

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2023-01252
U.S. Patent No.: 11,298,056
Issued: April 12, 2022
Application No.: 17/411,154
Filed: August 25, 2021

Title: METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION
DETECTION AND PROCESSING

PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 11,298,056

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LIST OF EXHIBITS

No.	Description
1201	U.S. Patent No. 11,298,056 (“the ’056 Patent”)
1202	U.S. Ser. No. 16/228,910, filed Dec. 21, 2018 (“Grandparent App.”)
1203	U.S. Ser. No. 17/245,719, filed Apr. 30, 2021 (“Parent App.”)
1204	U.S. Ser. No. 17/411,154, filed Aug. 25, 2021 (“’056 App.”)
1205	Prosecution History of Grandparent App. (“Grandparent FH”)
1206	Prosecution History of Parent App. (“Parent FH”)
1207	Prosecution History of ’056 Patent (“’056 Patent FH”)
1208	U.S. Pat. Appl. Pub. No. US 2019/0216373, published July 18, 2019 (“Harper 2019”)
1209	U.S. Pat. Appl. Pub. No. 2012/0108931, published May 3, 2012 (“Taub/Harper 2012”)
1210	U.S. Pat. Appl. Pub. No. 2013/0127627, published May 23, 2013 (“Hayter/Taub 2013”)
1211	U.S. Pat. Appl. Pub. No. 2014/0176338, published June 26, 2014 (“He/Taub 2014”)
1212	Declaration of Morten Jensen, dated July 21, 2023 (“Morten Jensen Decl.”)

MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

1. Real Party-In-Interest

Dexcom, Inc. is the sole real party-in-interest.

2. Related Matters

The '056 patent (EX1201) has been asserted in the following litigation:

- *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, Case No. 1:23-cv-00239 (DED), filed March 3, 2023.

The '056 patent is also the subject of contemporaneously-filed IPR proceeding, IPR2023-01251. *See* Petitioner's Explanation of Material Differences.

3. Lead And Back-Up Counsel, And Service Information

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Petitioner consents to service via email at the above email addresses.

Pursuant to 37 C.F.R. § 42.10(b), concurrently filed with this Petition is a Power of Attorney executed by Petitioner and appointing the above counsel.

Dexcom, Inc. (“Petitioner”) respectfully requests *inter partes* review (“IPR”) of claims 1-30 of U.S. Patent No. 11,298,056 B2 (“’056 patent”) (EX1201), identifying as assignee Abbott Diabetes Care Inc. (“Patent Owner”). For the reasons set forth below, these claims should be found unpatentable and cancelled.

I. INTRODUCTION

The ’056 patent’s claims are unpatentable for obviousness primarily over the 2019 publication of its grandparent application. The grandparent application lacked the required Section 112(a) support for the challenged claims to be entitled to that application’s filing date, making the application’s publication prior art to the claims.

The law permits patent applicants to daisy-chain patent applications back-to-back over many years changing the claims as they go along. Sometimes that latitude results in later-drafted patent claims so untethered to the applications’ disclosure that they cannot be backdated to an ancestor application’s filing date. This in turn sometimes makes the publication of an ancestor application prior art to the claims, rendering them unpatentable for anticipation or obviousness. *See, e.g., The Gillette Co. LLC v. Sphere USA, LLC*, PGR2022-00030, Paper 8 (P.T.A.B. Sept. 23, 2022) (granting Institution based in part on the “continuation” patent’s grandparent application with the same disclosure as the challenged patent lacking full scope written description support for certain claims, making the publication of that

grandparent application prior art, which prior art disclosed an embodiment of those claims and thus likely anticipated them). That is the case here.

This patent issued from a series of seven patent applications, starting in 2009. A decade later, the patent applicant further distanced the claims from the scope of the ancestor applications' disclosures. As a consequence, no '056 patent claim is entitled to an effective filing date earlier than April 30, 2021, the filing date of the patent's immediate parent application. More specifically, no claim has either sufficient written description or enablement support in the grandparent application, SN 16/228,910, filed on December 21, 2018 ("the Grandparent App.") (EX1202), or any earlier ancestor application.

As explained in Section IV C *infra*, the claims' full scope encompasses a glucose monitoring system capable of continuously monitoring and detecting the start and stop times of 17 identified categories of malfunctions and other "adverse conditions" and, when the adverse condition is corrected, immediately retrospectively displaying on a mobile phone accurate glucose values for that entire period of malfunction despite having not stored during that period any accurate glucose values. As explained in Section IV D *infra*, however, the Grandparent App.'s disclosure fails to enable that full scope of the claimed invention and also fails to lead a person of ordinary skill in the art to understand that the applicant

possessed that full scope of the alleged invention. For those and other reasons, no claim is entitled to be backdated before April 30, 2021.

The claims are obvious over the Grandparent App.'s publication, US 2019/0216373, published July 18, 2019 ("Harper 2019") (EX1208), combined with other applications of Patent Owner published in 2012 (EX1209), 2013 (EX1210), and 2014 (EX1211). Each qualifies as Section 102(a)(1) (AIA) prior art because the claims' effective filing date is no earlier than the April 30, 2021, filing date of their Parent App. (EX1203).

II. GROUNDS FOR STANDING PER SECTION 42.104(a)

Petitioner certifies that the '056 patent is available for IPR and that Petitioner is not barred or estopped from requesting an IPR challenging the patent claims on the grounds identified in this petition.

III. IDENTIFICATION OF CHALLENGE

A. Statement Of The Precise Relief Requested / Statutory Grounds

Petitioner requests *inter partes* review of all thirty claims of the '056 patent, as follows:

	Reference(s)	Basis	Claims
Ground 1	US 2019/0216373 published July 18, 2019 ("Harper 2019") (EX1208)	35 U.S.C. § 103 (AIA)	1-21, 23-30

	Reference(s)	Basis	Claims
	US 2012/0108931 (“Taub/Harper 2012”) (EX1209) US 2013/0127627 (“Hayter/Taub 2013”) (EX1210)		
Ground 2	Harper 2019 (EX1208) Taub/Harper 2012 (EX1209) Hayter/Taub 2013 (EX1210) US 2014/0176338 (“He/Taub 2014”) (EX1211)	35 U.S.C. § 103 (AIA)	22

This petition establishes a reasonable likelihood that the Petitioner will prevail in establishing that each claim is unpatentable.

With the filing of this petition, an electronic payment of \$52,750 for the requisite fees is being charged to deposit account no. 02-4550. 37 C.F.R. § 42.15(a). Any fee adjustments may be debited/credited to the deposit account.

B. No Examiner Addressed These Unpatentability Grounds

Neither “the same [n]or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). During *ex partes* prosecution, the Office did not address whether the claims lack Section 112(a) support in the Grandparent App., whether Harper 2019 or the other asserted references qualify as prior art, or whether the claims are unpatentable for

obviousness if Harper 2019 is prior art. (*See* EX1204, EX1205, EX1206.) Therefore, this petition should not be denied under Section 325(d).

IV. THE '056 PATENT

The '056 patent (EX1201), issued on April 12, 2022, from a series of seven applications: U.S. Patent Application No. 17/411,154 (the "'056 App.") (EX1204), filed on August 25, 2021, identified as a "continuation" of Parent App. No. 17/245,719 (EX1203), filed on April 30, 2021, identified as a "continuation" of Grandparent App. No. 16/228,910 (EX1202), filed on December 21, 2018, identified as a "continuation" of Application No. 15/061,774, filed on March 4, 2016, identified as a "continuation" of Application No. 13/925,694, filed on June 24, 2013, identified as a "continuation" of Application No. 12/769,635, filed on April 28, 2010, which claims priority from Provisional Application No. 61/173,600, filed on April 29, 2009. (*See* EX1201.)

A. The '056 Patent's Specification

The '056 patent describes a glucose monitoring system having in some embodiments the conventional components depicted in Fig. 1:

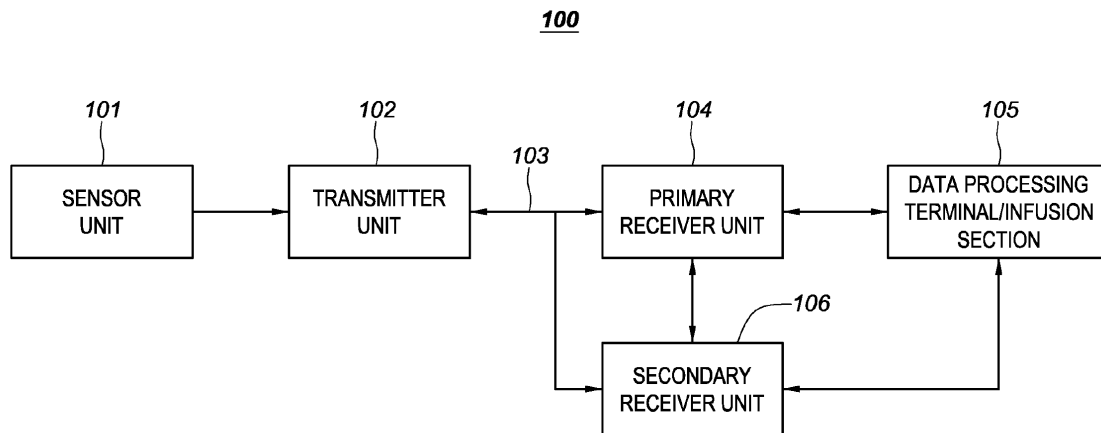


FIG. 1

The patent describes that periodic calibration of the sensor may be required to accurately calculate a user's analyte level ('056 10:59-66), but that there may be a "condition unsuitable for a sensor calibration event" (*id.* 11:6-8). It describes disabling the display of the glucose sensor values on the receiver's display "if a required calibration event is unsuccessful over a permitted time period" (*id.* 12:26-28), leading to a gap in the data displayed as depicted in Fig. 7A (*id.* 12:30-39). Once successful calibration of the sensor data occurs, the data gap is backfilled as depicted in Fig. 7B. (*Id.* 12:62-13:5.)

