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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE INC.,
Petitioner,

v.

DEXCOM, INC.,
Patent Owner.

Case No. IPR2024-00841

Patent No. 10,709,364

PATENT OWNER'S PRELIMINARY RESPONSE

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LISTING OF EXHIBITS

Exhibit	Description
2001	Forlenza et al., Factory-Calibrated Continuous Glucose Monitoring: How and Why It Works, and the Dangers of Reuse Beyond Approved Duration of Wear. Diabetes Technology and Therapeutics. 2019 Apr; 21(4):222-229.
2002	Vaddiraju et al., Technologies for continuous glucose monitoring: current problems and future promises. Journal of Diabetes Science and Technology. 2010 Nov; 4(6):1540-62.
2003	Stephens Inc., Research Bulletin – DexCom, Inc. (Mar. 28, 2018)
2004	Choleau et al., Calibration of a subcutaneous amperometric glucose sensor. Part 1. Effect of measurement uncertainties on the determination of sensor sensitivity and background current. Biosensors & Bioelectronics. 2002 Aug; 17(8):641-6.
2005	Ward et al., Rise in background current over time in a subcutaneous glucose sensor in the rabbit: relevance to calibration and accuracy. Biosensors & Bioelectronics. 2000 Mar; 15(1-2):53-61.
2006	Koschinsky et al., Sensors for glucose monitoring: technical and clinical aspects. Diabetes/Metabolism Research and Reviews. 2001 Mar-Apr; 17(2):113-23.
2007	Frost et al., Implantable chemical sensors for real-time clinical monitoring: progress and challenges. Current Opinion in Chemical Biology. 2002 Oct; 6(5):633-41.
2008	Lodwig et al., Continuous Glucose Monitoring with Glucose Sensors: Calibration and Assessment Criteria. Diabetes Technology & Therapeutics. 2003; 5(4):572-86.

I. INTRODUCTION

Patent Owner (“DexCom”) is a pioneer in the field of continuous glucose monitoring (“CGM”) systems. Since 1999, DexCom has been a leader in developing innovative technology that has transformed how people manage diabetes.

Diabetes mellitus is a disorder in which a person’s blood sugar (glucose) can become dangerously high (hyperglycemia) or dangerously low (hypoglycemia), which can lead to complications such as kidney failure, ulcers, and bleeding. EX1001, 1:35-46. It is therefore important for diabetics to monitor their body’s glucose levels so they can take action before the glucose levels become too high or low.

Historically, diabetics have used self-monitoring blood glucose (SMBG) devices that require pricking a finger (also known as a “fingerstick”) to collect a blood sample, which is then introduced to a separate glucose meter device to measure the level of glucose in the blood. EX1001, 1:47-49. This can be painful and inconvenient, so a person will normally only be willing to do this a few times per day. EX1001, 1:49-52. However, without more frequent monitoring, diabetics risk not detecting a dangerously hyperglycemic or hypoglycemic condition until it is too late. EX1001, 1:52-55.

Since 2006, however, DexCom has provided FDA-approved “continuous” glucose monitors (CGMs) to more continuously, more conveniently, and less painfully monitor glucose levels. These CGMs include a device worn on the user’s skin, with a small sensor inserted transcutaneously (through the skin) to detect glucose in the subcutaneous body fluids. The sensor is configured to respond by outputting an electric current when glucose is present around the sensor. The on-skin device wirelessly transmits data on the amount of detected glucose to a receiver device, which may have a display where the user can “continuously” view their current glucose levels.

DexCom’s G5 model was the world’s first real-time CGM approved for adults and children two years and older. Today, DexCom’s G6 model is the first FDA-approved “integrated CGM” (iCGM), which reliably and securely transmits glucose data to digitally connected devices, including automated insulin-dosing systems. It is also transformative as a real-time CGM that can be used without requiring any self-monitoring blood glucose measurements (e.g., without fingersticks). In 2022, the FDA approved DexCom’s newest G7 model, which further improves accuracy and still requires no fingersticks.

Although any CGM may be able to replace fingersticks taken for monitoring glucose levels throughout the day, prior-art CGMs still required an initial “calibration” using a fingerstick measurement to set up the device to accurately

map the sensor's electrical signal output to the user's current glucose level after the sensor was inserted into the body, as well as additional, periodic fingerstick calibrations to correct for drift in the mapping over time as the device was used. Before the '364 Patent's 2005 priority date (and for some time thereafter before DexCom's innovation was brought to market), CGM systems "all required user calibrations whereby ... (SMBG) fingerstick values ... were used to correlate the sensor signal with a patient's blood glucose value." EX2001 at 222; EX2002 at 1551 ("[A]ll current CGM devices ... mandate that the patient calibrate his/her CGM device by means of conventional test strips at least once per day").

DexCom, however, developed "advancement[s] in the algorithms used within the GCM systems to translate the sensor signal into a glucose value," allowing calibration parameters to be "identified based on an initial factory calibration" without a further reference measurement after the user inserts the sensor. EX2001 at 222, 224. This helped make DexCom's G6 "the first ever CGM device to truly eliminate the need for fingersticks to calibrate"—"A TRUE Game Changer." EX2003 at 1. "The ability of a provider to tell a patient 'you no longer need to poke your finger' is truly transformative for the field." EX2001 at 222. It "enables therapies ... to move to a realm of decreased patient burden long thought to be impossible." EX2001 at 222.

One parameter that can be important for calibration, in order to accurately determine what glucose concentration is being detected by a sensor that is outputting a given amount of electrical current, is the sensor's sensitivity—e.g., the amount by which this particular sensor's electrical output will increase for each unit of increase in glucose concentration around the sensor. EX1001, 17:51-58, 77:16-18, 89:40-47. A glucose sensor's sensitivity can be tested *in vitro* (e.g., in a laboratory, by exposing the sensor to solutions of various concentrations of glucose) when the sensor is manufactured, but it has been well known that a sensor's glucose sensitivity will typically change once the sensor is placed in a person's body (*in vivo*). See, e.g., EX2004 at 641-645; EX2007 at 636. If the electrical output of a glucose sensor in a person's body is interpreted by assuming that the sensor's sensitivity is its *in-vitro* sensitivity, but the sensor's *in-vivo* sensitivity is actually quite different, the resulting glucose-level readings will not be accurate, which could have dangerous consequences for a diabetic. For this reason, one or more fingerstick measurements using a separate SMGB device were conventionally taken once the CGM sensor was inserted in the body, to determine what glucose levels correspond to the electrical output levels of that sensor, and thus determine the sensor's sensitivity *in vivo*. See, e.g., EX2004 at 641-645; EX2006 at 117; EX2007 at 636; EX2008 at 574, 577.

In the '364 Patent, DexCom developed a particular way to achieve the long-sought breakthrough of CGM calibration without a fingerstick, by developing sensors whose *in-vivo* sensitivity could be accurately predicted from their *in-vitro* sensitivity—an accomplishment that the prior art had been unable to achieve. Although DexCom's sensors' sensitivities do change when placed *in vivo*, DexCom achieved a predictive relationship whereby a known correction function could be determined in advance and applied to correct for the difference between the sensor's *in-vitro* and *in-vivo* sensitivities, thereby arriving at the *in-vivo* sensitivity that will be applied to interpret the sensor's output once it is inserted in the body. By empirically determining the appropriate corrections for that sensitivity difference, DexCom provided a way to pre-calibrate the sensor for accurate use in a person's body without requiring reference measurements after the sensor was inserted.

