

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. IPR2024-00521

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

PATENT OWNER'S RESPONSE

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<i>TQ Delta, LLC v. Cisco Sys., Inc.</i> , 942 F.3d 1352 (Fed. Cir. 2019)	35
<i>Xerox Corp. v. Bytemark, Inc.</i> , IPR2022-00624, Paper 9 (P.T.A.B. Aug. 24, 2022)	35, 46, 62

Other Authorities

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TABLE OF EXHIBITS

Exhibit No.	Description
2001	March 3, 2023 Complaint for Patent Infringement, <i>Abbott Diabetes Care Inc., v. DexCom Inc.</i> , No. 23-239-KAJ (D. Del. Mar. 3, 2023)
2002	Notice of Opposition to a European Patent No EP 3 069 279 B1 (July 26, 2021)
2003	Joint Claim Construction Chart, <i>Abbott Diabetes Care Inc., v. DexCom Inc.</i> , No. 23-239-KAJ (D. Del. Mar. 21, 2023)
2004	July 28, 2023 E-mail from DexCom (Hoeschen) to Abbott with proposed Scheduling Order for Case No. 23-239 (D. Del.)
2201	STS-7 User's Guide
2202	DexCom G4 Platinum Continuous Glucose Monitoring System User's Guide
2203	FDA Premarket Approval (PMA) for DexCom G5 Mobile Continuous Glucose Monitoring System
2204	<i>Not used</i>
2205	<i>Not used</i>
2206	<i>Not used</i>
2207	CareLink™ Personal Getting Started Guide
2208	Declaration of Nathaniel E Frank-White (Internet Archive) Re Ex. 2207
2209	<i>Not used</i>
2210	<i>Not used</i>
2211	<i>Not used</i>
2212	<i>Not used</i>
2213	Declaration of Eugene E. Wright, Jr. MD
2214	Curriculum Vitae of Eugene E. Wright, Jr. MD
2215	Declaration of Aaron Striegel, Ph.D.
2216	Cappon et al., <i>Continuous Glucose Monitoring Sensors for Diabetes Management: A Review of Technologies and Applications</i> , J. Diab. Metab. 43:383-397 (2019)

Exhibit No.	Description
2217	American Diabetes Association, <i>Role of Continuous Glucose Monitoring in Diabetes Treatment</i> (2018), available at https://pubmed.ncbi.nlm.nih.gov/30958664/
2218	The MiniMed Paradigm® REAL-Time Insulin Pump User Guide
2219	DexCom STS-7 Continuous Glucose Monitoring System User's Guide Submitted Under FCC ID PH29402
2220	DexCom G6 Continuous Glucose Monitoring System User Guide
2221	Abbott FreeStyle Navigator Continuous Glucose Monitoring System User's Guide
2222	Abbott FreeStyle Libre 3 Continuous Glucose Monitoring System User's Manual
2223	U.S. Patent No. 10,085,640
2224	U.S. Patent No. 9,996,668
2225	Das et al., <i>Review—Electrochemistry and Other Emerging Technologies for Continuous Glucose Monitoring Devices</i> , ECS Sensors Plus (2022)
2226	Almurashi et al., <i>Emerging Diabetes Technologies: Continuous Glucose Monitors/Artificial Pancreases</i> , J. Indian Inst. Sci. (2023)
2227	Deposition Transcript of Brian Gross in IPR2023-01251 (05/02/2024) (Ex. 2027)
2228	Centers for Disease Control and Prevention—National Diabetes Statistics Report, available at https://www.cdc.gov/diabetes/php/data-research/index.html
2229	Garg et al., <i>Flash Glucose Monitoring: The Future Is Here</i> , Diabetes Tech. & Therapeutics 19.S2 (2017)
2230	DexCom SEVEN Plus Users Guide
2231	DexCom G5 Mobile CGM System User Guide
2232	DexCom's Initial Proposed Claim Constructions in C.A. No. 23-239-KAJ (Feb. 28, 2024)
2233	Atmel Product Guide (Winter 2008), available at https://media.digikey.com/pdf/Data%20Sheets/Atmel%20PDFs/Products%20Select%20Guide.pdf

Exhibit No.	Description
2234	Atmel - ATmega169P Datasheet, <i>available at</i> https://ww1.microchip.com/downloads/en/DeviceDoc/doc8018.pdf
2235	American Diabetes Association (ADA) Standards of Medical Care in Diabetes—2007, <i>available at</i> https://diabetesjournals.org/care/article/30/suppl_1/S4/24065/Standards-of-Medical-Care-in-Diabetes-2007
2236	<i>Not used</i>
2237	<i>Not used</i>
2238	<i>Not used</i>
2239	Bergenstal, Ahmann et al., <i>Recommendations for Standardizing Glucose Reporting and Analysis to Optimize Clinical Decision Making in Diabetes: The Ambulatory Glucose Profile (AGP)</i> , J. Diabetes Tech. & Therapeutics 15(3), 198-211 (2013)
2240	Deposition Transcript of Brian Gross in IPR2023-01251 (10/10/2024) (Ex. 2040)
2241	Deposition Transcript of Andrew Ahmann in IPR2023-01251 (10/11/2024) (Ex. 2041)
2242	Reply Declaration of Brian D. Gross in IPR2023-01251 (09/06/2024) (Ex. 1057)
2243	Declaration of Brian D. Gross, dated February 9, 2024 (Ex. 1208 served with the Petition and marked Ex. 2243 at the Gross Deposition on 11/21/2024)
2244	Deposition Transcript of Brian Gross (11/21/2024)
2245	Declaration of Nathaniel E Frank-White (Internet Archive) Re Ex. 2218
2246	Reply Declaration of Andrew Ahmann in IPR2023-01251 (09/04/2024) (Ex. 1055)
2247	Declaration of Brian D. Gross in IPR2023-01251 (07/24/2023) (Ex. 1008)
2248	Record of Oral Hearing in IPR2023-01251, Paper 39 (Nov. 25, 2024)
2249	Institution Decision in IPR2023-01251, Paper 11 (Feb. 5, 2024)

Exhibit No.	Description
2250 ¹	Excerpt comprising pages 65, 66, and 73 of Ex. 1211 highlighted during Gross Deposition (11/21/2024)

¹ During Mr. Gross’s deposition on 11/21/2024, Patent Owner’s counsel highlighted pages 65, 66, and 73 of Ex. 1211, intending to mark them Ex. 2243. However, Ex. 1208 was inadvertently marked Ex. 2243. Therefore, the highlighted pages have been marked Ex. 2250. (*See* Ex. 2244 at 79:13-16; 80:2-9; 88:2-8; 136:13-137:7.)

I. INTRODUCTION

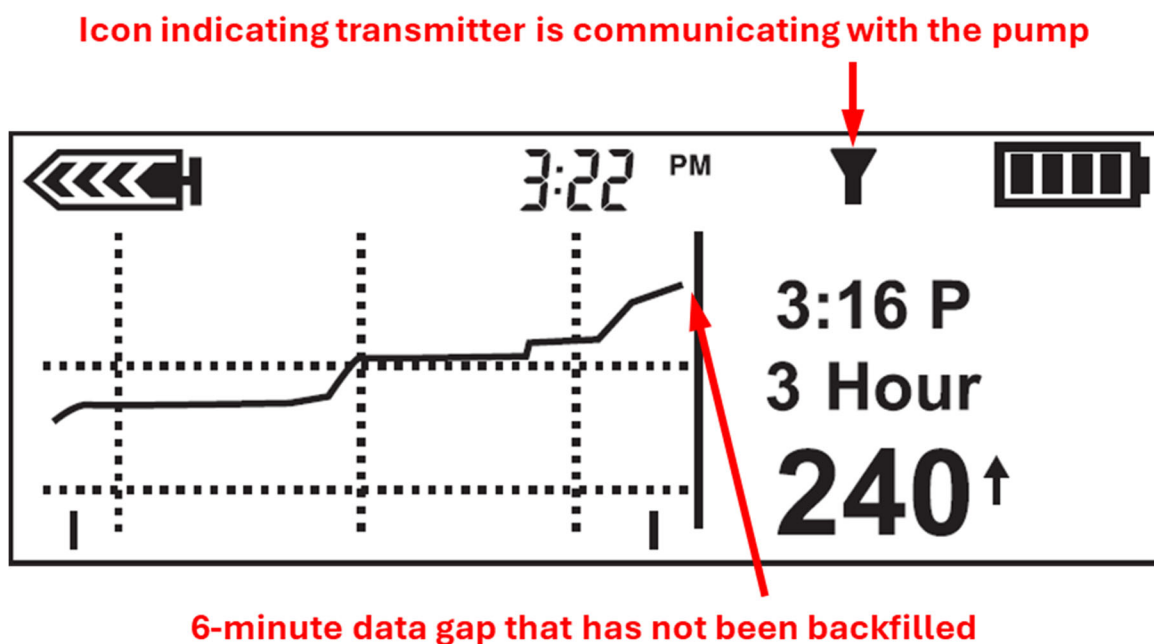
The Board should uphold the patentability of claims 13 and 29. Each depends from claim 1, and Petitioner has not shown that claim 1 would be obvious in view of Patel-2009 (Ex. 1212) and the Paradigm documentation (Ex. 1211). Consequently, both Grounds 1 and 2 fail for that reason alone. Petitioner's challenge to claim 13 in Ground 1 also fails for the same reasons, as Petitioner relies only on its faulty claim 1 arguments for the additional elements of claim 13. (*See* Pet. at 59-62.)

In Ground 2, claim 29 is patentable over the addition of Goldsmith for multiple reasons. First, starting with the Patel-2009/Paradigm combination, Petitioner argues a POSITA would add a Goldsmith watch that communicates both directly *and* indirectly with an on-body sensor/transmitter. But Petitioner provides no reason why a POSITA would combine such a watch with Patel-2009/Paradigm. Second, Petitioner cherry-picks details from Goldsmith's embodiments to its benefit, but then ignores other details about those embodiments that would be necessary for an operable system. Third, in Petitioner's combination, Goldsmith's watch does not have "a limited number of functions as compared with the receiver unit" as required by claim 29. To the contrary, Petitioner's expert, Mr. Gross, testified that, in relevant part, the watch would have the same functionality as the receiver. (*Infra* §VII.D.) Accordingly, the Board should uphold the patentability of the Challenged Claims.

For Grounds 1 and 2, the combination of Patel-2009 and the Paradigm documentation does not meet every element of claim 1. Element [1.K], for example, recites that “after the adverse condition is corrected,” the receiver unit outputs to the display “processed sensor data for the time period corresponding to the adverse condition such that the data gap is backfilled.” (Ex. 1201 at 16:8-12.) Petitioner has no prior art that discloses this element. Petitioner expressly confirms that Patel-2009 does not disclose it. (Pet. at 40-41.) Petitioner instead relies on a frequently asked question (“FAQ”) in the Paradigm documentation, but that too fails to disclose the element. The FAQ explains that when the transmitter and pump are out of range, the transmitter will store up to 40 minutes of glucose data. However, nowhere does the Paradigm documentation state that, if any of the missed data is later received, it is displayed on the pump’s screen to backfill a data gap. (*Infra* §V.A.)

During oral argument in IPR2023-01251, a previous IPR between the parties involving different claims of the 056 patent, Petitioner’s counsel admitted that the Paradigm documentation is “missing” “a before and after picture of the exact same data where there was a data gap and then there wasn’t a data gap.” (Ex. 2248 at 18:14-16.) Petitioner therefore concedes there is no express disclosure of [1.K] in the Paradigm documentation, and resorts to Mr. Gross’s opinions about context of the FAQs and an alleged urgency to display all missing data. But those opinions are contradicted by overwhelming evidence, including Mr. Gross’s own opinions about

claim 19, Petitioner’s products at the time that did not backfill missing data, Petitioner’s own patents that provide many reasons why *not* to backfill missing data, the Standards of Medical Care for treating diabetes at the time, and opinions from Petitioner’s other expert in IPR2023-01251, Dr. Andrew Ahmann. (*See infra* §V.A.4.) The Paradigm user guide also refutes Petitioner’s argument. It illustrates a 6-minute data gap on the pump’s screen that has not been backfilled despite (i) the transmitter “send[ing] glucose data from the sensor to the insulin pump every minute and updat[ing] every five minutes” (Ex. 1211 at 7) and (ii) the transmitter being in communication with the pump at the time of the illustrated screenshot:



(*Id.* at 65 (annotated).)

Petitioner fares no better with element [1.L]. That element requires backfilled data to be displayed as “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.” (Ex. 1201 at 16:13-20.) For this element, Petitioner juxtaposes two graphics from the Paradigm user guide that have no relation to one another and certainly do not convey a sequence of events. Thus, Petitioner identifies nothing—no statement, image, or otherwise—from the Paradigm documentation that meets [1.L]. Equally fatal is that Mr. Gross offers no opinion about whether [1.L] would be obvious (outside of his erroneous conclusion that the juxtaposed graphics disclose it).

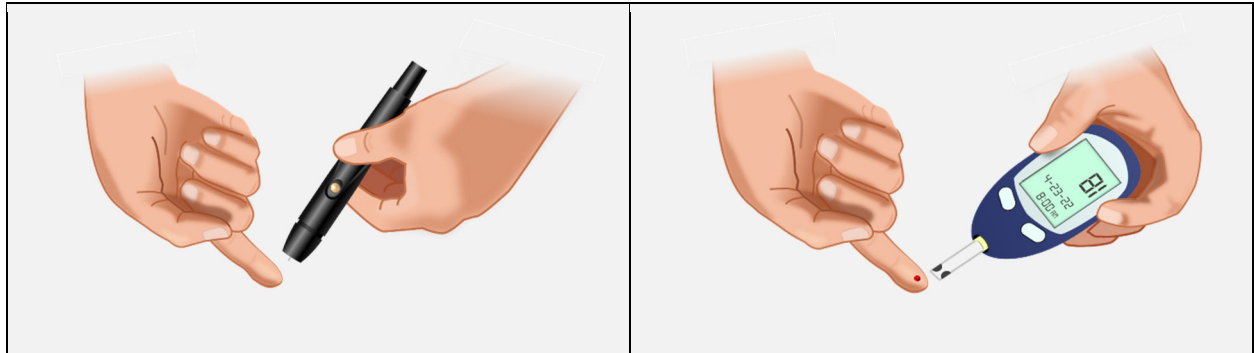
Because both Challenged Claims depend from claim 1, Petitioner’s failure to show that claim 1 is met by combining Patel-2009 and the Paradigm documentation defeats the entire petition.