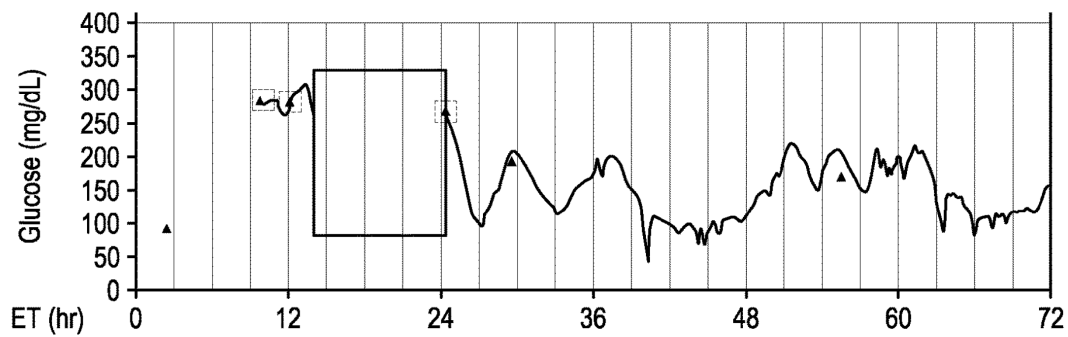


FIG. 7A

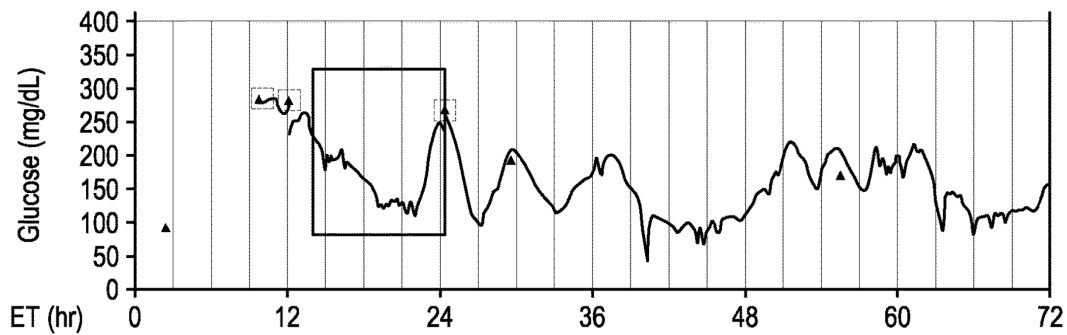


FIG. 7B

B. The Prosecution History

The as-filed claims of the December 21, 2018, Grandparent App. (EX1202 at 21-24) were cancelled in favor of a new set of claims by a preliminary amendment dated April 4, 2019 (EX1205 at 118-125). Those new claims published with Harper 2019 (EX1208 at 16-17). They lacked several features of the later-drafted '056 patent claims, including the “or both” claim language ('056 16:6) discussed below.

The claims of the Parent App. (EX1203) were amended on the application's filing date of April 30, 2021 (EX1206 at 156-164), and later allowed as is (*id.* at 12-13). Those claims added “or both” language. (*See id.* at 157.)

The claims of the '056 App. (EX1204 at 21-24) were amended on the application's filing date of August 25, 2021 (EX1207 at 1-8), subjected to further amendments on December 20, 2021 (*id.* at 279-285), and then allowed.

C. The Claims And Their Full Scope

1. Claim 1

Claim 1 ('056 15:24-16:20) concerns a “glucose monitoring system for backfilling data gaps” that appear in the display of calibrated sensor-measured glucose values, caused by the system's detection of a malfunction or other “adverse condition.” The system has three components. A glucose sensor is configured in part to provide sensor data. (*Id.* 15:27-30.) A data processing and transmitter unit coupled to the glucose sensor comprises a power supply, processor, memory, and an RF transceiver. (*Id.* 15:31-36.) This unit's claim-recited functions (*id.* 15:37-51) are discussed later herein. A receiver unit comprises a processor, memory, an RF transceiver, and a display. (*Id.* 15:52-54.) Its claim-recited functions (*id.* 15:55-64, 16:8-12) are discussed later herein. Claim 1 also recites functions of the “system” itself, including being configured to “detect an adverse condition.” (*Id.* 15:65-16:3.) It also recites the *operation* of the system, in the claim's second wherein clause with

the “or both” language added, in part, by the Parent App. (EX1203): “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.” (’056 16:4-7.)

2. Full Scope Of Claim 1

The primary issue presented by this petition is the effective filing date of each claim. To show entitlement to a filing date of an ancestor application under 35 U.S.C. § 120, the patent owner has the initial burden of production to show that the ancestor application provides full scope and other written description support and full scope and other enablement support for the claim under Section 112(a). (*See* Sections VIII A and B *infra*.) A threshold issue, therefore, is to identify the full scope of the claims.

Patent claim constructions normally identify what a claim term *requires*. But, often, a construction identifies not what a claim or claim term requires but what it *encompasses*, *i.e.*, includes. Determining what the claims encompass is the first analytical step when determining whether the “full scope” of a claim is supported by an application’s disclosure. *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1241 (Fed. Cir. 2003). When asserting herein that a claim element *encompasses* something, Petitioner takes no position on whether it also *requires* that something.

The full scope of each challenged claim encompasses processors of the claimed system being programmed to perform the full scope of functions and

operations of claim 1's four wherein clauses ('056 15:65-16:20), for the full scope of 17 "adverse conditions," including being programmed to: (1) continuously monitor for and detect all of those adverse conditions, and when they start and stop; (2) store throughout a 72-hour or longer time period experiencing an adverse condition, in a memory of the data processing and transmitter unit ("transmitter"), calibrated sensor data generated from data received from the sensor during that time period, but *not programmed* to store in that memory that received uncalibrated sensor data; and (3) display on a mobile phone or other receiver display, immediately after correction of any detected adverse condition, a line graph of accurate glucose values for the entire adverse-condition time period, despite not having stored accurate glucose values during that time period. We explain this full scope in greater detail below.

Full scope of 17 adverse conditions: Claim 1 recites that the "system is configured to detect an adverse condition." ('056 15:65-66.) The dependent claims and the specification identify the following 17 categories¹ of "adverse condition": (1) a "sensor communication error" ('056 claim 3, 13:65); (2) "a signal error associated with the glucose sensor" (claim 4); (3) "a signal error associated with the

¹ Petitioner takes no position on the extent to which these categories overlap or are clear.

data processing and transmitter unit” (claim 5); (4) “a signal error associated with the receiver unit” (claim 6); (5) “a system malfunction associated with the data processing and transmitter unit” (claim 7); (6) “a system malfunction associated with the receiver unit” (claim 7); (7) “an inability of the receiver unit to display or output at least a portion of [the] first line graph” (claim 8); (8) “a sensor instability condition” (claim 9, 13:61); (9) “a calibration failure condition” (claim 10, 13:61-62); (10) “a monitoring system failure condition” (claim 11, 13:62); (11) a “sensor misposition error” (claim 13, 13:64-65); (12) a “temperature measurement outside a predetermined range” (claim 14, 13:65-66); (13) “an analyte level exceeding a predetermined threshold” (claim 15, 14:2); (14) “a rate of change of an analyte level exceeding a predetermined threshold” (claim 16, 14:2-4); (15) “a data unavailability condition” (claim 17, 14:5); (16) “a signal error associated with the blood glucose reference data” (claim 25, *see* 14:4); and (17) an “early signal attenuation condition of the sensor” (13:64). Thus, the full scope of claim 1 encompasses having the claimed functions and operation for the full range of these 17 “adverse conditions.”

Continuously monitor for and detect all 17 adverse conditions, and when they start and stop: Claim 1 recites that the glucose monitoring system is “configured to detect *an* adverse condition.” (*Id.*) (emphasis added). As a rule of claim construction, “an” refers, with rare exceptions, to one *or more*. *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356-57 (Fed. Cir. 2000). The ’056 patent expressly adopts this

rule: “as used herein and in the appended claims, the singular forms ‘a’, ‘an’, and ‘the’ include plural referents unless the context clearly dictates otherwise.” (’056 3:50-52.) Thus, by referring to detecting “an” adverse condition, the full scope of claim 1 encompasses a processor programmed to detect all 17 adverse conditions.

Claim 1’s first wherein clause indicates that the claim encompasses a system that detects the “start of the adverse condition” (*id.* 16:2-3) and its fourth wherein clause indicates that the claim encompasses a system that detects “an end of the adverse condition” (*id.* 16:19-20). Dependent claim 18 similarly recites displaying data “immediately after the correction of the adverse condition,” which implies “immediately” detecting when the adverse condition stops. Thus, claim 1 encompasses detecting exactly when the adverse condition starts and stops, which implies continuously monitoring for such adverse conditions and their correction. Therefore, claim 1 encompasses the processor(s) being programmed to continuously monitor for all 17 of those adverse conditions to detect when they start and stop.

Store throughout 72-hour or longer adverse-condition time period: Claim 1’s second wherein clause requires certain data to be stored “during a time period corresponding to the adverse condition,” whose full scope includes during the entire time period(s) of the adverse condition(s). (’056 16:4-7.) The claims do not limit the length of the adverse-condition time period(s). But the specification states that the

sensor may be configured for calibration 72 hours after insertion (*id.* 11:8-13), which implies that the detected adverse condition may be as long as 72 hours, or longer.

