

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

WAVEFORM TECHNOLOGIES, INC.,
Patent Owner.

Case IPR2017-01051
Patent 7,529,574 B2

Before BENJAMIN D. M. WOOD, JON B. TORNQUIST, and
ELIZABETH M. ROESEL, *Administrative Patent Judges*.

ROESEL, *Administrative Patent Judge*.

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

In this *inter partes* review, instituted pursuant to 35 U.S.C. § 314, Dexcom, Inc. (“Petitioner”) challenges the patentability of claims 1–19 of U.S. Patent No. 7,529,574 B2 (Ex. 1001, “the ’574 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, 4–12, and 15–19 of the ’574 patent are unpatentable. We determine that Petitioner has not shown by a preponderance of the evidence that claims 2, 3, 13, and 14 of the ’574 patent are unpatentable. We grant Patent Owner’s Contingent Motion to Amend as to claims 21, 24, and 25 (proposed substitutes for claims 10, 13, and 14 of the ’574 patent) and deny the motion as to claims 20, 22, 23, and 26–29 (proposed substitutes for claims 9, 11, 12, 15–17, and 19 of the ’574 patent). We dismiss Patent Owner’s Motion to Exclude as moot.

I. BACKGROUND

A. *Procedural History*

Petitioner filed a Petition seeking *inter partes* review of claims 1–19 of the ’574 patent. Paper 1 (“Pet.”). Patent Owner filed a Preliminary Response. Paper 5 (“Prelim. Resp.”). We instituted *inter partes* review of all challenged claims, based on only one of the five grounds of unpatentability presented in the Petition. Paper 7 (“Institution Decision” or “Dec.”), 2, 4, 32.

Patent Owner filed a Response and a Contingent Motion to Amend. Paper 17 (“PO Resp.”); Paper 18 (“Mot.”). Petitioner filed a Reply and a Response to the Motion to Amend. Paper 23 (“Pet. Reply”); Paper 22 (“Pet.

Opp.”). Patent Owner filed a Reply to Petitioner’s Response to the Motion to Amend. Paper 27 (“PO Reply”). With prior authorization of the Board, Petitioner filed a Sur-Reply to the Motion to Amend (Paper 29, “Pet. Sur-Reply”), and Patent Owner filed Responses to Observations of Dr. Smith’s testimony (Paper 36).

Following the Supreme Court’s decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018), we modified our Institution Decision to include review of all grounds presented in the Petition. Paper 30. With the Board’s prior authorization, Petitioner filed a Reply regarding the subsequently instituted grounds (Paper 37), and Patent Owner filed a Sur-Reply (Paper 42).

Patent Owner filed a Motion to Exclude Exhibit 1037 filed with Petitioner’s Reply (Paper 37) and portions of the Reply discussing that exhibit. Paper 41. Petitioner filed a response (Paper 44), and Patent Owner filed a reply (Paper 45) concerning the Motion to Exclude.

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 2009.

With the Preliminary Response, Patent Owner filed a declaration of John L. Smith, Ph.D. Ex. 2001. With the Patent Owner Response, Patent Owner filed a second declaration of Dr. Smith. Ex. 2008. With its Reply to Petitioner’s Response to the Motion to Amend, Patent Owner filed a third declaration of Dr. Smith. Ex. 2024. Petitioner cross-examined Dr. Smith three times and filed transcripts of his deposition testimony as Exhibits 1021, 1031, and 1032.

Oral argument was held July 13, 2018, and a transcript was entered in the record. Paper 47 (“Tr.”).

B. Related Matters

The parties identify the following district court proceeding involving the ’574 patent: *WaveForm Technologies, Inc. v. Dexcom, Inc.*, No. 3:16-cv-536-MO (D. Or., filed March 28, 2016). Pet. 88; Paper 3 (Patent Owner Mandatory Notices—37 C.F.R. § 42.8).

In addition, Patent Owner identifies the following *inter partes* review proceedings involving Dexcom, Inc. as Petitioner and WaveForm Technologies, Inc. as Patent Owner: IPR2016-01679, involving U.S. Patent No. 7,146,202 B2, and IPR2016-01680, involving U.S. Patent No. 8,187,433 B2. Paper 3, 2.

C. The ’574 Patent (Ex. 1001)

The ’574 patent was issued May 5, 2009 from Application No. 10/640,980, filed August 14, 2003. Ex. 1001, [45], [21], [22].

The ’574 patent relates to an indwelling analyte sensor, for example, a glucose sensor. Ex. 1001, 1:18–19. According to the ’574 patent, the problem addressed is that of producing a dip coating of curable viscous material to form, e.g., a glucose oxidase enzyme layer, over an electrochemically active surface, where the coating has a thickness sufficient to produce an adequate response to the presence of glucose. *Id.* at 1:6–14, 2:8–10. The solution described by the ’574 patent is to provide at least one nub of dielectric material that extends outwardly from the electrochemically active surface to allow a greater portion of curable viscous liquid to adhere to the electrochemically active surface and provide a supportive structure for

the curable liquid before and during the curing and for the resulting membrane system. *Id.* at 1:22–25, 1:29–34, 2:6–10.

An embodiment is shown in Figures 1 and 2, which are reproduced below:

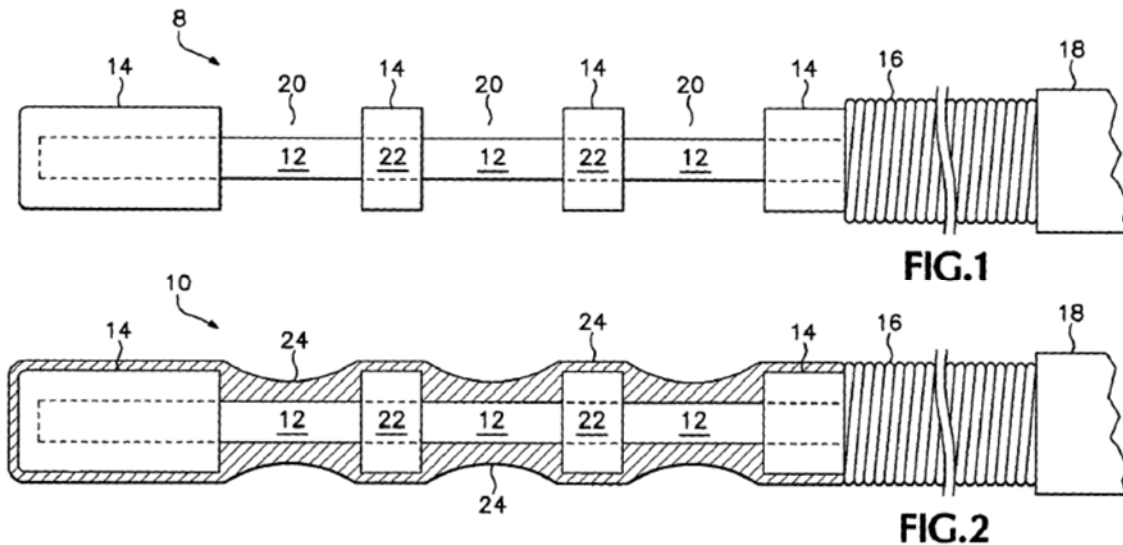


Figure 1 of the '574 patent shows a work piece formed as part of the construction of a biosensor, and Figure 2 shows a sensor constructed from the work piece of Figure 1. Ex. 1001, 1:43–47.

As shown in Figure 2, analyte (typically glucose) sensor 10, includes platinum wire 12, polyimide layer 14, silver wire 16 wrapped about a portion of layer 14, and stainless steel retractor lead 18. *Id.* at 1:53–56.

Referring to the structures shown in Figures 1 and 2, the '574 patent provides the following disclosure regarding construction of a biosensor:

Three cavities 20, each 2 mm long, are formed by laser ablating polyimide layer 14 to form a work piece 8 (FIG. 1). The polyimide between the cavities 20, forms a set of annular plates 22, that are supported by the adherence of the polyimide 14 onto wire 12. In an embodiment, nubs, such as annular plates 22, may be spaced longitudinally from the active surface of wire 12. After the laser machining operation, the work piece

is ready to be dip coated with the material 24 that permits it to detect glucose. Typically, material 24 is comprised of a set of layers that are constructed through a sequence of dip coating operations interspersed with curing operations. These layers typically include an interferent excluding layer, a glucose oxidase layer and a permselective layer as described in U.S. Pat. No. 5,165,407, which is hereby incorporated by reference as if fully set forth herein. The surface of each viscous fluid tends to form a shape somewhat like a catenary curve between plates 22.

Ex. 1001, 1:57–2:6.

According to the '574 patent, plates 22 allow a greater portion of viscous fluid to adhere to the electrochemically active surface than would adhere without plates 22. *Id.* at 2:6–8.

D. Illustrative Claims

The '574 patent issued with 19 claims, of which claims 1 and 9 are independent. All 19 claims are challenged in the Petition. Claims 1 and 9 are illustrative of the challenged claims and are reproduced below with bracketed numerals added to correspond with Petitioner's identification of the First, Second, Third, and Fourth elements of each claim:

1. An indwelling analyte sensor, comprising:
 - [1] an electrochemically active surface;
 - [2] at least two nubs of dielectric material extending outwardly from said electrochemically active surface and [3] forming a cavity along said electrochemically active surface and between said at least two nubs; and
 - [4] a membrane system comprising an enzyme layer, said enzyme layer surrounding said at least two nubs and said electrochemically active surface at least along said cavity.

Ex. 1001, 2:20–29.

9. An indwelling analyte sensor, comprising:

[1] an electrochemically active surface defining a sensing region along a portion of said electrochemically active surface;

[2] a plurality of nubs of dielectric material extending outwardly from said electrochemically active surface, [3] said plurality of nubs spaced along said electrochemically active surface; and

[4] a membrane system comprising an enzyme layer, said enzyme layer surrounding said sensing region of said electrochemically active surface to form an active sensing region and surrounding said plurality of nubs.

Id. at 2:46–57.

In its Contingent Motion to Amend, Patent Owner proposes to substitute claims 20–29 for claims 9–19 of the '574 patent. Mot. 1, 4–6. Claim 20 is illustrative of the proposed substitute claims and is reproduced below from Patent Owner's claim listing:

An indwelling analyte sensor, comprising:

an electrochemically active surface defining a sensing region along a portion of said electrochemically active surface;

a plurality of nubs of dielectric material extending outwardly from said electrochemically active surface, said plurality of nubs spaced along said electrochemically active surface; and

a membrane system comprising an enzyme layer, a permselective layer and an interferent excluding layer, said enzyme layer surrounding said sensing region of said electrochemically active surface to form an active sensing region and surrounding said plurality of nubs, wherein the enzyme is glucose oxidase, thereby forming an indwelling analyte sensor for detecting glucose.

Mot. 4.¹

¹ Additions to issued claim 9 are underlined.

E. Petitioner's References

Petitioner's patentability challenges are based on the following references:

Wilson et al., US 5,165,407, issued November 24, 1992, Ex. 1003 ("Wilson");

Hagiwara, JP S57-110236, published July 9, 1982, Ex. 1005 ("Hagiwara");²

Michael R. Ryan et al., *Biosensor for Neurotransmitter L-Glutamic Acid Designed for Efficient Use of L-Glutamate Oxidase and Effective Rejection of Interference*, ANALYST, 122, 1419–1424 (1997), Ex. 1008 ("Ryan");

Say et al., US 6,175,752 B1, issued January 16, 2001, Ex. 1022 ("Say"); and

Richard F. Taylor and Jerome S. Schultz, eds., *Handbook of Chemical and Biological Sensors*, Institute of Physics Publishing (1996), Ex. 1024 ("Handbook").

Wilson, Hagiwara, Ryan, Say, and the Handbook are each asserted as prior art under 35 U.S.C. § 102(b). Pet. 8–9; Pet. Opp. 7 n.7.

F. Asserted Grounds of Unpatentability

The Petition asserts five grounds of unpatentability. Pet. 9. Initially, we instituted *inter partes* review based on only the following ground: whether claims 1–19 of the '574 patent are unpatentable under 35 U.S.C. § 103(a) as obvious in view of Hagiwara. Dec. 32. Subsequently

² Exhibit 1005 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).

(Paper 30), we instituted *inter partes* review of the remaining grounds, which are based on Wilson, either under 35 U.S.C. § 102(b) or under 35 U.S.C. § 103(a) in view of Hagiwara and/or Ryan (hereinafter, the “Wilson-Based Grounds”). Pet. 9.

In its Response to the Motion to Amend, Petitioner asserts that proposed substitute claims 20 and 22–29 are unpatentable under 35 U.S.C. § 103(a) as obvious in view of Hagiwara, either alone or in view of the Handbook, Wilson, or Say. Pet. Opp. 7–24. Petitioner also asserts that proposed substitute claim 26 is unpatentable under 35 U.S.C. § 112, first paragraph. *Id.* at 7, 24–25.

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. *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015). “[G]iving claims their broadest reasonable interpretation . . . does not include giving claims a legally incorrect interpretation.” *Id.* (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”).

In the Institution Decision, we provided express constructions for the terms, “nubs,” “surrounding said at least two nubs,” and “surrounding said plurality of nubs.” Dec. 7–11. Neither party challenges those constructions (see PO Resp. 12–13), which we adopt for purposes of this decision. For completeness, we repeat our discussion of those terms below. We also discuss the term, “plate,” which appears in both the issued and proposed substitute claims, and the term, “permselective,” which appears in proposed substitute claim 20.

1. “nubs” (*claims 1 and 9*)

Petitioner contends that the term, “nubs,” should be construed as “protruding structures” and that this term includes the proximal and distal dielectric portions 14 shown in Figures 1 and 2 of the ’574 patent. Pet. 12.

Patent Owner agrees with Petitioner’s proposed construction. Prelim. Resp. 15.

We adopt the parties’ agreed construction. That construction is consistent with and supported by claims 1 and 9, which recite that nubs of dielectric material extend outwardly from the electrochemically active surface. Ex. 1001, 2:22–23, 2:50–51.

The parties' agreed construction is also supported by Figures 1 and 2 of the '574 patent, which show areas adjacent to cavities 20 where polyimide layer 14 has not been removed and protrudes from the surface of wire 12. *Id.* at 1:57–61, Figs. 1 and 2. The '574 patent discloses: “[t]he polyimide between the cavities 20[] forms a set of annular plates 22 . . .” (*id.* at 1:59–60) and “[i]n an embodiment, nubs, such as annular plates 22, may be spaced longitudinally from the active surface of wire 12” (*id.* at 1:61–63).³ These disclosures demonstrate that the term “nubs” includes, but is not limited to, annular plates 22. *In re Am. Acad. Of Sci. Tech Ctr.*, 367 F.3d 1359, 1369 (Fed. Cir. 2004) (“We have cautioned against reading limitations into a claim from the preferred embodiment described in the specification, even if it is the only embodiment described, absent clear disclaimer in the specification.”). That conclusion is reinforced by dependent claims 2 and 3, which depend from claim 1 and recite nubs in the form of a plate or an annular plate. *Id.* at 2:30–33; *see also* 3:1–4 (claims 13 and 14 depend from claim 9 and recite nubs in the form of a plate or an annular plate).

