

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 PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND	4
	A. Summary of the 056 Patent	4
	B. Prosecution of the 056 Patent.....	10
III.	OVERVIEW OF PETITION CHALLENGES	13
IV.	PETITIONER’S ASSERTED REFERENCES	16
	A. Patel-2009 (Ex. 1012)	16
	B. Paradigm® REAL-Time Documentation (Ex. 1011)	17
	C. Patel-2008 (Ex. 1015)	23
	D. Causey (Ex. 1017).....	23
V.	LEVEL OF ORDINARY SKILL IN THE ART	24
VI.	CLAIM CONSTRUCTION	24
VII.	PETITIONER HAS NOT MET ITS BURDEN OF PROVING A REASONABLE LIKELIHOOD THAT THE CLAIMS ARE UNPATENTABLE.....	25
	A. Legal Standard.....	25
	B. Ground 1: Patel-2009 in view of Paradigm® REAL-Time Documentation Does Not Render the Claimed Inventions Obvious.....	26
	1. Neither Patel-2009 nor Paradigm® REAL-Time Documentation Expressly or Inherently Discloses Elements [1.K] and [1.L]	27
	C. Ground 2: Patel-2009 and Paradigm® REAL-Time Documentation in view of Causey Does Not Render the Claimed Inventions Obvious	41

D.	Ground 3: Patel-2008 and Incorporated References Do Not Render the Claimed Inventions Obvious	42
1.	Patel-2008 Does Not Incorporate the Disclosures of Mastrototaro, Shahmirian, and Causey in Their Entireties	42
2.	The Petition Fails to Articulate a Legally Sufficient Motivation to Combine Patel-2008 and the Incorporated Disclosures	47
3.	The Combination of Patel-2008, Mastrototaro, Shahmirian and Causey Does Not Expressly or Inherently Disclose element [1.K] and [1.L]	49
VIII.	CONCLUSION.....	56

TABLE OF AUTHORITIES

Cases

<i>Abiomed, Inc. v. Maquet Cardiovascular, LLC</i> , IPR2017-01204, -01205, Paper 9 (P.T.A.B. Oct. 23, 2017)	25
<i>Advanced Display Sys., Inc. v. Kent State Univ.</i> , 212 F.3d 1272 (Fed. Cir. 2000)	42
<i>Arendi S.A.R.L. v. Apple Inc.</i> , 832 F.3d 1355 (Fed. Cir. 2016)	49
<i>B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.</i> , 72 F.3d 1577 (Fed. Cir. 1996)	49
<i>Cisco Sys., Inc. v. C-Cation Techs., LLC</i> , IPR2014-00454, Paper 12 (P.T.A.B. Aug. 29, 2014).....	53, 54, 55
<i>Comcast Cable Commc'ns, LLC v. Promptu Sys. Corp.</i> , 838 Fed. Appx. 555 (Fed. Cir. 2021).....	48
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966).....	25
<i>Harari v. Lee</i> , 656 F.3d 1331 (Fed. Cir. 2011)	42, 43, 47
<i>In re Kubin</i> , 561 F.3d 1351 (Fed. Cir. 2009)	25
<i>In re Van Os</i> , 844 F.3d 1359 (Fed. Cir. 2017)	16
<i>InTouch Techs., Inc. v. VGO Comm'cns, Inc.</i> , 751 F.3d 1327 (Fed. Cir. 2014)	38
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	51
<i>LBT IP I LLC v. Apple Inc.</i> , 2023 WL 3914920 (Fed. Cir. June 9, 2023).....	52

