

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ABBOTT DIABETES CARE INC.,  
Petitioner,

v.

DEXCOM, INC.,  
Patent Owner.

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IPR2024-00890  
Patent 11,020,031 B1

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

JURGOVAN, *Administrative Patent Judge*.

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

## I. INTRODUCTION

Petitioner Abbott Diabetes Care Inc. filed a Petition (Paper 1, “Pet.”) pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of claims 1–2, 4, 6–15, and 20–22 (“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.

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. 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 litigations 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 IPR2024-00891 (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.

In IPR2024-00891, Petitioner filed on the same date a parallel petition to challenge claims 23–26 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:<br>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:<br>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. Petitioner ranked the Petition filed in this proceeding as first. *Id.* at 3. Accordingly, we need not reach the issue of parallel petitions in this proceeding, and instead address the issue in our institution decision in IPR2024-00891.

*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.

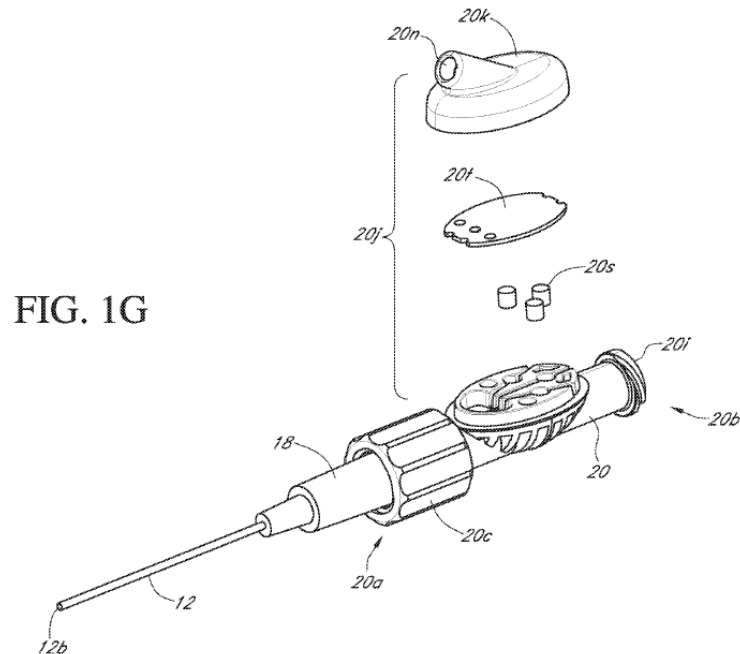


Figure 1G above is an exploded view of an analyte sensor system. *Id.* at 16:34–38. In Figure 1G, the analyte sensor system has fluid coupler 20 with housing 20j configured for electrical connection of the analyte sensor to electronics. *Id.* at 40:7–11. Housing 20j includes cover 20k and electrical 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.

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

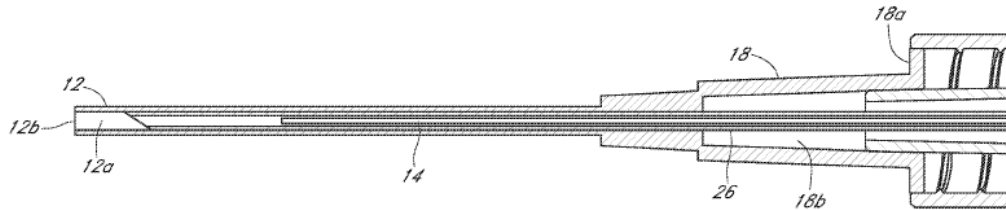


FIG. 1E

Figure 1E above is a cutaway view of a portion of the analyte sensor system. *Id.* at 16:32–33. Analyte sensor 14 may be configured to extend through catheter lumen 12a and out of orifice 12b into the host's blood stream, or it may reside entirely within the catheter. *Id.* at 36:47–55. Analyte sensor 14 generates an electric signal based on the analyte (e.g., glucose) concentration in the host's bloodstream. *Id.* at 36:65–37:7. Analyte sensor 14 passes through connector 18 and fluid coupler 20 and connects to the sensor electronics which use the signal from the sensor to determine analyte concentration in the host. *Id.* at 38:25–29. Analyte sensor 14 may include electrodes and a membrane with an enzyme which reacts with an analyte to generate electrical current measured by the sensor electronics. *Id.* at 28:12–24, 37:20–37, 68:36–47.

The '031 patent's glucose monitoring system uses a conversion function that map's the sensor's electrical current output to a corresponding glucose concentration in units useful to the user. *Id.* at 141:14–36. The conversion function is linear and has the form  $y = mx + b$  where  $y$  is the output from the sensor,  $x$  is the glucose concentration,  $m$  (the line's slope) is the sensor's "sensitivity," and  $b$  is the "baseline" signal (the sensor's output when there is zero glucose present). *Id.* at 139:27–40, 140:12–141:31, 204:63–67.

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 1 and 14 are independent. Claims 2, 4, and 6–13 depend, directly or indirectly, from claim 1, and claims 15 and 20–22 depend directly from claim 14.

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

1. [Pre] A system for monitoring a glucose concentration, the 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 inserted into 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 is configured to generate a signal, wherein the magnitude of the signal depends upon a glucose concentration existing at the in vivo portion of the transcutaneous glucose sensor inserted into the body of the host;
  - [d] electronics configured to operably connect to the transcutaneous glucose sensor, wherein the electronics comprises a memory,

- [e] *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.*

Ex. 1001, 257:43–67 (emphases added).