The parties note that their agreed construction is the same as that proposed by Patent Owner and adopted by the District Court in the related litigation. Pet. 11; Prelim. Resp. 15; Ex. 1007, 3. We are not bound by the construction given a term by the District Court because the District Court applies a different claim construction standard than we are required to apply.

³ This sentence was added by amendment to the Specification during prosecution (Ex. 1004, 119); however, neither party contends that it constitutes new matter that should not be relied upon to construe the meaning of “nubs.” *See Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1353 (Fed. Cir. 2000) (the court must determine what the claim term meant at the time the patentee filed the application).

Power Integrations, Inc. v. Lee, 797 F.3d 1318, 1326 (Fed. Cir. 2015).

When such a claim construction is made of record, however, we must acknowledge it and “assess whether it is consistent with the broadest reasonable construction of the term” being construed. *Id.* Here, for the reasons discussed above, we determine that the District Court’s construction is consistent with the broadest reasonable construction for “nubs.”

Accordingly, consistent with the parties’ agreement, we construe the term, “nubs,” to mean “protruding structures.”

2. “surrounding said at least two nubs” (claim 1)
“surrounding said plurality of nubs” (claim 9)

Petitioner contends that the phrase, “surrounding said at least two nubs . . . at least along said cavity” should be interpreted to mean “encircle at least a portion of the nubs (e.g., as the enzyme layer cross-sectionally encircles the end cap and proximal insulation portions depicted in Fig. 2 of the ’574 patent).” Pet. 13–14.

Patent Owner agrees with Petitioner that, in the context of the ’574 patent, the term, “surrounding,” should be construed to mean “encircling.” Prelim. Resp. 16. Patent Owner proposes that the phrase, “surrounding said at least two nubs and said electrochemically active surface at least along said cavity” should be construed to mean: “encircling said at least two nubs and said electrochemically active surface at least along said cavity.” *Id.* at 16–17.

Neither party explicitly addresses the meaning of the phrase, “surrounding said plurality of nubs,” in claim 9. This phrase is similar to claim 1’s recitation, “surrounding said at least two nubs.” Unlike claim 1, however, claim 9 does not recite the phrase, “at least along said cavity.” In

the context of claim 1, we are not persuaded that the phrase, “at least along said cavity,” modifies the phrase, “surrounding said at least two nubs.” We therefore construe only the word “surrounding,” as used in the phrases of claims 1 and 9 set forth in the heading above.

We adopt the parties’ agreement that the term “surrounding” means “encircling.” The parties’ agreed construction is supported by Figure 2 of the ’574 patent, which shows what appears to be a partial cross-section along a plane through the central axis of sensor 10, with material 24 encircling the portion of the sensor to the left of silver wire 16, including polyimide layer 14 and annular plates 22.

The parties’ agreed construction is further supported by the prosecution history, where Applicants stated:

In a general sense, the term “surround” is intended to mean that the membrane provides a covering/coating encircling the stated underlying element(s). When considering the scope of the term, reference to Figure 2 shows that the membrane system does not simply cover or abut an end of the device, but rather encircles the active surface and the nub(s).

Ex. 1004, 25–26.

Patent Owner objects to the phrase, “at least a portion of,” in Petitioner’s proposed construction. Pet. 14; Prelim. Resp. 17 n.5. Petitioner relies on Patent Owner’s district court claim construction brief as support for this portion of its proposed construction. Pet. 12–13. According to Patent Owner’s district court brief, Figure 2 of the ’574 patent shows a portion of polyimide layer 14 beneath silver wire coil 16 and not surrounded by membrane 24. *Id.* Petitioner does not, however, show that the portion of polyimide layer 14 beneath silver wire coil 16 is a “nub.” Therefore, we are

not persuaded that the intrinsic evidence supports the phrase, “at least a portion of,” in Petitioner’s proposed construction.

Patent Owner also objects to Petitioner’s proposed parenthetical language, “(e.g., as the enzyme layer cross-sectionally encircles the end cap and proximal insulation portions depicted in Fig. 2 of the ’574 patent).” Pet. 14; Prelim. Resp. 17 n.5. Petitioner’s proposed parenthetical provides an example of the meaning of the claim term with reference to the embodiment shown Figure 2 of the ’574 patent. This example is not necessary to define the claim term, and we therefore decline to adopt it as part of the claim construction.

Accordingly, consistent with the parties’ agreement, we construe the term, “surrounding,” to mean “encircling.”

3. “plate” (*claims 2, 3, 13, and 14*)

Claim 2 depends from claim 1 and recites: “wherein at least one of said at least two nubs is in the form of a plate.” Ex. 1001, 2:30–31. Claim 3 likewise depends from claim 1 and recites: “wherein at least one of said at least two nubs comprises an annular plate.” *Id.* at 2:32–33. Dependent claims 13 and 14 depend from claim 9 and contain the same recitation as claims 2 and 3, respectively. *Id.* at 3:1–4.

Petitioner contends that “[a] plate in the context of the ’574 patent is a portion of material emanating from a center point.” Pet. 52. Patent Owner contends that “plate” should be construed as “a disc-shaped nub.” PO Resp. 13. The parties agree that “annular” means “ring-shaped” (Pet. 53) or in “the form of a ring” (PO Resp. 13).

We adopt Patent Owner’s proposed construction for the term “plate.” That construction—“a disc-shaped nub”—is supported by the Specification

and claims of the '574 patent. Independent claims 1 and 9 each recites: “nubs of dielectric material extending outwardly from said electrochemically active surface.” Ex. 1001, 2:22–23, 2:50–51. Claims 2 and 13 depend from claims 1 and 9, respectively, and each recites: “at least one of said at least two nubs is in the form of a plate.” *Id.* at 2:30–31, 3:1–2. The term “plate” must be construed as having a narrower meaning than the term “nub” because otherwise claims 2 and 13 would not further limit claims 1 and 9, as required by statute. 35 U.S.C. § 112, fourth paragraph. The Specification describes an “annular plate” as an example of a “nub” (Ex. 1001, 1:61–62), thus reinforcing that “plate” has a narrower meaning than “nub.” Petitioner agrees that “plate” has a narrower meaning than “nub.” Tr. 7:4–7. Our construction is supported by Figures 1 and 2, which show side views of annular plates 22, which appear to be disc-shaped objects surrounding wire 12. *Id.* at Figs. 1, 2; *see also id.* at 1:43–47 (brief description of the drawings). Our construction is further supported by the description of annular plates 22 as being formed between cavities 20 by laser-ablating polyimide layer 14 on either side of each plate. *Id.* at 1:57–61.

Petitioner does not contest Patent Owner’s assertion that a “plate” is a “flat, disc-shaped object.” *Compare* PO Resp. 13, *with* Pet. Reply 30; *see also* Tr. 7:8–24. We reject Petitioner’s contention that a “plate” is “a portion of material emanating from a center point.” Pet. 52. Petitioner’s definition would require a spherical shape, which is not supported by the Specification or drawings of the '574 patent. Even if Petitioner’s construction does not require a spherical shape, it would blur the distinction between a “nub” and a “plate.”

Accordingly, we adopt Patent Owner's proposed construction and construe a "plate" as a "disc-shaped nub."

4. *"permselective layer" (proposed substitute claim 20)*

Petitioner contends that "permselective layer" should be construed as "a layer that is 'selectively permeable to certain molecules or ions.'" Pet. Opp. 5 (quoting Ex. 1020, a dictionary definition for "permselective").

Patent Owner contends that "permselective membrane" means "a membrane that regulates the passage of different molecules at different rates." PO Reply 5 (citing Ex. 2008 ¶ 74).⁴ Patent Owner relies on Dr. Smith's testimony that "a 'permselective layer' serves to slow glucose diffusion (without significantly slowing oxygen diffusion) sufficient to ensure that the glucose and oxygen are in proper balance." Ex. 2008 ¶ 74. Patent Owner's proposed construction is not, however, limited to a layer that regulates diffusion of glucose and oxygen.

Based on the record before us and for the reasons explained below, we construe "permselective layer" as "a layer that regulates the passage of different molecules or ions at different rates." Our construction is similar to Patent Owner's proposed construction, with the addition of "ions" as species whose passage can be regulated.

Our construction is supported by the intrinsic evidence, including the Specification of the '574 patent (Ex. 1001) and Wilson (Ex. 1003), which is incorporated by reference in the '574 patent.

⁴ The term recited in proposed substitute claim 20 is "permselective layer," not "permselective membrane." We view Patent Owner's proposed construction as applying equally to the term recited in the claim.

The '574 patent discloses that, to form a glucose sensor, a work piece is coated with “a set of layers,” which “typically include an interferent excluding layer, a glucose oxidase layer and a permselective layer.” Ex. 1001, 1:52–53, 1:63–2:4. For details regarding these layers, the '574 patent refers to Wilson, which is incorporated by reference in the '574 patent. *Id.* at 2:1–4. The layers listed in the '574 patent—(1) an interferent excluding layer, (2) a glucose oxidase layer, and (3) a permselective layer—correspond one-to-one with Wilson’s disclosure of: (1) an inner membrane made of, e.g., cellulose acetate or Nafion (Ex. 1003, 2:66–3:2, 3:26–30, 5:34–36, 5:58–61, 6:5–7, 6:22–25, 6:36–38, 7:43–44, 8:41–42); (2) a glucose oxidase (GOx) enzyme layer (*id.* at 2:66–3:2, 5:36–38, 5:61–65, 6:7–15, 6:34–35, 7:44–45, 8:42–43); and (3) an outer membrane made of polyurethane (*id.* at 3:3–14, 6:64–7:12, 7:45–46, 8:45–47). Petitioner argues that each of Wilson’s three layers is a permselective membrane. Pet. Opp. 4. We disagree. In view of the one-to-one correspondence of the layers, as outlined above, and Wilson’s characterization of the polyurethane layer, as discussed below, we agree with Patent Owner (PO Reply 6) that the “permselective layer” in the '574 patent corresponds to Wilson’s outer polyurethane layer.

Wilson’s description of an outer polyurethane layer supports our construction for “permselective layer.” According to Wilson, the polyurethane layer “provides a diffusional barrier for glucose which slows down the flow of glucose and creates a linear sensor response over the concentration ranges of interest.” Ex. 1003, 3:11–14. In addition, Wilson states that this membrane “regulate[s] the passage of molecules therethrough to an extent that the enzymatic reaction between the indicating surface and

these molecules is determined by the rate of diffusion through the membrane, and not the enzymatic reaction kinetics.” *Id.* at 3:17–22. These descriptions support our construction, which defines a “permselective layer” as “a layer that regulates the passage of different molecules or ions at different rates.”

Our construction is also supported by extrinsic evidence, namely the Handbook (Ex. 1024), which Petitioner relies upon as a prior art reference and both parties rely upon as support for their respective constructions. PO Reply 8; Pet. Sur-Reply 2. The Handbook states:

Permselectivity is the ability of a membrane to allow a high flux of one chemical species (typically the analyte) while reducing or eliminating the flux of other species (chemical or sensor interferences).

Ex. 1024, 356.

The Handbook provides an “extreme example” of a permselective membrane, where the rate of diffusion of specific ions through the membrane is “vanishingly small.” *Id.* In contrast to this “extreme example,” the Handbook states that “[m]ore commonly, permselective membranes create a differential in the transport rate of different species.” *Id.* The Handbook’s definition and description of permselectivity demonstrates that a “permselective layer” is a layer that regulates the passage of different chemical species at different rates, i.e., high flux versus low or no flux. *Id.* The Handbook’s description also demonstrates that a permselective layer may regulate the passage of various chemical species, including both molecules and ions. *Id.*

Our construction is also supported by the undisputed testimony of Dr. Smith that a “permselective layer” in the ’574 patent “refers to a

membrane that regulates the passage of different molecules at different rates, and in the preferred embodiment, the two molecules are oxygen and glucose.” Ex. 2024 ¶ 11.

Both Wilson’s description of an outer polyurethane layer and the Handbook’s description of permselectivity demonstrate that Petitioner’s proposed construction is inaccurate or incomplete to the extent that it omits any requirement that a “permselective layer” regulate the passage of different molecules or ions at different rates. Ex. 1003, 3:11–14, 3:17–22; Ex. 1024, 356.

Accordingly, we construe “permselective layer” as “a layer that regulates the passage of different molecules or ions at different rates.”

B. Principles of Law

Regarding the issued claims of the ’574 patent, all of which are challenged in the Petition, Petitioner bears the burden of proving unpatentability, 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).

Regarding the proposed substitute claims presented in Patent Owner’s Contingent Motion to Amend, Patent Owner does not bear the burden of persuasion to demonstrate the patentability of the substitute claims. *Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (en banc). Rather, as a result of the current state of the law and USPTO rules and guidance,⁵

⁵ See *Aqua Products*, 872 F.3d 1290; Memorandum “Guidance on Motions to Amend in view of *Aqua Products*” (Nov. 21, 2017)

the burden of persuasion lies with Petitioner to show that the proposed substitute claims are unpatentable by a preponderance of the evidence.

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 (“POSITA”) provided by Petitioner’s declarant, Dr. Vachon. Dec. 11 (citing Ex. 1006 ¶ 28). That definition is: a person having a bachelor’s degree or the equivalent training or experience in mechanical engineering, bioengineering, or related field and at least three years of experience relating to biosensor research and development, or a master’s degree or the equivalent training or experience in mechanical engineering, bioengineering, or related field, and at least one year of experience relating to biosensor research and development. *Id.* Patent

(https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf); *Bosch Automotive Service Solutions, LLC v. Matal*, 878 F.3d 1027 (Fed. Cir. 2017); *Bosch Automotive Service Solutions, LLC v. Iancu*, Order on Petition for Panel Rehearing, No. 2015-1928 (Fed. Cir. Mar. 15, 2018).

Owner's declarant accepts and applies this definition of a POSITA for purposes of his opinions. Ex. 2008 ¶ 30. Neither party's declarant indicates that any proffered opinion would change depending on the level of ordinary skill in the art.

Therefore, consistent with our Institution Decision, we adopt Dr. Vachon's definition of a POSITA. Ex. 1006 ¶ 28. 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 and Smith, 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 POSITA. Regarding Dr. Vachon, we rely in particular on his experience as director of glucose sensor research and development at MiniMed Inc. 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. 2008 ¶¶ 3–5, App. A. There is no contention that either of these declarants is not qualified to testify as an expert in this case.

D. Prior Art References

1. Hagiwara (Ex. 1005)

Hagiwara discloses an intravenous polarography⁶ sensor for measuring the concentration of blood components, such as oxygen or

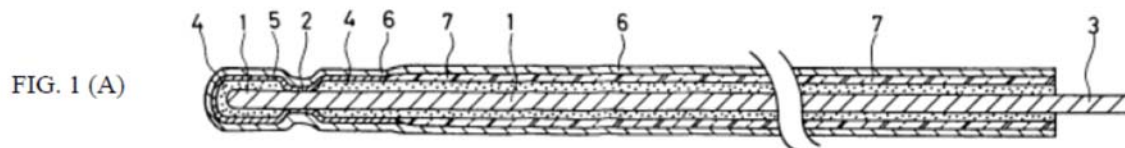
⁶ Both sides' experts explain that polarography is an electrochemical analysis technique. Ex. 1006 ¶ 66; Ex. 2001 ¶ 37.