<i>Mastercard Int’l Inc. v. Stambler</i> , CBM2015-00044, Paper 32 (P.T.A.B. July 6, 2016)	47, 48, 49
<i>Medichem, S.A. v. Rolabo, S.L.</i> , 437 F.3d 1157 (Fed. Cir. 2006)	25
<i>Net MoneyIN, Inc. v. VeriSign, Inc.</i> , 545 F.3d 1359 (Fed. Cir. 2008)	48
<i>Paice LLC v. Ford Motor Co.</i> , 881 F.3d 894 (Fed. Cir. 2018)	passim
<i>Southwire Co. v. Cerro Wire LLC</i> , 870 F.3d 1306 (Fed. Cir. 2017)	15, 35
<i>TQ Delta, LLC v. Cisco Sys., Inc.</i> , 942 F.3d 1352 (Fed. Cir. 2019)	36, 41, 54, 55
<i>Xerox Corp. v. Bytemark, Inc.</i> , IPR2022-00624, Paper 9 (P.T.A.B. Aug. 24, 2022).....	34, 40, 41

TABLE OF EXHIBITS

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

I. INTRODUCTION

Patent Owner Abbott Diabetes Care Inc. submits this Preliminary Response to the Petition filed by DexCom, Inc. (“Petitioner”) requesting *inter partes* review of claims 1-12, 14-28, and 30 (the “Challenged Claims”) of U.S. Patent No. 11,298,056 (“056 Patent”). Each of the Petition’s three grounds depends on references that contain ***no disclosure*** of several key claim elements, and nothing from a developed record can cure these deficiencies. Consequently, Petitioner is not likely to succeed in proving that any Challenged Claim is unpatentable.

In Ground 1, for example, Petitioner correctly acknowledges that its primary reference, Patel-2009, does not disclose claim elements [1.I] and [1.L].¹ See Pet. at 42-44, 46-48. Collectively, these elements relate to detecting an adverse condition in the system, displaying a data gap on the display of a receiver unit that results from the adverse condition, and then displaying backfilled data in the gap as a line graph on the receiver’s display. Ex. 1001 at 15:65-16:20. Given Patel-2009’s lack of disclosure, Petitioner relies exclusively on the Paradigm® REAL-Time documentation (Ex. 1011) for these claim elements. See Pet. at 42-44, 46-48. But that documentation does not disclose the claimed features either.

¹ For purposes of this Preliminary Response, Patent Owner adopts the claim element labels used in the Petition.

The Paradigm® REAL-Time documentation discloses an insulin pump that displays a trend graph of the user's glucose data. Distinct from a trend graph of glucose data displayed on the insulin pump, glucose data stored in the pump may be uploaded through a wired connection to a personal computer (PC) running the CareLink™ Personal software application. The CareLink™ Personal software can then be used to generate historical reports based on the uploaded data. This is one place where the Petition goes awry—***the historical reports are not displayed on the insulin pump***, which Petitioner contends is the claimed receiver. Rather, the historical reports are displayed or saved as a PDF file on the user's PC. Yet, the Petition mistakenly relies on frequently asked questions about ***historical reports*** as purported evidence about the trend graphs displayed by the insulin pump.

Adding to its errors, Petitioner then mischaracterizes two illustrations of the insulin pump's trend graph display in the Paradigm® REAL-Time documentation to incorrectly suggest that the documentation discloses the claimed backfilling. The figures are from two different chapters of a user guide and have no relation to one another. One figure is from Chapter 5 and is provided as an example for how to interpret aspects of the trend graph display. Ex. 1011 at 64. The other figure is from a note in Chapter 6 and illustrates how the trend graph will appear when there is a weak signal. *Id.* at 73. Neither illustration is described as being part of a sequence of events that includes the other illustration, and there is no express or implied

disclosure of the claimed backfilling of a displayed data gap, as Petitioner contends. Moreover, as explained below, these are not the only claim elements missing from the Patel-2009 and Paradigm® REAL-Time combination. For at least these reasons, Ground 1 is not a basis upon which trial should be instituted.

Ground 2 fares no better because it challenges only claims that depend from claim 1 and relies on the same, deficient prior art combination as Ground 1 for the elements of independent claim 1.

