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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. IPR2024-00890

Patent No. 11,020,031

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	Stephens Inc., Research Bulletin – DexCom, Inc. (Mar. 28, 2018)
2003	Lodwig et al., Continuous Glucose Monitoring with Glucose Sensors: Calibration and Assessment Criteria. Diabetes Technology & Therapeutics. 2003; 5(4):572-86.
2004	Koschinsky et al., Sensors for glucose monitoring: technical and clinical aspects. Diabetes/Metabolism Research and Reviews. 2001 Mar-Apr; 17(2):113-23.
2005	U.S. Patent Application Publication No. 2006/0020192
2006	U.S. Patent Application Publication No. 2006/0036143
2007	American Heritage Medical Dictionary (2007), p. 132 (definition of “catheter”), p. 420 (definition of “interstitial fluid”)
2008	Dorland’s Illustrated Medical Dictionary, 31 st Edition (2007), p. 728 (definition of “fluid, interstitial”)
2009	U.S. Patent Application Publication No. 2006/0281985

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, 1:39-55. 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 blood glucose meter device to measure the level of glucose in the blood. EX1001, 1:56-61, 68:8-9. This can be painful and inconvenient, so a person will normally only be willing to do this a few times per day. EX1001, 1:58-63. However, without more frequent monitoring, diabetics risk not detecting a dangerously hyperglycemic or hypoglycemic condition until it is too late. EX1001, 1:63-2:4.

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 '031 Patent's 2008 priority date (and for some time thereafter before DexCom's innovation was brought to market), CGM systems "all required user calibrations whereby self-monitoring of blood glucose (SMBG) fingerstick values through a home blood glucose meter (BGM) were used to correlate the sensor signal with a patient's blood glucose value." EX2001 at 222.

DexCom, however, developed "advancement[s] in the algorithms used within the CGM 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 fingerstick reference measurement after the user inserts the sensor. EX2001 at 222, 224. "To remove the need for SMBG calibrations, the G6 uses a calibration function, which corrects for sensor drift over the 10-day wear period by keeping track of the day since insertion and adjusting the calibration function, which converts interstitial current to glucose, based on the day." EX2001 at 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." EX2002 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, 30:64-31:5. 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*). 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*.¹

¹ Examples of DexCom’s innovations to remove the need for such initial fingerstick calibration upon sensor insertion are discussed in pending IPR2024-00841 regarding DexCom’s Patent 10,709,364.

Another issue that affects calibration of a CGM's glucose sensor is "drift," whereby the sensor's sensitivity (among other things) changes over time while the sensor is inserted in the body. EX1001, 21:36-48. Prior to the '031 Patent, sensitivity drift had "proved a major problem for many types of C[G]M sensors,"² because when "the sensor sensitivity changes over time, ... unreliable glucose concentration values may possibly be obtained, and system recalibration is required." EX2003 at 577. This is one reason why prior-art "glucose sensors require[d] calibration by the patient several times per day by means of a conventional capillary blood glucose measurement" (i.e., fingerstick). EX2003 at 574; EX2004 at 116 & 118 ("[D]rift can result in a complete loss of correlation between changes in the sensor signal and glucose levels," necessitating "repeated re-calibration which requires blood glucose measurements at least once per day.").

The prior art had taught that "[r]ecalibration of the C[G]M system at certain time intervals is mandatory with most types of sensor, as it is virtually impossible to predict the drift of the sensor signal"—thus, "glucose electrodes require several calibrations per day" and "other C[G]M systems require only one calibration daily." EX2003 at 577. However, with the '031 Patent, DexCom achieved a

² EX2003 uses "CM" to denote "continuous glucose monitoring," which is abbreviated herein as "CGM." See EX2003, Abstract.

sensor design in which the sensor's drift follows an "expected profile" of particular amounts of sensitivity changes over time, which can be characterized and documented via "numerous in vitro and/or in vivo experiments." EX1001, 216:44-52. Specifying this drift profile provides DexCom's system with "a priori sensitivity information," where this "prior information (e.g., obtained from in vivo or in vitro tests) determines [the] sensitivity of the sensor," allowing the sensor to "be completely calibrated e.g. without the need for reference analyte values" (e.g., fingerstick recalibrations). EX1001, 216:44-48, 140:12-34. Thus, DexCom's innovation with the '031 Patent of a drift profile was a significant step in achieving no-fingerstick calibration for CGM. DexCom's G6 CGM device, for example, embodies the '031 Patent's drift profile by "us[ing] a calibration function that has time-varying functions for sensor offset and gain [sensitivity], which can account for drift over 10 days." EX2001 at 224.

Petitioner ("Abbott") introduced a competing product to DexCom's first CGM in 2008, and today incorporates DexCom's drift-compensation innovation in Abbott's glucose monitors. The parties are currently in litigation, where DexCom asserts that Abbott's products infringe the '031 Patent. In this IPR2024-00890 and copending IPR2024-00891, Abbott alleges that certain of the asserted claims are unpatentable over Zhang (EX1004) or Shin (EX1008). But neither Zhang nor Shin discloses a device that applies a sensitivity drift profile in the manner described

and claimed in the '031 Patent. And Zhang does not even disclose the same type of transcutaneous glucose sensor system required by the challenged claims.

As discussed in further detail below, Abbott's Petition fails to demonstrate unpatentability of any of the challenged claims. Institution should be denied.

II. THE '031 PATENT

The '031 Patent's specification discloses a number of innovations for an "Analyte Sensor" (EX1001, Title) claimed in several related patents. An "analyte" is "a substance or chemical constituent in a biological sample" (EX1001, 19:36-43), and the particular analyte of interest as relevant to this proceeding is glucose in a person's body. An aspect claimed in the '031 Patent is the ability to apply to a "transcutaneous glucose sensor" a "profile" that is based on "a priori information related to expected sensitivity changes associated with a length of time the ... sensor has been inserted" (claim 1) or that is "associated with a drift in a sensitivity of the ... sensor over time" (claim 14).

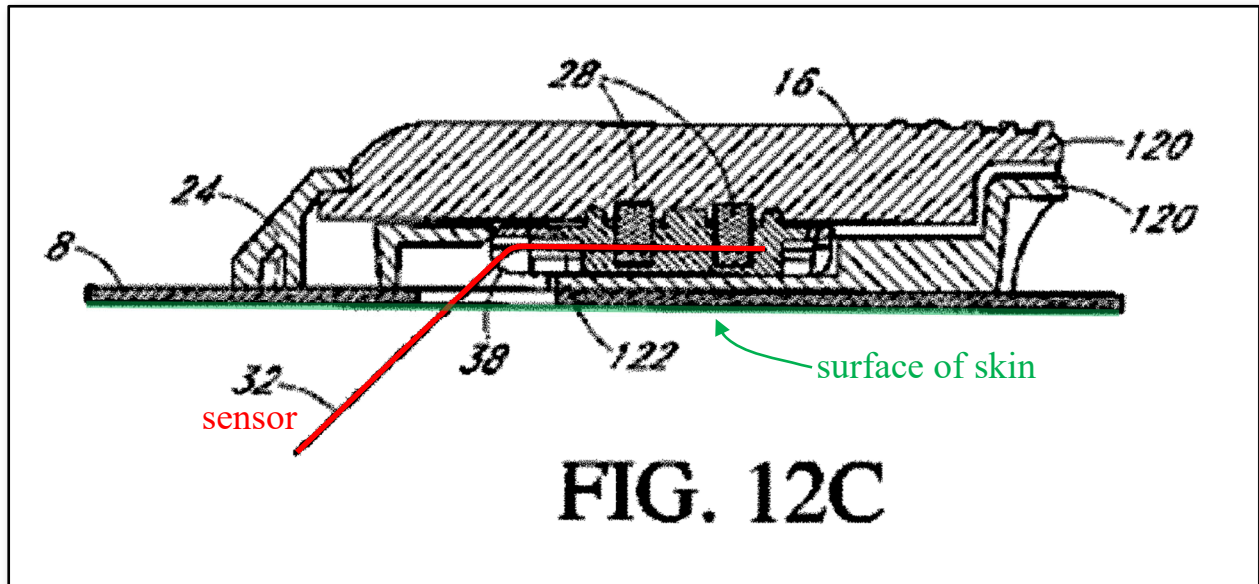
A. Background and Disclosed Innovations

The '031 Patent describes innovations directed to meeting "an urgent need for devices and methods that offer continuous, robust analyte [e.g., glucose] monitoring, to improve patient care and lower medical costs." EX1001, 33:42-44. Different physical forms of continuous analyte monitoring devices can incorporate the innovative calibration techniques disclosed in the '031 Patent, so that the

techniques “can be used in any setting in which frequent or continuous analyte monitoring is desirable,” including “in the hospital, the doctor’s office, long-term nursing facilities, or even in the home. EX1001, 33:54-59. Some types of monitoring devices described in the specification are more appropriate to clinical institutions, such as a monitoring device “coupled to additional IV [intravenous] and diagnostic devices, such as a saline bag, and automated blood pressure monitor, or a blood chemistry monitor device,” where the analyte sensor is “operatively coupled to a catheter” of the IV fluid exchanging system “to measure analyte concentration within the host’s blood stream.” EX1001, 34:42-35:2. Other disclosed embodiments of glucose monitoring devices utilizing the ’031 Patent’s innovative techniques may be more appropriate for use in the home or out and about in the patient’s daily life, such as embodiments where “the sensor is a needle-type continuous analyte sensor, configured as disclosed in U.S. Patent Publication No. US-2006-0020192-A1 [EX2005] and U.S. Patent Publication No. US-2006-0036143-A1 [EX2006], both of which are incorporated [in the ’031 Patent’s specification] by reference in their entirety.” EX1001, 37:26-31.

In the “needle-type” sensor embodiments, the glucose sensor is “transcutaneous.” EX1001, 86:1, 87:21. That is, the sensor pierces the skin such that part of the sensor (the *in vivo* portion) is inserted through and under the skin, while the rest of the sensor (the *ex vivo* portion) remains outside the skin, where it

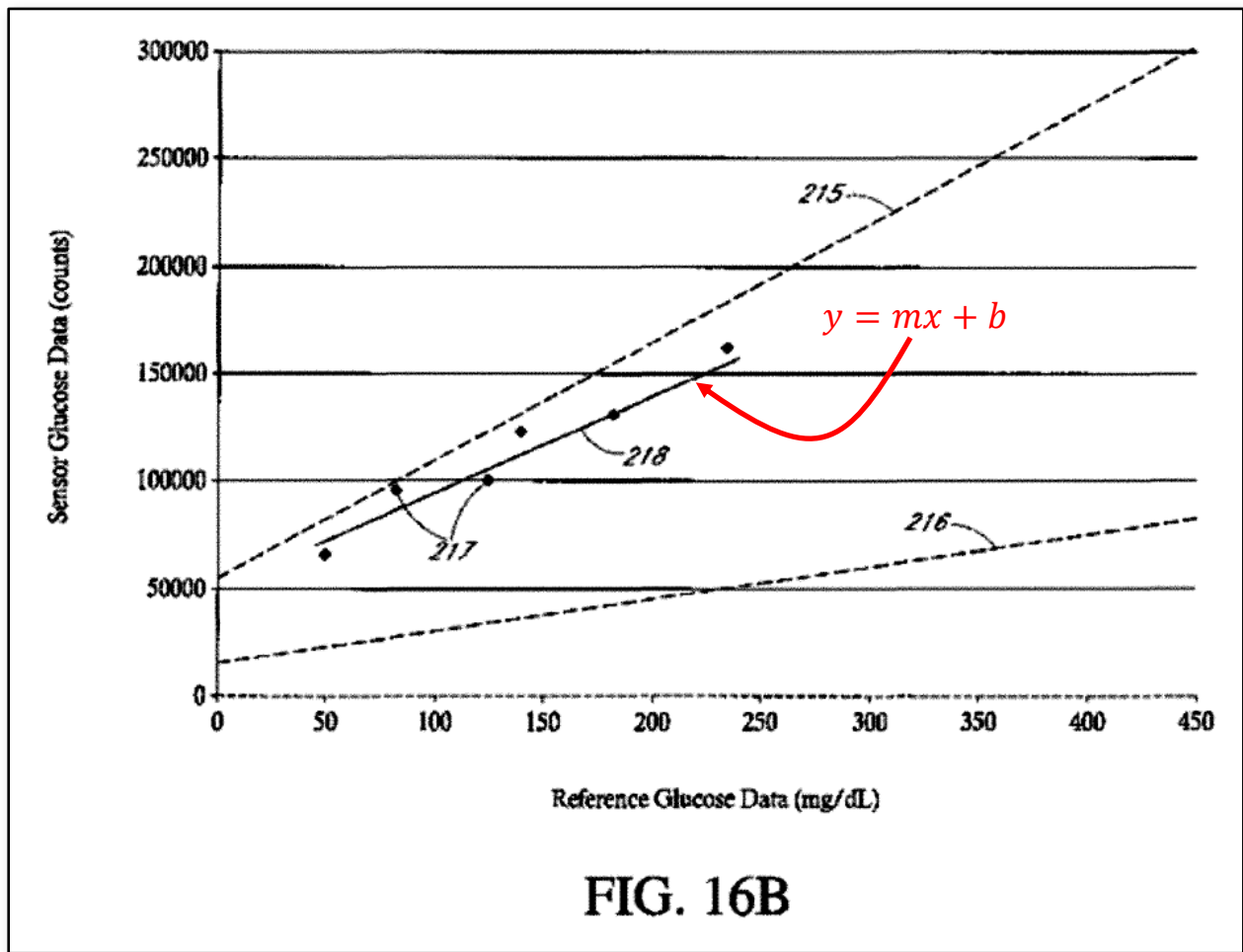
may connect with electronics to deliver glucose sensing data. EX2005, [0065]-[0066], [0107]; EX2006, [0067]-[0068], [0109]. An example is illustrated in FIG. 12C of EX2005 and EX2006 (both incorporated by reference at EX1001, 37:26-31), annotated below:



The challenged claims of the '031 Patent (e.g., independent claims 1, 14) are directed specifically to these types of systems having “a transcutaneous glucose sensor” comprising “an ex vivo portion configured to remain outside of a body of a host” and “an in vivo portion configured to be inserted within the body of the host.” This is in contrast to Zhang’s system, which does not use a transcutaneous sensor. *See infra* Section IV.B.

The '031 Patent’s glucose monitoring systems use 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, 141:14-36. In embodiments of the '031 Patent, the conversion function is linear, in the form of $y=mx+b$, 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, 139:27-40, 140:12-141:31, 204:63-67; EX2005, FIG. 16B (annotated below):



The sensor's conversion function at a given point in time can be calculated from a "calibration set" of "matched data pairs"—e.g., the various reference

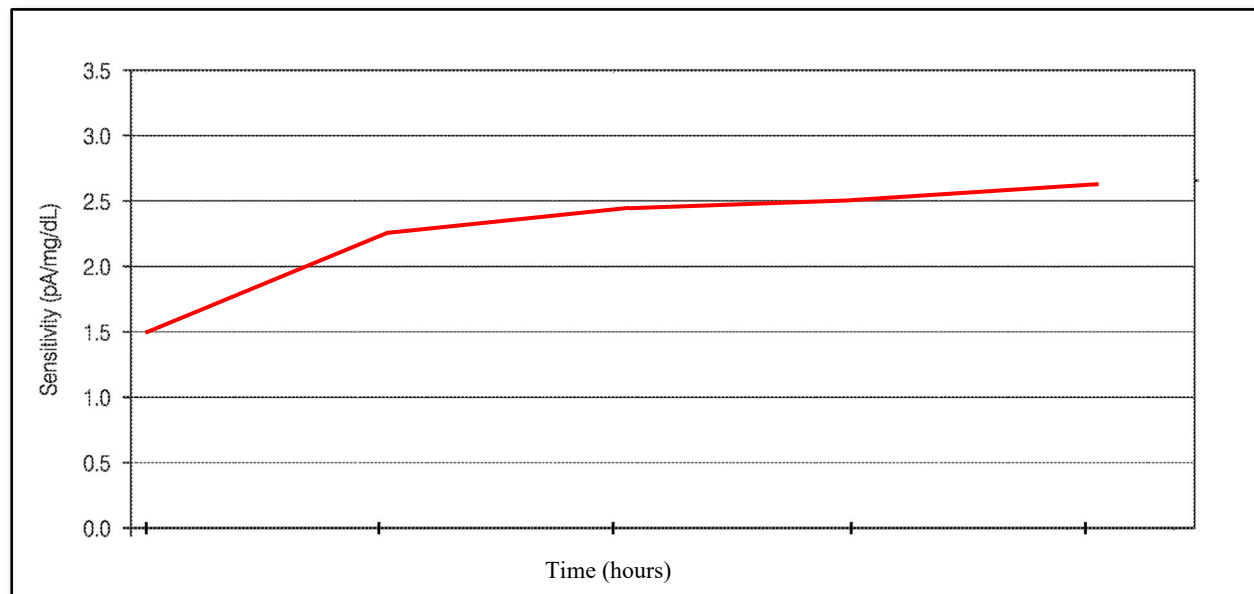
measurements 217 in the figure above—by performing “a linear least squares regression” to “calculate[] a slope and an offset using the equation $y=mx+b$ ” to find the conversion function that best fits the matched pairs. EX1001, 138:66-139:40. Each sensor output (y_i) from the CGM sensor is matched with 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.

