

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE INC.,
Petitioner,

v.

DEXCOM, INC.,
Patent Owner.

IPR2024-00841
Patent 10,709,364 B2

Before JAMES A. TARTAL, JON M. JURGOVAN, and
FREDERICK C. LANEY, *Administrative Patent Judges*.

JURGOVAN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Petitioner Abbott Diabetes Care Inc. filed a Petition (Paper 1, “Pet.”) pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of claims 1–3, 5–6, and 8–10 (“the challenged claims”) of U.S. Patent No. 10,709,364 B2 (Ex. 1001, “the ’364 patent”).

Patent Owner DexCom, Inc. filed a Preliminary Response (Paper 6, “Prelim. Resp.”). Patent Owner argues that the Petition fails to satisfy the requisite threshold for instituting review on the merits. In addition, Patent Owner asserts that institution should be denied under § 325(d).

For reasons provided below, we determine on behalf of the Director (*see* 37 C.F.R. § 42.4(a)) that the record demonstrates a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims on the merits, so we grant institution of the petitioned *inter partes* review. *See* 35 U.S.C. § 314(a). We decline to exercise our discretion to deny institution under § 325(d).

II. BACKGROUND

A. *Real Parties-in-Interest and Related Proceedings*

Petitioner identifies itself (i.e., Abbott Diabetes Care Inc.) and Abbott Diabetes Care Sales Corp. and Abbott Laboratories as real parties-in-interest. Pet. 7 (Petitioner’s Mandatory Notices). Petitioner is directly owned by Abbott Laboratories, and Petitioner directly owns Abbott Diabetes Care Sales Corp. *Id.* Patent Owner identifies itself (i.e., DexCom, Inc.) as the real party-in-interest. Paper 4, 1 (Patent Owner’s Mandatory Notices).

Petitioner and Patent Owner identify the following district court litigations as related to this proceeding: *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, Case No. 1:23-cv-00239 (D. Del.); *DexCom, Inc. v. Abbott*

Diabetes Care, Inc. et al., Case No. 1-22-cv-00605 (consolidated with *Abbott Diabetes Care, Inc. et al. v. DexCom, Inc.*, Case No. 1:21-cv-01699). Pet. 7; Paper 4, 2–3.

Petitioner and Patent Owner identify as related to this proceeding the following *inter partes* review proceedings concerning patents asserted by Patent Owner in the district court litigation: IPR2022-00913 (U.S. Patent No. 11,000,213 B2); IPR2022-00914 (U.S. Patent No. 11,000,213 B2); IPR2022-00921 (U.S. Patent No. 10,993,642 B2); IPR2024-00922 (U.S. Patent No. 10,993,642 B2). Pet. 8; Paper 4, 3.

B. The '364 Patent

The '364 patent is titled “System and Methods for Processing Analyte Sensor Data for Sensor Calibration.” Ex. 1001, code (54). In its background, the '364 patent explains that diabetes mellitus is a pancreatic disorder which may cause high blood sugar (hyperglycemic condition) or low blood sugar (hypoglycemic condition) which can be detrimental to a person suffering from the disorder. *Id.* at 1:35–46.

Monitoring blood glucose levels conventionally required uncomfortable finger pricking methods to measure glucose level two to four times per day, which was not frequent enough to detect hyperglycemic or hypoglycemic conditions. Ex. 1001, 1:47–55. Hence, long term sensors implanted in a diabetic person were developed to continuously monitor blood glucose levels. *Id.* at 1:55–62.

Such long term sensors require calibration to accurately indicate blood glucose level. *See, e.g.*, Ex. 1001, 16:27–28. A glucose monitor typically uses a conversion function that map's the sensor's electrical current output to a corresponding glucose concentration in units useful to the user. *Id.* at

82:35–51. The conversion function is linear and has the form $y = mx + b$ where y is the output from the sensor, x is the glucose concentration, m (the line's slope) is the sensor's "sensitivity," and b is the "baseline" signal (the sensor's output when there is zero glucose present). *Id.* at 17:45–62.

Figure 22A of the '364 patent is reproduced below.

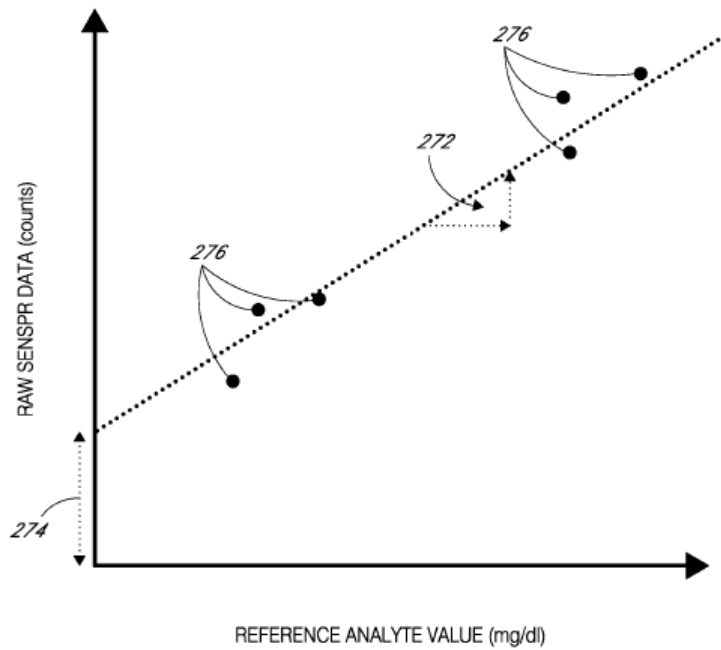


FIG. 22A

Figure 22A above is a graph of a regression performed on a calibration set to create a conversion function using a least squares technique on matched data pairs 276. Ex. 1001, 78:17–20. The x-axis represents reference analyte data, the y-axis represents sensor data, and the regression calculates the slope (m) 272 and offset (b) 274, which defines the conversion function. *Id.* at 78:21–25.

Figure 2 of the '364 patent is partially shown below.

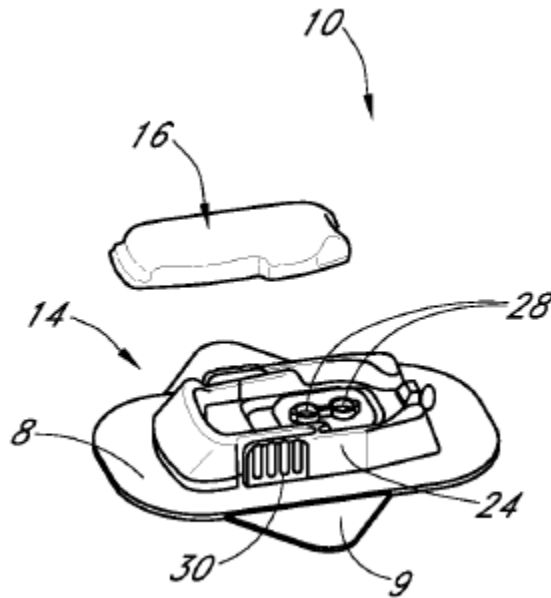


Figure 2 above shows a transcutaneous analyte sensor system 10. Ex. 1001, 19:53–54. Sensor 10 includes mounting unit 14 including base 24 adapted for mounting on the skin of a host for transdermal insertion of sensor 32 (which is a needle shown in Figure 4) through the skin of the host. *Id.* at 19:59–62. Contacts 28 provide electrical contact between the sensor and electronics unit 16. *Id.* at 19:62–64. Electronics unit 16 measures levels of analyte via the sensor. *Id.* at 20:17–19. Electronics unit 16 performs calibration reset when inserted into mounting unit 14 and/or when it initially communicates with sensor 32.

