outer surface of the core “comprises” the oxide, the electrochemically active metal is “*in contact with*” the core’s outer surface when it touches the oxide.

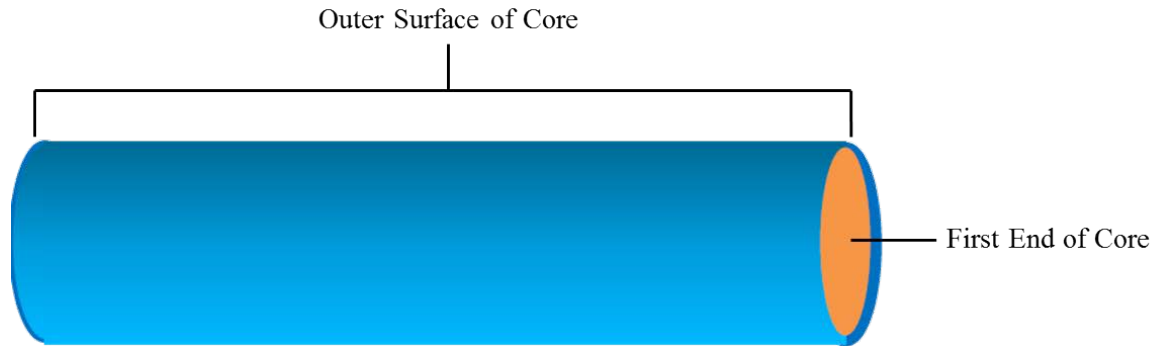
For these reasons, applicant’s construction of “*in contact with*” to mean “touching” is consistent with embodiments in which the outer surface of the core comprises a passivated oxide surface.

C. “*outer surface of the core*” and “*first end of the core.*”

The Oregon district court has entered its claim construction rulings in the co-pending infringement litigation captioned *WaveForm Technologies, Inc. v. Dexcom, Inc.*, Case No. 3:16-cv-00536-MO (D. Or.). Relevant excerpts of the parties' claim construction briefing is attached as Exhibit 2030, and Judge Mosman's ruling on the disputed claim terms is attached as Exhibit 2031.

In the Oregon district court, the dispute relating to the “surround[], cover[] and in contact with” terms in claims 1 and 11 turned on the meaning of the terms “*outer surface of the core*” and “*first end of the core.*” Dexcom advocated the narrowest possible construction, contending that claims 1 and 11 both require the electrochemically active metal to entirely surround, cover and be in contact with the entire core, *including* the end surfaces. (Ex. 2030 at 10-17, 31-41.) WaveForm argued that claims 1 and 11 differentiate between “*an outer surface of the core*” and “*a first end of the core,*” and that Dexcom's reading would improperly nullify dependent claim 11. (*Id.* at 4-8, 19-29.) WaveForm proposed that the “*outer surface of the core*” should be construed to mean the “cylindrical surface of the core” and the “*first end of the core*” should be construed to mean the “distal tip of

the core.”⁵ These two surfaces of the core are represented in the simplified diagram of a wire provided below:



Dexcom argued against WaveForm's broader construction by contending that nothing in the patent specification suggests any cause of differential plating of the "outer surface" of the core and the "first end" of the core. (*Id.* at 10-11.)

WaveForm, however, pointed to portions of the '202 patent specification disclosing various methods for manufacturing a plated wire that can differentially coat these two surfaces of the core. (*Id.* at 2-3, 21-23.)

These include, for example, the drawn-filled tube ("DFT") method that "produces a filled tube that typically is far longer than is necessary, but is available

⁵ In its Petition, Dexcom repeatedly states that the "first end of the core" is the "distal tip" of the core. (Paper 1 at 15, 27-28.) Dexcom also stated in its co-pending Petition on related Patent No. 8,187,433 that "[w]ires are understood generally to be cylindrical in shape." *See Dexcom, Inc. v. WaveForm, Techs., Inc.*, Case No. IPR2016-01680, Paper 1 at 21.

to be **cut** to whatever length is desired.” (Ex. 1001 at 2:52-54 (emphasis added).)

WaveForm expert, Dr. John Smith, explained that when a platinum-clad tantalum wire is cut, tantalum cross-sections are exposed at the cut ends of the wire.

(Ex. 2005 at 4-5; *see also* Ex. 2027 at ¶¶ 74-78). Dr. Smith further explained that the cutting process may cause platinum on the outer surface of the core to be smeared across the exposed tantalum end surface. (*Id.*) Dr. Smith provided a tutorial illustrating the impact of cutting on the end surfaces, with a PowerPoint presentation depicting the resulting smearing of platinum across the cut surfaces, selected excerpts of which are attached as Ex. 2032. (*Id.*)

As would have been understood by a POSA, the end surfaces of a wire produced by the DFT method (as well as other disclosed methods) may, or may not, be covered, depending on a number of factors. (Ex. 2005 at 3, 6; *see also* Ex. 2027 at ¶¶ 73-79.) Consequently, applicant's strategy of separately claiming surrounding and covering an “*outer surface of the core*” in claim 1, and further covering and surrounding a “*first end of the core*” in dependent claim 11, is rooted in the detailed disclosures of the '202 patent specification.

Additionally, during prosecution of the related '433 patent, the Examiner applied the pending application claims to a prior art patent to Palermo (U.S. Patent No. 6,139,510), consistent with WaveForm's proposed construction of the “*outer surface*” and “*first end*” claim terms. (Ex. 2033 at 2-3, 10-11 (discussion relating

to application claims 1 and 13)). As the Examiner noted, Palermo discloses a guide wire for use in a catheter, in which an end cap is placed over the end surface of the wire before the wire is plated with a noble metal. (*Id.*; *see also* Ex. 2034 at Figs. 5A, 5B (element 110).) As a result, the outer surface of the wire is plated, but the protected end surface is not. (*See* Ex. 2033 at 10-11.)

In applying the '433 application claims to Palermo, the Examiner rejected application claim 1 because Palermo teaches “surrounding and covering” the “outer surface” of the wire with platinum. (*Id.* at 2-3.) However, the Examiner provisionally allowed application claim 13 because Palermo does not teach plating the “first end” surface of the wire. (*Id.* at 10-11.)

Applicants ultimately distinguished Palermo on other grounds. However, the Examiner's application of the '433 application claims to Palermo shows that he construed the “*outer surface*” and “*first end*” terms the same way that WaveForm does, confirming the reasonableness of WaveForm's proposed constructions. *St. Clair Intellectual Prop. Consultants, Inc. v. Canon Inc.*, 412 Fed. Appx. 270, 276 (Fed. Cir. Jan. 10, 2011) (“Because an examiner... can be considered one of ordinary skill in the art, his construction of the asserted claims carries significant weight.”); *In re Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002).

In view of the foregoing, Judge Mosman adopted WaveForm's proposals and construed the “*outer surface of the core*” to mean “the cylindrical surface of

the core,” and the “*first end of the core*” to mean the “distal tip of the core.”⁶

(Ex. 2031.) To the extent the Board decides these two terms should be construed in this proceeding, Patent Owner proposes that the same constructions be adopted here.

III. THE WILSON/ROSENBLATT COMBINATION FAILS TO RENDER OBVIOUS CLAIMS 1-3, 5, 6, AND 9-11 OF THE '202 PATENT

The combination of Wilson and Rosenblatt fails to make out even a *prima facie* case of obviousness because, alone or in combination, these references fail to teach or suggest two required elements of the '202 patent claims. First, neither reference discloses a “*structurally flexible core*.” Second, neither reference teaches an electrochemically active metal “*in contact with*” a structurally flexible core. In fact, to the extent Rosenblatt is relevant at all, it expressly teaches away from that claim limitation.

⁶ In the *Markman* claim construction process, WaveForm used the term “distal tip” to mean the distal end surface of the core. (Ex. 2027 at ¶¶ 76-79; Ex. 2032.) In distinguishing Macur during prosecution of the '202 patent, applicants used the distal tip term to refer to a distal portion of the “outer surface” of the core. (*See supra* at 11, 15.) In this paper, Patent Owner uses the “distal tip” term as it was used in the district court claim construction process.

A. Overview of the Wilson Article.

The Wilson article is a short journal article published in *Clinical Chemistry* in 1992. (See Ex. 1004.) It describes a partially implantable glucose sensor that was tested in rats. (*Id.* at 3.) Figure 3 of the Wilson article, reproduced below, depicts the glucose sensor:

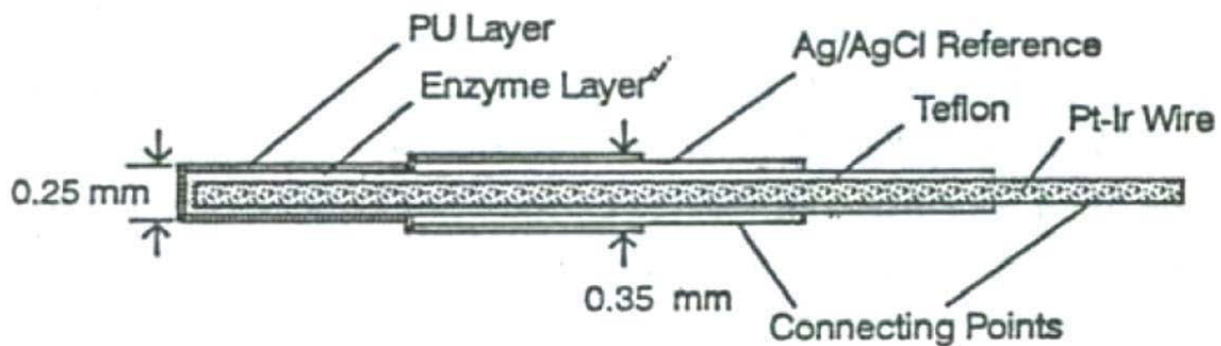


Fig. 3. Diagram of the implantable sensor
PU, polyurethane

As can be seen, the Wilson sensor wire is made of a platinum-iridium alloy. There is no plated layer on Wilson's sensor wire. Wilson's platinum-iridium alloy cannot be considered structurally flexible. As noted in the Background section of the '202 patent, a platinum wire is "a weak metal that is easily broken..." (Ex. 1001 at 1:21-23.) A platinum-iridium alloy is even more prone to breaking than platinum. (*See infra* at section III(C)). The Wilson sensor thus lacks a structurally flexible core and further lacks an electrochemically active metal plated onto a core. (Ex. 2029 at ¶¶ 128-132, 134.)

