

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE INC.

Petitioner,

v.

DEXCOM, INC.

Patent Owner.

Case No. IPR2024-00891

Patent No. 11,020,031

PETITION FOR *INTER PARTES* REVIEW

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Exhibit No.	Description of Exhibit
1001	U.S. Patent No. 11,020,031 (“’031 patent”)
1002	Declaration of Dr. Anthony Edward George Cass
1003	Prosecution File History of U.S. Patent No. 11,020,031
1004	Zhang et al., <i>System and Method for Sensor Recalibration</i> , U.S. Patent Application Publication No. 2005/0143636 (published June 30, 2005) (“ Zhang ”)
1005	David A. Gough, <i>Method and Membrane Applicable to Implantable Sensor</i> , U.S. Patent No. 4,650,547 (issued Mar. 17, 1987)
1006	David A. Gough et al, <i>Complete Glucose Monitoring Systems with an Implantable, Telemetered Sensor Module</i> , U.S. Patent No. 4,703,756 (issued Nov. 3, 1987)
1007	Wayne A. Morgan et al., U.S. Patent Application Publication No. 2003/0076082, <i>Implantable Sensor Electrodes and Electronic Circuitry</i> (published Apr. 24, 2003) (“ Morgan ”)
1008	John J. Shin et al., <i>Real Time Self-Adjusting Calibration Algorithm</i> , U.S. Patent Application Publication No. 2005/0004439 (published Jan. 6, 2005) (“ Shin ”)
1009	John J. Mastrototaro et al., <i>Glucose Sensor</i> , U.S. Design Application No. 29/101,218 (U.S. Design Patent D433,755, issued Nov. 14, 2000) (the “ 218 application ”)
1010	John J. Mastrototaro et al., <i>Glucose Monitor Calibration Methods</i> , U.S. Patent No. 6,424,847 (issued July 23, 2002) (“ Mastrototaro ”)
1011	James Say et al., <i>Analyte Monitoring Device and Methods of Use</i> , U.S. Patent No. 6,175,572 (issued Jan. 16, 2001) (“ Say ”)
1012	Benjamin J. Feldman et al., <i>A Method of Calibrating an Analyte-Measurement Device, and Associated Methods, Devices and Systems</i> , U.S. Patent Application Publication No. 2005/0239154 (published Oct. 27, 2005) (“ Feldman ”)

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Exhibit No.	Description of Exhibit
1013	William Peter Van Antwerp et al., <i>Hydrophilic, Swellable Coatings for Biosensors</i> , U.S. Patent No. 5,786,439 (issued July 28, 1998) (“ Van Antwerp ”)
1014	Marc D. Breton et al., <i>Method, System and Computer Program Product for Real-Time Detection of Sensitivity Decline in Analyte Sensors</i> , U.S. Patent Application Publication No. 2008/0172205 (published July 17, 2008) (“ Breton ”)
1015	John P. Willis, <i>Biofouling Self-Compensating Biosensor</i> , U.S. Patent Application Publication No. 2007/0299617 (published Dec. 27, 2007) (“ Willis ”)
1016	Sridhar G. Iyengar et al., <i>Method and Apparatus for Assay of Electrochemical Properties</i> , U.S. Patent Application Publication No. 2005/0069892 (published Mar. 31, 2005) (“ Iyengar ”)
1017	Adam Heller et al., <i>Analyte Monitoring Devices and Methods of Use</i> , U.S. Patent No. 6,560,471 (issued May 6, 2003) (“ Heller-2003 ”)
1018	Leann M. Lesperance et al., <i>Calibration of the Continuous Glucose Monitoring System for Transient Glucose Monitoring</i> , <i>Diabetes Technology & Therapeutics</i> , Vol. 9, No. 2, pp. 183-190 (2007) (“ Lesperance ”)
1019	Eva Dock et al., <i>Multivariate Data Analysis of Dynamic Amperometric Biosensor Responses From Binary Analyte Mixtures—Application of Sensitivity Correction Algorithms</i> , 65 <i>Talanta</i> 298-305 (2005) (“ Dock ”)
1020	David M. Fraser, <i>An Introduction to in vivo Biosensing: Progress and Problems</i> , in David M. Fraser, <i>Biosensors in the Body: Continuous In Vivo Monitoring</i> , Ch. 1, pp. 1-56 (John Wiley & Sons Ltd. 1997) (“ Fraser ”)
1021	Milena Koudelka-Hep, <i>Electrochemical Sensors for in vivo Glucose Sensing</i> , in David M. Fraser, <i>Biosensors in the Body: Continuous In Vivo Monitoring</i> , Ch. 2, pp. 57-77 (John Wiley & Sons Ltd. 1997) (“ Koudelka-Hep ”)

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Exhibit No.	Description of Exhibit
1022	Michael Schlosser and Manfred Ziegler, <i>Biocompatibility of Active Implantable Devices</i> , in David M. Fraser, <i>Biosensors in the Body: Continuous In Vivo Monitoring</i> , Ch. 5, pp. 139-170 (John Wiley & Sons Ltd. 1997) (“ Schlosser ”)
1023	George S. Wilson and Yanan Zhang, <i>Introduction to the Glucose Sensing Problem</i> , in David D. Cunningham and Julie A. Stenken, <i>In Vivo Glucose Sensing</i> , Ch. 1, pp. 1-27 (John Wiley & Sons, Inc. 2010) (“ Wilson ”)
1024	Marisha L. Godek and David W. Granger, <i>The Macrophage in Wound Healing Surrounding Implanted Devices</i> , in David D. Cunningham and Julie A. Stenken, <i>In Vivo Glucose Sensing</i> , Ch. 2, pp. 29-58 (John Wiley & Sons, Inc. 2010) (“ Godek ”)
1025	Timothy Henning, <i>Commercially Available Continuous Glucose Monitoring Systems</i> , in David D. Cunningham and Julie A. Stenken, <i>In Vivo Glucose Sensing</i> , Ch. 5, pp. 113-156 (John Wiley & Sons, Inc. 2010) (“ Henning ”)
1026	K. Nishida et al., <i>Development of a ferrocene-mediated needle-type glucose sensor covered with newly designed biocompatible membrane, 2-methacryloyloxyethyl phosphorylcholine -co-n-butyl methacrylate</i> , 21 Medical Progress through Technology 91-103 (1995) (“ Nishida ”)
1027	Adam Heller, <i>Implanted Electrochemical Glucose Sensors for the Management of Diabetes</i> , 1 Annu. Rev. Biomed. Eng. 153 (1999) (“ Heller ”)
1028	S.J. Alcock and A.P.F. Turner, <i>Continuous Analyte Monitoring to Aid Clinical Practice</i> , 13 IEEE Engineering in Medicine and Biology 319-325 (1994) (“ Alcock ”)
1029	Megan C. Frost and Mark E. Meyerhoff, <i>Implantable Chemical Sensors For Real-Time Clinical Monitoring: Progress And Challenges</i> , 6 Current Opinion in Chemical Biology 633-641 (2002) (“ Frost ”)

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Exhibit No.	Description of Exhibit
1030	N. Wisniewski et al., <i>Characterization of Implantable Biosensor Membrane Biofouling</i> , 366 Fresenius J Analytical Chemistry 611-621 (2000) (“ Wisniewski ”)
1031	Scheduling order, Sept. 2023, from <i>Abbott Diabetes Care Inc. et al. v. DexCom, Inc.</i> , No. 1:23-cv-00239 (D. Del)
1032	Declaration of Sylvia D. Hall-Ellis, Ph.D.

I. INTRODUCTION

Petitioner requests review of claims 23-46 (the “challenged claims”) of U.S. Patent No. 11,020,031 (the “’031 patent”), which is assigned to DexCom, Inc. (“DexCom”). The challenged claims relate to glucose monitors with sensors that measure a subject’s glucose level in real time. The purportedly inventive feature of the challenged claims relates to information on expected changes in the sensor’s sensitivity over time. Such changes—also called “drift”—were known and had been well-documented by the asserted priority date.

The ’031 patent purports to disclose several embodiments of using drift information. These embodiments include the use of “a priori information” or “a profile” of *ranges* or *boundaries* within which sensitivity is expected to change over time.

As shown in this petition, the prior art already taught systems and methods that use drift information as claimed in the ’031 patent. Zhang and Shin each describe using a priori information on expected sensor sensitivity changes that occur over time (e.g., information obtained from prior empirical studies of sensor use) for glucose monitoring. Therefore, Zhang and Shin each disclose the purportedly inventive feature of the challenged claims. The other elements of the challenged claims are also disclosed in Zhang and Shin and otherwise were well known in the art as of the asserted priority date.

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Accordingly, none of the challenged claims is patentable over Zhang or Shin.

II. MANDATORY NOTICES AND FEE AUTHORIZATION

A. Real Party-in-Interest under 37 C.F.R. 42.8(b)(1)

The real parties-in-interest are Abbott Diabetes Care Inc., Abbott Diabetes Care Sales Corp., and Abbott Laboratories. Abbott Diabetes Care Inc. is the Petitioner. Abbott Diabetes Care Inc. is directly owned by Abbott Laboratories. Abbott Diabetes Care Inc. directly owns Abbott Diabetes Care Sales Corp.

B. Related Matters under 37 C.F.R. 42.8(b)(2)

DexCom has asserted the challenged claims (claims 23-46) against Abbott Diabetes Care Inc. and Abbott Diabetes Care Sales Corp., as a counterclaim for infringement in *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, No. 1:23-cv-00239 (D. Del) (hereinafter, the “district court litigation”). DexCom asserted the ’031 patent in its Answer, Affirmative Defenses, and Counterclaims, electronically served on Petitioner Abbott Diabetes Care Inc. on May 12, 2023, and hand-served on Abbott Diabetes Care Sales Corp. on May 15, 2023. Petitioner contends that the asserted claims of the ’031 patent are not infringed.

Petitioner is challenging claims 1, 2, 4, 6-15, and 20-22 of the ’031 patent in a contemporaneously-filed petition, in IPR2024-00890.

C. Lead and Back-Up Counsel under 37 C.F.R. 42.8(b)(3)

Lead Counsel	Back-Up Counsel
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D. Service Information under 37 C.F.R. 42.8(b)(4)

Service information is provided in the designation of counsel above.

Petitioner consents to service of all documents via electronic mail at the email addresses above and at abbott-ipr@cov.com.

E. Payment of Fees under 37 C.F.R. §42.103

The Office is authorized to charge the fee set forth in 37 C.F.R. §42.15(a)(1), and any other fees due, to Deposit Account No. 60-3160. Review of twenty-four claims is requested.

III. CLAIM LISTING

A. Claim 23

23[pre]	A method for monitoring a glucose concentration, the method comprising:
23[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;
23[b]	generating sensor data derived at least in part from the transcutaneous glucose sensor;
23[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; and
23[d]	displaying the glucose concentration value.

B. Claim 24

24	The method of claim 23 wherein the in vivo portion of the transcutaneous glucose sensor comprises a substantially planar configuration.
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C. Claim 25

25	The method of claim 23 wherein the drift profile accounts for a break-in of the transcutaneous glucose sensor after the in vivo portion of the transcutaneous glucose sensor has been inserted into the body of the host.
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D. Claim 26

26	The method of claim 23 wherein the drift profile accounts for a change in sensitivity over time of the in vivo portion of the transcutaneous glucose sensor to the glucose concentration within the body of the host.
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E. Claim 28

28	The method of claim 23 wherein the drift profile accounts for a change in baseline over time associated with the in vivo portion of the transcutaneous glucose sensor and a change in sensitivity over time of the in vivo portion of the transcutaneous glucose sensor to the glucose concentration within the body of the host.
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F. Claim 29

29	The method of claim 23 wherein the shift over time is an elapsed time measured from the beginning of the sensor session.
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G. Claim 30

30	The method of claim 23 wherein the shift over time is associated at least in part with a change in one or more physical properties of an environment surrounding the in vivo portion of the transcutaneous glucose sensor within the body of the host.
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H. Claim 31

31	The method of claim 30 wherein the one or more physical properties of the environment surrounding the in vivo portion of the transcutaneous glucose sensor within the body of the host is associated with at least one of: trauma, wound healing, blockage of a surface of the transcutaneous glucose sensor, inflammation, blood clotting, or biofouling.
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I. Claim 27

27	The method of claim 23 wherein the drift profile accounts for a change in baseline over time associated with the in vivo portion of the transcutaneous glucose sensor.
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J. Claim 32

32	The method of claim 23 wherein the shift over time is associated at least in part with a physical property of the transcutaneous glucose sensor, wherein the physical property corresponds to a membrane of the in vivo portion of the transcutaneous glucose sensor.
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K. Claim 33

33	The method of claim 23 wherein the shift over time is an elapsed time measured from the insertion of the in vivo portion of the transcutaneous glucose sensor within the body of the host.
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L. Claim 34

34	The method of claim 23 wherein the drift profile has a first slope associated with a first time and a second slope associated with a second time, wherein the first time is different from the second time, wherein the first slope is different from the second slope.
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M. Claim 35

35[pre]	A sensor system comprising:
35[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,
35[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;
35[c]	wherein the transcutaneous glucose sensor generates a signal associated with a glucose concentration within the body of the host; and

35[d]	electronics configured to receive the signal from the transcutaneous glucose sensor,
35[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,
35[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.