C. Overview of Challenged Claims

Of the challenged claims, claims 1, 5, and 10 are independent. Claims 2–3 depend from claim 1, and claims 6 and 8–9 depend from claim 5.

Claim 1, which is representative, is shown below with limitation identifiers indicated in brackets and disputed claim language emphasized in italics.

1. [Pre] A glucose monitoring system comprising:
 - [a] a transcutaneous electrochemical glucose sensor comprising an in vivo portion and an ex vivo portion,
 - [b] wherein the transcutaneous electrochemical sensor is characterized by an in vivo sensitivity and an in vitro sensitivity, wherein the in vivo sensitivity is different from the in vitro sensitivity,
 - [c] and *wherein the in vitro sensitivity is predictive of the in vivo sensitivity due to a relationship therebetween;*
 - [d] sensor electronics configured to be operably connected to the transcutaneous electrochemical glucose sensor;
 - [e] a processor configured to be operably connected to the sensor electronics;
 - [f] a memory configured to be operably connected to the processor,
 - [g] wherein the memory has stored therein information associated with the in vivo sensitivity of the transcutaneous electrochemical glucose sensor, *wherein the information associated with the in vivo sensitivity is based at least in part on corrections for the difference between the in vivo sensitivity and the in vitro sensitivity of the transcutaneous electrochemical glucose sensor.*

Ex. 1001, 92:55–93:10 (emphases added).

D. Asserted Prior Art

Petitioner relies on the following reference as prior art against claims 1–3, 5–6, and 8–10 of the '364 patent. Pet. 13.

Name	Reference	Exhibit No.
Gross	US 6,275,717 B1	1004

Patent Owner does not dispute that Gross is prior art against claims 1–3, 5–6, and 8–10 of the '364 patent. *See generally* Prelim. Resp.

E. Asserted Grounds

Petitioner asserts the following grounds of unpatentability. Pet. 13.

Reference(s)/Basis	35 U.S.C. § ¹	Claim(s) Challenged
Gross	102/103	1–3, 5–6, 8–10

F. Testimonial Evidence

Petitioner relies on the proffered expert witness testimony of Dr. Anthony Edward Cass (Exhibit 1002). Patent Owner does not rely on opposing expert witness testimony. *See generally* Prelim. Resp.

III. PRELIMINARY MATTER

Patent Owner asserts that we should exercise our discretion to deny institution under § 325(d). Prelim. Resp. 36–38. Petitioner disagrees. Pet. 72–74.

In evaluating discretionary denial under § 325(d), the Board follows a two-part framework: (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially

¹ Amendments to 35 U.S.C. § 103 enacted by the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”) took effect on March 16, 2013. The '364 patent claims priority to U.S. Provisional Application 60/660,743 filed March 10, 2005. Ex. 1001, code (22). Therefore, we apply the pre-AIA version of § 103.

the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”).

The *Advanced Bionics* framework is further informed by the factors set forth in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*Becton, Dickinson*”). *Becton, Dickinson* identifies the following non-exclusive factors: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art; (e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments. *Becton, Dickinson*, Paper 8 at 17–18 (§ III.C.5, first paragraph). Factors (a), (b) and (d) relate to *Advanced Bionics* part (1), and factors (c), (e) and (f) relate to *Advanced Bionics* part (2). *Advanced Bionics*, Paper 6 at 10.

Under *Advanced Bionics* part (1), there is no dispute that Gross was presented to the Office. Pet. 73; Prelim. Resp. 37. Gross is listed on the ’364 patent as a reference cited during examination. Ex. 1001, 8.

Under *Advanced Bionics* part (2), Petitioner asserts that the examiner erred under *Becton, Dickinson* factors (c) and (f) by not relying on Gross to reject any claim, and by overlooking or not appreciating Gross's materiality to the challenged claims. Pet. 73. Patent Owner argues that the Examiner's reasons for allowance stated that the prior art of record, which would include Gross, did not teach the independent claim limitations involving "information associated with [the/an] *in vivo* sensitivity" that "is based at least in part on corrections for [the/a] difference between the *in vivo* sensitivity and [the/an] *in vitro* sensitivity." Prelim. Resp. 37 (citing Ex. 1003, 811–812) (alterations in original). Patent Owner argues that the examiner correctly determined that Gross did not have these claimed features. *Id.*

After considering the arguments and evidence, we agree with Petitioner's contentions concerning the prosecution history. During examination of the '364 patent, Patent Owner filed an information disclosure statement listing over 3,900 documents spanning 273 pages of the file history. Pet. 24 (citing Ex. 1003, 225–501). Thereafter, Patent Owner submitted rewritten and new claims during examination of the '364 patent, and a notice of allowance issued 16 days later. *Id.* (citing Ex. 1003, 805).

By Petitioner's calculations, to consider all of the documents submitted in the information disclosure statement in relation to the amended or new claims, the examiner would have had to consider 245 documents per day. Pet. 24. Although there was technical error in the examination by overlooking or not appreciating Gross's materiality to the '364 patent's claims, as a practical matter, the examiner's task was made extremely

difficult by the lengthy information disclosure statement that Patent Owner submitted.

For the reasons provided above, we decline to exercise our discretion to deny institution under § 325(d).

IV. PETITIONER’S GROUNDS OF UNPATENTABILITY

A. Legal Standards

Before considering Petitioner’s and Patent Owner’s contentions, we address in this section legal standards relevant to this proceeding.

1. Petitioner’s Burden

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

2. Anticipation

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). The prior art elements must be “arranged as in the claim.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369, 1371 (Fed. Cir. 2008).

3. *Obviousness*

A patent claim is unpatentable under 35 U.S.C. § 103 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 (“POSITA” or “POSA”) to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of 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.² *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. *Level of Ordinary Skill in the Art*

In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (internal quotation marks and citation omitted). The applied prior art may reflect an appropriate level of skill. *Okajima v. Bourdeau*, 261 F.3d 1350, 1354–55 (Fed. Cir. 2001).

Petitioner asserts that

A person of ordinary skill in the art (“POSA”), as of the claimed priority date, would have had a bachelor’s degree in biomedical engineering, chemical engineering, chemistry, or a related or

² Neither Petitioner nor Patent Owner have submitted any such objective evidence in the record at this time. Pet. 71; *see generally* Prelim. Resp.

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, including some experience with algorithms for calibrating such devices, or equivalent experience. Such experience could include either formal coursework in signal processing, computer science, or electrical engineering, or it could also be obtained during on-the-job experience. A person with less or different education but more relevant practical experience, or vice versa, may also meet this standard. A POSA may have been part of an interdisciplinary team with others having the relevant experience set forth above and/or with clinicians. The prior art also evidences the level of skill in the art.

Pet. 24 (citing Ex. 1002 ¶ 60).

Patent Owner does not dispute Petitioner’s proposed level of ordinary skill in the art. Prelim. Resp. 15.

Petitioner’s proposed level of skill in the art is consistent with the ’364 patent and the asserted prior art except that we set the level to “at least two . . . years of experience.” Otherwise, we agree with and will use Petitioner’s proposed level for this Decision.