Notably, the Wilson article provides an abbreviated description of a glucose sensor that was more fully described and claimed in U.S. Patent No. 5,165,407 to Wilson (“the Wilson patent”). (Ex. 2002). The Wilson patent was cited to, and considered by, the Patent Office during prosecution of WaveForm’s ’202 patent. (Ex. 1001 at “References Cited.”) The claims of the ’202 patent were allowed to issue over the Wilson patent.

Wilson’s CGM technology plays a role in the story of the ’202 patent and further confirms its non-obviousness. A WaveForm predecessor, National Applied Science (“NAS”), took a license under the Wilson patent in the 1990s from the University of Kansas. (Ex. 2035 at ¶ 7.) A NAS subsidiary, iSense Corporation (“iSense”), began working with the Wilson CGM device, including its platinum-iridium sensor wire. iSense discovered a significant problem with that device that Wilson apparently had failed to recognize—Wilson’s platinum-iridium wire lacked the structural flexibility needed to withstand repeated bending and flexing that occurs when a wire is partially implanted in a user. (*Id.* at ¶ 10.) Indeed, a platinum-iridium sensor wire fractured in the body of co-inventor Dr. Ken Ward during *in vivo* testing. (*Id.* at ¶ 11.)

That was a disturbing incident, and iSense began work on finding a new wire construction that was sufficiently flexible and robust that it would be able to withstand such repeated flexing. (*Id.* at ¶ 12.) In June 2003, iSense filed a patent application on a novel solution, which involved a sensor having platinum-clad tantalum core. That was the provisional application that ultimately gave rise to the '202 and '433 patents. (*Id.* at ¶ 13.)

Thus, it was an important shortcoming in Wilson's platinum-iridium sensor wire that led to iSense's discovery of the solution described and claimed in the '202 patent. The fact that iSense was the first to discover the problem with Wilson's sensor wire, seven years later, is further probative of non-obviousness. *See, e.g. Leo Pharm. Prods. v. Rea*, 726 F.3d 1346, 1354 (Fed. Cir. 2013).

B. Overview of Rosenblatt.

Rosenblatt does not teach any type of sensor. Instead, it relates to the use of electrochemistry for industrial production of chlorine, chlorates, and percompounds. (Ex. 1005 at 1:24-27, 1:59-61, 4:30-35, 6:3-9; Ex. 2029 at ¶ 93.) This is accomplished by causing chemical brine to flow through an array of charged electrodes in large liquid baths, which results in the passing of hundreds or thousands of amps of current. (Ex. 2029 at ¶ 93.)

Rosenblatt discloses that due to the highly corrosive nature of the chemicals involved, there are a limited number of materials that can be used to make the Rosenblatt anode. (Ex. 1005 at 1:29-32.) The graphite anodes used in prior art systems disintegrated under these conditions and had to be replaced, leading to costly shut-downs of commercial production. (*Id.* at 1:41-45.)

The Rosenblatt anodes need to have relatively large surface areas to have the capacity to carry high currents and maximize chemical production. (Ex. 2029 at ¶¶ 93-94.) Indeed, the Rosenblatt anodes have diameters up to 40x larger than the sensor wires disclosed in the '202 patent. (*Id.* at ¶¶ 101, 153.) While the Rosenblatt anodes are subjected to harsh, corrosive chemicals, they are not bent or flexed, and need not be robust or flexible. (*Id.* at ¶¶ 102-103.) Rosenblatt makes no mention of flexibility, and Dexcom expert Vachon admits that the Rosenblatt anodes were not designed to be flexible and, in fact, preferably are not moved. (Ex. 2036 at 47:5-9.)

Rosenblatt discloses that metals of the platinum group have ideal chemical characteristics for use in this type of anode, but are very expensive. (Ex. 1005 at 1:32-38.) Tantalum is desirable due to its corrosion resistance and is far less

expensive than platinum. (*Id.* at 1:59-64.) Tantalum surfaces, however, oxidize to form a non-conductive film that will cause the flow of electricity to stop. (*Id.* at 1:64-70.) For this reason, tantalum cannot be used by itself as the anode in an electrochemical system.

Rosenblatt claims to have developed a method for making platinized tantalum anodes. Rosenblatt explains that tantalum and platinum do not bond well to one another, and the proclivity of the tantalum surface to oxidize further impairs bonding. (*Id.* at 2:1-21; 5:43-48.) Rosenblatt claims to have solved these adhesion problems by stripping the oxide film off of the tantalum wire and depositing a thin platinum layer onto the tantalum before the oxide film can regenerate. (*Id.* at, *e.g.*, 2:68-3:28, 3:40-55, 6:57-73; Ex. 2029 at ¶ 97.) However, even without an oxide film, the weak bonding between platinum and tantalum makes creation of a tantalum-platinum anode challenging. (*See* Ex. 1005 at 2:1-21; Ex. 2029 at ¶ 97.)

Rosenblatt claims to have improved bonding by subjecting the platinized tantalum to extremely high temperatures either in a high vacuum or an inert atmosphere, causing a separate alloy layer to form. (Ex. 1005 at 3:62-4:14.) This alloy layer has distinctive chemical, physical, electrical and mechanical

characteristics that differentiate it from its constituent metals. (Ex. 2029 at section IX and ¶ 98.) After creating the alloy, a thick layer of platinum is deposited on the alloy layer. (Ex. 1005 at 4:46-5:36). The Rosenblatt configuration thus includes three distinct layers, including an intermediate alloy layer that separates the pure platinum and tantalum layers.

C. The Wilson/Rosenblatt Combination Fails to Make Out a *Prima Facie* Case of Obviousness.

Rosenblatt is non-analogous prior art that would not have been consulted by a POSA attempting to design a partially implantable sensor wire. However, the Board need not reach that question, because the Wilson/Rosenblatt combination fails to teach or suggest at least two required claim elements.

First, the combination fails to teach or suggest an electrochemically active metal “*in contact with*” a structurally flexible core, as required by every instituted claim of the '202 patent. To the contrary, Rosenblatt teaches that it is essential to create a distinct alloy layer that intervenes between, and separates, the platinum and tantalum layers, so that they do not touch. This intervening layer prevents the “contact” required by the claims of the '202 patent. (Ex. 2029 at ¶ 135).

Second, as Petitioner's expert, Dr. David Vachon, admitted on cross-examination, Petitioner has no evidence that either Wilson or Rosenblatt teach,

expressly or inherently, a “*structurally flexible core*.” (Ex. 2036 at 99:10-17, 114:22-25, 118:8-14). With respect to Wilson, Dr. Vachon initially contended that the platinum-iridium wire is structurally flexible, but later conceded that he has no actual evidence of that and that he could not form a definite opinion on this point. (*Id.* at pp. 115:1-118:14.) As noted in the Background section of the '202 patent, a platinum wire is “a weak metal that is easily broken...” (Ex. 1001 at 1:25-26.) A platinum-iridium alloy is even more brittle and prone to fatigue breakage than platinum. (Ex. 2029 at section IX(D) and ¶¶ 90-91.) Further, while the '202 specification discloses that platinum-iridium is suitable for use as the electrochemically active plated layer, the patent makes no similar disclosure concerning platinum-iridium's suitability to serve as core material. (*Id.* at ¶ 131.) That is a meaningful omission. Indeed, as WaveForm employee Ellen Anderson testifies, it was the non-robustness of a platinum-iridium wire that led to the '202 patent. (Ex. 2035 at ¶¶ 11-13.) Petitioner has thus failed to carry its burden of proving that the Wilson sensor possesses a “structurally flexible core.” (Ex. 2029 at 128-132.)

Regarding Rosenblatt, Dr. Vachon concedes that Rosenblatt never uses the word “flexible” and that you cannot determine from Rosenblatt whether it would

have a structurally flexible core. (Ex. 2036 at 99:10-17, 109:1-7). In fact, Dr. Vachon testified that the Rosenblatt anode would be *inflexible*. (*Id.* at 47:1-9.) (“...[P]utting a flexible wire into a large bath that is going to want to move, you wouldn't want that. You want [a wire] to be stable in a bath for production [of chemicals].”) So, by its own expert's admissions, Petitioner has also failed to establish that Rosenblatt teaches a structurally flexible core. Patent Owner's expert agrees that Rosenblatt fails to teach a “*structurally flexible core*.” (Ex. 2029 at ¶ 133.)

This proposed combination thus fails to make out a *prima facie* case of obviousness because it fails to teach, expressly or inherently, at least two required claim limitations. *See, e.g., Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1376 (Fed. Cir. 2011). As to inherency, Petitioner is unable to meet the high standard that applies. It is not enough that it is merely *possible* that the disclosure *may* encompass the claimed feature. Instead, to satisfy the requirements for inherency, the reference must *necessarily* disclose the claim limitation. *Par Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1195-96 (Fed. Cir. 2014). As Dr. Vachon has candidly admitted, that is not the case here.

D. Rosenblatt is Non-Analogous Art That Would Not Have Been Consulted by a POSA in the Sensor Arts.

A prior art reference is in an analogous field of art only when it is either “from the same field of endeavor, regardless of the problem addressed,” or “is reasonably pertinent to the particular problem with which the inventor is involved.” *In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir. 2011). Neither condition is satisfied here.

First, Rosenblatt does not relate to the same field of endeavor. Rosenblatt concerns use of large electrodes for industrial production of chemicals, such as chlorates. (Ex. 1005 at 1:24-27, 1:59-61, 4:30-35, 6:3-9.) In contrast, the '202 patent concerns use of small, partially implantable sensors for measuring analyte concentrations in body fluid. Dexcom's expert, Dr. Vachon, admitted that in developing his own invention relating to the deposition of electrochemically active metals onto an anode, he “didn't even think of [the chemical production] field at” that time. (Ex. 2036 at 76:22-25.)

Second, Rosenblatt is not pertinent to the particular problem with which the inventors of the '202 patent were involved. The inventors of the '202 patent were concerned with developing a partially implantable analyte sensor capable of

withstanding repeated flexing in a user's body without breaking. (Ex. 1001 at 1:19-38.) Rosenblatt has nothing to do with flexing or with structural flexibility of a sensor wire. Rosenblatt describes the very different problem of costly commercial production stoppages to replace a *chemically* degraded anode. (Ex. 1005 at 1:38-45.) The invention of Rosenblatt is intended to make anodes able to withstand the caustic chemicals that are used in the large scale production of chlorates. (*Id.* at 1:19-23.) Rosenblatt discloses that there are few materials suited for this purpose (*id.* at 1:29-32), and further discloses tantalum as an attractive choice because it is nonreactive with the corrosive chemicals to which it will be subjected. (*Id.* at 1:59-63.)

