

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. IPR2024-00841
Patent No. 10,709,364

PETITION FOR *INTER PARTES* REVIEW

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PETITIONER’S EXHIBIT LIST

Exhibit No.	Description of Exhibit
1001	U.S. Patent No. 10,709,364 (“’364 patent”)
1002	Declaration of Dr. Anthony Edward George Cass
1003	Prosecution File History of U.S. Patent No. 10,709,364
1004	Gross et al., <i>Device and Method of Calibrating and Testing a Sensor for In Vivo Measurement of an Analyte</i> , U.S. Patent No. 6,275,717 (issued Aug. 14, 2001) (“ Gross ”)
1005	Feldman et al., <i>A Method of Calibrating an Analyte-Measurement Device, and Associated Methods, Devices and Systems</i> , U.S. Patent Appln. Pub. No. 2005/0239154 (Oct. 27, 2005) (“ Feldman ”)
1006	Feldman et al., <i>A Continuous Glucose Sensor Based on Wire Enzyme™ Technology—Results from a 3-Day Trial in Patients with Type 1 Diabetes</i> , <i>Diabetes Technology & Therapeutics</i> , Vol. 5, No. 5, pp. 769-779 (2003) (“ Feldman-2003 ”)
1007	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> , <i>Medical Progress through Technology</i> , Vol. 21, No. 2., pp. 91-103 (May 1995) (“ Nishida ”)
1008	Velho et al., <i>Strategies for calibrating a subcutaneous glucose sensor</i> , <i>Biomed. Biochim. Acta</i> , Vol. 48, No. 11/12, pp. 957-964 (1989) (“ Velho ”)
1009	Ward et al., <i>A new amperometric glucose microsensor: in vitro and short-term in vivo evaluation</i> , <i>Biosensors & Bioelectronics</i> , Vol. 17, pp. 181-189 (2002) (“ Ward ”)
1010	Mastrototaro et al., <i>Glucose Monitor Calibration Methods</i> , U.S. Patent No. 6,424,847 (issued July 23, 2002) (“ Mastrototaro ”)
1011	Say et al., <i>Analyte Monitoring Device and Methods of Use</i> , U.S. Patent No. 6,175,572 (issued Jan. 16, 2001) (“ Say ”)

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Exhibit No.	Description of Exhibit
1012	Heller <i>et al.</i> <i>Implanted Electrochemical Glucose Sensors for the Management of Diabetes</i> , Annu. Rev. Biomed. Eng., Vol. 1, pp. 153-175 (1999) (“ Heller ”)
1013	<i>Biosensors in the Body: Continuous in vivo Monitoring</i> , Ch. 1: An Introduction to in vivo Biosensing: Progress and Problems (David M. Fraser) (pp.1-56), Ch. 2: Electrochemical Sensors for in vivo Glucose Sensing (Milena Koudelka-Hep) (pp. 57-77) (ed. David M. Fraser, John Wiley & Sons Ltd. 1997) (“ Fraser ”)
1014	Scheduling Order, <i>Abbott Diabetes Care Inc. et al. v. DexCom, Inc.</i> , No. 1:23-cv-00239 (D. Del. Sept. 19, 2023)
1015	Declaration of Sylvia D. Hall-Ellis, Ph.D.

I. INTRODUCTION

Petitioner requests review of claims 1-3, 5, 6, and 8-10 (the “challenged claims”) of U.S. Patent No. 10,709,364 (the “’364 patent”), which is assigned to DexCom, Inc. (“DexCom” or “Patent Owner”). The challenged claims relate to glucose monitors with electrochemical sensors that measure a subject’s glucose level in real time. Such monitors, called continuous glucose monitors (“CGMs”), were known, and the challenged claims mostly recite standard CGM components like “sensor electronics” and operational steps like “receiving” sensor data. The purportedly inventive elements of the claims relate to calibration of the CGM’s output based on the sensor’s sensitivity. The sensitivity is different when measured in the laboratory (in vitro) and in the subject (in vivo), and the challenged claims recite that the sensor’s calibration is based on information that can correct for that difference. But all of that also was already disclosed in the prior art, in the Gross patent (“Gross”).

Indeed, *all* sensors are characterized by an in-vitro sensitivity and an in-vivo sensitivity, and these sensitivities frequently differ from each other, as Gross discloses. A sensor’s sensitivity in a given environment is an inherent feature of the sensor, and it was common to test sensor sensitivity in different environments (particularly in vitro and in vivo) as part of the routine testing conducted to characterize a sensor. Gross also discloses sensors in which the in-vitro sensitivity

is predictive of in-vivo sensitivity, and a calibration method that corrects for differences between those sensitivities once the sensor is inserted into a subject.

In short, and for the reasons detailed below, none of the challenged claims is patentable over Gross.

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 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).

DexCom asserted the '364 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 '364 patent are not infringed.

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Patents in the same family as the '364 patent have been challenged in the following *inter partes review* proceedings, and decisions from certain of those proceedings are currently under appeal, as indicated below:

Patent No.	IPR Proceeding No.	CAFC Appeal No(s).
11,000,213	IPR2022-00913	24-1449, 24-1506
11,000,213	IPR2022-00914	24-1450, 24-1507
10,993,642	IPR2022-00921	24-1326
10,993,642	IPR2022-00922	24-1327

DexCom has also asserted U.S. Patent Nos. 11,000,213 and 10,993,642 against Petitioner in the district court, in Case Nos. 1:22-00605 (consolidated) (D. Del.), 1:21-cv-01699 (D. Del.).

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

Petitioner designates the following counsel:

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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) for this Petition to Deposit Account No. 60-3160. Review of eight claims is requested. The undersigned further authorizes payment for any additional fees that may be due in connection with this petition.

III. CLAIM LISTING

A. Claim 1

1[Pre]	A glucose monitoring system comprising:
1[a]	a transcutaneous electrochemical glucose sensor comprising an in vivo portion and an ex vivo portion,
1[b]	wherein the transcutaneous electrochemical sensor is characterized by an in vivo sensitivity and an in vitro sensitivity, wherein the in vivo sensitivity is different from the in vitro sensitivity,
1[c]	and wherein the in vitro sensitivity is predictive of the in vivo sensitivity due to a relationship therebetween;
1[d]	sensor electronics configured to be operably connected to the transcutaneous electrochemical glucose sensor;
1[e]	a processor configured to be operably connected to the sensor electronics;
1[f]	a memory configured to be operably connected to the processor,
1[g]	wherein the memory has stored therein information associated with the in vivo sensitivity of the transcutaneous electrochemical glucose sensor, wherein the information associated with the in vivo sensitivity is based at least in part on corrections for the difference between the in vivo sensitivity and the in vitro sensitivity of the transcutaneous electrochemical glucose sensor.

B. Claim 2

2	The glucose monitoring system of claim 1, wherein the relationship between the in vivo sensitivity and the in vitro sensitivity is established empirically by performing a clinical study and comparing in vivo sensitivities with in vitro sensitivities of a plurality of transcutaneous glucose sensors.
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C. Claim 3

3	The glucose monitoring system of claim 1, wherein the in vivo sensitivity is greater than the in vitro sensitivity.
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D. Claim 5

5[Pre]	A method for calibrating data from a transcutaneous electrochemical glucose sensor, the method comprising:
5[a]	receiving sensor data from the transcutaneous electrochemical glucose sensor after at least a portion of the transcutaneous electrochemical glucose sensor is inserted in a host, wherein the sensor data is indicative of a glucose concentration in the host;
5[b]	and calibrating, using a processor, the sensor data received from the transcutaneous electrochemical glucose sensor,
5[c]	wherein the calibrating is based at least in part on information associated with an in vivo sensitivity of the transcutaneous electrochemical glucose sensor, wherein the information associated with the in vivo sensitivity is based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity for the transcutaneous electrochemical glucose sensor.

E. Claim 6

6	The method for calibrating data from a transcutaneous electrochemical glucose sensor of claim 5, wherein the calibrating requires no user calibrations after the at least a portion of the transcutaneous electrochemical glucose sensor is inserted in the host.
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F. Claim 8

8	The method for calibrating data from a transcutaneous electrochemical glucose sensor of claim 5, wherein the in vitro sensitivity for the transcutaneous electrochemical glucose sensor is based at least in part on sampling a plurality of transcutaneous electrochemical glucose sensors prior to inserting the at least a portion of the transcutaneous electrochemical glucose sensor in the host.
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G. Claim 9

9	The method for calibrating data from a transcutaneous electrochemical glucose sensor of claim 8, wherein the in vitro sensitivity is calculated
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	at least in part by examining a signal response of each of the plurality of transcutaneous electrochemical glucose sensors to a set of known glucose concentrations.
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H. Claim 10

10[Pre]	A method for providing calibrated glucose information based on sensor data from a transcutaneous electrochemical glucose sensor, the method comprising:
10[a]	receiving, by a processor, post-implantation sensor data from the transcutaneous electrochemical glucose sensor, wherein the sensor data is indicative of a glucose concentration in a host;
10[b]	receiving, by the processor, information associated with an in vivo sensitivity of the transcutaneous electrochemical glucose sensor, wherein the information associated with the in vivo sensitivity is based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity for the transcutaneous electrochemical glucose sensor;
10[c]	generating calibrated sensor data, using the processor, by using the information associated with the in vivo sensitivity of the transcutaneous electrochemical glucose sensor to calibrate the sensor data received from the transcutaneous electrochemical glucose sensor;
10[d]	and providing the calibrated sensor data to a user to facilitate monitoring a glucose level of the host.

IV. REQUIREMENTS UNDER 37 C.F.R. 42.104

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the '364 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging the '364 patent on the grounds identified here.

B. Identification of Challenge and Statement of Precise Relief Requested

Petitioner challenges claims 1-3, 5, 6, and 8-10 of the '364 patent and requests that these claims be found unpatentable in view of U.S. Patent No. 6,275,717 ("Gross") (Ex-1004), under pre-AIA §102(b) and/or pre-AIA §103(a):

Ground	Challenged Claims	Basis for Challenge
1	1-3, 5, 6, and 8-10	Anticipated by and/or obvious over Gross (pre-AIA §102(b), pre-AIA §103(a))

This petition is accompanied by the declaration of Dr. Anthony Edward George Cass (Ex-1002).

V. TECHNOLOGY BACKGROUND

CGMs monitor a user's glucose concentration, often for diabetes management. One type of CGM uses a transcutaneous electrochemical 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 (or calibration) function. *See* Ex-1002, ¶¶25-29.

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, as part of sensor calibration, sensor output

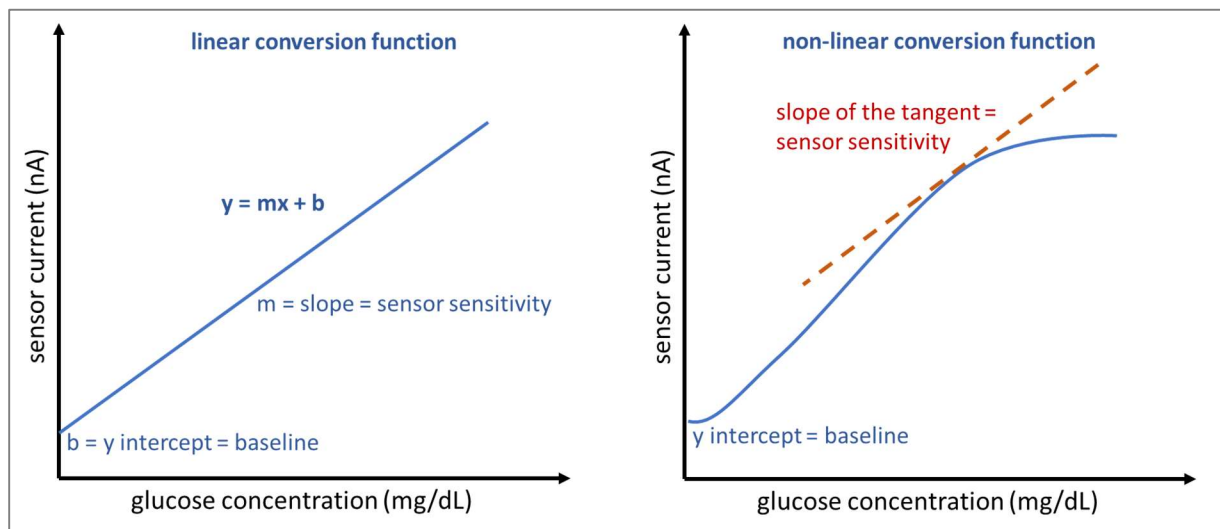
(in counts or units of current) is matched with a reference or known glucose concentration (in units such as mg/dL); matched pairs of data points are plotted—for example, with sensor output in counts or units of current as the y-axis value, and a reference glucose concentration as the x-axis value—and a function describing the relationship of the plotted data points is empirically determined. The empirically-determined conversion function may be a linear or a non-linear function. 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. *See* Ex-1002, ¶¶30-32.

The conversion function typically defines calibration parameters, such as sensor sensitivity and baseline. Sensor sensitivity is the amount of sensor current generated per unit of glucose concentration 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 (in other words, it is the background current produced by the sensor). Ex-1002, ¶33.

When the relationship between glucose concentration x and sensor output y is a linear relationship, the conversion function may be expressed by the equation $y = mx + b$, where the slope m is the sensor sensitivity and the y-intercept b is the

sensor baseline. When the relationship between glucose concentration and sensor output is a non-linear relationship, such as, for example, an exponential or logarithmic relationship, 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. Ex-1002, ¶¶34-35.