C. Claim Construction

We interpret the ’364 patent claims “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b). This “includ[es] construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*

“Petitioner interprets the claims ‘in accordance with the ordinary and customary meaning . . . as understood by one of ordinary skill in the art.’” Pet. 25 (alteration in original). Petitioner asserts that “the Board need not

expressly construe the terms of the challenged claims to resolve the controversy.” *Id.* (citing *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017)).

Although Patent Owner argues that Petitioner interprets certain claim language so as to render it superfluous or non-sensical (Prelim. Resp. 27–28, 30), for reasons explained later in this decision (*see* § IV.D.2.iv and §IV.D.2.viii, *infra*), we do not agree with Patent Owner’s argument on the current record.

Accordingly, we apply the ordinary and customary meaning to the claim terms without express construction.

D. Anticipation and Obviousness over Gross

Petitioner asserts that claims 1–3, 5–6, and 8–10 of the ’364 patent are anticipated by and would have been obvious over Gross. Pet. 35–71. Patent Owner disagrees. Prelim. Resp. 15–36.

We conclude that the record demonstrates a reasonable likelihood that Petitioner would prevail with respect to challenged claims 1–3, 5–6, and 8–10 at least as to anticipation for the following reasons.

1. Gross (Ex. 1004)

Gross is titled “Device and Method of Calibrating and Testing a Sensor for In Vivo Measurement of an Analyte.” Ex. 1004, code (54). Gross discloses a method of calibrating an analyte sensor in vivo by determining a calibration function applied to sensor signals to provide a calibrated output. *Id.* at code (57).

Gross's Figure 1A is provided below.

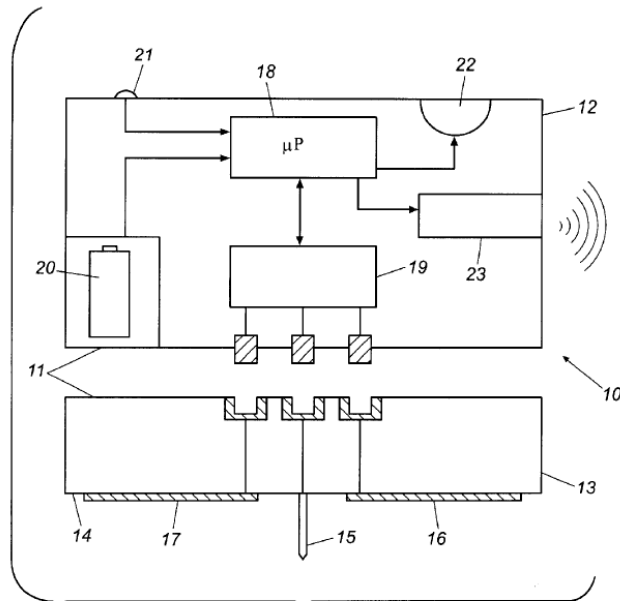


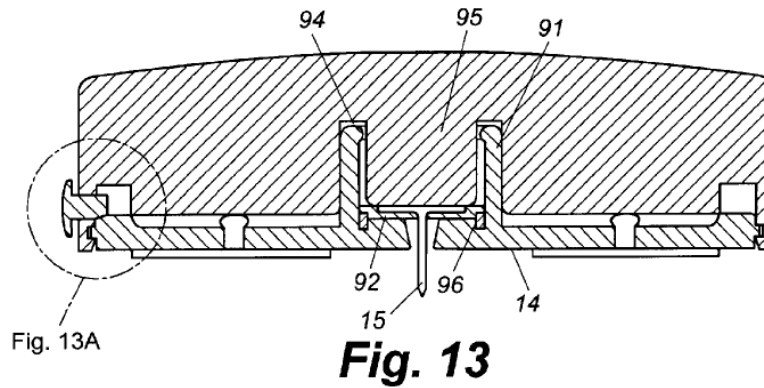
Fig. 1A

Gross's Figure 1A above discloses monitor device 10 that includes first part 12 with electronic controlling circuitry, and second part 13 that includes working electrode 15, counter electrode 16, and reference electrode 17. Ex. 1004, 9:50–57. Working electrode 15 is a platinum-iridium enzymatic sensor in the form of a needle. *Id.* at 9:58–60.

When first part 12 and second part 13 are assembled, electrodes 15, 16, 17 of the second part connect to voltage controller 19 that further connects to microprocessor 18. Ex. 1004, 9:64–65. Microprocessor 18 has a memory. *Id.* at 13:9–10. Microprocessor 18 controls the voltage applied between working electrode 15 and reference electrode 16. *Id.* at 9:65–10:1. Voltage controller 19 and microprocessor 18 are powered by battery 20. *Id.* at 10:2–3. Push button 21 starts or stops operation of the device. *Id.* at 10:3–5. Alarm 22 alerts the user of excessively high or low glucose levels.

Id. at 10:5–6. Monitor device 10 communicates with a display unit with low power radio transmitter 23. *Id.* at 10:10–12.

Gross's Figure 13 is shown below.



Gross's Figure 13 shows monitor device 10 with first part 12 and second part 13 assembled together, which causes needle electrode 15 to move downward through the host's skin where it is positioned to monitor blood glucose level. Ex. 1004, 9:35–36, 18:40–45. First part 12, containing electronic circuitry, is reusable, whereas second part 13, with needle electrode 15, is disposable. *Id.* at 10:60–65.

Gross's Figure 5 is reproduced below.

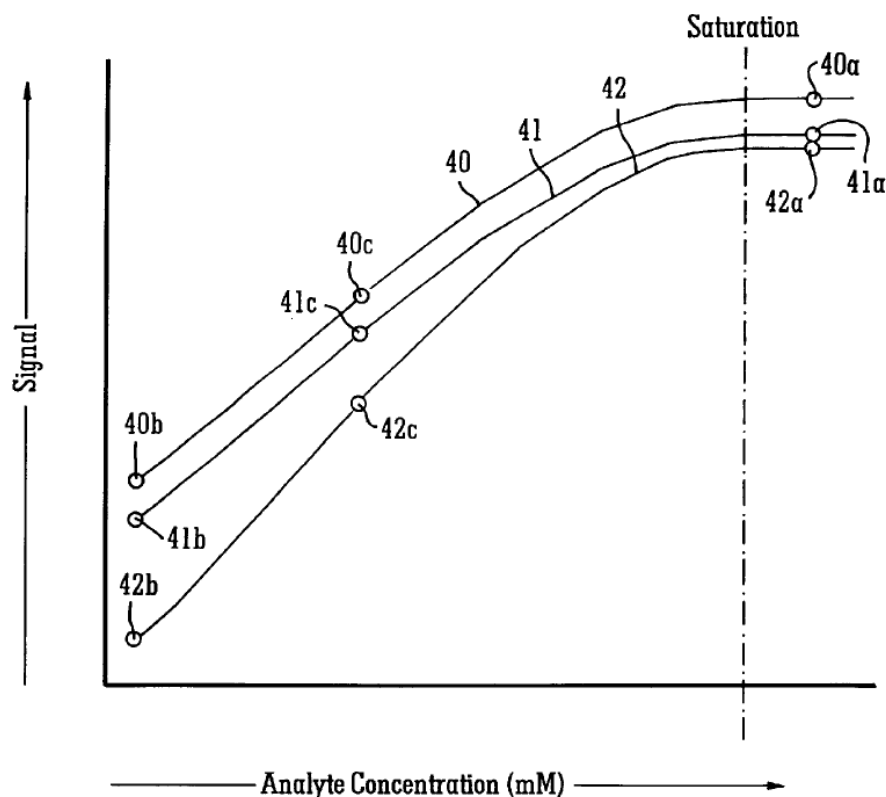


FIG. 5

Gross's Figure 5 shows a plot of signal strength versus analyte concentration showing characteristic performance curves of three different sensor needles from the same batch. Ex. 1004, 13:42–43. Curve 40 is the theoretical performance curve measured in the manufacturing facility for a batch of needles. *Id.* at 13:46–50. “Curve 41 is the measured performance curve of a first sensor needle in vivo and curve 42 is the measured performance for a second sensor needle in vivo.” *Id.* at 13:51–53.