II. BACKGROUND OF THE INVENTION

A. Diabetes and Glucose Monitoring

The inventions claimed in U.S. Patent No. 11,298,056 (“056 patent”) improve the lives of people with diabetes who monitor blood sugar using continuous glucose monitors (“CGMs”). (Ex. 2213 ¶¶39-41, 121.) “Diabetes” refers to several conditions with different causes and prognoses, all involving high blood sugar, or “hyperglycemia.” (*Id.* ¶¶34-38.) Traditionally, blood glucose monitors (“BGMs”) were used to track glucose levels. (*Id.* ¶¶47-50.) A person would insert a test strip into a meter, prick a finger to draw blood, and then place a drop of blood onto the

strip. (*Id.* ¶48.) The BGM then provided a blood glucose concentration at that point in time (also called “fingerstick measurements”). (*Id.*)



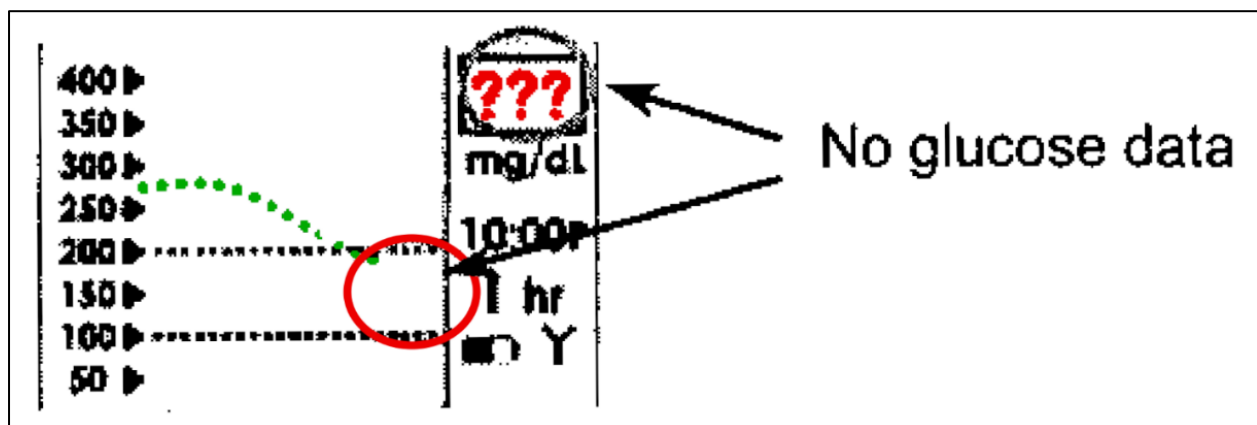
CGMs were first approved by the FDA in 1999. (Ex. 2213 ¶55; Ex. 2217 at 3; Ex. 2225 at 6.) The first two approved CGMs, from Medtronic, did not allow for real-time display of glucose data and therefore had no display at all. (Ex. 2213 ¶55; Ex. 2225 at 6.) Instead, these CGMs were retrospective in that glucose data was stored during the three-day wear life, and then the data was downloaded by a physician for retrospective analysis. (*Id.*; Ex. 2241 at 17:3-18:19.)

By 2009, only a few commercially-available CGMs displayed glucose information during use, including, *e.g.*, Medtronic’s Guardian REAL-Time System;² DexCom’s STS, STS-7, and SEVEN Plus; and Abbott’s FreeStyle Navigator. (Ex. 2213 ¶¶57-59; Ex. 2217 at 3; Ex. 2225 at 4-11; Ex. 2226 at 3-6.) These early-

² The Medtronic Paradigm® REAL-Time System, which is the product described in Ex. 1211, was an insulin pump that included optional components from the Guardian REAL-Time System. (*See, e.g.*, Ex. 1211 at 13, 15, 37, 83.)

generation devices were relatively inaccurate and prone to errors, such as errors with their calibration and communications. (Ex. 2213 ¶¶75-79.) Sometimes these errors caused unintended alarm messages to be displayed, while other times they resulted in gaps in CGM data. (*Id.* ¶¶95-110.)

Petitioner's products were a case in point. A User's Guide for Petitioner's STS-7 system explained that "[a]t times [the] STS-7 System will not display glucose information or provide alerts," which can happen when the system "needs another [blood glucose] fingerstick reading[] for calibration because the STS-7 Sensor readings do not match [the user's] blood glucose meter readings." (Ex. 2201 at 38-40; Ex. 2213 ¶¶97-102.) When this occurred, "Glucose Data Gaps" appeared in the user's glucose levels on the display device. (Ex. 2201 at 38-40; Ex. 2213 ¶¶99-101.) In the STS-7 User's Guide, Petitioner could only caution users about data gaps (see below) but offered no option to recover the lost data.



(Ex. 2201 at 39 (color added).)

As depicted above, the STS-7 display showed continuous glucose readings (green dots) followed by a data gap (red circle), and provided an alert (“???” (in red)) indicating that “No glucose data” was available. Indeed, during a clinical study involving 72 participants who wore the STS-7 System for seven days, more than 25% of the data was lost for 31% of the systems and more than 50% of the data was lost for 18%. (*Id.* at 63.) The STS-7 User’s Guide explained that “[s]ometimes sensors fail to provide readings after calibration” and therefore the readings were simply “skipped.” (*Id.*)

Calibration failures were not the only types of adverse conditions for which Petitioner’s STS-7 was unable to backfill data gaps on the user’s display. (Ex. 2201 at 38-40; Ex. 2213 ¶¶99-101.) For example, the STS-7 also suffered data gaps when the transmitter and receiver went out of range:

4.6.1 MISSING GLUCOSE READINGS – NO “Y”

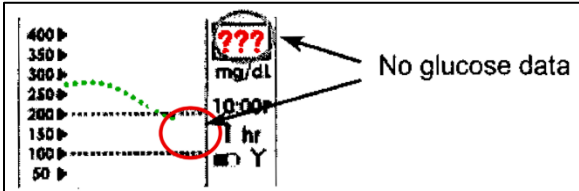
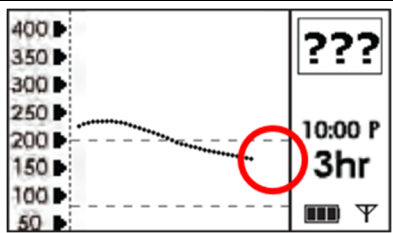
- Anytime you see the Antenna Icon “Y” in the Status Box instead of a glucose reading the STS Receiver has “missed” the last glucose reading sent by the Transmitter to the Receiver.

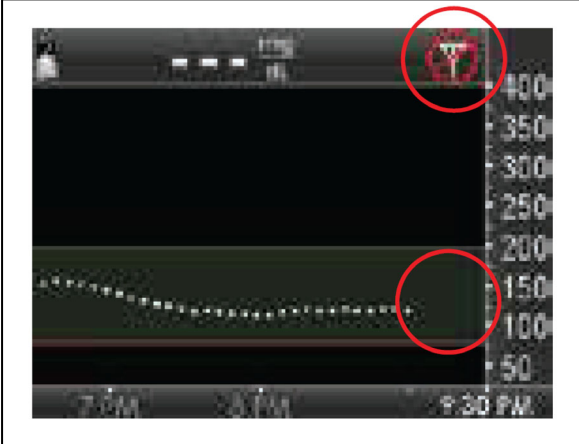
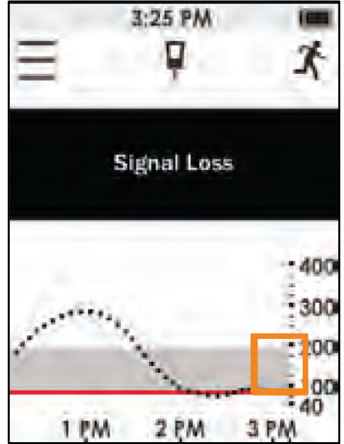
The diagram shows a portion of the STS-7 display. On the left is a vertical axis for glucose levels in mg/dl, ranging from 50 to 400 in increments of 50. A dotted line represents a glucose trend. A red circle is drawn on the graph, indicating a data gap. To the right of the graph is a status box containing a 'Y' icon, the text 'mg/dl', a digital clock showing '10:00', and a battery icon. An arrow points from the text 'No glucose data' to the 'Y' icon in the status box.

- Make sure your STS Receiver is within 5 feet of the STS Transmitter/STS Sensor Pod. If it is not, move your STS Receiver closer and wait at least 5 minutes. The “Y” icon in the Status Box should go away and you will receive a STS-7 glucose reading in the next 5-10 minutes.
- If you are still having trouble receiving STS-7 readings because of this problem, contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664).

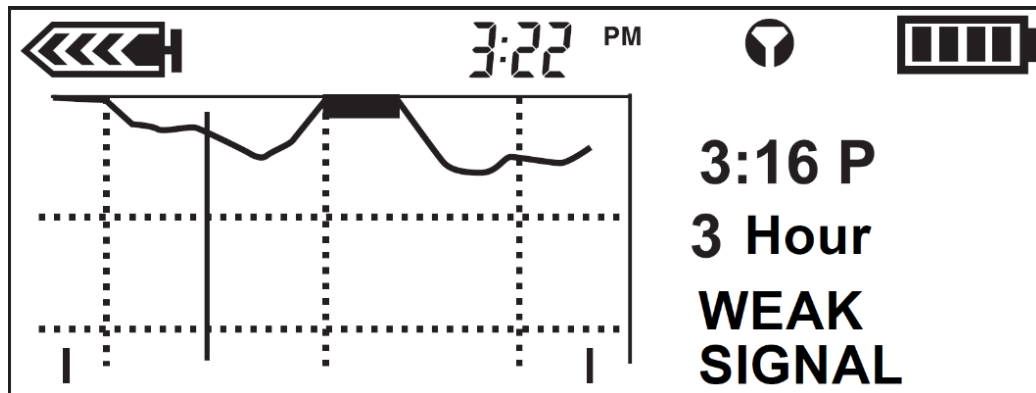
(Ex. 2201 at 38; Ex. 2213 ¶¶99.)

None of Petitioner’s CGM products were able to backfill missing data on a user’s CGM display until 2016—a full *seven years after* Patent Owner’s priority date. (Ex. 2213 ¶¶103-105; Ex. 2202 at 9, 93; Ex. 2203 at 1; 2230 at 52, 64, 71, 76-77; Ex. 2231 at 204-205.) They all displayed data gaps in trend graphs when adverse conditions occurred, but there was no solution to backfill the missing data on the display.

Dexcom’s STS-7 CGM System	Dexcom’s SEVEN Plus CGM System
	
Ex. 2201 at 39 (color added)	(Ex. 2230 at 71 (annotated))

Dexcom’s G4 CGM System	Dexcom’s G5 CGM System
	
(Ex. 2202 at 93)	(Ex. 2231 at 205)

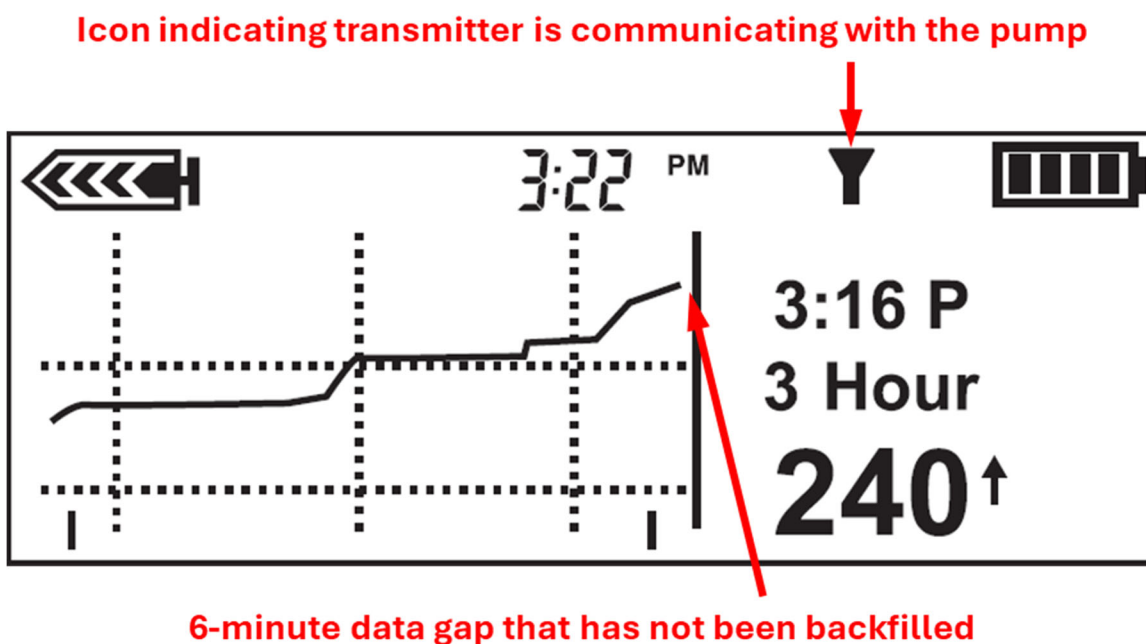
The Paradigm documentation also fails to teach backfilling missing data in a line graph on a CGM display. (Ex. 2213 ¶106.) The Paradigm® REAL-Time system was an insulin pump that included an optional sensor and MiniLink™ Transmitter. (Ex. 1211 at 15.) The Paradigm user guide explains that there may be instances “when the pump does not receive data for a period of time.” (*Id.* at 73.) When this happened, the user might “see a Weak Signal recorded on the sensor graphs” and what Petitioner argues is a data gap. (*Id.*; Pet. at 4.)



(Ex. 1211 at 73.) Nowhere does the Paradigm user guide state or even suggest retrieving or displaying the missing data. (Ex. 2213 ¶110.) Instead, it instructed the user to “[m]ove the pump closer to the transmitter or move the transmitter and the pump to a new location on [the user’s] body.” (Ex. 1211 at 73; Ex. 2213 ¶110.) If the pump did not “receive[] a signal from the transmitter for more than 40 minutes,” the pump displayed a Lost Sensor alarm instead of the trend graph. (Ex. 1211 at 73; Ex. 2213 ¶¶107-108.) The same would happen for other problems, such as a low transmitter battery, bad transmitter, bad sensor, and calibration errors. (Ex. 1211 at

73-75; Ex. 2213 ¶109.) In each instance, the pump displayed an alarm message rather than a trend graph. (Ex. 1211 at 73-75; Ex. 2213 ¶109.)

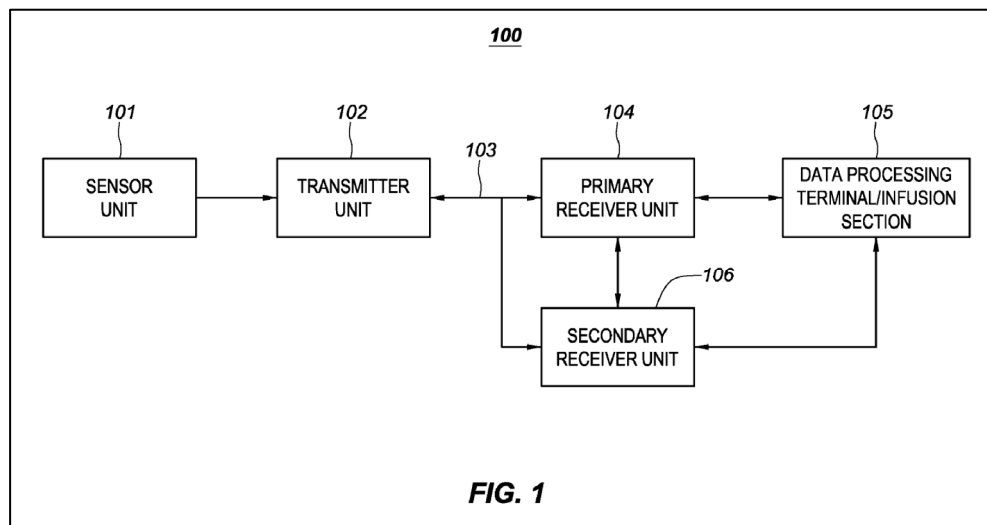
In fact, the Paradigm user guide illustrates a persistent data gap in a trend graph that has **not** been backfilled, undermining Petitioner’s characterization of what the FAQs allegedly disclose. Specifically, the Paradigm transmitter “sen[t] glucose data from the sensor to the insulin pump every minute and update[ed] every five minutes.” (Ex. 1211 at 7.) However, in the image below from the Paradigm user guide, the transmitter is communicating with the pump and yet a data gap of at least 6 minutes has persisted:



(Ex. 1211 at 65 (annotated).) The Paradigm user guide therefore shows a data gap on the pump’s screen that has **not** been backfilled despite meeting Petitioner’s criteria (*i.e.*, less than 40 min. and in communication).

