UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

Case No. IPR2023-01251

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

PATENT OWNER'S RESPONSE

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Exhibit No.	Description
2001	STS-7 User's Guide
2002	DexCom G4 Platinum Continuous Glucose Monitoring System User's Guide
2003	FDA Premarket Approval (PMA) for DexCom G5 Mobile Continuous Glucose Monitoring System
2004	U.S. Patent No. 6,809,653
2005	U.S. Patent No. 7,098,803
2006	U.S. Patent No. 7,324,012
2007	CareLink™ Personal Getting Started Guide
2008	Declaration of Nathaniel E Frank-White (Internet Archive)
2009	FCC Frequency Table
2010	Bluetooth Basics
2011	LinkedIn Summary of Brian Gross
2012	U.S. Patent No. 9,577,934
2013	Declaration of Eugene E. Wright, Jr. MD
2014	Curriculum Vitae of Eugene E. Wright, Jr. MD
2015	Declaration of Aaron Striegel, Ph.D.
2016	Cappon et al., *Continuous Glucose Monitoring Sensors for Diabetes Management: A Review of Technologies and Applications*, J. Diab. Metab. 43:383-397 (2019)
2017	American Diabetes Association, *Role of Continuous Glucose Monitoring in Diabetes Treatment* (2018), *available at* https://pubmed.ncbi.nlm.nih.gov/30958664/
2018	The MiniMed Paradigm® REAL-Teim Insulin Pump User Guide
2019	DexCom STS-7 Continuous Glucose Monitoring System User's Guide Submitted Under FCC ID PH29402

[1] Exhibits 2001-2010 were submitted with Patent Owner's Preliminary Response. Exhibits 2011-2034 are new and filed concurrently herewith.

Exhibit No.	Description
2020	DexCom G6 Continuous Glucose Monitoring System User Guide
2021	Abbott FreeStyle Navigator Continuous Glucose Monitoring System User's Guide
2022	Abbott FreeStyle Libre 3 Continuous Glucose Monitoring System User's Manual
2023	U.S. Patent No. 10,085,640
2024	U.S. Patent No. 9,996,668
2025	Das et al., *Review—Electrochemistry and Other Emerging Technologies for Continuous Glucose Monitoring Devices*, ECS Sensors Plus (2022)
2026	Almurashi et al., *Emerging Diabetes Technologies: Continuous Glucose Monitors/Artificial Pancreases*, J. Indian Inst. Sci. (2023)
2027	Deposition Transcript of Brian Gross (May 2, 2024)
2028	Centers for Disease Control and Prevention—National Diabetes Statistics Report, *available at* https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-undiagnosed-diabetes.html.
2029	Garg et al., *Flash Glucose Monitoring: The Future Is Here*, Diabetes Tech. & Therapeutics 19.S2 (2017)
2030	DexCom SEVEN Plus Users Guide
2031	DexCom G5 Mobile CGM System User Guide
2032	DexCom's Initial Proposed Claim Constructions in C.A. No. 23-239-KAJ (Feb. 28, 2024)
2033	Atmel Product Guide (Winter 2008), *available at* https://media.digikey.com/pdf/Data%20Sheets/Atmel%20PDFs/Products%20Select%20Guide.pdf
2034	Atmel - ATmega169P Datasheet, *available at* https://ww1.microchip.com/downloads/en/DeviceDoc/doc8018.pdf

I. INTRODUCTION

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"). CGMs sample glucose levels continuously throughout the day. The data can be output graphically on the receiver's display in real time or imported into software for later in-depth retrospective analysis. Conditions can occur, however, that adversely affect the functioning of the system, which can cause data gaps.

The 056 patent describes and claims an innovative solution to address data gaps in the data displayed graphically on the receiver. The system detects an adverse condition. When it does, the system stores data (sensor data, processed sensor data, or both) in memory. After the adverse condition is addressed, processed sensor data corresponding to the adverse condition is output to the receiver's display such that the data gap in the displayed graph is backfilled. (*See infra* §II.B.)

Petitioner contends this type of backfilling would have been obvious at the time of the invention, in 2009. But Petitioner's own products show otherwise. A user guide for Petitioner's STS-7 product sold at the time stated that "[a]t times [the] STS-7 System will not display glucose information" (Ex. 2001 at 38), and that when this occurred, "Glucose Data Gaps" would appear in the user's displayed glucose data (*id.* at 38-40). The STS-7 offered no option for backfilling the missing data.

That remained true for all of Petitioner's CGM products until 2016, a full ***seven years after*** Patent Owner's priority date. (Ex. 2003 at 1.) Like Petitioner's commercial products, none of Petitioner's prior art taught this invention either.

As Patent Owner's expert, Dr. Eugene Wright, Jr., explains, one of the primary goals for CGMs in 2009 was to collect, organize, analyze, and summarize CGM data to transform it into actionable information. (Ex. 2013 ¶¶85-86.) That goal was achieved by importing CGM data, along with other health-related information (*e.g.*, diet, exercise, insulin doses, etc.) into software that analyzed the data and generated different types of retrospective historical reports. (*Id.* ¶87; Ex. 1039 at 3.) Clinicians such as Dr. Wright used these reports to help patients better manage their diabetes. (Ex. 2013 ¶¶54, 87-88, 191; Ex. 1039 at 7; Ex. 1040 at 4.)

In 2009, CGMs were nascent technology and only a few commercial products existed. (Ex. 2013 ¶¶55-48; Ex. 2017 at 3; Ex. 2025 at 4-11; Ex. 2026 at 3-6.) These early CGMs were too inaccurate and unreliable to be used for contemporaneous treatment decisions. (Ex. 2013 ¶¶75-78, 81-82; Ex. 2016 at 3, 6; Ex. 2026 at 4-5.) Regulatory agencies, including the FDA, required patients to perform additional fingerstick measurements to make treatment decisions, including to calculate insulin doses. (Ex. 2013 ¶¶81-83; Ex. 2016 at 3, 6; Ex. 1011 at 10, 15.) Therefore, at the time of the invention, the emphasis was on preserving CGM data for retrospective analysis in historical reports, not ensuring that every bit of data was displayed in real

time on the patient's receiver. (Ex. 2013 ¶¶86-90, 195; Ex. 1039 at 7.) Indeed, none of the prior art Petitioner relies on discloses backfilling a data gap on a CGM display, yet all of it discloses preserving the data for historical analysis. (*See infra* §V.A.1.)

Petitioner contends that ***only one reference***, the Paradigm® REAL-Time documentation (Ex. 1011)[2] used in Grounds 1 and 2, expressly discloses the claimed backfilling on a CGM display. (Pet. at 45-48.) For the remaining prior art, including all the prior art in Ground 3, Petitioner contends that a POSITA would have recognized that this feature could be achieved by piecing together disparate teachings from the art. (*Id.* at 101-102.) Neither contention has merit.

The Paradigm documentation discloses preserving CGM data for historical, retrospective reports. It does not, as Petitioner contends, teach backfilling data gaps on a CGM display. Petitioner's contention is based on an isolated statement from Medtronic's website in 2007, not in any technical literature about the Paradigm. The statement—that data can be "re-populated in the insulin pump"—refers to storing data "in the insulin pump" so that it is available "when reviewing historical reports." (*See infra* §V.A.1.) The evidence shows that "re-populated data" was used in the context of "historical reports," and that historical reports were generated by Medtronic's CareLink™ software for PCs. Historical reports were not viewed on the

[2] Hereinafter, "Paradigm documentation."

Paradigm insulin pump or any other CGM display, and the term "historical reports" does not refer to historical *data* on the insulin pump. Thus, there is no express or implied disclosure in the Paradigm documentation of backfilling data gaps on a CGM display. (*See infra* §V.A.1; *see also* Paper 11 at 33.)

Petitioner's remaining contention, that the invention would have been obvious in view of other prior art, is equally meritless. For one, it is belied by Petitioner's own commercial products that did not backfill, demonstrating the hindsight approach taken by Petitioner and Mr. Gross. Second, it is based on unsupported and clinically inaccurate opinions from Mr. Gross. For example, he opines that a POSITA would have found it obvious to backfill data gaps on a CGM display "to assist in diabetes management, insulin dosing decisions, and prevention or treatment of hyper or hypo-glycemia." (Ex. 1008 ¶60.) While that may sound plausible in 2024, it is factually and clinically incorrect for 2009. As explained above, CGMs were neither used nor approved for use in that manner in 2009 because they were too inaccurate and unreliable. (Ex. 2013 ¶¶81-82.) Regulatory agencies, including the FDA, thus required fingerstick measurements for treatment decisions, including insulin dosing decisions. (*Id.*) Mr. Gross's opinions are therefore fundamentally flawed, as are Petitioner's contentions based on them.

Underlying Petitioner's and Mr. Gross's arguments is the assumption that any data preserved during an adverse condition must be used to backfill a data gap on a

CGM display, and that not doing so would amount to "withhold[ing]" data. (Paper 9 at 2.) That assumption is erroneous. The evidence shows that, in 2009, there were practical reasons not to display the missing data on the receiver. For example, memory in the receiver may have been allocated in such a way that missing data, once received, was stored in long-term memory (and available for download) but not in short-term memory used for the receiver's display. (Ex. 2015 ¶¶42-52.) In addition, Petitioner's 2016 patent filings describe several other reasons not to display missing data, such as to avoid user confusion, to prevent action based on stale data, and to preserve data gaps to indicate when issues occurred. (*See infra* §V.A.1.)

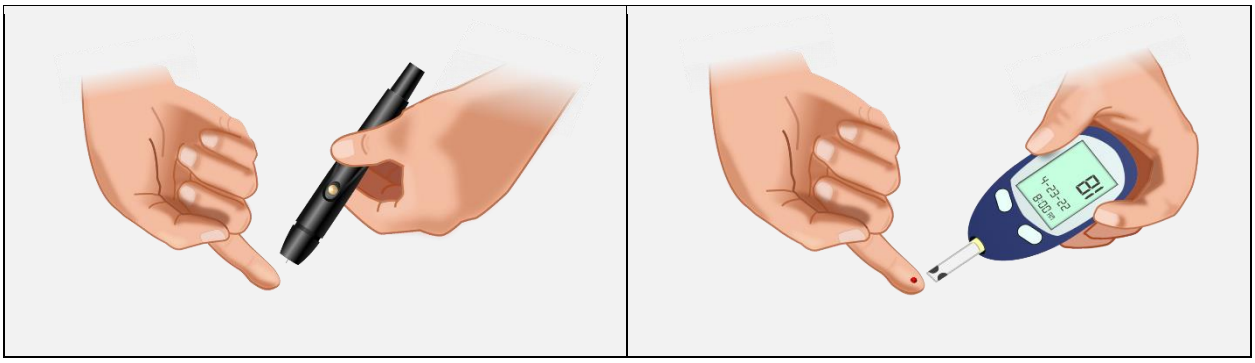
When the claimed inventions are viewed from the perspective of a POSITA in 2009, Petitioner has failed to meet its burden to show that any Challenged Claim is unpatentable and, therefore, the Board should uphold the patentability of the Challenged Claims.

II. BACKGROUND OF THE INVENTION

A. Diabetes and Glucose Monitoring

"Diabetes" refers to several conditions with different causes and prognoses, all involving high blood sugar, or "hyperglycemia." (Ex. 2013 ¶¶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.*)



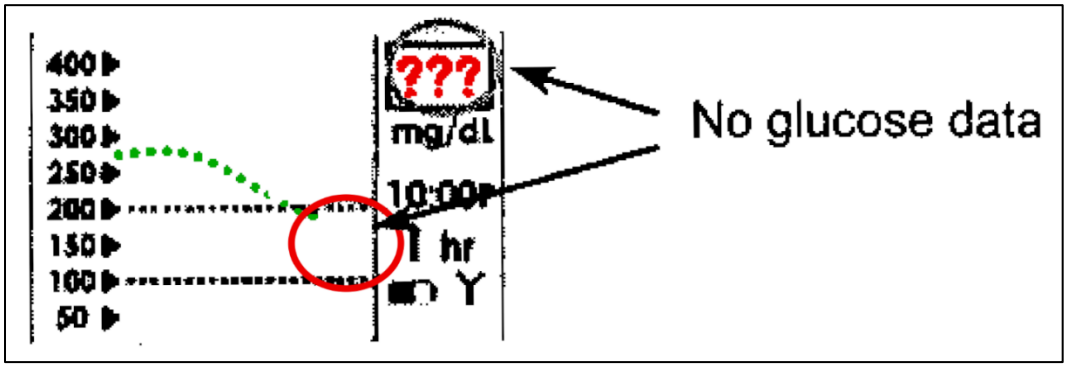
CGMs were first approved by the FDA in 1999. (Ex. 2013 ¶55; Ex. 2017 at 3; Ex. 2025 at 6.) The first two approved CGMs, from Medtronic, did not allow for real-time display of glucose data and therefore had no display at all. (Ex. 2013 ¶55; Ex. 2025 at 6.) Instead, they were retrospective in that glucose data was stored during the three day wear life, and then the data was downloaded by a physician for retrospective analysis. (Ex. 2013 ¶55.)