Like the prior art (discussed above in Section I), the ’031 Patent recognizes that it is not enough to calculate a glucose sensor’s *in-vivo* conversion function just once, because the function’s parameters (sensitivity and/or baseline) tend to “drift” (change) over time while the sensor is inserted in the body. EX1001, 21:36-48, 142:18-22, 201:39-62, 210:3-38. However, in a departure from the prior art, with the ’031 Patent, DexCom designed a system where “prior information can be provided for m [sensitivity] and/or b [baseline], thereby enabling calibration to occur with fewer paired measurements” (e.g., fewer fingersticks). EX1001, 140:12-17. In fact, in DexCom’s system, “both m and b are known a priori, matched pairs are not needed for calibration, and the sensor can be completely calibrated e.g. without the need for reference analyte values (e.g. values obtained [from fingerstick tests] after implantation *in vivo*.)” EX1001, 140:31-34. As discussed above in Section I, part of this ability to calibrate the sensor over the

course of the device's use without need for fingerstick recalibrations comes from *a priori* knowledge of what the sensor's sensitivity will be at various points in time because of the sensor's drift, where that knowledge is "obtained from previous sensor uses, such as numerous in vitro and/or in vivo experiments" on sensors of the same design/manufacture. EX1001, 216:44-46.

Thus, in the '031 Patent, the "prior information" that is "provided for m" to "determine[] [the] sensitivity of the sensor" to "be used by the calibration procedure" so that "both m and be are known a priori" (EX1001, 140:12-34)—i.e., the "a priori sensitivity information" (EX1001, 213:13-14, 216:44-48)—not only includes knowledge of what sensitivity to use when the sensor is first inserted (EX1001, 140:22-28), but also "includes ... an expected profile (e.g., an expected pattern and/or amount of sensitivity change/drift over time)" (EX1001, 213:9-25) that specifies what the sensitivity is expected to be and thus what sensitivity to use in the conversion function at each future point in time while the sensor is used. EX1001, 216:44-48. "For example, during the first hour of sensor use, the expected profile may be a line having a slope and/or a curvature within a first range" that specifies what the sensor's sensitivity is expected to be at each point in time during the first hour, "while during the second hour of use the expected profile may be a line having a slope and/or curvature within a second range." EX1001, 216:48-52. Such a sensitivity drift profile could be illustrated as below

(using exemplary sensitivity values from the experiment disclosed in Example 11 (252:15-253:2) and FIG. 25 of the '031 Patent):



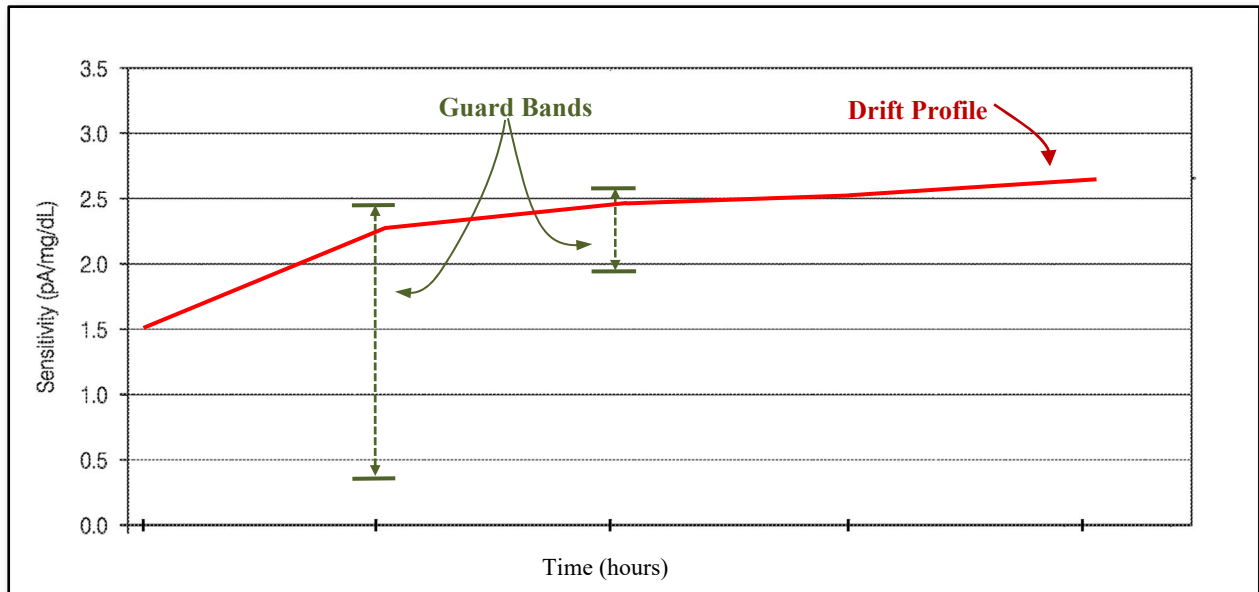
Using such *a priori* sensitivity information including initial *in-vivo* sensitivity plus the drift profile, together with *a priori* knowledge specifying the conversion function's baseline, the '031 Patent's "sensor can be completely calibrated e.g. without the need for reference analyte values" (fingersticks), because "both m and b are known a priori" and therefore "matched pairs are not needed for calibration." EX1001, 140:28-34.

While these techniques are sufficient to calibrate the sensor without fingersticks, the '031 Patent does also allow for occasional fingerstick measurements (or other types of reference measurements) to be taken over a "predetermined time period" (EX1001, 210:66-211:15) for purposes of evaluating

whether the sensor's actual sensitivity is deviating from the expected profile established *a priori* for the conversion function. EX1001, 210:39-217:42. Such “[d]eviations from the expected pattern can be indicative of noise on the sensor, sensor failure, and/or the like,” so “the system is configured to evaluate and/or consider a deviation from the expected profile ... to determine if a system failure has occurred.” EX1001, 210:56-60, 213:25-32.

To define the outer bounds of how much deviation from the profile is acceptable before implementing “Diagnostics and Fail-Safes” (EX1001, 210:56-60), the '031 Patent uses the expected drift profile to “define[] a range of acceptable change in sensitivity, such as described with reference to a cone of possible acceptable and/or feasible sensitivity changes” around the profile, where the profile is “a line having a slope and/or curvature.” EX1001, 216:42-61, 213:33-214:9 (“the a priori sensitivity information defines a range (e.g., within boundaries and/or guard bands) of acceptable change (increase and/or decrease) in sensitivity”).

An example of this can be illustrated as follows:



In this manner, “the system is configured to use a priori information to set tolerances for sensitivity and/or baseline drift” in a way that “discriminate[s] between measured changes in sensitivity and/or baseline from signal artifacts, such as by using tolerance limits based on historical/empirical data.” EX1001, 236:32-41. If the sensor’s actual sensitivity as determined through reference measurements differs a little bit from the expected profile (within the guard bands / tolerance limits), that may reflect a normal difference in drift between sensors; but too large of a difference more likely indicates an “error, or unexpected condition” that requires “fail-safe” measures. EX1001, 223:36-41. Applying this “predetermined threshold” to evaluate deviations from the expected drift profile “allows for drift in the sensitivity of the sensor, but prevents large fluctuations in

the sensitivity values, which may be caused by noise and/or other errors in the system.” EX1001, 223:47-65.

B. Challenged Claims

In this proceeding, Abbott challenges independent claims 1 and 14 of the '031 Patent, together with some of their dependent claims.

Claim 1 is reproduced in part below:

1. A system for monitoring a glucose concentration, the system comprising:
a transcutaneous glucose sensor comprising:
an ex vivo portion configured to remain outside of a body of a host; and
an in vivo portion configured to be inserted into the body of the host [...];
[...]; and
electronics configured to operably connect to the transcutaneous glucose sensor, wherein the electronics comprises a memory,
wherein the memory stores information associated with a profile wherein the profile is based at least in part on a priori information related to expected sensitivity changes associated with a length of time the in vivo portion of the transcutaneous glucose sensor has been inserted into the body of the host.

As the claim recites, the system uses “*a transcutaneous glucose sensor*” that has “*an ex vivo portion*” configured to remain outside the host’s body while the

sensor's "*in vivo portion*" is inserted into the body.³ Further, the electronics that operatively connect to the sensor store in memory information associated with a "***profile***" that is based at least in part on "*a priori information related to **expected sensitivity changes***" associated with the length of time the sensor has been inserted into the host's body.

Independent claim 14 recites similar limitations:

14. A method of monitoring a glucose concentration, the method comprising:
beginning a sensor session associated with use of **a transcutaneous glucose sensor, wherein the transcutaneous glucose sensor comprises:**
 an ex vivo portion configured to remain outside of a body of a host; and
 an in vivo portion configured to be inserted within the body of the host [...];
[...]; and
calibrating the sensor data based at least in part on a priori information, wherein the a priori information comprises a profile associated with a drift in a sensitivity of the in vivo portion of the transcutaneous glucose sensor over time.

³ Bold and bold italics emphases herein are added unless otherwise specified. Plain italics indicate claim language and Latin-language terms.

As discussed below, the Petition’s two grounds of purported unpatentability fail because Zhang does not satisfy any of the above-emphasized limitations, and Shin does not satisfy the “*profile*”-related limitations of the challenged 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, 17-18), because the Petition fails to demonstrate unpatentability even under that definition.

IV. GROUND 1 (BASED ON ZHANG) FAILS AS TO ALL CHALLENGED CLAIMS

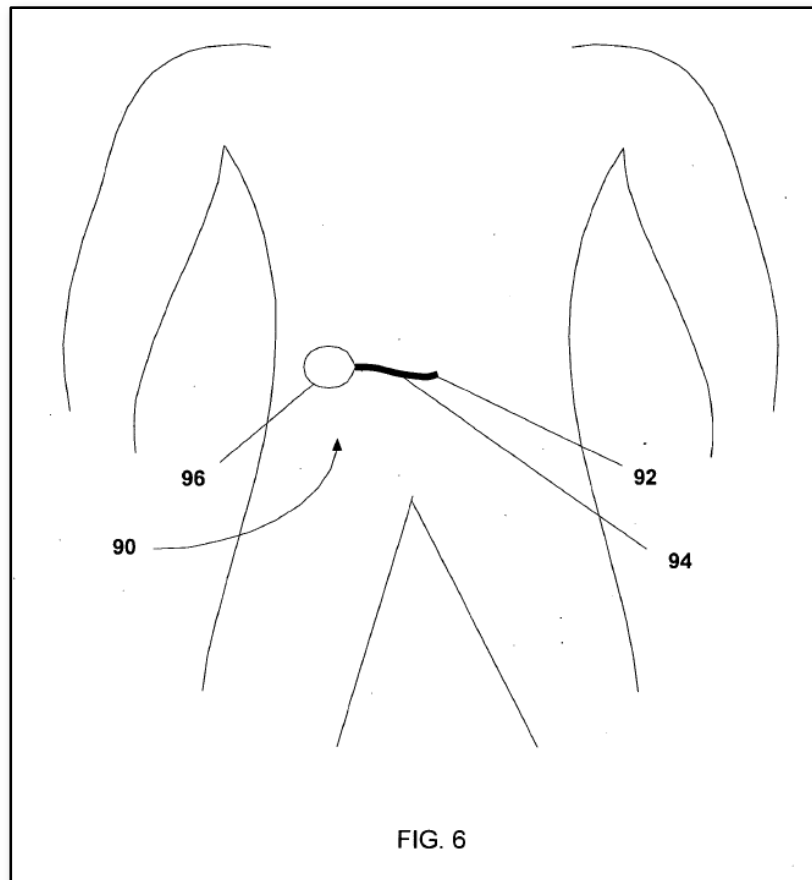
Ground 1 alleges that all challenged claims (of which claims 1 and 14 are independent) are “[a]nticipated and/or rendered obvious by Zhang.” Petition, 7. Ground 1 fails to demonstrate unpatentability of any challenged claim, for two independent reasons. First, Zhang’s system does not employ *a transcutaneous glucose sensor* as required by all challenged claims. *See* Section IV.B, *infra*. Second, Zhang does not meet the *profile* limitations of independent claims 1 and 14. *See* Section IV.C, *infra*.

A. Overview of Zhang (EX1004)

1. Zhang's Implantable Sensor

Zhang “relates to recalibration techniques ... for implantable sensors.”

Zhang, [0002]. “FIG. 6 shows an implanted sensing system in which” Zhang’s recalibration techniques “may be used.” Zhang, [0063].



The system includes “an insulin pump” 96, “a catheter 94 having one end attached to the pump 96, and a sensor 92 disposed at another end of the catheter 94.” Zhang, [0063]. The catheter 94 is a tube through which the pump 96 “deliver[s] medication or other fluids, such as insulin,” into the patient’s body.

Zhang, [0063]; *see* EX2007 at 132 (American Heritage Medical Dictionary: “catheter” is “[a] hollow, flexible tube inserted into a body cavity, duct, or vessel to allow the passage of fluids or distend a passageway”). The sensor 92 is at the “end of the catheter 94” that is inside the patient’s body, such as “in an artery or a vein” where the catheter delivers insulin into the patient’s “blood.” Zhang, [0063], [0027]. There, the sensor is in contact with the patient’s “bodily fluids” where the catheter is delivering insulin, so the sensor can sense the amount of glucose present at that site. Zhang, [0027].

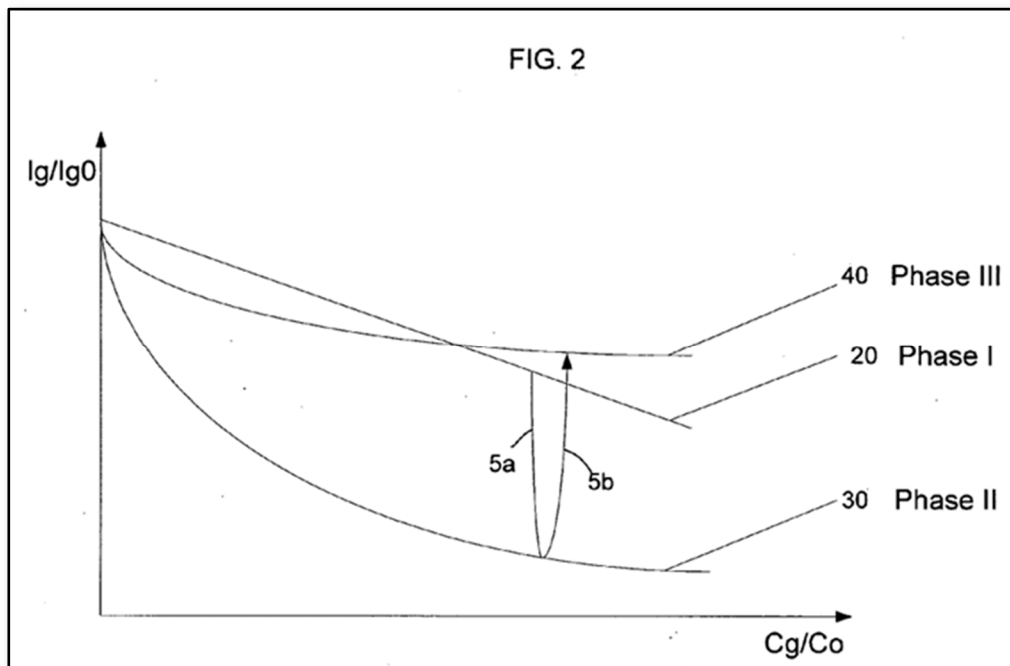
Zhang’s sensor 92 is thus implanted fully inside the body, at the “end” of the catheter that is inserted into the body for delivering insulin into the body. Zhang, [0063]. Zhang’s sensor is not a *transcutaneous sensor* having an *ex vivo portion* configured to remain outside of the patient’s body, as discussed below in Section IV.B.

2. Zhang’s Recalibration Techniques

In Zhang’s “Description of Related Art,” Zhang notes that “[t]he accuracy of a sensing system is generally limited by the drift characteristics of the sensing element over time and the amount of environmental noise introduced into the output of the sensing element.” Zhang, [0004]. Zhang explains that in the conventional “Related Art,” “the sensing system is periodically calibrated, or recalibrated” to “accommodate the drift ... and the noise.” Zhang, [0004]. The

problem, according to Zhang, is that “[t]ypical recalibration routines” had assumed that systems could compensate for these effects by applying “simple *linear* adjustments,” even though “[m]any sensing systems include sensing elements that exhibit *non-linear* outputs or outputs that change in a non-linear fashion over time.” Zhang, [0006].

As further background to explain the context and motivation for Zhang’s recalibration techniques, Zhang explains that “[s]ensors typically exhibit different characteristics during the useful life of the sensor” and “typically have three phases: (1) initialization phase, (2) stable phase, and (3) end of life phase.” Zhang, [0032]. Zhang illustrates this with a generalized diagram of “a normalized calibration curve for the three phases of the sensor life [] shown in FIG. 2.” Zhang, [0033].



