

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE INC.,
Petitioner,

v.

DEXCOM, INC.,
Patent Owner.

IPR2024-00891
Patent 11,020,031 B1

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

JURGOVAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner Abbott Diabetes Care Inc. filed a Petition (Paper 1, “Pet.”) pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of claims 23–46 (“the challenged claims”) of U.S. Patent No. 11,020,031 B1 (Ex. 1001, “the ’031 patent”).

Patent Owner DexCom, Inc. filed a Preliminary Response (Paper 7, “Prelim. Resp.”). In its Preliminary Response, Patent Owner argues that the Petition fails to satisfy the requisite threshold for instituting review on the merits. Patent Owner also asserts that the Petition should not be instituted due to the existence of a parallel petition filed by Petitioner against the same patent.

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

II. PRELIMINARY MATTER

In IPR2024-00890, Petitioner filed on the same date a parallel petition to challenge claims 1–2, 4, 6–15, and 20–22 of the ’031 patent on grounds similar to those asserted in this proceeding. In its “Explanation of Parallel Petitions” (Paper 3), Petitioner provides the following table to explain the claims challenged and grounds of unpatentability asserted in each petition:

Petition	Challenged claims of the '031 patent	Ground
Petition 1: IPR2024-00890	1-2, 4, 6-15, 20-22	Ground 1: §102 and/or §103 over Zhang
	1-2, 4, 6-15, 20-22	Ground 2: §102 and/or §103 over Shin
Petition 2: IPR2024-00891	23-46	Ground 1: §102 and/or §103 over Zhang
	23-46	Ground 2: §102 and/or §103 over Shin

Paper 3, 2.

We decided to institute *inter partes* review of claims 1–2, 4, 6–15, and 20–22 of the '031 patent in IPR2024-00890. We now address whether Petitioner has shown that a second parallel petition challenging claims 23–46 of the '031 patent, specifically, the Petition in this case, is warranted.

Petitioner contends that two petitions were required because of the large number of claims (40 claims, including five independent claims) asserted by Patent Owner against Petitioner in district court litigation. Paper 3, 1. Petitioner states that due to the large number of claims and their lengthy claim elements, additional words were needed to challenge the asserted claims despite Petitioner's best efforts to narrow the patentability issues presented to the Board. *Id.* at 2.

Petitioner further contends that “the burden of addressing the grounds of both petitions would not be substantially greater than the burden of addressing the grounds of either petition alone” and “the Board and the parties can obtain efficiencies by holding a single oral hearing and consolidating depositions in both proceedings.” *Id.* at 2–3.

In its “Patent Owner's Response to Petitioner's Explanation of Parallel Petitions” (Paper 8), Patent Owner asserts that the Consolidated

Trial Practice Guide states that one petition should be sufficient for the vast majority of cases, and that this is not one of the “rare” cases where two petitions would be needed. Paper 8, 1 (citing Patent Trial and Appeal Board Consolidated Trial Practice Guide¹ (Nov. 21, 2019) (“CTPG”) at 59). Patent Owner asserts that Petitioner filed two petitions solely to present multiple grounds for every challenged claim. *Id.* Patent Owner argues the number of challenged claims is not large because there is significant overlap among claim limitations. *Id.* at 2–3. Patent Owner asserts that in other cases involving even more claims, the Board has denied institution of parallel petitions, and that the case Petitioner relies on involved 89 claims. *Id.* at 2–3. Patent Owner further argues that Petitioner does not allege that it could not have addressed all challenged claims in one petition with fewer grounds, and does not demonstrate a need to use multiple petitions. *Id.* at 4–5.

Under the circumstances presented here, we find that discretionary denial is not warranted for the Petition in this case due to the parallel petition in IPR2024-00890. Given the large number of claims asserted by Patent Owner against Petitioner in the district court litigation, we do not consider two petitions asserting two single-reference grounds against forty claims including five independent claims to be excessive. The CTPG provides that assertion of a large number of claims in litigation is one circumstance under which more than one petition may be necessary. CTPG at 59. Furthermore, the two petitions challenge different claims of the ’031 patent. Claim length and subject matter complexity also justify the additional briefing presented by two petitions for which Patent Owner has been afforded the same amount

¹ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

of briefing to respond. The two petitions were filed on the same date so the potential for gamesmanship is diminished. And certain efficiencies may be gained between the two proceedings since the same patent and prior art are involved, such as, for example, holding depositions and oral hearings for the two cases together.

For the foregoing reasons, we decline to exercise our discretion to deny the Petition in this proceeding because of the parallel petition.

III. BACKGROUND

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

Petitioner identifies itself (i.e., Abbott Diabetes Care Inc.) and Abbott Diabetes Care Sales Corp. and Abbott Laboratories as real parties-in-interest. Pet. 2 (Petitioner's Mandatory Notices). Petitioner is directly owned by Abbott Laboratories, and Petitioner directly owns Abbott Diabetes Care Sales Corp. *Id.* Patent Owner identifies itself (i.e., DexCom, Inc.) as the real party-in-interest. Paper 4, 1 (Patent Owner's Mandatory Notices).

Petitioner and Patent Owner ("the parties") identify the following district court litigation as related to this proceeding: *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, Case No. 1:23-cv-00239 (D. Del.). Pet. 2; Paper 4, 2.

Patent Owner identifies as related to this proceeding the following *inter partes* review proceedings concerning patents asserted by Patent Owner in the district court litigation: IPR2024-00797 (U.S. Patent No. 10,375,222); IPR2024-00840 (U.S. Patent No. 9,119,528); IPR2024-00841 (U.S. Patent No. 10,709,364); IPR2024-00853 (U.S. Patent No. 11,213,204); IPR2024-00859 (U.S. Patent No. 11,510,625); IPR2024-00860 (U.S. Patent

No. 11,510,625); IPR2024-00861 (U.S. Patent No. 9,801,541); and IPR2024-00890 (U.S. Patent No. 11,020,031). Pet. 2; Paper 4, 2.

Patent Owner also identifies several U.S. patent applications to which the '031 patent claims priority, and that claim priority from the application (U.S. Patent Application No. 17/132,664) that issued as the '031 patent. Paper 4, 1.

B. The '031 Patent (Ex. 1001)

The '031 patent is titled “Analyte Sensor.” Ex. 1001, code (54). The '031 patent relates generally to systems and methods for monitoring an analyte, such as glucose, in a host. *Id.* at 1:21–35. In its background, the '031 patent explains that diabetes mellitus is a pancreatic disorder which may cause high blood sugar (hyperglycemic condition) or low blood sugar (hypoglycemic condition) which can be detrimental to a diabetic person suffering from the disorder. *Id.* at 1:38–55.

Conventionally, a diabetic's blood sugar level was tested using uncomfortable finger pricking methods two to four times per day, which was burdensome on hospital staff, and not performed frequently enough to detect hyperglycemic or hypoglycemic conditions. *Id.* at 1:56–2:4. The '031 patent states that there was “an urgent need for devices and methods that offer continuous, robust analyte monitoring, to improve patient care and lower medical costs.” *Id.* at 33:42–44. The '031 patent states that its “continuous, robust analyte monitoring system” reduces interaction required to measure the host's glucose concentration, and provides regular or continuous monitoring of blood glucose level. *Id.* at 33:44–53.

Figure 1G of the '031 patent is shown below.

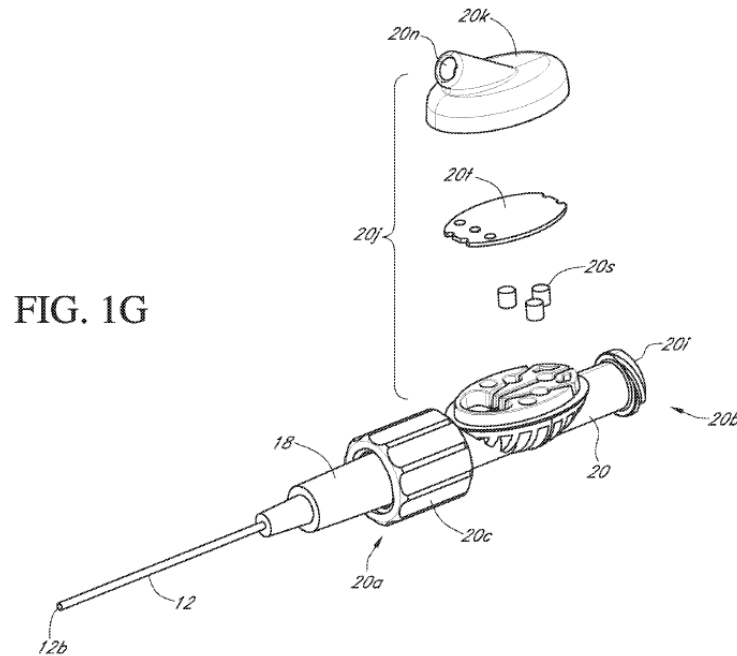


Figure 1G above is an exploded view of an analyte sensor system. *Id.* at 16:34–38. In Figure 1G, the analyte sensor system has fluid coupler 20 with housing 20j configured for electrical connection of the analyte sensor to electronics. *Id.* at 40:7–11. Housing 20j includes cover 20k and electrical connector 20n. *Id.* at 40:11–13. The analyte sensor system has an ex vivo portion with electrical connectors 20s connected to sensor electronics on printed circuit board (PCB) 20t disposed within housing 20j. *Id.* at 40:17–28. Catheter 12 is a thin flexible tube with a lumen 12a and orifice 12b. *Id.* at 35:51–65. Connector 18 joins catheter 12 with skirt 20c of housing 20j. *Id.* at 35:65–67, 37:38–54.

The in vivo conversion function tends to drift over time while the sensor is inserted in the body. *Id.* at 21:36–48. The '031 patent discloses that if the sensitivity *m* and baseline *b* are known a priori, then the sensor can be recalibrated for drift without the need for reference analyte values obtained from additional fingerstick tests. *Id.* at 140:31–34. A priori knowledge is garnered by determining the sensor's sensitivity over time obtained from previous uses, such as in vitro or in vivo experiments on sensors of the same design or manufacture. *Id.* at 216:44–46.

C. Overview of Challenged Claims

Of the challenged claims, claims 23, 35, and 42 are independent. Claims 24–34 depend from claim 23, claims 36–41 depend from claim 35, and claims 43–46 depend from claim 42, directly or indirectly.

Claim 23 is shown below with limitation identifiers indicated in brackets and disputed claim language emphasized in italics.

23. [Pre] A method for monitoring a glucose concentration, the method comprising:
- [a] 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;*
 - [b] generating sensor data derived at least in part from the transcutaneous glucose sensor;
 - [c] *determining a glucose concentration value based at least in part on the sensor data and information associated with a drift profile, wherein the drift profile is associated with a shift over time in measurement characteristic of the transcutaneous glucose sensor to the glucose concentration within the body of the host resulting from*

*the in vivo portion of the transcutaneous glucose sensor
being within the body of the host for a period of time;*

[d] and displaying the glucose concentration value.