Store calibrated sensor data derived from sensor data received during the adverse-condition time period but not store that sensor data: Claim 1 recites that the transmitter is configured to “receive the sensor data from the glucose sensor ...” (’056 15:39) and to “process the sensor data using calibration data to provide processed sensor data ...” (*id.* 15:42-43). Thus, “sensor data” referenced elsewhere in the claim at least includes uncalibrated sensor data the transmitter receives from the glucose sensor, and “processed sensor data” referenced elsewhere in the claim at least includes this calibrated sensor data generated by the transmitter from that sensor data. And both terms encompass data that is bad (inaccurate) on account of some adverse condition. This is confirmed by claim 1’s second wherein clause, which includes storing “sensor data” and/or “processed sensor data” “during a time period corresponding to the adverse condition.” (*Id.* 16:4-7.)

As noted, the second wherein clause (*id.*) refers to both “sensor data” and “processed sensor data.” It recites that during the adverse-condition time period, “sensor data, processed sensor data, *or both*” are stored in the memory of the transmitter. (*Id.*) (emphasis added). As explained below, this “or both” claim language is critical to the claims’ effective filing date.

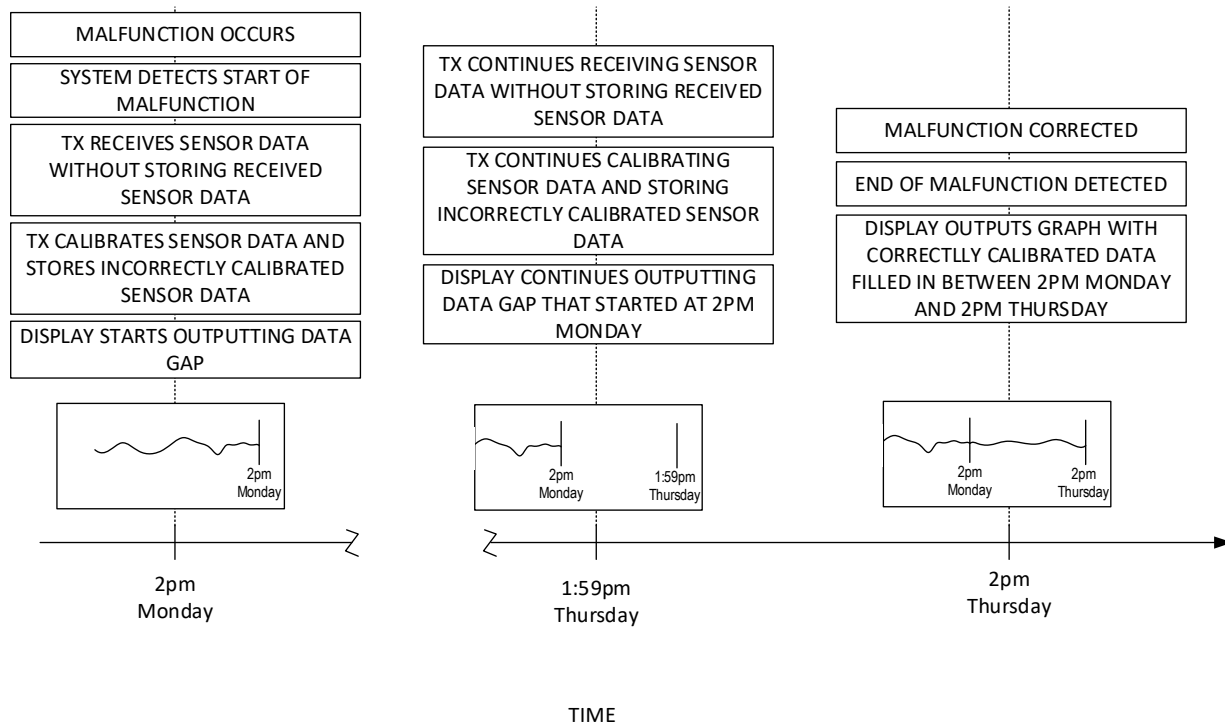
Per the ordinary meaning of “or both,” the full scope of this claim language encompasses three different modes of operation during the adverse-condition time period: (1) the transmitter stores uncalibrated sensor data received from the glucose sensor, but no calibrated data derived from processing that received uncalibrated sensor data; (2) the transmitter stores calibrated data derived from processing the uncalibrated sensor data, but not that uncalibrated sensor data; and (3) the transmitter stores both uncalibrated and calibrated data in the transmitter’s memory. The second mode of operation encompassed by this “or both” claim language in which any raw, unprocessed data received from the sensor during the adverse-condition period is *not* stored, is particularly problematic vis-à-vis the limited disclosure of the Grandparent App. (EX1202), as explained in Section IV D *infra*.

Display on the display of a mobile phone or other receiver unit, immediately after any detected adverse condition is corrected, accurate glucose values for the entire adverse-condition time period: Claim 1 recites that “the receiver unit is configured to output to the display, after the adverse condition is corrected,” processed (i.e., calibrated) “sensor data for the time period corresponding to the adverse condition.” (’056 16:8-12.) This encompasses outputting that calibrated data “immediately” after correction of the adverse condition, as that “immediately” limitation is recited in dependent claim 18. And it encompasses outputting *accurate* glucose values, for the entire adverse time period, as implied by the beginning and

ending data points of the backfilled second line graph in '056 patent Fig. 7B matching exactly the adjacent data points of the first (presumably accurate) line graph.

Dependent claim 22 recites that “the receiver unit comprises a mobile phone” ('056 17:21), so the full scope of the “receiver unit” in each claim encompasses a mobile phone.

Thus, as shown in the below illustration created for this petition, the full scope of claim 1 is a genus that includes a system programmed to immediately, upon the end of a 72-hour or longer adverse condition, output accurate (correctly calibrated) glucose values for an entire adverse-condition time period, for any and all of the 17 adverse conditions, despite having not stored any accurate uncalibrated sensor data received during that time period but instead having stored in the transmitter only calibrated glucose measurement values that are incorrect on account of an “adverse condition.” ('056 13:60-62.)



3. The Dependent Claims

Dependent claims 3-11, 13-17, and 25 each identifies a category of “adverse condition,” preceded by “comprises.” For example, claim 6 recites: “wherein the adverse condition comprises a signal error associated with the receiver unit.” Despite identifying only one category of adverse condition, these dependent claims also have a full scope encompassing all 17 adverse conditions identified in the ’056 patent. This is so because the primary plain meaning of “comprises” is “includes without being limited to.” Therefore, claim 1’s references to “an adverse condition” and “the adverse condition” (’056 15:66-16:20) still encompass, even in the context of these dependent claims identifying one adverse condition after the open-ended word “comprises,” one or more of the 17 adverse conditions, and the dependent claims

merely require that at least one of those adverse conditions be of the category recited in the dependent claim. Thus, these dependent claims are narrower than claim 1 in what they *require* but their full scope still *encompasses* a capability to detect any and all 17 adverse conditions identified in the patent and perform the other claimed functions and operations therefor.

The other dependent claims also encompass what claim 1 encompasses.

D. The Grandparent App. As Filed

The Grandparent App. (EX1202) did not describe or enable the full scope of the genus of any '056 patent claim.

For example, the Grandparent App. (EX1202) did not describe or enable performing the “receiver unit” functions on a mobile phone, as *encompassed* by each claim and *required* by claim 22. (Morten Jensen Decl., ¶¶ 51-53.) On the contrary, the Grandparent App. distinguished the primary “receiver unit” from the “secondary receiver unit” (each identified in the '056 patent's Fig. 1 block diagram) describing only the latter as possibly having sufficiently few functions and features to be embodied in a mobile phone. (EX1202 [0028].) “Alternatively,” it continued, the secondary receiver unit may have the same functions and features as the primary receiver, but without describing this full-featured alternative as being embodied in a mobile phone. (*Id.*) It also described the secondary receiver unit as performing the display-disabling methods of Fig. 4 (*id.* [0055]) and Fig. 5 (*id.* [0056]) but did *not*

describe it as performing the data-backfilling methods of Figs. 6 and 7 (*see id.* [0058]-[0062]). Thus, the Grandparent App. neither described nor enabled the claims' "receiver unit" (which is configured to backfill data) comprising a mobile phone. Yet that is part of each claim's full scope as confirmed by dependent claim 22's recitation that "the receiver unit comprises a mobile phone." This disparity alone suffices to bar backdating the claims to the filing date of the Grandparent App.

As another example, the Grandparent App. purported to incorporate by reference "exemplary calibration protocols, routines and techniques" described in a patent and three patent applications (EX1202 [0051]) but did not describe how to use those techniques to successfully and immediately recover from a prolonged period of malfunction without having stored in the transmitter during that malfunction period *accurate* calibrated or uncalibrated sensor data. Yet that is part of each claim's full scope.

Similarly, the Grandparent App. asserted that "once 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" (EX1202 [0060]) and that "upon correction or rectification of the condition or conditions/parameters which resulted in the analyte monitoring system disabling the output results associated with the monitored real time analyte levels, the parameters associated with the correction or rectification may be used to retrospectively correct

or process data or signals so that the missing gaps in analyte related data may be processed and backfilled” (*id.* [0062]). But these assertions were mere aspirations. The Grandparent App. gave no example of how to do this and no algorithm or circuit for how to do this, successfully and immediately, for the full scope of 17 adverse conditions, especially when no accurate uncalibrated data received from the sensor was stored in the transmitter (or elsewhere) during that time period. In other words, the Grandparent App. did not describe or enable how to “retrospectively correct” bad data stored by the transmitter (or missing data) for the full range of adverse conditions that made that data bad or missing. (Morten Jensen Decl., ¶¶ 54-57.) It did 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.

Nor did the Grandparent App. (EX1202) describe or enable how to detect the full scope of 17 adverse conditions, and to continuously monitor for those adverse conditions to detect exactly when they start and stop. It gave no example of doing this and no algorithm or circuit for doing this for the full scope of adverse conditions. For example, it 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 predetermined threshold, a

temperature measurement outside a predetermined range, or any combination thereof.” (Ex1202 [0053].) (*See* Morten Jensen Decl., ¶¶ 41-42, 44-48.)