B. The 056 Patent

Unlike the prior art, the 056 patent is directed to a CGM system for backfilling data gaps on a user display while a user monitors glucose levels. (Ex. 1201 at 15:24-26; Ex. 2213 ¶116.) Figure 1 illustrates a block diagram of an example system for practicing the claimed inventions:



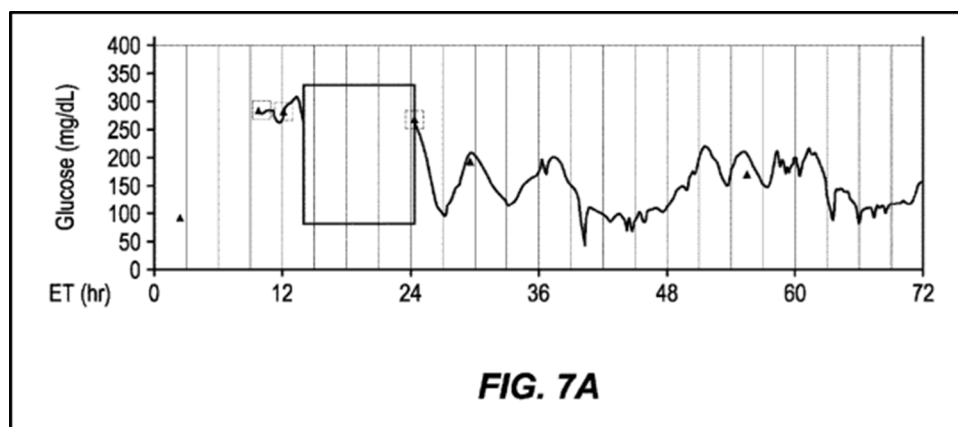
(*Id.* at FIG. 1.)

The data processing and transmitter unit (102) 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.” (Ex. 1201 at 15:39-41; Ex. 2213 ¶117.) 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.” (Ex. 1201 at 15:42-47; Ex. 2213 ¶117.)

The processed sensor data is transmitted “over a Bluetooth wireless communication link.” (Ex. 1201 at 15:48-51; Ex. 2213 ¶117.)

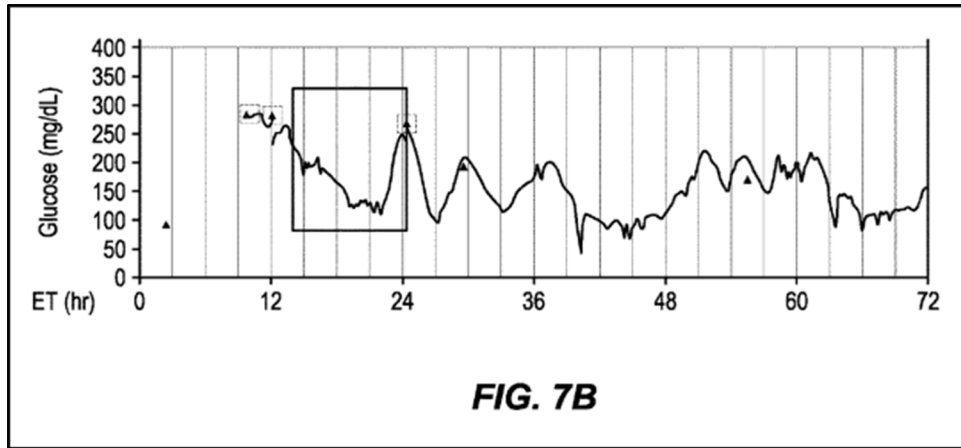
In claim 1, the receiver unit is configured to receive “the processed sensor data over the Bluetooth wireless communication link,” and to output to the display of the receiver unit “a numerical value representing the processed sensor data” and “a first line graph that is a substantially continuous depiction of the processed sensor data over time.” (Ex. 1201 at 15:56-64; Ex. 2213 ¶117.) In claim 29, a watch is included in the system as a secondary receiver unit. (Ex. 1201 at 18:19-25.) The watch is configured “to include a limited number of functions as compared with the receiver unit” and “receive[s] processed sensor data from the data processing and transmitter unit.” (*Id.*)

As the user monitors glucose levels, the claimed system is “configured to detect an adverse condition” that “results in the receiver unit displaying a data gap.” (Ex. 1201 at 15:65-16:3; Ex. 2213 ¶118.) An example of such a data gap is shown in FIG. 7A below.



The specification explains that adverse conditions that may cause a data gap 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[.]” (Ex. 1201 at 13:19-27 Ex. 2213 ¶119.) Many of these adverse conditions are recited in dependent claims such as Challenged Claim 13, which recites that “the adverse condition comprises a sensor misposition error.” (Ex. 1201 at 16:56-57.)

As recited in claim 1, “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.” (Ex. 1201 at 16:4-7; Ex. 2213 ¶120.) After the adverse condition is corrected, the receiver unit outputs to the display the “processed sensor data for the time period corresponding to the adverse condition such that the data gap is backfilled.” (Ex. 1201 at 16:8-12; Ex. 2213 ¶120.) An example is illustrated in FIG. 7B below.



Thus, unlike the prior art and contrary to conventional wisdom and practice in 2009, the claimed monitoring system is able to recover and display glucose data from a time period associated with an adverse condition. (Ex. 1201 at 12:54-61, 13:27-30; Ex. 2213 ¶121.)

III. PETITIONER'S GROUNDS

Petitioner advances two grounds against the Challenged Claims:

GROUND	CLAIMS	BASIS
1	13	Allegedly obvious over Patel-2009 (Ex. 1212) in view of Paradigm® REAL-Time documentation (Ex. 1211)
2	29	Allegedly obvious over Patel-2009 and Paradigm® REAL-Time documentation in view of Goldsmith (Ex. 1251)

IV. CLAIM CONSTRUCTION

All claim terms in the 056 patent should be given their plain and ordinary meanings. Petitioner has identified no reason to depart from them. Nonetheless, in

concurrent district court litigation, Petitioner proposed narrow constructions for “adverse condition” (all claims) and “sensor misposition error” (claim 13). (Ex. 2232 at 4.) Petitioner does not, however, apply those narrow constructions in the Petition. (See Pet. at 24-27.) Instead, Petitioner provides no construction for “adverse condition” at all, acquiescing that its plain and ordinary meaning should apply, and then purports to apply Patent Owner’s “apparent positions on what is encompassed by the language ‘sensor misposition error’ in claim 13 and ‘receive processed sensor data from the data processing and transmitter unit’ in claim 29.” (*Id.* at 24.)

For purposes of this response, Patent Owner applies Petitioner’s litigation position regarding “sensor misposition error” in claim 13 and “receive processed sensor data from the data processing and transmitter unit” in claim 29. Patent Owner does not waive its right, however, to argue constructions for any claim term of the 056 patent in this or in any other proceeding.

V. BOTH GROUNDS: PETITIONER HAS NOT SHOWN THAT ALL ELEMENTS OF INDEPENDENT CLAIM 1 ARE MET

Challenged Claims 13 and 29 each depend from independent claim 1. Petitioner, however, has not shown that claim 1 is obvious in view of Patel-2009 and the Paradigm documentation (Pet. at 42-59) because both fail to disclose claim elements [1.I], [1.K] and [1.L]. Together, these elements recite that the system “detect[s] an adverse condition,” which “results in the receiver unit displaying a data gap.” (Ex. 1201 at 15:65-16:3 ([1.I]).) After the adverse condition is corrected, the

claimed system must display on the receiver unit “processed sensor data for the time period corresponding to the adverse condition such that the data gap is backfilled.” (Ex. 1201 at 16:8-12 ([1.K]).) In turn, that displayed data must include “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.” (*Id.* at 16:13-20 ([1.L]).)

As detailed below, element [1.L] requires outputting backfilled data to the receiver’s display as a second line graph. For this element, Petitioner cobbles together two unrelated graphics from different chapters of the Paradigm user guide. (Pet. at 46-48; Ex. 2213 ¶¶208-212.) As the Board explained in IPR2023-01251, these graphics neither expressly nor impliedly disclose element [1.L]. (Ex. 2249 at 33.) That should be dispositive of both Grounds 1 and 2.

For element [1.K], Petitioner’s arguments hinge on the meaning of “data re-populated in the insulin pump.” The evidence shows that this phrase refers to storing data in the insulin pump’s memory for later historical reports, not for displaying it on the pump’s screen. (Ex. 2213 ¶167.) Petitioner’s arguments are refuted by, among other things, an illustrated screenshot in the Paradigm user guide in which *a persistent 6-minute data gap has not been backfilled* even though it should have been according to Petitioner’s arguments. (Ex. 1211 at 65.)

A. Claim Element [1.K] Is Not Disclosed In Petitioner’s Prior Art

Element [1.K] recites that 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.” (Ex. 1201 at 16:8-12.) This language, by its terms, requires the receiver to not only receive but to also *display* the backfilled data.

Despite citing Patel-2009 in its analysis of [1.K], Petitioner readily admits that Patel-2009 does not disclose this element:

Patel-2009 does not provide for glucose graphs to convey that glucose data is missing during failed communication or to display glucose data that is synchronized when communication is re-established.

(Pet. at 40-41; Ex. 2213 ¶¶201-203.) Petitioner therefore relies exclusively on the Paradigm documentation for this element, but that too fails to disclose it. Indeed, during oral argument in IPR2023-01251, Petitioner’s counsel admitted that the Paradigm documentation is “missing” “a before and after picture of the exact same data where there was a data gap and then there wasn’t a data gap.” (Ex. 2248 at 18:14-16.)

1. The FAQs Disclose Storing Later-Received Data In The Pump For Historical Reports, Not Displaying It

The Paradigm documentation discloses that the pump could receive up to 40 minutes of missed data for analysis in retrospective historical reports. Nowhere does

the Paradigm documentation teach or suggest **both** receiving **and** displaying backfilled data on the insulin pump's screen. (Ex. 2213 ¶¶167, 171.) It is telling that Petitioner does not argue that the Paradigm user guide, or any other technical literature for the Paradigm product, teaches element [1.K]. (Pet. at 57; Ex. 2213 ¶¶168-169.) One would expect the user guide to teach users about such an important feature at the time if it existed. (Ex. 2213 ¶169.) But the user guide says nothing about displaying a data gap, receiving missing data, or backfilling missing data on a trend graph. (*Id.*) It merely tells the user to “[m]ove the pump closer to the transmitter or move the transmitter and the pump to a new location on [their] body” if the pump is not receiving data from the transmitter. (Ex. 1211 at 73.)

Instead of relying on technical literature, Petitioner cites two FAQs from Medtronic's 2007 website regarding the MiniLink REAL-Time Transmitter for alleged disclosure of [1.K]. (Pet. at 57.) The first FAQ that Petitioner cites states:

How much data does the MiniLink REAL-Time Transmitter store? If I move outside of the six foot (two meters) transmission range – will I lose my data?

When the MiniLink REAL-Time Transmitter is separated from the insulin pump for more than six feet (approximately 2 meters), the transmission is considered "out of range." The transmitter holds 40 minutes worth of memory, so even though your system is "out of range," continuous glucose monitoring (CGM) data can be re-populated in the insulin pump.

If your system is out-of-range for longer than 40 minutes, when reviewing historical reports you would notice "data gap" where information is missing during this period of time.

(Ex. 1211 at 8.) Petitioner focuses on the phrase, “re-populated *in the insulin pump*,” but that statement says nothing about “output[ting]” backfilled glucose data “*to the display*” on the pump, which Petitioner argues is the claimed receiver. (Pet. at 53; Ex. 2213 ¶¶167, 169, 171, 181-182.)

This FAQ instead teaches re-populating data in the pump’s memory so that it is available when generating historical reports, for example, using Medtronic’s CareLink™ Personal software (“CareLink”). (Ex. 2213 ¶¶172-175.) CareLink “allow[ed] the discovery of patterns and problems that meter software and logbooks would not uncover.” (Ex. 2207³ at 3.) CareLink was installed on the user’s personal computer and received glucose-related information uploaded from the Paradigm insulin pump. (*See* Ex. 1211 at 11-12.) “Once uploaded, this information [could] be converted into CareLink Personal reports.” (Ex. 2207 at 7; Ex. 2213 ¶¶93-94.) The CareLink™ Personal Getting Started guide (“CareLink Guide”) explains that “[i]t is these reports that reveal the patterns in [the user’s] blood glucose levels and help [them] and [their] healthcare provider better manage [their] diabetes.” (Ex. 2207 at 7.)

The CareLink Reports page is shown below:

³ *See* Ex. 2208 (Declaration of Nathaniel E Frank-White (Internet Archive)).



CareLink PERSONAL
THERAPY MANAGEMENT SOFTWARE FOR DIABETES

[My Info](#) - [Preferences](#) - [Help](#) - [Log-Off](#)

Home

Upload

Logbook

Reports

Reports One at a Time | [Batch Reporting](#)

[Understanding My Reports](#)

Quick View Summary

Daily Summary

Data Table

Modal Day Periods

Modal Day Hourly

Trends Summary

Device Settings

Sensor Daily Overlay

Sensor Weekly Logbook

Sensor Overlay by Meal

Sensor Overlay by Meal

Start Date:
End Date:



This report presents sensor glucose data in the context of pre-meal and post-meal target ranges, as well as Evening and Sleeping time periods.

It is designed to assist you in seeing how well your glucose stayed within your target range before and after meals, in the evening and during sleeping time.

Reports require [Acrobat® Reader®](#)

[Privacy Statement](#) - [Terms of Use](#) - [Contact Us](#) - [FAQ](#)
[My Info](#) - [Preferences](#) - [Help](#) - [Log-Off](#)

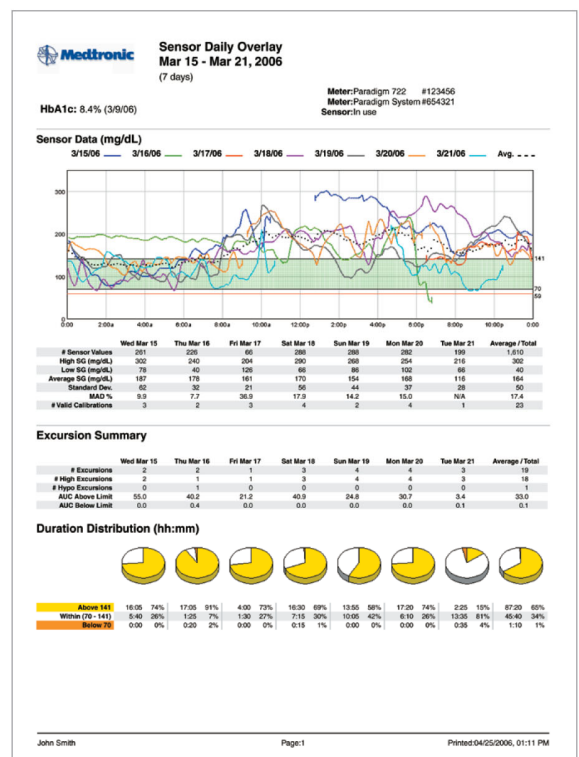
(Ex. 2207 at 16.) The CareLink Guide explains that “[r]eports are displayed in PDF format” and “can be viewed online, saved, printed and/or e-mailed.” (*Id.*; Ex. 2213 ¶¶94, 174.) One example historical report is the “Sensor Daily Overlay” report, reproduced below, which illustrates graphs of CGM sensor readings for a historical seven-day period.