N. Claim 36

36	The sensor system of claim 35 wherein the change over time in the relationship is associated at least in part with a change in one or more physical properties of an environment surrounding the in vivo portion of the transcutaneous glucose sensor within the body of the host.
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O. Claim 37

37	The sensor system of claim 36, wherein the one or more physical properties of the environment surrounding the in vivo portion of the transcutaneous glucose sensor within the body of the host include trauma, wound healing, blockage of a surface of the transcutaneous glucose sensor, inflammation, blood clotting, or biofouling.
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P. Claim 38

38	The sensor system of claim 35 wherein the change over time in the relationship is associated with the implantation of the in vivo portion of the transcutaneous glucose sensor within the body of the host.
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Q. Claim 39

39	The sensor system of claim 35 wherein the change over time in the relationship is over an elapsed time measured from a beginning of a sensor session after implantation of the in vivo portion of the transcutaneous glucose sensor within the body of the host.
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R. Claim 40

40	The sensor system of claim 35 wherein the change over time in the relationship is over an elapsed time measured from the implantation of the in vivo portion of the transcutaneous glucose sensor within the body of the host.
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S. Claim 41

41	The sensor system of claim 35 wherein the change over time in the relationship is associated at least in part with a physical property of the transcutaneous glucose sensor, wherein the physical property of the transcutaneous glucose sensor corresponds to membrane of the in vivo portion of the transcutaneous glucose sensor.
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T. Claim 42

42[pre]	A method for monitoring a glucose concentration, the method comprising:
42[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;
42[b]	wherein the transcutaneous glucose sensor is configured to generate a signal;
42[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;

42[d]	generating a glucose concentration value based at least in part on the calibrating; and
42[e]	displaying the glucose concentration value.

U. Claim 43

43	The method of claim 42 wherein the time the relationship changes is an elapsed time measured from the beginning of the sensor session.
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V. Claim 44

44	The method of claim 42 wherein the relationship changes as a function of time is associated at least in part with a change in one or more physical properties of an environment surrounding the in vivo portion of the transcutaneous glucose sensor within the body of the host.
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W. Claim 45

45	The method of claim 44 wherein the one or more physical properties of the environment surrounding the in vivo portion of the transcutaneous glucose sensor within the body of the host include trauma, wound healing, blockage of a surface of the transcutaneous glucose sensor, inflammation, blood clotting, or biofouling.
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X. Claim 46

46	The method of claim 42 wherein the relationship changes as a function of time is associated at least in part with a physical property of the transcutaneous glucose sensor, wherein the physical property of the transcutaneous glucose sensor corresponds to a membrane of the in vivo portion of the transcutaneous glucose sensor.
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IV. REQUIREMENTS UNDER 37 C.F.R. 42.104

A. Grounds for Standing

Petitioner certifies that the '031 patent is available for *inter partes* review

and that Petitioner meets the eligibility requirements set forth in 37 C.F.R.

42.104(a).

B. Identification of Challenges and Statement of Precise Relief Requested

Ground	Claims	Challenge
1	23-46	Anticipated and/or rendered obvious by Zhang (pre-AIA-§102(b), pre-AIA-§103(a))
2	23-46	Anticipated and/or rendered obvious by Shin (pre-AIA-§102(b), pre-AIA-§103(a))

V. TECHNOLOGY BACKGROUND

Continuous glucose monitors (“CGMs”) monitor a user’s glucose concentration, often for diabetes management. One type of CGM uses a transcutaneous sensor that is inserted through a user’s skin, and that produces an electrical current that varies depending on the user’s glucose concentration within the sensor’s range of operation. CGMs convert the amount of current generated by the sensor into a glucose level in conventional glucose concentration units (e.g., mg/dL) using a conversion function.

The conversion function is determined by a process of sensor calibration. Sensor calibration involves defining a relationship between sensor output (current) and glucose concentration. Typically, sensor output (in counts or units of current) is matched with a reference or known glucose concentration (in units such as mg/dL); matched pairs of data points are plotted—with sensor output in counts or

units of current as the y-axis value, and a reference glucose concentration as the x-axis value—and a function describing the relationship of the plotted data points is empirically determined. The empirically-determined conversion function (or calibration curve) may be linear or non-linear. The conversion function ideally should allow for the calculation of a glucose concentration for any sensor output over the sensor's operating range (such calculation is also sometimes referred to as data calibration) and for the full wear life of the sensor.

The conversion function typically defines calibration parameters, such as sensor sensitivity and baseline.¹ Sensor sensitivity is the amount of sensor current generated per unit of glucose in contact with the sensor and is a measure of the sensor's responsiveness to a concentration of glucose. Baseline (which is sometimes called offset) is the current produced (if any) when no glucose is in contact with the sensor; it is the background current produced by the sensor.

¹ When the relationship between glucose concentration x and sensor output y is linear, the conversion function may be expressed by the equation $y = mx + b$, where the slope m is sensor sensitivity and the y-intercept b is sensor baseline. When the relationship is non-linear, the slope or sensitivity of the sensor may be the first-order derivative of the conversion function (i.e., the slope of the tangent at a given x-axis value), while the baseline is the y-intercept of the function.

Many different factors, including factors related to sensor design and materials, as well as factors concerning the in-vivo environment surrounding the sensor, affect sensor output with respect to glucose concentration. Because some of these factors are not constant and are known to change during sensor wear, sensor sensitivity and baseline also can change during sensor wear. Changes during sensor wear in sensor sensitivity and/or baseline (and the empirically-determined relationship) are often referred to as “drift.” Ex-1002, ¶¶27-47.

VI. THE '031 PATENT

A. Specification²

The '031 patent relates to “systems and methods for measuring an analyte in a host” (Ex-1001, 1:24-25), and notes that “continuous analyte sensors define a relationship between a sensor-generated signal and a reference measurement that is meaningful to a user (for example, blood glucose in mg/dL)” (*id.*, 143:3-6). “This defined relationship must be monitored to ensure that the continuous analyte sensor maintains a substantially accurate calibration,” and “[u]nfortunately, both sensitivity m and baseline b changes can occur during in vivo sensor use, which requires calibration updates.” Ex-1001, 143:6-12. These changes may be caused by

² The description of the '031 patent provided herein is not an admission that the '031 patent adequately describes or enables any claim.

“blockage of sensor surface area due to cells and/or blood clotting at the membrane, blood flow/sheer rate, blood pH, temperature, hematocrit, [and] interfering drugs.” *Id.*, 143:16-20.

The '031 patent describes methods that are stated to detect aberrant sensitivity changes, by using prior sensitivity information—e.g., sensitivity information obtained from prior in-vitro or in-vivo tests. *Id.*, 140:12-34, 143:6-12, 213:9-13. The patent refers to a “profile” of expected changes in sensitivity over time: “it has been found that sensor profiles tend to follow an empirically determined pattern of drift within a range of about $\pm 5\%$, $\pm 10\%$, $\pm 15\%$, $\pm 20\%$, $\pm 25\%$.” *Id.*, 210:54-56. “[A]n expected profile” can be “an expected pattern and/or amount of sensitivity change/drift over time.” *Id.*, 210:44-50; *id.*, 213:14-16 (describing “an expected pattern of drift” wherein “during the first hour or so, of sensor use (e.g., after start-up and/or re-start-up after a period of disuse), sensitivity tends to change rapidly; after this period, the sensitivity increase tends to level off and/or plateau,” and noting that “other sensitivity profiles are possible based on sensor design”), 213:28-32 (describing embodiments where “the system is configured to evaluate and/or consider a deviation from the expected profile in combination with additional information,” such as “completion of break-in,” “to determine if a system failure has occurred”).

The patent also refers to “an expected range” within which sensitivity

changes over time, and describes embodiments where “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,” such “an acceptable change in sensitivity” being “related to how long the sensor has been in use, implanted and/or energized.” Ex-1001, 213:33-43; *see id.*, 213:14-19.

The patent further describes embodiments where “a change in sensitivity is evaluated using a ‘cone’ of feasible sensitivity values of the sensor.” *Id.*, 213:44-45. In such embodiments, “aberrant sensitivity changes” are detected “whenever the sensitivity value (e.g., amount of sensitivity change, a calculated change in sensitivity over a time period) falls (e.g., occurs) outside of the cone of possibility.” *Id.*, 213:46-50. “[T]he cone of possible sensitivity values” can be “defined in terms of a range of allowable (or feasible) sensitivity change for a time point during a sensor session.” *Id.*, 213:50-53. In addition, “[t]he range of allowable sensitivity change can change over time during a sensor session, for example, by allowing a greater sensitivity change during an earlier time period of a sensor session than a later time period of a sensor session.” *Id.*, 213:53-57. The patent also notes that “sensitivity information ... can be obtained from analysis of data sets (e.g., a priori information).” *Id.*, 213:57-59. *See* Ex-1002, ¶¶48-52.

B. Prosecution History

The '031 patent was filed on December 23, 2020, in a chain of applications

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claiming priority to an application filed on November 7, 2008.³ DexCom filed the application for the '031 patent with eighteen claims and a Track One request for prioritized examination. Ex-1003, 1-442.

One week after filing the application, DexCom cancelled claims 1-18 and added claims 19 and 20, which are shown below:

AMENDMENTS TO THE CLAIMS	
1-18.	(Cancelled)
19.	(New) A method comprising: calibrating sensor data.
20.	(New) A transcutaneous analyte sensor system comprising: a transcutaneous analyte sensor; and sensor electronics operably connectable to the transcutaneous analyte sensor.

On January 4, 2021, DexCom filed an IDS listing over 3,230 references and spanning 166 pages. Ex-1003, 449-618. In a Non-Final Office Action mailed on March 2, 2021, the Examiner electronically initialed and included the typed phrase “All references considered except where lined through” at the bottom of each page of the IDS. Ex-1003, 759-924. None of the references were “lined through.” *See id.*

In the Office Action, the Examiner rejected claims 19 and 20 for lacking

³ Petitioner has applied the asserted 2008 priority date solely for the purpose of this petition and does not concede that any challenged claim is entitled to the 2008 priority date.

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novelty. Ex-1003, 634-639. On March 15, 2021, DexCom filed a Response cancelling claim 19, significantly amending claim 20 (which eventually issued as claim 1), and adding over forty new claims. *Id.*, 926-937. The amendments to claim 20 are shown below:

AMENDMENTS TO THE CLAIMS

Please cancel claim 19 without prejudice.

Please amend claim 20 and add claims 21-65 as follows.

1-18. (Canceled)

19. (Canceled)

20. (Currently Amended) A ~~transcutaneous analyte sensor~~ system for monitoring a glucose concentration, the system comprising:

a transcutaneous ~~analyte~~ 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, 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;

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; and

sensor electronics configured to operably ~~connectable~~ connect to the transcutaneous ~~analyte~~ glucose sensor, wherein the electronics comprises a memory, wherein the memory stores information associated with a profile, wherein the profile is based at least in part on *a priori* information related to expected sensitivity changes associated with a length of time the *in vivo* portion of the transcutaneous glucose sensor has been inserted into the body of the host.

On March 16, 2021, only *one day* after DexCom significantly amended claim 20 and added over forty claims, an examiner interview was conducted where the Examiner “agreed that the claim amendments filed on March 15, 2021 were

patentable in light of the prior art.” Ex-1003, 953. That same day, DexCom filed an amendment modifying the application’s priority claim, as well as a Terminal Disclaimer against several patents. *Id.*, 951-955.

A Notice of Allowance was mailed on March 26, 2021, less than twelve days after re-written claim 20 and the new claims were first presented. Assuming the Examiner worked twenty-four hours-a-day for those twelve days to compare the previously disclosed references with the amended claims, the Examiner would have had only five minutes per reference, with about seven seconds per claim. The ’031 patent issued on June 1, 2021. *See* Ex-1002, ¶¶58-65.

C. The Challenged Claims

The claims of the ’031 patent recite systems and methods for monitoring glucose concentration with a transcutaneous glucose sensor, using information related to drift. Of the five independent claims, claims 23, 35, and 42 are being challenged in this petition. These claims describe the information limitation as follows:

- “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” (claim 23);

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- “information associated with an expected change over time in a relationship between the signal and the glucose concentration within the body of the host” (claim 35);
- “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” (claim 42).

Claim 23 recites a “measurement characteristic of the transcutaneous glucose sensor to the glucose concentration,” while claims 35 and 42 each refer to a “relationship between the signal and the/a glucose concentration.” These recitations encompass sensor *sensitivity* and/or *baseline*.⁴ In addition, all three claims require a shift or change over time, in the measurement characteristic (claim 23) or in the relationship (claims 35 and 42), and thus encompass shifts or changes over time in sensor sensitivity and/or in baseline. Claims 35 and 42 further refer to “an expected” change or relationship.

⁴ Each of claims 35 and 42 recites a change over time in a “relationship between the signal” and the “glucose concentration”—this relationship is described by the conversion function, which defines calibration parameters such as sensitivity and baseline. *See* note 1, *supra*.

Notwithstanding the different recitations in the independent claims, these claims encompass the same embodiments that are disclosed in the prior art, as detailed below. Ex-1002, ¶¶54-57, ¶92, ¶211.

VII. LEVEL OF ORDINARY SKILL IN THE ART

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. Ex-1002, ¶67.

VIII. CLAIM CONSTRUCTION UNDER 37 C.F.R. 42.104(b)(3)

In the district court litigation, Petitioner has proposed that the term “drift profile” recited in claims 23, 25-28, and 34 means “profile of a change in baseline

and/or sensitivity of the sensor signal over time.” DexCom has asserted that the term be given its plain and ordinary meaning, which, according to DexCom, is a “set of information associated with sensor measurement characteristic changes over time.”⁵ Petitioner respectfully submits that the Board need not expressly construe the term “drift profile,” or any other terms, to decide the issues presented herein; with respect to the term “drift profile,” claims 23-34 are anticipated and/or rendered obvious by Zhang and by Shin under either construction. Petitioner otherwise interprets the claims “in accordance with the ordinary and customary meaning ... as understood by one of ordinary skill in the art,” 37 C.F.R.

