

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

Case No. IPR2023-01252

U.S. Patent No. 11,298,056

PATENT OWNER'S PRELIMINARY RESPONSE

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2001	Gross Declaration in IPR2023-01251
2002	Defendant's Answering Claim Construction Brief, C.A. No. 21-977-KAJ (Aug. 3, 2022)
2003	Memorandum Opinion, Claim Construction, C.A. No. 21-977-KAJ (Mar. 22, 2023)
2004	FDA Approves DexCom G5® Mobile Continuous Glucose Monitoring System
2005	Discover Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) System
2006	iPhone User Guide for iOS 8.4 Software

CLAIM LISTING

Claim / Element	Claim Language
1.Pre	A glucose monitoring system for backfilling data gaps that occur while a user monitors glucose levels, the glucose monitoring system comprising:
1.A	a glucose sensor, a portion of which is configured to be positioned under skin of the user, wherein the glucose sensor is configured to sample a biological fluid of the user to provide sensor data;
1.B	a data processing and transmitter unit coupled to the glucose sensor, the data processing and transmitter unit comprising a power supply, a processor of the data processing and transmitter unit, memory of the data processing and transmitter unit, and a radio frequency transceiver of the data processing and transmitter unit,
1.C	wherein the data processing and transmitter unit is configured to: receive the sensor data from the glucose sensor and store the sensor data in the memory of the data processing and transmitter unit;
1.D	process the sensor data using calibration data to provide processed sensor data, wherein the calibration data comprises data associated with a sensitivity of the glucose sensor, and wherein the processed sensor data is stored in the memory of the data processing and transmitter unit; and
1.E	transmit the processed sensor data over a Bluetooth wireless communication link using the radio frequency transceiver of the data processing and transmitter unit; and
1.F	a receiver unit comprising a processor of the receiver unit, memory of the receiver unit, a radio frequency transceiver of the receiver unit, an antenna, and a display,
1.G	wherein the receiver unit is configured to: receive, using the antenna and the radio frequency transceiver of the receiver unit, the processed sensor data over the Bluetooth wireless communication link,

1.H	output to the display of the receiver unit, a numerical value representing the processed sensor data,
1.I	output to the display of the receiver unit, a first line graph that is a substantially continuous depiction of the processed sensor data over time,
1.J	wherein the glucose monitoring system is configured to detect an adverse condition, wherein the adverse condition results in the receiver unit displaying a data gap such that the first line graph displayed on the receiver unit has an end corresponding to a time associated with a start of the adverse condition;
1.K	wherein, during a time period corresponding to the adverse condition, sensor data, processed sensor data, or both, are stored in the memory of the data processing and transmitter unit;
1.L	wherein the receiver unit is configured to output to the display, after the adverse condition is corrected, processed sensor data for the time period corresponding to the adverse condition such that the data gap is backfilled, and
1.M	wherein the processed sensor data for the time period corresponding to the adverse condition that is outputted to the display after the adverse condition is corrected comprises a second line graph having a first end corresponding to the time associated with the start of the adverse condition and a second end corresponding to a time associated with an end of the adverse condition.
2	The glucose monitoring system of claim 1, wherein the first line graph and the second line graph are outputted to a same graph comprising a first axis having a time unit of measurement and a second axis having a glucose concentration unit of measurement.
3	The glucose monitoring system of claim 1, wherein the adverse condition comprises a sensor communication error.
4	The glucose monitoring system of claim 1, wherein the adverse condition comprises a signal error associated with the glucose sensor.

5	The glucose monitoring system of claim 1, wherein the adverse condition comprises a signal error associated with the data processing and transmitter unit.
6	The glucose monitoring system of claim 1, wherein the adverse condition comprises a signal error associated with the receiver unit.
7	The glucose monitoring system of claim 1, wherein the adverse condition comprises a system malfunction associated with the data processing and transmitter unit or a system malfunction associated with the receiver unit.
8	The glucose monitoring system of claim 1, wherein the adverse condition comprises an inability of the receiver unit to display or output at least a portion of [the] first line graph.
9	The glucose monitoring system of claim 1, wherein the adverse condition comprises a sensor instability condition.
10	The glucose monitoring system of claim 1, wherein the adverse condition comprises a calibration failure condition.
11	The glucose monitoring system of claim 1, wherein the adverse condition comprises a monitoring system failure condition.
12	The glucose monitoring system of claim 1, wherein the glucose sensor comprises a working electrode and a counter electrode.
13	The glucose monitoring system of claim 1, wherein the adverse condition comprises a sensor misposition error.
14	The glucose monitoring system of claim 1, wherein the on body unit further comprises a temperature sensor, and wherein the adverse condition comprises a temperature measurement outside a predetermined range.
15	The glucose monitoring system of claim 1, wherein the adverse condition comprises an analyte level exceeding a predetermined threshold.
16	The glucose monitoring system of claim 1, wherein the adverse condition comprises a rate of change of an analyte level exceeding a predetermined threshold.
17	The glucose monitoring system of claim 1, wherein the adverse condition comprises a data unavailability condition.

18	The glucose monitoring system of claim 1, wherein the receiver unit is further configured to display the second line graph immediately after the correction of the adverse condition.
19	The glucose monitoring system of claim 1, wherein the receiver unit is further configured to wait a predetermined period of time after the correction of the adverse condition before displaying the second line graph.
20	The glucose monitoring system of claim 1, wherein the data processing and transmitter unit, the receiver unit, or both is further configured to store time information associated with the adverse condition.
21	The glucose monitoring system of claim 1, wherein the data processing and transmitter unit and at least a portion of the glucose sensor are disposed within a single integrated housing.
22	The glucose monitoring system of claim 1, wherein the receiver unit comprises a mobile phone.
23	The glucose monitoring system of claim 1, wherein the time period associated with the adverse condition comprises at least one hour.
24	The glucose monitoring system of claim 1, wherein the glucose monitoring system is further configured for periodic calibration, and wherein the calibration data is based at least in part on glucose reference data received after the portion of the glucose sensor has been positioned under the skin of the user.
25	The glucose monitoring system of claim 24, wherein the adverse condition comprises a signal error associated with the blood glucose reference data.
26	The glucose monitoring system of claim 24, wherein the glucose monitoring system is further configured for calibration twelve hours after the portion of the glucose sensor has been positioned under the skin of the user.
27	The glucose monitoring system of claim 1, wherein the data processing and transmitter unit is configured to transition from a low-power mode to an operating mode, and wherein the data processing and transmitter unit consumes more

	power from the power supply in the operating mode than in the low-power mode.
28	The glucose monitoring system of claim 1, wherein the power supply of the data processing and transmitter unit is configured to provide power for about three months of continuous operation.
29	The glucose monitoring system of claim 1, further comprising a secondary receiver unit, wherein the secondary receiver unit is configured to include a limited number of functions as compared with the receiver unit, wherein the secondary receiver unit is configured to receive processed sensor data from the data processing and transmitter unit, and wherein the secondary receiver unit is a watch.
30	The glucose monitoring system of claim 1, wherein the glucose sensor is further configured to continuously sample the biological fluid of the user to provide the sensor data.

I. INTRODUCTION

Patent Owner Abbott Diabetes Care Inc. submits this Preliminary Response to the Petition filed by DexCom, Inc. (“Petitioner”) requesting *inter partes* review of claims 1-30 (the “Challenged Claims”) of U.S. Pat. No. 11,298,056 (the “056 Patent”). For at least the following reasons, the Petition fails to show there is a reasonable likelihood that Petitioner would prevail with respect to any Challenged Claim. Therefore, institution should be denied.

The Board should deny institution without even reaching Petitioner’s prior art challenges. All the challenges hinge on failed attacks against the 056 Patent’s priority claim to its grandparent application (“GP Application”) and rely exclusively on references that postdate the GP Application. Petitioner is thus litigating §112 under the guise of *inter partes* review, and the §112 issues raised are not typical. Indeed, Petitioner argues that numerous “features” it conjures up, which are not recited in the claims, are allegedly “encompassed by” them and lack written description (“WD”) and enablement support in the GP Application. Petitioner’s §112 arguments are meritless for several reasons.

First, contrary to the Petition, the law does not require a specification to disclose or enable, in complete detail, every possible feature or variant that Petitioner could dream up as “encompassed” by the claims. Indeed, the inventor need not describe “every conceivable and possible future embodiment of his invention”; the

inventor may instead describe “a broadly claimed invention without describing all species that [the] claim encompasses.” *Cordis v. Medtronic Ave*, 339 F.3d 1352, 1365 (Fed. Cir. 2003). Petitioner’s approach of identifying fringe embodiments encompassed by the Challenged Claims that purportedly lack support in the GP Application fails as a matter of law.

Second, Petitioner ignores that the WD and enablement requirements turn on the knowledge and skill of a POSITA, the predictability of the relevant technology, and the criticality of the allegedly undisclosed subject matter. *Ariad Pharms. v. Eli Lilly*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). Petitioner’s failure to explain how the GP Application would be understood by a POSITA in view of these factors is another reason its arguments fail as a matter of law. In fact, many of Petitioner’s arguments about what POSITAs would not have known or been able to accomplish are undermined by opinions from its own expert about the knowledge and skill of a POSITA (and at a much earlier date) in a concurrent IPR against the 056 Patent.¹

Third, Petitioner’s fringe examples are based largely on misinterpretations of the claims. When the claims are viewed in their proper scope, they are fully supported by the GP Application. For example, Petitioner misconstrues the term, “sensor data, processed sensor data, or both, are stored,” and contends that the GP

¹ IPR2023-01251 (the “1251 IPR”).

Application must support “three different modes of operation,” including one in which the transmitter stores processed sensor data but not the underlying sensor data. Pet. at 14. The system does not operate in a separate mode in which one data type must be stored to the exclusion of the other. The Challenged Claims are directed to a system that can store both data types, which Petitioner does not dispute is described in the GP Application.

Fourth, Petitioner fails to recognize that the Challenged Claims would not necessarily be deprived of WD and enablement support in the GP Application even if Petitioner’s fringe examples might result in inoperative embodiments. *Allergan v. BTL Healthcare Techs.*, PGR2021-00020, Paper 16 at 22 (P.T.A.B. June 16, 2021) (“[T]he mere existence of [inoperative] embodiments does not necessarily negate enablement.”); *Ex Parte Kundra*, 2017 Pat. App. LEXIS 471, at *17 (P.T.A.B. Jan. 26, 2017) (an inoperative embodiment encompassed by the claims “does not ... demonstrate a lack of written description”).

Finally, Petitioner is wrong that the Challenged Claims “pluck claim elements from disparate parts” of the GP Application, and lack “blaze marks” to the claimed combination. On the contrary, an objective review of the GP Application from the perspective of a POSITA shows that each claimed feature is described as part of a complete, integrated invention.

When the correct legal standards and claim constructions are applied, it is clear that the GP Application provides §112 support for the Challenged Claims. Thus, the Challenged Claims are entitled to the priority date of the GP Application and cannot be obvious over the publication of that application. Accordingly, the Board should deny institution.

II. BACKGROUND

A. Summary of the 056 Patent

The 056 Patent relates to continuous glucose monitors (“CGM”). CGMs continuously monitor blood sugar in the body, called glucose, and are relied upon by diabetics to manage their glucose levels. Diabetes results in glucose levels that can cause severe health problems.

Historically, glucose monitoring involved “fingerstick” measurements. These required pricking and drawing blood from a finger, putting the blood on a test strip, inserting it into a monitor, and waiting for a test value. That method was painful and invasive and had to be repeated frequently. Consequently, patients would not do all the fingersticks needed to adequately monitor their glucose levels and prevent the disease’s progression.

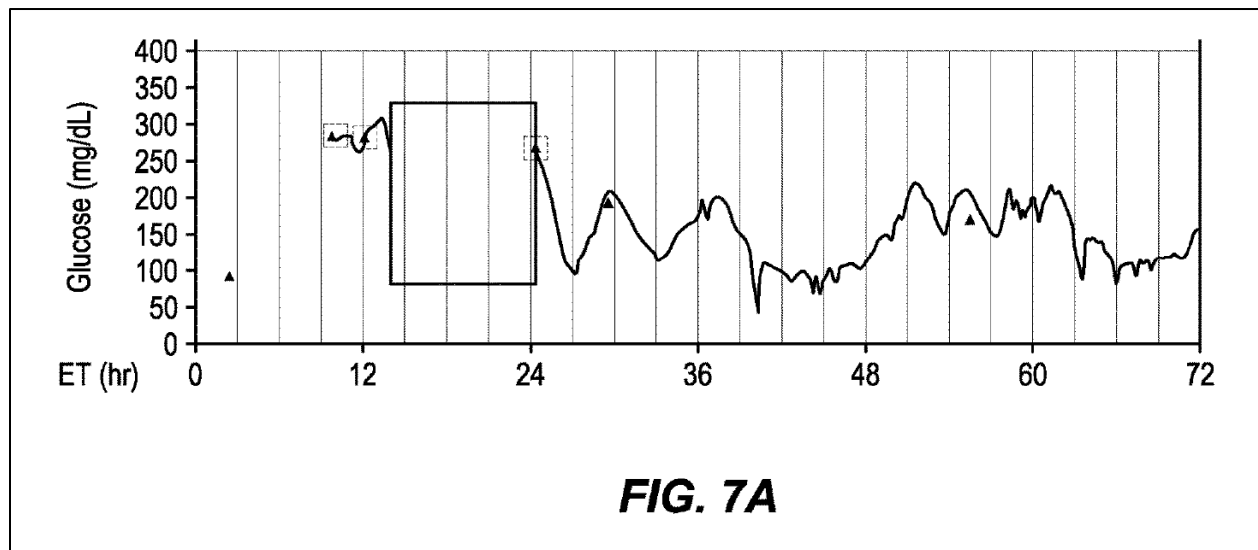
The 056 Patent describes and claims a glucose monitoring system for backfilling data gaps that occur while a user monitors glucose levels. Ex. 1201 at 12:40-13:38, 15:24-26, FIG. 1. The claimed system comprises “a glucose sensor”

and “a data processing and transmitter unit coupled to the glucose sensor.” *Id.* at 4:56-5:3, 15:27-32, FIGS. 1, 2. A portion of the sensor is “configured to be positioned under skin of the user” and “sample a biological fluid of the user to provide sensor data.” *Id.* at 5:48-67, 11:26-49, 15:27-30. The data processing and transmitter unit comprises “a processor,” “memory,” and “a radio frequency transceiver.” *Id.* at 4:56-5:3, 6:1-18, 7:34-57, 8:28-40, 15:31-36, FIG. 2. The claimed glucose monitoring system further comprises “a receiver unit,” which includes “a processor,” “memory,” “a radio frequency transceiver,” “an antenna,” and “a display.” *Id.* at 4:56-5:3, 6:19-33, 9:42-10:58, 15:52-54, FIG. 3.