By 2009, a few CGMs were commercially-available that displayed glucose information during use, including, *e.g.*, Medtronic's Guardian REAL-Time System;[3] DexCom's STS, STS-7, and SEVEN Plus; and Abbott's FreeStyle Navigator. (Ex. 2013 ¶¶57-58; Ex. 2025 at 8.) These early-generation devices were relatively

[3] The Medtronic Paradigm® REAL-Time System, which is the product described in Ex. 1011, was an insulin pump that included optional CGM components from the Guardian REAL-Time System. (*See, e.g.*, Ex. 1011 at 13, 15, 37, 83.)

inaccurate and prone to errors, such as errors with their calibration and communications. (*Id.* ¶¶75-78.) Sometimes these errors caused unintended alarm messages to be displayed, while other times they resulted in gaps in CGM data. (*Id.* ¶95.)

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. 2001 at 38-40; Ex. 2013 ¶¶99-101.) When this occurred, "Glucose Data Gaps" appeared in the user's glucose levels on the display device. (Ex. 2001 at 38-40; Ex. 2013 ¶¶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.



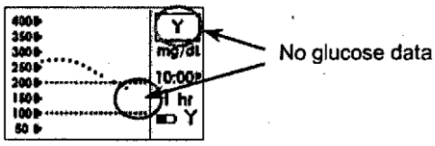
(Ex. 2001 at 39 (color added).)

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. 2001 at 38-40; Ex. 2013 ¶¶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.

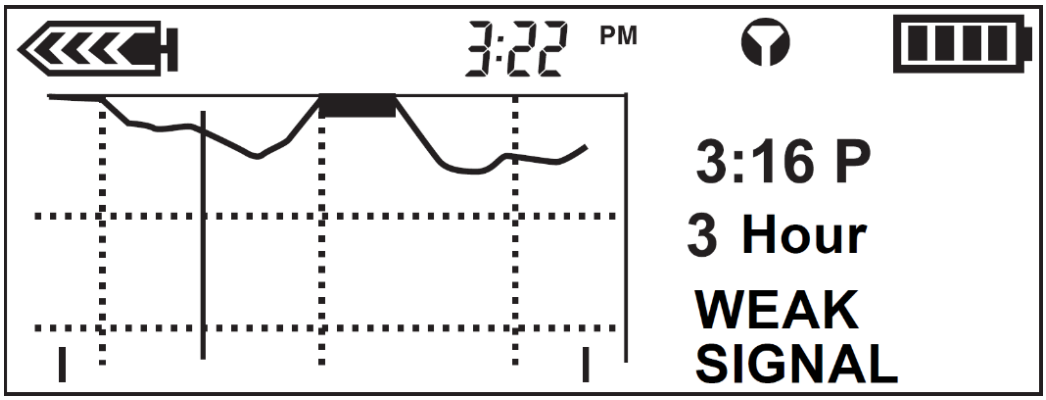


- Make sure your STS Receiver is within 5 feet of the STS Transmitter/STS Sensor Pod. If it is not, move your STS Receiver closer and wait at least 5 minutes. The "Y" icon in the Status Box should go away and you will receive a STS-7 glucose reading in the next 5-10 minutes.
- If you are still having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

(Ex. 2001 at 38; Ex. 2013 ¶99.)

None of Petitioner's CGM products were able to backfill missing data on a user's CGM display until 2016. (Ex. 2013 ¶¶103-105; Ex. 2002 at 9, 93; Ex. 2003 at 1; 2030 at 52, 64, 71, 76-77; Ex. 2031 at 204-205.)

The Paradigm documentation also fails to teach backfilling missing data on a CGM display in real time. The Paradigm® REAL-Time system was an insulin pump that included an optional sensor and MiniLink™ Transmitter. (Ex. 1011 at 15.) The Paradigm user guide explains that there may be instances "when the pump does not receive data for a period of time." (Ex. 1011 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 3.)



(Ex. 1011 at 73.) Nowhere does the Paradigm user guide state or even suggest retrieving or displaying the missing data. (Ex. 2013 ¶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. 1011 at 73; Ex. 2013 ¶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. 1011 at 73; Ex. 2013 ¶¶107-108.) The same would happen for other problems, such as a low transmitter battery, bad transmitter, bad sensor, and calibration errors. (Ex. 1011 at 73-75; Ex. 2013 ¶109.) In each instance, the pump displayed an alarm message rather than a trend graph. (Ex. 1011 at 73-75; Ex. 2013 ¶109.)

B. The 056 Patent

Unlike the prior art, the 056 patent is directed to a CGM system for backfilling data gaps in the user display while a user monitors glucose levels. (Ex. 1001 at 15:24-26.) The claimed glucose monitoring system comprises "a glucose sensor" and "a data processing and transmitter unit coupled to the glucose sensor." (*Id*. at 15:27-32.) A portion of the glucose sensor is "configured to be positioned under skin of the user" and "sample a biological fluid of the user to provide sensor data." (*Id*. at 15:27-30.) The data processing and transmitter unit comprises "a processor," "memory," and "a radio frequency transceiver." (*Id*. at 15:31-36.) The system further comprises "a receiver unit," which includes "a processor," "memory," "a radio frequency transceiver," "an antenna," and "a display." (*Id*. at 15:52-54.)

The data processing and transmitter unit is configured to "receive the sensor data from the glucose sensor and store the sensor data in the memory of the data processing and transmitter unit." (*Id*. at 15:39-41.) It is further configured to "process the sensor data using calibration data to provide processed sensor data,

wherein the calibration data comprises data associated with a sensitivity of the glucose sensor, and wherein the processed sensor data is stored in the memory of the data processing and transmitter unit." (*Id*. at 15:42-47.) The processed sensor data is transmitted "over a Bluetooth wireless communication link." (*Id*. at 15:48-51.) The receiver unit, in turn, 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." (*Id*. at 15:56-64.)

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." (*Id*. at 15:65 to 16:3.) An example of such a data gap is shown in FIG. 7A below.

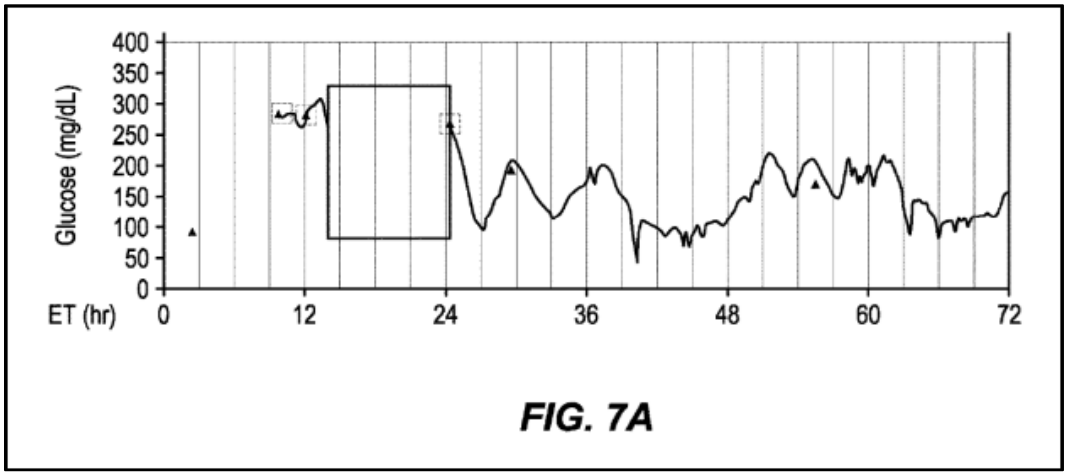


FIG. 7A

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[.]" (*Id.* at 13:19-27.)

As claimed, "during a time period corresponding to the adverse condition, sensor data, processed sensor data, or both, are stored in the memory of the data processing and transmitter unit." (*Id*. at 16:4-7.) 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." (*Id*. at 16:8-12.) An example is illustrated in FIG. 7B below.

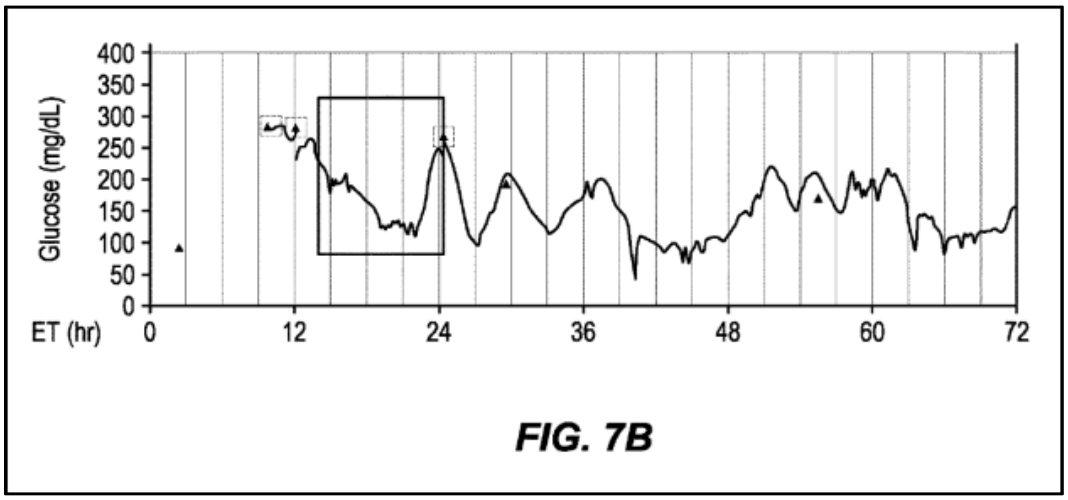


FIG. 7B

Thus, unlike the prior art and contrary to conventional wisdom and practice in 2009, the monitoring system of claim 1 is able to recover and display glucose data from the time period associated with an adverse condition. (*Id*. at 12:54-61, 13:27-30.)

III. PETITIONER'S PRIOR ART GROUNDS

Petitioner advances three grounds against the Challenged Claims:

GROUND	CLAIMS	BASIS
1	1–3, 5-8, 11-12, 17-24, 26-28 and 30	Allegedly obvious over Patel-2009 in view of Paradigm® REAL-Time Documentation
2	4, 9-10, 15-16 and 25	Allegedly obvious over Patel-2009 and Paradigm® REAL-Time Documentation in view of Causey
3	1-12, 14-18, 20-28 and 30	Allegedly obvious over Patel-2008 and Incorporated References

The ***only reference*** that Petitioner alleges discloses backfilling a data gap on a CGM display—one of the key limitations—is the Paradigm documentation. (*See* Pet. at 45-48.) Thus, for five of the six references relied upon for these Grounds, including ***every reference relied upon for Ground 3***, Petitioner does not allege that ***any of them*** discloses backfilling a data gap on a CGM display. (*See id.* at 101-102.)

As for the Paradigm documentation, Petitioner points to a ***single statement*** in a response to a frequently asked question (FAQ) on a website that merely says "data is re-populated in the insulin pump" when the transmitter is brought back into range with the pump. (Pet. at 45 (relying on page 8 of Ex. 1011).) But this statement is referring to storing data "in the insulin pump" to preserve it for historical reports, not to display it on the receiver. (*Infra* §V.A.1.)