§42.100(b). *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

IX. SUMMARY OF PRIOR ART

A. Zhang (Ex-1004)

Zhang published on June 20, 2005, and qualifies as prior art under at least pre-AIA-35 U.S.C. §102(b). Zhang was not considered during prosecution of the '031 patent.

Zhang describes calibration methods for implantable sensors that measure a

⁵ *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, 1:23-cv-00239-KAJ (D. Del.), Dkt. 123 at 33.

characteristic of a patient's body, preferably a glucose level. Ex-1004, ¶0027. The sensor can include an enzyme electrode that is used "for direct contact with patient fluids." *Id.*, ¶0028. Zhang describes sensor electrodes using the enzyme glucose oxidase to generate currents, such that "a measurement of the currents can be used to determine the amount of glucose present in the blood." *Id.*, ¶0029; *see id.*, ¶0030. Ex-1002, ¶¶71-82.

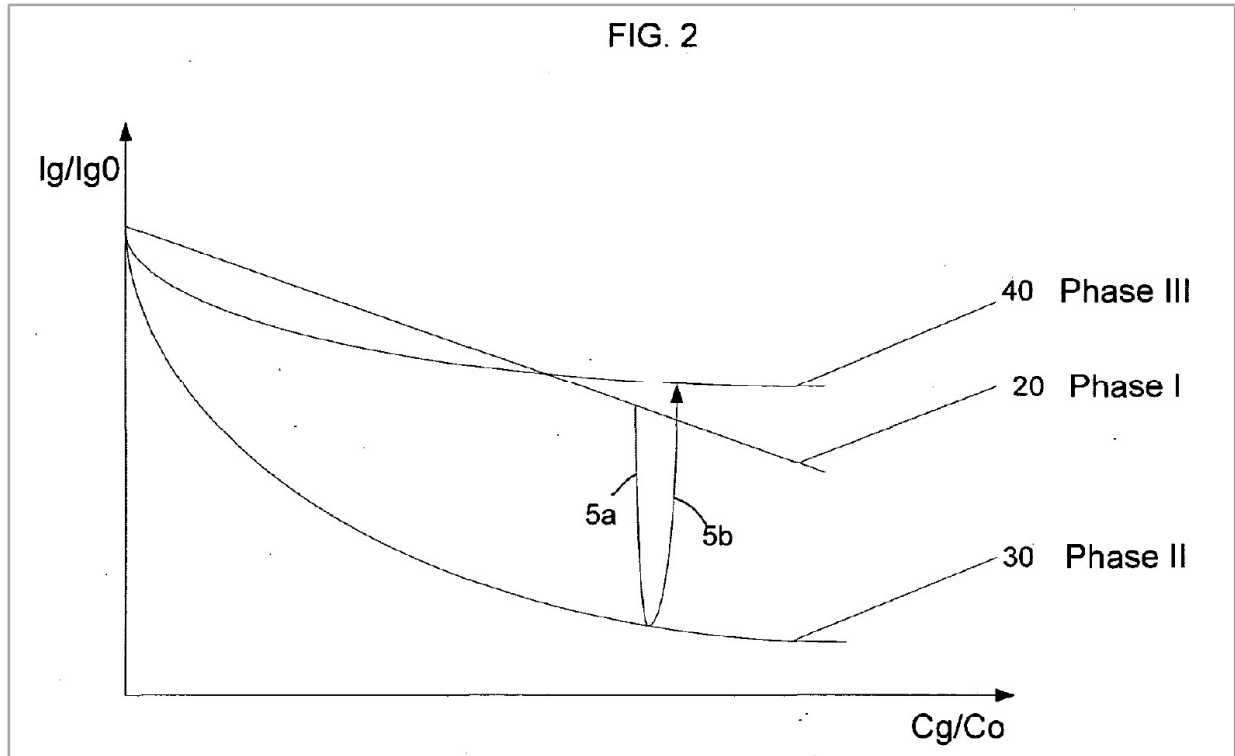
Zhang explains that "[s]ensors typically exhibit different characteristics during the useful life of the sensor" and "typically have three phases: (1) initialization phase, (2) stable phase, and (3) end of life phase." Ex-1004, ¶0032. Zhang teaches that the readings from the sensor need to be adjusted, to account for the different sensor characteristics in each of these three phases. *Id.* Zhang describes "a calibration scheme" that "can be used to properly calibrate the sensor regardless of the phase of the sensor life and to identify which phase the sensor is in." *Id.* Zhang's calibration scheme "adjusts the calibration curve throughout the life of the sensor. Having a constantly updated calibration curve assures that accurate sensor readings are obtained regardless of the phase of the sensor." *Id.*, ¶0040.

Specifically, the calibration curve undergoes "curve shape adjustments" so that the shape of the calibration curve appropriately reflects the particular phase of sensor life that applies at that point in time. *Id.*, ¶¶0051-61, FIG. 4. "[A]djustments

may be made to the shape of the measured curve, i.e., the shape of the sensor calibration curve. The adjustments to the calibration curve may be used to provide calculation of the sensor output.” Ex-1004, ¶0051. Zhang uses expected curve shapes (generated from empirical data collected from prior use of sensors) to adjust the shape of the measured curve during sensor use; Zhang refers to the expected curve shapes as “the expected normalized calibration curves.” *Id.*, ¶0033; *see also id.*, ¶0021.

Zhang teaches how to adjust the shape of the calibration curve in ¶¶0033-0061 and by reference to FIG. 2. FIG. 2 shows three normalized curve shapes, each curve shape corresponding to one of the three phases of sensor life; Zhang explains that each curve reflects “a sensitivity period” and characterizes the varying relationships between sensor current and glucose concentration over time periods following sensor insertion. *Id.*, ¶¶0033-40. The curves in FIG. 2 thus show how “sensor output current with respect to glucose concentration” (and thus sensor sensitivity⁶) changes in each phase of sensor life, and each curve in FIG. 2 shows sensor sensitivity for a particular phase of sensor life. *Id.* Zhang’s FIG. 2 is reproduced below:

⁶ *See* note 1, *supra*.



Zhang explains that “[t]he curve shapes 20, 30, and 40 are the calibration curve shapes of each phase of the sensor life,” and that “[a]rrow 5a, 5b represent a typical life cycle of the calibration curves as the sensor changes from one phase to another phase.” Ex-1004, ¶0033. During sensor wear, reference blood glucose values are obtained, and, in combination with prior knowledge of the phases and associated normalized calibration curves, the system is recalibrated. *Id.*, ¶0040. Updating the calibration curve by this method contributes to more accurate sensor readings. *Id.* Specifically, as a sensor progresses through the three phases, its output with respect to glucose concentration (and thus its sensitivity) first will be described by the shape of curve 20, then by the shape of curve 30 (arrow 5a showing the shift from curve 20 to curve 30), and then by the shape of curve 40

(arrow 5b showing the shift from curve 30 to curve 40). Zhang thus teaches a profile, based on the shift between three curve shapes over time, that is used to update the calibration curve. The updated calibration curve is then used to generate sensor readings, i.e., calibrate sensor data. *Id.*, ¶¶0041-62. *See id.*, ¶0033 (“...sensor recalibrations will be performed not only based on independent characteristic values (e.g., blood meter values) but with use of the expected normalized calibration curves...”); FIGS. 4, 5c (each referring to “curve shape adjustment”).

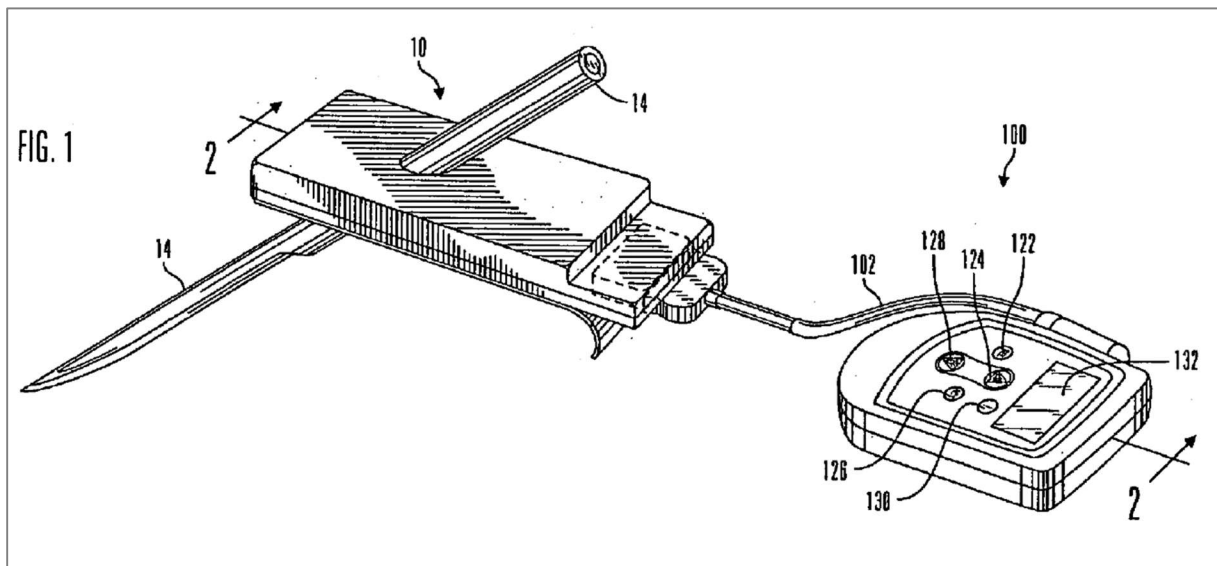
The normalized curve shapes depicted in FIG. 2 are “the calibration curve shapes of each phase of the sensor life as determined based on empirical data collected from the use of sensors” (*id.*, ¶0033)—in other words, the shape of each curve in FIG. 2 was determined based on prior information, on empirical data collected from prior use of the sensors. *See id.*, ¶¶0015-0017; *id.*, ¶0016 (“Generating a calibration curve may include compiling a priori empirical values of sensors similar to the sensor being calibrated.”).

B. Shin (Ex-1008)

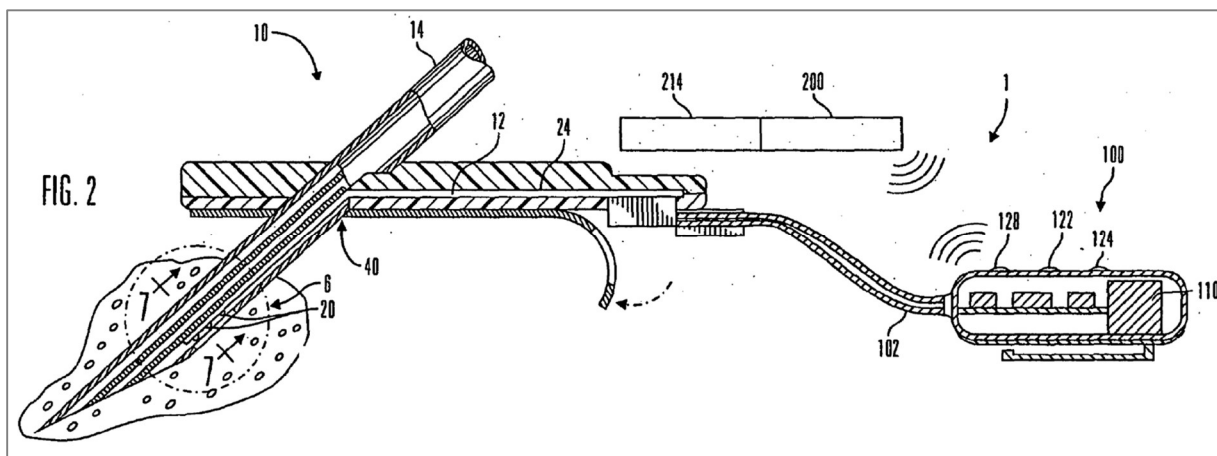
Shin published on January 6, 2005, and is prior art at least under pre-AIA-35 U.S.C. §102(b). There is no evidence that Shin was substantively considered during prosecution of the '031 patent; DexCom line-listed Shin in an IDS along with over 3,200 other references, and the Examiner never cited Shin in any

rejection.

Shin describes “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.” Ex-1008, ¶0054. Shin’s system includes multiple components: “the glucose monitor 100, which attaches to the glucose sensor set 10; and the data processor 200.” *Id.*, ¶0059.



Id., FIG. 1.



Ex-1008, FIG. 2. The electrochemical 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.*, ¶0057.

Shin also teaches “[a] method of calibrating glucose monitor data includ[ing] collecting the glucose monitor data over a period of time at predetermined intervals [and] ... calculation of the calibration characteristics.” Ex-1008, Abstract; *id.*, ¶¶0005-0028, ¶¶0054-0182 (generally teaching analyte sensors and methods for calibrating the sensors).