However, Rosenblatt also explains in considerable detail the difficult problems associated with use of tantalum, including (i) the weak or non-existent attraction between platinum and tantalum; and (ii) oxidation of the tantalum surface. (*Id.* at 1:64-2:21.) The oxide film is non-conductive and can stop the flow of electrical current across the anodic surface. (*Id.* at 1:64-70.) And, the oxide surface further attenuates the already weak attraction between tantalum and platinum. (*Id.* at 5:43-48.) Rosenblatt describes a complex and presumably costly

multi-step procedure for overcoming these problems. (*Id.* at 2:72-3:26; 3:67-4:8; 5:4-13; *see also* Ex. 2029 at ¶¶ 141-146.)

The Rosenblatt problems relating to chemical corrosion of an anode have nothing to do with the problems faced by designers of glucose analyte sensors. Unlike Rosenblatt, analyte sensors do not involve manufacture of electrodes that are used in large scale industrial production of corrosive chemicals. Nor do they involve possible disintegration of an anode that will result in a costly shut-down of commercial production. Instead, the '202 patent and Wilson disclose small disposable sensors wires that are partially implanted in a user's body for a period of days and then discarded. (Ex. 1001 at 4:31-46; Ex. 1004 at 6; Exhibit 2029 at 26-27, 116.)

The inventors of the '202 patent addressed the problem of tiny sensor wires physically breaking inside users' bodies as the result of repeated bending and flexing. Given that Rosenblatt does not discuss the need for a flexible and robust wire, or the risk of wire breakage from repeated flexing, Rosenblatt is not reasonably pertinent to the particular problem with which the inventors of the '202 patent were involved. (Ex. 2029 at ¶¶ 124-125, 133.)

E. Rosenblatt Teaches Away from the Electrochemically Active Metal Being “*in contact with*” the Outer Surface of the Core.

Rosenblatt expressly teaches away from a key element of the '202 patent claims, namely, that the electrochemically active metal be “in contact with” (*i.e.*, touching) the core. Rosenblatt teaches that in order to create a viable platinum-tantalum anode, an intervening alloy layer must be created between the pure tantalum and platinum layers, thus preventing the contact required by the '202 patent claims. Indeed, claim 1 of the Rosenblatt patent describes this separation with clarity: “[the] platinum metal layer becomes bonded to [the alloy] on its outer surface and *is separated from* the [tantalum] base by an interlayer of an alloy” (Ex. 1005 at 6:27-30.)

Rosenblatt describes the inherent difficulties of plating a platinum layer onto a tantalum base: “Electroplating of a platinum metal onto a tantalum base results in a coating that may easily be stripped from the base.” (Ex. 1005 at 2:8-10.) Rosenblatt explains that this problem of weak adhesion is exacerbated by the persistent natural oxidation of a tantalum surface on exposure to ambient air:

When ... no precautions are taken to prevent the formation of the surface film during the heating treatments, the [oxide] film becomes considerable and is

not completely dissolved into the tantalum mass, thus preventing the platinum deposit from joining directly to the pure tantalum.

(Ex. 1005 at 5:43-48; Ex. 2029 at ¶ 156.)

Rosenblatt claims to have circumvented the problems associated with adhering platinum to tantalum by creating a third metal layer positioned between the tantalum and the platinum. (Ex. 1005 at 4:46-60, 6:28-30, 6:39-45, 6:68-71.) As Dr. Vachon admits, this alloy layer has unique and distinctive chemical, physical, and electrochemical characteristics that differentiate it from the surrounding pure metals. (Ex. 2036 at 140:7-14; *see also* Ex. 2029 at section IX and ¶ 157.) For example, Rosenblatt suggests that atomic attraction forces exist between the alloy layer and the surrounding platinum and tantalum layers that do not exist between pure platinum and pure tantalum, without which, platinum and tantalum do not satisfactorily bond. (Ex. 1005 at 2:1-4, 2:16-21; *see also* Ex. 2029 at ¶ 158.)

Thus, Rosenblatt teaches directly away from the '202 patent claim requirement that the platinum be "in contact with" (or touching) the tantalum core. Such teaching away provides strong evidence of non-obviousness. *See Allergan,*

Inc. v. Sandoz, Inc., 796 F.3d 1293, 1304-7 (Fed. Cir. 2015); *Crocs, Inc. v. ITC*, 598 F.3d 1294, 1308-11 (Fed. Cir. 2010).

F. Even if Rosenblatt were Analogous Art, It Would Not Have Motivated a POSA to Choose Tantalum for a Partially Implantable Analyte Sensor.

Rosenblatt discloses two primary motivations to use tantalum and platinum together in an electrode. First, Rosenblatt discloses a need to find an anode material that can withstand the harsh conditions involved in industrial manufacture of chemicals like chlorine. (Ex. 1005 at 1:27-32, 1:62-63.) Prior anode materials used for this purpose, such as graphite, disintegrated under the corrosive conditions involved, requiring a costly production shut-down for anode replacement. (*Id.* at 1:41-52.) Second, Rosenblatt discloses a motivation to avoid the high costs of a pure platinum anode in these large industrial anodes. (*Id.* 1:36-38.)

However, neither Wilson nor the '202 patent disclose use of harsh, corrosive chemicals, so that motivation does not apply in the context of small analyte sensors meant to be partially implanted in a user's body. (Ex. 2029 at ¶ 139.) That leaves cost as the sole motivation provided by Rosenblatt for creating a platinum-tantalum electrode. However, for reasons discussed below, the cost considerations driving selection of tantalum in Rosenblatt have little or no application in the context of

partially implantable sensors such as disclosed in the '202 patent. (Ex. 2029 at ¶ 140.) So, even if Rosenblatt were in an analogous field art, cost considerations alone would not have provided a motivation to select tantalum for an analyte sensor.

Tantalum, though less expensive than platinum, is by no means an inexpensive material. It is a rare metal that sells for approximately \$4500/kg. (Ex. 2029 at ¶ 147.) There are many considerably less expensive sensor wire materials available, including stainless steel, copper, polymers, and glass fiber. (See Ex. 1001 at 2:27, 2:41-42; *see also* Ex. 2029 at ¶ 147.) Moreover, Rosenblatt teaches that tantalum requires complex and costly procedures necessary to bond it to platinum. Rosenblatt's lack of concern for flexibility, combined with the high cost of tantalum, and the complicated and expensive manufacturing process it discloses, would have dissuaded a POSA in the sensor arts from pursuing a tantalum core on the basis of cost alone.

G. The POSA Would Not Have Had a Reasonable Expectation of Success in Combining Wilson and Rosenblatt to Achieve the Claimed Invention.

As has been well known for decades, alloys generally are less malleable and more brittle than their constituent metals. (Ex. 2029 at ¶¶ 57-59.) This is

particularly true for tantalum and platinum alloys, which are notoriously unstable, brittle and prone to breaking. (Ex. 2029 at Section IX.D. and IX.E., and ¶¶ 149-152.) Moreover, platinum and tantalum alloys become progressively more brittle and inflexible with repeated bending or flexing. (*Id.*) So, a tantalum-platinum alloy wire subjected to the repeated bending and flexing described in the '202 patent would become increasingly brittle, leading to formation of fissures, fractures and failure. (*Id.*) As the breakdown of the tantalum/platinum alloy progresses, it likely would lead to portions of the surrounding platinum layer flaking off. (*Id.*) This would result in a wire whose outer surface is incompletely covered by the platinum active layer, violating a key requirement of the '202 patent claims.

The POSA in 2003 would have been well aware of these characteristics of tantalum/platinum alloys, and would have understood that such an alloy would not have been reasonably likely to produce a sensor that functions as claimed in the '202 patent. (*Id.* at ¶ 152.)

H. If Dr. Vachon's Interpretation is Accepted, the Wilson and Rosenblatt Combination Teaches Away From a "*Structurally Flexible Core*."

In his May 4 deposition, Dr. Vachon expressed the opinion that the Rosenblatt "core" may include the intermediate alloy layer. (Ex. 2036 at 123:6-

124:11.) Rosenblatt itself provides no support for such an opinion. To the contrary, Rosenblatt describes the central metal as the core. For example, describing an alternative embodiment in which a platinized tantalum tube is slipped over a copper rod, Rosenblatt describes the copper rod as the “core.” (Ex. 1005 at 5:67 – 6:2; *see also* Ex. 2036 at 131:5-9) (Dr. Vachon agreeing that the copper is the “core” of this alternative Rosenblatt embodiment). This disclosure is reinforced by the dictionary definition of “core,” which is “a central ... part usu[ally] distinct from the enveloping part by a difference in nature.” (Ex. 2037.)

However, if Dr. Vachon's opinion that the platinum-tantalum alloy may be part of the core is accepted, that would constitute an admission that Rosenblatt teaches away from a structurally flexible core. For all the reasons discussed in sections III(C) and III(G) above, the tantalum-platinum alloy is not structurally flexible, and a core including that alloy could not be considered structurally flexible. (Ex. 2029 at IX.D. and IX.E., and ¶¶ 149-152.)