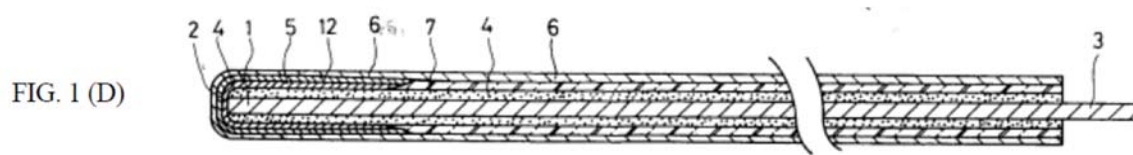
glucose, in animals and humans. Ex. 1005, 1 (Title), 2:46–3:2, 4:1–6, 4:16–21. Hagiwara discloses an embodiment that comprises a metal wire having an electrode reaction surface; an insulating layer covering the metal wire excluding the electrode reaction surface; a plastic layer containing dispersed enzyme and covering the electrode reaction surface and the insulating layer; and a blood coagulation inhibiting coating covering the plastic layer. *Id.* at 2:31–40 (claim 7).

Hagiwara explains how polarography can be used to measure the concentration of substances in aqueous solution. Ex. 1005, 3:3–46. According to Hagiwara, substances such as glucose that are difficult to measure using “direct polarography” can be measured using “indirect polarography,” whereby enzymes for the target substance are fixed on reaction surfaces of the measuring electrode and in the vicinities thereof. *Id.* at 3:26–32, 4:1–6.

Hagiwara’s disclosed invention aims to solve the problem of blood coagulation caused by interaction of blood with electrode surfaces. Ex. 1005, 4:12–14, 4:16–21. Hagiwara’s solution is to provide a coating containing heparin as an anticoagulant. *Id.* at 4:38–41.

Hagiwara illustrates four embodiments in Figures 1(A) through 1(D). Petitioner relies on the embodiments shown in Hagiwara Figures 1(A) and 1(D), which are reproduced below:





Hagiwara Figure 1(A) shows a polarography sensor including precious metal wire 1, electrode reaction surface 2, connecting terminal 3, insulating layer 4, contamination inhibiting coating 5, blood coagulation inhibiting coating 6, and metal tube 7. Ex. 1005, 5:2–22. According to Hagiwara, coating 6 is formed by repeatedly immersing the polarography sensor in an aqueous solution of plastic and homogeneously dispersed heparin, removing the sensor from the solution, and allowing it to dry. *Id.* at 5:29–45. Hagiwara discloses that, while electrode reaction surface 2 is provided on a side surface of precious metal wire 1 in Figure 1(A), the front end surface of precious metal wire 1 may be an electrode reaction surface, as illustrated in Figure 1(D). *Id.* at 5:45–6:2.

Hagiwara Figure 1(D) shows a polarography sensor that forms an electrode for indirect (enzymatic) polarography, which includes enzyme-containing porous plastic layer 12, in addition to elements 1–7 listed in the preceding paragraph. Ex. 1005, 6:42–46; *see also id.* at 5:2–22 (describing elements 1–7, which are common to Figs. 1(A) and (D)). According to Hagiwara, layer 12 is formed between contamination inhibiting coating 5 and blood coagulation inhibiting coating 6. Ex. 1005, 6:42–46.

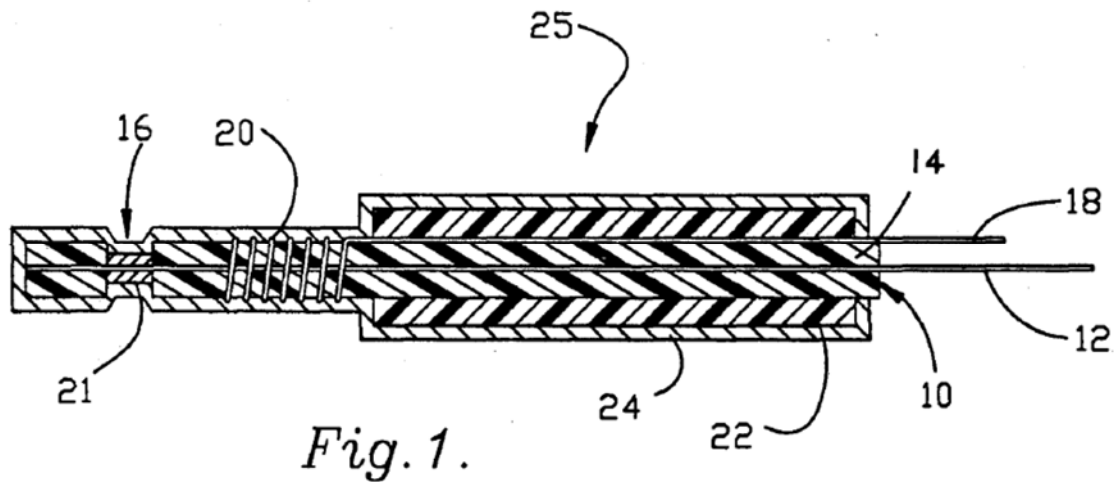
2. Wilson (Ex. 1003)

Wilson discloses an implantable enzymatic sensor for detecting an analyte, such as glucose.⁷ Ex. 1003, [57], 1:10–22, 2:7–15. Wilson

⁷ Wilson is incorporated by reference in the '574 patent. Ex. 1001, 2:1–4.

discloses a sensor electrode comprising a platinum-iridium wire coated with Teflon insulation. A short section of the insulation is removed to define a recessed enzyme-receiving circumferential zone, and enzyme is immobilized on the exposed section of the wire. *Id.* at 2:40–43, 2:52–3:2. A permeable protective layer of polyurethane covers at least the enzymatic indicating surface and preferably the entire electrode. *Id.* at 3:3–11.

An embodiment is shown Figure 1, which is reproduced below:



Wilson Figure 1 shows glucose sensor 25, including section 10 of platinum-iridium wire 12 having Teflon coating 14, enzymatic indicating layer 21 within cavity 16, reference electrode 18 including coil 20, Teflon tubing 22, and outer polyurethane membrane 24. Ex. 1003, 4:36–37, 4:64–5:3, 5:10–23, 5:36–38, 6:64–7:5.

Wilson Example 1 discloses a method for constructing the glucose sensor shown in Figure 1. *Id.* at 4:56–7:12. According to Wilson, the Teflon coating is cut and pulled out to form cavity 16 and expose a corresponding section of wire 12. *Id.* at 5:1–9. An inner membrane is applied to the exposed wire section, and a circumferentially extending enzymatic indicating layer 21 is formed within cavity 16. *Id.* at 5:33–38.

Wilson discloses two methods for immobilizing enzyme on the exposed section of wire 12. *Id.* at 5:33–6:63. According to the first method, the portion of the sensor to the left of coil 20 is dipped into a solution of cellulose acetate. *Id.* at 5:47–61. The resulting cellulose acetate membrane is covalently coupled to bovine serum albumin (BSA), which is subsequently reacted with activated enzyme. *Id.* at 5:61–65. Wilson refers to Sternberg⁸ for the details of the enzyme reaction step. *Id.* at 5:65–68.

According to Wilson's second method for immobilizing enzyme, the sensor is first coated with cellulose acetate, Nafion, or other polymer. Enzyme is then physically adsorbed by dropping a solution of enzyme within cavity 16. The polymer is subsequently cross-linked by exposure to glutaraldehyde vapor. *Id.* at 6:1–63.

Wilson discloses that preparation of the sensor of Figure 1 is completed by dip-coating the assembly with polyurethane to form outer membrane 24. *Id.* at 6:64–7:12.

3. *Remaining References*

In view of our disposition of the issues raised by the Petition and Patent Owner's Contingent Motion to Amend, we do not need to discuss in detail the remaining references, Ryan, Say, or the Handbook.

⁸ Robert Sternberg et al., *Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development*, Anal. Chem. 60, 2781–2786 (1988), Ex. 1009 (“Sternberg”). Sternberg is incorporated by reference in Wilson. Ex. 1003, 6:65–68.

E. Obviousness Based On Hagiwara (Claims As Issued)

Petitioner contends that claims 1–19 are unpatentable as obvious over Hagiwara. Pet. 37–63. Patent Owner opposes. PO Resp. 14–40. We address the parties’ arguments and evidence below.

1. Independent Claims 1 and 9: Element-by-Element Analysis

a. Preamble

The preamble of claim 1 recites: “an indwelling analyte sensor.” Ex. 1001, 2:20. The preamble of claim 9 is identical to the preamble of claim 1. *Compare id.*, with *id.* at 2:46.

Petitioner contends that Hagiwara discloses the preamble of claims 1 and 9, directing us to Hagiwara’s disclosure of “a polarography sensor used by being inserted into a blood vessel.” Pet. 41 (citing Ex. 1005, 2:46–3:1). According to Petitioner, Hagiwara’s sensor is configured to reside within a blood vessel and to measure analytes, such as glucose. *Id.* (citing Ex. 1005, 6:42–7:5); *see also id.* at 58 (same contentions for claim 9 as for claim 1).

Patent Owner contends it would not have been obvious to use Hagiwara for an indwelling sensor. PO Resp. 15. According to Patent Owner, Hagiwara’s heparin coating presents “known dangers” such that a POSITA seeking to construct an indwelling sensor “would not have been inclined to look to Hagiwara at all.” PO Resp. 17 (citing Ex. 2008 ¶¶ 39–43). Patent Owner further contends that “Hagiwara teaches away from the known, safe approach of immobilizing the heparin.” *Id.*

Aside from its heparin argument, Patent Owner does not dispute Petitioner’s contention that Hagiwara discloses an indwelling analyte sensor, such as a glucose sensor. Petitioner’s contention is supported by the cited disclosures of Hagiwara. Ex. 1005, 2:46–3:1, 6:42–7:5. The ’574 patent

does not define “indwelling” or specify where or how long a sensor needs to dwell within a human or animal to qualify as “indwelling.” Under these circumstances, Hagiwara’s disclosure of an intravenous sensor for measuring analyte within a blood vessel for longer than five hours qualifies as “indwelling.” *Id.* at 4:1–6, 7:32–36, 7:46–8:1, Figs. 2, 3.

We are persuaded that a POSITA would have considered Hagiwara for purposes of solving the problem addressed by the ’574 patent, notwithstanding any “known dangers” of Hagiwara’s heparin coating. PO Resp. 17. As discussed above, the problem addressed by the ’574 patent relates to dip coating to form an enzyme layer of sufficient thickness over an electrochemically active surface. Ex. 1001, 1:6–14, 2:8–10. The claimed solution involves nubs of dielectric material and an enzyme layer surrounding the nubs. *Id.* at 2:6–8, 2:22–29. For these claim elements, Petitioner directs us to Hagiwara’s teachings regarding dip coating membrane layers over an electrochemically active surface and the resulting structure. Pet. 44–45 (citing Ex. 1005, 5:10–13, 5:38–41, Fig. 1(A)). A POSITA would have considered these teachings relevant to the problem addressed by the ’574 patent, even if he had concerns about the safety of Hagiwara’s heparin coating. Any such concerns do not detract from the viability of Hagiwara’s membrane structure. *Belden Inc. v. Berk-Tek LLC*, 805 F. 3d 1064, 1076 (Fed. Cir. 2015) (“[a] reference must be considered for everything it **teaches** by way of technology and is not limited to the particular **invention** it is describing and attempting to protect,” quoting *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985) (emphases in original)).

Furthermore, Petitioner persuades us that the “known dangers” of heparin would not have dissuaded a POSITA from relying on Hagiwara. Pet. Reply 19–21. Patent Owner contends that heparin “can . . . be fatal in large doses” and “can cause a dangerous condition known as heparin-induced thrombocytopenia (HIT).” PO Resp. 16 (citing Ex. 2008 ¶¶ 41–42, which in turn cite Exs. 2015 and 1016). For the following reasons, however, we are persuaded that the risk of heparin-induced complications are not sufficiently pertinent to Hagiwara that a POSITA would have avoided the reference.

First, Petitioner persuades us that a POSITA would have known how to reduce the risk of heparin-induced complications by selecting the proper type and amount of heparin. Pet. Reply 19. Patent Owner’s evidence suggests that the risk of HIT can be reduced by using low molecular weight heparins (“LMWH”) instead of unfractionated heparin (“UHF”). Ex. 2016, 4.⁹ Petitioner’s evidence confirms that “HIT is less frequently observed while patients are on LMWH than when they are given UFH.” Ex. 1018, 42:1:1–3; *see also* Ex. 1021, 94:18–21 (in 2003 it was known that some types of heparin are less associated with HIT than unfractionated heparin).

Second, Petitioner asserts, without opposition from Patent Owner, that the dosages that caused HIT according to Patent Owner’s evidence are substantially greater than the amount of heparin that could be released from Hagiwara’s coating. Pet. 20–21 (Patent Owner’s evidence analyzes cases of HIT from heparin doses “at levels 9 to 900 times greater than the doses suggested by Hagiwara.”); *see also id.* at 19 (estimating amount of heparin

⁹ We cite to Exhibits 2015 and 2016 using the page numbers added by Patent Owner at the bottom right corner of each page.

in Hagiwara's coating). Furthermore, Hagiwara teaches that heparin "dissolves gradually into the blood," further reducing the dosage level. Ex. 1005, 4:28–29.

Third, Petitioner's evidence demonstrates that, in the decades since publication of Hagiwara, heparin coatings have been commonly suggested for use on indwelling analyte sensors. Ex. 1022, 6:35–42, 26:64–27:6 (Say, filed in 1998, disclosing implanted analyte sensor having an anticlotting agent, e.g., heparin, disposed on a portion of the substrate that is implanted); Ex. 1014, 74:9–17, 159:50–53 (patent filed in 2008 disclosing analyte sensor having a heparin coating to prevent blood clotting, where the sensor can be implanted for an extended period, e.g., 30 or more days). As shown by Petitioner's evidence, the risks of heparin-induced complications have not discouraged those skilled in the art from proposing heparin coatings for use on indwelling analyte sensors.

Accordingly, we are persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches an indwelling analyte sensor, as recited in the preamble of claims 1 and 9, and that a POSITA would have relied on Hagiwara, notwithstanding its teachings regarding a heparin coating.

b. First Element

The First Element of claim 1 recites: "an electrochemically active surface." Ex. 1001, 2:21. The First Element of claim 9 recites: "an electrochemically active surface defining a sensing region along a portion of said electrochemically active surface." *Id.* at 2:47–49.

Petitioner contends that the First Element is disclosed by precious metal wire 1 and electrode reaction surface 2 of Hagiwara's Figure 1(A)

embodiment. Pet. 41–42 (citing Ex. 1005, 3:3–5, 5:3–5, 5:9–11, Fig. 1(A)); *id.* at 58–59 (same citations for claim 9).

Patent Owner does not dispute that Hagiwara discloses the First Element of claims 1 and 9.

Petitioner contends that the “electrochemically active surface” of claims 1 and 9 corresponds to the surface of Hagiwara’s precious metal wire 1, and the “sensing region” of claim 9 corresponds to Hagiwara’s electrode reaction surface 2. Pet. 42, 59. Petitioner’s contention is supported by Hagiwara, including claim 7, Figure 1(A), and the description of that embodiment. Hagiwara claim 7 discloses a “polarography sensor comprising: a metal wire having at least an electrode reaction surface made of a precious metal.” Ex. 1005, 2:31–32. According to Hagiwara, the “measuring electrode (working electrode) [may be] made of a precious metal such as platinum, gold, and the like.” *Id.* at 3:3–5. In describing the Figure 1(A) embodiment, Hagiwara states that the “portion of the side surface of the precious metal wire 1 that is exposed from the insulating layer 4 . . . is the electrode reaction surface 2.” *Id.* at 5:9–11. Hagiwara thus discloses an electrochemically active surface corresponding to the surface of precious metal wire 1, and a sensing region corresponding to Hagiwara’s electrode reaction surface 2.