Zhang's FIG. 2 illustrates "the calibration curve *shapes* of each phase of the sensor life as determined based on empirical data collected from the use of sensors." Zhang, [0033]. "[P]hase 1 of the sensor's life" is "when it is initially placed in a patient," before "the sensor stabilizes" and "settles into its environment." Zhang, [0037]. As FIG. 2 illustrates with line 20, "the initial output of the sensor current with respect to glucose concentration" is "virtually completely linear during the first phase." Zhang, [0037]. But once the sensor "stabilizes in its environment," it "enters phase 2" where "the current output of the sensor with respect to glucose concentration tends to become non-linear" as FIG. 2 illustrates with curve 30. Zhang, [0037]-[0038]. Zhang explains that "the sensor may remain in this stabilized state" (Phase II, illustrated conceptually in FIG. 2 by curve 30) "for periods of one year or more." Zhang, [0038]. Then "[e]ventually, at the sensor's end of life," it enters Phase III (illustrated conceptually in FIG. 2 by curve 40), where its response "is relatively flat for higher glucose concentrations, thereby rendering the sensor essentially ineffective for measurement." Zhang, [0039].

Thus, with reference to the generalized diagram in FIG. 2, Zhang explains that all or nearly all of the sensor's useful life—"periods of one year or more"—is spent in Phase II where the sensor's response is non-linear. Zhang, [0038]. Phase I where the sensor's response is "linear" is less useful because the sensor is still in

“initialization” and “get[ting] used to its environment” and not yet “stabilize[d].”

Zhang, [0032], [0037]. And in Phase III “at the sensor’s end of life,” the sensor’s flat response “render[s] the sensor essentially ineffective for measurement.”

Zhang, [0039]. This is Zhang’s explanation for why its recalibration techniques focus on creating a ***non-linear*** calibration curve rather than a linear one. Zhang, [0006], [0037]-[0040], [0064].

However, Zhang further explains that attempts to fit non-linear curves using truly non-linear functions are costly in terms of processing power and tend to be inaccurate. Zhang, [0064]. Therefore, Zhang presents a technique to “us[e] a ***linear*** regression” to approximate the sensor’s “***non-linear*** curve.” Zhang, [0064].

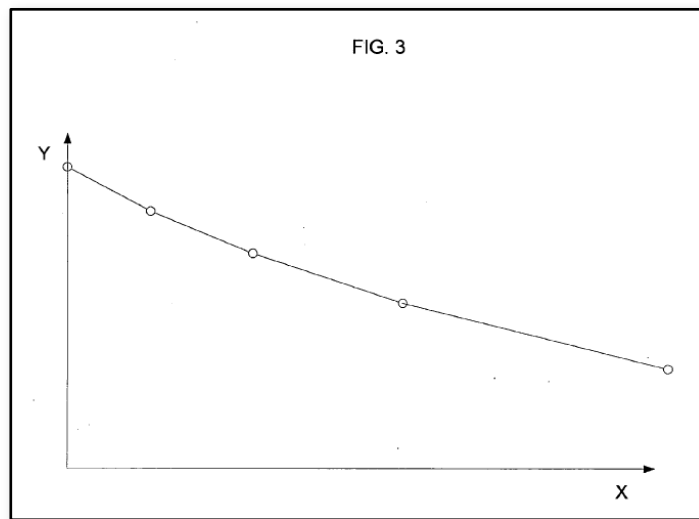
Zhang ([0064]) explains:

Using a linear regression rather than a non-linear regression provides many advantages. For example, the amount of processing power saved by using a linear regression rather than a non-linear regression is dramatic. Processing power is critical in battery operated or otherwise powered implantable systems. Moreover, linear regressions are far more stable than non-linear regressions when input data varies widely. Stability is critical in medical diagnostic and treatment systems such as an implantable insulin pump, for example.

Therefore, Zhang uses “a five-point piecewise linear approximation ... to approximate the calibration curve.” Zhang, [0040].

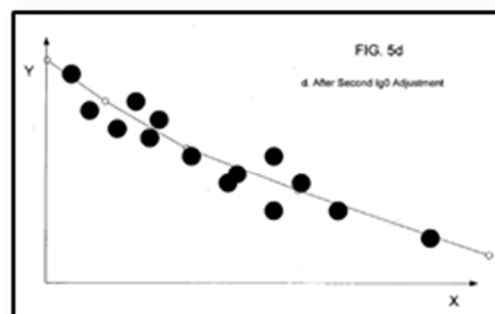
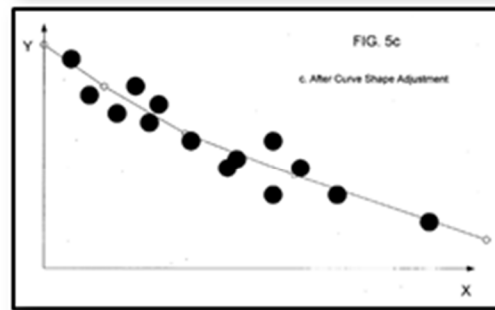
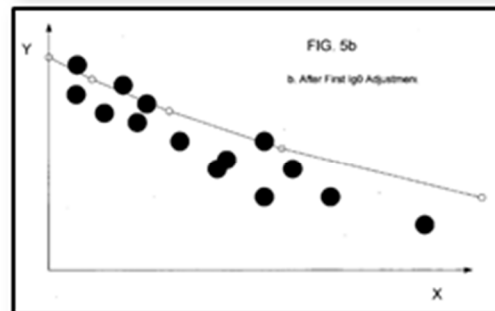
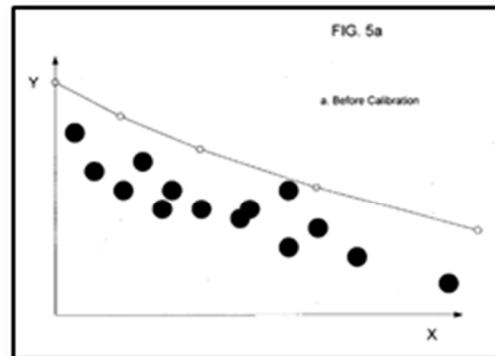
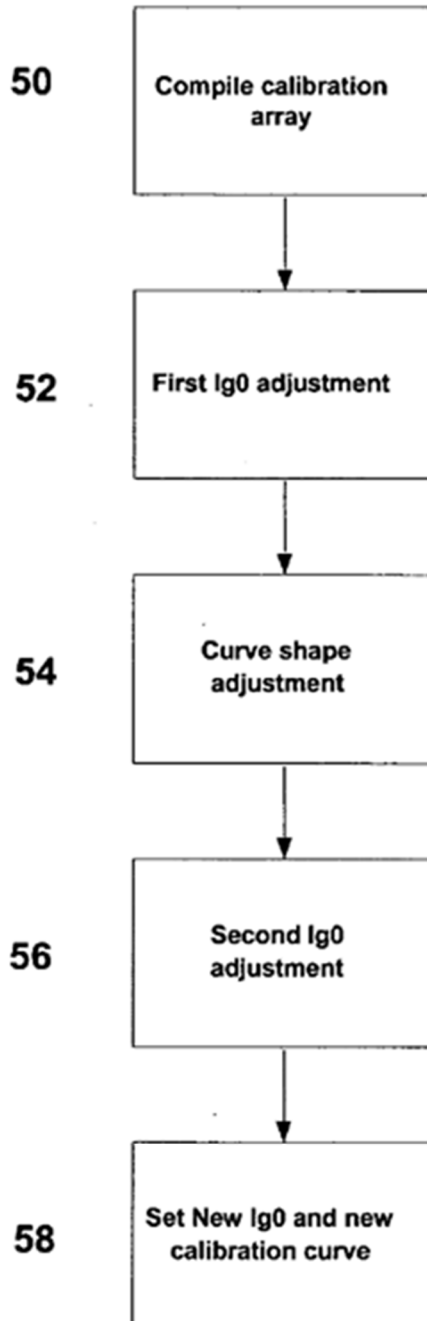
In other words, instead of using a smooth curve, the curve is broken into five points and the line between each two consecutive points is assumed to be linear, as illustrated in FIG. 3. The piecewise linear approximation has been shown to reduce the complexity of the performed calculations while maintaining accurate results.

Zhang, [0040].

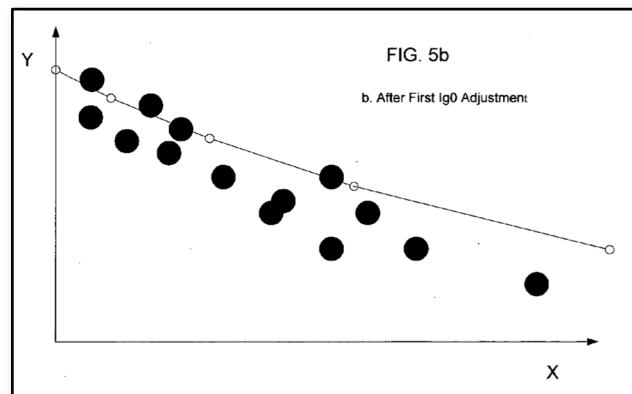
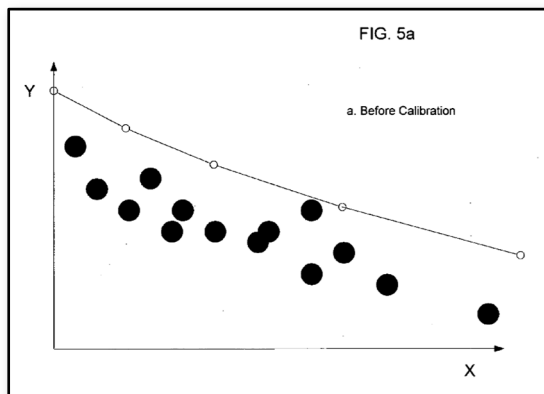


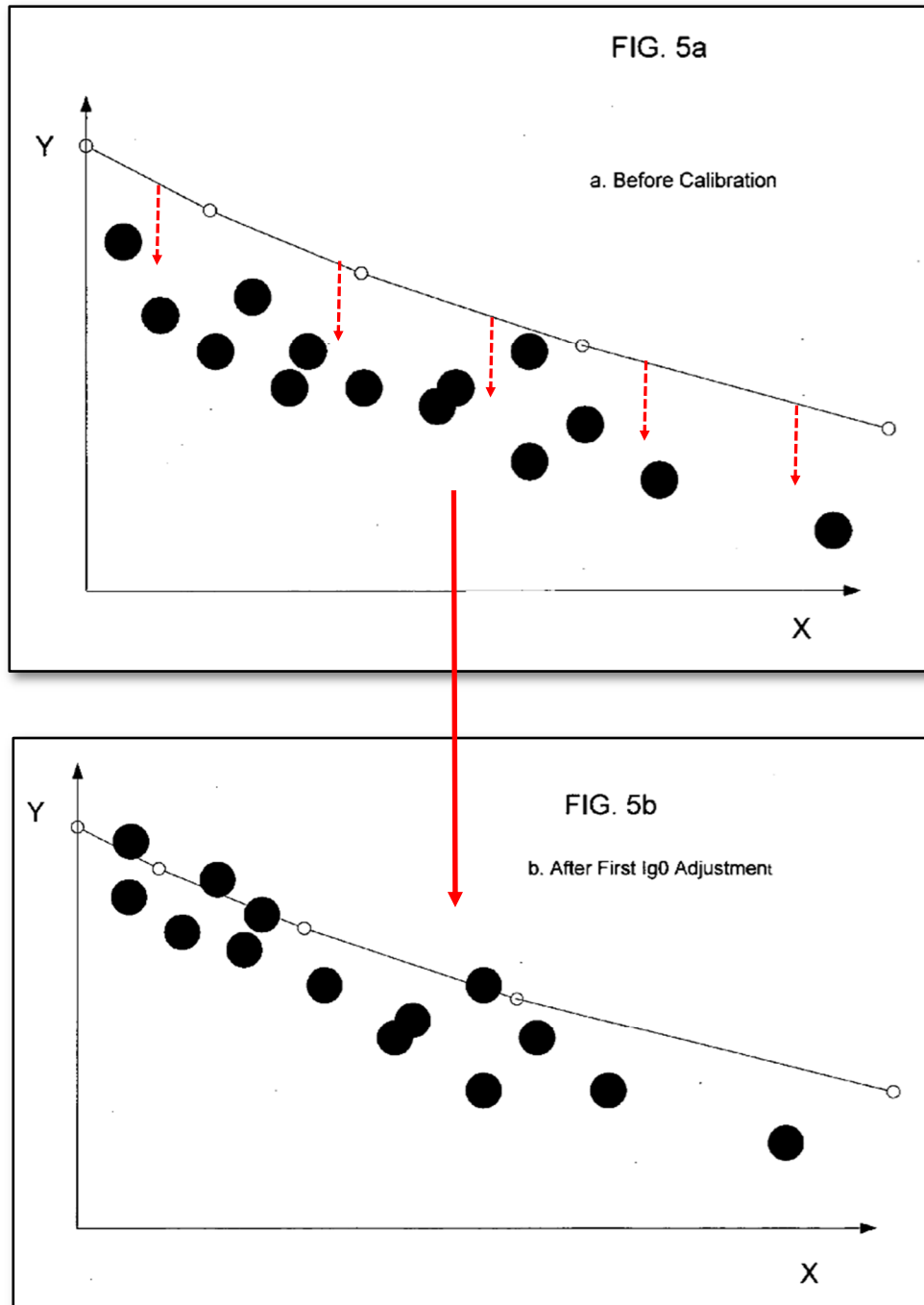
Zhang thus calibrates its sensor using a non-linear “curve” that is actually made of five points connected to each other by straight lines, as in FIG. 3. Zhang, [0011], [0040], [0064]. As the sensor’s true response gradually shifts over time, Zhang “adjusts the calibration curve” by collecting reference “blood meter values” (e.g., fingersticks) from “the last three weeks” to “calibrate the sensor” by mathematically adjusting the curve to better fit these recent reference values. Zhang, [0040], [0035], [0043], [0041], [0007]-[0008], [0017]. This process is shown in FIGs. 4-5 (reproduced below and juxtaposed). Zhang, [0033].

FIG. 4



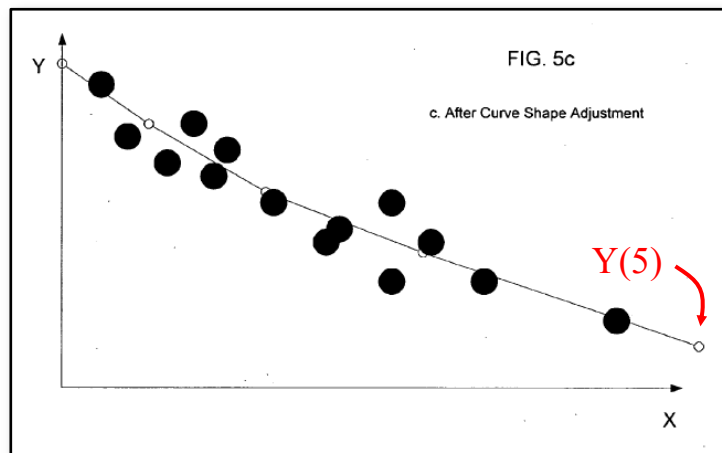
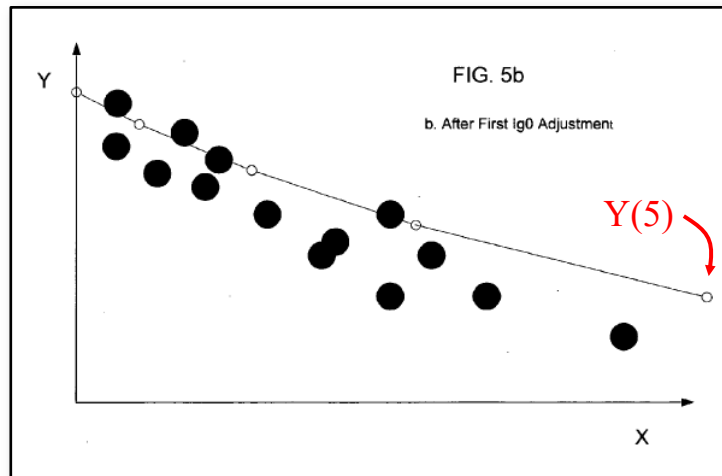
This process begins once “a calibration array is compiled from independent glucose readings, such as readings from a blood glucose meter” from the most recent “three weeks”—i.e., step 50 in FIG. 4. Zhang, [0041]-[0042]. This produces the dots in FIG. 5, which are “x-y coordinates” that “correlate” each “blood glucose meter” reading with “the sensor reading” taken at the same time. Zhang, [0045], [0062]. First, in step 52, the process compensates for “base line shift” by adjusting “the nominal glucose current (I_{g0}),” by “calculat[ing] the mean shift, the shift to the calibration curve in the y-direction” to shift the curve vertically to where the dots (recent fingerstick readings) begin on the graph. Zhang, [0043]-[0050]. This decreases the vertical distance between the curve and the left-most dots, as in the example from FIG. 5a to FIG. 5b (annotated below). Zhang, [0062].