IV. HAGIWARA DOES NOT ANTICIPATE CLAIMS 1-3, 6, 8, 10, AND 11 OF THE '202 PATENT

Hagiwara does not anticipate claims 1-3, 6, 8, 10, and 11 of the '202 patent for at least three reasons:

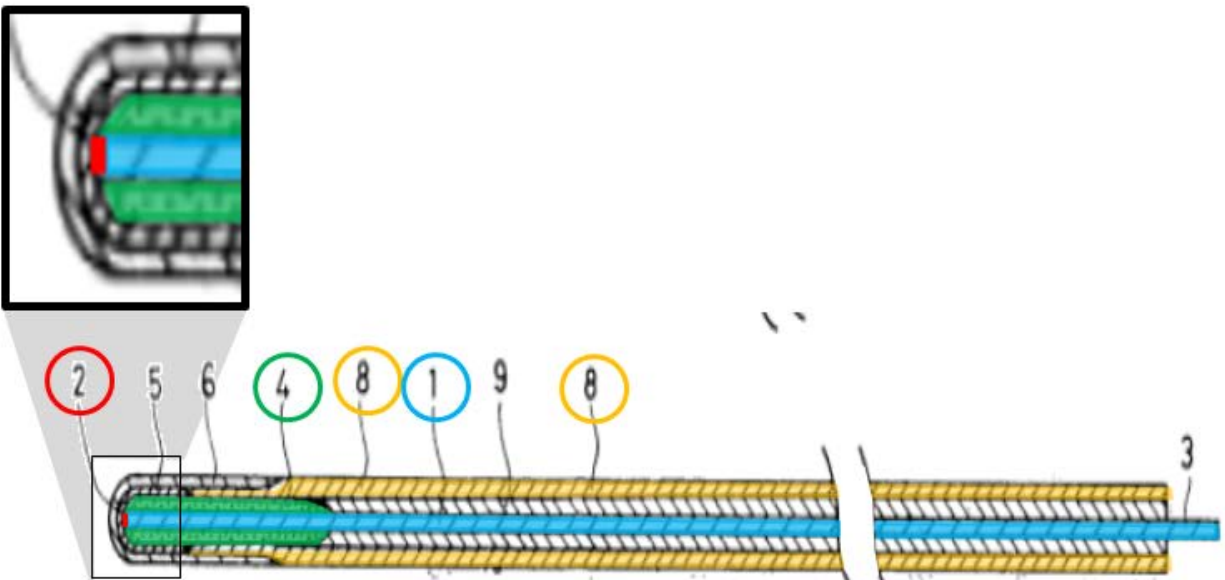
1. Hagiwara fails to expressly or inherently disclose a sensor having a “*structurally flexible core*,” as the Board has defined that term.
2. Hagiwara fails to teach an electrochemically active metal “*covering, surrounding, and in contact with*” a structurally flexible core.
3. Hagiwara fails to teach a sensor having a structurally flexible core for measuring glucose concentration as recited in claim 10 of the '202 patent.

A. Overview of Hagiwara

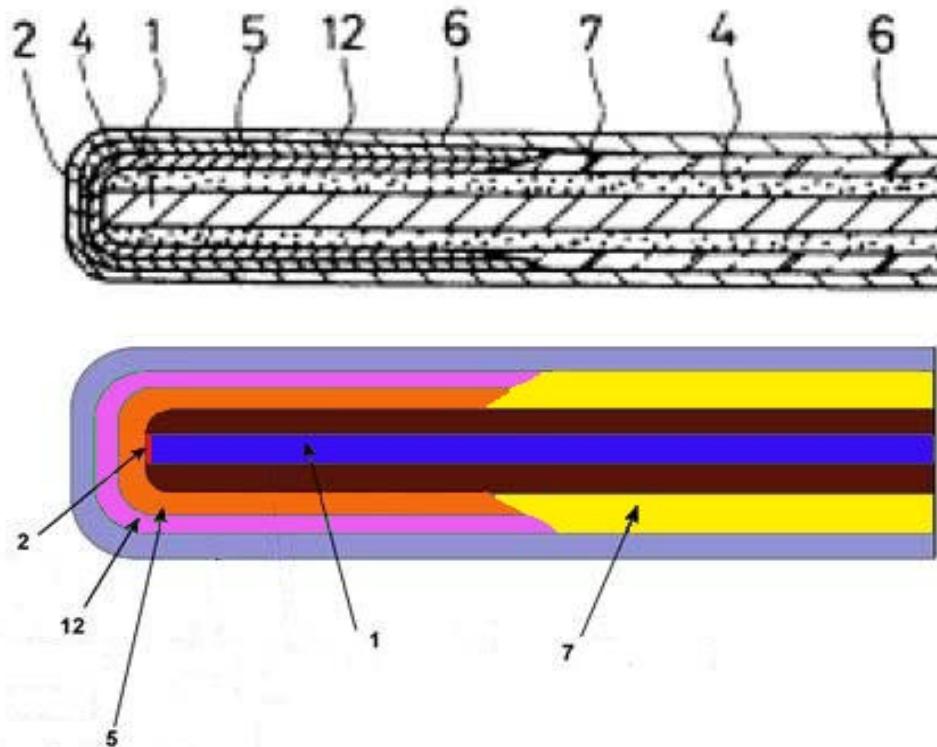
Hagiwara discloses polarography sensors that are threaded through the vasculature of immobilized patients for purposes of measuring analytes in their blood. (Ex. 1007 at 4:1-6.) Hagiwara depicts four principal embodiments in Figures 1(A)-1(D). (*Id.* at 10.) Two of those embodiments, Fig. 1(B) and 1(D), shown below, are relevant to this analysis:

The Figure 1(B) embodiment (a colorized version of which is reproduced below), is described as a flexible measuring electrode. (*Id.* at 6:12-13.) Fig. 1(B) shows a precious metal wire **1** (blue) surrounded at its front end by a hardened insulating coating made of glass or enamel **4** (green), except at the electrode reaction surface **2** (red) at the distal tip surface of the sensor. (*Id.* at 6:14-22.) The

portion of the wire not covered by the hardened insulating coating is covered by an insulating coating **9** made of flexible resin. (*Id.* at 6:17-18.) The insulating coatings (**4**, **9**) are encircled by a flexible tube **8** (yellow) made of Teflon, silicon, or the like. (*Id.* at 6:15.) This is the only embodiment that Hagiwara describes as “flexible.”



The Figure 1(D) embodiment (a colorized version of which is reproduced below), is described as a sensor for indirect polarography by enzymatic reaction. (Ex. 1007 at 6:42-43.) Figure 1(D) shows a precious metal wire **1** (blue) encircled by an insulating layer **4**, except at the electrode reaction surface **2** (red) at the distal tip of the sensor. (*See id.* at 5:45-6:2.) A porous plastic layer **12** homogenously disperses and fixes an enzyme on the contamination inhibition coating **5** of the electrode reaction surface. (*Id.* at 6:42-45.) The insulating layer is encircled by a metal electrode protecting tube **7** (yellow), which is surrounded by plastic coating **6**.



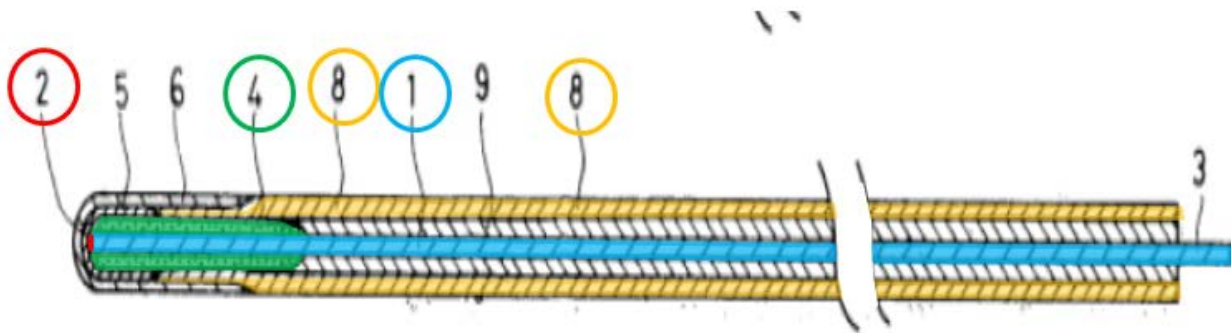
B. Hagiwara Does Not Expressly or Inherently Disclose a Sensor Having a “structurally flexible core.”

1. A “structurally flexible core” must be both flexible and robust.

In its institution decision, the Board offered a preliminary construction of “structurally flexible core” to mean: “a core that is robust and able to be flexed or bent repeatedly.” For purposes of this proceeding, Patent Owner does not challenge that construction.

2. Hagiwara’s disclosure of “flexible” embodiment 1(B) fails to teach a robust “structurally flexible core.”

Petitioner’s contention that Hagiwara teaches a “structurally flexible core” rests on Hagiwara’s disclosure of an embodiment depicted in Figure 1(B). (See Paper 1 at 31-34.) Hagiwara states that the sensor illustrated in Figure 1(B) includes “a flexible tube 8 made of Teflon, silicon, or the like ...” (Ex. 1007 at 6:15.) A colorized version of Figure 1(B), reproduced below, shows that the flexible tube 8 (yellow) is not a “core” of any kind, but is instead an exterior tube surrounding interior layers, including core wire 1 (blue):



Hagiwara's additional disclosures concerning the Figure 1(B) sensor suggest that the core wire is not robust. (Ex. 2029 at ¶¶ 165-167.) In particular, at its distal end, the noble metal wire 1 is covered with a hardened insulating coating 4 (green) made of glass or enamel. (Ex. 1007 at 6:16-17.) A POSA would have understood that this hardened coating is at least partly intended to protect the insertion end of the core wire from stresses that may be encountered as the wire is threaded up through the vasculature and into the heart. (Ex. 2029 at ¶ 166.)

These disclosures suggest that the wires used in the Hagiwara sensors are weak and susceptible to fracture, requiring that they be reinforced and protected by more robust surrounding structures. (*Id.* at ¶¶ 165-167.)

Hagiwara's disclosure that the core wire is made of precious metals, such as gold or platinum, confirms the inference. (Ex. 1007 at 3:2-5.) Precious metals such as platinum and gold are considered "soft" metals that do not well-endure repeated bending and flexing. (Ex. 2029 at ¶ 167.) To this point, the '202 patent describes platinum as a weak core metal prone to breakage. (Ex. 1001 at 1:21-23.) And, gold's fatigue resistance is no greater than that of platinum. (Ex. 2029 at ¶ 167.) This strategy of protecting a weak precious metal core wire with a hardened encircling structure is fundamentally different from the strategy of the '202 patent, which utilizes a robust and flexible core wire, without need for reinforcing structures. (*Id.* at ¶ 168.)

3. Hagiwara's generic disclosure of a "base metal" also fails to disclose a "*structurally flexible core*."

Other than the reference to "flexible" embodiment 1(B), Petitioner appears to rely on a single sentence in Hagiwara to argue that Hagiwara teaches a "structurally flexible core." That sentence states in relevant part that: "[B]ecause only the electrode reaction surface requires noble metal properties ... *base metal wires* with precious metal wires connected only to the front end thereof *may be used*" (Ex. 1007 at 7:27-29 (emphases added).)