Ex. 1001, 259:30–50 (emphases added).

Claim 35 is shown below with limitation identifiers indicated in brackets and disputed claim language emphasized in italics.

35. [Pre] A sensor system comprising:

- [a] *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 implanted within the body of the host,
- [b] wherein the in vivo portion comprises: an electrode; and a membrane disposed over at least a portion of the electrode, wherein the membrane comprises at least one enzyme;
- [c] wherein the transcutaneous glucose sensor generates a signal associated with a glucose concentration within the body of the host;
- [d] electronics configured to receive the signal from the transcutaneous glucose sensor,
- [e] wherein the electronics comprises a memory, *wherein the memory stores information associated with an expected change over time in a relationship between the signal and the glucose concentration within the body of the host,*
- [f] *wherein the electronics is configured to generate a glucose concentration value based at least in part on the signal and the information associated with the expected change over time in the relationship.*

Ex. 1001, 260:33–56 (emphases added).

Claim 42 is shown below with limitation identifiers indicated in brackets and disputed claim language emphasized in italics.

42. [Pre] A method for monitoring a glucose concentration, the method comprising:

- [a] 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;*
- [b] wherein the transcutaneous glucose sensor is configured to generate a signal;
- [c] *calibrating the transcutaneous glucose sensor by applying a priori information, wherein the a priori information comprises an expected relationship between the signal and a glucose concentration existing within the body of the host, wherein the relationship changes as a function of time;*
- [d] generating a glucose concentration value based at least in part on the calibrating; and
- [e] displaying the glucose concentration value.

Ex. 1001, 261:20–262:9 (emphases added).

D. Asserted Prior Art

Petitioner relies on the following references as prior art against the challenged claims of the '031 patent. Pet. 10.

Name	Reference	Exhibit No.
Zhang	US 2005/0143636 A1	1004
Shin	US 2005/0004439 A1	1008

Patent Owner does not dispute that Zhang and Shin are prior art against the challenged claims of the '031 patent. *See generally* Prelim. Resp.

E. Asserted Grounds

Petitioner asserts the following grounds of unpatentability. Pet. 10.

Ground	Reference(s)/Basis	35 U.S.C. § ²	Claim(s) Challenged
1	Zhang	102/103	23–46
2	Shin	102/103	23–46

F. Testimonial Evidence

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

IV. PETITIONER’S GROUNDS OF UNPATENTABILITY

A. Legal Standards

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

1. Petitioner’s Burden

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

² Amendments to 35 U.S.C. § 103 enacted by the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”) took effect on March 16, 2013. The ’031 patent claims priority to U.S. Application No. 12/267,525 filed November 7, 2008. Ex. 1001, code (63). Therefore, we apply the pre-AIA version of § 103.

shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

2. *Anticipation*

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

3. *Obviousness*

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art (“POSITA” or “POSA”) to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness.³ *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. *Level of Ordinary Skill in the Art*

In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art;

³ Neither Petitioner nor Patent Owner have submitted any such objective evidence in the record at this time. Pet. 77; *see generally* Prelim. Resp.

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

Petitioner asserts that

A person of ordinary skill in the art (“POSA”) as of the asserted priority date would have had a bachelor’s degree in biomedical engineering, chemical engineering, chemistry, or a related or equivalent field, and two or more years of experience researching, developing, designing and/or evaluating (or supervising the same) medical devices for measuring analyte levels, including some experience with algorithms for calibrating such devices, or equivalent experience. Such experience could include either formal coursework in signal processing, computer science, or electrical engineering, or it could also be obtained during on-the-job experience. A person with less or different education but more relevant practical experience, or vice versa, may also meet this standard. A POSA may have been part of an interdisciplinary team with others having the relevant experience set forth above and/or with clinicians. The prior art also evidences the level of skill in the art.

Pet. 20 (citing Ex. 1002 ¶ 67).

Patent Owner does not dispute Petitioner’s proposed level of ordinary skill in the art “because the Petition fails to demonstrate unpatentability even under that definition.” Prelim. Resp. 19.

Petitioner’s proposed level of skill in the art is consistent with the ’031 patent and the asserted prior art except that we set the level to “at least two . . . years of experience.” Otherwise, we agree with and will use Petitioner’s proposed level for this Decision.

C. Claim Construction

We interpret the '031 patent claims “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b). This “includ[es] construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*

Petitioner contends that, in the district court litigation, it proposed that the term “drift profile” in claims 23, 25–28, and 34 means a “profile of a change in baseline and/or sensitivity of the sensor signal over time.” Pet. 20–21. According to Petitioner, Patent Owner asserted in the district court litigation that the term “drift profile” should be given its plain and ordinary meaning, which is a “set of information associated with sensor measurement characteristic changes over time.” *Id.* at 21. Petitioner asserts that we need not expressly construe the term “drift profile” or any other terms to decide this case, and argues that “claims 23–34 are anticipated and/or rendered obvious by Zhang and by Shin under either construction.” *Id.* Petitioner states that it otherwise interprets the claims in accordance with the ordinary and customary meaning. *Id.*

In its Preliminary Response, Patent Owner does not address, at least not directly, Petitioner’s contentions regarding claim construction. Patent Owner states, however, that “the ‘drift profile’ is a plot of changes in the sensor’s conversion function, representable as a line (having a slope and/or curvature) whose horizontal axis is time.” Prelim. Resp. 53.

Since Petitioner does not propose any alternative construction for “drift profile” or construction of any other term in this proceeding, there is

no dispute over claim terms that we need to decide to resolve. Accordingly, we will apply the ordinary and customary meaning of the claim terms in our analysis of the challenge grounds without express construction. *See Nidec, supra. Id.* (citing *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017)).

We note in passing, however, that Patent Owner’s stated definition of “drift profile” in its Preliminary Response seems to comport both with Petitioner’s proposal in the district court litigation⁴ as well as how the ’031 patent’s specification uses the terms “drift” and “profile” in the context of “sensitivity.” *See* Ex. 1001, 21:36–48 (discussing “drift”), 210:39–60 (discussing “profile”).

D. Anticipation and Obviousness over Zhang

Petitioner asserts that claims 23–46 of the ’031 patent were anticipated by Zhang, and would have been obvious thereover. Pet. 29–57. Patent Owner disagrees. Prelim. Resp. 31–59.

We discuss below Zhang’s disclosure and Petitioner’s and Patent Owner’s contentions for the disputed claim language. As will be explained, Patent Owner indicates potential deficiencies in Zhang which suggest on this record that Petitioner’s Shin ground is perhaps stronger. Accordingly, we will focus most of our attention on the Shin ground at this point in the

⁴ The conversion function to convert a sensor’s signal to glucose concentration may be represented by the linear equation $y=mx + b$ where m is the slope or sensitivity, and the y -intercept b is the baseline or background of the signal. Ex. 1001, 21:21–35 (discussing “drift,” “shift,” and “change”), 139:27–40 (discussing “conversion function”). Thus, Petitioner’s proposal for “drift profile” in the district court litigation does not seem materially different from what Patent Owner proposes for the term in its Preliminary Response.

proceeding. However, we discuss the Zhang ground below to impart our understanding of the record and issues presented for possible further development at trial.

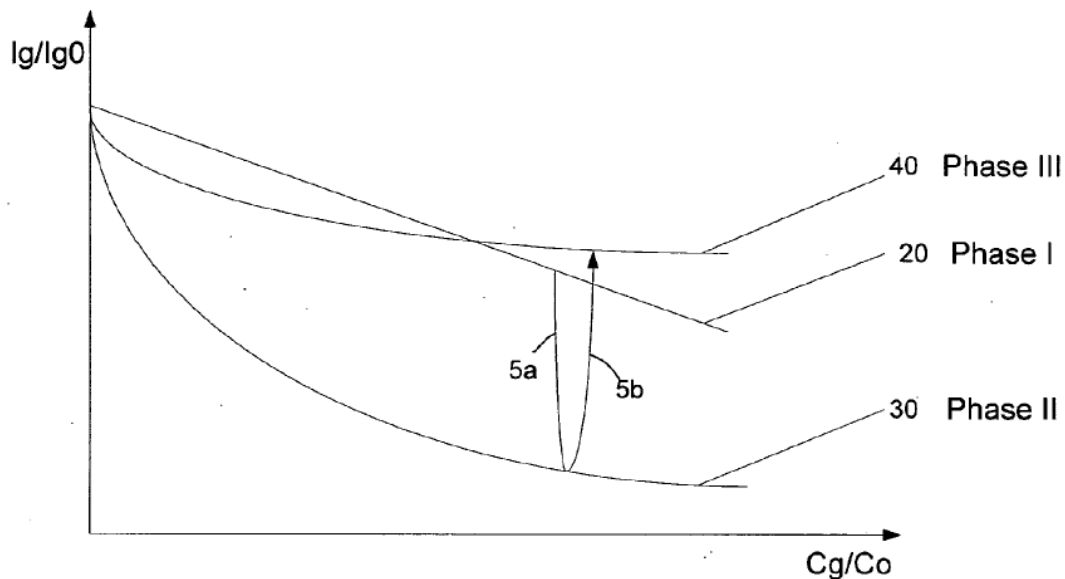
1. Zhang (Ex. 1004)

Zhang is titled “System and Method For Sensor Recalibration.” Ex. 1004, code (54). Zhang discloses calibration techniques for use with implantable sensors that measure glucose level in a patient’s body. *Id.* ¶ 27.

Zhang discloses that sensors typically exhibit different characteristics during their useful life, and typically have three phases: (1) initialization phase; (2) stable phase; and (3) end of life phase. *Id.* ¶ 32. Zhang seeks to provide a calibration scheme to identify a sensor’s phase of life and properly calibrate it for that phase. *Id.*

Zhang’s Figure 2 is shown below.

FIG. 2



Zhang’s Figure 2 above is a plot of normalized sensor current versus glucose concentration showing calibration curves 20, 30, and 40 for the three phases

of sensor life. *Id.* ¶¶ 33–40. The curves are determined based on empirical data collected from use of the sensors. *Id.* Arrow 5a, 5b in Figure 2 represents a typical life cycle of the calibration curves as the sensor change from one phase to another. *Id.*

Zhang approximates the calibration curves using a five-point piecewise linear approximation wherein the curve is broken into five points and the line between each two consecutive points is assumed linear. *Id.*

¶ 40. According to Zhang, piecewise linear approximation reduces complexity of calculations while maintaining accurate results. *Id.* Linear regression may be used to determine the slope and intercept from which to determine adjustments to the sensor's calibration curve to account for its phase of life. *Id.* at ¶¶ 41–61.

Zhang's Figure 6 is shown below.