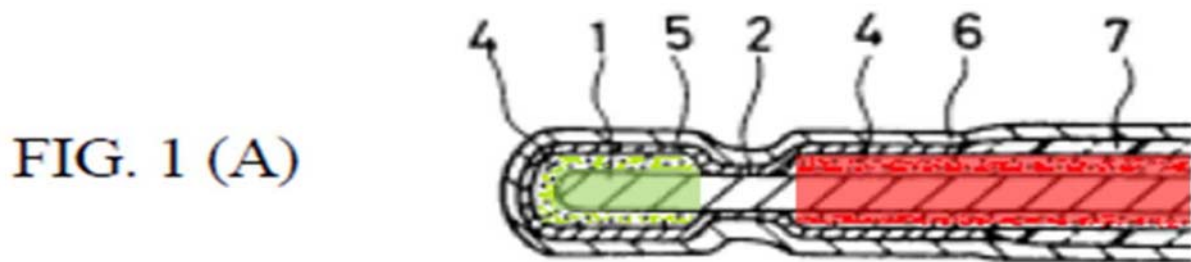
Accordingly, we are persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches the First Element of claims 1 and 9.

c. Second Element

The Second Element of claim 1 recites: “at least two nubs of dielectric material extending outwardly from said electrochemically active

surface.” Ex. 1001, 2:22–23. The Second Element of claim 9 recites: “a plurality of nubs of dielectric material extending outwardly from said electrochemically active surface.” *Id.* at 2:50–51.

Petitioner contends that the Second Element is disclosed by the portions of Hagiwara’s insulating layer 4 highlighted in green and red in the following annotated and excerpted version of Hagiwara Figure 1(A), which is reproduced from the Petition:



Polarography Sensor

Pet. 42–44 (citing Ex. 1005, 5:3–11, Fig. 1(A)); *see also id.* at 59 (same contentions for claim 9 as for claim 1).

Patent Owner does not dispute that Hagiwara discloses the Second Element of claims 1 and 9.

We agree with and adopt Petitioner’s contention, which is supported by Hagiwara, including Figure 1(A), which shows “at least two nubs of dielectric material extending outwardly from said electrochemically active surface” in the same way that this feature is shown by the proximal and distal portions of polyimide layer 14 in Figures 1 and 2 of the ’574 patent. The parties agree that these portions of layer 14 are “nubs” under their agreed claim construction, which we have adopted. Pet. 11; Prelim. Resp. 15; *see* Section II.A.1., *supra*.

Accordingly, we are persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches the Second Element of claims 1 and 9.

d. Third Element

The Third Element of claim 1 recites: “forming a cavity along said electrochemically active surface and between said at least two nubs.” Ex. 1001, 2:23–25. The Third Element of claim 9 recites: “said plurality of nubs spaced along said electrochemically active surface.” *Id.* at 2:51–53.

Petitioner contends that the Third Element is disclosed by Hagiwara Figure 1(A), referring to the above annotated version of the figure. Pet. 44 (claim 1); *id.* at 59–60 (claim 9). For claim 1, Petitioner contends that “a reaction surface cavity 2 . . . is present between the green and red highlighted insulation layer 4 dielectric nubs.” *Id.* at 44. For claim 9, Petitioner contends that insulation layer 4 nubs, indicated in red and green, are spaced along the electrochemically active surface of noble metal wire 1. *Id.* at 59.

Patent Owner does not dispute that Hagiwara discloses the Third Element of claims 1 and 9.

We agree with and adopt Petitioner’s contention, which is supported by Hagiwara Figure 1(A) and the description of that embodiment. Hagiwara discloses that, in Figure 1(A), insulating layer 4 covers an outer surface of the front end of precious metal wire 1, except for electrode reaction surface 2. Ex. 1005, 5:3–4. According to Hagiwara, “the portion of the side surface of the precious metal wire 1 that is exposed from the insulating layer 4 . . . is the electrode reaction surface 2.” *Id.* at 5:10–11. Hagiwara’s description of Figure 1(A) demonstrates that the portions of insulating layer 4 on either

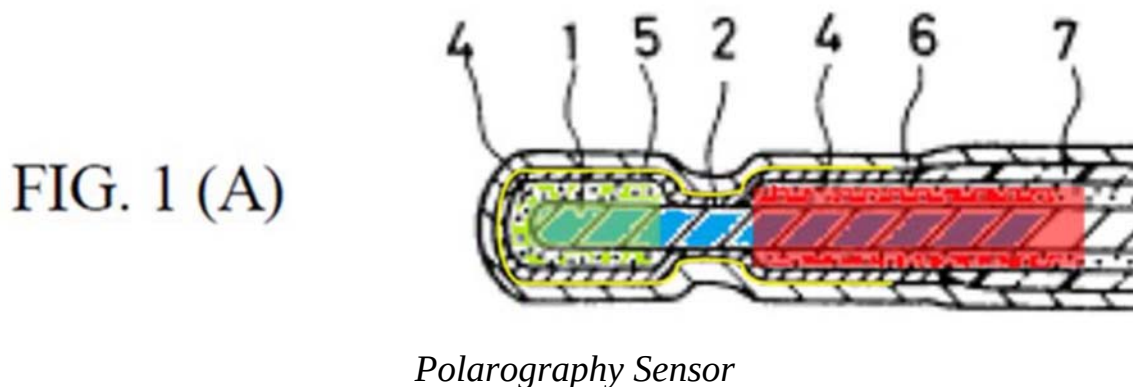
side of electrode reaction surface 2 are “nubs” that are spaced along the electrochemically active surface of precious metal wire 1 and form a cavity along electrode reaction surface 2 and between the two nubs.

Accordingly, we are persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches the Third Element of claims 1 and 9.

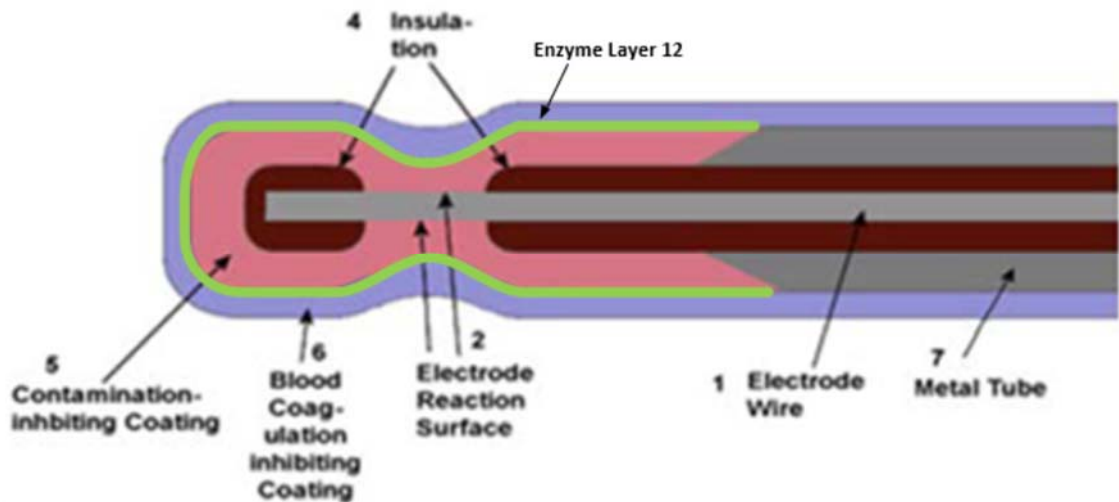
e. Fourth Element

The Fourth Element of claim 1 recites: “a membrane system comprising an enzyme layer, said enzyme layer surrounding said at least two nubs and said electrochemically active surface at least along said cavity.” Ex. 1001, 2:26–29. The Fourth Element of claim 9 recites: “a membrane system comprising an enzyme layer, said enzyme layer surrounding said sensing region of said electrochemically active surface to form an active sensing region and surrounding said plurality of nubs.” *Id.* at 2:54–57.

Petitioner contends that the Fourth Element is taught by a combination of Hagiwara’s Figure 1(A) embodiment and an enzyme layer, as disclosed by Hagiwara’s Figure 1(D) embodiment. Pet. 45–47 (claim 1); *id.* at 60 (claim 9). Petitioner illustrates its proposed combination with the following figures, which are reproduced from the Petition and the Reply:



Pet. 46, 60.



Polarography Sensor

Pet. Reply 11.¹⁰

Although Patent Owner contends it would not have been obvious to combine the enzyme layer from Hagiwara's Figure 1(D) embodiment with Hagiwara's Figure 1(A) embodiment (PO Resp. 1–2, 17–40), Patent Owner does not dispute that Petitioner's proposed combination, as illustrated above, discloses the Fourth Element of claims 1 and 9. See Ex. 1021, 170:16–19, 170:24–171:5 (Dr. Smith admits that Petitioner's illustration has nubs and an enzyme layer surrounding at least two nubs and the electrochemically active surface at least along said cavity). Aside from the issue of motivation, Patent Owner also does not dispute that Petitioner's illustrations (Pet. 46, Pet. Reply 11) show how a POSITA would have combined the enzyme layer of Hagiwara's Figure 1(D) embodiment with Hagiwara's Figure 1(A) embodiment.

¹⁰ Petitioner's illustration in the Reply is a modification of Patent Owner's rendition of Hagiwara Figure 1(A). See PO Resp. 9; Ex. 2008 ¶ 46 (same figure, without Enzyme Layer 12). The illustration was marked as Exhibit Q during the deposition of Dr. Smith. Ex. 1021, 167:13–168:3.

We determine that Petitioner's proposed combination is supported by Hagiwara, including Figure 1(A) and the description of that embodiment.¹¹ Hagiwara Figure 1(A) shows layers 5 and 6 covering the front end of the sensor. Ex. 1005, Fig. 1(A). Hagiwara discloses that "[t]he outermost surface of this polarography sensor is a plastic coating 6" and "contamination inhibiting coating 5 is provided between [a] the electrode reaction surface 2 and the insulating layer 4 in the vicinity thereof, and [b] the plastic coating 6." *Id.* at 5:11–12, 5:15–17 (bracketed letters added for clarity and consistency with Fig. 1(A)). Hagiwara discloses that layer 6 is formed by an immersion and drying operation. Specifically, the "polarography sensor with the contamination inhibiting coating 5 formed in the vicinity of the front end thereof is immersed in the plastic solution . . . , removed, and then held in mid-air to thus evaporate the plastic solvent and form a thin coating." *Id.* at 5:37–40; *see also id.* at 5:41 ("[t]his . . . operation is normally repeated two or three times"). Hagiwara thus teaches that layers 5 and 6 are sequential coatings that surround electrode reaction surface 2, as well as portions of insulation layer 4 in the vicinity of electrode reaction surface 2.

Petitioner's proposed combination is also supported by Hagiwara Figure 1(D) and Hagiwara's description of that embodiment. Hagiwara Figure 1(D) shows electrode reaction surface 2 at the front tip of precious metal wire 1 and enzyme layer 12 between layers 5 and 6. Ex. 1005, 5:45–6:2, Fig. 1(D). Hagiwara provides the following description of Figure 1(D):

¹¹ The issue of motivation to combine is discussed in Sections II.E.2. and II.E.3. below.

FIG. 1 (D) is a polarography sensor that forms an electrode for indirect polarography for applying an enzymatic reaction where a porous plastic layer 12 is formed that homogeneously disperses and fixes an enzyme on the contamination inhibiting coating 5 of the electrode reaction surface 2 of the measuring electrode classified in the embodiment described in FIG. 1 (A), which plastic layer is, in turn, covered by the blood coagulation inhibiting coating 6.

Id. at 6:43–46.

Hagiwara thus teaches that, in the Figure 1(D) embodiment, enzyme layer 12 is formed between layers 5 and 6 in order to provide an indirect polarography sensor.

Accordingly, we are persuaded that Petitioner's proposed combination is supported by Hagiwara's Figure 1(A) and 1(D) embodiments and teaches the Fourth Element of claims 1 and 9.

2. *Whether Petitioner Has Shown a Motivation to Combine Hagiwara's Figures 1(A) and 1(D) Embodiments*

Petitioner contends it would have been obvious to modify Hagiwara's Figure 1(A) embodiment to add an enzyme layer, as disclosed by Hagiwara's Figure 1(D) embodiment. Pet. 47–52 (citing Ex. 1006 ¶¶ 147–156). Petitioner contends the proposed combination would “expand the sensor's universe of detectable analytes,” for example, by enabling “glucose sensing instead of oxygen.” Pet. 48–49. According to Petitioner, Hagiwara teaches “a sensor that can be easily adapted for sensing one of several different analytes through the selection and incorporation of the appropriate enzyme layer.” *Id.* at 50 (citing Ex. 1005, 3:3–30). Petitioner contends the “only difference” between its proposed combination and Hagiwara's Figure 1(D) is the location of the sensor window on the side versus at the tip of the sensor, which Petitioner asserts are “alternate form factors.” Pet. 40, 52; *see also* Ex. 1006 ¶¶ 147, 73 (same). Petitioner contends that Hagiwara provides an express teaching, suggestion, and motivation to combine Figure 1(D)'s enzyme layer into the Figure 1(A) embodiment “to form an electrode of ‘long and slender form’ for use in intravenous indirect polarography.” *Id.* at 51–52 (quoting Ex. 1005, 4:1–6).

Patent Owner contends there would have been no reason to combine Hagiwara Figure 1(A) with Figure 1(D). PO Resp. 17–27. According to Patent Owner, Hagiwara does not explicitly teach the combination of Figure 1(D)'s enzyme layer and a sensor with a reaction surface on the side, like Figure 1(A). *Id.* at 18. Patent Owner argues that Petitioner fails to show that a POSITA would have been motivated to make this combination. *Id.* at 18–27.

After considering the parties' arguments and evidence, we determine that a preponderance of the evidence establishes it would have been obvious to modify Hagiwara's Figure 1(A) embodiment to add an enzyme layer, as disclosed by Hagiwara's Figure 1(D) embodiment.¹²

Our determination is supported by the express teachings of Hagiwara. Hagiwara teaches a polarography sensor for measuring the concentration of substances in blood by "direct polarography" or "enzymatic (indirect) polarography." Ex. 1005, 1 (Title), 2:46–4:6, 4:16–21. In direct polarography, the concentration of an oxidizing substance, such as oxygen, or a reducing substance, such as hydrogen, is measured at a measuring electrode. *Id.* at 3:3–26. In indirect polarography, the target substance, such as glucose, undergoes an enzyme-catalyzed reaction, and the concentration of either the reactants or products is measured by polarography. *Id.* at 3:26–46. According to Hagiwara, substances that are difficult to measure by direct polarography can be measured "by fixing enzymes . . . on reaction surfaces of measuring electrodes and in the vicinities thereof." *Id.* at 3:28–29. For target substances other than glucose, Hagiwara states that indirect polarography enables measurement "with much higher selectivity (specificity) than with direct polarography," when an enzyme for the target substance is fixed to the measuring electrode. *Id.* at 3:38–43. Hagiwara thus expressly provides at least two reasons or motivations for including an enzyme layer in a polarography sensor: (1) to enable measurement of glucose and other substances that are difficult to measure by direct

¹² As discussed in the preceding section, Petitioner's proposed combination, with enzyme layer 12 between layers 5 and 6 of Hagiwara Figure 1(A), is supported by Hagiwara and teaches the Fourth Element of claims 1 and 9.

polarography; and (2) to enable higher selectivity (specificity) than is possible with direct polarography. *Id.* at 3:26–30, 3:38–43.