This disclosure of a "base metal" is ambiguous at best, and it fails to inherently disclose a structurally flexible core. In the context of plated metal products, the "base metal" is the metal upon which some other metal is plated. (Ex. 2029 at ¶ 171.) This could refer to countless metals and their alloys, many of which could not be deemed "structurally flexible. The term "base metal" can also be used to refer to a common and inexpensive metal, in contrast to a precious metal, again a large and diverse group of metals. (*Id.* at ¶ 172.) Finally, "base metal" can refer to a broad class of metals that readily oxidize on exposure to air. (*Id.* at ¶ 173.) Hagiwara's brief reference provides insufficient information to determine which of these usages is intended, a fact that was admitted by Dr. Vachon. (*Id.* at ¶¶ 174-176; Ex. 2036 at 156:23-157:3). Regardless, each of these definitions encompasses a host of metals, many of which clearly do not meet any reasonable definition of the "*structurally flexible core*" term. (*Id.*)

From the above, there is no express disclosure of a “*structurally flexible core*.” Nor can Petitioner meet the high threshold for inherent disclosure of such a core. Hagiwara’s bare disclosure of “base metals,” a class that includes some metals that may be flexible and robust, and many others that are not, does not inherently disclose a “*structurally flexible core*.” As is well-established, for inherency to apply it is not enough that the missing disclosure *may* be present. Rather, the missing disclosure must *necessarily* be present as a consequence of the explicit teaching. *Motorola Mobility, LLC v. ITC*, 737 F.3d 1345, 1350 (Fed. Cir. 2013); *see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1262 (Fed. Cir. 1989) (“Under [defendant’s] theory, a claim to a genus would inherently disclose all species. We find [this] argument wholly meritless....”). Because Hagiwara fails to expressly or inherently teach a “*structurally flexible core*,” it does not anticipate any claim of the ’202 patent.

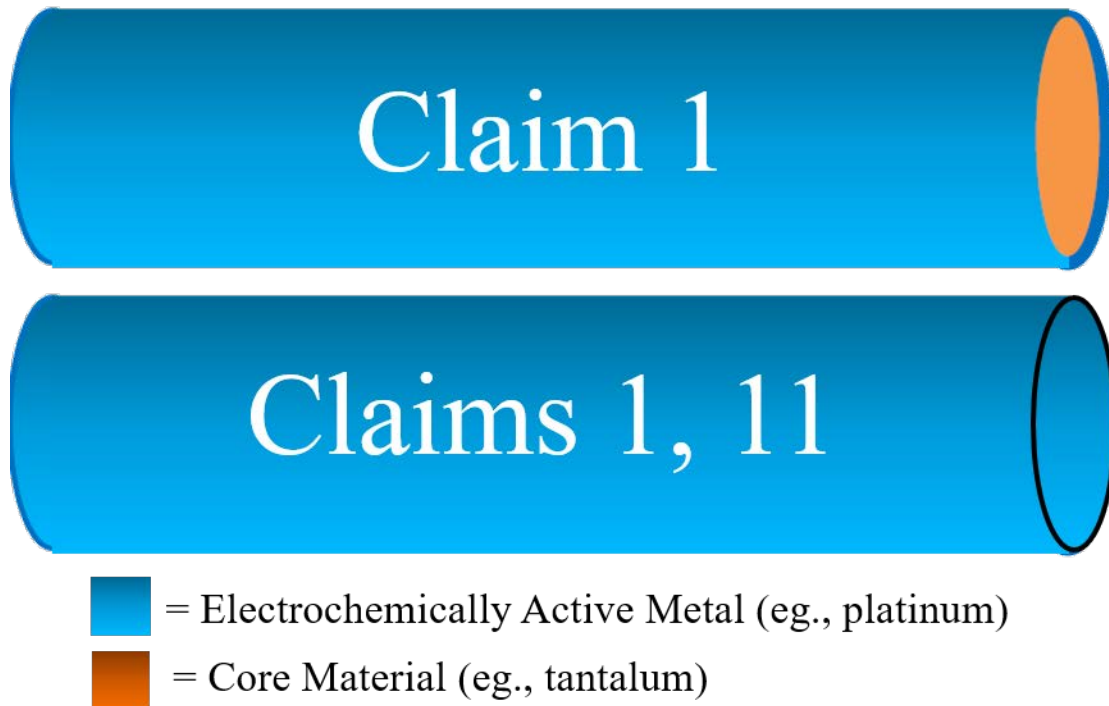
C. Hagiwara Does Not Teach an Electrochemically Active Metal “*covering, surrounding, and in contact with*” an Outer Surface of a Structurally Flexible Core.

Patent Owner proposes that the claim term “*covering, surrounding, and in contact with*” be construed to mean: “entirely surrounding and covering, and touching.” In claim 1 of the ’202 patent, that means that the electrochemically active metal entirely surrounds and covers, and touches an “*outer surface of the core*.” (Ex. 1001 at 4:60-62.) In claim 11, it means that the electrochemically

active metal further surrounds and covers, and is touching a “*first end of the core.*”

(*Id.* at 6:3-6.) The arrangements of claims 1 and 11 are schematically depicted

below:

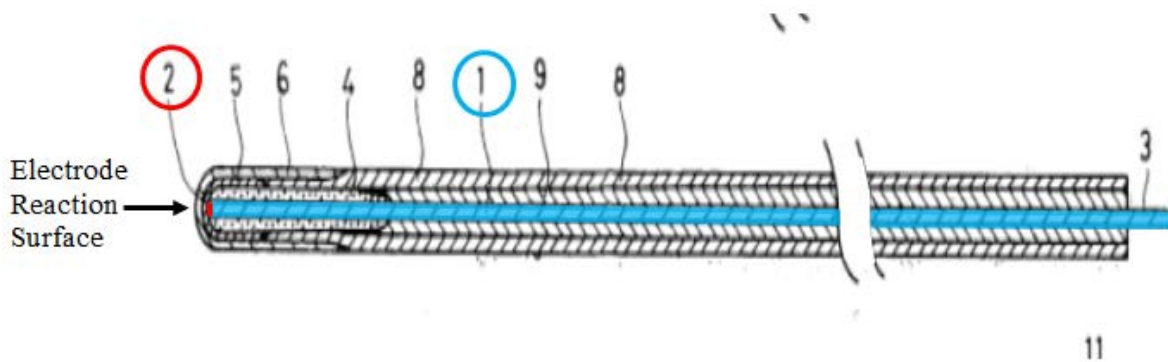


Hagiwara does not teach either of these limitations. Petitioner's argument that it does relies upon a single sentence in Hagiwara, which states in relevant part:

[B]ecause only the electrode reaction surface requires noble metal properties, that is, non-variability, base metal wires with precious metal wires connected only to the front ends thereof may be used, furthermore, base metal wires, with precious metals vapor deposited or plated on the front ends thereof, may also be used.

(Paper 1 at 34-35; Ex. 1007 at 7:27-29 (emphasis added).)

This arrangement is depicted in a colorized version of Hagiwara Fig. 1(B) below, showing a precious metal (red) deposited only on electrode reaction surface **2** at the front end of the core wire **1** (blue):



The Hagiwara statement that petitioner relies on does not teach an electrochemically active metal surrounding and covering the entire outer surface of the core wire, as required by claim 1 of the '202 patent. Instead, Hagiwara teaches just the opposite – that the electrochemically active metal should contact only the “*first end*” of the core, and does not surround and cover the entire “*outer surface*” of the core – or even any portion of it. Because Hagiwara fails to teach the “surrounding” and “covering” claim limitations of claim 1, it does not anticipate any claims of the '202 patent.

D. Hagiwara Does Not Teach a Sensor for Measuring Glucose Concentration, as Recited in Claim 10 of the '202 patent.

Petitioner also argues that Hagiwara teaches measuring glucose concentration, as recited in dependent claim 10 of the '202 patent. (Paper 1 at 42-43; Ex. 1006 ¶¶ 168-70.) However, Hagiwara explains that use of its sensor to

measure glucose requires an enzyme, specifically, glucose oxidase. (Ex. 1007 at 3:30-37; *see also* Ex. 2027 at Section XI.) Accordingly, Petitioner's anticipation argument implicitly relies on combining two of the four Hagiwara embodiments: the "flexible" sensor disclosed in Figure 1(B), and the sensor disclosed in Figure 1(D), which includes an enzyme layer. (*See* Ex. 1007 at 6:12-26 and 6:42-7:5.)

Petitioner made this same anticipation argument based on the Hagiwara 1(B)/1(D) combination in its petition for *inter partes* review in co-pending Case IPR2016-01680. (IPR2016-01680 Paper 1 at 21-22.) The Board rejected the argument, and denied institution on that ground, stating as follows:

Petitioner contends that claims 1–3, 6, and 9–11 of the '433 patent are anticipated by ... [the combination of] Hagiwara's Figure 1(B) embodiment and ... Hagiwara's Figure 1(D) embodiment ...

Patent Owner argues that Petitioner's anticipation ground impermissibly mixes and matches features of different embodiments of Hagiwara ...

We agree with Patent Owner. To anticipate a patent claim under § 102, a prior art reference must disclose "within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim" ...

....

Contrary to Petitioner's assertion[], Hagiwara does not state that the features of Figs. 1(A)–1(D) are interchangeable ... Hagiwara discloses specific instances where a particular feature of one embodiment is applicable to other embodiments. Enzyme-containing layer 12 is not, however, one of those features . . .

Accordingly, we conclude that Petitioner has not demonstrated a reasonable likelihood of prevailing on its contention that claims 1–3, 6, and 9–11 of the '433 patent are anticipated by Hagiwara.

(IPR2016-01680 Paper 10 at 16-18 (internal citations omitted).)

In its '433 IPR petition, Dexcom apparently based its anticipation argument on the Hagiwara 1(B)/1(D) combination because claim 1 of the '433 patent expressly recites use of an enzyme. However, claim 10 of the '202 patent also requires use of an enzyme to measure glucose concentration. (Ex. 2027 at Section XI.) Accordingly, Petitioner's anticipation argument relating to claim 10 ultimately relies upon the same 1(B)/1(D) combination that the Board rejected in its decision on the '433 *inter partes* review petition. For this additional reason, Hagiwara does not anticipate claim 10 of the '202 patent.

V. THE HAGIWARA/ROSENBLATT COMBINATION DOES NOT RENDER OBVIOUS CLAIM 5 OF THE '202 PATENT

As discussed above, Hagiwara does not teach either a “*structurally flexible core*” or an electrochemically active metal “*surrounding, covering, and in contact with*” an “*outer surface of the core.*” Rosenblatt provides no teaching to remedy these deficiencies.