Shown below are two hypothetical plots, where the first plot depicts a linear relationship and the second plot depicts a non-linear relationship between sensor output and glucose concentration. In the first plot, the slope of the line, m , is sensor sensitivity. In the second plot, the slope of the tangent at a given glucose concentration is sensor sensitivity:



Accordingly, regardless of whether the empirically-derived conversion function is linear or non-linear, the function (and its corresponding calibration line or curve) is information associated with the sensitivity of the sensor. Ex-1002, ¶¶36-37.

The conversion function, and therefore sensor sensitivity, can be determined in different environments and under different conditions. In-vivo sensitivity generally refers to a sensor's sensitivity in the in-vivo environment, when the sensor has been inserted into a host. In-vitro sensitivity generally refers to a sensor's sensitivity in a laboratory or manufacturing environment; in-vitro sensitivity can be determined, for example, by measuring sensor output when sensors are placed in a series of beakers, each beaker containing a solution having a known glucose concentration.¹ Ex-1002, ¶¶38-40.

VI. THE '364 PATENT

A. Patent Specification²

The '364 patent relates to “systems and methods for analyte sensor data processing” and particularly “to calibration of sensors.” Ex-1001, 1:29-31. The patent focuses on embodiments for calibrating “long term sensor data using sensor data from another sensor,” such as a “short term” sensor. *Id.*, 2:4-16; *see generally*

¹ The '364 patent sometimes refers to the in-vitro environment as the “benchtop” environment. E.g., Ex-1001, 17:37-40, 18:5-9, 74:65-75:3.

² The description of the '364 patent is provided for background and is not an admission that the '364 patent adequately describes or enables any challenged claim.

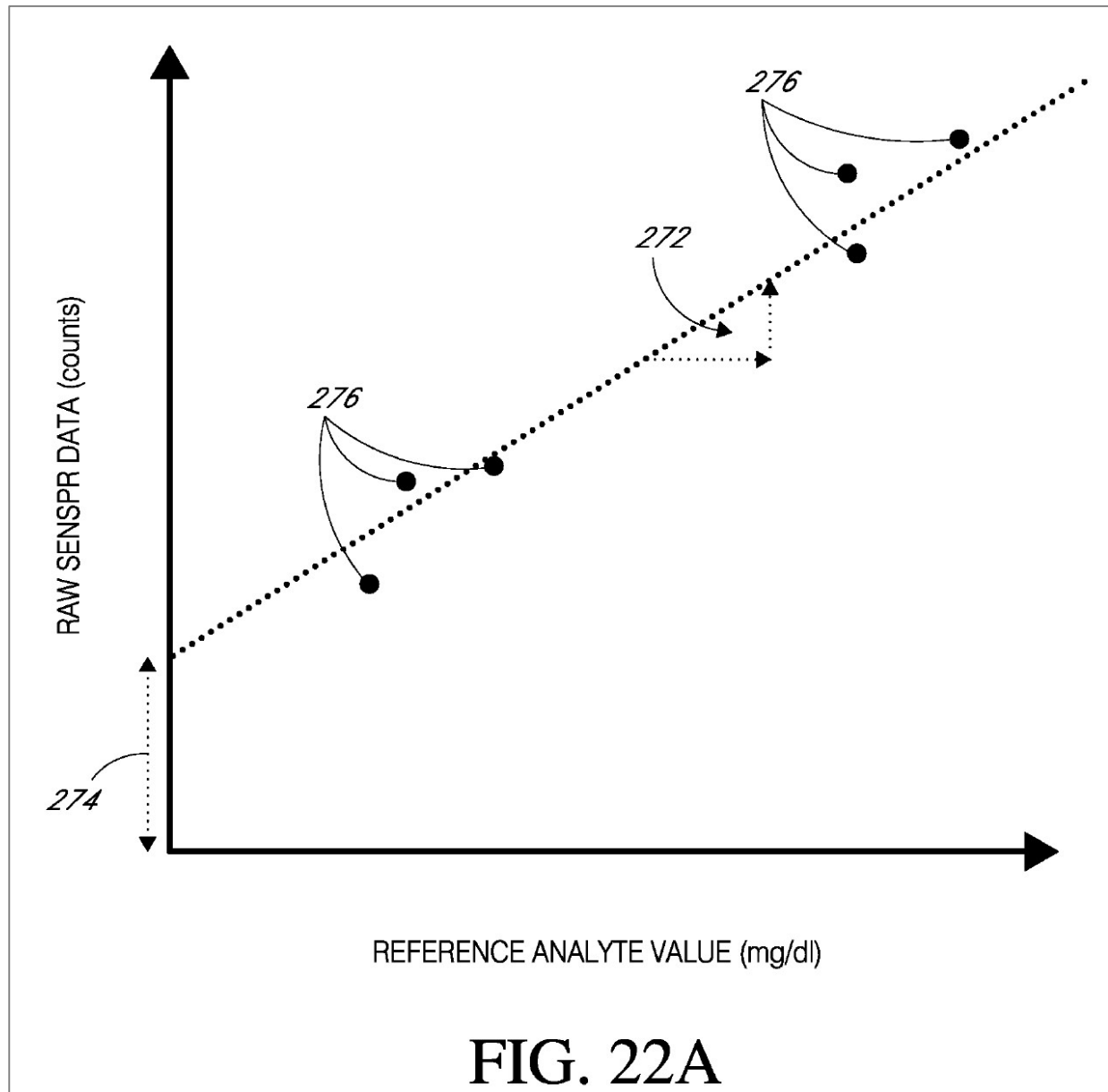
1:66-4:45 (Summary of Invention). Such embodiments for performing sensor calibration described in the patent require reference data, obtained via measurements taken by a short-term sensor implanted in the host, to calibrate a long-term sensor (also implanted in the host). E.g., *id.*, 2:13–4:45.

The patent also describes well-known techniques for calibrating sensor data, such as by using “matched data pairs.” The patent explains that “matched data pairs” refers to “reference data (e.g., one or more reference analyte data points) matched with substantially time corresponding sensor data (e.g., one or more sensor data points).” *Id.*, 12:18-24; *see also* Abstract (“The sensor can be calibrated using a calibration set of one or more matched sensor and reference analyte data pairs.”). The patent describes embodiments of using matched data pairs to derive a conversion function (which in the ’364 patent embodiments is a linear equation, $y=mx+b$), for converting sensor signal data into glucose concentration values. *Id.*, 78:24-25, 79:49. FIG. 22A illustrates an embodiment of using matched data pairs to derive a conversion function. As explained in the ’364 patent:

FIG. 22A is a graph that illustrates a regression performed on a calibration set to create a conversion function in one exemplary embodiment. In this embodiment, a linear least squares regression is performed on the initial calibration set. The x-axis represents reference analyte data; the y-axis represents sensor data. The graph pictorially illustrates regression of the matched pairs 276 in the calibration set. Regression calculates a slope 272

and an offset 274 ($y=mx+b$), which defines the conversion function.

Ex-1001, 78:17-25. FIG. 22A is reproduced below:



The “reference analyte” values can be blood glucose values. *Id.*, 80:37-40 (describing the graph in FIG. 22B, for which the x-axis label is “Reference Glucose Data (mg/dL),” and explaining that the “x-axis represents reference

glucose data (blood glucose) from a reference glucose source in mg/dL”).

The ’364 patent also describes an embodiment of a conversion function, which in the case of the ’364 patent is a linear equation:

As discussed herein, calibration of an enzyme-electrode based glucose sensor consists of solving the line

$$y=mx+b$$

for m and b, where y denotes the sensor signal (in units of A/D counts), x the estimated glucose concentration (mg/dl), m the sensor sensitivity to glucose (counts/mg/dl), and b the baseline signal unrelated to glucose (counts).

Ex-1001, 89:40-47; *see also id.*, 17:51-58; Ex-1002, ¶¶41-44.

B. Asserted Priority Date

The ’364 patent claims priority to a provisional application filed on March 10, 2005. Ex-1003, 219. Petitioner has applied the asserted 2005 priority date solely for the purpose of this petition and does not concede that any challenged claim is entitled to the 2005 priority date.

C. The Challenged Claims

The challenged claims (claims 1-3, 5, 6, and 8-10) relate to glucose monitoring systems and to methods for calibrating glucose sensor data, where the systems store and the methods use information that is “based at least in part on corrections” for a difference between the sensor’s in-vitro sensitivity and in-vivo sensitivity. Claims 1, 5, and 10 are independent claims.

Claim 1 is a system claim that recites the following limitations:

- a sensor that “is characterized by an in vivo sensitivity and an in vitro sensitivity, where the in vivo sensitivity is different from the in vitro sensitivity, and wherein the in vitro sensitivity is predictive of the in vivo sensitivity due to a relationship therebetween;” and
- “a memory” that “has stored therein information associated with the in vivo sensitivity” of the sensor, where such information “is based at least in part on corrections for the difference between the in vivo sensitivity and the in vitro sensitivity” of the sensor.

Notably, claim 1 does ***not*** require any prior knowledge or prior information (information obtained prior to sensor insertion) regarding the relationship between in-vitro sensitivity and in-vivo sensitivity, or regarding how the sensitivities differ from each other. And claim 1 does ***not*** require that the stored information be obtained prior to sensor insertion.

Independent claims 5 and 10 are method claims. These claims require calibrating sensor data (claim 5) or generating calibrated sensor data (claim 10), using “information associated with an in vivo sensitivity” of the sensor, wherein such information “is based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity” for the sensor. ***Claims 5 and 10 do not recite the “predictive” relationship limitation of claim 1.*** Regarding the

“corrections for a difference” limitation, claims 5 and 10, like claim 1, do not require any prior information regarding a difference in sensitivities. Thus none of the independent claims requires any prior information or prior knowledge regarding sensor sensitivity. In particular, the independent claims do not require that any information about sensitivity differences, or about the in-vitro/in-vivo sensitivity relationship, be known or obtained prior to sensor insertion.³

The remaining challenged claims are dependent claims. Dependent claim 2 requires that the relationship between the in-vivo sensitivity and in-vitro sensitivity referenced in claim 1 be “established empirically by performing a clinical study.” Dependent claim 3 requires that the in-vivo sensitivity is greater than the in-vitro sensitivity. Dependent claim 6 requires “no user calibrations after” sensor insertion into the host. And dependent claims 8 and 9 relate to the in-vitro sensitivity of the sensor. *See* Ex-1002, ¶¶46-52.

D. Prosecution History

The ’364 patent was filed as the seventh application in a chain of

³ This aspect of the independent claims—the absence of any requirement for prior information on sensor sensitivity—stands in contrast to claims at issue in IPR2022-00913, IPR2022-00914, IPR2002-00921, and IPR2022-00922, which concerned patents in the same family as the ’364 patent. *See* section II.B, *supra*.

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continuation applications and claims priority to a provisional application filed on March 10, 2005. Ex-1003, 219. DexCom filed the '364 patent with twenty claims on November 21, 2019, along with a "Track One" request for prioritized examination. *Id.*, 1, 69-71. On December 16, 2019, and shortly after its request was granted, DexCom filed an IDS that listed over 3,900 documents and spanned 273 pages. *Id.*, 225-501. On January 2, 2020, DexCom canceled claims 1-20 and added claims 21 and 22, which are shown below:

AMENDMENTS TO THE CLAIMS

- 1-20. (Canceled)
- 21. (New) A glucose monitoring system comprising:
 - a transcutaneous glucose sensor having an in vivo portion and an ex vivo portion.
- 22. (New) A method for calibrating data from a transcutaneous glucose sensor, the method comprising:
 - receiving sensor data from the transcutaneous glucose sensor after the transcutaneous glucose sensor is implanted in a host, wherein the sensor data is indicative of a glucose concentration in the host; and
 - calibrating, using a processor, the sensor data received from the transcutaneous glucose sensor.

Id., 502-508.

In a Non-Final Office Action mailed on January 22, 2020, while the two claims shown above were pending and only about a month after the IDS was submitted, the Examiner electronically initialed and included the typed phrase "All references considered except where lined through" at the bottom of each page of

the 273-paged IDS. Ex-1003, 510-792. None of the documents listed in the IDS were “lined through.” *Id.* In the same Office Action, the Examiner rejected claims 21 and 22 for lacking novelty. *Id.* On March 9, 2020, DexCom filed a Response that did not argue that unamended claims 21 and 22 were patentable; instead DexCom significantly amended claims 21 and 22 (which issued as claims 1 and 2), and added eight new claims (which issued as claims 3-10). *Id.*, 794-803. The amendments to claim 21 are shown below:

AMENDMENTS TO THE CLAIMS

1-20. (Canceled)

21. **(Currently Amended)** A glucose monitoring system comprising:

a transcutaneous electrochemical glucose sensor ~~having~~ comprising an *in vivo* ~~in-vivo~~ portion and an *ex vivo* ~~ex-vivo~~ portion, wherein the transcutaneous electrochemical sensor is characterized by an *in vivo* sensitivity and an *in vitro* sensitivity, wherein the *in vivo* sensitivity is different from the *in vitro* sensitivity, and wherein the *in vitro* sensitivity is predictive of the *in vivo* sensitivity due to a relationship therebetween;

sensor electronics configured to be operably connected to the transcutaneous electrochemical glucose sensor;

a processor configured to be operably connected to the sensor electronics;

a memory configured to be operably connected to the processor, wherein the memory has stored therein information associated with the *in vivo* sensitivity of the transcutaneous electrochemical glucose sensor, wherein the information associated with the *in vivo* sensitivity is based at least in part on corrections for the difference between the *in vivo* sensitivity and the *in vitro* sensitivity of the transcutaneous electrochemical glucose sensor.

A Notice of Allowance was mailed on March 25, 2020, sixteen days after re-written claims 21 and 22 and new claims 23-30 were first presented. Ex-1003, 805. Assuming the Examiner worked around the clock, twenty-four hours a day for those sixteen days, the Examiner would have needed to review at least 245 IDS documents per day, to compare each IDS document with the amended claims. The '364 patent issued on July 14, 2020. *Id.*, 858; Ex-1001. *See* Ex-1002, ¶¶53-59.

