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Paper 35
Date: October 27, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE INC,
Petitioner,

v.

DEXCOM, INC.,
Patent Owner.

IPR2022-00908
Patent 10,702,193 B2

Before SCOTT A. DANIELS, MITCHELL G. WEATHERLY, and FREDERICK C. LANEY, *Administrative Patent Judges.*

DANIELS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

Abbott Diabetes Care Inc., ("Abbott" or "Petitioner"), filed a Petition requesting *inter partes* review ("IPR") of claims 1–3 and 11–13 of U.S. Patent No. 10,702,193 B2 (Ex. 1001, "the '193 patent"). Paper 2 ("Pet."). Dexcom, Inc., ("Dexcom" or "Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp.").

On October 31, 2022, we instituted trial for claims 1–3 and 11–13 of the '193 patent on all grounds of unpatentability alleged in the Petition. Paper 13 ("Decision to Institute" or "Inst. Dec."). After institution of trial, Patent Owner filed a Patent Owner Response. Paper 19 ("PO Resp.). Petitioner timely filed a Reply. Paper 23 ("Pet. Reply). Subsequently, Patent Owner filed a Sur-Reply to address certain arguments raised in Petitioner's Reply. Paper 27 ("PO Sur-Reply).

A hearing for this proceeding was held on August 3, 2023. The transcript of the hearing has been entered into the record. Paper 34 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a).

For the reasons that follow, we determine that Petitioner has met its burden of showing by a preponderance of the evidence that claims 1–3 and 11–13 are unpatentable.

A. Real Parties in Interest

Petitioner states that Abbott Diabetes Care Inc., Abbott Diabetes Care Sales Corp., and Abbott Laboratories are the real parties in interest and Abbott Diabetes Care Inc, is the Petitioner. Pet. 4. Petitioner points out that "Abbott Diabetes Care Inc. is directly owned by Abbott Laboratories," and "Abbott Diabetes Care Inc. directly owns Abbott Diabetes Care Sales Corp."

Id. Patent Owner states that Dexcom Inc., is the sole real party in interest. Paper 4, 1.

B. Related Matters

The parties indicate that the '193 patent and related U.S. Patent Nos. 10,702,215, 11,000,213, 10,980,452, and 10,993,642, are at issue in at least one of *Abbott Diabetes Care Inc. v. Dexcom, Inc.*, Case No. 1:21-cv-01699, and *DexCom, Inc. v. Abbott Diabetes Care Inc. et al.*, Case No. 1:22-cv-00605, in the U.S. District Court for the District of Delaware.[1] Pet. 2; Paper 4, 2.

Petitioner indicates that it has filed other *inter partes* review proceedings including the above noted patents as follows: IPR2022-00909 (US 10,702,215); IPR2022-00913 and IPR2022-00914 (US 11,000,213); IPR2022-00917 and IPR2022-00918 (US 10,980,452); and IPR2022-00921 and IPR2022-00922 (US 10,993,642). Paper 4, 2.

C. The '193 Patent (Ex. 1001)

The '193 patent, titled "Analyte Sensing Biointerface," describes a blood glucose sensor including "a sensing electrode incorporated within a non-conductive matrix comprising a plurality of passageways extending through the matrix to the sensing electrode." Ex. 1001, codes 54, 57. Figures 6A–B of the '193 patent are reproduced below.

[1] *DexCom, Inc. v. Abbott Diabetes Care Inc. et al.*, Case No. 1:22-cv-00605, in Delaware was transferred from the United States District Court for the Western District of Texas (Case No. 6:21-cv-00690)). Paper 4, 2.

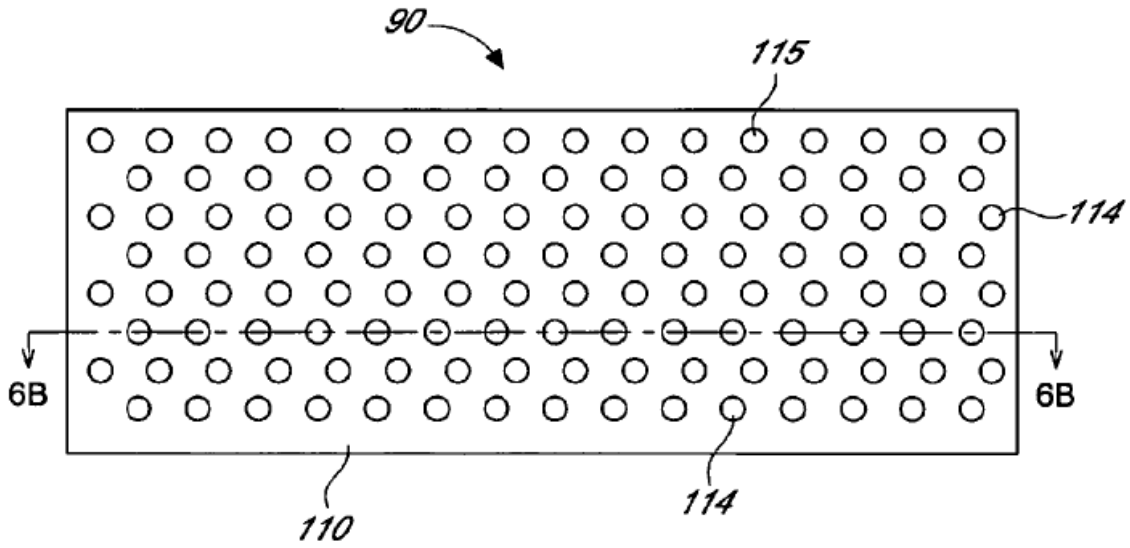


FIG. 6A

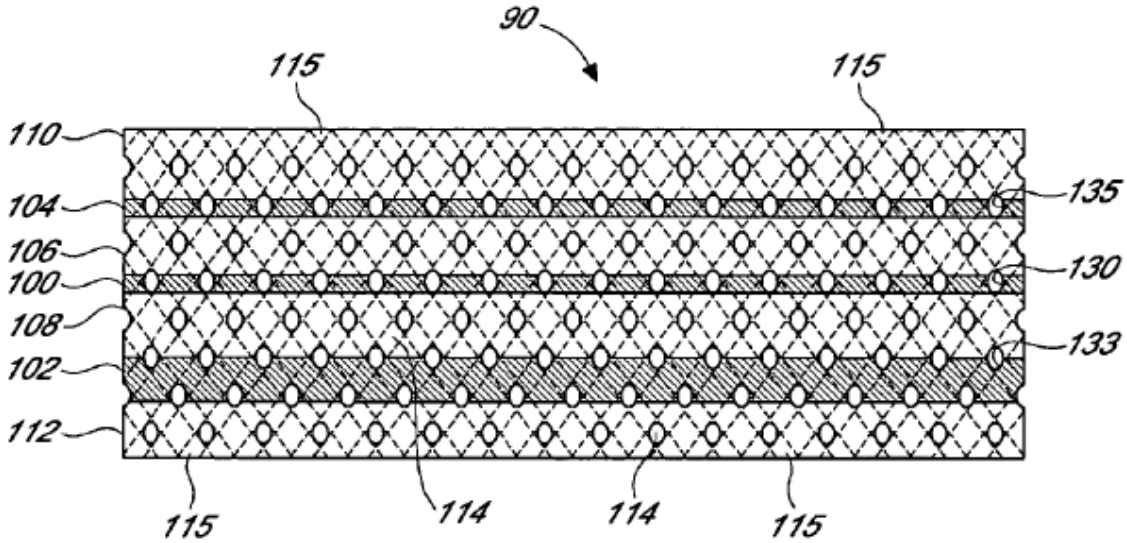


FIG. 6B

Figures 6A–B of the '193 patent illustrate respectively surface 110 (Fig. 6A) and a cross-sectional view (Fig. 6B) of sensing cell-disruptive biointerface 90. *Id.* at 20:65–67. Openings 115 are formed on and through all surfaces and layers of the biointerface. *Id.* The '193 patent explains that in this embodiment "[c]onductive layer 100 is the working electrode, conductive

layer 102 is the counter electrode, and conductive layer 104 is the reference electrode." *Id.* at 21:2–5. The '193 patent explains further that

> [t]he working electrode 100 is separated from the counter electrode 102 and reference electrode 104 by non-conductive layers 106 and 108. The counter electrode 102 and reference electrode 104 are separated from tissue surrounding the implant by non-conductive layers 110 and 112.

Id. at 21:5–10.

According to the '193 patent, the sensing functions and detection of an analyte in previous implantable glucose sensors degrade over time due to a host's foreign body response ("FBR") to the implant. *Id.* at 1:63–66. The '193 patent explains that the "FBR is a local inflammatory response that results in the formation of a barrier cell layer 40 around the surface of the implant 47. This layer generally consists of macrophages and foreign body giant cells 41." *Id.* at 2:4–1. Figure 1 is reproduced below.

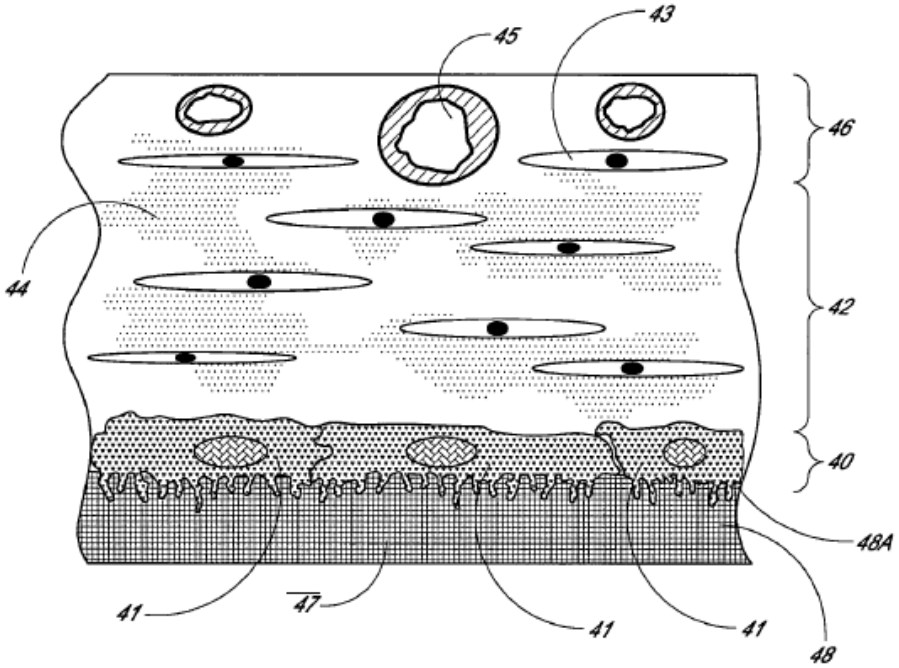


FIG. 1

Figure 1 illustrates implant 47 with a surface blocked by layers of tissue including fibrous matrix 44, macrophages and foreign body giant cells 41, blood vessels 45, and fibrolasts 43. *Id.* at 2:3–6.

The '193 patent describes a way to improve detection of an analyte where "[t]he biointerface is constructed of a barrier cell disruptive material 49 that is incorporated on the surface of the biosensor 50. The material disrupts the continuity of cells 41 so that an impermeable barrier cell layer does not form." *Id.* at 7:44–48. Figure 2 is reproduced below.

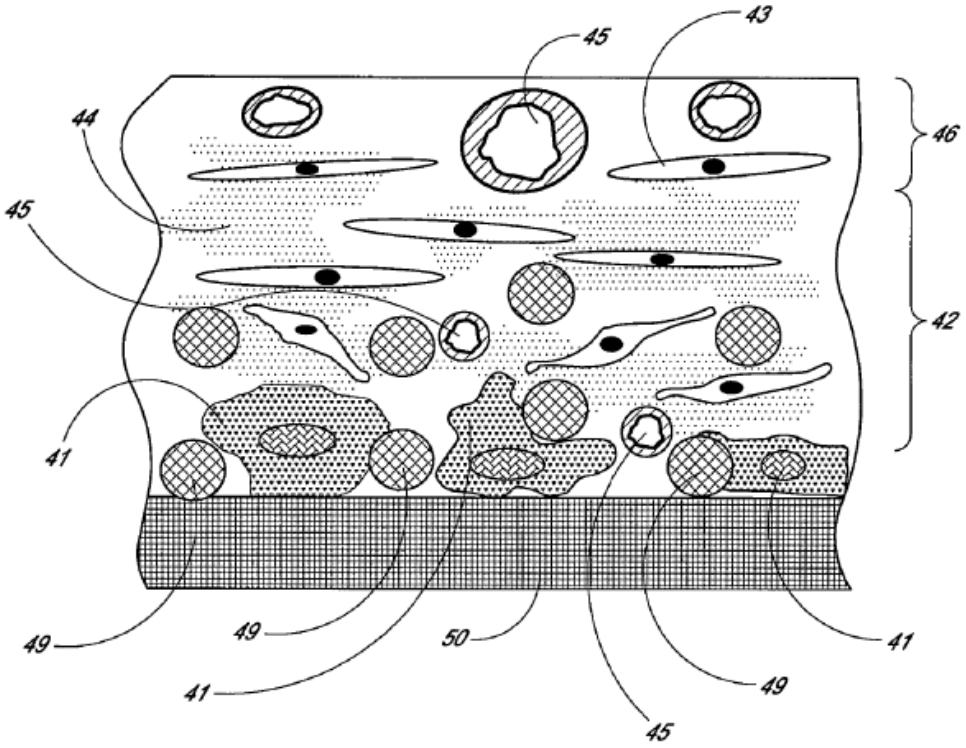


FIG. 2

Figure 2 illustrates in cross-section, sensor 50 including cell disruptive material 49 intended to disrupt the formation of a cell barrier layer.