A. Rosenblatt is Non-Analogous Art.

For the same reasons discussed *supra* at section III(D), Rosenblatt is non-analogous prior art that would not have been considered by a POSA in the sensor arts attempting to develop a fracture-resistant sensor.

B. Even if Rosenblatt is Found Analogous, a POSA Would Not Have Been Motivated to Combine Rosenblatt and Hagiwara to Arrive at the Invention of Claim 5.

Hagiwara is missing at least two elements required by claim 5: (i) a tantalum core, and (ii) an electrochemically active metal “*surrounding, covering and in contact with*” the “*outer surface*” of the tantalum core. There is no teaching or suggestion in Rosenblatt that would have motivated the person of ordinary skill in the art to modify Hagiwara to arrive at the invention of claim 5.

First, there is no disclosure in either Hagiwara or Rosenblatt of a “*structurally flexible core.*” At most, Hagiwara mentions a flexible exterior sheath surrounding a core. *See supra* at section IV(B)(2). And, Petitioner's expert, Dr. Vachon, conceded that one cannot determine whether Rosenblatt discloses a

structurally flexible core, and he opined that the Rosenblatt anode, in fact, should be inflexible. (Ex. 2036 at 47:5-9, 99:10-17) (“... [P]utting a flexible wire into a large bath that is going to want to move, you wouldn't want that. You want [a wire] to be stable in a bath for production.”) (Ex 2029 at ¶ 133.)

The principal motivation for a platinum-tantalum anode in Rosenblatt is selection of an anode that will not degrade in a caustic chemical environment. However, neither the '202 patent nor Hagiwara describe any harsh industrial chemicals that will corrode an anode. (Ex. 2029 at ¶ 188.) So the principal factor driving the choice of a core material in Rosenblatt—avoiding intense corrosion of the anode—is absent in the context of partially implantable analyte sensors.

That leaves cost as the sole remaining motivation for modifying Hagiwara. The cost factor, however, provides no reason to select tantalum for the Hagiwara sensor given that tantalum is substantially more expensive than other “base metals” that could be chosen. (Ex. 2029 at ¶ 189; Ex. 1001 at 2:27, 2: 41-42.)

Moreover, Hagiwara teaches that a precious metal need only be deposited on the electrode reaction surface, which comprises just a small area at the distal tip of the wire. (Ex. 1007 at 7:26-31; *see supra* at section IV(C).) In contrast, Rosenblatt suggests that the oxidation of an exposed tantalum surface requires the entire

tantalum surface to be platinized.⁷ So, modifying Hagiwara in view of Rosenblatt would substantially increase costs by requiring the expensive precious metal to be deposited along the full length of the four-foot long Hagiwara 1(B) embodiment, rather than just on the electrode reaction surface. (Ex. 2029 at ¶¶ 190-191. Ex. 2036 at 143:22-144:4.) This provides a strong cost disincentive to modify Hagiwara following the teachings of Rosenblatt. So, the cost factor militates against modifying Hagiwara in view of Rosenblatt to arrive at the invention of claim 5.

C. Rosenblatt Expressly Teaches Away From the Electrochemically Active Metal Being “*in contact with*” the “*outer surface of the core*.”

For the same reasons discussed *supra* at section III(E), Rosenblatt teaches away from having the electrochemically active metal “*in contact with*” the core. Instead, Rosenblatt teaches deliberately creating an intervening alloy layer which separates the electrochemically active metal and the core so that they do not touch.

⁷ Rosenblatt teaches away from the '202 patent on this point as well, insofar as the '202 patent teaches that an oxide layer on a tantalum core can be beneficial to functioning of the sensor by preventing unpredictable electrical activity. (Ex. 1001 at 3:24-32.) Rosenblatt, on the other hand, teaches that formation of an oxide layer is invariably detrimental to functioning of the anode.

This teaching away provides strong evidence of non-obviousness. *See Allergan*, 796 F.3d at 1304-7; *Crocs*, 598 F.3d at 1308-11.

D. The POSA Would Not Have Had a Reasonable Expectation of Success in Combining Hagiwara and Rosenblatt to Achieve the Invention of Claim 5.

For the same reasons discussed *supra* at section III(G), a POSA would not have had a reasonable expectation of success in using Rosenblatt's teachings to modify Hagiwara to achieve the invention of claim 5. Specifically, the Rosenblatt tantalum-platinum alloy layer would be brittle and subject to failure, defeating the purpose of claim 5, which is to provide a structurally flexible core that reduces instances of breakage.

E. If Dr. Vachon's Interpretation is Accepted, the Hagiwara-Rosenblatt Combination Lacks a "*structurally flexible core*."

As discussed *supra* at section III(H), Patent Owner disagrees with Dr. Vachon's opinion that the platinum-tantalum alloy may be part of the Rosenblatt core. However, if Dr. Vachon's interpretation is accepted, then the Hagiwara-Rosenblatt combination fails to teach or suggest a "*structurally flexible core*." That is because the alloy is brittle and likely to fail on repeated bending and flexing. (Ex. 2029 at section IX(E) and ¶ 193.)

VI. THE OBJECTIVE INDICIA OF NON-OBVIOUSNESS CONFIRM THE NON-OBVIOUSNESS OF THE '202 PATENT CLAIMS

A. Petitioner Dexcom Experienced the Problem Described in the '202 Patent: Breakage of [REDACTED] Sensor Wires in Users' Bodies.

Between 2006 and 2012, Dexcom sold three successive generations of continuous glucose monitoring (CGM) sensors, [REDACTED]

[REDACTED]⁸ Dexcom experienced serious problems with these [REDACTED] sensor wires breaking in user's bodies [REDACTED]

[REDACTED] (Ex. 2041 (list of all MDRs⁹ filed on Dexcom's CGM devices from 2008-2014).) [REDACTED]

[REDACTED] (Ex. 2042 at 9; Ex. 2043 at 2-4.) [REDACTED]

⁸ Dexcom documents referenced herein are authenticated in the Declaration of Jason A. Wrubleski, submitted herewith as Exhibit 2040.

⁹ A manufacturer is required to submit a Medical Device Report (or "MDR") if it learns that a device "[m]ay have caused or contributed to a death or serious injury; or [h]as malfunctioned and... would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50(a).

[REDACTED]

[REDACTED] (Ex. 2044 at 5.)

This problem finally came to a head in 2009, [REDACTED]

[REDACTED]

[REDACTED].¹⁰ (See Ex. 2045 at 2-3, 5-6.) After conducting an investigation, in 2010, FDA sent Dexcom a Warning Letter admonishing Dexcom for failing to file MDRs relating to these events. (Ex. 2046 at 1-2.) In this Warning Letter, FDA instructed Dexcom to modify its product label to prominently include the following cautionary statement: “NOT APPROVED FOR USE IN CHILDREN OR ADOLESCENTS.”

We are recommending that the firm add additional Warning and Precaution statements to the labeling, the patient education brochure, and the website as follows:

- Under the Warnings section, warn the user: (1) not to remove a retained sensor probe distal segment, unless it is clinically indicated; and (2) to contact the health care provider for medical advice in the event of a sensor probe fracture.
- Revise the Precautions bullet to state: The SEVEN and SEVEN PLUS Systems **are not approved for use** in children or adolescents, pregnant women or persons on dialysis, and move this bullet to the Warnings section.
- Add a Limitations of Use section to reiterate the above warning: The SEVEN and SEVEN PLUS Systems **are not approved for use** in children or adolescents, pregnant women or persons on dialysis, and move it to the Warnings section.

(Ex. 2046 at 2.)

10 [REDACTED]

[REDACTED]

[REDACTED] See *Leo Pharm.*, 726 F.3d at 1354.

[REDACTED]

[REDACTED]

[REDACTED] (Ex. 2047 at 3.) [REDACTED]

[REDACTED] (*Id.*) [REDACTED]

[REDACTED]

[REDACTED] (Exs. 2048 at 26-27; 2047 at 4.)

[REDACTED]

[REDACTED]

[REDACTED] (Exs. 2047 at 4; 2044 at 1.) Notably,

Dexcom admits that it learned about the '202 patent no later than 2008, [REDACTED]

[REDACTED]

[REDACTED] (Ex. 2049 at 3-4.)

B. Dexcom Solved its Sensor Wire Breakage Problem by Adopting the Solution Claimed in the '202 Patent.

Dexcom launched its G4 Platinum sensor system ("G4 Platinum") with much fanfare in 2012. [REDACTED]

[REDACTED] (Ex. 2027 at ¶¶

96-98). As discussed *infra* at section VI(C)(2), Dexcom's sales and stock market capitalization skyrocketed after release of the infringing G4 Platinum. For example, the stock chart reproduced below shows the near-vertical rise in

Dexcom's stock price that coincided with its 2012 launch of the G4 Platinum

product:



Dexcom publicly announced that its G4 Platinum sensor had an improved

sensor wire, [REDACTED]

[REDACTED] (Exs. 2050 at 2-3; 2051 at 7.)

[REDACTED] (See Ex. 2047 at 4.) [REDACTED]

[REDACTED] (Ex. 2043 at 3; Ex. 2041.)

C. The Objective Indicia Weigh Against a Finding of Obviousness.

Evidence of objective indicia:

[M]ay often be the most probative and cogent evidence of nonobviousness in the record. Such evidence can establish that an invention appearing to have been obvious in light of the prior art was not ... [F]act finders must withhold judgment on an obviousness challenge until it considers all relevant evidence, including that relating to objective considerations.

Intri-Plex Techs., Inc. v. Saint-Gobain Performance Plastics Rencol Ltd.,

IPR2014-00309, Paper 83 at 35-36 (P.T.A.B. March 23, 2014) (citations omitted).

Objective evidence can include commercial success of the patented product by increased sales and market share, improved profit margins resulting from use of the claimed invention, or failure of the inventor and others to achieve the claimed invention. *See, e.g., WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1337 (Fed. Cir. 2016) (“Demonstrating that an invention has commercial value... weighs in favor of non-obviousness.”).

Commercial success can be based on sales either by a patent holder or by an accused infringer. *See WBIP*, 829 F.3d at 1329-30. To rely on objective evidence of non-obviousness, the patent holder must show that a “nexus” exists between the objective evidence and features of the claimed invention. *See, e.g., In re Huai-Hung Kao*, 639 F.3d 1057, 1069-70 (Fed. Cir. 2011). Nexus is presumed where

“the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent.” *Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1361 (Fed. Cir. 1999); *see also World Bottling Cap, LLC v. Crown Packaging Tech., Inc.*, IPR2015-01651, Paper 34 at 17 (P.T.A.B. Jan. 19, 2017) (finding nexus upon showing “that the claimed invention is not a subcomponent of, but rather the entirety of, the product sold”).