20

Sensor Daily Overlay

This report is based on continuous glucose monitoring for up to seven days. You choose the seven days of glucose sensor tracings you want to see, and this report layers them on top of each other for comparison. Each day has a different color tracing so you can easily tell them apart, making it easy to recognize similar patterns from day to day and even hour to hour. The Sensor Daily Overlay report also helps you identify specific days that you may want to look at in more detail using a Daily Summary report.

*Share any regularly repeating patterns with your healthcare provider.
Talk to him or her about what you might be doing at those times.



(Ex. 2207 at 14; *see also id.* at 13, 15-19.)

The explicit context for this cannot be ignored. The Paradigm FAQs reference “historical reports” three times. Immediately after the sentence Petitioner relies on, the FAQ says “[i]f your system is out-of-range for longer than 40 minutes, when reviewing *historical reports* you would notice ‘data gap’ where information is missing during this period of time.” (Ex. 1211 at 8.) The very next FAQ says that only the last 40 minutes of data would be “re-populated” when the transmitter and insulin pump were out-of-range and that “[w]hen reviewing *historical reports*, you would notice a ‘data gap’ where information is missing during this period of time.” (*Id.*) A few pages later, another FAQ says that “[w]hen *downloading data and*

reviewing historical reports, you will notice ‘data gap’ where information is missing during this period of time.” (*Id.* at 13.)

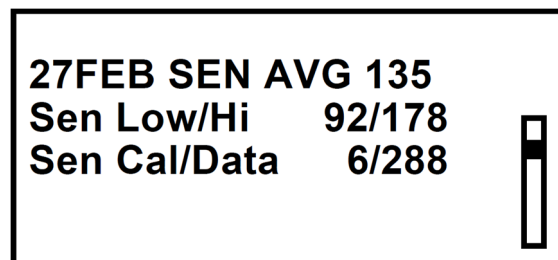
Thus, in every instance that “re-populated” is used in an FAQ, it is used in conjunction with “historical reports.” (Ex. 2213 ¶¶172-175.) Never is it used in conjunction with an output to a display of the pump. And because data was “downloaded” and reviewed in “historical reports,” “historical reports” necessarily refers to retrospective reports generated by computer software, such as CareLink. (*Id.* ¶175; Ex. 2207 at 11-20.) A skilled artisan, with that context in mind, would understand the re-populated data is recorded for future reporting rather than displayed for viewing on the pump. (Ex. 2213 ¶¶167, 172-175.)

2. Historical *Data* Is Not The Same As Historical Reports

The term “historical reports” should not to be confused with historical *data*—it is very different, especially to users monitoring their glucose levels and their healthcare team. Although the insulin pump stored the last 90 days of historical data (for downloading to a computer), there is nothing in the cited art that suggests data was viewable as a trend graph on the pump beyond a rolling 24 hours. (Ex. 2213 ¶¶177, 180; Ex. 2215 ¶¶34-41, 47, 57-62.) Rather, if the historical data were viewed on the insulin pump, only the high, low, and average glucose values for each day were available, and they could be viewed only in tabular form. (Ex. 2215 ¶¶36-40;

Ex. 2218⁴ at 124-126; Ex. 1211 at 3 (linking to “MiniMed Paradigm 522K/722K User Guide for Pediatrics”).)

As explained in another Paradigm User Guide (Ex. 2218), “[t]he pump data management feature allows [the user and their healthcare professional] to view and manage ... basal and bolus insulin delivery, BG data, and food intake with averages up to 31 days.” (Ex. 2218 at 124; Ex. 2215 ¶¶36-40.) Users could “view the details of each day individually,” or they could “average the data over a specified time period” for up to 31 days. (Ex. 2218 at 124; Ex. 2215 ¶¶36-40.) An example screenshot of how the personal history was displayed is shown below:



(Ex. 2218 at 124.) Thus, there is nothing to suggest that the personal history data stored (*i.e.*, re-populated) in the insulin pump was viewable on trend graphs. (Ex. 2215 ¶¶34-41, 47, 49-56.)

There is also no evidence that the term “report” used in the FAQs refers to anything other than a report generated by computer software, such as CareLink, from historical data downloaded from the pump. (Ex. 2213 ¶¶94, 174-175.) In IPR2023-

⁴ See Ex. 2245 (Declaration of Nathaniel E Frank-White (Internet Archive)).

01251, Petitioner’s reply declarant, Dr. Andrew Ahmann, confirmed that he was aware of no evidence that “uses the word ‘report’ to describe the graph on a user display of a CGM device.” (Ex. 2241 at 131:12-20.) Dr. Ahmann’s own article, for example, which he co-authored with leading practitioners in the field, used “*report*,” by consensus, to refer to retrospective historical reports, not graphs on a user display. (Ex. 2241 at 126:18-130:11; *see also* Ex. 2239 at 200 (“Each of [three commercial CGM] manufacturers provides software to download and analyze the CGM data and generate a report or series of reports.”).)

Dr. Ahmann’s understanding of the evidence and use of the term “report” in his own work are consistent with Petitioner’s other exhibits:

- Ex. 1230 at 6:35-40 (“A software is used to download the data, ... and display the data in various formats including charts, forms, *reports*, ... and the like.”);
- Ex. 1239 at 6 (“There is a tremendous amount of information in the *reports* generated from real-time continuous glucose monitoring [such as] *reports* generated by the CareLink software... .”); and
- Ex. 1240 at 300 (“A second way to look at CGM data is in the retrospective analysis of CGM *reports*.”), 303 (“Retrospective analysis of downloaded data is the primary tool the health care provider has in making recommendations to the patient wearing a RT-CGM. The provider must be familiar with the different *reports* provided by each RT-CGM system.”), 304 (providing examples).

Therefore, even if the missing data were displayed in tabular form on the insulin pump's screen, elements [1.K] and [1.L] would not be met because they require displaying processed sensor data as "a second line graph" on the receiver "such that [a] data gap is backfilled." (Ex. 1211 at 16:8-20.) But as Petitioner's own counsel admitted, the Paradigm documentation "does not have a before and after picture of the exact same data where there was a data gap and then there wasn't a data gap." (Ex. 2248 at 18:14-16.)

Patent Owner's expert, Dr. Aaron Striegel, explains how a POSITA could have implemented an embedded system, such as an insulin pump, based on the very limited technical disclosure in Ex. 1211. (Ex. 2215 ¶¶42-56.) For example, such a system with a display could have dedicated memory for display functionality and dedicated memory for long-term storage. (*Id.* ¶¶42-47.) The memory for display functionality would be a type of RAM to enable fluid interaction with the user interface, such as allowing the user to scroll through the displayed trend graph. (*Id.* ¶¶42-45.) That type of memory, however, would be volatile (*i.e.*, erased when powered down), and so a POSITA would include long-term memory, such as flash memory, to store data for longer periods of time. (*Id.* ¶¶42, 46-47.) Data received in real-time could be stored in both memories, but when missing data is later received (*i.e.*, re-populated data), it would be stored only in long-term memory. (*Id.* ¶¶47-56.) Thus, the display memory would contain missing values, resulting in a data gap

shown on the display, while the long-term memory would preserve all data, which could be downloaded for historical analysis. (*Id.* ¶¶49-56.)

Besides two FAQs in the Paradigm documentation, Petitioner does not argue that *any prior art* discloses backfilling missing data on a CGM display. (Ex. 2213 ¶183.) On the other hand, Petitioner’s prior art *clearly discloses* downloading stored data for retrospective analysis:

- Ex. 1211 (Paradigm) at 11-12 (describing CareLink);
- Ex. 1212 (Patel-2009) at [0047] (“Logged data can be downloaded from the characteristic monitor 200 to a PC, PDA, or the like, for detailed data analysis.”), [0081];
- Ex. 1215 (Patel-2008) at [0032] (“This data can then be uploaded to a web based diabetes management server like Carelink.”), [0048];
- Ex. 1217 (Causey) at 9:51-59 (“the information, programs and data may be downloaded to a remote or local PC, laptop, station, or the like, for analysis and review by a MiniMed or a trained health care professional”);
- Ex. 1219 (Mastrototaro) at [0041] (“Logged data can be downloaded from the characteristic monitor 200 to a personal computer, laptop, or the like, for detailed data analysis.”), [0037], [0071]; and

- Ex. 1223 (Shahmirian) at [0063] (“In preferred embodiments, information is transmitted from the BG monitoring system 20 to the infusion pump 30 via the relay device 10, and then downloaded to a storage media from the infusion pump 30.”), [0074], [0082].

(Ex. 2213 ¶¶183-190.) Petitioner’s evidence therefore shows that, at the time of the invention, the emphasis was on preserving CGM data for retrospective analysis, not backfilling missing data on a display. (Ex. 2213 ¶¶183-192, 86-90.)

3. The Paradigm User Guide Refutes Petitioner’s Arguments That Later-Received Data Backfilled Data Gaps On The Pump’s Screen

As explained above, the Paradigm user guide includes two trend graphs that each contain 6-minute data gaps that have not been backfilled despite meeting Petitioner’s criteria—*i.e.*, the gaps are less than 40 minutes and the transmitter is in communication with the pump at the time of the illustrated graphs. (Ex. 1211 at 65.) These graphs refute Petitioner’s arguments. For example, the Medtronic Paradigm® REAL-Time System included a transmitter that, “[w]hen connected to a sensor that is inserted in the body, ... automatically initialize[d] the sensor and beg[an] to periodically transmit sensor glucose readings to the pump using a radio signal.” (Ex. 1211 at 37.) The “transmitter sen[t] glucose data from the sensor to the insulin pump every minute and update[d] every five minutes.” (*Id.* at 7.) Thus, the pump received glucose readings every minute when the transmitter was in communication with the

insulin pump. (*Id.*) An icon on the pump's screen indicated whether the transmitter and pump were in communication:

Sensor icons

There are various icons that appear at the top of your pump screen, such as the time, battery and reservoir icons. The following two icons appear if you are using the sensor.

The sensor icon  appears once you start your sensor. (Refer to Chapter 4 for starting your sensor.)

The sensor icon  changes when the sensor is connected to the transmitter and communicating with the pump.

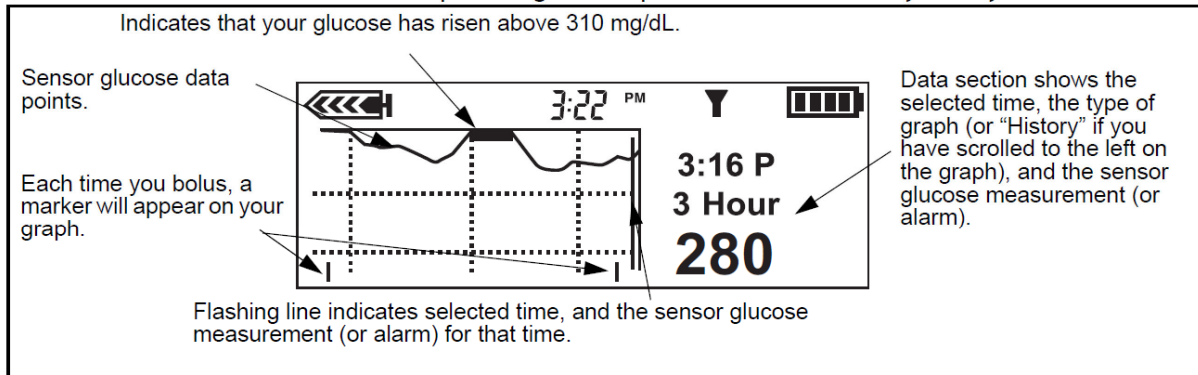
When your sensor and transmitter are connected, and communication is lost this icon  will re-appear.

(*Id.* at 43 (highlights added). As Petitioner's expert, Mr. Gross, confirmed on cross-examination, a solid black sensor icon (yellow highlights) indicated the transmitter was in communication with the pump, whereas a hollowed out sensor icon (blue highlights) indicated that communication had been lost. (Ex. 2244 at 74:3-75:4.)

Mr. Gross testified that the trend graphs reproduced below (from page 64 of the user guide) were "depiction[s] according to Medtronic [of] what the user should expect to see on the user display of the Paradigm" when there was continuous communication (*i.e.*, no adverse conditions). (Ex. 2244 at 71:5-23.)

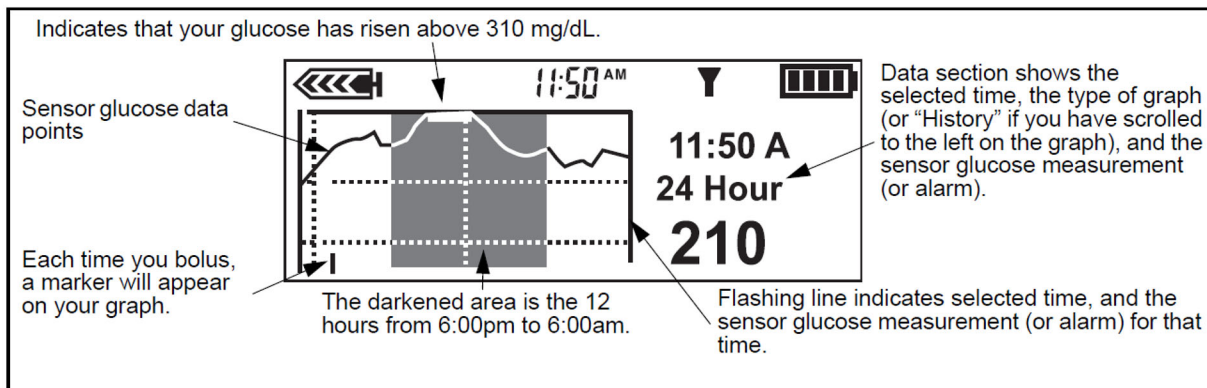
3 hour graph

To scroll through your sensor glucose data points and any alarms that you may have received, press the down button. Below is an example along with explanations of a screen you may see.



24 hour graph

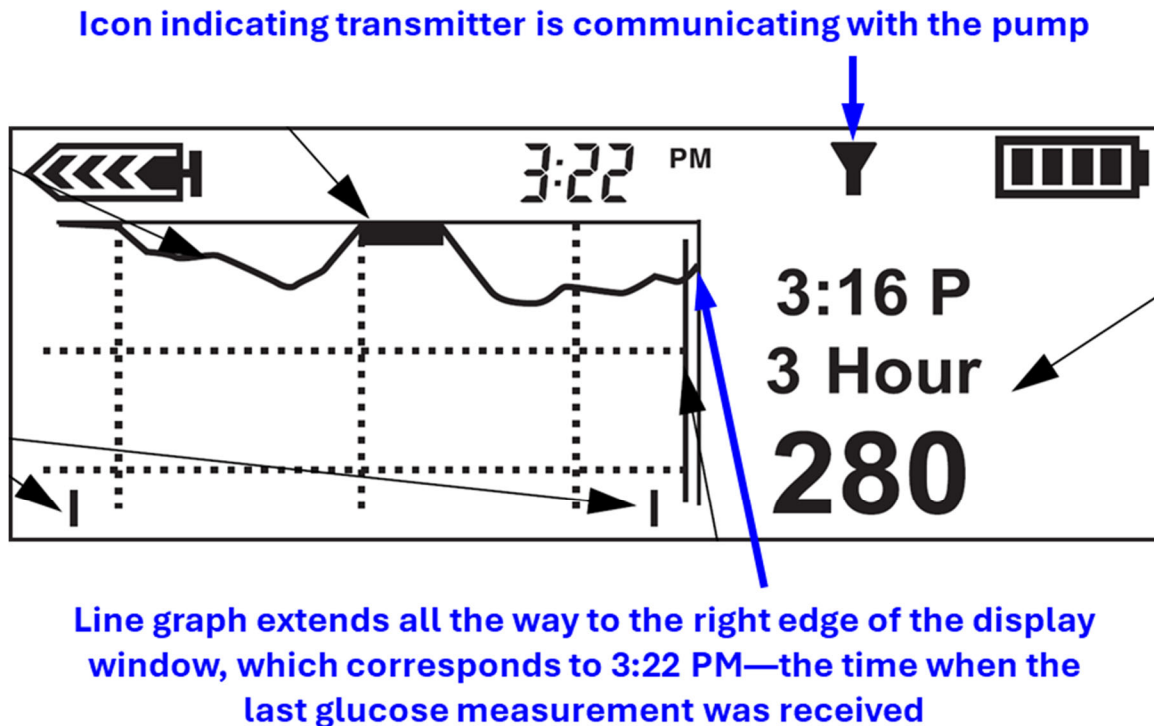
To view the current glucose and a graph of the most recent 24 hours of data, press **ESC** twice from the HOME screen:



(Ex. 1211 at 64.)