Shin teaches that a “calibration factor called a sensitivity ratio (SR)...is calculated for a particular glucose sensor 12. The SR [the sensitivity ratio or blood glucose level/Valid ISIG value] is a calibration factor used to convert the Valid ISIG value [electrical current signal] (Nano-Amps) into a blood glucose level (mg/dl or mmol/l).” *Id.*, ¶0082. Alternatively, Shin teaches using a modified SPSR (“MSPSR”) as a calibration factor; the MSPSR accounts for a sensor “hav[ing] a less linear performance at very high blood glucose levels.” *Id.*, ¶0093.⁷

Shin teaches comparing the MSPSR to valid sensitivity ranges. Specifically,

⁷ In Shin, the relationship between sensor output and glucose concentration is linear (Ex-1008, ¶¶0087-0102), and the SPSR (or MSPSR) is the inverse of the slope m and thus is the inverse of sensor sensitivity.

Shin teaches that, during calibration, “the MSPSR is compared to a valid sensitivity range to determine if the newly calculated MSPSR is reasonable.” Ex-1008, ¶0103. Shin describes a particular embodiment using “a valid MSPSR range of 1.5 to 15” that “has been determined based upon valid glucose sensor sensitivity measurements made in-vitro.” *Id.* Shin also teaches that “[o]ther valid sensitivity ranges may be applied depending on the types of sensors to be calibrated, the range of acceptable sensitivity levels for the various sensor types, the manufacturing consistency expected for the sensors, environmental conditions, how long the sensor has been in use, or the like.” *Id.*

Shin thus teaches checking for changes in sensor sensitivity using a priori information. In particular, Shin teaches comparing the calibration factor (the MSPSR) to pre-determined “valid sensitivity ranges” that can be based on “how long the sensor has been in use.” *Id.*, ¶0103. Ex-1002, ¶¶83-91.

X. GROUNDS OF INVALIDITY⁸

A. Ground 1: Zhang Anticipates and/or Renders Obvious Claims 23-46

1. Claim 23

- a. 23[Pre]. “A method for monitoring a glucose concentration, the method comprising:”

Zhang describes a method for monitoring glucose concentration. Ex-1004, ¶¶0007-08, ¶0014, ¶0027. Ex-1002, ¶92.

⁸ In the district court litigation, Petitioner contends that the challenged claims are not enabled, and DexCom has disputed these contentions. Petitioner’s contentions herein, unlike its district court contentions, rely on the “presumption ... that both the claimed and unclaimed disclosures in a prior art patent are enabled,” and DexCom bears “the burden of proving the nonenablement of” the prior art relied upon herein. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). Further, DexCom should not be heard to “demand[] a more detailed level of disclosure from the prior art than it provides in its own patent.” *DexCom, Inc. v. Abbott Diabetes Care Inc.*, IPR2022-00605, Paper 29 (P.T.A.B. July 10, 2023) at 41-42 (citing *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1381 (Fed. Cir. 2013); *In re Publicover*, 813 F. App’x 527, 532 (Fed. Cir. 2020).

- b. 23[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;”

Zhang describes methods for calibrating glucose sensor data, whereby sensor readings are processed. Ex-1004, ¶¶0037-63. By teaching obtaining and then processing sensor output, Zhang teaches beginning a sensor session. Ex-1002, ¶¶94-96.

Zhang’s sensor session is associated with the use of a transcutaneous glucose sensor comprising an ex-vivo portion configured to remain outside the body and an in-vivo portion configured to be inserted into the body. Zhang explains that the sensor “can be implanted in and/or through subcutaneous, dermal, sub-dermal, inter-peritoneal or peritoneal tissue,” and that the sensor may be used in interstitial fluid. Ex-1004, ¶0027.

Should it be determined that Zhang does not expressly or inherently disclose that its glucose sensors include sensors having an ex-vivo portion, such sensors would have been obvious in view of the POSA’s knowledge that many glucose sensors described in the art—including sensors used commercially—were transcutaneous sensors having an ex-vivo portion. Indeed, a transcutaneous sensor

having an ex-vivo portion was a common feature of commercial CGMs.⁹ The POSA would have recognized that systems with such sensors offer advantages over systems with fully implanted sensors; for example, systems with a transcutaneous sensor as claimed can be “worn continuously by changing the systems every 3-7 days” and “are inserted by the user at home” and thereby “allow a user to choose how often and at what times they want to wear the device.” Henning, 129. Systems with transcutaneous sensors provide flexibility, in contrast to long-term systems with sensors that are “implanted in the body,” which “require a long-term commitment to the use of the device” and where “[i]nserting the long-

⁹ E.g., Henning, 131-132 (“All the on-market CGM devices have similar components....The sensor has a glucose-oxidase-based working electrode located under the skin and electrical contacts located above the skin.”). Henning was publicly available as of November 2009 (Ex-1032, ¶70), and all of the chapter’s forty-one references are dated prior to November 2008 (DexCom’s asserted priority date). “Publications published after the date of invention have long been allowed ‘as evidence of the state of the art existing on the filing date of an application.’” *Disney Enterprises, Inc. v. Kappos*, 923 F. Supp. 2d 788, 801 (E.D. Va. 2013) (quoting *In re Hogan*, 559 F.2d 595, 605 & n.17 (C.C.P.A. 1977) and citing cases).

term device and retrieving it from the body” would “likely be done in a physician’s office.” *Id.* The POSA would have reasonably expected success in using a transcutaneous sensor as claimed given the successful use of such sensors in the art. Moreover, Zhang teaches that its calibration scheme is a “generalized method [that] may be applied to a variety of glucose sensors.” Ex-1004, ¶0031. *See also id.*, ¶0033 (“[F]urther research has proved that most sensors behave similarly and these calibration curves can be used with other type of sensors.”). Ex-1002, ¶¶97-98.

c. 23[b]. “generating sensor data derived at least in part from the transcutaneous glucose sensor;”

Zhang’s method involves generating sensor data at least in part from the sensor. The electrodes of the sensor, which are implanted in the user, generate current, and this current is measured to generate sensor data. Ex-1004, ¶0029 (“a measurement of the currents can be used to determine the amount of glucose present in the blood”), ¶¶0042-62 (referring to “glucose electrode readings” and “nominal glucose current”). Ex-1002, ¶¶99-100.

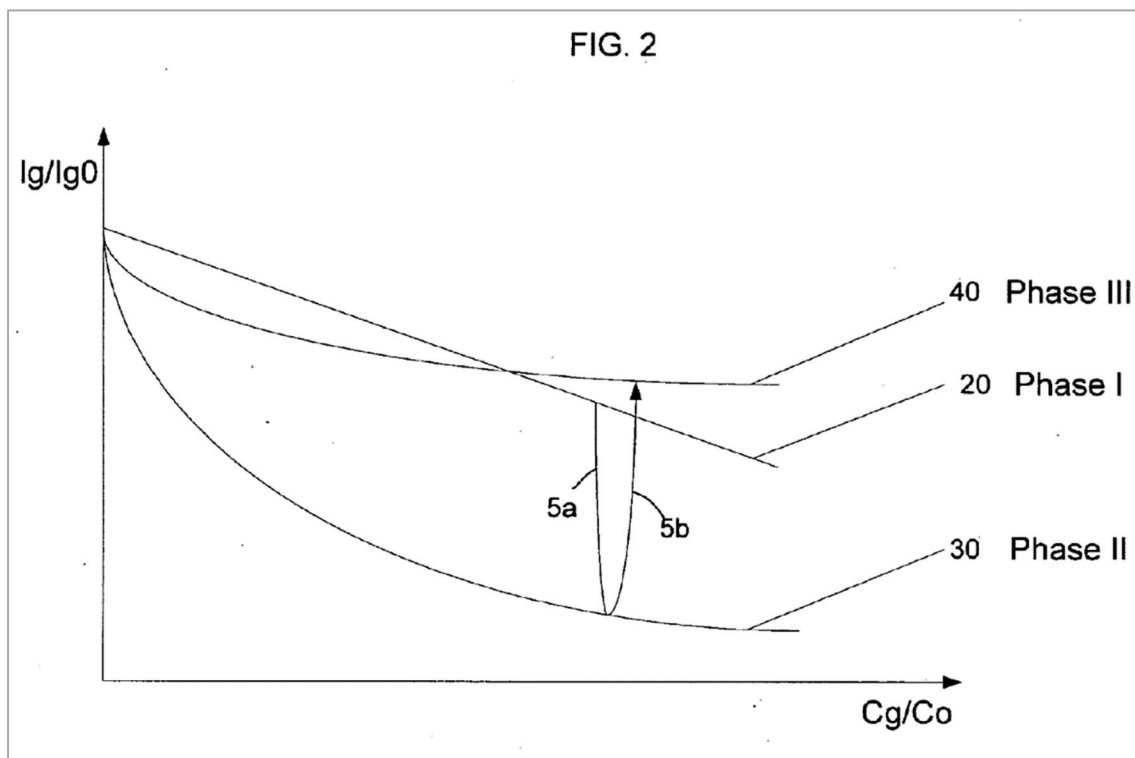
- d. 23[c]. “determining a glucose concentration value based at least in part on the sensor data and information associated with a drift profile, wherein the drift profile is associated with a shift over time in measurement [sic] characteristic of the transcutaneous glucose sensor to the glucose concentration 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;”

Zhang’s method involves determining a glucose concentration value based at least in part on the sensor data and on pre-determined, normalized calibration curves for each of the three phases of sensor life, as described below. Zhang’s normalized calibration curves and shifts between curves constitute a “drift profile,” wherein the “drift profile” is associated with “a shift over time” in 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. Thus 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 claim 23[c]. Ex-1002, ¶¶101-109.

Zhang teaches calibrating the sensor output and determining a glucose concentration value, using normalized calibration curves. Ex-1004, ¶¶0031-63. The curves reflect a shift over time of sensor output with respect to glucose concentration, as the sensor progresses through the three phases of sensor life. *Id.*, ¶¶0033-40. This shift over time is a result of the length of time the sensor has been

inserted in the host and reflects a shift in sensor sensitivity (a “measurement characteristic” as claimed) over time. *Id.* Thus Zhang’s three curves and the shifts between them over time constitute a “drift profile” as claimed.

Zhang depicts an embodiment of normalized calibration curves in FIG. 2; FIG. 2 shows three curves “for the three phases of the sensor life” (Ex-1004, ¶0033) and is reproduced below:



As Zhang explains in ¶¶0037-39, each of the curves in FIG. 2 has a different shape, the different shapes showing that each phase of sensor life is associated with different sensor sensitivities. In other words, each curve reflects sensor sensitivities

for a particular phase of sensor life.¹⁰ Zhang then describes “a continuum of change” in sensor sensitivity; as time moves forward and the sensor progresses through the different phases, sensitivity follows the shape of the three normalized curves, and the calibration curve is adjusted to account for each shift in curve shape (each shift being a change in sensor sensitivity):

[P]hase 1 of the sensor’s life may be viewed as a sensitivity period during the initial output of the sensor current with respect to glucose concentration. As can be seen in FIG. 2, line 20 is virtually completely linear during the first phase. This linearity represents the sensor output when it is initially placed in a patient. However, as the sensor stabilizes and enters phase 2, the current output of the sensor with respect to glucose concentration tends to become non-linear. The curve shape moves from line 20 to curve 30, as shown by the arrow 5a. ... The curve shift between line 20 and curve 30, represented by arrow 5a, represent[s] a

¹⁰ For the linear relationship between sensor output and glucose concentration shown as “line 20” for phase I, the relationship is expressed by the equation $y = mx + b$, where the slope m is the sensor sensitivity. For the non-linear relationships shown by curve 30 and curve 40 (for phase II and phase III, respectively), the slope or sensitivity of the sensor at a given concentration is the slope of the tangent on the curve at that concentration. Zhang’s three curves have slopes that differ from each other and thus the curves exhibit different sensor sensitivities.

continuum of change in the sensor output current with respect to glucose concentration[.]...Toward the end of the sensor life, the sensor output current tends to change less and less with respect to glucose concentration. Curve 30 moves toward curve 40 as represented by arrow 5b.

Ex-1004, ¶¶0037-39; *id.*, ¶0040 (“the present invention adjusts the calibration curve throughout the life of the sensor”), ¶0051, ¶¶0061-62, Zhang’s claims 34-37.

The three curves in FIG. 2 and the shifts between them as time progresses are a “drift profile” as recited in claim 23[c] because they reflect the shift in sensor sensitivity that occurs over time (i.e., as a result of the sensor being within the body of the host).

Furthermore, Zhang teaches that “sensor recalibrations will be performed not only based on independent characteristic values (e.g., blood meter values) but with use of the expected normalized calibration curves.” Ex-1004, ¶0033. The sensor recalibrations are used in determining a glucose concentration. *Id.*, ¶0029, ¶0033-35, ¶¶0040-62; *id.*, ¶0061 (“[T]he sensor output can be calculated using the new calibration curve derived from the recalibration procedure of FIG. 4.”).

e. 23[d]. “and displaying the glucose concentration value.”