Claim 14 is shown below with limitation identifiers indicated in brackets and disputed claim language emphasized in italics.

- 14. [Pre] A method of 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 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] generating sensor data at least in part from a signal received from the in vivo portion of the transcutaneous glucose sensor;
  - [d] 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.*

Ex. 1001, 258:44–65 (emphases added).

#### *D. Asserted Prior Art*

Petitioner relies on the following references as prior art against the challenged claims of the '031 patent. Pet. 13.

| Name  | Reference          | Date          | Exhibit No. |
|-------|--------------------|---------------|-------------|
| Zhang | US 2005/0143636 A1 | Jun. 30, 2003 | 1004        |
| Shin  | US 2005/0004439 A1 | Jan. 6, 2005  | 1008        |

Patent Owner does not dispute at this time 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. 7.

| Ground | Reference(s)/Basis | 35 U.S.C. § <sup>1</sup> | Claim(s) Challenged |
|--------|--------------------|--------------------------|---------------------|
| 1      | Zhang              | 102/103                  | 1–2, 4, 6–15, 20–22 |
| 2      | Shin               | 102/103                  | 1–2, 4, 6–15, 20–22 |

*F. Testimonial Evidence*

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

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<sup>1</sup> 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.

### III. PETITIONER’S GROUNDS OF UNPATENTABILITY

#### A. *Legal Standards*

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

##### 1. *Petitioner’s Burden*

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

##### 2. *Anticipation*

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

##### 3. *Obviousness*

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art (“POSITA” or “POSA”) to which said subject matter pertains. *KSR Int’l Co. v. Teleflex*

*Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness.<sup>2</sup> *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

*B. Level of Ordinary Skill in the Art*

In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (quoting *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986)). 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” or “POSITA”) 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

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

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. 17–18 (citing Ex. 1002 ¶ 68).

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. 18.

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, on this record, 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 interprets the claims ‘in accordance with the ordinary and customary meaning . . . as understood by one of ordinary skill in the art.’” Pet. 18 (alteration in original). Petitioner asserts that “the Board need not expressly construe the terms of the challenged claims to resolve the controversy.” *Id.* (citing *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017)).

Patent Owner does not address Petitioner's contention that the ordinary and customary meaning should apply to the terms of the challenged claims.

As the parties do not present any dispute over the meaning of any claim term, 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*.

*D. Anticipation and Obviousness over Zhang*

Petitioner asserts that claims 1–2, 4, 6–15, and 20–22 of the '031 patent were anticipated by Zhang, and would have been obvious thereover. Pet. 26–53. Patent Owner disagrees. Prelim. Resp. 18–59.

We address Zhang's disclosure and the parties' contentions for the limitations that appear to be central to resolution of this matter.

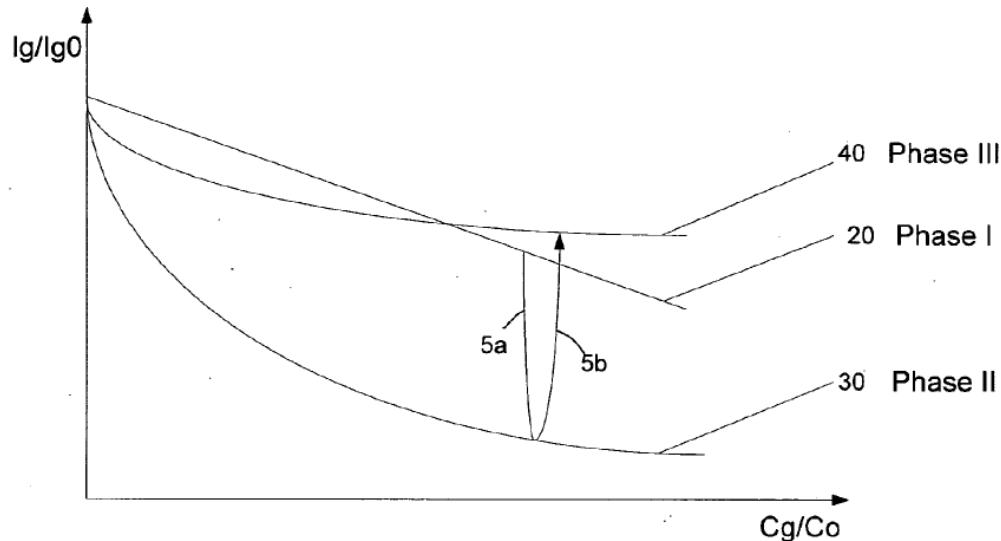
*1. Zhang (Ex. 1004)*

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 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 changes 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.* ¶¶ 41–61.

Zhang's Figure 6 is shown below.