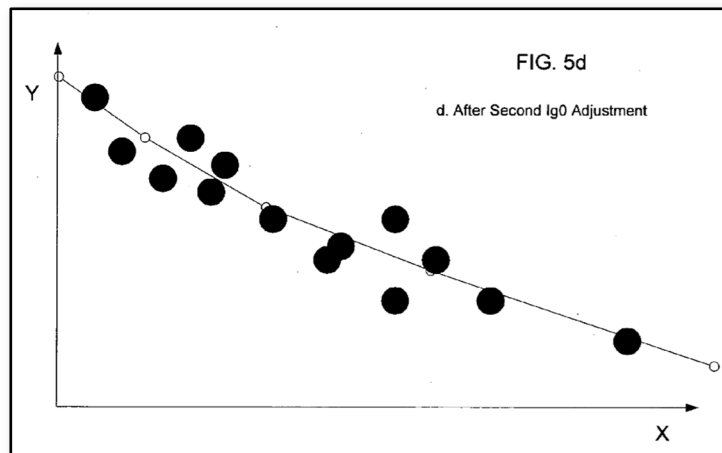
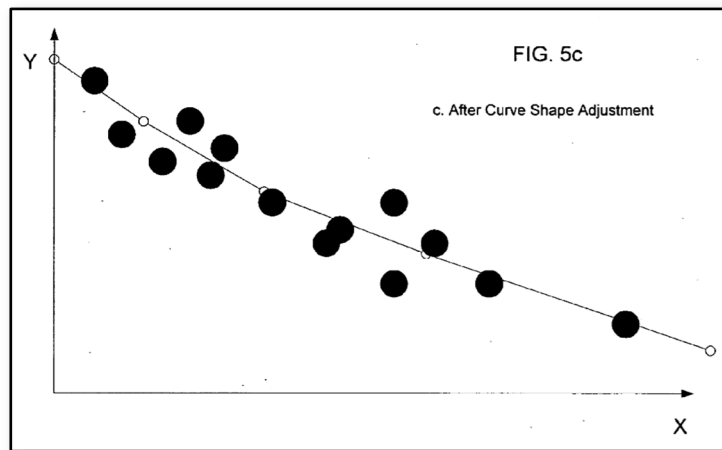


Next, step 54 of the process adjusts “the shape of the sensor calibration curve” in two parts. Zhang, [0051]-[0060]. First, a new “linear regression” is performed on the dots (i.e., reference blood glucose measurements) “to determine the last recalibration point”—i.e., the “one of the five points on the calibration

curve corresponding to the highest glucose concentration,” called “Y(5).” Zhang, [0051]-[0057]. Second, “[t]he remaining calibration points” Y(1)-Y(4) are “then determined as follows: $\Delta Y(i)/(1 - y(i)) = H * \Delta Y(i + 1)/(1 - y(i + 1))$,” where “the variable H is set to 0.9 if the sensor is gaining sensitivity and 0.7 when the sensor losing sensitivity.” Zhang, [0058]-[0060]. This step changes the calibration curve’s tilt so that its right-most end is “lined up” with “the high-end points” of the dots, as in the example from FIG. 5b to FIG. 5c (annotated below). Zhang, [0062].



Finally, step 56 performs “a second I_{g0} adjustment”—i.e., another smaller vertical shift of the calibration curve for “fine tuning” to line it up with the dots (fingerstick reference measurements) “to ensure the maximum accuracy.” Zhang, [0061]-[0062]. As the example from FIG. 5c to FIG. 5d illustrates, this can be a very small shift as “the curve is likely to change only slightly with respect to the reference points during the second I_{g0} adjustment.” Zhang, [0062].



The above process is how, in Zhang’s recalibration technique, “a non-linear curve may be adjusted using a linear regression.” Zhang, [0064]. As can be seen

above, all of the adjustment steps are dependent on fitting the curve to reference measurements (e.g., fingersticks) taken while the sensor is inserted and in use in the patient. The only aspect of the adjustment that is not directly specified by the reference measurements is “the variable H” in the equation for adjusting the curve shape in step 54, which “is set to 0.9 if the sensor is gaining sensitivity and 0.7 when the sensor losing sensitivity.” Zhang, [0059]. Notably, Zhang’s system does not know *a priori* what calibration curve to use at different points in time during the life of the sensor. Zhang’s system must obtain reference measurements, such as fingersticks, during the sensor’s use to *measure* what the sensor’s response currently is and then determine its calibration curve to match that response.

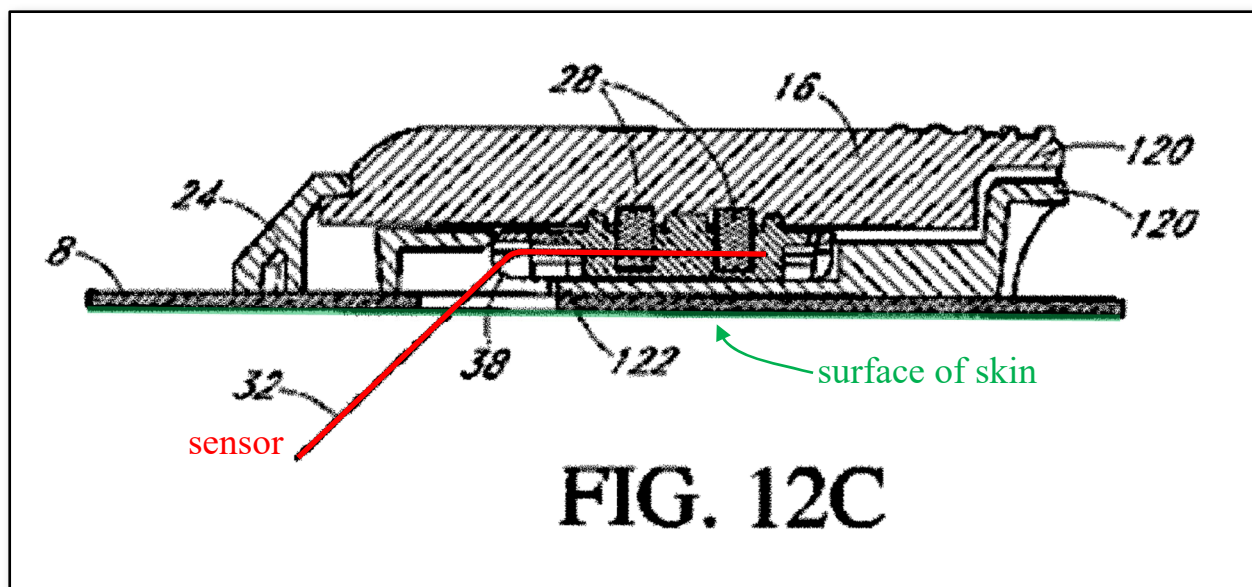
B. Ground 1 Fails Because the Petition Does Not Establish That Zhang Discloses or Renders Obvious the Transcutaneous Glucose Sensor of Independent Claims 1 and 14

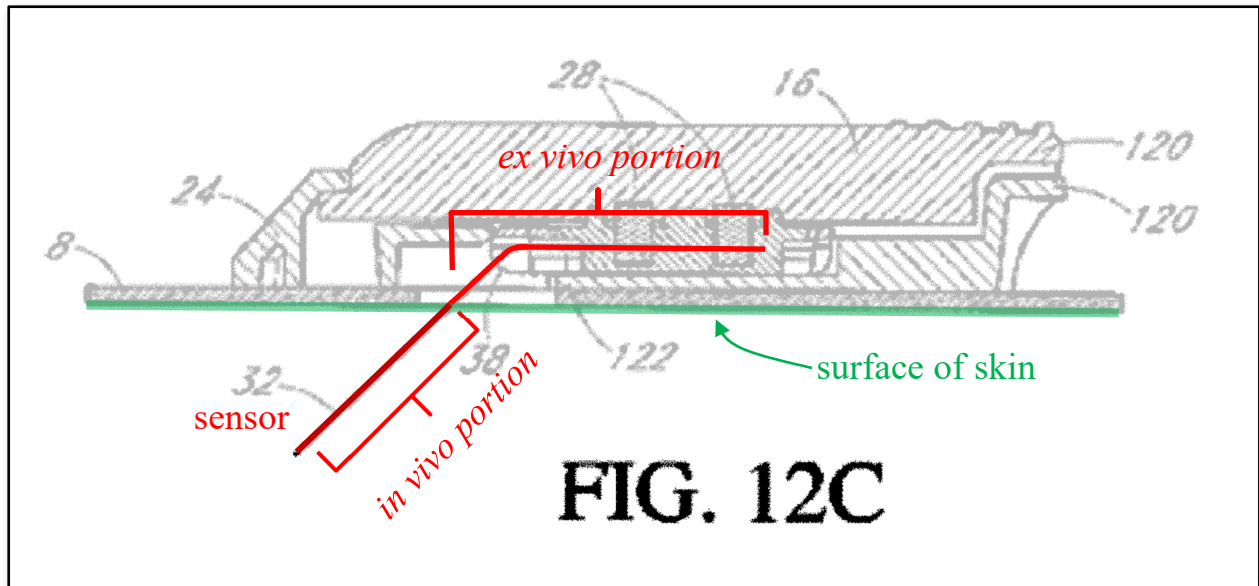
All of the challenged claims require “*a transcutaneous glucose sensor*” that comprises not only “*an in vivo portion*” but also “*an ex vivo portion configured to remain outside of a body of a host.*” Ground 1 of Abbott’s Petition alleges that “Zhang’s glucose sensor is a transcutaneous sensor comprising an ex vivo portion configured to remain outside the body” and, alternatively, that “glucose sensors having an ex-vivo portion would have been obvious.” Petition, 27-29.

For the reasons discussed below, both of Abbott’s arguments fail.

1. The Petition Fails to Demonstrate That Zhang’s Sensor Is Transcutaneous with an Ex Vivo Portion

As the claim language recites, the “*transcutaneous glucose sensor*” of the challenged claims must extend through the skin of the host when inserted, such that the sensor has both “*an ex vivo portion configured to remain outside of a body of a host*” and “*an in vivo portion configured to be inserted [into/within] the body of the host.*” As discussed above (Section II.A, *supra*), an example of such a transcutaneous sensor is illustrated in FIG. 12C of EX2005 and EX2006 (both incorporated by reference in the ’031 Patent at EX1001, 37:26-31), annotated below:

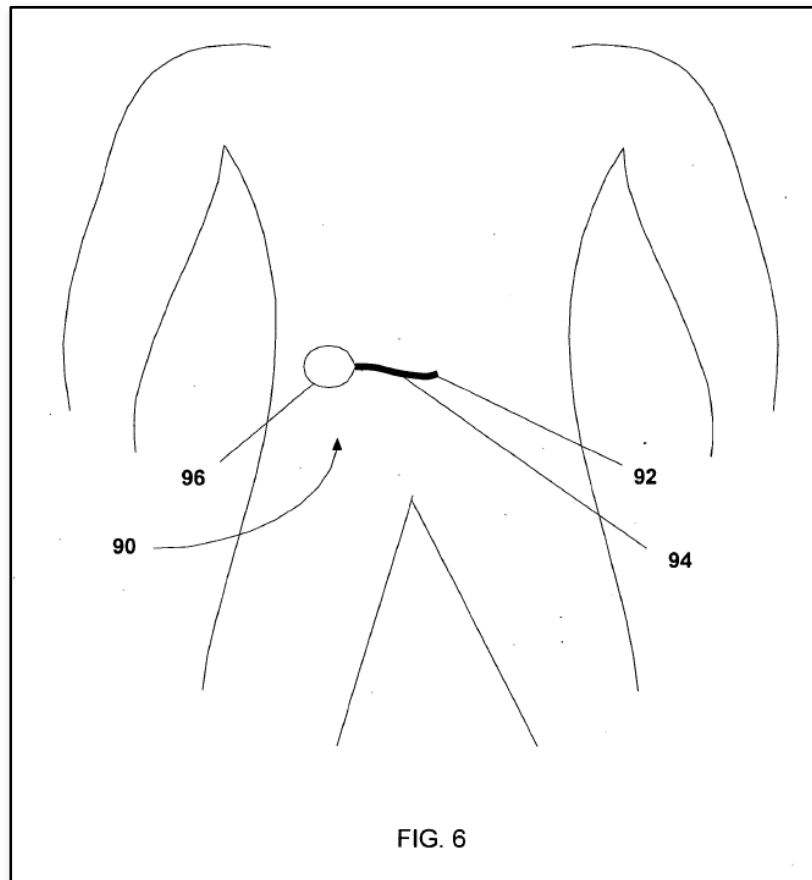




As this figure illustrates, in the claimed configuration it is the *sensor* that resides partially piercing through the skin while the device is in use, such that only part of the *sensor* (the *in vivo portion*) is inserted through the skin into the body, while the rest of the *sensor* (the *ex vivo portion*) remains outside the body, on the other side of the skin. Zhang’s system is not this type of system, and does not use this type of sensor.

As discussed above (Section IV.A.1, *supra*), Zhang’s system is “an implanted sensing system” used with “an insulin pump.” Zhang, [0063]. As shown in Zhang’s FIG. 6 (reproduced below), in this system the pump 96 “deliver[s] medication or other fluids, such as insulin, for example, through the catheter 94 to a patient,” which means the catheter is inserted in the patient’s body. Zhang, [0063]. The catheter has “one end attached to the pump 96,” and the sensor

92 is “disposed at another end of the catheter 94”—i.e., at the end of the catheter where the insulin is delivered into the body. Zhang, [0063]. That means the sensor is fully inside the patient’s body, at the end of the catheter.



Zhang explains that the pump 96 may be “an implantable insulin pump,” and discusses no other configuration for the pump-and-sensor system. Zhang, [0064], [0031]. Thus, in the only configuration Zhang actually discloses, the *entire system* (pump, catheter, sensor, and all) is implanted fully inside the patient’s body, and no component of the system is *transcutaneous*. But even if Zhang had disclosed a system where the pump 96 was outside of the body, the *sensor* 92 would still be

fully inside the body. If anything, only the catheter might be disposed crossing through the skin, but the “end of the catheter” where the sensor resides (Zhang, [0063]) must be inside the body in order to deliver the insulin into the patient’s body.

Thus, Zhang’s sensor has no “*ex vivo portion configured to remain outside of a body of a host*” and is not a “*transcutaneous*” glucose sensor as the challenged claims require. Abbott’s Petition fails to prove otherwise.

Abbott’s Petition alleges that “Zhang’s glucose sensor is a transcutaneous sensor comprising an ex-vivo portion configured to remain outside the body, and an in-vivo portion configured to be inserted into the body.” Petition, 27. But the Petition’s entire argument for how Zhang allegedly discloses this is the following single sentence:

Zhang explains that the sensor “can be implanted in and/or through subcutaneous, dermal, sub-dermal, inter-peritoneal or peritoneal tissue,” and that “the implantable sensor may be used in ... interstitial fluid....” Ex-1004, ¶0027. Ex-1002, ¶¶95-96.

Petition, 27 (ellipses original); *see also* Petition, 50 (“*See claim 1[a], §X.A.1.b, for elements of claim 14[a] concerning the sensor itself.*”).

Thus, the Petition’s only argument is to quote, without explanation, from paragraph [0027] of Zhang—quotations that nowhere use the term “*transcutaneous*” or discuss in any way any “*ex vivo portion*” of a sensor that is

“*configured to remain outside of a body of a host.*” This falls far short of Abbott’s burden to provide “a detailed explanation of the significance of the evidence” in its Petition. 37 C.F.R. §42.22(a)(2). “[M]ere conclusory statements” are insufficient. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

Moreover, nothing in the statements Abbott quotes from [0027] of Zhang says that any portion of Zhang’s sensor remains outside of the host’s body. The first sentence from [0027] from which Abbott quotes says, “Also embodiments of the present invention are not limited to implantation in an artery or vein, but can be implanted in and/or through subcutaneous, dermal, sub-dermal, inter-peritoneal or peritoneal tissue.” All that sentence says is that Zhang’s sensor can be “*implanted*” in other body tissues or cavities besides blood vessels. And in the process of being “implanted” in various locations, the sensor will pass “through” various tissues, on its way in to the body. But nothing in that unremarkable teaching says that a portion of the sensor will *remain outside of* the body after implantation. Zhang’s [0063] (and [0031] and [0064]) explicitly teaches the opposite—that the sensor is “disposed at [the] end of the catheter” that is inside the body for delivering insulin into the body.

The second quotation from [0027] that Abbott’s Petition provides is that “the implantable sensor may be used in ... interstitial fluid....” Petition, 27. Again, that says nothing about using a “*transcutaneous*” sensor with an “*ex vivo portion*”

remaining outside of the body. Interstitial fluid is fluid inside the body, and is present in many locations throughout the body. *See* EX2007 at 420 (“interstitial fluid” is “[t]he fluid in spaces between the tissue cells”); EX2008 (interstitial fluid is “the extracellular fluid that bathes the cells of most tissues”). Placing Zhang’s “*implantable* sensor” in a location in the body where interstitial fluid is present does not in any way mean that part of the sensor remains outside of the body. As discussed above, Zhang (e.g., at [0063]-[0064], [0031], etc.) teaches otherwise—that the sensor is implanted fully inside the body.