In operation, the data processing and transmitter unit is configured to receive “sensor data from the glucose sensor and store the sensor data in the memory of the data processing and transmitter unit.” *Id.* at 8:28-40, 15:39-41. It is further configured to “process the sensor data using calibration data to provide processed sensor data, wherein the calibration data comprises data associated with a sensitivity of the glucose sensor, and wherein the processed sensor data is stored in the memory of the data processing and transmitter unit.” *Id.* at 2:14-30, 10:59-11:5, 12:9-25, 12:40-61, 15:42-47. The processed sensor data is transmitted “over a Bluetooth wireless communication link.” *Id.* at 5:48-67, 7:20-33, 15:48-51, FIG. 1. The receiver unit is configured to receive “the processed sensor data over the Bluetooth wireless communication link” and output to the display “a numerical value

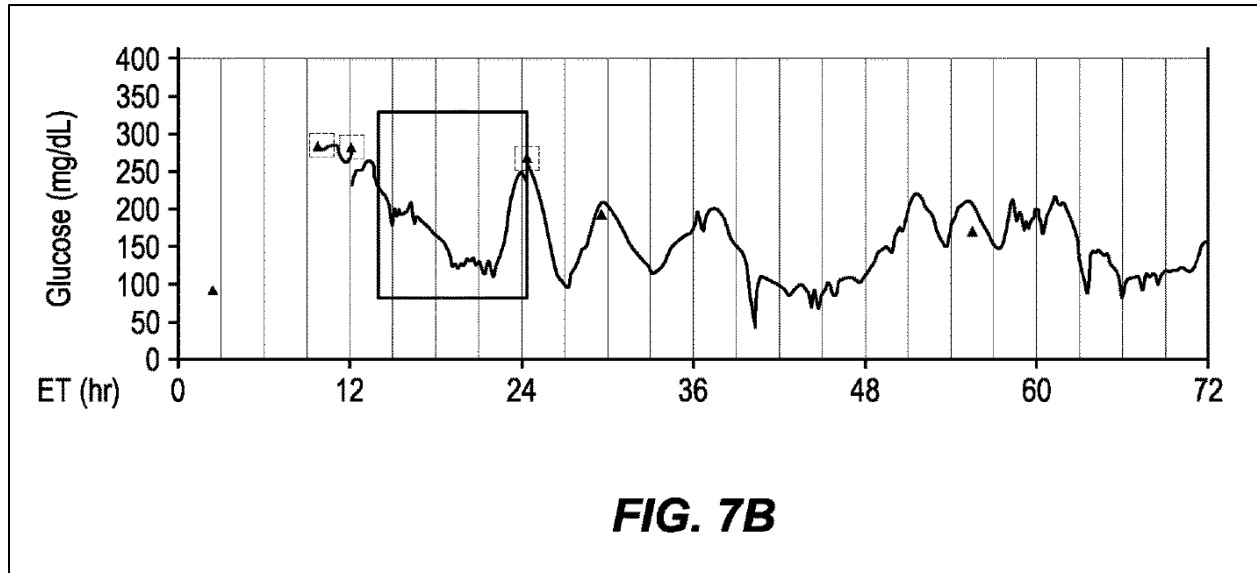
representing the processed sensor data” and “a first line graph that is a substantially continuous depiction of the processed sensor data over time.” *Id.* at 5:48-67, 6:19-33, 7:20-33, 11:50-64, 15:56-64.

As the user monitors their glucose levels, the claimed monitoring system is “configured to detect an adverse condition” that “results in the receiver unit displaying a data gap.” *Id.* at 1:60-2:30, 6:19-33, 9:29-41, 10:49-59, 11:6-25, 12:26-39, 15:65-16:3. An example is shown in FIG. 7A below.



The specification explains that adverse conditions can include “for example, [an] inability to promptly calibrate the sensor, system malfunction, sensor dislodging, signal errors associated with the sensor, transmitter unit, receiver unit, and the like, or any other variables or parameters that result in the inability of the analyte monitoring system to display or output the real-time monitored analyte level.” *Id.* at 13:19-27.

As claimed, “during a time period corresponding to the adverse condition, sensor data, processed sensor data, or both, are stored in the memory of the data processing and transmitter unit.” *Id.* at 8:28-40, 12:9-25, 14:39-55, 16:4-7. After the adverse condition is corrected, the receiver unit outputs to its display the “processed sensor data for the time period corresponding to the adverse condition such that the data gap is backfilled.” *Id.* at 11:50-64, 12:40-13:5, 14:39-55, 16:8-12, Fig. 7B. An example is illustrated in FIG. 7B below.



Thus, the improved monitoring system of claim 1 is able to recover and display glucose data from the time period associated with an adverse condition, thereby providing the user with a more complete view of their glucose levels. *Id.* at 12:54-61, 13:27-30.

B. Prosecution of the 056 Patent

Petitioner argues that “the Office did not address whether the claims lack Section 112(a) support in the Grandparent App.” Pet. at 4. This assertion is not based on any facts of record and contradicts the presumption that examiners have done their jobs, including a thorough analysis of the WD and enablement requirements. MPEP § 706.03; *Amgen v. Hoechst Marion Roussel*, 314 F.3d 1313, 1327 (Fed. Cir. 2003) (“We must presume the examiner did his job, and if he truly thought that the specification taught or enabled only the use of exogenous DNA, the asserted claims would not have issued.”). This presumption is reflected in the Patent Act. 35 U.S.C. § 282; *Cellspin Soft v. Fitbit*, 927 F.3d 1306, 1319 (Fed. Cir. 2019).

Unlike situations where an IPR challenger brings new prior art to the Office’s attention, which can cast doubt on the presumption of validity, examiners have all of the facts before them for §112 analyses. Here, the same examiner examined all eight applications in the 056 Patent family. He did not reject the 056 Patent claims under §112, nor did he find that the claims lacked priority to the GP Application and were therefore invalid over it. Petitioner thus flips the law on its head and ***presumes that the examiner did not do his job***, and overlooked the countless §112 issues raised in the Petition. The Board should reject Petitioner’s inverted presumption that flouts statute and precedent.

III. OVERVIEW OF PETITION CHALLENGES

The Petition advances two grounds against the Challenged Claims:

Ground	Claims	Basis
1	1-21, 23-30	Allegedly obvious under 35 U.S.C. § 103(a) over U.S. 2019/0216373 (“Harper”), US 2012/0108931 (“Taub/Harper”), and US 2013/0127627 (“Hayter/Taub”)
2	22	Allegedly obvious under 35 U.S.C. § 103(a) over Harper, Taub/Harper, Hayter/Taub, and US 2014/0176338 (“He/Taub”)

The primary reference in both grounds—Harper—is the publication of the GP Application. The GP Application and the 056 Patent have essentially identical specifications. Petitioner, however, argues that the GP Application lacks WD and enablement support for features “encompassed” by the Challenged Claims and, therefore, those claims are obvious over Harper in view of the other references. Accordingly, Petitioner’s Grounds rise or fall with its §112 arguments.

IV. LEVEL OF SKILL IN THE ART

For purposes of this Preliminary Response, Patent Owner does not dispute that POSITAs would have the education and technical background set forth in the Petition as of the critical date, December 21, 2018. *See* Pet. at 26. However, this definition does not include additional experience that POSITAs would have according to Petitioner’s declarant in the 1251 IPR, including that “POSITAs may be part of an interdisciplinary team with others having relevant experience in the

areas set forth above and/or with clinicians involved in diagnosis, treatment, and patient management relevant to the use of medical devices for monitoring physiological signals.” Ex. 2001 ¶¶51-52. For purposes of this Response, Patent Owner does not dispute that POSITAs would also have this additional experience as of December 21, 2018.

V. CLAIM CONSTRUCTION

A. “an adverse condition”

Challenged Claim 1 recites that the glucose monitoring system is “configured to detect an adverse condition.” Ex. 1201 at 15:65-66. Petitioner asserts that the dependent claims and/or specification of the 056 Patent disclose 17 specific adverse conditions and, therefore, “the full scope of ‘adverse condition’ ... should be construed to include” those 17 adverse conditions. Pet. at 27.

To the extent Petitioner contends that “adverse condition” should be construed to require all 17 of those conditions, Petitioner is wrong. “Adverse condition” should be construed to mean “one or more adverse conditions.” Claim 1 does not recite any specific adverse condition, and the construction of a claim term is not a list of everything it could possibly encompass. *Nissan N. Am. v. Diamond Coating Techs.*, IPR2014-01546, Paper 49 at 12 (P.T.A.B. Apr. 20, 2016). Thus, while “adverse condition” *encompasses* each of the specific adverse conditions identified, it does not require each or even any of them.

B. “sensor data, processed sensor data, or both, are stored”

Although not identified in the Petition’s “Claim Construction” section, the Petition nevertheless construes “sensor data, processed sensor data, or both, are stored” as recited in claim 1. According to Petitioner, this claim term “encompasses three different modes of operation during the adverse-condition time period.” Pet. 13-14. In a first mode, the transmitter allegedly stores sensor data, but not processed sensor data. *Id.* In a second mode, the transmitter allegedly stores processed sensor data, but not sensor data. *Id.* In a third mode, the transmitter allegedly stores both sensor data and processed sensor data. *Id.* Petitioner relies on this construction to argue that each alleged mode is distinct and must be separately disclosed in the GP Application for priority, and that the alleged second mode “is particularly problematic.” *Id.* at 14.

Petitioner’s argument mischaracterizes what this claim limitation means and what it encompasses. Claim 1 is directed to a system where the type of data stored relates to the nature of the adverse condition at issue. The 056 Patent specification teaches that “gaps in monitored analyte levels using an analyte monitoring system” can be “due to, for example, [an] inability to promptly calibrate the sensor, system malfunction, sensor dislodging, signal errors associated with the sensor, transmitter unit, receiver unit, and the like, or any other variables or parameters that result in the inability of the analyte monitoring system to display or output the real-time

monitored analyte level.” Ex. 1201 at 13:19-27. The missing data “may be retrospectively *filled* or *reprocessed* so that the data gap is closed and [the] continuously monitored analyte level does not have any or substantially [any] missing data.” *Id.* at 13:27-30 (emphasis added).

Adverse conditions in which the missing data is “*retrospectively filled*” relate to situations when the sensor data was correctly processed, and the processed sensor data is accurate, but it cannot be output to the receiver’s display. One example is when signal errors cause the Bluetooth wireless signal to break down such that the receiver does not receive at least a portion of the processed sensor data. In such circumstances, the transmitter need only store the processed sensor data to “retrospectively fill[]” the data gap, although it may also store the underlying sensor data.

Adverse conditions in which data is “*retrospectively ... reprocessed*” relate to situations where the processed sensor data was not accurate and therefore was not output to the display. For example, in the context of a calibration issue, the 056 Patent specification teaches that “the display or output of processed sensor data may be disabled if a required calibration event is unsuccessful over a permitted time period.” Ex. 1201 at 12:26-28, 12:10-13 (if “the sensor 101 is not calibrated ... the primary receiver unit stores the analyte related sensor data ... and temporarily disables display of the sensor data”). “[B]ased on the parameters associated with [a

subsequent] successful calibration, the previously unprocessed data during the display time out period may be retrieved ... and processed using calibration data.” *Id.* at 12:48-52. As a result, “the gap in the output display illustrating the processed and calibrated signals may be filled.” *Id.* at 12:59-61. Accordingly, where the nature of the adverse condition causes the processed sensor data to be inaccurate such that the sensor data must be “reprocessed,” the system of claim 1 stores unprocessed “sensor data.”

The examples above illustrate why the system of claim 1 stores both “sensor data” and “processed sensor data” in certain circumstances (*i.e.*, “or both”). For example, in the event that two consecutive adverse conditions occur, one that impacts the accuracy of data and calls for reprocessing sensor data (*e.g.*, calibration failure), and one that subsequently impacts the ability of the receiver to output processed sensor data (*e.g.*, wireless communication failure), the system of claim 1 stores both.