1. A presumption of nexus exists in this case.

Patent Owner's CGM device is currently in the FDA approval process, so there have been no sales of WaveForm's sensor system. However, Dexcom has been selling infringing sensor systems since 2012. As discussed *infra* at section VI(C)(2), Dexcom has enjoyed tremendous commercial success, and improved profitability, selling its infringing G4 Platinum and G5 Mobile CGM (“G5”) systems versus the first three generations of its CGM systems, [REDACTED]

A presumption of nexus exists with respect to at least claims 1-3, 5-6 and 9 of the '202 patent because those method claims are co-extensive with the method of using Petitioner's accused G4 Platinum and G5 products. *Tec Air*, 192 F.3d at 1361; *see also World Bottling Cap*, IPR2015-01651, Paper 34 at 17. The

¹¹ [REDACTED]

[REDACTED] (See Ex. 2052 at 3.)

'202 patent claims are generally directed to a method of measuring the concentration of an analyte in a patient's body by: (i) providing a sensor having certain claimed characteristics; (ii) placing at least a portion of the sensor into the body; and (iii) measuring electric current produced by the sensor and forming a measurement of analyte concentration based on the current measurement.

(Ex. 1001 at 4:55-67.) Dependent claim 9 recites that at least a portion of the sensor is placed in the body for at least 24 hours. Dependent claim 10 recites that the analyte comprises glucose. Other dependent claims recite specific features of the sensor, including, for example, claim 5, which adds that the sensor core comprises tantalum.

Documents produced by Petitioner in the co-pending district court litigation establish that users of the G4 Platinum and G5 products practice each of the methods claimed in the '202 patent. (Ex. 2027 at ¶ 90 and App. B.) Users of both accused Dexcom products follow the claimed methods by: (i) providing¹² a

¹² Under controlling Federal Circuit precedent, a “providing” step may be performed by either the manufacturer or the user of a device. *Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1369 (Fed. Cir. 2012) (“It is clear that [defendant provides] the [device] by manufacturing and selling its [products]. It is also clear under that same definition, however, that anyone who takes [the device]

sensor; (ii) placing at least a portion of the sensor into a body; and (iii) measuring the electric current produced by the sensor and forming a measurement of glucose concentration based on the current measurement. (Ex. 2027 at ¶ 93, App. B.)

Under Federal Circuit precedent, this co-extensivity between the '202 patent claims and use of Petitioner's accused CGM products gives rise to a presumption of nexus. *WBIP*, 829 F.3d at 1329. It is Petitioner's burden to rebut that presumption, which it "cannot [do] with argument alone—it must present evidence." *Id.*

2. Dexcom's G4 Platinum and G5 products have enjoyed tremendous commercial success.

To say that Dexcom has enjoyed commercial success with its G4 Platinum and G5 products is an understatement. Nearly all of Dexcom's revenues are from sales of CGM systems and replacement sensors. (Ex. 2053 at ¶ 15.) Since the 2012 launch of its G4 Platinum product, [REDACTED] [REDACTED] its annual product sales and stock price have each grown by over 460%, and its market capitalization has increased by over 600%. (Ex. 2053 at ¶ ¶ 15, 21-22, 28.) [REDACTED]

[REDACTED] Dexcom has grown to become the world's largest seller of CGM devices

from the kitchen cabinet and places it on the counter... can satisfy the 'providing' step.")

[REDACTED] (Ex. 2053 at ¶ 28.) The onset of that growth coincided precisely with its release of the G4 Platinum product, which it told the world had an improved, [REDACTED] sensor wire. (Exs. 2050 at 2-3; 2051 at 7.)

Dexcom has suggested it will argue that the commercial success of the G4 Platinum and G5 products is due to factors other than its improved platinum-clad tantalum sensor wire. Patent Owner, however, need not prove that the improved sensor wire is the only reason for the runaway success of Dexcom's improved sensor. Rather, it is sufficient to show that the improved platinum-tantalum wire contributed to that success. *Ecolochem, Inc. v. Southern Cal. Edison Co.*, 227 F.3d 1361, 1378 (Fed. Cir. 2000). Given the presumption of nexus, it is Dexcom's burden to prove that the improved sensor wire played no role in the success of its accused products. *Id.*; *WBIP*, 829 F.3d at 1331.

3. Petitioner has enjoyed significantly improved profitability.

The '202 patent teaches two major improvements over platinum sensors. The first benefit is improved flex resistance. (Ex. 1001 at 1:10-23.) The second benefit is that a platinum-plated wire can be far less costly than a pure platinum wire. (*Id.* at 1:29-38.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Ex. 2053 at ¶ 25.) [REDACTED]

[REDACTED]

[REDACTED] (Ex. 2053

at ¶ 26.)

Commercial success relevant to objective indicia of non-obviousness includes use of the invention to reduce costs of production and thereby improve profit margins. *In re Natural Alternatives, LLC*, 659 Fed. Appx. 608, 615 (Fed. Cir. Aug. 31, 2016) (reversing PTO obviousness rejection and finding claims non-obvious where claimed element “can now be used in a deicing mixture with... high cost effectiveness”); *Won-Door Corp. v. Cornell Iron Works, Inc.*, 981 F. Supp. 2d 1070, 1077 (D. Utah 2013) (“Defendant concedes that the [invention] creates cost savings. Therefore, the Court finds that there is a sufficient nexus between the patented device and the financial success associated with the device.”). The evidence makes clear that Petitioner has enjoyed that type of commercial success from its use of the invention claimed in the '202 patent.

4. Dexcom gained access to an important new market.

In its 2010 Warning Letter, the FDA expressed great concern about the dangers to the health and safety of children who were making “off-label” use of Petitioner’s CGM sensors using the pure platinum wire. The FDA requested that Dexcom modify its label to include a prominent warning that its sensors were not

suitable for use in children or adolescents. (Ex. 2046 at 2.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Based on the 2010 Warning Letter, Petitioner understood that it would not obtain pediatric approval until [REDACTED]

[REDACTED]

[REDACTED] (Ex. 2046 at 1-2). After receiving FDA's approval of the improved G4 wire for adults, Dexcom filed for pediatric approval in February 2013. One year later, the G4 Platinum became the first CGM system ever approved for patients as young as two years old. (Ex. 2053 at ¶ 17.) Dexcom's use of the '202 patent invention in its G4 Platinum product opened the gates to this important new market for Dexcom.

In its first earnings call following the FDA's pediatric approval, Dexcom's president, Kevin Sayer, told analysts that "[w]e are very pleased by the initial response of parents and practitioners to the pediatric product offering and have seen the percentage of orders from pediatric patients continue to grow to approximately 20% of our current pipeline opportunities." (Ex. 2053 at ¶ 18.) Mr. Sayer also stated the company's goal of growing the pediatric market to comprise "30% of the overall patient base." (*Id.*) In early 2016, he confirmed that "obviously, we've gotten a boost [from pediatrics] because we've been growing above our projected rates of 35% to 40%." (*Id.*) Information provided by Dexcom suggests that Dexcom's pediatric sales have, in fact, increased by over 650% since the FDA approval, representing an ever-growing share of Dexcom's total product sales. (*Id.* at ¶¶ 19-20.)

Respectfully submitted,
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CERTIFICATE OF COMPLIANCE

This brief complies with the applicable word-count limitation under 37 C.F.R. Section 42.24(d) because it contains 13,998 words, including headings, footnotes, and quotations, but excluding the caption, table of contents, table of cases and authorities, signature block, appendix of exhibits, and any certificates of counsel.

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APPENDIX OF EXHIBITS

Exhibit No.	Description
2001	Declaration of John L. Smith, Ph.D.
2002	U.S. Patent No. 5,165,407, issued November 24, 1992 to George S. Wilson <i>et al.</i>
2003	Declaration of Matthew J. Schurman, Ph.D.
2004	Excerpts from "Plaintiff's Opening <i>Markman</i> Claim Construction Brief," <i>AgaMatrix, Inc. v. Dexcom, Inc.</i> , D. Or. No. 3:16-cv-00536-MO, Dkt. No. 56
2005	Excerpts from "Declaration of John L. Smith, Ph.D. in Support of Plaintiff's Opening <i>Markman</i> Brief," <i>AgaMatrix, Inc. v. Dexcom, Inc.</i> , D. Or. No. 3:16-cv-00536-MO, Dkt. No. 57
2006	<i>Availability of Stainless Steel Grades</i> , British Stainless Steel Association, available at http://www.bssa.org.uk/topics.php?article=684&featured=1 (accessed Nov. 17, 2016)
2007	Excerpts from <i>Dictionary of Metals</i> . Reference Information Library, added to ASM Handbooks Online: Desk Editions and General References, ASM International, 2013
2008	<i>Tantalum – An Overview</i> , Azo Materials, available at http://www.azom.com/properties.aspx?ArticleID=1207 (accessed September 30, 2016)
2009	<i>Stainless Steel – Grade 316 (UNS S31600)</i> , Azo Materials, available at http://www.azom.com/properties.aspx?ArticleID=863 (accessed September 30, 2016)
2010	Excerpt from D. Wilson and L.A. Carlsson, Mechanical Testing of Fiber-Reinforced Composites, <i>Mechanical Testing and Evaluation</i> , Vol 8, <i>ASM Handbook</i> , ASM International, 2000, pp. 905–932