VII. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSA”), as of the claimed 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, ¶60.

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

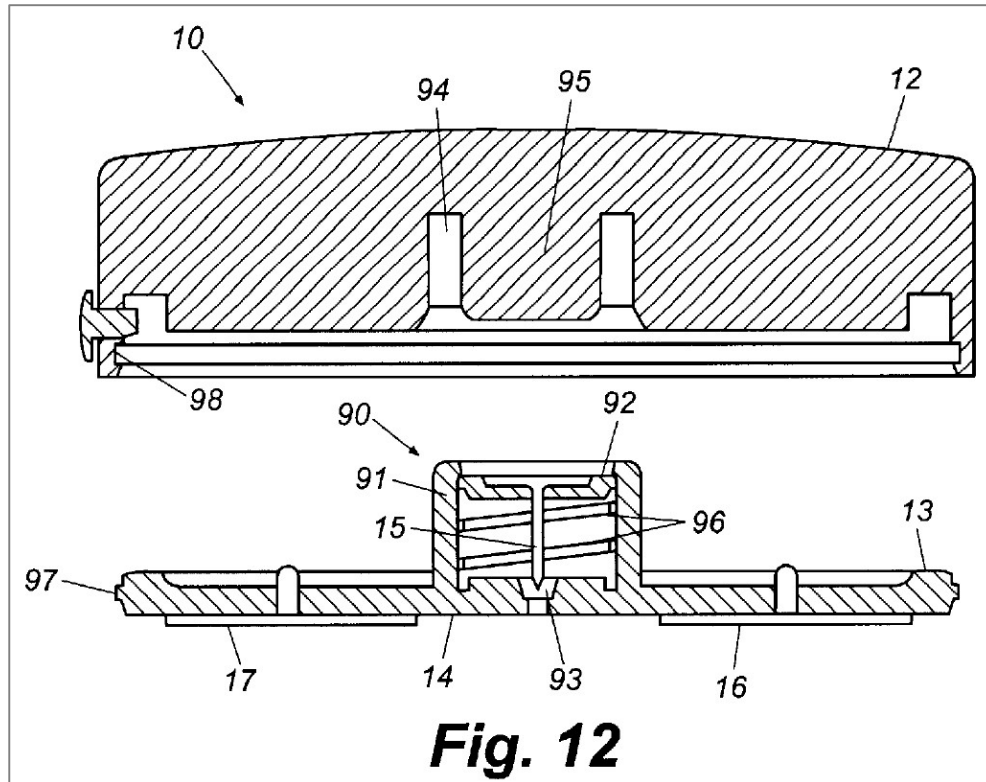
Petitioner interprets the claims “in accordance with the ordinary and customary meaning ... as understood by one of ordinary skill in the art,” 37 C.F.R. § 42.100(b), and respectfully submits that the Board need not expressly construe the terms of the challenged claims to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“we need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’”) (citation omitted).

IX. SUMMARY OF PRIOR ART: GROSS

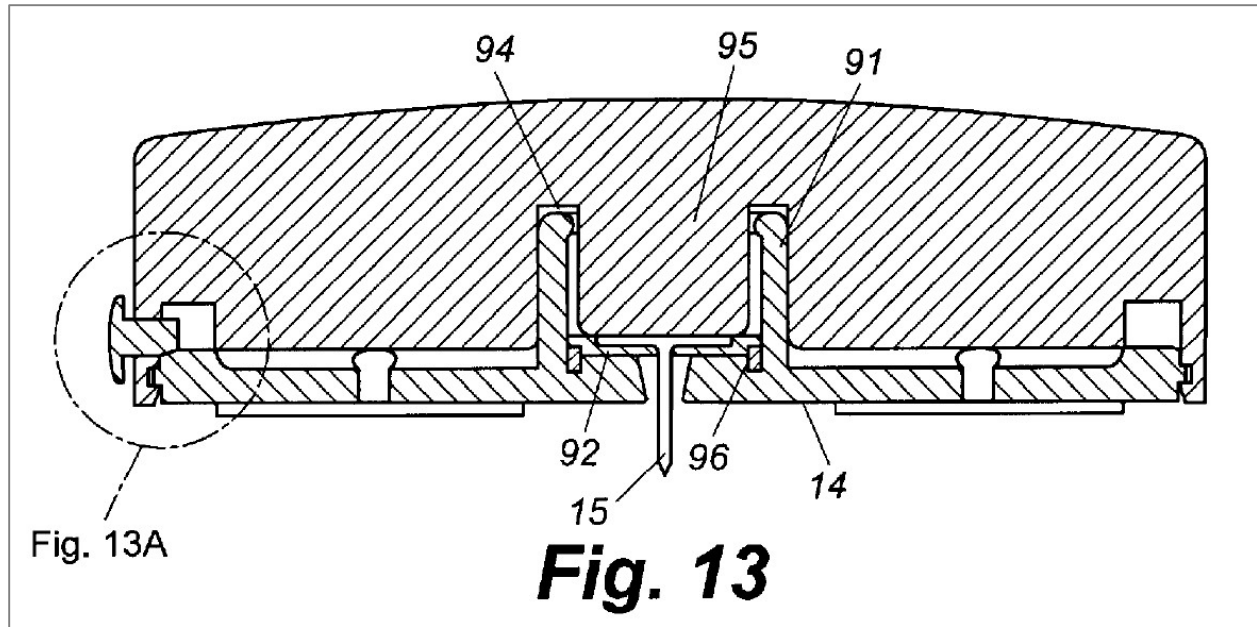
Gross issued on August 14, 2001, and qualifies as prior art to the ’364 patent under at least pre-AIA 35 U.S.C. §102(b). There is no evidence that Gross was substantively considered during prosecution of the ’364 patent; DexCom line-listed Gross in an IDS along with over 3,900 other references during prosecution of the ’364 patent, and the Examiner never cited Gross in any rejection during prosecution. *See* Ex-1002, ¶65.

A. Transcutaneous electrochemical glucose monitoring device

Gross describes analyte sensors and methods for calibrating the sensors. Ex-1004, 2:33-8:55, 10:60-14:61. More specifically, Gross describes a two-part monitor device 10: a first part 12 with electronic controlling circuitry and a second part 13 that includes a transcutaneous electrochemical sensor needle 15. *Id.*, 18:29-45, FIG. 12; *see also id.*, 10:62-11:4, FIG. 1A.



In FIG. 13 copied below, Gross illustrates the sensor needle 15 extending through the lower surface 14 of the second part 13 of the device. Gross teaches that the lower surface of the device is to be applied to the user's skin, such that, when applied to the skin, a portion of the sensor penetrates the skin and is in vivo, beneath the user's skin, and a portion of the sensor remains ex vivo, outside of the user's skin. Ex-1004, 5:11-21, 18:35-45, FIG. 13.



The monitor device includes a microprocessor, memory, and a display unit for displaying calibrated glucose levels. Ex-1004, 6:62-64, 9:64-65, 10:10-16, 14:30-35. *See also* Ex-1002, ¶¶66-68.

B. Calibration

Gross teaches methods of calibration that “tak[e] into account the condition of the sensor and the conditions encountered in use.” Ex-1004, 2:55-56. Gross discloses that the curves representing the relationship between sensor output and glucose concentration (and thus the underlying mathematical functions defining these curves) vary in different environments, such as an in-vitro environment and an in-vivo environment. *Id.*, 9:9-14, 13:42-53, 15:1-13, FIG. 5, FIG.6; *see also id.*, 1:41-50, 12:45-54. Ex-1002, ¶69.

Using Gross’s terminology, a curve representing the relationship between

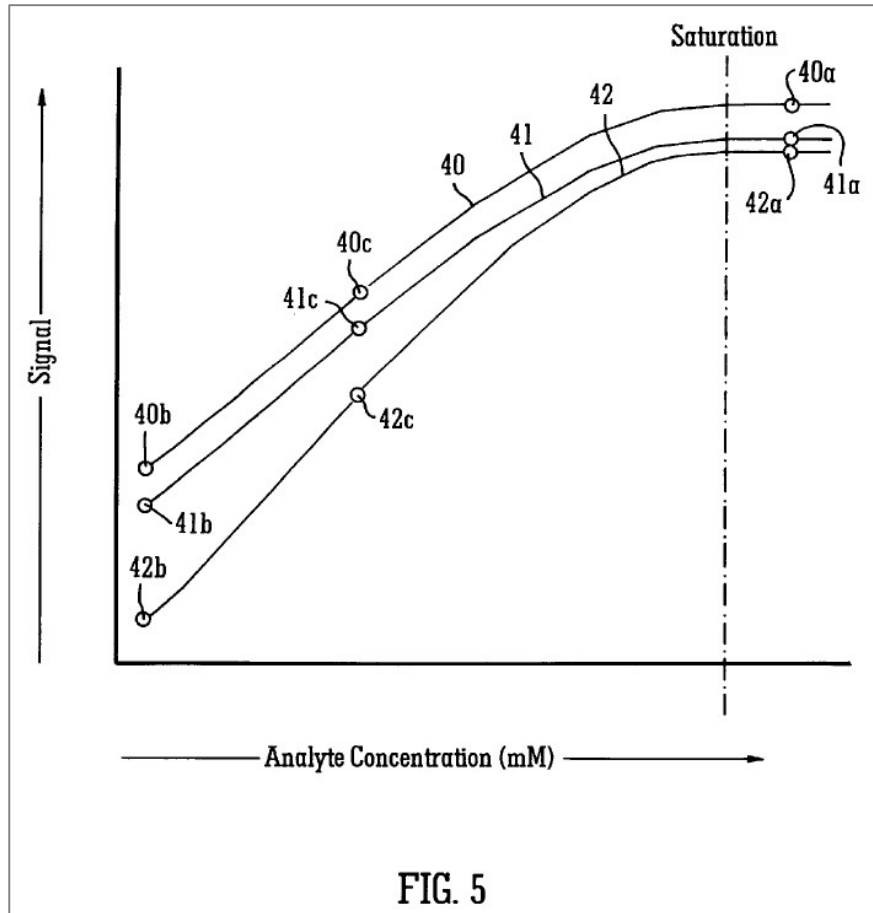
sensor output and glucose concentration in an in-vitro environment is referred to as a “theoretical sensor performance curve.” Ex-1004, 4:9. A “theoretical sensor performance curve can be determined during the design of the sensor, can be measured for individual sensors during production, or can be measured for a manufactured batch of sensors on a statistical basis.” *Id.*, 4:9-12. In one embodiment, “the theoretical or laboratory-calibrated performance curve [is] measured in the manufacturing facility for the batch of sensor needles[,] ... from tests carried out on a statistically valid sample.” *Id.*, 13:46-53; *see also id.*, 2:48-51 (explaining that “the theoretical response of the sensor ... can be determined beforehand,” i.e., before use of the sensor in a host), 14:5-9 (referring to the “theoretical” curve also as the “laboratory-measured signal-concentration curve”), 14:22-23 (referring to the “theoretical (laboratory measured) curve 40”). Ex-1002, ¶70.

Gross refers to a curve representing the relationship between sensor output and glucose concentration in an in-vivo environment as a “measured performance curve.” Ex-1004, 3:65-67; *see also id.*, 8:31-44. As explained further below, Gross teaches “extrapolating” this measured performance curve from: (i) two sensor signals measured in vivo and (ii) the knowledge that the theoretical (in-vitro) and measured (in-vivo) curves, while different from each other, share “basic common parameters,” i.e., a “common shape” and “similarity in basic shape.” *Id.*, 3:40-44,

4:12-16, 14:48-49, 15:1-13. Gross utilizes this observation of the similarity in curve shape between the theoretical (in-vitro) curve and the measured (in-vivo) curve in improved methods of calibration. Ex-1002, ¶71.

The steps of Gross's calibration process are described in detail below, with reference to FIG. 5, which is a graph with analyte (e.g., glucose) concentration on the x-axis, and sensor signal on the y-axis. Three curves are shown in FIG. 5: curve 40, curve 41, and curve 42. As explained in more detail below, curve 40 is a "theoretical" sensor performance curve and shows the relationship between sensor output and glucose concentration in vitro. Ex-1004, 13:46-50. And each of curve 41 and curve 42 is a "measured performance curve," showing the relationship between sensor output and glucose concentration in vivo for an individual sensor. *Id.*, 13:51-53. FIG. 5 is copied below.⁴ Ex-1002, ¶¶72-73.

⁴ A comparison of curves 40, 41, and 42 in FIG. 5 shows that the calibration parameters (sensor sensitivity and baseline) are not the same for the three curves. For example, in-vivo curve 41 is offset on the y-axis when compared to in-vitro curve 40, reflecting that the baseline in the in-vivo environment is different than the in-vitro baseline for a first sensor. In-vivo curve 42 is also offset on the y-axis when compared to in-vitro curve 40. In addition, the slope of curve 42 is steeper than the slope of curve 40 at lower concentrations of glucose. These differences in



First, a theoretical sensor performance curve “can be determined during the design of the sensor, can be measured for individual sensors during production, or can be measured for a manufactured batch of sensors on a statistical basis.” Ex-1004, 4:9-12; *see also id.*, 12:30-35 (“The batch of sensor needles ... will have been calibrated in the factory. This is most usually achieved by taking a

offset and slope show that the baseline and sensitivity in the in-vivo environment are different from the baseline and sensitivity in the in-vitro environment for the tested sensor.

statistically representative sample of needles from a production batch, carrying out a laboratory calibration (using a standard glucose solution, for example)”). Such in-vitro calibration information of a sensor batch “can be encoded on” the monitor device. *Id.*, 12:37-38. An example of a theoretical sensor performance curve over the operating range of a sensor is curve 40 in FIG. 5; curve 40 is the “theoretical or laboratory-calibrated performance curve measured in the manufacturing facility for the batch of sensor needles. This curve is the mean calibration curve for the batch of needles, measured from tests carried out on a statistically valid sample.” *Id.*, 13:46-50. Ex-1002, ¶74.