Hagiwara discloses four polarography sensor embodiments, which are illustrated in Figures 1(A) through 1(D). Ex. 1005, 4:43–44. The Figure 1(A) embodiment is described in detail (*id.* at 5:2–6:11), and each of the Figure 1(B) through 1(D) embodiments is described as a variation of the Figure 1(A) embodiment (*id.* at 6:12–7:5). Whereas Hagiwara’s Figure 1(A) embodiment is a direct polarography sensor with no enzyme layer, Hagiwara’s Figure 1(D) embodiment is an indirect polarography sensor and includes an enzyme layer. *Compare id.* at 5:2–18 (description of Fig. 1(A)), *with id.* at 6:43–7:5 (description of Fig. 1(D)). Aside from the enzyme layer, Hagiwara Figures 1(A) and 1(D) also differ with respect to the location of the electrode reaction surface (sensor window). Whereas Hagiwara Figure 1(A) shows electrode reaction surface 2 on a side surface of precious metal wire 1, Hagiwara Figure 1(D) shows electrode reaction surface 2 on the front end surface of precious metal wire 1. *Id.* at 5:45–6:2, Figs. 1(A), (D).

Hagiwara expressly teaches that the side surface and end surface are alternative locations for the sensor window. Ex. 1005, 5:45–6:2, 6:20–22. Although this teaching explicitly pertains to the Figure 1(A) and 1(B) embodiments, we find that a POSITA would have understood the teaching as equally applicable to an embodiment having an enzyme layer, such as Hagiwara Figure 1(D). Our finding is supported by Hagiwara claim 7, which is directed to a polarography sensor having an enzyme layer and is not limited to an end sensor window. Claim 7 recites “an electrode reaction surface” and an enzyme layer that covers “the electrode reaction surface and the insulating layer outer surface in the vicinity thereof.” *Id.* at 2:31–40.

Claim 7 does not specify the location of the electrode reaction surface and is broad enough to encompass either a side sensor window, as shown in Hagiwara Figure 1(A), or an end sensor window, as shown in Hagiwara Figure 1(D). Our finding is further supported by the undisputed testimony of Dr. Vachon that “[o]ver the years, sensors in the 1(A) and 1(D) configurations have provided alternate form factors.” Ex. 1006 ¶ 73 (referring to the side sensor window of Hagiwara Fig. 1(A) and the end sensor window of Hagiwara Fig. 1(D)). Although the experts disagree as to which of these alternatives would have been the better choice (*compare* Ex. 1006 ¶ 155, *with* Ex. 2008 ¶¶ 54–57, 87–95), there is no dispute that an end sensor window and a side sensor window were known alternatives prior to the ’574 patent. *See* Tr. 43:22–44:3.

The record thus supports a motivation to combine a polarography sensor having a side sensor window, as disclosed by Hagiwara’s Figure 1(A) embodiment, with an enzyme layer, as disclosed by Hagiwara’s Figure 1(D) embodiment. The proposed combination modifies Hagiwara Figure 1(A) in the manner expressly taught by Hagiwara: by adding an enzyme layer between layers 5 and 6, with the enzyme layer covering the electrode reaction surface and the insulating layer in the vicinity thereof. Ex. 1005, 2:36–38, 3:30–31, 6:43–46, Fig. 1(D). As Hagiwara expressly teaches, the modification would have provided an indirect polarography sensor capable of measuring a variety of target substances, such as glucose, uric acid, and ascorbic acid, by incorporating the appropriate enzyme for these substances. *Id.* at 3:26–4:6, 6:46–7:5.

The evidence thus shows that an enzyme layer would benefit Hagiwara’s Figure 1(A) embodiment in the same way that an enzyme layer

benefits Hagiwara's Figure 1(D) embodiment. *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991 (Fed. Cir. 2009) (finding motivation to combine features of separate embodiments disclosed in a single reference, reasoning: "Just as the stent in figure 3B benefits from the two layers, . . . so would the stent in figure 4 benefit from the same two coating layers.")). Furthermore, the enzyme layer, the side sensor window, and the remaining components of Hagiwara's Figure 1(A) embodiment would perform the same functions in Petitioner's proposed combination, as they were known to perform in Hagiwara's disclosed embodiments. Patent Owner does not assert that the combination of an enzyme layer and a side sensor window yields unexpected results. *KSR*, 550 U.S. at 417 ("when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious," quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)).

We have considered Patent Owner's arguments regarding motivation to combine, but are nevertheless persuaded that Petitioner has met its burden of proof that a preponderance of the evidence supports Petitioner's obviousness contention.

Patent Owner argues that Hagiwara already discloses an enzyme-based indirect polarography sensor in Figure 1(D), so the need for such a sensor is "already fulfilled." PO Resp. 18–19. Hagiwara's disclosure of one enzyme-based embodiment does not mean there is no motivation to make other enzyme-based embodiments. That is especially true here, where the only difference between Petitioner's proposed combination and Hagiwara's enzyme-based embodiment in Figure 1(D) is the location of the sensor

window on the side versus the end of the sensor, which were undisputedly known alternatives.

Next, Patent Owner argues that “[a]ll four Hagiwara sensor embodiments are of ‘long and slender form,’ but the proposed combination would have been thicker” due to the additional membrane. PO Resp. 19–20 (quoting Ex. 1005, 4:1–6). We are persuaded that Petitioner has shown a motivation to combine, notwithstanding Patent Owner’s argument. Even if there would have been no improvement in the length or cross-sectional dimensions of the sensor, we are nevertheless persuaded that a demand for an enzyme-based indirect polarography sensor would have motivated a POSITA to make the proposed combination. Pet. 47–52.

Next, Patent Owner argues that “[t]he risk of damage to the end of the sensor would not have been a motivation to combine Hagiwara’s embodiments” because Hagiwara’s catheter prevents damage to the sensor during insertion and because a sensor with a side sensor window creates a greater risk of damage and vascular injury and reduces exposure to blood, as compared with a sensor with an end sensor window. PO Resp. 20–25. We have considered Patent Owner’s arguments, but, for the reasons discussed above, we are persuaded that Petitioner has established a motivation to combine, notwithstanding the conflicting expert testimony regarding the disadvantages of a side sensor window versus an end sensor window. Neither of the expert opinions on this topic is supported by objective facts or data. Ex. 1006 ¶ 155;¹³ Ex. 2008 ¶¶ 54–57, 87–95; Ex. 2009, 92:8–97:12. For this reason, we give little or no weight to either side’s expert testimony

¹³ Dr. Vachon cites “WO 01/13102, Vadgama” (Ex. 1006 ¶ 155), however, this reference was not submitted as an exhibit in this proceeding.

on this topic. 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”); *Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997) (nothing in the Federal Rules of Evidence or Federal Circuit jurisprudence requires the fact finder to credit unsupported assertions of an expert witness). As discussed above, however, there is no disagreement that a side sensor window was a known alternative to an end sensor window. Ex. 1006 ¶¶ 73, 155; Tr. 43:22–44:3. That undisputed fact, together with Petitioner’s other evidence, is sufficient to establish a motivation to combine.

Patent Owner additionally argues “there is no teaching in Hagiwara that an indirect polarography sensor using an enzyme could have been constructed with a side-facing sensing window.” PO Resp. 26. We disagree. Hagiwara teaches that the sensing window may be located either on the side or at the tip of the sensor. Ex. 1005, 5:45–6:2, 6:20–22. This teaching is not limited to direct polarography sensors, e.g., Hagiwara Figure 1(A), and applies equally to indirect polarography sensors, e.g., Hagiwara Figure 1(D). As support for this finding, we rely on Hagiwara claim 7, which is directed to an indirect (enzyme-based) polarography sensor and covers sensor windows in either location. *Id.* at 2:31–40. We also rely on the undisputed testimony of Dr. Vachon, which supports that a side sensor window and an end sensor window were known alternatives, regardless of whether the sensor has an enzyme layer. Ex. 1006 ¶¶ 73, 155. Moreover, Patent Owner’s argument is contradicted by Hagiwara’s description of the method of making the Figure 1(A) embodiment, which contains as much or more detail than the ’574 patent regarding how to form membrane layers

over a side-facing window. *Compare* Ex. 1005, 5:37–40 (describing an immersion and drying operation, which is repeated two or three times”), *with* Ex. 1001, 1:66–2:1 (“a sequence of dip coating operations interspersed with curing operations”).

3. *Whether Petitioner Has Shown that the Proposed Combination Would Have Worked for its Intended Purpose and Had a Reasonable Expectation of Success*

Petitioner contends that the combination of Hagiwara’s Figure 1(A) embodiment and an enzyme layer, “would have been predictable and successful, as evidenced by the arrangement of the same three membrane layers in the same order in the Fig. 1(D) embodiment, with the only difference being the use of a tip-sensor window in Fig. 1(D) instead of side-sensor window.” Pet. 52.

Patent Owner, on the other hand, argues that a POSITA “would not have had a reasonable expectation of success because the resulting sensor would be inoperable to sense key analytes, such as glucose.” PO Resp. 15. According to Patent Owner, neither Hagiwara’s Figure 1(D) embodiment, nor Petitioner’s proposed modification of Hagiwara’s Figure 1(A) embodiment would have worked for its intended purpose without additional modifications, which Patent Owner characterizes as a “daunting challenge” involving “complex design considerations.” *Id.* at 27–40; *see id.* at 33, 37 (quoted text). The additional modifications Patent Owner contends would be necessary are: changing the polarity of the electrode and adding additional membrane functionality, including an interference excluding membrane, a permselective membrane, and a bioprotective membrane. *Id.* at 30–40 (citing Ex. 2008 ¶¶ 62, 64–71, 73, 74, 77, 81, 82; Ex. 1006 ¶ 101).

After considering the parties' arguments and evidence, we determine that a preponderance of the evidence establishes that a POSITA would have had a reasonable expectation that an enzyme layer, as disclosed by Hagiwara's Figure 1(D) embodiment, would have been compatible with a side sensor window and other features, as disclosed by Hagiwara's Figure 1(A) embodiment, and that these components would function successfully when combined. Our finding is supported by Hagiwara, which demonstrates how membrane layers can be formed over a side sensor window (Ex. 1005, 5:15–17, 5:37–41, Fig. 1(A)) and also demonstrates how an enzyme layer that covers an electrode reaction surface and the insulating layer in the vicinity thereof works to measure glucose and other analytes by indirect polarography (*id.* at 2:31–40, 3:26–4:6, 6:42–7:5, Fig. 1(D)). Our finding is further supported by the '574 patent, whose sparse disclosure demonstrates there was a high level of skill and knowledge in the art regarding the structure, function, and method of making an indwelling analyte sensor with an enzyme layer. This is particularly true with respect to an interferent excluding layer, a glucose oxidase layer, and a permselective layer, all of which the '574 patent discloses by reference to the prior art Wilson patent. Ex. 1001, 2:1–4.

We have considered Patent Owner's arguments, but are nevertheless persuaded that Petitioner has met its burden of proof and that a preponderance of the evidence shows that Petitioner's proposed combination would have worked for its intended purpose and had a reasonable expectation of success.

In contrast to Patent Owner’s cited cases,¹⁴ there is no argument here that Petitioner’s proposed combination would have led to inoperability or changed the basic principle of operation of Hagiwara’s enzyme-based embodiment. Indeed, there is no contention that an enzyme layer is incompatible with a side sensor window or other features of Hagiwara Figure 1(A). Nor is there any argument that Hagiwara teaches away from the proposed combination or undermines Petitioner’s proffered reasons to combine.

Although Patent Owner argues that Hagiwara fails to address various problems—permselectivity, bioprotection, and interference exclusion (PO Resp. 32–38)—and that these problems presented a “daunting challenge” and “complex design considerations” (*id.* at 33, 37), the preponderance of the evidence shows that a POSITA would have known how to solve these problems. Patent Owner relies extensively on paragraph 101 of Dr. Vachon’s testimony as support for its arguments. PO Resp. 30, 34, 38–39. Contrary to Patent Owner’s argument, however, Dr. Vachon testified it would have been “straightforward” for a POSITA to modify Hagiwara

¹⁴ Patent Owner (PO Resp. 27–29) cites the following cases: *KSR*, 550 U.S. at 416; *United States v. Adams*, 383 U.S. 39, 52 (1966); *Plas-Pak Indus. v. Sulzer Mixpac AG*, 600 F. App’x. 755 (Fed. Cir. 2015); *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009); *Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999); *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001); *In re Fritch*, 972 F.2d 1260, 1265 n.12 (Fed. Cir. 1992); *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984); *In re Ratti*, 270 F.2d 810, 813 (C.C.P.A. 1959); *In re Schulpen*, 390 F.2d 1009, 1012 (C.C.P.A. 1968); *Ex parte Cullen*, No. 2008-6125, 2009 WL 2970438, at *4 (B.P.A.I. Sept. 15, 2009); *Ex parte Seyyedy*, No. 2009-1696, 2009 WL 1212782, at *10 (B.P.A.I. May 4, 2009).

Figure 1(A) to add the membranes necessary to create a sensor capable of measuring glucose. Ex. 1006 ¶ 101. Furthermore, Dr. Vachon's testimony does not support that additional membranes would be required to measure other analytes, such as lactate. *Id.* Dr. Vachon's testimony regarding the "straightforward" addition of membranes is reinforced by the '574 patent, which discloses an interferent excluding layer and a permselective layer solely by reference to the prior art Wilson patent. Ex. 1001, 2:1–4. In other words, the '574 patent admits that these features were known in the art and that it was known how to combine them with an enzyme layer and other features of a glucose sensor.

Neither the '574 patent, nor the Wilson patent discloses a bioprotective membrane or its function of blocking catalase. *Cf.* PO Resp. 35–36. To the extent that bioprotection was critical to enable an operable glucose sensor, the '574 patent assumes this feature was known in the art. Accordingly, we agree with Petitioner that Patent Owner seeks to hold Hagiwara to a higher standard of knowledge and skill in the art than is demonstrated by the sparse disclosure of the '574 patent. Pet. Reply 28.¹⁵ *See Trustees of Columbia Univ. in City of New York v. Illumina, Inc.*, 620 F. App'x 916, 929 (Fed. Cir. 2015) (relying on disclosure of challenged patent as substantial evidence sufficient to support Board's finding of a reasonable expectation of success in combining prior art references and synthesizing the claimed nucleotide).