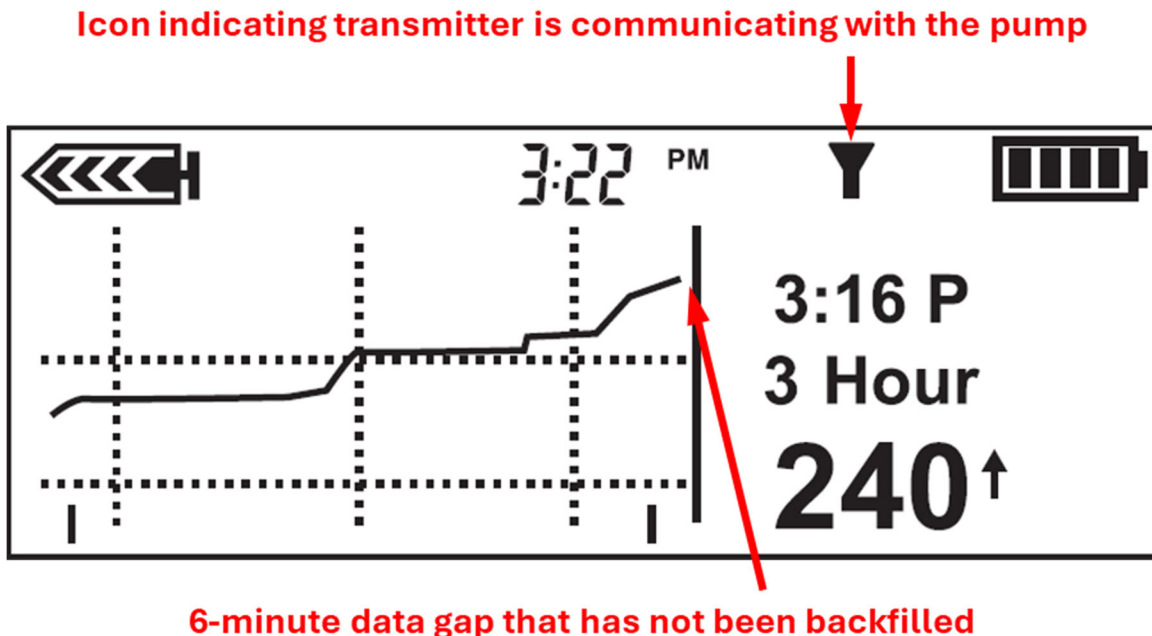
As shown in the above images, Mr. Gross confirmed that the “signal connection status icon” at the top of the trend graphs indicates that “the sensor is connected to the transmitter and communicating with the pump.” (Ex. 2244 at 75:25-76:9.) Mr. Gross then confirmed that “the line graph extends all the way to the right edge of the display window,” which corresponds to 3:22 PM in the 3-hour graph (top) and 11:50 AM in the 24-hour graph (bottom). (*Id.* at 76:10-16.) Finally, Mr.

Gross confirmed that “we can assume [a] measurement was last received at that minute,” (*i.e.*, 3:22 PM in the 3-hour graph). (*Id.* at 76:18-22.) The 3-hour trend graph from page 64 is reproduced below with annotations corresponding to Mr. Gross’s testimony:



(Ex. 1211 at 64 (annotated).)

But the trend graphs on page 65 of the user guide contain a 6-minute data gap that has not been backfilled, *even though the status icon indicates the transmitter is in communication with the insulin pump*. One such graph is reproduced below:



(Ex. 1211 at 65 (annotated).)

Based on Petitioner’s argument that the Paradigm insulin pump displayed up to 40 minutes of backfilled data, and that the trend graph was “updated with average glucose readings every five minutes” (Pet. at 37), the 6-minute data gap shown above should have been backfilled—but it is not. This refutes Petitioner’s argument that the Paradigm insulin pump displayed backfilled data.

Mr. Gross attempted to explain away this evidence on cross-examination but had no credible response. First, with respect to the trend graph above, Mr. Gross confirmed that the current time displayed is also 3:22 PM, and that the transmitter is in communication with the pump at that time. (Ex. 2244 at 76:23-77:12.) Mr. Gross further confirmed that the glucose line graph does not go all the way to the current time at the right side of the graph (*i.e.*, there is a data gap). (*Id.* at 78:9-15; *see also*

Ex. 2250 at 1 (page 65 of Ex. 1211 with line representing the current time highlighted in yellow during Mr. Gross's deposition).) But according to Mr. Gross, that detail is not relevant to what the user guide is explaining on page 65. He claims that "the images depicted on ... page 65 are incomplete because the artist was trying to illustrate these trend arrows and wasn't so concerned about other aspects of the display." (Ex. 2244 at 95:16-96:2 ("It is possible that the image with the gross value and the arrow was sufficient to explain to the user what it means and the information in the rest of the display may not be relevant.")) Mr. Gross's explanation is not credible given the clear illustrations of trend graphs on pages 64 and 65, and the differences between them.

4. Mr. Gross's Opinions Are Contradicted By Substantial Evidence And Should Not Be Permitted To Plug Holes In Petitioner's Prior Art

Besides the FAQs, Petitioner relies heavily on Mr. Gross's declaration for element [1.K]. (Pet. at 57.) Indeed, Petitioner repeatedly cites paragraphs 54-61 and 80 of the Gross declaration to supply teachings that are clearly missing from the prior art, including disclosure of entire claim elements. (*See, e.g.*, Pet. at 20, 21, 22, 23, 24, 32, 41, 42, 49, 52, 53, 56, 57, 59, 61, 62, 74.) But Mr. Gross's opinions in these paragraphs should not be credited, and in fact are contradicted by overwhelming evidence. (Ex. 2213 ¶¶156-163.)

First and foremost, in IPR2023-01251, Petitioner’s clinical expert, Dr. Ahmann, testified that, among all the sources Mr. Gross cites in paragraphs 60 and 80 of his declaration, there is “no specific discussion of backfilling data in a CGM device.” (Ex. 2241 at 67:16-68:7.) This confirms that Petitioner has no evidence from prior art of any system that backfilled missing data on a CGM display. Moreover, while Dr. Ahmann testified that he reviewed paragraphs 51-61 and 80 of Mr. Gross’s declaration, he commented only on paragraphs 60 and 80. (Ex. 2246 ¶25.) Dr. Ahmann expressed no opinion about Mr. Gross’s statements in paragraphs 51-59 or 61 of his declaration, and therefore offered no additional support for Mr. Gross’s conclusory opinions in those paragraphs.

Second, Mr. Gross’s opinions in paragraphs 54-61 and 80, and especially paragraphs 60 and 80, should be disqualified because he lacks clinical expertise. (Ex. 2213 ¶¶123-125, 128-129, 131-133.) Mr. Gross says that a POSITA may be part of an interdisciplinary team with “others having relevant experience ... and/or with *clinicians involved in diagnosis, treatment, and patient management.*” (Ex. 1208 ¶52; Ex. 2227 at 147:11-25.) Though he acknowledged the necessity of clinical expertise, Mr. Gross then opines about clinical issues, such as in paragraphs 60 and 80 where he opines about “diabetes management, insulin dosing decisions, and prevention or treatment of hyper and hypo-glycemia.” (Ex. 1208 ¶60; Ex. 2213 ¶¶131-133, 146-147.) Mr. Gross has no clinical experience and is not qualified to

opine about these clinical aspects of CGMs, particularly to conclude that POSITAs would find it obvious to backfill missing data on a CGM display because of them. (Ex. 2213 ¶¶126-133.)

For example, Mr. Gross is not a medical doctor and he has never prescribed a CGM (Ex. 2227 at 36:14-17), helped a diabetic select a CGM (*id.* at 36:18-21), instructed a person with diabetes on how to use a CGM (*id.* at 48:18-20), helped a person with diabetes determine target thresholds to manage their glucose levels (*id.* at 48:21-25), calculated a bolus or basal insulin dose (*id.* at 38:2-7), or administered insulin (*id.* at 36:25-37:4). He was also unfamiliar with basic clinical terms, such as “adjunctive use,” “non-adjunctive use,” and “MARD” (a common measure of a CGM’s accuracy) (*Id.* at 50:11-20.) In short, Mr. Gross lacks clinical experience, especially from the 2009 timeframe, to opine about topics such as “diabetes management, insulin dosing decisions, and prevention or treatment of hyper or hypoglycemia.” (Ex. 2213 ¶¶131-133.) His opinions in paragraphs 60 and 80 are not from the perspective of a POSITA (as he has defined it). (*Id.* ¶133.)

In IPR2023-01251, Petitioner recognized these defects with Mr. Gross’s opinions and tried to rehabilitate him on reply with opinions from Dr. Ahmann. Those attempts proved futile. Mr. Gross argued in his reply declaration that he was “qualified to opine on the perspective of a POSITA” because his opinions were allegedly “informed by Dr. Ahmann’s clinical perspective.” (Ex. 2242 ¶28.) But Dr.

Ahmann’s “clinical perspective” is irrelevant because Mr. Gross rendered his opinions more than a year *before* Dr. Ahmann was even involved in that IPR. In fact, to date, Mr. Gross has never met or even spoken with Dr. Ahmann. (Ex. 2244 at 37:2-9.) Dr. Ahmann’s reply declaration in IPR2023-01251 did not somehow retroactively qualify Mr. Gross to opine on subject matter for which he lacks expertise and clinical experience, whether in that IPR or in this IPR.

Third, paragraphs 54-61 of the Gross declaration, and especially paragraphs 55-57, make broad assertions about what a POSITA would allegedly have known or done. However, these assertions lack evidentiary support. (*See* Ex. 1208 ¶¶54-61; Ex. 2213 ¶¶134-138.) Such opinions should be disregarded. *TQ Delta v. Cisco*, 942 F.3d 1352, 1362 (Fed. Cir. 2019) (refusing to accept *ipse dixit* expert testimony); *Xerox v. Bytemark*, IPR2022-00624, Paper 9 at 15 (P.T.A.B. Aug. 24, 2022) (precedential) (“Dr. Jones does not cite to any additional supporting evidence or provide any technical reasoning to support his statement. Thus, the cited declaration testimony is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight.”). Also, Mr. Gross’s statements in these paragraphs merely reiterate aspects of the 056 patent, demonstrating that Mr. Gross used the patent as a roadmap for hindsight. (*See* Ex. 2213 ¶¶137-138.)

With no express evidence of backfilling missing data on a CGM display, Petitioner’s reliance on Mr. Gross’s unsupported and conclusory opinions to supply the missing evidence is improper. *Apple v. Mullen Indus.*, IPR2023-00087, Paper 10 at 19 (P.T.A.B. May 3, 2023); (*Consolidated Trial Practice Guide* (“CTPG”) at 36 (Nov. 2019) (“[I]n an obviousness analysis, conclusory assertions from a third party about general knowledge in the art cannot, without supporting evidence of record, supply a limitation that is not evidently and indisputably within the common knowledge of those skilled in the art.”).

Fourth, the flaws in Mr. Gross’s opinions, particularly those in paragraphs 60 and 80, are compounded because they are historically and clinically inaccurate. For example, Mr. Gross opines that “POSITAs would have found it obvious to display previously missing data to the user in order to present as much accurate data as possible to assist in diabetes management, insulin dosing decisions, and prevention or treatment of hyper and hypo-glycemia.” (Ex. 1208 ¶60.) Mr. Gross bases that opinion largely on the Paradigm documentation. (*See id.* (citing Ex. 1211 at 15, 18, 23-27).) But at the time the Paradigm documentation was created in 2007, the American Diabetes Association (“ADA”) did not recommend using CGMs to manage glucose levels at home, and declared it was also “premature” to use them in a hospital “except in a research setting.” (Ex. 2235 at S31.) This is significant, as Dr. Ahmann described the ADA’s Standards of Medical Care as the “most authoritative”

and “the most reliable standards of care” that are “most often cited and most often implemented into institutional practices.” (Ex. 2241 at 14:20-15:3.) In fact, as of the 056 patent’s priority date in 2009, *no CGMs* were approved by regulatory agencies (e.g., FDA) for making diabetes treatment decisions, including insulin dosing decisions. (Ex. 2213 ¶¶80-83; Ex. 2216 at 3, 6; Ex. 1211 at 10, 15.) Instead, patients were required to perform supplemental fingerstick measurements. (*Id.*)

Additionally, Mr. Gross’s underlying presumption is that CGMs in 2009 provided “accurate” data. This too is incorrect. (Ex. 2213 ¶¶75-79.) CGMs generally, and the Medtronic Paradigm® REAL-Time system specifically, were known to be relatively inaccurate. (*Id.* ¶¶75-79, 148-155.) The Paradigm CGM sensor was inaccurate by about 19%, meaning that, on average, glucose levels measured with Medtronic’s CGM differed from the patient’s actual glucose levels by that amount. (Ex. 2213 ¶¶77, 150; Ex. 1211 at 85.) In some instances, the CGM readings were off by an astonishing 90 mg/dL. (Ex. 2213 ¶152.) At times, the CGM readings indicated the patient’s glucose levels were higher or lower than they actually were. (*Id.* ¶155.) And sometimes the CGM readings indicated glucose levels were trending in one direction when they were trending in the opposite direction. (*Id.* ¶154.) Thus, like other 2009-era CGMs including Petitioner’s, the Paradigm was often inaccurate and unreliable, and could not be relied on for contemporaneous treatment decisions. (Ex. 2213 ¶¶75-78; 149-155, 197.)

Fifth, additional evidence undermines Mr. Gross’s opinions in paragraphs 54-61 and 80, and particularly paragraphs 60 and 80. For one, Petitioner released several CGM products between 2006 and 2016 that displayed data gaps but did not backfill them. (*See supra* §II.A.) In fact, Petitioner warned patients that its CGM products were “not designed to replace a blood glucose meter” and that, “[e]specially during Glucose Data Gaps,” users should “rely on [their] blood glucose meter.” (Ex. 2201 at 38.) Had backfilling data gaps been obvious as Petitioner alleges, Petitioner would have solved the problem. (Ex. 2213 ¶156.) Mr. Gross did not consider Petitioner’s prior products or these commercial realities in forming his opinions. (Ex. 2244 at 36:10-21.)