Abbott’s Petition’s citation to its expert’s testimony—“Ex-1002, ¶¶95-96” (Petition, 27)—adds nothing to the Petition’s showing, as the cited testimony merely repeats the same conclusory assertion and the same unexplained quotations from Zhang’s [0027] as in the Petition. Expert testimony that “does not cite to any additional supporting evidence or provide any technical reasoning to support” the Petition’s “conclusory assertion” is “entitled to little weight.” *Xerox Corp. v. Bytemark Inc.*, IPR2022-00624, Paper 9 at 15 (Aug. 24, 2022) (precedential).

The Board has consistently denied institution of IPR petitions that, like Abbott’s, alleged that a claim limitation was met via conclusory arguments and unexplained accompanying quotations that do not state what is recited in the claim. *E.g., Sprint Spectrum LP et al v. Intellectual Ventures II LLC*, IPR2018-01764, Paper 11 at 22-23 (May 6, 2019) (denying institution of petition that “simply

quotes” a “passage” from a reference, “states its conclusion that [the reference] teaches [the claimed limitation], and cites to the testimony of” an expert who, “in turn, repeats [p]etitioner’s argument without elaboration or citation to additional evidence”); *see also AviaGames Inc. v. Skillz Platform Inc.*, IPR2022-00531, Paper 13 at 16-17 (Aug. 4, 2022).

Nothing in Abbott’s Petition’s only citation to Zhang (Petition, 27, quoting from Zhang, [0027]) supports Abbott’s contention that Zhang discloses its system including or using “*a transcutaneous glucose sensor*” that comprises “*an ex vivo portion configured to remain outside of a body of a host.*” Abbott’s assertion of anticipation by Zhang thus fails for all challenged claims.

2. The Petition Fails to Demonstrate That It Would Have Been Obvious to Modify Zhang’s System to Use a Transcutaneous Sensor Having an Ex Vivo Portion

Abbott’s alternative assertion that “glucose sensors having an ex-vivo portion would have been obvious” to use in Zhang’s system (Petition, 27-29) fails for two independent reasons: lack of sufficient motivation, and failure to demonstrate reasonable expectation of success.

a. The Petition Fails to Demonstrate Sufficient Motivation to Replace the Implanted Sensor with a Transcutaneous Sensor in Zhang’s System Calibrated with Zhang’s Techniques

A claim “is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex*

Inc., 550 U.S. 398, 418 (2007). Demonstrating obviousness requires establishing that a POSA “would have been motivated to combine or modify the teachings in the prior art and would have had a reasonable expectation of success in doing so.” *Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 160 (Fed. Cir. 2021) (internal quotation marks and citations omitted).

Abbott’s Petition alleges that “glucose sensors having an ex-vivo portion would have been obvious in view of the POSA’s knowledge that many glucose sensors described in the art—including sensors used commercially—were transcutaneous sensors having an ex-vivo portion.” Petition, 27. That is not a legally sufficient basis to find motivation-to-combine to establish obviousness. “It does not suffice to meet the motivation to combine requirement to recognize that two alternative arrangements ... were both known in the art.” *Virtek Vision Int’l. ULC v. Assembly Guidance Sys.*, 97 F.4th 882, 886 (Fed. Cir. 2024). “The mere fact that these possible arrangements existed in the prior art does not provide a reason that a skilled artisan would have *substituted* the” sensor in *Zhang’s system* “with the” transcutaneous sensor used in other systems. *Id.* at 887. “It does not suffice to simply be known. A reason for combining must exist.” *Id.* at 888 (holding that “an assertion that because two coordinate systems were ... ‘known,’ that satisfies the motivation to combine analysis” is “an error as a matter of law”). Even if a feature was “*very* well-known” in other systems, that does “not provide[]

sufficient evidence for why a person of skill would be motivated to add” that feature to **Zhang’s** system in particular. *Fanduel, Inc. v. Interactive Games LLC*, 966 F.3d 1334, 1343-44 (Fed. Cir. 2020).

Abbott’s Petition next alleges that “[t]he POSA would have recognized” that systems with transcutaneous sensors “offer advantages over systems with fully implanted sensors.” Petition, 28-29. Again, this argument misses the mark. Asserting that **other** types of systems that used transcutaneous sensors had “advantages” does not establish sufficient motivation to change to a transcutaneous sensor in **Zhang’s** system. *See Intel Corp. v. Qualcomm Inc.*, IPR2019-00047, Paper 35 at 40-41 (Jul. 8, 2020) (“The benefits that Petitioner identifies ... are simply advantages of using carrier aggregation in general, not a reason to use the specific hardware of Uehara with the carrier aggregated signal of the Feasibility Study.”).

As discussed above (Section IV.B.1, *supra*), Zhang’s system is “an implanted sensing system” where the sensor is implanted fully inside the body. Zhang, [0063]. The sensor is designed to stay there for a long time—“for periods of one year or more.” Zhang, [0038]. That is the reason for Zhang to use its recalibration techniques—to allow the long-term implanted sensing system to “maintain acceptable levels of accuracy for extended periods of time.” Zhang, [0006]; *see also id.*, [0064] (“Stability is critical in ... an **implantable insulin**

pump....”). Abbott’s own Petition acknowledges that “systems with a transcutaneous sensor” differ from Zhang’s because they are short-term devices, “in *contrast* to long-term systems with sensors that are ‘implanted in the body,’ which ‘require a long-term commitment to the use of the device.’” Petition, 28 (quoting EX1025 at 129). It may be true that “systems with a transcutaneous sensor” that “are inserted by the user at home” and then removed and replaced by another system “every 3-7 days” provide “advantages over systems with fully implanted sensors” like Zhang’s (Petition, 28), but those advantages also nullify the reasons for and conflict with the execution of Zhang’s recalibration techniques. Abbott’s Petition fails to provide any sufficient reason why a POSA would have been motivated to replace the implantable sensor with a transcutaneous sensor in *Zhang’s* system that uses *Zhang’s* recalibration techniques—a deficiency that is fatal given that the Petition relies on Zhang’s recalibration techniques to meet other limitations of the challenged independent claims (e.g., Petition, 36-40, 50-52).

For example, Zhang’s recalibration techniques are entirely directed to “sensing systems [that] include sensing elements that exhibit non-linear outputs or outputs that change in a non-linear fashion over time.” Zhang, [0006]. As discussed above (Section IV.A.2, *supra*), that is why Zhang uses “a five-point piecewise linear approximation ... each time” Zhang recalibrates, “to approximate the calibration curve.” Zhang, [0040]. This allows “a *non-linear* curve [to] be

adjusted using a linear regression.” Zhang, [0064]. But Abbott’s Petition does not even attempt to allege (let alone *prove* with *evidence*) that the short-term transcutaneous sensor that only lasts “3-7 days” that Abbott’s Petition alleges would be obvious to use in Zhang’s system (Petition, 28) would ever have the type of non-linear calibration curve that Zhang’s recalibration techniques are designed for—e.g., would ever reach Phase II of the long-term sensor in Zhang’s FIG. 2. Indeed, there is every reason to believe that the transcutaneous sensor discussed in the Petition at 28 would have a *linear* response throughout its useful life. For example, the Henning reference (EX1025) that Abbott itself relies on in the Petition at 28 teaches that such sensor systems had a “calibration *line*” that “describes the response of the sensor” (EX1025 at 134), and Abbott’s Ground 2 asserts that the Shin reference uses a transcutaneous sensor (Petition, 54) and has a linear response (Petition, 25 n.7). Therefore, Abbott’s Petition fails to demonstrate that a POSA would have been motivated to modify Zhang’s system to use a short-term transcutaneous sensor but still use Zhang’s recalibration techniques that the Petition relies upon.

As another example, Zhang’s recalibration technique relies on compiling a “calibration array ... compiled from blood glucose meter readings, which have been taken and recorded for [the] particular sensor over a period of time, such as, for example, *three weeks*,” to create the plot of dots for piecewise linear regression

in FIG. 5. Zhang, [0041], [0043] (step 52 of recalibration process uses “data over the last *three weeks* from the glucose sensor ... to adjust the value of the nominal glucose current”). Abbott’s Petition does not even attempt to explain why or how a POSA would allegedly use in this system a transcutaneous sensor that lasts only “*3-7 days*” (Petition, 28), and somehow still apply to it Zhang’s recalibration technique that requires *weeks* of data before it can perform even a single recalibration. Abbott’s own Henning reference explains that “[b]ecause of the inconvenience and cost of pricking your finger and making a glucose measurement, the person with diabetes often performs testing less than twice per day.” EX1025 at 114. Abbott’s Petition makes no attempt to explain how two blood glucose meter readings per day in a sensor that lasts only 3-7 days would ever provide enough data points for even a single five-point piecewise linear regression recalibration in Zhang, much less for repeating such recalibrations over the short 3-7 day life of the sensor.

For all these reasons, Abbott’s Petition fails to demonstrate sufficient motivation-to-combine to support a finding of obviousness of modifying Zhang’s system to use “*a transcutaneous sensor*” having “*an ex vivo portion configured to remain outside of a body of a host,*” as required by all challenged claims.

b. The Petition Fails to Demonstrate Reasonable Expectation of Success in Replacing the Implanted Sensor with a Transcutaneous Sensor in Zhang’s System Calibrated with Zhang’s Techniques.

For similar reasons, Abbott’s Petition fails to demonstrate that a POSA would have had a reasonable expectation of success in modifying Zhang’s system to use “*a transcutaneous sensor*” having “*an ex vivo portion configured to remain outside of a body of a host*,” as required by all challenged claims.

“[W]here a party argues a skilled artisan would have been motivated to combine references, it must show the artisan would have had a reasonable expectation of success from doing so.” *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017) (internal quotation marks and citation omitted); *see also Eli Lilly & Co. v. Teva Pharms. Int’l GmbH*, 8 F.4th 1331, 1344 (Fed. Cir. 2021) (“patent challenger’s burden” to prove reasonable expectation of success is an “***additional requirement***” from proving motivation to combine). Abbott’s Petition fails this requirement.

As discussed above, Abbott’s Petition alleges that it would have been obvious to use a short-term transcutaneous sensor (with a lifespan of “3-7 days”) in Zhang’s system (Petition, 28) while relying on Zhang’s recalibration techniques, but the Petition fails to establish that such a short-term transcutaneous sensor would have the type of non-linear response curve that Zhang’s recalibration techniques are specifically designed for. By the same token, the Petition fails to

establish that a POSA would have had reasonable expectation of success in applying those recalibration techniques involving five-point piecewise regression to calibrate such a short-term transcutaneous sensor.

As also discussed above, Abbott’s Petition fails to address the fact that Zhang’s recalibration techniques require preliminary data gathering over a significantly longer timeframe (e.g., three weeks) than the entire lifespan (3-7 days) of the short-term transcutaneous sensor with which Abbott’s Petition proposes to replace Zhang’s long-term implanted sensor. Abbott’s Petition makes no attempt to explain how Zhang’s recalibration techniques that require weeks of data gathering could or would work with a transcutaneous sensor that is only useable for a few days. In this way as well, Abbott’s Petition fails to establish that a POSA would have had a reasonable expectation of success in using a short-term transcutaneous sensor in place of Zhang’s long-term implanted sensor in Zhang’s system while applying Zhang’s recalibration techniques.

Abbott’s Petition argues that “[t]he POSA would have reasonably expected success in using a transcutaneous sensor as claimed given the successful use of such sensors in the art.” Petition, 29. But even if *other* types of systems successfully used short-term transcutaneous sensors, that does not establish that a POSA would have expected success using a short-term transcutaneous sensor in *Zhang’s* system—particularly using *Zhang’s* recalibration techniques that the

Petition relies on for meeting other limitations of the challenged claims. *See Abbott Diabetes Care Inc. f/k/a TheraSense, Inc. v. DexCom, Inc.*, IPR2022-00913, Paper 44 at 36 (Nov. 2, 2023) (“Merely pointing to certain references that taught specific systems that purportedly used pre-insertion in vitro sensitivity to predict post-insertion in vivo sensitivity does not show that a [POSA] simply knew how to ‘predict’ the same in any other potential system, much less the particular system of Heller.”); *3Shape A/S et al v. Align Tech., Inc.*, IPR2019-00149, Paper 13 at 16 (Jun. 18, 2019) (“The mere existence of some similarities between the two systems does not” demonstrate that a POSA “would have had a reasonable expectation of success in using the specific feature of” one reference’s “disclosure in” the other reference’s “system”).

Abbott’s Petition also argues that “Zhang teaches that its calibration scheme is a ‘generalized method [that] may be applied to a variety of glucose sensors.’” Petition, 29 (quoting Zhang, [0031]). But the Petition’s selective quotation omits the rest of the sentence and the surrounding context, which state:

Therefore, the generalized method for recalibration of a sensor according to an embodiment of the present invention may be applied to a variety of sensors, including, but not limited to, biological parameter sensors, physical parameter sensors and the like. For example, the generalized method may be applied to *a variety of glucose sensors used in conjunction with implantable insulin pumps.*

Zhang at [0031] thus consistently describes the “variety of sensors” as *implantable* while potentially being capable of sensing various different “parameter[s].” Nowhere does this passage state that the recalibration techniques are applicable to short-term transcutaneous sensors.

Finally, Abbott’s Petition quotes (without explanation) Zhang at [0033] as stating that “further research has proved that most sensors behave similarly and these calibration curves can be used with other type of sensors.” Petition, 29. Again, the Petition’s selective quotation omits the rest of the sentence, which states in full, “Although the normalized calibration curves in FIG. 2 were originally derived based on *glucose* sensors, further research has proved that most sensors behave similarly and these calibration curves can be used with other type of sensors.” Zhang, [0033]. This sentence is thus referring to sensors that sense something other than *glucose*—not to sensors that are not fully implanted. Again, nothing in this sentence states that Zhang’s recalibration techniques are applicable to short-term transcutaneous sensors.

For all these reasons, Abbott’s Petition fails to demonstrate sufficient reasonable expectation of success to support a finding of obviousness of modifying Zhang’s system to use “*a transcutaneous sensor*” having “*an ex vivo portion configured to remain outside of a body of a host*,” as required by all challenged claims. Ground 1 therefore fails for this additional reason.

C. Ground 1 Fails Because the Petition Does Not Establish That Zhang Discloses or Renders Obvious the “Profile”-Related Limitations of Independent Claims 1 and 14

The system of claim 1 (and challenged dependent claims 2, 4, and 6-13) requires that “*the memory stores information associated with a profile wherein the profile is based at least in part on a priori information related to expected sensitivity changes associated with a length of time the ... sensor has been inserted into the body of the host.*”

The method of claim 14 (and challenged dependent claims 15 and 20-22) requires “*calibrating the sensor data based at least in part on a priori information, wherein the a priori information comprises a profile associated with a drift in a sensitivity of the ... sensor over time.*”

Ground 1 of Abbott’s Petition alleges that Zhang discloses each of these limitations (Petition, 36-40, 50-52), and does not present any alternative obviousness argument.

For the reasons discussed below, Abbott’s assertions fail.

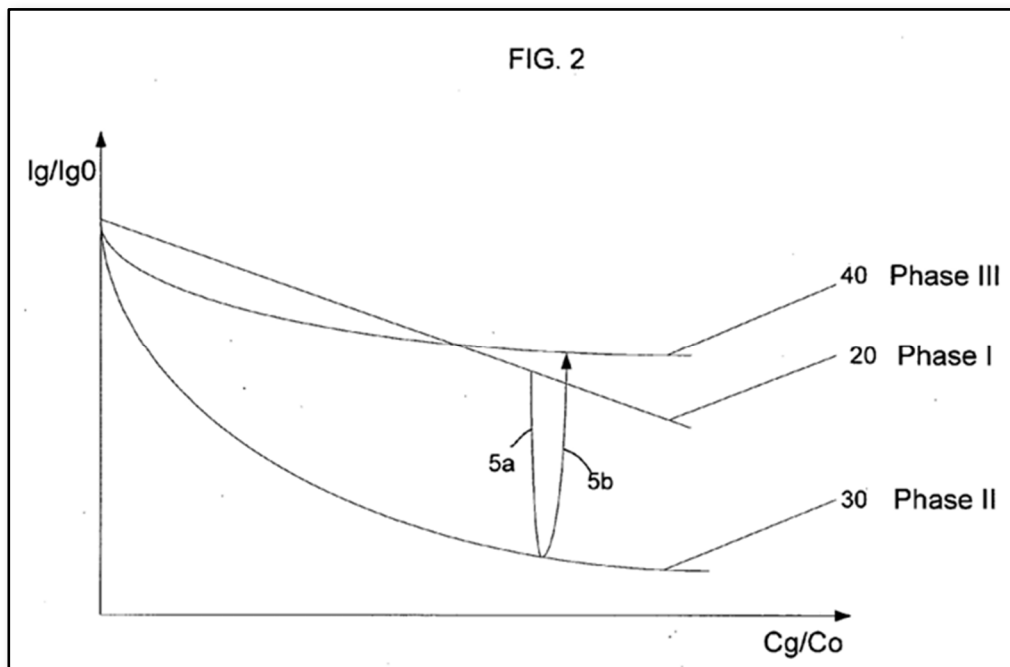
1. The Petition Fails to Demonstrate That Zhang’s “*memory stores*” Zhang’s FIG. 2 Curves As Alleged (Claim 1 and Dependents)

Independent claim 1 requires that the sensor system’s “*memory stores information associated with a profile*” that meets further recited requirements regarding “*a priori information related to expected sensitivity changes.*” Abbott’s

Petition alleges that Zhang meets these limitations because allegedly Zhang’s system’s “memory has stored therein normalized calibration curves for the different phases of sensor life,” where the “normalized calibration curves” are depicted in Zhang’s FIG. 2. Petition, 36-37. But Abbott’s assertion that the curves in FIG. 2 are *stored in the sensor system’s memory* is a single sentence in the Petition that cites *no evidence* in Zhang to support that assertion. See Petition, 36 (stating, “In Zhang’s system, the memory has stored therein normalized calibration curves for the different phases of sensor life,” with no supporting citation).