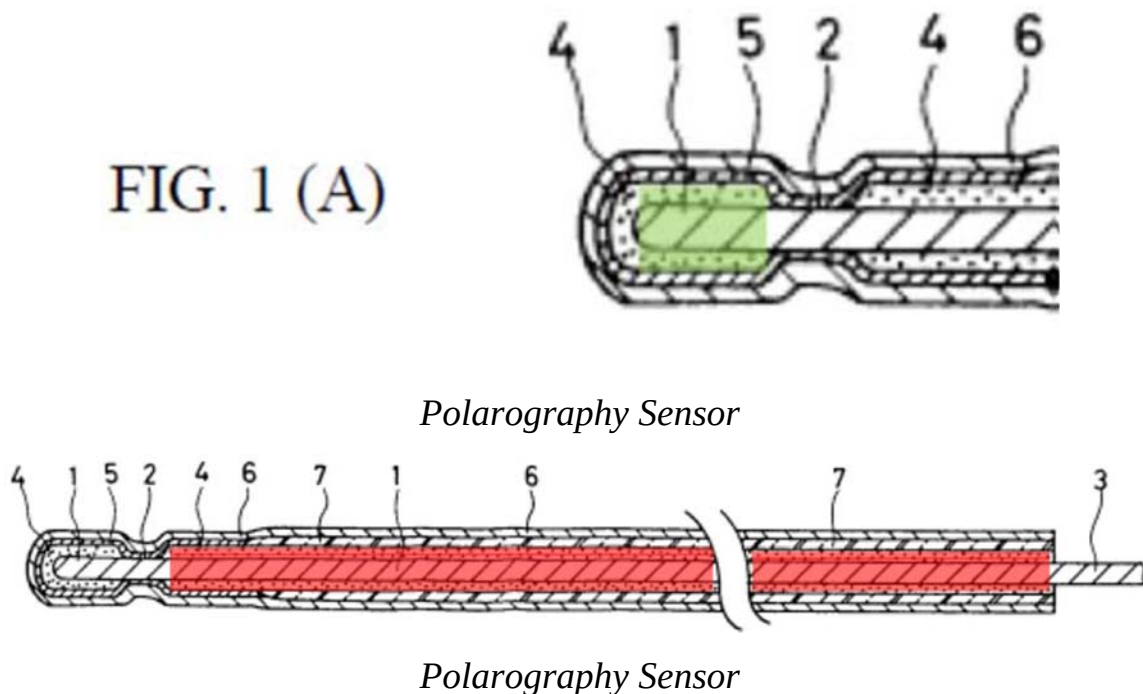
¹⁵ As discussed in Section II.G.1. below, we also find that Hagiwara discloses a permselective layer and an interferent excluding layer.

4. *Dependent Claims 2–8 and 10–19*

a. *Claims 2 and 13*

Claim 2 depends from claim 1 and recites: “at least one of said at least two nubs is in the form of a plate.” Ex. 1001, 2:30–31. Claim 13 depends from claim 9 and contains the same recitation. *Id.* at 3:1–2.

Petitioner contends that Hagiwara discloses two different nubs in the form of a plate, referring to the portions of insulation layer 4 highlighted in green and red in the following annotated versions of Hagiwara Figure 1(A), which are reproduced from the Petition:



Pet. 53 (citing Ex. 1006 ¶¶ 103–106); *see also id.* at 63 (same contentions for claim 13 as for claim 2). Petitioner contends that each of the highlighted portions emanates from a centerpoint of the electrode. *Id.* at 53.

Patent Owner disputes Petitioner’s contentions for claims 2, 3, 13, and 14, arguing that Hagiwara does not disclose or suggest a flat or disc-shaped

nub, like annular plates 22 shown in Figure 2 of the '574 patent. PO Resp. 40–41.

Petitioner's contention that Hagiwara discloses the limitation of claims 2 and 13 relies on a claim construction for "plate" that we have declined to adopt. As discussed in Section II.A.3. above, we adopt Patent Owner's construction for "plate" as meaning "a disc-shaped nub." Petitioner has not shown that either of the highlighted portions of Hagiwara's dielectric layer is disc-shaped. Petitioner argues that a "sub-portion of dielectric can be defined as having a width less than its diameter." Pet. Rely 31. Defining such a sub-portion would require hindsight based on the '574 patent. Petitioner has not shown that Hagiwara discloses or suggests a disc-shaped nub.

Accordingly, we are not persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches or suggests the limitation of claims 2 and 13.

b. Claims 3 and 14

Claim 3 depends from claim 1 and recites: "at least one of said at least two nubs comprises an annular plate." Ex. 1001, 2:32–33. Claim 14 depends from claim 9 and contains the same recitation. *Id.* at 3:3–4.

Petitioner's contentions for claims 3 and 14 are similar to its contentions for claims 2 and 13, except that Petitioner additionally contends that the green and red highlighted portions of Hagiwara's dielectric layer are ring-shaped. Pet. 54 (citing Ex. 1006 ¶¶ 107–110); *see also id.* at 63 (same contentions for claim 14 as for claim 3). For the same reasons as discussed above with respect to claims 2 and 13, Petitioner has not shown that

Hagiwara discloses or suggests a “plate,” which we have construed as a “disc-shaped nub.”

Accordingly, we are not persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches or suggests the limitation of claims 3 and 14.

c. Claims 4 and 15

Claim 4 depends from claim 1 and recites: “wherein said electrochemically active surface is defined as part of a lengthwise body.” Ex. 1001, 3:34–35. Claim 15 depends from claim 9 and contains the same recitation. *Id.* at 4:6–7.

Petitioner contends that Hagiwara teaches the additional limitation of claims 4 and 15. Pet. 54–55, 63. Patent Owner presents no argument regarding dependent claims 4 and 15 separate from its arguments regarding independent claims 1 and 9.

Referring to Hagiwara Figure 1(A), Petitioner contends that “precious metal wire 1 that forms the electrochemically active surface is defined as part of a lengthwise body sensor.” Pet. 55 (citing Ex. 1006 ¶¶ 111–113). Petitioner’s contention is supported by Hagiwara’s characterization of the polarography sensor electrodes as “long and slender.” Ex. 1005, 4:3. Petitioner’s contention is further supported by Hagiwara Figure 1(A), which shows a cross-sectional view of an elongated “needle like” sensor, with precious metal wire 1 embedded in the middle of the sensor and extending through the full length of the sensor. *Id.* at 4:43–5:5, Fig. 1(A). Petitioner’s contention is still further supported by Hagiwara’s disclosure of the sensor’s dimensions—a diameter of 0.3 to 2.0 mm and a length of 100 to 200 mm (*id.* at 4:45–46)—which are indicative of a “lengthwise body.”

It is unclear whether Petitioner contends that the “lengthwise body” recited in claims 4 and 15 corresponds to Hagiwara’s precious metal wire 1 or to Hagiwara’s sensor, as shown in Figure 1(A). Either way, we find that the limitation of claims 4 and 15 is met because the surface of Hagiwara’s precious metal wire 1 (corresponding to the “electrochemically active surface” recited in the claims) is defined as part of a lengthwise body (either Hagiwara’s precious metal wire 1 or Hagiwara’s sensor).

Accordingly, we are persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches or suggests the limitation of claims 4 and 15.

d. Claims 5 and 16

Claim 5 depends from claim 1 and recites: “wherein said lengthwise body is circular in cross-section.” Ex. 1001, 3:36–37. Claim 16 depends from claim 9 and contains the same recitation. *Id.* at 4:8–9.

Petitioner contends that Hagiwara discloses the additional limitation of claims 5 and 16. Pet. 55–56, 63. Patent Owner presents no argument regarding dependent claims 5 and 16 separate from its arguments regarding independent claims 1 and 9.

Referring to Hagiwara, Petitioner contends “the wires of all of its embodiments have diameters, indicating that the wires are cylindrical and have circular cross-sections.” Pet. 55 (citing Ex. 1005, 4:44–45). The diameters disclosed in Hagiwara pertain to the sensor as a whole, not the precious metal wire at the center. Ex. 1005, 4:44–45 (“the diameters of the four types of polarography sensors illustrated in FIG. 1(A) through FIG. 1(D) are all 0.3 to 2.0 mm”). Nevertheless, we find that Hagiwara discloses the limitation of claims 5 and 16, regardless of whether the “lengthwise

body” corresponds to Hagiwara’s precious metal wire 1 or to Hagiwara’s sensor, as shown in Figure 1(A). The evidence shows that both are circular in cross-section. Hagiwara discloses that the sensor has a diameter, indicating that the sensor is circular in cross-section. Ex. 1005, 4:43–45. Furthermore, Hagiwara discloses that the Figure 1(A) embodiment includes precious metal wire 1, which is covered by various layers, including metal tube 7. *Id.* at 5:2–18. A POSITA would recognize that both a wire and a tube are circular in cross-section.

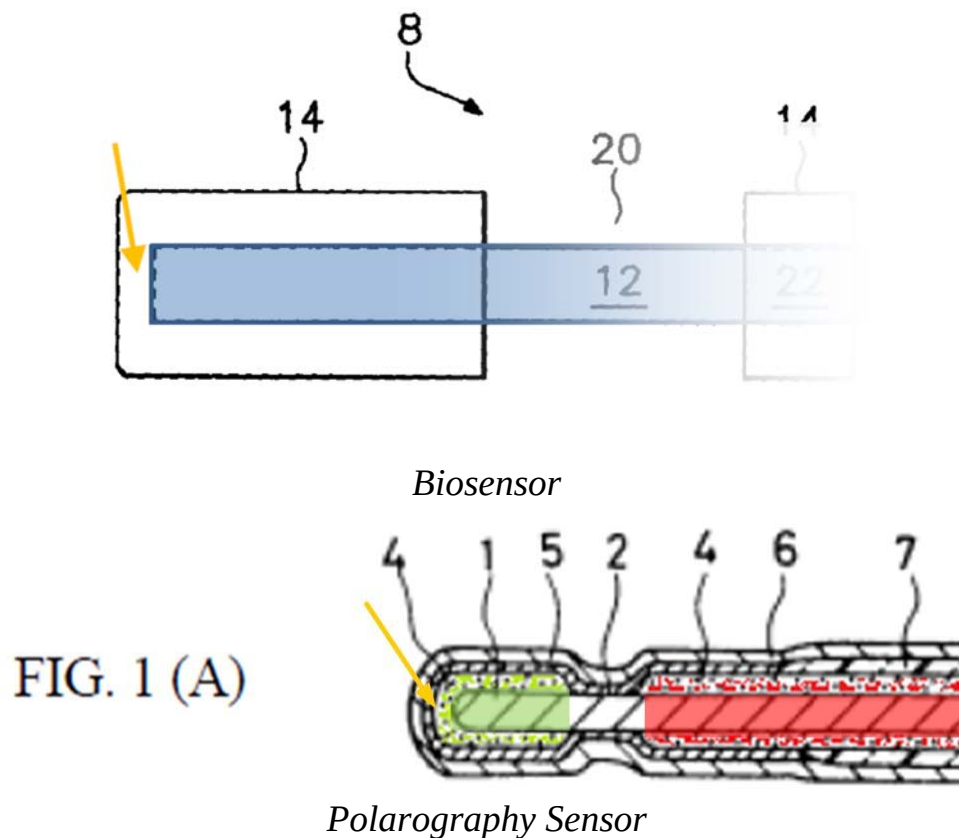
Accordingly, we are persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches or suggests the limitation of claims 5 and 16.

e. Claims 6 and 17

Claim 6 depends from claim 1 and recites: “wherein at least one of said at least two nubs is displaced longitudinally from said electrochemically active surface.” Ex. 1001, 3:38–40. Claim 17 depends from claim 9 and contains the same recitation. *Id.* at 4:1–3.

Petitioner contends that claims 6 and 17 would have been obvious in view of Hagiwara. Pet. 56–57, 63. Patent Owner presents no argument regarding dependent claims 6 and 17 separate from its arguments regarding independent claims 1 and 9.

Relying on Patent Owner’s claim construction in the related district court proceeding (Ex, 1002, 24), Petitioner contends that Hagiwara Figure 1(A) shows an end nub displaced longitudinally from the electrochemically active surface in the same way that Patent Owner contends Figure 1 of the ’574 patent shows this limitation. Pet. 56–57. As support for this contention, Petitioner presents the following comparison:



Id. The top figure above shows Patent Owner’s annotated version of Figure 1(A) of the ’574 patent, in which “[t]he end nub is displaced longitudinally from the electrochemically active surface 12, as indicated by the orange arrow.” *Id.* (quoting Ex. 1002, 24). The bottom figure above shows Petitioner’s annotated version of Hagiwara Figure 1(A), with a yellow arrow identifying the end nub. *Id.*

Petitioner’s comparison shows persuasively that Hagiwara Figure 1(A) shows at least one nub displaced longitudinally from the electrochemically active surface in the same way that Patent Owner contends Figure 1 of the ’574 patent shows this limitation.

Accordingly, we are persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches or suggests the limitation of claims 6 and 17.

f. Claims 7 and 18

Claim 7 depends from claim 1 and recites: “wherein said membrane system includes multiple membranes.” Ex. 1001, 3:41–42. Claim 18 depends from claim 9 and contains the same recitation. *Id.* at 4:4–5.

Petitioner contends that claims 7 and 18 would have been obvious in view of Hagiwara. Pet. 57, 63. Patent Owner presents no argument regarding dependent claims 7 and 18 separate from its arguments regarding independent claims 1 and 9.

Petitioner contends that its proposed combination of Hagiwara Figure 1(A) and the enzyme layer of Hagiwara Figure 1(D) satisfies the limitation of claims 7 and 18. Pet. 57. According to Petitioner, its proposed combination has multiple membranes, including contamination inhibiting coating 5, enzyme layer 12, and heparin-containing layer 6. *Id.* We agree with and adopt Petitioner’s contention, which is supported by Hagiwara Figures 1(A) and 1(D) and the description of those embodiments, as discussed above in connection with the Fourth Element of claims 1 and 9. *See* Section II.E.1.e., *supra*.

Accordingly, we are persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches or suggests the limitation of claims 7 and 18.

g. Claims 8 and 19

Claim 8 depends from claim 1 and recites: “wherein said membrane system defines an external surface of said sensor.” Ex. 1001, 3:43–44. Claim 19 depends from claim 9 and contains the same recitation. *Id.* at 4:6–7.

Petitioner contends that claims 8 and 19 would have been obvious in view of Hagiwara. Pet. 58, 63. Patent Owner presents no argument regarding dependent claims 8 and 19 separate from its arguments regarding independent claims 1 and 9.

Petitioner contends that Hagiwara's heparin membrane 6 defines an external surface of the sensor. Pet. 58. Petitioner's contention is supported by Hagiwara's disclosure that "[t]he outermost surface of this polarography sensor is a plastic coating 6." Ex. 1005, 5:11–12.

Accordingly, we are persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches or suggests the limitation of claims 8 and 19.

h. Claim 10

Claim 10 depends from claim 9 and recites: "wherein said electrochemically active surface extends through at least two of said plurality of nubs." Ex. 1001, 3:57–59.

Petitioner contends that claim 10 would have been obvious in view of Hagiwara. Pet. 60–61. Patent Owner presents no argument regarding dependent claim 10 separate from its arguments regarding independent claim 9.

Petitioner contends that "noble metal wire 1 of the Hagiwara sensor extends the length of the sensor including through the insulator layer 4 nubs." Pet. 61 (citing Ex. 1005, Fig. 1(A)). Petitioner's contention is supported by Hagiwara Figure 1(A) and the description of that embodiment.