Ground 3 suffers from the same types of deficiencies as Ground 1. For Ground 3, Petitioner acknowledges that its primary reference, Patel-2008, does not disclose elements [1.K] and [1.L], which collectively relate to displaying backfilled data as a line graph on the receiver unit's display. Ex. 1001 at 16:8-20. To make up for this deficiency, Petitioner improperly rearranges the order of sentences in Shahmirian to make it appear as though Shahmirian teaches element [1.K]. Pet. at 101. It does not. Petitioner also includes a sentence about Causey, but makes no effort to explain the purported relevance to element [1.K]. *Id.* For claim element [1.L], the Petition first acknowledges that Patel-2008's data gap is never backfilled and then, without explaining any reason or citing any prior art reference, provides a single, conclusory sentence stating that "POSITAs would have found it obvious to display missing data on the same graph when retransmitted or newly calibrated." Pet. at 102.

For these and other reasons below, the Board should deny institution.

II. BACKGROUND

A. Summary of the 056 Patent

The technology of the 056 Patent relates to continuous glucose monitors, or CGMs. CGMs continuously monitor blood sugar in the body, called glucose, and are relied upon by people with diabetes to manage their glucose levels. Diabetes results in glucose levels that can cause severe health problems such as heart attack, stroke, kidney disease, blindness, amputation, and even death.

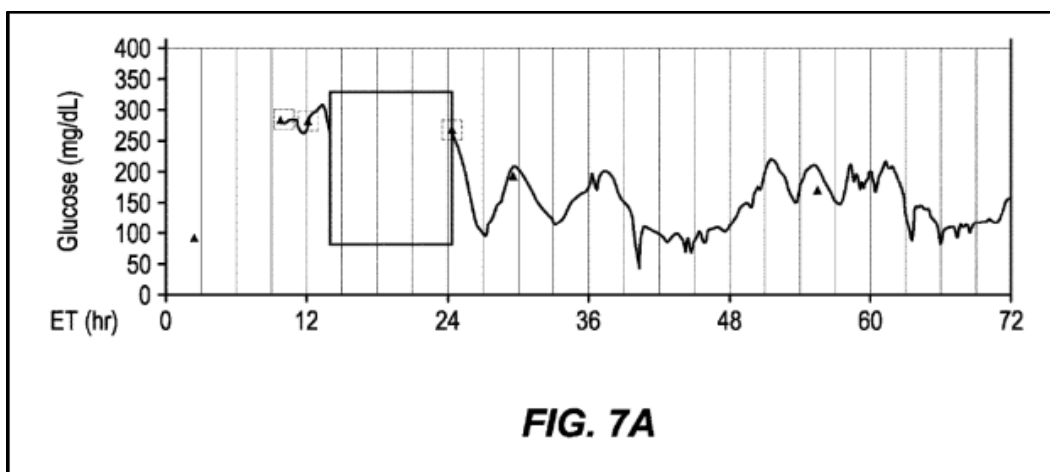
Historically, glucose monitoring involved “fingerstick” measurements, which required a person to prick and draw blood from their finger, put the blood on a test strip, insert the strip into a monitor, and wait for a single test value. That method was painful and invasive and had to be repeated frequently. Consequently, persons with diabetes would not do all the fingersticks needed to adequately monitor their glucose levels and prevent the disease’s progression and deadly effects.

The 056 Patent describes and claims a CGM system for backfilling data gaps that occur 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 claimed glucose monitoring system further comprises “a receiver unit,” which includes “a processor,” “memory,” “a radio frequency transceiver,” “an antenna,” and “a display.” *Id.* at 15:52-54.