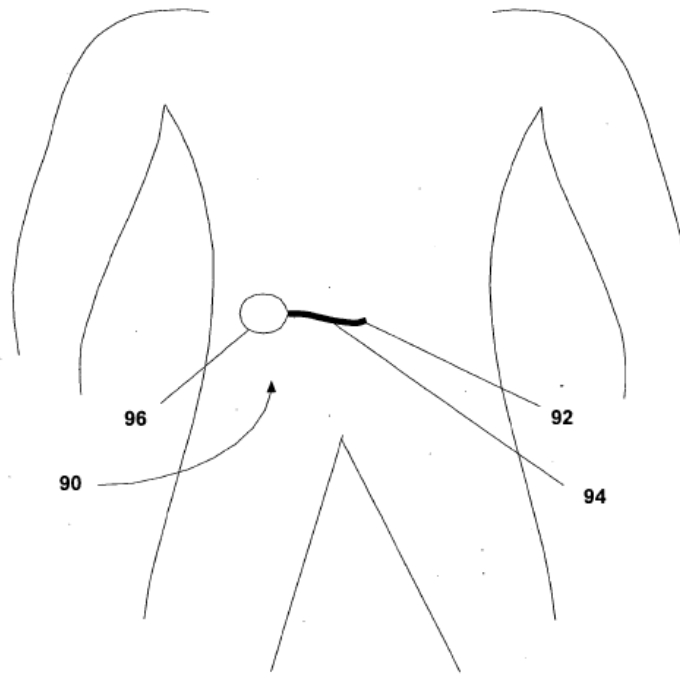


FIG. 6

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 1 and 14

We now address Petitioner's contention that Zhang discloses or renders obvious claim 1 and claim 14, and Patent Owner's arguments disputing Petitioner's contentions. Pet. 26–40 (claim 1), 49–52 (claim 14); Prelim. Resp. 18–59.

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

Claim 1 recites limitation 1a as “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.” Ex. 1001, 257:45–49 (emphasis added). Claim 14 recites similar limitation 14a. *Id.* at 258:47–52.

Petitioner asserts that Zhang discloses this limitation or renders it obvious. Pet. 27–29. Specifically, Petitioner relies on the following excerpt from Zhang as disclosing a transcutaneous glucose sensor:

[E]mbodiments 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. 30–46. 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 33–34. 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. 33–34. 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.”<sup>3</sup> Pet. 27–28 (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 28. 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 29 (citing Ex. 1025, 129).

Although general knowledge of a POSITA is considered in the obviousness inquiry, Exhibit 1025, on which Petitioner relies, appears to 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. 29 (citing Ex. 1004 ¶¶ 31, 33; Ex. 1002 ¶¶ 97–98).

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<sup>3</sup> Continuous Glucose Monitors. *See* Pet. 8.

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. 37–42 (citing *Virtek Vision Int’l. ULC v. Assembly Guidance Sys.*, 97 F.4th 882, 886 (Fed. Cir. 2024)). According to Patent Owner, Zhang’s sensing system is implanted for long periods of time, and thus requires Zhang’s in vivo recalibration techniques to ensure accuracy over the sensor’s lifetime following implantation. *Id.* at 39–40. Patent Owner contends Petitioner’s noted advantages of transcutaneous glucose sensors “nullify the reasons for and conflict with the execution of Zhang’s recalibration techniques.” *Id.* at 40.

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. 29. 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. 43–46. 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 43–44. Relatedly, 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 44. 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 44–45 (citing Pet. 29; 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 45–46 (citing Pet. 29; Ex. 1004 ¶ 33).

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 of its use. On this record, Patent Owner does not establish the facts necessary to support these arguments.

(ii) *Profile Based on A Priori Information*

Limitation 1e of claim 1 recites 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.” Ex. 1001, 257:62–67.

Petitioner contends that Zhang discloses this feature of claim 1. Pet. 36–40 (citing Ex. 1002 ¶¶ 119–125). Specifically, Petitioner contends that, in Zhang’s system, the memory stores normalized calibration curves for the different phases of sensor life, and these curves and the adjustment for shifting between different shapes of these curves over the sensor’s life constitute “a profile” such that Zhang’s memory stores “information associated with a profile” as claimed. Pet. 36–39 (citing Ex. 1004 ¶¶ 33, 37–40, 51, 61–62, Fig. 2). Petitioner further asserts the sensitivity changes occur while the sensor is inserted into a host. *Id.* at 36 (citing Ex. 1002 ¶ 120).

In addition, Petitioner contends that Zhang’s profile is “based at least in part on a priori information related to expected sensitivity changes” of the sensor over time because each of Zhang’s normalized curves reflects sensor sensitivity (i.e., the slope of the curve at a given point) at each phase of sensor life. *Id.* at 36–37 (citing Ex. 1004 ¶¶ 33, 37–39). Petitioner further asserts that Zhang’s curves are generated using “a priori empirical values of sensors similar to the sensor being calibrated.” *Id.* (citing Ex. 1004 ¶¶ 16, 33, Fig. 2).

Patent Owner argues that Petitioner fails to show that Zhang’s memory stores Zhang’s calibration curves. Prelim. Resp. 47–52. Patent

Owner alleges that Petitioner's contention is based only on a single-sentence assertion and is supported by no evidence. *Id.* at 48 (citing Pet. 36–37). According to Patent Owner, Zhang's Figure 2 is merely “conceptual” and shows “background research” to explain why each sensor will have a non-linear curve for its calibration and why Zhang chose to use a five-point piecewise linear approximation to create each sensor's actual curve. *Id.* at 48–52 (citing Ex. 1004 ¶¶ 15–16, 33, 37–38, 40–62, 64, Figs. 4, 5, claims 34 and 36; Pet. 35). Patent Owner further alleges that Petitioner cites Zhang's discussion of adjusting a curve based on an array of data, but argues that this does not relate to the calibration curves of Zhang's Figure 2, and does not disclose that such curves are stored in memory in Zhang's sensor system. *Id.* at 52 (citing Ex. 1004 ¶¶ 7, 13, 41).