Given the dearth of prior art on point, Petitioner relies heavily on the Gross declaration to construe the FAQ in Grounds 1 and 2 and to supply missing claim elements in Ground 3. For example, Petitioner repeatedly cites paragraphs 54-61, and especially paragraphs 58 and 60, of the Gross declaration. (*See, e.g.*, Pet. at 29, 44, 45, 48, 50, 51, 53, 54, 55, 56, 66, 67, 68, 69, 70, 71, 72, 100, 101, 102, 103, 104, 105, 107, 109.)

But Mr. Gross's opinions in these paragraphs are conclusory and lack evidentiary support, and were contrived using the 056 patent as a blueprint. (*See infra* §V.A.1; Ex. 2013 ¶¶134-155.) Further, such conclusory testimony cannot supply missing claim elements or read into the prior art things the references do not actually teach. *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.").

Consequently, Petitioner fails to establish that the Challenged Claims were obvious at the time of the invention.

IV. CLAIM CONSTRUCTION

Petitioner proposed a narrow construction for "adverse condition" in concurrent district court litigation but not in the Petition. (Ex. 2032 at 4.) In the litigation, Petitioner argues that "adverse condition" should be construed to mean "a detected system malfunction, error, or failure that results in an inability or disabling of the monitoring system to display or output processed data." (*Id.*)

Patent Owner nonetheless believes that all claim terms should be given their plain and ordinary meaning and therefore applies such meanings in this IPR. 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. PETITIONER DID NOT MEET ITS BURDEN ON GROUNDS 1 & 2

A. Patel-2009 and the Paradigm Documentation Fail To Disclose Claim Elements [1.K] and [1.L]

Claim 1 is the sole independent claim of the 056 patent. Elements [1.K] and [1.L] are key. 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. 1001 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]).)

Neither Patel-2009 nor the Paradigm documentation discloses either element. 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.) As the Board agreed, these graphics neither expressly nor impliedly disclose element [1.L]. (Paper 11 at 33.) That should be dispositive of Grounds 1 and 2. For element [1.K], Petitioner's entire case for Grounds 1 and 2 hinges on the meaning of "data re-populated in the insulin pump." As demonstrated below, the evidence shows that this phrase refers to storing data in the insulin pump's memory for later historical reports, not for display to the user on the receiver.

In relation to both elements, Petitioner concedes that 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 28-29.) To supply the missing elements, Petitioner relies on (i) the Paradigm documentation and (ii) alternatively, its expert's testimony. (Pet. at 45-48.) The former lacks disclosure while the latter is foreclosed by clear authority that bars expert testimony from supplying missing claim elements. *Apple*, IPR2023-00087, Paper 10 at 19; *CTPG* at 36.

1. The Paradigm Documentation Does Not Disclose [1.K]

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. 1001 at 16:8-12.) This language, by its terms, requires that the receiver not only receive but also ***display*** the backfilled data. The Paradigm documentation nowhere suggests ***both*** receiving ***and*** displaying backfilled data in this way.

Petitioner does not even argue that the Paradigm user guide, or any other technical literature for the Paradigm, teaches this limitation. (Pet. at 45.) Instead, Petitioner relies on a statement from an FAQ from Medtronic's website regarding the MiniLink REAL-Time Transmitter. (*Id.*) The FAQ 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. 1011 at 8.) Petitioner relies on the phrase, "re-populated ***in the insulin pump***[4]," 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 41; Ex. 2013 ¶¶168-169.)

The FAQ instead teaches re-populating the data in the pump's memory so that it is available when generating historical reports using Medtronic's separate CareLink™ Personal software ("CareLink"). (Ex. 2013 ¶¶172-175.) CareLink "allow[ed] the discovery of patterns and problems that meter software and logbooks would not uncover." (Ex. 2007 at 3.) CareLink was installed on the user's personal computer and received glucose-related information uploaded from the Paradigm Insulin Pump. (*See* Ex. 1011 at 11-12.) "Once uploaded, this information [could] be converted into CareLink Personal reports." (Ex. 2007 at 7.) 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." (*Id.*)

The CareLink Reports page is shown below:

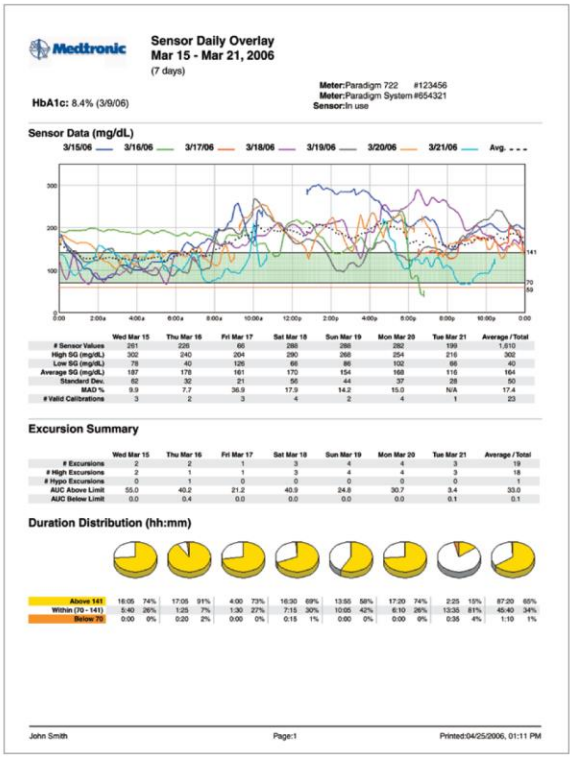
[4] All emphasis added unless otherwise indicated.

(Ex. 2007 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. 2013 ¶¶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.

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.



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

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. 1011 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, an FAQ says that "[w]hen ***downloading data and reviewing historical reports***, you will

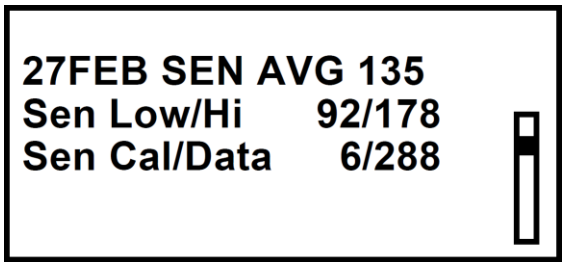
notice 'data gap' where information is missing during this period of time." (*Id.* at 13.)

Thus, in every instance that "re-populated" is used in an FAQ, it is used in conjunction with "historical reports." (Ex. 2013 ¶¶172-175.) And because data was "downloaded" and reviewed in "historical reports," there is no doubt that "historical reports" refers to retrospective reports generated by CareLink. (*Id.* ¶175; Ex. 2007 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 immediate viewing at the pump. (*Id.* ¶175.)

Moreover, the term "historical reports" should not to be confused with historical *data*. (Paper 11 at 30.) Although the insulin pump stored historical data (for downloading to a computer), there is nothing in the cited art that suggests the data was viewable as a trend graph on the pump beyond a rolling 24 hours. (Ex. 2015 ¶¶41, 47.) In the institution decision, the Board appears to assume that the insulin pump could retrospectively display trend graphs (and therefore, backfilled data) using historical data. (Paper 11 at 30.) The Board's assumption is based on a fact sheet in the Paradigm documentation stating that the user can "view up to 31 days of your personal history on your insulin pump screen." (Paper 11 at 28 (citing Ex. 1011 at 24, 26).) The assumption, however, is not correct.

As explained in the fact sheet in Ex. 1011, the 90 days (or up to 31 days together) of personal history was not viewable in trend graphs—it was viewable in tabular form. (Ex. 2015 ¶¶36-40; Ex. 2018 at 124-126.) Two pages earlier, the fact sheet explains that "blood glucose, insulin delivered, and bolus details" were "viewable by individual day or as an average of up to 31 days." (Ex. 1011 at 24.) Examples of this are provided in Exhibit 2018, which is a user guide for the Paradigm insulin pump for pediatric indications. (*See* Ex. 1011 at 3 (linking to "MiniMed Paradigm 522K/722K User Guide for Pediatrics").)

As explained therein, "[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. 2018 at 124.) 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. (*Id.*) An example screenshot of how the personal history was displayed is shown below:



(Ex. 2018 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. Therefore, even if the missing data were displayed in tabular form (as discussed in

the fact sheet), 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. 1001 at 16:8-20.)

Patent Owner's expert, Dr. Aaron Striegel, explains how a POSITA would have implemented an embedded system, such as an insulin pump, based on the disclosure of Ex. 1011. For example, such a system with a display could have dedicated memory for display functionality and dedicated memory for long-term storage. (Ex. 2015 ¶42.) 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.) Data received in real-time could be stored in both memories, but when missing data is later received (*i.e.*, backfilled data), it would only be stored in long-term memory. (*Id.* ¶¶47-50.) 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.)

Were there any doubt, it is telling that there is no disclosure in the Paradigm ***user guide*** that suggests displaying backfilled data on the pump's screen. (Ex. 2013

¶¶168-169.) One would expect the user guide to teach users about such an important feature if it existed. (*Id.* ¶169.) But the user guide says nothing about storing or displaying backfilled data. (*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. 1011 at 73.)

Also telling is that, besides a single FAQ, Petitioner does not argue that ***any prior art*** discloses backfilling missing data on a CGM display. (Ex. 2013 ¶183.) On the other hand, every reference in Petitioner's Grounds ***does disclose*** downloading stored data for retrospective analysis:

- Ex. 1011 (Paradigm) at 11-12 (describing CareLink);
- Ex. 1012 (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. 1015 (Patel-2008) at [0032] ("This data can then be uploaded to a web based diabetes management server like Carelink."), [0048];
- Ex. 1017 (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. 1019 (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. 1023 (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].

Petitioner's own 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. 2013 ¶¶183-192, 86-90.)

Besides the FAQ, Petitioner relies on Mr. Gross's declaration for [1.K]. (Pet. at 45.) Indeed, Petitioner relies on paragraphs 54-61 of the Gross declaration, and especially paragraphs 58-60, as a crutch throughout the Petition when there is a clear absence of teaching in the prior art. (*Id.*) But Mr. Gross's opinions in these paragraphs should not be credited because (i) he bases his opinions on clinical considerations but lacks clinical expertise with CGMs, (ii) while opining about what POSITAs would allegedly know, he relies on the 056 patent as a roadmap for hindsight, and (iii) his opinions are contradicted by the state of the art at the time of the invention, as well as by Petitioner's own patent filings. (Ex. 2013 ¶¶134-163.)

First, Mr. Gross's opinions in paragraphs 54-61, and especially paragraph 60, should be disqualified because he lacks clinical expertise. 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. 1008 ¶52; Ex. 2027 at 147:11-25.) Mr. Gross then opines in paragraph 60 about "diabetes management, insulin dosing decisions, and prevention or treatment of hyper and hypo-glycemia." (Ex. 1008 ¶60.) But 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. 2013¶¶126-133.)

For example, Mr. Gross is not a medical doctor and he has never prescribed a CGM (Ex. 2027 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 hypo-

glycemia." His opinions in paragraph 60 are not from the perspective of a POSITA (as he has defined it). (Ex. 2013 ¶133.)

Second, paragraphs 54-61 of the Gross declaration, and especially paragraphs 55-57, contain sweeping statements about what a POSITA would allegedly have known or done with no evidentiary support. (*See* Ex. 1008 ¶¶54-61.) 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 simply recite aspects of the 056 patent, demonstrating that Mr. Gross used the patent as a roadmap for hindsight. (*See* Ex. 2013 ¶¶137-138.)

Third, the flaws in Mr. Gross's opinions, particularly those in paragraph 60, 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. 1008 ¶60.) But as of 2009, ***no CGMs*** were approved

by regulatory agencies (*e.g.*, FDA) for making diabetes treatment decisions, including insulin dosing decisions. (Ex. 2013 ¶¶81-83; Ex. 2016 at 3, 6; Ex. 1011 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. Not so. (Ex. 2013 ¶¶75-78.) CGMs generally, and the Medtronic Paradigm® REAL-Time system specifically, were known to be relatively inaccurate. (*Id.* ¶¶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. 2013 ¶77; Ex. 1011 at 85.) In some instances, the CGM readings were off by an astonishing 90 mg/dL. (Ex. 2013 ¶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, the Paradigm was often inaccurate and unreliable, and could not be relied on for contemporaneous treatment decisions. (Ex. 2013 ¶¶75-78.)