Thus, when claim 1 is viewed in light of the specification, it is clear that the claimed system “is configured to detect an adverse condition,” and, based on the nature of the adverse condition(s) detected, “sensor data, processed sensor data, or both, are stored in the memory of the data processing and transmitter unit.” Ex. 1201 at 15:65-66, 16:4-7. Stated differently, the system stores the data type needed to address the detected adverse condition(s).

Thus, the correct construction of this limitation is (i) storing at least sensor data, (ii) storing at least processed sensor data, or (iii) storing both. The system does not operate in a separate mode in which one type of data must be stored to the exclusion of the other, where the only stored data is bad or inaccurate, as Petitioner's construction requires. Petitioner's view that the alleged "three modes" are mutually exclusive is therefore incorrect.

Indeed, claim 1 uses the transitional phrase "comprising," which "is well understood to mean 'including but not limited to' ... [and] to signify that the claims do not exclude the presence in the accused device or method of factors in addition to those explicitly recited." *CIAS v. Alliance Gaming*, 504 F.3d 1356, 1360 (Fed. Cir. 2007). Thus, with "comprising" claims, there is a presumption that the recited elements are only part of the device, and that the claim does not exclude additional, un-recited elements. *Crystal Semiconductor v. TriTech Microelecs. Int'l*, 246 F.3d 1336, 1348 (Fed. Cir. 2001).

Moreover, when "or" is used in a claim, it is usually interpreted as inclusive, and not exclusive, *i.e.*, just A or just B. *B-50.com v. InfoSync Servs.*, 2014 WL 285096, at *6 (N.D. Tex. Jan. 27, 2014) ("In its inclusive sense, 'or' means 'A or B, or both.' ... In its exclusive sense, 'or' means 'A or B, but not both.' ... Although 'or' is used in both senses ... '[t]he meaning of *or* is usually inclusive.'"); *Teva Pharms. v. Eli Lilly*, 2021 WL 723337, at *11-13 (D. Mass. Feb. 24, 2021).

That the claims encompass adverse conditions that do not impact the system's ability to process sensor data, allowing for the storage of processed sensor data in some circumstances, is reinforced by the district court's claim construction in ongoing litigation where Patent Owner is asserting patents related to the 056 Patent. There, Petitioner argued that the (nearly-identical) specification of the related patents did not support wireless communication failures as provided in the example above. Ex. 2002 at 46-47. Specifically, Petitioner argued that the term "failure mode condition," which is used in those patents instead of "adverse condition," should be construed to mean a "condition that requires disabling the output of sensor data." *Id.* at 46. In support, Petitioner argued that the claims were limited to data gaps caused only when "one or more conditions ... may result in **unreliable** data." *Id.*

The Court disagreed. Pointing to several claims, including those reciting signal errors associated with the transmitter or receiver unit, the Court explained that these claims "suggest[ed] a definition of 'failure mode condition' that reaches wider than 'a condition that requires disabling the output of sensor data' because they recite conditions adversely affecting function without any requirement of the disabling of output data." Ex. 2003 at 31. The Court further explained that these claims "suggest that a wireless communication error constitutes a 'failure mode condition,' directly countering [Petitioner's] construction." *Id.* at 31, 35-36.

Consistent with the Court’s understanding of the specification and the plain language of the claims, the claimed “adverse conditions” in the 056 Patent include scenarios where the sensor data is accurately calibrated, but cannot be output to the display, such as in the case of a “signal error” as recited in claim 4. Hence, the system of claim 1 encompasses scenarios in which the system need only store “processed sensor data” in order to “retrospectively fill[]” data gaps.

Petitioner’s “exclusive” construction is wrong for another reason. Petitioner argues that the GP Application does not provide WD or enablement support because it does not disclose an embodiment where the transmitter stores processed sensor data without storing sensor data during an adverse condition period. Pet. at 20-27, 33, 36. But if that is the case, then Petitioner’s proposed construction cannot be correct because claims should not be construed to exclude the embodiments in the specification. *Hyperphrase Techs. v. Google*, 260 Fed. Appx. 274, 280 (Fed. Cir. 2007). Therefore, should the Board agree with Petitioner that the GP Application lacks §112 support for a transmitter that stores processed sensor data, but not sensor data, during an adverse condition, the Board should likewise reject Petitioner’s interpretation of this “storing” limitation because it excludes all disclosed embodiments.

For purposes of this Preliminary Response, Patent Owner does not construe any other claim terms of the 056 Patent, but reserves the right to propose new or additional constructions in this or other proceedings.

VI. THE GP APPLICATION PROVIDES WRITTEN DESCRIPTION AND ENABLEMENT SUPPORT FOR THE CHALLENGED CLAIMS

Petitioner has not met its burden of persuasion to show that the GP Application lacks WD and enablement support for the Challenged Claims and, thus, that Harper is prior art to, and renders obvious, the Challenged Claims. In an IPR, “the burden of persuasion is on the petitioner to prove ‘unpatentability by a preponderance of the evidence,’ ... and that burden never shifts to the patentee.” *Dynamic Drinkware v. Nat’l Graphics*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). Thus, Petitioner has the ultimate burden of persuasion on whether Harper qualifies as prior art, and that burden does not shift to Patent Owner even if the burden of production on the issue does. *Flex Logix Techs. v. Venkat Konda*, IPR2020-00260, Paper 55 at 14 (P.T.A.B. July 29, 2021). Patent Owner’s “burden of production may be met either by ‘producing additional evidence’ or by ‘presenting persuasive argument based on new evidence or evidence already of record.’” *Google v. IPA Techs.*, 34 F.4th 1081, 1085 (Fed. Cir. 2022). In this case, the evidence shows that the Challenged Claims have WD and enablement support in the GP Application.

A. Petitioner’s Challenges Rely On Misapplications Of Settled Written Description And Enablement Law

Petitioner’s strategy is transparent: conjure up extreme examples of hypothetical embodiments that Petitioner contends are covered by the Challenged Claims and then argue that the GP Application lacks §112 support for those examples. *See* Pet. at 8-28. Taking Petitioner’s approach to its illogical conclusion, Petitioner also could have argued that claim 1 “encompasses” an indestructible sensor and that, because the GP Application does not disclose a sensor that is impossible to destroy, the claims are not entitled to claim priority to the GP Application. That is essentially the type of arguments the Petition is premised on, but such arguments are contrary to settled law. Indeed, Petitioner misapplies precedent and ignores aspects of it that refute Petitioner’s approach.

1. The Correct Written Description Standard Supports Patent Owner

a. Petitioner Misapplies Written Description Law

To support its argument that the fringe embodiments it identifies must be found in the GP Application for the Challenged Claims to have priority to that application, Petitioner quotes the Federal Circuit in asserting that a disclosure “must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed” such that “the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad*, 598 F.3d at 1351; Pet. at 31.

According to Petitioner, because the fringe embodiments are purportedly “claimed subject matter” that is found nowhere in the GP Application, the GP Application cannot show the inventor “had possession of the claimed subject matter as of the filing date” of the GP Application. But Petitioner ignores case law defining **how** to determine whether a disclosure reasonably conveys to a POSITA that the inventor possessed the claimed subject matter.

For example, it “is in itself of no moment” that “a claim may be broader than the specific embodiment disclosed in a specification.” *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1124 (Fed. Cir. 2004). Indeed, the inventor need not describe “every conceivable and possible future embodiment of his invention”; instead, a “specification may ... contain a written description of a broadly claimed invention without describing all species that [the] claim encompasses.” *Cordis*, 339 F.3d at 1365. Further, “[a] claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language.” *LizardTech v. Earth Res. Mapping*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) “That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before.” *Id.*

Thus, “it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art

that the inventor possessed the invention.” *Id.*; see *Ariad*, 598 F.3d at 1352 (WD requirement “does not demand either examples or an actual reduction to practice” or “any particular form of disclosure ... or that the specification recite the claimed invention *in haec verba*”).

Accordingly, Petitioner’s argument that the GP Application must explicitly disclose all of Petitioner’s fringe examples encompassed by the full scope of the claims is contrary to law. See *PNC Bank v. United Servs. Automobile Ass’n*, IPR2021-01071, Paper 21 at 17 (P.T.A.B. Jan. 10, 2022) (Petitioner’s contention that an application lacks WD support for a claim “*merely because* the scope of the claim includes a configuration that is not expressly described in that document ... reflects a misunderstanding of the law—a claim *can* be broader than the embodiments disclosed”); *3Shape A/S v. Align Tech.*, IPR2021-01120, Paper 15 at 20 (P.T.A.B. Jan. 11, 2022) (“Ancestral Applications can provide written description support for the challenged claims without specifically disclosing an embodiment” encompassed but not required by the claims).

Importantly, “the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.” *Ariad*, 598 F.3d at 1351. The following factors should be considered for evaluating the adequacy of the disclosure: “the existing knowledge in the particular field, the extent and content of

the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.” *Id.* “[W]hen the field of the invention is a ‘predictable art,’ involving a mature technology such as electrical or mechanical arts”—**like here**—“and where the knowledge and level of skill in the art is high”—**like here**—“a lower level of detail is required to satisfy the written description requirement.” *Renesas Elecs. v. Broadcom*, IPR2019-01040, Paper 35 at 59 (P.T.A.B. Nov. 12, 2020). Here, Petitioner fails to address the predictability of the art or analyze how the level of skill at the GP Application’s filing date impacts how a POSITA would understand and implement that Application’s teachings. That failure is a sufficient basis to deny the Petition. *Thermo Fisher Scientific v. The Regents of the Univ. of Calif.*, IPR2018-01347, Paper 10 at 24, 33 (P.T.A.B. Jan. 22, 2019) (finding petitioner failed to show, “for the purpose of institution,” that earlier applications lacked WD support because petitioner did not address the predictability of the art); *Bilstad*, 386 F.3d at 1126 (vacating Board’s decision on WD because it “erred in failing to consider knowledge of one skilled in the art and the level of predictability in the field”).

Another important factor is whether an allegedly unclaimed limitation is “critical to,” *In re Global IP Holdings*, 927 F.3d 1373, 1376-77 (Fed. Cir. 2019), or the “heart of the invention.” *PNC Bank*, IPR2021-01071, Paper 21 at 18-19 (rejecting argument that priority application disclosing *separate* mobile and image capture devices lacked WD support for a claim that *encompassed* an *integrated*

mobile and image capture device because the application did not suggest that separate devices was the “heart of the invention” and was “agnostic to whether” such devices are separate or integrated); *Ethicon Endo-Surgery v. U.S. Surgical*, 93 F.3d 1572, 1582 n.7 (Fed. Cir. 1996) (“If [the applicant] did not consider the precise location of the lockout to be an element of his invention, he was free to draft [his claim] broadly ... to exclude the lockout’s exact location as a limitation. ... Such a claim would not be unsupported by the specification even though it would be literally infringed by undisclosed embodiments.”); *Medtronic v. Teleflex Innovations*, 69 F.4th 1341, 1354 (Fed. Cir. 2023) (similar).

Here, Petitioner focuses on a litany of purportedly undisclosed “features” without considering whether any is “critical to” or the “heart of the invention,” or even whether they were already within the knowledge of a POSITA. Indeed, as described below, many of Petitioner’s arguments about what a POSITA would not have known or been able to glean from the GP Application contradict its expert’s opinions about the level of skill in the art almost a decade before the GP Application’s filing date. *See* Section VI.B.1, *infra*. The Petition thus fails as a matter of law for this additional reason.

b. Petitioner’s Case Law Does Not Support Its Written Description Arguments

Petitioner’s cases are not apt. In each, the specification limited the invention to include specific limitations not recited in the claims, which resulted in a finding

that the scope of the claims was not supported by the specification. *See* Pet. at 31-33.

For example, in *D Three Enterprises v. SunModo*, 890 F.3d 1042 (Fed. Cir. 2018), the priority application did not disclose a specific bracket as an “optional feature” or “contemplate[] the use of other types of attachment brackets in a washerless assembly,” nor did it disclose “an assembly with a washer below the flashing” or a “statement on the flexibility of the position of the washer.” *Id.* at 1047-52. Similarly, in *Tronzo v. Biomet*, 156 F.3d 1154 (Fed. Cir. 1998), the generically claimed “cup” lacked WD support because the specification “assert[ed] the advantages of the conical shape over prior art shapes” of cups. *Id.* at 1159. In *Gentry Gallery v. Berkline*, 134 F.3d 1473 (Fed. Cir. 1998), “the original disclosure clearly identifie[d] the console as the only possible location for the controls,” but the claims did not limit the location of the controls. *Id.* at 1479. In *Atl. Rsch. Mktg. Sys. v. Troy*, 659 F.3d 1345 (Fed. Cir. 2011), a claim was construed to cover a handguard accessory for a rifle that was “supported solely by clamping to the barrel nut,” but the specification “[did] not disclose an invention where the yoke/barrel nut attachment point provides *complete* support for the handguard accessory.” *Id.* at 1353-54.