Zhang’s method is for determining and monitoring, and thereby allowing for the management of, a patient’s glucose level, and the POSA would have understood that Zhang’s method involves and/or renders obvious displaying the

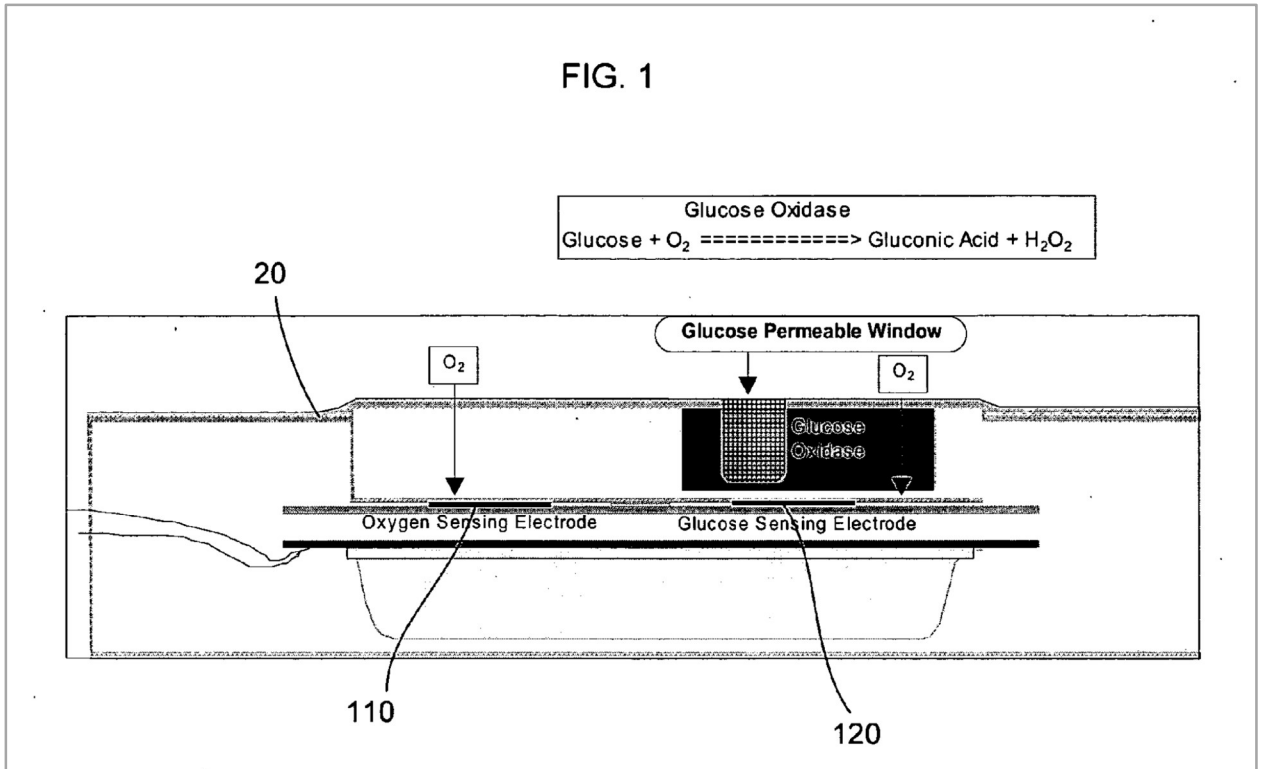
glucose concentration value for this purpose. Ex-1002, ¶¶110-112.

For example, Zhang teaches determining and monitoring “a characteristic of a patient’s body,” which in preferred embodiments is “glucose level.” Ex-1004, ¶0027. “[E]mbodiments of the present invention are primarily described in the context of glucose sensors used in the treatment of diabetes,” though they are “applicable to a wide variety of patient treatment programs where a physiological characteristic is monitored.” *Id.* Zhang thus teaches monitoring a characteristic such as glucose level for patient treatment programs, including for the treatment of diabetes. The POSA would have understood that, in order for the patient or healthcare provider to respond appropriately to a glucose concentration value determined by the system and thereby manage the patient’s glucose level, the system displays the glucose concentration value. Indeed, commercial CGMs on the market at this time were known to include displays for showing the determined glucose concentration values. Ex-1002, ¶112.

2. Claim 24

Zhang’s sensor has the claimed planar configuration. Ex-1002, ¶¶113-114.

Ex-1004, FIG. 1:



3. Claim 25

Zhang’s profile accounts for “a break-in” of the glucose sensor. The “first phase” (also called “initialization phase”) in Zhang corresponds to “a break-in,”¹¹

¹¹ The ’031 patent defines “break-in” broadly to include “electrochemical break-in,” “membrane break-in,” and “sensor break-in.” “Sensor break-in” encompasses both “electrochemical break-in” and “membrane break-in.” Ex-1001, 24:50-56, 28:25-30, 29:58-30:6. The patent explains that “sensor break-in” “refers without limitation to the time (after implantation) during which the sensor’s signal is becoming substantially representative of” glucose concentration, and that, “[i]n

and as discussed above for claim 23, Zhang’s profile includes this first phase of sensor life. Specifically, Zhang explains that first phase, phase 1, is the sensor sensitivity period corresponding to when the sensor “is initially placed in a patient” (Ex-1004, ¶¶0037) and “becomes used to its environment” (*id.*, ¶¶0032)—i.e., when the sensor is breaking in. Ex-1002, ¶¶115-117.

4. Claim 26

See claim 23[c], §X.A.1.d. Each curve in FIG. 2 corresponds to a different phase of sensor life and reflects the sensor’s sensitivities for a particular phase of sensor life. Zhang’s drift profile (the three curves and the shifts from one curve to another during sensor wear) accounts for the expected sensitivity changes associated with the length of time the sensor has been inserted in the host’s body. Ex-1004, ¶¶0037-39; Ex-1002, ¶¶118-119.

5. Claim 27

Zhang’s FIG. 2 shows that at least the curve for phase III (curve 40) has a different baseline from the curves for the earlier phases of sensor life. Zhang also teaches embodiments involving adjustments to the baseline of the calibration curve. Ex-1004, ¶¶0043-50, ¶¶0061-62, FIG. 4. Zhang thus teaches embodiments

some embodiments, sensor break-in occurs prior to obtaining a meaningful calibration of the sensor output.” Ex-1001, 29:60-30:4.

where the shifts in the calibration curve shape are accompanied by changes to the baseline, and Zhang thereby teaches embodiments where “the drift profile accounts for a change in baseline over time,” in addition to a change in sensitivity over time.

Claim 27 also would have been obvious based on Zhang and the knowledge in the art that baseline (as well as sensitivity) often shifts over time. Indeed, Zhang explains that there may be a baseline shift. Ex-1004, ¶¶0043-46, ¶¶0061.

Accounting for a change in baseline (in this case, expected changes in baseline) over time in Zhang’s drift profile would have been obvious because Zhang’s drift profile already includes normalized curves, each such curve intercepting the y-axis and thus having a baseline value, and the POSA understood that baseline, like sensor sensitivity, often changes over time. Zhang’s normalized calibration curves (each curve having a baseline value) would account for changes in baseline (as well as curve shape, and therefore sensor sensitivity) as a sensor progresses through the different phases of sensor life. The different baseline values, like Zhang’s different curve shapes, would be based on empirical data collected from prior sensor use. During calibration, baseline adjustments as well as curve shape adjustments would be made based on the expected changes in both baseline and curve shape. Ex-1002, ¶¶120-122.

6. Claim 28

See claims 26 and 27, §X.A.4, §X.A.5. Ex-1002, ¶123.

7. Claim 29

The shift in sensor sensitivity over time described in Zhang corresponds to a shift over an elapsed time measured from the beginning of the sensor session, which is also the time when the sensor has been inserted into the host. Ex-1002, ¶¶124-126.

Zhang explains that phase 1 “represents the sensor output when it is initially placed in a patient.” Ex-1004, ¶0037. Zhang teaches calibrating sensor data starting at this time; Zhang teaches that “after a sensor has been implanted into a patient, readings from the sensor need[] to be adjusted for the first phase of the sensor life as the sensor becomes used to its environment.” *Id.*, ¶0032; *id.*, ¶¶0031-62. Zhang thus teaches that the shift in sensor sensitivity over time (during the three phases, and beginning with phase 1 when the sensor is initially placed in a patient) corresponds to a shift over a time period measured from the beginning of the sensor session.

8. Claim 30

In Zhang, the sensitivity changes, exhibited by the shifts between the three normalized curves in FIG. 2 and corresponding to the three phases of sensor life, are associated at least in part with a change in a physical property of the environment surrounding the in-vivo portion of the glucose sensor. Ex-1002, ¶¶127-132.

Zhang teaches that the curve shape representing each phase and shown in FIG. 2 was determined “based on empirical data collected from the use of sensors.” Ex-1004, ¶0033. At the same time, the POSA understood that the in-vivo environment surrounding the sensor is not constant and that such environmental changes affect sensor sensitivity. For example, it was known that the host’s body reacts to sensor implantation; such host reactions include inflammatory reactions (which in turn increase temperature) and the migration of cells towards the sensor.¹²

As Zhang teaches that sensor sensitivity changes through the three phases (initialization phase, stable phase, and end-of-life phase), with the curve shape and thus sensor sensitivities of each phase determined *empirically*, from the testing of sensors, and as the POSA knew that the environment around the sensor is also

¹² The ’031 patent includes “blockage of sensor surface area due to cells and/or blood clotting at the membrane, biofouling, blood flow/sheer rate, blood pH, [and] temperature” among the physical properties of the sensor or the surrounding fluid that can produce fluctuations in sensitivity and/or baseline. Ex-1001, 143:12-23; *id.*, claim 31 (reciting “wound healing, blockage of a surface of the transcutaneous glucose sensor, inflammation, blood clotting, or biofouling” as physical properties of an environment surrounding the in-vivo portion of the sensor).

changing during these phases (with such changes affecting sensitivity and contributing to the observed changes in the curve shape), the POSA would have understood that *at least part* of the sensitivity changes in the three phases are associated with a change in a physical property of the environment.

Claim 30 alternatively would have been obvious in view of Zhang and a POSA's knowledge that environmental changes at the site of sensor implantation affect sensor sensitivity. The POSA would have understood that empirical observations of changes in sensor output with respect to glucose concentration (and therefore sensitivity changes) over time necessarily account for sensitivity changes caused by such environmental changes. The POSA would have found it obvious that Zhang's curve shapes depicting expected sensitivity changes over time, which Zhang expressly teaches were determined empirically, are associated at least in part with a change in a physical property of an environment surrounding the in-vivo portion of the sensor. Ex-1002, ¶¶133.

9. Claim 31

Claim 31 enumerates causes for the changes in the environment surrounding the in-vivo portion of the sensor. At least some of these causes (e.g., wound healing, inflammation) were known to inevitably occur following insertion of the sensor into the host. Accordingly, the shift over time that is associated at least in part with a change in a physical property of the environment surrounding the in-

vivo portion of the sensor (*see* claim 30) is necessarily a shift associated with at least one of trauma, wound healing, etc., as recited in claim 31. At a minimum, it would have been obvious to account for drift associated with one of the enumerated causes. Ex-1002, ¶¶134-136.

10. Claim 32

As discussed below for claim 35[b], Zhang discloses and/or renders obvious a membrane; the shift over time taught in Zhang and discussed above would have been understood as being associated in part with “a physical property correspond[ing] to a membrane of the in vivo portion” of the sensor, as recited in claim 32. Ex-1002, ¶¶137-139.

Like the environment surrounding the in-vivo portion of the sensor, the membrane of the sensor also changes over time. It had been well documented that biological materials inevitably become deposited on the membrane; such process was commonly referred to as “membrane biofouling.” It was also well documented that membrane biofouling affects sensor sensitivity. The sensitivity shift over time taught in Zhang, which is based on empirical data, must be, or would have been understood as being, associated at least in part with membrane biofouling. Alternatively, the POSA would have found it obvious that Zhang’s curves and shifts in sensitivity are associated with a change in a physical property of the membrane. Ex-1002, ¶¶31-33, ¶140.

11. Claim 33

The shift over time reflected in Zhang’s drift profile corresponds to an elapsed time measured from the insertion of the sensor into the host’s body. Zhang explains that sensor output during phase 1, shown by line 20 during this first phase, “represents the sensor output when it is initially placed in a patient.” Ex-1004, ¶¶0037. Zhang also teaches that sensor output is calibrated at this time. *Id.*, ¶¶0031-62. Thus Zhang teaches that the subsequent shift(s) in curve shape (and thus sensor sensitivity) over time corresponds to a time period measured from the insertion of the sensor into host’s body. Ex-1002, ¶¶141-142.

12. Claim 34

As explained above with respect to claim 23[c], each of Zhang’s three normalized curves has a different slope or different slopes, and each curve is associated with a different time period (phase I, phase II, and phase III, respectively) of sensor life. Ex-1004, ¶¶0033, ¶¶0037-39. *See* note 10, *supra*. Ex-1002, ¶¶143-144.