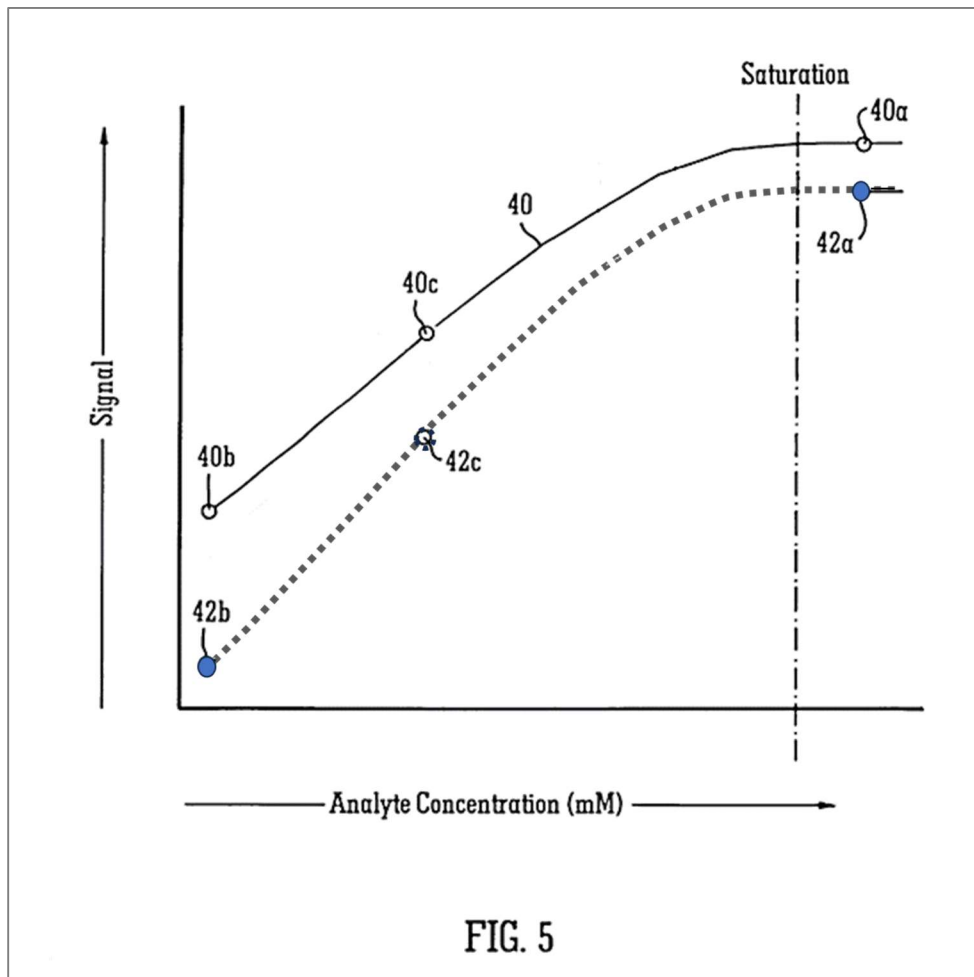
Second, a measured performance curve (a curve representing the relationship between sensor output and glucose concentration in an in-vivo environment) can be extrapolated based the knowledge that in-vitro and in-vivo curves have the same basic shape and by measuring the endpoints of the in-vivo curve. In FIG. 5, “[c]urve 41 is the measured performance curve of a first sensor needle in vivo and curve 42 is the measured performance curve of a second sensor needle in vivo.” Ex-1004, 13:51-53. Ex-1002, ¶75.

The steps of generating a measured performance curve (e.g., curve 41 or curve 42 in FIG. 5) include measuring the endpoints of the curve. When Gross’s sensor is inserted in a patient, the microprocessor is used to detect up to two sensor signals from the device: a saturation signal and, in some embodiments, a baseline

signal. Ex-1004, 3:17-44, 4:17-24, 12:55-13:41, 14:54-61. The saturation signal is a “maximum measurable signal,” and the baseline signal corresponds to background current when substantially no glucose is near the sensor. *Id.*, 2:57-3:18, 8:25-27, 12:55-13:41. The saturation signal is measured after a coating of glucose on the sensor rapidly dissolves upon implantation and puts the sensor into a saturation regime, a level where the sensor signal has reached its maximum, becoming insensitive to further increases in glucose concentration. *Id.*, 12:55-13:10. The baseline signal (if desired) is measured after applying a prolonged pulse to consume all the charge carriers near the sensor needle, thereby effectively eliminating the effect of glucose on the sensor output. *Id.*, 13:19-26. The saturation signal and the baseline signal constitute the “endpoints” of the sensor’s range of operation; for curve 42 in FIG. 5, the saturation signal endpoint and baseline signal endpoint are points 42a and 42b, respectively. *Id.*, 3:42, FIG. 5. Ex-1002, ¶76.

Gross teaches that, because in-vitro curve 40 and in-vivo curve 42 have a similar shape, measuring the two endpoints 42a and 42b for curve 42 allows the points of the curve between these endpoints to be calculated: “two endpoints may enable the intervening points to be calculated with accuracy.” Ex-1004, 4:19-21; *see also id.*, 14:48-53 (explaining that “the similarity in basic shape between all three curves 40,41,42” makes it “possible to deduce the mapping of the entire curve [e.g., curve 42] from a small number of measurements”). Ex-1002, ¶77.

Annotated FIG. 5 below shows which points on curve 42 are the measured saturation signal and baseline signal endpoints (solid blue points 42a and 42b on curve 42), and shows with a dotted line that the intervening points of curve 42 (including point 42c) have been extrapolated based on the measured endpoints and on the knowledge that curve 42 has the same basic shape as the theoretical sensor performance curve, curve 40 (curve 41 from Gross's FIG. 5 has been removed in the annotated figure below):



Ex-1002, ¶78.

Gross further teaches that, as a result of comparing endpoints 42a to 40a, and endpoints 42b to 40b, a calibration function that maps intermediate points from curve 42 onto curve 40 is derived. Ex-1004, 14:10-53. The calculated calibration function “provides complete information for the microprocessor to provide a calibrated output for any subsequent measured signal which lies on” curve 42 during operation. *Id.*, 14:24-27. *See also id.*, 14:32-35 (The microprocessor “provides, as an output which is transmitted to the display unit, the calibrated measurement ... which can then be displayed in meaningful units.”), 14:36-38 (“The same basic principles apply to the calibration of the individual sensor needle which has the characteristic measured curve 42.”). Specifically, when calibrating sensor output from a sensor having “characteristic measured curve 42,” the derived or calculated calibration function

must take into account the fact that the difference between the saturation signals 40a, 42a is considerably less than the difference between the base line signals 40b, 42b. Thus, in order to map a measured point 42c onto the corresponding point 40c on theoretical curve 40, the microprocessor must apply a concentration-dependent calibration function in which the amount added to (or subtracted from) the measured signal 42c, when mapping this signal to point 40c, varies in accordance with the position of this point along curve 42c. Nevertheless, it will be appreciated that the similarity in basic shape between all three curves 40, 41, 42 makes the mapping of any measured curve to the

theoretical curve a relatively simple operation, in which it is possible to deduce the mapping of the entire curve from a small number of measurements.

Id., 14:38-53. Gross also explains the calibration process in its Summary:

[T]he calibration function correlates the measured performance curve with a theoretical sensor performance curve for which there is stored a calibrated output, such that any further sensor signal measurement from the sensor can be calibrated by correlating the point on the measured performance curve to which the measurement relates with a corresponding point on the theoretical sensor performance curve, and hence with the corresponding calibrated output.

Id., 8:31-41. Ex-1002, ¶¶79-81.

X. GROUND OF INVALIDITY⁵

A. Ground 1: Gross Anticipates and/or Renders Obvious Claims 1-3, 5, 6, and 8-10

1. Independent Claim 1

a. 1[Pre]. “A glucose monitoring system comprising:”

Gross discloses an “analyte monitor device for the in vivo measurement of

⁵ In the co-pending district court litigation, Petitioner contends that the challenged claims are not enabled, which DexCom has disputed. Petitioner’s contentions herein, unlike its invalidity contentions in the district court, rely on the

an analyte,” where “a particularly preferred analyte is glucose.” Ex-1004, 4:24-25, 6:28-67, 9:45-47. Ex-1002, ¶83.

- b. *1[a]. “a transcutaneous electrochemical glucose sensor comprising an in vivo portion and an ex vivo portion,”*

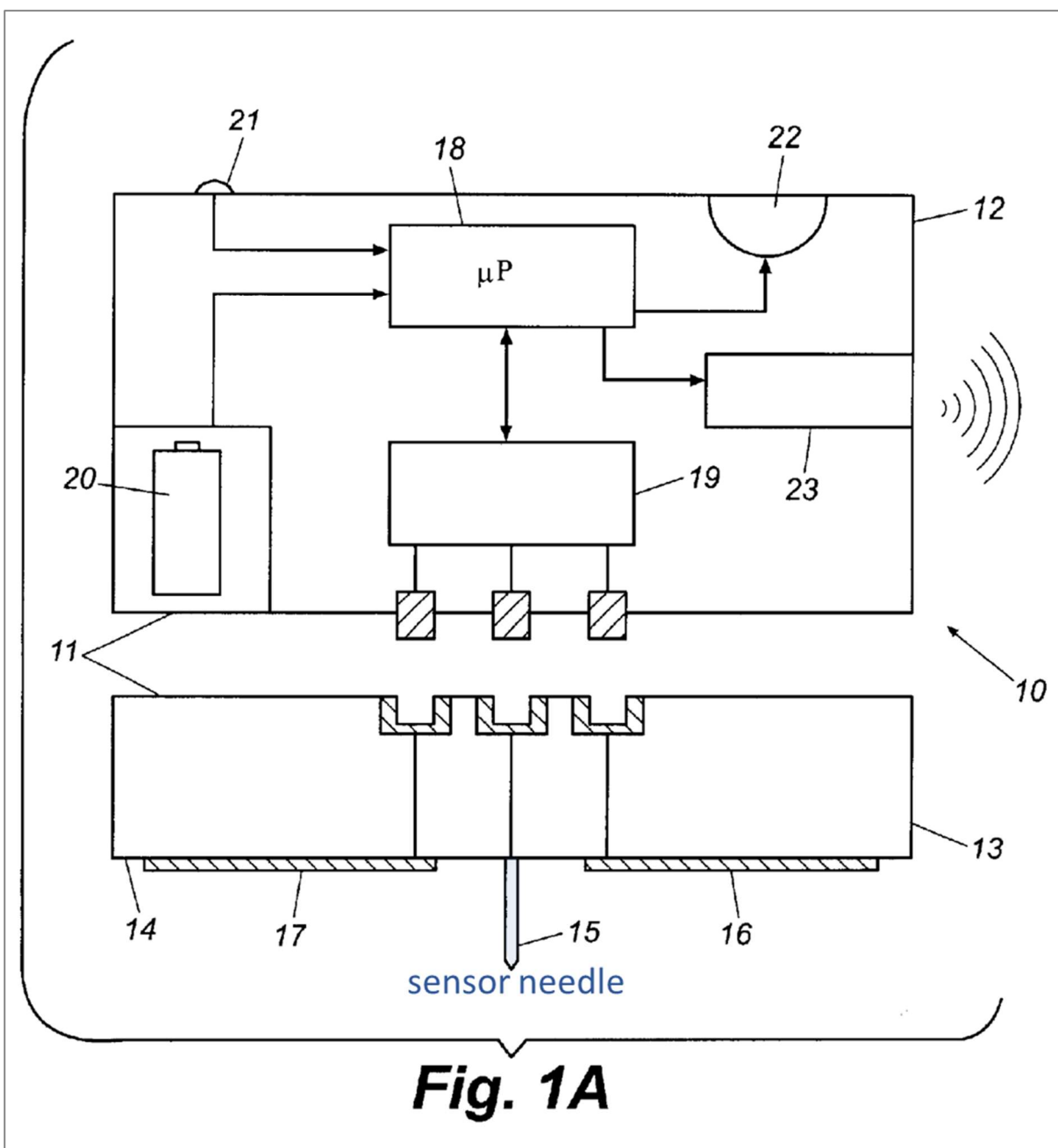
Gross’s monitor device includes a sensor that comprises an in-vivo portion and an ex-vivo portion. The device includes sensor needle 15, which “penetrates the skin to a predetermined depth” to contact subcutaneous tissue. Ex-1004, 5:7-21, 10:61-11:4. The sensor remains connected to other portions of the device, such as the reusable first part 12, that remain above the skin. *Id.* Gross also teaches an embodiment in which the sensor needle extends through an aperture in the lower surface 14 of second part 13 and into the skin of the subject. *Id.*, 18:35-45, FIG.13. Gross’s sensor needle therefore is a transcutaneous sensor comprising an in-vivo