Different from disruptive material 49, and referring back to Figures 6A–B, above, the '193 patent describes forming a biointerface with openings 115 and pores formed in the biointerface material itself, for

example by drilling or etching, having the benefit that "[o]ver time, as the host's tissue grows in and through the passageways of the biocompatible matrix, a mature bed of vascularized tissue will form, enabling long term measurement of the analyte in vivo." *Id.* at 20:43–46.

D. Challenged Claims

Claims 1 and 11 are independent. Each of claims 2–3, and 12–13 ultimately depends from independent claims 1 and 11 respectively. Claim 1 illustrates the claimed subject matter and is reproduced below:

> 1[Pre].[2] A transcutaneous continuous glucose sensor system comprising:
>
> 1[a] a substantially planar sensor, the sensor comprising:
>
> 1[b] a first conductive layer associated with a first electrode;
>
> 1[c] a first non-conductive layer located at least in part over the first conductive layer;
>
> 1[d] a second conductive layer associated with a second electrode, wherein the second conductive layer is located at least in part over the first non-conductive layer;
>
> 1[e] a second non-conductive layer located at least in part over the second conductive layer,
>
> 1[f] a third conductive layer associated with a third electrode, wherein the third conductive layer is located at least in part over the second non-conductive layer; and
>
> 1[g] a membrane located over at least a portion of a working electrode;
>
> 1[h] wherein at least one of the first electrode, the second electrode, or the third electrode is the working electrode,

[2] The Board refers to Petitioner's nomenclature 1[Pre] – 1[i] for certain claim limitations.

1[i] and wherein the working electrode is configured to measure a signal indicative of a glucose concentration.

Ex. 1001, 55:43–65. Independent Claim 11 is similarly worded to claim 1 but specifically requires the second electrode to be "a working electrode." *Id.* at 56:29–50.

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E. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–3 and 11–13 would have been unpatentable based on the following grounds:[3]

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–3, 11–13	102	'996 Publication[4]
2	1–3, 11–13	103(a)[5]	Feldman[6]
3	1–3, 11–13	103(a)	Allen[7]
4	1–3, 11–13	103(a)	Shah,[8] Allen

II. ANALYSIS

A. Legal Standards

A "prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of

[3] Petitioner supports its challenge with a Declaration of John L. Smith, Ph.D. (Ex. 1002). and Patent Owner supports its arguments presented during trial with the Declaration of Mark A. Tapsak, Ph.D. (Ex. 2011).
[4] Ex 1007, US Patent Appl'n Pub. No. 2006/0257996 A1 (Nov. 16, 2006).
[5] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application from which the '193 patent issued has an effective filing date prior to March 16, 2013, the pre-AIA version of § 103 applies. *See* Ex. 1001, code (63).
[6] Ex. 1008, US Patent Appl'n Pub. No. 2005/0215871 A1 (Sept. 29, 2005).
[7] Ex. 1009, US Patent No. 5,322,063 (Jun. 21, 1994).
[8] Ex. 1010, US Patent Appl'n Pub. No. 2004/0061232 A1 (Apr. 1, 2004).

the document, but must also disclose those elements 'arranged as in the claim.'" *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). "A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference." *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103(a); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). "[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *KSR*, 550 U.S. at 416 (citing *United States v. Adams*, 383 U.S. 39, 50–51 (1966)). The question of 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) when in evidence, objective evidence of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).[9]

The Supreme Court made clear that we apply "an expansive and flexible approach" to the question of obviousness. *KSR*, 550 U.S. at 415.

[9] The parties do not present evidence or arguments regarding secondary considerations.

Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id.* at 417. To support this conclusion, however, it is not enough to show merely that the prior art includes separate references covering each separate limitation in a challenged claim. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). Rather, obviousness additionally requires that a person of ordinary skill at the time of the invention "would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention." *Id.*

Accordingly, an obviousness determination generally requires a finding "that a person of ordinary skill in the art would have been motivated to combine or modify the teachings in the prior art and would have had a reasonable expectation of success in doing so." *Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 160 (Fed. Cir. 2021) (citing *OSI Pharms.*, 939 F.3d at 1382 (quoting *Regents of Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1291 (Fed. Cir. 2018)). "Whether the prior art discloses a claim limitation, whether a skilled artisan would have been motivated to modify or combine teachings in the prior art, and whether she would have had a reasonable expectation of success in doing so are questions of fact." *Strathclyde*, 17 F.4th at 160. In determining whether there would have been a motivation to combine prior art references to arrive at the claimed invention, it is insufficient to simply conclude the combination would have been obvious without identifying any reason why a person of skill in the art would have made the combination. *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1366 (Fed. Cir. 2017). Moreover, in determining the differences between the prior art and the claims, the question under 35

U.S.C. § 103(a) is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 164 (Fed. Cir. 1985) ("It is elementary that the claimed invention must be considered as a whole in deciding the question of obviousness."); *see also Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537 (Fed. Cir. 1983) ("[T]he question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious. Consideration of differences, like each of the findings set forth in *Graham*, is but an aid in reaching the ultimate determination of whether the claimed invention *as a whole* would have been obvious.").

As a factfinder, we also must be aware "of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning." *KSR*, 550 U.S. at 421. Applying these general principles, we consider the evidence and arguments of the parties.

B. Level of Ordinary Skill in the Art

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). "This reference point prevents . . . factfinders from using their own insight or, worse yet, hindsight, to gauge obviousness." *Id.* Moreover, "the inquiry into whether any 'differences' between the invention and the prior art would have rendered the invention obvious to a skilled artisan necessarily depends on such artisan's knowledge." *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337 (Fed. Cir. 2020) (citing *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1349, 1353 (Fed. Cir. 2010) (affirming the district court's grant of summary judgment of invalidity in part because the obviousness "analysis requires an assessment

of the '. . . background knowledge possessed by a person having ordinary skill in the art'" (emphasis added))).

Factors pertinent to a determination of the level of ordinary skill in the art include: (1) educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of workers active in the field. *Env't Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381–82 (Fed. Cir. 1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id.* Moreover, these factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art. *Daiichi Sankyo Co. Ltd, Inc. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

In determining a level of ordinary skill, we also may look to the prior art, which may reflect an appropriate skill level. *Okajima*, 261 F.3d at 1355.

Additionally, the Supreme Court informs us that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421.

In our Institution Decision we determined, in accordance with Petitioner's proposal, that a person of ordinary skill in the art at the time of the '193 patent

> would have had a Bachelor's degree in biomedical engineering, mechanical engineering, chemical engineering, chemistry (or a related or equivalent field) and two or more years of experience researching, developing, designing and/or evaluating (or supervising the same) medical devices for measuring analyte levels, e.g., analyte sensors, or equivalent experience. A person

> with less or different education but more relevant practical experience, or vice versa, may also meet this standard.

Pet. 21–22 (citing Ex. 1002 ¶¶ 77–79). Patent Owner proposes a similar level of ordinary skill in the art including the same educational requirements but with 2–4 years of experience with medical devices for measuring analyte levels. PO Resp. 17 (citing Ex. 2011 ¶ 26).

Because there is no material dispute as to Petitioner's suggested level of ordinary skill in the art, and because Petitioner's assessment is consistent with the '193 patent, Patent Owner's proposed level of ordinary skill, and the asserted prior art, we continue our reliance on Petitioner's proposed level of ordinary skill in the art.

C. Claim Construction

We construe claims using the principles set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–17 (Fed. Cir. 2005) (en banc), and related cases. 37 C.F.R. § 42.100(b) (2021). Under that precedent, the words of a claim are generally given their "ordinary and customary meaning," which is the meaning the term would have to a person of ordinary skill at the time of the invention, in the context of the entire patent including the specification. *Phillips*, 415 F.3d at 1312–13.

As set forth in the table below, Patent Owner informs us of the parties proposed claim constructions for "substantially planar sensor" and "conductive/non-conductive" from the District Court litigation. PO Resp. 26 (citing Ex. 1020, 2–3, 7).

Claim Term	Patent Owner's Proposed Construction	Petitioner's Proposed Construction
Substantially planar sensor	Plain and ordinary meaning, *i.e.*, "a sensor comprising a plurality of substantially planar layers"	Indefinite OR "sensor that is largely but not necessarily wholly situated along a single plane"
Conductive/non-conductive	Plain meaning	Indefinite

There is no dispute over the meaning of "conductive/non-conductive" in this proceeding. In our Institution Decision we determined that "substantially planar" need not be expressly construed as the claim language appears to be sufficiently clear on its face. We did find persuasive Petitioner's argument and Dr. Smith's testimony that a person of ordinary skill in the art would have understood Feldman and Allen's sensors to be "substantially planar" within the plain and ordinary meaning of that term. Inst. Dec. 12 (citing Ex. 1002 ¶ 299).

Although the parties propose different constructions for "substantially planar sensor" before the District Court, we need not make a determination in this proceeding as to which construction is correct. On the complete record now before us, the parties neither make substantive arguments as to which construction is correct nor argue that this Decision should be resolved by the Board adopting one or the other construction. Also, our Decision would not change based on either construction. To that end, as set forth below, we determine that Feldman discloses a "substantially planar sensor" under either parties' construction.

D. Ground 2: Claims 1–3 and 11–13 — Alleged Obviousness over Feldman (Ex. 1008)

Our patentability analysis of the challenged claims for obviousness in view of Feldman is dispositive. For the reasons below, and on the complete record before us, Petitioner has shown by a preponderance of the evidence that claims 1–3 and 11–13 would have been obvious over Feldman.

1. Feldman (Ex. 1008)

Titled "Analyte Sensor, and Associated System and Method Employing a Catalytic Agent," Feldman describes several embodiments of *in vivo* blood glucose analyte biosensors and specifically "relates to analyte sensors that make use of any of a variety of transducing mechanisms, and which may be placed internally, transcutaneously, or externally, relative to a body." Ex. 1008 ¶ 2. Feldman's Figure 2A, illustrating a two-electrode analyte sensor is reproduced below.

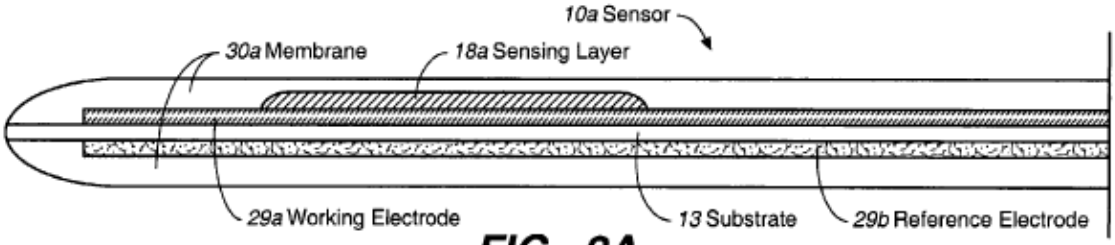


FIG._2A

Feldman's Figure 2A illustrates a two-electrode analyte sensor 10a including working electrode 29a separated from reference electrode 29b by substrate 13. *Id.* ¶ 97. Feldman explains that "[s]ensors having other configurations such as a three-electrode design can be prepared using similar methods." *Id.* ¶ 94.

In another embodiment, shown in Figure 4A–B, Feldman discloses a three-electrode sensor "with a portion of the sensor transcutaneously inserted

into the subcutaneous space." *Id.* ¶ 105. Feldman's Figure 4A is reproduced below.

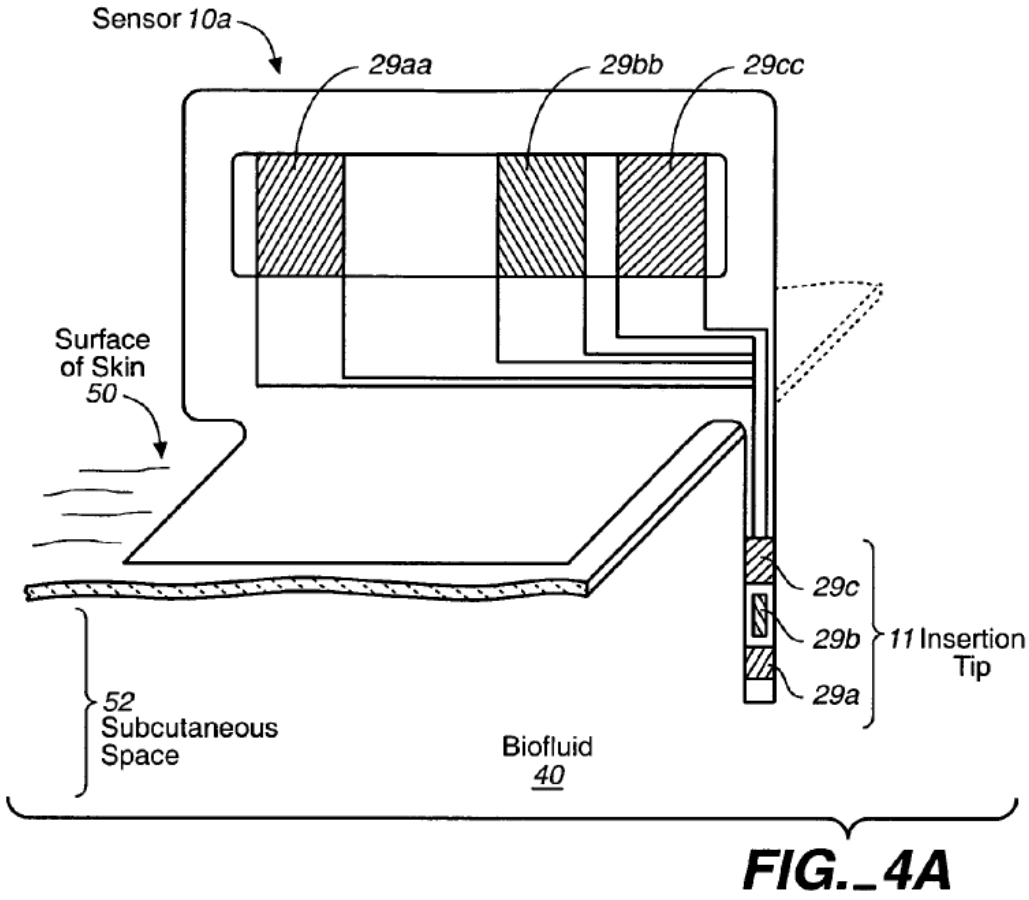


FIG._4A

Feldman's figure 4A illustrates insertion tip 11 of sensor 10a inserted in subcutaneous space 52 below the surface of skin 50. In this embodiment, sensor 10a includes insertion tip 11 having three-electrodes: working electrode 29a; reference electrode 29b; and counter electrode 29c. *Id.* ¶ 105. The electrodes, which are beneath the skin surface 50, are connected via electrically conductive traces to respective contact portions 29aa, 29bb, and 29cc above the skin surface. *Id.*

Figure 4B, reproduced below illustrates an exploded view of an end-most portion of sensor insertion tip 11.