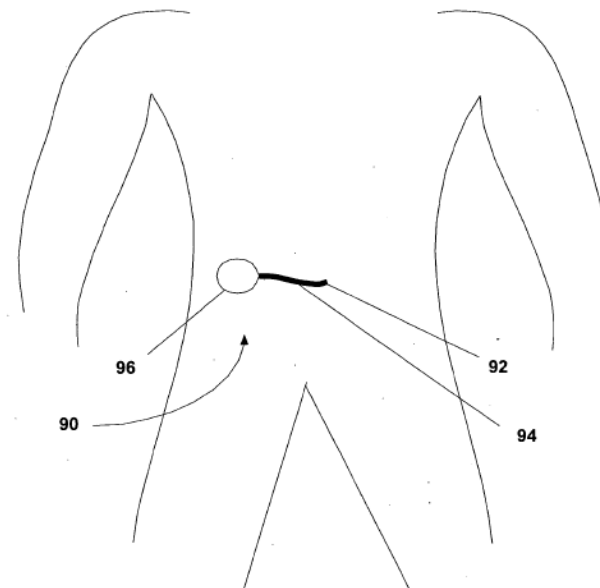


FIG. 6

Zhang's Figure 6 discloses an implanted sensing system 90 including sensor 92, catheter 94, and pump 96. *Id.* ¶ 64. Sensor 92 may be a glucose

sensor, and pump 96 may be an insulin pump. *Id.* Sensor 92 may be calibrated as described. *Id.* Calibrated sensor 92 may send signals to pump 96, enabling the pump to accurately deliver insulin through catheter 94 to a patient. *Id.*

2. *Claims 23, 35, and 42*

We now address Petitioner’s contention that Zhang discloses or renders obvious claims 23, 35, and 42, and Patent Owner’s arguments disputing Petitioner’s contentions. Pet. 29–37 (claim 23), 45–53 (claim 35), 54–56 (claim 42); Prelim. Resp. 31–59.

(i) *Transcutaneous Glucose Sensor with Ex Vivo Portion*

Claim 23 recites limitation 1a as “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.” Ex. 1001, 259:32–38 (emphasis added). Claim 35 recites similar limitation 35a. *Id.* at 260:34–39. Claim 42 recites similar limitation 42a. *Id.* at 261:22–28.

Petitioner asserts that Zhang discloses limitation 23a, limitation 35a, and limitation 42a or renders them obvious. Pet. 30–32, 46, 54. Specifically, Petitioner relies on the following excerpt from Zhang as disclosing a transcutaneous glucose sensor:

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. Such sensors typically communicate a signal from the implantable sensor to either an internal or external monitor. The implantable sensor is primarily adapted for use with blood.

Ex. 1004 ¶ 27.

Patent Owner argues that Zhang fails to disclose or render obvious a “*transcutaneous* glucose sensor” including an “ex vivo portion” as claimed. Prelim. Resp. 32–38. For example, Patent Owner argues that Zhang’s entire system (pump, catheter, sensor, and all) is implanted fully inside the patient’s body, and thus is entirely in vivo such that no component of the system is transcutaneous. *Id.* at 34–35. Zhang, however, also refers to implantation “through subcutaneous . . . tissue.” Ex. 1004 ¶ 27.

On this record, whether Zhang expressly or inherently discloses a “*transcutaneous* glucose sensor” that has “an ex vivo portion configured to remain outside of a body of a host” remains an issue for resolution at trial. *See, e.g.*, Prelim. Resp. 34–35. Zhang’s sensor is described as “implantable” and thus appears to be entirely in vivo. *See, e.g.*, Ex. 1004 ¶ 27.

As an alternative to its anticipation argument, Petitioner contends that it would have been obvious to use transcutaneous sensors having an ex vivo portion because it “was a common feature of commercial CGMs.”⁵ Pet. 30–31 (citing Ex. 1025, 131–132). Petitioner asserts that such transcutaneous sensors offer advantages over fully implanted sensors because they can be worn continuously, and can be inserted at home, allowing users the freedom to choose when they want to wear the device. *Id.* at 31. In contrast, Petitioner argues, implanted sensors require long-term commitment to use the device, and insertion and retrieval would “likely be done at a physician’s office.” *Id.* at 31–32 (citing Ex. 1025, 129).

Although general knowledge of a POSITA is considered in the obviousness inquiry, Exhibit 1025, on which Petitioner relies, appears to

⁵ Continuous Glucose Monitors. *See* Pet. 8.

have been published after the priority application for the '031 patent.
Ex. 1025, 3. We will await development of a full trial record before addressing, if necessary, whether the general knowledge of a POSITA would have rendered it obvious to modify or replace Zhang's implantable sensor with an ex vivo portion.

Petitioner asserts 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" and Zhang's disclosure that its "calibration scheme is a 'generalized method [that] may be applied to a variety of glucose sensors.'" Pet. 32 (citing Ex. 1004 ¶¶ 31, 33; Ex. 1002 ¶¶ 97–98).

Patent Owner argues that the mere existence of transcutaneous glucose sensors in the prior art is insufficient to establish a reason to combine them with Zhang's system. Prelim. Resp. 38–43 (citing *Virtek Vision Int'l. ULC v. Assembly Guidance Sys.*, 97 F.4th 882, 886 (Fed. Cir. 2024)). Patent Owner asserts that because a transcutaneous sensor's use is short-term, only three to seven days, the sensor response would be linear and never have the non-linear calibration curve for which that Zhang's recalibration techniques are designed. Prelim. Resp. 41–43 (citing Pet. 27 n.7, 31, 57–58; Ex. 1004 ¶¶ 6, 40–41, 43, 64, Fig. 2; Ex. 1025, 114, 134). Thus, Patent Owner contends that Petitioner's noted advantages of transcutaneous glucose sensors "nullify the reasons for and conflict with the execution of Zhang's recalibration techniques." *Id.* at 41.

Although we agree with Patent Owner that Petitioner must show a reason to combine a transcutaneous glucose sensor with Zhang's system, Patent Owner's argument assumes without sufficient evidence that the period of use of a transcutaneous sensor is so short that the sensor's response

remains linear and does not exhibit nonlinear behavior for which Zhang's recalibration techniques would be useful. Patent Owner's argument is largely unsupported attorney argument and is thus unavailing. *See Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017) ("Attorney argument is not evidence"). We will await development of the trial record to decide this issue, if necessary.

Petitioner contends 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." Pet. 32. Petitioner asserts that Zhang's "calibration scheme is a 'generalized method [that] may be applied to a variety of glucose sensors.'" *Id.* (citing Ex. 1004 ¶¶ 31, 33; Ex. 1002 ¶¶ 97–98).

Patent Owner argues that the Petition fails to demonstrate a reasonable expectation of success in replacing the implanted sensor with a transcutaneous sensor in Zhang's system calibrated with Zhang's techniques. Prelim. Resp. 44–47. Patent Owner asserts that Petitioner has not shown that a POSA would have had a reasonable expectation of success in applying Zhang's recalibration techniques for long-term implanted sensors to a short-term transcutaneous sensor. *Id.* at 44–45. Specifically, Patent Owner argues that Petitioner fails to explain how Zhang's recalibration techniques that require three weeks of data gathering would work with a transcutaneous sensor that is only useable for a few days. *Id.* at 45. Patent Owner further asserts that successful use of transcutaneous sensors does not establish that a POSA would have expected success in using them in Zhang's system. *Id.* at 45–46 (citing Pet. 32; Ex. 1004 ¶ 31). In addition, Patent Owner argues that Petitioner selectively quotes Zhang as teaching that its generalized method

may be applied to a variety of glucose sensors, but that the surrounding context of these quotes makes clear that Zhang is discussing glucose sensors for use with implantable insulin pumps or with sensors that detect analytes other than glucose, and nowhere does Zhang state that its recalibration techniques are applicable to short-term transcutaneous sensors. *Id.* at 46–47 (citing Pet. 32; Ex. 1004 ¶¶ 31, 33, Fig. 2).

As already discussed, Patent Owner’s attorney argument does not establish that a transcutaneous glucose sensor’s response would be strictly linear over the period of time during which it is used. On this record, Patent Owner does not establish the facts necessary to support its arguments.

(ii) *Determining Glucose Concentration with Information Associated with Drift Profile*

Limitation 23c of claim 23 recites “*determining a glucose concentration value based at least in part on . . . information associated with a drift profile.*” Ex. 1001, 259:41–43.

Limitation 35f of claim 35 recites “*generat[ing] a glucose concentration value based at least in part on . . . information associated with the expected change.*” *Id.* at 260:52–55.

Limitation 42c of claim 42 recites “*calibrating the transcutaneous glucose sensor by applying a priori information . . . compris[ing] an expected relationship.*” *Id.* at 262:1–3.

Petitioner contends that Zhang discloses these features of claims 23, 35, and 42. Pet. 33–36, 53, 55–56. Specifically, for limitation 23c, Petitioner asserts that Zhang’s system determines glucose concentration based at least in part on the sensor signal and pre-determined normalized calibration curves for each of three phases of sensor life. *Id.* at 33 (citing

Ex. 1002 ¶¶ 101–109). Petitioner alleges that Zhang’s normalized calibration curves, as well as the shifts between them, constitute a “drift profile” associated with “shift over time” in the sensor’s sensitivity (a “measurement characteristic” of the sensor to the glucose concentration) resulting from the sensor being within the body of the host for a period of time. *Id.* Petitioner thus asserts that Zhang’s method involves “determining a glucose concentration value based at least in part on the sensor data and information associated with a drift profile,” as recited in limitation 23c. *Id.* at 33–36 (citing Ex. 1004 ¶¶ 29, 31–63, Fig. 2). Petitioner further asserts that Zhang discloses that sensor recalibrations are performed using independent characteristic values (e.g., blood meter values) and expected normalized calibration curves, and that the sensor recalibrations are used to determine glucose concentration. *Id.* at 36 (citing Ex. 1004 ¶¶ 29, 33–35, 40–62, Fig. 4).

Petitioner contends that Zhang similarly discloses limitation 35f and limitation 42c. Pet. 53, 55–56 (citing Ex. 1004 ¶¶ 16, 29, 33–35, 40–62; Ex. 1002 ¶¶ 175–176). For limitation 35e, which provides antecedent basis for “information associated with an expected change over time” in limitation 35f, Petitioner contends that Zhang’s Figure 2 curves are determined “based on empirical data collected from the use of the sensors” and thus are pre-determined. *Id.* at 51–52 (citing Ex. 1004 ¶¶ 7, 13, 15–16, 33, claim 34, claim 36; Ex. 1002 ¶¶ 167–174). In addition, Petitioner asserts that “[t]he normalized calibration curves stored in Zhang’s memory are ‘information associated with an expected change over time in a relationship between the signal and the glucose concentration within the body of the host’” as recited in limitation 35e which is applied in calibrating the sensor

as recited in limitation 35f. *Id.* at 51. Accordingly, Petitioner asserts that Zhang discloses limitation 35f. *Id.*

For limitation 42c, Petitioner contends that Zhang's three curve shapes and the adjustment from one curve shape to another over time comprise "an expected relationship between the signal and a glucose concentration existing within the body of the host" as claimed. Pet. 55. Petitioner asserts that Zhang's Figure 2 curves are determined from empirical data from use of the sensors and are thus "a priori information." *Id.* at 56 (citing Ex. 1004 ¶¶ 16, 33). Petitioner further asserts that the "a priori information" is applied to calibrate the sensor. *Id.* (citing Ex. 1004 ¶¶ 33, 40). Thus, Petitioner contends that Zhang discloses limitation 42c.