13. Claim 35

- a. 35[Pre]. “A sensor system comprising:”

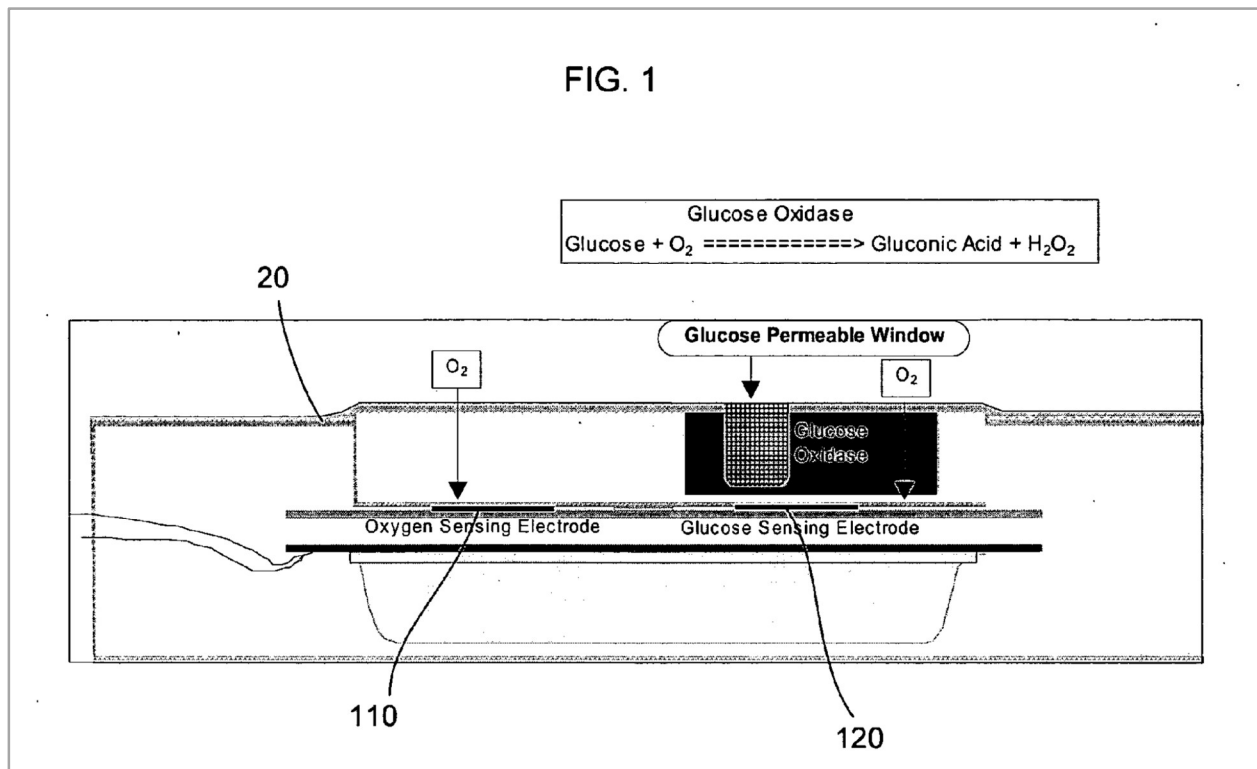
Zhang describes a system comprising a sensor to monitor glucose concentration. Ex-1004, ¶¶0008, ¶¶0015, ¶¶0027; Ex-1002, ¶145.

- b. 35[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,”

See claim 23[a], §X.A.1.b. Ex-1002, ¶146.

- c. 35[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;”

Zhang discloses and/or renders obvious this claim element. Zhang describes a glucose sensor that comprises an electrode and that relies on the glucose oxidase enzyme to detect the level of glucose. Ex-1004, ¶¶0028-29, FIG. 1:



As shown in FIG. 1, the enzyme glucose oxidase is contained within a specific region of the sensor. The POSA would have understood that, for the enzyme to be

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contained as shown, the enzyme is immobilized. The POSA further would have reasonably understood that the enzyme is contained in the area shown using a material that immobilizes the enzyme while also allowing glucose and oxygen to diffuse into the area and the enzyme to catalyze the reaction between glucose and oxygen; the POSA would have understood such material to be a “membrane.”¹³ E.g., *VirnetX Inc. v. Apple Inc.*, 2023 WL 6933812 (Fed. Cir. Oct. 20, 2023) (affirming Board’s decision from an *inter partes* reexamination that prior art reference anticipated claim where person of ordinary skill in the art ““would reasonably understand or infer from the part art reference’s teaching”” that every limitation was disclosed in the reference, even though the reference did not expressly disclose every claim limitation) (quoting *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1340–41 (Fed. Cir. 2020)). Additionally, the area containing the enzyme is over the glucose sensing electrode. Ex-1002, ¶¶147-149.

Zhang also incorporates by reference several documents that disclose

¹³ The '031 patent does not define the term “membrane.” The patent however consistently uses the term to encompass a material or layer that controls the diffusion of substances (e.g., oxygen, glucose, hydrogen peroxide) and/or stabilizes and immobilizes the enzyme. Ex-1001, 103:20-25, 121:63-122:3, 129:3-5; *see id.*, 86:49-45.

glucose sensors having an electrode with a membrane disposed thereon, wherein the membrane comprises an enzyme. Zhang in ¶10028 incorporates by reference Patent Nos. 4,650,547 (Ex-1005) and 4,703,756 (Ex-1006), each of which describes glucose sensors having an electrode with a membrane comprising an enzyme. Ex-1005, 6:3-41, FIG. 5; Ex-1006, 3:13-15 (The “sensor contacts glucose oxidase which is impregnated in a membrane and disposed about the sensor.”), 4:27-36.¹⁴ Ex-1002, ¶150.

Should it be determined that Zhang does not expressly or inherently disclose a membrane as claimed, this feature would have been obvious based on CGMs described in the art and on the knowledge of how those CGMs operate. CGMs commonly employed the enzyme glucose oxidase, which required containment or immobilization, and a preferred technique in the art for containing or immobilizing enzymes, and the technique used in commercial systems, was with the use of a membrane. Ex-1002, ¶151 (citing Koudelka-Hep, which explains that, “[i]n the vast majority of sensors,” the glucose oxidase “is immobilised by glutaraldehyde

¹⁴ “When a document is ‘incorporated by reference’ into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein.” *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001).

cross-linking” to form “gel-like membranes having good mechanical stability and thickness of several μm ,” and Henning, which refers to the “enzyme-containing membrane that covers the metal conductor” of the “working electrode of the sensor” as one of the components common to commercial CGMs). The POSA would have been motivated to use such technique (i.e., a membrane), and thereby would have been motivated to use a sensor as recited in claim 35[b], and would have had a reasonable expectation of success in doing so, at least because using a membrane to immobilize the enzyme had been practiced successfully in commercial and other systems described in the art. Ex-1002, ¶¶151-155.

- d. 35[c] “wherein the transcutaneous glucose sensor generates a signal associated with a glucose concentration within the body of the host;”

Zhang’s glucose sensor is configured to generate a signal (current), the magnitude of which depends on glucose concentration. Zhang describes a sensor “designed to send a particular current depending on the amount of oxygen present near” an “oxygen sensing electrode 110” and a “glucose sensing electrode 120 placed in the proximity of glucose oxidase to ascertain the oxygen depletion” around the sensor, and thus the amount of glucose present, based on a “fairly linear relationship” between oxygen and current. Ex-1004, ¶0029 (“a measurement of the currents can be used to determine the amount of glucose present in the blood”). Zhang also describes a hydrogen peroxide sensor that “measure[s] the amount of

hydrogen peroxide produced as a result of the reaction between oxygen and glucose in the presence of the glucose oxidase enzyme.” *Id.*, ¶0030. Ex-1002, ¶¶156-158.

- e. 35[d]. “electronics configured to receive the signal from the transcutaneous glucose sensor,”

Zhang’s system comprises electronics configured to receive signals from the glucose sensor. In Zhang’s systems, sensor readings are processed in a calibration method as described above. Ex-1004, ¶¶0037-63. For sensor readings to be processed (i.e., calibrated), Zhang’s system comprises electronics configured to receive the signals from the sensor. Indeed, Zhang discloses “a processor connected to the sensor for processing” the sensed parameter. *Id.*, ¶0013. The processor thus comprises electronics configured to receive sensor signals. Ex-1002, ¶¶159-161.

Zhang in ¶0029 also incorporates by reference Morgan’s disclosure. Morgan “relates to the field of sensor electronics” and discusses electronics (a “data converter”) configured to receive sensor signals. Morgan, FIGS. 1, 5, ¶0003, ¶0010, ¶0013, ¶0027, ¶0034, ¶0036, ¶¶0038-39, ¶0043. Ex-1002, ¶162.

This claim element also would have been obvious in view of the POSA’s knowledge of CGMs and their basic components, which included electronics that receive sensor signals and perform functions such as processing the signals received from the sensor. Ex-1002, ¶¶163-166.

- f. 35[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,”

Zhang’s electronics comprises a memory—the memory stores “the expected normalized calibration curves” generated using the a priori, empirical data and that are used in processing (i.e., calibrating) sensor readings. Ex-1004, ¶¶0015-16 (describing generating a calibration curve using a priori values), ¶0033 (explaining “the calibration curve shapes of each phase of the sensor life” shown in FIG. 2 are “based on empirical data collected from the use of the sensors”), claims 34, 36; *see also id.*, ¶0007, ¶0013. To use pre-generated normalized calibration curves when processing sensor readings, the electronics must comprise a memory for storing such curves. Ex-1002, ¶¶167-168.

Glucose monitoring systems comprising electronics with memory also would have been obvious. Shin and Say, for example, each describe this basic configuration of glucose monitoring systems. Ex-1002, ¶¶169-171.

The 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 claim 35[e]. 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.

Specifically, and as explained above, each of the three curves in Zhang's FIG. 2 has a different shape, the different shapes showing that each phase of sensor life is associated with different sensor sensitivities.¹⁵ These 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 claim 35[e]. Ex-1002, ¶¶172-173.

In addition, the curves in FIG. 2 were determined "based on empirical data collected from the use of the sensors" and thus are pre-determined. Ex-1004, ¶0033; *see id.* ¶0016 (referring to "a priori empirical values of sensors similar to the sensor being calibrated").¹⁶ In other words, the curves reflect "expected" changes over time, as required by claim 35[e]. Ex-1002, ¶174.

¹⁵ *See* note 10, *supra*.

¹⁶ In the district court litigation, DexCom has asserted that the challenged claims encompass embodiments where a priori drift information is obtained from prior studies involving only sensors other than the sensor in the claimed system or the sensor being calibrated. Solely for the purpose of this petition and not for any other purpose, Petitioner has applied DexCom's interpretation of the challenged claims.

- g. 35[ff]. “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.”

See claim 23[c], §X.A.1.d. Zhang’s system (the electronics therein) determines a glucose concentration based at least in part on the sensor signal and the normalized calibration curves. Zhang teaches that “sensor recalibrations will be performed not only based on independent characteristic values (e.g., blood meter values) but with use of the expected normalized calibration curves.” Ex-1004, ¶0033. The sensor recalibrations are used in determining a glucose concentration. *Id.*, ¶0029, ¶0033-35, ¶¶0040-62; *id.*, ¶0061 (“[T]he sensor output can be calculated using the new calibration curve derived from the recalibration procedure of FIG. 4.”). Ex-1002, ¶¶175-176.

14. Claim 36

See claims 30, 35[e], §X.A.8, §X.A.13.f, which explain how Zhang’s curve shape adjustments account for a shift or change over time in sensor sensitivity, such change being associated at least in part with a change in a physical property of the in-vivo environment surrounding the sensor. Ex-1002, ¶¶177-178.

15. Claim 37

See claim 31, §X.A.9. Ex-1002, ¶¶179-180.

16. Claim 38

As discussed above for claims 30-31, it was known that the host’s body

reacts to sensor implantation, and that such reactions affect sensor sensitivity. Because Zhang's three curve shapes are empirically-determined, they are associated with the expected changes in sensor sensitivity that inevitably accompany sensor implantation. At a minimum, it would have been obvious to account for drift resulting from such reactions. Ex-1002, ¶¶181-183.

17. Claim 39

See claim 29, §X.A.7. Ex-1002, ¶¶184-185.

18. Claim 40

See claim 33, §X.A.11. Ex-1002, ¶¶186-187.

19. Claim 41

See claim 32, §X.A.10. Ex-1002, ¶¶188-189.

20. Claim 42

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

Zhang describes a method of monitoring glucose concentration. Ex-1004, ¶0007, ¶0014, ¶0027.

- b. 42[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;"

Zhang describes methods for calibrating glucose sensor data, where sensor readings are adjusted as described above (see §X.A.1, §X.A.13). By teaching

obtaining and then processing sensor output, Zhang teaches beginning a sensor session. *See* claim 23[a], §X.A.1.b, for elements concerning the sensor itself.

- c. 42[b]. “wherein the transcutaneous glucose sensor is configured to generate a signal;”

Zhang’s glucose sensor is configured to generate a signal. The electrodes of the sensor, which are implanted in the user, generate current. Ex-1004, ¶0029, ¶¶0042-62. *See* claim 35[d], 35[f], §X.A.13.e, §X.A.13.g.

- d. 42[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;”

Zhang’s method also involves calibrating the sensor by applying a priori information as recited in claim 42[c].

As discussed above, Zhang’s calibration method adjusts the calibration curve shape over time, and each adjustment changes the curve slope(s), and in this way Zhang’s method accounts for sensor sensitivity changes over time. *See* §IX.A, §X.A.1.d, §X.A.13.f. Zhang’s three curve shapes and the adjustment from one curve shape to another (from the curve shape for phase I, to the curve shape for phase II, to the curve shape for phase III, each adjustment accounting for expected changes in sensor sensitivity over time) comprise “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 claim 42[c].¹⁷

In addition, Zhang’s three curve shapes are determined from empirical data collected from use of the sensors (Ex-1004, ¶0033, ¶0016) and thus are “a priori information.” This a priori information is applied to the sensor, to calibrate the sensor. *Id.*, ¶0033, ¶0040. Zhang thus describes calibrating the sensor by “applying a priori information,” wherein the a priori information comprises “an expected relationship” as recited in claim 42[c].

- e. 42[d]. “generating a glucose concentration value based at least in part on the calibrating; and”

See claims 23[c], 35[f], §X.A.1.d, §X.A.13.g.

- f. 42[e]. “displaying the glucose concentration value.”

See claim 23[d], §X.A.1.e. Ex-1002, ¶¶190-202.

21. Claim 43

See claim 29, §X.A.7. Ex-1002, ¶¶203-204.