The in vivo needle of curve 41 is calibrated by providing on it an amount of glucose ensuring saturation and maximum sensor signal 41a is measured. Ex. 1004, 13:59–62. Voltage pulses are then used to cause glucose concentration to drop to base line level resulting in sensor signal

41b. *Id.* at 13:64–14:4. The microprocessor then compares each of these signals 41a, 41b with corresponding signals 40a, 40b on the theoretical curve 40. *Id.* at 14:5–9. Since the calibration curves for needles from the same batch have the same basic shape, calibration curve 41 for the in vivo sensor needle can be mapped onto known points of theoretical calibration curve 40. *Id.* at 14:10–18. The microprocessor calculates a calibration function to map curve 41 onto curve 40 so that the microprocessor can generate a calibrated output for any measured signal on curve 41. *Id.* at 14:19–27.

2. *Claim 1*

We now consider Petitioner’s and Patent Owner’s contentions with regard to each limitation of claim 1. Pet. 35–52; Prelim. Resp. 22–36. Patent Owner disputes whether limitation 1c and limitation 1g are disclosed by Gross, but does not dispute the remaining limitations at this time. On the present record, as discussed below, we determine that Petitioner has demonstrated sufficiently that each limitation of claim 1 is disclosed by Gross.

(i) *Preamble*

The preamble of claim 1 recites “A glucose monitoring system comprising:” Ex. 1001, 92:55.

Petitioner contends that “Gross discloses an ‘analyte monitor device for the in vivo measurement of an analyte,’ where ‘a particularly preferred analyte is glucose.’” Pet. 35–36 (citing Ex. 1004, 4:24–25, 6:28–67, 9:45–47; Ex. 1002 ¶ 83).

Patent Owner does not dispute Petitioner’s contention that Gross discloses claim 1’s preamble.

We find that Petitioner has shown sufficiently that the preamble of claim 1 is disclosed by Gross, and thus do not reach the issue of whether the preamble is limiting.

(ii) *Limitation 1a: Sensor with In Vivo/Ex Vivo Portions*

Limitation 1a recites “a transcutaneous electrochemical glucose sensor comprising an in vivo portion and an ex vivo portion.” Ex. 1001, 92:56–57.

Petitioner contends that Gross’s sensor comprises an in vivo portion (Gross’s second part 13) and an ex vivo portion (Gross’s first part 12). Pet. 36–38 (citing Ex. 1004, 1:21–24, Figs. 1A, 13; Ex. 1002 ¶¶ 84–88).

Petitioner asserts that second part 13 of Gross’s sensor includes sensor needle 15 which “penetrates the skin to a predetermined depth” to contact subcutaneous tissue, and is thus “transcutaneous.” Pet. 36 (citing Ex. 1004, 5:7–21, 10:61–11:4).

Petitioner further alleges that Gross’s needle 15 is a platinum-iridium needle containing glucose oxidase. Pet. 39 (citing Ex. 1004, 11:11–34, 11:60–64). Petitioner states that Gross discloses that glucose reacts with oxygen and water to generate hydrogen peroxide. *Id.* (citing Ex. 1004, 11:11–23, 11:60–64). The platinum in Gross’s sensor needle reacts with hydrogen peroxide, resulting in free electrons that generate electrical current when voltage is applied between working electrode (sensor needle) 15 and counter electrode 16. *Id.* (citing Ex. 1004, 11:31–34). Petitioner asserts that Gross discloses that the glucose concentration is proportional to the magnitude of the electrical current. *Id.* (citing Ex. 1004, 1:21–24; 11:24–34).

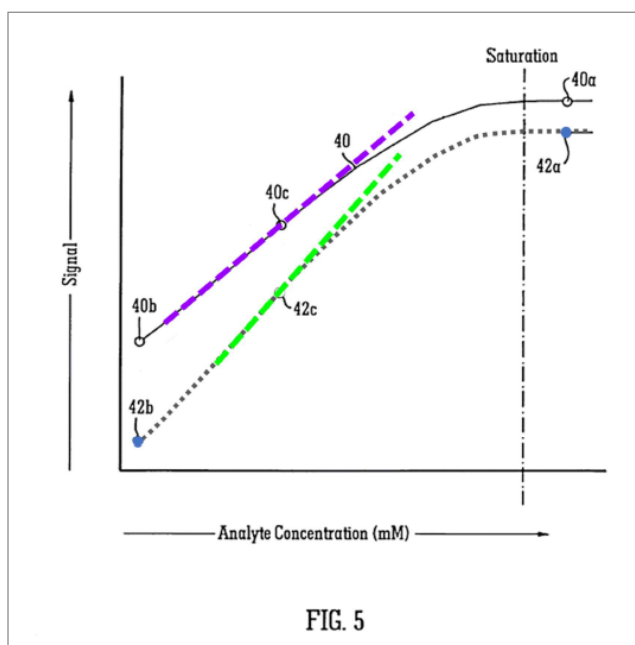
Patent Owner does not dispute Petitioner’s contentions that Gross discloses limitation 1a.

On this record, we find that Petitioner shows sufficiently that Gross discloses limitation 1a.

(iii) Limitation 1b: In Vivo and In Vitro Sensitivities

Limitation 1b recites “wherein the transcutaneous electrochemical sensor is characterized by an in vivo sensitivity and an in vitro sensitivity, wherein the in vivo sensitivity is different from the in vitro sensitivity.” Ex. 1001, 92:57–59.

Petitioner contends that Gross discloses a transcutaneous electrochemical glucose sensor that is characterized by an in-vivo sensitivity and by an in-vitro sensitivity that differ from each other. Pet. 40–41. To explain its contentions, Petitioner provides an annotated version of Gross’s Figure 5 as shown below.



Petitioner annotates Gross’s Figure 5 above to show that the sensitivities represented by tangents or slopes of “theoretical” (in vitro) sensor

performance curve 40 and “measured” (in vivo) sensor performance curve 42 at corresponding points 40c, 42c are different. *Id.* at 40–41 (citing Ex. 1004, 14:39–41).

Patent Owner does not dispute Petitioner’s contentions that Gross discloses limitation 1b.

On this record, we find that Petitioner shows sufficiently that Gross discloses limitation 1b.

(iv) *Limitation 1c: In Vitro Sensitivity is Predictive of In Vivo Sensitivity*

Limitation 1c recites “wherein the in vitro sensitivity is predictive of the in vivo sensitivity due to a relationship therebetween.”