Patent Owner argues that Zhang does not disclose these limitations of claims 23, 35, and 42. Prelim. Resp. 48–51. Specifically, Patent Owner asserts that Zhang's Figure 2 curves (*see* § IV.D.1, *supra*) are not applied to recalibrate an individual sensor system. Pet. 48. Patent Owner avers that Zhang's Figure 2 curves are "background research" and "conceptual" to show why Zhang assumes each individual sensor will have a non-linear curve and why Zhang uses a "five-point piecewise linear approximation" to create each sensor's actual curve. *Id.* at 48–51 (citing Ex. 1004 ¶¶ 40, 64, Fig. 2). According to Patent Owner, Zhang's recalibration techniques rely on measuring the actual current response of the sensor as it changes at each point in time during its use by taking fingerstick glucose measurements, and then mathematically adjusting the sensor's calibration curve to fit the measured blood glucose meter values by piecewise linear regression. *Id.* at 50–51 (citing Ex. 1004 ¶¶ 33, 40–62, Figs. 2, 4, 5). Patent Owner presents similar arguments for limitation 35f and limitation 42c. *Id.* at 51–59.

On this record, we do not agree with Patent Owner's arguments. Our understanding is that Zhang's Figure 2 curves are not merely "conceptual" or "background research," but are representative of actual calibration curves that Zhang uses to calibrate sensor data to generate blood glucose concentration values, as Petitioner contends. Pet. 33.

For example, Zhang states that "a new nominal glucose current and new calibration curve may be set for the sensor" and that "after recalibration, the sensor output can be calculated using the new calibration curve derived from the recalibration procedure." Ex. 1004 ¶¶ 60–61. Hence, Zhang appears to store and use curves similar to what is shown in Zhang's Figure 2 to calibrate its sensor.

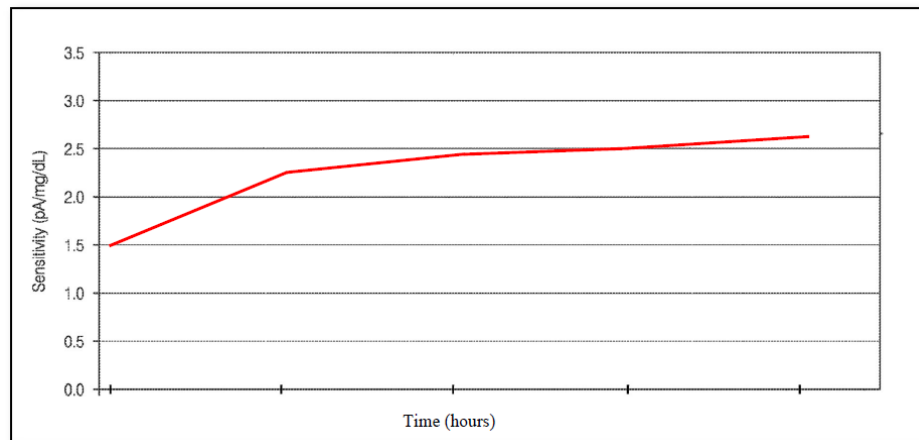
Furthermore, Zhang discloses that its new calibration curve $Y'(i)$ can be calculated from the old calibration curve $Y(i)$ by using the equation $Y'(i) = Y(i) + \Delta Y(i)$ where $\Delta Y(i)$ is the difference between the old and new calibration curves and the i index represents time. Ex. 1004 ¶¶ 55, 60–61. Hence, Zhang's sensor generates glucose concentration using different calibration curves over the life of the sensor as its output changes over time. Thus, we agree with Petitioner on this record that Zhang's normalized calibration curves and the shifts between them, satisfy limitations 23c, 35f, and 42c, including their respective "information associated with a drift profile," "information associated with an expected change," and "a priori information . . . associated with an expected relationship" recitations.

For limitation 23c of claim 23, Patent Owner argues that Zhang's Figure 2 curves and the shifts between them are not a "drift profile" as that term is used in the '031 patent. Prelim. Resp. 51–56. Patent Owner asserts that

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.

Id. at 52–53 (citing Ex. 1001, 216:48–52).

Patent Owner provides the following figure in support of its contention:



Id. at 53. Patent Owner asserts that the above figure shows how a sensitivity “drift profile” could be illustrated as a function of sensitivity versus time.

Id.

Patent Owner argues that each curve in Zhang’s Figure 2 is a conversion function of sensor current to glucose concentration. *Id.* at 53–55. Patent Owner asserts that each of Zhang’s Figure 2 curves “would only represent a sensitivity at a given point in time, and not how sensitivity *drifts* over time.” *Id.* at 55. Patent Owner argues that each of Zhang’s Figure 2 curves is thus not a “drift profile” as claimed. *Id.* at 55.

Patent Owner further argues that while Petitioner contends that each shift between curve shapes in Zhang’s Figure 2 represents a change in sensitivity over time, Petitioner “does not attempt to explain how or why

those *shifts* between curves of different *shapes* are a line having a slope and/or curvature so as to constitute a claimed ‘profile.’” *Id.* at 55–56.

Patent Owner asserts that Zhang’s Figure 2 curves are non-linear, and Petitioner did not explain how shifts “between those non-linear curves are (or even could be) formed as a claimed ‘profile.’” *Id.* at 56.

On this record, the adjustments between Zhang’s Figure 2 calibration curves on which Petitioner relies seem to incorporate the “drift profile” that Patent Owner contends is missing from Zhang. In other words, these adjustments appear to represent the change at points of the curve and thus seem to represent the change in slope (sensitivity) of the curve.

As to Patent Owner’s argument that Petitioner did not explain how shifts between non-linear curves could be formed as the claimed “drift profile,” Zhang discloses adjusting the calibration curve in “piecewise linear fashion” to approximate the non-linear curve with linear segments, so we are not convinced on this record that the nonlinearity of Zhang’s curves would preclude the adjustments between curves from being considered the claimed “profile” because of their nonlinearity. *See, e.g.*, Ex. 1004 ¶ 40.

Nonetheless, we will await development of the full trial record before making a determination on whether Zhang discloses the claimed “drift profile.” To the extent the parties dispute what a “drift profile” is in the context of the ’031 patent, the parties should set forth clearly what their proposed constructions are on the trial record.⁶

⁶ If either party intends to argue a claim construction at trial, including what is the plain and ordinary meaning of a term, they should do so in a clearly designated section of their briefing. *See* CTPG 46, 49; *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008) (“A

To the extent that the parties dispute whether limitations 23c, 35f, and 42c preclude calibration curves derived from blood glucose measurements taken with blood drawn from finger sticks, the parties should clearly set forth their construction on the trial record and explain why the limitations are or are not disclosed by Zhang.

(iii) *Memory Stores Information Associated with an Expected Change*

Limitation 35e of claim 35 recites “wherein the memory stores information associated with an expected change over time in a relationship between the signal and the glucose concentration within the body of the host.” Ex. 1001, 260:49–52.

Petitioner contends that Zhang discloses limitation 35e. Pet. 51–52. Specifically, Petitioner asserts that Zhang’s electronics comprises a memory storing expected normalized calibration curves generated using a priori empirical data, that are used to calibrate sensor readings. *Id.* at 51 (citing Ex. 1004 ¶¶ 7, 13, 15–16, 33). Petitioner contends that “[t]o use pre-generated normalized calibration curves when processing sensor readings, the electronics must comprise a memory for storing such curves.” *Id.* at 51 (citing Ex. 1002 ¶¶ 167–168). Petitioner adds that “[g]lucose monitoring systems comprising electronics with memory also would have been obvious.” *Id.* (citing Ex. 1002 ¶¶ 169–171).

Petitioner argues that “[t]he normalized calibration curves stored in Zhang’s memory are ‘information associated with an expected change over

determination that a claim term ‘needs no construction’ or has the ‘plain and ordinary meaning’ may be inadequate when a term has more than one ‘ordinary’ meaning or when reliance on a term’s ‘ordinary’ meaning does not resolve the parties’ dispute.”). Claim construction arguments should not be relegated to patentability arguments on the facts.

time in a relationship between the signal and the glucose concentration within the body of the host,” as recited in limitation 35e. *Id.* at 51. Moreover, Petitioner asserts that “Zhang’s normalized curves account for expected changes in sensor sensitivity over time, and such expected sensitivity changes are information associated with an expected change over time in a relationship between the signal and the glucose concentration.” *Id.* at 51–52.

Petitioner contends that Zhang’s three curves and their associated sensitivities “show the change over time in sensor sensitivity, which results in a ‘change over time in a relationship between the signal and the glucose concentration within the body’” as recited in limitation 35e. *Id.* at 52 (citing Ex. 1002 ¶¶ 172–173).

Petitioner further asserts Zhang’s Figure 2 curves “were determined ‘based on empirical data collected from the use of the sensors’ and thus are pre-determined.” *Id.* at 52 (citing Ex. 1004 ¶¶ 16, 33). Petitioner avers that Zhang’s “curves reflect ‘expected’ changes over time” as required by limitation 35e. *Id.* (citing Ex. 1002 ¶ 174).

Patent Owner argues that Zhang’s Figure 2 curves “are **not** disclosed as being used when processing sensor readings” and Petitioner “does not prove that they are.” Prelim. Resp. 57. Patent Owner asserts Zhang’s curves are merely “observations in research on sensors in general” and that “Zhang does not know what a particular individual sensor’s response will actually be at particular points in time” and accordingly “**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.” *Id.*

Patent Owner contends that Zhang’s “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” and “is unrelated to any change over time” and thus is unrelated to Zhang’s Figure 2 curves. Prelim. Resp. 57–58 (citing Ex. 1004 ¶¶ 15–16, 33, claim 34, claim 36). Patent Owner alleges that “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.” *Id.* at 58.

In addition, Patent Owner argues that Zhang’s “array of data” and “calibration array” are unrelated to Zhang’s Figure 2 curves and are arrays of blood glucose meter measures reflecting the sensor’s actual current response while the sensor is in use. *Id.* (citing Ex. 1004 ¶¶ 7, 13, 41). Patent Owner thus argues that Zhang does not disclose that its Figure 2 curves are stored in its sensor system’s memory, and Petitioner fails to so demonstrate. *Id.*

As previously noted, Zhang discloses “a new nominal glucose current and new calibration curve may be set for the sensor” and that “after recalibration, the sensor output can be calculated using the new calibration curve derived from the recalibration procedure.” Ex. 1004 ¶¶ 60–61. Hence, Zhang appears to store and use curves similar to what is shown in Zhang’s Figure 2 to calibrate its sensor. Accordingly, on the current record, we do not find Patent Owner’s argument availing.