As another example, with respect to claim 19, in IPR2023-01251, Mr. Gross opined that “POSITAs would have found it obvious to wait a predetermined time (*e.g.*, one, two, three update cycles) before displaying re-populated glucose data.” (Ex. 2247 ¶129.) Given that the Paradigm and other CGMs used 5-minute update cycles, it is Mr. Gross’s opinion that withholding 15 minutes of data (three cycles at five minutes each) or more before displaying it to the user would have been acceptable. (Ex. 2213 ¶¶157-158.) This contradicts his opinions that it was critical to display missing data “to assist in diabetes management, insulin dosing decisions, and prevention or treatment of hyper and hypo-glycemia.” (Ex. 1208 ¶60; Ex. 2213 ¶¶157-158, 192-196.)

Lastly, Petitioner’s own 2016 patent filings undermine Mr. Gross’s opinions that it would be critical (or obvious) to display backfilled data. (Ex. 2213 ¶¶159-162.) Indeed, Petitioner identified several practical reasons not to. In U.S. Patent No. 10,085,640, Petitioner explained that it might not make sense to backfill data because “some of the data may become stale to certain components of the system, backfilling may consume too much battery power of one or more components ..., and/or a component ... requesting the backfilled data may only be configured to display a certain range of data.” (Ex. 2223 at 30:25-32.) Backfilling data gaps on a CGM display might also cause confusion:

Another challenge arises with distinguishing between data that was received as scheduled upon transmission or through a backfill process. When a user misses an alarm because a device was out of range, but looks at their smartphone and sees that glucose data is available in the time range of when an alarm should have issued, the user can become confused or assume there was an error with the alarm. However, the smartphone did not have the data at the time of the alarm but instead backfilled the data subsequently.

(*Id.* at 36:37-46; Ex. 2213 ¶161.) As Dr. Wright explains, user confusion could be avoided by providing the relevant information in other ways, such as with an alarm or a trend arrow. (Ex. 2213 ¶161.) An alarm or trend arrow could inform the user about impending hypoglycemia, for example, without masking gaps in the data and avoiding the risks of backfilling data gaps as Petitioner explains in its patents. (*Id.*)

In U.S. Patent No. 9,996,668, Petitioner explained additional reasons why backfilling may not be desirable:

- The user might miss data during the nighttime while they're asleep, and therefore “may not want backfill data to be automatically displayed because the automatic insertion of backfill data may mask the nighttime gap(s) in data and mask that the receiver was not receiving data.” (Ex. 2224 at 5:32-40.)
- The data “may be stale in the sense that it might not capture the current glucose state of the host wearing the sensor.” (*Id.* at 7:21-23.)
- “With stale data, a user may not want to take action based on the sensor data, while with more current non-backfill data, a user may take action based on the sensor data.” (*Id.* at 7:23-26.)
- “Data backfilling may consume power at the transmitter and/or receiver (which can reduce available battery resources).” (*Id.* at 18:59-61.)

In light of the above, Mr. Gross's opinions at paragraphs 54-61 and 80 of his declaration (and any similar opinions) should be given no weight and should not be permitted to plug holes in the absence of disclosure in the prior art—especially in view of Petitioner's own patents that contradict Mr. Gross's opinions about an alleged urgency to show missing data. *Apple*, IPR2023-00087, Paper 10 at 19; (Ex. 2213 ¶163.)

When the scope and content of the prior art is viewed in the proper historical and clinical context, it is evident that “data re-populated *in* the insulin pump” refers to preserving data for retrospective analysis in historical reports. (Ex. 2213 ¶¶181-182.) Thus, Petitioner’s prior art does not disclose element [1.K].

B. If Petitioner Argues The Paradigm User Guide Does Not Show A 6-Minute Data Gap, Then Its Analysis Of Element [1.I] Fails

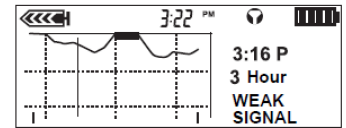
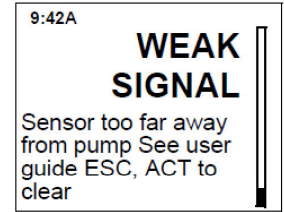
As previewed above, Mr. Gross attempted to explain away the persistent 6-minute data gaps shown on page 65 of the Paradigm user guide. (*See supra* §V.A.3.) In his opinion, the authors of the user guide were focused on explaining trend arrows and the rest of the display was allegedly not relevant, including the data gaps shown in the trend graphs. (Ex. 2244 at 95:16-96:2.) He testified similarly about the trend graphs shown on page 66 of the user guide, claiming the focus there is on double arrows and not on other aspects of the graphs. (*Id.* at 94:15-95:15.)

If this same logic is applied to the trend graph shown on page 73 of the Paradigm user guide, which Petitioner claims illustrates a data gap, then Petitioner has no evidence that claim element [1.I] is met. For example, the Paradigm user guide provides the following information about a weak signal alert:

Weak signal

Alerts you when the pump does not receive data for a period of time, as set in Missed Data. Move the pump closer to the transmitter or move the transmitter and the pump to a new location on your body.

NOTE - You may see a Weak Signal recorded on the sensor graphs without receiving an alert. An alert condition will start once the pump has not received sensor data for the length of time set in Missed data (page 13).



(Ex. 1211 at 73.) Petitioner relies on the trend graph in the above graphic to allege the Paradigm documentation discloses a data gap within the scope of element [1.I]. (See Pet. at 54-56.) But based on Mr. Gross’s logic, the purpose of this page of the user guide is to explain what a weak signal is, and to illustrate that an alert may be displayed on the home screen while a textual notice of “WEAK SIGNAL” may accompany the trend graph. (See Ex. 2250 at 3 (page 73 of Ex. 1211 with alert highlighted in green and textual notice highlighted in pink during Mr. Gross’s deposition).) The trend graph itself is not relevant.

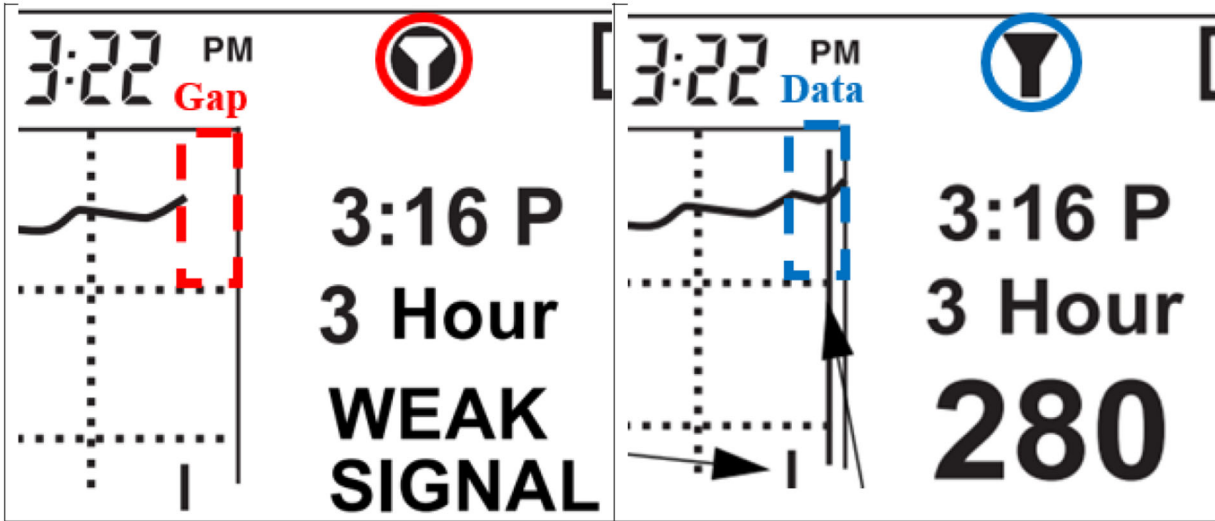
Thus, based on Mr. Gross’s own logic, page 73 of the user guide does not illustrate a data gap as Petitioner contends for element [1.I]. This is another claim element missing from Petitioner’s prior art.

C. Petitioner Has No Evidence That Discloses Element [1.L]

Element [1.L] relates back to [1.K] and recites that the backfilled data “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.” (Ex. 1201 at 16:13-20.) The Board previously agreed with Abbott that Petitioner’s only evidence for [1.L], a conflation of two unrelated graphics, does not disclose this element. (Ex. 2249 at 33.) That is fatal for two reasons. First, Petitioner’s expert, Mr. Gross, offers *no opinion* that displaying backfilled data as claimed in [1.L] would be obvious, and therefore has no testimony to plug holes in Petitioner’s prior art. Second, Petitioner’s clinical expert in IPR2023-01251, Dr. Ahmann, testified there would be benefits to displaying backfilled data differently. As the Board noted during oral argument in that IPR, this “cut[s] against” Petitioner because there is no evidence in the Paradigm documentation about how backfilled data would allegedly be displayed. (Ex. 2248 at 20:13-24.) Consequently, Petitioner has *no evidence* that element [1.L] is met.

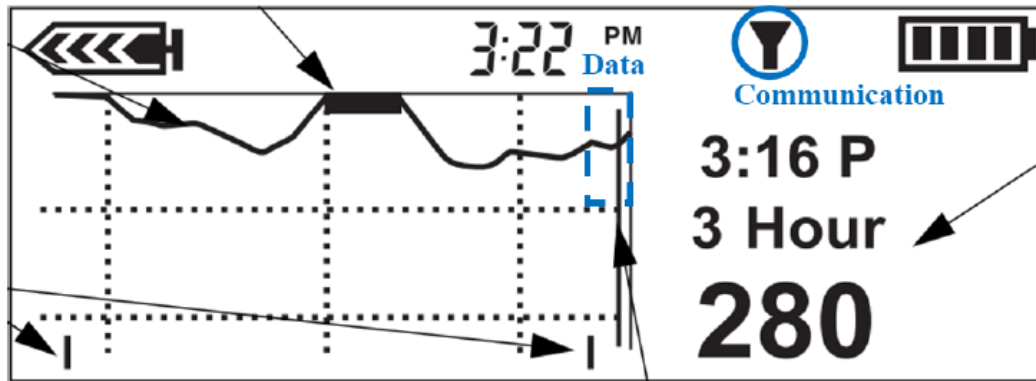
Petitioner relies on only the Paradigm user guide for element [1.L]. (See Pet. at 57-59.) But Petitioner juxtaposes two annotated artist renderings of the pump’s display taken from different chapters of the user guide to create the incorrect impression that a data gap in a line graph is subsequently filled in on the same display. (Pet. at 58-59; Ex. 2213 ¶¶208-212.) The Petition includes the following composite figure to incorrectly suggest that the two figures illustrate a sequence of events where a gap first appears and then is filled in on the display.



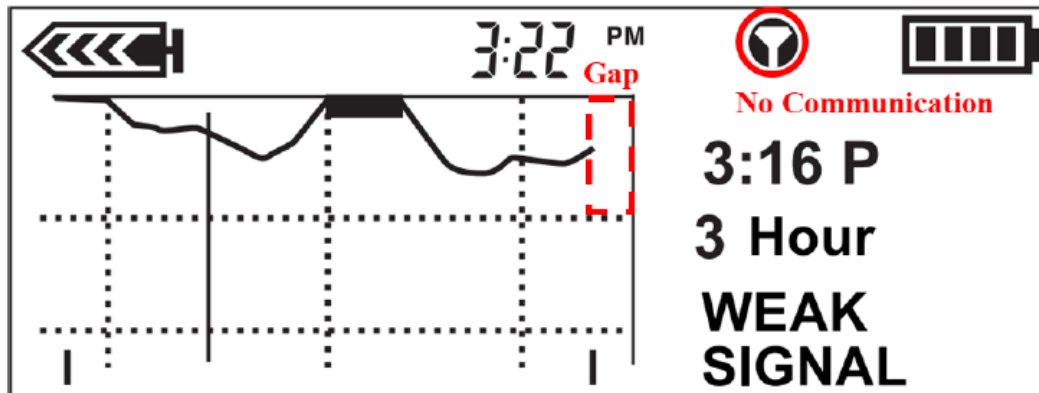
(*Id.* at 59.)

As the Board explained in IPR2023-01251, “[t]here is no express or implicit disclosure in Ex. [1211] that the Chapter 5 rendering is showing a backfilled data gap from the Chapter 6 rendering.” (Ex. 2249 at 33; Ex. 2213 ¶213.) Indeed, there is no description in the user guide of a gap in the displayed line graph, *i.e.*, the 3-hour trend graph, that is backfilled. (Ex. 2213 ¶¶211-212.) The user guide does not describe any relationship between the two artist renderings, or the left and right portions of Petitioner’s composite figure. (*Id.*) Rather, the right portion of the composite figure is from a section of Chapter 5 of the user guide, titled “Reading your graphs” (*see* Ex. 1211 at 64), while the left portion is from a section of Chapter 6, titled “Sensor alarm conditions” (*see id.* at 73).

Moreover, the hypothetical scenarios illustrated in the figures are not the same. (Ex. 2213 ¶212.) In Chapter 5, the illustration shows that the insulin pump is in communication with the transmitter at 3:22 PM.



(Pet. at 58.) In Chapter 6, the illustration shows that the insulin pump is not in communication with the transmitter at 3:22 PM.



(*Id.*) They are not, as Petitioner attempts to portray, a sequence of events in time, nor could they be since both are showing the same time of 3:22 PM. (Ex. 2213 ¶¶211-212.)

Petitioner's *failure to identify any prior art disclosure* of claim element [1.L] should be dispositive of Grounds 1 and 2. Petitioner does not rely on any other

portion of Ex. 1211 for claim element [1.L] and the only additional citations are to three paragraphs of Mr. Gross’s declaration. (*See* Pet. at 57-59.) Paragraphs 114 and 115 of the Gross declaration, however, merely parrot the Petition and add nothing. (*Compare* Ex. 1208 ¶¶114-115, *with* Pet. at 57-59); *Xerox*, IPR2022-00624, Paper 9 at 15. And Mr. Gross’s opinion in paragraph 60 (cited on page 59 of the Petition) is irrelevant to claim element [1.L] because he does not opine about any graphical display of backfilled data, much less offer an opinion that it would have been obvious to display it exactly as recited in claim element [1.L]. (Ex. 1208 ¶60.) Additionally, Mr. Gross’s opinion in paragraph 60 should be given no weight for the reasons explained above. (*See supra* §V.A; Ex. 2213 ¶214.) Besides, Dr. Ahmann confirmed that Mr. Gross cites no source in paragraph 60 that discusses “backfilling data in a CGM device” (Ex. 2241 at 67:16-68:7), and conclusory expert testimony cannot be used to supply a missing claim element as Petitioner attempts here. *Apple*, IPR2023-00087, Paper 10 at 19.

Moreover, Dr. Ahmann, admitted that it would be beneficial to display backfilled data differently than non-backfilled data. (Ex. 2241 at 95:23-96:8, 97:8-98:23.) During oral argument in IPR2023-01251, the Board explained that Dr. Ahmann’s admissions “cut against” Petitioner “[b]ecause the *Paradigm* documentation nowhere says ... the backfilled data will be shown in another color or thicker line or distinguished in some way.” (Ex. 2248 at 20:21-24.) Thus, the lack

of evidence from prior art and an absence of opinion testimony, coupled with Dr. Ahmann's admissions about the benefits of displaying backfilled data differently, demonstrate that Petitioner has not met its burden on [1.L], and therefore, all of claim 1. Consequently, the patentability of Challenged Claims 13 and 29 should be upheld, as they each depend directly from claim 1.