Unlike its cited cases, Petitioner does not assert that the GP Application limits the scope of the disclosed inventions to require specific features that must be recited

in the claims for there to be WD support. Accordingly, Petitioner’s case law is not on point. *Crown Packaging Tech. v. Ball Metal Beverage Container*, 635 F.3d 1373, 1382 (Fed. Cir. 2011) (distinguishing *Tronzo* and other cases because they involved a “specification [that] unambiguously limited the scope of invention”).²

2. The Correct Enablement Standard Supports Patent Owner

Petitioner’s enablement arguments hinge on a selective and incomplete recitation of the law. Petitioner cites *Amgen v. Sanofi*, 143 S. Ct. 1243, 1254 (2023) for the proposition that “the specification must enable the full scope of the invention as defined by the claims.” Pet. at 35-36. Petitioner then argues that the GP Application lacks enablement support for the full scope of the Challenged Claims because it does not enable a POSITA to make or use an embodiment having features that ***are not even recited in the claim***. *Id.* at 36-39.

The law, however, is clear that “the specification need not include a working example of every possible embodiment to enable the full scope of the claims.” *Bayer*

² Petitioner relies on the institution decision in *Gillette v. Sphere USA* (Pet. at 1-2, 63), but the Board vacated that decision. PGR2022-00030, Paper 31 at 29-30, 35-37, 43 (P.T.A.B. Sept. 19, 2023) (finding WD support for feature encompassed by, but not recited in, the claims partly because the specification did not suggest the feature was critical to the invention).

HealthCare v. Baxalta, 989 F.3d 964, 982 (Fed. Cir. 2021). Indeed, the Petition omits the following important language from *Amgen*:

That is not to say a specification always must describe with particularity how to make and use every single embodiment within a claimed class. [I]t may suffice to give an example ... if the specification also discloses “some general quality ... running through” the class that gives it “a peculiar fitness for the particular purpose.” ... In some cases, disclosing that general quality may reliably enable a [POSITA] to make and use all of what is claimed, not merely a subset.

Nor is a specification necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing.

Amgen, 143 S. Ct. at 1255 (emphasis added). Therefore, that the GP Application might not explicitly describe a particular embodiment that Petitioner dreamed up does not undermine the sufficiency of its enabling disclosure.

The Federal Circuit has also explained that the “enablement requirement is often more indulgent than the written description requirement” and that the “specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without ‘undue experimentation.’” *Amgen v. Hoechst Marion Roussel*, 314 F.3d 1313, 1334 (Fed. Cir. 2003) (emphasis added). The Petition does not show that the GP Application fails to do this.

The “*Wands*” factors are used to assess whether a disclosure would require undue experimentation and include “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Moreover, “a considerable amount of experimentation is permissible,” *Wyeth & Cordis v. Abbott Labs.*, 720 F.3d 1380, 1386 (Fed. Cir. 2013), and even “extensive experimentation does not necessarily render the experiments unduly extensive where the experiments involve repetition of known or commonly used techniques.” *Cephalon v. Watson Pharms.*, 707 F.3d 1330, 1338 (Fed. Cir. 2013). Further, a “patent need not teach, and preferably omits, what is well known in the art.” *Spectra-Physics v. Coherent*, 827 F.2d 1524, 1534 (Fed. Cir. 1987). Notably, Petitioner does not even cite *Wands*, much less examine the relevant *Wands* factors in its enablement arguments.

At bottom, Petitioner’s argument appears to be that the Challenged Claims are not enabled because they encompass a “mode of operation” that is “particularly problematic” because it results in storing no sensor data or inaccurate sensor data in circumstances where the GP Application does “not describe or enable how to ‘reverse engineer’ the nature and extent of glucose-value errors caused by the

adverse condition so as to correct that error retrospectively and display accurate data.” Pet. at 14, 19. Petitioner’s “mode of operation” theory relies on an incorrect claim construction as discussed above, and further below. *See* Section V.B, *supra*; Section VI.B.1, *infra*. Even if Petitioner’s “mode of operation” theory were correct and the claims encompass the mode Petitioner relies upon, a claim does not lack enablement support just because it can encompass an inoperative embodiment. *Allergan*, PGR2021-00020, Paper 16 at 22.

Otherwise, the Petition includes only conclusory allegations that practicing the full scope of the claimed inventions would require undue experimentation, without ***any evaluation*** of the *Wands* factors. Petitioner’s failure to meet its burden of persuasion should be dispositive. *See McRO v. Bandai Namco Games Am.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020) (“Whether undue experimentation is required ‘is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.’”); *Hospira v. Genentech*, IPR2017-00739, Paper 16 at 15 (P.T.A.B. July 27, 2017) (finding Petitioner’s enablement argument unpersuasive partly because it failed to address *Wands*).

In sum, Petitioner selectively and incorrectly applies WD and enablement law while ignoring key aspects that show its analysis is misguided and incomplete. Accordingly, the Board should find Petitioner has not satisfied its burden.

B. The GP Application Provides Written Description and Enablement Support for the Challenged Claims

As shown below, when the correct legal standards and claim constructions are applied, the evidence demonstrates that the Challenged Claims have §112 support in the GP application.

Performing a WD and enablement analysis starts with defining the predictability of the art and the level of skill in the art. The inventions of the Challenged Claims are in the field of electronics, which is a predictable field. *PNC Bank*, IPR2021-01071, Paper 21 at 21. The skill level of a POSITA is high: a Bachelor's degree in biomedical, electrical, or computer engineering, and two years of industry experience or a Master's degree. Pet. at 26. And the issues of WD and enablement, including the state of the art, are viewed through the eyes of a POSITA as of December 21, 2018 for this proceeding because that is the GP Application's filing date.

With these factors in mind, Patent Owner now addresses Petitioner's specific WD and enablement arguments as best as they can be identified and understood.

1. “sensor data, processed sensor data, or both, are stored”

As discussed above, this claim term should be construed to mean (i) storing at least sensor data, (ii) storing at least processed sensor data, or (iii) storing both. *See supra* Section V.B. The GP Application discloses storing sensor data and processed sensor in the transmitter unit during an adverse condition and, thus,

provides §112 support for this “storing” limitation. To begin, the GP Application discloses an apparatus including:

[A]n interface configured to receive sensor data, a first memory configured to store the received sensor data, a processor coupled to the memory and configured to process the stored sensor data, a second memory coupled to the processor and configured to store the processed sensor data, and a display unit coupled to the second memory and configured to display the processed sensor data, wherein the processor is further configured to detect a condition unsuitable for calibration of a sensor for a predetermined time period, disable display of processed sensor data, determine a successful calibration of the sensor, retrieve one or more parameters associated with the successful calibration, process the sensor data during the time period of disabled display of sensor data with the one or more parameters associated with the successful calibration, and display the processed sensor data for the time period of disabled information output.

Ex. 1202 at [0077]. The GP Application also discloses that “once the system recovers after a successful calibration event, the calibrated sensor data is once again displayed (and stored). ... [T]he previously unprocessed data during the display time out period may be retrieved ... and processed using calibration data.” *Id.* at [0059] (emphasis added).

The GP Application further discloses that the transmitter unit includes a processor and “a memory ... for storing data such as ... data signals received from

the sensor unit 101.” *Id.* at [0041]. The transmitter unit can perform processing routines that the receiver unit performs, including storing sensor data, processing the sensor data “using calibration data,” and storing “the calibrated sensor data.” *Id.* at [0054]-[0059].

Thus, the GP Application explicitly discloses storing unprocessed and processed sensor data in the transmitter unit during the adverse condition period regardless of how long it lasts for, including 72 hours.³ To the extent Petitioner argues that the unprocessed and processed data are disclosed as being stored in different memories, claim 1 does not preclude that. Claim 1 recites “memory of the data processing and transmitter unit” and does not limit the physical implementation of that “memory.”

Moreover, Petitioner’s declarant in the 1251 IPR opines that a POSITA, *as of 2009*, nine years before the GP Application, would have been skilled in calibrating data and saving it to memory, and, in particular, would have:

- “had knowledge of signal processing ... and the knowledge and skills to smooth, filter, digitize, encode, condition, calibrate, and convert signals from a glucose sensor into calculated glucose concentration values, save these values in memory as necessary to perform processing and computations, and

³ Petitioner acknowledges that the GP Application teaches storing processed and unprocessed sensor data during the adverse condition period. Pet. at 21.

ultimately display these values numerically and graphically”;

- “been skilled in programing a microprocessor to run calibration, calculation, or filtering algorithms and other processing routines on glucose data ... [and] known how to program a microprocessor to store glucose data throughout processing, including ... calculated glucose values in various types of memory”; and
- “been skilled a[t] programming a microprocessor to respond to [adverse] conditions by ... prompting or delaying calibration, storing glucose data in memory.”

Ex. 2001 ¶¶54, 56 (emphasis added).⁴

In view of these skills attributed to a POSITA by Petitioner’s declarant, the POSITA would have understood from the GP Application how to make and use a transmitter unit that could store processed and unprocessed sensor data without undue experimentation.

For the sake of argument, even if claim 1 were construed to encompass storing processed data, but not unprocessed data, as Petitioner proposes, the GP Application describes and enables doing so. As discussed above and as Petitioner acknowledges, the GP Application describes storing sensor data and processed sensor data during

⁴ For purposes of this Preliminary Response, Patent Owner does not dispute that a POSITA would have had these skills in 2018.

an adverse condition. If both could be stored, only one could be stored, especially given the knowledge of a POSITA according to Petitioner’s declarants.

Even if storing only inaccurate processed data, but not the underlying sensor data, were (i) encompassed by the claims as Petitioner contends, and (ii) resulted in an inoperative embodiment (*e.g.*, where the adverse condition affects the reception or accuracy of the underlying sensor data), that inoperative embodiment does not necessarily deprive the GP Application of WD or enablement support. *See Allergan*, PGR2021-00020, Paper 16 at 22 (“[T]he mere existence of [inoperative] embodiments does not necessarily negate enablement.”); *Kundra*, 2017 Pat. App. LEXIS 471 at *17 (an inoperative embodiment encompassed by the claims “does not ... demonstrate a lack of written description”).

2. “output to the display ... processed sensor data for the time period corresponding to the adverse condition”

The GP Application also discloses this limitation: “Upon successful processing of the sensor data during the period of disabled output, the processed sensor data during this time period is backfilled, or the gap in the processed continuous sensor data are filled in the display (630). By way of an example, FIGS. 7A and 7B illustrate the replacement of a period of unprocessed sensor data with corresponding backfilled processed sensor data.” Ex. 1202 ¶[0060]. Further details are provided *infra* Section VI.B.8.

Petitioner argues that this limitation encompasses “displaying immediately after correction of the adverse condition, for each adverse condition, accurate glucose values for the entire adverse-condition period, despite:

- a. not having received glucose-measurement [*i.e.*, sensor] data from the sensor during that period due to the adverse condition;
- b. not having received accurate glucose-measurement [*i.e.*, sensor] data from the sensor during that period due to the adverse condition;
- c. not having stored accurate glucose-measurement [*i.e.*, sensor] data received from the sensor during that period; and/or
- d. having stored only inaccurate, calibrated glucose-measurement [*i.e.*, processed sensor] data during that period.”

Pet. at 14-15, 25-26. Petitioner then argues the GP Application does not have §112 support for doing so. *Id.* at 18-20.

Petitioner’s argument lacks merit for several reasons. First, items “c” and “d” stem from Petitioner’s faulty conclusion that claim 1 recites three distinct modes of operation. Again, the transmitter stores “sensor data, processed sensor data, or both” so that the missing data can be backfilled on the user’s display. *See* Section V.B. Petitioner’s items “c” and “d” are erroneous because they hinge on there being a distinct mode of operation in which the underlying sensor data was not stored, and only (inaccurate) processed sensor data was stored (*i.e.*, alleged “second mode”).

Second, to the extent Petitioner’s arguments are credited and they include a scenario in which no, or only inaccurate, sensor data is stored (*e.g.*, items “a” and “b”), Petitioner has merely identified an inoperative embodiment, which does not mean the limitation lacks support. *See Allergan*, PGR2021-00020, Paper 16 at 22; *In re Geerdes*, 491 F.2d 1260, 1265 (C.C.P.A. 1974) (“[I]t is possible to argue that process claims encompass inoperative embodiments on the premise of unrealistic or vague assumptions, but that is not a valid basis for rejection.”); *In re Anderson*, 471 F.2d 1237, 1242 (C.C.P.A. 1973); *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

When a specification discloses operative embodiments encompassed by a claim—as demonstrated throughout this Response—the specification provides sufficient §112 support for the claim even if it may encompass inoperative embodiments. *Ex Parte Vale*, 2016 Pat. App. LEXIS 8038, *9 (P.T.A.B. Sep. 8, 2016); *Ex Parte Nicolaou*, 2007 Pat. App. LEXIS 4312, *16 (P.T.A.B. Nov. 13, 2007).

Accordingly, Petitioner’s identification of a hypothetical inoperative example that Petitioner asserts is encompassed by claim 1 does not support a finding that the GP Application lacks §112 support for the claim.

3. “configured to detect an adverse condition”

Petitioner argues that the full scope of “detect an adverse condition” is “[c]ontinuously monitor for and detect all 17 adverse conditions, and when they start and stop.” Pet. at 11-12 (emphasis added). As an initial matter, this limitation does not **require** that “all 17 adverse conditions” be monitored for and detected by a claimed system, and the full scope of the claim is detecting one or more adverse conditions. *See supra* Section V.A.