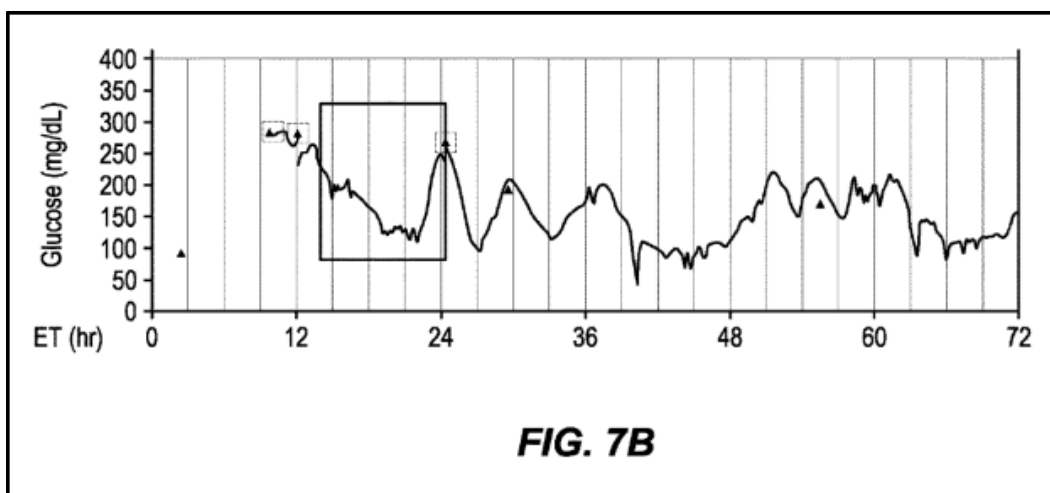
In operation and as claimed, the data processing and transmitter unit can be configured to “receive the sensor data from the glucose sensor and store the sensor data in the memory of the data processing and transmitter unit.” *Id.* at 15:39-41. It is further configured to “process the sensor data using 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 his or her glucose levels, the claimed monitoring system is “configured to detect an adverse condition” that “results in the receiver unit displaying a data gap.” *Id.* at 15:65 to 16:3. An example is shown in FIG. 7A below.



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

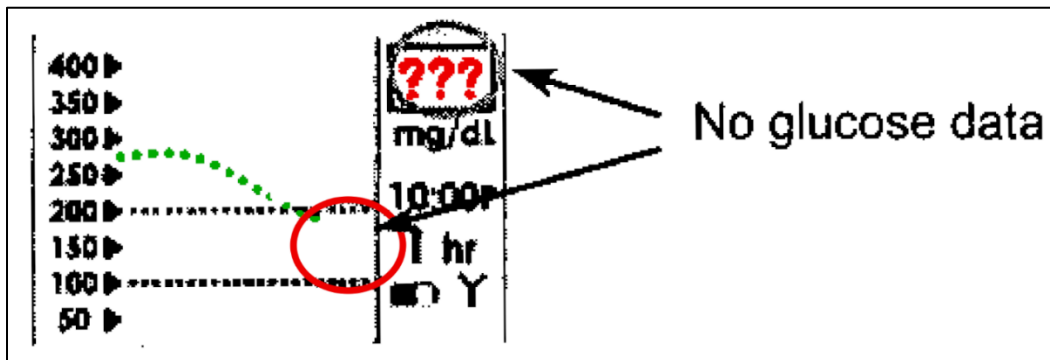
As claimed, “during a time period corresponding to the adverse condition, sensor data, processed sensor data, or both, are stored in the memory of the data processing and transmitter unit.” *Id.* at 16:4-7. After the adverse condition is corrected, the receiver unit outputs to the display the “processed 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.



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

Although Petitioner contends that the claimed backfilling invention was obvious, at the time of the invention, Petitioner's own commercial CGM product, the STS-7, lacked the ability to recover missing data to backfill data gaps on a receiver unit's display when adverse conditions occurred in the system. A user guide for Petitioner's STS-7 CGM 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. When this occurred, "Glucose Data Gaps" appeared in the user's glucose levels on the display device. *See id.* at 38-40.

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.



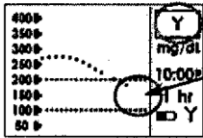
Id. at 39 (color added).