Nor did the Grandparent App. (EX1202) describe or enable how to immediately display accurate glucose values for the entire adverse-condition time period when: (1) no sensor data had been received by the transmitter during that period due to a sensor or other malfunction; (2) only inaccurate sensor data had been received by the transmitter during that period; or (3) only inaccurate calibrated sensor data had been stored during that period without storage of accurate uncalibrated sensor data. (*See* Morten Jensen Decl., ¶¶ 49-50 (no clear disclosure of transmitter unit calibrating sensor data during adverse-condition period or storing such calibrated data without storing uncalibrated data received from the sensor).)

To establish entitlement to the Grandparent App.’s 2018 filing date, or an earlier filing date, Patent Owner has the initial burden of production to show, *inter alia*, that the Grandparent App. provided full scope written description and enablement support for *all* of the above functions and features individually and in combination. *See infra* at VII, VIII A and B. Patent Owner will be unable to satisfy that burden.

We address below, more specifically, the disclosure of the following parts of the Grandparent App.: (1) its “apparatus” embodiment; (2) its Figs. 6 and 7 methods;

(3) its claims as filed; (4) its remaining express disclosures; and (5) its purportedly incorporated materials.

Apparatus Embodiment: The Grandparent App. disclosed an “apparatus” as “another embodiment.” (EX1202 [0007], [0077]-[0085].) Its description of this apparatus embodiment lacked at least the following features within the full scope of the claims.

1. No disclosure of how to detect or continuously monitor for the adverse conditions other than perhaps certain “condition[s] unsuitable for calibration of a sensor” (*id.* [0077]).
2. No transmitter with RF transceiver, or memory thereof.
3. No Bluetooth link.
4. No storing of calibrated sensor data without storing received sensor data, during an adverse-condition time period.
5. No receiver unit.
6. No calibration of sensor data or transmission of calibrated sensor data.
7. No storing of sensor data and calibrated sensor data in the same memory. It disclosed that received sensor data and calibrated sensor data are stored in a “first memory” and “second memory” respectively. (*Id.* [0077].)

8. No display of a first line graph or second line graph, or of a numerical glucose value.

Figs. 6 and 7 Methods: The Grandparent App. disclosed methods related to Figs. 6 and 7. (EX1202 [0058]-[0076].) Their description lacked at least the features and claim scope labelled 1 through 5, above, lacking from the hardware embodiment. Also, it implied that calibrated sensor data is *not* stored during an adverse-condition time period. (EX1202 [0059] (after system recovery after successful calibration, “the calibrated sensor data is once again displayed (and stored)”).)

As-filed Claims: The Grandparent App. claims as filed (EX1202 at 21-24) lacked at least the same features and claim scope identified above for the “apparatus” embodiment and the “methods” related to Figs. 6 and 7.

Remainder of Express Disclosure: The remainder of the Grandparent App.’s (EX1202) express disclosure likewise lacked many of the claims’ features and scope, including the following.

- No disclosure of how to detect the full scope of 17 adverse conditions and how to continuously monitor for those adverse conditions to detect exactly when they start and stop. The Grandparent App. gave a brief black-box description of a “leak detection circuit” to determine whether measured sensor data are corrupt (EX1202 Fig. 2, item 214 and [0045]), but did not

disclose any structure or algorithm sufficient to perform that function, and did not disclose that circuit as continuously monitoring for signal leakage to detect the exact start and stop times of the adverse condition. (*See* Morten Jensen Decl., ¶¶ 34-37, 40, 45-47.) Similarly, its discussion of detecting conditions unsuitable for calibration provided no example, algorithm, or circuit for determining whether “successful calibration” occurred, and was otherwise limited. (*Id.*, ¶¶ 41-43, 48.)

- No disclosure of storing calibrated sensor data without storing received uncalibrated sensor data from which that calibrated data is derived.
- No disclosure of a transmitter performing calibration and storing calibrated data in the same memory as stored received sensor data. The Grandparent App. disclosed the transmitter performing the routines of Figs. 4 and 5, which included determining whether the sensor was calibrated and if not, storing sensor data in the receiver unit (EX1202 [0055], [0057]), but did not describe the transmitter performing the calibration or storing the calibrated data.

Purportedly Incorporated References: The Grandparent App. purported to incorporate about 100 references “for all purposes.” (EX1202 [0009], [0045],

[0051].)² The Grandparent App. did not disclose particular combinations of features or configurations of any of this mass of incorporated material with any other incorporated material or with any expressly disclosed embodiment. For example, the Grandparent App. did not disclose any particular combination of its “apparatus” embodiment or its Figs. 6 or 7 method embodiment, on the one hand, with any particular embodiment in the incorporated materials. There was, in other words, a forest of trees but no blaze marks through the trees to the later-claimed particular combinations of elements to guide a skilled artisan without foreknowledge of those future claims. And even if combined with hindsight knowledge of the claims, which is improper, Patent Owner has the burden of production to show that the incorporated materials disclose and enable the full scope of the claims, including but not limited to how to continuously monitor for the full scope of 17 adverse conditions and detect exactly when they start and stop, and how to successfully and immediately recover from those adverse conditions after having stored in the transmitter (or elsewhere) no accurate calibrated or uncalibrated sensor data.

² If and when Patent Owner seeks to rely on any allegedly incorporated disclosure, Petitioner will address whether and the extent to which such disclosure may be relied upon to provide written description or enablement support for a claim.

In sum, without limiting the above points or relieving Patent Owner of its burden of production to show entitlement to an earlier effective filing date, the Grandparent App. lacked both full scope written description support and full scope enablement support of the claims in at least the following respects both individually and in combination:

1. detecting all 17 adverse conditions identified in the '056 patent;
2. continuously monitoring for those adverse conditions to detect exactly when they start and stop;
3. storing during a 72-hour or longer adverse-condition period calibrated sensor data in the transmitter's memory but not the sensor data received from the sensor during that period;
4. 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 data from the sensor during that period due to the adverse condition;
 - b. not having received accurate glucose-measurement data from the sensor during that period due to the adverse condition;
 - c. not having stored accurate glucose-measurement data received from the sensor during that period; and/or

- d. having stored only inaccurate, calibrated glucose-measurement data during that period; and
- 5. performing the claims' "receiver unit" functions on a mobile phone.

V. LEVEL OF SKILL IN THE ART, AND STATE OF THE ART

The person of ordinary skill in the art in December 2018 ("POSITA") would have had a Bachelor of Science degree in biomedical engineering, or similar field, such as electrical or computer engineering, and two years of industry experience or research working with medical devices and systems for measuring biomedical signals, for example levels of blood analytes, such as glucose, in a patient and transmitting indications of such levels of analytes to a receiving device for reporting the measurements. Additional education, such as a Master's degree in biomedical engineering could substitute for the industry experience as it typically involves at least two years of additional study, which can be focused on medical devices including data electronics and analysis systems, as well as a thesis or project spanning several semesters to implement a substantial project. (Morten Jensen Decl. ¶ 19.)

VI. CLAIM CONSTRUCTION

The Board should construe the full scope of the claims' "adverse conditions." This full scope necessarily includes the adverse conditions recited by the dependent claims (3-5, 7, 9-10, 13, 17 and 25) and those identified in the specification. *See AK*

Steel, 344 F.3d at 1242 (full scope of independent claim must encompass what is recited in dependent claim).

Based on this intrinsic evidence, the full scope of “adverse condition” in the claims should be construed to include these 17 conditions: (1) a “sensor communication error” (claim 3, 13:65); (2) “a signal error associated with the glucose sensor” (claim 4); (3) “a signal error associated with the data processing and transmitter unit” (claim 5); (4) “a signal error associated with the receiver unit” (claim 6); (5) “a system malfunction associated with the data processing and transmitter unit” (claim 7); (6) “a system malfunction associated with the receiver unit” (claim 7); (7) “an inability of the receiver unit to display or output at least a portion of [the] first line graph” (claim 8); (8) “a sensor instability condition” (claim 9, 13:61); (9) “a calibration failure condition” (claim 10, 13:61-62); (10) “a monitoring system failure condition” (claim 11, 13:62); (11) a “sensor misposition error” (claim 13, 13:64-65); (12) a “temperature measurement outside a predetermined range” (claim 14, 13:65-66); (13) “an analyte level exceeding a predetermined threshold” (claim 15, 14:2); (14) “a rate of change of an analyte level exceeding a predetermined threshold” (claim 16, 14:2-4); (15) “a data unavailability condition” (claim 17, 14:5); (16) “a signal error associated with the blood glucose reference data” (claim 25, *see* 14:4); and (17) “early signal attenuation condition of the sensor” (13:64).

For *inter partes* review, claim terms should be given their ordinary meaning to a person of ordinary skill in the art on the effective filing date, in view of the specification and file history. 83 Fed. Reg. 51340; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). Unless otherwise expressly discussed, Petitioner herein applies the ordinary meaning of all claim terms as of April 2021, the filing date of the Parent App. Petitioner does not, however, waive any argument in any litigation that claim terms in the '056 patent have a particular meaning and/or are indefinite. Nor does Petitioner waive its right to raise additional issues of claim construction in any proceeding.

VII. THE CITATION OF INTERVENING PRIOR ART SHIFTS THE BURDEN OF PRODUCTION TO PATENT OWNER TO SHOW ENTITLEMENT TO AN EARLIER EFFECTIVE FILING DATE

Patent Owner bears the initial burden *of production* to show for each claim, that the claim is entitled to be backdated to the Grandparent App.'s filing date. "[A] patent's claims are not entitled to an earlier priority date merely because the patentee claims priority." *In re NTP, Inc.*, 654 F.3d 1268, 1276 (Fed. Cir. 2011); *see also* 35 U.S.C. § 120 (AIA) (providing the benefit of an earlier application's filing date only where that application "disclosed" the claimed "invention" "in the manner provided by section 112(a) (other than the requirement to disclose the best mode)"). "[W]hen a patent owner attempts to antedate an asserted prior art reference, the patent owner assumes a temporary burden of production." *Parus Holdings, Inc. v. Google LLC*,

70 F.4th 1365, 1371 (Fed. Cir. 2023) (affirming PTAB finding that patent owner failed to satisfy its burden of production to show that the continuation patent's ancestor application provided written description support for the claims, making the publication of that application prior art, which prior art combined with another reference rendered the claims unpatentable for obviousness).