¹⁷ *See* Ex-1001, 216:47-52: “For example, during the first hour of sensor use, the expected profile may be a line having a slope and/or curvature within a first range; while during the second hour of use the expected profile may be a line having a slope and/or curvature within a second range.”

22. Claim 44

See claim 30, §X.A.8. Ex-1002, ¶¶205-206.

23. Claim 45

See claim 31, §X.A.9. Ex-1002, ¶¶207-208.

24. Claim 46

See claim 32, §X.A.10. Ex-1002, ¶¶209-210.

B. Ground 2: Shin Anticipates and/or Renders Obvious Claims 23-46

1. Claim 23

- a. 23[Pre]. “A method for monitoring a glucose concentration, the method comprising:”

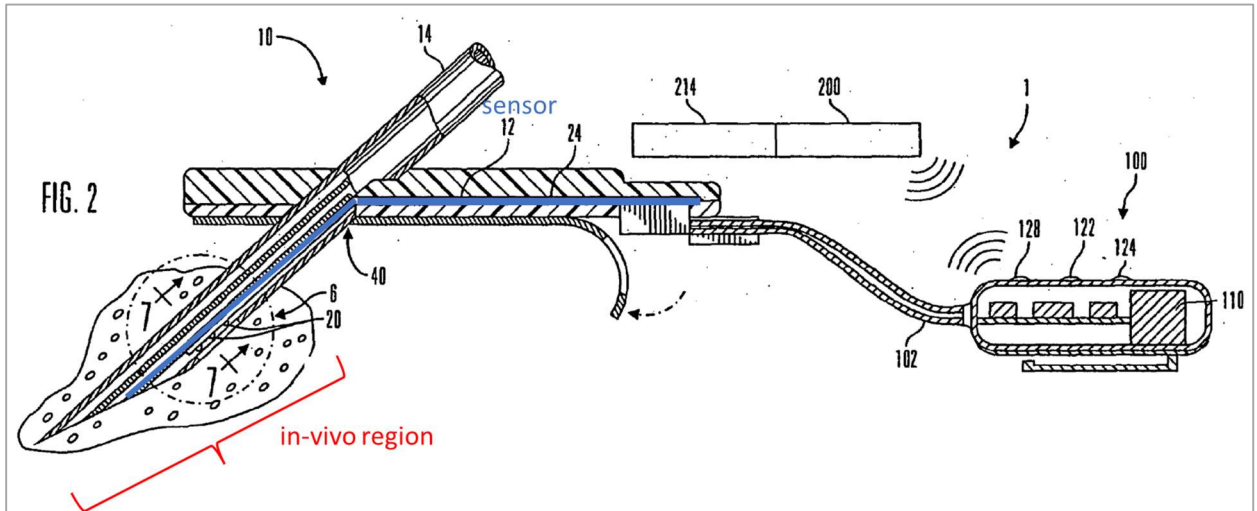
Shin describes a method for monitoring glucose concentration in a host. E.g., Ex-1008, ¶0054; Ex-1002, ¶211.

- b. 23[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;”

Shin teaches beginning a sensor session with a transcutaneous glucose sensor. E.g., Ex-1008, ¶0006 (“[A] method of calibrating glucose monitor data includes obtaining glucose monitor data at predetermined intervals over a period of time.”).

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.*, ¶¶0057. FIG. 2 illustrates both the in-vivo and ex-vivo portions of the sensor. The in-vivo portion of the sensor extends into in-vivo “region 6” shown in FIG. 2, which is reproduced below with annotations in blue (for the sensor) and red (for the in-vivo region):



As shown above, a portion of the sensor 12 remains with the sensor set 10 and thus outside of the user’s body. Ex-1002, ¶¶213-216.

- c. 23[b]. “generating sensor data derived at least in part from the transcutaneous glucose sensor;”

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.” Ex-1008, ¶¶0069.

Ex-1002, ¶¶217-218.

- d. 23[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;”

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. In Shin’s calibration method, the calibration factor (each calculated modified single-point sensitivity ratio (MSPSR) (Ex-1008, ¶0093)) is compared to a pre-determined valid sensitivity range, and the valid sensitivity ranges used over time can be ranges that depend on how long the sensor has been in use (*id.*, ¶0103)—i.e., the ranges are “a drift profile.” As a result of this comparison, the system either accepts or rejects the MSPSR for calibration and the determination of a glucose concentration value. In this way, 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 claim 23[c]. Ex-1002, ¶¶219-222.

Specifically, Shin teaches that each MSPSR is compared to “a valid sensitivity range” to determine if it is reasonable. Ex-1008, ¶0103. Shin provides a

particular valid MSPSR range of 1.5 to 15 that “has been determined based upon valid glucose sensor sensitivity measurements made in-vitro” and further explains that “[o]ther valid sensitivity ranges may be applied depending on ... how long the sensor has been in use.” *Id.* Thus, in embodiments of Shin, 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.” *Id.*

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 claim 23[c]), 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 claim 23[c]. In Shin, different valid sensitivity ranges can be used, each range associated with a length of time of sensor use; thus the ranges relate to expected sensitivity changes over time, during sensor use. Such valid sensitivity ranges that depend on the length of time of sensor use constitute “a drift profile.” *Compare* Ex-1008, ¶0103 to Ex-1001, 213:5-43 (e.g., 213:33-36 (“[T]he a priori sensitivity information includes and/or provides an expected profile (e.g., an expected pattern and/or amount of sensitivity change/drift over time)... In 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

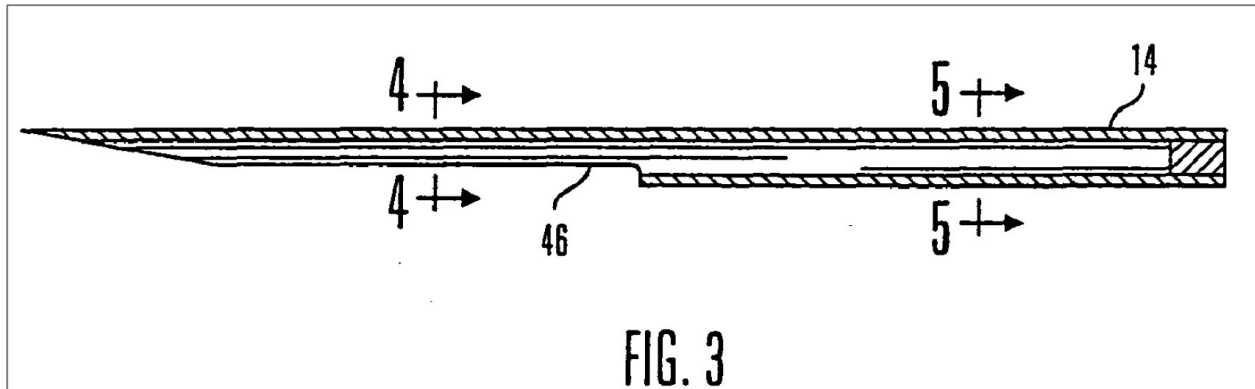
sensitivity.”)), 216:44-61 (e.g., 216:48-56: “[D]uring the first hour of sensor use, the expected profile may be a line having a slope and/or curvature within a first range; while during the second hour of use the expected profile may be a line having a slope and/or curvature within a second range. In some embodiments, the a priori sensitivity information defines a range of acceptable change in sensitivity, such as described with reference to a cone of possible acceptable and/or feasible sensitivity changes.”).

e. 23[d]. “and displaying the glucose concentration value.”

Shin’s method involves displaying the determined glucose concentration values. Shin describes “a display 214 that is used to display the calculated results of the raw glucose sensor data received via a download from the glucose monitor 100” and that can display other information including “graphs of historical data,” among other things. Ex-1008, ¶¶0062. Ex-1002, ¶¶223-224.

2. Claim 24

Shin’s sensor has the claimed planar configuration. Ex-1002, ¶¶225-226. Ex-1008, FIG. 3:



3. Claim 25

Shin's drift profile—the valid sensitivity ranges—accounts for a break-in of the sensor as recited in claim 25, at least because Shin teaches using such ranges during time periods when break-in is occurring; thus the ranges, which reflect expected sensitivity changes over time, necessarily account for, or reasonably would have been understood as accounting for, sensitivity changes resulting from break-in. Ex-1002, ¶¶227-233.

In certain of Shin's embodiments, calibration begins after the glucose sensor is "initialized"/"stabilized." Ex-1008, ¶0066, ¶0068. Initialization is stated to take "an hour or less" *Id.*, ¶0067, ¶0068. Shin also describes embodiments that "omit the initialization/stabilization process" (*id.*, ¶0067) and where calibration begins following sensor insertion.

Thus Shin's method calibrates sensor data, using the drift profile discussed above, as soon as initialization is complete (*id.*, ¶0069) or following sensor insertion and without an initialization period. In both embodiments, Shin's drift

profile (the valid sensitivity ranges, which Shin teaches are predetermined based on how long the sensor has been use) accounts for break-in.¹⁸

In Shin's embodiments where there is an initialization period before sensor data are calibrated, calibration begins when there is still "break-in" as recited claim 25; there is still "break-in" after the initialization period because "break-in" as recited in claim 25 includes more than just electrochemical break-in and can be ongoing during and after a first calibration. *See* note 11, *supra*. Thus, Shin's drift profile (the valid sensitivity ranges), which is used for calibration after Shin's initialization but still when "break-in" as recited in claim 25 is occurring, necessarily accounts for, or reasonably would have been understood as accounting for, the sensitivity changes that are expected during such "break-in."

In Shin's embodiments where there is no initialization period and calibration begins following sensor insertion, Shin's drift profile necessarily accounts for, or reasonably would have been understood as accounting for, the sensitivity changes occurring during the break-in that was known to occur following sensor insertion.

Claim 25 alternatively would have been obvious in view of the POSA's knowledge that glucose sensors undergo break-in and the desire to improve

¹⁸ While both of Shin's embodiments fall within claim 25, either embodiment alone would be sufficient to show that Shin anticipates claim 25.

calibration methods. The POSA using valid sensitivity ranges that are based on expected sensitivity changes over time, as expressly taught in Shin, would have used valid sensitivity ranges that account for break-in, for time periods starting from sensor insertion and for time periods after the first hour of sensor wear (after Shin's initialization period, when break-in is still occurring), to improve sensor calibration. Ex-1002, ¶234.

4. Claim 26

See claim 23[c], §X.B.1.d. Ex-1002, ¶¶235-236.

5. Claim 27

Shin's drift profile—the valid sensitivity ranges disclosed in Shin, ¶0103—accounts for a change in baseline over time. Shin teaches that calculation of the MSPSR accounts for a baseline shift (away from zero) and teaches comparing each calculated MSPSR to a valid sensitivity range to determine if the MSPSR is reasonable. Because each of Shin's valid sensitivity ranges is used to determine whether the MSPSR (which includes a correction for a baseline change) is reasonable or not, each range accounts for baseline as well as sensitivity changes over time. Ex-1002, ¶¶237-241.

Claim 27 also would have been obvious based on Shin, the POSA's knowledge that baseline often shifts over time, and the POSA's desire to improve calibration and detect aberrant changes in sensitivity and baseline (*see* §X.A.5). The POSA would have found it obvious to compare a calculated or experimental

baseline to a valid baseline range, in addition to comparing each calculated sensitivity ratio (Shin's MSPSR) to a valid sensitivity range as expressly disclosed in Shin. The valid baseline ranges, like Shin's expressly disclosed valid sensitivity ranges, would be determined in advance, from the same sensor testing conducted to determine the valid sensitivity ranges. *See* Ex-1008, ¶0103. Such a modification of Shin's method would require an algorithm modification but no additional testing, and thus the POSA would have reasonably expected success in making this modification. Ex-1002, ¶242.

6. Claim 28

See claims 26 and 27, §X.B.4, §X.B.5. Ex-1002, ¶¶243-244.

7. Claim 29

Shin's valid sensitivity ranges (or drift profile) account for a shift over an elapsed time measured from the beginning of the sensor session. Shin explains that each MSPSR is compared to a valid sensitivity range during calibration. Ex-1008, ¶0103. Shin teaches embodiments where calibration begins after "initialization"/"stabilization" (*id.*, ¶¶0066-68) and also teaches embodiments that "omit the initialization/stabilization process" (*id.*, ¶0067). In the latter embodiments, calibration begins immediately following sensor insertion; the beginning of calibration and the determination of glucose concentration values thus corresponds to the time of sensor insertion, i.e., the beginning of the sensor session. In these embodiments, the drift profile accounts for shifts in sensitivity

from this time. Ex-1002, ¶¶245-246.

8. Claim 30

The expected sensitivity changes reflected in Shin's valid sensitivity ranges are associated at least in part with a change in a physical property of the sensor's in-vivo environment. As discussed above, the valid sensitivity ranges are based on how long the sensor has been in use. Shin's valid sensitivity ranges that are based on the length of time the sensor has been in use necessarily account for sensitivity changes associated at least in part with a change in the environment over time. Indeed, Shin recognizes that physical properties of the environment affect sensor sensitivity. Ex-1008, ¶¶0117, ¶¶0141. Ex-1002, ¶¶247-248.

In addition, the POSA understood that the in-vivo environment surrounding the sensor changes over time, and that such environmental changes affect sensor sensitivity over time. Thus the POSA would have found it obvious that Shin's valid sensitivity ranges that depend on the length of time of sensor use are associated with such environmental changes. Ex-1002, ¶249.