As discussed above, the "electrochemically active surface" recited in the claims corresponds to the surface of Hagiwara's precious metal wire 1. Also as discussed above, the "plurality of nubs" corresponds to the portions

of Hagiwara's insulating layer 4 on either side of electrode reaction surface 2, which are highlighted in green and red in Petitioner's excerpted and colored version of Hagiwara Figure 1(A). Pet. 43.

As shown in Hagiwara Figure 1(A), precious metal wire 1 extends through the length of the sensor, including through the “nubs” of insulating layer 4. Our finding is supported by Hagiwara's disclosure that “[a]n outer surface of a precious metal wire 1, except an electrode reaction surface 2 . . . is covered with an insulating layer 4.” Ex. 1005, 5:3–5. Our finding is further supported by Hagiwara's disclosure that “the portion of the side surface of the precious metal wire 1 that is exposed from the insulating layer 4 . . . is the electrode reaction surface 2.” *Id.* at 5:10–11.

Accordingly, we are persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches or suggests the limitation of claim 10.

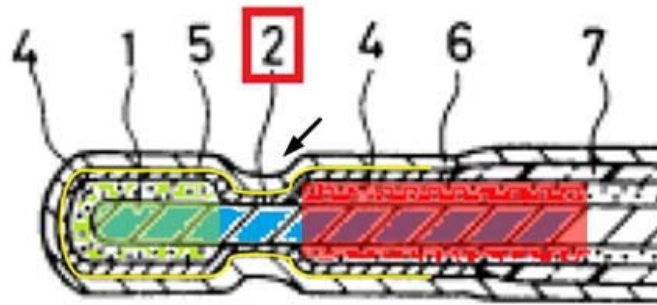
i. Claim 11

Claim 11 depends from claim 9 and recites: “wherein said membrane system defines a substantially catenary curve-shaped surface between at least two of said plurality of nubs.” Ex. 1001, 3:60–62.

Petitioner contends that claim 11 would have been obvious in view of Hagiwara. Pet. 61–62. Patent Owner presents no argument regarding dependent claim 11 separate from its arguments regarding independent claim 9.

Petitioner contends that Hagiwara Figure 1(A) shows the limitation of claim 11 and illustrates its contention with the following annotated version of Hagiwara Figure 1(A):

FIG. 1 (A)

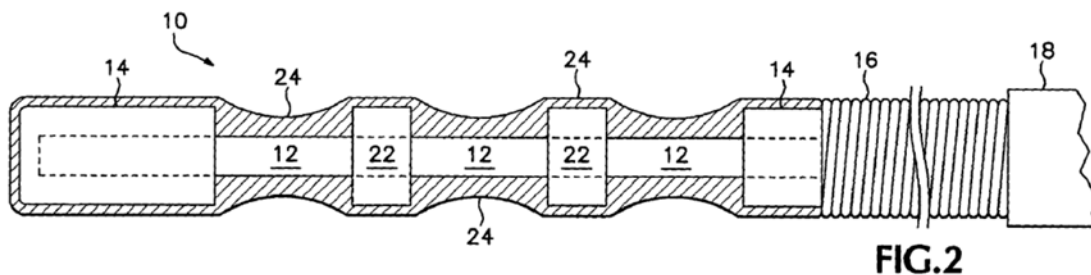


Polarography Sensor

Pet. 62.

According to Petitioner, the arrow in the above figure identifies as a catenary curve-shaped surface between the green and red highlighted “nubs” of insulating layer 4. *Id.* at 61.

Reproduced below is Figure 2 of the ’574 patent, which shows material 24 with “a shape somewhat like a catenary curve between plates 22.” Ex. 1001, 2:5–6.



Biosensor

Comparing Hagiwara Figure 1(A) with Figure 2 of the ’574 patent, we agree with Petitioner that Hagiwara’s membrane layers define “a substantially catenary curve-shaped surface between . . . two . . . nubs,” as recited in claim 11. On this record, the curved shape of layer 6 in area of electrode reaction surface 2 in Hagiwara Figure 1(A) is indistinguishable from the curved shape of material 24 between plates 22 in Figure 2 of the ’574 patent.

Petitioner contends that the membrane shape shown in Hagiwara Figure 1(A) results from a dip coating process. *Id.* We agree that Hagiwara teaches forming the outermost layer—layer 6—by dip coating. Ex. 1005, 5:37–40. Hagiwara is silent, however, on the methods for forming layers 5 and 12.¹⁶

Although we do not accept Petitioner’s contention that Hagiwara teaches dip coating all the membrane layers, we are nevertheless persuaded Petitioner has shown that Hagiwara teaches or suggests the limitation of claim 11. Claim 9 and 11 of the ’574 patent are product claims, not process claims, and the limitation of claim 11 describes the structure of the product, not the process of making it. According to the ’574 patent, “a shape somewhat like a catenary curve between plates 22” results from a dip coating process using a viscous fluid. Ex. 1001, 1:65–2:1, 2:4–6. Under a broadest reasonable interpretation, however, the limitation of claim 11 is not limited to a dip coating process.

Accordingly, we are persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches or suggests the limitation of claim 11.

j. Claim 12

Claim 12 depends from claim 9 and recites: “wherein said membrane system has an outer surface and said outer surface defines a concave curve curving toward said electrochemically active surface between at least two of said plurality of nubs.” Ex. 1001, 3:63–67.

¹⁶ Layer 12 is the enzyme layer and is represented by a yellow line in Petitioner’s annotated version of Hagiwara Figure 1(A).

Petitioner contends that claim 12 would have been obvious in view of Hagiwara. Pet. 62–63. Patent Owner presents no argument regarding dependent claim 12 separate from its arguments regarding independent claim 9.

Petitioner contends that Hagiwara Figure 1(A) shows the limitation of claim 12, illustrating its contention with the same annotated figure as reproduced above for claim 11. Comparing Hagiwara Figure 1(A) with Figure 2 of the '574 patent, we agree with Petitioner that the outer surface of Hagiwara's membrane layers defines "a concave curve curving toward said electrochemically active surface between . . . two . . . nubs," as recited in claim 12. On this record, the curved shape of layer 6 in area of electrode reaction surface 2 in Hagiwara Figure 1(A) is indistinguishable from the curved shape of material 24 between plates 22 in Figure 2 of the '574 patent.

Accordingly, we are persuaded that Petitioner has shown by a preponderance of the evidence that Hagiwara teaches or suggests the limitation of claim 12.

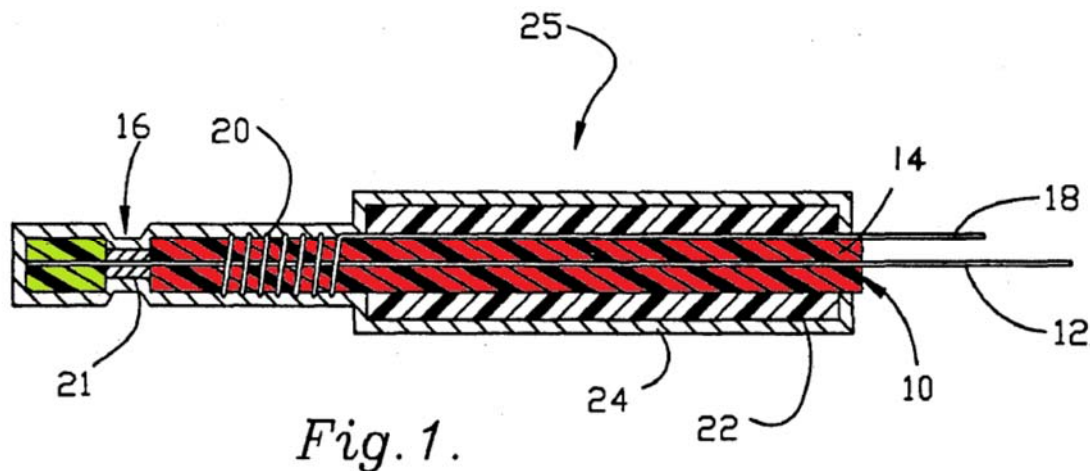
5. *Conclusion Regarding Obviousness Based On Hagiwara (Claims As Issued)*

We conclude that Petitioner has shown by a preponderance of the evidence that claims 1, 4–12, and 15–19 of the '574 patent are unpatentable as obvious in view of Hagiwara. We conclude that Petitioner has not shown by a preponderance of the evidence that claims 2, 3, 13, and 14 of the '574 patent are unpatentable as obvious in view of Hagiwara.

F. Wilson-Based Grounds (Claims As Issued)

In view of our determination that Petitioner has shown by a preponderance of the evidence that claims 1, 4–12, and 15–19 of the '574 patent are unpatentable as obvious in view of Hagiwara, we do not reach Petitioner's Wilson-Based Grounds as to these claims.

Claims 2, 3, 13, and 14 of the '574 patent recite that at least one nub is in the form of a "plate" or an "annular plate." Ex. 1001, 2:30–33, 3:1–4. Petitioner contends that these limitations are disclosed by Wilson, referring to the portion of insulation layer 14 highlighted in green in the following colored version of Wilson Figure 1, which is reproduced from the Petition:



Glucose Sensor

Pet. 29–30 (addressing anticipation of claims 2, 3); *see also id.* at 37 (same contentions for claims 13 and 14 as for claims 2 and 3); *id.* at 69–70, 83 (Petitioner's obviousness contentions rely on Wilson alone to teach limitations of claims 2, 3, 13, and 14). Petitioner contends that the green portion of insulation layer 14 emanates from a centerpoint of the electrode. *Id.* at 29 (referring to Wilson Fig. 1).

Petitioner's contention that Wilson discloses the limitation of claims 2, 3, 13, and 14 relies on a claim construction for "plate" that we have

declined to adopt. As discussed in Section II.A.3. above, we adopt Patent Owner’s construction for “plate” as meaning “a disc-shaped nub.” Petitioner has not shown that the green highlighted portion of Wilson’s insulation layer is disc-shaped.

Accordingly, we determine that Petitioner has not shown by a preponderance of the evidence that claims 2, 3, 13, and 14 of the ’574 patent are unpatentable based on the Wilson-Based Grounds.

Alternatively, for the reasons as set forth in the Institution Decision, we determine that Petitioner has not shown by a preponderance of the evidence that independent claims 1 and 9 are unpatentable based on the Wilson-Based Grounds and that Petitioner’s arguments and evidence regarding dependent claims 2, 3, 13, and 14 do not remedy the deficiencies in its arguments and evidence regarding claims 1 and 9. Dec. 18–31. We have considered Petitioner’s Reply (Paper 37), but are not persuaded by Petitioner’s arguments. The fact that Wilson’s insulating material is not limited to Teflon (*id.* at 12–13) is not a teaching to use an insulating material to which dip-coated cellulose acetate would adhere (*cf.* Dec. 23), much less a teaching of an enzyme layer surrounding at least two nubs of dielectric material, as recited in claims 1 and 9. Petitioner’s reliance on Zhang (Ex. 1035) and additional portions of Wilson (Ex. 1003) to show a claim limitation for the first time in the Reply is untimely because this evidence was not included in the Petition. 35 U.S.C. § 312(a)(3); 37 C.F.R. §§ 42.22(a)(2), 42.23(b); *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (petitioners are obligated “to make their case in their petition to institute”).

Even if considered, Petitioner’s additional evidence does nothing to contradict our finding that Wilson teaches depositing an enzyme layer only on the exposed metal surface, not the Teflon insulating layer. Dec. 21–23, 26; Ex. 1003, 5:33–38, Fig. 1. Our finding is further supported by Dr. Smith’s uncontradicted testimony that, as a result of Wilson’s dipping, drying, and soaking process, “the cellulose acetate would have been quantitatively removed from the surface of the Teflon” such that “[t]here would be no measurable, no detectable amount of cellulose acetate left on the Teflon after that procedure.” Ex. 1032, 29:23–30:10. Neither Hagiwara nor Ryan remedies the deficiency in Wilson because neither reference discloses the missing limitation— an enzyme layer surrounding at least two nubs of dielectric material. Although Hagiwara discloses forming a heparin-containing plastic coating on nearly the entire outermost surface of the sensor (Ex. 1005, 5:37–41, 5:44–45), Petitioner fails to articulate a sufficient rationale for modifying Wilson’s enzyme layer in view of that teaching. Dec. 26–27. Petitioner’s new evidence regarding commercial scalability of dip coating (Ex. 1037) is irrelevant. Motivation to use dip coating is not the issue because Wilson already discloses forming an enzyme layer by dip coating. Ex. 1003, 5:48–54.

Accordingly, for this alternative reason, we determine that Petitioner has not shown by a preponderance of the evidence that claims 2, 3, 13, and 14 of the ’574 patent are unpatentable based on the Wilson-Based Grounds.

G. Patent Owner’s Contingent Motion to Amend

At the oral hearing, Patent Owner clarified the contingency that underlies its motion to amend. Patent Owner requests cancellation of claims 9–19 of the ’574 patent and entry of proposed substitute claims 20–29, if any

of claims 9–19 is found unpatentable. *See* Tr. 57:1–11, 66:25–67:7; *see also* Mot. 1. In view of our determination that Petitioner has shown unpatentability of claims 9–12 and 15–19 of the ’574 patent, we consider Petitioner’s challenges to Patent Owner’s proposed substitute claims.¹⁷

1. *Obviousness Based on Hagiwara (Proposed Substitute Claims)*

Petitioner contends that proposed substitute claims 20 and 22–29 are unpatentable as obvious over Hagiwara. Pet. Opp. 7–14. Patent Owner disagrees. Mot. 13–19; PO Reply 9–16.

Patent Owner’s proposed substitute claim 20 retains all of the features of claim 9 and additionally recites: “a permselective layer and an interferent excluding layer” and “wherein the enzyme is glucose oxidase, thereby forming an indwelling analyte sensor for detecting glucose.” Mot. 4, 6. Below we address these recitations of proposed claim 20, and then we address the proposed substitutes for the dependent claims.

a. *Independent Claim 20: Permselective Layer*

Petitioner contends that Hagiwara’s layers 5 and 6 are both permselective layers, as recited in proposed substitute claim 20. Pet. Opp. 8. Patent Owner disagrees. Mot. 16–17; PO Reply 9–10.

As discussed above, we construe “permselective layer” as “a layer that regulates the passage of different molecules or ions at different rates.” Under that construction, we find that Hagiwara’s layer 6 is a permselective layer. Hagiwara discloses that heparin-containing layer 6 may be made from

¹⁷ There is no dispute that Patent Owner’s proposed substitute claims meet the requirements of 35 U.S.C. §§ 316(d)(1) and (3) and 37 C.F.R. § 42.121(a)(2) and (3), i.e., they are reasonable in number, they respond to a ground of unpatentability involved in the trial, and they do not enlarge the scope of the claims or introduce new subject matter.