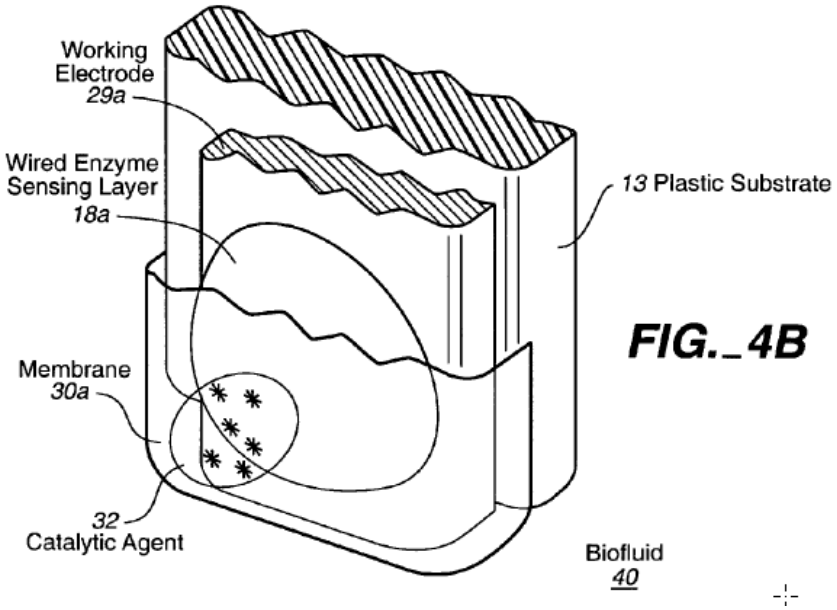


FIG._4B

Figure 4B illustrates cut-away view of sensor insertion tip 11, showing membrane 30a, enhanced with catalytic agent 32 covering sensing layer 18a atop working electrode 29a and plastic substrate 13.

2. Independent Claim 1

Our analysis below focuses on claim 1, and applies with respect to the same limitations in claim 11. *See* Pet. 35–53 (with the exception of the specific sequence of the three electrodes, Petitioner relies on the same arguments and evidence presented for claim 1 to demonstrate that claim 11 is obvious over Feldman).

(a) Petitioner's Arguments

i. Preamble — 1[Pre] transcutaneous continuous glucose sensor system comprising:

To the extent the preamble is limiting, Petitioner argues that "Feldman discloses that 'sensing systems are generally applied to the continuous sensing of an analyte' and that its 'biosensors are . . . described in relation to transcutaneous, amperometric glucose sensors.'" Pet. 36 (quoting Ex. 1008, ¶¶ 12, 71).

ii. Limitation 1[a] — a substantially planar sensor, the sensor comprising:

Petitioner argues that Feldman's Figure 4A, above, illustrates that the "electrochemical components of the sensor 10a are situated in a single plane . . . [t]hus, the sensor 10a of Feldman is a substantially planar sensor." Pet. 37 (citing Ex. 1002 ¶ 195). Dr. Smith testifies that although Figure 4 also illustrates a supporting flap that is not planar with the sensor, "this flap does not contain components related to the operation of the sensor. As such, a POSITA would have understood the sensor 10a to be a substantially planar sensor regardless of this flap." Ex. 1002 ¶ 196.

Dr. Smith testifies further that, although the electrodes on insertion tip 11 in Figure 4A are staggered,

> insertable portions of transcutaneous continuous glucose sensors are very small in size, with a thickness on the order of microns, to minimize discomfort to the patient . . . a POSITA would have understood that the conductive layers associated with the electrodes in the insertion tip 11 and the corresponding conductive traces in FIG. 4A of Feldman are extremely thin, and, therefore, the sensor is substantially situated in a single plane.

Id. ¶ 195, n.4.

iii. Limitation 1[b] — a first conductive layer associated with a first electrode;

Petitioner argues that Feldman's embodiments in Figures 2A and 4A–B illustrate, respectively, two and three electrode transcutaneous sensors. Pet. 38–43. By way of example, Petitioner provides the following annotated version of Figure 4 from Feldman below, illustrating a three-electrode transcutaneous sensor.

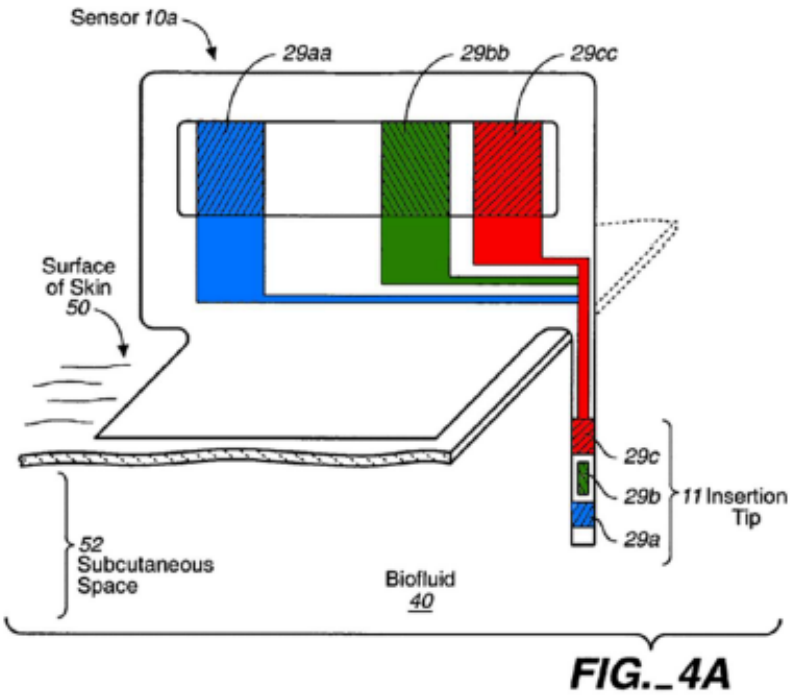


FIG._4A

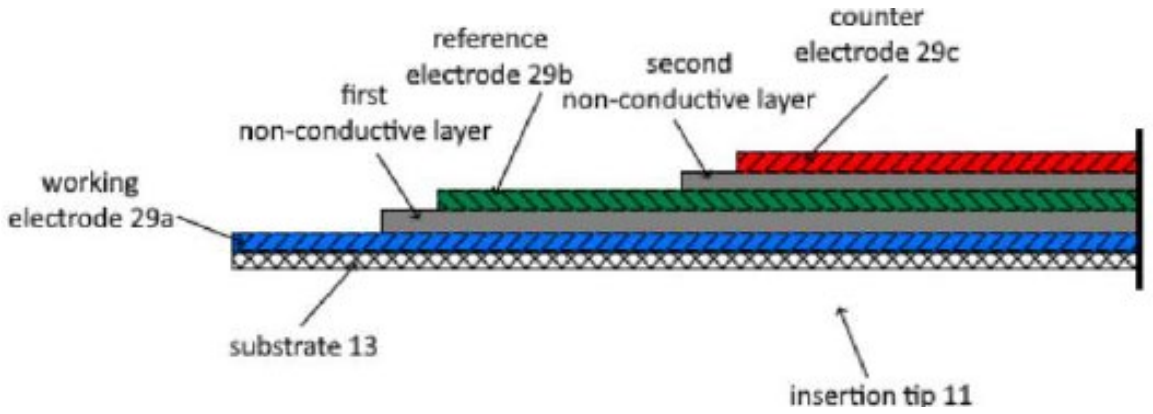
Id. at 39. With respect to the first conductive layer, as well as the second, and third conductive layer, Petitioner explains that in Feldman's Figure 4A "[t]he three conductive layers associated with the electrodes are connected to layered conductive traces that terminate at '[c]ontact portions of a working electrode 29*aa*, a reference electrode 29*bb*, and a counter electrode 29*cc*' located on the 'portion of the sensor 10a situated above the skin surface 50.'" *Id.* (quoting Ex. 1008 ¶ 105).

iv. Limitation 1[c] — a first non-conductive layer located at least in part over the first conductive layer;

For this limitation Petitioner relies on Feldman's Figures 2A and 4A, and the testimony of Dr. Smith who explains that "[a] POSITA also would have understood that it would have been obvious to include non-conductive layers between the conductive layers associated with the electrodes in order

to prevent a short circuit between the electrodes." Ex. 1002 ¶ 212 (citing Ex. 1013, 9:20–21).

Dr. Smith prepared the following annotated cross-sectional representation of insertion tip 11 to show how a person of ordinary skill in the art would have understood the structure of insertion tip 11 and a three-electrode sensor as shown below in Feldman's Figures 4A–B. *Id.* ¶ 209.



Dr. Smith's annotated cross-sectional representation of Feldman's insertion tip 11, above, illustrates layered working electrode 29a (blue), reference electrode 29b (green), and counter electrode 29c (red), where the electrodes are separated by a first and second non-conductive layers (grey). Dr. Smith testifies that

> [s]ince all three electrodes in FIG. 4A are implanted under the skin, it would have been obvious to a POSITA to expose the electrodes on the distal portion of the insertion tip 11, such as by staggering, in order for the biofluid 40 to contact a larger surface area of all three electrodes (in contrast to a stacked design in which the electrodes are not staggered).

Id. ¶ 210. Dr. Smith testifies further that "contacting a larger surface area of the electrodes with the biofluid would allow for more effective operation of the sensor of Feldman that has all three electrodes implanted under the skin." *Id.*

v. Limitation 1[d] — a second conductive layer associated with a second electrode, wherein the second conductive layer is located at least in part over the first non-conductive layer;

Petitioner argues based on Dr. Smith's annotated cross-sectional representation of insertion tip 11 from Feldman's Figure 4A, above, that "the green layer is a second conductive layer associated with a second electrode (conductive Ag/AgCl reference electrode 29b)." Pet. 44 (citing Ex. 1002 ¶ 221).

vi. Limitation 1[e] — a second non-conductive layer located at least in part over the second conductive layer,

Following from Dr. Smith's annotated cross-sectional representation of insertion tip 11 and Feldman's Figure 4A, Petitioner argues that "a second non-conductive layer (gray) is located at least in part over the second conductive layer (green)." *Id.* at 45 (citing Ex. 1002 ¶ 225).

vii. Limitation 1[f] — a third conductive layer associated with a third electrode, wherein the third conductive layer is located at least in part over the second non-conductive layer;

Again, based at least in part on Dr. Smith's annotated cross-sectional representation of insertion tip 11 and Feldman's Figure 4A, Petitioner argues that "the red layer is a third conductive layer associated with a third electrode (counter electrode 29c) located at least in part over a second non-conductive layer (gray)." *Id.* (citing Ex. 1002 ¶ 226).

viii. Limitation 1[g] — a membrane located over at least a portion of a working electrode;

Dr. Smith testifies that from observing Feldman's Figures 4B, reproduced below, a person of ordinary skill in the art would have understood "that 'FIGS. 4A and 4B, together, illustrate a fully fabricated

sensor, with a catalytic agent incorporated into a protective membrane.'" Ex. 1002 ¶ 239 (quoting Ex. 1008 ¶ 105).