Furthermore, the underlined words that Petitioner added are based on unsupported inferences. Petitioner argues that the fourth “wherein” clause of claim 1 “indicates that the claim encompasses a system that detects ‘an end of the adverse condition.’” Pet. at 12. But that clause merely states that “processed sensor data for the time period corresponding to the adverse condition” is “outputted to the display **after** the adverse condition is corrected.” Ex. 1201 at 16:13-15 (emphasis added). No specific manner of “detec[tion]” of “an end of the adverse condition” is recited.

As another example, Petitioner argues that because claim 18 recites that the receiver is “configured to display the second line graph immediately after the correction of the adverse condition,” it “implies ‘immediately’ **detecting** when the adverse condition stops.” Pet. at 12 (emphasis added). There is no such requirement in the claims. The backfilled data could be output as a result of correcting the adverse condition, such that no “immediate[.]” detecting of “when the adverse condition

stops” is required. See Ex. 1201 at 16:13-15 (“processed sensor data ... is outputted to the display after the adverse condition is corrected”), 17:5-7 (“the second line graph” is displayed “immediately after the correction of the adverse condition”).

While claim 1 might *encompass* a system with the capabilities Petitioner identifies, the examples above exemplify Petitioner’s strategy of simply adding words to claim 1, with little or no basis, including without support from its expert (see Ex. 1212 ¶17), and then arguing that they lack WD and enablement support in the GP Application. Pet. at 10-12, 19-20, 25. The law does not require explicit disclosure of Petitioner’s added words. “[A] claim *can* be broader than the embodiments disclosed.” *PNC Bank*, IPR2021-01071, Paper 21 at 17. Where allegedly undisclosed features are not critical to, or the “heart of the invention,” express description of those features is not required to satisfy §112. *Id.* at 18 (“Petitioner identifies nothing whatsoever in the ’247 application suggesting that it is important—much less the ‘very heart of the invention’—that the described image capture device be in a housing entirely separate from the described general purpose computer.”). Here, Petitioner does not argue, and identifies nothing in the specification that suggests, its added words are critical to or the heart of the invention. *Id.* at 20; *Global IP*, 927 F.3d at 1377. Petitioner’s arguments are thus legally erroneous.

In any event, the GP Application **does** disclose to a POSITA a monitoring system that continuously monitors for and detects at least one adverse condition and when it starts and stops, and enables a POSITA to make and use the same. For example, the GP Application discloses monitoring for and detecting a calibration issue:

There are time periods where the sensor characteristics or the user's physiological condition renders the condition unsuitable for a sensor calibration event. ... If a predetermined calibration event is triggered but a successful calibration does not result, after a certain time period ..., the receiver unit may no longer display the monitored and processed glucose information.

Other conditions may also result in rendering the condition unsuitable for sensor calibration including ... detection of a failure mode of a sensor, sensor data values being outside a predetermined range, rate of change of sensor data values being above a predetermined threshold, a temperature measurement outside a predetermined range, or any combination thereof.

[W]hen a scheduled calibration event fails and the associated grace period for calibration does not occur, the output display of the processed, calibrated sensor data is disabled (610). Referring to FIG. 6, once the system recovers after a successful calibration event, the calibrated sensor data is once again displayed (and stored). ... [B]ased on the parameters associated with the successful calibration, the previously unprocessed data during the display time out period may be

retrieved ... and processed using calibration data, such as a sensitivity ratio for conversion of analyte related sensor data to analyte levels.

Upon successful processing of the sensor data during the period of disabled output, the processed sensor data during this time period is backfilled, or the gap in the processed continuous sensor data are filled in the display (630).

Ex. 1202 at [0052]-[0053], [0059]-[0060].

Additionally, Petitioner's declarant in the 1251 IPR opines that as early as 2009, a POSITA would have had "specific knowledge of glucose monitoring" and "would have been skilled in ... programming a microprocessor with programs stored in memory." Ex. 2001 ¶56. Further, the POSITA "would have been skilled at programming a microprocessor to detect" a number of adverse conditions, such as "the failed reception of glucose data, sensor instability, rapidly changing glucose values, glucose level excursions, faulty or interrupted glucose readings, and other conditions associated with measuring, transmitting, receiving, and calibrating glucose data." *Id.* (emphasis added). A POSITA also "would have known how to program and reprogram microprocessor-controlled devices ... to perform

computations, monitoring, detection, alarm, data management, display and other functions associated with physiological monitoring.” *Id.* ¶57 (emphasis added).⁵

In view of the above, in December 2018, a POSITA in the predictable field of electrical engineering would have understood that the GP Application discloses a monitoring system configured to continuously monitor for and detect at least one adverse condition and when it starts and stops and would have understood how to make and use such a system without undue experimentation. Indeed, there is no evidence that programming a glucose monitoring system to do so would have been unpredictable or even difficult in December 2018, and Petitioner does not show otherwise.

Petitioner asserts that the GP Application “gave no example of,” and “no algorithm or circuit for,” continuously monitoring for and detecting the 17 adverse conditions and when they start and stop. Pet. at 19. In particular, Petitioner asserts that the GP Application “does not describe how to monitor for and detect signal errors and malfunctions associated with the transmitter, or sensor communication errors, if such errors do not result in ‘sensor data values being outside a predetermined range, rate of change of sensor data values being above a

⁵ For purposes of this Preliminary Response, Patent Owner does not dispute that a POSITA would have had these skills in 2018.

predetermined threshold, a temperature measurement outside a predetermined range, or any combination thereof.” *Id.* at 19-20. Not only are these assertions based on an incorrect construction and understanding of the scope of “detect an adverse condition,” but they fail to consider the predictability of the art and are contradicted by the testimony of Petitioner’s declarant in the 1251 IPR.

Indeed, given the skills attributed to a POSITA by Petitioner’s 1251 IPR declarant (*e.g.*, Ex. 2001 ¶¶55-57), a POSITA in 2018 would not have needed examples of an algorithm or circuit to understand that the GP Application discloses a monitoring system configured to continuously monitor for, and detect the start and stop of, all 17 adverse conditions—including signal errors, malfunctions associated with the transmitter, and sensor communication errors—and would have understood how to program a microprocessor to perform those functions without any undue experimentation. *Cephalon*, 707 F.3d at 1338.

The Petition argues elsewhere, without any support, that a POSITA “would need to experiment to discover how to program the processor to detect and continuously monitor for the full range of 17 adverse conditions, and their exact start and stop times.” Pet. at 37. This attorney argument lacks expert support and is contradicted by Petitioner’s declarant in the 1251 IPR. See Ex. 2001 ¶¶55-57. Indeed, as discussed immediately above, given the skills of a POSITA in 2018, any such experimentation would not be undue, and Petitioner has not shown otherwise.

In support of its argument, Petitioner quotes a statement from *Idenix Pharms. v. Gilead Scis.*, 941 F.3d 1149, 1161 (Fed. Cir. 2019) that it is the specification, not the knowledge of a POSITA, that must supply the novel aspects of the invention. Pet. at 37-38. That quote is irrelevant because the features Petitioner asserts are not disclosed in the GP Application are ***features not recited in the claims***. It is illogical for the “novel aspects” of a claimed invention to include features that are not claimed.

When viewed through the proper lens, the GP Application provides §112 support for “configured to detect an adverse condition.”

4. “receiver unit comprises a mobile phone”

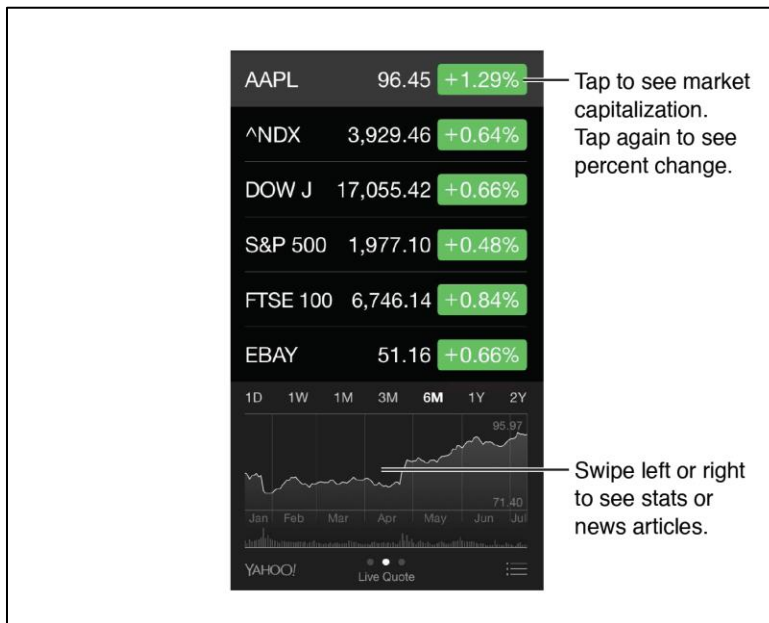
Petitioner asserts that this limitation is not supported in the GP Application because the Application allegedly describes the receiver unit as a mobile phone only when it has “sufficiently few functions and features.” Pet. at 17-18, 26. In claim 1, however, the receiver unit requires only a processor, memory, an RF transceiver, an antenna, and a display. Ex. 1201 at 15:52-54. And the only functions recited for the claimed receiver unit are (i) receiving processed sensor data over Bluetooth, (ii) displaying a data gap, and (ii) outputting processed sensor data as a numerical value and line graphs. *Id.* at 15:55-16:20. These “limited number of functions and features” are less than all of the functions and features described for the primary receiver unit 104 in the specification, and there is no suggestion that use of a mobile phone is not

described and enabled for these particular functions. The primary receiver unit 104 described as a preferred embodiment can also include “an analyte test strip, e.g., blood glucose test strip, interface 301” (Ex. 1202 at [0046]), which would not be part of a mobile phone, but also is not claimed. Therefore, even if the GP Application discloses that the receiver comprises a mobile phone when it has a “limited number of functions and features” as Petitioner contends, that is what is claimed in claim 1.

Indeed, in **December 2018**, mobile phones were well-known to include all of the claimed components, and be capable of performing all of the claimed functions, as the claimed receiver unit. In 2015, Petitioner’s own G5 CGM System could “send[] glucose data directly to a smartphone.” Ex. 2004 at 1. The G5 CGM System displayed glucose values as a numerical value and in graphical form on the user’s iPhone. Ex. 2005 at 6.



Also in 2015, the iPhone 6 could receive data over Bluetooth and display graphics and numerical data over time. Ex. 2006 at 40, 113.



Also, Petitioner’s declarant in the 1251 IPR opines that a POSITA (in 2009) would have had “the knowledge and skills to implement Bluetooth and other wireless communication protocols between multiple devices like ... cell phones.” Ex. 2001 ¶54.

Given the high level of skill in the art, the predictability and state of the art in December 2018, and the specific knowledge of the operation of mobile phones that Petitioner’s declarant attributes to a POSITA, a POSITA reading the GP Application in 2018 would have (i) understood that the inventor possessed an invention where the “receiver unit comprises a mobile phone” and (ii) known how to make and use the invention.

5. Dependent Claims

Petitioner does not separately argue that any dependent claim lacks §112 support in the GP Application. *See* Pet. at 16-17. Nevertheless, each dependent claim has WD and enablement in the GP Application as shown in Section VI.B.8.

6. Other Features Petitioner Alleges Are Not Described or Enabled

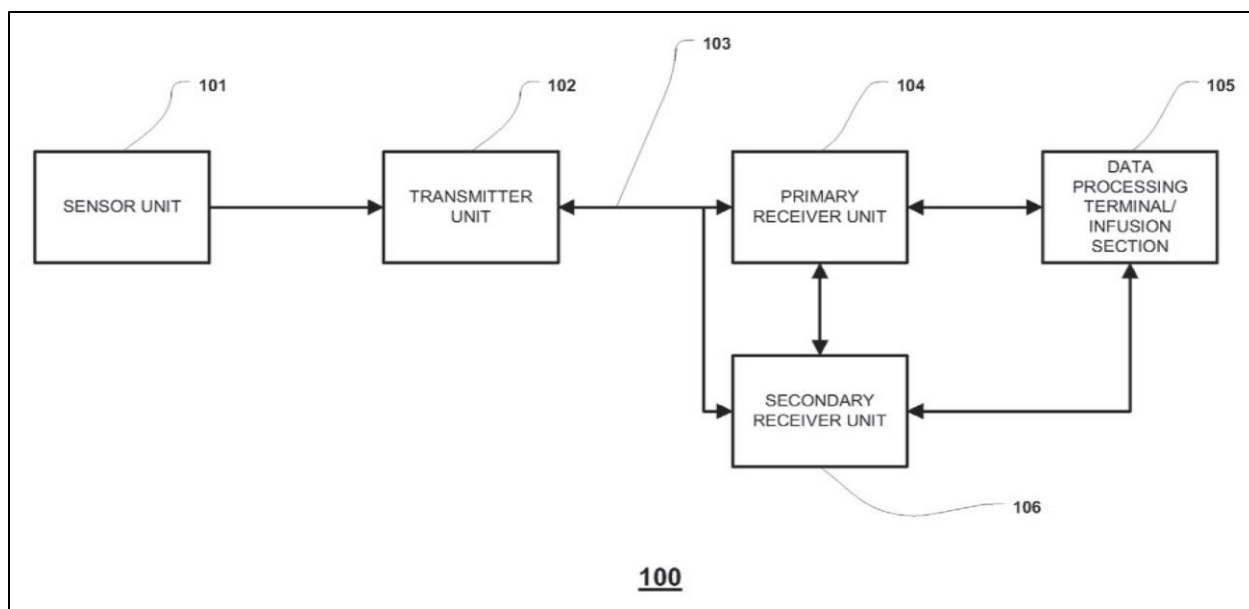
On pages 21-24 of the Petition, Petitioner asserts that certain features that are allegedly encompassed by claim 1 are not disclosed by portions of the GP Application that Petitioner characterizes as the “Apparatus Embodiment,” the “Figs. 6 and 7 Methods,” the “As-filed Claims,” the “Remainder of Express Disclosure,” and the “Purportedly Incorporated References.” In other words, Petitioner cherry-picks and isolates portions of the GP Application and argues that those portions do not describe or enable features Petitioner asserts are encompassed by claim 1. In doing so, Petitioner mischaracterizes the GP Application which, as discussed below, explains that embodiments described throughout the specification can be implemented in view of Figures 1-3 and their corresponding descriptions. Moreover, whether the WD requirement is satisfied involves “an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art,” *Ariad*, 598 F.3d at 1351, and “[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the [reference] coupled with information known in the art without undue

experimentation.” *U. S. v. Telectronics*, 857 F.2d 778, 785 (Fed. Cir. 1988). Petitioner’s approach of separating the GP Application into distinct portions and reviewing each individually for §112 support is contrary to law. *Packet Intelligence v. NetScout Sys.*, 965 F.3d 1299, 1318 (Fed. Cir. 2020) (enablement and WD inquiries “focus on the specification as a whole”).