Petitioner ("Abbott") introduced a competing product to DexCom's first CGM in 2008, and today incorporates DexCom's sensitivity-correction innovation in Abbott's glucose monitors. The parties are currently in litigation, where DexCom asserts that Abbott's products infringe both the '364 Patent and a related patent 11,000,213 ("the '213 Patent"), which share a specification. Abbott earlier filed IPRs challenging the asserted claims of the '213 Patent, and the Board found those claims not unpatentable over Gross (EX1004), because Gross's glucose

monitor requires an *in-vivo* calibration that takes a reference measurement after insertion of the sensor into the body. *See, e.g.*, IPR2022-00913, Paper 44 at 43-57 (Nov. 2, 2023). Now, Abbott is attempting to apply the same Gross reference to the '364 Patent.

But Gross remains fundamentally different from the invention described and claimed in the '364 Patent. Rather than attempting to pre-calibrate sensors by identifying corrections that can be applied to *in-vitro*-measured sensitivity to arrive at accurately predicted *in-vivo* sensitivity, Gross is emphatic that “sensors characterized by a laboratory batch calibration” in the factory “are unsatisfactory because such calibration does not permit the performance of the sensor *in vivo* to be accurately predicted in all cases.” Gross, 1:51-55. “Therefore, a further calibration occurs *in vivo*” by performing a calibration measurement after insertion. Gross, 12:55-61. Gross’s post-insertion calibration measurement may not be a fingerstick, but Gross’s way of avoiding a fingerstick is not the same as DexCom’s technique in the '364 Patent. Gross merely uses a different type of post-insertion reference measurement to calibrate the sensor. Gross does not arrive at *in-vivo* sensitivity information for the sensor “based at least in part on corrections for a difference between the *in vivo* sensitivity and [the] *in vitro* sensitivity” as the '364 Patent’s claims require, which is what allows embodiments in the '364 Patent to

pre-calibrate sensors *without* need for a post-insertion reference glucose measurement.

As discussed in further detail below, the Petition's sole ground, which is based on Gross, fails to demonstrate unpatentability of any of the challenged claims. Institution should be denied.

II. THE '364 PATENT

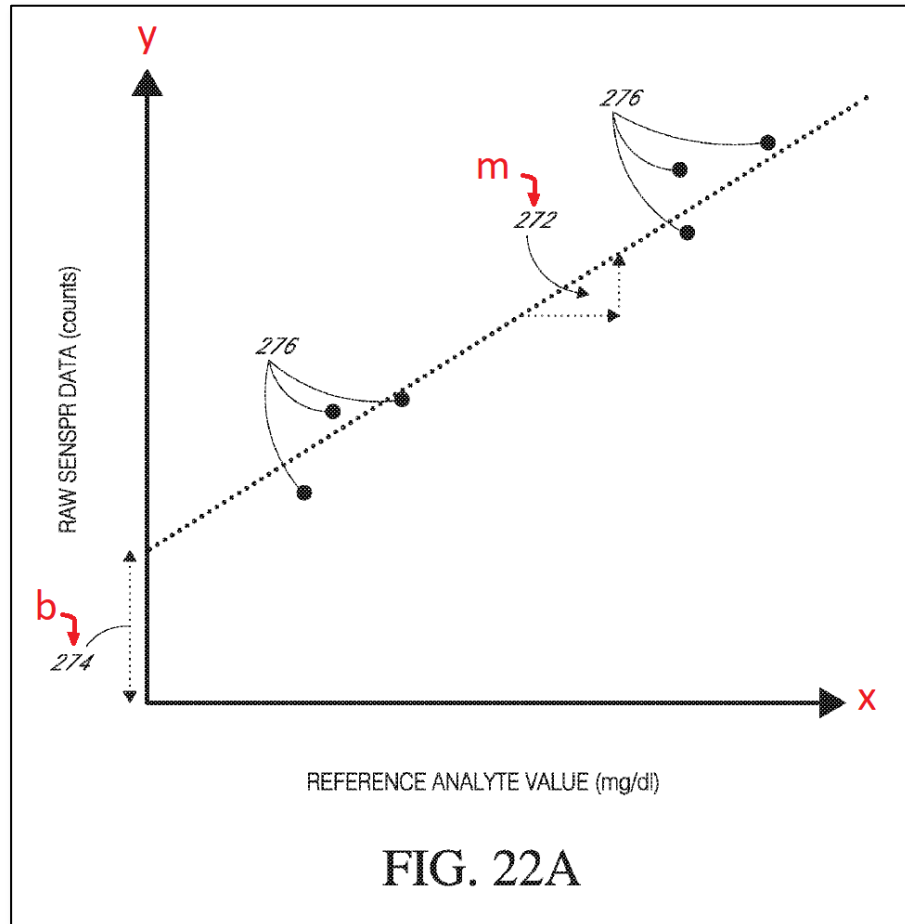
The '364 Patent's specification discloses a number of innovations in "Processing Analyte Sensor Data for Sensor Calibration" (EX1001, Title) claimed in several related patents. An aspect claimed in the '364 Patent is the ability to calibrate sensor data using "information associated with the in vivo sensitivity" of the sensor that is "based at least in part on corrections for a difference between the in vivo sensitivity and [the] in vitro sensitivity" of the sensor.

A. Background and Disclosed Innovations

As the '364 Patent explains, a glucose monitor typically uses a conversion function that maps the sensor's output (e.g., an electrical current output) to a corresponding glucose concentration in units that are useful to the user. EX1001, 82:35-51. In embodiments of the '364 Patent, the conversion function is linear, such that calibration to determine the conversion function would "consist[] of solving the line $y=mx+b$," 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).

EX1001, 17:45-62, FIG. 22A (annotated below).



“[A]nalyzing sensor data from measurements taken by the sensor of a controlled solution [i.e., *in-vitro* measurements] (e.g., prior to inserting the sensor)” can “determine the sensitivity of the sensor and/or the baseline signal” when the sensor is manufactured and has not yet been inserted in someone’s body. EX1001, 17:64-18:2, 79:52-56. But measuring the *in-vitro* sensor parameters alone was not enough to obtain reliable *in-vivo* calibration in the patient’s body. In the state of the art before the ’364 Patent’s priority date, it was “well known that

the sensor sensitivity is different when evaluated *in vitro* or *in vivo*” (EX2004 at 641), and that “*in vitro* data does not accurately predict *in vivo* performance” (EX2005 at 56).

Therefore, prior-art CGMs required further reference measurements once the sensor was inserted in the body, to determine how much the **m** (sensitivity) and **b** (baseline) had shifted post-insertion and perform an *in-vivo* calibration.