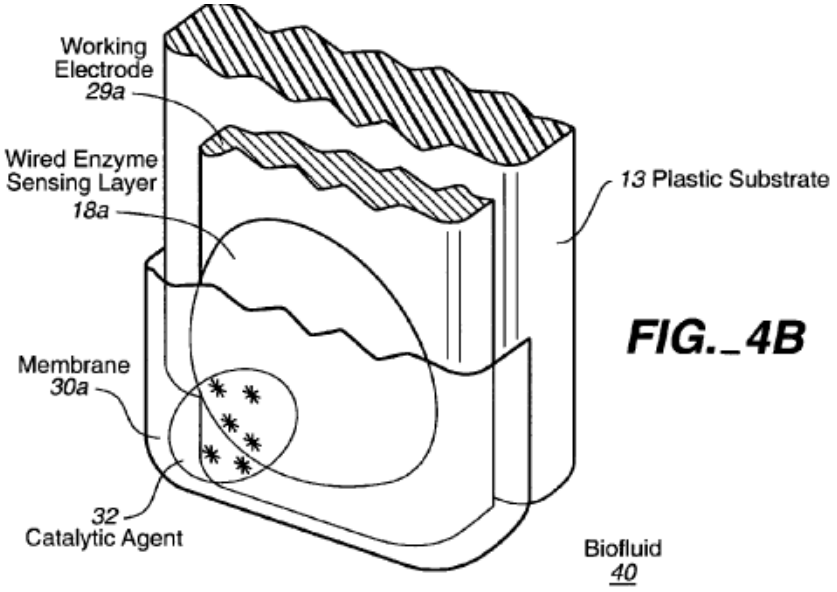


FIG._4B

Feldman's Figure 4B, above, is a cutaway view of working electrode 29a where

> a wired enzyme sensing layer 18a rests on top of a portion of the working electrode 29a. Overlaying the sensing layer and a portion of the electrode, depicted transparently, is an interfacing membrane 30a, and associated with and dispersed throughout the membrane is a catalytic agent 32, the membrane covering the Sensing layer 18a of the enzyme-based electrochemical sensor.

Ex. 1008 ¶ 105. We point out that Dr. Smith's representation of insertion tip 11 from Figure 4A, above, shown with respect to limitation 1[e] does not illustrate membrane 30a or catalytic agent 32.

ix. Limitation 1[h] — wherein at least one of the first electrode, the second electrode, or the third electrode is the working electrode,

As discussed above, Petitioner argues "Feldman discloses that 29a is the working electrode." Pet. 49 (citing Ex. 1002 ¶ 242).

x. Limitation 1[i] — and wherein the working electrode is configured to measure a signal indicative of a glucose concentration.

Petitioner argues that Feldman "discloses that the transduced signal is correlated to an amount or concentration of analyte." *Id.* (citing Ex. 1008 ¶ 37, Fig. 5). Petitioner points out that Feldman "further discloses a graph of electrical current versus glucose concentration for electrochemical sensors." *Id.* (citing Ex. 1008 ¶ 22, Fig. 5). Dr. Smith testifies that "a POSITA would have understood that, in the case of an electrochemical glucose sensor as disclosed in Feldman, the working electrode is configured to measure the electrical current that is indicative of a glucose concentration." Ex. 1002 ¶ 246.

(b) Patent Owner's Arguments

Patent Owner's main argument is that "Feldman neither discloses nor teaches the stacked layer three-electrode structure of the claimed invention." PO Resp. 38, 42–60. Patent Owner argues that "the Petition cites no other evidence suggesting POSITAs would even consider using a stacked layer design for three-electrode partially *implantable in-body* sensors." *Id.* at 38–39. Patent Owner contends that the background references asserted by Petitioner to show stacking of electrodes, including Hyland, Say, and Dobson, are irrelevant and would not have been considered by a person of ordinary skill in the art because they are non-invasive, that is they describe *ex vivo*, not *in vivo* sensors. *Id.* at 39, 60–62.

Patent Owner makes several other arguments, including whether the opinions of declarant Dr. Smith should be accorded little weight because he is not sufficiently experienced with *in vivo* sensors; and whether Feldman qualifies as prior art under pre-AIA § 102(e)(1) because Feldman's

application was published after the priority date of the challenged claims. *Id.* at 26–28, 41. We address Patent Owner's arguments below in detail, beginning with an evaluation of the correlation between Dr. Smith's testimony and experience, and then considering whether Feldman qualifies as prior art to the '193 patent.

(c) Analysis

We consider below the arguments and evidence presented by both parties.

i. Dr. Smith and the Level of Ordinary Skill in the art.

Patent Owner argues that "Dr. Smith has not shown any direct experience with partially invasive glucose sensors that are the subject of the challenged claims." PO Resp. 26 (citing Ex. 1002 ¶¶ 140, 147–145, 147). Patent Owner argues specifically that not only does Dr. Smith lack experience with *in vivo* sensors, but "gave conflicting testimony on the Dobson gas sensor, first testifying that he would not put it in the human body, but then testifying that a POSITA would consider putting it in the human body." *Id.* at 27 (citing Ex. 2009, 22–23). Patent Owner further argues that Dr. Smith's testimony is unreliable because he "testified that he could conceive of no other way to implement the Feldman sensor than the way disclosed in his declaration," despite other prior art references, such as Say, which discloses a common electrode on substrate sensor. *Id.* (citing Ex. 2009 106–107, 109–110).

Petitioner responds arguing that Patent Owner is mischaracterizing Dr. Smith's knowledge and experience and that "Dr. Smith has ample experience with *in vivo* sensors." Pet. Reply 27 (citing Ex. 1002 ¶¶ 6–9, Appendix A; Ex. 2009, 45:5–46:10). Petitioner points out that "Dr. Smith

offered to expand on this experience during his deposition, but DexCom's attorney declined his offer." *Id.* (citing Ex. 2009, 47:4–12). Petitioner contends that Patent Owner is also mischaracterizing Dr. Smith's testimony about the Dobson gas sensor, and that actually, Dr. Smith "pointed to the biocompatible *membrane* of Dobson as possibly being inside the body, not the lead electrodes." *Id.* at 28 (citing Ex. 2009, 13:5–23, 25:14–26:5).

Having considered the complete record before us, we find the evidence does not support the premise that Dr. Smith lacks appropriate knowledge and experience with *in vivo* sensors or that his testimony is compromised by his analysis of Dobson. Dr. Smith easily has sufficient experience with blood glucose monitoring and the electrochemical instruments and systems used to measure a patient's blood glucose level *in vivo*. Ex. 1002 ¶¶ 5–9. By way of background and education, Dr. Smith holds a Bachelor of Science degree in chemistry from Butler University and a Ph.D. in analytical chemistry from the University of Illinois. *Id.* ¶ 5. Dr. Smith testified that he has worked for 34 years specifically in the blood glucose monitoring field, explaining that his "work includes development of novel electrochemical instrumentation, development of automated clinical laboratory instrumentation, research and development of blood glucose meters and test strips, *development of transcutaneous intravascular glucose measurement systems*, and development of noninvasive glucose measurement systems." *Id.* ¶ 6 (emphasis added). Among his positions, for 12 years Dr. Smith was Vice President of Research, Development, and Engineering Worldwide and Chief Scientific Officer at LifeScan, Inc., a division of Johnson & Johnson. *Id.* ¶ 8. Dr. Smith testifies that he is an inventor on eleven "issued patents relat[ing] to glucose monitoring, four

relate to clinical laboratory instrumentation, and two relate to novel electrochemical instrumentation." *Id.* ¶ 9.

We appreciate that Dr. Smith's background includes patents and publications relating to *non-invasive* blood glucose monitoring, but he testified that he also worked with invasive/transcutaneous continuous glucose-monitoring systems and techniques. When asked during his deposition, Dr. Smith testified that at LifeScan he worked on both non-invasive and invasive blood glucose monitoring devices:

> Q. So outside of your work as a -- as a witness in litigation, have you worked on development of any continuous glucose-monitoring devices?
>
> A. Yes.
>
> Q. When did you work on those continuous glucose-monitoring devices?
>
> A. The first experience with them was at LifeScan where we did research work on continuous glucose-monitoring devices and explored different ways that those measurements could be made, and we applied for some patent applications on those shortly after I retired.
>
> . . .
>
> Q. Okay. And were those noninvasive glucose-monitoring devices that you worked on?
>
> A. Those continuous glucose-monitoring devices I referred to were invasive/transcutaneous continuous glucose-monitoring devices. I also worked on a number of noninvasive continuous monitoring devices.

Ex. 2009, 44:25–45:22. Dr. Smith was asked several times, specifically, if his work included invasive glucose monitoring:

> Q. And did that work involve invasive continuous glucose-monitoring devices?

> A. As well as noninvasive glucose continuous monitoring devices, yes.
>
> . . .
>
> Q. And were the patents that you referred to for LifeScan in the area of invasive continuous glucose monitoring?
>
> A. Yes, those were.

Id. at 46:7–20. Here, we find Dr. Smith's testimony directly and expressly contradicts Patent Owner's assertions as to his lack of experience or familiarity with invasive glucose monitoring devices.

With respect to the Dobson gas sensor device, we find both counsel's questions and Dr. Smith's answers straightforward. Patent Owner's counsel asked

> Q. And would you ever place Dobson inside the body of a patient?
>
> A. It's my understanding that the intent of Dobson was to make a measurement outside the body and, therefore, it wouldn't -- I would not expect to place it inside the body.
>
> . . .
>
> Q. So yeah, would a POSITA in 2005 ever place a portion of Dobson inside a body?
>
> A. That is not an intent of Dobson, but it's entirely possible that it could be done. The measurement could be made by placing this sensor partially within the body.

Id. at 22:9–23:5. Dr. Smith is clear that Dobson did not intend an invasive glucose monitoring sensor. Dr. Smith stated that possibly "it could be done." *Id.* at 28:3. And, with respect to the issue of lead in Dobson, Dr. Smith agreed that "[i]f the lead were exposed to the body of the patient, there's a potential that it could be toxic." *Id.* at 24:15–18. It is not at all a persuasive argument by Patent Owner, based on this testimony, that Dr.

Smith was specifically advocating for placing lead material inside a patient's body.

Counsel's follow up questions were answered similarly by Dr. Smith:

> Q. But it's your testimony today that Dobson is not a noninvasive sensor?
>
> A. . . . I see that Dobson says on page 3 that it's preferable to make a noninvasive measurement, and one example of a noninvasive measurement is to place this sensor outside the body. I don't see that he contends that this is truly a noninvasive sensor – necessarily a noninvasive sensor.

Id. at 27:10–19. Dr. Smith's answers were consistent in his deposition, that Dobson mainly discloses a non-invasive sensor.

In context, we find that Dr. Smith's conclusions relating to Dobson are well founded and internally consistent. He clearly understood that Dobson related to non-invasive measurements. *Id.* at 26:23–27:6. Dr. Smith simply opined, when asked, that a POSITA might not rule out invasive use because part of the sensor with "films that are gas permeable could be implanted in the body." *Id.* at 26:4–5. We disagree with Patent Owner's characterization of his testimony as "conflicting." PO Resp. 27 (citing Ex. 2009, 22–23).

Patent Owner also argues that Dr. Smith's testimony is unreliable because he "testified that he could conceive of no other way to implement the Feldman sensor than the way disclosed in his declaration." *Id.* Patent Owner argues that Dr. Smith's testimony conflicts with Say, incorporated by reference in Feldman, showing electrodes in a side-by-side arrangement on a single substrate. *Id.*

Considering Feldman, and reading Dr. Smith's deposition testimony as to Feldman's Figures 4A–B in context as well as the asserted arrangement

in Dr. Smith's cross-section of insertion tip 11 depicting stacked conductive traces, we do not read and understand his testimony as intending to say there was no other way to arrange electrodes. Ex. 2009, 99:4–111:6. We read Dr. Smith's testimony as consistently opining that a person of ordinary skill in the art, specifically considering Feldman's Figure 4A–B, would have understood insertion tip 11 as a layered or stacked arrangement of conductive traces. *See id.* at 105:22–106:4 (Dr. Smith testifying that "a POSITA would know that in order for those three conductive traces to travel down the vertical section of the substrate toward the insertion tip, they would need to be insulated from each other with nonconductive layers in order to allow the sensor to operate."). As for Figure 4A, Dr. Smith explained during his deposition that

> [i]n Feldman, the conductive traces coming from the three contact areas 29aa, 29bb, and 29cc, all move to the right and -- and then pass downward in one undifferentiated rectangular pathway that indicates to me that all three of those electrodes are positioned on top of each other, and that in order for this to be a functioning sensor, there would need to be a nonconductive layer between each of the two pairs of electrodes in the insertion tip -- in the vertical portion of Figure 4A that ends in the insertion tip.

Id. at 103:7–16.

During the deposition Patent Owner's counsel consistently pointed to Feldman's Figure 4A, and Dr. Smith consistently reiterated his opinion regarding the embodiment shown in Figure 4A. For example, Dr. Smith was asked "are you aware of any other way that you could construct the sensor in *Feldman Figure 4A*?" *Id.* at 107:18–20 (emphasis added). Dr. Smith replied that "I'm not aware of any other way to construct those three vertical traces *in the insertion tip of Figure 4A*." *Id.* at 107:22–24 (emphasis added). We do not consider this testimony as impugning Dr. Smith's credibility, but

instead reflects a consistency of his opinion regarding what an ordinary skilled artisan would have understood from Feldman's Figure 4A. Specifically, we credit Dr. Smith's opinion that although Feldman does not provide a detailed verbal description of the conductive trace arrangement at insertion tip 11, a person of ordinary skill in the art would understand Figure 4 to include "the three conductive layers associated with the electrodes are located overtop each other in a stacked fashion in a similar manner to that depicted in Figure 2A with respect to the working electrode 29a and the silver/silver chloride counter/reference electrode 29b." *Id.* at 104:3–8 (quoting Ex. 1002 ¶ 205).

Moreover, Patent Owner has not explained sufficiently *why* Dr. Smith's failure to acknowledge other ways to arrange conductive traces, for example as described in U.S. Patent No. 6,565,509 B1 to Say (Ex. 2015), undercuts the reliability of his testimony as to the drawing disclosure in Feldman's Figure 4A. We reproduce Figure 2 of Say below, in comparison to Feldman's Figure 4A.