Several allegedly undescribed and non-enabled features discussed on pages 21-24 of the Petition have already been addressed above. The other allegedly undescribed and non-enabled features discussed at pages 21-25 of the Petition are now addressed.

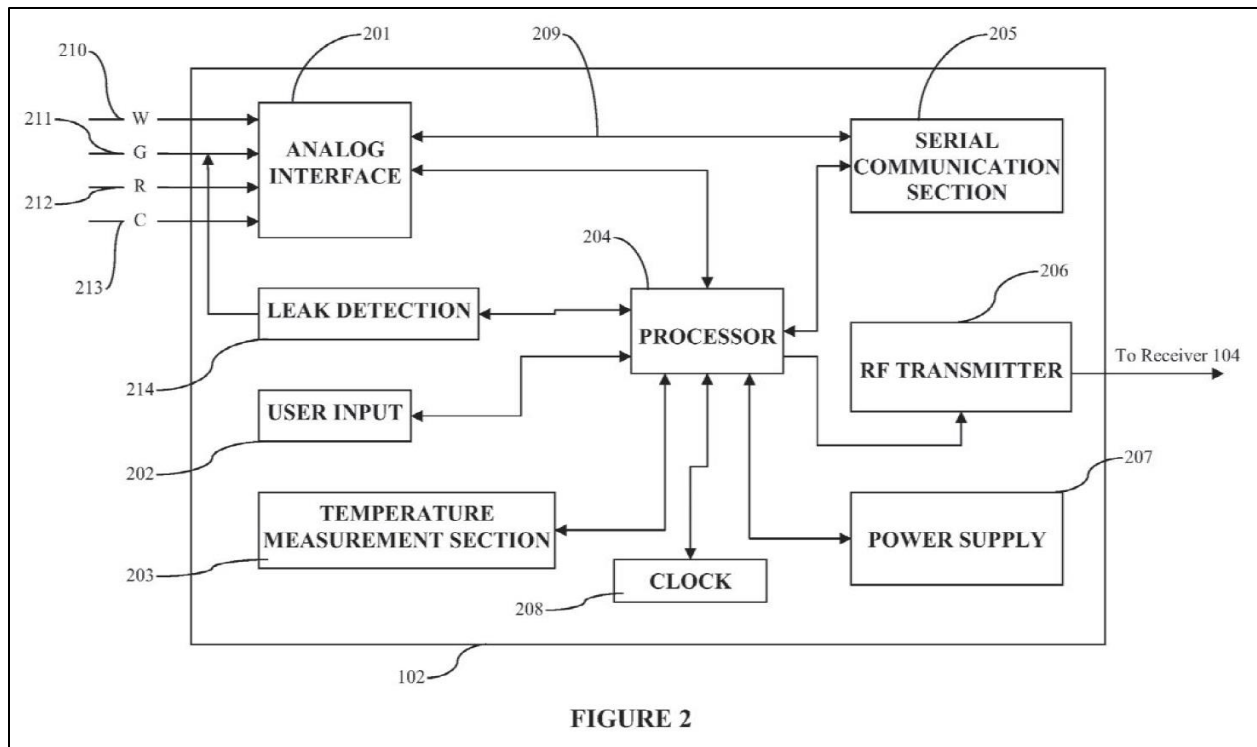
Petitioner argues that an “Apparatus Embodiment,” which Petitioner asserts is disclosed at paragraphs [0007] and [0077]-[0085] of the GP Application, does not disclose a transmitter unit with an RF transceiver or memory, a Bluetooth link, a receiver unit, or displaying a first line graph, second line graph, or numerical glucose value. Pet. at 21-22. Those features are disclosed.

Figures 1, 2, and 3 provide the framework for the systems and methods described throughout the specification. “FIG. 1 illustrates a block diagram of a data monitoring and management system for practicing ***one or more embodiments of the present disclosure.***” Ex. 1202 at [0010] (emphasis added).



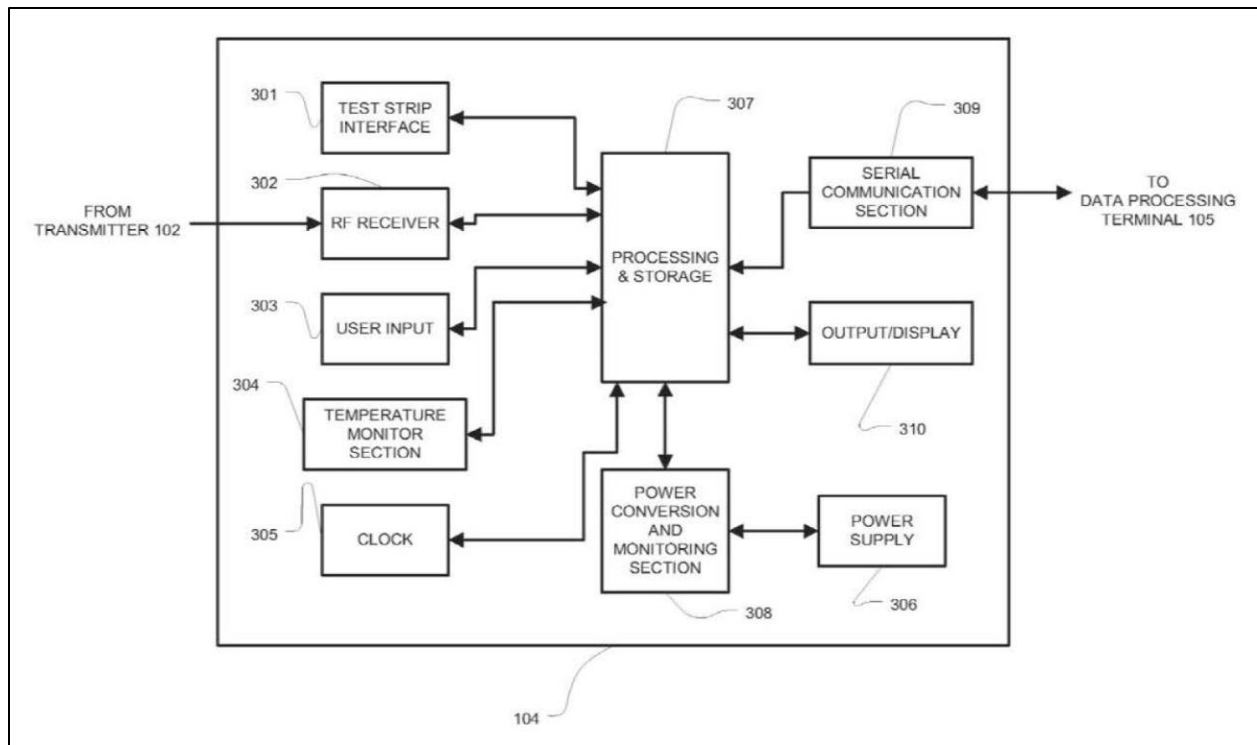
The “communication link 103” shown in FIG. 1 may include “a Bluetooth® enabled communication protocol.” Ex. 1202 at [0037].

“FIG. 2 is a block diagram of the transmitter unit of the data monitoring and management system shown in FIG. 1 in accordance with one embodiment of the present disclosure.” Ex. 1202 at [0011].



The “data processing and transmitter unit 102” “may include a transceiver.” Ex. 1202 at [0027]. The GP Application further explains that “the transmitter processor 204 also includes a memory (not shown) for storing data.” *Id.* at [0041].

“FIG. 3 is a block diagram of the receiver/monitor unit of the data monitoring and management system shown in FIG. 1 in accordance with one embodiment of the present disclosure.” Ex. 1202 at [0012].



The specification explains that processed data is “output for display (440) to a user on a display unit 310 (FIG. 3) of the primary receiver unit 104.” Ex. 1202 at [0055]. “[T]he display of the processed sensor data comprises a graphical representation of the processed sensor data,” as well as “numerical values.” *Id.* at [0055]. And FIGS. 7A and 7B show first and second line graphs.

Therefore, a POSITA would have (i) understood from the four corners and disclosures of the GP Application that the inventor possessed a system having a transmitter with an RF transceiver and memory, a receiver, and a Bluetooth link, and that displays a first line graph, second line graph, and numerical glucose values, and (ii) been able to make and use a system including those features without undue experimentation.

Petitioner further asserts that the Apparatus Embodiment does not disclose “calibration of sensor data or transmission of calibrated sensor data.” Pet. at 21. As explained above, FIG. 1 provides a block diagram of a system “for practicing ***one or more embodiments of the present disclosure***,” while FIGS. 2 and 3 provide details of the transmitter unit 102 and the receiver unit 104 of FIG. 1, respectively. Embodiments described throughout the specification can therefore be implemented in view of these figures and their corresponding descriptions. Indeed, the methods of FIGS. 4, 5, and 6 are expressly described with references to FIGS. 1, 2, and 3. Ex. 1202 at [0054]-[0060]. Moreover, the processing routines of FIGS. 4 and 5 are described as being performed in either the transmitter unit 102 or the receiver unit 104. *Id.* at [0055], [0057].

In relation to FIG. 4, the specification explains that the receiver unit determines if the sensor is calibrated, and if it is, the receiver unit processes the sensor data and outputs the “processed and calibrated analyte sensor data” on its display unit 310. *Id.* at [0057]-[0058]. When this processing is performed in the transmitter unit 102 (*id.* at [0055] (“the processing routine described in conjunction with FIG. 4 is performed or executed in ... the transmitter unit 102”), the transmitter unit transmits calibrated sensor data to the receiver unit to be output to the display unit 310.

In relation to FIG. 5, the specification explains that if “the sensor 101 is not calibrated or [a] calibration condition for calibrating the sensor 101 is not met, ... the primary receiver unit stores the analyte related sensor data ... and temporarily disables display of the sensor data.” *Id.* at [0057]. This temporary time out can result in “a gap in the output display during which the necessary calibration did not occur in a timely manner.” *Id.* at [0058]. The method of FIG. 6 explains how to backfill such a gap. For example, “based on the parameters associated with the successful calibration, the previously unprocessed data during the display time out period may be retrieved ... and processed using calibration data, such as a sensitivity ratio for conversion of analyte related sensor data to analyte levels.” *Id.* at [0059].

Thus, a POSITA would have understood from the four corners and express disclosures of the GP Application that the inventor possessed a transmitter unit that processes sensor data and transmits the processed sensor data, and been able to make and use a system including those features without undue experimentation.

Petitioner argues that the “Remainder of Express Disclosure” does not disclose the “transmitter performing calibration and storing calibrated data in the same memory as stored received sensor data.” Pet. at 23. As discussed above, the GP Application does disclose that the transmitter can perform processing routines, including calibration. Furthermore, as also discussed *supra*, a POSITA would have understood from at least the disclosures of Paragraphs [0041], [0054]-[0057], and

[0059] of the GP Application that the transmitter unit can store both processed and unprocessed sensor data.

7. Patent Owner's WD Arguments Do Not Rely On Hindsight

Petitioner argues that Patent Owner cannot use hindsight to “pluck claim elements from disparate parts” of the GP Application’s disclosure, and that the GP Application lacked “blaze marks to the claims’ above-identified combination of full-scope features.” Pet. at 33-35. Petitioner’s argument is meritless.

First, as discussed immediately above, the GP Application does not describe the components of the CGM system as “disparate parts.” FIG. 1 of the GP Application is an overall block diagram of the system, while FIGS. 2 and 3 are block diagrams specifically of the transmitter unit and the receiver unit. The GP Application then describes the methods of FIGS. 4, 5, and 6 being carried out using the hardware of FIGS. 1, 2, and 3. Thus, “blaze marks” are provided in the GP Application. And the WD requirement involves an inquiry into the four corners of the specification from the perspective of a POSITA and does not require that all embodiments encompassed by a claim be disclosed in the specification, or that each possible embodiment be discussed in isolation. As discussed *supra*, given the level of skill in and the predictability of the art, a POSITA would have understood from the GP application, without use of hindsight, that the Challenged Claims have WD support in the GP Application.