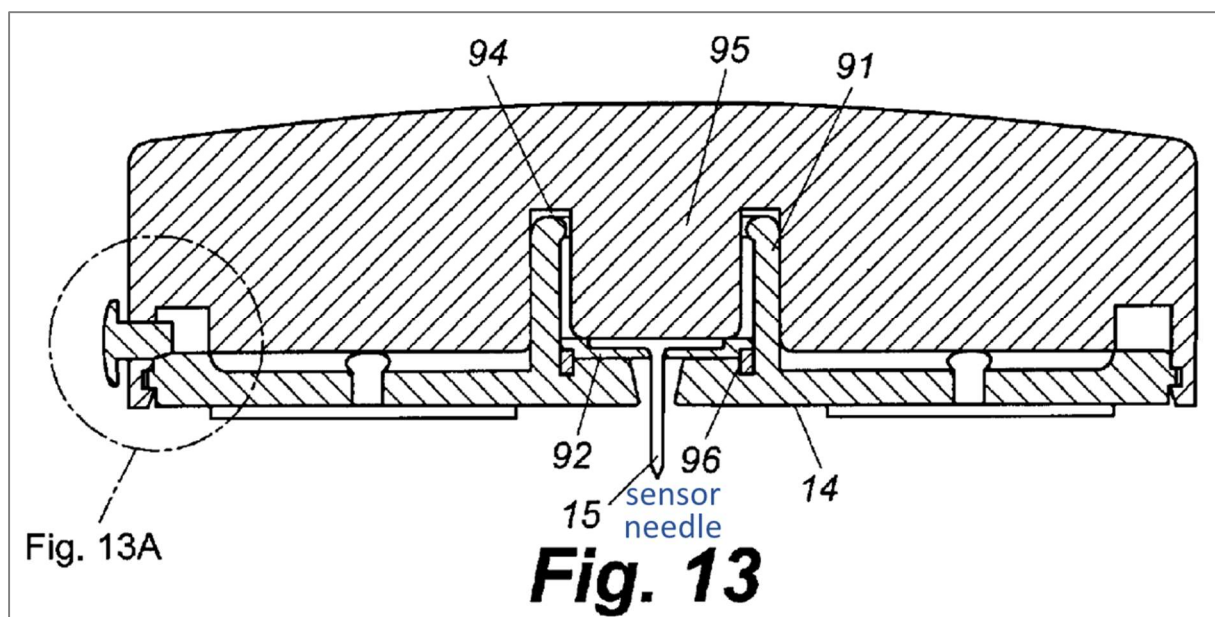
“presumption ... that both the claimed and unclaimed disclosures in a prior art patent are enabled,” and DexCom bears “the burden of proving the nonenablement of” Gross. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). Further, DexCom should not be heard to “demand[] 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 at 41-42 (P.T.A.B. July 10, 2023) (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).

portion (the portion inserted through the skin into the subcutaneous tissue) and an ex-vivo portion (the portion outside the skin that extends into the second part).⁶ Ex-1002, ¶¶84-87.

Gross's FIGS. 1A and 13 are reproduced below, with sensor needle 15 labeled in each figure:

⁶ The portion of Gross's sensor needle 15 that extends into the skin is an "in vivo portion" as defined by the '364 patent at 11:58-64, and the portion of Gross's sensor needle 15 that remains outside the body and connected to the other parts of the device is an "ex vivo portion" as defined by the '364 patent at 11:46-52. *See also* Ex-1001, 27:46-52 (describing the "in vivo portion" and "ex vivo portion" of the sensor).





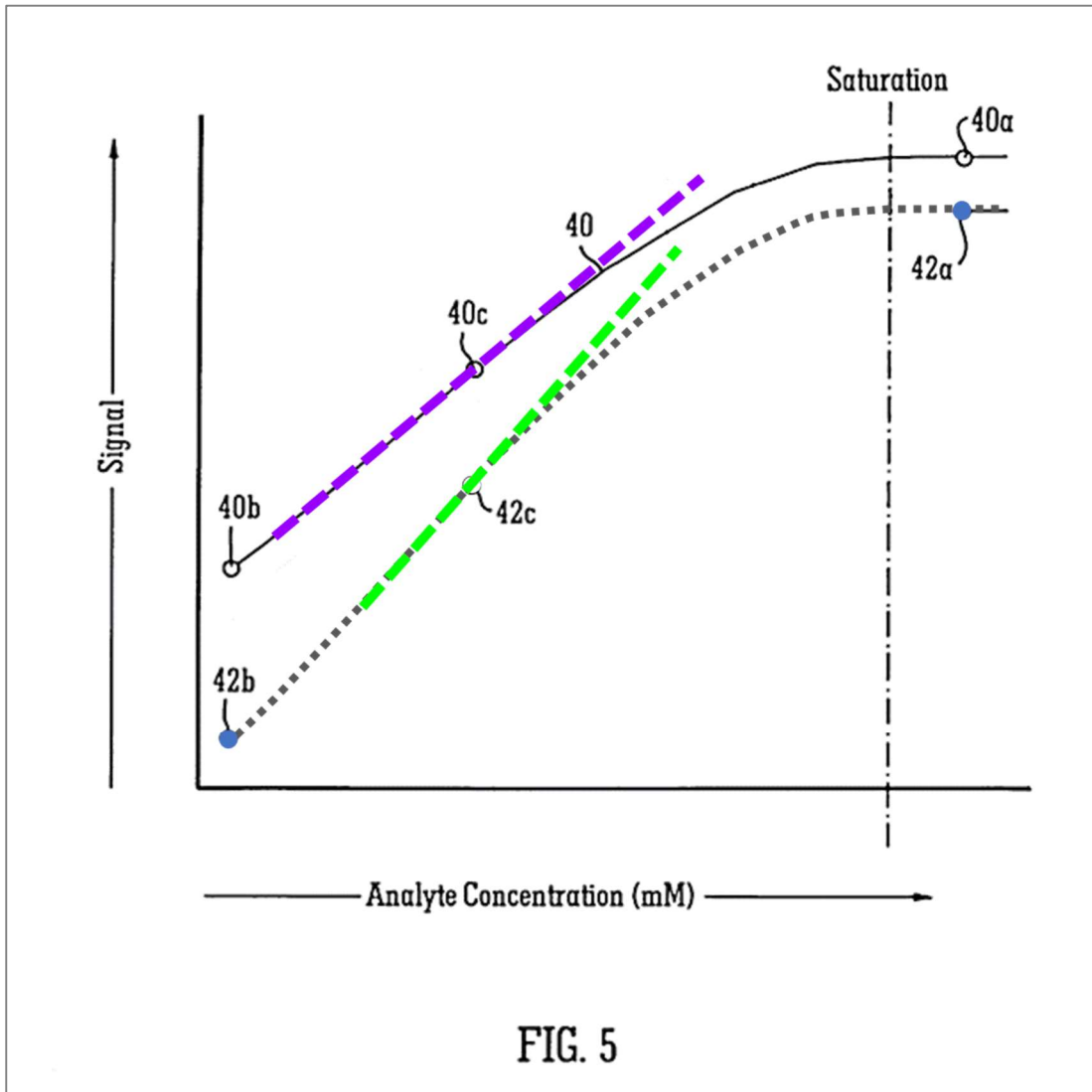
Gross's sensor is also an electrochemical glucose sensor. The needle is a platinum-iridium needle containing glucose oxidase. Ex-1004,10:25-61, 11:11-34. In operation, glucose reacts with oxygen and water to generate hydrogen peroxide. *Id.*, 11:11-23, 11:60-64. The hydrogen peroxide "serves as a source of electrons which are free to act as charge carriers if a potential is applied between the working electrode (sensor needle) 15 and the counter electrode 16." *Id.*, 11:31-34. The hydrogen peroxide "is broken down by the platinum in the sensor needle which forms an electrode of an electrical circuit. The level of concentration of glucose is proportional to the magnitude of the current." *Id.*, 1:21-24; *see also id.*, 11:24-34. Gross's electrochemical sensor thus operates in the same way as described in the '364 patent for "an enzymatic electrochemical sensor for detecting glucose." Ex-1001, 29:13-24. Ex-1002, ¶88.

- c. 1[b]. “wherein the transcutaneous electrochemical sensor is characterized by an in vivo sensitivity and an in vitro sensitivity, wherein the in vivo sensitivity is different from the in vitro sensitivity,”

Gross describes a transcutaneous electrochemical glucose sensor that is characterized by an in-vivo sensitivity and by an in-vitro sensitivity that differ from each other.

Gross’s FIG. 5 depicts a “theoretical” (in-vitro) sensor performance curve 40 and a “measured” (in-vivo) performance curve 42 of a sensor. As previously described, in a plot with analyte concentration on the x-axis and sensor signal on the y-axis (as in Gross’s FIG. 5), sensor sensitivity corresponds to the slope of the curve (e.g., the slope of the tangent on a point on the curve). As shown in annotated FIG. 5 below, the tangent of an intermediate point on curve 42 has a greater (steeper) slope than the tangent of the corresponding intermediate point on curve 40. (Compare the slopes of the dashed lines, which are the tangents for intermediate points 40c and 42c; if the tangents had the same slope, they would be parallel to each other and would not intersect at any point; but as can be seen below, extending each tangent out would result in the two tangents intersecting each other.) The different slopes of the tangents of curves 40 and 42 are a consequence of that fact that the difference between signals 40a and 42a is “considerably less” than the difference between signals 40b and 42b. Ex-1004, 14:39-41. The different slopes of these tangents means that the in-vitro sensitivity

at this intermediate point (i.e., at the particular glucose concentration on the x-axis for points 40c and 42c) differs from the in-vivo sensitivity.



Accordingly, Gross teaches a sensor characterized by an in-vivo sensitivity and an in-vitro sensitivity, wherein the in-vivo sensitivity is different from the in-vitro sensitivity. Ex-1002, ¶¶89-93.

- d. 1[c]. “and wherein the in vitro sensitivity is predictive of the in vivo sensitivity due to a relationship therebetween;”

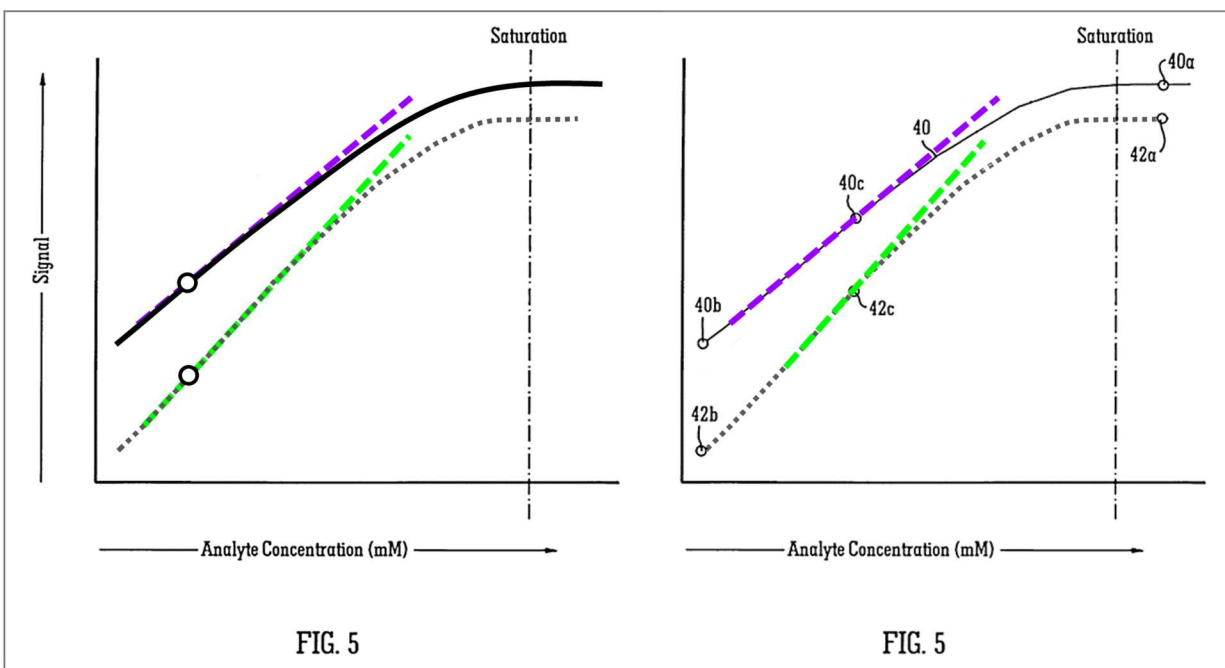
Claim element 1[c] requires that the in-vitro sensitivity is “predictive” of the in-vivo sensitivity “due to a relationship therebetween,” such that the in-vitro sensitivity could be used to estimate the in-vivo sensitivity. Claim 1[c] does not require any particular kind of “relationship” between in-vitro and in-vivo sensitivities; nor does it require any particular level or degree by which the in-vitro sensitivity must be “predictive of” the in-vivo sensitivity. The specification also imposes no such limits; rather, the specification makes clear that a “predictive relationship” includes relationships where in-vitro sensitivity approximates in-vivo sensitivity (although the sensitivities cannot be equal, given claim element 1[b]). Ex-1001, 79:56-63; *see also id.*, 18:5-9.⁷

Gross teaches that, for the sensor having measured performance curve 42, the in-vitro sensitivity is predictive of the sensor’s in-vivo sensitivity due to a relationship between these sensitivities.