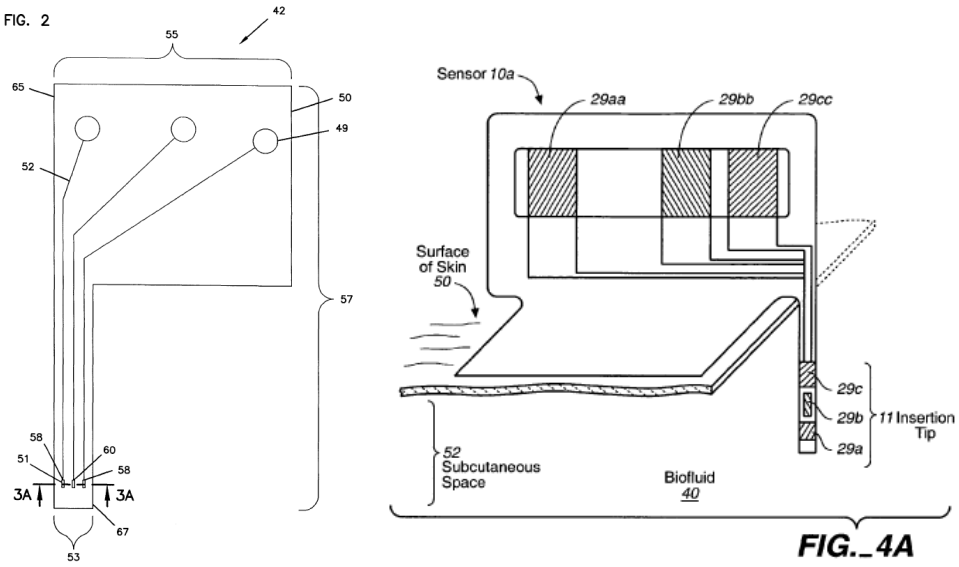


Figure 2 from Say is shown on the left compared to Feldman's Figure 4A on the right. We appreciate that Say discloses what appears to be three conductive traces side-by-side and separated from one another on top of a substrate. Comparing these drawings, Feldman's Figure 4A is quite different from Say's Figure 2. Figure 4A shows the conductive traces 29aa, 29bb, and 29cc, initially next to one another, but then traces 29aa and 29bb disappearing *behind* conductive trace 29cc. Patent Owner has shown that there were known alternative methods of arranging conductive traces on, in or through a substrate. But this does not render unreliable Dr. Smith's testimony as to what a person of ordinary skill in the art would understand considering Feldman's Figure 4A. That is—that the conductive traces do not appear side-by-side as in Say, but "that the three conductive layers associated with the electrodes disclosed in FIG. 4A of Feldman are [] located overtop each other in a stacked fashion (similar to FIG. 2A) so that the conductive traces from the contact portions connect to each corresponding electrode." Ex. 1002 ¶ 207.

Overall, we do not find Patent Owner's arguments and evidence to undermine Dr. Smith's credibility, experience, and testimony with respect to invasive and non-invasive glucose monitoring systems, Dobson or what a person of ordinary skill in the art would understand from Feldman's Figure 4A.

ii. Whether Feldman is Prior Art

Patent Owner next argues that Feldman is not prior art. PO Resp. 41. Patent Owner argues specifically that "Petitioner does not dispute, and thus concedes, that Feldman is not prior art under pre-AIA Section 102(a)." *Id.* Patent Owner contends that Feldman was published September 29, 2005,

almost 5 months after the April, 15, 2005, priority date to which the '193 claims are entitled. *Id.*

The problem with Patent Owner's argument is that Petitioner asserts Feldman as a prior art reference under pre-AIA 35 U.S.C. 102(e) which states in pertinent part:

> A person shall be entitled to a patent unless –
>
> . . .
>
> the invention was described in — (1) an application for patent, published under section 122(b), by another *filed in the United States* before the invention by the applicant for patent . . .

Assuming that the challenged claims are entitled to a priority date as early as April 15, 2005, and we are not entirely persuaded that they are, Feldman predates the earliest possible priority date to which the claims of the '193 patent are entitled because Feldman was filed on December 7, 2004, more than 4 months prior to the asserted April 15, 2005 priority date.

Feldman is a U.S. Application Publication, which published September 29, 2005, *and was filed in the U.S.* on December 7, 2004. Ex. 1008, Codes (22) (43). As explained in the MPEP "[p]re-AIA 35 U.S.C. 102(e) allows the use of certain international application publications *and U.S. patent application publications*, and certain U.S. patents as prior art under pre-AIA 35 U.S.C. 102(e) *as of their respective U.S. filing dates*." MPEP 2136 (emphases added). Patent Owner argues specifically that Feldman "is a September 29, 2005, publication that published after the '193 Patent's priority date." PO Resp. 41. While true, Patent Owner incorrectly relies upon the *publication* date of Feldman, as opposed to Feldman's *filing* date of December 7, 2004, which sets the effective date on which Feldman is prior art under 102(e).

To the extent Patent Owner argues that Feldman's application publication "is insufficient evidence of the contents of the Feldman application as filed," we disagree. PO Resp. 41 (citing FRE 1002–1003). With few exceptions, the Federal Rules of Evidence apply to *inter partes* proceedings. 37 CFR § 42.62. Although incorrect, it could potentially be argued that unlike a US Patent, a US Patent Application Publication is not self-authenticating and should therefore be excluded as prior art evidence in this trial. Patent Owner, however, did not timely object to Feldman (Exhibit 1008) under 37 C.F.R. § 42.64(b)(1). Paper 15. Nor did Patent Owner file a motion to exclude Feldman or any evidence in this proceeding. Nor could it have in this case without an underlying objection to Feldman. *See* 37 C.F.R. § 42.64(c). This is important. Without such an objection Petitioner was not provided the opportunity to offer supplemental evidence. *See LKQ Corp. v. Clearlamp LLC*, IPR2013-00020, Paper 17 at 3 (PTAB Mar. 5, 2013) ("This process allows the party relying on the evidence to which an objection is timely served, the opportunity to correct, by serving supplemental evidence within so many days of the service of the objection."). Moreover, Patent Owner has not offered any plausible reason that the filing and publication dates of Feldman are incorrect and has not explained legally or factually why the Board should not rely on the filing date information printed on the face page of Feldman. PO Resp. 41. Also, it is likely that Federal Rule of Evidence 902 (5) applies here. This Rule states:

> The following items of evidence are self-authenticating; they require no extrinsic evidence of authenticity in order to be admitted:
>
> . . .
>
> (5) *Official Publications*. A book, pamphlet, or other publication purporting to be issued by a public authority.

Fed. R. Evid. 902(5). For all the reasons above, we are persuaded on the complete record before us that Feldman is prior art under [p]re-AIA 35 U.S.C. 102(e).

iii. Whether Feldman Discloses to a Person of Ordinary Skill in the Art a Stacked Three-Electrode in vivo Glucose Sensor

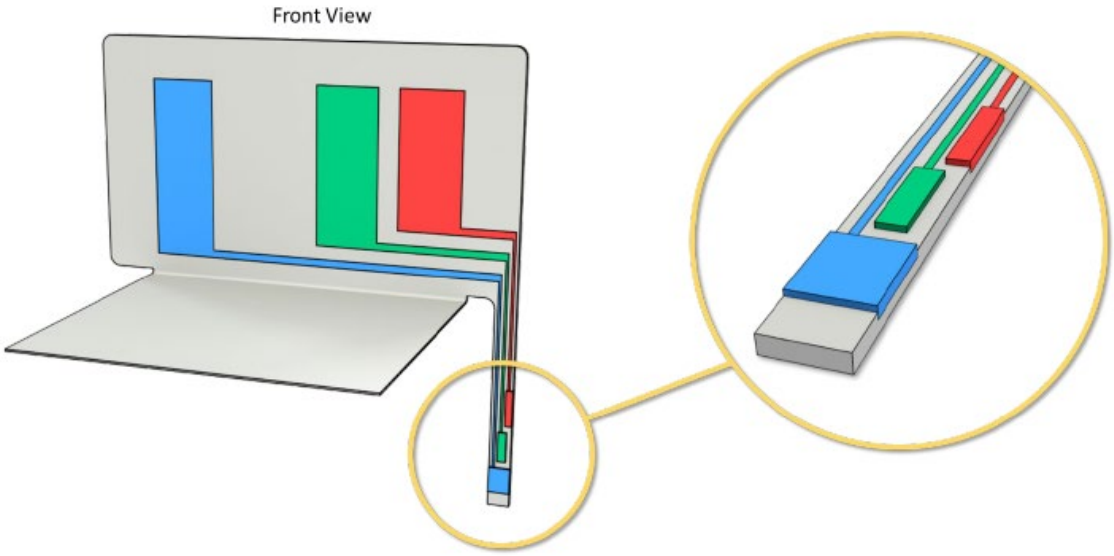
Considering claim 1, specifically limitations 1[b]–[f], Patent Owner makes a series of arguments relating to Petitioner's reliance on Feldman as disclosing a stack of three electrodes separated by two non-conductive layers for *in vivo* glucose sensors. PO Resp. 42–62. Patent Owner argues that neither Feldman, nor Feldman as it would have been understood by a person of ordinary skill in the art, discloses or teaches in any manner a stacked, three-electrode layered structure as claimed. *Id.* These arguments assert the lack of written description and detailed drawings in Feldman of any such arrangement, and address the additional background references, some incorporated by reference in Feldman, which Petitioner relies upon which arguably disclose electrode and insulation layer stacking relating to *ex vivo* glucose sensors. Patent Owner's arguments assert alternative glucose sensor conductive trace designs purportedly taught by Feldman, alternatives that do not include a first and second non-conductive layers. We address these arguments and others below.

Patent Owner argues specifically that "[w]hile Feldman contemplates a sensor having three electrodes as depicted in the high-level Fig. 4A, nothing in Feldman or its incorporated references suggest that the three-electrode design would include a stack of conductive and non-conductive layers, as recited in the claims." PO Resp. 46 (citing Ex. 2011 ¶ 87). To support this argument, Patent Owner specifically argues that neither Mao

(Ex. 1011) nor Say (Ex. 2016), as incorporated by reference in Feldman, "disclose either a two-electrode structure or three electrodes disposed on a single substrate." *Id.*

We agree that Mao and Say do not disclose a stacked layer three-electrode structure. However, Petitioner does not rely on Mao or Say for their particular electrode and insulating structure. Petitioner relies on Mao to explain that "biosensors typically employ two or three electrodes, including at least one measuring or working electrode and one reference electrode." Pet. 46 (citing Ex. 1011 ¶ 5). Petitioner does not appear to specify a particular portion of Say as evidence upon which it relies.

Patent Owner argues further, considering Say, that "a POSITA would utilize Say-461's teachings in understanding how to implement the Feldman Fig. 4A sensor . . . [o]ne configuration describes three electrodes/traces positioned on one side of a substrate." PO Resp. 50 (citing Ex. 2016, Fig. 2). Patent Owner's declarant, Dr. Tapsak, testifies that Say is "consistent with Feldman Fig. 4A, which depicts the electrode portions 29aa-29cc in the ex vivo portion of the sensor as next to each other in one plane (e.g., on one side of the substrate 13)." Ex. 2011 ¶ 93. Dr. Tapsak testifies further that "[w]ith knowledge of this Say-461 configuration, a POSITA would interpret the connections in Fig. 4A as traces between 29a–29c and 29aa–29cc on one side of the substrate 13." *Id.* Still considering Say, Dr. Tapsak provides a first illustration example of Feldman's Figure 4A, reproduced below, as he testifies that a person of ordinary skill in the art would have understood Figure 4A.



Dr. Tapsak's first illustration of his interpretation of Figure 4A shows the electrode traces side-by-side on top of a single substrate and is captioned "[b]ased on Feldman 4A, all traces on one side of substrate." *Id.* ¶ 106. In summary, Dr. Tapsak testifies that

> Say-461 informs the POSITA that the electrode traces would be disposed either (i) all co-planar on one side of a substrate or (ii) on opposing sides of the substrate, with one trace on one side of the substrate and two traces co-planar on the other side of the substrate. In either configuration, there are at least two co-planar electrode traces and there is no stacked layer three-electrode arrangement.

Id. ¶ 96.