“Claims in a patent or patent application are not entitled to priority under § 120 at least until the patent owner *proves* entitlement to the PTO, the Board, or a federal court.” *Nat. Alts. Int’l, Inc. v. Iancu*, 904 F.3d 1375, 1380 (Fed. Cir. 2018) (emphasis in original). Thus, while Petitioner has the burdens of production and persuasion on showing unpatentability, Patent Owner has the burden of production to show that it is entitled to backdate the claims to an effective filing date of the Grandparent App. to antedate Harper 2019 as prior art. “[O]nce a challenger (the alleged infringer) has introduced sufficient evidence to put at issue whether there is prior art alleged to anticipate the claims being asserted, prior art that is dated earlier than the apparent effective date of the asserted patent claim, the patentee has the burden of going forward with evidence and argument to the contrary.” *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1329 (Fed. Cir. 2008); *see D Three Enters., LLC v. SunModo Corp.*, 890 F.3d 1042, 1049 (Fed. Cir. 2018) (same); *In re Katz*, 639 F.3d 1303, 1322 (Fed. Cir. 2011) (same).

This burden-shifting law applies even when, as here, the applications from which the patent issued are designated “continuation” applications. *Rsch. Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859 (Fed. Cir. 2010); accord *In re NTP*, 654 F.3d at 1276; *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364 (Fed. Cir. 2016).

This burden-shifting law applies in Patent Office proceedings. See *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1379-80 (Fed. Cir. 2015) (patent owner has burden of production in *inter partes* review to show entitlement to provisional filing dates); *Penumbra, Inc. v. RapidPulse, Inc.*, IPR2021-01466, Paper 34 (P.T.A.B. Mar. 10, 2023) (patent owner failed its burden of production to show claims had adequate written description support in provisional application); *Samsung Elecs. Co. v. Hardin*, IPR2022-01331, Paper 14 (P.T.A.B. Feb. 7, 2023) (for purposes of an Institution Decision, the patent owner failed to satisfy its burden of production to show that an ancestor application, in a series of “continuation” applications, provided written description support for the claims); *MaxLite, Inc. v. Jiaxing Super Lighting Elec. Appliance Co.*, IPR2020-00208, Paper 40 (P.T.A.B. Apr. 29, 2022) (patent owner failed its burden of production to show that each claim element was supported by a foreign ancestor application); *Aquestive Therapeutics, Inc. v. Neurelis, Inc.*, IPR2019-00451, Paper 44 (P.T.A.B. Aug. 6, 2020) (patent owner failed to meet its burden of production to show that claims were supported by a provisional application); *Inguran LLC v. Premium Genetics (UK) Ltd.*, PGR2015-

00017, Paper 22 (P.T.A.B. Dec. 20, 2016) (patent owner failed to satisfy its burden of production to show that the ancestor application provided written description support for each element of the claim). In short, the Parent App.’s filing date is each claim’s earliest effective filing date absent a contrary showing by Patent Owner.

**VIII. THE GRANDPARENT APP. AS
FILED DID NOT SUPPORT THE CLAIMS**

**A. The Grandparent App. Lacked Written
Description Support For The Claims’ Full Scope**

“What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002). This is the Patent Act’s written description requirement. 35 U.S.C. § 112(a) (AIA) (“the [patent’s] specification shall contain a written description of the invention”). A patent’s 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 Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (emphasis added) (internal quotation marks, brackets, and citations omitted).

The application’s disclosure of the claimed subject matter must be: (1) express or necessarily present, *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998);

(2) complete, *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1995); (3) unambiguous, *Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998); (4) specific, *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1322 (Fed. Cir. 2000); and (5) as broad as the claim, *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478-80 (Fed. Cir. 1998).

“[T]he written description must lead a person of ordinary skill in the art to understand that the inventors possessed the *entire scope* of the claimed invention.” *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1337 (Fed. Cir. 2021) (emphasis added); *cf. Atl. Rsch. Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1355 (Fed. Cir. 2011) (claims held invalid because they “exceed in scope the subject matter that [applicant] chose to disclose to the public in the written description”); *Synthes USA, LLC v. Spinal Kinetics, Inc.*, 734 F.3d 1332, 1341-45 (Fed. Cir. 2013) (claim invalid for lack of written description support because construed to cover “openings” in an implant, but specification disclosed only peripheral grooves not slots or channels).

A Federal Circuit decision on a mechanical assembly illustrates this demanding statutory mandate. In *D Three Enters.*, 890 F.3d at 1049, the Federal Circuit affirmed summary judgment that two sets of genus patent claims related to solar panel roof mounting assemblies were unsupported by the limited embodiments disclosed in the ancestor patent application. The first set of genus patent claims required no washer. The ancestor application disclosed a washerless assembly but

only with a particular type of attachment bracket. The Court held that this limited, single-embodiment disclosure did not support the broader scope of the claims, which encompassed a washerless assembly with attachment brackets not limited to the disclosed bracket. *Id.* at 1050-51. The second set of genus claims required a washer, without specifying its location relative to the flashing. The ancestor application disclosed embodiments with a washer but the washer was consistently above the flashing. The Court held that this limited disclosure did not support claims not requiring that the washer be above the flashing. *Id.* at 1052.

Section IV C *supra* identifies in part the full scope of features, capabilities, and operation encompassed by each claim. But the Grandparent App. did not describe such features, capabilities, and operation in the manner required by the above precedents, as described in part *supra* at IV D.

To try to justify backdating these claims to the Grandparent App.’s filing date, Patent Owner might attempt to use hindsight *guided by the issued claims* to pluck claim elements from disparate parts of that application’s express disclosures and approximately 100 other separate disclosures that the ’056 patent purports to incorporate by reference. But that is contrary to well-settled law. Governing precedents prohibit “[w]orking backward from a knowledge of [the claims], that is by hindsight,” and seeking “to derive written description support from an amalgam

of disclosures plucked selectively from” the application. *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013).

Judge Giles Rich, one of the two co-authors of the 1952 Patent Act, explained this principle:

It is ... easy to imagine that the compound of claim 13 might have been named in the specification. Working backward from a knowledge of chlorpropamide, that is by hindsight, it is all very clear what route one would travel through the forest of the specification to arrive at it. But [we must] look[] at the problem ... from the standpoint of one with no foreknowledge of the specific compound.

In re Ruschig, 379 F.2d 990, 995 (C.C.P.A. 1967); *see Hyatt v. Dudas*, 492 F.3d 1365, 1371 (Fed. Cir. 2007) (affirming *ex parte* rejection of claims on ground that “while each element may be *individually* described in the specification, the deficiency was the lack of adequate description of their *combination*”).

Ruschig also explained a related governing principle applicable to Patent Owner’s expected attempt to backdate the claims here:

It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one’s way through the woods where the trails have disappeared — or have not yet been made, which is more like the case here — to be confronted simply by a large number of unmarked trees. Appellants are pointing

to trees. We are looking for blaze marks which single out particular trees. We see none.

In re Ruschig, 379 F.2d at 994-995; *see Purdue Pharma*, 230 F.3d at 1326-27 (“[O]ne cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.”).

Here, the Grandparent App. lacked blaze marks to the claims’ above-identified combination of full-scope features. Therefore, due in part to the lack of full scope written description support, no claim is entitled to an effective filing date earlier than the April 2021 filing date of the Parent App.³

**B. The Grandparent App. Lacked
Enablement Support For The Claims’ Full Scope**

Lack of full scope *enablement* support is a second reason why no claim is entitled to an effective filing date earlier than April 2021.

“[T]he specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable.” *Amgen Inc. v. Sanofi*, 143 S. Ct. 1243, 1254 (2023). “If a patent claims an entire class of processes,

³ Petitioner does not concede that the claims are supported by the Parent App. or the ’056 App. but those issues are not before the Board on this petition.

machines, manufactures, or compositions of matter, the patent’s specification must enable a person skilled in the art to make and use the entire class.” *Id.* This “important doctrine” requiring full scope enablement support “prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented. Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage.” *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012); *see Trustees of Boston Univ. v. Everlight Elecs. Co.*, 896 F.3d 1357, 1364 (Fed. Cir. 2018) (“BU notes that there is no dispute as to enablement of five out of the six referenced permutations and argues ‘[t]hat is sufficient.’ We disagree. Our precedents make clear that the specification must enable the full scope of the claimed invention.”); *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1160 (Fed. Cir. 2019) (“an enabling disclosure must ‘be commensurate in scope with the claim’”); *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1000 (Fed. Cir. 2008) (“Because the asserted claims are broad enough to cover both movies and video games, the patents must enable both embodiments.”).

The Grandparent App. lacked enablement support for the full scope of the claims everywhere it lacked written description support. For example, it did not enable a skilled artisan to program a glucose monitoring system to detect and continuously monitor the full scope of 17 adverse conditions, or to program

processors of the claimed system to immediately output 72 or more hours of accurate glucose values immediately after correction of an adverse condition despite not having saved accurate calibrated or uncalibrated sensor data for that time period.

To carry out the full scope of the claims would require at best an enormous amount of non-routine, undue experimentation. For each encompassed type of adverse condition, the artisan would, for example, need to experiment to discover how to convert stored but incorrectly calibrated data into accurate glucose values, and how to recreate missing sensor data, accounting for the nature of the adverse condition causing the calibrated data to be incorrect or missing, and program a processor to then use those experimentation results to immediately calculate for display accurate glucose values for a days-long adverse condition, upon correction of the adverse condition. Moreover, the artisan 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.