“Typically, calibration requires at least two independent, paired measurements ($x_1, y_1; x_2, y_2$)”—e.g., the various reference measurements 276 shown in FIG. 22A above—“to solve for **m** and **b**” once the sensor is inserted in the body (“*in vivo*”). EX1001, 17:59-62, 78:17-25. Each sensor output (y_i) from the CGM sensor would be matched with a known glucose concentration (x_i) from the same time (e.g., the patient’s glucose level determined by a concurrent fingerstick test) to produce the matched pairs for *in-vivo* calibration of the CGM.

Before the ’364 Patent’s priority date, the art taught that such *in-vivo* sensor calibration was mandatory in transcutaneous glucose monitoring systems because *in-vivo* sensitivity was not predictable from *in-vitro* sensitivity. For example:

Koschinsky (Diabetes/Metabolism Research and Reviews 2001) reviewed state-of-the-art transcutaneous glucose monitors and explained that at least one *in-vivo* finger-stick calibration was “mandatory,” and that it “remain[ed] to be

clarified” whether just one fingerstick (“one-point calibration”) could be used instead of two (“two-point calibration”). EX2006 at 117.

Choleau (Biosensors & Bioelectronics 2002) explained that “[a] crucial issue in glucose sensing is the calibration of the system,” and that “[s]ince it is well known that the sensor sensitivity is different when evaluated *in vitro* or *in vivo* ..., an *in vivo* sensor calibration is mandatory.” EX2004 at 641. Choleau then focuses on comparing one-point and two-point *in vivo* (fingerstick) calibration techniques. EX2004 at 641-645.

Frost (Current Opinion in Chemical Biology 2002) explained that “most implantable sensors are calibrated after implantation by taking a blood sample” because “employing a single *in vitro* calibration before continuous *in vivo* measurements has not proven to be possible,” due partly to “changes in calibration due to the biological response of the host.” EX2007 at 636.

Lodwig (Diabetes Technology & Therapeutics 2003) assessed known CGM calibration techniques and explained that “a general *in vitro* calibration by the manufacturer appears not to be possible.” EX2008 at 574. Therefore at least one-point or two-point calibration by fingersticks “is necessary.” EX2008 at 577.

Thus, the consensus in the prior art was that pre-calibrated glucose sensors could not be accurately used *in vivo* without performing a further post-insertion calibration measurement, because *in-vivo* sensitivity was known to be different and

unpredictable from *in-vitro* sensitivity. As discussed below (Section IV, *infra*) Gross subscribed to that same consensus, which is why in Gross “a further calibration occurs *in vivo*.” Gross, 12:55.

Unlike Gross, DexCom’s innovation in the ’364 Patent broke with the prior art’s consensus that *in-vivo* sensitivity could not be predicted from *in-vitro* sensitivity. DexCom designed a system where “prior information is available for m [*in-vivo* sensitivity] and/or b [*in-vivo* baseline],” such that “both m and b are known a priori,” and “the sensor can be completely calibrated e.g. without the need for reference analyte values (e.g. values obtained after implantation *in vivo*).” EX1001, 17:62-18:13, 79:48-80:3. In particular, DexCom developed a CGM system where “a predictive relationship exists between *in vitro* sensitivity and *in vivo* sensitivity, $m \approx f(m_{in\ vitro})$,” such that the function “ f ” can be used to correct for the difference between a sensor’s *in-vitro* sensitivity (“ $m_{in\ vitro}$ ”) and its *in-vivo* sensitivity (“ m ”) to pre-calibrate the sensor with the corrected “ m ”. EX1001, 79:60-80:3.

In the ’364 Patent, DexCom further disclosed an example where DexCom experimentally demonstrated the correction applied to *in-vitro* sensitivity to arrive at *in-vivo* sensitivity for a particular batch of sensors. EX1001, 89:6-26 (Example I). “Least-squares regression was used to define the predictive relationship between *in-vitro* and *in-vivo* sensitivities (e.g., $m_{in\ vivo} = 2.99 * m_{in\ vitro} + 26.62$), as

shown in FIG. 27.” EX1001, 89:13-16. Thus, starting with a sensor’s measured *in-vitro* sensitivity, DexCom applied a difference correction by multiplying the *in-vitro* sensitivity by 2.99 and adding 26.62. EX1001, 89:13-20. This purely mathematical correction (involving no *in-vivo* reference measurements) produced the predicted *in-vivo* sensitivity which was then successfully applied when the sensor was inserted into a patient to accurately detect and report the patient’s glucose levels. EX1001, 89:13-22, FIGs. 28-29.

B. Challenged Claims

The ’364 Patent includes independent claims 1, 5, and 10. Claim 1 is reproduced below.

1. A glucose monitoring system comprising:
a transcutaneous electrochemical glucose sensor comprising an
in vivo portion and an ex vivo portion, 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, and
wherein the in vitro sensitivity is predictive of the in vivo
sensitivity due to a relationship therebetween;
sensor electronics configured to be operably connected to the
transcutaneous electrochemical glucose sensor;
a processor configured to be operably connected to the sensor
electronics;
a memory configured to be operably connected to the processor,
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.**

As the claim recites, the glucose sensor in the glucose monitoring system has an *in-vitro* and an *in-vivo* sensitivity that are different from each other, and the monitoring system's memory has stored therein information associated with the sensor's *in-vivo* sensitivity. And that stored information must be "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."

Independent claims 5 and 10 recite similar limitations:

5. A method for calibrating data from a transcutaneous electrochemical glucose sensor, the method comprising:
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; and
calibrating, using a processor, the sensor data received from the transcutaneous electrochemical glucose sensor, 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.**

10. A method for providing calibrated glucose information based on sensor data from a transcutaneous electrochemical glucose sensor, the method comprising:
 - 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;
 - 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;**
 - 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; and
 - providing the calibrated sensor data to a user to facilitate monitoring a glucose level of the host.

The Petition's sole ground, based on Gross, does not satisfy the above-discussed limitations of the independent claims.

III. PERSON OF ORDINARY SKILL IN THE ART (“POSA”)

For purposes of this preliminary response only, DexCom does not challenge the Petition's definition of a POSA (Petition, 24), because the Petition fails to demonstrate unpatentability even under that definition.

IV. GROSS IS FUNDAMENTALLY DIFFERENT FROM THE '364 PATENT'S CLAIMED INVENTION.

As discussed above (Section II.A), DexCom's '364 Patent discloses and claims a glucose monitoring system where the sensor's *in-vivo* sensitivity is mathematically predictable from its *in-vitro* sensitivity, such that the amount of difference between the *in-vitro* sensitivity and the *in-vivo* sensitivity can be known before sensor implantation, and the *in-vivo* sensitivity for use in operating the implanted sensor can be arrived at by applying corrections for that difference. This removes the need for taking any reference glucose measurement to calibrate the sensor system once it is inserted in the body.