Second, Petitioner’s cited cases are inapt. Those cases involved situations where (i) the specification did not describe the actual functioning variants that the *limitations of the claim* at issue together defined (*Novozymes A/S v. DuPont Nutrition Biosciences APS*), (ii) the chemical compound of the claim at issue was not identified, and there were no “guides” in the specification to lead a POSITA to the *claimed* compound (*In re Ruschig*), (iii) the specification did not provide adequate description of the *combination* of *claimed* elements (*Hyatt v. Dudas*), and (iv) the claims were directed at a ratio between two variables, but the specification disclosed a multitude of parameters without directing a POSITA to the *claimed* ratio (*Purdue Pharma v. Faulding*). Each cited case involved a lack of disclosure of *claimed features*. And, all but *Hyatt* involved inventions in the unpredictable chemical and pharmaceutical arts.

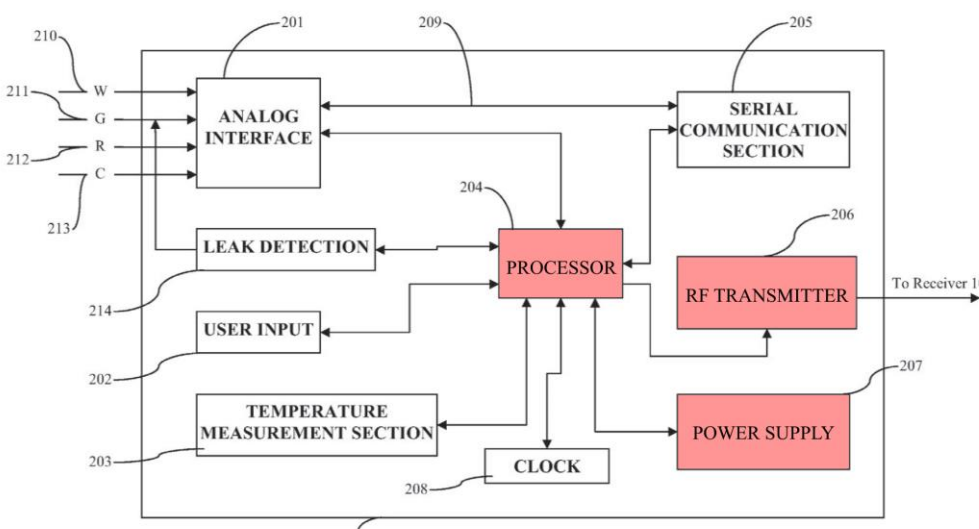
In contrast, Petitioner argues that the GP Application does not explicitly describe an embodiment having features that ***are not*** recited in the claims, *e.g.*, “*continuously* monitoring for 17 adverse conditions,” “displaying *immediately* after correction,” *etc.* The specification need not disclose all embodiments encompassed by the claims to provide WD support, especially where the art is predictable. *Hologic v. Smith & Nephew*, 884 F.3d 1357, 1362-63 (Fed. Cir. 2018) (“in predictable arts and where the element not depicted is conventional[,]” written description need not show “every claimed element” or every species in the claimed genus).

8. Claim Chart Showing WD and Enablement Support

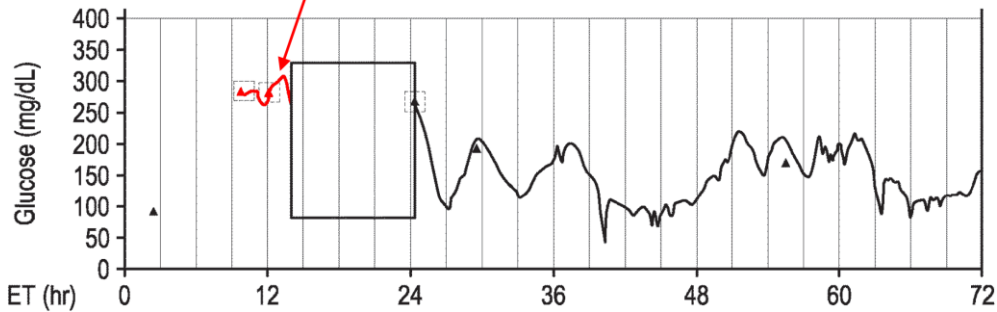
As explained above, Petitioner’s reliance on case law is incorrect and incomplete, and Petitioner’s arguments that the Challenged Claims lack WD or enablement support in the GP Application lack merit. To further assist the Board, the claim chart below provides exemplary disclosures showing how each Challenged Claim has WD and enablement support in the GP Application (Ex. 1202) under the correct claim constructions and legal standards.⁶

Claim	Example Support in GP Application
1.Pre	[0025]: “FIG. 1 illustrates a data monitoring and management system such as, for example, analyte (e.g., glucose) monitoring system 100 in accordance with one embodiment of the present disclosure.” [0059]: “FIG. 6 illustrates backfilling gaps in sensor data in one embodiment of the present disclosure.”
1.A	[0030]: “[T]he sensor unit 101 is physically positioned in or on the body of a user whose analyte levels is being monitored. The sensor unit 101 may be configured to continuously sample the analyte level of the user and convert the sampled analyte level into a corresponding data signal for transmission by the data processing and transmitter unit.” [0026]: “Analytes that may be monitored include ... glucose.”

⁶ Claim labels correspond to the labels in the Claim Listing near the beginning of this document. Also, disclosure for claim 1 applies to each dependent claim.

1.B	[0027]: “The analyte monitoring system 100 includes ... a data processing and transmitter unit 102 coupleable to the sensor unit 101.” [0038]: “FIG. 2 is a block diagram of the transmitter unit of the data monitoring and management system shown in FIG. 1.”  FIGURE 2 [0041]: “[T]he transmitter processor 204 includes a memory (not shown).” [0027]: “[D]ata processing and transmitter unit 102 ... may include a transceiver.”
1.C	[0041]: “[T]he transmitter processor 204 includes a memory (not shown) for storing data such as ... the data signals received from the sensor unit 101.”
1.D	[0051]: “Calibration ... is used to ensure the analyte related data signals received at a transmitter unit 102 ... are correctly converted to corresponding analyte levels.” [0055/0057]: “[T]he processing routine described in conjunction with [FIG. 4 or FIG. 5] is performed or executed in ... the transmitter unit 102 ... based on analyte data received from the sensor 101.”

	[0059]: “[T]he previously unprocessed data during the display time out period may be retrieved ... and processed using calibration data, such as a sensitivity ratio for conversion of analyte related sensor data to analyte levels.” [0007]: “Embodiments include an interface configured to receive sensor data, a first memory configured to store the received sensor data, a processor coupled to the memory and configured to process the stored sensor data, a second memory coupled to the processor and configured to store the processed sensor data.”
1.E	[0030]: “[T]ransmitter unit 102 transmits analyte information to the primary receiver unit 104 via communication link 103.” [0037]: “[T]he communication link 103 may include ... a Bluetooth® enabled communication protocol.”
1.F	[0046]: “FIG. 3 is a block diagram of the receiver/monitor unit of the data monitoring and management system shown in FIG. 1.” <pre> graph LR 102[FROM TRANSMITTER 102] --> 302[RF RECEIVER] 302 --> 307[PROCESSING & STORAGE] 301[TEST STRIP INTERFACE] --> 307 303[USER INPUT] --> 307 304[TEMPERATURE MONITOR SECTION] --> 307 305[CLOCK] --> 307 307 --> 309[SERIAL COMMUNICATION SECTION] 309 --> 105[TO DATA PROCESSING TERMINAL 105] 307 --> 310[OUTPUT/DISPLAY] 310 --> 308[POWER CONVERSION AND MONITORING SECTION] 308 --> 306[POWER SUPPLY] 306 --> 307 </pre> 104 FIGURE 3 [0027]: “[R]eceiver unit 104 may include a transceiver.”

	[0032]: “[T]he analog interface section may include an RF receiver and an antenna for receiving and amplifying the data signals from the data processing and transmitter unit 102.”
1.G	[0030]: “[D]ata processing and transmitter unit 102 transmits analyte information to the primary receiver unit 104 via communication link 103.” See elements [1.E], [1.F].
1.H	[0055]: “[T]he processed sensor data may be displayed as numerical values.”
1.I	[0055]: “[T]he display of the processed sensor data comprises a graphical representation of the processed sensor data.” First line graph that is a substantially continuous depiction of the processed sensor data over time  FIG. 7A
1.J	See <i>supra</i> Section VI.B.3 (referring to disclosure in [0052]-[0053], [0059]-[0060]). See: [0005]: “Embodiments include receiving sensor data from an analyte sensor of a sensor monitoring system, processing the received sensor data with time corresponding calibration data, outputting the processed sensor data, detecting one or more adverse conditions

associated with the sensor monitoring system, disabling the output of the sensor data during a adverse condition time period ...”

[0045]: “[A]lso shown is a leak detection circuit 214 coupled to the guard electrode (G) 211 and the processor 204 in the transmitter unit 102 of the data monitoring and management system 100. The leak detection circuit 214 in accordance with one embodiment of the present disclosure may be configured to detect leakage current in the sensor unit 101 to determine whether the measured sensor data are corrupt or whether the measured data from the sensor 101 is accurate.”

[0058]: “[T]he display or output of processed sensor data may be disabled if a required calibration event is unsuccessful over a permitted time period Thereafter, upon successful calibration, the system resumes display of the processed and calibrated analyte sensor data. However, there may be a time period or a gap in the output display during which the necessary calibration did not occur in a timely manner.”

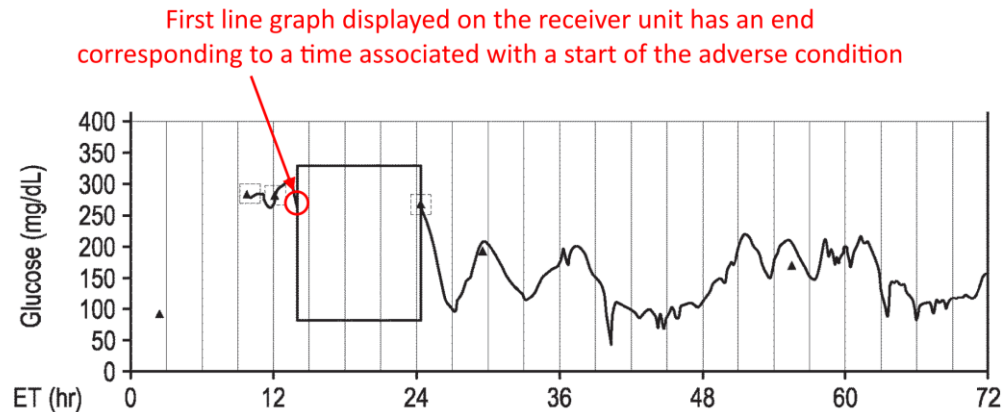


FIG. 7A

1.K See *supra* Section VI.B.1 (referring to disclosure in [0041], [0054]-[0059], [0077]).

1.L See *supra* Section VI.B.2 (referring to disclosure in [0060]).

See:

[0060]: “[O]nce successful calibration of the sensor data occurs, the calibration parameters from this calibration event may be used to process the sensor data during the period of disabled output or display (620). Upon successful processing of the sensor data during the period of disabled output, the processed sensor data during this time period is backfilled, or the gap in the processed continuous sensor data are filled in the display (630). By way of an example, FIGS. 7A and 7B illustrate the replacement of a period of unprocessed sensor data with corresponding backfilled processed sensor data”

[0077]: “[T]he processor is further configured to detect a condition unsuitable for calibration of a sensor for a predetermined time period, disable display of processed sensor data, determine a successful calibration of the sensor, retrieve one or more parameters associated with the successful calibration, process the sensor data during the time period of disabled display of sensor data with the one or more parameters associated with the successful calibration, and display the processed sensor data for the time period of disabled information output.”