As depicted above, Petitioner's 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 CGM 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% of the systems. *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. For example, the STS-7 also suffered irreparable data gaps when the transmitter and receiver went out of range:

4.6.1 MISSING GLUCOSE READINGS – NO “Y”

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



The diagram shows a portion of a CGM display. On the left is a glucose trend graph with a y-axis ranging from 50 to 400 mg/dL in increments of 50. A dotted line represents the glucose trend. To the right of the graph is a status box. The status box contains a 'Y' icon at the top, followed by 'mg/dL', then '10:00', then '1 hr', and finally another 'Y' icon at the bottom. An arrow points from the text 'No glucose data' to the 'Y' icon at the top of the status box.

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

Id. at 38.

All of Petitioner's other commercial products were also unable to backfill missing data on a user's CGM display until 2016. *See, e.g.*, Ex. 2002 at 9 (“Glucose Data Gaps”), 93. Indeed, from 2004, when Petitioner launched its first CGM product, the STS, until 2016, when Petitioner incorporated a backfilling feature into its G5 CGM system (Ex. 2003 at 1), none of Petitioner's commercial CGM products could backfill missing data. And after having incorporated the claimed invention of the 056 patent into its later-generation products, Petitioner now relies on hindsight to argue that the invention was obvious. Petitioner's arguments are belied by its own

actions and the fact that its commercial products lacked the claimed functionality for over a decade after the time of the invention.

B. Prosecution of the 056 Patent

The 056 Patent issued from U.S. Application No. 17/411,154 (the “154 Application”), filed on August 25, 2021, which was the eighth non-provisional application in a family of patents claiming priority to U.S. Provisional Application No. 61/173,600. The same Examiner examined the 056 Patent and its predecessor non-provisional parent applications.

A preliminary amendment was filed with the 154 Application that canceled original claims 1-22 and added new claims 23-52. Ex. 1002 at 1-8. Claims 23-52 were subsequently rejected in a November 9, 2021 office action on the ground of non-statutory double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 8,483,967, and over claims 1-30 of U.S. Patent No. 11,116,431, both of which are parent patents to the 056 Patent. *See id.* at 237-241. On December 20, 2021, the Applicant amended claims 23, 26-31, 33, 35-37, 39-48, and 50; added new claims 53-58; and canceled claims 24-25, 32, 34, and 51-52. *Id.* at 278-287. These amendments persuaded the Examiner to withdraw the double-patenting rejection.²

² Petitioner incorrectly suggests that the non-statutory double patenting rejection was “overcome with terminal disclaimers.” Pet. at 8.

Id. at 297. The 154 Application was thus allowed on February 7, 2022 and issued as the 056 Patent on April 12, 2022.

Several of the references and disclosures cited in the Petition were considered during prosecution. For example, Patel-2009 (*i.e.*, U.S. Pub. 2009/0085766) was submitted to the Examiner in an IDS among only 18 references. *See* Ex. 1002 at 85. The Examiner subsequently crossed out one of the references and indicated that “all references [were] considered except where lined through.” *Id.* at 319. Thus, the Examiner considered Patel-2009 and allowed the claims of the 056 Patent over it. The Petition attempts to suggest that Patel-2009 was buried “among 700 references submitted via IDS.” Pet. at 115. But this suggestion is clearly wrong given that Patel-2009 was included in an IDS among only 18 references.

Shahmirian was also considered by the Examiner. Beginning with the first non-provisional application in the 056 Patent family, the Applicant identified Shahmirian (*i.e.*, U.S. Pub. 2004/0122353) to the PTO in an IDS. *See* Ex. 1007 at 171. Shahmirian remained on all IDS documents submitted for each family member, including the 056 Patent. *See, e.g.*, Ex. 1002 at 73. The same examiner examined all applications in the family, and he was therefore familiar with Shahmirian’s teachings since at least November 2010 when the first IDS was submitted. Ex. 1007 at 187. The Examiner allowed the claims of the 056 Patent over Shahmirian as well.