While at least some of this functionality was known by December 2018 (*see* Hayter/Taub 2013 (EX1210)), it is the specification of the Grandparent App. that must enable the POSITA to practice the full scope of the claim. “It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.... A patent owner is ‘required to provide an enabling disclosure in the specification; it cannot simply

rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification.” *Idenix Pharms.*, 941 F.3d at 1159-61.

More particularly, the disclosure must allow the skilled artisan to carry out the full scope *by following* the teachings of the application. *Nat’l Recovery Techs. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999) (“If, *by following the steps set forth in the specification*, one of ordinary skill in the art is not able to replicate the claimed invention without undue experimentation, the claim has not been enabled as required by § 112, paragraph 1.”) (Emphasis added); *Trustees of Boston Univ.*, 896 F.3d at 1363 (“But the inquiry is not whether it was, or is, possible to make the full scope of the claimed device—a scope that here covers a monocrystalline growth layer directly on an amorphous layer. The inquiry is whether the patent’s specification taught one of skill in the art how to make such a device without undue experimentation as of the patent’s effective filing date.”). There is no such teaching in the Grandparent App. for the full scope of adverse conditions. As one example, the Grandparent App. gives no example, circuit, or algorithm for immediately detecting the correction of each of the 17 adverse conditions and then immediately displaying accurate glucose values for the 7-hour or longer adverse-condition time period, despite having not stored during that period accurate calibrated or uncalibrated sensor data in the transmitter or elsewhere.

Therefore, for this second reason, no claim is entitled to an effective filing date earlier than the April 2021 filing date of the Parent App.

While this petition has identified multiple material disparities between the scope of the Grandparent App.'s disclosure versus the scope of the '056 patent claims, even a single claim element lacking full scope support is enough to defeat backdating of the claims to that application's filing date.

In addition to the lack of *full scope* written description and enablement, the Grandparent App. does not disclose and enable *any* embodiment of the following claim elements, *see infra* at IX A (discussing Harper 2019, the publication of the Grandparent App.), which are additional reasons why it does not support the '056 patent claims:

- (claim 1) (15:42-45) transmitter 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”;
- (claim 1) (15:45-47) “wherein the processed sensor data is stored in the memory of the data processing and transmitter unit”;
- (claim 1) (15:65-16:3) system “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”; and

- (claim 22) (17:21) “the receiver unit comprises a mobile phone”.

IX. THE CLAIMS ARE OBVIOUS

Patent Owner is not expected to deny that the claims would be obvious over the asserted references if those references qualify as prior art, as any such argument by Patent Owner would concede invalidity of the claims under Section 112(a).

Harper 2019 (EX1208) (the publication of the Grandparent App.) discloses or teaches at least one embodiment of most elements of each claim. Petitioner relies on teachings in the other Patent Owner references (Taub/Harper 2012 (EX1209); Hayter/Taub 2013 (EX1210); and He/Taub 2014 (EX1211)), in whole or in part for the remaining elements.

A. This Prior Art Teaches An Embodiment Of Each Claim

Sections 112(a) and 103 of the Patent Act are asymmetrical. While Section 112(a) (with Section 120) requires that a claim’s full scope be described and enabled (not merely rendered obvious) by an ancestor application to establish an effective filing date, a Section 103 challenge needs show only that *some embodiment* within the claim is rendered obvious. *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1281 (Fed. Cir. 2015) (“It is a ‘long-established rule that “claims which are broad enough

to read on obvious subject matter are unpatentable even though they also read on nonobvious subject matter.””).

The claims list: (1) components of the system; (2) functional capabilities of a component; (3) functional capabilities of the system; and (4) operation of the system. Below we so group the claim limitations and map them to the asserted prior art.

1. The Prior Art References Disclose An Embodiment Of The Claims’ Components

The claims’ components are conventional: a glucose sensor, data processing and transmitter unit, and receiver unit for all claims, and certain other components in selected dependent claims. Harper 2019 (EX1208) disclosed an embodiment of each component, except for the receiver unit comprising a mobile phone (claim 22), as follows:

- (claim 1) (15:27) “a glucose sensor”: Harper 2019 [0027], [0079], Fig. 1.
- (claim 1) (15:31-36) “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”: Harper 2019 [0027], Fig. 2.

- (claim 1) (15:52-54) “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”: Harper 2019 [0027], Fig. 3.
- (claim 12) (16:54-55) “the glucose sensor comprises a working electrode and a counter electrode”: Harper 2019 [0002].
- (claim 14) (16:58-59) “wherein the on body unit (sic) further comprises a temperature sensor”: Harper 2019 [0038], [0044], Fig. 2.
- (claim 21) (17:17-19) “the data processing and transmitter unit and at least a portion of the glucose sensor are disposed within a single integrated housing”: Harper 2019 [0030] (“the 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”).
- (claim 22) (17:21) “the receiver unit comprises a mobile phone”: Harper 2019 does *not* disclose this element. But, He/Taub 2014 (EX1211) discloses that “the receiver unit 130 may include a mobile phone.” (He/Taub 2014 [0031], Fig. 3.)
- (claim 29) (18:19-24) “secondary receiver unit, ... wherein the secondary receiver unit is a watch”: Harper 2019 [0027], [0028] (“the secondary

receiver unit 106 may be configured substantially in a smaller compact housing or embodied in a device such as a wrist watch, ...”), Fig. 1.

2. The Prior Art References Disclose An Embodiment Of The Claims’ Components’ Functional Capabilities

Harper 2019 (EX1208) discloses an embodiment of the claimed glucose-sensor’s capabilities.

- (claim 1) (15:27-30) “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”: Harper 2019 [0003], [0054].
- (claim 30) (18:26-28) “continuously sample the biological fluid of the user to provide the sensor data”: Harper 2019 [0030].

Harper 2019 (EX1208) and Taub/Harper 2012 (EX1209) combined disclose and teach an embodiment of the claimed data processing and transmitter unit’s capabilities.

- (claim 1) (15:39-41) “receive the sensor data from the glucose sensor and store the sensor data in the memory of the data processing and transmitter unit”: Harper 2019 [0041] (“the transmitter processor 204 also includes a memory (not shown) for storing data such as ... the data signals received from the sensor unit 101”); Taub/Harper 2012 Figs. 1-2 (data processing

- unit 120), [0060] (in the on-body unit, “a data storage unit, such as a memory, may be provided for storage of analyte data points over a short term, e.g., several hours or minutes, or over a long term, e.g., several days or weeks”), [0054] (data processing unit 120 obtains signals from the sensor representative of an analyte level), [0055] (data processing unit 120 may provide signals to the receiving unit periodically or “upon the occurrence of an event, e.g., a hyperglycemic event or a hypoglycemic event,” and “may further include local memory in which it may record ‘logged data’ or buffered data collected over a period of time and provide the some or all of the accumulated data to monitor unit 140 periodically”), [0058] (data processing unit may provide, on demand, analyte trend data for a period of several days or weeks), [0076]-[0077].
- (claim 1) (15:42-45) “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”: Harper 2019 does not disclose this element although it does disclose the transmitter processing the data received from the sensor (Harper 2019 claims 30 and 38 (one or more processors of the transmitter unit process stored sensor data for time period associated with failure mode condition, which processed sensor data is output for display)). Taub/Harper 2012 discloses this element:

- [0067] (“Sensor 110 may be configured to continuously sample the analyte level of the user and convert the sampled analyte level into a corresponding data signal for analysis and/or transmission by data processing unit 120.”), [0076] (processor 321 may be in receiver unit or data processing unit), [0080] (processor 321 “determine[s] a calibration adjustment” based in part on a reference measurement), [0083] (“Calibration is the process where the conversion factor for the calculation of glucose from sensor data is determined, where the conversion factor (or sensitivity) is a ratio of the electrical current generated by the analyte sensor to the reference glucose value associated in line with this current signal.”), [0084] (transmitter’s processor or receiver’s processor performs calibration at various intervals “to determine the sensitivity of the sensor”), [0086]-[0090] (describing calibration procedure of Figs. 4 and 5), Figs. 4-5.
- (claim 1) (15:45-47) “and wherein the processed sensor data is stored in the memory of the data processing and transmitter unit”: Harper 2019 discloses that its transmitter has a memory for storing information and a processor for processing such stored information (EX1208 [0041]) and discloses calibration of “analyte related data signals” received at the transmitter (*id.* [0051]), but does not disclose this claim element. Taub/Harper 2012, however, discloses and teaches this claim element.

When the transmitter generates calibrated sensor data from the sensor data received from the sensor, as described immediately above, in these types of prior art CGM systems with a receiver/display in communication with the transmitter, that data needs to be stored for at least some length of time somewhere before it is displayed. The two most practical options for storing this calibrated sensor data are: store it in the transmitter unit's memory at least until it is transmitted to the receiver or immediately transmit it to the receiver for storage without storing it at the transmitter. As Taub/Harper 2012 explains, two modes of operation of these types of CGM devices are an "on demand" mode where the transmitter transmits data to the receiver only on demand from the receiver, and a periodic transmission mode. (EX1209 [0055], [0058].) To accumulate the data before it is sent to the receiver, Taub/Harper 2012 discloses that its transmitter unit has a memory for storing its data over a period of time, and, as described above, that data includes calibration data: [0055] (data processing unit 120 may provide signals to receiving unit periodically or "upon the occurrence of an event, e.g., a hyperglycemic event or a hypoglycemic event," and "data processing unit 120 may further include local memory in which it may record 'logged data' or buffered data collected over a period of time and provide the some or all of the

- accumulated data to monitor unit 140 periodically”), [0058] (data processing unit may provide, on demand, analyte trend data for a period of several days or weeks), [0060] (In the on-body unit, “a data storage unit, such as a memory, may be provided for storage of analyte data points over a short term, e.g., several hours or minutes, or over a long term, e.g., several days or weeks.”), [0076]-[0077].
- (claim 1) (15:48-51) “transmit the processed sensor data over a Bluetooth wireless communication link using the radio frequency transceiver of the data processing and transmitter unit”: Harper 2019 [0037] (“analyte signals” received over Bluetooth from data processing and transmitter unit).
 - (claim 20) (17:14-15) “store time information associated with the adverse condition”: Harper 2019 claim 32 (“storing time information associated with the failure mode condition”).
 - (claim 27) (18:10-13) “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.”: Harper 2019 [0042].