Fourth, other evidence undermines Mr. Gross's opinions in paragraphs 54-61, and particularly paragraph 60. 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. 2001 at 38.) Had backfilling data gaps been obvious, Petitioner would have solved the problem. Mr. Gross did not consider Petitioner's prior products or these commercial realities.

As another example, with respect to claim 19, Mr. Gross opines that "POSITAs would have found it obvious to wait a predetermined time (*e.g.*, one, two, three update cycles) before displaying re-populated[5] glucose data." (Ex. 1008 ¶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. 2013 ¶¶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. 1008 ¶60; Ex. 2013 ¶¶157-158.)

Lastly, Petitioner's own 2016 patent filings undermine Mr. Gross's opinions that it would be critical (or obvious) to display backfilled data. (Ex. 2013 ¶¶159-162.) Indeed, Petitioner identified several practical reasons not to. In U.S. Patent No.

[5] It is noteworthy that Mr. Gross uses the term "re-populated glucose data" here to refer to ***data stored in the insulin pump*** as Patent Owner interprets that phrase.

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. 2023 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.)

In U.S. Patent No. 9,996,668, Petitioner listed 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. 2024 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 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. *Apple*, IPR2023-00087, Paper 10 at 19; (Ex. 2013 ¶163.)

In the institution decision, the Board commented that the FAQ Petitioner relies on "appears in a section of Paradigm REAL-Time relating to the MiniLink REAL-Time Transmitter," and that there was no "mention of the separate CareLink product." (Paper 11 at 31 (citing Ex. 1011 at 8).) But the Institution Decision omitted the last sentence that refers to "historical reports," which are generated by the separate CareLink product.

Can I swim, shower, or bathe with the MiniLink Transmitter?
Yes, the transmitter is waterproof, so you can swim, shower, or bathe with the transmitter and glucose sensor connected. The transmitter with the glucose sensor connected can be worn for a depth of eight feet (2.4 meters) for 30 minutes. However we do not recommend immersing them in very hot water (like a jacuzzi).

There should be no problems due to rain, splashing, or the accidental submersion in water. To participate in water activities, you can easily disconnect from your insulin pump.

As long as the transmitter is within 6 feet (approximately 2 meters) of the insulin pump, continuous glucose monitoring (CGM) data will be displayed on the insulin pump's screen. If the MiniLink REAL-Time Transmitter and insulin pump are out-of-range for longer than 40 minutes, only the last 40 minutes will be re-populated. When reviewing historical reports, you would notice a "data gap" where information is missing during this period of time.

Thus, Petitioner's argument that the FAQ must be referring to data on the pump's screen because it appears in a section related to the transmitter is incorrect because the very next sentence in that same FAQ refers to CareLink reports as well. Moreover, the MiniLink Transmitter was used to transmit data to the insulin pump regardless of whether the data was re-populated in memory for historical reports or displayed on the pump's screen. (Ex. 2013 ¶179.)

Lastly, although Petitioner cites Patel-2009 in its analysis of [1.K], it does not contend that Patel-2009 teaches that element. (Pet. at 45; Paper 11 at 26.) Nor could it because Patel-2009 "does not provide for glucose graphs to convey that glucose data is missing … or to display glucose data that is synchronized." (Pet. at 28-29.) Instead, Patel-2009's disclosure of "synchronizing" data is similar to the Paradigm

documentation's disclosure of re-populating data in the pump's memory—both refer to storing data and neither refers to displaying it. (Ex. 2013 ¶¶201-203.)

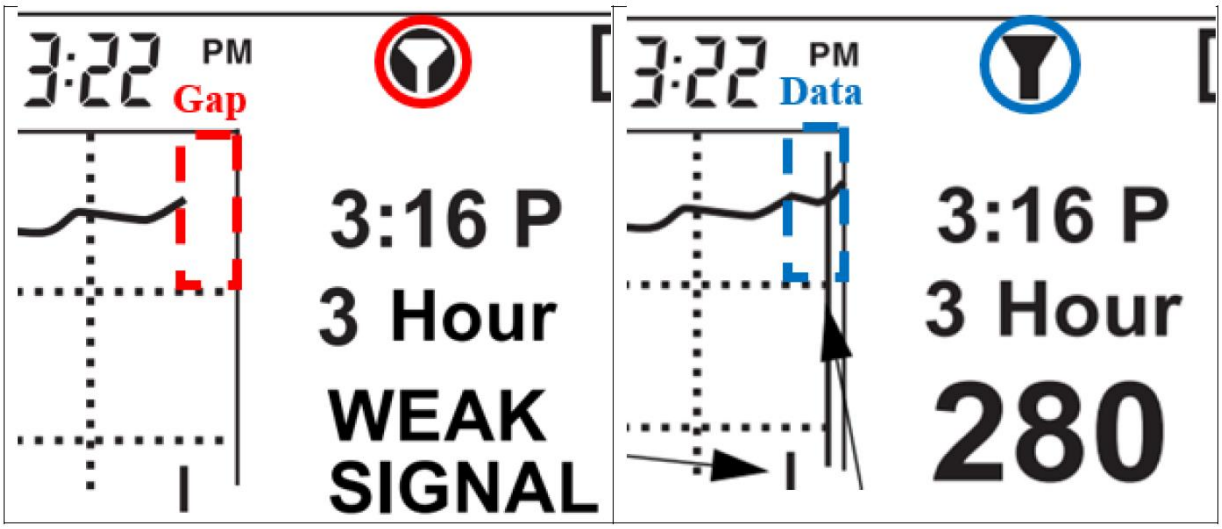
When the scope and content of the prior art is viewed in the proper historical and clinical context, it is evident that "data re-populated ***in*** the insulin pump" refers to preserving data for retrospective analysis in historical reports. Thus, Petitioner's prior art does not disclose element [1.K].

2. The Paradigm Documentation Does Not Disclose [1.L]

Element [1.L] of the 056 patent 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. 1001 at 16:13-20.) For element [1.L], Petitioner's argument depends on conflating two unrelated graphics from different chapters of the Paradigm user guide. These graphics have nothing to do with each other, and certainly are not "described as being part of a sequence of events." (Paper 11 at 32-33.) As the Board correctly found, "[t]here is no express or implicit disclosure in Ex. 1011 that the Chapter 5 rendering is showing a backfilled data gap from the Chapter 6 rendering." (*Id.* at 33.)

Petitioner relies on only the Paradigm user guide for element [1.L]. (*See* Pet. at 46-48.) Petitioner juxtaposes two annotated artist renderings of the pump's display taken from different chapters of the user guide to create the impression that a data

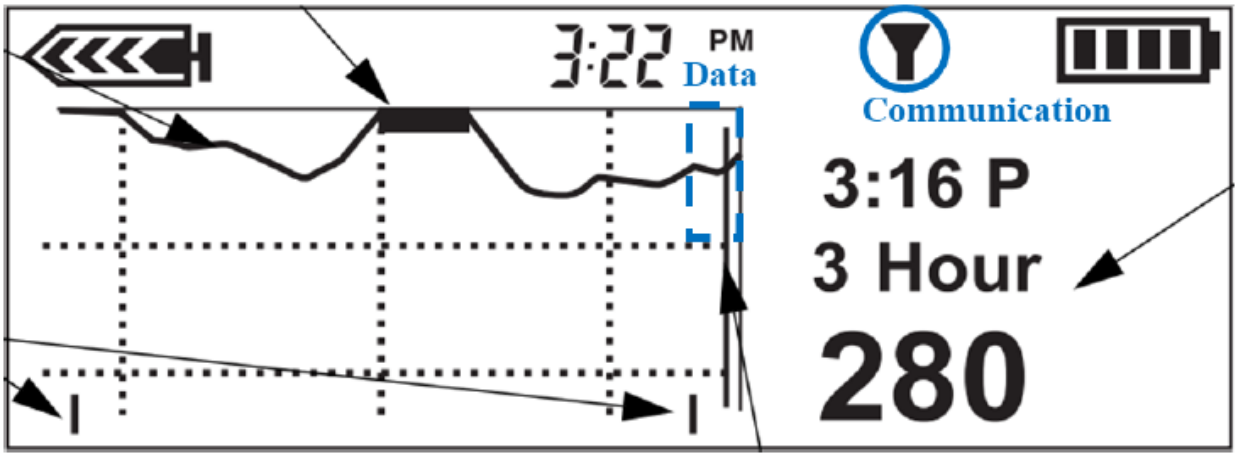
gap in a line graph is subsequently filled in on the same display. (Pet. at 46-47.) The Petition includes the following composite figure to incorrectly suggest that the two figures illustrate a sequence of events where a gap first appears and then is filled in on the display.



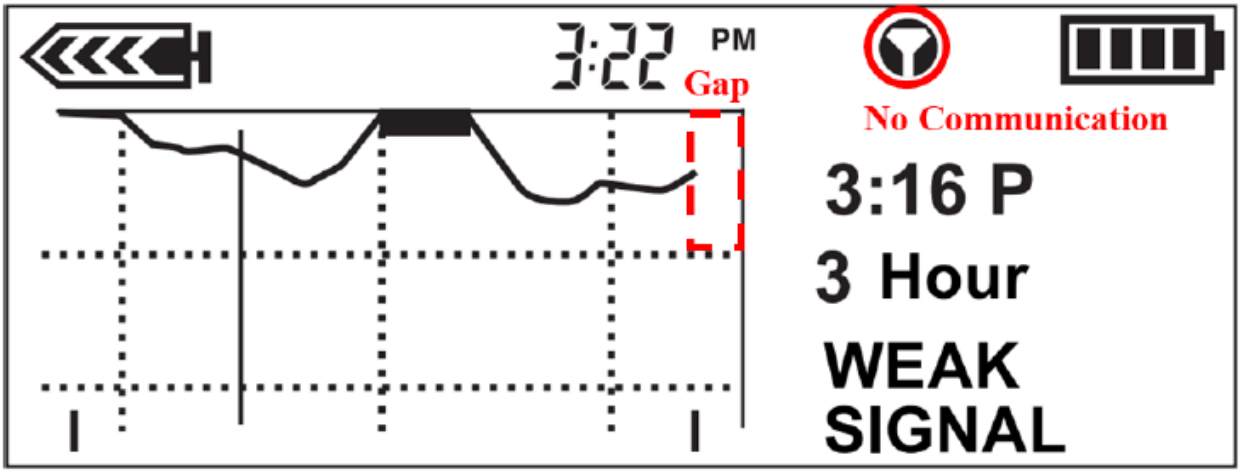
(*Id.* at 47.)

As the Board found, Petitioner's characterization of the User Guide is wrong. (Paper 11 at 33.) 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. 2013 ¶211.) 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. 1011 at 64), while the left portion is from a portion of Chapter 6, titled "Sensor alarm conditions" (*see id.* at 73).

Moreover, the hypothetical scenarios illustrated in the figures are not the same. (Ex. 2013 ¶212.) In Chapter 5, the illustration shows that the insulin pump is in communication with the transmitter at 3:22 PM.



(Pet. at 47.) In Chapter 6, the illustration shows that the insulin pump is not in communication with the transmitter at 3:22 PM.



(*Id.* at 46). 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. 2013 ¶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. 1011 for claim element [1.L] and the only additional citations are to three paragraphs of Mr. Gross's declaration. (*See* Pet. at 46-48.) Paragraphs 114 and 115 of the Gross declaration, however, merely parrot the Petition and add nothing. (*Compare* Ex. 1008 ¶¶114-115, *with* Pet. at 46-48); *Xerox*, IPR2022-00624, Paper 9 at 15. And Mr. Gross's opinion in paragraph 60 (cited on page 48 of the Petition) should be given no weight for the reasons explained above. (*See supra* §V.A.1; Ex. 2013 ¶214.) Besides, expert testimony cannot be used to supply a missing claim element as Petitioner attempts here. *Apple*, IPR2023-00087, Paper 10 at 19. Thus, Grounds 1 and 2 should fail for this additional reason.