Gross calibrates its sensor system in a fundamentally different way. Gross uses “[a] method of calibrating an analyte sensor ***in vivo***” (Gross, Abstract)¹ (i.e., what the '364 Patent's invention ***avoids*** having to do), not pre-calibrating by

¹ Bold italics emphases herein are added unless otherwise specified.

applying corrections to an *in-vitro* sensitivity. Consistent with other prior-art systems that required *in-vivo* calibration (unlike DexCom's invention as discussed *supra* Section II.A), in Gross's system, because "when the sensor is actually used, it is in a different environment from that in which the batch was calibrated," "it has been found that sensors characterised by a laboratory batch calibration are unsatisfactory because such [*in-vitro*] calibration does not permit the performance of the sensor in vivo to be accurately predicted in all cases." Gross, 1:43-55. Therefore, after Gross's sensor is initially "calibrated in the factory," "a **further** calibration occurs in vivo" after the sensor "enters the body." EX1004, 12:29-58. Like in the prior art that DexCom's patent distinguishes (*supra* Section II.A), Gross's further *in-vivo* calibration takes direct reference measurements to form matched pairs of *in-vivo* sensor electrical current outputs and known glucose concentrations at those times to determine how to interpret the sensor's output *in vivo*, as discussed below:

Before Gross's sensor system is applied to a user's body, it is pre-programmed with a "theoretical or laboratory-calibrated performance curve" that was "measured in the manufacturing facility." Gross, 13:44-50, 14:19-23. An example of that laboratory-calibrated (e.g., *in-vitro*) curve is illustrated in Gross's FIG. 5 as curve 40. Gross, 13:42-48.

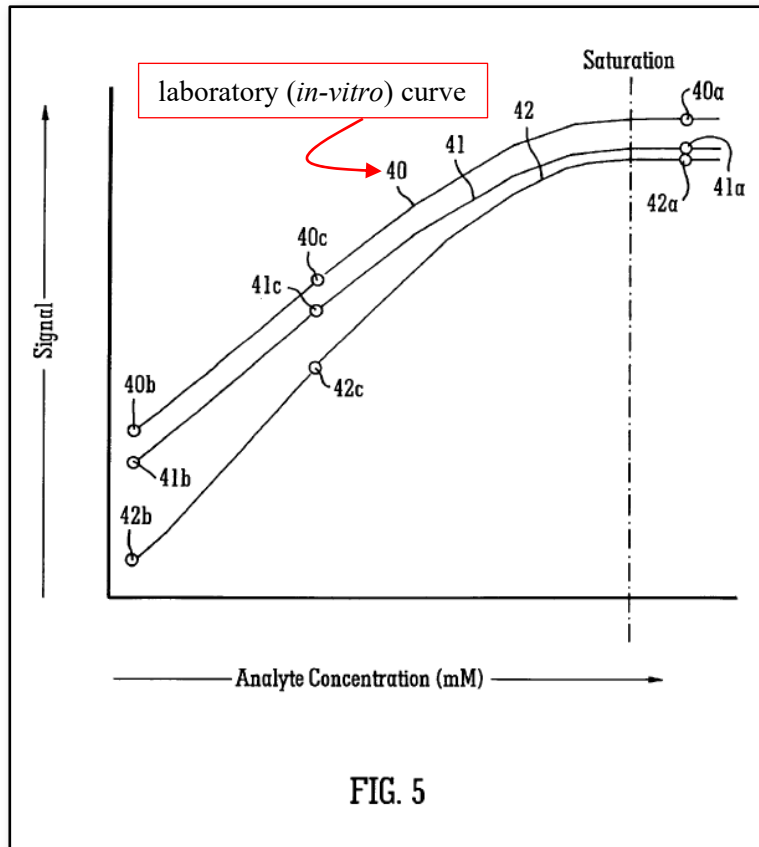
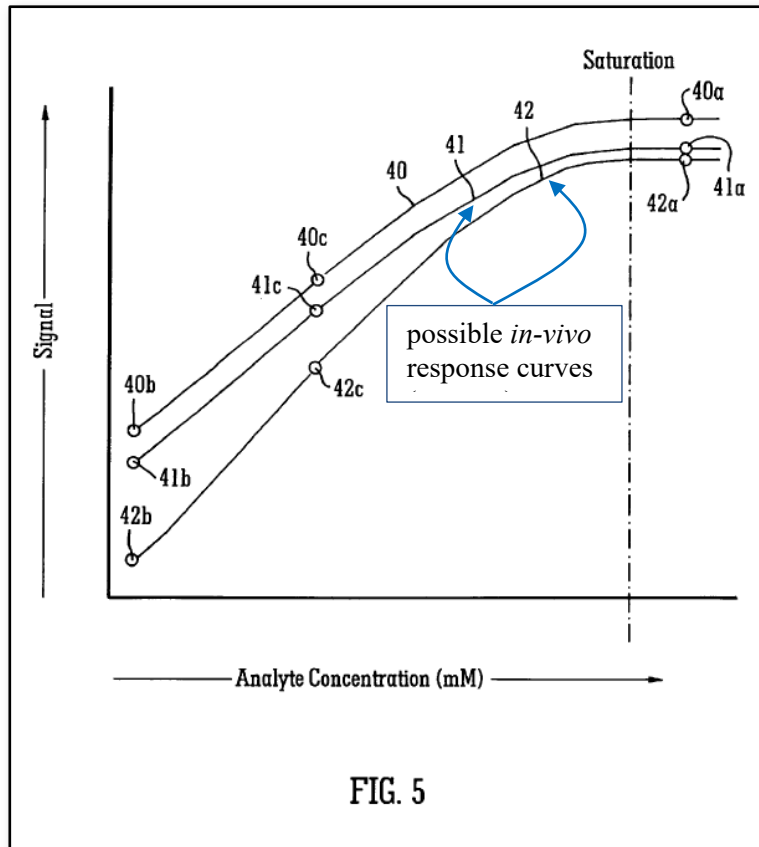


FIG. 5

Gross, FIG. 5 (annotated)

But Gross's *in-vitro* curve 40 cannot be used to interpret the sensor's output *in vivo*, because Gross's sensor's response changes unpredictably when the sensor is inserted in someone's body. FIG. 5 illustrates this with two example possibilities for the sensor's *in-vivo* response curve—curves 41 and 42. Gross, 13:51-53.



Gross, FIG. 5 (annotated)