In fact, the curves in Zhang’s FIG. 2 are not disclosed as being stored in the memory of any individual sensor system in Zhang, and Abbott’s Petition does not prove that they are. As discussed above (Section IV.A.2, *supra*), the generalized curves that Zhang shows in FIG. 2 are just the background research that provides the context and reasoning for why Zhang chose to assume that each individual sensor will have “a non-linear curve” for its own calibration curve and why Zhang chose to use a “five-point piecewise linear approximation” to create each sensor’s actual curve. Zhang, [0064], [0040]. The general illustration in FIG. 2 of Zhang’s research results merely “represent[s] a *typical* life cycle” of a hypothetical generic sensor, and illustrates generically that the response “tends to become non-linear” in Phase II and “tends to change less and less with respect to glucose concentration”

in Phase III, as visually illustrated by arrows 5a and 5b in FIG. 2. Zhang, [0033], [0037], [0039].



This is just a conceptual illustration of “calibration curve *shapes* of each phase of the sensor life” (Zhang, [0033])—there are no numbers (e.g., current or glucose concentration values) given in FIG. 2, and Zhang does not disclose storing or applying any actual curves from FIG. 2 in an individual sensor system. Zhang uses FIG. 2 as a demonstration for the reader that Zhang’s sensors tend to spend most of their useful life (“periods of one year or more”) in a non-linear Phase II (Zhang, [0037]-[0038]), and that the sensors’ responses tend to move downward toward a lowest point (arrow 5a) and then upward after that (arrow 5b).

Beyond illustrating that background, the curves in Zhang’s FIG. 2 have no role in an individual sensor system, and Zhang nowhere says they are stored in a

sensor system's memory. As discussed above (Section IV.A.2, *supra*), Zhang's recalibration techniques rely on *measuring* (e.g., using fingerstick tests) the actual current response of the sensor as it changes at each point in time during use of the sensor system, and then mathematically adjusting the sensor's calibration curve to fit the *measured* blood glucose meter values by piecewise linear regression. Zhang notes that "sensor recalibrations" are "based on independent characteristic values (e.g., blood meter values)" and "with use of the expected normalized calibration curves as ... described in greater detail ... with respect to FIGS. 4 and 5." Zhang, [0033]. As discussed above (Section IV.A.2, *supra*), Zhang's detailed description of the recalibration process with respect to FIGs. 4-5 makes clear that the way the expected normalized calibration curves are used (Zhang, [0033]) is merely to motivate the fact that the sensor's actual calibration curve is assumed to be non-linear and approximated by five-point piecewise linear regression and that the variable H in the curve-adjustment equation is set to different values when the actual measured curve is observed to be moving downward vs. moving upward. Zhang, [0041]-[0062], [0040], [0059].

In a different section of the Petition on the preceding claim element, Abbott alleges that Zhang discloses in [0015]-[0016] that its sensor system has "a memory that stores 'the expected normalized calibration curves.'" Petition, 35. But Zhang at [0015]-[0016] says no such thing and does not mention "the expected

normalized calibration curves.” In that passage, Zhang states that the sensor’s very first calibration curve is “generat[ed] ... based on a priori empirical values” of “sensors similar to the sensor being calibrated,” but this is only the sensor’s *initial* curve that is set as a starting point—it is unrelated to any change over time (and thus similarly separate from and unrelated to the curves illustrating typical changes over time in FIG. 2). *See* Zhang, [0015]-[0016] & claims 34 & 36 (also cited by Petition at 35) (reciting *initially* “generating a calibration curve based on a priori empirical values” but then *recalibrating* using “data values from the sensor”—e.g., fingerstick reference measurements). As discussed above and in Section IV.A.2, *supra*, for recalibrating the sensor as its response changes over time, Zhang relies on *measuring* how the response has changed by obtaining reference blood glucose meter measurements, and does not use stored curves.

Abbott’s Petition at 35 further quotes Zhang’s statement at [0033] that recalibrations are performed “with use of the expected normalized calibration curves,” but the Petition omits the rest of Zhang’s sentence: “*as will be described* in greater detail below with respect to FIGs. 4 and 5.” As discussed above in this Section, Zhang’s description of FIGs. 4-5 at [0041]-[0062] make clear that the recalibration process does not involve storing curves from FIG. 2 in an individual sensor system’s memory, and relies instead on fitting linear regressions to fingerstick reference measurements at each point in time. The only “use” of FIG. 2

is as background for the choice of five-point piecewise linear regression and values for the variable H. *See* discussion above and in Section IV.A.2, *supra*.

Finally, the Petition at 35 cites Zhang at [0007] and [0013] as discussing adjusting a curve based on “an array of data,” but that array has nothing to do with FIG. 2. As discussed above (Section IV.A.2, *supra*) and elsewhere throughout Zhang, this “calibration array is compiled from *independent glucose readings*, such as *readings from a blood glucose meter* taken simultaneously during the life of the sensor” ... “over a period of time, such as, for example, three weeks.” Zhang, [0041]. This array of *blood glucose meter* measurements (e.g., fingersticks) is how the system *measures* what the sensor’s actual response currently is, based on the recent measurements taken while the sensor has been in use (e.g., over the most recent three weeks of the individual sensor’s life).

Zhang thus does not disclose that the curves illustrated in FIG. 2 are stored in the memory of Zhang’s sensor system, and Abbott’s Petition fails to demonstrate that it does.

Abbott’s Petition thus fails to establish that Ground 1 meets the requirements of independent claim 1 and its challenged dependents.

2. The Petition Fails to Demonstrate That Zhang “*calibrat[es] the sensor data*” Using Zhang’s FIG. 2 Curves As Alleged (Claim 14 and Dependents)

Independent claim 14 requires “*calibrating the sensor data based at least in part on a priori information*” that “*comprises a profile associated with a drift in a sensitivity*” of the sensor “*over time.*” Abbott’s Petition alleges that Zhang meets these limitations because allegedly Zhang’s recalibration technique “adjusts the [sensor’s] calibration curve over time,” where “[e]ach adjustment involves a shift, from a normalized calibration curve with one shape to a different normalized calibration curve having a different shape,” and the “normalized calibration curve shapes” are those in Zhang’s FIG. 2. Petition, 51-52.

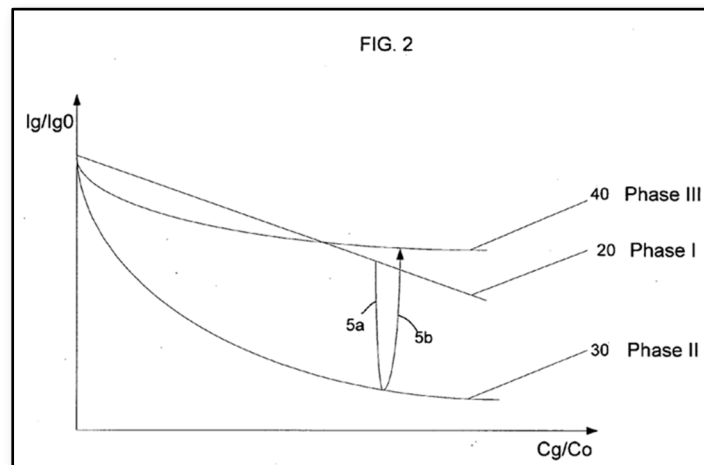
But as discussed above (Section IV.C.1, *supra*, regarding claim 1), the curves illustrated in Zhang’s FIG. 2 are ***not*** applied to recalibrate an individual sensor system at points in time during the sensor’s use, and the actual recalibration of an individual sensor system does ***not*** adopt any of the FIG. 2 curves. While the curves in FIG. 2 illustrate Zhang’s observations in research on sensors in general, Zhang does not know what a particular individual sensor’s response will actually be at particular points in time. Therefore, Zhang’s system ***measures*** the sensor’s actual response at each point in time using reference blood glucose meter measurements, and mathematically adjusts the sensor’s calibration curve to match those recent measurements. Zhang’s system thus does not do what Abbott’s

Petition alleges it does to meet claim 14, for similar reasons that it does not meet claim 1 in the manner Abbott's Petition alleges.

Abbott's Petition thus fails to establish that Ground 1 meets the requirements of independent claim 14 and its challenged dependents.

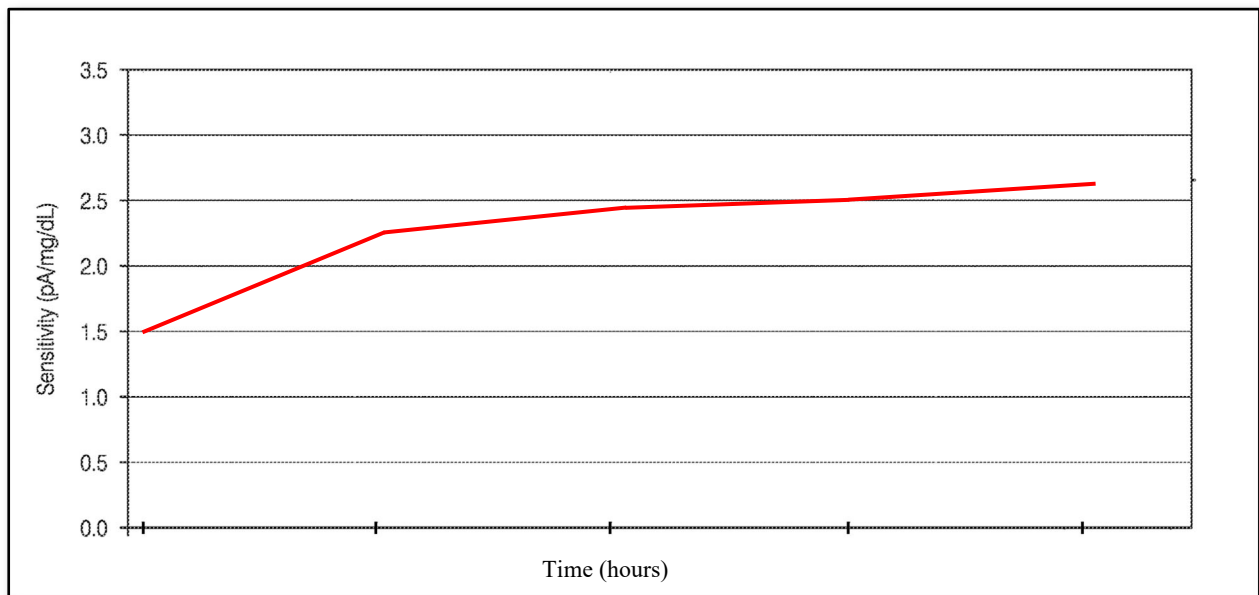
3. The Petition Fails to Demonstrate That Zhang Stores or Uses a Claimed "*profile*" (All Challenged Claims)

Independent claim 1 requires that the sensor system's "*memory stores information associated with a profile*" that meets further recited requirements regarding "*a priori information related to expected sensitivity changes,*" and independent claim 14 requires the use of "*a profile associated with a drift in a sensitivity of the ... sensor over time.*" Abbott's Petition asserts that "Zhang's profile" is "the three curves in FIG. 2 and the shifts" between them. Petition, 39, 51.

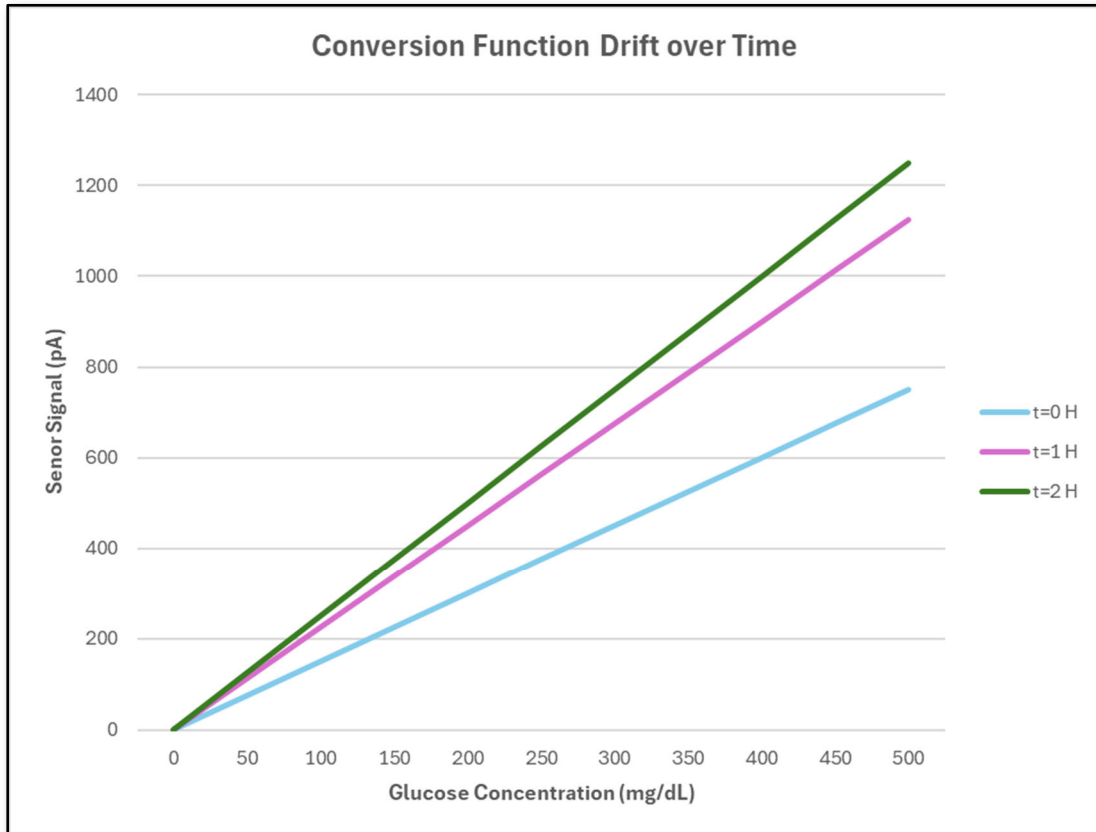


But Zhang's FIG. 2 curves and the shifts between them are not a "*profile*" as that term is used in the '031 Patent.

As discussed above (Section II.A, *supra*), an expected sensitivity change “*profile*” or drift “*profile*” in the ’031 Patent provides “an expected pattern and/or amount of sensitivity change/drift over time” (EX1001, 213:9-25) that specifies what the sensitivity is expected to be and thus what sensitivity to use in the conversion function at each future point in time while the sensor is used. EX1001, 216:44-48. In particular, the “*profile*” is representable as “a line having a slope and/or curvature” that specifies how the sensor’s sensitivity will change over the time period spanned by the line, where the line’s “slope and/or curvature” may be different for different time periods spanned by the line. EX1001, 216:48-52. Such a sensitivity drift “*profile*” could be illustrated as below (using exemplary sensitivity values from the experiment disclosed in Example 11 (252:15-253:2) and FIG. 25 of the ’031 Patent):



It should be appreciated that the sensitivity change/drift “*profile*” (which plots a parameter’s change over *time*) is not the sensor’s conversion function (which plots the sensor’s electrical output for different glucose concentrations *at a given point in time*). The drift “*profile*” is a plot of *changes* in the sensor’s conversion function, representable as a line (having slope and/or curvature) whose horizontal axis is time, as in the illustration above. In that above example, the sensitivity drift “*profile*” illustrated by the line specifies that the sensor’s conversion function will have a slope (sensitivity) of 1.5 at time 0 hours, a slope of ~2.25 at time 1 hour, and a slope of nearly 2.5 at time 2 hours. These changing conversion functions could be illustrated as in the following example:



As discussed above (Section II.A, *supra*) using such a drift “*profile*” to specify the conversion function over time allows the ’031 Patent’s “sensor [to] be completely calibrated e.g. without the need for reference analyte values” (fingersticks), because—unlike in Zhang—the parameters for the ’031 Patent’s time-varying conversion function (including sensitivity) “are known a priori” and therefore “matched pairs are not needed for calibration.” EX1001, 140:28-34.