VI. PETITIONER DID NOT MEET ITS BURDEN ON GROUND 3

Petitioner's third ground depends on combining four different references. But a skilled artisan would not have been motivated to combine the teachings of those references, and even after combining multiple references, the petition still cannot point to any prior art that discloses claim elements [1.I], [1.K], or [1.L]. The petition instead turns to Mr. Gross's declaration to supply those claim elements, despite clear authority precluding such. *Apple*, IPR2023-00087, Paper 10 at 19.

A. The Petition Fails to Establish a Motivation to Combine

For Ground 3, Petitioner relies on Patel-2008, Mastrototaro, Shahmirian, and Causey. (Pet. at 72-115.) Petitioner's alleged motivation for combining these references is premised on incorporation by reference. Specifically, Petitioner argues that Patel-2008 incorporates by reference "***the disclosures*** of *Mastrototaro* (EX1019), *Shahmirian* (EX1023), and *Causey* (EX1017)" such that they are effectively part of Patel-2008. (Pet. at 74-75.) Petitioner assumes that, if the entire disclosures are incorporated into Patel-2008, then that is enough to establish a motivation to combine. (*See* Pet. at 82.) Petitioner is wrong for two reasons: (i) Patel-2008 does not incorporate the entire disclosures of the other references and (ii) even if it had, Petitioner was still required to explain why a POSITA would have been motivated to select and combine the disparate teachings from the references, which Petitioner did not do.

Recognizing the problems with incorporation by reference, Petitioner argues: "Alternatively, POSITAs would have been motivated to integrate the glucose sensor and transmitter in *Mastrototaro*, bi-directional communications of *Shahmirian*, and monitoring/display functionalities of *Causey*." (Pet. at 83.) But Petitioner again rests on incorporation by reference. It argues that a POSITA would have been motivated to combine these references because each is "expressly incorporated into the diabetes management system of Patel-2008," and "each is a Medtronic MiniMed

continuous glucose monitoring component referenced by citation." (Pet. at 83-84.) Like its primary argument, Petitioner again failed to provide any reason why a POSITA would select and combine the disparate teachings from the references other than the fact that they are Medtronic references and incorporated to some degree (but not in relevant part) into Patel-2008. As shown below, Petitioner has failed to establish a legally sufficient motivation to combine.

1. Patel-2008 Incorporates Specific Subject Matter From the Other Ground 3 References

Patel-2008 does not incorporate the subject matter on which Petitioner relies from Mastrototaro, Shahmirian, and Causey. "To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." *Advanced Display v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). The "specific material" incorporated can be the disclosure of an entire document, or disclosure from specific portions of a document. *Harari v. Lee*, 656 F.3d 1331, 1335 (Fed. Cir. 2011). Here, Patel-2008 incorporates specific portions, but not the portions on which Petitioner relies.

In each instance, Patel-2008 identifies specific subject matter from Mastrototaro (specifically glucose transmitters and subcutaneous glucose sensors), Causey (specifically consumer electronic devices (CEDs) and connectors), and Shahmirian (specifically connectors). For example, Patel-2008 states that the

"glucose monitoring device 120 includes ***a glucose transmitter 125 and a subcutaneous glucose sensor 130 of the type described [in]*** U.S. Pat. No. 5,391,250 entitled 'Method of Fabricating Thin Film Sensors', U.S. Pat. No. 6,484,046 entitled 'Electrochemical Analyte Sensor,' U.S. Pat. Nos. 5,390,671, 5,568,806 and 5,586,553, entitled 'Transcutaneous Sensor Insertion Set,' U.S. Pat. No. 6,809,653 entitled 'Telemetered Characteristic Monitor System And Method of using The Same,' and U.S. patent application Ser. Nos. 09/377,472, 11/225,790, 11/225,296, ***11/322,568*** **[Mastrototaro]** and entitled 'Telemetered Characteristic Monitor System And Method Of Using The Same,' all of which are specifically incorporated by reference herein." (Ex. 1015 at [0033].)

Notably, Patel-2008 does not state that the "***disclosures*** of the ... applications are hereby incorporate[d] by reference," which was the language in *Harari* (*see* 656 F.3d at 1335-36), or that Mastrototaro is "incorporated herein by this reference," which was the language in *Paice v. Ford Motor*, 881 F.3d 894, 907 (Fed. Cir. 2018). Nor does Patel-2008 state that any reference is incorporated "in its entirety." A POSITA would therefore understand that, by prefacing the incorporation language with "a glucose transmitter 125 and a subcutaneous glucose sensor 130 of the type described [in]" a laundry list of references, Patel-2008 is incorporating that specific subject matter from those references and not full disclosures. *Zenon Envtl. v. U.S. Filter*, 506 F.3d 1370, 379 (Fed. Cir. 2007); *Google v. Uniloc 2017*, IPR2020-00756,

Paper 30 at 56-57 (P.T.A.B. Oct. 12, 2021). Patel-2008 makes similar incorporation statements about the CEDs and connectors of Causey (*see* Ex. 1015 at [0034]) and the connector of Shahmirian (*see id.* at [0035]).

Petitioner, however, relies on disclosures of these references outside of those specifically incorporated by Patel-2008. For example, Petitioner relies on Shahmirian for teachings outside of the "connector" (or its associated "communications") as follows:

- **[1.D]**: executing calibration algorithms to convert sensor data, determining "data associated with a sensitivity of the glucose sensor," and storing data in memory (Pet. at 91-92);
- **[1.F]**: receiver having a processor, memory, transceiver, antenna, and display (*id.* at 94-95);
- **[1.I]**: detecting adverse conditions (*id.* at 100);
- **[1.J]**: storing raw and calibrated glucose data in memory (*id.* at 101); and
- **[1.K]**: outputting data to the display (*id.* at 101).

Because this subject matter is not "specifically incorporated by reference" into Patel-2008, Petitioner's first motivation to combine argument, which is premised on incorporating full disclosures, necessarily fails.

Even if Patel-2008 had incorporated the entireties of Mastrototaro, Shahmirian, and Causey, that does not establish that it would have been obvious ***to combine the teachings*** of those four references to arrive at the claimed inventions. Rather, Petitioner was still required to show that "it would have been obvious to modify [Patel-2008] to arrive at the patented invention." *Arendi v. Apple*, 832 F.3d 1355, 1361 (Fed. Cir. 2016); *see also, Net MoneyIN v. VeriSign*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) ("[I]t is not enough that the prior art reference … includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention."); *Nat'l Environmental Prods. v. Dri-Steem*, IPR2014-01502, Paper 13 at 12 (P.T.A.B. Apr. 3, 2015) ("It is not sufficient to demonstrate that each of the components in a challenged claim is known in the prior art. ... The Petitioner also must explain how a [POSITA] would combine the elements disclosed in [a single reference], and why such a person would be motivated to do so.").

Petitioner, however, made no attempt to explain why a skilled artisan would have selected Mastrototaro, Causey, or Shahmirian, or their teachings, ***even if*** Patel-2008 incorporated their full disclosures. (Ex. 2013 ¶¶222-225.) For example, Mastrototaro is one of ten references mentioned in paragraph [0033] of Patel-2008. (Ex. 1015 at [0033].) Petitioner does not explain why a POSITA would have selected teachings from Mastrototaro over the other nine references. (Ex. 2013 ¶226.) Similarly, paragraph [0034] of Patel-2008 identifies twelve PDAs/Smartphones and

two patents besides Causey. (*See id.* at [0034].) Yet Petitioner fails to provide ***any reason*** why a POSITA would have selected Causey's CED over the others specifically identified or disclosed in one of the other references. (Ex. 2013 ¶227.) It is evident that Petitioner cherry-picked portions of Mastrototaro and Causey with hindsight in an attempt to reconstruct the claimed invention.

This is further evident from the disclosures in those references that Petitioner relied on from among dozens of disclosed embodiments and features. For example, claim element [1.D] requires "process[ing] the sensor data using calibration data" in the data processing and transmitter unit. (Ex. 1001 at 15:31-47.) Such processing could also be performed in the receiver unit. (Ex. 2013 ¶228.) Mastrototaro discloses both. (*Id.*; Ex. 1019 at [0035].) Petitioner maps paragraph [0035] of Mastrototaro onto this claim element (Pet. at 91), but nowhere provides a rationale for doing so. (Ex. 2013 ¶228.) Petitioner never explains why it would be desirable or advantageous to process sensor data in the transmitter instead of the receiver. That is improper hindsight reconstruction. *Grain Processing v. Am. Maize-Prods.*, 840 F.2d 902, 907 (Fed. Cir. 1988).

In sum, regardless of whether Patel-2008 incorporates full disclosures or specific disclosures from the other Ground 3 references, Petitioner failed to provide any reason other than the incorporation by reference as to why a POSITA would have been motivated to combine disparate teachings from those references.

2. Petitioner's Alternative Motivation to Combine Argument Also Fails

Petitioner argues that, if Mastrototaro, Shahmirian, and Causey are not effectively part of Patel-2008, then a POSITA would have been motivated to combine these references because each is "expressly incorporated into the diabetes management system of *Patel*-2008" and "each is a Medtronic MiniMed continuous glucose monitoring component referenced by citation." (Pet. at 83-84.) Thus, Petitioner's "alternative" argument is also based on Patel-2008 identifying portions of Mastrototaro, Shahmirian, and Causey for incorporation by reference.

Like its primary argument, Petitioner again fails to explain ***why*** a POSITA would have been motivated to combine these references, or specific portions of these references. (*See supra* §VI.A.1.) For example, Petitioner provides no explanation for why a POSITA would select Mastrototaro or Causey from among the other incorporated references, or why specific disclosures from them, such as Mastrototaro's processing of sensor data in the transmitter, would be chosen over numerous other disclosed embodiments and features. (*See supra* §VI.A.1.)

More fundamentally, Petitioner does not explain why a POSITA would have been motivated to replace any of Patel-2008's components in the first place. (Ex. 2013 ¶224.) Patel-2008 purports to describe a fully functioning system. (*See, e.g.*, Ex. 1015 at [0006]-[0012].) Petitioner says a POSITA would have been motivated to replace Patel-2008's transmitter and sensor with Mastrototaro's, Patel-2008's

connector and communications with Shahmirian's, and Patel-2008's CED with Causey's. (Pet. at 83.) But Petitioner does not identify any aspect of Patel-2008's system that was deficient or in need of improvement. Nor does Petitioner identify any aspect of the other Ground 3 references that would improve Patel-2008's system or provide any specific advantages. (Ex. 2013 ¶224.)

Accordingly, Petitioner's motivation to combine arguments fail to provide "an apparent reason to combine the known elements in the fashion claimed by the patent at issue," *KSR v. Teleflex*, 550 U.S. 398, 418 (2007), and, thus, are legally insufficient to establish obviousness. *TriVascular v. Samuels*, 812 F.3d 1056, 1066 (Fed. Cir. 2016) (forbidding "hindsight reconstruction of references ... without any explanation as to *how* or *why* the references would be combined"); *HTC. v. Lemaire Illumination Techs.*, IPR2019-00090, Paper No. 7, at 25 (P.T.A.B. Apr. 12, 2019) ("Petitioner's expressed motivations to combine teachings are not sufficiently specific as to the manner of the proposed combination. Petitioner simply identifies a feature of Kaelin and a feature of Okino, and then concludes that the teachings are combinable."); *Comcast Cable v. Promptu*, IPR2018-00340, Paper 58 at 26 (P.T.A.B. Mar. 29, 2019).

3. Gross's Opinions Fail To Establish A Motivation To Combine

The Petition attempts to support its threadbare "motivation to combine" argument by referencing, without explanation, ¶¶190-192 of the Gross declaration. (Pet. at 84.) None of these paragraphs rescue the Petition.

Paragraph 190 merely parrots the Petition's insufficient assertions and therefore adds nothing. *Xerox*, IPR2022-00624, Paper 9 at 15 ("Dr. Jones' declaration … merely repeats, *verbatim*, the conclusory assertion for which it is offered to support … and is entitled to little weight.").