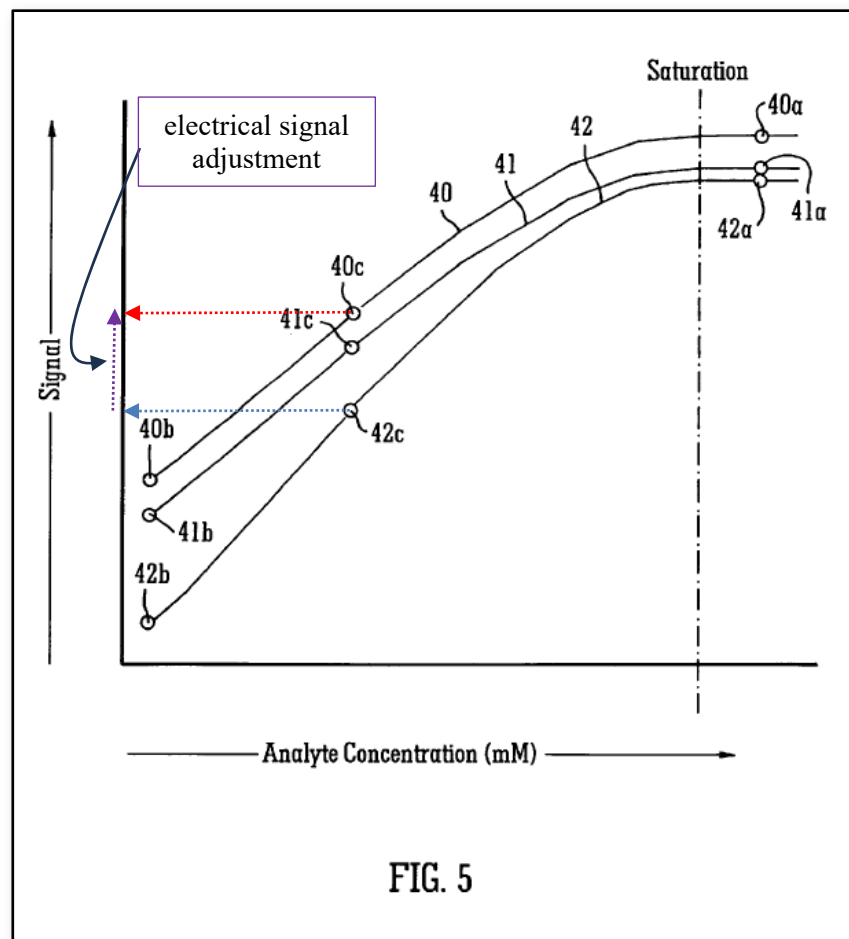
As the figure demonstrates, one sensor's *in-vivo* response curve 41 can be quite different from another sensor's *in-vivo* response curve 42, and both can be quite different from the *in-vitro* curve that they were each pre-programmed with. And like the other prior art discussed above (*supra* Section II.A), Gross's system has no way of knowing what a given sensor's *in-vivo* curve will be without directly measuring it after the sensor is inserted. Gross performs this measurement as follows:

Gross's sensor needle has a "glucose coating" that "dissolves almost immediately" once the sensor "enters the body," introducing enough glucose around the sensor to "saturate[] the glucose oxidase enzyme." Gross, 12:55-58. When the enzyme in the sensor "is saturated by glucose," the sensor produces its "maximum measurable signal" of electric current. Gross, 12:59-61. It can be determined in the laboratory that the sensor's enzyme becomes saturated at glucose concentration G_1 ; therefore, at the point where the sensor's electrical output reaches a maximum beyond which it doesn't increase further, the system knows the glucose concentration is G_1 . Gross, 13:3-14. This maximum sensor signal 41a or 42a provides a matched pair measuring one end of the sensor's *in-vivo* curve. Gross, 13:59-64.

Gross then obtains a second matched-pair measurement of the *in-vivo* curve by applying a prolonged voltage to the sensor to remove all the glucose possible from the sensor's environment and obtain a baseline electrical current signal, which the system knows is at the baseline (lowest possible) glucose concentration G_3 . Gross, 13:19-26. This minimum sensor signal 41b or 42b provides a second matched pair measuring the other end of the sensor's *in-vivo* curve. Gross, 14:1-4.

Gross's "microprocessor compares each of these signals 41a, 41b with the corresponding signals on the theoretical or laboratory-measured signal-concentration curve 40" to determine how to adjust future electrical current outputs

from the sensor *in vivo* to accurately map them to glucose concentrations. Gross, 14:5-35. For example, if a measurement from the sensor 42 during its operation in the person's body produces an electrical current 42c, the microprocessor "map[s] the measured point 42c onto the corresponding point 40c on theoretical curve 40," by "apply[ing] a concentration-dependent calibration function in which [an] amount [is] added to (or subtracted from) the measured signal 42c" to "map[]" this signal to point 40c." Gross, 14:41-47.



Gross, FIG. 5 (annotated)

Thus, after Gross's *in-vivo* calibration, the way Gross's system works is by measuring an electrical output from the sensor, adjusting it by some amount (as determined from the information learned from the *in-vivo* calibration reference measurements) to move it to the *in-vitro* curve, and then applying the *in-vitro* curve to map the adjusted electrical current level to a corresponding glucose concentration. Gross, 14:10-53, 15:1-13 ("a subsequent measurement 46c of 0.38 mA can then be correlated to a value of 0.41 mA on the reference curve, which in turn corresponds to a glucose concentration of 4 mM (72 mg/dlit)").

Gross's system is thus very different from the system disclosed in the '364 Patent and discussed above (*supra* Section II.A), where the '364 Patent's sensor has an *in-vitro*-determined conversion function with an *in-vitro* sensitivity (slope), the sensor's *in-vivo* sensitivity of its *in-vivo* conversion function has a known relationship to its *in-vitro* sensitivity (e.g., $m_{in\ vivo} = 2.99 * m_{in\ vitro} + 26.62$), and thus the system can know the sensor's *in-vivo* conversion function simply by applying that mathematical relationship to arrive at the sensor's *in-vivo* sensitivity based on that correction for the difference between the two. EX1001, 89:6-26, 79:48-80:3, 17:62-18:13.

V. INSTITUTION SHOULD BE DENIED BECAUSE THE PETITION FAILS TO ESTABLISH THAT GROSS ANTICIPATES OR RENDERS OBVIOUS ANY CHALLENGED CLAIM.

Abbott's Petition alleges that all challenged claims are "[a]nticipated by and/or obvious over Gross." Petition, 13. As discussed below, the Petition fails to establish that Gross discloses certain limitations recited in each independent claim, for which the Petition provided no alternative obviousness analysis. Therefore both the Petition's anticipation and obviousness allegations fail.

A. Abbott's Anticipation Allegation Fails.

"Anticipation requires that a single prior art reference disclose each and every limitation of the claimed invention, either expressly or inherently." *SRI Int'l Inc. v. Cisco Syst., Inc.*, 930 F.3d 1295, 1306 (Fed. Cir. 2019). The disclosure must be "within the four corners of the document." *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

Each of the '364 Patent's independent claims (claims 1, 5, and 10) requires the use of "information associated with [the/an] in vivo sensitivity of the transcutaneous electrochemical glucose sensor." In claim 1, that information must be stored in the memory of the glucose monitoring system; in claims 5 and 10 that information must be involved in calibrating sensor data received from the sensor. And in each independent claim, the information associated with *in-vivo* sensitivity must be "based at least in part on corrections for [the/a] difference between the in

vivo sensitivity and [the/an] in vitro sensitivity [of/for] the transcutaneous electrochemical glucose sensor.” The claims thus require two separate elements: (1) information associated with *in-vivo* sensitivity, and (2) corrections for a difference between *in-vivo* and *in-vitro* sensitivities. And the one element has to be “based ... on” the other.