Petitioner contends the remaining limitations of claims 23, 35, and 42 are disclosed by Zhang, and indicates the evidence it relies on to support its

contentions. Pet. 29–37 (claim 23), 45–53 (claim 35), 54–56 (claim 42). Patent Owner does not dispute Petitioner’s contentions or evidence for the remaining limitations at this time.

3. *Dependent Claims 24–34, 36–41, and 43–46*

Petitioner contends that Zhang discloses dependent claims 24–34, 36–41, 43–46. Pet. 37–45, 53–54, 56–57. Other than as addressed above, Patent Owner does not dispute Petitioner’s contentions or evidence for these claims at this time.

4. *Conclusion for Ground 1*

For the reasons explained, we will await full development of a trial record to decide whether using a “transcutaneous glucose sensor” in Zhang’s system was disclosed by Zhang or would have been obvious when viewed with a POSA’s general knowledge, and whether Zhang discloses a “drift profile” as recited in limitation 23c.

E. *Anticipation and Obviousness over Shin*

Petitioner asserts that claims 23–46 of the ’031 patent were anticipated by, and would have been obvious over, Shin. Pet. 57–77. Patent Owner disagrees. Prelim. Resp. 64–75.

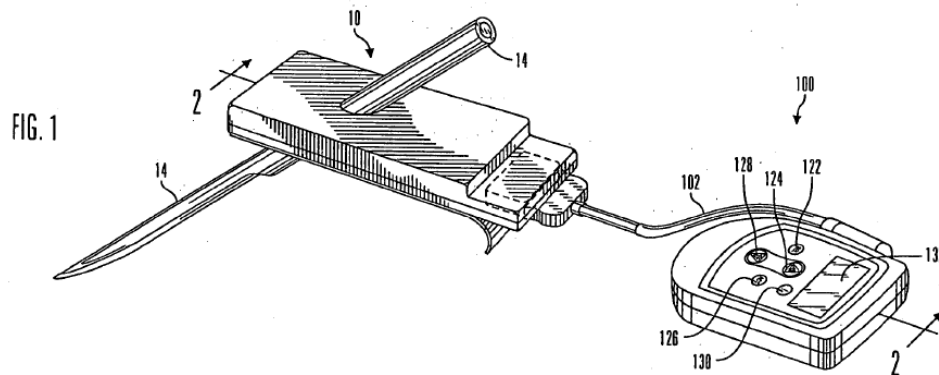
In this section, we address Shin’s disclosure and Petitioner’s and Patent Owner’s contentions for the challenged claims. We conclude on the current record that Petitioner has presented a reasonable likelihood to prevail in demonstrating unpatentability of at least one of these claims as anticipated by Shin.

1. *Shin (Ex. 1008)*

Shin is titled “Real-Time Self-Adjusting Calibration Algorithm.” Ex. 1008, code (54). Shin discloses “calibration methods for a glucose

monitor that is coupled to a sensor set to provide continuous data recording of readings of glucose levels from a sensor for a period of time.” *Id.* ¶ 54.

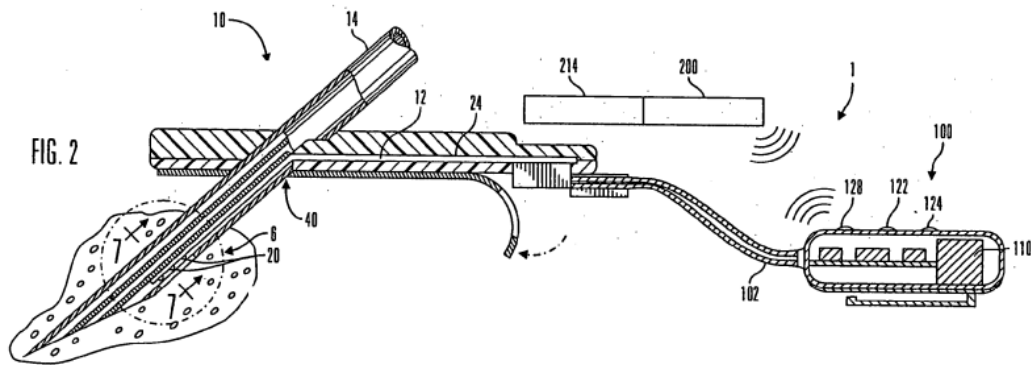
Shin’s Figure 1 is shown below.



Shin’s Figure 1 above shows glucose monitor 100 worn by a user and a glucose sensor set 10 that is attached to the user’s body by electrically conductive cable 102. *Id.* ¶ 56. Glucose sensor set 10 includes needle 14 disclosed in U.S. Patent No. 5,586,553, which Shin incorporates by reference. *Id.* ¶ 64. Needle 14 is hollow and used for transcutaneous placement of sensor 12 and its electrodes at the selected site in the user’s body as described in U.S. Patent Nos. 5,390,671; 5,391,250; 5,482,473; and 5,586,553, which Shin incorporates by reference. *Id.* ¶ 57.

Glucose monitor 100 includes display 132 to assist the user in programming the glucose monitor 100, entering data, stabilizing, calibrating, downloading data, or the like. *Id.* ¶ 62. Buttons 122, 124, 126 and 128 on the glucose monitor 100 may be used to program the monitor 100, to record data, insert flags to correlate data with external events for later analysis, input calibration values, or the like. *Id.* ¶ 63.

Shin’s Figure 2 is shown below.



Shin’s Figure 2 above is a cross-section of subcutaneous glucose sensor insertion set 10 and glucose monitor device 100. *Id.* ¶ 32. As shown in Shin’s Figure 2, electrodes 20 of the glucose sensor 12 terminate in the user’s subcutaneous tissue. *Id.* ¶ 57.

Glucose monitor 100 records and stores data from glucose sensor 12 and includes a data port or wireless transmitter and/or receiver for transferring data to and/or from a data processor 200 such as a computer, communication station, or dedicated processor. *Id.* ¶ 58.

To calibrate glucose monitor 100, Shin uses a calibration factor called a sensitivity ratio (SR) which is the detected blood glucose level (in mg/dl or mmol/l) divided by the detected continuous electrical current signal (ISIG) (in Nano-Amps). *Id.* ¶ 82. Blood glucose reference readings are entered into the glucose monitor 100 periodically throughout each day of use. *Id.* ¶¶ 85–86.

Shin's Figure 12 is reproduced below.

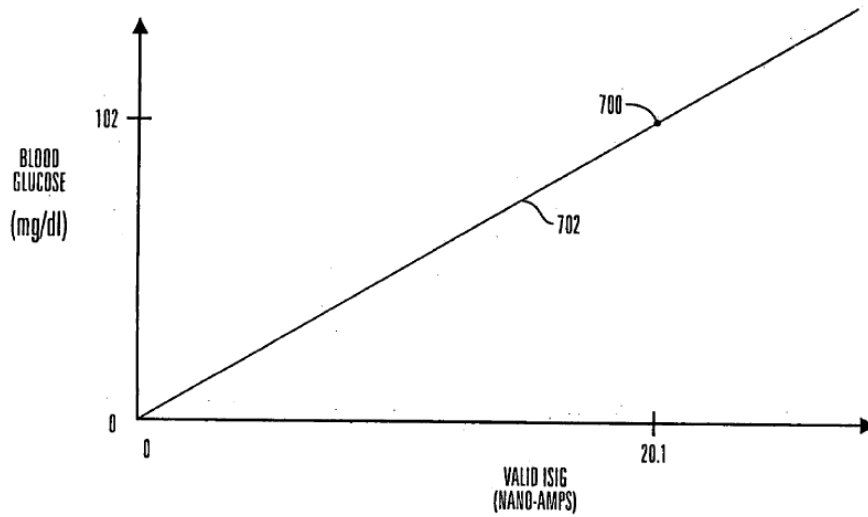


FIG. 12

Referring to Shin's Figure 2 above, a single-point sensitivity ratio (SPSR) is derived from a single point by assuming that blood glucose level is zero when current level is zero at the origin, and determining the line that passes from the origin through the point 700 determined by the blood glucose reading. *Id.* ¶¶ 88–89. Shin defines the SPSR as:

$$\text{SPSR} = \frac{\text{Blood Glucose Reference Reading}}{\text{Valid ISIG}}$$

Shin discloses that more sensitive glucose sensors have less linear performance at higher current (ISIG) values. *Id.* ¶ 93. Therefore, if the SPSR is less than a sensitivity threshold value, then Shin uses a modified MSPSR to calculate the calibration factor according to the equation:

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

Id. In Shin's preferred embodiments, if the SPSR is 7 or greater, the offset value is 0, and if the SPSR is less than 7, the offset value is 3. *Id.*

Shin further discloses that the MSPSR may be compared to a valid sensitivity range to determine if a newly calculated MSPSR is reasonable,

and states that a valid MSPSR range of 1.5 to 15 may be employed. *Id.*

¶ 103. Shin states MSPSR values outside of this range result in a calibration error alarm to notify the user of a potential problem. *Id.* Shin states that other valid sensitivity ranges may be applied depending on how long the sensor has been in use, among other factors. *Id.*

2. *Claim 23*

We now address Petitioner’s contentions for each limitation of claim 23, and Patent Owner’s arguments concerning limitation 23c, which is the only limitation of claim 23 that Patent Owner disputes at this time.

(i) *Preamble*

The preamble of claim 23 recites “method for monitoring a glucose concentration, the method comprising:” Ex. 1001, 259:30–31.

Petitioner contends that “Shin describes a method for monitoring glucose concentration in a host.” Pet. 57 (citing Ex. 1008 ¶ 54; Ex. 1002 ¶ 211).

Petitioner shows sufficiently that Shin discloses claim 23’s preamble. Thus, we need not, and do not, decide whether the preamble is limiting.

(ii) *Limitation 23a: Beginning Session Associated with Use of Transcutaneous Glucose Sensor*

Limitation 23a recites “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.” Ex. 1001, 259:32–39.

Petitioner states that Shin discloses limitation 23a. Pet. 57–58. Specifically, Petitioner asserts that Shin discloses beginning a sensor session

with a transcutaneous glucose sensor. *Id.* at 57 (citing Ex. 1008 ¶ 6).
Petitioner argues that Shin’s glucose sensor 12 “extends from the glucose sensor set 10 into the user’s body with electrodes 20 of the glucose sensor 12 terminating in the user’s subcutaneous tissue.” *Id.* at 57–58 (citing Ex. 1008 ¶ 57). We agree with Petitioner that Shin’s glucose sensor as disclosed is “transcutaneous.”

Petitioner further contends that Shin’s Figure 2 (*see* § IV.E.1, *supra*) illustrates that Shin’s glucose sensor has in-vivo and ex-vivo portions. Prelim. Resp. 58. The in-vivo portion extends into in-vivo “region 6” while another portion is outside of the user’s body. *Id.* (citing Ex. 1008, Fig. 2 (annotated); Ex. 1002 ¶¶ 213–216). We find that Petitioner shows sufficiently that Shin’s glucose sensor has in-vivo and ex-vivo portions as claimed.

