

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

WAVEFORM TECHNOLOGIES, INC.,
Patent Owner.

Case IPR2016-01679
Patent 7,146,202 B2

Before ERICA A. FRANKLIN, JON B. TORNQUIST, and
ELIZABETH M. ROESEL, *Administrative Patent Judges*.¹

ROESEL, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318 and 37 C.F.R. § 42.73

¹ Administrative Patent Judge Erica A. Franklin replaces former panel member Brian P. Murphy, who is no longer with the Patent Trial and Appeal Board.

In this *inter partes* review, instituted pursuant to 35 U.S.C. § 314, Dexcom, Inc. (“Petitioner”) challenges patentability of claims 1–3, 5, 6, and 8–11 of U.S. Patent No. 7,146,202 B2 (Ex. 1001, “the ’202 patent”), owned by Waveform Technologies, Inc. (“Patent Owner”).

We have jurisdiction under 35 U.S.C. § 6. This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–3, 6, 8, and 11 of the ’202 patent are unpatentable. We determine that Petitioner has not shown by a preponderance of the evidence that claims 5, 9, and 10 of the ’202 patent are unpatentable.

I. BACKGROUND

A. *Procedural History*

Petitioner filed a Petition seeking *inter partes* review of claims 1–3, 5, 6, and 8–11 of the ’202 patent. Paper 1 (“Pet.”). Patent Owner filed a Preliminary Response. Paper 7 (“Prelim. Resp.”). We instituted *inter partes* review of all challenged claims. Paper 10 (“Institution Decision” or “Dec.”).

Patent Owner filed a Response. Paper 29 (“PO Resp.”). Petitioner filed a Reply. Paper 37 (“Pet. Reply”).²

With the Petition, Petitioner filed a Declaration of David Vachon, Ph.D. Ex. 1006. Patent Owner cross-examined Dr. Vachon and filed a transcript of his deposition testimony as Exhibit 2036.

² We rely on the public, redacted versions of Patent Owner’s Response and Petitioner’s Reply.

With the Preliminary Response, Patent Owner filed declarations of John L. Smith, Ph.D. (Ex. 2001) and Matthew J. Schurman, Ph.D. (Ex. 2003). With the Patent Owner Response, Patent Owner filed declarations of Dr. Smith (Ex. 2027),³ Dr. Schurman (Ex. 2029), Ellen M. Anderson (Ex. 2035), and Serena Morones (Ex. 2053). Petitioner cross-examined each of these witnesses and filed transcripts of each witness's deposition testimony as follows: Dr. Smith (Ex. 1037), Dr. Schurman (Ex. 1039), Ms. Anderson (Ex. 1041), and Ms. Morones (Ex. 1033).

Oral argument was held December 7, 2017, and a transcript was entered in the record. Paper 52 ("Tr.").

As further discussed below, each party filed a motion to exclude evidence submitted by the opposing party.

B. Related Matters

The parties identify the following district court proceeding involving the '202 patent: *WaveForm Technologies, Inc. v. Dexcom, Inc.*, No. 3:16-cv-00536-MO (D. Or.). Pet. 64–65; Paper 14, 2 (Patent Owner's updated mandatory notices).

In addition, the parties identify the following *inter partes* review proceedings: *Dexcom, Inc. v. WaveForm Technologies, Inc.*, IPR2016-01680, involving U.S. Patent No. 8,187,433 B2 ("the '433 patent");⁴ and *Dexcom, Inc. v. WaveForm Technologies, Inc.*, IPR2017-01051, involving

³ We rely on the public, redacted version of Exhibit 2027.

⁴ The '433 patent (Ex. 2028) was issued from U.S. Application No. 11/538,340, filed October 3, 2006, which is a division of U.S. Application No. 10/869,133, filed June 16, 2004, which issued as the '202 patent (Ex. 1001).

U.S. Patent No. 7,529,574. Paper 14, 2; Paper 44, 2 (Petitioner’s updated mandatory notices).

C. Instituted Grounds of Unpatentability

We instituted *inter partes* review on the following three grounds of unpatentability asserted in the Petition:

Reference[s]	Statutory Basis	Challenged Claims
Wilson ⁵ and Rosenblatt ⁶	§ 103(a)	1–3, 5, 6, and 9–11
Hagiwara ⁷	§ 102(b)	1–3, 6, 8, 10, and 11
Hagiwara and Rosenblatt	§ 103(a)	5

C. The ’202 Patent

The ’202 patent, titled “Compound Material Analyte Sensor,” was issued December 5, 2006. Ex. 1001, at (54). The ’202 patent relates to a sensing element adapted to be inserted, at least in part, into a mammalian body. *Id.* at Abstract, 1:42–44. The ’202 patent discloses that the sensing element includes a core of a structurally robust material and a plated portion comprising an electrochemically active metal. *Id.* at Abstract, 1:44–46. The sensing element may be used in a method for continuous sensing of an

⁵ G. S. Wilson et al., *Progress toward the Development of an Implantable Sensor for Glucose*, 38(9) Clin. Chem. 1613–17 (1992). Ex. 1004.

⁶ U.S. Patent No. 2,719,797, issued October 4, 1955. Ex. 1005.

⁷ Japanese Unexamined Patent Application Publication No. S57-110236, published July 9, 1982. Ex. 1007. Exhibit 1007 includes an English translation (pages 1–16), a translation certificate (page 17), a certified copy of the Japanese publication (pages 19–30), and a cover letter (page 18).

analyte, such as glucose, within a mammalian body. *Id.* at Abstract, 1:47–52.

According to the '202 patent, the disclosed sensing element addresses problems with platinum wire sensors, including: (1) platinum is a weak metal that is susceptible to sensor fatigue and breakage when subjected to flexure caused by bodily movement; and (2) platinum is expensive and can strain the budget for sensor production. *Id.* at 1:12–38.

An embodiment of a sensing element is depicted in Figure 1, which is reproduced below:

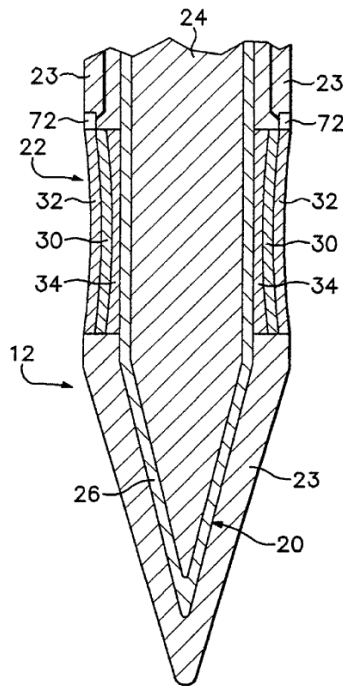


Figure 1, above, shows sensing element 12 including bimetallic wire 20, membrane system 22 coated on at least a portion of wire 20, and protective layer 23, e.g., polyimide, coated on portions of wire 20 not coated with membrane system 22. Ex. 1001, 2:10–23. Wire 20 includes core 24 and electrochemically active layer 26. *Id.* at 2:24–28. Membrane system 22, also referred to as sensing region 22, includes reactive layer 30

containing enzyme, permselective layer 32, and interferent reducing layer 34. *Id.* at 3:48–4:8.

The '202 patent discloses that wire core 24 may be made of any structurally robust material, such as tantalum, stainless steel, nitinol (an alloy of nickel and titanium), polymeric material, or glass fiber. *Id.* at 2:33–41. Electrochemically active layer 26 may be made of a noble metal, such as platinum, palladium, gold, or a combination of one of these with iridium. *Id.* at 2:41–43. The '202 patent discloses various methods for making plated wire 20, including electroplating, foil cladding, plasma vapor deposition, and sputtering. *Id.* at 2:47–3:47.

In operation, a voltage is placed on wire 20 relative to a reference electrode. Glucose and oxygen (or glucose only) reacts with the enzyme in layer 30 producing hydrogen peroxide, which permeates layer 34 and causes an electric current to be produced in wire 20. The current flow is indicative of the concentration of glucose in body fluid. *Id.* at 2:10–15, 3:48–4:8. According to the '202 patent, sensing element 12 may be inserted into the body for a number of days, or it may be used as a single use sensing element indwelling for less than three minutes. *Id.* at 4:32–46.

D. Illustrative Claim

The '202 patent includes 12 claims, of which claims 1 and 12 are independent. We instituted *inter partes* review of claims 1–3, 5, 6, and 8–11—all claims challenged in the Petition. Claim 1 is illustrative of the challenged claims and is reproduced below:

1. A method for measuring the concentration of an analyte within an animal body having body fluids, comprising:
 - (a) providing a sensor having:

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

Ex. 1001, 4:55–67.

II. ANALYSIS

A. *Claim Construction*

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016). Under that standard, we give claim terms their ordinary and customary meaning, as understood by a person of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). The Board, however, may not “construe claims during IPR so broadly that its constructions are *unreasonable* under general claim construction principles. . . . ‘[T]he protocol of giving claims their broadest reasonable interpretation . . . does not include giving claims a legally incorrect interpretation.’” *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (citation omitted). “Even under the broadest reasonable interpretation, the Board’s construction ‘cannot be divorced from the specification and the record evidence,’” and “[t]he PTO should also

consult the patent’s prosecution history in proceedings in which the patent has been brought back to the agency for a second review.” *Id.* (citations omitted).

We address certain claim terms below. No other claim term requires express construction for purposes of resolving the patentability disputes on this record. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy”).

1. “*structurally flexible*”

Claim 1 of the ’202 patent recites: “a sensor having a structurally flexible core.” Ex. 1001, 4:57–58. In the Institution Decision, we preliminarily construed “a structurally flexible core” to mean “a core that is robust and able to be flexed or bent repeatedly.” Dec. 9.

The “robust” portion of our construction was based on descriptions in the Specification of ’202 patent, including the disclosure that “wire core 24 may be of any structurally robust material” and statements that the sensor core is made of a “structurally robust” material. *Id.* at 7–8 (quoting Ex. 1001, Abstract, 1:44, 1:52–53, 1:61–62, 2:24–26, 2:33–41, 3:17–18, 3:23–24). We also relied upon the Specification’s disclosure that fatigue, weakness, and breakage are undesirable characteristics of an indwelling wire sensor. *Id.* at 8 (citing Ex. 1001, 1:12–28).