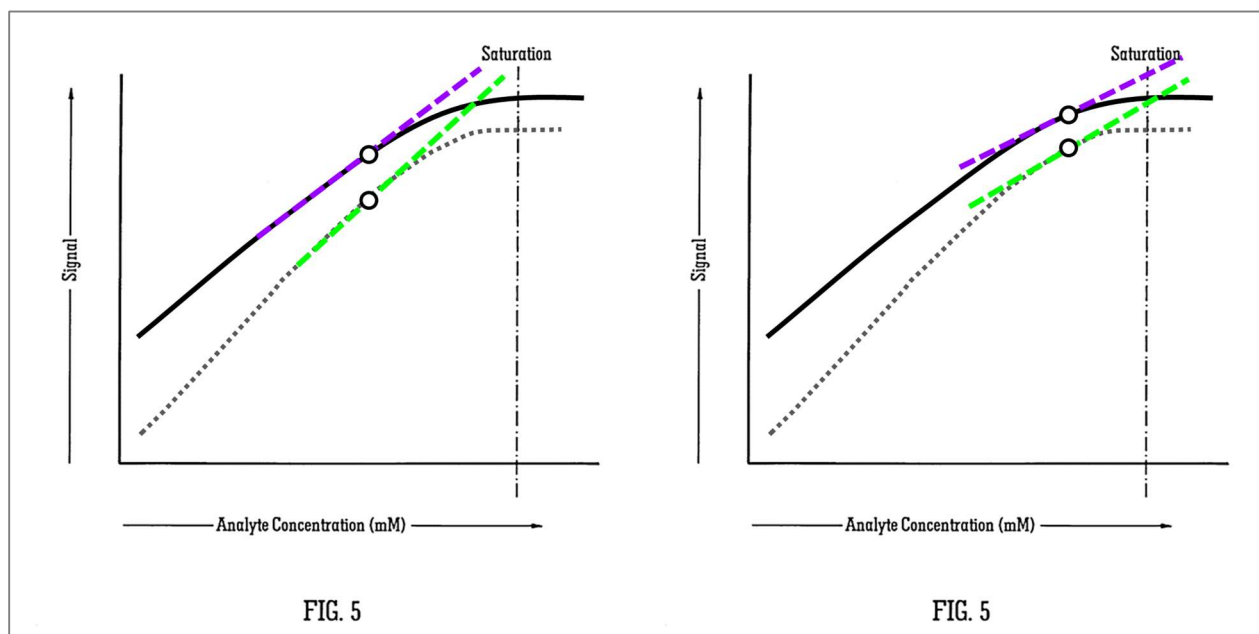
⁷ The ’364 patent provides, *as an example*, the generic function “ $m \approx f(m_{in\ vitro})$ ” to describe “a predictive relationship” between sensitivities. Ex-1001, 79:56-63. In this example, any function “f” is suitable for approximating (“ $\approx$ ”) in-vivo sensitivity from in-vitro sensitivity.

Gross teaches that a sensor's measured (in-vivo) performance curve 42 has a similarity in basic shape to theoretical (in-vitro) performance curve 40. Ex-1004, 14:48-53. This similarity in basic shape allows for the estimation or prediction of intermediate points on curve 42, after the baseline and saturation endpoints are measured. Gross teaches extrapolating the intermediate points on curve 42 (the points between the measured endpoints) from curve 40, based on the basic shape of curve 40; in other words, curve 40 is usable for the prediction of the shape of curve 42. In this way, Gross teaches a predictive relationship between both the points of theoretical (in-vitro) performance curve 40 and measured (in-vivo) performance curve 42, and the slopes of the curves. Ex-1004, 14:10-53; *see also id.*, 4:17-21; Ex-1002, ¶¶94-97.

The following annotated graphs illustrate the predictive relationship between in-vitro and in-vivo sensor sensitivity taught in Gross. Each graph below shows the tangent on in-vitro curve 40 (purple dashed line) and the tangent on in-vivo curve 42 (green dashed line), each tangent representing sensitivity at a particular analyte concentration. The second graph on the right below shows the tangents at a concentration corresponding to points 40c and 42c, and is the same graph provided above in the discussion of claim 1[b]:



As shown above in each graph, the slopes of the tangents (i.e., the sensitivities) differ from each other but are similar to each other, due to the similarity in shapes of curve 40 (in-vitro) and curve 42 (in-vivo). The two graphs below show tangents on curve 40 and curve 42 at higher analyte concentrations:



At these concentrations too, the slopes of the tangents (i.e., the sensitivities) differ from, but are nevertheless similar to, each other. All four graphs above thus illustrate that, at various analyte concentrations, the in-vitro sensitivity (as represented by the slopes of the tangents of curve 40) is similar to and *predictive of* in-vivo sensitivity (as represented by the slopes of the tangents of curve 42), due to the similarity in basic shapes of curve 40 and curve 42. Ex-1002, ¶¶98-101.

Accordingly, because Gross teaches that in-vitro curve 40 is predictive of in-vivo curve 42 due to a relationship between the curves (they have the same basic shape), Gross also teaches that there is a relationship between the in-vitro sensitivity and the in-vivo sensitivity (e.g., the slopes of the tangents of the respective curves at a given glucose concentration) and that the in-vitro sensitivity is predictive of the in-vivo sensitivity due to such relationship. Ex-1002, ¶102.

- e. 1[d]. “sensor electronics configured to be operably connected to the transcutaneous electrochemical glucose sensor;”

Gross’s monitor device includes sensor electronics configured to be operably connected to the sensor.⁸ Gross’s monitor device includes a housing having first

⁸ The ’364 patent defines “operably connected” broadly to refer to, without limitation, “one or more components being linked to another component(s) in a

and second parts. Ex-1004, 9:50-52. The monitor device can include “reusable first part 12, which includes the electronic controlling circuitry, and disposable second part 13, which includes the enzymatic sensor needle 15.” *Id.*, 10:62-65. The transcutaneous electrochemical sensor needle 15 is operably connected to the electronic controlling circuitry. *Id.*, 9:64-10:9. *See also id.*, FIG. 1A (showing parts 12 and 13, and sensor needle 15), 18:59-64 (“The first part 12 and second part 13 are each provided with the requisite electrical connections (not shown) to connect the electrodes 15-17 to the electronic controlling circuitry provided in second part 13. Thus, the second part 13 can be a reusable electronic controller module and first part 12 can be a disposable electrode module.”); *see also id.*, 4:41-57, 7:31-48. Ex-1002, ¶¶103-105.

- f. *1[e]. “a processor configured to be operably connected to the sensor electronics;”*

Gross’s system also includes a microprocessor. Gross’s microprocessor is labeled 18 in FIG. 1A. Ex-1004, 9:64-10:3. The microprocessor performs several functions, including measuring current (e.g., *id.*, 12:55-59), storing (in the microprocessor’s memory) sensor signals (*id.*, 13:3-29), and calibrating sensor data (*id.*, 14:5-53). For example, Gross explains that “the microprocessor 18 measures

manner that allows transmission of signals between the components, e.g., wired or wirelessly.” Ex-1001, 12:43-50.

the current flowing through the circuit of which the working electrode 15 and the counter electrode 16 form a part thereof.” *Id.*, 11:48-51. The microprocessor also monitors and records sensor signals as voltage is applied. *Id.*, 13:3-41.

The microprocessor is operably connected to the sensor electronics. To perform the functions mentioned above, the microprocessor must be operably connected to the sensor electronics—i.e., the microprocessor must be linked to sensor electronics in a manner that allows the transmission of signals between the microprocessor and the sensor electronics (such signals including the sensor signals that are monitored and recorded by the microprocessor). *See* note 8, *supra*. In addition, Gross explains that “[t]he electrodes 15,16,17 are connected to a microprocessor 18 via a voltage controller 19,” and that the microprocessor controls the voltages supplied by the voltage controller 19 to the electrodes. Ex-1004, 9:64-10:9. FIG. 1A shows a connection between the microprocessor 18 and the voltage controller 19, which in turn connects to sensor 15. *See also* claim 1[d]; Ex-1002, ¶¶106-109.

- g. 1[f]. “a memory configured to be operably connected to the processor,”

Gross’s system includes a memory, and the data and instructions for operation of the microprocessor, including instructions for calibrating sensor data, are stored in this memory. E.g., Ex-1004, 13:9-10, 14:19-53. Thus the memory is operably connected to the processor. In addition, system components such as a

memory operably connected to a processor were well-known in the art and were components common to many glucose monitoring systems described in the art. Ex-1002, ¶¶110-115.

- h. 1[g]. “wherein the memory has stored therein information associated with the in vivo sensitivity of the transcutaneous electrochemical glucose sensor, wherein the information associated with the in vivo sensitivity is based at least in part on corrections for the difference between the in vivo sensitivity and the in vitro sensitivity of the transcutaneous electrochemical glucose sensor.”

The information stored in the system’s memory includes the “concentration-dependent calibration function” that is used to map in-vivo measured signals (lying on measured performance curve 42) to the theoretical performance curve (in-vitro curve 40) during use to provide a calibrated output in meaningful units. Ex-1004, 14:41-47. This calibration function is “information associated with the in vivo sensitivity” of the sensor, wherein such information “is based at least in part on corrections for the difference between the in vivo sensitivity and the in vitro sensitivity” of the sensor, as recited in claim 1[g].⁹ See Ex-1002, ¶¶116-122.

⁹ The “corrections for a/the difference” claim element is recited in each independent claim. Nothing in the claims themselves requires that “corrections for a/the difference” between sensitivities be corrections for the full difference between sensitivities. And neither the phrase “corrections for a/the difference,” nor

As discussed above, Gross teaches that there can be a difference between the in-vivo and in-vitro sensitivities that characterize a sensor, as demonstrated by the difference in the slopes of curves 40 and 42 in FIG. 5. The difference in the slopes of curves 40 and 42 is a consequence of the difference between signals 40a and 42a being “considerably less” than the difference between signals 40b and 42b. *Id.*, 14:39-41. Gross’s “concentration-dependent calibration function” corrects for the difference between curves 40 and 42, and therefore also for the difference in sensitivities defined by these curves. As Gross explains,

[T]he calibration function must take into account the fact that the difference between the saturation signals 40a, 42a is considerably less than the difference between the base line signals 40b, 42b. Thus, in order to map a measured point 42c onto the corresponding point 40c on theoretical curve 40, the microprocessor must apply a concentration-dependent

any similar language relating to correcting for a difference between in-vitro sensitivity and in-vivo sensitivity, appears anywhere in the ’364 patent specification; thus the specification does not provide any guidance on this claim element. Accordingly, the language “corrections for the difference” (claim 1) and “corrections for a difference” (claims 5 and 10) should be construed under its plain and ordinary meaning and should encompass correcting for *any* difference in sensitivities in the in-vitro versus in-vivo environments.

calibration function in which the amount added to (or subtracted from) the measured signal 42c, when mapping this signal to point 40c, varies in accordance with the position of this point along curve 42c.

Id.,14:41-47. The concentration-dependent calibration function thus takes into account and corrects for differences between curve 40 (in-vitro) and curve 42 (in-vivo), including differences between the slopes, i.e., sensitivities, of these curves.

Accordingly, the concentration-dependent calibration function is “based at least in part on corrections for the difference between the in vivo sensitivity and the in vitro sensitivity,” and thereby also is information “associated with” the in-vivo sensitivity, as recited in claim 1[g]. Information (such as Gross’s concentration-dependent calibration function) that “is based at least in part on corrections for the difference between *the in vivo sensitivity* and the in vitro sensitivity” necessarily is information “*associated with* the in vivo sensitivity,” as recited in claim 1[g]. In addition, because the conversion function (in this case, Gross’s concentration-dependent calibration function) encompasses calibration parameters including sensitivity, the conversion function is “information *associated with* the in vivo sensitivity.”¹⁰

¹⁰ Nothing in the claim language or the specification imposes a requirement for determining a slope (sensitivity), in order to store “information associated with the

Gross also teaches that, once in-vivo saturation and baseline signals are recorded and the microprocessor calculates the calibration function (such as the concentration-dependent calibration function in the case of curve 42 and curve 40), the microprocessor applies the calibration function to subsequently measured signals; thus the calibration function is stored in the system's memory. E.g., Ex-1004, 14:23-27 ("The calculation of a calibration function mapping curve 41 [or curve 42] onto curve 40 provides complete information for the microprocessor to provide a calibrated output for *any subsequent measured signal* which lies on curve 41 [or curve 42].").¹¹

in vivo sensitivity [that] is based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity" of the sensor. In other words, information can be "based at least in part on corrections for the difference between the in vivo sensitivity and the in vitro sensitivity," and also be "associated with" the in-vivo sensitivity, without an in-vivo sensitivity value being calculated.

¹¹ Unless otherwise noted, all emphases shown in quoted text throughout the petition have been added by Petitioner.

2. **Claim 2: “The glucose monitoring system of claim 1, wherein the relationship between the in vivo sensitivity and the in vitro sensitivity is established empirically by performing a clinical study and comparing in vivo sensitivities with in vitro sensitivities of a plurality of transcutaneous glucose sensors.”**

Claim 2 requires that the in-vitro/in-vivo sensitivity relationship be established empirically by performing a clinical study of a plurality of sensors. A clinical study is a study in humans; clinical studies were and still are routinely performed in the art, during research and development and as part of the regulatory approval process for devices such as CGMs. Ex-1002, ¶125, ¶132.

Gross anticipates and/or renders obvious claim 2.¹² Gross expressly discloses examining in-vitro sensitivities of a plurality of sensors and that “it is

¹² In the district court litigation in which DexCom has asserted claim 2 against Petitioner, DexCom has asserted, in its infringement contentions, that claim 2 encompasses embodiments where the clinical study “of a plurality” of sensors is a clinical study involving *only* sensors *other than* the sensor in the claimed system (e.g., the clinical study is performed using sensors from the same batch as the sensor in the claimed system, but the study does not involve the sensor that is in the claimed system). Solely for the purpose of this petition and not for any other purpose, including any other proceeding involving the ’364 patent or any of its family members, Petitioner has applied DexCom’s interpretation of claim 2.

known” that sensors from the same batch will have similar in-vitro and in-vivo calibration curves. The POSA would have understood that, to have such knowledge about the in-vitro/in-vivo calibration curves, a study examining sensor performance in vivo (i.e., a clinical study) necessarily had to have been performed. In addition, the POSA would have found it obvious to have performed such a clinical study, to be able to compare sensor in-vivo and in-vitro performance and acquire the knowledge expressly disclosed in Gross. *See* Ex-1002, ¶¶123-133.