In the '364 Patent's description, the claimed information associated with *in-vivo* sensitivity is embodied as the *in-vivo* sensitivity parameter “m” (or “ $m_{in\ vivo}$ ”), which is applied in the conversion function $y=mx+b$ to map the sensor's electrical output to the corresponding glucose concentration in the body. EX1001, 17:51-18:13, 82:35-51, 89:6-26. And the claimed corrections for the difference between *in-vivo* and *in-vitro* sensitivities are embodied as a function $m_{[in\ vivo]}=f(m_{in\ vitro})$, an example of which is provided as “ $m_{in\ vivo}=2.99*m_{in\ vitro}+26.62$ ”. EX1001, 17:51-18:13, 89:6-26. The claimed information associated with *in-vivo* sensitivity ($m_{in\ vivo}$) is “based on” the claimed corrections for the difference (e.g., “ $m_{in\ vivo}=2.99*m_{in\ vitro}+26.62$ ”) because $m_{in\ vivo}$ is derived as the result of plugging $m_{in\ vitro}$ into the corrections-for-the-difference function.

The problem for Abbott is that Gross's calibration techniques are not the same as the '364 Patent's. Gross does not store or apply an *in-vivo* sensitivity parameter $m_{in\ vivo}$, and does not base one on corrections for a difference between *in-vivo* and *in-vitro* sensitivities. Instead, as discussed *supra* Section IV, Gross pre-

programs its sensor system with just an *in-vitro* curve, and then takes post-insertion reference measurements to determine how to adjust the sensor's electrical output signals *in vivo* to make the *in-vitro* curve applicable to the adjusted electrical current levels. In mapping the '364 Patent's claims to Gross, Abbott's Petition attempts to fit a square peg into a round hole.

For both the information associated with *in-vivo* sensitivity and the corrections for a difference between sensitivities claim limitations, the only thing in Gross that Abbott's Petition alleges to be a corresponding element is Gross's "concentration-dependent calibration function" (EX1004, 14:41-47), which, in Abbott's words, "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." Petition, 48. This "concentration-dependent calibration function" is a set of "amount[s] added to (or subtracted from) the measured [electrical] signal 42c, when mapping this signal to" *in-vitro* curve 40. EX1004, 14:41-47. It is the amount by which Gross's system adjusts the sensor's electrical current output *in vivo* to make the adjusted electrical current level interpretable using the *in-vitro* curve.

Abbott's Petition alleges that Gross's "concentration-dependent calibration function" is ***both*** the claimed information associated with *in-vivo* sensitivity ***and*** the claimed corrections for a difference between *in-vivo* and *in-vitro* sensitivities in

the '364 Patent's independent claims. *See* Petition, 48 (for claim 1, alleging “the ‘concentration-dependent calibration function’ ... is ‘information associated with the in vivo sensitivity’ of the sensor”), 49 (for claim 1, alleging “Gross’s ‘concentration-dependent calibration function’ corrects ... for the difference in sensitivities”), 61 (for claim 5, alleging “[t]he calibration function constitutes information ‘*associated with an in-vivo sensitivity*’”) (emphasis original), 62 (for claim 5, alleging “the calibration function also corrects for a difference in the sensitivities”), 69 (for claim 10, alleging that Gross’s “concentration-dependent calibration function” is both claimed elements “as explained above for claim 1[g] and 5[c]”).

Abbott’s two-to-one mapping of claim elements to Gross’s “concentration-dependent calibration function” is improper and fails to establish disclosure in Gross of the limitations required by the independent claims, for multiple independent reasons. As discussed further in the sections below, Abbott’s mapping and arguments improperly fail to give meaning to all of the claim terms, improperly render claim language superfluous, and improperly assert a mapping in which an element is “based on” itself. And in reality, any *in-vivo* information in Gross’s calibration data is what any “corrections” in Gross’s calibration function are themselves “based on”—not the other way around.

1. Abbott’s Petition’s Mapping of the Challenged Claims to Gross Improperly Fails to Give Meaning to Separate Claim Limitations and Renders Claim Language Superfluous.

In attempting to justify mapping both the claimed information associated with *in-vivo* sensitivity and the claimed corrections for a difference between *in-vivo* and *in-vitro* sensitivities to the same “concentration-dependent calibration function” in Gross, Abbott’s Petition alleges that “the concentration-dependent calibration function is ‘based at least in part on corrections for the difference between the in vivo sensitivity and the in vitro sensitivity,’ **and thereby also** is information ‘associated with’ the in-vivo sensitivity, as recited in claim 1[g].” Petition, 50. The Petition continues, alleging that “[i]nformation ... that ‘is based at least in part on corrections for the difference between *the in vivo sensitivity* and the in vitro sensitivity’ **necessarily is** information ‘associated with the in vivo sensitivity,’ as recited in claim 1[g].” Petition, 50 (plain italics original; bold italics emphasis added); *see also id.*, 61 (asserting the same for claim 5), 69 (asserting that claim 10 is met for the same reasons).

Abbott thus interprets the ’364 Patent’s independent claims such that **any** and **all** information that “is based at least in part on corrections for [the/a] difference between the in vivo sensitivity and [the/an] in vitro sensitivity” is **also** the claimed “information associated with [the/an] in vivo sensitivity.” This

interpretation is improper, as it openly fails to give meaning to both separately recited elements in the claims.

It is well-settled law that “meaning should be given to all of a claim’s terms.” *Dell Inc. v. Acceleron, LLC*, 818 F.3d 1293, 1300 (Fed. Cir. 2016); *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (“[C]laims are interpreted with an eye toward giving effect to all terms in the claim.”). The ’364 Patent’s “information associated with [the/an] in vivo sensitivity” limitation and the limitation that the information must be “based at least in part on corrections for [the/a] difference between the in vivo sensitivity and [the/an] in vitro sensitivity” are two separately recited limitations having different language and terms. The latter limitation requires the information to be based at least in part on corrections for a difference between two sensitivities; the former limitation requires the information to be associated with a specific *one* of the sensitivities (the *in-vivo* sensitivity). Like the construction that the Federal Circuit found “unreasonable” in *Dell*, Abbott’s interpretation here improperly “treats the claim as if it said simply” the latter limitation without including the former limitation. 818 F.3d at 1300. Abbott’s assertion that one of the limitations is automatically met whenever the other limitation is met “runs counter to the claim-construction principle that meaning should be given to all of a claim’s terms.” *Id.*

It is also well-settled law that interpreting claims in a manner that renders claim language “superfluous [is] a methodology of claim construction that” the Federal Circuit “has denounced.” *Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007). If any and all information that is based at least in part on corrections for a difference between *in-vivo* and *in-vitro* sensitivities were necessarily the claimed “information associated with the in vivo sensitivity” as Abbott’s Petition alleges (Petition, 50, 61, 69), then the challenged independent claims would simply recite the use of “information based on corrections for the difference” between the sensitivities; there would be no reason to also recite “information associated with the in vivo sensitivity.” Abbott’s interpretation (on which Abbott’s mapping of the claims to Gross relies) improperly renders the recited “information associated with [the/an] in vivo sensitivity” superfluous, and should be rejected.

Abbott’s allegation that the challenged claims are anticipated by Gross thus relies on a facially improper claim interpretation, and fails for all challenged claims for this reason alone.

2. Abbott’s Petition’s Mapping of the Challenged Claims to Gross Improperly Asserts That Gross’s Calibration Function Is “based at least in part on” Itself.