Mastrototaro's disclosure was also considered by the Examiner, and although the specific document that Petitioner relies on was not, the disclosure was. There are at least three other references in the Mastrototaro patent family that share nearly identical disclosures with Mastrototaro and that were before the PTO during prosecution; namely, U.S. Patent No. 6,809,653 (the "653 patent") (Ex. 2004), U.S. Patent No. 7,098,803 (the "803 patent") (Ex. 2005), and U.S. Patent No. 7,324,012 (the "012 patent") (Ex. 2006). The few differences between these patents and Mastrototaro are not material here and relate to an alternative embodiment in which Mastrototaro's transmitter can be connected directly to the sensor instead of with a cable. But as Petitioner notes, this is merely a "modified" system that allows for "direct connection without a cable." Pet. at 88. Notably, each of the 653, 803, and 012 patents were considered by the Examiner.

Specifically, both the 653 and 803 patents were identified to the PTO in an IDS beginning with the first non-provisional application in the 056 Patent family. *See, e.g.*, Ex 1007 at 168-169. Like Shahmirian, they remained on all IDS documents submitted for each family member, including the 056 Patent. *See* Ex. 1002 at 69-70. Similarly, the 012 patent was identified to the PTO in connection with the third non-provisional application in the 056 Patent family—U.S. Serial No. 15/061,774. *See* Ex. 1005 at 103. It too remained on all IDS documents submitted for the remaining family members, including the 056 Patent. *See* Ex. 1002 at 71. And despite having

reviewed Mastrototaro’s disclosure through these three related patents, the Examiner nevertheless allowed the claims of the 056 Patent over it.

The Petition does not mention any of these facts. Instead, the Petition misleadingly focuses on the prosecution of the first non-provisional application in the family, not the 056 Patent, and then asserts that none of the cited references were “considered during prosecution.” See Pet. at 7-8. As demonstrated above, that is not correct with regard to the 056 Patent.

III. OVERVIEW OF PETITION CHALLENGES

The Petition 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 under 35 U.S.C. § 103 over Patel-2009 in view of Paradigm® REAL-Time
2	4, 9-10, 15-16 and 25	Allegedly obvious under 35 U.S.C. § 103 over Patel-2009 and Paradigm® REAL-Time in view of Causey
3	1-12, 14-18, 20-28 and 30	Allegedly obvious under 35 U.S.C. § 103 over Patel-2008 and Incorporated References

None of these grounds provides a basis upon which trial should be instituted.

Grounds 1 and 2 both depend on the Paradigm® REAL-Time documentation for claim element [1.L]: “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. However, there is no disclosure of this element in the Paradigm® REAL-Time documentation.

To create the impression that such disclosure exists, the Petition juxtaposes two unrelated illustrations of trend graphs from the documentation and asserts that “[c]omparing these two graphs, POSITAs **would recognize** that a data gap existing during reception failure is re-populated once communication is re-established.” Pet. at 47 (emphasis added). Not so. The trend graphs that Petitioner relies on are from two different chapters of a user guide and have no relation to one another. Moreover, the portion of the Frequently Asked Questions (“FAQ”) that Petitioner cites refer to **historical reports** that are generated by software on the user’s PC—not to the trend graph displayed on the insulin pump, which is the alleged “receiver unit.”

In Ground 3, neither the primary reference, Patel-2008, nor any alleged Incorporated Reference,³ discloses elements [1.K] and [1.L]. Ex. 1001 at 16:8-20.

³ U.S. Publication 2006/0202859 to Mastrototaro (Ex. 1019), U.S. Publication 2004/0122353 to Shahmirian (Ex. 1023), and U.S. Patent No. 6,641,533 (Ex. 1017) to Causey.

For element [1.K], Petitioner relies on Shahmirian and Causey and again asserts “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 (emphasis added).