Petitioner contends that Gross discloses that for a sensor having measured performance curve 42, the in vitro sensitivity is predictive of the sensor’s in vivo sensitivity due to a relationship between their sensitivities. Pet. 42–45. Petitioner argues that Gross’s sensor’s measured (in vivo) performance curve 42 is similar in shape to theoretical (in vitro) performance curve 40, which allows for prediction of intermediate points on curve 42 from curve 40. *Id.* at 43 (citing Ex. 1004, 14:48–53). Petitioner asserts that Gross discloses a predictive relationship between points of curves 40 and 42 and the slopes of the curves corresponding to the claimed sensitivities. *Id.* (citing Ex. 1004, 4:17–21, 14:10–53; Ex. 1002 ¶¶ 94–97).

Petitioner provides annotated versions of Gross’s Figure 5 to illustrate the predictive relationship between in vitro and in vivo sensitivity disclosed in Gross. Pet. 43–45. Petitioner notes that the sensitivities (slopes) of curves 40, 42 differ at corresponding analyte concentrations but are similar due to the similar shapes of the curves. *Id.* at 45 (citing Ex. 1002 ¶¶ 98–101).

Petitioner asserts that

Accordingly, because Gross teaches that in-vitro curve 40 is predictive of in vivo curve 42 due to a relationship between the curves (they have the same basic shape), Gross also teaches that there is a relationship between the in-vitro sensitivity and the in-vivo sensitivity (e.g., the slopes of the tangents of the respective curves at a given glucose concentration) and that the in-vitro sensitivity is predictive of the in-vivo sensitivity due to such relationship.

Pet. 45 (citing Ex. 1002 ¶ 102).

Patent Owner disputes Petitioner's contentions. Prelim. Resp. 32–36. Specifically, Patent Owner argues that Gross has no mathematical function to predict in vivo sensitivity and must directly measure the sensor's performance in vivo and then calculate corrections for its calibration function based on measured in vivo performance. *Id.* at 32–33 (citing Ex. 1004, 12:55–13:26, 13:59–14:53). Patent Owner asserts that the '364 patent requires going in the reverse direction, with information associated with in vivo sensitivity being based on the claimed corrections. *Id.* (citing Ex. 1001, 79:59–80:3, 89:6–26).

Patent Owner's argument relates to differences in what the predictive relationship is and how it was obtained in Gross as compared to what the '364 patent describes. These differences do not appear to be recited in the claims. In the '364 patent, the function $m_{in\ vivo}=2.99*m_{in\ vitro}+26.62$ relates the in vivo and in vitro sensitivities. Ex. 1001, 89:6–26. In Gross, the concentration-dependent calibration function relates curves 40 and 42, and therefore their sensitivities. *Id.* at 14:10–47. Gross's calibration function can be used to predict in vivo sensitivity from in vitro sensitivity. Thus, on

the current record, Patent Owner’s argument does not undermine Petitioner’s showing for limitation 1c.

Patent Owner does not otherwise dispute Petitioner’s contentions that Gross discloses limitation 1c.

On the present record, we find that Petitioner shows sufficiently that Gross discloses limitation 1c.

(v) *Limitation 1d: Sensor Electronics*

Limitation 1d recites “sensor electronics configured to be operably connected to the transcutaneous electrochemical glucose sensor.” Ex. 1001, 92:64–65.

Petitioner contends that Gross’s monitor device includes sensor electronics configured to be operably connect to the sensor. Pet. 45–46. Specifically, Petitioner asserts that Gross’s monitoring device has a reusable first part 12 that includes electronic controlling circuitry, and a disposable second part 13 which includes enzymatic sensor needle 15 which is operably connected to the circuitry. *Id.* at 45–46 (citing Ex. 1004, 4:41–57, 7:31–48, 9:50–52; 9:64–10:9, 10:62–65, 18:59–64, Fig. 1A; Ex. 1002 ¶¶ 103–105).

Patent Owner does not dispute Petitioner’s contention that Gross discloses limitation 1d.

On the current record, we find that Petitioner demonstrates sufficiently that Gross discloses limitation 1d.

(vi) *Limitation 1e: Processor*

Limitation 1e recites “a processor configured to be operably connected to the sensor electronics.” Ex. 1001, 92:66–67.

Petitioner contends that Gross’s microprocessor 18 performs several functions, including measuring current, storing sensor signals, and

calibrating sensor data. Pet. 46–47 (citing Ex. 1004, 9:64–10:3, 11:48–51, 12:55–59, 13:3–41, 14:5–53).

Petitioner asserts that Gross’s microprocessor is operably connected to the sensor electronics. Pet. 46. Specifically, Petitioner contends that to perform the disclosed functions, the microprocessor must be operably connected to the sensor electronics, and Gross discloses that the electrodes 15, 16, 17 are connected to microprocessor 18 via a voltage controller 19, and the microprocessor controls the voltages supply by the voltage controller 19 to the electrodes. *Id.* at 47 (citing Ex. 1004, 9:64–10:9). Petitioner further notes that Gross’s Figure 1A shows a connection between microprocessor 18 and voltage controller 19, which in turn connects to sensor electrode 15. *Id.* (citing Ex. 1002 ¶¶ 106–109).

Patent Owner does not dispute Petitioner’s contention that Gross discloses limitation 1e.

On the current record, we find that Petitioner demonstrates sufficiently that Gross discloses limitation 1e.

(vii) Limitation 1f: Memory

Limitation 1f recites “a memory configured to be operably connected to the processor.” Ex. 1001, 93:1–2.

Petitioner contends Gross discloses a memory operably connected to the microprocessor, that stores data and instructions for operation of the microprocessor, including instructions for calibrating sensor data. Pet. 47 (citing Ex. 1004, 13:9–10, 14:19–53). Petitioner contends that system components such as memory were well-known in the art and were common to many glucose monitoring systems disclosed in the art. *Id.* at 47–48 (citing Ex. 1002 ¶¶ 110–115).

Patent Owner does not dispute Petitioner's contention that Gross discloses limitation 1f.

On the current record, we find that Petitioner demonstrates sufficiently that Gross discloses limitation 1f.

(viii) Limitation 1g: Information Stored in Memory

Limitation 1g recites “wherein the memory has stored therein information associated with the in vivo sensitivity of the transcutaneous electrochemical glucose sensor, wherein the information associated with the in vivo sensitivity is based at least in part on corrections for the difference between the in vivo sensitivity and the in vitro sensitivity of the transcutaneous electrochemical glucose sensor.” Ex. 1001, 93:2–9.

Petitioner contends that [t]he information stored in the system's memory includes the “concentration-dependent calibration function” that is used to map in-vivo measured signals (lying on measured performance curve 42) to the theoretical performance curve (in-vitro curve 40) during use to provide a calibrated output in meaningful units.” Pet. 48 (citing Ex. 1004, 14:41–47). According to Petitioner, “[t]his calibration function is ‘information associated with the in vivo sensitivity’ of the sensor, wherein such information ‘is based at least in part on corrections for the difference between the in vivo sensitivity and the in vitro sensitivity’ of the sensor,” as recited in limitation 1g. *Id.* at 48–50 (citing Ex. 1004, 14:39–47, Fig. 5; Ex. 1002 ¶¶ 116–122). Petitioner asserts that Gross discloses that once in vivo saturation and baseline signals are recorded, the microprocessor calculates the calibration function and applies it to subsequently measured signals such that the calibration function is stored in the system's memory. *Id.* at 51 (citing Ex. 1004, 14:23–27).