Consequently, on this record, Petitioner sufficiently shows that Shin discloses limitation 23a.

(iii) *Limitation 23b: Generating Sensor Data*

Limitation 23b recites “generating sensor data derived at least in part from the transcutaneous glucose sensor.” Ex. 1001, 259:39–40.

Petitioner contends that Shin discloses that “the 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.” Pet. 58 (citing Ex. 1008 ¶ 69; Ex. 1002 ¶¶ 217–218).

On the current record, we find that Petitioner shows sufficiently that Shin discloses limitation 23b.

(iv) *Limitation 23c: Sensor Configured to Generate Signal Whose Magnitude Depends on Glucose Concentration*

Limitation 23c recites

determining a glucose concentration value based at least in part on the sensor data and information associated with a drift profile, wherein the drift profile is associated with a shift over time in measurement characteristic of the transcutaneous glucose sensor to the glucose concentration within the body of the host resulting from the in vivo portion of the transcutaneous glucose sensor being within the body of the host for a period of time.

Ex. 1001, 259:41–49.

Petitioner contends that “Shin teaches calibrating sensor data and determining a glucose concentration value, using predetermined valid sensitivity ranges that are based on how long the sensor has been in use.” Pet. 59. Specifically, Petitioner asserts that Shin’s calibration method uses a calibration factor (each calculated modified single-point sensitivity ratio (MSPSR) that is compared to a pre-determined valid sensitivity range, and the valid sensitivity ranges over time can be ranges that depend on how long the sensor has been in use. *Id.* (citing Ex. 1008 ¶¶ 93, 103). In other words, according to Petitioner, the ranges are a “drift profile.” *Id.* Petitioner argues that Zhang’s “system either accepts or rejects the MSPSR for calibration and the determination of a glucose concentration value.” *Id.* Accordingly, Petitioner contends that “Shin discloses determining a glucose concentration value based at least in part on sensor data and on ‘information associated with a drift profile, wherein the drift profile is associated with a shift over time in measurement characteristic of the’ sensor,” as recited in limitation 23c. *Id.* (citing Ex. 1002 ¶¶ 219–222).

Petitioner avers that Shin compares the MSPSR to a valid sensitivity range to determine if it is reasonable. *Id.* (citing Ex. 1008 ¶ 103).

According to Petitioner, Shin states that a valid MSPSR range of 1.5 to 15 has been determined from in-vitro measurements, but “[o]ther valid sensitivity ranges may be applied depending on . . . how long the sensor has been in use.” *Id.* Petitioner argues that

Shin’s valid sensitivity ranges that depend on how long the sensor has been in use constitute “a drift profile” (and thus also “information associated with a drift profile” as recited in [limitation 23c]), wherein the drift profile is associated with a shift over time in a measurement characteristic of the sensor (in this case, sensor sensitivity) resulting from the sensor being within the host’s body for a period of time as recited in [limitation 23c].

Id. at 60. In other words, Petitioner contends that different valid sensitivity ranges can be used, each associated with a length of time of use, and that the composite of these ranges constitutes a “drift profile,” and thus also “information associated with a drift profile.” *Id.* at 60–61 (citing Ex. 1008 ¶ 103; Ex. 1001, 213:5–43; 213:13–25, 213:33–36, 213:50–52, 216:44–61).

Patent Owner argues that Shin discloses limitation 23c rests on Paragraph 103 of Shin. Prelim. Resp. 64 (citing Pet. 59–61, 73–74, 76–77). Patent Owner avers that, contrary to Petitioner’s contention, Shin does not state that the system rejects the MSPSR if outside the valid sensitivity range, only that Shin’s system calibrates sensor data if inside the range, and generates a calibration error alarm to notify the user of a potential problem if outside the range. *Id.* at 65. Patent Owner argues that 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. *Id.* at 65–66.

We do not agree with Patent Owner’s argument on the current record. If the MSPSR is outside the “valid sensitivity range” and thus is not

“reasonable,” it seems unlikely that a POSA would use it to calibrate data in Shin’s system. Ex. 1008 ¶ 103. And it has not been shown on this record that limitation 23c requires the sensor data to be rejected and not calibrated if the MSPSR falls outside of a “valid sensitivity range” such as Shin’s.

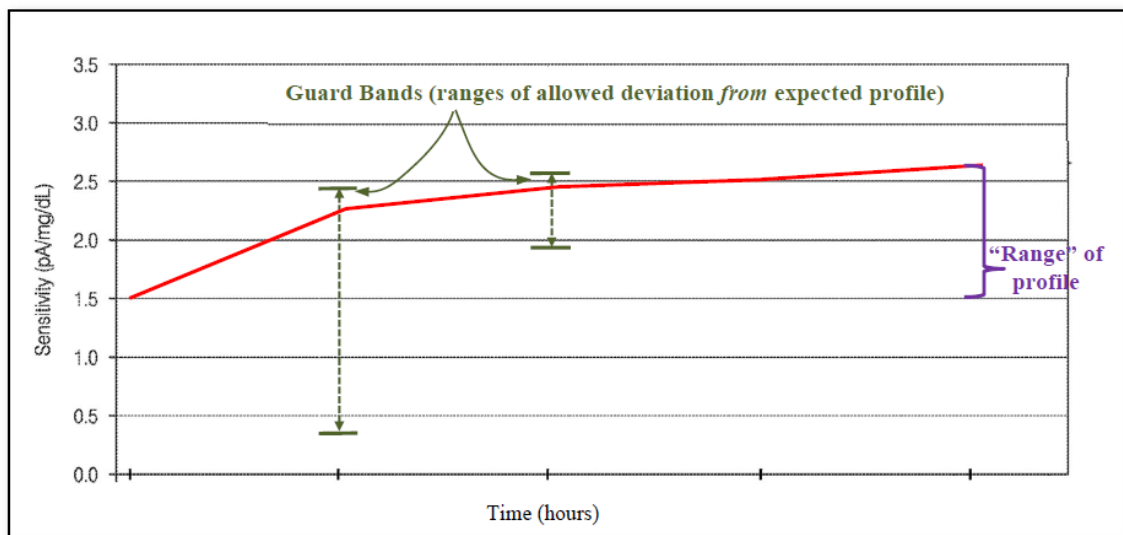
Furthermore, Patent Owner asserts that Shin does not disclose the use of “information associated with a drift profile” as recited in limitation 23c of claim 23. Prelim. Resp. 71–74. Specifically, Patent Owner argues that Petitioner fails to demonstrate that Shin’s “valid sensitivity ranges” are the claimed “drift profile” because they allegedly “relate to expected sensitivity changes over time.” *Id.* at 71 (citing Pet. 60). Patent Owner argues that “Shin’s ‘*valid*’ sensitivity ranges’ do not relate to *expected* sensitivity changes.” *Id.* Patent Owner avers that Shin thus fails to disclose a “drift profile” as claimed. Prelim. Resp. 72 (citing *id.* at § V.B.2).

On this record, we do not find Patent Owner’s arguments availing. Shin appears to use “valid sensitivity range” to determine if MSPSR is reasonable, i.e., falls within an “expected” range. Ex. 1008 ¶ 103. To the extent Patent Owner wishes to advocate for a particular meaning for “*expected* sensitivity changes” that would preclude Shin’s “*valid* sensitivity ranges” or the use of Shin’s glucose meter readings, Patent Owner should make its construction clear on the trial record.

Patent Owner further argues that the “drift profile” of the ’031 patent provides the sensitivity change/drift over time and is representable as “a line having a slope and/or curvature” that specifies how the sensor’s sensitivity changes over time. Prelim. Resp. 72 (citing *id.* at §§ II.A., IV.C.2, V.B.2; Ex. 1001, 213:9–25, 216:48–52). Patent Owner argues that Shin’s “valid sensitivity ranges” are not representable as such a line, and thus are not a

“drift profile” as claimed. *Id.* Patent Owner further argues that the ’031 patent distinguishes between the claimed “drift profile” and ranges (e.g., guard bands or cones) of acceptable deviation from the “profile.” Prelim. Resp. 72–74 (citing *id.* §§ II.A., V.B.2; Ex. 1001, 213:13–36, 216:44–61; Pet. 60–61).

Patent Owner insists that Shin’s “valid sensitivity ranges” are not the claimed “drift profile,” but as we presently understand the language of limitation 23c of claim 23, what is required is “information associated with a drift profile,” not the “drift profile” itself. We show below Patent Owner’s figure in support of its arguments to illustrate this point:



Prelim. Resp. 73. In the Patent Owner’s figure above, the valid sensitivity ranges (black dotted lines and bars) bound the “drift profile” (red line). On the present record, we agree with Petitioner that Shin’s valid sensitivity ranges bound or encompass the “drift profile” and are similar to the guard bands in Patent Owner’s figure above. Shin’s valid sensitivity ranges may thus be considered “information associated with a drift profile” as claimed.

To the extent the parties dispute the meanings of “drift profile” and “information associated with a drift profile,” their proposed constructions should be made clear on the trial record.

We further note that Patent Owner’s arguments are supported largely by attorney argument, which is not evidence. *See Icon Health, supra*.

On the current record, Petitioner shows sufficiently that Shin discloses limitation 23d of claim 23.

(v) *Limitation 23d: Displaying Glucose Concentration Value*

Limitation 23d recites “displaying the glucose concentration value.” Ex. 1001, 259:50.

Petitioner contends that “Shin’s method involves displaying the determined glucose concentration values.” Pet. 61. Petitioner asserts that Shin’s display 214 is used to display the calculated results of raw glucose sensor data received via download from glucose monitor 100, and can display other information including “graphs of historical data” among other things. *Id.* (citing Ex. 1008 ¶ 62; Ex. 1002 ¶¶ 223–224).

On the present record, Petitioner shows sufficiently that Shin discloses limitation 23d.

(vi) *Conclusion for Claim 23*

Petitioner has shown sufficiently on this record that each limitation of claim 23 is disclosed by Shin notwithstanding Patent Owner’s arguments. Accordingly, Petitioner has shown a reasonable likelihood to prevail in demonstrating unpatentability of claim 23 of the ’031 patent as anticipated by Shin.

3. *Claim 35*

We now address Petitioner’s contentions for each limitation of claim 35, and Patent Owner’s arguments concerning limitations 35e and 35f, which are the only limitations of claim 35 that Patent Owner disputes at this time.

(i) *Preamble*

Claim 35’s preamble recites “A sensor system comprising:”
Ex. 1001, 260:33.

Petitioner contends that “Shin describes a glucose monitor system comprising a sensor to detect glucose concentration.” Pet. 69 (citing Ex. 1008 ¶¶ 2, 31–32, 54, Figs. 1–2; Ex. 1002 ¶ 260).