The portion of our construction that requires that the core is “able to be flexed or bent repeatedly” was based, in part, on a dictionary definition. The McGraw Hill Dictionary of Scientific and Technical Terms defines “flexibility” as “the quality or state of being able to be flexed or bent repeatedly.” *Id.* at 9 (citing Ex. 3001, 620). As stated in our Institution

Decision, this definition is consistent with the description of a “structurally flexible” core in the ’202 patent. *Id.*

Our Institution Decision invited the parties to indicate whether they agree or disagree with our preliminary construction and to present arguments and evidence in support of, or in opposition to, our preliminary construction, and/or to propose a modification thereof. *Id.*

In its Response, Patent Owner states it “does not object to the Board’s proposed construction,” asserting that it “reflects the key point that a ‘structurally flexible core’ must be one that is sufficiently robust to withstand repeated bending and flexing.” PO Resp. 5. According to Patent Owner, the Specification of the ’202 patent demonstrates that “flexibility alone is not enough; the structurally flexible core material must also be robust.” *Id.* (citing Ex. 1001, 1:22).

Petitioner argues that the Board’s preliminary construction improperly reads a “robustness” requirement into “structurally flexible” that the prosecution history prohibits. Pet. Reply 3. More particularly, Petitioner argues that a “robustness” requirement is impermissible because applicant struck “robust” from the claims during prosecution. *Id.* at 5.

After reviewing the portion of the prosecution history cited by Petitioner, we are persuaded that our preliminary construction was incorrect to the extent it imposed a requirement for robustness apart from flexibility. Claim 1 of the ’202 patent was prosecuted as claim 35. Ex. 1002, 22. When first presented, claim 35 recited: “a sensor having . . . a core of structurally robust material.” *Id.* at 77–78. The Examiner rejected that claim over

Sohrab⁸ and Smart,⁹ asserting that Sohrab taught a sensor having a core wire made of structurally robust material. *Id.* at 70. In response to that rejection, Applicants amended the claim to recite, “a sensor having a structurally flexible core,” instead of “a sensor having a core of structurally robust material.” *Id.* at 57. In other words, Applicants removed the word “robust” and replaced it with the word “flexible.” *Id.* The claim was allowed without the word “robust.” *Id.* at 20, 28.

We agree with Petitioner that, in view of this prosecution history, it is inappropriate for us to construe the term, “structurally flexible core,” as requiring that the core be “robust.” Although the ordinary meaning of “flexible” may imply some degree of robustness (*see* Ex. 3001, 620), the prosecution history does not support reading the term “robust” back into the claim after it was removed by Applicants during prosecution. *Laryngeal Mask Co. v. Ambu A/S*, 618 F.3d 1367, 1373 (Fed. Cir. 2010) (“it would be improper to read a . . . limitation back into” the claim after it was deleted from the claim during prosecution).

Patent Owner argues that Applicants’ claim amendment was made to distinguish “rigid piercing elements” as disclosed in Sohrab and Smart. Tr. 31:8–21; *see also* Ex. 1002, 63 (Applicants’ remarks: “Neither Sohrab nor Smart provide any teaching of a flexible core, but rather teach the use of rigid piercing elements.”).

Patent Owner’s argument does not persuade us to read a requirement for robustness back into the claim after it was removed by Applicants during prosecution. The impropriety of reading such limitations back into the claim

⁸ U.S. Patent No. 6,501,976, issued December 31, 2002.

⁹ U.S. Patent Publication No. 20020137998, published September 26, 2002.

applies “[r]egardless of why [applicant] amended its claims” to remove the limitation. *Laryngeal*, 618 F.3d at 1373. Patent Owner’s argument does not convince us that there is a requirement for robustness beyond what is implicit in the ordinary meaning of “flexible.” Applicants’ claim amendment (Ex. 1002, 57) demonstrates that there is no requirement for robustness separate from a requirement that the core be “flexible,” i.e., that it can be flexed or bent repeatedly.

Alternatively, Patent Owner argues that the claim construction should specify that the core is able to be bent or flexed repeatedly “without breaking.” Tr. 34:8–12; *see also* Ex. 2029 ¶¶ 24, 31. After considering Patent Owner’s proposal, we determine that it is unnecessary to add the words, “without breaking,” to the construction. Although these words are not expressly stated, they are implied by our construction, which provides, “able to be flexed or bent repeatedly.” Logic dictates that a metal core that breaks when flexed or bent cannot be flexed or bent “repeatedly.”

In view of the foregoing, we revise the claim construction provided in the Institution Decision to remove the requirement that the core be “robust.” We construe the term, “structurally flexible,” to mean “able to be flexed or bent repeatedly.”

Our construction is consistent with the Specification of the ’202 patent, which does not define the term, “structurally flexible,” but indicates that the use of tantalum or nitinol for the sensor core is “desireable because they are both naturally flexible.” Ex. 1001, 2:37–39. The Specification indicates that such flexibility “is of particular importance if [the sensor] is to be inserted in a patient and worn for a period of days.” *Id.* at 2:39–40. By implication, a sensor that is implanted in a patient for a period of days would

need to be able to be flexed or bent repeatedly. *See id.* at 1:14 (discussing “flexure caused by bodily movement”). Our construction is also supported by the dictionary definition for “flexibility”: “able to be flexed or bent repeatedly.” Ex. 3001, 620.

2. “*in contact with*”

Claim 1 recites “a layer of electrochemically active metal *surrounding, covering, and in contact with* said outer surface of said core.” Ex. 1001, 4:60–62 (emphasis added). In the Institution Decision, we directed the parties to provide and justify an express construction for the term, “surrounding, covering, and in contact with,” as recited in claim 1. Dec. 13. We further directed the parties that, in providing an express construction, they should address the ’202 patent specification and prosecution history in detail, including whether, and to what extent, any relevant subject matter was surrendered by a narrowing claim amendment. *Id.*

The parties agree that the term “surrounding, covering” should be construed to mean “entirely surrounding and covering.” PO Resp. 5; Pet. Reply 7. As support for reading the word “entirely” into the claim, Patent Owner relies on the prosecution history, arguing that incomplete coverage of the core’s outer surface was clearly and unmistakably disclaimed. PO Resp. 12–16 (citing Ex. 1002, 33–34). Petitioner does not respond to Patent Owner’s prosecution history disclaimer argument. We determine that, for purposes of resolving the patentability disputes presented on this record, it is not necessary to determine whether the word “entirely” should be read into the claim.

The parties agree that the term “in contact with” should be construed to mean “touching.” PO Resp. 5; Pet. Reply 6. As support for this construction, Patent Owner relies on a dictionary definition for “contact” (Ex. 2026), the prosecution history and disclosed embodiments of the ’202 patent, and claims 7 and 16 of the related ’433 patent. PO Resp. 17–23 (citing Exs. 1001, 1002, 2026, 2028, 3002). Petitioner, however, asserts that Patent Owner’s construction for “in contact with” does not preclude an intervening layer. Pet. Reply 6. We address the parties’ arguments and evidence below.

Patent Owner argues that the dictionary definition for “contact” is “touching” and that applicants disavowed any broader meaning during prosecution. PO Resp. 17–19 (citing Exs. 1002, 2026). As support for a prosecution history disavowal, Patent Owner directs us to Applicants’ remarks distinguishing Macur.¹⁰ *Id.* at 17–18 (citing Ex. 1002, 34). There, Applicants argued:

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.

Ex. 1002, 34. Thereafter, the Examiner allowed the claims. *Id.* at 20. Applicants’ claim amendment and remarks persuade us that Applicants disavowed a claim construction for “in contact with” that is broad enough to encompass an intervening layer between the electrochemically active metal and the outer surface of the core.

¹⁰ U.S. Patent No. 3,957,613, issued May 18, 1976. Ex. 3002.

Patent Owner relies on claim 16 of the '433 patent, arguing that the term, “in contact with,” is used in that claim consistent with its ordinary meaning, “touching.” PO Resp. 20 (citing Ex. 2028, 6:19–27). Patent Owner additionally argues that claim 16 is directed to a three-layer embodiment that is not encompassed by claim 1 of the '202 patent. *Id.* at 19, 21. We are persuaded by both of these arguments. Claim 16 of the '433 patent describes three metal layers: a stainless steel core, a layer of gold “in contact with” the outer surface of the core, and a layer of platinum “in contact with” the layer of gold. Ex. 2028, 6:19–27. In each instance, claim 16 uses the term, “in contact with,” consistent with its ordinary meaning, “touching.” Whereas claim 16 of the '433 patent expressly recites an intervening layer of gold between the outer surface of the core and the layer of platinum (an electrochemically active metal), no such intervening layer is permitted by the language of claim 1 of the '202 patent, which recites that the electrochemically active metal is “in contact with” the outer surface of the core.

Both parties rely on claim 7 of the '433 patent as relevant to the meaning of “in contact with” in claim 1 of the '202 patent. PO Resp. 22–23; Pet. Reply 6. Claim 7 depends from claim 1 of the '433 patent. Ex. 2028, 5:7. Similar to claim 1 of the '202 patent, claim 1 of the '433 patent recites “a continuous layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core.” *Id.* at 4:56–58. Claim 7 recites: “wherein said outer surface of said core comprises a passivated oxide surface.” *Id.* at 5:7–9. Patent Owner argues, “[b]ecause 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.” PO

Resp. 23. Petitioner, on the other hand, argues that claim 7 shows that “[t]he core can comprise an intervening layer, such as a passivated oxide layer.”

Pet. Reply 6.

We determine that claim 7 of the ’433 patent is consistent with the ordinary meaning of “contact” and Applicants’ disavowal of an intervening layer between the electrochemically active metal layer and the outer surface of the core. According to claim 7, the “passivated oxide surface” is **part of** the outer surface of the core (Ex. 2028, 5:7–9), not an “intervening layer,” as disclaimed during prosecution (Ex. 1002, 34).

Accordingly, we construe the term “in contact with” to mean “touching,” as proposed by Patent Owner.

B. Principles of Law

Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish the facts supporting its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A patent claim is unpatentable as anticipated under 35 U.S.C. § 102 “when the same device or method, having all of the elements contained in the claim limitations, is described in a single prior art reference.” *Crown Operations Int’l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002). To anticipate, the 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.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

A patent claim is unpatentable as obvious under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Obviousness is resolved based on underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

C. Level of Ordinary Skill in the Art

For purposes of our Institution Decision, we accepted the definition of a person of ordinary skill in the art (“POSA”) provided by Petitioner’s declarant, Dr. Vachon. Dec. 14 (citing Ex. 1006 ¶ 22). That definition is: a bachelor’s degree or equivalent training or experience in mechanical engineering, bioengineering, or a related field and at least three years of experience relating to biosensor research and development. *Id.* Patent Owner’s declarants accept and apply this definition of a POSA for purposes of their opinions. Ex. 2027 ¶ 34 (Dr. Smith); Ex. 2029 ¶ 18 (Dr. Schurman). None of the parties’ declarants indicates that any proffered opinion would change depending on the level of ordinary skill in the art. *See* Ex. 2027 ¶ 35 (Dr. Smith’s opinions would not change, regardless of which definition is adopted).