Abbott’s Petition acknowledges that the claimed “*profile*” of *a priori* sensitivity information in the ’031 Patent is representable as “a line having a slope and/or curvature” (where the line’s slope/curvature can differ for different time periods) (Petition, 52 n.19), but fails to demonstrate that Zhang’s FIG. 2 “curve shapes and the shifts between them” are such a “*profile*.” Indeed, they are not.

To the extent that Abbott had tried to argue that *each curve* (or all of them together) in Zhang’s FIG. 2 is a line having a slope and/or curvature and therefore is a claimed “*profile*,” that argument fails because each curve in Zhang’s FIG. 2 can only represent a sensor response *at a single point in time*. The horizontal axis in Zhang’s FIG. 2 is not time; it is normalized glucose concentration. Zhang, [0035]. Any line/curve in Zhang’s FIG. 2 represents what a sensor’s output would be at different glucose concentrations at one point in time (like in a single conversion function as discussed above), and does not span any change over time. Even if it were assumed that each curve in Zhang’s FIG. 2 has some sensitivity as

Abbott asserts (Petition, 37-38 n.13), that curve would only represent a sensitivity at a given point in time, and not how sensitivity *changes* or *drifts* over time. Thus, no curve in Zhang’s FIG. 2 is a “*profile*” as in the ’031 Patent and the challenged claims. See claim 1 (“*profile*” based on “*a priori information related to expected sensitivity changes*”), claim 14 (“*profile associated with a drift ... over time*”).

Abbott’s Petition asserts that “[e]ach shift between curve shapes” in Zhang’s FIG. 2 “represents a change in sensitivity over time” (Petition, 51), but Abbott does not attempt to explain how or why those *shifts* between curve *shapes* are a line having a slope and/or curvature so as to constitute a claimed “*profile*.” In contrast to linear conversion functions which each have a single slope (sensitivity), such that the parameter’s change over time can be plotted as a line, the non-linear shapes in Zhang’s FIG. 2 are more complex, and Abbott’s Petition presents no explanation whatsoever for how the “shift[s]” between those non-linear curves are (or even could be) formed as a claimed “*profile*.”

For this additional reason, Abbott’s Petition fails to establish that Ground 1 meets the requirements of any challenged claim.

4. Ground 1 Presents No Alternative Obviousness Arguments for the “*profile*”-Related Limitations

Abbott’s Petition only asserts that Zhang *discloses* the “*profile*”-related limitations of the challenged independent claims (labeled “1[e]” and “14[d]” in Abbott’s Petition), and does not present any alternative obviousness arguments for

these limitations. Petition, 36-40, 50-52. Therefore, the Petition’s assertion in Ground 1 that the challenged claims are “rendered obvious by Zhang” (Petition, 7) fails for each of same the reasons as its anticipation assertion, discussed in this Section IV.C above.

V. GROUND 2 (BASED ON SHIN) FAILS AS TO ALL CHALLENGED CLAIMS

Ground 2 alleges that all challenged claims are “[a]nticipated and/or rendered obvious by Shin.” Petition, 7. Ground 2 fails to demonstrate unpatentability of any challenged claim, because Shin does not meet the *profile*-related limitations of independent claims 1 and 14.

A. Overview of Shin (EX1008)

Shin discusses “[a] method of calibrating glucose monitor data” that uses “reference glucose values” obtained from “a blood glucose meter”—i.e., ““finger stick[s].”” Shin, Abstract, [0168]. Like Zhang (discussed in Section IV.A.2, *supra*), Shin’s system does not know *a priori* what calibration factors to use at different points in time during the life of the system’s glucose sensor. Shin’s system must obtain fingerstick reference measurements during the sensor’s use to *measure* what the sensor’s response currently is and then determine its calibration factors to match that response.

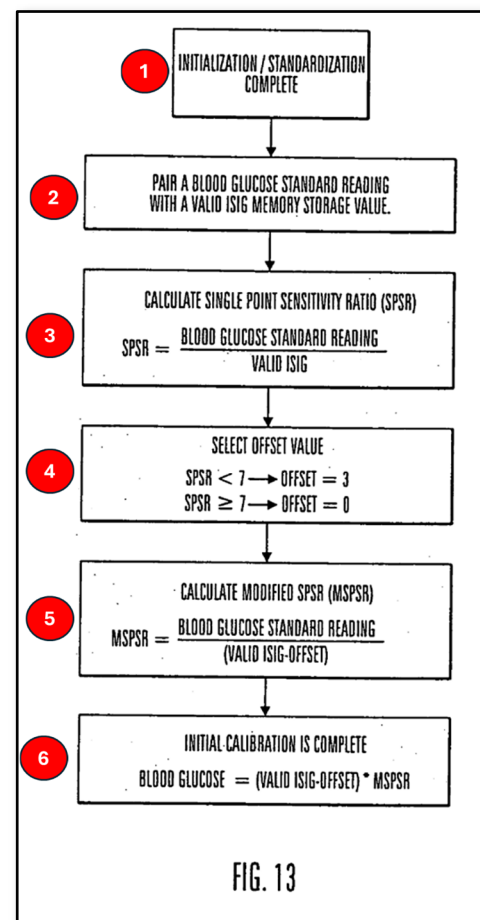
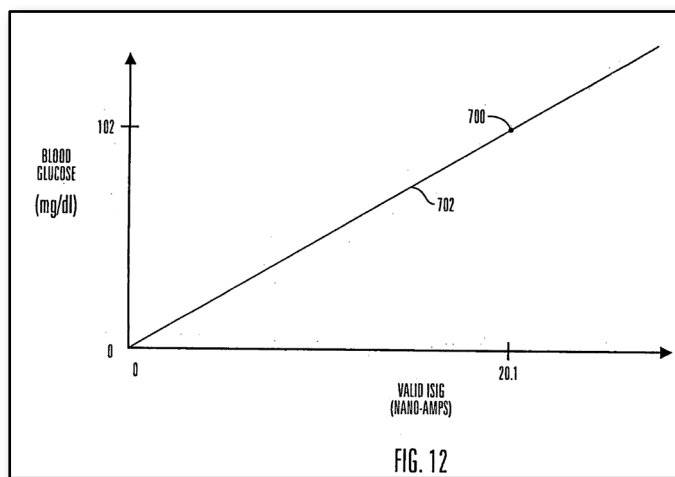
Shin’s “glucose monitor 100 measures a continuous electrical current signal (ISIG) generated by the glucose sensor 12 relative to a concentration of glucose

present in the subcutaneous tissue of the user's body.” Shin, [0069]. “To calibrate [Shin's] glucose monitor 100, the calibration factor called a sensitivity ratio (SR) (blood glucose level/Valid ISIG value) is calculated for a particular glucose sensor 12. The SR is a calibration factor used to convert the Valid ISIG value (Nano-Amps) into a blood glucose level (mg/dl or mmol/l).” Shin, [0082]. To perform this calibration, “the user obtains a blood glucose reference reading from a common glucose meter” (i.e., fingerstick), which “is used as a reference for calibration.” Shin, [0083]. “[B]lood glucose reference readings are collected several times per day but a new calibration factor is calculated only once per day.” Shin, [0086]. The sensor set is used for just “one to seven days before replacement.” Shin, [0065].

For calibration, Shin's system “must temporally correlate the blood glucose reference reading with a Valid ISIG value to establish a paired calibration data point.” Shin, [0083]. Embodiments in Shin can calibrate using “a single-point calibration technique” using “only one paired calibration data point” (i.e., one fingerstick) or “a modified linear regression technique” using “two or more paired calibration data points” (i.e., two or more fingersticks). Shin, [0087]. Shin's “[p]referred embodiments use [the] single-point calibration technique ... immediately after initialization/stabilization” when “only one” fingerstick measurement “is available,” and use the “linear regression technique” later “when

two or more” fingerstick measurements “are available.” Shin, [0087]. Abbott’s Petition focuses on the single-point calibration technique.

Shin’s single-point calibration technique, shown in FIGs. 12-13 reproduced and annotated below, “is based on the assumption that the Valid ISIG will be 0 when the blood glucose is 0,” such that the sensor’s linear response to glucose concentrations is a straight “line 702” starting at “the point (0,0)” and passing through the “single paired calibration point 700” (i.e., the fingerstick value). Shin, [0088]. “The slope of [this] line ... is the single-point sensitivity ratio (SPSR).” Shin, [0088]. This is the third step in FIG. 13, below.



If the SPSR calculated in step 3 of FIG. 13 “is less than 7, an offset value of 3 is used” to modify the SPSR to make it slightly larger, resulting in “a modified SPSR (MSPSR).” Shin, [0093]. The MSPSR is calculated as:

$$MSPSR = \frac{\text{Blood Glucose Reference Reading}}{(\text{Valid } ISIG - \text{offset})}$$

Shin, [0093]. This is step 5 in FIG. 13 above, after which “calibration is complete.” Shin, FIG. 13 (box 6).

Shin further states in [0103]:

In preferred embodiments the MSPSR is compared to a valid sensitivity range to determine if the newly calculated MSPSR is reasonable. In order to identify potential system problems, a valid MSPSR range of 1.5 to 15 is employed. This range has been determined based upon valid glucose sensor sensitivity measurements made in-vitro. MSPSR values outside this range result in a calibration error alarm (CAL ERROR) to notify the user of a potential problem. Other valid sensitivity ranges may be applied depending on the types of sensors to be calibrated, the range of acceptable sensitivity levels for the various sensor types, the manufacturing consistency expected for the sensors, environmental conditions, how long the sensor has been in use, or the like.

Shin provides no further detail on these “valid sensitivity ranges” or their implementation.

B. Ground 2 Fails Because the Petition Does Not Establish That Shin Discloses or Renders Obvious the “Profile”-Related Limitations of Independent Claims 1 and 14

The system of claim 1 (and challenged dependent claims 2, 4, and 6-13) requires that the “*memory stores information associated with a profile wherein the profile is based at least in part on a priori information related to expected sensitivity changes associated with a length of time the ... sensor has been inserted into the body of the host.*”

The method of claim 14 (and challenged dependent claims 15 and 20-22) requires “*calibrating the sensor data based at least in part on a priori information, wherein the a priori information comprises a profile associated with a drift in a sensitivity of the ... sensor over time.*”

Ground 2 of Abbott’s Petition alleges that Shin discloses each of these limitations (Petition, 58-60, 69-71), and does not present any alternative obviousness argument.

For the reasons discussed below, Abbott’s assertions fail.

1. The Petition Fails to Demonstrate That Shin Discloses a “*profile*” Based on “*a priori information related to expected sensitivity changes*” (Claim 1 and Dependents) or “*associated with a drift in a sensitivity*” (Claim 14 and Dependents)

Abbott’s Petition’s assertion that Shin discloses the “*profile*”-related limitations of claims 1 and 14 relies entirely on paragraph [0103] of Shin. Petition,

58-60, 69-71. That paragraph discusses a check that Shin’s system performs on the MSPSR (modified single-point sensitivity ratio) calculated in Shin’s single-point calibration procedure, “to determine if the newly calculated MSPSR is reasonable.” Shin, [0103]. The check compares the calculated MSPSR “to a valid sensitivity range” of “1.5 to 15” which is “based upon valid glucose sensor sensitivity measurements made in-vitro” (i.e., not changing over time). Shin, [0103]. Shin says that “[o]ther valid sensitivity ranges may be applied depending on” many factors, one of which is “how long the sensor has been in use.” Shin, [0103]. Beyond that, Shin says nothing more about these “[o]ther valid sensitivity ranges.”

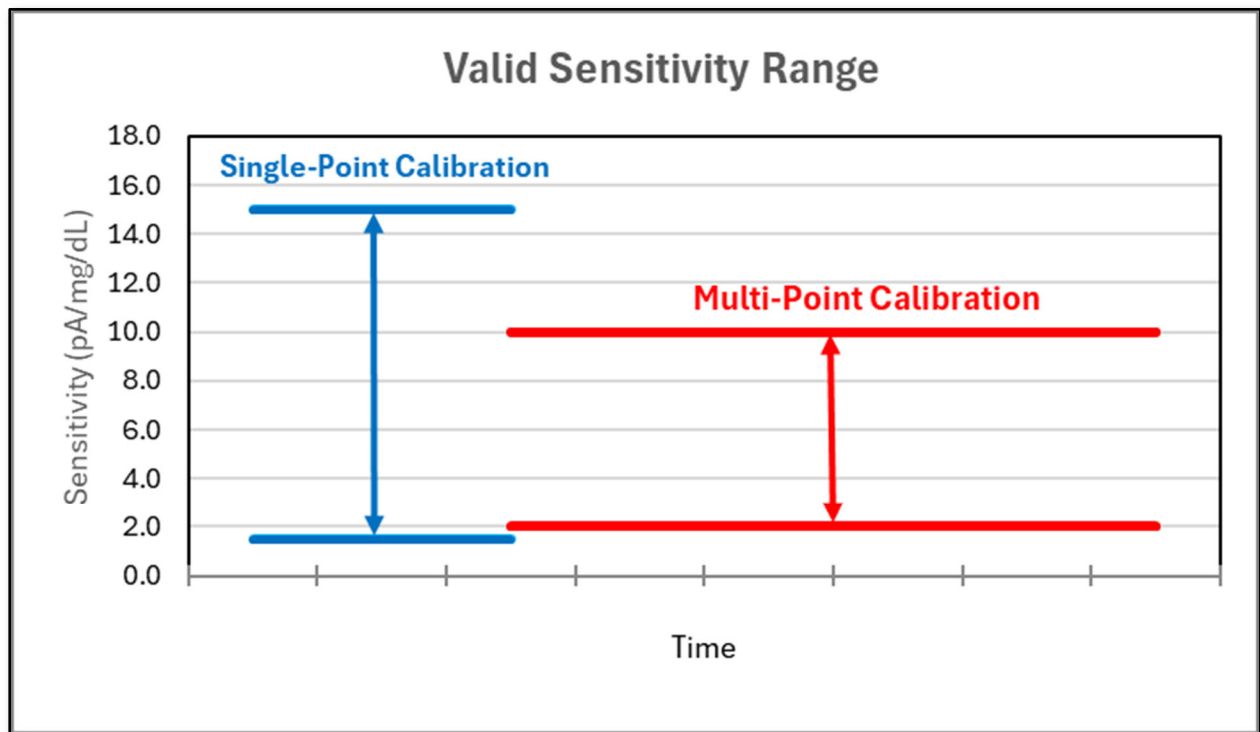
Abbott’s Petition alleges that “different valid sensitivity ranges that depend on the length of time of sensor use constitute ‘a profile.’” Petition, 59. And the Petition alleges that “the ranges relate to expected sensitivity changes over time” because “different valid sensitivity ranges can be used, each range associated with a length of time of sensor use.” Petition, 59. But even if Shin applied different “valid sensitivity ranges” at different lengths of time of sensor use, that does not mean the “valid sensitivity ranges” are based on a priori information related to “*expected sensitivity changes*.”

Claim 1 does not recite “*valid* sensitivity changes” or “ranges”—it specifically requires a priori information related to “*expected sensitivity changes*.”