We find that Petitioner shows sufficiently that Shin discloses claim 35’s preamble and thus do not reach whether the preamble is limiting.

(ii) *Limitation 35a: Transcutaneous Glucose Sensor*

Limitation 35a recites “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 implanted within the body of the host.”
Ex. 1001, 260:34–38.

Petitioner relies on its contentions for limitation 23a of claim 23 as meeting limitation 35a. Pet. 69 (citing *id.* § X.B.1.b; Ex. 1002 ¶¶ 261–262).

On this record, we find that Petitioner shows sufficiently that Shin discloses limitation 35a.

(iii) *Limitation 35b: Electrode and Membrane with Enzyme*

Limitation 35b recites “wherein the in vivo portion comprises: an electrode; and a membrane disposed over at least a portion of the electrode,

wherein the membrane comprises at least one enzyme.” Ex. 1001, 260:38–43.

Petitioner contends that the in-vivo portion of Shin’s sensor comprises electrodes 20 which terminate in the user’s subcutaneous tissue. Pet. 69 (citing Ex. 1008 ¶ 57, Fig. 2). We find that Petitioner has shown sufficiently that Shin discloses that the in-vivo portion of Shin’s glucose sensor comprises an electrode as claimed.

Petitioner also asserts that Shin’s sensor comprises “an enzyme coating.” *Id.* (citing Ex. 1008 ¶¶ 64–65). Petitioner argues that the “POSA would have understood that such coating serves to immobilize the enzyme (such that the enzyme cannot diffuse away, resulting in enzyme loss), while allowing glucose and oxygen to diffuse into the coating such that glucose can undergo the reaction catalyzed by the enzyme.” *Id.* Petitioner alleges that “the POSA would have understood such ‘enzyme coating’ to be a membrane comprising the enzyme.” *Id.* Petitioner further asserts that Shin “incorporates by reference documents disclosing a membrane comprising an enzyme that is disposed over an in-vivo portion of the electrode.” *Id.* at 69–70 (citing Ex. 1008 ¶ 57; Ex. 1009, 3, Fig. 1; Ex. 1002 ¶¶ 263–266). Alternatively, Petitioner argues that using a membrane was obvious because it was the preferred technique for immobilizing glucose oxidase in CGMs. *Id.* at 70 (citing *id.* § X.A.13.c; Ex. 1002 ¶ 267).

Reviewing the evidence on the current record, we find that Petitioner shows sufficiently that Shin discloses an enzyme-containing membrane (Shin’s coating) disposed over the electrode of the in-vivo portion of Shin’s sensor, and thus discloses limitation 35b.

(iv) *Limitation 35c: Generating Signal Associated with Glucose Concentration*

Limitation 35c recites “wherein the transcutaneous glucose sensor generates a signal associated with a glucose concentration within the body of the host.” Ex. 1001, 260:44–46.

Petitioner contends that “in Shin, ‘the 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.’” Pet. 70 (citing Ex. 1008 ¶¶ 69; Ex. 1002 ¶¶ 268–269).

On this record, Petitioner shows sufficiently for institution that Shin discloses limitation 35c.

(v) *Limitation 35d: Electronics Configured to Receive Signal*

Limitation 35d recites “electronics configured to receive the signal from the transcutaneous glucose sensor.” Ex. 1001, 260:47–48.

Petitioner contends that “Shin’s system comprises electronics configured to receive signals from the sensor.” Pet. 70–71 (citing Ex. 1008 ¶¶ 15, 58–62, Figs. 1, 2; Ex. 1002 ¶¶ 270–271).

On the present record, we find that Petitioner shows sufficiently that Shin discloses limitation 35d.

(vi) *Limitation 35e: Electronics Comprising Memory Storing Information Associated with Expected Change over Time*

Limitation 35e recites “wherein the electronics comprises a memory, wherein the memory stores information associated with an expected change over time in a relationship between the signal and the glucose concentration within the body of the host.” Ex. 1001, 260:48–52.

Petitioner contends that

Shin's electronics comprises memory that stores information associated with an expected change over time in sensor sensitivity. Because sensitivity defines in part a relationship between sensor signal and the glucose concentration within the host's body, this information also is associated with an expected change over time in such relationship.

Pet. 71 (citing Ex. 1002 ¶¶ 272–279).

Petitioner quotes Shin as stating that the

apparatus for calibrating glucose monitor data includes a glucose monitor, glucose sensor, a blood glucose meter and a processor. The glucose monitor includes a glucose monitor memory for storing glucose monitor data. The glucose sensor is electronically coupled to the glucose monitor to supply the glucose monitor data.

Id. (citing Ex. 1008 ¶¶ 15, 58). Petitioner states that the glucose monitor thus comprises a memory. *Id.* Petitioner further avers that Shin discloses embodiments where the glucose monitor stores “the necessary software to calibrate glucose sensor signals.” *Id.* at 72 (citing Ex. 1008 ¶ 61).

Petitioner asserts that “Shin's memory stores information associated with an expected change over time in sensor sensitivity.” *Id.* (citing Ex. 1008 ¶¶ 87–104). Specifically, Petitioner alleges that Shin discloses “that the calibration factor (the MSPSR) is compared to ‘valid sensitivity ranges,’ and such ranges can depend on ‘how long the sensor has been in use’” and “[a]ccordingly, different valid sensitivity ranges can be used, each range associated with a length of time of sensor use.” *Id.* (citing Ex. 1008 ¶ 103).

Petitioner asserts that “[t]he different valid sensitivity ranges that depend on the length of time of sensor use are based on expected sensitivity changes associated with sensor use.” *Id.* Petitioner contends that “[t]hus the

valid sensitivity ranges constitute “information associated with an expected change over time in a relationship between signal and the glucose concentration within the body of the host,” as recited in limitation 35e. *Id.* at 72–73 (citing Ex. 1008 ¶ 103; Ex. 1001, 213:5–43, 216:44–61).

Petitioner further asserts that “Shin’s valid sensitivity ranges must be stored in memory, because each calculated MSPSR is compared to a valid sensitivity range that has been predetermined and that therefore must be stored in the system.” *Id.* at 73. Specifically, Petitioner asserts that “Shin teaches that the example valid sensitivity range of 1.5 to 15 was determined in-vitro and thus prior to sensor insertion.” *Id.* (citing Ex. 1008 ¶ 103). Petitioner argues that Shin’s “range must be stored in system memory for the system to compare the MSPSR to it.” *Id.* Petitioner further avers that “[a] system with electronics comprising memory storing information to be used in calibration also would have been obvious, at least because such electronics were a basic and essential component of CGMs.” *Id.*

Patent Owner presents similar arguments to those we considered and found unavailing for limitation 23c of claim 23. Prelim. Resp. 64–66; *see* § IV.E.2.iv, *supra*. Specifically, Patent Owner argues that Shin does not disclose that its system rejects an MSPSR if outside of the valid sensitivity range, contrary to Petitioner’s assertion. Patent Owner does not explain how its argument relates to limitation 35e, and it is therefore unavailing.

On this record, we find that Petitioner shows sufficiently for institution that Shin discloses limitation 35e.

(vii) Limitation 35f: Electronics Configured to Generate Glucose Concentration Value

Limitation 35f recites “wherein the electronics is configured to generate a glucose concentration value based at least in part on the signal and the information associated with the expected change over time in the relationship.” Ex. 1001, 260:52–56.

Petitioner contends that “Shin’s system comprises electronics configured to calculate a glucose concentration value based at least in part on the sensor signal and the valid sensitivity ranges discussed above.” Pet. 73 (citing Ex. 1002 ¶¶ 280–283).

Petitioner asserts that Shin’s “glucose monitor (or the data processor) can contain the software to calibrate sensor signals and display a glucose concentration value” and “[t]hus, Shin’s electronics (which include the glucose monitor and the data processor) are configured to determine a glucose concentration value.” *Id.* (citing Ex. 1008 ¶¶ 60–61).

Petitioner asserts that Shin’s “electronics determine the glucose concentration value based at least in part on Shin’s valid sensitivity ranges—i.e., on the expected change over time in the relationship as claimed.” *Id.* at 74. Petitioner asserts that “[w]hen processing sensor data and determining a glucose concentration value, Shin’s system compares the MSPSR (Shin’s calibration factor, which is calculated daily in preferred embodiments) to a valid sensitivity range, where the range that is used in the comparison can depend on how long the sensor has been in use.” *Id.* (citing Ex. 1008 ¶¶ 82, 85). Petitioner notes that Shin states that “the MSPSR is compared to a valid sensitivity range to determine if the newly calculated MSPSR is reasonable.” *Id.* (citing Ex. 1008 ¶ 103). Petitioner contends that if the

MSPSR is outside of the valid sensitivity range for a particular day, then a calibration error alarm notifies the user of a potential problem. *Id.*

Petitioner argues that by comparing the MSPSR to a validity range that depends on how long the sensor has been in use, Shin's system determines whether or not to accept that MSPSR and calibrate sensor data and generate a glucose concentration value. *Id.* Petitioner avers that "Shin's system determines a glucose concentration value based at least in part on the information associated with the expected change in sensitivity, and thus in the relationship, over time." *Id.*

Patent Owner argues that "Shin does not teach that [its] 'valid sensitivity ranges' are based on ***expected*** sensitivity changes." *Id.* at 66. Particularly, Patent Owner asserts that "[s]pecifying that different ranges of sensitivities will be considered 'valid' at different times" does not disclose "that those ranges are based on '***expected*** sensitivity changes.'" *Id.* Furthermore, Patent Owner asserts that Shin 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" which is why Shin "relies on periodically ***measuring*** the sensor's response with reference to fingersticks (blood glucose meter readings) to determine what the sensor's sensitivity is." *Id.* at 66–67.

Patent Owner asserts that Shin's only example of "valid sensitivity ranges" at different points in time does not indicate "expected" sensitivity changes but merely different accuracy levels of single-point calibration versus multiple-point calibration (1.5 to 15 for single-point calibration; 2.0 to 10.0 for multiple-point calibration). *Id.* at 67–69 (citing Ex. 1008 ¶¶ 87, 103–104, 114, 141–147; Ex. 2009 ¶¶ 21–24, 39, 42–44, Fig. 4). Patent

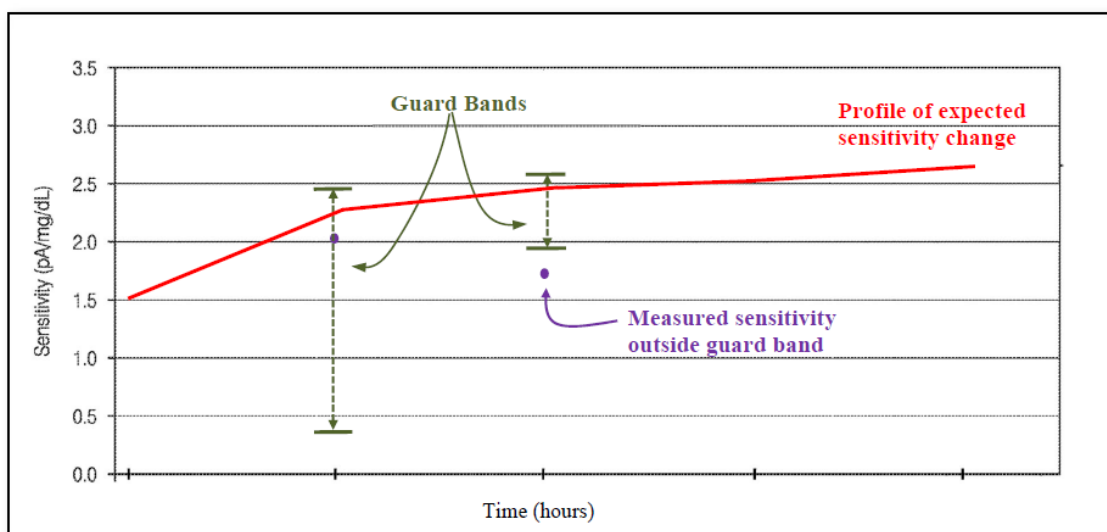
Owner argues that “Shin’s discussion of different ‘valid sensitivity ranges’ at different times in no way discloses that those ranges are different because of ‘**expected**’ sensitivity changes of the sensor.” *Id.* at 69.