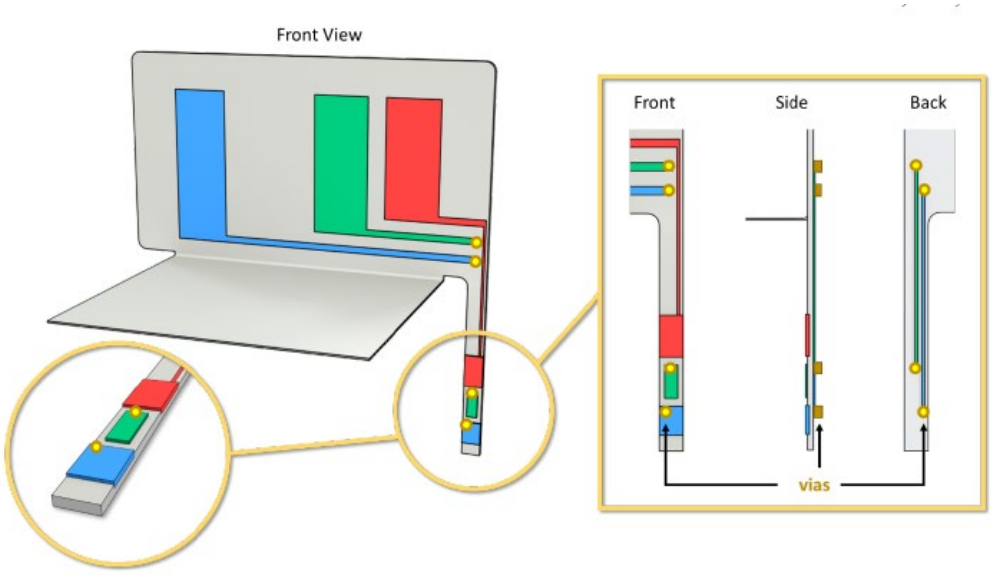
Dr. Tapsak testifies further that "[n]o evidence shows a POSITA would have been *motivated* or would have *reasonably expected to succeed* in implementing Feldman with electrodes and other layers over one another." *Id.* ¶ 97. Dr. Tapsak explains that consistent with Say, considering Feldman's Figure 4A,

> [b]ecause the ex vivo and in vivo portions of the sensor would be fabricated at the same time, the construction of the ex vivo portion informs a POSITA as to the construction of the in vivo

> insertion tip. As such, a POSITA would expect both the ex vivo and in vivo portions of the sensor to have all of the electrodes, along with their corresponding conductive traces, arranged on one planar substrate as indicated by the ex vivo portion in Fig. 4A.

Id. ¶ 103. Dr. Tapsak testifies that "the POSITA would be motivated to use Say-461's 'convenient' approach 'for ease of manufacture' because it 'reduc[es] the number of steps in the manufacturing process' and 'eas[es] the registration constraints in the process.'" *Id.* ¶ 105 (citing Ex. 2016, 15:46–60).

Dr. Tapsak also explains with a second illustration, reproduced below, that Feldman Figure 4A could be implemented with a single substrate using vias.



Dr. Tapsak's second illustration of another interpretation of Feldman's Figure 4A shows the electrode traces connected by vias on a single substrate, the illustration is captioned "Feldman Fig. 4A modified to use vias." *Id.* ¶ 106. Based on these alternatives that were known ways of insulating and fabricating electrode traces, Dr. Tapsak testifies that "the POSITA would have been discouraged from modifying Feldman Fig. 4A as proposed by the

Petition. To do so would deviate from the convenient and easily manufactured sensor of Say-461, without any evidenced benefit." *Id.* ¶ 107.

We acknowledge, based on Dr. Tapsak's testimony in this proceeding, that it is possible to insulate three traces from each other in different ways. For example, Dr. Smith explained that the prior art to Shah (Ex. 1010) "discloses a method of forming electrical contacts (using vias) through a dielectric layer using temporary pillars." Ex. 1002 ¶ 126. To an extent, we credit Dr. Tapsak's testimony that a person of ordinary skill in the art would have known that conductive traces on Feldman's insertion tip could be insulated and fabricated in different ways. As shown in Say's exemplary Figure 2, similar to what Dr. Tapsak illustrates in his first alternative drawing above, one fabrication might align the traces next to one another on top of a single substrate. Ex. 2011 ¶ 93 (citing Ex. 2016, Fig. 2). And, Dr. Tapsak's second illustration reveals using vias to locate traces on both sides of a single substrate. *Id.* ¶ 94. As in our Institution Decision, we do not find the existence of these alternatives to meaningfully undermine Dr. Smith's testimony. Even if there were better or more convenient ways to arrange the traces and substrates, that fact alone does not demonstrate that a person of ordinary skill in the art would not have considered Feldman's Figure 4A to have described layering the traces on two substrates as Dr. Smith proposes. *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012) (The Federal Circuit explaining that "[t]his court has further explained that just because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes.").

On the other hand, Petitioner's declarant, Dr. Smith presented testimony and drawings, reproduced below, as to the what a person of ordinary skill in the art would have understood from Figure 4A.

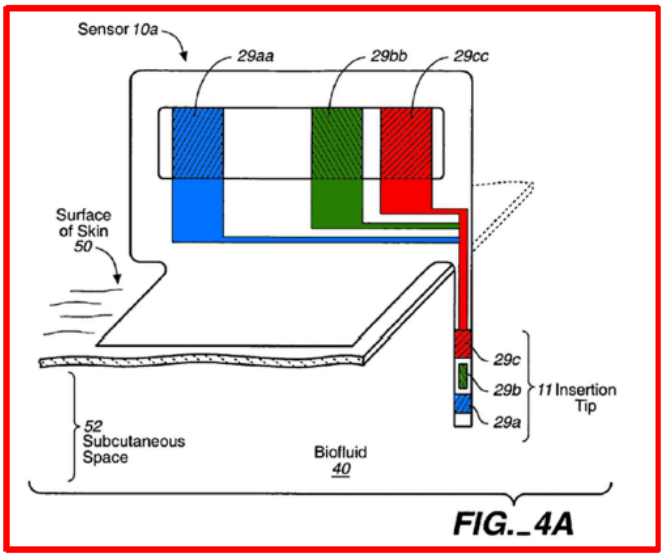
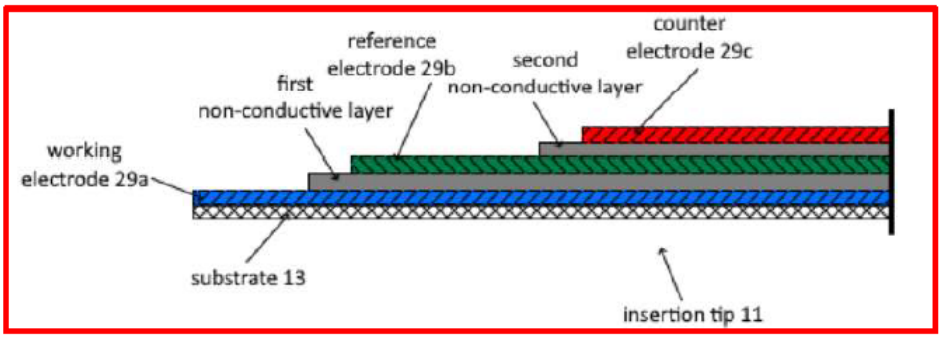
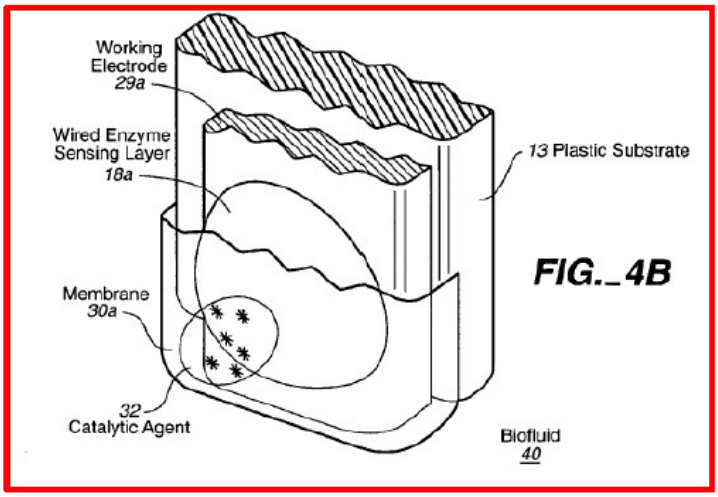


Figure 4A from Feldman, as annotated by Dr. Smith illustrates, in color, the different conductive traces 29aa, 29bb, and 29cc. Ex. 1002 ¶ 202.

Dr. Smith's illustration of a proposed cross-section of insertion tip 11, based on Figure 4A, is reproduced below.



Dr. Smith's illustration showing "a cross-sectional view of a three-electrode sensor that would have been obvious to a POSITA based on Figure 4A of Feldman (and related disclosures in Feldman)." *Id.* ¶ 209. In support of his opinion that a person of ordinary skill in the art would have understood Feldman in the manner depicted above, Dr. Smith also relies on Feldman's Figure 4B reproduced below.



Feldman's Figure 4B illustrates the extreme end of insertion tip 11 showing the substrate 13 and working electrode 29a. *Id.* ¶ 204. Dr. Smith testifies that despite the fact that Feldman does not textually describe the layering of the three electrodes, "from the depictions in FIGS. 4A and 4B, a POSITA would have understood that the three conductive layers associated with the electrodes are located overtop each other in a stacked fashion." *Id.* ¶ 205. Considering annotated Figure 4A, Dr. Smith explains that

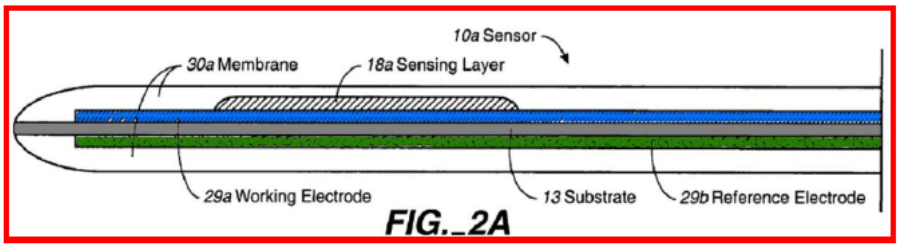
> the conductive trace connecting 29aa to 29a (shown in blue) is behind (under) the conductive trace connecting 29bb to 29b (shown in green), which is itself behind (under) the "topmost" conductive trace connecting 29cc to 29c (shown in red). This is why only the topmost conductive trace is visible in the portion leading to the electrodes.

Id. ¶ 206. Considering, together, all of the figures in Feldman, Dr. Smith further testifies that

> [a] POSITA reading Feldman would have readily understood that the three conductive layers associated with the electrodes disclosed in FIG. 4A of Feldman are likewise located overtop each other in a stacked fashion (similar to FIG. 2A) so that the conductive traces from the contact portions connect to each corresponding electrode.

Id. ¶ 207. Dr. Smith explains that a person of ordinary skill in the art would have known with such a stacked, or layered design, "to expose the electrodes on the distal portion of the insertion tip 11, such as by staggering, in order for the biofluid 40 to contact a larger surface area of all three electrodes." *Id.* ¶ 210. According to Dr. Smith, a person of ordinary skill in the art would also have known "to include non-conductive layers between the conductive layers associated with the electrodes in order to prevent a short circuit between the electrodes. I note, for instance, that Hyland evidences the need for 'the electrodes [to] each be separated by an insulating material' so 'the cell can operate.'" *Id.* ¶ 212 (citing Ex. 1013, 9:20–21).

As an alternative to the arrangement of Figure 4, Dr. Smith points to Feldman's Figure 2A, an annotated version by Dr. Smith of which is reproduced below, which is a cross-section of a two-electrode sensor including a working electrode 29a (blue) and a reference electrode 29b (green) separated by non-conductive substrate 13 (grey).



Dr. Smith's annotated version of Figure 2A from Feldman illustrates a two-electrode sensor 10a. Dr. Smith testifies that considering the three electrodes shown in Feldman's Figure 4, "[i]t would have been obvious to a POSITA, based on these teachings of Feldman, to modify the insertion tip of FIG. 2A to include a separate counter electrode as disclosed in Feldman." *Id.* ¶ 229. An annotated version of Feldman's Figure 2A by Dr. Smith, including counter electrode 29c, is reproduced below.

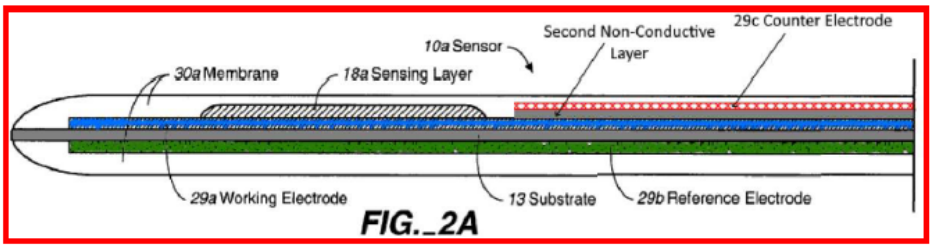


FIG._2A

Dr. Smith's annotated version of Feldman's Figure 2A is shown above including the addition of a third counter electrode 29c (red), separated from working electrode 29a by a second non-conductive layer (grey). For this alternative, Dr. Smith testifies that a person of ordinary skill in the art

> would have understood that the added conductive layer associated with the counter electrode 29c (shown in red) would necessarily need to be conductive for the sensor to function. It was well known to a POSITA at the time of the alleged invention that a non-conductive layer in between the conductive layers associated with the working electrode 29a and the counter electrode 29c is an obvious way to isolate the conductive electrodes in order to prevent a short circuit.

Id. ¶ 231. Dr. Smith further testifies that a person of ordinary skill in the art "would have been motivated to include the counter electrode 29c in this location because it would allow the biofluid 40 to contact larger surface area of all three electrodes (in contrast to a stacked design in which the electrodes are not staggered)." *Id.* ¶ 33.

In summary, Dr. Tapsak has presented two alternatives, one with the electrode traces side-by-side on top of a substrate, and another one where vias connect two traces through to the opposing side of the substrate. Ex. 2011 ¶¶ 93–94. And Dr. Smith has also presented two alternatives, a first based on Figure 4A–B about which Dr. Smith testifies that a person of ordinary skill in the art "would have understood that it would have been obvious to include a non-conductive layer between the conductive layers associated with the reference electrode 29b and the counter electrode 29c in

order to prevent a short circuit between the electrodes." Ex. 1002 ¶ 225. Dr. Smith's second alternative, based on Figure 2A, modifies the two-electrode embodiment into a three-electrode embodiment having a first and second non-conductive layer to insulate the electrodes from one another.