We do not agree with Patent Owner's arguments at this stage of the proceeding because they seem to contradict Zhang's disclosure. For example, Zhang discloses that “a new calibration curve may be set for the sensor” and “the sensor output can be calculated using the new calibration curve.” *See* Pet. 40 (citing Ex. 1004 ¶¶ 60–61). Thus, Zhang appears to disclose that the sensor stores at least two calibration curves (i.e., the “new calibration curve” ( $Y'(i)$ ) and the one that existed before it ( $Y(i)$ ). *See* Ex. 1004 ¶ 60. Furthermore, Patent Owner does not address Petitioner's assertion that the claimed profile comprises adjustments in addition to calibration curves. Pet. 36. Patent Owner's arguments thus do not undermine Petitioner's showing for limitation 1e of claim 1 for purposes of institution.

Limitation 14d of claim 14 recites “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.” *Id.* at 258:61–65.

Petitioner contends that Zhang discloses this feature of claim 14. Pet. 50–52 (citing Ex. 1002 ¶¶ 178–181). Specifically, Petitioner asserts that “Zhang’s method involves calibrating sensor data” as claimed. *Id.* at 50–51 (citing Ex. 1004 ¶¶ 27, 40). Petitioner avers that Zhang’s normalized calibration curves and curve adjustments are based on a priori information because they are derived from empirical data collected from use of sensors. *Id.* at 52 (citing Ex. 1004 ¶¶ 16, 33, Fig. 2). Petitioner alleges that applying Zhang’s normalized calibration curves and curve adjustments to calibrate sensor data discloses a priori information that comprises a profile as claimed. *Id.* (citing Ex. 1004 ¶¶ 40, 61). Petitioner further contends that Zhang’s calibration curve shapes and the shifts between them constitute “a profile associated with a drift in sensitivity” of the sensor “over time” as recited in claim 14. *Id.* at 51–52 (citing Ex. 1004 ¶¶ 32–39, Fig. 2).

Patent Owner argues that Zhang’s Figure 2 calibration curves “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” Zhang’s Figure 2 curves. Prelim. Resp. 53. Rather, Patent Owner contends that Zhang’s Figure 2 curves represent “observations in research on sensors in general.” *Id.* Patent Owner asserts that “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.” *Id.*

On this record, we do not agree with Patent Owner’s argument. As explained, Zhang discloses that “a new calibration curve may be set for the

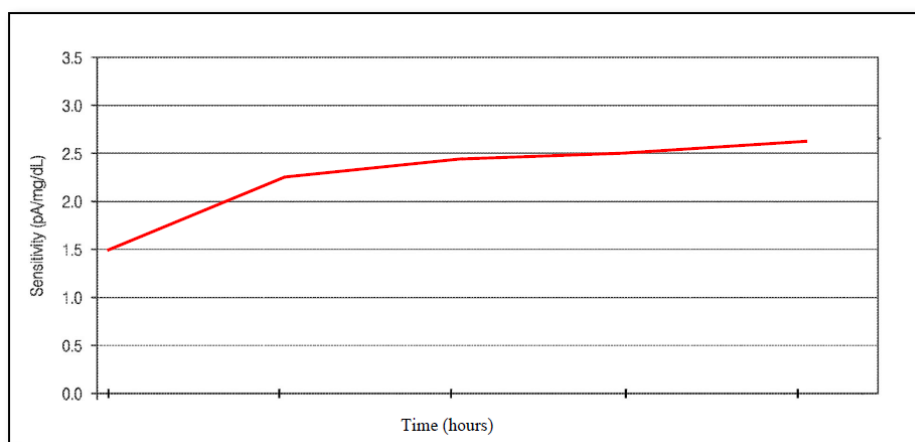
sensor” and “the sensor output can be calculated using the new calibration curve.” Pet. 52 (citing Ex. 1004 ¶ 61). Thus, Zhang appears to state that the sensor stores the old and new calibration curves.

For limitation 1e of claim 1 and limitation 14d of claim 14, Patent Owner argues that Zhang’s Figure 2 curves and the shifts between them are not a “profile” as that term is used in the ’031 patent. Prelim. Resp. 54–58. 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 55 (citing Ex. 1001, 216:48–52).

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



*Id.* at 55. 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 56–57.

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 *changes* or *drifts* over time." *Id.* at 57–58. Patent Owner argues that each of Zhang's Figure 2 curves is thus not a "profile" as claimed. *Id.* at 56–58.

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 curve *shapes* are a line having a slope and/or curvature so as to constitute a claimed 'profile.'" *Id.* at 58. 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.*

On this record, the adjustments between Zhang's Figure 2 calibration curves on which Petitioner relies seem to incorporate the "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 "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 "profile."

To the extent the parties dispute what a “profile” is in the context of the ’031 patent, the parties should set forth clearly what their proposed constructions are on the trial record.<sup>4</sup>

Petitioner contends that the remaining limitations of claim 1 and claim 14 are disclosed by Zhang, and indicates the evidence it relies on to support its contentions. Pet. 29–36 (claim 1), 50 (claim 14). Patent Owner does not dispute Petitioner’s contentions or evidence for the remaining limitations at this time.

3. *Dependent Claims 2, 4, 6–13, 15, and 20–22*

Petitioner contends that Zhang discloses dependent claims 2, 4, 6–13, 15, and 20–22. Pet. 40–49, 53. 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 “profile” as recited in limitation 1e and limitation 14d.

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<sup>4</sup> 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 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.