Patent Owner further avers that the ranges (boundaries or guard bands) and cone of possible sensitivity values disclosed in the ’031 patent that Petitioner mentions are not related to the claimed “**expected**” change. *Id.* at 70 (citing Pet. 83; Ex. 1001, 213:33–36, 213:50–53). Patent Owner asserts that the ’031 patent “discusses the ‘expected [drift] profile’ and the guard bands as **different** types or parts of the total *a priori* information that can be applied in calibration.” *Id.* According to Patent Owner,

[t]he ‘expected profile’ is ‘e.g., an expected pattern and/or amount of sensitivity change/drift over time’ 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 . . . 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.

Id. (citing Ex. 1001, 213:9–53, 216:48–52). Patent Owner argues that the claimed “expected change” cannot be met by Shin’s “valid sensitivity ranges.” *Id.* at 71.

On this record, we do not agree with Patent Owner’s arguments. To explain our view, we refer to the figure below that Patent Owner presented with its arguments.



Prelim. Resp. 71. Patent Owner’s figure above shows the expected change in sensitivity (red line) and the guard bands or ranges at different points in time (black dotted arrows and bars). Shin’s valid sensitivity ranges may be viewed as guard bands that bound or encompass the expected change in sensitivity over time in Patent Owner’s figure above.

Specifically, Shin discloses that a newly calculated MSPSR (calibration factor) is compared to a valid sensitivity range to determine if the MSPSR is reasonable, i.e., that its change from the previous range is an “*expected* change.” 1008 ¶ 103. Shin further states that “[o]ther valid sensitivity ranges may be applied depending on . . . how long the sensor has been in use” among other factors. *Id.* Thus, on this record, Shin discloses the “expected change *over time*.” The composite of Shin’s valid sensitivity ranges over time bounds or encompasses what Patent Owner refers to as the “profile of expected sensitivity change” over time in Patent Owner’s above figure.

Accordingly, on this record, we agree with Petitioner that Shin’s valid sensitivity ranges may be regarded “information associated with the

expected change over time in the relationship” “between the signal and the glucose concentration within the body of the host,” as claimed. Shin appears to use the valid sensitivity range to determine if MSPSR is reasonable, i.e., whether the MSPSR is within the valid sensitivity range and thus constitutes an “expected change.” Pet. 74 (citing Ex. 1008 ¶ 103).

To the extent Patent Owner advocates a particular meaning for “information associated with the expected change over time in the relationship” or terms therein that would preclude Shin’s “valid sensitivity ranges” or use of Shin’s glucose meter readings from finger sticks, Patent Owner should make its construction clear on the trial record.

(viii) Conclusion for Claim 35

Petitioner has shown sufficiently on this record that each limitation of claim 35 is disclosed by Shin notwithstanding Patent Owner’s arguments. Accordingly, Petitioner has shown a reasonable likelihood to prevail in demonstrating unpatentability of claim 35 of the ’031 patent as anticipated by Shin.

1. Claim 42

We now address Petitioner’s contentions for each limitation of claim 42, and Patent Owner’s arguments concerning limitation 42c, which is the only limitation of claim 42 that Patent Owner disputes at this time.

(i) Preamble

Claim 42’s preamble recites “A method for monitoring a glucose concentration, the method comprising:” Ex. 1001, 261:20–21.

Petitioner contends that “Shin describes a method for monitoring glucose concentration in a host.” Pet. 75 (citing Ex. 1008 ¶ 54).

We find that Petitioner shows sufficiently that Shin discloses claim 42's preamble and thus we do not reach whether the preamble is limiting.

(ii) *Limitation 42a: Beginning Sensor Session Associated with Use of Transcutaneous Glucose Sensor*

Limitation 42a recites “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.” Ex. 1001, 261:22–28.

Petitioner relies on its contentions for limitation 23a of claim 23 in asserting that Shin discloses limitation 42a. Pet. 76 (citing *id.* § X.B.1.b).

On this record, we find that Petitioner shows sufficiently that Shin discloses limitation 42a.

(iii) *Limitation 42b: Transcutaneous Glucose Sensor Configured to Generate a Signal*

Limitation 42b recites “wherein the transcutaneous glucose sensor is configured to generate a signal.” Ex. 1001, 261:29–30.

Petitioner relies on its contentions for limitation 23b of claim 23 and limitation 35c of claim 35 in asserting that Shin discloses limitation 42b. Pet. 76 (citing *id.* § X.B.1.c, § X.B.13.d).

On the current record, we find that Petitioner shows sufficiently that Shin discloses limitation 42b.

(iv) *Limitation 42c: Calibrating Transcutaneous Glucose Sensor by Applying A Priori Information*

Limitation 42c recites “calibrating the transcutaneous glucose sensor by applying a priori information, wherein the a priori information comprises an expected relationship between the signal and a glucose concentration

existing within the body of the host, wherein the relationship changes as a function of time.” Ex. 1001, 262:1–6.

Petitioner contends that “Shin teaches calibrating the sensor by applying a priori information comprising expected sensitivity changes over time,” “which is an expected relationship between sensor signal and glucose concentration” as recited in limitation 42c. Pet. 76. Petitioner alleges that “Shin teaches that each calculated MSPSR is compared to a pre-determined valid sensitivity range, and that the valid sensitivity ranges used over time can be ranges that depend on how long the sensor has been in use.” *Id.* (citing Ex. 1008 ¶ 103). Petitioner argues that “[a]s a result of this comparison, the system either accepts or rejects the MSPSR, and if the MSPSR is accepted sensor calibration proceeds.” *Id.* Accordingly, Petitioner avers that Shin discloses calibrating the sensor “by applying a priori information” (the pre-determined valid sensitivity ranges) comprising “an expected relationship between the signal and a glucose concentration existing within the body of the host, wherein the relationship changes as a function of time,” as recited in limitation 42c. *Id.* at 76–77 (citing § X.B.1.d (regarding limitation 23c); § X.B.13.g (regarding limitation 35f)).

Patent Owner presents similar arguments to those we discussed for limitation 23c and limitation 35f, which we find unavailing. Prelim. Resp. 64–71. Specifically, Patent Owner argues that Shin does not state that the calculated MSPSR (calibration factor) is rejected if outside of the valid sensitivity range. Prelim. Resp. 64. As explained before, however, if the MSPSR is outside the “valid sensitivity range” and thus is not “reasonable” according to Shin, it seems unlikely that a POSA would use it to calibrate

data. Ex. 1008 ¶ 103. In any case, how Patent Owner’s argument relates to the claim language has not been explained sufficiently on this record.

Likewise, Patent Owner’s arguments concerning lesser or greater accuracy using single-point calibration versus multiple-point calibration does not seem apropos given Petitioner’s argument that Shin discloses that “[o]ther valid sensitivity ranges may be applied depending on . . . how long the sensor has been in use.” Prelim. Resp. 67–69. The composite of Shin’s valid sensitivity ranges bounds or encompasses (i.e., “comprises”) what Patent Owner asserts is the “profile of expected sensitivity change” and thus whether those valid sensitivity ranges are more or less accurate seems irrelevant to whether they disclose that “a priori information comprises an expected relationship between the signal and a glucose concentration existing within the body of the host” as claimed.

Although Patent Owner argues that “expected profile” or “expected relationship” and guard bands are different types of a priori information, Patent Owner does not explain why Shin’s valid sensitivity ranges are not guard bands that comprise the “expected relationship” and thus satisfy the claim limitation of “a priori information [that] comprises an expected relationship between the signal and a glucose concentration existing within the body of the host.”

On this record, Petitioner shows sufficiently for institution that Shin discloses limitation 43c.

(v) *Limitation 42d: Generating Glucose Concentration Value*

Limitation 42d recites “generating a glucose concentration value based at least in part on the calibrating.” Ex. 1001, 262:7–8.

Petitioner contends that Shin discloses this limitation for the reasons stated for limitation 23c of claim 23 and limitation 35f of claim 35. Pet. 77 (citing *id.* § X.A.1.d, § X.A.13.g).

On the present record, we find that Petitioner shows sufficiently that Shin discloses limitation 42d.

(vi) *Limitation 42e: Displaying Glucose Concentration Value*

Limitation 42e recites “displaying the glucose concentration value.” Ex. 1001, 262:9.

Petitioner contends that Shin discloses this limitation for the reasons stated for limitation 23d of claim 23. Pet. 77 (citing *id.* at § X.B.1.e; Ex. 1002 ¶¶ 296–307).

On this record, we find that Petitioner shows sufficiently that Shin discloses limitation 42e.

(vii) *Conclusion for Claim 42*

Petitioner has shown sufficiently on this record that each limitation of claim 42 is disclosed by Shin notwithstanding Patent Owner’s arguments. Accordingly, Petitioner has shown a reasonable likelihood to prevail in demonstrating unpatentability of claim 42 of the ’031 patent as anticipated by Shin.

2. *Dependent Claims 24–34, 36–41, and 43–46*

Petitioner contends that Shin discloses dependent claims 24–34, 36–41, and 43–46. Pet. 61–68, 75, 77. Other than as addressed above, Patent Owner does not dispute Petitioner’s contentions or evidence for these claims at this time.

We have reviewed Petitioner’s contentions and evidence for these claims and find that Petitioner shows sufficiently for institution that the

limitations of these dependent claims are disclosed by Shin. Hence, Petitioner has demonstrated a reasonable likelihood to prevail in demonstrating unpatentability of dependent claims 24–34, 36–41, and 43–46 as anticipated by Shin on the present record.

V. CONCLUSION

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

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), the petitioned institution of *inter partes* review of claims 23–46 of the '031 patent is *granted*; and

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

IPR2024-00891
Patent 11,020,031 B1

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