Patent Owner disputes Petitioner's contentions. Prelim. Resp. 26–36. Specifically, Patent Owner argues that Petitioner improperly maps the claimed information associated with in vivo sensitivity and corrections for a difference between in vivo and in vitro sensitivities to the same “concentration-dependent calibration function” in Gross. *Id.* at 26. Patent Owner argues that this interpretation is improper because it fails to give meaning to separately recited elements in the claims, and renders claim language superfluous. *Id.* at 26–28.

We do not agree with Patent Owner's argument on the current record. Gross's calibration function is associated with in vivo sensitivity (the slope of in vivo curve 40 in Gross's Figure 5) and is based on corrections for differences in in vivo and in vitro sensitivity of the sensor (the difference in slopes for corresponding concentrations on in vivo curve 40 and in vitro curve 42 in Gross's Figure 5). *See* Ex. 1004, 13:59–14:67, Fig. 5. On this record, Petitioner's mapping of the limitation 1g to Gross's calibration function neither fails to give meaning to separate claim elements nor renders claim language superfluous, contrary to Patent Owner's argument.

Accordingly, on the present record, we find that Petitioner shows sufficiently that Gross discloses limitation 1g.

(ix) *Conclusion for Claim 1*

Petitioner has shown sufficiently on this record that each limitation of claim 1 is disclosed by Gross. Accordingly, Petitioner has shown a reasonable likelihood to prevail in demonstrating unpatentability of claim 1 of the '364 patent as anticipated by Gross.

3. *Claim 2*

Claim 2 depends from claim 1 and recites “wherein the relationship between the in vivo sensitivity and the in vitro sensitivity is established empirically by performing a clinical study and comparing in vivo sensitivities with in vitro sensitivities of a plurality of transcutaneous glucose sensors.” Ex. 1001, 93:10–14.

Petitioner contends that Gross anticipates and/or renders obvious claim 2. Pet. 52. Petitioner contends that a clinical study is a study in humans, and clinical studies were routinely performed in the art during research and development and as part of the regulatory approval process for devices such as CGMs. *Id.* (citing Ex. 1002 ¶¶ 125, 132).

Specifically, Petitioner contends that Gross discloses determining in-vitro sensitivity by examining a batch of sensors at the factory, and applying that in vitro sensitivity determination to all sensors in the batch. Pet. 53 (citing Ex. 1004, 4:9–12, 12:30–37, 13:46–48). Petitioner avers that Gross further discloses that “the sensors in the batch are intended to be used in vivo (in a host), and that once inserted into a host, each sensor’s in-vivo performance curve is expected to have the same basic shape as the pre-determined in-vitro performance curve.” *Id.* at 54 (citing Ex. 1004, 4:9–16, 14:10–15). Petitioner argues that a POSITA would have understood that the knowledge that the in vivo curve will have the same in vitro curve for sensors in the same batch was determined empirically and would have entailed a clinical study. *Id.* at 54–55 (citing Ex. 1004, 14:10–11; Ex. 1002 ¶ 130). Petitioner further asserts that glucose sensors were routinely characterized and studied in clinical trials, and a POSA would have examined the in vitro/in vivo sensitivity relations of sensors empirically

through a clinical trial as was routine in the art. *Id.* at 55–56 (citing Ex. 1006; Ex. 1007; Ex. 1002 ¶¶ 131–133).

Patent Owner does not dispute Petitioner’s contentions that Gross discloses claim 2.

On the current record, Petitioner presents a reasonable likelihood of to prevail in demonstrating unpatentability of claim 2 of the ’364 patent as anticipated by Gross.

4. *Claim 3*

Claim 3 depends from claim 1 and recites “wherein the in vivo sensitivity is greater than the in vitro sensitivity.” Ex. 1001, 93:16–17.

Petitioner contends that Gross’s Figure 5 discloses this limitation for the sensor having in vivo curve 42. Petitioner asserts that “[e]specially at low glucose concentrations, the slope of the tangent on in vivo curve 42 is greater than the slope of the tangent on in-vitro curve 40, and therefore the in-vivo sensitivity is greater than the in-vitro sensitivity at these glucose concentrations.” *Id.* at 56. Petitioner reiterates its contentions for limitation 1b showing its annotated version of Gross’s Figure 5 and how the in vivo sensitivity (slope) at point 42c is greater than the in vitro sensitivity (slope) at point 40c. *Id.* at 56–57. Petitioner contends that Gross therefore discloses a sensor characterized by an in vivo sensitivity and in vitro sensitivity, as required by claim 3 of the ’364 patent. *Id.* at 58 (citing Ex. 1002 ¶¶ 134–139).

Patent Owner does not dispute Petitioner’s contentions that Gross discloses claim 3.

Petitioner demonstrates a reasonable likelihood to prevail in demonstrating unpatentability of claim 3 as anticipated by Gross.

5. *Claim 5*

Petitioner asserts that Gross anticipates and renders obvious claim 5. Pet. 58–62. Patent Owner disputes Petitioner’s contentions under the same arguments discussed for claim 1. We consider Petitioner’s and Patent Owner’s contentions for each limitation of claim 5 and conclude that Petitioner presents a reasonable likelihood that claim 5 was anticipated by Gross.

(i) *Preamble*

The preamble of claim 5 recites “method for calibrating data from a transcutaneous electrochemical glucose sensor, the method comprising.” Ex. 1001, 93:26–27.

Petitioner contends that Gross discloses “‘a method of calibrating an analyte sensor,’ where ‘a particularly preferred analyte is glucose.’” Pet. 58 (citing Ex. 1004, 4:24–40). Petitioner contends that, “as discussed above for claim 1, Gross’s calibration method is for ‘a transcutaneous electrochemical glucose sensor.’” *Id.* (citing *id.* § X.A.1.b; Ex. 1002 ¶¶ 140–142).

Patent Owner does not dispute Petitioner’s contentions that Gross discloses claim 5’s preamble.

On the current record, we find that Petitioner shows sufficiently that the preamble of claim 5 is disclosed by Gross. Consequently, we do not decide whether the preamble is limiting.

(ii) *Limitation 5a: Receiving Sensor Data*

Limitation 5a recites “receiving sensor data from the transcutaneous electrochemical glucose sensor after at least a portion of the transcutaneous electrochemical glucose sensor is inserted in a host, wherein the sensor data is indicative of a glucose concentration in the host.” Ex. 1001, 93:28–32.

Petitioner contends that Gross discloses “that the sensor output received after sensor insertion into the host corresponds to a glucose concentration in the host.” Pet. 58 (citing Ex. 1004, 1:12–26, 10:60–12:24). Petitioner notes that Gross discloses ““when a voltage is applied to the working electrode 15, the microprocessor 18 measures the current flowing through the circuit of which the working electrode 15 and the counter electrode 16 form a part thereof.”” *Id.* (citing Ex. 1004, 11:48–51). Petitioner contends that “Gross further teaches that this current measured by the microprocessor is indicative of a glucose concentration in the host.” *Id.* at 58–59 (citing Ex. 1004, 11:10–34; Ex. 1002 ¶¶ 143–146).

Patent Owner does not dispute Petitioner’s contentions that Gross discloses limitation 5a.

On the current record, we find that Petitioner shows sufficiently that Gross discloses limitation 5a.

(iii) Limitation 5b: Calibrating

Limitation 5b recites “calibrating, using a processor, the sensor data received from the transcutaneous electrochemical glucose sensor.” Ex. 1001, 93:33–35.

Petitioner contends that

Gross’s method involves calibrating sensor data, and Gross teaches using a processor to perform the calibration. As discussed above, Gross’s system stores information (e.g., the measured performance curve 42) and uses this information to calculate a concentration-dependent calibration function that is then also stored and applied to subsequently measured signals, to calibrate those signals and generate calibrated output.