VI. GROUND 1: THE PATENTABILITY OF CLAIM 13 SHOULD BE UPHELD BECAUSE PETITIONER RELIES ON THE SAME FAULTY ARGUMENTS AS INDEPENDENT CLAIM 1

Petitioner rests on the same arguments for claim 13 as it does for claim 1. (*See* Pet. at 59-62.) It argues that, under its interpretation of Patent Owner's infringement contentions, "a 'sensor misposition error' that encompasses signal loss is rendered obvious by Patel-2009 and Paradigm REAL-Time." (*Id.* at 60.) Petitioner makes no additional arguments and does not include a mapping for claim 13 that differs in any way from its claim 1 arguments. (*See id.* at 59-62.)

Therefore, because Petitioner fails to show that claim 1 is obvious in view of Patel-2009 and the Paradigm documentation, Petitioner likewise fails to show that claim 13 is obvious for the same reasons.

VII. GROUND 2: THE PATENTABILITY OF CLAIM 29 SHOULD BE UPHELD FOR SEVERAL INDEPENDENT REASONS

Dependent claim 29 adds a secondary receiver unit to the system of claim 1, where the secondary receiver unit is a watch. Claim 29 further recites that the

secondary receiver unit has a limited number of functions compared with the receiver unit of claim 1:

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.

(Ex. 1201 at 18:19-25.)

In Ground 2, Petitioner adds Goldsmith to the Patel-2009/Paradigm combination. But the Patel-2009/Paradigm/Goldsmith combination does not render claim 29 obvious for several reasons.

First, Petitioner combines two alternative Goldsmith embodiments (direct versus indirect communication between the transmitter and watch), but ignores features of those embodiments that are essential to rendering operable Petitioner's combined system.

Second, although Petitioner argues a POSITA would be motivated to add Goldsmith's watch to the Patel-2009/Paradigm combination, Petitioner provides no credible reason or evidence for configuring the watch to communicate both directly *and* indirectly with the on-body sensor/transmitter relied on in Patel-2009.

Third, based on Petitioner’s combination, Goldsmith’s watch does not have “a limited number of functions as compared with the receiver unit” as required by claim 29. Indeed, Petitioner does not even compare functions of Goldsmith’s watch to the claimed receiver unit to make the assessment. Instead, Petitioner erroneously compares functions of different Goldsmith embodiments. Consequently, Petitioner has not shown that claim 29 is obvious.

A. Summary of Goldsmith

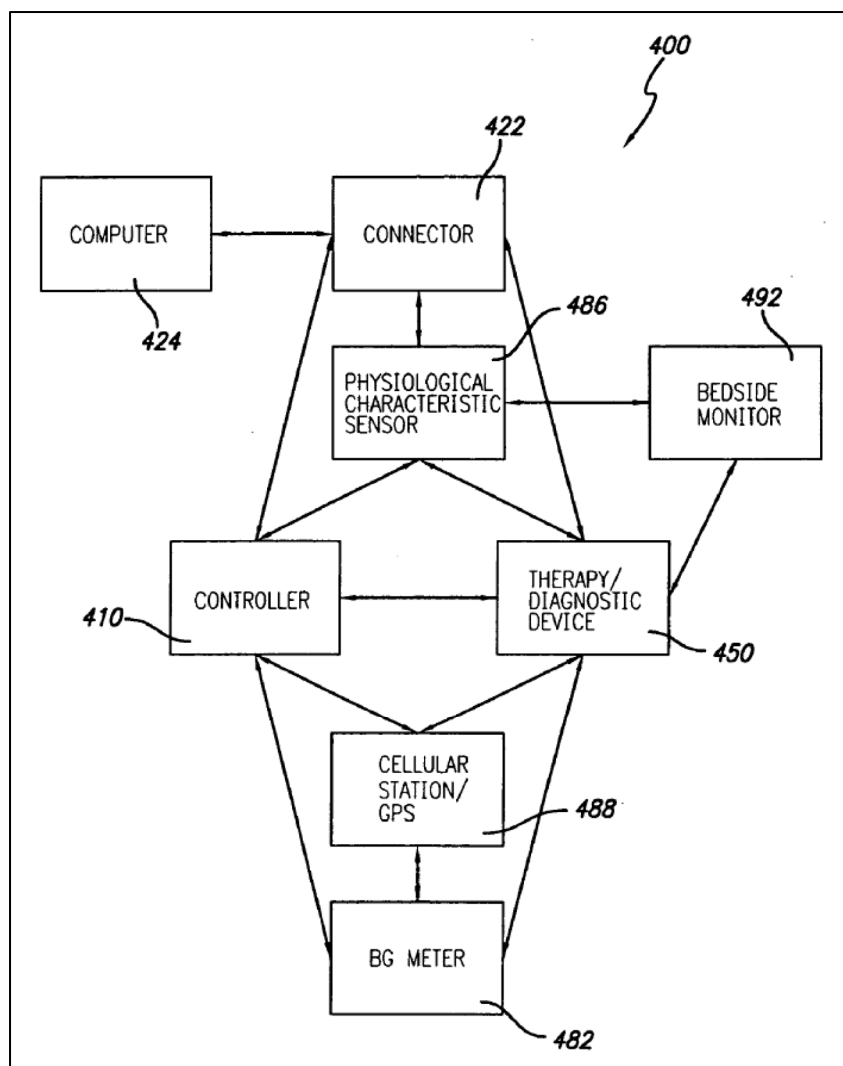
Goldsmith discloses “[a]n infusion system that includes a watch controller device and a communication system to transmit the communications from the watch controller device to an infusion device pump that controls delivery of fluids to the user’s body.” (Ex. 1251 at Abstract; Ex. 2215 ¶66.) Goldsmith describes various alternative embodiments in which the controller has varying degrees of functionality. (Ex. 2215 ¶ 66.) For example, Goldsmith discloses:

In some embodiments, the infusion system 400 may include multiple controllers that can communicate with one infusion device 450. In other embodiments, there is one controller 410 communicating to one infusion device 450. The controller may also be integrated into the infusion device in some embodiments. In yet another embodiment, the BG meter 482 may be integrated into the controller 410, sharing one housing, to both communicate with the infusion pump device 450. In this embodiment, the controller is separate from the infusion pump device. In this embodiment, the infusion device 450 serves as the

central hub with most of the intelligence of the system 400. In yet another embodiment, the controller device 410 may be a key fob, in which case, the controller device 410 would serve simply as a virtual keyboard to input data and commands to the infusion device 450.

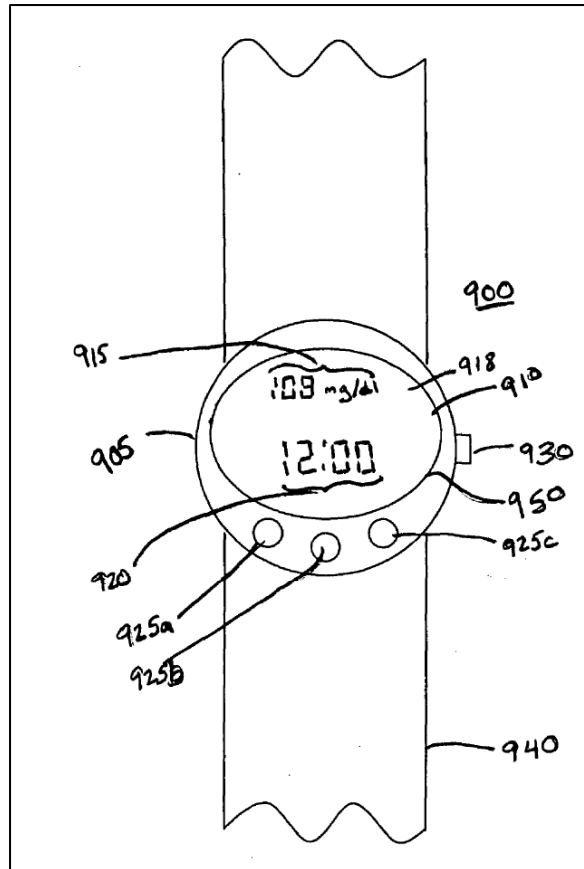
(Ex. 1251 at [0050]; Ex. 2215 ¶66.)

Goldsmith's infusion system may include "[o]ptional peripheral devices" including a "physiological characteristic sensor device, such as a telemetered glucose monitoring system (TGMS) sensor." (Ex. 1251 at [0050]; Ex. 2215 ¶67.) Figure 7 of Goldsmith shows "*potential* communication paths *within embodiments* of the infusion system." (Ex. 1251 at [0049]; Ex. 2215 ¶67.)



(Ex. 1251 at FIG. 7.)

In some embodiments, Goldsmith’s controller is a watch controller that “may interact with one or more devices, such as infusion pumps and analyte monitors.” (Ex. 1251 at [0085]; Ex. 2215 ¶68.) “FIG. 9A shows a front view of a watch controller device.” (Ex. 1251 at [0085]; Ex. 2215 ¶68.)



(Ex. 1251 at FIG. 9A.) In this embodiment, “[t]he watch controller device 900 includes ... a communication system (not shown) contained in the housing 905 for transmitting a communication or command from the user to the infusion device or analyte monitor.” (Ex. 1251 at [0085]; Ex. 2215 ¶69.) “The watch controller device may include one or more input devices 925a, 925b, 925c, 930 on the controller device housing, such as keys, buttons or the like, for the user to input data or commands.” (Ex. 1251 at [0085]; Ex. 2215 ¶69) “The display 910 also may display at least a portion of whatever information and/or graph is being displayed on the

infusion device display or on the analyte monitor display.” (Ex. 1251 at [0086]; Ex. 2215 ¶69.)

Goldsmith explains that the watch controller may receive glucose data in alternative ways. (Ex. 2215 ¶70.) For example, “[t]he display of the watch controller device may display data directly from a pump.” (Ex. 1251 at [0087]; Ex. 2215 ¶70.) “Alternatively, data may be received directly from a sensor transmitter on the patient’s skin.” (Ex. 1251 at [0087]; Ex. 2215 ¶70.) “The display may display what the user is inputting to transmit to the infusion device or analyte sensor monitor.” (Ex. 1251 at [0087]; Ex. 2215 ¶70.)

In the embodiment of FIG. 10, Goldsmith’s watch includes “[a] processor 1012 contained in the housing 1015 [that] is adapted to process data and commands inputted by the user, and a transmitter/transceiver 1018 contained in the housing 1015 and coupled to the processor 1012 [that] transmits such communications, including data indicative of the determined concentration of the BG in the user, to the infusion device 1050.” (Ex. 1251 at [0088]; Ex. 2215 ¶71.)

B. Petitioner Cherry-Picks Passages In Goldsmith Based On Hindsight And Combines Multiple, Incompatible Embodiments

Petitioner’s mapping for claim 29 is a jumbled collection of disparate teachings from Goldsmith that fails to explain, with particularity, how all of the limitations of claim 29 are met. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (“In an IPR, the petitioner has the burden from the onset to

show with particularity why the patent it challenges is unpatentable.”). In particular, Petitioner combines two disparate embodiments of Goldsmith that use different modes of communication (“direct communication” and “indirect communication”), but then ignores important details about the embodiments necessary to render Petitioner’s new system operable. (Ex. 2215 ¶72.)

For alleged “direct communication,” Petitioner relies on paragraph [0088] of Goldsmith to argue that “the watch controller’s ‘transceiver 1018 receives information from an analyte sensing device 1060.’” (Pet. at 82; Ex. 2215 ¶73.) For the Patel-2009/Paradigm/Goldsmith combination, Petitioner argues that “a POSITA would recognize that this results in data ‘received directly from a sensor transmitter on the patient’s skin’ being displayed by the watch controller device.” (Pet. at 82; Ex. 2215 ¶73.)

For alleged “indirect communication,” Petitioner relies on paragraph [0087] of Goldsmith to argue that, instead of receiving data directly from a sensor/transmitter on the patient’s skin, “the watch controller may display data directly from a pump.” (Pet. at 83; Ex. 2215 ¶74.) For the Patel-2009/Paradigm/Goldsmith combination, Petitioner argues that “a POSITA would recognize that this involves receiving processed sensor data via the monitor (*e.g.*, infusion pump) (*e.g.*, the monitor serving as an intermediary device between the sensor and the watch controller) using the same two-way communication link

(illustrated in red) that the watch controller’s transmitter/transceiver 1018 uses to transmit communications to the infusion device 1050.” (Pet. at 83; Ex. 2215 ¶74.)

But Goldsmith’s alternative embodiments with different modes of communication are not compatible in the manner Petitioner claims. (Ex. 2215 ¶75.) For example, in Goldsmith’s embodiment illustrated in FIG. 10 and described in paragraph [0088], which Petitioner relies on for “direct communication,” the watch controller device 1010 “is adapted to process data and commands *inputted by the user*” and “transmits such communications, *including data indicative of the determined concentration of the BG in the user, to the infusion device 1050.*” (Ex. 1251 at [0088]; Ex. 2215 ¶75.) Thus, according to Petitioner’s mapping for claim element [1.F], the “receiver unit” (*i.e.*, insulin pump) would simultaneously receive glucose data from *two different sources*. (Ex. 2215 ¶76.) It would receive glucose data (1) directly from the on-body sensor/transmitter (Pet. at 52-53), and (2) from Goldsmith’s watch as explained in paragraph [0088] of Goldsmith (“direct communication”). (Ex. 2215 ¶76.)

Petitioner’s mapping, however, does not account for the transmission of glucose data to the infusion device (*i.e.*, receiver unit of claim 1) *from the watch*, or explain how this would work. (Ex. 2215 ¶77.) Instead, Petitioner sidesteps this critical problem altogether by cherry-picking only the portion of Goldsmith that describes the watch as receiving glucose data from the sensor/transmitter on the

user's body, and then ignoring that the same watch also transmits user-inputted data and glucose data to the infusion device 1050. (Ex. 1251 at [0088]; Ex. 2215 ¶77.) It is impermissible for Petitioner to “pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” *In re Wesslau*, 354 F.2d 238, 241 (CCPA 1965); *Bank of Am., N.A. v. Nant Holdings IP, LLC*, IPR2021-01081, Paper 46 at 33 (P.T.A.B. Jan. 9, 2023).

Petitioner's errors are compounded by the fact that, in the “indirect communication” configuration, Goldsmith's watch displays “data directly from a pump,” with the pump serving as an “intermediary device between the sensor and the watch controller” (Pet. at 83), *as well as* from the sensor/transmitter according to the “direct communication” (*id.* at 82). (Ex. 2215 ¶78.) While Petitioner argues that a POSITA would have found it obvious to configure Goldsmith's watch to receive glucose data “*both* directly from the on-body glucose sensor/transmitter device *as well as* indirectly via the pump or other handheld device” (Pet. at 75), Petitioner ignores that, in such a configuration, both the watch and the pump would also *transmit* processed glucose data *to each other*. (Ex. 2215 ¶78.) Nowhere does the Petition account for the transmission of glucose data from multiple sources to each of the watch and the monitor. (*See id.* at 76-83; Ex. 2215 ¶78.)

Petitioner’s proposed combination fails also because Petitioner argues the watch would be configured as a simple display, but then cherry-picks details from an embodiment in which the watch is the main controller of the system. (Ex. 2215 ¶79.) Specifically, Petitioner argues that “a POSITA would have found it obvious to implement the watch with ‘no user settings and very little memory’ and ‘the functions ... all, or substantially all, contained on the infusion pump device.’” (Pet. at 77 (citing Ex. 1251 at [0054]); Ex. 2215 ¶79.) The portion of Goldsmith that Petitioner cites states in full:

In certain embodiments, the controller device has no user settings and very little memory, because all, or substantially all, needed data and instructions will be sent to the controller device by the infusion pump device. Thus, the functions are all, or substantially all, contained on the infusion pump device in such embodiments.