Based on these four alternate embodiments proposed by the parties' respective experts, we find that a person of ordinary skill in the art would have understood that an *in vivo* sensor could be implemented in several ways. The declarants have provided probative testimony for each alternative that a person of ordinary skill in the art would have considered several ways of implementing the three-electrode version in Feldman's Figure 4A. Patent Owner's alternate embodiments, do not demonstrate, however, that Petitioner's stacked cross-section insertion tip would *not* have also been known and obvious to a person of ordinary skill in the art.

Based on the entire record, we find, consistent with our review of Figures 2A and 4A, that Petitioner and Dr. Smith have explained persuasively that a person of ordinary skill in the art would have understood that "the three conductive layers associated with the electrodes are located overtop each other in a stacked fashion in a similar manner to that depicted in FIG. 2A with respect to the working electrode 29a and the Ag/AgCl counter/reference electrode 29b." Ex. 1002 ¶ 205. For example, reproduced below are Dr. Smith's annotated version of Feldman's Figure 4A side-by-side with Dr. Tapsak's alternative figure based on Say.

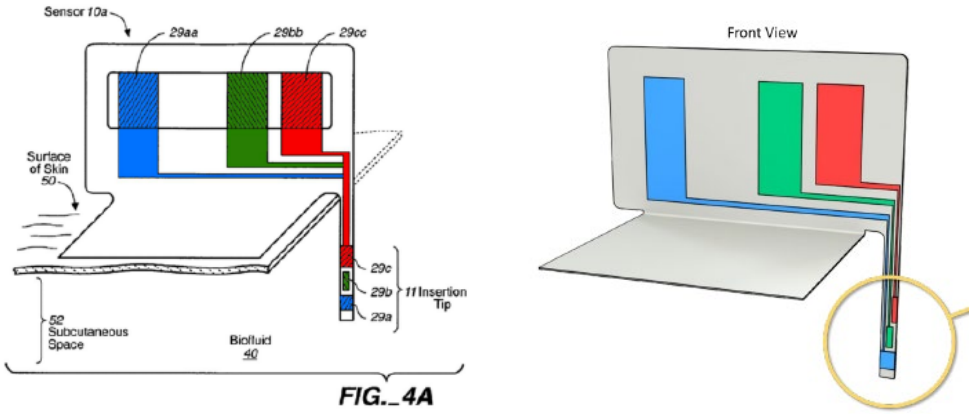
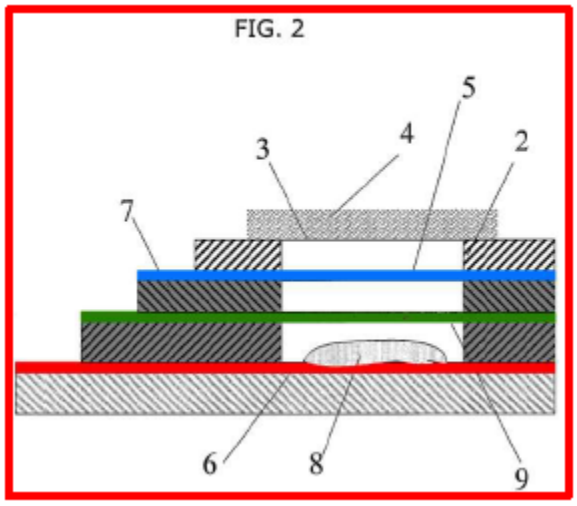


Figure 4A as annotated by Dr. Smith is shown on the left, as compared to the alternative version of Feldman's Figure 4 provided by Dr. Tapsak on the right.

Dr. Smith's annotated Figure 4A *does not* show the traces side-by-side like in Say. And, as is evident from Say, it would have reasonably been well within the level of skill of a skilled artisan to have drawn the traces side-by-side in Feldman if that were intended. We find that Figure 4A unambiguously depicts traces 29aa and 29bb being obscured from view by trace 29cc. Even if other interpretations are possible, we find persuasive Dr. Smith's testimony that "[t]he conductive trace connecting 29aa to 29a (shown in blue) is behind (under) the conductive trace connecting 29bb to 29b (shown in green), which is itself behind (under) the 'topmost' conductive trace connecting 29cc to 29c (shown in red))." Ex. 1002 ¶ 206.

We are also persuaded that a person of ordinary skill in the art, who both parties agree is a highly educated and experienced person, understood that one way of insulating the electrode traces would have been to separate them by stacking with non-conductive layers so that they do not short-circuit one another. Ex. 1013, 9:20–21 (Hyland explaining that "the electrodes must each be separated by an insulating material 7."). Dr. Smith provides an annotated version of Hyland's Figure 2, reproduced below.



Hyland's Figure 2 as annotated by Dr. Smith illustrating insulating material 7 between electrodes 5, 6, and 9. Dr. Smith testifies that Hyland "discloses an electrochemical cell with a conductive working electrode 5, a conductive reference electrode 9, and a conductive counter electrode 6, each 'separated by an insulating material.'" Ex. 1002 ¶ 48. To the extent that Hyland is not an implantable *in vivo* glucose sensor, U.S. Patent No. 5,322,063 to Allen discloses an implantable glucose sensor illustrating in Figure 2, reproduced below, counter, working, and reference electrodes 12, 13, and 14, with leads 15 similarly separated by two layers of non-conductive electrical insulator 17.

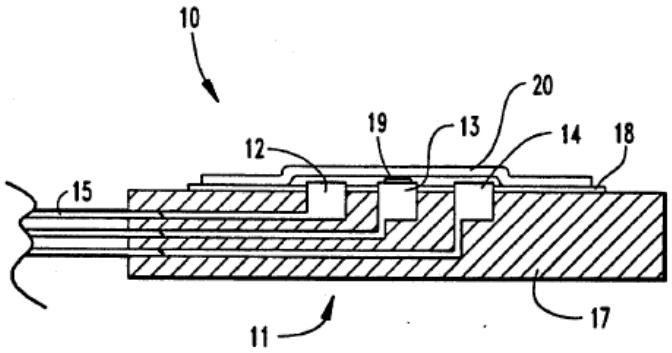


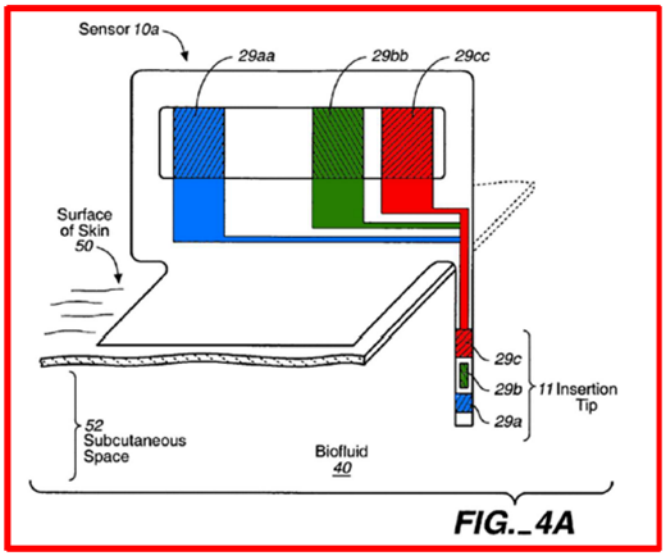
Fig.2

Figure 2 from Allen "shows in schematic form an implantable portion of a glucose sensor." Ex. 1009, 4:21–23.

Given the knowledge and level of ordinary skill in the art and observing Feldman's Figure 4A as annotated by Dr. Smith, reproduced below, we credit Dr. Smith's testimony explaining that a person of ordinary skill in the art would have understood that

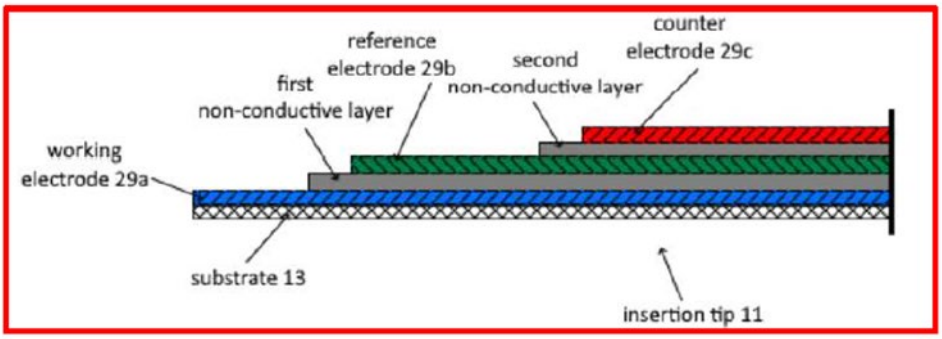
> the conductive trace connecting 29aa to 29a (shown in blue) is behind (under) the conductive trace connecting 29bb to 29b (shown in green), which is itself behind (under) the "topmost" conductive trace connecting 29cc to 29c (shown in red). This is why only the topmost conductive trace is visible in the portion leading to the electrodes.

Ex. 1002 ¶ 206.



Feldman's Figure 4A as annotated by Dr. Smith illustrates transcutaneous glucose sensor 10a including insertion tip 11. We further credit Dr. Smith's testimony that a person of ordinary skill in the art would have understood that one way of arranging the conductive traces for each of the working electrode 29a, reference electrode 29b, and counter electrode 29c, would

have been in a "stacked and staggered arrangement" on insertion tip 11 as shown for example in Dr. Smith's cross-sectional figure below.



Dr. Smith's cross-sectional figure illustrates working electrode 29a, the reference electrode 29b, and the counter electrode 29c separated by non-conductive layers and arranging "the insertion tip 11, such as by staggering, in order for the biofluid 40 to contact a larger surface area of all three electrodes." Ex. 1002 ¶ 210.

As discussed above, Patent Owner mainly argues that, contrary to Dr. Smith's interpretation of Figure 4A, a person of ordinary skill in the art "would interpret the connections in Fig. 4A as traces between 29a–29c and 29aa–29cc on one side of the substrate 13." PO Resp. 50. Or, alternatively, "a POSITA would alternatively interpret Feldman Fig. 4A as using vias to run conductive traces of two electrodes through the substrate to an opposing side of the substrate. *Id.* at 51 (citing Ex. 2011 ¶ 94; Ex. 1002 ¶ 235). To the extent Dr. Topsak's alternatives are viable ways of fabricating the insertion tip, they do not meaningfully detract from the alternatives Dr. Smith proposes with stacked and layered conductive traces.

Another argument Patent Owner makes is that "Petitioner's 'layered conductive traces,' shown in its modified insertion tip 11 (reproduced below) are inconsistent with the co-planar electrode portions 29aa-29cc shown in the ex vivo portion of the sensor." *Id.* 56–57. In other words,

Patent Owner argues that the co-planar conductive traces on the *ex vivo* portion of the sensor cannot become stacked or layered conductive traces in the *in vivo* portion of the sensor. Dr. Tapsak testifies that this is "[b]ecause the ex vivo and in vivo portions of the sensor would be fabricated at the same time, the construction of the ex vivo portion informs a POSITA as to the construction of the in vivo insertion tip." Ex. 2011 ¶ 103. This is, frankly, a weak response that provides little reason to doubt Petitioner's contentions and supporting evidence. Whatever is meant by "the ex vivo portion *informs* a POSITA as to the construction of the in vivo insertion tip," this does not explain that a person of ordinary skill in the art would have been unable to manufacture conductive traces that are co-planar on part of a device and non-co-planar, i.e., layered, or stacked, on another. *Id.* (emphasis added). In fact, Dr. Tapsak was asked this very question during his deposition, and demurred:

> Q. Okay. Is it your opinion that a POSITA could not have made the structure in the way that Dr. Smith testified?
>
> []
>
> A. In this case, I'll refer to page 63, paragraph 96, where I state: "Nothing in Feldman or its incorporated references suggest a three-electrode sensor with a stack of conductive and nonconductive layers as recited in the challenged claims."

Ex. 1027, 150:6–15.

Supported as it is by this testimony, Patent Owner argued that nothing in Feldman suggests a person of ordinary skill in the art would have been motivated to implement Feldman's Figure 4A as layered conductive traces. PO Resp. 56. There is, however, no requirement in the obviousness analysis that a reference itself provide expressly the modification or alteration. *See Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir.

1985) ("The issue of obviousness is determined entirely with reference to a hypothetical 'person having ordinary skill in the art.' It is only that hypothetical person who is presumed to be aware of all the pertinent prior art."), *see also In re Sovish*, 769 F.2d 738, 743 (Fed. Cir. 1985) (one of ordinary skill in the art is presumed to have skills apart from what the prior art references expressly disclose). We disagree with Patent Owner, based on a complete picture of the prior art and the level of skill and knowledge of an ordinary artisan which, together, discloses that stacked, i.e. layered, electrodes separated by insulating material were known structures to those of ordinary skill in the art.

Patent Owner argues that the background references relied upon by Petitioner and Dr. Smith, specifically Hyland and Dobson, fail to "describe[] transcutaneous or indwelling glucose sensors." PO Resp. 61. Patent Owner asserts that "Hyland describes use of its cell in a skin-prick blood test, further confirming Hyland discloses a test strip type sensor for use outside the body." *Id.* Patent Owner contends that "Dobson's device measures the 'gas permeability of human skin,' such as by placing the device 'on the skin over a vein or artery.'" *Id.* (citing Ex. 1012, Abstract, 5:52–53).