Therefore, we adopt Dr. Vachon’s definition of a POSA. Ex. 1006 ¶ 22. We also rely on the cited prior art references as reflecting the level of

ordinary skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

After reviewing the qualifications of Drs. Vachon, Smith, and Schurman, as set forth in their respective declarations and curriculum vitae, we find that each of these declarants is qualified to testify from the perspective of a POSA. Regarding Dr. Vachon, we rely in particular on his experience as director of glucose sensor research and development at MiniMed from 1998 to 2001, where he worked on an implantable electrochemical glucose sensor. Ex. 1006 ¶ 8, App. A. Regarding Dr. Smith, we rely in particular on his experience relating to blood glucose monitoring systems as head of research and development at LifeScan, Inc. from 1987 to 1998. Ex. 2027 ¶ 3, App. A. Regarding Dr. Schurman, we rely in particular on his experience as a consultant in the field of glucose monitoring and insulin delivery and as chief technology officer of GlucoLight Corporation from 2002 to 2009, where he worked on development of a non-invasive glucose monitor. Ex. 2029 ¶¶ 5, 7, App. A. There is no contention that any of these declarants is not qualified to testify as an expert in this case.

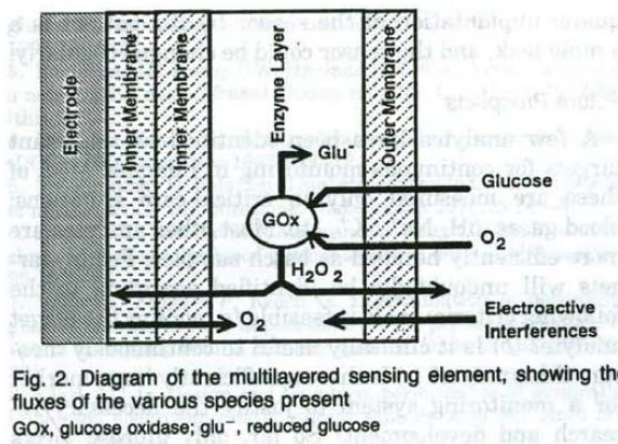
D. Prior Art References

1. Wilson (Ex. 1004)

Wilson is an article published in 1992 entitled, “Progress toward the Development of an Implantable Sensor for Glucose.” Ex. 1004. There is no dispute that Wilson is prior art to the ’202 patent under 35 U.S.C. § 102(b). Pet. 6; Ex. 1009 (declaration of librarian, Morris M. Jackson, attesting to facts relating to public accessibility of Wilson as of September 1992).

Wilson discusses the development of a needle-shaped glucose sensor that is flexible and implanted subcutaneously using a catheter. Ex. 1004, 1613(1).¹¹ According to Wilson, the device had been used to monitor glucose concentrations for as long as ten days in rats. *Id.*

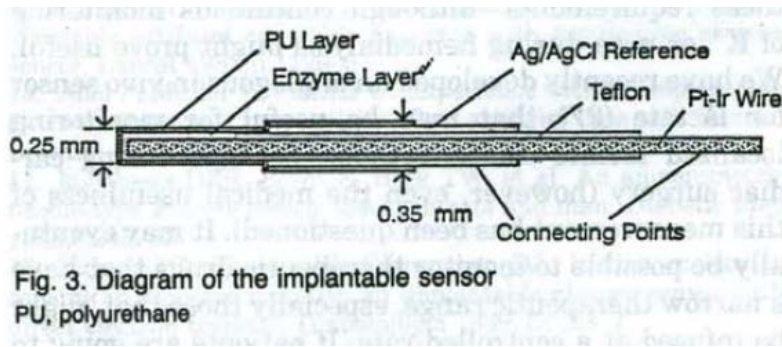
Wilson's glucose sensor is schematically illustrated in Figure 2, which is reproduced below:



Wilson Figure 2 is a schematic diagram of a multilayered sensing element, including an electrode, a pair of inner membranes, an enzyme layer, and an outer membrane. Ex. 1004, 1615, Fig. 2. In Figure 2, glucose and oxygen are shown flowing through the outer membrane to the enzyme layer, where they react to form hydrogen peroxide and reduced glucose (gluconic acid). *Id.*; see also *id.* at 1614(1) (reaction of glucose with oxygen to form gluconic acid and hydrogen peroxide). Hydrogen peroxide is shown migrating through the inner membranes to the electrode, where it is oxidized to form oxygen. *Id.* at 1615, Fig. 2.

A cross-section of Wilson's glucose sensor is illustrated in Figure 3, which is reproduced below:

¹¹ We use parenthetical numbers following the internal page numbers to indicate the first and second columns on each page.



Wilson Figure 3 is a sectional diagram depicting an implantable sensor, including a platinum-iridium (Pt-Ir) wire, a Teflon layer, an enzyme layer, a polyurethane (PU) layer, and a silver-silver chloride (Ag/AgCl) reference electrode. Ex. 1004, 1615, Fig. 3. Wilson discloses that “[b]ecause the sensor is extremely flexible, we can implant it by using a short (3 cm) stainless steel catheter (21 gauge), which is removed after the sensor is in place.” *Id.* at 1615 (1–2).

2. *Rosenblatt (Ex. 1005)*

Rosenblatt is a U.S. patent issued in 1955 entitled, “Platinizing Tantalum.” Ex. 1005. There is no dispute that Rosenblatt is prior art to the ’202 patent under 35 U.S.C. § 102(b). Pet. 6; Ex. 1005.

Rosenblatt discloses a process for producing platinum-coated tantalum for use as non-corroding anodes in electrochemical processes, such as the electrolysis of chlorides and the production of chlorine, chlorates, and per-compounds. Ex. 1005, 1:15–25, 6:3–9. According to Rosenblatt, platinum group metals are the “universal choice” for anodic material due to their corrosion resistance, but the high cost of these precious metals has prompted a search for substitutes, such as tantalum. *Id.* at 1:29–40, 1:57–64. Rosenblatt explains that tantalum cannot be used as an anode because it forms an oxide film and that prior attempts to coat tantalum with platinum

were unsatisfactory due to insufficient adherence between the metals. *Id.* at 1:64–2:21. Rosenblatt’s process aims to provide a thin, firmly adherent, practically inseparable coat of platinum on a tantalum base. *Id.* at 2:22–25.

In Rosenblatt’s process, a thin deposit of platinum metal is applied on the surface of a tantalum body, either by chemical deposition or electroplating. Ex. 1005, 2:40–43, 2:45–50; *see also id.* at 2:67–3:37 (chemical deposition); 3:38–3:60 (electroplating). Thereafter, the platinum metal deposit is bonded to the tantalum body by heating the whole to a high temperature under inert conditions. *Id.* at 2:43–45, 2:50–53; *see also id.* at 3:61–4:13 (bonding).

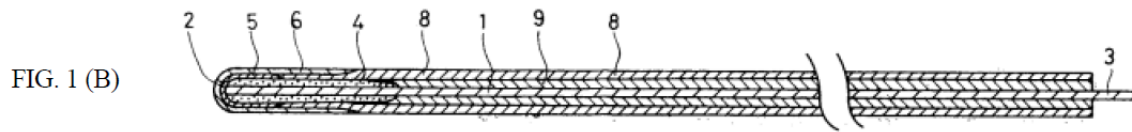
Rosenblatt discloses that the bonding treatment causes the platinum and tantalum metals to interdiffuse and become alloyed, forming a thin layer of platinum-tantalum alloy between the tantalum base and an outer layer of unalloyed platinum. *Id.* at 4:22–25, 4:46–51; *see also* 6:26–30 (claim 1). According to Rosenblatt, the resulting platinized tantalum is not attacked by hot aqua regia and behaves like a pure platinum electrode, without flaking off of the platinum film, even after extended use as an anode in a chlorine or chlorate production cell. *Id.* at 4:14–25, 4:51–56, 5:20–29.

3. *Hagiwara (Ex. 1007)*

Hagiwara is a 1982 Japanese patent publication titled, “Polarography Sensor.” Ex. 1007. There is no dispute that Hagiwara is prior art to the ’202 patent under 35 U.S.C § 102(b). Pet. 6; Ex. 1007.

Hagiwara discloses an intravenous polarography¹² sensor for measuring the concentration of blood components, such as oxygen or glucose, in animals and humans. Ex. 1007, 1 (Title), 2:46–3:2, 4:1–6, 4:17–21.¹³ Hagiwara’s sensor includes a metal wire having an electrode reaction surface made of a precious metal, an insulating layer, and a blood coagulation inhibiting coating. *Id.* at 1 (claim 1). According to Hagiwara, a measuring electrode is made of a precious metal such as platinum, gold, or silver, and a current flowing between the measuring electrode and a reference electrode is proportional to the concentration of oxygen or other target substance. *Id.* at 3:3–8, 3:20–23. Hagiwara explains that substances that are difficult to measure using “direct” polarography can be measured using “indirect” or “enzymatic” polarography, whereby enzymes for the target substance are fixed on reaction surfaces of the measuring electrode. *Id.* at 3:26–30, 4:1–6, 4:17–21. According to Hagiwara, glucose is one substance that can be measured in this manner. *Id.* at 3:30–37.

Hagiwara discloses four embodiments, depicted in Hagiwara Figures 1(A) through 1(D). Hagiwara Figure 1(B) is reproduced below:



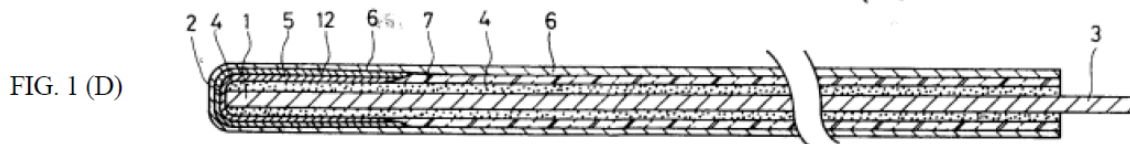
Hagiwara Figure 1(B) shows a polarography sensor that forms a flexible measuring electrode, including precious metal wire 1, electrode reaction

¹² Both parties’ experts explain that polarography is an electrochemical analysis technique. Ex. 1006 ¶ 66; Ex. 2027 ¶ 46.