- (claim 28) (18:15-17) “the power supply of the data processing and transmitter unit is configured to provide power for about three months of continuous operation.”: Harper 2019 [0042].

Harper 2019 (EX1208) discloses an embodiment of the claimed data receiver unit capabilities.

- (claim 1) (15:56-59) “receive, using the antenna and the radio frequency transceiver of the receiver unit, the processed sensor data over the Bluetooth wireless communication link”: Harper 2019 [0037] (“analyte signals” received over Bluetooth from data processing and transmitter unit), [0051] (calibration correctly converts data received from sensor to corresponding analyte levels).
- (claim 1) (15:60-61) “output to the display of the receiver unit, a numerical value representing the processed sensor data”: Harper 2019 [0055].
- (claim 1) (15:62-64) “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”: Harper 2019 Fig. 7A.
- (claim 1) (16:8-12) “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”: Harper 2019 Fig. 7B and [0060], [0061], [0067].

- (claim 1) (16:13-20) “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”: Harper 2019 Fig. 7B and [0060], [0061].
- (claim 2) (16:21-25) “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”: Harper 2019 Fig. 7B and [0060], [0061].
- (claim 18) (17:5-7) “display the second line graph immediately after the correction of the adverse condition”: Harper 2019 [0061].
- (claim 19) (17:9-11) “wait a predetermined period of time after the correction of the adverse condition before displaying the second line graph”: Harper 2019 [0061] (“the backfilled processed sensor data is not displayed immediately, but rather, after waiting a predetermined period of time”).
- (claim 20) (17:14-15) “store time information associated with the adverse condition”: Harper 2019 claim 32 (“storing time information associated with the failure mode condition”).

Harper 2019 discloses an embodiment of the claimed secondary receiver unit capabilities.

- (claim 29) (18:20-23) “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”: Harper 2019 [0028].

3. Harper 2019 And Hayter/Taub 2013 Combined Disclose An Embodiment Of The Claims’ System Capabilities

Harper 2019 (EX1208) and Hayter/Taub 2013 (EX1210) combined disclose an embodiment of the claimed system capabilities, i.e., capabilities a claim does not link to a particular component of the system.

- (claim 1) (15:24-25) “backfilling data gaps that occur while a user monitors glucose levels”: Harper 2019 Fig. 7B and [0060], [0061], [0067].
- (claim 1) (15:64-16:3) “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”: Harper 2019 discloses the idea of detecting at least one type of adverse condition resulting in displaying a data gap: Harper 2019 Fig. 7A and [0058] (“the display or output of processed sensor data may be disabled if a required

calibration event is unsuccessful over a permitted time period”), [0060] (“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).”). But Harper 2019 does not describe or enable how to *monitor* for any of the 17 adverse conditions to detect their exact start and stop times. Hayter/Taub 2013 (EX1210), however, discloses detecting and frequent monitoring (e.g., once per minute) of the functionality of components of the glucose monitoring system to detect malfunctions, including using threshold testing: [0048] (“the data processing module 260 may be configured or programmed to prompt or ping the on-body patch device 211 at a predetermined time interval such as once every minute, ... or any other suitable or desired programmable time interval to request functionality related data from the on-body patch device 211 which is received and is stored in one or more memory devices or components of the data processing module 260... to avoid a failure of the analyte sensor device from going unnoticed”), [0060] (“Essentially, each device in the analyte monitoring system is monitored by one or more of the other devices in the system.”), [0061] (“each device can perform a periodic self test and report this to the other device”), [0063] (“a first device 402 sends

a request that a functionality check of the components of a second device 404 be performed (406)”) [0064] (“The functionality check can include component testing that applies an input to the various components being tested, and receives an output based on the input. Any of a number of common techniques used in electronic devices can be applied to the functionality check of the present disclosure.”), [0066] (“The first device 402 then retrieves from storage a list that includes at least one predetermined criterion related to the functionality of the components of the second device 404 (418). In certain embodiments, the predetermined criterion may be a digital or coded threshold range used to define the proper operating range, whereby, the measured functional test output can be compared to the criterion threshold (e.g., above or below) or compared to the criterion range (e.g., within or outside) to determine functional test status of the component.”), [0067]-[0068], [0082], Fig. 5.

- (claim 3) (16:26-27) “wherein the adverse condition comprises a sensor communication error”: Harper 2019 [0067] (enabled by Hayter/Taub 2013 (EX1210)).
- (claim 4) (16:28-30) “wherein the adverse condition comprises a signal error associated with the glucose sensor”: Harper 2019 [0062] (enabled by Hayter/Taub 2013 (EX1210)).

- (claim 5) (16:31-33) “wherein the adverse condition comprises a signal error associated with the data processing and transmitter unit”: Harper 2019 [0062], claims 24 and 36 (enabled by Hayter/Taub 2013 (EX1210)).
- (claim 6) (16:34-36) “wherein the adverse condition comprises a signal error associated with the receiver unit”: Harper 2019 [0062], claims 24 and 36 (enabled by Hayter/Taub 2013 (EX1210)).
- (claim 7) (16:37-40) “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”: Harper 2019 [0062] (“system malfunction”); claim 25 (same); Hayter/Taub 2013 [0048] (“Similar [functionality checking] functionalities may be provided or programmed in the receiver unit or the reader device in certain embodiments.”), [0060] (“A safety issue with the receiver device, continuous glucose monitors (CGMs), ... in an analyte monitoring system is the susceptibility to single point failure associated with each device’s microprocessor, power supply, audio annunciators, transmitter, and transceiver.”), [0063] (“The first device 402 and the second device 404 in the analyte monitoring system 400 can be at least one of a receiver device, ... a glucose monitor, ... a continuous analyte monitor, a cellular phone, ...”), [0080] (“In certain embodiments, the receiver device ... will detect

if the transmitter in the continuous analyte sensor stops functioning. In certain embodiments, the ... continuous analyte sensor will detect if the transmitter in the receiver device stops functioning.”).

- (claim 8) (16:41-44) “wherein the adverse condition comprises an inability of the receiver unit to display or output at least a portion of the the (sic) first line graph”: Harper 2019 [0062] (“inability of the analyte monitoring system to display or output the real-time monitored analyte level”) (enabled by Hayter/Taub 2013 (EX1210)).
- (claim 9) (16:45-46) “wherein the adverse condition comprises a sensor instability condition”: Harper 2019 [0066] (enabled by Hayter/Taub 2013 (EX1210)).
- (claim 10) (16:47-49) “wherein the adverse condition comprises a calibration failure condition”: Harper 2019 [0066] (enabled by Hayter/Taub 2013 (EX1210)).
- (claim 11) (16:50-52) “wherein the adverse condition comprises a monitoring system failure condition”: Harper 2019 [0066] (enabled by Hayter/Taub 2013 (EX1210)).
- (claim 13) (16:56-57) “wherein the adverse condition comprises a sensor misposition error”: Harper 2019 [0067] (enabled by Hayter/Taub 2013 (EX1210)).

- (claim 14) (16:58-61) “wherein the adverse condition comprises a temperature measurement outside a predetermined range”: Harper 2019 [0067] (enabled by Hayter/Taub 2013 (EX1210)).
- (claim 15) (16:62-64) “wherein the adverse condition comprises an analyte level exceeding a predetermined threshold”: Harper 2019 [0068] (enabled by Hayter/Taub 2013 (EX1210)).
- (claim 16) (16:65-67) “wherein the adverse condition comprises a rate of change of an analyte level exceeding a predetermined threshold”: Harper 2019 [0068] (enabled by Hayter/Taub 2013 (EX1210)).
- (claim 17) (17:2-3) “the adverse condition comprises a data unavailability condition”: Harper 2019 [0068] (enabled by Hayter/Taub 2013 (EX1210)).
- (claim 23) (17:23-24) “the time period associated with the adverse condition comprises at least one hour”: Harper 2019 Figs. 7A and 7B (showing a data-gap period of about 9 hours).
- (claim 24) (17:26-30) “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”: Harper 2019 [0051], [0052], [0068].

- (claim 25) (18:2-3) “the adverse condition comprises a signal error associated with the blood glucose reference data”: Harper 2019 [0068] (enabled by Hayter/Taub 2013 (EX1210)).
- (claim 26) (18:5-7) “for calibration twelve hours after the portion of the glucose sensor has been positioned under the skin of the user”: Harper 2019 [0052].

**4. Harper 2019 Discloses An
Embodiment Of The Claims’ Operation**

Harper 2019 (EX1208) discloses an embodiment of the claimed system’s operations.

- (claim 1) (16:4-7) “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”: This second wherein clause (the “or both” clause) encompasses storing in the memory of the transmitter the *uncalibrated* data without storing calibrated data, which is suggested in Harper 2019. (Harper 2019 [0041] (“the transmitter processor 204 also includes a memory (not shown) for storing data such as ... the data signals received from the sensor unit 101”); claim 23 (“storing sensor data received from the analyte sensor for a time period associated with the failure mode condition”).)

5. A POSITA Would Have Been Motivated To Combine These Teachings To Arrive At An Embodiment Of The Claimed Combination, And Had A Reasonable Expectation Of Success In Doing So

For each of the elements for which Harper 2019 fails to disclose an embodiment, there was a motivation to combine with Harper 2019 the teachings of one of the other asserted references in a manner resulting in such element embodiment, and the combination of claim elements, and a reasonable expectation of success in doing so.