Pet. 59 (citing Ex. 1004, 8:31–42; 14:10–53). Petitioner contends that Gross’s calibration is performed by a processor. *Id.* (citing *id.* at

§§ X.A.1.f–g (regarding limitations 1e, 1f, and 1g); Ex. 1004, 14:19–47). Petitioner asserts that “Gross thus discloses calibrating, using a processor, the sensor data received from the sensor after sensor insertion.: *Id.* at 60–61 (citing Ex. 1004, 8:33–41; 14:19–53; Ex. 1002 ¶¶ 147–151).

Patent Owner does not dispute Petitioner’s contentions that Gross discloses limitation 5b.

On this record, we find that Petitioner shows sufficiently that Gross discloses limitation 5b.

(iv) *Limitation 5c: Information Associated with In Vivo Sensitivity*

Limitation 18c recites “wherein the calibrating is based at least in part on information associated with an in vivo sensitivity of the transcutaneous electrochemical glucose sensor, wherein the information associated with the in vivo sensitivity is based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity for the transcutaneous electrochemical glucose sensor.” Ex. 1001, 93:35–42.

Petitioner asserts that Gross’s calibration method employs a calibration function that is “associated with an in-vivo sensitivity” at least because the calibration function corrects for a difference between in vitro and in vivo sensitivities. Pet. 61 (citing *id.* § X.A.1.h; Ex. 1002 ¶¶ 152–153). Petitioner contends Gross’s calibration function corrects for a difference between in vivo and in vitro sensitivities, and is thus “based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity,” as claimed. *Id.* at 61–62 (citing *id.* §§ X.A.1.c–d, X.A.3; Ex. 1004, 14:36–47; Ex. 1002 ¶¶ 154–155). Accordingly, Petitioner contends that “when Gross provides calibrated output, Gross’s calibration function corrects for the difference between in-vivo curve 42 and

in-vitro curve 40 and by doing so corrects for the difference in sensitivities that are defined by these curves.” *Id.* at 62 (citing Ex. 1002 ¶¶ 156–158).

Patent Owner disputes Petitioner’s contentions for limitation 5c using the same arguments asserted against limitation 1g, which we find do not undermine Petitioner’s contentions at this stage of the proceeding. *See* § IV.D.2.viii, *supra*. Specifically, Patent Owner argues that Petitioner’s reliance on Gross’s calibration function as both “associated with an in-vivo sensitivity” and “based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity” as claimed improperly conflates the two limitations and renders the claim language superfluous. Prelim. Resp. 28–36. We do not agree as Petitioner has shown sufficiently that Gross’s calibration function is both “associated with an in-vivo sensitivity” and “based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity.” *See, e.g.*, Ex. 1004, 13:59–14:67.

Patent Owner does not otherwise dispute Petitioner’s contentions that Gross discloses limitation 5c.

On the current record, we find that Petitioner shows sufficiently that Gross discloses limitation 5c.

(v) *Conclusion for Claim 5*

On the current record, Petitioner has shown sufficiently that each limitation of claim 5 is disclosed by Gross. Accordingly, we find that Petitioner has presented a reasonable likelihood that claim 5 was anticipated by Gross.

6. *Claim 8*

Claim 8 depends from claim 5 and recites “wherein the in vitro sensitivity for the transcutaneous electrochemical glucose sensor is based at least in part on sampling a plurality of transcutaneous electrochemical glucose sensors prior to inserting the at least a portion of the transcutaneous electrochemical glucose sensor in the host.” Ex. 1001, 94:11–16.

Petitioner contends that

Gross’s calibration method does not require any user calibrations after the sensor is inserted into the host. The microprocessor calculates the calibration function based on a theoretical performance (in-vitro) curve (for example, a laboratory-measured curve such as a curve determined at the factory), and a measured (in-vivo) performance curve determined by the system when the needle 15 enters the body, without any user measurements.

Pet. 63 (citing Ex. 1004, 12:55–13:41).

Specifically, Petitioner contends that “Gross’s system initiates a process for obtaining and recording saturation and baseline signals and then generating a measured (in-vivo) performance curve and calculating a calibration function to be used for calibrating subsequently measured sensor signals” and “[t]he calibration process is run by the microprocessor and does not rely on or require any user calibrations.” Pet. 63–64 (citing Ex. 1004, 12:55–13:26, 14:5–53; Ex. 1002 ¶¶ 159–161).

Patent Owner does not dispute Petitioner’s contentions that Gross discloses claim 8.

On the current record, we find that Petitioner presents a reasonable likelihood that claim 8 was anticipated by Gross.

7. *Claim 9*

Claim 9 depends from claim 8 and recites “wherein the in vitro sensitivity is calculated at least in part by examining a signal response of each of the plurality of transcutaneous electrochemical glucose sensors to a set of known glucose concentrations.” Ex. 1001, 94:17–22.

Petitioner contends that Gross discloses and renders obvious claim 9. Pet. 65 (citing Ex. 1002 ¶¶ 165–167). Petitioner asserts that Gross discloses that laboratory calibration (*see* claim 8) is performed by measuring sensor response ‘using a standard glucose solution, for example.’” *Id.* (citing Ex. 1004, 12:30–37). Petitioner notes that Gross discloses that in vitro curve 40 in Gross’s Figure 5 is a “laboratory-measured signal-concentration curve” that includes sensor signal measurements including in vitro saturation signal 40a and in vitro baseline signal 40b. *Id.* at 65–66 (citing Ex. 1004, 14:5–9, 14:38–41). Petitioner thus contends that the claimed “set of known glucose concentrations” in Gross includes at least a concentration corresponding to saturation, and a concentration (which could be zero) corresponding to baseline. *Id.* at 66 (citing Ex. 1:33–41).

Petitioner further asserts that “[c]alculating in-vitro sensitivity at least in part by examining sensor signal response to a set of known glucose concentrations also would have been obvious in view of the routine practice of examining sensor response in the in-vitro environment.” Pet. 66 (citing Ex. 1008, 6, 8, Fig. 4; Ex. 1002 ¶¶ 169–175). Petitioner asserts that “[t]esting sensor response to multiple glucose concentrations (and thereby having a number of matched pairs, from which to empirically derive the in-vitro conversion function) increased the accuracy of the empirically-derived in-vitro conversion function, and testing sensors in vitro was well within the

skill of researchers working in the field.” *Id.* at 66–67 (citing Ex. 1002 ¶ 175).

Patent Owner does not dispute Petitioner’s contentions that Gross discloses claim 9.

On the current record, we find that Petitioner presents a reasonable likelihood that claim 9 was anticipated by Gross.

8. *Claim 10*

Petitioner contends that claim 10 was anticipated by, and would have been obvious over, Gross. Pet. 67–71. Patent Owner disputes Petitioner’s contentions under the same arguments discussed for claim 1. We consider Petitioner’s and Patent Owner’s contentions for each limitation of claim 5 and conclude that Petitioner presents a reasonable likelihood that claim 5 was anticipated by Gross.

(i) *Preamble*

The preamble of claim 10 recites “A method for providing calibrated glucose information based on sensor data from a transcutaneous electrochemical glucose sensor, the method comprising:” Ex. 1001, 94:23–25.