¹³ We cite the page and line numbers of replacement Exhibit 1007, which Petitioner filed on March 14, 2017 pursuant to the Board’s request. See Dec. 15 n.10.

surface 2, connecting terminal 3, hard insulating coating 4, contamination inhibiting coating 5, blood coagulation inhibiting coating 6, flexible tube 8, and insulating coating 9. Ex. 1007, 6:12–26; *see also id.* at 5:2–22 (describing elements 1–6, which are common to Figs. 1(A) and (B)).

Hagiwara Figure 1(D) is reproduced below:



Hagiwara Figure 1(D) shows a polarography sensor that forms an electrode for indirect (enzymatic) polarography, which includes metal tube 7 and enzyme-containing porous plastic layer 12, in addition to elements 1–6 listed in the preceding paragraph. Ex. 1007, 6:42–46; *see also id.* at 5:2–22 (describing elements 1–7, which are common to Figs. 1(A) and (D)).

Hagiwara describes an alternative embodiment where, in the polarography sensors of Figures 1(A) through 1(D), precious metal wire 1 may be replaced by “base metal wires, with precious metals vapor deposited or plated on the front ends thereof.” *Id.* at 7:26–31.

Hagiwara discloses that a measuring electrode according to Figure 1(B) is inserted in a vein using a catheter, and electrolytic solution, which surrounds a reference electrode, flows through the catheter into the blood, creating an electrical link between the electrodes. *Id.* at 7:6–16, Fig. 2. Hagiwara describes an example in which an intravenous polarography sensor according to Figure 1(B) was used to measure blood oxygen levels in the femoral arteries of an anesthetized dog. *Id.* at 7:32–8:33, Fig. 3.

E. Obviousness Based On Wilson and Rosenblatt

Petitioner contends that claims 1–3, 5, 6, and 9–11 of the '202 patent are unpatentable as obvious in view of Wilson and Rosenblatt. Pet. 9–28. Patent Owner opposes. PO Resp. 28–45. We address the parties' arguments below.

1. Claim 1

Petitioner contends that it would have been obvious to substitute platinum-coated tantalum, as described by Rosenblatt, for the platinum-iridium wire disclosed in Wilson Figure 3, and that the resulting sensor would meet the limitations of claim 1. Pet. 12–22. Petitioner contends that Wilson in view of Rosenblatt discloses “a layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core,” as recited in claim 1. *Id.* at 14 (quoting Ex. 1001, 4:60–62). As support for that contention, Petitioner directs us to Rosenblatt's disclosure of depositing platinum metal on a tantalum body and heating the whole to bond the platinum metal to the tantalum body. *Id.* (quoting Ex. 1005, 2:40–45). Petitioner also directs us to Rosenblatt's disclosure of electroplating as one way to deposit platinum on tantalum. *Id.* at 14–15 (citing Ex. 1005, 2:44–50).

Patent Owner argues that the combination of Wilson and Rosenblatt fails to teach or suggest an electrochemically active metal “in contact with” the core. PO Resp. 34. According to Patent Owner, Rosenblatt teaches that creation of an intervening alloy layer is essential and prevents the “contact” required by claim 1 of the '202 patent. *Id.* at 34, 40–41.

After considering the parties' arguments and evidence, we determine that Petitioner has not shown by a preponderance of the evidence that the

combination of Wilson and Rosenblatt teaches or suggests the “in contact with” limitation of claim 1 of the ’202 patent.

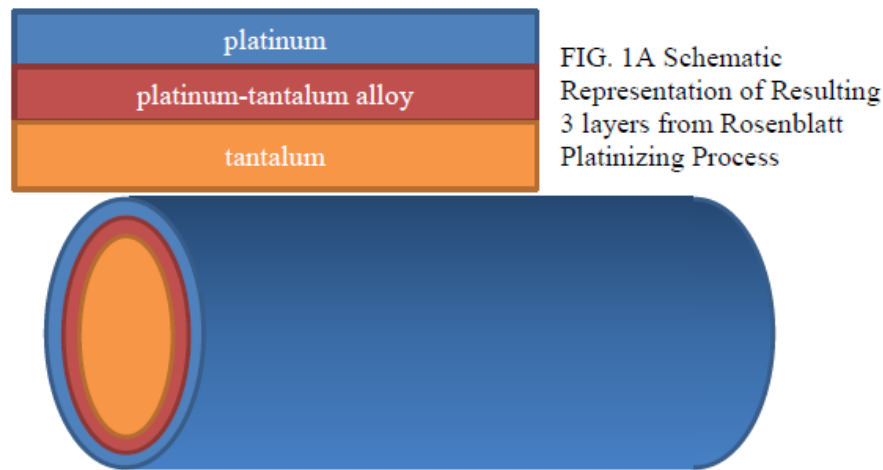
As explained below, Rosenblatt teaches that an intervening alloy layer is essential to achieving sufficient adherence between a platinum coating and a tantalum base. Ex. 1005, 1:71–2:25, 2:40–53, 4:14–25, 4:46–56. Neither the Petition nor the Vachon Declaration (Ex. 1006) addresses Rosenblatt’s intervening alloy layer, nor how the “in contact with” limitation of claim 1 is taught or suggested by the combination of Wilson and Rosenblatt, notwithstanding the intervening alloy layer. Petitioner’s reply arguments do not overcome this deficiency in Petitioner’s evidence. Pet. Reply 15–18.

Petitioner relies on Rosenblatt, not Wilson, to teach the “in contact with” limitation of claim 1. Pet. 14–15. Rosenblatt discloses a process for coating tantalum with platinum to produce an anode. Ex. 1005, 1:15–23. According to Rosenblatt, known processes, such as electroplating, are “unsatisfactory” because they “do not produce a coat of platinum metal which adheres with sufficient tenacity to the tantalum base,” “result[] in a coating that may easily be stripped from the base,” and/or produce coats of platinum that “are not truly bonded to the tantalum.” *Id.* at 2:5–6, 2:9–10, 2:13, 2:17–18. To address these problems, Rosenblatt discloses a two-step process for providing a firmly adherent coat of platinum on a tantalum base. *Id.* at 2:22–25, 2:40–50. First, a thin deposit of platinum metal is applied on the surface of the tantalum body by electroplating or chemical decomposition. *Id.* at 2:40–43, 2:45–50; *see also id.* at 2:67–3:37 (chemical deposition); 3:38–3:60 (electroplating). Second, the platinum metal deposit is bonded to the tantalum body by heating the whole to a high temperature under inert conditions. *Id.* at 2:43–45; *see also id.* at 3:61–4:13 (bonding).

Rosenblatt teaches that the bonding process is essential to provide sufficient adherence between the platinum coating and the tantalum base and to allow use of platinized tantalum as an anode. More specifically, Rosenblatt teaches that “the thin deposits [of platinum metal] . . . are not firm deposits until they have been subsequently bonded” in the manner taught by Rosenblatt. Ex. 1005, 2:50–53. Similarly, Rosenblatt teaches that “[a] platinum layer on a tantalum strip which has not been subjected to the bonding treatment . . . will upon being immersed in aqua[] regia become completely dissolved.” *Id.* at 4:14–17.

Rosenblatt discloses that the bonding process results in an intervening alloy layer between the platinum metal and the tantalum base. Rosenblatt discloses, in particular, that the bonding treatment “causes the platinum and tantalum metals to interdiffuse and become alloyed” thereby forming “a thin layer of platinum-tantalum alloy” between the tantalum base and an outer layer of unalloyed platinum. Ex. 1005, 4:22–25, 4:46–51. Claim 1 of Rosenblatt discloses that the platinum metal layer “is separated from the base by an interlayer of an alloy of the platinum with the base metal.” *Id.* at 6:26–30.

Both Petitioner and Patent Owner rely on the following schematic representation of the three layers that result from Rosenblatt’s platinizing process:



Prelim. Resp. 39; Pet. Reply 17. The above schematic representation shows a cylindrical shape having three layers: a tantalum core shown in orange, an intermediate platinum-tantalum alloy layer shown in red, and an outer platinum layer shown in blue.

In the structure taught by Rosenblatt, as illustrated by the above schematic representation, the platinum layer is not “in contact with” or touching the outer surface of the tantalum core. There is an intervening alloy layer that separates the platinum layer from the tantalum core. Ex. 1005, 4:22–25, 4:46–51, 6:26–30. As discussed above, this intervening alloy layer results from a bonding step, which Rosenblatt teaches is essential to achieving sufficient adherence between the platinum metal and the tantalum core. *Id.* at 2:43–45, 2:50–53, 3:61–4:13, 4:14–17.

Our findings regarding Rosenblatt are supported by the testimony of Dr. Schurman, who testifies:

Rosenblatt teaches that an alloy later [*sic*, layer] must be created between the pure platinum and pure tantalum layers, separating those layers and thus preventing them from being “*in contact with*” (or touching) one another, as required by the ’202 patent claims.

Ex. 2029 ¶ 135.

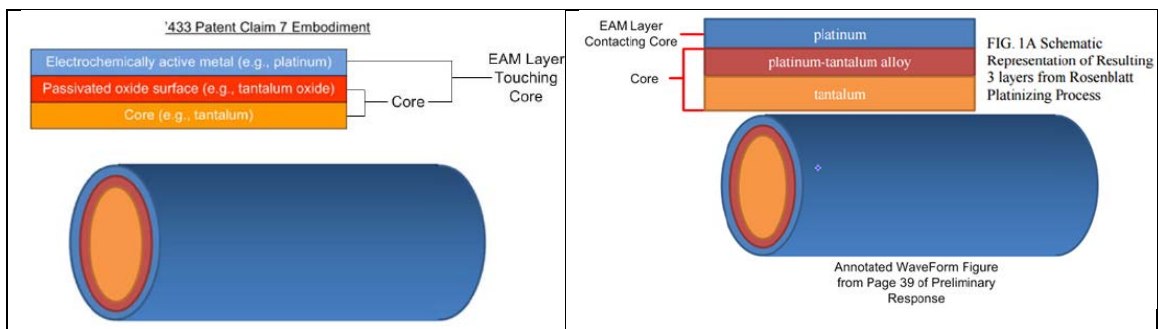
We have considered Petitioner’s reply arguments, but they do not persuade us that Petitioner has met its burden to show that the combination of Wilson and Rosenblatt teaches or suggest the “in contact with” limitation of claim 1.