The primary motivation to combine is found in Harper 2019 itself. Harper 2019 implies aspirations and/or requirements for certain features—calibrating and storing calibrated data during an adverse-condition time period, continuously monitoring for the adverse conditions, and using a mobile phone for some receiver functions—but without explaining how to implement such features. This motivated the skilled artisan to apply the teachings of the related references to implement embodiments of those aspirations and requirements, as explained below.

As a general matter, the three other asserted references were natural references to consider for a skilled artisan looking to implement the aspirations of Harper 2019. The four references are closely related. Each is a published patent application of Patent Owner and allegedly describes ideas of employees that appear to have been working together in the same or related groups. The second named inventor of

Taub/Harper 2012 is Wesley Scott Harper, the sole named inventor of Harper 2019. The first named inventor of Taub/Harper 2012 is Marc Barry Taub, the second named inventor of both Hayter/Taub 2013 and He/Taub 2014. Each reference relates in part to similar continuous glucose monitoring systems, having a glucose sensor, an on-body transmitter, and a remote receiver/display. (*See* Fig. 1 of each of EX1208-EX1211; EX1208 [0025]-[0037]; EX1209 [0054]-[0069]; EX1210 [0022]-[0038]; EX1211 [0021]-[0030].) The respective earliest ancestor filing dates for the four references are in a relatively tight succession of 2009 (EX1208), 2010 (EX1209), 2011 (EX1210), and 2012 (EX1211). Thus, each reference flows from overlapping workers at the same company (and location) in the same general time period, working on the same type of device having a similar overall architecture. All of this would suggest to the skilled artisan looking to implement the aspirations of Harper 2019, that the references' respective teachings likely were overlapping, complementary and compatible.

As noted, the elements for which Harper 2019 does not disclose or teach an embodiment are:

- (claim 1) (15:42-45) transmitter 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”;

- (claim 1) (15:45-47) “wherein the processed sensor data is stored in the memory of the data processing and transmitter unit”;
- (claim 1) (15:64-16:3) system 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”; and
- (claim 22) (17:21) “the receiver unit comprises a mobile phone”.

Regarding calibration on the transmitter, Harper 2019 disclosed the importance of calibration (EX1208 [0051]), that the transmitter can determine whether the sensor is calibrated (*id.* [0054]) and that the transmitter *processed* the stored sensor data (*id.* claims 30 and 38), but did not disclose (nor preclude) the transmitter performing the *calibration* processing. Taub/Harper 2012 (EX1209), however, disclosed at length the transmitter performing sensor-sensitivity calibration processing, providing a way to implement the calibration discussed in Harper 2019. Taub/Harper 2012 discloses the transmitter communicating processed sensor data to the receiver immediately (once every 250 milliseconds) or on demand (EX1209 [0057]), and Harper 2019 is consistent with that, disclosing that “real-time” transmissions of analyte data is optional. (EX1208 [0073], [0082].) *See also supra* at IX A 3. Nothing in Harper 2019 discourages using the above-cited teachings

of Taub/Harper 2012 to implement on the transmitter the calibration-related aspirations identified in Harper 2019, nor suggests that a skilled artisan would have difficulty doing so. Doing the calibration on the transmitter is one of only a few practical ways to implement the calibration Harper 2019 requires, the primary other choice being doing calibration at the receiver unit, and it does not undermine any purpose identified in Harper 2019.

The same motivations and expectations of success apply to storage of the calibrated sensor data on the transmitter. Both Harper 2019 (EX1208) and Taub/Harper 2012 (EX1209) disclose the transmitter having a memory and storing data for later transmission to the receiver, as explained *supra* at IX A 2. For the reasons explained immediately above, a skilled artisan had a motivation and reasonable expectation of success to include in that stored transmitter-processed sensor data transmitter-calibrated sensor data.

Regarding Hayter/Taub 2013's disclosure of monitoring for and detecting a range of adverse conditions in a glucose monitoring system, a skilled artisan would see that functionality as being an aspiration of Harper 2019 albeit without any disclosure of how to achieve it. That would motivate the artisan to look at Patent Owner's later-developed patent publications for disclosures achieving that aspiration, and to Hayter/Taub 2013 in particular. Hayter/Taub 2013's title announces that it deals with surviving from failures in an analyte monitoring system:

“Mitigating Single Point Failure Of Devices In An Analyte Monitoring System.” (EX1210, title.) The first sentence of Hayter/Taub 2013’s Summary confirms this: “Embodiments of the present disclosure include methods for mitigating single point failure of at least one device in an analyte monitoring system.” (*Id.* [0004].) Scanning the Figures, the artisan would see overlap with Harper 2019, including that it and Hayter/Taub 2013 identify the same five components of the glucose monitoring system. (Compare EX1210 Fig. 1 with EX1208 Fig. 1.) Also, Fig. 3 of each reference depicting the receiver unit is substantively identical with only a few changes to the names of the same components. Nothing in Harper 2019 discourages using the above-cited teachings of Hayter/Taub 2013 to implement the aspirations identified in Harper 2019, or suggests any difficulty doing so, and doing so would advance, not undermine, the purposes expressed in Harper 2019.

Regarding He/Taub 2014’s disclosure of claim 22’s mobile phone, the Board may take judicial notice that by April 2020, a year before the claims’ earliest effective filing date, powerful mobile phones with exceptional display capabilities were ubiquitous. While Harper 2019 disclosed that only reduced-functionality secondary receivers were suitable for a mobile phone, that disclosure carried over from 2010, the filing date of the first non-provisional application leading to the ’056 patent. By 2020, the desirability and practicality of using a mobile phone—which a user likely would have with them throughout most of their day for other reasons—

for displaying useful medical information to a user was even greater, motivating the artisan otherwise implementing the designs of Harper 2019 to adopt He 2013's teaching that the receiver unit be a mobile phone.

Finally, to the extent that the Board finds that the Grandparent App. (and thus Harper 2019) does disclose an embodiment of a claim element that this Petition asserts the Grandparent App. is missing, Petitioner relies on such a finding as further support for its obviousness grounds based primarily on Harper 2019.

**6. There Are No Known Objective Indicia
Of Non-Obviousness Having A Nexus To
The Delta Between Harper 2019 And The Claims**

Harper 2019 is the closest prior art reference. Petitioner is unaware of any objective indicia of non-obviousness having a nexus to the delta between the claims and that reference.

**X. THE BOARD, C.C.P.A. AND FEDERAL CIRCUIT
HAVE FOUND PATENT CLAIMS ANTICIPATED OVER
PUBLISHED ANCESTOR DISCLOSURES THAT FAILED
TO SUPPORT AN EFFECTIVE FILING DATE FOR THE CLAIMS**

Finally, to reinforce that there is no inconsistency in finding that the Grandparent App. fails to support the claims but its publication (Harper 2019) contributes to their obviousness, Petitioner notes that the Federal Circuit and C.C.P.A. have held the same disclosure to *anticipate* a claim (not merely render it obvious as asserted here) but not support it under Section 112. *See, e.g., Chester v. Miller*, 906 F.2d 1574 (Fed. Cir. 1990) (patent claims held anticipated by a published

parent patent application, even though those claims were not supported by that parent disclosure under Section 112); *In re Lukach*, 442 F.2d 967 (C.C.P.A. 1971) (publication of a British counterpart to a grandparent patent application anticipated claims even though those claims were not supported under Section 112 by that grandparent application).

The Board has ruled likewise. As noted, in *The Gillette Company*, PGR2022-00030, the Board granted Institution based in part on the “continuation” patent’s grandparent application with the same disclosure as the challenged patent lacking adequate Section 112 support for certain claims, making the publication of that grandparent application prior art, which prior art disclosed an embodiment of those claims and thus likely anticipated them on the Institution record. *See id.*, Paper 8 (P.T.A.B. Sept. 23, 2022); *see also U.S. Endodontics, LLC v. Gold Standard Instruments, LLC*, PGR2015-00019, Paper 54 (P.T.A.B. Dec. 28, 2016) (the published ancestor application (“Luebke”) did not support, but anticipated, issued claims: “a determination that Luebke anticipates claims 12-16 is not inconsistent with the enablement and written description analyses set forth above, in which we determine that the disclosure of the ’991 patent (and, therefore, the disclosure of Luebke 2008) fails to support the full scope of the claims”). In *Smith & Nephew, Inc. v. Arthrex, Inc.*, IPR2017-00275, Paper 36 (P.T.A.B. May 2, 2018), *aff’d*, 35 F.4th 1328 (Fed. Cir. 2022), the Board again found that the same disclosure anticipated

claims it did not support under Section 112, because “the [claims’] broad recitation of an ‘eyelet’ is anticipated by the narrower disclosure in [the ancestor] of the suture loop.”

XI. CONCLUSION

Petitioner respectfully requests institution for all claims on Grounds 1 and 2.

Respectfully submitted,

August 1, 2023

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**CERTIFICATE OF COMPLIANCE WITH
TYPE-VOLUME LIMITATION PURSUANT TO 37 C.F.R. § 42.24**

This brief complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(1)(i).

The brief contains 13,445 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a).

The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2013 in a 14-point Times New Roman font.

August 1, 2023

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CERTIFICATE OF SERVICE
IN COMPLIANCE WITH 37 C.F.R. § 42.6(E)(4)

The undersigned certifies that the **Petition for *Inter Partes* Review of U.S. Patent No. 11,298,056 and Exhibits 1201 – 1212** were served on August 1, 2023, via **Express Mail** on the Patent Owner at the following address of record as listed on the USPTO Patent Center:

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A copy of the **Petition for *Inter Partes* Review of U.S. Patent No. 11,298,056** only was served on litigation counsel for Patent Owner via email to ADC-MNAT@morrisnichols.com and MHM-ADC@mcandrews-ip.com.

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