*E. Anticipation and Obviousness over Shin*

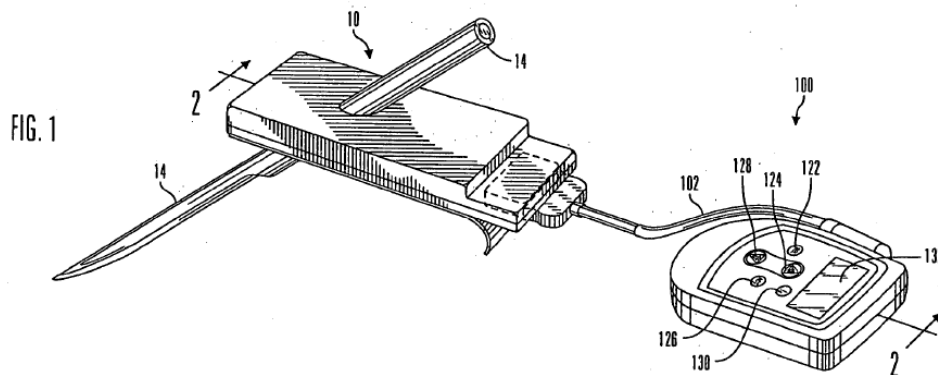
Petitioner asserts that claims 1–2, 4, 6–15, and 20–22 of the '031 patent are anticipated by, and would have been obvious over, Shin. Pet. 54–71. Patent Owner disagrees. Prelim. Resp. 59–74.

In this section, we address Shin's disclosure and the parties' contentions for the challenged claims. We conclude that, on the current record, Petitioner has presented a reasonable likelihood it will prevail in demonstrating the 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.

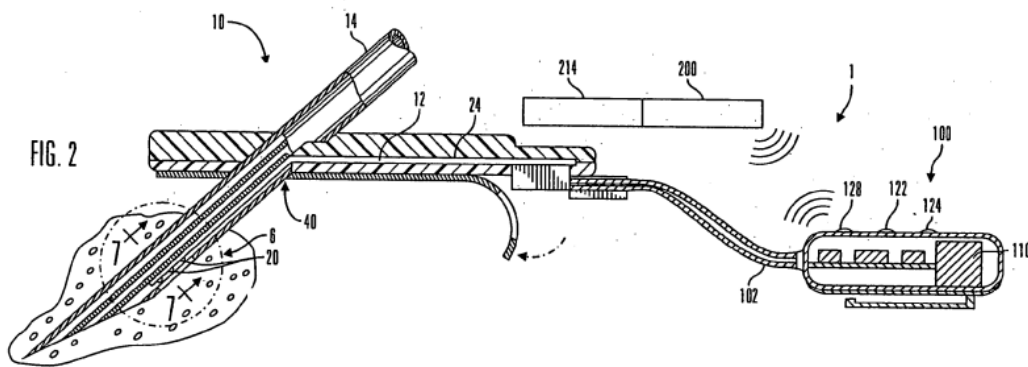


Shin's Figure 1 above shows glucose monitor 100 worn by a user and a glucose sensor set 10 that is attached to the user's body by electrically conductive cable 102. *Id.* ¶ 56. Glucose sensor set 10 includes needle 14 disclosed in U.S. Patent No. 5,586,553, which Shin incorporates by reference. *Id.* ¶ 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.

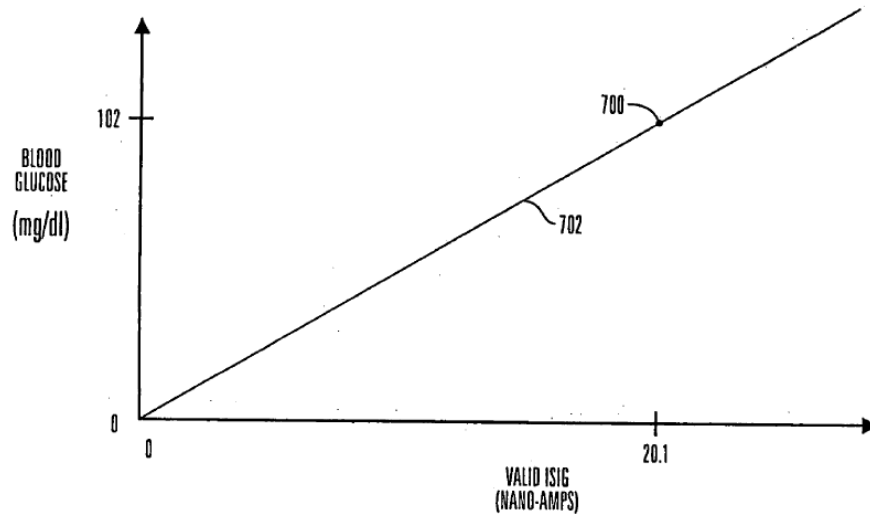


FIG. 12

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 1*

We now address Petitioner’s contentions for each limitation of claim 1, and Patent Owner’s arguments concerning limitation 1e, which is the only limitation Patent Owner disputes at this time.

### (i) *Preamble*

The preamble of claim 1 recites “A system for monitoring a glucose concentration, the system comprising:” Ex. 1001, 257:43–44.

Petitioner contends that Shin’s glucose monitor system comprises a sensor to detect glucose concentration. Pet. 54 (citing Ex. 1008 ¶¶ 2, 31–32, 54, Figs. 1, 2; Ex. 1002 ¶ 187).

Petitioner shows sufficiently that Shin discloses claim 1’s preamble. Thus, we need not, and do not, decide whether the preamble is limiting.

### (ii) *Limitation 1a: Transcutaneous Glucose Sensor*

Limitation 1a 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 inserted into the body of the host.” Ex. 1001, 257:45–49.