First, Petitioner argues that “platinum and tantalum are touching” in Rosenblatt’s alloy layer. Pet. Reply 15. Petitioner’s assertion may be true as a technical matter, but it does not address the language of claim 1, which recites: “a layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core.” Ex. 1001, 4:60–62. Petitioner was required to prove that the prior art teaches or suggests a layer of electrochemically active metal, e.g., platinum, “in contact with” the outer surface of the core, e.g., tantalum. Petitioner does not explain how this claim limitation can be met by an alloy layer in which tantalum and platinum are intimately united. In addition, Petitioner does not present evidence that the tantalum/platinum alloy in the proposed combination of Wilson and Rosenblatt would be “electrochemically active.”

Next, Petitioner relies on claim 7 of the ’433 patent, arguing that “platinum and tantalum are touching more so” in Rosenblatt’s alloy than in the claim 7 embodiment “where an oxide surface separates the central portion of the core and electrochemically active layer.” Pet. Reply 15. Petitioner’s argument is not consistent with the language of the claims. Claim 1 of the ’202 patent requires that the electrochemically active metal layer be “in contact with” the **“outer surface”** of the core, **not** with a **“central portion”** of the core, as argued by Petitioner. Claim 7 of the ’433 patent recites: “wherein said outer surface of said core comprises a

passivated oxide surface.” Ex. 2028, 5:7–9. Claim 7 recites an oxide surface as **part of** the outer surface of the core, not an intervening layer **between** the electrochemically active metal layer and the outer surface of the core.

Next, Petitioner compares Rosenblatt’s three-layer structure with the embodiment described in claim 7 of the ’433 patent using the following illustrations:



Pet. Reply 16–17. Each of the above illustrations shows a cylindrical shape having three layers: a core shown in orange, an intermediate layer shown in red, and an outer layer shown in blue. Relying on the above illustrations, Petitioner contends that Rosenblatt’s platinum-tantalum alloy layer (shown in red) is part of the core in the same way as the passivated oxide surface of the claim 7 embodiment (also shown in red) is part of the core. *Id.*

We agree with Petitioner that claim 7 of the ’433 patent demonstrates that a “structurally flexible core” can be multilayered. Pet. Reply 16. Petitioner has not, however, provided evidence sufficient to show that Rosenblatt’s platinum-tantalum alloy layer is part of a multilayered core. Although Petitioner contends that Rosenblatt’s alloy layer is the outer surface of the core (Tr. 7:1–7), Petitioner’s contention is contradicted by the testimony of its own expert. Dr. Vachon testified that, in Rosenblatt, the

outer surface of the core is the outer surface of the tantalum, not the outer surface of the alloy layer.

Q. So, Paragraph 79, you wrote that Rosenblatt discloses an electrode having a tantalum core; correct?

A. I did.

Q. So, the outer surface of the core in Rosenblatt, is the outer surface of the tantalum; correct?

A. Yes.

Ex. 2036, 90:17–23 (referencing paragraph 79 of Exhibit 1006).

As support for its argument that Rosenblatt's alloy layer is the outer surface of the core, Petitioner directs us to pages 123 to 124 of Dr. Vachon's deposition. Tr. 59:6–10. There, Dr. Vachon testified that he "might" and "probably would" define the core as "tantalum with the other layer over it." Ex. 2036, 124:2–4. But that testimony does not refer to Rosenblatt, and it is unclear whether "the other layer" referenced by Dr. Vachon corresponds to Rosenblatt's alloy layer. *Id.* In fact, Dr. Vachon disagrees that an alloy layer is even formed in Rosenblatt's process. *Id.* at 106:12–108:9. Furthermore, Dr. Vachon elaborated that his definition of a "core" is "something that I would start with before I put the platinum down onto it" or a "center portion that you are going to deposit something onto." *Id.* at 124:5–11. The record properly before us is insufficient to show that Rosenblatt's alloy layer fits Dr. Vachon's definition of a "core."¹⁴

¹⁴ For the first time at the oral hearing, Petitioner relied on an alternative embodiment disclosed in Rosenblatt. Tr. 12:13–14:7. The alternative embodiment is a three-step process whereby a thin primary coat of platinum is applied to a tantalum base, the primary coat is bonded to the tantalum base, and then a second coat of platinum is applied. Ex. 1005, 4:70–5:29. At the oral hearing, Petitioner argued that the primary coat, after bonding, corresponds to the outer surface of the core. Tr. 14:8–20. That argument

Accordingly, we are not persuaded that Dr. Vachon's testimony supports Petitioner's argument that Rosenblatt's alloy layer is the outer surface of the core.

Next, Petitioner argues that it relies not only on Rosenblatt's bonding technique, but also on Rosenblatt's electroplating technique. Pet. Reply 17. We are not persuaded, however, that Rosenblatt's disclosure of electroplating teaches the "in contact with" limitation of claim 1. Rosenblatt's only disclosure of electroplating is either in the context of an unsatisfactory prior art technique (Ex. 1005, 2:8–10) or as part of a platinizing process that includes a bonding step that results in the intervening alloy layer discussed above (*id.* at 2:40–50, 3:38–3:60, 4:22–25, 4:46–51, 4:74–5:13).

Accordingly, we determine that Petitioner has not shown by a preponderance of the evidence that the combination of Wilson and Rosenblatt teaches or suggests the "in contact with" limitation of claim 1. Thus, we conclude that Petitioner has not met its burden to prove that claim 1 of the '202 patent is unpatentable as obvious in view of Wilson and Rosenblatt.

2. *Claims 2, 3, 5, 6, and 9–11*

Claims 2, 3, 5, 6, and 9–11 of the '202 patent depend, directly or indirectly, from claim 1 and recite limitations relating to the metals that comprise the electrochemically active metal and the core (claims 2, 3, and

was not presented in the briefs and is therefore waived. Even if the argument were not waived, it is not supported by expert testimony and is contradicted by Dr. Vachon's testimony previously discussed. Ex. 2036, 90:17–23.

5), the presence of a sensing surface (claim 6), the length of time the sensor is placed in an animal body (claim 9), the analyte being measured (claim 10), and coverage of a first end of the core by electrochemically active metal (claim 11). Petitioner contends that the combination of Wilson and Rosenblatt teaches or suggests the limitations of dependent claims 2, 3, 5, 6, and 9–11. Pet. 22–28.

The deficiencies in Petitioner’s arguments and evidence regarding the “in contact with” limitation of independent claim 1, as discussed above, are not remedied by Petitioner’s arguments and evidence regarding dependent claims 2, 3, 5, 6, and 9–11. We therefore conclude that Petitioner has not met its burden to prove that claims 2, 3, 5, 6, and 9–11 of the ’202 patent are unpatentable as obvious in view of Wilson and Rosenblatt for the same reasons as discussed above with respect to claim 1.

3. *Secondary Considerations*

We conclude that Petitioner has not met its burden of proof to show obviousness in view of Wilson and Rosenblatt, even without considering Patent Owner’s evidence of secondary considerations of non-obviousness.

F. Anticipation Based On Hagiwara

Petitioner contends that claims 1–3, 6, 8, 10, and 11 of the ’202 patent are anticipated by Hagiwara. Pet. 28–45. Patent Owner opposes. PO Resp. 45–56. We address the parties’ arguments below.

1. Claim 1

a. Preamble

The preamble of claim 1 recites: “A method for measuring the concentration of an analyte within an animal body having body fluids.” Ex. 1001, 4:55–56.

Petitioner contends that Hagiwara discloses the preamble of claim 1, directing us to Hagiwara’s description of a polarography sensor used by being inserted into a blood vessel and Hagiwara’s disclosure of analytes, such as glucose. Pet. 30–31 (citing Ex. 1007, 2–3).

Patent Owner does not dispute that Hagiwara discloses the preamble of claim 1. In fact, Patent Owner asserts that “Hagiwara discloses polarography sensors that are threaded through the vasculature of immobilized patients for purposes of measuring analytes in their blood.” PO Resp. 46 (citing Ex. 1007, 4:1–6).

Relying on the disclosures of Hagiwara cited by Petitioner, we find that Petitioner has shown that Hagiwara discloses the preamble of claim 1. Ex. 1007, 2:46–3:2, 4:1–6.

b. Claim element (a)(i)

Claim 1 recites: “(a) providing a sensor having: (i) a structurally flexible core having an outer surface.” Ex. 1001, 4:57–58.

Petitioner contends that this claim element is disclosed by the flexible polarography sensor of Hagiwara’s Figure 1(B), together with Hagiwara’s description of an alternative embodiment in which a precious metal wire is replaced by a base metal wire plated or vapor deposited with precious metal. Pet. 31–34 (citing Ex. 1007, 6–7).

Patent Owner argues that Hagiwara does not expressly or inherently disclose a sensor having a “structurally flexible core.” PO Resp. 49–52. More particularly, Patent Owner argues that Hagiwara’s flexible Figure 1(B) embodiment fails to teach a robust core and that Hagiwara’s disclosure of a base metal wire is generic and fails to teach a flexible core. *Id.*

After considering the parties’ arguments and evidence, we find that that Hagiwara discloses claim element (a)(i) quoted above. Our finding is based on Hagiwara’s Figure 1(B) embodiment, which is described as “a polarography sensor that forms a flexible separation type measuring electrode.” Ex. 1007, 6:12–13. Our finding is supported by Hagiwara’s description of Figure 1(B) as comprising “flexible tube 8 made of Teflon, silicon, or the like” and “insulating coating 9 made of a flexible resin.” *Id.* at 6:15, 6:18. Our finding is further supported by Hagiwara’s disclosure that “most of [the] polarography sensor [of Figure 1(B)] is flexible.” *Id.* at 6:19.¹⁵

Our finding is also based on Hagiwara’s disclosure that, in the polarography sensor of Figure 1(B), the precious metal wire may be replaced by a base metal wire having precious metal vapor deposited or plated on its front end. Ex. 1007, 7:26–31. Our finding is supported by Dr. Vachon’s testimony that, because the sensor of Hagiwara Figure 1(B) is required to be flexible, “the wire core material must also be flexible.” Ex. 1006 ¶ 140.

¹⁵ Hagiwara discloses that the front end of the sensor of Figure 1(B) is covered with a hard insulating coating made of glass or enamel, which is not taught as flexible. Ex. 1007, 6:16–17. There is no argument that this hard front end precludes Hagiwara’s Figure 1(B) embodiment from meeting the “structurally flexible core” limitation of claim 1.

We have considered Patent Owner’s arguments, but are nevertheless persuaded that Petitioner has met its burden of proof. Patent Owner argues that Hagiwara fails to teach a robust core. PO Resp. 49–50. That argument is not sufficient to rebut Petitioner’s showing for two reasons: First, it relies on a requirement for robustness that is not properly included in the claim construction for “structurally flexible.” See Section II.A.1, *supra*. Second, Patent Owner discusses whether precious metals, such as platinum or gold, can withstand repeated bending and flexing (*id.* at 50), but does not address the properties of a base metal core that is vapor deposited or plated with precious metal, as taught by Hagiwara (Ex. 1007, 7:30–31) and relied upon by Petitioner (Pet. 32, 34).