Specifically, Gross teaches determining sensor in-vitro sensitivity by examining a plurality of sensors (of a given batch) at the factory, and applying that in-vitro sensitivity determination to all sensors in the batch. Gross teaches determining, at the factory, the in-vitro performance curve (e.g., theoretical performance curve 40 in FIG. 5) for a batch of sensors “by taking a statistically representative sample of needles from a production batch, carrying out a laboratory calibration (using a standard glucose solution, for example) and applying the results of this calibration for all of the needles in the batch.” Ex-1004, 12:30-37; *id.*, 13:46-48 (“Curve 40 is the theoretical or laboratory-calibrated performance curve measured in the manufacturing facility for the batch of sensor needles.”), 4:9-12 (“The theoretical sensor performance curve can be determined during the design of the sensor, can be measured for individual sensors during production, or can be measured for a manufactured batch of sensors on a statistical basis.”).

Gross further teaches that the sensors in the batch are intended to be used in vivo (in a host), and that once inserted into a host, each sensor's in-vivo performance curve is expected to have the same basic shape as the pre-determined in-vitro performance curve. *Id.*, 14:10-15 (“[I]t is known that the calibration curves for needles from the same batch will all have the same basic shape....”); *see also id.*, 4:9-16. Gross thus teaches *prior knowledge* that the in-vitro and in-vivo performance curves will have the same basic shape; and as discussed above, these curves include information on sensor sensitivity in the in-vitro or in-vivo environments.

The POSA would have reasonably understood that this knowledge—that the in-vivo curve will have the same basic shape as the in-vitro curve for sensors from the same batch—was determined empirically; further, examining in-vivo sensor performance empirically necessarily would have entailed a clinical study. Ex-1002, ¶130. Thus, by teaching that “it is known” that the in-vitro and in-vivo performance curves “for needles from the same batch will all have the same basic shape” (Ex-1004, 14:10-11), Gross discloses that the relationship between in-vivo and in-vitro sensor performance (i.e., the relationship between curve 40 and curve 42, that the curves have a similarity in basic shape), and thus between in-vivo sensitivity and in-vitro sensitivity, is established empirically by performing a clinical study and comparing sensor performance (and thus also in-vivo

sensitivities with in-vitro sensitivities) of a plurality of sensors, as recited in claim 2. *See, 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)).

Claim 2 also would have been obvious based on Gross’s teachings and the knowledge in the art of how glucose sensors were and still are routinely characterized and studied. The POSA would have been familiar with research conducted in the field, where glucose monitoring systems comprising transcutaneous electrochemical sensors were routinely tested in vitro (as is also expressly disclosed in Gross) and in humans to, among other things, examine and compare sensor performance in the in-vitro and in-vivo environments. *E.g.*, Nishida (Ex-1007) (reporting a study examining in-vitro and in-vivo performance of a transcutaneous glucose sensor); Feldman-2003 (Ex-1006) (same); *see also* Ex-1002, ¶132. Given that testing sensors in vitro and in vivo (in clinical studies) was standard practice in the art, as a routine step in characterizing sensors and as part of the marketing approval process, the POSA would have had reason to conduct such

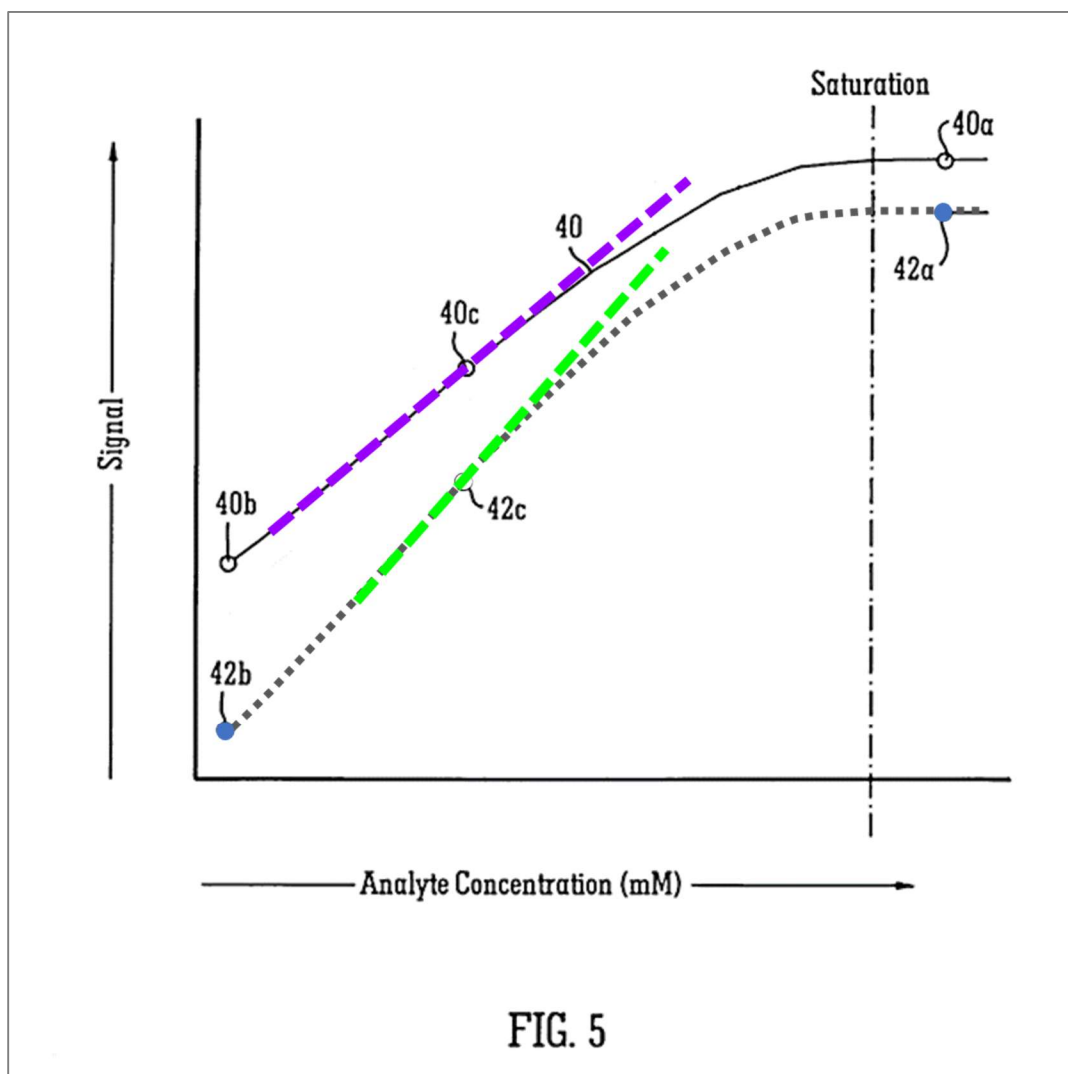
routine testing for any sensors, including sensors to be used in the systems disclosed in Gross. In other words, the POSA would have had reason to examine the in-vitro/in-vivo sensitivity relationship of sensors empirically, through a clinical trial, at least because such testing was standard, routine practice in the art for sensors under development as of the asserted priority date. Ex-1002, ¶¶131-133.

3. Claim 3: “The glucose monitoring system of claim 1, wherein the in vivo sensitivity is greater than the in vitro sensitivity.”

Gross teaches this limitation for the sensor having in-vivo curve 42 shown in FIG. 5. Especially at low glucose concentrations, the slope of the tangent on in-vivo curve 42 is greater than the slope of the tangent on in-vitro curve 40, and therefore the in-vivo sensitivity is greater than the in-vitro sensitivity at these glucose concentrations. *See also* claim 1[b].

As explained above, in a plot of analyte concentration on the x-axis and sensor signal on the y-axis (as in Gross’s FIG. 5), sensor sensitivity corresponds to the slope of the curve (e.g., the slope of the tangent on a point on the curve). Annotated FIG. 5 below shows the tangent (green dashed line) at point 42c on in-vivo curve 42, and the tangent (purple dashed line) at corresponding point 40c on in-vitro curve 40. The slope of the tangent at point 42c (i.e., the slope of the green dashed line) is greater than the slope of the tangent at point 40c (i.e., the slope of

the purple dashed line):¹³



¹³ The '364 patent at 81:5-6 acknowledges that a higher slope equates to a higher sensitivity, and that a lower slope equates to a lower sensitivity, as the patent recites “higher slope (sensitivity)” and “lower slope (sensitivity)” when discussing regression lines calculated from a plot of “matched data pairs” of “sensor data and time-correspondence reference glucose data.” Ex-1001, 80:50-81:7.

Gross therefore teaches a sensor characterized by an in-vivo sensitivity and an in-vitro sensitivity, wherein the in-vivo sensitivity is greater than the in-vitro sensitivity, as required by claim 3 of the '364 patent. *See* Ex-1002, ¶¶134-139.

4. Independent Claim 5

- a. 5[Pre]. “A method for calibrating data from a transcutaneous electrochemical glucose sensor, the method comprising:”

Gross teaches “a method of calibrating an analyte sensor,” where “a particularly preferred analyte is glucose.” Ex-1004, 4:24-40. And as discussed above for claim 1, Gross’s calibration method is for “a transcutaneous electrochemical glucose sensor.” *See* section X.A.1.b. Ex-1002, ¶¶140-142.

- b. 5[a]. “receiving sensor data from the transcutaneous electrochemical glucose sensor after at least a portion of the transcutaneous electrochemical glucose sensor is inserted in a host, wherein the sensor data is indicative of a glucose concentration in the host;”

Gross teaches that the sensor output received after sensor insertion into the host corresponds to a glucose concentration in the host. Ex-1004, 10:60-12:24; *see also id.*, 1:12-26. Gross explains that, “when a voltage is applied to the working electrode 15, the microprocessor 18 measures the current flowing through the circuit of which the working electrode 15 and the counter electrode 16 form a part thereof.” *Id.*, 11:48-51. Gross further teaches that this current measured by the microprocessor is indicative of a glucose concentration in the host. The current measured is based on the amount of hydrogen peroxide produced at the surface of

the needle, and the amount of hydrogen peroxide produced in turn depends on, and therefore is indicative of, the concentration of glucose present in the host. *Id.*, 11:10-34. Specifically, Gross explains that “glucose in the blood, plasma or serum present in the subcutaneous region” diffuses to the sensor needle and reacts with oxygen and water in the presence of glucose oxidase, producing hydrogen peroxide at sensor needle 15, and that “the rate of hydrogen peroxide generation at platinum-iridium needle 15 is theoretically proportional to the concentration of glucose in the bloodstream.” *Id.*, 11:11-23. Ex-1002, ¶¶143-146.

- c. 5[b]. “and calibrating, using a processor, the sensor data received from the transcutaneous electrochemical glucose sensor.”

Gross’s method involves calibrating sensor data, and Gross teaches using a processor to perform the calibration. As discussed above, Gross’s system stores information (e.g., the measured performance curve 42) and uses this information to calculate a concentration-dependent calibration function that is then also stored and applied to subsequently measured signals, to calibrate those signals and generate calibrated output. Ex-1004, 14:10-53; *see also id.*, 8:31-42. Such calibration is performed by a processor. E.g., *id.*, 14:19-47 (explaining how the microprocessor provides a calibrated output for subsequently measured signals that lie on a measured (in-vivo) performance curve). *See also* sections X.A.1.f, X.A.1.g, and X.A.1.h for claim 1[e], 1[f], and 1[g], respectively.

Specifically, when the microprocessor receives sensor data, the microprocessor uses the calibration function to determine the corresponding point on the in-vitro curve (theoretical performance curve 40) and transmits the calibrated output to the display unit. Ex-1004, 14:19-53. As Gross explains:

[W]hen a signal 41c is measured, the microprocessor calculates the corresponding point 40c and provides, as an output which is transmitted to the display unit, the calibrated measurement corresponding to point 40c which can then be displayed in meaningful units. The same basic principles apply to the calibration of the individual sensor needle which has characteristic measured curve 42.

Id., 14:31-38. *See also id.*, 8:33-41:

[T]he calibration function correlates the measured performance curve with a theoretical sensor performance curve for which there is stored a calibrated output, such that any further sensor signal measurement from the sensor can be calibrated by correlating the point on the measured performance curve to which the measurement relates with a corresponding point on the theoretical sensor performance curve, and hence with the corresponding calibrated output.

Accordingly, in the case of curve 40 and curve 42 and the concentration-dependent calibration function, the microprocessor applies the concentration-dependent calibration function to sensor data, to calculate the corresponding point on the in-vitro curve (theoretical performance curve 40) and then transmits the

calibrated output to the display unit. Gross thus discloses calibrating, using a processor, the sensor data received from the sensor after sensor insertion. Ex-1002, ¶¶147-151.

- d. 5[c]. “wherein the calibrating is based at least in part on information associated with an in vivo sensitivity of the transcutaneous electrochemical glucose sensor, wherein the information associated with the in vivo sensitivity is based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity for the transcutaneous electrochemical glucose sensor.”

Gross’s calibration method discussed above for claim 5[b] “is based at least in part on information associated with an in vivo sensitivity” of the sensor because such information is “based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity” for the sensor, as recited in claim 5[c].

Gross’s calibration method employs a calibration function. Ex-1004, 14:10-53. The calibration function constitutes information “*associated with an in-vivo sensitivity,*” at least because the calibration function corrects for a difference between in-vitro and in-vivo sensitivities. *See* section X.A.1.h, discussing claim 1[g]. Ex-1002, ¶¶152-153.

In addition, because applying the calibration function to sensor data corrects for a difference between in-vivo sensitivity and in-vitro sensitivity, the calibration function also is information “based at least in part on corrections for a difference

between the in vivo sensitivity and an in vitro sensitivity,” as claimed. The calibration function maps intermediate points on in-vivo curve 42 to the corresponding points on in-vitro curve 40 and thereby corrects for a difference between these curves. Ex-1004, 14:36-47. In correcting for a difference between the curves, the calibration function also corrects for a difference in the sensitivities underlying these curves, as the function defining each curve includes sensitivity. Ex-1002, ¶¶154-155.