As discussed above, each of the independent claims requires that “information associated with [the/an] in vivo sensitivity of the transcutaneous

electrochemical glucose sensor” is “based at least in part on corrections for [the/a] difference between the in vivo sensitivity and [the/an] in vitro sensitivity [of/for] the transcutaneous electrochemical glucose sensor.” This requires two elements, where the first element (information associated with *in-vivo* sensitivity) is “based at least in part on” the second element (corrections for a difference between *in-vivo* and *in-vitro* sensitivities).

As also discussed above, Abbott’s Petition purports to map **both** of these claim elements to the same “concentration-dependent calibration function” in Gross. The Petition asserts that “the ‘concentration-dependent calibration function’ ... is ‘information associated with the in vivo sensitivity’ of the sensor.” Petition, 48 (addressing claim 1), *see also* Petition, 61 (addressing claim 5), 69 (addressing claim 10). And the Petition asserts that the same “concentration-dependent calibration function” is not only “based at least in part on” corrections for a difference between *in-vivo* and *in-vitro* sensitivities, but in fact **is** the correction for the difference between *in-vivo* and *in-vitro* sensitivities. Petition, 49 (“Gross’s ‘concentration-dependent calibration function’ corrects ... for the difference in sensitivities defined by these curves.”), 50 (“The concentration-dependent calibration function ... corrects for ...differences between the slopes, i.e., sensitivities, of these curves.”), 61-62 (“the calibration function corrects for a

difference between in-vitro and in-vivo sensitivities”), 69 (applying to claim 10 the same reasoning “explained above for claim 1[g] and 5[c]”).

This further demonstrates the impropriety of Abbott’s mapping of the challenged claims to Gross. Gross’s “concentration-dependent calibration function” cannot be both the claimed corrections for a difference between *in-vivo* and *in-vitro* sensitivities **and** the claimed “information associated with the in vivo sensitivity” that must be “based at least in part on” the corrections. That would require the calibration function to be “based ... on” itself, which does not make sense. *See, e.g., Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1255 (Fed. Cir. 2010) (“If the hinged arm and the spring means are one and the same, then the hinged arm must be ‘connected to’ itself and must ‘extend between’ itself and a mounting means, a physical impossibility. A claim construction that renders asserted claims facially nonsensical cannot be correct.”) (internal citation and quotation omitted); *see also id.* at 1254 (“Where a claim lists elements separately, the clear implication of the claim language is that those elements are distinct components of the patented invention.”) (internal citation and quotations omitted); *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1328, 1336 (Fed. Cir. 2001) (where claim recited “reproducing information in material objects,” the “material object cannot be the information itself,” because “then claim 1 would require the information to be reproduced in itself,” and

“[s]uch a construction is illogical and does not accord with the plain import of the claim language”).

The Board and the Federal Circuit have both explained in other cases that a claim reciting that an element A is “based on” an element B requires the element B to separately exist or occur **before** (i.e., as a precedent to) element A. *See, e.g., Masimo Corp. v. Sotera Wireless, Inc.*, No. 2022-1415, 2023 WL 6307959, at *2-3 (Fed. Cir. Sept. 28, 2023) (affirming Board’s finding that the plain meaning of “trigger[ing] a second alarm **based on** ... exceeding the second alarm threshold” is that “crossing the second alarm threshold **is a ‘condition precedent’** to the trigger of an alarm” and “require[s] [the] condition to be met before an alarm is triggered”); *Rovi Guides, Inc. v. Vidal*, No. 2020-1994, 2022 WL 1152311, at *1-2 (Fed. Cir. Apr. 19, 2022) (claim reciting “control circuitry configured to ... cause an indication corresponding to the archived copy to be displayed” “based on determining that the archived copy is available” means “the availability determination must occur before the indication is displayed”—“[o]therwise, the display step would not be ‘*based on*’ the availability check”) (emphasis original).

Gross’s “concentration-dependent calibration function” does not, and cannot, precede itself. Gross’s “concentration-dependent calibration function” is one element and is not “based at least in part on” itself. Abbott’s Petition thus fails

to demonstrate that Gross meets the limitations of any of the independent claims, for this additional reason.

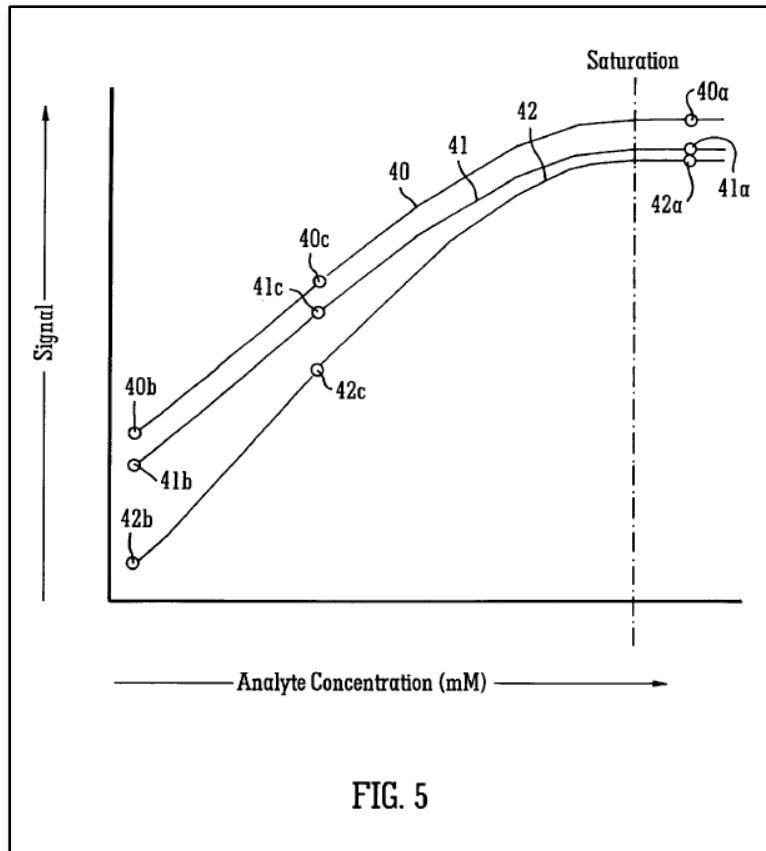
3. In Gross, Any Corrections Are Based on *In-Vivo* Sensor Performance Information, Not the Other Way Around.

As discussed above (*supra* Section IV), Gross's *in-vivo* calibration works fundamentally differently from the '364 Patent's pre-calibration which predicts the *in-vivo* sensitivity from the *in-vitro* sensitivity. If anything, Gross's calibration method is backwards from what the '364 Patent's claims require. Gross has no way to predict the *in-vivo* sensitivity; therefore Gross must first directly measure the sensor's performance *in vivo* (after insertion in the patient), and **then** calculate any corrections to its calibration function based on the measured *in-vivo* performance. In contrast, the '364 Patent's claims require going in the reverse direction, with the information associated with the *in-vivo* sensitivity being **based on** the claimed corrections.