Next, Patent Owner argues that Hagiwara’s disclosure of a base metal “could refer to countless metals and their alloys, many of which could not be deemed ‘structurally flexible.’” PO Resp. 51 (citing Ex. 2029 ¶¶ 171–176). Patent Owner’s argument and Dr. Schurman’s testimony do not address Hagiwara’s teaching that a plated base metal wire can be used in the flexible sensor of Figure 1(B). Ex. 1007, 7:26–31. They also do not address Dr. Vachon’s testimony that, because the sensor of Hagiwara Figure 1(B) is required to be flexible, “the wire core material must also be flexible.” Ex. 1006 ¶ 140. Therefore, Patent Owner’s argument and Dr. Schurman’s testimony are not sufficient to rebut Petitioner’s evidence.

Accordingly, we determine that Petitioner has shown by a preponderance of the evidence that Hagiwara discloses “a sensor having a structurally flexible core having an outer surface,” as recited in claim 1.

c. Claim element (a)(ii)

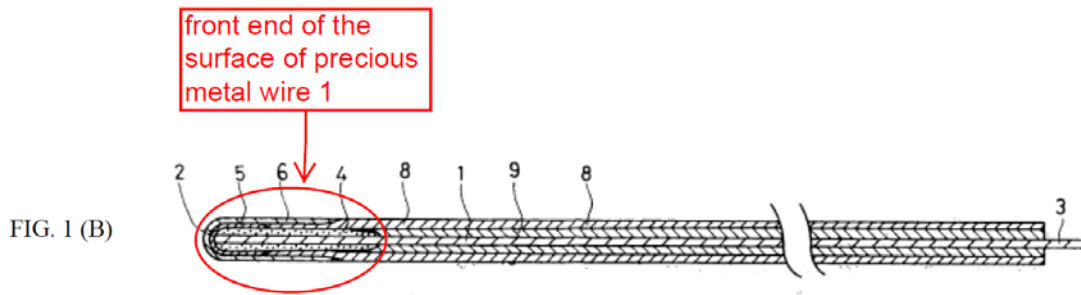
Claim 1 recites: “(a) providing a sensor having: . . . (ii) a layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core.” Ex. 1001, 4:57–62.

Petitioner contends that Hagiwara discloses this claim element, again relying on Hagiwara’s disclosure that a precious metal-plated wire may be used in place of a precious metal wire in the flexible Figure 1(B) embodiment. Pet. 34–35 (citing Ex. 1007, 7).

Patent Owner argues that Hagiwara does not teach an electrochemically active metal “covering, surrounding, and in contact with” an outer surface of a structurally flexible core and instead teaches that “the electrochemically active metal should contact only the ‘first end’ of the core.” PO Resp. 52–54.

After considering the parties’ arguments and evidence, we find that Hagiwara discloses claim element (a)(ii) quoted above. Our finding is based on Hagiwara’s description of the Figure 1(B) embodiment, when read together with Hagiwara’s disclosure that the precious metal wire in Figure 1(B) may be replaced by a precious metal-plated base metal wire. Ex. 1007, 6:12–26, 7:26–31, Fig. 1(B).

More specifically, when describing the Figure 1(B) embodiment, Hagiwara discloses: “the front end of the surface of the precious metal wire 1 is covered with the hard insulating coating 4 made of glass or enamel.” *Id.* at 6:16–17, 12:33–34 (amendment (12)). This description identifies the “front end” as the portion of the sensor that is covered with the hard insulating coating 4, as shown by our annotation of Hagiwara Figure 1(B) below:

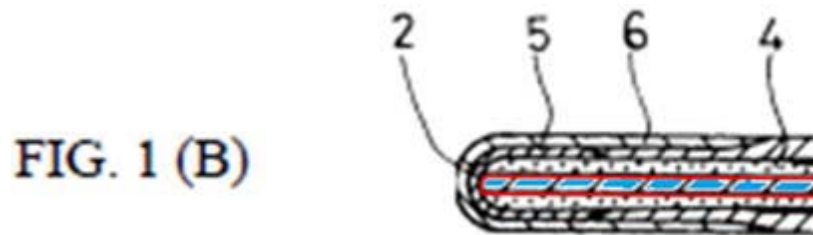


Hagiwara Figure 1(B), above, shows a polarography sensor. Our annotation (arrow text box and circle) identifies what Hagiwara calls “the front end of the surface of precious metal wire 1.” *Id.* at 6:16–17, 12:33–34. As illustrated by the above annotation, the “front end” includes a cylindrical surface of the metal wire.

Hagiwara uses the same “front end” terminology when describing an alternative embodiment in which the precious metal wire is replaced by a base metal wire that is vapor plated or deposited with precious metal. Ex. 1007, 7:30-31. In particular, Hagiwara discloses: “base metal wires, with precious metals vapor deposited or plated on the front ends thereof, may also be used.” *Id.* We find that the term, “front end,” as used by Hagiwara to describe this alternative embodiment, is not limited to electrode reaction surface 2 at the distal tip of the base metal wire, as argued by Patent Owner. PO Resp. 54. Patent Owner’s argument is inconsistent with Hagiwara’s description of the Figure 1(B) embodiment, which uses the term “front end” to refer to the surface covered with hard insulating coating 4. Ex. 1007, 6:16. Patent Owner’s argument is also inconsistent with Hagiwara’s disclosure that, in the Figure 1(B) embodiment, the electrode reaction surface may be either “on the front end surface of the precious metal wire 1” or “on a side surface of the precious metal wire 1.” *Id.* at 6:20–22. In the latter case, the precious metal would need to be deposited or

plated on the side surface, i.e., the cylindrical surface, of the wire. See Ex. 1007, Fig. 1(A).

Our finding is further supported by Dr. Vachon's testimony. Dr. Vachon provides the following excerpted and modified version of Hagiwara Figure 1(B) to illustrate Hagiwara's alternative embodiment having precious metal plated on a base metal wire:



Ex. 1006 ¶ 139. Hagiwara Figure 1(B), as excerpted and modified above, shows the front end of a polarography sensor. According to Dr. Vachon, a base wire is shown in blue and a noble metal electroplated coating on its front end is shown in red. *Id.* Dr. Vachon testifies that one technique for plating, as disclosed in Hagiwara, is electroplating, “which would result in coverage of the entire external surface of the Hagiwara central wire.” *Id.*

Accordingly, we determine that Petitioner has shown by a preponderance of the evidence that Hagiwara discloses a sensor having “a layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core,” as recited in claim 1.

d. Claim element (b)

Claim 1 recites: “(b) placing at least a portion of said sensor into said animal body.” Ex. 1001, 4:63–64.

Petitioner contends that Hagiwara discloses step (b) of claim 1 and directs us to Hagiwara's teaching that the flexible polarography sensor of

Figure 1(B) “can . . . be inserted deep (for example to the heart) along the inside of a vein.” Pet. 36 (quoting Ex. 1007, 6:19–20).

Patent Owner does not dispute that Hagiwara discloses step (b) of claim 1. In fact, Patent Owner asserts that “Hagiwara discloses polarography sensors that are threaded through the vasculature of immobilized patients for purposes of measuring analytes in their blood.” PO Resp. 46 (citing Ex. 1007, 4:1–6).

Relying on the disclosure of Hagiwara cited by Petitioner, we find that Petitioner has shown that Hagiwara discloses step (b) of claim 1, quoted above. Ex. 1007, 4:1–6, 6:19–20; *see also id.* at 7:6–11, 7:32–40, Fig. 2 (intravenous polography sensor of Figure 1(B) inserted in a vein or in the femoral arteries of a dog).

e. Claim element (c)

Claim 1 recites: “(c) measuring any electric current produced by said sensor and forming a measurement of analyte concentration based on said current measurement.” Ex. 1001, 4:65–67.

Petitioner contends that Hagiwara discloses step (b) of claim 1 and directs us to Hagiwara’s disclosure that polarography can be used to measure that the concentration of an oxidizing substance, such as oxygen, or a reducing substance, such as hydrogen, in an aqueous solution. Pet. 36–38 (quoting Ex. 1007, 2:46–3:2, 3:3–24). According to the Hagiwara excerpt quoted by Petitioner, the concentration of oxidizing or reducing substances can be measured based on the electric current flowing between a measuring electrode and a reference electrode. *Id.* at 38 (quoting Ex. 1007, 3:21–24).

Patent Owner does not dispute that Hagiwara discloses step (c) of claim 1.

Relying on the disclosures of Hagiwara cited by Petitioner, we find that Petitioner has shown that Hagiwara discloses step (c) of claim 1, quoted above. Ex. 1007, 2:46–3:2, 3:3–24.

Accordingly, we determine that Petitioner has shown by a preponderance of the evidence that claim 1 of the '202 patent is anticipated by Hagiwara.

2. *Claim 2*

Claim 2 depends from claim 1 and recites: “wherein said electrochemically active metal comprises a noble metal.” Ex. 1001, 5:1–2.

Petitioner contends that Hagiwara discloses the limitation of claim 2 and directs us to Hagiwara’s description of using a base metal wire vapor deposited or plated with precious (noble) metal in the flexible Figure 1(B) embodiment. Pet. 39 (citing Ex. 1007, 7).

Patent Owner does not dispute that Hagiwara discloses the limitation of claim 2.

Relying on the disclosures of Hagiwara cited by Petitioner, we find that Petitioner has shown that Hagiwara discloses the limitation of claim 2, quoted above. Ex. 1007, 7:26–31.

Accordingly, we determine that Petitioner has shown by a preponderance of the evidence that claim 2 of the '202 patent is anticipated by Hagiwara.

3. *Claim 3*

Claim 3 depends from claim 2 and recites: “wherein said noble metal comprises at least one of platinum, palladium, and gold.” Ex. 1001, 5:2–4.

Petitioner contends that Hagiwara discloses a noble metal plated electrode that utilizes platinum, palladium, or gold plating. Pet. 39–40. As

support for this contention, Petitioner directs us to Hagiwara's disclosure of a precious metal-plated wire in place of the precious metal wire in the flexible Figure 1(B) embodiment and Hagiwara's disclosure that the precious metal electrode can be made of "platinum, gold, and the like." *Id.* at 39 (citing Ex. 1007, 7 and quoting *id.* at 3:5).

Patent Owner does not dispute that Hagiwara discloses the limitation of claim 3.