1.M

First end corresponding to the time associated with the start of the adverse condition

Second end corresponding to a time associated with an end of the adverse condition

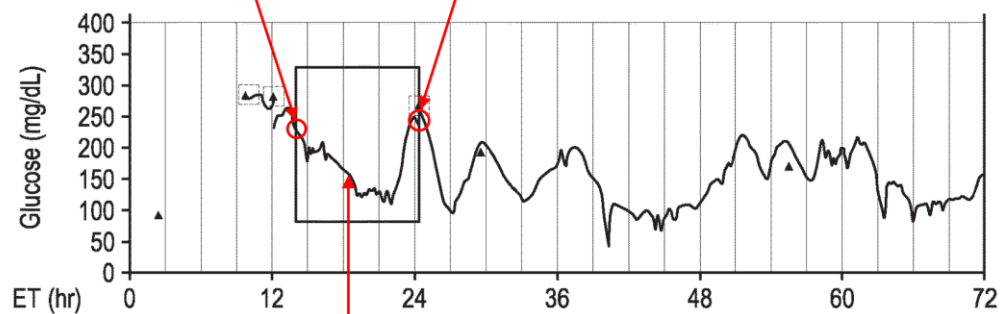
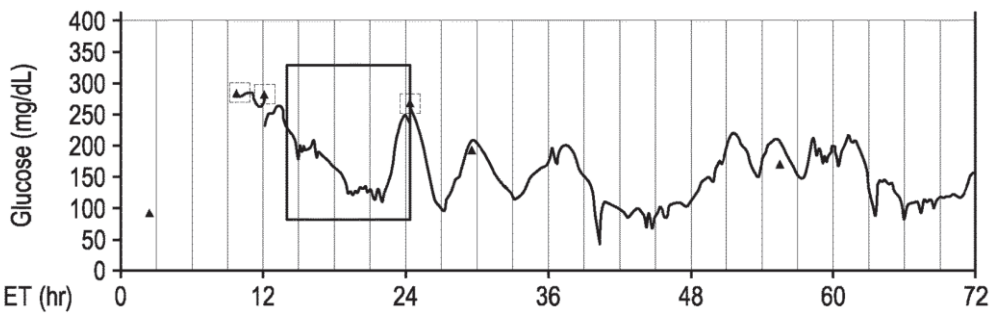
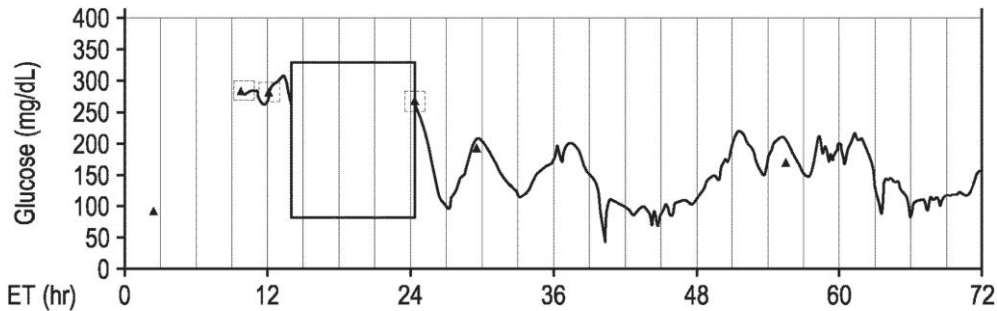


FIG. 7B

See element [1.L].

2	 FIG. 7B
3	[0067]: “The sensor instability condition may include one or more of an early signal attenuation condition of the sensor, sensor misposition error, sensor communication error, temperature measurement outside a predetermined range, or a combination thereof.”
4	[0062]: “[G]aps in monitored analyte levels using an analyte monitoring system due to, for example, inability to promptly calibrate the sensor, system malfunction, sensor dislodging, signal errors associated with the sensor, transmitter unit, receiver unit, and the like, or any other variables or parameters that result in the inability of the analyte monitoring system to display or output the real-time monitored analyte level, may be retrospectively filled or reprocessed so that the data gap is closed and the continuously monitored analyte level does not have any or substantially missing data.”
5	<i>Id.</i>
6	<i>Id.</i>
7	<i>Id.</i>
8	<i>Id.</i>
9	[0066]: “The one or more detected adverse conditions may include one or more of a sensor instability condition, a calibration failure condition, or a monitoring system failure condition.”

10	<i>Id.</i>
11	<i>Id.</i>
12	[0038]: “[T]here are provided four contacts, three of which are electrodes—work electrode (W) 210, guard contact (G) 211, reference electrode (R) 212, and counter electrode (C) 213, each operatively coupled to the analog interface 201 of the data processing and transmitter unit 102 for connection to the sensor unit 101”
13	[0067]: “sensor misposition error”
14	[0044]: “[T]he temperature measurement section 203 of the data processing and transmitter unit 102 is configured to monitor the temperature of the skin near the sensor insertion site.” [0067]: “temperature measurement outside a predetermined range”
15	[0044]: “The calibration failure condition may include one or more of an analyte level exceeding a predetermined threshold, a rate of change of analyte level exceeding a predetermined threshold, a signal error associated with the reference data, a data unavailability condition, or a combination thereof.”
16	<i>Id.</i>
17	<i>Id.</i>
18	[0061]: “In one embodiment, the backfilled processed sensor data is displayed immediately upon calculation.” [0075]: “The processed sensor data for the time period of disabled information output may be displayed substantially immediately upon processing.”
19	[0076]: “The processed sensor data for the time period of disabled information output may be displayed only after waiting a predetermined period of time.”

	[0061]: “[T]he backfilled processed sensor data is not displayed immediately, but rather, after waiting a predetermined period of time.”
20	[0069]: “[T]he method may include storing the processed sensor data with the associated time information based on the analyte level detection time by the sensor.”
21	[0030]: “[T]he data processing and transmitter unit 102 may be physically coupled to the sensor unit 101 so that both devices are integrated in a single housing.”
22	<i>See supra</i> Section VI.B.4.
23	 FIG. 7A
24	[0051]: “Periodic calibration of the sensor unit 101 (FIG. 1) of an analyte monitoring system 100 ... may be required for accurate calculation of a user's analyte level.” [0059]: “[T]he subset of analyte related sensor data that were previously unprocessed or uncalibrated due to unsuccessful contemporaneous calibration may be processed using ... calibration data such as the sensitivity ratio determined from the most recent successful calibration event.”
25	[0068]: “The calibration failure condition may include ... a signal error associated with the reference data.”

26	[0052]: “[T]he sensor may be configured for periodic calibration, such as ... 12 hours after insertion.”
27	[0042]: “The data processing and transmitter unit 102 is also configured such that the power supply section 207 is capable of providing power to the transmitter for a minimum of about three months of continuous operation, e.g., after having been stored for about eighteen months such as stored in a low-power (non-operating) mode. In one embodiment, this may be achieved by the transmitter processor 204 operating in low power modes in the non-operating state, for example, drawing no more than approximately 1 μ A of current.”
28	<i>Id.</i>
29	[0028]: “[A]n optional secondary receiver unit 106 ... is ... configured to receive data transmitted from the data processing and transmitter unit 102 [T]he secondary receiver unit 106 may be configured to include a limited number of functions and features as compared with the primary receiver unit 104. As such, the secondary receiver unit 106 may be ... embodied in a ... wrist watch”
30	See element [1.A].

With respect to dependent claims 3-11, 13-17, and 25 that recite specific adverse conditions, as discussed *supra*, a POSITA in 2018 would have understood that the GP Application describes detecting each specific adverse condition and how to program a processor to detect each of the adverse conditions without undue experimentation. To the extent that any of the adverse conditions recited in the dependent claims could be stretched to include scenarios that make it impossible to recover data for purposes of backfilling the displayed gap, these scenarios are either

not encompassed by the claims or are merely inoperative embodiments. *Allergan*, PGR2021-00020, Paper 16 at 22; *Kundra*, 2017 Pat. App. LEXIS 471 at *17.

C. The Board Should Not Give Weight to the Testimony of Petitioner's Expert

Petitioner cites the declaration of its expert, Dr. Jensen, in support of its WD arguments,⁷ but the Board should not credit his testimony. Dr. Jensen failed to apply the correct standards in his WD and enablement analysis. Regarding WD, he does not acknowledge that the specification need not contain explicit disclosure of all possible embodiments and unclaimed features within the scope of the claims, never considers the predictability of the art or the criticality of the features that are allegedly not disclosed or whether they are the heart of the invention, and makes conclusory assertions that the GP Application lacks certain features without explaining why a POSITA, in view of their high level of skill and the predictability of the art, would have understood the GP Application to not have enough detail to satisfy the WD requirement. *See* Ex. 1212 ¶¶13-15, 31-57.

Regarding enablement, Dr. Jensen does not address the *Wands* factors or acknowledge that the specification need not describe how to make and use every possible embodiment within the scope of a claim, and makes conclusory assertions that the GP Application does not enable certain features without explaining why, or

⁷ Petitioner does not cite Dr. Jensen's declaration for enablement. Pet. at 35-40.

providing evidence that, a POSITA would not have been able to make and use a device having those features using their high level of skill and routine experimentation. *See id.* ¶¶16, 31-57.

Furthermore, Dr. Jensen admitted he did not “review[] the materials said to be incorporated by reference.” *Id.* ¶30. However, “[p]atents that are incorporated by reference are ‘effectively part of the host [patents],’ and “[c]laims must be read in light of the specification [which] includes any patents incorporated by reference.” *Finjan v. ESET*, 51 F.4th 1377, 1382 (Fed. Cir. 2022). Thus, Dr. Jensen’s analysis is incomplete and unreliable because he did not consider subject matter incorporated into the GP Application.

Because Dr. Jensen’s findings are conclusory and not based on a correct application of the law or on the complete intrinsic record, his testimony should not be given any weight. *LG Elecs. v. Wi-Lan*, IPR2018-00709, Paper 15 at 5 (P.T.A.B. Dec. 4, 2018) (finding expert’s testimony about why disclosures “did not provide written description support was conclusory and, therefore, entitled to little or no weight”).

VII. THE BOARD SHOULD DENY INSTITUTION UNDER § 314(a)

The Board should deny institution for discretionary reasons. The Board’s *Trial Practice Guide* advises that petitioners should “avoid submitting a repository of all the information that a judge could possibly consider, and instead focus on

concise, well-organized, easy-to-follow arguments supported by readily identifiable evidence of record.” *Consolidated Trial Practice Guide* at 39 (Nov. 2019). “This requirement is ‘of the utmost importance’ ... because ‘a detailed and clear explanation of the challenge at the outset is necessary so that the parties and the Board can complete the trial within the statutorily prescribed timeframe.’” *Uber Techs. v. Surgetech*, IPR2023-00735, Paper 13 at 12 (P.T.A.B. Oct. 12, 2023). Thus, denial is appropriate when a Petition includes voluminous and excessive grounds and fails to identify them with particularity. *Id.* at 20.

Here, Petitioner’s Grounds are based on meandering §112 arguments that are not presented with clarity or particularity. The Petition is not consistent or clear in its characterization of what specific features allegedly fall within the full scope of the claims or in arguing why the GP Application does not describe or enable those features. For example, pages 9-15 of the Petition identify five underlined characterizations of features that Petitioner asserts fall within the full scope of the Challenged claims, but recaps of those features on pages 15 and 25 of the Petition differ from the language of the underlined characterizations. Adding to the confusion, Petitioner elsewhere refers to other features not referred to on pages 9-15 of the Petition that it alleges are not described or enabled in the GP Application. *See* Pet. at 21-23, 39-40. Further obscuring things, and adding to the permutations of §112 arguments Patent Owner must address, in the places where Petitioner argues

that the GP Application does not describe or enable features encompassed by the Challenged Claims, the features discussed do not clearly match up to the underlined characterizations of features that Petitioner asserts fall within the full scope of the Challenged Claims. *Id.* at 17-23. Although it is unclear exactly what are the “features” that are purportedly not disclosed and/or enabled, depending on how they are counted, the number is between 20 and 30.

Thus, the muddled and excessive §112 arguments in the Petition fail to present “with particularity ... the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim.” 35 U.S.C. § 312(a)(3). Consequently, it will be difficult, if not impossible for “the parties and the Board [to] complete the trial within the statutorily prescribed timeframe,” and the Board should exercise its discretion to deny institution.

VIII. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Board refuse to institute.

Dated: November 10, 2023

/Peter J. McAndrews/

Peter J. McAndrews

Registration No. 38,547

McANDREWS, HELD & MALLOY

500 West Madison St., Suite 3400

Chicago, IL 60661

CERTIFICATE OF SERVICE

I hereby certify that the Patent Owner's Preliminary Response to Petition for *Inter Partes* Review Pursuant to 37 C.F.R. § 42.107 in connection with *Inter Partes* Review Case IPR2023-01252 was served on this 10th day of November, 2023 by electronic mail to the following:

Lead Counsel	Back-Up Counsel
John D. Vandenberg KLARQUIST SPARKMAN, LLP 121 SW Salmon Street, Suite 1600 Portland, Oregon, 97204 503-595-5300 (phone) 503-595-5301 (fax) john.vandenberg@klarquist.com	Andrew M. Mason KLARQUIST SPARKMAN, LLP 121 SW Salmon Street, Suite 1600 Portland, Oregon, 97204 503-595-5300 (phone) 503-595-5301 (fax) andrew.mason@klarquist.com
	Amy Haspel KLARQUIST SPARKMAN, LLP 121 SW Salmon Street, Suite 1600 Portland, Oregon, 97204 503-595-5300 (phone) 503-595-5301 (fax) amy.haspel@klarquist.com

Dated: November 10, 2023

/Peter J. McAndrews/

Peter J. McAndrews
Registration No. 38,547
McANDREWS, HELD & MALLOY
500 West Madison St., Suite 3400
Chicago, IL 60661
Telephone: (312) 775-8000

CUSTOMER NUMBER: 23446

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned attorney for the Patent Owner declares that this Patent Owner Preliminary Response has a total of 13,937 words, according to Microsoft Word® word count tool, excluding the parts of the Response exempted by 37 C.F.R. § 42.24(a)(1).

Dated: November 10, 2023

/Peter J. McAndrews/

Peter J. McAndrews

Registration No. 38,547

McANDREWS, HELD & MALLOY

500 West Madison St., Suite 3400

Chicago, IL 60661

Telephone: (312) 775-8000