Exhibit No.	Description
2011	<i>Richard G. Sass</i> , available at https://contactwellness.org/?page_id=53
2012	<i>W. Kenneth Ward, MD</i> , available at https://contactwellness.org/?page_id=236
2013	Excerpt from L.C. Casteletti, A.L. Neto, G.E. Totten, “Nitriding of Stainless Steels,” <i>Heat Treating of Irons and Steels</i> . Vol 4D, <i>ASM Handbook</i> , ASM International, 2014, pp. 418–438
2014	Excerpt from Morris, ed. <i>Academic Press Dictionary of Science and Technology</i> , 1992 by ACADEMIC PRESS, Inc., p. 1357.
2015	<i>Soft Annealed 302 Stainless Steel</i> , Precision Steel Warehouse, Inc., available at http://www.precisionsteel.com/stainless-steel/type-302/soft-annealed (accessed December 5, 2016)
2016	<i>301 Stainless Steel Full Hard</i> , Precision Steel Warehouse, Inc., available at http://www.precisionsteel.com/stainless-steel/type-301/full-hard (accessed December 5, 2016)
2017	Nickel Development Institute, <i>Design Guidelines for the Selection and Use of Stainless Steel</i> , available at https://www.nickelinstitute.org/~Media/Files/TechnicalLiterature/DesignGuidelinesfortheSelectionandUseofStainlessSteels_9014_.pdf (accessed December 5, 2016)
2018	Confirmatory Patent Assignment from AgaMatrix, Inc. to WaveForm Technologies, Inc. (dated January 13, 2017)
2019	Electronic Patent Assignment System Confirmation Receipt regarding Assignment (dated January 18, 2017)
2020	Declaration of Aldrich in Support of Motion to Appear Pro Hac Vice (dated April 13, 2017)
2021	Declaration of Wrubleski in Support of Motion to Appear Pro Hac Vice (dated May 2, 2017)
2022	[Proposed] Stipulated Protective Order (IPR2016-01679)

Exhibit No.	Description
2023	[Proposed] Stipulated Protective Order (IPR2016-01679) – redline comparison with default protective order
2024	Definition of “surround,” Merriam-Webster’s Collegiate Dictionary, 10 th Ed. (2000)
2025	Definition of “cover,” Merriam-Webster’s Collegiate Dictionary, 10 th Ed. (2000)
2026	Stevenson, Angus, and Christine A. Lindberg. “Contact.” Def. 1. <i>New Oxford American Dictionary</i> . 3rd ed. Oxford: Oxford UP, 2010. 374. Print
2027	Declaration of John L. Smith, Ph.D.
2028	U.S. Patent No. 8,187,433, issued May 29, 2012 to W. Kenneth Ward, <i>et al.</i>
2029	Declaration of Matthew J. Schurman, Ph.D.
2030	Excerpts from “Plaintiff’s Opening <i>Markman</i> Claim Construction Brief,” <i>AgaMatrix, Inc. v. Dexcom, Inc.</i> , D. Or. No. 3:16-cv-00536-MO, Dkt. No. 56; “Defendant Dexcom, Inc.’s Opening Claim Construction Brief”, Dkt. No. 55; “Plaintiff’s Response To Defendant’s Opening Claim Construction Brief”, Dkt. No. 73; and “Defendant Dexcom, Inc.’s Responsive Claim Construction Brief”, Dkt. No. 79
2031	Claim Construction Table, <i>AgaMatrix, Inc. v. Dexcom, Inc.</i> , D. Or. No. 3:16-cv-00536-MO, Dkt. No. 113
2032	Excerpts from Plaintiff AgaMatrix, Inc.’s <i>Markman</i> tutorial
2033	October 12, 2011 Office Action for Application No. 11/538,340 (U.S. Patent No. 8,187,433)
2034	U.S. Patent No. 6,139,510, issued October 31, 2000 to Thomas J. Palermo
2035	Declaration of Ellen M. Anderson

Exhibit No.	Description
2036	Transcript of the deposition of David J. Vachon, Ph.D., taken May 4, 2017
2037	Definition of "core," Merriam-Webster's Collegiate Dictionary, 10 th Ed. (2000)
2038	Correspondence between Matthew W. Johnson, counsel for Petitioner Dexcom, Inc., and Jason A. Wrubleski, counsel for Patent Owner WaveForm Technologies, Inc.
2039	Correspondence between M. Andrew Woodmansee, attorney for Petitioner Dexcom, Inc., and Nika Aldrich, attorney for Patent Owner WaveForm Technologies, Inc.
2040	Declaration of Jason A. Wrubleski
2041	DEXCOM 405083
2042	DEXCOM 339482-339491
2043	DEXCOM 573754-574040
2044	DEXCOM 610460-610471
2045	DEXCOM 607755-607846
2046	DEXCOM 610210-610213
2047	DEXCOM 607968-607980
2048	DEXCOM 608622-608648
2049	Dexcom Supplemental Response To AgaMatrix Interrogatory No. 5, <i>AgaMatrix, Inc. v. Dexcom, Inc.</i> , D. Or. No. 3:16-cv-00536-JE
2050	Excerpt from Dexcom, Inc.'s Securities and Exchange Commission Form 10K Annual Report for the fiscal year ended December 31, 2012
2051	DEXCOM 454827-454848

Exhibit No.	Description
2052	Excerpt from DEXCOM-PMA011455-011666
2053	Declaration of Serena Morones
2054	U.S. Patent No. 9,606,080, issued March 28, 2017 to Satheesh Babu G. Thekkedath, <i>et al.</i>
2055	Excerpt from DEXCOM 405207-405320
2056	U.S. Food and Drug Administration Pre-Market Approval Supplement regarding Defendant Dexcom Inc.'s G5 Mobile Continuous Glucose Monitoring System
2057	Excerpt from PMA P120005, U.S. Food and Drug Administration Summary of Safety and Effectiveness Data for Dexcom, Inc.'s G4 PLATINUM Continuous Glucose Monitoring System
2058	Excerpt from Dexcom G4 PLATINUM Continuous Glucose Monitoring System User's Guide
2059	Excerpt from Dexcom G5 Mobile Continuous Glucose Monitoring System User's Guide
2060	DEXCOM 451792-451796
2061	Excerpt from DEXCOM 008336-008528
2062	Huang, Chih-Feng et al., "Ta-Pt Alloys as gate Materials for Metal-Oxide-Semiconductor Field Effect Transistor Application," <i>Japanese Journal of Applied Physics</i> , Vol. 48, 2009
2063	Excerpts from <i>Dictionary of Metals</i> . Reference Information Library, added to ASM Handbooks Online: Desk Editions and General References, ASM International, 2013
2064	Vaithinathan, Kris et al., "Features and Benefits of Different Platinum Alloys"

Exhibit No.	Description
2065	Mitchell, T.E. et al., "Mechanical Properties of Some Tantalum Alloys," <i>Canadian Journal of Physics</i> , Vol. 45, 1967, pp. 1047-1062
2066	Intentionally left blank.
2067	Excerpt from "Properties of Pure Metals" (Ta), <i>Properties and Selection: Nonferrous Alloys and Special-Purpose Materials</i> , Vol. 2, <i>ASM Handbook</i> , ASM International, 1990, pp. 1099-1201
2068	Excerpt from "Properties of Pure Metals" (Pt), <i>Properties and Selection: Nonferrous Alloys and Special-Purpose Materials</i> , Vol. 2, <i>ASM Handbook</i> , ASM International, 1990, pp. 1099-1201
2069	Pt-Ta (Platinum – Tantalum) Phase diagram (Landolt-Börnstein New Series IV/5)
2070	U.S. Patent No. 3,165,400, issued January 12, 1965 to Amedee Roy, <i>et al.</i>
2071	Darling, A.S., "Iridium Platinum Alloys – A Critical Review of Their Constitution and Properties," <i>Platinum Metals Review</i> , Vol. 4, No. 1, 1960, pp. 18-26
2072	U.S. Patent No. 7,529,574, issued May 5, 2009 to Lawrence B. Jansen, <i>et al.</i>
2073	Definition of "base metal," McGraw-Hill Dictionary of Scientific and Technical Terms, 6 th Ed. (2003)
2074	Definitions of "base metal" and "precious metal," New Oxford American Dictionary, 3 rd Ed. (2010)
2075	Vieria, Ginger, "DexCom Approved for Use in Children with Type 1 Diabetes," <i>DiabetesDaily.com</i> , available at https://www.diabetesdaily.com/blog/2014/02/dexcom-approved-for-use-in-children-with-type-1-diabetes/ (accessed May 11, 2017)
2076	DEXCOM 628736

Exhibit No.	Description
2077	DEXCOM 296270-296289
2078	<p>“FDA Approval for DexCom’s G4 PLATINUM – Analyst Blog,” <i>Zacks.com</i>, available at http://www.nasdaq.com/aspx/stockmarketnewsstoryprint.aspx?storyid=fda-approval-for-dexcoms-g4-platinum-analyst-blog-cm324536 (accessed May 11, 2017)</p>
2079	<p>Malandrino, Jill, “DXCM: Improving the Quality of Life for Children with Diabetes,” <i>TheStreet.com</i>, available at https://www.thestreet.com/story/12312091/1/dxcm-improving-the-quality-of-life-for-children-with-diabetes.html (accessed May 11, 2017)</p>
2080	<p>Pedersen, Amanda, “FDA approves first CGM for use in pediatrics as young as 2 years,” <i>MedicalDeviceDaily.com</i>, available at https://www.medicaldevicedaily.com/servlet/com.accumedia.web.Dispatcher?next=bioWorldHeadlines_article&forceid=85426 (accessed May 11, 2017)</p>
2081	<p>“DexCom (DXCM) Kevin Ronald Sayer on Q4 2015 Results – Earnings Call Transcript,” <i>SeekingAlpha.com</i>, available at https://seekingalpha.com/article/3922776-dexcom-dxcm-kevin-ronald-sayer-q4-2015-results-earnings-call-transcript (accessed March 22, 2017)</p>
2082	Correspondence between Matthew Johnson, attorney for Petitioner Dexcom, Inc., and Jason Wrubleski, attorney for Patent Owner WaveForm Technologies, Inc.
2083	Excerpts from DEXCOM 630106-632393
2084	U.S. Patent No. 2,795,541, issued June 11, 1957 to Josef Muller, <i>et al.</i>
2085	Excerpt from Schwartz, Mel, <i>Brazing</i> , 2 nd Ed., 2003, p. 305
2086	Excerpt from J.B. Lambert, “Refractory Metals and Alloys,” <i>Properties and Selection: Nonferrous Alloys and Special-Purpose Materials</i> , Vol. 2, <i>ASM Handbook</i> , ASM International, 1990, pp. 557-585

Exhibit No.	Description
2087	"Tantalum", <i>Plansee.com</i> , available at https://www.plansee.com/en/materials/tantalum.html (accessed May 23, 2017)
2088	U.S. Patent No. 3,793,164, issued February 19, 1974 to James L. Kolb, <i>et al.</i>

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on the 30th day of May, 2017, a complete and entire copy of this **PATENT OWNER’S RESPONSE** was served on counsel of record by filing this document through the PTAB E2E System, as well as by delivering a copy via electronic mail to the Petitioner’s known representatives at the e-mail addresses noted below:

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