Relying on the disclosures of Hagiwara cited by Petitioner, we find that Petitioner has shown that Hagiwara discloses the limitation of claim 3, quoted above. Ex. 1007, 3:5, 7:26–31.

Accordingly, we determine that Petitioner has shown by a preponderance of the evidence that claim 3 of the '202 patent is anticipated by Hagiwara.

4. Claim 6

Claim 6 depends from claim 1 and recites: "wherein said layer of electrochemically active metal is adapted to provide at least one sensing surface." Ex. 1001, 5:9–11.

Petitioner contends that Hagiwara discloses a sensing surface in the form of electrode reaction surface 2 of the Figure 1(B) embodiment, which Hagiwara discloses may include precious metal plated on a base metal wire. Pet. 40 (citing Ex. 1007, 3, 6, 7).

Patent Owner does not dispute that Hagiwara discloses the limitation of claim 6.

Relying on the disclosures of Hagiwara cited by Petitioner, we find that Petitioner has shown that Hagiwara discloses the limitation of claim 6, quoted above. Ex. 1007, 3:3–37 (describing electrochemical reactions that

occur on reaction surfaces of precious metal measuring electrode and at reference electrode); *id.* at 6:20–22 (describing location of electrode reaction surface 2 in Figure 1(B) embodiment); *id.* at 7:26–31 (describing alternative embodiment in which precious metal electrode is replaced by base metal wire vapor deposited or plated with precious metal).

Accordingly, we determine that Petitioner has shown by a preponderance of the evidence that claim 6 of the '202 patent is anticipated by Hagiwara.

5. *Claim 8*

Claim 8 depends from claim 1 and recites: “wherein said placing at least a portion of said sensor into said animal body comprises placing said at least a portion of said sensor in said animal body for less than 3 minutes.” Ex. 1001, 5:16–19.

Petitioner contends that Hagiwara discloses the limitation of claim 8 and directs us to Hagiwara Figure 3, which shows oxygen levels detected by the flexible sensor of Figure 1(B) when implanted in a dog. Pet. 41–42 (citing Ex. 1007, 7–8). Petitioner contends that Figure 3 shows that the sensed oxygen level settles to a baseline, accurately reflecting the blood oxygen level, within two minutes after the sensor is exposed to blood. *Id.* at 42 (citing Ex. 1007, 8). Relying on Dr. Vachon’s testimony, Petitioner contends, “Hagiwara thus discloses a sensor that could accurately sense an analyte, even when being removed from the body in under 3 minutes.” *Id.* (citing Ex. 1006 ¶¶ 164–167).

Patent Owner does not dispute that Hagiwara discloses the limitation of claim 8.

Relying on the disclosures of Hagiwara cited by Petitioner and the undisputed testimony of Dr. Vachon regarding Hagiwara Figure 3, we find that Petitioner has shown that Hagiwara discloses the limitation of claim 8, quoted above. Ex. 1007, 7:32–8:17, Fig. 3; Ex. 1006 ¶¶ 164–167.

Accordingly, we determine that Petitioner has shown by a preponderance of the evidence that claim 8 of the '202 patent is anticipated by Hagiwara.

6. *Claim 10*

Claim 10 depends from claim 1 and recites: “wherein said analyte comprises glucose.” Ex. 1001, 6:1–2.

Petitioner contends that Hagiwara teaches measuring the concentration of various analytes, including glucose, “through the incorporation of an enzyme layer into the described sensors.” Pet. 43 (citing Ex. 1007, 3).

Patent Owner argues that Petitioner implicitly relies on a combination of Hagiwara’s Figure 1(B) and Figure 1(D) embodiments—the same argument the Board rejected when Petitioner’s anticipation ground was denied institution in IPR2016-01680. PO Resp. 55–56.

We agree with Patent Owner. Petitioner’s case for dependent claim 10 relies on “incorporation of an enzyme layer into the described sensors.” Pet. 43. We are not persuaded, however, that Hagiwara teaches incorporating an enzyme layer into a flexible sensor. Petitioner relies on Hagiwara’s general teachings regarding fixing enzymes on the reaction surfaces of measuring electrodes. Ex. 1007, 3:28–32, 3:42–43, 4:1–6, 4:18–21. Petitioner does not, however, direct us to a teaching in Hagiwara to fix enzymes on the reaction surfaces of the measuring electrodes of a flexible

sensor, such as the Figure 1(B) embodiment. Hagiwara teaches that the flexibility of the Figure 1(B) enables the sensor to “be inserted deep (for example to 20 the heart) along the inside of a vein.” *Id.* at 6:19–20. For example, Hagiwara teaches that the Figure 1(B) embodiment can be used to measure oxygen levels in the femoral arteries of an anesthetized dog. *Id.* at 7:32–38. Petitioner does not direct us to any explicit or implicit teaching in Hagiwara that a flexible sensor, such as the Figure 1(B) embodiment, would be useful or desirable for measuring glucose.

Petitioner argues that Hagiwara describes “trivial adjustments necessary to change any of Hagiwara’s oxygen sensors into sensors for detecting other analytes, such as glucose” and that “[g]lucose sensing applies to the entirety of the Hagiwara ‘present invention.’” Pet. Reply 25. We are not persuaded by these arguments. Hagiwara teaches a first embodiment—Figure 1(A)—and two separate modifications of that embodiment: Figure 1(B) is a flexible sensor for detecting oxygen levels, and Figure 1(D) is a glucose sensor. Ex. 1007, 5:2–22, 6:12–26, 6:43–7:5. There is no teaching of a flexible glucose sensor in Hagiwara. For anticipation, “it is not enough that the prior art reference . . . includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.” *Net MoneyIN*, 545 F.3d at 1371. Unless a reference discloses “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, it cannot be said to prove prior invention of the thing claimed” and, thus, “cannot anticipate under 35 U.S.C. § 102.” *Id.*

Petitioner additionally argues that “a POSITA knew that heart glucose level monitoring was important.” Pet. Reply 25 (citing Ex. 1029,¹⁶ 14:61–67). Petitioner’s reply evidence (Ex. 1029) discloses an implantable sensor for measuring blood pressure in the heart, where “the system can also be used with an implantable sensor for sensing manifestations of other physical parameters such as . . . blood glucose.” Ex. 1029, Abstract, 14:61–67. That evidence does not support Petitioner’s argument that “a POSITA knew that heart glucose level monitoring was important.” Pet. Reply 25. The cited teaching does not suggest that an implantable blood glucose sensor should be located in the heart. Petitioner’s reply evidence at best suggests adding a blood glucose sensing feature to a device for sensing blood pressure in the heart. There is no teaching or suggestion to convert a flexible sensor for measuring oxygen levels in the heart to a flexible sensor for measuring glucose levels in the heart. Moreover, even if accepted, Petitioner’s reply argument would at best support obviousness of dependent claim 10 in view of Hagiwara and Brockway, not anticipation by Hagiwara, as asserted in the Petition for this instituted ground.

Accordingly, we determine that Petitioner has not shown by a preponderance of the evidence that claim 10 of the ’202 patent is anticipated by Hagiwara.

7. *Claim 11*

Claim 11 depends from claim 1 and recites: “wherein said core further comprises at least a first end, and wherein said electrochemically

¹⁶ Brockway, US 6,409,674 B1, issued June 25, 2002 (“Brockway”).

active layer further surrounds, covers, and is in contact with said at least a first end of said core.” Ex. 1001, 6:3–6.

Petitioner contends that Hagiwara discloses the limitation of claim 11, relying on Hagiwara’s disclosure that a precious metal-plated wire may be used in place of a precious metal wire in the flexible Figure 1(B) embodiment. Pet. 43–44 (citing Ex. 1007, 7). Relying on Dr. Vachon’s testimony, Petitioner contends, “[b]ecause Hagiwara discloses using a base wire electroplated with a noble metal in its flexible sensor of Fig. 1(B), it discloses a core whose electroplating surrounds, covers, and is in contact with said at least a first end of said core.” *Id.* at 44 (citing Ex. 1006 ¶¶ 171–175). Dr. Vachon testifies that “the distal end portion 2 of the Hagiwara sensor must be plated with a noble metal in order to function properly.” Ex. 1006 ¶ 172.

Patent Owner does not dispute that Hagiwara discloses the limitation of claim 11. In fact, Patent Owner concedes that Hagiwara teaches precious metal deposited on electrode reaction surface 2 at the distal tip of core wire 1 in Hagiwara’s Figure 1(B) embodiment and that the electrochemically active metal should contact the “first end” of the core. PO Resp. 46–47, 54.

Relying on the disclosures of Hagiwara cited by Petitioner, the undisputed testimony of Dr. Vachon, and Patent Owner’s admission, we find that Petitioner has shown that Hagiwara discloses the limitation of claim 11, quoted above. Ex. 1007, 7:26–31, Fig. 1(B); Ex. 1006 ¶¶ 171–175; PO Resp. 46–47, 54.

Accordingly, we determine that Petitioner has shown by a preponderance of the evidence that claim 11 of the '202 patent is anticipated by Hagiwara.

G. Obviousness Based On Hagiwara and Rosenblatt

Petitioner contends that claim 5 of the '202 patent is unpatentable as obvious in view of Hagiwara and Rosenblatt. Pet. 45–47. Patent Owner opposes. PO Resp. 57–60. We address the parties' arguments below.

1. Claim 5

Claim 5 depends from claim 1 and recites “wherein said core comprises tantalum.” Ex. 1001, 5:7–8.

Petitioner contends that Rosenblatt discloses that platinum coated tantalum can be used in electrochemical sensors as an alternative to platinum wire sensors. Pet. 45 (citing Ex. 1005, 1:72–2:1). Petitioner further contends that Hagiwara describes a flexible core plated with a noble metal in its Figure 1(B) embodiment. *Id.* (citing Ex. 1007, 6, 7). Petitioner contends that a POSA would have been motivated to combine the teachings of Hagiwara and Rosenblatt, providing three reasons: (i) both references are in the analogous arts of electrochemical electrodes, (ii) Hagiwara expressly teaches using a plated electrode as a substitute for a solid precious metal electrode, and (iii) Rosenblatt discloses that platinum coated tantalum can be used as a less expensive alternative to platinum wire in electrochemical sensors. *Id.* at 45–47.

Relying on its opposition to Petitioner's Wilson/Rosenblatt combination, Patent Owner argues that Rosenblatt teaches away from the electrochemically active metal “in contact with” the core and instead teaches

an intervening alloy layer that separates the electrochemically active metal and the core so that they do not touch. PO Resp. 59.