Petitioner contends that “Gross’s method provides ‘calibrated glucose information based on sensor data,’ as recited in the preamble of claim 10.” Pet. 67 (citing Ex. 1004, 14:23–27, 14:30–38; Ex. 1002 ¶¶ 176–177).

Patent Owner does not dispute Petitioner’s contention that Gross discloses claim 10’s preamble.

On the present record, we find that Petitioner has shown sufficiently that the preamble of claim 14 is disclosed by Gross, and thus do not reach the issue of whether the preamble is limiting.

(ii) *Limitation 10a: Receiving Post-Implantation Sensor Data*

Limitation 10a recites “receiving, by a processor, post-implantation sensor data from the transcutaneous electrochemical glucose sensor, wherein the sensor data is indicative of a glucose concentration in a host.” Ex. 1001, 94:26–29.

Petitioner contends that Gross discloses that its microprocessor measures current after sensor needle (“working electrode”) 15 is inserted into the host. Pet. 67–68 (citing Ex. 1004, 10:60–11:57). Petitioner contends that “[t]his current is ‘post-implantation sensor data’ received by a processor ‘from the transcutaneous electrochemical glucose sensor’” as recited in limitation 10a. *Id.* at 68. In addition, Petitioner states that Gross discloses that the “this current measured by the microprocessor is indicative of a glucose concentration in the host.” *Id.* (citing Ex. 1004, 11:10–34; Ex. 1002 ¶¶ 178–180).

Patent Owner does not dispute Petitioner’s contentions that Gross discloses limitation 10a.

On the current record, we find that Petitioner shows sufficiently that Gross discloses limitation 10a.

(iii) *Limitation 10b: Information Associated with In Vivo Sensitivity Based on Corrections and In Vitro Sensitivity*

Limitation 10b recites “receiving, by the processor, information associated with an in vivo sensitivity of the transcutaneous electrochemical glucose sensor, wherein the information associated with the in vivo sensitivity is based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity for the transcutaneous electrochemical glucose sensor.” Ex. 1001, 94:30–36.

Petitioner contends that “[i]n Gross’s calibration method, the processor receives ‘information associated with an in vivo sensitivity’ of the sensor, ‘wherein the information associated with the in vivo sensitivity is based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity for the transcutaneous electrochemical glucose sensor,’” as recited in limitation 10b. Pet. 68–69.

Specifically, Petitioner asserts that “[t]o calibrate sensor data for a sensor having measured (in-vivo) performance curve 42, Gross’s method applies a concentration-dependent calibration function that maps the sensor data to theoretical performance curve 40” as Petitioner explained for limitation 5b. Pet. 69 (citing Ex. 1002 ¶¶ 181–182).

Petitioner contends that “[t]his concentration-dependent calibration function is ‘information associated with an in vivo sensitivity’ of the sensor that is ‘based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity,’ as Petitioner explained for limitations 1g and 5c. Pet. 69. Petitioner further asserts that “because Gross’s microprocessor receives and uses the calibration function when providing calibrated glucose information based on sensor signals lying on the intermediate points of curve 42, Gross’s microprocessor receives and uses ‘information associated with an in vivo sensitivity’ of the sensor that is ‘based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity,’” as recited in limitation 10b. *Id.* (citing Ex. 1002 ¶ 183).

Patent Owner disputes Petitioner’s contentions for limitation 10b using the same arguments discussed for limitation 1g, which we find do not undermine Petitioner’s contentions. *See* § IV.D.2.viii, *supra*. Specifically,

Patent Owner argues that Petitioner's reliance on Gross's calibration function as both "associated with an in-vivo sensitivity" and "based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity" improperly conflates the two limitations and renders the claim language superfluous. Prelim. Resp. 28–36. We do not agree Patent Owner's argument on the current record as Petitioner has shown sufficiently that Gross's calibration function is both "associated with an in-vivo sensitivity" and "based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity." *See, e.g.*, Ex. 1004, 13:59–14:67.

Patent Owner does not otherwise dispute Petitioner's contentions that Gross discloses limitation 10b.

On the current record, we find that Petitioner shows sufficiently that Gross discloses limitation 10b.

(iv) Limitation 10c: Generating Calibrated Sensor Data

Limitation 10c recites "generating calibrated sensor data, using the processor, by using the information associated with the in vivo sensitivity of the transcutaneous electrochemical glucose sensor to calibrate the sensor data received from the transcutaneous electrochemical glucose sensor." Ex. 1001, 94:37–41.

Petitioner contends that "[i]n Gross's method, the microprocessor generates calibrated sensor data by using the concentration-dependent calibration function to calibrate the data received from the sensor," as Petitioner explained for limitations 5b and 5c. Pet. 70. Specifically, Petitioner alleges that "the microprocessor uses the calibration function to map sensor data (measured signals corresponding to intermediate points on

curve 42) to corresponding points on theoretical curve 40 and thereby calibrate the sensor data.” *Id.* (citing Ex. 1004, 14:10–53). Petitioner avers that “[t]he concentration-dependent calibration function is information associated with the in vivo sensitivity of the sensor,” as recited in limitation 10c. *Id.* (citing Ex. 1002 ¶¶ 184–185) (referring back to Petitioner’s contentions for limitations 1g, 5b, and 5c).

Patent Owner does not dispute Petitioner’s contentions that Gross discloses limitation 10c.

On the current record, we find that Petitioner shows sufficiently that Gross discloses limitation 10c.

(v) *Limitation 10d: Providing Calibrated Data to User*

Limitation 10d recites “providing the calibrated sensor data to a user to facilitate monitoring a glucose level of the host.” Ex. 1001, 94:42–43.

Petitioner contends that “[t]he purpose of Gross’s system and method is to provide calibrated sensor data to the user, so that the user can meaningfully monitor his/her glucose level” and that “[t]o this end, Gross teaches a display unit that includes a visual LCD display” which “provides ‘a visual output of the measured analyte levels.’” Pet. 70 (citing Ex. 1004, 9:48–49, 10:10–14, 15:5–20). Petitioner argues that “Gross explains that ‘the microprocessor calculates the corresponding point 40c and provides, as an output which is transmitted to the display unit, the calibrated measurement corresponding to point 40c which can then be displayed in meaningful units.’” *Id.* at 70–71 (citing Ex. 1004, 14:30–35) (emphasis omitted). Petitioner contends that Gross’s providing a “calibrated measurement” as a visual output on the display unit with glucose levels

“displayed in meaningful units” discloses limitation 10d. *Id.* at 71 (citing Ex. 1002 ¶¶ 186–187).

Patent Owner does not dispute Petitioner’s contentions that Gross discloses limitation 10d.

On the current record, we find that Petitioner shows sufficiently that Gross discloses limitation 10d.

(vi) *Conclusion for Claim 10*

On the current record, Petitioner has shown sufficiently that each limitation of claim 10 is disclosed by Gross. Accordingly, we find that Petitioner has presented a reasonable likelihood that claim 10 was anticipated by Gross.

V. CONCLUSION

For the above reasons, we conclude the record demonstrates a reasonable likelihood that Petitioner would prevail with respect to at least challenged claim, so we grant institution of the petitioned *inter partes* review per 35 U.S.C. § 314(a) for all challenged claims and all grounds. *See* 37 C.F.R. § 42.108(a).

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), the petitioned institution of *inter partes* review of claims 1–3, 5–6, and 8–10 of the ’364 patent is *granted*; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial and that the trial will commence on the entry date of this decision.

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Patent 10,709,364 B2

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