“various types of cellulose esters,” such as “acetyl cellulose.” Ex. 1005, 5:21–25. Acetyl cellulose is a synonym for cellulose acetate. Petitioner’s evidence shows that cellulose acetate membranes “exhibit significant permselectivity toward anions.” Ex. 1009, 2781. Dr. Smith testified that a cellulose acetate layer can be used to exclude ascorbate and urate, but not acetaminophen. Ex. 1021, 129:16–25; *see also* Ex. 1003, 5:58–61 (“cellulose acetate membrane . . . discriminates well against ascorbate and urate”). Dr. Smith’s testimony supports that a cellulose acetate layer, as disclosed in Hagiwara, is a permselective layer, as we have construed that term, because it regulates the passage of different molecules or ions (ascorbate, urate, and acetaminophen) at different rates. Although there is evidence that Hagiwara’s layer 6, e.g., cellulose acetate, does not regulate the flow of glucose and oxygen (Ex. 2008 ¶ 74, Ex. 2024, 13 n.4; Ex. 1021, 135:21–23), neither Patent Owner’s proposed claim construction (PO Reply 5), nor the construction we adopt for “permselective layer” requires that the passage of these particular molecules be regulated.

Accordingly, we find that Hagiwara teaches a “permselective layer,” as recited in proposed substitute claim 20.

b. Independent Claim 20: Interferent Excluding Layer

Petitioner contends that Hagiwara’s contamination inhibiting coating 5 is an interferent excluding layer, as recited in proposed substitute claim 20. Pet. Opp. 8–9. Patent Owner disagrees. Mot. 16–17; PO Reply 9–10.¹⁸

¹⁸ Although Patent Owner relies on Dr. Vachon’s testimony (PO Reply 10, citing Ex. 2009, 16:4–14; 56:8–13; 74:21–25), the cited testimony does not discuss cellulose acetate as an interferent excluding layer.

We find that Hagiwara’s contamination inhibiting coating is an interferent excluding layer. Hagiwara discloses cellulose acetate as a contamination inhibiting coating. Ex. 1005, 8:5–6. Dr. Smith testified that a cellulose acetate layer can be used to exclude ascorbate and urate. Ex. 1021, 129:16–22; *see also* Ex. 1003, 5:58–61 (“cellulose acetate membrane . . . discriminates well against ascorbate and urate”). Patent Owner agrees that ascorbate and urate are “common interfering substances” that interfere with the measurement of glucose. Mot. 17.

Accordingly, we find that Hagiwara teaches an “interferent excluding layer,” as recited in proposed substitute claim 20.

c. Independent Claim 20: Glucose Sensor

Petitioner contends that Hagiwara discloses an indwelling analyte sensor for detecting glucose that uses a glucose oxidase as the enzyme, as recited in proposed substitute claim 20. Pet. Opp. 9–10. Patent Owner does not dispute Petitioner’s contention.¹⁹

We find that Petitioner has shown that its proposed combination of Hagiwara Figure 1(A) and the enzyme layer of Figure 1(D) discloses the “wherein” clause of proposed substitute claim 20, i.e., “wherein the enzyme is glucose oxidase, thereby forming an indwelling analyte sensor for detecting glucose.” Mot. 20. Our finding is supported by Hagiwara, which discloses that “a variety of enzymes like glucose oxidase for measuring glucose . . . can be used as the enzyme.” Ex. 1005, 6:46–7:2. We find that

¹⁹ Patent Owner’s argument regarding motivation to combine Hagiwara’s Figure 1(A) and 1(D) embodiments (PO Reply 10–13) is addressed in Sections II.E.2. and II.E.3. above.

Hagiwara discloses “an indwelling analyte sensor” for the reasons discussed in Section II.E.1.a. above.

Accordingly, we find that Hagiwara teaches the “wherein” clause of proposed substitute claim 20.

d. Independent Claim 20: Conclusion

We determine that Petitioner has shown by a preponderance of the evidence that proposed substitute claim 20 is unpatentable as obvious in view of Hagiwara for the reasons discussed above in Section II.E.1–3. (addressing claim 9) and Sections II.G.1.a.–c. (addressing the additional limitations of claim 20).

e. Dependent Claim 21

Patentability of Patent Owner’s proposed substitute claim 21 is undisputed. Pet. Opp. 2 (“Dexcom does not oppose entry and allowance of claim 21 in this proceeding.”).

f. Dependent Claims 22, 23, 27, and 28

Proposed substitute claims 22, 23, 27, and 28 are substantively unchanged from claims 11, 12, 16, and 17, for which they are proposed as substitutes. Mot. 5–6. We determine that Petitioner has shown by a preponderance of the evidence that proposed substitute claims 22, 23, 27, and 28 are unpatentable as obvious in view of Hagiwara for the same reasons as discussed above for claims 11, 12, 16, and 17 of the ’574 patent. See Sections II.E.6.d., e., i., and j., *supra*.

g. Dependent Claims 24 and 25

We determine that Petitioner has not shown by a preponderance of the evidence that proposed substitute claims 24 and 25 are unpatentable as

obvious in view of Hagiwara for the same reasons as discussed above for claims 13 and 14. *See* Sections II.E.6.a. and b., *supra*.

h. Dependent Claim 29

Patent Owner’s proposed substitute claim 29 retains all of the features of claim 19 and additionally recites: “a covering comprising silver surrounds at least a portion of dielectric.” Mot. 6. Patent Owner explains that “[t]he silver functions as a reference electrode thereby resulting in a reference electrode being physically integrated into the sensor.” *Id.* at 18; *see also* PO Reply 13 (“the claims reciting silver concern the reference electrode”).

Petitioner contends that Hagiwara discloses the added limitation of claim 29, referring to the integrated Ag/AgCl reference electrode of Hagiwara’s Figure 1(C) embodiment. Pet. Opp. 10–11. Petitioner further contends that it would have been obvious to combine this feature of Figure 1(C) with the Figure 1(A) and 1(D) embodiments. *Id.* at 11–13.

Patent Owner argues that Hagiwara Figure 1(C) does not have a covering comprising silver surrounding a portion of dielectric. Mot. 18. Patent Owner contends it would not have been obvious to combine the integrated silver reference electrode of Hagiwara Figure 1(C) with the Figure 1(A) design. PO Reply 14–15.

We find that Hagiwara discloses a covering comprising silver surrounding at least a portion of dielectric. Our finding is supported by Hagiwara claim 5, which discloses “a standard reference electrode provided on the insulating layer outer surface.” Ex. 1005, 2:24–25. Our finding is further supported by Hagiwara’s description of Figure 1(C) as showing “a needle like composite electrode, having a measuring electrode 1 and a

standard reference electrode 10, inside an integrated sensor.” *Id.* at 6:27–28. Hagiwara discloses forming standard reference electrode 10 made of Ag/AgCl by depositing silver on a shaved front end portion of metal tube 7 and then performing chloride argention. *Id.* at 6:30–34. As shown in Hagiwara Figure 1(C), the silver/silver chloride standard reference electrode 10 surrounds insulating layer 4. *Id.* at Fig. 1(C). We find that Hagiwara’s standard reference electrode 10 is a covering comprising silver surrounding at least a portion of dielectric, as recited in claim 29.

We find that a POSITA would have been motivated to combine Hagiwara’s integrated reference electrode of Figure 1(C) with Petitioner’s proposed combination of the Figure 1(A) and 1(D) embodiments. Our finding is supported by Hagiwara, which discloses the composite electrode of Figure 1(C) as an alternative to the external reference electrode of the Figure 1(A), 1(B), and 1(D) embodiments. Ex. 1005, 7:22–25. Our finding is further supported by Hagiwara’s description of Figure 1(C) as having features the same as Figure 1(A) and 1(B), except for the reference electrode. *Id.* at 6:29–30, 6:39–41. Our finding is still further supported by Patent Owner’s argument that “[a]ll electrochemical sensors require two electrodes,” which “can be accomplished either by providing an external [reference] electrode that is in fluid communication with the blood, or it can be done by integrating the reference electrode into the sensor.” PO Reply 13–14 (citing Ex. 2024 ¶¶ 43–49).

In contrast to the integrated reference electrode of Figure 1(C), Hagiwara’s Figure 1(A), 1(B), and 1(D) embodiments have a “separation type” measuring electrode and an external reference electrode. *Id.* at 5:2–3, 6:12–13, 7:7–8, 7:11–14, Fig. 2; Ex. 2024 ¶ 44 (“Hagiwara proposed three

sensors that use an external reference electrode.”). Petitioner shows that a POSITA would have been motivated to substitute the integrated reference electrode of Figure 1(C) for the external reference electrode of Figures 1(A), 1(B), and 1(D), in order to avoid the “external gadgetry” shown in Figure 2 and make the electrode setup “less cumbersome.” Pet. Opp. 12 (quoting Dr. Smith’s testimony at Ex. 2008 ¶ 58 and Ex. 1021, 150:12–14, 151:12–15). Petitioner also shows that an integrated reference electrode was well known and predictably would have worked. *Id.* at 12–13 (citing, Ex. 1003, Fig. 1; Ex. 1026,²⁰ Fig. 1; Ex. 1027,²¹ Fig. 1; Ex. 1028,²² Fig. 5).

Patent Owner does not dispute that an integrated reference electrode was well known and desirable for purposes of a subcutaneous, tissue-dwelling sensor. PO Reply 15. Instead, Patent Owner argues that Petitioner’s proposed combination would have been undesirable “for the intravascular measurement purposes to which Hagiwara’s sensors are limited.” *Id.* We are not persuaded by Patent Owner’s argument, which views the motivations of a POSITA too narrowly. *KSR*, 550 U.S. at 419–420 (“any need or problem known in the field of endeavor at the time of the invention” can provide a reason for combining claim elements); *id.* at 420 (in considering whether there would have been a reason to combine prior art

²⁰ Dilbir S. Bindra et al., *Design and in Vitro Studies of a Needle-Type Glucose Sensor for Subcutaneous Monitoring*, Anal. Chem., 63, 1692–1696 (1991).

²¹ Francis Moussy et al., *Performance of Subcutaneously Implanted Needle-Type Glucose Sensors Employing a Novel Trilayer Coating*, Anal. Chem., 65, 2072–2077 (1993).

²² Hitchcock et al., U.S. Patent No. 6,965,791 B1, filed March 26, 2003, issued Nov. 15, 2005.

elements, it is error to look only to the primary problem addressed by a prior art reference). Even if Petitioner's proposed modification would have been unsatisfactory for purposes of an intravascular sensor, as argued by Patent Owner, the undisputed benefits of an integrated reference electrode for purposes of a subcutaneous, tissue-dwelling sensor persuade us that the combination would have been obvious. Ex. 1026, 1693-1, Fig. 1, (needle-shaped glucose sensor with integrated reference electrode has "convenient design for a subcutaneous sensor and is believed to minimize inflammation"); Ex. 1027, 2072-1 ("Due to the potential hazards of intravascular glucose sensing most studies have focused on the development of needle-type glucose sensors for subcutaneous glucose monitoring."); Ex. 1028, 1:34–36 ("The glucose level in the subcutaneous interstitial fluid very closely approximates the glucose level in the blood, with a negligible time lag.").

i. Dependent Claim 26

Patent Owner's proposed substitute claim 26 depends from proposed substitute claim 29. Claim 26 retains all of the features of claim 15 and additionally recites: "the covering comprising silver is in the form of a continuous layer." Mot. 5.

Petitioner contends that that its proposed combination of Hagiwara Figures 1(A), 1(C), and 1(D) discloses the added limitation of proposed substitute claim 26. Pet. Opp. 13. Patent Owner presents no argument regarding nonobviousness of proposed substitute claim 26 separate from its arguments regarding proposed substitute claim 29.

We find that Hagiwara discloses a covering comprising silver in the form of a continuous layer. Our finding is supported by Hagiwara Figure

1(C), which shows standard reference electrode 10 made of Ag/AgCl in the form of a continuous layer. Ex. 1005, Fig. 1(C). Our finding is further supported by Hagiwara's disclosure that standard reference electrode 10 is made by depositing silver on a shaved front end portion of metal tube 7 and then performing chloride argention. *Id.* at 6:30–34.

For the reasons discussed above in connection with proposed claim 29, we find that Petitioner has shown a motivation to combine Hagiwara's integrated reference electrode of Figure 1(C) with Petitioner's proposed combination of the Figure 1(A) and 1(D) embodiments.

j. Conclusion Regarding Obviousness Based on Hagiwara (Proposed Substitute Claims)

We conclude that Petitioner has shown by a preponderance of the evidence that proposed substitute claims 20, 22, 23, and 26–29 are unpatentable as obvious in view of Hagiwara. We conclude that Petitioner has not shown by a preponderance of the evidence that proposed substitute claims 21, 24 and 25 are unpatentable as obvious in view of Hagiwara.

2. Remaining Grounds of Unpatentability Asserted by Petitioner (Proposed Substitute Claims)

In view of our determination that Petitioner has shown by a preponderance of the evidence that proposed substitute claims 20, 22, 23, and 26–29 are unpatentable as obvious in view of Hagiwara, we do not reach Petitioner's remaining grounds of unpatentability as to these claims.

Regarding proposed substitute claims 24 and 25, Petitioner's contentions regarding the Handbook, Wilson, and Say do not remedy the deficiencies in Petitioner's contentions regarding Hagiwara, as discussed above. Accordingly, we conclude that a preponderance of the evidence does

not show that proposed substitute claims 24 and 25 are unpatentable as obvious based on Hagiwara in view of the Handbook, Wilson, or Say.

H. Patent Owner's Motion to Exclude

Patent Owner moves to exclude Petitioner's Exhibit 1037 and corresponding portions of the Reply (Paper 37) on the grounds that Petitioner improperly introduces Exhibit 1037 to remedy its prima facie case of obviousness for the Wilson-Based Grounds. Paper 41, 1.

As discussed above, we do not reach the Wilson-Based Grounds with respect to claims 1, 4–12, and 15–19 of the '574 patent. As for claims 2, 3, 13, and 14, we determine that Petitioner has not shown unpatentability based on the Wilson-Based Grounds, even if Exhibit 1037 and the corresponding portions of Petitioner's Reply (Paper 37) are not excluded, because Petitioner does not offer Exhibit 1037 to cure the deficiency we noted in Wilson. See Section II.F, *supra*. For this reason, we *dismiss as moot* Patent Owner's motion.

III. CONCLUSION

1. Petitioner has shown by a preponderance of the evidence that claims 1, 4–12, and 15–19 of the '574 patent are unpatentable.

2. Petitioner has not shown by a preponderance of the evidence that claims 2, 3, 13, and 14 of the '574 patent are unpatentable.

3. Petitioner has shown by a preponderance of the evidence that Patent Owner's proposed substitute claims 20, 22, 23, and 26–29 are unpatentable.

4. Petitioner has not shown by a preponderance of the evidence that Patent Owner's proposed substitute claims 21, 24 and 25 are unpatentable.

IV. ORDER

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

ORDERED that, based on a preponderance of the evidence, claims 1, 4–12, and 15–19 of the '574 patent are unpatentable;

FURTHER ORDERED that, based on a preponderance of the evidence, claims 2 and 3 of the '574 patent are not unpatentable;

FURTHER ORDERED that Patent Owner's Contingent Motion to Amend is *granted* as to proposed claims 21, 24, and 25, which are substitutes for claims 10, 13, and 14 of the '574 patent, which should be cancelled; and

FURTHER ORDERED that Patent Owner's Contingent Motion to Amend is *denied* as to proposed substitute claims 20, 22, 23, and 26–29;

FURTHER ORDERED that Patent Owner's Motion to Exclude Exhibit 1037 and corresponding portions of the Reply (Paper 37) is *dismissed as moot*;

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.

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