After considering the parties' arguments and evidence and for reasons similar to those discussed above in connection with Petitioner's obviousness ground based on Wilson and Rosenblatt, we determine that Petitioner has not shown by a preponderance of the evidence that the combination of Hagiwara and Rosenblatt teaches or suggests the "in contact with" limitation of dependent claim 5.

As discussed above, Rosenblatt teaches that an intervening alloy layer is essential to achieving sufficient adherence between a platinum coating and a tantalum base. Ex. 1005, 1:71–2:25, 2:40–53, 4:14–25, 4:46–56. Neither the Petition nor the Vachon Declaration (Ex. 1006) addresses Rosenblatt's intervening alloy layer, nor how the "in contact with" limitation of claim 5 is taught or suggested by the combination of Hagiwara and Rosenblatt, notwithstanding the intervening alloy layer. Petitioner's reply arguments (Pet. Reply 26), do not address the "in contact with" limitation and do not overcome this deficiency in Petitioner's evidence.

We acknowledge our determination that Hagiwara discloses all limitations of claim 1, including the "in contact with" limitation. Claim 5 depends from claim 1 and recites "wherein said core comprises tantalum." Ex. 1001, 5:7–8. When the two claims are read as a whole, claim 5 requires an electrochemically active metal "in contact with" the outer surface of a core comprising tantalum. *Id.* at 4:60–62, 5:7–8. For this limitation, Petitioner relies on Rosenblatt's disclosure of platinum coated tantalum. Pet. 45. For the same reasons as discussed above in connection with Petitioner's ground based on Wilson and Rosenblatt, we determine that

Petitioner has not shown that Rosenblatt teaches or suggests an electrochemically active metal, e.g., platinum, “in contact with” the outer surface of a tantalum core. Petitioner does not direct us to any teaching in Hagiwara that remedies this deficiency in Rosenblatt. Hagiwara does not, in fact, disclose a core comprising tantalum.

Accordingly, we determine that Petitioner has not shown by a preponderance of the evidence that the combination of Hagiwara and Rosenblatt teaches or suggests the “in contact with” limitation of claim 5. We conclude that Petitioner has not met its burden to prove that claim 5 of the ’202 patent is unpatentable as obvious in view of Hagiwara and Rosenblatt.

2. Secondary Considerations

We conclude that Petitioner has not met its burden of proof to show obviousness of claim 5 in view of Hagiwara and Rosenblatt, even without considering Patent Owner’s evidence of secondary considerations.

H. Motions to Exclude

1. Petitioner’s Motion to Exclude

Petitioner moves to exclude portions of Patent Owner’s Exhibit 2025, the Declaration of Ellen Anderson, and corresponding portions of Patent Owner’s Response (PO Resp. 30, 35) on the grounds that the testimony is inadmissible hearsay and that Ms. Anderson lacks personal knowledge of facts asserted in the testimony. Paper 41, 1, 14.

Patent Owner relies on Ms. Anderson’s testimony to support its contentions regarding circumstances that led to the ’202 patent, including an alleged problem with the sensor disclosed in Wilson. PO Resp. 30, 35. We

have not relied on Exhibit 2025 or the corresponding portions of Patent Owner's Response as support for this Decision. For this reason, we *dismiss as moot* Petitioner's motion.

2. *Patent Owner's Motion to Exclude*

a. *Exhibits 1014–1019*

Patent Owner moves to exclude Petitioner's Exhibits 1014–1019 and corresponding portions of the Reply (Pet. Reply 2, 22 n.3) on the grounds that Petitioner improperly relies upon these exhibits to assert new grounds of unpatentability in the Reply. Paper 42, 1–3, 7–9.

Petitioner relies on Exhibits 1014–1019 to show prior art processes of applying platinum to tantalum and prior art use of platinum-clad tantalum as medical electrodes, as well as to show it was known in the art to substitute platinum-plated tantalum electrodes for pure platinum to reduce costs. Pet. Reply 2, 22 n.3.

We agree with Patent Owner that Petitioner's Exhibits 1014–1019 should be excluded from evidence and that the corresponding portions of the Reply (Pet. Reply 2, 22 n.3) should not be considered. None of these exhibits was made of record at the institution stage. Although Carter (Ex. 1014), Haley (Ex. 1015), Beer (Ex. 1016), and Bartig (Ex. 1017) were cited in the Petition and/or Vachon Declaration (Pet. 19–20, 47; Ex. 1006 ¶¶ 98–101, 181), these references were not filed as exhibits with the Petition, and they were excluded from consideration in the Institution Decision. Dec. 18 n.11 (citing 37 C.F.R. § 42.104(b)). Petitioner did not challenge the Board's exclusion of these references, for example, by requesting rehearing of the Institution Decision. Nor did Petitioner seek authorization for a motion to submit supplemental information. 37 C.F.R. § 42.123(a).

Instead, Petitioner filed these exhibits for the first time with its Reply. We agree with Patent Owner that Petitioner’s Reply relies on Exhibits 1014–1019 to fill a gap in its prima facie case in view Patent Owner’s argument that Rosenblatt fails to teach the “in contact with” limitation of claim 1. PO Resp. 34, 36; Pet. Reply 2. Specifically, Petitioner argues, “[t]o the extent there were any difficulties applying platinum to tantalum in 1950 (the time of Rosenblatt), . . . those complexities were solved in the 53 years prior to the ’202 patent filing.” Pet. Reply 2 (citing Exs. 1014–1019). In other words, to the extent the Board is not persuaded by Rosenblatt, then Petitioner relies on Carter (Ex. 1014), Haley (Ex. 1015), Beer (Ex. 1016), Bartig (Ex. 1017), Williams (Ex. 1018), and Dahl (Ex. 1019) to show platinum-clad tantalum electrodes. *Id.*

Under our rules and trial practice guide, evidence necessary to make out a prima facie case of unpatentability may not be introduced for the first time in the reply brief. 37 C.F.R. § 42.23(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012) (“Examples of indications that a new issue has been raised in a reply include new evidence necessary to make out a prima facie case for the . . . unpatentability of an original . . . claim, and new evidence that could have been presented in a prior filing.”). Federal Circuit case law indicates that a motion to exclude is a proper vehicle for enforcing our rule and trial practice guide regarding the scope of evidence that may be submitted with a reply brief. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1081 (Fed. Cir. 2015) (“a party may move to exclude evidence . . . as improper under the response-only regulation, under the Trial Practice Guide’s advice”); *see also Genzyme Therapeutic Prods. L.P. v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1368 (Fed. Cir. 2016) (“[i]f

[patent owner] had wanted the Board to disregard those references, it could have filed a motion to exclude them,” citing 37 C.F.R. § 42.64(c) and *Belden, supra*); *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359 (Fed. Cir. 2016) (not error for the Board to exclude Petitioner’s new theory of invalidity supported by new evidence not relied upon in the Petition).

Under the circumstances of this case, it would violate the Administrative Procedures Act (“APA”)’s requirement for notice and opportunity to respond, if we were to rely upon Carter (Ex. 1014), Haley (Ex. 1015), Beer (Ex. 1016), or Bartig (Ex. 1017) as evidence to show that the “in contact with” limitation of claim 1 was taught or suggested by the prior art, when that evidence was first submitted and relied upon in Petitioner’s Reply. Pet. Reply 2, 22 n.3. These references were expressly excluded in the Institution Decision because they had not been made of record as exhibits at that time. Dec. 18 n. 11. Patent Owner was entitled to rely upon our exclusion of these references, particularly since Petitioner took no action to have them made of record any earlier than the time that the reply brief was filed. Williams (Ex. 1018) and Dahl (Ex. 1019) fare no better because they were not cited in the Petition or Vachon Declaration, and they were not made of record any earlier than the reply brief. *See EmeraChem Holdings LLC v. Volkswagen Group of Am., Inc.*, 859 F.3d 1341, 1348–52 (Fed. Cir. 2017) (APA’s notice and opportunity to respond requirements not satisfied where Institution Decision did not sufficiently notify patent owner that it would rely on reference for limitations of dependent claims).

b. Exhibit 1021

Patent Owner also moves to exclude Petitioner's Exhibit 1021. Paper 42, 3–5, 9–11. Petitioner relies on Exhibit 1021 to oppose Patent Owner's proposed construction for "outer surface." Pet. Reply 8. We determine that it is not necessary to provide an express construction for this claim term, and we have not relied on Exhibit 2025 or the corresponding portions of Petitioner's Reply as support for this Decision. For this reason, we *dismiss as moot* Patent Owner's motion.

III. CONCLUSION

1. Petitioner has not demonstrated by a preponderance of the evidence that that claims 1–3, 5, 6, and 9–11 of the '202 patent are unpatentable under 35 U.S.C. § 103(a) as obvious in view of Wilson and Rosenblatt.

2. Petitioner has demonstrated by a preponderance of the evidence that claims 1–3, 6, 8, and 11 of the '202 patent are unpatentable under 35 U.S.C. § 102(b) as anticipated by Hagiwara.

3. Petitioner has not demonstrated by a preponderance of the evidence that claim 10 of the '202 patent is unpatentable under 35 U.S.C. § 102(b) as anticipated by Hagiwara.

4. Petitioner has not demonstrated by a preponderance of the evidence that that claim 5 of the '202 patent is unpatentable under 35 U.S.C. § 103(a) as obvious in view of Hagiwara and Rosenblatt.

IV. ORDER

Accordingly, in consideration of the foregoing, it is hereby:

ORDERED claims 1–3, 6, 8, and 11 of the '202 patent are held unpatentable under 35 U.S.C. § 102(b);

ORDERED that Petitioner has not shown that claims 5, 9, and 10 of the '202 patent are unpatentable;

FURTHER ORDERED that Petitioner's motion to exclude Exhibit 2025 is *dismissed as moot*;

FURTHER ORDERED that Patent Owner's motion to exclude is *granted*, as it pertains to Exhibits 1014–1019, and *dismissed as moot*, as it pertains to Exhibit 1021;

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2016-01679
Patent 7,146,202 B2

FOR PETITIONER:

Matthew W. Johnson
David B. Cochran
Vishal V. Khatri
JONES DAY
mwjohnson@jonesday.com
dcochran@jonesday.com
vkhatri@jonesday.com

FOR PATENT OWNER:

Steven J. Prewitt
Scott D. Eads
Karri Kuenzli Bradley
Nicholas F. Aldrich, Jr.
Jason A. Wrubleski
SCHWABE, WILLIAMSON & WYATT, P.C.
SPrewitt@schwabe.com
seads@schwabe.com
kbradley@schwabe.com
naldrich@schwabe.com
jwrubleski@schwabe.com