Petitioner agrees that Hyland and Dobson relate to *ex vivo* sensors, and replies that "[n]evertheless, their teachings upon which the Petition relies *as background evidence* are relevant to design considerations for *in vivo* sensors." Pet. Reply 21. We understand that Petitioner was using these references as background. Hyland and Dobson, *inter alia*, are relied upon to show conductive layers being separated by non-conductive layers, albeit in an *ex vivo* device. Pet. 40–41. Additionally, Dr. Smith explains that "Hyland discloses that a 'working electrode [that] is preferably formed from carbon, palladium, gold or platinum, for example in the form of a conductive

ink.'" Ex. 1002 ¶ 215 (citing Ex. 1013, 8:17–19). Dr. Tapsak even agreed that conductive ink was well known to be used with *in vivo* sensors as well as *ex vivo*.

> Q. Are conductive inks used in transcutaneous glucose sensors for conducting -- Let me rephrase the question. Are conductive inks used in transcutaneous glucose sensors, to your knowledge?
>
> []
>
> A. In what time period?
>
> Q. Well, let's – let's just go with up through today, are you familiar with conductive inks being used for glucose sensors?
>
> A. Today, yes.
>
> Q. And so like when do you recall conductive inks first being used in such sensors?
>
> A. I'm sorry. I'm going to need a clarification to your question.

Ex. 1027, 57:8–18. Dr. Tapsak dodges a direct answer to this question but he does not expressly dispute that conductive inks were known to be used in *ex vivo* and *in vivo* applications when Feldman was filed. And, Dr. Tapsak did agree that a person of ordinary skill in the art, in the time frame of 2003–2004, long before the '193 patent was filed, would have considered *ex vivo* sensors relevant when developing *in vivo* sensors.

> Q. Okay. So in the -- in the time before you left Dexcom, when -- when the company was working on this transition to percutaneous sensors, I want to focus on kind of that -- that time and what a POSITA would have been thinking. I'm not necessarily talking here about Dexcom; I just want to talk about that time period.

> Would a -- Would a POSITA who is designing a transcutaneous sensor have considered the test strip sensors to be a relevant technology to the work they were doing?
>
> []
>
> A. They would.

Id. at 60:12–24. We are persuaded that Hyland and Dobson, despite the fact that they describe *ex vivo* glucose monitoring and test devices, would be relevant such that a person of ordinary skill in the art would have been aware of and considered these references as background information and technology. Dobson, for instance, expressly describes:

> a transcutaneous gas sensor comprises a series of essentially flat, flexible components, the components being in order:—
>
> a first non-porous film of high polymeric material, at least an area of which is permeable to the gas to be sensed;
>
> a working electrode;
>
> a first porous insulating layer;
>
> a reference electrode;
>
> a second porous insulating layer;
>
> a counter electrode; and
>
> a second non-porous film of high polymeric material;
>
> the three electrodes and the *two insulating layers* being of approximately the same area.

Ex. 1012, 1:22–37 (emphasis added). We do not see it as any particular technological leap that a person of ordinary skill in the art who would have known about layering electrodes and insulating layers in *ex vivo* glucose sensors, would consider layering the electrodes and insulating layers in a stacked arrangement in an *in vivo* sensor. *See KSR*, 550 U.S. at 401 (The Supreme Court explaining that "if a technique has been used to improve one

device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"). We appreciate that Dr. Tapsak has provided alternative conductive trace arrangements that a person of ordinary skill in the art would have considered. Ex. 2011 ¶¶ 104–107. Noticeably absent from his testimony is any reason or assertion that Dr. Smith's asserted arrangement, based on Figures 4A–B in Feldman, would have been technologically infeasible or beyond the skill level of an ordinary artisan in the field of glucose monitoring sensors.

With respect to *why* a person of ordinary skill in the art would understand Feldman to teach a stacked and staggered arrangement of electrodes and non-conductive layers, and expose the ends thereof in the manner suggested by Dr. Smith, we find Petitioner's arguments and Dr. Smith's reasoning and testimony persuasive. Dr. Smith explained that in Figure 4B "the working electrode 29a is stacked on a plastic substrate 13, and the wired enzyme sensing layer 18a is in turn stacked on top of the working electrode 29a and exposed to the interfacing membrane 30a." Ex. 1002 ¶ 211. We appreciate that the complete cross-section of layered and staggered electrode and insulation structure of insertion tip 11 is not shown in Figure 4B. Dr. Smith acknowledges that "[n]either the reference electrode 29b nor the counter electrode 29c is shown in FIG. 4B because the more-proximal location of the insertion tip 11 in which they are located is not depicted in FIG. 4B." *Id.* On the other hand, Dr. Smith testifies that

> [a] POSITA also would have understood that it would have been obvious to include non-conductive layers between the conductive layers associated with the electrodes in order to prevent a short circuit between the electrodes. I note, for instance, that Hyland evidences the need for "the electrodes [to]

> each be separated by an insulating material" so "the cell can operate."

Id. ¶ 212 (citing Ex. 1013, 9:20–21). Dr. Smith further testifies based on Feldman's disclosure in Figures 4A–B that a person of ordinary skill in the art would have staggered the layered electrode and insulation structure on insertion tip 11 "to extend the non-conductive layers further than the subsequent conductive layer above it to ensure the conductive layers are isolated from one another, which, as I discussed above, is necessary to prevent a short circuit." *Id.* ¶ 213. Although Patent Owner and Dr. Tapsak have presented alternative designs, there is no persuasive argument or evidence in the record to undermine Petitioner's contention that a staggered and layered electrode arrangement, as proposed by Dr. Smith, would likewise have been yet another feasible alternative known to a skilled artisan that would have been reasonably expected to work for its intended purpose.

Overall, considering all the evidence and arguments in the record, we are persuaded that Petitioner has shown, by a preponderance of evidence, that Feldman's Figures 4A–B would have been understood and interpreted by a person of ordinary skill in the art as encompassing limitations 1[b]–[f].

(d) Conclusion for independent claim 1

Based on the complete record before us and for the reasons expressed above, we are persuaded that Petitioner has shown a preponderance of evidence that claim 1 would have been obvious over Feldman.

(e) Conclusion for independent claim 11

Independent claim 11 includes mostly the same limitations as claim 1 but requires the electrodes be arranged in a specific order, "the first electrode is a counter electrode," "the second electrode is a working electrode," and "the third electrode is a reference electrode." Ex. 1001, 56:29–49.

Petitioner argues that a person of ordinary skill in the art "would have been motivated to try alternative sequences of the three electrodes in the sensors shown above, for instance, where the counter electrode 29c (red) is the first (bottom) electrode and the reference electrode 29b (green) is the third (top) electrode." Pet. 50. Dr. Smith testifies that arranging the electrodes in the manner as recited in claim 11 "would merely have been choosing from a finite number of predictable sequences of the three electrodes with a reasonable expectation of success. Indeed, there are only six possible permutations of the three electrodes in this structure." Ex. 1002 ¶ 262. Dr. Smith testifies further that a person of ordinary skill in the art "would have been motivated to try alternative sequences of the three electrodes to balance the sensitivity and responsiveness of the sensor with the resistance between electrodes when operating the sensor." *Id.* Dr. Smith explains also that a person of ordinary skill in the art "would have had a reasonable expectation of success in trying alternative sequences of the three electrodes because the sequence of the electrodes is not critical to the operability of the sensor." *Id.* ¶ 264.

In support of his testimony, Dr. Smith points out that "Hyland further discloses that '[t]he counter and working electrodes 6 and 5 may be positioned such that the reference electrode 9 is located between them, as is depicted in Figure 2, or the counter and working electrodes 6 and 5 may be adjacent.'" *Id.* ¶ 265 (quoting Ex. 1013, 12:10–12). Dr. Smith also notes that "Hyland further discloses that the counter electrode 6 may be located at the base, as shown in FIG. 2, or at the top of the electrochemical cell." *Id.* (citing Ex. 1013, 25:8–10).

Patent Owner argues that for "independent claim 11, the Petition relies largely on its mappings of claim 1 (Petition, 50–53 (relying on

mappings for Elements 1[Pre], 1[a–g]), and it fails to meet its burden at least for the reasons specified above for independent claim 1." PO Resp. 62–63.

We find Petitioner's arguments and Dr. Smith's testimony and supporting evidence persuasive, namely, that a person of ordinary skill in the art would have considered "trying alternative sequences of the three electrodes because the sequence of the electrodes is not critical to the operability of the sensor." Ex. 1002 ¶ 264. Indeed, Dr. Smith's testimony that a person of ordinary skill in the art "would have been motivated to try alternative sequences of the three electrodes to balance the sensitivity and responsiveness of the sensor with the resistance between electrodes," is unrebutted on the record. *Id.* ¶ 262.

Based on the complete record before us and for the reasons expressed above, and also with respect to the same limitations as in claim 1, we are persuaded that Petitioner has shown a preponderance of evidence that claim 11 would have been obvious over Feldman.

3. Claims 2–3 and 12–13

Claims 2 and 3 recite:

> 2. The transcutaneous continuous glucose sensor system of claim 1, wherein the membrane comprises an enzyme.
>
> 3. The transcutaneous continuous glucose sensor system of claim 2, wherein the membrane further comprises a resistance domain located over the enzyme.

Ex. 1001, 55:66–56:3. Claims 12 and 13 depend from claim 11 and introduce substantially the same limitations as those recited in claims 2 and 3 respectively. *Compare id.*, *with id.* at 56:50–54.

Petitioner argues that "Feldman discloses that '[s]ensor fabrication typically consists of depositing an enzyme-containing sensing layer laid over a working electrode.'" Pet. 53 (quoting Ex. 1008 ¶¶ 22, 94; citing Ex. 1002

¶¶ 250–251, 277). Petitioner further argues that for "claims 3 and 13, Feldman further discloses 'casting the diffusion-limiting membrane layer over the [enzyme-containing] sensing layer.'" *Id.* (quoting Ex. 1008 ¶¶ 22, 94; Ex 1002 ¶¶ 254–255, 279). Petitioner points out also, that "Mao, which is incorporated by reference in Feldman, *id.* ¶ 94, explains that the diffusion-limiting membrane 'regulat[es] or limit[s] the flux of glucose to the sensing layer.'" *Id.* at 53 (quoting Ex. 1011 ¶ 7).

Patent Owner does not substantively dispute that Feldman, and Mao as incorporated by reference in Feldman, disclose the additional limitations of claims 2–3 and 12–13. *See*, *e.g.*, PO Resp. 62 (Patent Owner arguing that "[e]ach of claims 2 and 3 depends from independent claim 1, and each is patentable for at least the reasons specified above for independent claim 1.").

As for each of dependent claims 2–3 and 12–13, we have considered, and on the complete record before us, accept as our own, Petitioner's arguments and evidence set forth at page 53 of the Petition. Accordingly, we determine that Petitioner has shown by a preponderance of the evidence that claims 2–3 and 12–13 would have been obvious over Feldman.

E. Ground 1: Claims 1–3 and 11–13 — Anticipation based on '996 Publication (Ex. 1007)

Because we determine that claims 1–3 and 11–13 would have been obvious over Feldman, we need not determine whether these same claims are also anticipated by the '996 Publication. *Cf. In re Gleave*, 560 F.3d 1331, 1338 (Fed. Cir. 2009) (not reaching other grounds of unpatentability after affirming a ground based on anticipation); *see also Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984) (explaining that an administrative agency is at liberty to reach a decision based on a dispositive issue because doing so "can not only save the parties, the [agency], and [the

reviewing] court unnecessary cost and effort," but "can greatly ease the burden on [an agency] commonly faced with a . . . proceeding involving numerous complex issues and required by statute to reach its conclusion within rigid time limits").

F. Grounds 3 and 4: Claims 1–3 and 11–13 — Obviousness over Allen (Ex. 1009) (Ground 3) or Shah (Ex. 1010) and Allen (Ex. 1005)

Because we determine that claims 1–3 and 11–13 would have been obvious over Feldman, we need not determine whether these same claims are also obvious over Allen or Shah and Allen. *See Gleave*, 560 F.3d. at 1338.

III. CONCLUSION[10]

For the reasons discussed above, we determine Petitioner meets its burden of establishing, by a preponderance of the evidence, that the challenged claims are unpatentable, as summarized in the following table:

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–3, 11–13	102	'996 Publication[11]		

[10] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

[11] Because Petitioner's contentions regarding the obviousness of claims 1–3 and 11–13 in view of Feldman are dispositive of the challenged claims, we do not reach this asserted ground. *See Gleave*, 560 F.3d. at 1338.

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–3, 11–13	103(a)	Feldman	1–3, 11–13	
1–3, 11–13	103(a)	Shah[12]		
1–3, 11–13	103(a)	Shah and Allen[13]		
Overall Outcome			1–3, 11–13	

IV. ORDER

For the reasons given, it is

ORDERED that, based on a preponderance of the evidence, claims 1–3 and 11–13 of the '193 patent have been shown to be unpatentable; and

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

[12] Because Petitioner's contentions regarding the obviousness of claims 1–3 and 11–13 in view of Feldman are dispositive of the challenged claims, we do not reach this asserted ground. *See Gleave*, 560 F.3d. at 1338.
[13] Because Petitioner's contentions regarding the obviousness of claims 1–3 and 11–13 in view of Feldman are dispositive of the challenged claims, we do not reach this asserted ground. *See Gleave*, 560 F.3d. at 1338.

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