Paragraphs 191 and 192 state that a POSITA would have been motivated to "combine the sensor and transmitter of *Mastrototaro*, the communications of *Shahmirian*, and the monitor control programs of *Causey* to effectuate a diabetes management system with the monitoring, communication, and display functionalities disclosed in *Patel*-2008" and "incorporate the monitoring, communication, and display functionalities features of *Mastrototaro*, *Shahmirian*, and *Causey* to convey as much accurate glucose information to a user as possible without providing inaccurate information." (Ex. 1008 at ¶¶191-192.) These bare, conclusory statements do not explain why or how a POSITA would have combined the transmitter of Mastrototaro, the communications of Shahmirian, and the monitor control programs of Causey with Patel-2008's teachings to arrive at the specific

inventions of the Challenged Claims, and are not tethered to any specific claim limitations. (Ex. 2013 ¶¶229-231.)

Mr. Gross's statement in paragraph 192 that POSITAs would be motivated "to convey as much glucose information to a user as possible without providing inaccurate information" stems from his paragraph 60. (*See* Ex. 1008 ¶192.) As explained above, Mr. Gross's opinions in paragraph 60 should be given no weight because they are untethered from the state of the art in 2009 and are contradicted by clinical uses of CGMs at that time. (*See supra* §V.A.1.)

Finally, the Petition does not include the content from paragraphs 191 or 192 of the Gross declaration or explain how or why it supports Petitioner's alleged motivation to combine. Consequently, the Board should not consider Mr. Gross's paragraphs 191 or 192. *Cisco v. C-Cation Techs.*, IPR2014-00454, Paper 12 at 10 (P.T.A.B. Aug. 29, 2014) (Precedential) (refusing to "consider arguments that are not made in the Petition, but are instead incorporated by reference to the cited paragraphs ... of [expert] [d]eclaration."); *Instrumentation Lab. v. Hemosonics*, IPR2017-00855, Paper 55 at 23 (P.T.A.B. Feb. 13, 2019) ("Petitioner ... provides no

substantive discussion of the contents of the cited paragraphs in the Mize declaration.").[6]

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For the foregoing reasons, the Petition fails to establish a sufficient motivation to combine the Ground 3 references.

B. The Ground 3 References Do Not Disclose Several Limitations of Independent Claim 1

Even if Petitioner had sufficiently established a motivation to combine the four Ground 3 references, the combination still would not disclose several elements of claim 1. Element [1.I] is missing because the prior art does not teach ***detecting*** an adverse condition that causes a ***data gap*** to appear on a CGM display. For element [1.K], Shahmirian describes two separate embodiments that individually do not disclose displaying or backfilling a data gap and, if combined, would at most display only "the most recent sensor measurement," not backfilled data. Causey teaches the opposite of [1.K] and always displays data, even if the data will later be updated. And for [1.L], Petitioner identifies no disclosure in the prior art and instead depends,

[6] In the Institution Decision, the Board pointed to ¶¶55, 70-71 of the Gross declaration for "motivation to combine." (Paper 11 at 43.) However, Petitioner did not rely on those paragraphs. (Pet. at 83-84 (citing ¶¶56-57, 190-193 of Ex. 1008).)

improperly, on its expert's testimony to establish this missing element. Each is an independent reason why Petitioner's Ground 3 arguments fail.

1. The Combination Does Not Teach Or Suggest [1.I]

Element [1.I] recites "wherein the glucose monitoring system is configured to detect an adverse condition, wherein the adverse condition results in the receiver unit displaying a data gap such that the first line graph displayed on the receiver unit has an end corresponding to a time associated with a start of the adverse condition." The Petition states that "*Patel*-2008 discloses detecting failed reception of sensor data and indicating missing data with 'a blank white space during the time no data was received.'" (Pet. at 100.) Not so. Petitioner does not identify any disclosure in Patel-2008 that teaches or suggests that Patel-2008 "is configured to ***detect*** an adverse condition." (Ex. 2013 ¶234.)

Petitioner cites paragraph [0057] of Patel-2008, but that paragraph merely states that Figure 7(b) "shows an example of missing data 728 and how the data bar 718 shows a blank white space during the time no data was received." (Ex. 1015 at [0057].) There is no explanation for how or why "missing data 728" is displayed, let alone any aspect of the system that "detects" an adverse condition that led to the display of "missing data 728." (Ex. 2013 ¶¶235-237.)

Petitioner also cites paragraph [0044] of Patel-2008, but that paragraph discloses that "[s]oftware can provoke the CED to place a telephone call to selected

phone numbers based on" events such as "out-of-range BG readings, imminent or current hypo- or hyper glycemic events, sensor calibration requirements, and the like." (Ex. 1015 at [0044].) Thus, Patel-2008 teaches that these types of "events" result in the CED making calls, not displaying a data gap. (Ex. 2013 ¶¶238-241.) Moreover, the "missing data 728" in Figure 7(b) was the result of not receiving data, not one of these types of events.

The Petition also states with respect to [1.I]:

> *Shahmirian* and *Causey* detect additional adverse conditions. *Shahmirian* discloses verifying receipt of sensor data by echoing it back to the transmitter to detect missing or inaccurate data. EX1023, [0102], [0111]. *Causey* discloses monitoring sensor data signals to determine conditions like rapidly changing, extreme, faulty, or interrupted glucose data and prompting or delaying calibration accordingly. EX1017, 22:28-45. EX1008, ¶¶60, 212.

(Pet. at 100-101.)

The cited portions of Shahmirian, however, teach that data is retransmitted from a BG monitoring system to an infusion pump if it was received inaccurately. (Ex. 2013 ¶¶245-247.) It does not teach that detection of inaccurate data results in the infusion pump displaying a data gap, but instead the opposite. (Ex. 1023 at [0102], [0111]; Ex. 2013 ¶¶245-247.)

The cited portion of Causey merely describes the unremarkable process of periodically re-calibrating a CGM with blood glucose reference measurements,

which was routine at the time. (Ex. 2013 ¶¶249-251; Ex. 2001 at 25; Ex. 2002 at 78.) For example, when certain events occurred, Causey teaches that the calibration might need to be delayed or performed. (Ex. 1017 at 22:28-45; Ex. 2013 ¶¶252-253.) What Causey does not disclose is that any such event, or the prompting or delaying of calibration, would cause a data gap to be displayed. (Ex. 2013 ¶253.)

Thus, neither Shahmirian nor Causey teach or even suggest that detection of events results in the monitor displaying a data gap. (Ex. 2013 ¶254.) The Petition also does not explain how or why a POSITA would have combined the teachings of the cited portions of Patel-2008, Shahmirian, and Causey to arrive at the element [1.I].

Finally, the paragraphs of the Gross declaration that Petitioner cites likewise fail to show that the cited references teach [1.I]. First, paragraphs 211-212 merely parrot the Petition and, therefore, are insufficient for the same reasons. *Xerox*, IPR2022-00624, Paper 9 at 15. Second, Petitioner relies on paragraph 60 of the Gross declaration, but that paragraph (among others) should be given no weight. (*See supra* §V.A.1); *Cisco*, IPR2014-00454, Paper 12 at 10. Consequently, Petitioner's failure to show that the Ground 3 references disclose claim element [1.I] is dispositive of Ground 3.

2. The Combination Does Not Teach Or Suggest [1.K]

As discussed above, 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. 1001 at 16:8-12.) Petitioner rearranges Shahmirian's disclosure to create the impression that this element is disclosed. (Pet. at 101.) It is not. (Ex. 2013 ¶257.)

In the first Shahmirian embodiment, "[o]nce the sensor data is received, the infusion pump 30 shows ***the most recent*** sensor measurement on the display 100." (Ex. 1023 at [0103].) This disclosure merely says that the system displays data, which is to be expected during normal operation. (Ex. 2013 ¶259.) Displaying "the most recent" data is the opposite of backfilling a data gap. (*Id.*) Notably, this portion of Shahmirian makes no mention of an adverse condition or backfilling an alleged data gap. (*Id.*)

In the second "alternative" Shahmirian embodiment, "the infusion pump 30 indicates to the BG monitoring system 20 the most recent sensor data that the infusion pump 30 has received, and in response, the BG monitoring system 20 sends any additional sensor data that the BG monitoring system 20 has that has not been received by the infusion pump 30." (Ex. 1023 at [0103].) Critically, ***Shahmirian is***

silent about what the system does with the "additional sensor data" in this embodiment. (Ex. 2013 ¶261.)

If Shahmirian's two embodiments were combined as Petitioner argues, then the "additional sensor data" received would not be displayed because only "***the most recent*** sensor measurement [are shown] on the display 100." (Ex. 1023 at [0103]; Ex. 2013 ¶263.) Thus, the combination of Shahmirian's embodiments does not disclose element [1.K].

Considering that Shahmirian is a Medtronic reference, the data could be stored so that it can be downloaded for retrospective analysis like the Paradigm system. (Ex. 2013 ¶261.) This is supported by Shahmirian's disclosure. (*Id.*; Ex. 1023 at [0063] ("In preferred embodiments, the BG monitoring system 20 stores information in a memory (not shown) of the BG monitoring system 20 ***for subsequent review and/or downloading to a storage media***."). The "additional sensor data" might also be used "in a closed loop algorithm to automatically adjust the delivery of fluid, such as insulin, in the infusion pump 30." (Ex. 1023 at [0104]; Ex. 2013 ¶262.)

What Shahmirian does ***not say*** is that the "additional sensor data" is graphically displayed on the receiver. (Ex. 2013 ¶263.) That is absent from Shahmirian just as it is absent from the other prior art of record. Thus, the "alternative" embodiment that Petitioner relies on is not a disclosure of outputting to a display processed sensor data for the time period corresponding to an adverse

condition such that a data gap is backfilled. (*Id.* ¶264.) The alternative embodiment does not disclose ***displaying*** any data (only receiving), any adverse condition, or that the "additional sensor data" corresponds to when an adverse condition occurred, let alone backfilling a data gap of a line graph on the display.

Thus, neither Shahmirian embodiment, alone or in combination, discloses element [1.K]. (*Id.*) Moreover, although Shahmirian clearly describes the two relied upon disclosures as "alternative embodiments," the Petition fails to explain how or why a POSITA would have modified and combined the different embodiments to meet the claimed invention, much less articulate any rational underpinning for doing so. *KSR*, 550 U.S. at 418. That the different embodiments are proximate to each other in the specification does not abrogate Petitioner's obligation to explain why it would have been obvious to combine them. *First Alert v. Walter Kidde Portable Equip.*, IPR2023-00896, Paper 14 at 20 (P.T.A.B. Dec. 13, 2023) ("We agree with Patent Owner that the record fails to support sufficient reasoning as to why the various embodiments of Malewski would have been combined to meet the Limitations [1c] and [1d].").

Petitioner further contends that Causey "discloses updating display of glucose data to show newly calibrated glucose values and differences with previously displayed data." (Pet. at 101.) The Petition does not explain how this alleged disclosure meets the claimed functionality of "output[ting] 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. 1001 at 16:8-12; Ex. 2013 ¶267.) That is because Causey teaches the opposite of element [1.K]. (Ex. 2013 ¶268.) ***Instead of displaying a data gap***, Causey takes the opposite approach and ***always displays data***, even if it will be updated. (*Id.*; Ex. 1017 at 15:48-65 ("the calibrated data … can be displayed to provide a user with updated trend and glucose level data").) Because Causey never displays a data gap, it cannot disclose backfilling one.

To summarize, Petitioner points to two separate embodiments of Shahmirian and one of Causey to argue that the Ground 3 references teach [1.K]. Yet none of the embodiments outputs to a display processed sensor data for the time period corresponding to an adverse condition such that a data gap in a displayed line graph is backfilled. Accordingly, claim 1 would not have been obvious over that art.

Petitioner argues that "POSITAs would recognize that retransmission or calibration of previously missing glucose data and the display of this data would fill in associated missing data gaps." (Pet. at 102.) As an initial matter, the Federal Circuit has repeatedly held that such arguments cannot supply a missing claim element. *DSS Tech. Mgmt. v. Apple*, 885 F.3d 1367, 1375-77 (Fed. Cir. 2018); *Arendi*, 832 F.3d at 1361-63; *K/S Himpp v. Hear-Wear*, 751 F.3d 1362, 1366 (Fed. Cir. 2014). In any event, neither reference discloses displaying data gaps, much less

filling in data gaps. (Ex. 2013 ¶271.) Thus, this statement is conclusory, lacks supporting evidence, and fails to explain how or why a POSITA would have modified and/or combined the specific teachings of Shahmirian and Causey to arrive at the claimed functionality in element [1.K].