Petitioner states that Shin discloses limitation 1a. Pet. 54. Petitioner relies on Shin disclosing that 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.* (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 that Shin’s glucose sensor has in-vivo and ex-vivo portions. The in-vivo portion extends into in-vivo “region 6” while another portion is outside of the user’s body. *Id.* at 54–55 (citing Ex. 1008, Fig. 2 (annotated); Ex. 1002 ¶¶ 188–190). 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 1a.

(iii) *Limitation 1b: Electrode and Membrane with Enzyme*

Limitation 1b 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, 257:49–54.

Petitioner contends that the in-vivo portion of Shin’s sensor comprises electrodes 20 which terminate in the user’s subcutaneous tissue. Pet. 55 (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.” Pet. 55. Petitioner alleges that “the POSA would have understood such ‘enzyme coating’ to be a membrane comprising the enzyme.” *Id.* at 55–56 (citing Ex. 1002 ¶¶ 191–193). 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 56 (citing Ex. 1008 ¶ 57; Ex. 1009, 3; Ex. 1002 ¶ 194). Alternatively, Petitioner argues that using a membrane was obvious because it was the preferred technique for immobilizing glucose oxidase in CGMs. *Id.* (citing Ex. 1002 ¶ 195).

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 1b.

(iv) *Limitation 1c: Sensor Configured to Generate Signal Whose Magnitude Depends on Glucose Concentration*

Limitation 1c recites “wherein the transcutaneous glucose sensor is configured to generate a signal, wherein the magnitude of the signal depends upon a glucose concentration existing at the in vivo portion of the transcutaneous glucose sensor inserted into the body of the host.” Ex. 1001, 257:55–59.

Petitioner contends that Shin operates as recited in limitation 1c. Pet. 56–57. Specifically, Petitioner relies on Shin’s disclosure stating “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.” *Id.* at 56–57 (citing Ex. 1008 ¶ 69; Ex. 1002 ¶¶ 196–197).

On the current record, we find that Petitioner sufficiently shows that Shin discloses limitation 1c.

(v) *Limitation 1d: Sensor Electronics Comprising Memory*

Limitation 1d recites “electronics configured to operably connect to the transcutaneous glucose sensor, wherein the electronics comprises a memory.” Ex. 1001, 257:60–62.

Petitioner contends that Shin's “‘electronics’ includes the ‘glucose monitor,’ which is operably connected to the sensor and which comprises a memory.” *Id.* at 57 (citing Ex. 1008 ¶ 15). Petitioner quotes Shin as disclosing 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.

Pet. 57 (citing Ex. 1008 ¶ 15). Petitioner also notes that Shin discloses that “[t]he glucose monitor 100 generally includes the capability to record and store data as it is received from the glucose sensor 12.” *Id.* at 57–58 (citing Ex. 1008 ¶¶ 58–60). Petitioner further states that Shin discloses “embodiments where the glucose monitor stores ‘the necessary software to calibrate glucose sensor signals.’” *Id.* at 58 (citing Ex. 1008 ¶ 61). Petitioner asserts that “[t]hus Shin's sensor is operably connected to the glucose monitor, and the glucose monitor comprises a memory.” *Id.*

On the present record, we find that Petitioner shows sufficiently that Shin discloses limitation 1d.

(vi) *Limitation 1e: Memory Stores Profile*

Limitation 1e recites “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.” Ex. 1001, 257:62–67.

Petitioner contends that “Shin’s memory stores information associated with a profile that is based at least in part on a priori information related to expected sensor sensitivity changes over time.” Pet. 58 (citing Ex. 1008 ¶¶ 87–104; Ex. 1002 ¶¶ 202–206).

Specifically, Petitioner argues 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 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 ‘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 host, as recited in limitation 1e. *Id.* at 58–59.

Petitioner further 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 profile.” *Id.* at 59 (citing Ex. 1008 ¶ 103;

Ex. 1001, 213:5–43; 213:13–25, 213:33–36, 213:50–52, 216:44–61).

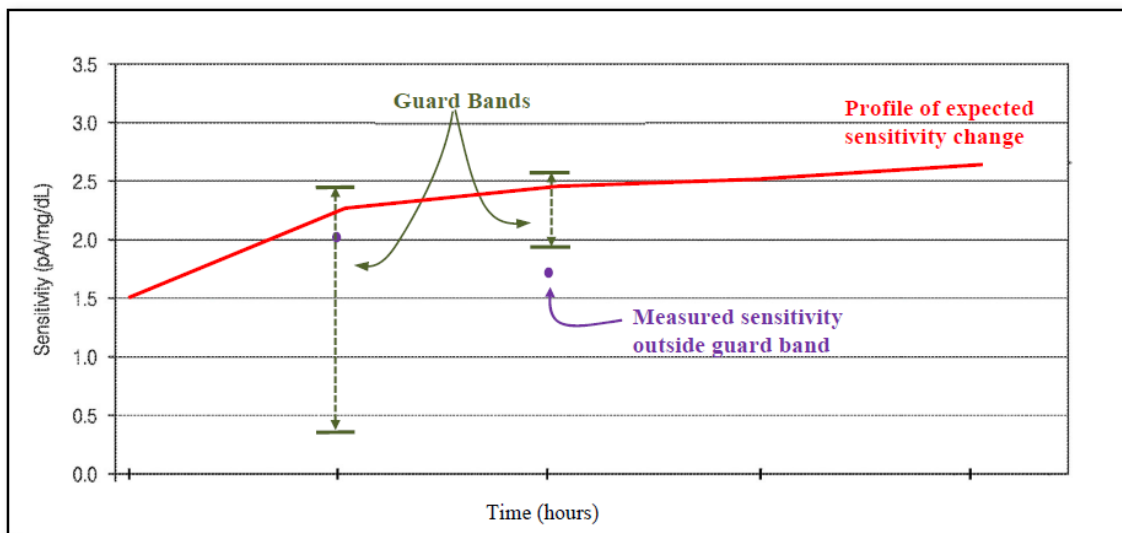
Petitioner asserts that the valid sensitivity ranges are predetermined, and thus, Shin’s profile is based on “a priori information.” *Id.* (citing Ex. 1008 ¶ 103). Petitioner argues that Shin’s profile is stored in memory because each calculated MSPSR is compared to a valid sensitivity range that has been predetermined and must therefore be stored in the system. *Id.* at 59–60 (citing Ex. 1008 ¶ 103). Petitioner asserts 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.* at 60 (citing Ex. 1002 ¶¶ 206–207).