Specifically, each of these curves (in-vivo curve 42 and in-vitro curve 40) defines sensor sensitivity. For example, curve 42 defines sensor in-vivo sensitivity: the slope of the tangent on curve 42, at a given glucose concentration, is sensor in-vivo sensitivity at that glucose concentration. The same principle applies for curve 40. *See* section X.A.1.c. In addition, each of these curves is associated with different sensitivities over a range of glucose concentrations. *See* sections X.A.1.c, X.A.1.d, and X.A.3.

Accordingly, when Gross provides calibrated output, Gross’s calibration function corrects for the difference between in-vivo curve 42 and in-vitro curve 40 and by doing so corrects for the difference in sensitivities that are defined by these curves. Ex-1002, ¶¶156-158.

- 5. Claim 6: “The method of calibrating data from a transcutaneous electrochemical glucose sensor of claim 5, wherein the calibrating requires no user calibrations after the at least a portion of the transcutaneous electrochemical glucose sensor is inserted in the host.”**

Gross’s calibration method does not require any user calibrations after the sensor is inserted into the host. The microprocessor calculates the calibration function based on a theoretical performance (in-vitro) curve (for example, a laboratory-measured curve such as a curve determined at the factory), and a measured (in-vivo) performance curve determined *by the system* when the needle 15 enters the body, without any user measurements. Ex-1004, 12:55-13:41.

Specifically, Gross’s system initiates a process for obtaining and recording saturation and baseline signals and then generating a measured (in-vivo) performance curve and calculating a calibration function to be used for calibrating subsequently measured sensor signals. E.g., *Id.*, 12:55-13:26 (explaining how the microprocessor controls the process for obtaining and recording saturation and baseline signals I_1 and I_9 “for calibration purposes”), 14:5-9 (explaining that the microprocessor “compares” the recorded saturation and baseline signals “with the corresponding signals on the theoretical or laboratory-measured signal-concentration curve 40” to generate “a calibration function”), 14:10-53 (explaining how the system calibrates sensor data, without user intervention). The calibration process is run by the microprocessor and does not rely on or require any user

calibrations. Ex-1002, ¶¶159-161.

6. **Claim 8: “The method of calibrating data from a transcutaneous electrochemical glucose sensor of claim 5, wherein the in vitro sensitivity for the transcutaneous electrochemical glucose sensor is based at least in part on sampling a plurality of transcutaneous electrochemical glucose sensors prior to inserting the at least a portion of the transcutaneous electrochemical glucose sensor in the host.”**

Gross teaches examining the in-vitro sensitivity by sampling a plurality of sensors prior to sensor insertion in the host. Gross teaches that the calibration process includes determining, at the factory, the in-vitro curve “by taking a statistically representative sample of needles from a production batch, carrying out a laboratory calibration (using a standard glucose solution, for example) and applying the results of this calibration for all of the needles in the batch.” Ex-1004, 12:30-37, 13:46-48 (“Curve 40 is the theoretical or laboratory-calibrated performance curve measured in the manufacturing facility for the batch of sensor needles.”). As explained above, the in-vitro curve defines in-vitro sensitivity. *See* section X.A.1.c; Ex-1002, ¶¶162-163.

To the extent Gross is understood as teaching that the “statistically representative sample of needles from a production batch”—i.e., the plurality of sensors—excludes the sensor that is part of the claimed system, Gross still teaches a system as recited in claim 8 under DexCom’s interpretation of the claim.

DexCom has construed claim 8 as encompassing embodiments where the recited

“plurality” of sensors excludes the sensor that is part of the claimed system and includes only other sensors. Petitioner has applied this interpretation of the claim solely for the purpose of this petition, and does not concede that this interpretation is correct. The same reasoning applies for claim 9; see below. *See* note 12, *supra*. Ex-1002, ¶164.

7. **Claim 9: “The method of calibrating data from a transcutaneous electrochemical glucose sensor of claim 8, wherein the in vitro sensitivity is calculated at least in part by examining a signal response of each of the plurality of transcutaneous electrochemical glucose sensors to a set of known glucose concentrations.”**

Gross discloses and/or renders obvious claim 9. As explained above for claim 8, Gross teaches examining the in-vitro sensitivity by sampling a plurality of sensors prior to sensor insertion in the host. Gross further teaches calculating in-vitro sensitivity by examining each of the plurality of sensors using “a set of known glucose concentrations,” as recited in claim 9. Claim 9 also would have been obvious based on Gross and the typical, in-vitro characterization testing of glucose sensors that researchers conducted in the field. Ex-1002, ¶¶165-175.

Gross teaches that the laboratory calibration (*see* claim 8) is performed by measuring sensor response “using a standard glucose solution, for example.” Ex-1004, 12:30-37. An example in-vitro curve is shown in FIG. 5, which in turn shows at least two sensor signal measurements, 40b and 40a. E.g., *id.*, 14:5-9 (referring to signal 40a and signal 40b on the “laboratory-measured signal-

concentration curve”). 40a is the in-vitro saturation signal and 40b is the in-vitro baseline signal. *Id.*, 14:38-41. Thus the “set of known glucose concentrations” in Gross includes at least a concentration corresponding to saturation, and a concentration (which could be zero) corresponding to baseline. *See also id.*, 1:33-41 (calibrating a sensor can include measuring a “standard solution of the analyte for which they are intended, and thereby determining the signal strength achieved from a known concentration of analyte”).

Calculating in-vitro sensitivity at least in part by examining sensor signal response to a set of known glucose concentrations also would have been obvious in view of the routine practice of examining sensor response in the in-vitro environment. As evidenced by the literature in the field, it was routine practice to examine sensor response to multiple glucose concentrations in vitro, and to report in-vitro sensitivity based on such testing. Ex-1002, ¶¶169-175. For example, Velho describes examining sensors in vitro, to determine their in-vitro characteristics including sensitivity; the sensors were tested in a buffered solution “during stepwise increases of the glucose concentration from 0 to 30 mmol/l.” Ex-1008, 6; *see also id.*, 8 (Fig. 4, showing that four glucose concentrations were used to determine the in-vitro calibration curve). Testing sensor response to multiple glucose concentrations (and thereby having a number of matched pairs, from which to empirically derive the in-vitro conversion function) increased the

accuracy of the empirically-derived in-vitro conversion function, and testing sensors in vitro was well within the skill of researchers working in the field. Ex-1002, ¶175.

8. Independent Claim 10

- a. 10[Pre]. “A method for providing calibrated glucose information based on sensor data from a transcutaneous electrochemical glucose sensor, the method comprising:”

Gross’s method provides “calibrated glucose information based on sensor data,” as recited in the preamble of claim 10. E.g., Ex-1004, 14:23-27 (“The calculation of a calibration function mapping curve 41 onto curve 40 provides complete information *for the microprocessor to provide a calibrated output for any subsequent measured signal* which lies on curve 41.”), 14:30-35, 14:36-38 (same principles apply to curve 42). *See* discussions above for claim 5[pre], 5[b]. Ex-1002, ¶¶176-177.

- b. 10[a]. “receiving, by a processor, post-implantation sensor data from the transcutaneous electrochemical glucose sensor, wherein the sensor data is indicative of a glucose concentration in a host;”

Gross teaches that the microprocessor measures the current after the sensor needle 15 (which Gross also refers to as “working electrode 15,” Ex-1004, 11:33) is inserted into the host. Ex-1004, 10:60-11:57. “[W]hen a voltage is applied to the working electrode 15, the microprocessor 18 measures the current flowing through the circuit of which the working electrode 15 and the counter electrode 16 form a

part thereof.” *Id.*, 11:48-51. This current is “post-implantation sensor data” received by a processor “from the transcutaneous electrochemical glucose sensor,” as recited in claim 10[a].

Gross further teaches that this current measured by the microprocessor is indicative of a glucose concentration in the host. The current measured is based on the amount of hydrogen peroxide produced at the surface of the needle, and the amount of hydrogen peroxide produced in turn depends on, and therefore is indicative of, the concentration of glucose present in the host. *Id.*, 11:10-34. Gross explains that “glucose in the blood, plasma or serum present in the subcutaneous region” diffuses to the sensor needle and reacts with oxygen and water in the presence of glucose oxidase, producing hydrogen peroxide at sensor needle 15, and that “the rate of hydrogen peroxide generation at platinum-iridium needle 15 is theoretically proportional to the concentration of glucose in the bloodstream.” *Id.*, 11:11-23. Ex-1002, ¶¶178-180.

- c. 10[b]. “receiving, by the processor, information associated with an in vivo sensitivity of the transcutaneous electrochemical glucose sensor, wherein the information associated with the in vivo sensitivity is based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity for the transcutaneous electrochemical glucose sensor;”

In Gross’s calibration method, the processor receives “information associated with an in vivo sensitivity” of the sensor, “wherein the information

associated with the in vivo sensitivity is based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity for the transcutaneous electrochemical glucose sensor,” as recited in claim 10[b].

To calibrate sensor data for a sensor having measured (in-vivo) performance curve 42, Gross’s method applies a concentration-dependent calibration function that maps the sensor data to theoretical performance curve 40. *See* claim 5[b].

Thus, to provide calibrated glucose information to the user, the processor receives and uses the calibration function to calibrate the sensor data. Ex-1002, ¶¶181-182.

This concentration-dependent calibration function is “information associated with an in vivo sensitivity” of the sensor that is “based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity,” as explained above for claim 1[g] and 5[c]. Accordingly, because Gross’s microprocessor receives and uses the calibration function when providing calibrated glucose information based on sensor signals lying on the intermediate points of curve 42, Gross’s microprocessor receives and uses “information associated with an in vivo sensitivity” of the sensor that is “based at least in part on corrections for a difference between the in vivo sensitivity and an in vitro sensitivity,” as recited in claim 10[b]. Ex-1002, ¶183.

- d. 10[c]. “generating calibrated sensor data, using the processor, by using the information associated with the in vivo sensitivity of the transcutaneous electrochemical glucose sensor to calibrate the sensor data received from the transcutaneous electrochemical glucose sensor;”

In Gross’s method, the microprocessor generates calibrated sensor data by using the concentration-dependent calibration function to calibrate the data received from the sensor, as explained above for claim 5[b], 5[c]. Specifically, the microprocessor uses the calibration function to map sensor data (measured signals corresponding to intermediate points on curve 42) to corresponding points on theoretical curve 40 and thereby calibrate the sensor data. Ex-1004, 14:10-53. The concentration-dependent calibration function is information associated with the in vivo sensitivity of the sensor, as recited in claim 10[c]. *See* claim 1[g], 5[b], 5[c], 10[b]. Ex-1002, ¶¶184-185.

- e. 10[d]. “and providing the calibrated sensor data to a user to facilitate monitoring a glucose level of the host.”

The purpose of Gross’s system and method is to provide calibrated sensor data to the user, so that the user can meaningfully monitor his/her glucose level. E.g., Ex-1004, 15:5-20. To this end, Gross teaches a display unit that includes a visual LCD display. *Id.*, 10:10-14. The display unit provides “a visual output of the measured analyte levels.” *Id.*, 9:48-49. Gross explains that “the microprocessor calculates the corresponding point 40c and provides, *as an output which is transmitted to the display unit, the calibrated measurement corresponding to*

point 40c which can then be displayed in meaningful units.” Id., 14:30-35. By providing, as a visual output on the display unit, “the calibrated measurement” of glucose levels “displayed in meaningful units,” Gross teaches the element of claim 10[d]. Ex-1002, ¶¶186-187.

XI. OBJECTIVE INDICIA

Petitioner is not aware of any evidence of objective indicia that would rebut a finding of obviousness. Petitioner may rebut any purported objective evidence of non-obviousness raised by Patent Owner.

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 U.S.C. §314(a). No other petitions have been filed against the ’364 patent and thus the *General Plastic* factors for serial petitions do not weigh against institution.

Under *Apple Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper 11 (March 20, 2020) (precedential), the district court litigation is still at an early stage, and trial on issues including the validity of the ’364 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-1014 (D. Del. Scheduling Order, Sept. 2023). In addition, the other *Fintiv* factors would not justify denying institution. 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). When evaluating discretionary denial arguments under §325(d), the Board looks to “(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential).

In applying this test, 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) (“*Becton, Dickinson*”). These factors include “the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for

rejection.” *Id.* at 17; *see also Edwards Life Sciences Corp. v. Colibri Heartinvalve, LLC*, IPR2020-01649, Paper 8 at 20-21 (P.T.A.B. Mar. 26, 2021) (declining to exercise discretionary denial where prior-art references were not substantively considered during prosecution).

Here, Gross was cited in an IDS with over 3,900 other documents. Even though the first *Advanced Bionics* prong is therefore satisfied,¹⁴ *see Advanced Bionics*, Paper 6 at 7-8, 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 did not rely on Gross to reject any claims and thus did not meaningfully address Gross. Furthermore, under *Becton, Dickinson* factor (f), the Examiner erred by overlooking or not appreciating Gross’s materiality to the challenged claims, as described above. *See STMicroelectronics, Inc. v. Trustees of Purdue Univ.*,

¹⁴ 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.”).

IPR2022-00309, Paper 14 at 12–13 (P.T.A.B. July 6, 2022) (finding that petitioner 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 '364 patent be instituted and that the challenged claims be cancelled as unpatentable pursuant to 35 U.S.C. § 318(b).

Date: April 26, 2024

Respectfully submitted,

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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 12,099 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: April 26, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6 and 42.105, I hereby certify that on April 26, 2024, I caused a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 10,709,364, 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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