Petitioner further argues that, "[a]lternatively, considering *Shahmirian* and *Causey*'s disclosures, POSITAs would have found it obvious to re-populate glucose data gaps with retransmitted or newly calibrated data following failed communication or calibration." (Pet. at 102.) This bald, conclusory statement should be rejected. It does not explain ***why*** a POSITA would have found such functionality obvious (in view of Shahmirian's and Causey's disclosures or otherwise) or explain how any evidence demonstrates such alleged obviousness. Petitioner's only purported support is paragraphs 58-60 of the Gross declaration. (Pet. at 102.) Mr. Gross's opinions in paragraphs 58-60, however, should be given no weight for the reasons explained above. (*See supra* §V.A.1.)

Because neither Causey nor Shahmirian, nor a combination of them, discloses element [1.K], Petitioner has failed to show claim 1 would have been obvious over the Ground 3 references.

3. The Combination Does Not Teach Or Suggest [1.L]

Element [1.L] recites "wherein the processed sensor data for the time period corresponding to the adverse condition that is outputted to the display after the

adverse condition is corrected comprises a second line graph having a first end corresponding to the time associated with the start of the adverse condition and a second end corresponding to a time associated with an end of the adverse condition." (Ex. 1001 at 16:13-20.)

Petitioner asserts that "Patel-2008 discloses a glucose line graph with a missing data gap" and cites FIG. 7(a). (Pet. at 102.) Petitioner then states that "POSITAs would have found it obvious to display missing data on the same graph when retransmitted or newly calibrated." (*See id*. (citing Ex. 1008 ¶¶60, 218).) That is all. Petitioner provides no explanation, reasoning, or evidence for why a POSITA would have allegedly found it obvious to modify Patel-2008 in that way, especially given that it does not teach displaying missing data. (Ex. 2013 ¶¶277-280.) Moreover, the statement does not even address the specific language of [1.L]. Such "a conclusory assertion with no explanation is inadequate to support a finding that there would have been a motivation to combine" because "[t]his type of finding, without more, tracks the *ex post* reasoning *KSR* warned of and fails to identify any actual reason why a skilled artisan would have combined the elements in the manner claimed." *TQ Delta*, 942 F.3d at 1359.

Petitioner resorts to citing paragraph 60 of the Gross declaration. (Pet. at 102.) The Board should disregard paragraph 60 for the reasons previously explained. (*See supra* §V.A.1.) The Board should also disregard paragraph 60 because Petitioner

does not incorporate Mr. Gross's opinions from that paragraph into the Petition. *Cisco*, IPR2014-00454, Paper 12 at 10. Even if the Board were to credit Mr. Gross's opinions, paragraph 60 is generic and not specific to Ground 3. (Ex. 2013 ¶281.) Thus, Petitioner still fails to explain how and why the specific Ground 3 references would be combined to reach the claimed functionality of element [1.L.]. Finally, Petitioner's citations to paragraphs 217-218 of the Gross declaration add nothing because those paragraphs repeat exactly what the Petition says. (*Compare* Pet. at 102, *with* Ex. 1008 ¶¶217-218); *Xerox*, IPR2022-00624, Paper 9 at 15.

Thus, claim 1 is not unpatentable also because element [1.L] is not found in the prior art.

VII. MANY DEPENDENT CLAIMS ARE NOT UNPATENTABLE FOR ADDITIONAL REASONS

Because claims 2-12, 14-18, 20-28 and 30 depend from claim 1, they are likewise not unpatentable for at least the same reasons as claim 1. These claims are also not unpatentable for additional reasons.

A. Claim 4

Claim 4 recites that "the adverse condition comprises a signal error associated with the glucose sensor." (Ex. 1001 at 16:28-30.)

1. Grounds 1 and 2

For Ground 2, Petitioner relies on Causey and argues that it "detect[s] faulty or interrupted glucose readings and prompting or delaying calibration based on these

faulty or interrupted readings." (Pet. at 67.) Petitioner assumes this means "data that was not calibrated … could not be displayed." (*Id.*) Petitioner is mistaken. (Ex. 2013 ¶290.)

Nowhere does Causey say that it stops displaying glucose readings for ***any reason***, including when calibration is delayed. (*Id.*) The portion of Causey that Petitioner cites says that "the microprocessor 216 could indicate that the calibration test should be delayed if the sensor data signals from the sensor monitor 212 are changing too rapidly." (Ex. 1017 at 22:32-35.) But that is how CGMs worked at the time—they required periodic calibration, but not when glucose levels were changing rapidly. (Ex. 2013 ¶¶251-252; Ex. 1011 at 61 ("Avoid calibrating your sensor during times of rapid glucose change."); Ex. 2002 at 78 ("Do not calibrate if your blood glucose is changing at a significant rate, typically more than 2 mg/dL per minute.").) The systems continued using the previous calibration parameters until a new calibration was entered. (Ex. 2013 ¶252.)

This is what Causey discloses: "[T]he calibrated data using results from the characteristic meter 2300 can be displayed to provide a user ***with updated trend and glucose level data***. This may also be used to ***update*** and ***show differences*** between the newly calibrated (or additional calibration) data and the data ***as it was prior to the new calibration*** (or additional calibration)." (Ex. 1017 at 15: 59-65.) Thus, instead of displaying a data gap as Petitioner assumes, Causey teaches the opposite:

continue displaying glucose data until a new calibration measurement is entered, and then go back and replace the displayed data with updated values. (Ex. 2013 ¶¶291-292.) Mr. Gross's opinions in paragraphs 59-60, which are based partly on this disclosure from Causey, are therefore wrong because Mr. Gross makes the same incorrect assumptions as Petitioner, which is another reason Mr. Gross's opinions in these paragraphs should be given no weight. (*See supra* §V.A.1.)

2. Ground 3

For Ground 3, Petitioner refers back to its argument for Ground 2. (Pet. at 103.) Thus, Petitioner failed to show that claim 4 is unpatentable under Ground 3 for the same reasons it failed under Ground 2.

B. Claims 5 and 6

Claim 5 recites that "the adverse condition comprises a signal error associated with the data processing and transmitter unit" while claim 6 recites that it is "associated with the receiver unit." (Ex. 1001 at 16:31-36.)

1. Grounds 1 and 2

In its perfunctory analysis under Ground 1, Petitioner does not identify any "signal error," or explain what signal error is allegedly associated with the data processing and transmitter unit or receiver unit. (Pet. at 49-50) It merely says that "[o]ut-of-range, interference, and other communication failures are associated with both the transmitter (transmission failure) and the pump (reception failure)." (*Id.* at

50.) But that does not explain how either claim 5 or 6 is met. Moreover, the Paradigm documentation contradicts Petitioner's arguments. It explains that wireless "interference will ***not*** cause any incorrect data to be sent and will not cause any harm to your pump, transmitter or meter." (Ex. 1011 at 40.)

Petitioner cites to paragraph 119 of the Gross declaration and its generic statement that "POSITAs would recognize signal errors associated with either the transmitter or receiver as obvious causes of missing glucose data." (Pet. at 50.) But in paragraph 119, Mr. Gross repeats exactly the same generic statement as the Petition and then references paragraph 58 of his declaration. (Ex. 1008 ¶119.) In paragraph 58, Mr. Gross again fails to identify any alleged signal error and simply makes broad, unsupported statements about what a POSITA would have allegedly known that should be disregarded. (*Id.* ¶58; *see supra* §V.A.1.) Thus, Petitioner failed to show by ***any*** evidence, much less a preponderance, that claims 5 or 6 are unpatentable.

2. Ground 3

For Ground 3, Petitioner asserts that "*Patel*-2008 discloses displaying a missing data gap when glucose data is not communicated from the transmitter to the monitor of a diabetes monitoring system" and that "[c]ommunication failures are associated with the transmitter, monitor, or both." (Pet. at 103.) First, Patel-2008 provides no details on the underlying cause of the data gap. It merely states "FIG.

7(b) shows an example of missing data 728 and how the data bar 718 shows a blank white space during the time no data was received." (Ex. 1015 at [0057].) Second, Petitioner does not identify any disclosure from Patel-2008 about "signal errors" as required in claims 5 and 6, or why "[c]ommunication failures" are allegedly relevant.

Petitioner states that "[a]lternatively, POSITAs would recognize transmission and reception errors as obvious causes of missing glucose data." (Pet. at 104.) This statement is not only conclusory, but it does not explain what is even meant by "transmission and reception errors," much less provide any evidence of them. And Petitioner's citation to the Gross declaration does not save it because Mr. Gross merely repeats the Petition's same, conclusory statement, and recursively cites paragraphs that should be disregarded. (*See supra* §V.A.1.) Thus, Petitioner has not shown that claims 5 or 6 are unpatentable.

C. Claim 7

Claim 7 recites that "the adverse condition comprises a system malfunction associated with the data processing and transmitter unit or … the receiver unit." (Ex. 1001 at 16:37-40.)

1. Grounds 1 and 2

For Ground 1, Petitioner's two-sentence analysis is insufficient to meet its burden. Petitioner claims that "[o]ut-of-range, interference, and other problems with communication, transmission, and/or reception are malfunctions," but fails to

explain why. (Pet. at 50.) Indeed, a transmitter and receiver going out of range, or experiencing interference, is part of normal operation of electronic devices. Petitioner does not explain why either is a "malfunction," or what the "other problems" allegedly are. Further, Petitioner's undeveloped arguments are not based on prior art—they are based exclusively on Mr. Gross's say-so, which itself is unsupported by evidence. *TQ Delta*, 942 F.3d at 1362.

Mr. Gross's declaration also does not help Petitioner because he repeats exactly the Petition's two-sentence analysis. (Ex. 1008 ¶120.) Nor does Mr. Gross's recursive citation to paragraph 58 help, as it merely contains generic, unsupported statements that should be disregarded. (*See supra* §V.A.1.) Thus, Petitioner has failed to show that claim 7 is unpatentable under Ground 1.

2. Ground 3

For Ground 3, the Petition refers to "failed reception" of data, but makes no attempt to explain how or why that "is a malfunction associated with the transmitter, monitor, or both." (Pet. at 104.) It could simply mean the devices went outside of their wireless range. Petitioner also refers back to its analysis for claims 5-6 under Ground 3 (*i.e.*, VIII.D.5) and claims 5-7 under Ground 1 (*i.e.*, VI.F.4-5). Neither reference saves Petitioner for the reasons explained above for those claims. Finally, the Petition falls back to citing unsupported opinions from Mr. Gross (*i.e.*, ¶¶58-60) that should be disregarded (*see supra* §V.A.1) and proffering the generic statement

that "[a]lternatively, POSITAs would recognize transmitter and/or receiver malfunctions as an obvious cause of missing data." (Pet. at 104.) Petitioner failed to show how claim 7 is unpatentable under Ground 3.

D. Claim 21

Claim 21 recites that "the data processing and transmitter unit and at least a portion of the glucose sensor are disposed within a single integrated housing." (Ex. 1001 at 17:15-19.)

1. Grounds 1 and 2

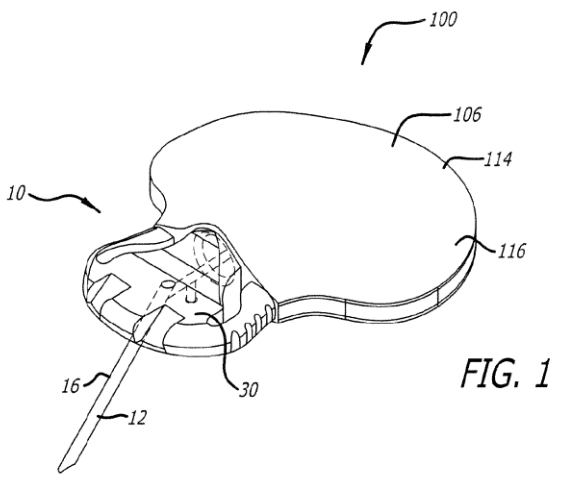
For Ground 1, Petitioner relies on Patel-2009, but that reference discloses the opposite of claim 21. (Ex. 2013 ¶300-301.) Petitioner admits that Patel-2009's "transceiver 100 ***fits directly onto*** … the sensor set 10." (Pet. at 56.) That is because the transceiver 100 and sensor set 10 are separate components that are detachably coupled by the user after sensor insertion rather than being "disposed within a single integrated housing." (Ex. 2013 ¶301; Ex. 1012 at [0061] (transceiver has "circuitry and/or a mechanism for ***detecting connection to the sensor set 10***"; "the batteries have a life in the range of 3 months to 2 years").)