Patent Owner argues that Petitioner fails to demonstrate that Shin’s “**valid** sensitivity changes” or “ranges” constitute a “profile” based on “a priori information related to **expected** sensitivity changes.” Prelim. Resp. 63–69. Specifically, Patent Owner argues that specifying **valid** sensitivity ranges does not disclose that those ranges are based on “**expected** sensitivity changes,” as claimed. *Id.* at 65. Patent Owner avers that because Shin allegedly does not use “expected sensitivity changes,” Shin has to rely on periodically measuring sensor response with blood glucose meter readings requiring finger sticks to draw blood. *Id.* at 65. According to Patent Owner, Shin teaches that multiple-point measurements may be used to determine a narrower range of sensitivities than single-point measurements, and appears to argue that this disclosure does not relate to “expected sensitivity changes” of the sensor. *Id.* at 65–67.

Patent Owner asserts that Petitioner relies on the ’031 patent’s statements 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” 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.” Prelim. Resp. 68 (citing Ex. 1001, 213:33–36, 213:50–53). Patent Owner argues that 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.” *Id.* Patent Owner indicates that the ’031 patent states that the “expected profile” is “e.g, an expected pattern or amount of sensitivity change/drift over time.” *Id.* at 68 (citing Ex. 1001, 213:9–25; 216:48–52; 213:25–53).

To illustrate its points, Patent Owner provides the following figure:



Prelim. Resp. 69. Patent Owner’s figure above shows the profile of expected sensitivity change (red line) and the guard bands or ranges at different points in time. Patent Owner argues Shin’s “valid sensitivity ranges” are not “expected sensitivity changes,” and do not meet the requirements of claim 1. *Id.*

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 advocates a particular meaning for "**expected** sensitivity changes" that would preclude Shin's "**valid** sensitivity ranges" or use of Shin's glucose meter readings, Patent Owner should make its construction clear on the trial record.

Patent Owner further argues that Petitioner fails to demonstrate that Shin stores or uses a claimed "profile." Prelim. Resp. 72–74. Specifically, Patent Owner argues that the claimed "profile" does not encompass Shin's "valid sensitivity ranges" because a "profile" is "a line having a slope and/or curvature" and Shin's "valid sensitivity ranges" are not such a line. *Id.* at 71–72 (citing Ex. 1001, 213:9–25, 216:48–52). Patent Owner asserts that 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 Petitioner cites." *Id.* at 72–74 (citing Pet. 59; Ex. 1001, 213:13–36, 213:50–53, 216:44–61).

Petitioner suggests that the composite of Shin's valid sensitivity ranges constitutes the claimed "profile." Pet. 59. Petitioner also asserts that the composite of Shin's valid sensitivity ranges constitutes the claimed "information associated with a profile," not the "profile" itself. *Id.* at 58–59.

From our understanding of the evidence concerning Petitioner's latter contention, the composite of Shin's valid sensitivity ranges over time (see guard bands in figure above) could be considered to be "information associated with" what Patent Owner considers to be a "profile" (see red line

in the figure above). In other words, the guard bands encompass or contain the “profile” and thus could be considered “information associated with a profile.” Petitioner shows sufficiently for institution that Shin’s valid sensitivity ranges are stored in memory and used to determine whether the sensor’s sensitivity is “reasonable” over time. Thus, Patent Owner’s argument does not undermine Petitioner’s contention on this record.

We further note that Patent Owner’s contentions are based largely on attorney argument, which is not evidence. *See Icon Health, supra*.

*(vii) Conclusion for Claim 1*

Petitioner has shown sufficiently on this record a reasonable likelihood that each limitation of claim 1 is disclosed by Shin notwithstanding Patent Owner’s arguments. Accordingly, Petitioner has shown a reasonable likelihood to prevail in demonstrating unpatentability of claim 1 of the ’031 patent as anticipated by Shin.

*3. Claim 14*

We now address Petitioner’s contentions for each limitation of claim 14, and Patent Owner’s arguments concerning limitation 14d, which is the only limitation Patent Owner disputes at this time.

*(i) Preamble*

Claim 14’s preamble recites “method of monitoring a glucose concentration, the method comprising:” Ex. 1001, 258:44–45.

Petitioner contends that Shin discloses method for monitoring glucose concentration in a host. Pet. 68–69 (citing Ex. 1008 ¶ 54; Ex. 1002 ¶ 233).

We find that Petitioner shows sufficiently that Shin discloses claim 14’s preamble and thus do not reach whether the preamble is limiting.