9. Claim 31

Claim 31 enumerates causes for the changes in the environment surrounding the in-vivo portion of the sensor. At least some of these causes (e.g., wound healing, inflammation) were known to inevitably occur following insertion of the sensor into the host. Accordingly, the shift over time that is associated at least in

part with a change in a physical property of the environment surrounding the in-vivo portion of the sensor (*see* claim 30) necessarily is a shift associated with at least one of trauma, wound healing, etc., as recited in claim 31. Ex-1002, ¶¶250-252.

10. Claim 32

As discussed below for claim 35[b], Shin discloses and/or renders obvious a membrane, and the shift over time taught in Shin and discussed above would have been understood as being associated in part with “a physical property correspond[ing] to a membrane of the in vivo portion” of the sensor, as recited in claim 32. Shin’s drift profile (Shin’s valid sensitivity ranges determined from expected sensitivity changes over time) necessarily is associated with the causes of sensitivity changes that contributed to those expected sensitivity changes, including causes that are associated with the membrane. At a minimum, claim 32 would have been obvious. Ex-1002, ¶¶253-254.

11. Claim 33

As discussed above for claim 29, Shin discloses embodiments where calibration begins following sensor insertion. In such embodiments, the shift in sensitivity over time (reflected in Shin’s valid sensitivity ranges) corresponds to an elapsed time measured from sensor insertion, as discussed in §X.B.7. Ex-1002, ¶¶255-256.

12. Claim 34

Shin's valid sensitivity ranges differ based on the length of time the sensor has been in use (inserted into the host), and as discussed above, constitute "a drift profile" as recited in claim 23. Each sensitivity range comprises a range of sensitivities (i.e., a range of slopes¹⁹). For sensitivity ranges that differ over time as taught in Shin (Ex-1008, ¶0103), the sensitivities (slopes) within one range, for one time period, will comprise sensitivities that differ from the sensitivities (slopes) in one or more subsequent ranges (for subsequent time periods). Accordingly, the valid sensitivity ranges that differ over time (the drift profile) comprise a first sensitivity (slope) associated with a first time, and a second sensitivity (slope) associated with a second time, where the slopes and times differ from each other.

It also would have been obvious for Shin's valid sensitivity ranges that are based on the length of time of sensor use to include ranges with different slopes, for different time periods, in view of the well-documented observation that sensor sensitivity drifts over time. Ex-1002, ¶¶257-259.

¹⁹ In Shin, the calibration factor is calculated using linear regression. Ex-1008, ¶¶0087-88, ¶¶0093-102. When solving for the calibration factor using linear regression as in Shin, the sensitivity corresponds to the slope of the line. Ex-1002, ¶¶39-41. Thus, a range of sensitivities corresponds to a range of slopes.

13. Claim 35

a. 35[Pre]. “A sensor system comprising:”

Shin describes a glucose monitor system comprising a sensor to detect glucose concentration. Ex-1008, ¶¶0002, ¶¶0031-32, ¶¶0054, FIGS. 1-2; Ex-1002, ¶260

b. 35[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,”

See claim 23[a], §X.B.1.b. Ex-1002, ¶¶261-262.

c. 35[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;”

The in-vivo portion of Shin’s sensor comprises an electrode. As discussed above with reference to FIG. 2, the “electrodes 20 of the glucose sensor 12 terminat[e] in the user’s subcutaneous tissue.” Ex-1008, ¶¶0057.

Shin’s glucose sensor also comprises “an enzyme coating.” *Id.*, ¶¶0064-65. 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—i.e., the POSA would have understood such “enzyme coating” to be a membrane comprising the enzyme.

Shin also incorporates by reference documents disclosing a membrane

comprising an enzyme that is disposed over an in-vivo portion of the electrode. Shin in ¶0057 incorporates by reference Application No. 29/101,218, entitled “Glucose Sensor,” which describes a glucose sensor where “the tips of one or more of the electrodes are covered with an enzyme.” Ex-1009, 3. The application continues to explain that “the glucose sensor may be covered with one or more membranes. Alternative variations may use different combinations or types of metals, enzymes, substrates and/or more or less membranes.” *Id.*, FIG 1. Ex-1002, ¶¶263-266.

A membrane as recited in claim 35[b] also would have been obvious, at least based on the knowledge that using a membrane was the preferred technique for immobilizing glucose oxidase in CGMs, including commercial CGMs. Ex-1002, ¶267. *See* §X.A.13.c.

- d. 35[c]. “wherein the transcutaneous glucose sensor generates a signal associated with a glucose concentration within the body of the host;”

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.” Ex-1008, ¶0069. Ex-1002, ¶¶268-269.

- e. 35[d]. “electronics configured to receive the signal from the transcutaneous glucose sensor,”

Shin’s system comprises electronics configured to receive signals from the

sensor. Ex-1008, ¶0015 (“The glucose sensor is electronically coupled to the glucose monitor to supply the glucose monitor data.”), ¶0058 (“The glucose monitor 100 generally includes the capability to record and store data as it is received from the glucose sensor 12 ...”), ¶¶0059-62, FIGS. 1-2. Ex-1002, ¶¶270-271.

- f. 35[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,”

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. Ex-1002, ¶¶272-279.

Shin explains: 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.” Ex-1008, ¶0015; *id.*, ¶0058 (“The glucose monitor 100 generally includes the capability to record and store data as it is received from the glucose sensor 12 ...”). Thus the glucose monitor comprises a memory. Shin

further teaches embodiments where the glucose monitor stores “the necessary software to calibrate glucose sensor signals.” *Id.*, ¶0061.²⁰

Shin’s memory stores information associated with an expected change over time in sensor sensitivity. Ex-1008, ¶¶0087-104. Shin teaches 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.” *Id.*, ¶0103. Accordingly, different valid sensitivity ranges can be used, each range associated with a length of time of sensor use.

The different valid sensitivity ranges that depend on the length of time of sensor use are based on expected sensitivity changes associated with sensor use. Thus 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 claim 35[e]. *Compare* Ex-

²⁰ Shin’s “electronics” also includes Shin’s data processor, which, in certain embodiments, includes the software for calibrating sensor data and thus includes the “memory” as recited in claim 35[e]. Ex-1008, ¶¶0059-60. Whether the “memory” storing the “information” as recited in claim 35[e] is in Shin’s glucose monitor or is in Shin’s data processor, Shin’s “electronics” meets the limitations of claim 35.

1008, ¶0103 to Ex-1001, 213:5-43, 213:33-36 (“In 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.”)), 216:44-61.

In addition, 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. Indeed, Shin teaches that the example valid sensitivity range of 1.5 to 15 was determined in-vitro and thus prior to sensor insertion (Ex-1008, ¶0103), and so that range must be stored in system memory for the system to compare the MSPSR to it. 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.

- g. 35[ff]. “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.”

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. Ex-1002, ¶¶280-283.

Shin explains that the glucose monitor (or the data processor) can contain the software to calibrate sensor signals and display a glucose concentration value. Ex-1008, ¶¶0060-61. Thus, Shin’s electronics (which include the glucose monitor

and the data processor) are configured to determine a glucose concentration value.

In addition, the 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. When 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 embodiments²¹) 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. “[T]he MSPSR is compared to a valid sensitivity range to determine if the newly calculated MSPSR is reasonable.” *Id.*, ¶0103. If the MSPSR on a particular day is outside of the valid sensitivity range for that day, then a calibration error alarm can notify the user of a potential problem. *Id.* In this way—by comparing each MSPSR to a valid sensitivity range that depends on how long the sensor has been in use, to determine whether or not to accept that MSPSR and calibrate sensor data and generate a glucose concentration value—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.

²¹ Ex-1008, ¶0085; *id.*, ¶0082 (explaining that a calibration factor is used to convert signal in nano-amps into “a blood glucose level (mg/dl or mmol/l)”).

14. Claim 36

See claims 30, 35[e], §X.B.8, §X.B.13.f. Ex-1002, ¶¶284-285.

15. Claim 37

See claim 31, §X.B.9. Ex-1002, ¶¶286-287.

16. Claim 38

As discussed above for claims 30-31, it was known that the host's body reacts to sensor implantation, and that such reactions affect sensor sensitivity. Because Shin's valid sensitivity ranges are predetermined, they are associated with the expected changes in sensor sensitivity that inevitably accompany sensor implantation. Ex-1002, ¶¶288-289.

17. Claim 39

See claims 29, 33, §X.B.7, §X.B.11. Ex-1002, ¶¶290-291.

18. Claim 40

See claims 29, 33, §X.B.7, §X.B.11. Ex-1002, ¶¶292-293.

19. Claim 41

See claim 32, §X.B.10. Ex-1002, ¶¶294-295.

20. Claim 42

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

Shin describes a method for monitoring glucose concentration in a host. Ex-1008, ¶0054.

- b. 42[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;”

See claim 23[a], §X.B.1.b.

- c. 42[b]. “wherein the transcutaneous glucose sensor is configured to generate a signal;”

See claims 23[b], 35[c], §X.B.1.c, §X.B.13.d.

- d. 42[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;”

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 claim 42[c]). 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. Ex-1008, ¶0103. As a result of this comparison, the system either accepts or rejects the MSPSR, and if the MSPSR is accepted sensor calibration proceeds. In this way, 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 42[c]. *See* claims 23[c], 35[f],

§X.B.1.d, §X.B.13.g.

- e. 42[d]. “generating a glucose concentration value based at least in part on the calibrating; and”

See claims 23[c], 35[f], §X.A.1.d, §X.A.13.g.

- f. 42[e]. “displaying the glucose concentration value.”

See claim 23[d], §X.B.1.e. Ex-1002, ¶¶296-307.

21. Claim 43

See claim 29, §X.B.7. Ex-1002, ¶¶308-309.

22. Claim 44

See claim 30, §X.B.8. Ex-1002, ¶¶310-311.

23. Claim 45

See claim 31, §X.B.9. Ex-1002, ¶¶312-313.

24. Claim 46

See claim 32, §X.B.10. Ex-1002, ¶¶314-315.

XI. OBJECTIVE INDICIA

Petitioner is not aware of any evidence of objective indicia that would rebut a finding of obviousness.

XII. THE BOARD SHOULD NOT USE ITS DISCRETION TO DENY INSTITUTION

A. 35 U.S.C. §314(a)

The Board should not exercise its discretion to deny institution under 35

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U.S.C. §314(a). No other petitions have previously been filed against the '031 patent and thus the *General Plastic* factors for serial petitions do not weigh against institution. The *Fintiv* factors under *Apple Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper 11 (March 20, 2020) (precedential) also would not justify denying institution. The district court litigation is still at an early stage, and trial on issues including the validity of the '031 patent is not scheduled to occur until July 2026, many months after this Board's likely 2025 due date for a final written decision if this IPR is instituted. Ex-1031 (Scheduling Order). In addition, the district court's claim construction process is just underway as of the filing of this petition. By the time of institution, fact discovery may still be ongoing, but expert discovery and pre-trial motions will not have begun. Discretionary denial is further inappropriate here because this petition presents compelling evidence of unpatentability. Accordingly, the *Fintiv* factors should not be applied to deny institution of this proceeding.

B. 35 U.S.C. §325(d)

The Board should likewise not deny institution under §325(d) because the two-part *Advanced Bionics* framework is not satisfied for both grounds. *See Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper No. 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential). In applying this framework, the Board considers the "*Becton, Dickinson*" factors. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (P.T.A.B.

Dec. 15, 2017) (precedential as to §III.C.5, first paragraph).

Ground 1 is based on Zhang, which was not previously presented to the Office, and thus the first *Advanced Bionics* prong is not satisfied for this ground. For Ground 2, Shin was cited in an IDS with over 3,230 other documents. Even though the first *Advanced Bionics* prong is satisfied for Ground 2,²² the second prong is not. The merits of this petition reflect the Examiner’s errors in a manner material to the patentability of the challenged claims. In particular, under *Becton, Dickinson* factor (c), the examiner signed an IDS citing Shin, the Examiner did not rely on Shin to reject any claims and thus did not meaningfully address Shin. Furthermore, under *Becton, Dickinson* factor (f), the Examiner erred by overlooking or not appreciating Shin’s materiality to the challenged claims, as described above. *See STMicroelecs., Inc. v. Trustees of Purdue Univ.*, IPR2022-00309, Paper 14 at 12–13 (P.T.A.B. July 6, 2022) (finding that petitioner

²² The Office has proposed changing this aspect of the §325(d) analysis. *See Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement*, 89 Fed. Reg. 28,693, 28,705 (Apr. 19, 2024) (“An initialed Information Disclosure Statement, without more, does not satisfy [the proposed §325(d) discretionary denial] standard.”).

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demonstrated examiner erred by not appreciating that IDS reference disclosed features recited in the challenged claims). Discretionary denial under §325(d) is not warranted here.

XIII. CONCLUSION

Petitioner respectfully requests that *inter partes* review of the '031 patent be instituted and that the challenged claims be cancelled as unpatentable pursuant to 35 U.S.C. §318(b).

Date: May 10, 2024

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CERTIFICATION UNDER 37 C.F.R. § 42.24(D)

I certify that the foregoing complies with the type-volume limitation of 37 C.F.R. § 42.24 and contains 13,994 words based on the word count indicated by the word-processing system used to prepare the paper, and excluding those portions exempted by § 42.24(a).

Date: May 10, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6 and 42.105, I hereby certify that on May 10, 2024, I caused a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 11,020,031, supporting exhibits, and Power of Attorney to be served via Priority Mail Express on the Patent Owner at the following correspondence address of record as listed on the USPTO Patent Center:

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