Petitioner points to Patel-2009's FIG. 1 and paragraph 56 for alleged support. (Pet. at 56-57.) Paragraph 56 explains that the "transceiver 100 is directly ***coupled to*** a sensor set 10." (Ex. 1012 at [0056].) It further explains that "the transceiver 100 is ***detachably coupled*** to the mounting base 30 housing the sensor set 10," and that

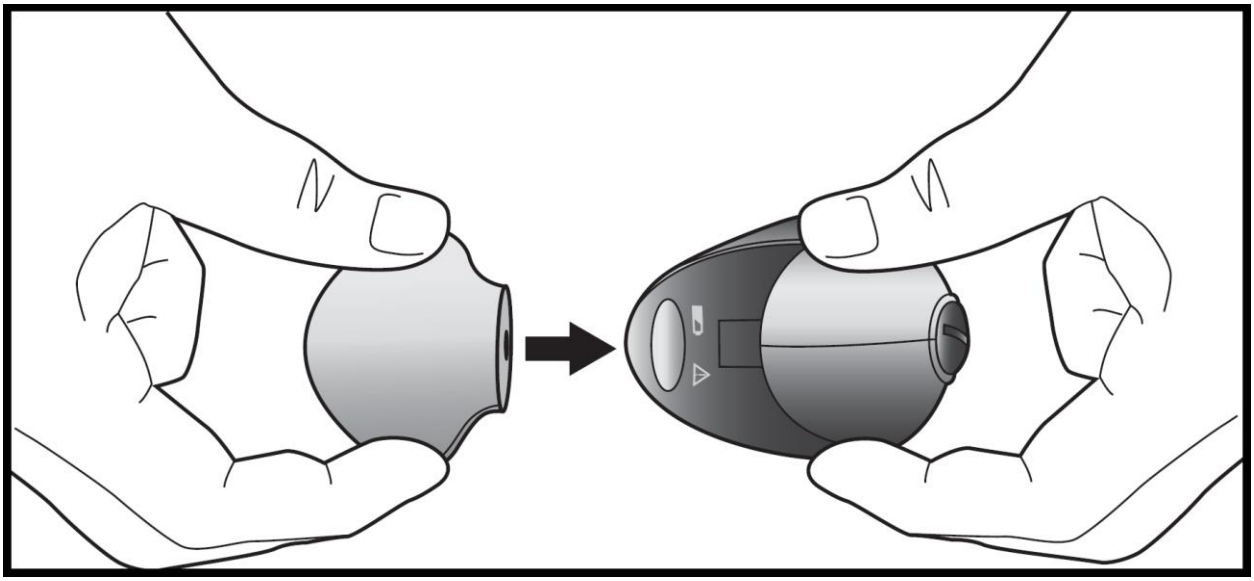
the "transceiver 100 is coupled to the sensor set ***after the sensor set has been placed into body 100 of the user***." (*Id.*) These two components are coupled "using a male/female connection." (*Id.*; Ex. 2013 ¶¶302-304.)

Patel-2009 even describes benefits of a separate transceiver and sensor: "the transceiver 100 may be ***detached from the sensor set 10*** while the sensor set 10 is implanted in the body 1000 of the user, ***thus allowing the transceiver 100 to independently attach to other complementary devices if desired***." (Ex. 1012 at [0056]; Ex. 2013 ¶305.) Thus, rather than being "disposed within a single integrated housing," Patel-2009 discloses that the data processing and transmitter unit and glucose sensor are detachably coupled to one another. (*See also* Pet. at 15 (identifying the same disclosure from Patel-2009's ¶56 in Patel-2009's provisional (Ex. 1014 at [0050]) to support the claim term, "a housing detachably coupled to a sensor located on a body of a user"); Ex. 2013 ¶306-307.)

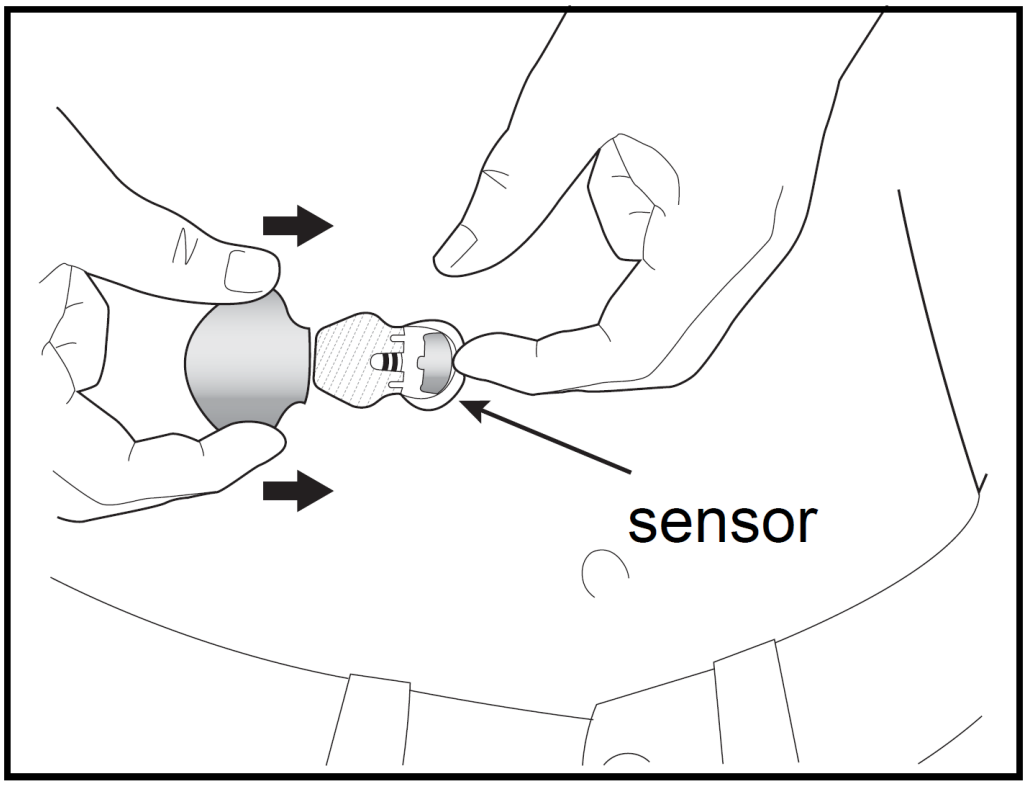
Finally, the transceiver shown in Figure 1 of Patel-2009 is the MiniLink transmitter that was used with the Paradigm system. (Ex. 2013 ¶308.)

	
(Ex. 1012 at Figure 1)	(Ex. 1011 at page 30)

As the Paradigm documentation explains, the battery in the MiniLink transmitter could be recharged by connecting it to a separate charger. (Ex. 1011 at 51-52.)



(Ex. 1011 at 52.) The female connector shown on the transceiver is how the MiniLink sensor connected. (Ex. 2013 ¶309.) As Patel-2009 describes, the transmitter "fits directly onto" the sensor base.



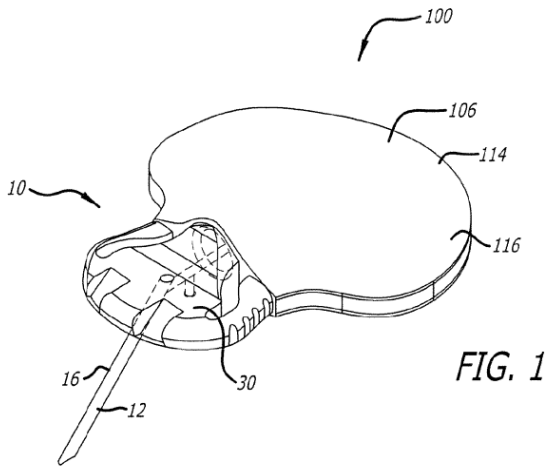
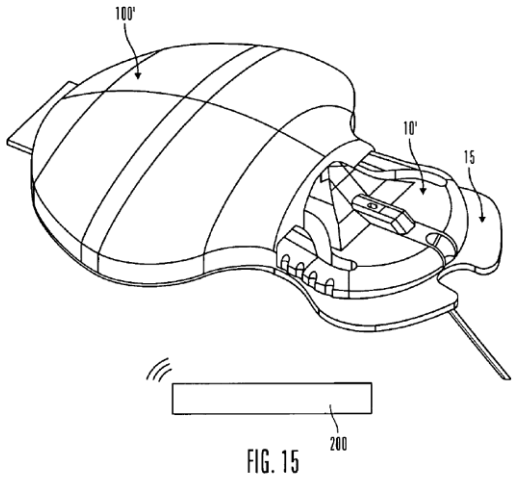
(Ex. 1011 at 59; Ex. 2013 ¶312.)

Thus, Patel-2009 describes a separate transmitter and sensor that are detachably coupled and are not "disposed within a single integrated housing."

2. Ground 3

For Ground 3, Petitioner makes the same argument as Ground 1 but with Mastrototaro instead of Patel-2009. (*See* Pet. at 110 ("Mastrototaro provides that transmitter 100' ***fits directly onto*** and is supported by sensor set 10' itself").) This is unsurprising because paragraph 56 of Patel-2009 that Petitioner relies on for Ground 1 has much of the same disclosure as paragraph 50 of Mastrototaro. (*Compare* Ex. 1012 at [0056], *with* Ex. 1019 at [0050]; Ex. 2013 ¶316.) Indeed, FIG. 1 of Patel-

2009 is almost the same as FIG. 15 of Mastrototaro, but from a different perspective. (Ex. 2013 ¶315.)

	
(Ex. 1012 (Patel-2009) at FIG. 1)	(Ex. 1019 (Mastrototaro) at FIG. 15)

Like Patel-2009, Mastrototaro also explains that in preferred embodiments, "the characteristic monitor transmitter 100' is ***coupled to*** a sensor set 10' using a ***male/female connection*** scheme." (Ex. 1019 at [0050].) It further explains that "the characteristic monitor transmitter 100' shall have a female connector interface 400 ***built into the housing 1100 of the characteristic monitor transmitter 100'***," and that "[d]etents at the female connector interface 400 are used to ***mate and lock with locking prongs located on the male sensor connector 600 of the sensor set 10'***." (*Id.*) Thus, instead of the "data processing and transmitter unit and at least a portion of the glucose sensor [being] disposed within a single integrated housing," Mastrototaro's transmitter housing has a female connector that receives a male

connector from the sensor set. (Ex. 2013 ¶¶317-320; Ex. 1019 at [0055] ("the batteries 110 have a life in the range of 3 months to 2 years").)

Mastrototaro notes "several advantages" of having "multiple components in the monitor system 1' (e.g., sensor set 10', transmitter 100' and characteristic monitor 20)," such as "facilitat[ing] upgrades or replacements, since one module or the other can be modified or replaced without requiring complete replacement of the monitor system 1'." (Ex. 1019 at [0050].) This is in contrast to "other embodiments" in which "the transmitter 100 was discarded along with the sensor set 10 after the 3 to 5 day use." (*Id.*; *see also* Pet. at 110 (erroneously contending that ***the embodiment of FIG. 15*** is discarded after 3 to 5 days instead of Mastrototaro explaining how that was a disadvantage of "other embodiments"); Ex. 2013 ¶321.) Thus, like Patel-2009 in Ground 1, Mastrototaro fails to disclose claim 21 in Ground 3. (Ex. 2013 ¶323.)

VIII. CONCLUSION

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

Date: May 22, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the Patent Owner's Response to Petition for *Inter Partes* Review Pursuant to 37 C.F.R. § 42.107 in connection with *Inter Partes* Review Case IPR2023-01251 was served on this 22nd day of May, 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 13,968 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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