(ii) *Limitation 14a: Beginning Sensor Session with Transcutaneous Glucose Sensor*

Limitation 14a 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, 258:46–52.

Petitioner contends that Shin’s glucose monitoring method involves beginning a sensor session, and refers to its discussion for claim 1’s limitation 1a as disclosing a transcutaneous glucose sensor with in-vivo and ex-vivo portions. Pet. 69 (citing Ex. 1008 ¶ 6; Ex. 1002 ¶¶ 234–236).

On this record, we find that Petitioner’s contentions for limitation 14a are sufficient for institution.

(iii) *Limitation 14b: Electrode and Membrane with Enzyme*

Limitation 14b 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, 258:51–57.

Petitioner contends that Shin discloses limitation 14b for the same reasons stated for claim 1’s limitation 1b. Pet. 69 (citing *id.* § X.B.1.c; Ex. 1002 ¶ 237).

Petitioner shows sufficiently that Shin discloses limitation 14b on this record.

(iv) *Limitation 14c: Generating Sensor Data at Least in Part from In Vivo Portion of Sensor*

Limitation 14c recites “generating sensor data at least in part from a signal received from the in vivo portion of the transcutaneous glucose sensor.” Ex. 1001, 258:58–60.

Petitioner contends that Shin discloses limitation 14c for the same reasons stated for claim 1’s limitation 1c. Pet. 69 (citing *id.* § X.B.1.d; Ex. 1002 ¶ 238).

On this record, Petitioner shows sufficiently for institution that Shin discloses limitation 14c.

(v) *Limitation 14d: Calibrating Sensor Data Based on A Priori Information with Profile*

Limitation 14d recites “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.” Ex. 1001, 258:61–65.

Petitioner contends that

Shin teaches calibrating sensor data using the predetermined valid sensitivity ranges that are based on how long the sensor has been in use, and thus teaches calibrating sensor data “based at least in part on a priori information,” wherein the a priori information is (and thus “comprises”) “a profile associated with a drift in a sensitivity of the in vivo portion” of the sensor “over time,”

as recited in limitation 14d. Pet. 69–70 (citing Ex. 1002 ¶¶ 239–241).

Petitioner contends that each calculated MSPSR (which is a calibration factor) is compared to a pre-determined valid sensitivity range that depends on how long the sensor has been in use. *Id.* at 70 (citing

Ex. 1008 ¶¶ 93, 103). According to Petitioner, “[s]uch valid sensitivity ranges are a profile associated with a drift in sensor sensitivity over time.” *Id.* If Shin’s system determines that the MSPSR is within a valid sensitivity range for that time, Petitioner contends that it is accepted and used to calibrate sensor data. *Id.*

Petitioner asserts that because Shin’s valid sensitivity ranges are predetermined, they are “a priori information” as recited in limitation 14d. Pet. 70. Petitioner further asserts that the valid sensitivity ranges are a “profile” related to expected sensitivity changes associated with how long the sensor has been asserted in the host, and that the “ranges” are a “profile associated with a drift in a sensitivity of the in vivo portion of the transcutaneous glucose sensor over time” as recited in limitation 14d. *Id.* at 70–71 (citing *id.* § X.B.1.f).

Patent Owner argues that Petitioner relies entirely on Shin’s Paragraph 103 to disclose limitation 14d, and asserts that this disclosure does not state that the Shin’s system rejects the MSPSR if it is outside of the range, or only calibrates sensor data if the MSPSR is inside the range. Prelim. Resp. 70. According to Patent Owner, Shin only states that MSPSR values outside the range result in a calibration error alarm to notify the user of a potential problem. *Id.* Patent Owner asserts 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,” for example. *Id.* at 70–71.

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.

Ex. 1008 ¶ 103. And it has not been shown on this record that limitation 14d requires the sensor data to be rejected and not calibrated if the MSPSR falls outside of the “valid sensitivity range.”

Patent Owner also asserts for limitation 14d the same argument it presented for limitation 1e that Petitioner fails to demonstrate that Shin stores or uses a claimed “profile.” Prelim. Resp. 71–74. Specifically, Patent Owner argues that the claimed “profile” as described in the ’031 patent is a line with a slope and/or curvature, and Shin’s “valid sensitivity ranges” are not such a line. *Id.* at 71.

As explained for limitation 1e (*see* § IV.E.2.vi, *supra*), Petitioner asserts that Shin’s “valid sensitivity ranges” are “a priori information.” Pet. 70. According to limitation 14d, this “a priori information comprises a profile.” On this record, Petitioner shows sufficiently that Shin’s “valid sensitivity ranges” encompass a “profile” as claimed, and thus satisfy limitation 14d.

(vi) *Conclusion for Claim 14*

Petitioner has shown sufficiently on this record that each limitation of claim 14 is disclosed by Shin notwithstanding Patent Owner’s arguments. Accordingly, Petitioner has shown a reasonable likelihood to prevail in demonstrating unpatentability of claim 14 of the ’031 patent as anticipated by Shin.

4. *Dependent Claims 2, 4, 6–13, 15, and 20–22*

Petitioner contends that Shin discloses dependent claims 2, 4, 6–13, 15, and 20–22. Pet. 60–68, 71. 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 2, 4, 6–13, 15, and 20–22 as anticipated by Shin on the present record.

#### IV. CONCLUSION

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

#### V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), the petitioned institution of *inter partes* review of claims 1–2, 4, 6–15, and 20–22 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.

IPR2024-00890  
Patent 11,020,031 B1

FOR PETITIONER:

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