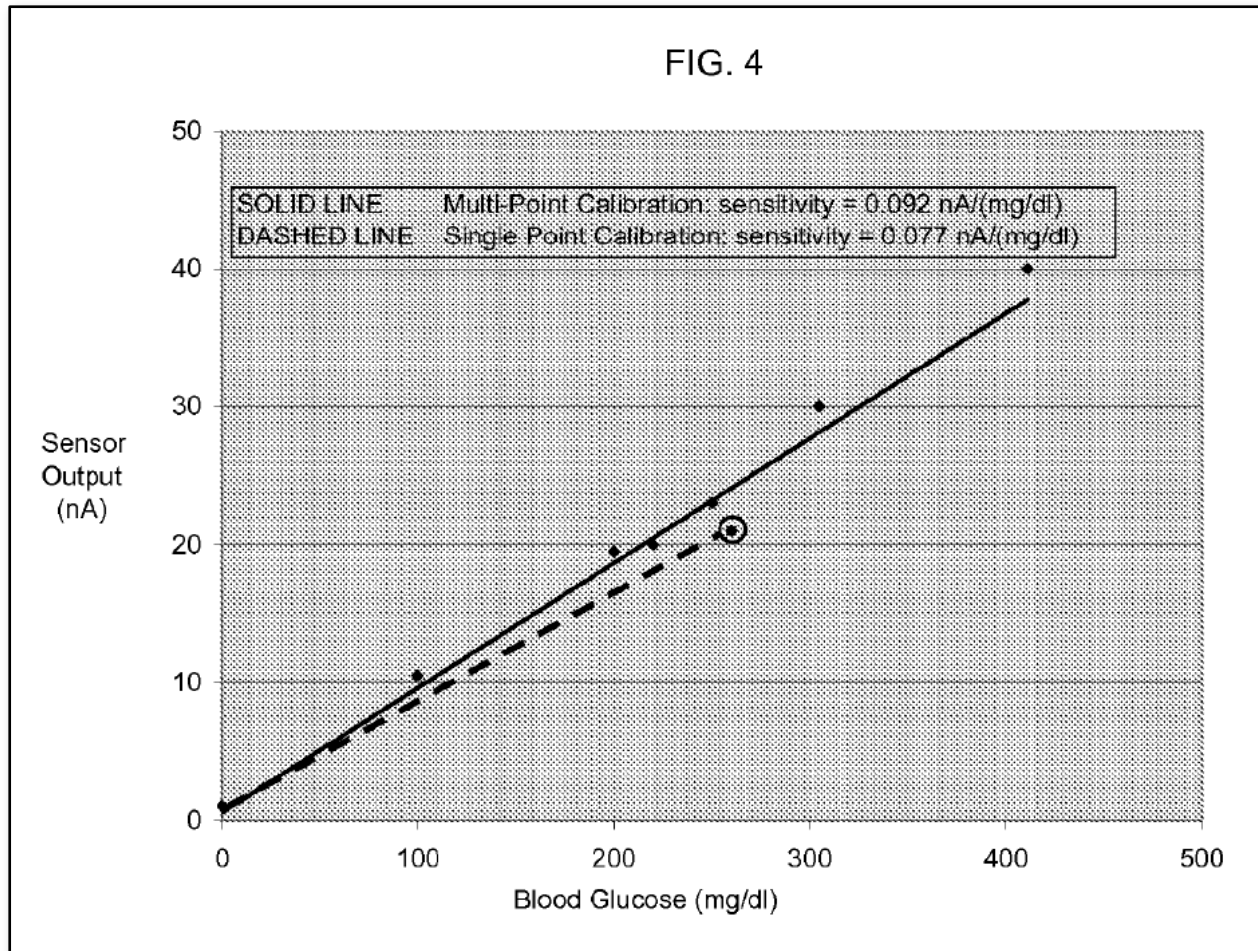
Specifying that different ranges of sensitivities will be considered “valid” at different times (for whatever reason Shin considers those ranges “valid,” which Shin does not explain) in no way discloses that those ranges are based on “*expected sensitivity changes*.” As discussed above (Section V.A, *supra*), Shin in fact has no knowledge of what the sensor’s sensitivity is *expected* to be at various points in time or how it is *expected* to change over time—that is why Shin’s system relies on periodically *measuring* the sensor’s response with reference to fingersticks (blood glucose meter readings) to determine what the sensor’s sensitivity is.

The only example in Shin of “valid sensitivity ranges” at different points in time does not indicate that the ranges reflect “*expected sensitivity changes*,” and instead suggests that the ranges reflect merely different levels of accuracy in measuring the sensor’s sensitivity when using more measurement data over time. As discussed above (Section V.A, *supra*), Shin teaches that preferably single-point calibration is used when the sensor is first “initializ[ed]/stabiliz[ed]” and “only one paired calibration data point is available,” and then “modified linear regression” is used later “when more than one paired calibration data point is available.” Shin, [0087], [0104]. And the later sensitivity values are calculated using “a weighted average” of previous sensitivity values. Shin, [0141]-[0147]. Shin states that the “valid sensitivity range” for the initial single-point calibration is “1.5 to 15” and

the “valid sensitivity range” for the later multi-point calibration is “2.0 to 10.0,” as illustrated below. Shin, [0103], [0114]. Notably, the later range is narrower, but does not extend higher or lower than the earlier range.



POSAs knew that “a multi-point calibration may lead to better accuracy than a single point calibration” in *measuring* a sensor’s sensitivity, even when that sensitivity is not changing. See EX2009, [0039]. This is because single-point calibration uses only one data point, which is more likely to produce a sensitivity calculation that differs from the sensor’s actual sensitivity due to noise or other factors, whereas a multi-point method that averages values is more likely to produce a measurement closer to the actual sensitivity, as the figure below demonstrates. EX2009, [0042]-[0044], [0021]-[0024].

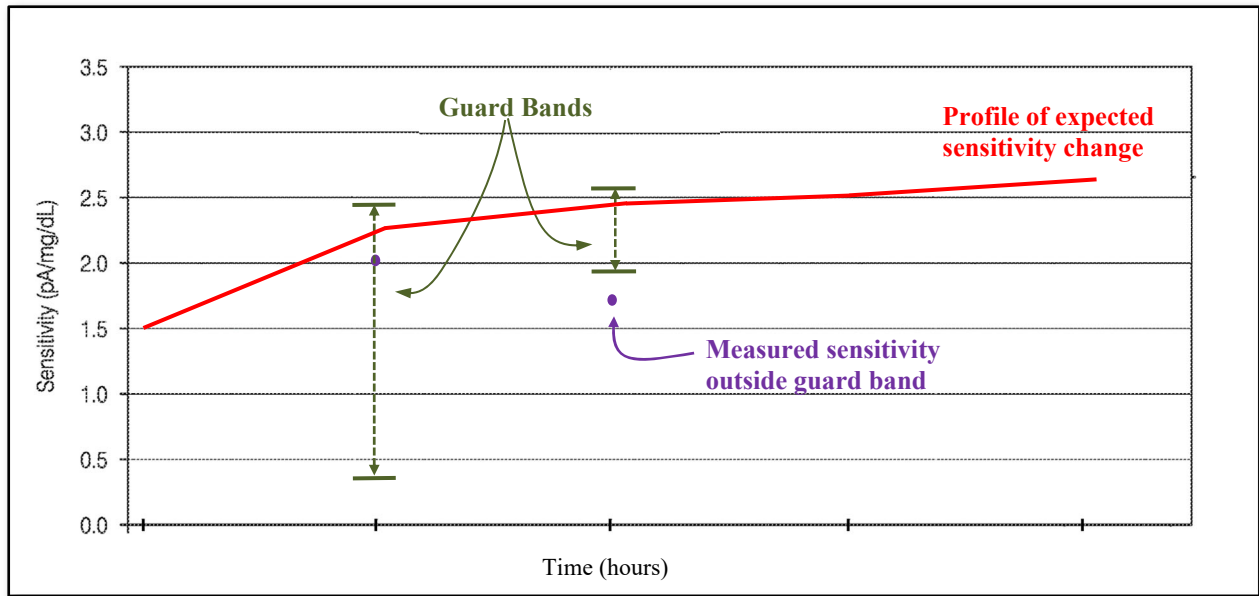


EX2009, FIG. 4, showing single-point measurement (dashed line) deviating more from actual sensitivity than multi-point measurement (solid line).

POSAs thus knew that Shin’s later multi-point calibrations would more accurately measure sensitivity than the initial single-point calibration, allowing the range of sensitivity *measurements* that are deemed “valid” to be set narrower for later points in time, regardless of whether the sensor’s actual sensitivity is expected to drift at all. Shin’s discussion of different “valid sensitivity ranges” at different times in no way discloses that those ranges are different because of “*expected sensitivity changes*” of the sensor.

Abbott's Petition quotes the '031 Patent as disclosing that "[i]n some embodiments, the a priori sensitivity information defines a range (e.g., within boundaries and/or guard bands) of acceptable change (increase and/or decrease) in sensitivity" (EX1001, 213:33-36) and that "[i]n one embodiment, the cone of possible sensitivity values is defined in terms of a range of allowable (or feasible) sensitivity change for a time point during a sensor session" (EX1001, 213:50-53). Petition, 59. But neither of those sentences is discussing the claimed "*profile*" that is based on "*a priori information related to **expected** sensitivity changes.*" As discussed above (Section II.A, *supra*), the '031 Patent discusses the claimed "*profile*" and the guard bands as *different* types or parts of the total *a priori* information that can be applied in calibration. The "expected profile" is "e.g., an expected pattern and/or amount of sensitivity change/drift over time" (EX1001, 213:9-25) representable as "a line having a slope and/or a curvature" that specifies what the sensor's sensitivity is expected to be at various points in time (EX1001, 216:48-52), while the "guard bands" or "cone" define an amount of "[d]eviation *from* the expected profile [that] can be indicative of a failure of a portion of the integrated system, a detrimental change in the host's condition, and/or the like" (EX1001, 213:25-53).

The below illustrates the distinction:



Nothing in Abbott’s Petition demonstrates that the claimed “*profile*” based on “*a priori information related to expected sensitivity changes*” can be met with anything other than information related to “*expected sensitivity changes.*” Shin’s “*valid* sensitivity ranges” are not “*expected sensitivity changes,*” and do not meet the requirements of claim 1.

For the same reasons, Shin’s “valid sensitivity ranges” are also not “*a profile associated with a drift in a sensitivity*” of the sensor, and do not meet the requirements of claim 14. *See* Petition, 70 (alleging the “valid sensitivity ranges” meet claim 14’s “*profile associated with a drift*” because they allegedly “relate[] to expected sensitivity changes”).

Abbott’s Petition thus fails to establish unpatentability of any challenged claim under Ground 2.

2. The Petition Fails to Demonstrate That Shin “*calibrat[es] the sensor data*” Using Shin’s Valid Sensitivity Ranges As Alleged (Claim 14 and Dependents)

Independent claim 14 requires “*calibrating the sensor data based at least in part on a priori information*” that “*comprises a profile associated with a drift in a sensitivity ... over time.*” Again, Abbott’s Ground 2 relies entirely on Shin’s paragraph [0103] to allegedly meet these limitations. Petition, 70-71. Abbott’s Petition alleges that Shin’s “valid sensitivity ranges are a profile associated with a drift in sensor sensitivity over time.” Petition, 70. And the Petition alleges that Shin “*calibrat[es] the sensor data*” **based on** Shin’s “valid sensitivity ranges” because allegedly “[a]s a result of this comparison [of the MSPSR to a valid sensitivity range], the system either accepts or rejects the MSPSR, and if the MSPSR is accepted, the system calibrates sensor data.” Petition, 70 (citing Shin at “¶0103”).

But Shin’s paragraph [0103] does not say that the system “rejects the MSPSR” if it is outside the range, and does not say that the system only “calibrates sensor data” if the MSPSR is inside the range. Shin’s paragraph [0103] only says that “MSPSR values outside this range result in a calibration error alarm (CAL ERROR) to notify the user of a potential problem.” Presenting an “alarm” to “**notify** the user of a potential problem” is not the same as rejecting the MSPSR and refusing to calibrate sensor data. The system may continue calibrating sensor

data using the calculated MSPSR until such time as the user decides to take some (unspecified) action on the “potential problem,” for example. Abbott’s Petition does not attempt to prove otherwise.

Abbott’s Petition thus fails to substantiate that Shin does what Abbott alleges it does to meet claim 14; therefore Ground 2 fails as to claim 14 and its challenged dependents.

3. The Petition Fails to Demonstrate That Shin Stores or Uses a Claimed “*profile*” (All Challenged Claims)

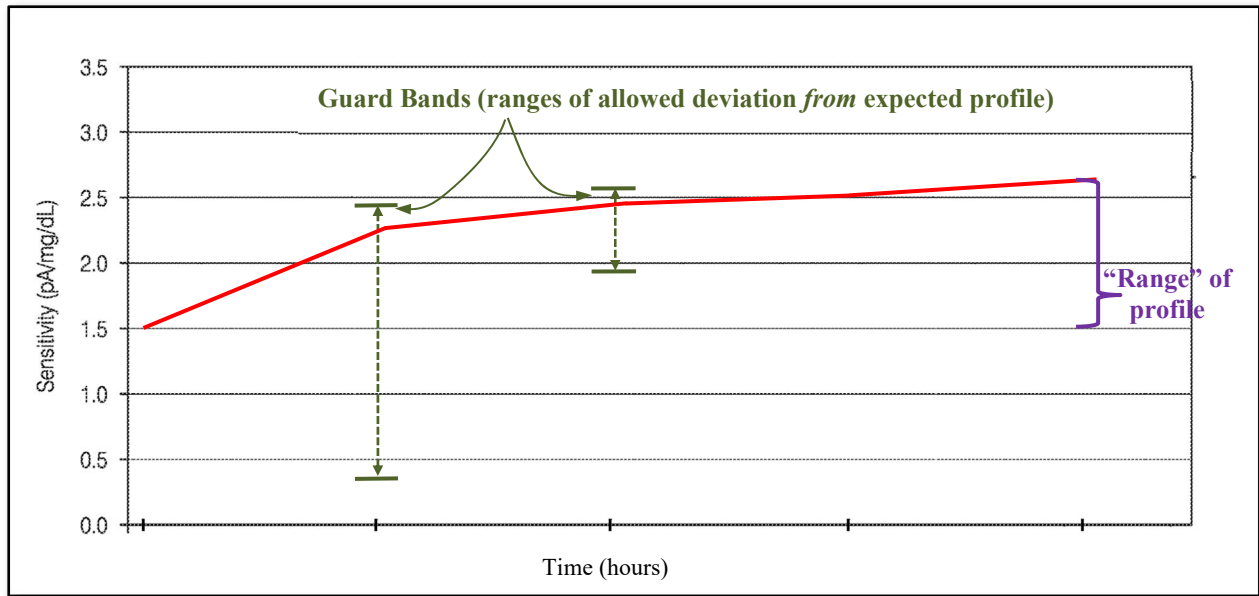
Independent claim 1 requires that the sensor system’s “*memory stores information associated with a profile*” that meets further recited requirements regarding “*a priori information related to expected sensitivity changes,*” and independent claim 14 requires the use of “*a profile associated with a drift in a sensitivity of the ... sensor over time.*” Abbott’s Petition asserts that Shin’s “valid sensitivity ranges” are the claimed “*profile.*” Petition, 59, 70. But the claimed “*profile*” does not encompass “valid sensitivity ranges” like Shin’s.

As discussed above (Sections II.A, IV.C.3, V.B.1, *supra*), an expected sensitivity change “*profile*” or drift “*profile*” in the ’031 Patent provides “an expected pattern and/or amount of sensitivity change/drift over time” (EX1001, 213:9-25) and is representable as “a line having a slope and/or curvature” that specifies how the sensor’s sensitivity will change over the time period spanned by the line. EX1001, 216:48-52. Shin’s “valid sensitivity ranges” are indisputably

not representable as a line having a slope and/or curvature, and are not such a claimed “*profile*.”

As also discussed above (Sections II.A, V.B.1, *supra*), the ’031 Patent individually describes and distinguishes between the claimed sensitivity change/drift “*profile*” on the one hand and the ranges (e.g., guard bands or cones) of acceptable deviation from the “*profile*” on the other, including in the passages of the specification that Abbott’s Petition cites:

At 213:13-25 (quoted at Petition, 59), the specification discusses that “sensor sensitivity tends to increase over time, wherein the increase tends to occur within an expected range,” referring to the vertical span over which the claimed “*profile*” (line) increases over time (as illustrated below). That is different from the subsequently discussed “range” of the “boundaries and/or guard bands” which define an amount of “[d]eviation *from* the expected profile” and are not the claimed “*profile*” itself. EX1001, 213:25-36 (also quoted at Petition, 59).



At 213:50-53 (quoted at Petition, 59), the specification is continuing to discuss the “range of allowable (or feasible) sensitivity change for a time point” as part of the allowable “[d]eviation *from* the expected profile” which is not the claimed “*profile*” itself, as already discussed in Section V.B.1 above. And at 216:44-61 (cited at Petition, 59), as discussed previously, the specification describes the claimed “*profile*” as representable as “a *line* having a slope and/or curvature,” separate and different from the “*cone* of possible acceptable and/or feasible sensitivity changes” that defines “a range of *acceptable* change in sensitivity.” The cone may be anchored to the “*profile*” as a range *around* the “*profile*,” but that range is not the “*profile*” itself.

“Valid sensitivity ranges” as in Shin thus are not a “*profile*” as described and claimed in the '031 Patent. The system described in the '031 Patent’s specification

has ***both*** a claimed “*profile*” and acceptable ranges of deviation ***from*** that “*profile*.” Shin has no such “*profile*,” and has only absolute “ranges” that are specified as “valid,” for reasons Shin does not explain.

For this additional reason, Abbott’s Petition fails to establish that Ground 2 meets the requirements of any challenged claim.

4. Ground 2 Presents No Alternative Obviousness Arguments for the “*profile*”-Related Limitations

Abbott’s Petition only asserts that Shin ***discloses*** the above-discussed “*profile*”-related limitations of the challenged independent claims (labeled “1[e]” and “14[d]” in Abbott’s Petition), and does not present any alternative obviousness arguments for these limitations.⁴ Petition, 58-60, 69-71. Therefore, the Petition’s assertion in Ground 2 that the challenged claims are “rendered obvious by Shin” (Petition, 7) fails for the same the reasons as its anticipation assertion, discussed in this Section V.B above.

VI. CONCLUSION

Abbott’s Petition fails to establish unpatentability of any challenged claim. Institution should be denied.

⁴ The Petition alleges in discussing 1[e] that storing Shin’s valid sensitivity ranges in memory would have been obvious (Petition, 60), but that would not remedy the deficiencies discussed in Section V.B above.

Respectfully submitted,
DexCom, Inc.

Date: 2024-09-18

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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 13,926 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: September 18, 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 September 18, 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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