(Ex. 1251 at [0054]; Ex. 2215 ¶79.) From this, Petitioner argues that “[l]imiting the watch implementation to a display *would forgo command and interface functions* that might be integrated in a receiver.” (Pet. at 77; Ex. 2215 ¶80.) But in the embodiments that Petitioner cherry-picks from, the watch plays a central role and is *not* configured merely as a display. (Ex. 2215 ¶80.)

For example, in Goldsmith’s embodiment illustrated in FIG. 10 and described in paragraph [0088], which Petitioner relies on for “direct communication,” Goldsmith explains that the watch includes “[a] processor 1012” that “is adapted *to*

process data and commands inputted by the user,” while “a transmitter/transceiver 1018 ... coupled to the processor 1012 transmits such communications, including data indicative of the determined concentration of the BG in the user, to the infusion device 1050.” (Ex. 1251 at [0088]; Ex. 2215 ¶81.)

Petitioner cannot have it both ways by first arguing that Goldsmith’s watch would be added to the Patel-2009/Paradigm system only as a display to “forgo command and interface functions,” but then cherry-picking from an embodiment in which the watch “process[es] data and commands.” (Ex. 2215 ¶82.) Petitioner simply ignores that portion of Goldsmith that does not fit its conclusory arguments. (Ex. 2215 ¶82); *Wesslau*, 354 F.2d at 241 (holding it is impermissible to “pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art”).

C. Petitioner’s Alleged Motivation To Combine Does Not Account For The Transmission And Reception Of Glucose Data To And From Multiple Sources

Petitioner’s alleged motivation to add Goldsmith’s watch to the Patel-2009/Paradigm combination is deficient for multiple reasons. (Ex. 2215 ¶¶83-91.) The configuration Petitioner proposes, in which Goldsmith’s watch would receive “glucose data, both directly from the on-body glucose sensor/transmitter device as well as indirectly via the pump or other handheld device” (Pet. at 75), is not

described in Goldsmith. (Ex. 2215 ¶83.) To the contrary, in the portions of Goldsmith that Petitioner cites, Goldsmith explains that “[t]he display of the watch controller device may display data directly from a pump” *or* “[a]lternatively, data may [be] received directly from a sensor transmitter on the patient’s skin.” (Ex. 1251 at [0087]; Ex. 2215 ¶83.) Goldsmith therefore describes “direct communication” and “indirect communication” as distinct alternatives. (Ex. 2215 ¶83.) Petitioner, however, combines these alternative embodiments into one confusing system without providing any explanation as to how or why. (Pet. at 72-75; Ex. 2215 ¶83.) It was Petitioner’s burden to explain “why a POSITA would have combined the different embodiments [of a single prior art reference] in the manner proposed.” *Intel Corp. v. Tela Innovations, Inc.*, IPR2019-01522, Paper 66 at 24-25 (P.T.A.B. Mar. 9, 2021); *see also In re Stepan*, 868 F.3d 1342, 145-46 n.1 (Fed. Cir. 2017).

Instead, Petitioner’s motivation to combine focuses only on why a POSITA would allegedly add Goldsmith’s watch as a secondary receiver. (See Pet. at 72-75; Ex. 2215 ¶84.) Petitioner argues that doing so would “achieve the benefits noted by Goldsmith, such as convenience and reduced noticeability.” (Pet. at 72; Ex. 2215 ¶84.) However, Petitioner offers no reason why a POSITA would **configure Goldsmith’s watch to receive glucose data from two different sources**. (Pet. at 75; Ex. 2215 ¶84.) Petitioner is simply silent on that point. (See Pet. at 72-75; Ex. 2215 ¶84.) This exposes Petitioner’s hindsight-driven approach.

To the extent Petitioner argues that it identifies alleged benefits from having both direct and indirect communication (arguments that appear in its claim mapping and not as part of a motivation to combine), Petitioner’s allegations are conclusory. (Ex. 2215 ¶85.) For example, in its claim mapping, Petitioner argues:

[D]irect communication would allow the watch to receive (and display) data even when the user was not in proximity to the infusion pump, cell phone, or other monitor device. This aligns with Goldsmith’s teachings on use of the watch to provide the user with an easier, more convenient, less obtrusive experience.

(Pet. at 80; Ex. 2215 ¶85.) But Goldsmith’s alleged teachings of an “easier, more convenient, less obtrusive experience” do not derive from any particular mode of communication, whether direct (as Petitioner alleges) or indirect. (Ex. 2215 ¶86.)

Petitioner’s alleged benefits of indirect communication are even weaker. (Ex. 2215 ¶¶87-90.) Again, in its claim mapping, Petitioner argues:

Indirect communication, on the other hand, would provide benefits relating to reducing a complexity of programming on the watch by capitalizing on any further data processing that the infusion pump, serving as an intermediary device between the watch and the sensor, could provide. EX1208, ¶¶124-127, 143.

(Pet. at 80; Ex. 2215 ¶87.) This is a textbook conclusory statement, wholly devoid of evidentiary support, that should be disregarded. *TQ Delta v. Cisco*, 942 F.3d 1352, 1359 (Fed. Cir. 2019); (Ex. 2215 ¶88). Indeed, Petitioner does not explain what

alleged “complexity of programming on the watch” it is referring to or provide any examples of such complexity with evidentiary support, much less explain why such complexity would be “reduc[ed].” (Ex. 2215 ¶88.)

Petitioner also does not explain what “further data processing ... the infusion pump” would perform. (Ex. 2215 ¶89.) To the contrary, Petitioner expressly touts the advantages of Patel-2009’s on-body transceiver processing all glucose data before it is transmitted, which Petitioner argues is one of the principal reasons to add Goldsmith’s watch in the first place:

The POSITA would have found it obvious for the watch to receive processed sensor data because, in the Patel-2009/Paradigm system, *the sensor data already is processed by the electronics coupled to the on-body sensor device*. The Patel-2009/Paradigm/Goldsmith system implements a watch controller “to receive processed sensor data.” The Patel-2009/Paradigm Combination includes *a glucose sensor transceiver that processes sensor data* by e.g., “perform[ing] data calibration and sensor glucose value calculation” to “convert raw sensor signals into calibrated processed glucose values using algorithms stored in the sensor transceiver.” *Processed sensor data is communicated from the glucose sensor transceiver to monitoring devices* (e.g., monitor, infusion pump, computer, PDA, Cell Phone) as calculated glucose values. Therefore, *the most obvious way* to implement a watch controller “interacting with a glucose sensor or an infusion pump that stores glucose values” to show “glucose values and optionally trending of glucose values” *would be for the watch*

controller to receive processed sensor data in the form of calculated glucose values.

(Pet. at 78-79 (internal citations omitted); Ex. 2215 ¶89.) According to Petitioner, all processing is performed in Patel-2009's "on body sensor device." (Ex. 2215 ¶90.) Therefore, Petitioner's alleged benefits of "indirect communication" ring hollow and are squarely contradicted by the Petition itself. (Ex. 2215 ¶90.)

Mr. Gross's declaration also does not help Petitioner. (Ex. 2215 ¶91.) The Petition cites ¶¶124-127 and 143 of the Gross declaration to support the alleged benefits of different modes of communication (*see* Pet. at 80), but Mr. Gross's declaration is an almost perfect carbon copy of the Petition except for a few words. (*Compare* Pet. at 67-69, *with* Ex. 1208 ¶¶124-127; *compare* Pet. at 79-80, *with* Ex. 1208 ¶ 143.) Mr. Gross provides no evidence for the conclusory assertions about alleged benefits, let alone explain what alleged complexity would be reduced or what further data processing the pump would perform. *Xerox v. Bytemark*, IPR2022-00624, Paper 9 at 15 (P.T.A.B. Aug. 24, 2022) (precedential) ("Dr. Jones does not cite to any additional supporting evidence or provide any technical reasoning to support his statement. Thus, the cited declaration testimony is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight.").

Petitioner's motivation to combine also fails to account for both the reception *and transmission* of glucose data to and from multiple sources. (Ex. 2215 ¶91.) As explained above, Petitioner ignored important details about Goldsmith's embodiments, such as the watch transmitting glucose data to the infusion device, even though the infusion device already receives glucose data from the on-body sensor/transmitter. (Ex. 2215 ¶91.) Because Petitioner ignored these details, the alleged motivations to combine focus only on why a POSITA would allegedly configure the watch *to receive* glucose data from both the on-body sensor/transmitter and the infusion device. (*Id.*) Petitioner failed to explain, however, why a POSITA would be motivated to combine the alternative embodiments with regard to *transmitting* glucose data from the watch to the infusion device as required in Goldsmith. (*See* Ex. 1251 at [0088]; Ex. 2215 ¶91.)

In sum, taking the 056 patent as a guide, Petitioner selected specific details of Goldsmith to reconstruct the claimed invention using hindsight while it ignored other details that render Petitioner's proposed combination incompatible. These errors permeate all of Ground 2 because Petitioner also failed to provide a motivation to combine disparate embodiments in Goldsmith.

D. Goldsmith's Watch Controller Does Not Include A Limited Number Of Functions As Compared With The Receiver Unit

Claim 29 requires, among other things, that the secondary receiver unit “include a limited number of functions as compared with the receiver unit.” (Ex. 1201 at 18:19-25; Ex. 2215 ¶92.) Petitioner, however, does not compare Goldsmith's watch to the original receiver unit of claim 1 (allegedly shown by Patel-2009). (Pet. at 77-78; Ex. 2215 ¶92.) Instead, Petitioner compares one Goldsmith embodiment to a second Goldsmith embodiment. (Ex. 2215 ¶92.) In other words, Petitioner compares the functionality of two secondary receivers (two watches) instead of comparing the secondary receiver to the first receiver from claim 1. (*Id.*) For claim 29, this is a fatal flaw in the Petition. (*Id.*)

Specifically, in Petitioner's Patel-2009/Paradigm/Goldsmith combination, the alleged receiver of claim 1 is a component of the Patel-2009 system, while the alleged secondary receiver unit is a Goldsmith watch. (Pet. at 52-53, 76-77; Ex. 2215 ¶93.) But, in the Petition, Petitioner never compares the functionality of any Patel-2009 receiver versus the functionality of a Goldsmith watch. (Pet. at 77-78; Ex. 2215 ¶93.) Instead, Petitioner compares the functionality of Goldsmith's alleged preferred embodiment (a watch capable of controlling an infusion pump (like the Paradigm)) versus the functionality of an alleged alternative embodiment that “would forgo command and interface functions.” (Pet. at 77; Ex. 2215 ¶93.) This is a red herring. A comparison of Goldsmith embodiments is irrelevant to claim 29.

On cross-examination, Mr. Gross testified that the “receiver unit” of claim 1 is “the device that receives the ... glucose sensor data and stores those values for display.” (Ex. 2244 at 104:11-16; Ex. 2215 ¶¶94.) According to Mr. Gross, that could be any one of the monitoring devices shown in FIG. 11 of Patel-2009, which include a “Blood Glucose Meter,” “Characteristic Monitor,” “Infusion Pump,” “Computer,” “PDA,” or “Cell Phone.” (See Ex. 1212 at FIG. 12; *see also* Ex. 2244 at 99:16-20, 100:20-25, 102:23-103:3, 103:10-12, 104:24-105:9; Ex. 2215 ¶¶94.) For these alleged receiver units, the only functions that Mr. Gross identified were (i) receiving glucose data from the on-body sensor/transceiver (Ex. 2244 at 104:11-16), (ii) “stor[ing] those values for display” (*id.*), and (iii) “displaying glucose levels and trend graphs” (*id.* at 118:23-119:1). (Ex. 2215 ¶¶94.)

But Goldsmith’s watch that Petitioner argues is the claimed “secondary receiver unit” *has all of the same functions*. (See Pet. at 75 (“The Patel-2009/Paradigm/Goldsmith Combination, implemented as described above, includes ... a wirelessly-connected watch that *receives glucose data*, both directly *from the on-body glucose sensor/transmitter device* as well as indirectly via the pump or other handheld device, and then *displays that glucose data on the watch display*.”), 75 (“Given the similarity of technology in *storing*, processing, transmitting, and displaying *sensor data in* the Patel-2009/Paradigm Combination and *Goldsmith* ...), 64 (“*Goldsmith’s watch controller* ‘interact[s] with one or more devices, such as

infusion pumps and analyte monitors’ ... and *displays glucose values 915 and trends 918* as shown in Figure 9A); Ex. 2215 ¶95).)

Neither Petitioner nor Mr. Gross identified any function the “receiver unit” of claim 1 performs in the Patel-2009/Paradigm/Goldsmith combination that the claimed “secondary receiver unit” does not also perform. (Ex. 2215 ¶96.) Although Petitioner argues that Goldsmith’s watch would be implemented such that it “would forgo command and interface functions that might be integrated in a receiver,” neither Petitioner nor Mr. Gross identified any “command and interface functions” that *are* performed by the alleged receiver unit in the Patel-2009/Paradigm combination. (*Id.*) Indeed, Mr. Gross confirmed on cross-examination that the on-body sensor/transceiver in the Patel-2009/Paradigm combination would control itself. (Ex. 2244 at 126:2-10 (“So the processor on the glucose sensor transceiver [of Patel-2009] clearly controls the glucose sensor transceiver.”); Ex. 2215 ¶96.) Thus, controlling the on-body sensor/transmitter is not a function of either the receiver unit or the secondary receiver unit. (Ex. 2215 ¶96.)

In addition, Petitioner makes no attempt to identify any motivation for a POSITA to select Goldsmith’s alleged alternative embodiment for a combination with Patel-2009/Paradigm. (Ex. 2215 ¶97.) To the contrary, Petitioner argues that “Goldsmith teaches both direct and indirect communication between the watch and the on-body unit” and “a POSITA would have recognized the benefits of

implementing the system such that the processed glucose data was sent both directly and indirectly to the watch.” (Pet. at 79-80; Ex. 2215 ¶97.) In other words, Petitioner argues that a POSITA would be motivated to use a Goldsmith watch with *more functionality* than the receiver unit of claim 1. (Ex. 2215 ¶97.) As described in the Petition, a POSITA allegedly would be motivated to select a Goldsmith watch such that the system would operate without the primary receiver (*i.e.*, the Goldsmith watch could replace all the functionality of the primary receiver) *plus* the Goldsmith watch could also operate in indirect communication (a function not identified for any primary receiver). (Pet. at 79-80; Ex. 2215 ¶97.) In short, Petitioner fails to identify any motivation (other than hindsight) to use the alternative Goldsmith embodiment (allegedly a watch that only receives and displays data) and instead identifies motivation to use a Goldsmith watch, which in relevant part, has more (not less) functionality than any alleged receiver unit from Patel-2009. (Ex. 2215 ¶97.) This also is fatal to the Petition with respect to claim 29.

Consequently, Petitioner failed to meet the element of claim 29 that requires the secondary receiver unit to “include a limited number of functions as compared with the receiver unit.”

VIII. CONCLUSION

The Board should find that the Challenged Claims are not unpatentable.

Date: December 6, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing Patent Owner's Response in connection with *Inter Partes* Review Case IPR2024-00521 was served on this 6th day of December, 2024 by electronic mail to the following:

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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 Response has a total of 13,295 words, according to Microsoft Word[®] word count tool, excluding the parts of the Response exempted by 37 C.F.R. § 42.24(a)(1).

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