In the '364 Patent, an *in-vitro* conversion function $y = m_{in\ vitro}x + b$ for the sensor is determined in the laboratory, and it has an *in-vitro* sensitivity (slope) $m_{in\ vitro}$. $m_{in\ vitro}$ is then put into a function of claimed "corrections for the difference between the in vivo sensitivity and the in vitro sensitivity," such as " $m_{in\ vivo} = 2.99 * m_{in\ vitro} + 26.62$ ". EX1001, 89:6-26. The resulting $m_{in\ vivo}$ is the claimed "information associated with the in vivo sensitivity," and it is "based at least in part on" the claimed "corrections for the difference" because the corrections (e.g., the

function “ $m_{in\ vivo}=2.99*m_{in\ vitro}+26.62$ ”) were known, they were applied to $m_{in\ vitro}$, and that produced $m_{in\ vivo}$. The claimed “information associated with the in vivo sensitivity” ($m_{in\ vivo}$) is determined **from** the corrections—based on the corrections as applied to the *in-vitro* sensitivity $m_{in\ vitro}$. And then the derived $m_{in\ vivo}$ is used to create a new *in-vivo* conversion function $y=m_{in\ vivo}x+b$ for use in interpreting the sensor’s output data in the body. EX1001, 79:59-80:3, 89:19-20.

Gross’s sensor calibration works differently, as previously discussed (*supra* Section IV). Unlike the ’364 Patent’s innovation, Gross has no known mathematical function that can be applied to a sensor’s *in-vitro* sensitivity to derive its *in-vivo* sensitivity. Instead, Gross must take measurements of the sensor’s *in-vivo* response curve to directly observe where that curve lies after the sensor is inserted in the body. Gross, 12:55-13:26, 13:59-14:53. For example, Gross takes reference measurements of points 42a and 42b to determine where *in-vivo* curve 42 is in FIG. 5. Gross, 13:59-14:9.



Once Gross’s system has directly measured where *in-vivo* curve 42 is, **then** the system can use that *in-vivo* information to determine “a concentration-dependent calibration function” specifying “the amount added to (or subtracted from) the measured signal 42c, when mapping this signal to point 40c.” Gross, 14:5-47. This “concentration-dependent calibration function” is the **end result** of the *in-vivo* sensor calibration—as Abbott’s Petition (at 34) asserts, it “provides complete information for the microprocessor to provide a calibrated output for any subsequent measured signal which lies on curve 41” (Gross, 14:23-27)—and this function is what Abbott’s Petition alleges to be the claimed “corrections for a

difference” between *in-vivo* and *in-vitro* sensitivity. Petition, 49, 61-62, 69; *see supra* Sections V.A.1-V.A.2. As the “concentration-dependent calibration function” in Gross is the end result and the “complete information” of the *in-vivo* calibration, there are no further calibration parameters that are derived or obtained (or that are in any other way) “based at least in part on” the concentration-dependent calibration function.

Any “corrections” involved in Gross’s concentration-dependent calibration function mapping between points on the *in-vivo* curve 42 and points on the *in-vitro* curve 40 are themselves “based on” the only information Gross’s system collects about *in-vivo* curve 42 (by directly measuring it once the sensor is inserted). And nothing in *in-vivo* curve 42 is based in any way on Gross’s concentration-dependent calibration function, which can only be determined after the *in-vivo* curve is measured. If anything, the relationship of elements in Gross’s system is more like the reverse of the relationship in the ’364 Patent’s claims.

Abbott’s Petition thus fails to establish that Gross’s system uses “information associated with [the/an] *in vivo* sensitivity of the transcutaneous electrochemical glucose sensor” wherein that information is “based at least in part on corrections for [the/a] difference between the *in vivo* sensitivity and [the/an] *in vitro* sensitivity [of/for] the transcutaneous electrochemical glucose sensor,” as the independent claims recite.

* * *

For each of the independent reasons discussed in Sections V.A.1-V.A.3 above, the Petition fails to establish that Gross anticipates any challenged claim.

B. Abbott’s Obviousness Allegation Fails.

Although Abbott’s Petition alleges that all challenged claims are “[a]nticipated by and/or obvious over Gross” (Petition, 13), the Petition only addresses the above-discussed limitations reciting “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” (labeled 1[g], 5[c], and 10[b] in the Petition) by alleging that they are disclosed by Gross. *See* Petition, 48-51, 61-62, 68-69. The Petition presents no alternative obviousness arguments for these limitations.

Accordingly, the Petition fails to demonstrate obviousness of any challenged claim over Gross for the same reasons the Petition fails to demonstrate anticipation of any challenged claim by Gross, discussed in Section V.A, *supra*.

VI. ALTERNATIVELY, INSTITUTION SHOULD BE DENIED UNDER §325(D)

Abbott’s Petition should be denied institution on the merits, for any of the independent reasons discussed above. Alternatively, the Board should exercise its discretion to deny institution under 35 U.S.C. §325(d) and *Advanced Bionics, LLC*

v. Med-El Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 (Feb. 13, 2020) (precedential).

Abbott’s Petition relies solely on Gross, a reference that was of record during prosecution and thus is listed on the ’364 Patent as a “Reference[] Cited.” EX1001, page 8. Abbott admits that “the first *Advanced Bionics* prong is therefore satisfied” (Petition, 73)—i.e., the same art was previously presented to the Office. IPR2019-01469, Paper 6 at 8.

As to the second *Advanced Bionics* prong—“whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims” (*id.*)—Abbott’s Petition alleges only that “the Examiner erred by overlooking or not appreciating Gross’s materiality to the challenged claims, as described above” (i.e., in the Petition’s sole “ground of invalidity”). Petition, 73. But the Petition’s invalidity ground is deficient, as discussed herein above.

In particular, the Examiner in prosecution provided “reasons for allowance,” in which the Examiner indicated specifically that “the prior art of record” 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.” EX1003 at 811-812. Those are the very limitations that, as explained herein above (*supra* Section V), still are and always have been missing from Gross.

The Examiner thus did not err. As the Examiner found, “the prior art of record,” including Gross, does not disclose the limitations required by the independent claims. EX1003 at 811-812. Abbott’s Petition in no way demonstrates that the Office erred in finding the ’364 Patent’s claims patentable. Both *Advanced Bionics* prongs are thus met, and institution should be denied.

VII. CONCLUSION

For each of the reasons discussed herein, Abbott’s Petition fails to demonstrate a reasonable likelihood that Gross anticipates or renders obvious any challenged claim. Institution should be denied.

Respectfully submitted,
DexCom, Inc.

Date: August 22, 2024

/Elisabeth Hunt/

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24, the undersigned certifies that the foregoing **PATENT OWNER's PRELIMINARY RESPONSE** contains 7,361 words excluding; a table of contents, a table of authorities, a certificate of service or word count, or appendix of exhibits or claim listing. Patent Owner has relied on the word count feature of the word processing system used to create this paper in making this certification.

Date: August 22, 2024

/Dara Del Rosario/
Dara Del Rosario
Paralegal
WOLF, GREENFIELD & SACKS, P.C.

CERTIFICATE OF SERVICE UNDER 37 C.F.R. § 42.6 (e)(4)

I certify that on August 22, 2024, I will cause a copy of the foregoing document, including any exhibits filed therewith, to be served via electronic mail, as previously consented to by Petitioner, upon the following:

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