In both cases, Petitioner is effectively arguing that claim elements [1.K] (Ground 3) and [1.L] (Ground 1) are inherent in the prior art reference. See Pet. at 47, 102 (“POSITAs **would recognize**” that the claim elements are met). However, the Federal Circuit has cautioned that “the use of inherency in the context of obviousness must be carefully circumscribed because ‘[t]hat which may be inherent is not necessarily known’ and that which is unknown cannot be obvious.” *Southwire Co. v. Cerro Wire LLC*, 870 F.3d 1306, 1310 (Fed. Cir. 2017) (citations omitted). Further, the Federal Circuit has “emphasized that ‘the limitation at issue necessarily must be present’ in order to be inherently disclosed by the reference[.]” *Id.* The Petition does not establish that claim elements [1.K] and [1.L] necessarily must be present in any of the identified references and, therefore, does not show that these elements are inherently disclosed.

For claim element [1.K] in Ground 3, Petitioner adds the conclusory assertion that, alternatively, “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 statement, however, is deficient on

its face because it does not identify or explain any reason why a POSITA would have purportedly found this obvious. *See In re Van Os*, 844 F.3d 1359, 1361 (Fed. Cir. 2017) (holding that “a conclusory assertion with no explanation is inadequate to support a finding” of obviousness.) Petitioner commits the same error for claim element [1.L] in Ground 3 and rests solely on one, conclusory sentence that simply states POSITAs would have found the element obvious without any supporting reason or evidence. This, too, should be disregarded. *Van Os*, 844 F.3d at 1361.

Petitioner has thus identified no prior art that teaches several key claim elements. Petitioner’s case instead rests on inherency and naked assertions that the invention was simply obvious. Not only do the assertions lack legal basis and factual support, they are also undermined by Petitioner’s decade-long failure to remedy the problem of data gaps in its own commercial products.

IV. PETITIONER’S ASSERTED REFERENCES⁴

A. Patel-2009 (Ex. 1012)

Patel-2009 was published on April 2, 2009 and is related to provisional application No. 60/976,886, filed on Oct. 2, 2007. The Petition readily concedes that “Patel-2009 does not provide for glucose graphs to convey that glucose data is

⁴ Patent Owner does not concede that any of Petitioner’s cited references are prior art to the claimed invention.

missing during failed communication or to display glucose data that is synchronized when communication is re-established.” Pet. at 28-29.

B. Paradigm® REAL-Time Documentation (Ex. 1011)

The Paradigm® REAL-Time documentation (Ex. 1011) is a composite exhibit purporting to be a collection of electronic documents describing the Paradigm® REAL-Time system, including an archived FAQ and a user guide, with alleged archival dates in October of 2007.

The Petition conflates trend graphs displayed on the Paradigm REAL-Time® Insulin Pump, which Petitioner argues is the claimed “receiver unit,” with historical reports, which are PDF files generated by CareLink™ software on a PC. For example, Petitioner repeatedly refers to the trend graphs on the insulin pump as “historical” graphs. *See, e.g.*, Pet. at 25 (“the Paradigm® Insulin Pump displays 3 and 24-hour **historical glucose graphs**”), 45 (“gaps in continuous glucose monitoring (CGM) data are entirely repopulated and do not persist in **historical graphs**”), 47 (“(CGM) data are re-populated with glucose data stored by the transmitter such that these gaps do not appear in **historical graphs**”) (emphasis added). However, the phrases “historical glucose graphs” and “historical graphs” appear nowhere in Exhibit 1011. Indeed, Petitioner’s subtle, but critically misleading, rewriting of Exhibit 1011 is demonstrated by the Petition’s assertion that “the Paradigm® Insulin Pump displays 3 and 24-hour **historical glucose graphs**

updated with average glucose readings every five minutes,” whereas Exhibit 1011 actually says that the insulin pump “[d]isplays 3-hour and 24-hour glucose ***trend graphs***.” *Compare* Pet. at 25, with Ex. 1011 at 15 (emphasis added).

The distinction is critical because the Petition relies on FAQs about ***historical reports*** generated by the CareLink™ software as alleged evidence about ***trend graphs*** displayed on the user’s insulin pump. Historical reports and trend graphs are not the same, nor are they generated or displayed on the same device.

Ex. 1011 discloses that the Paradigm REAL-Time® system comprises two major components: the MiniMed Paradigm 522 or 722 Insulin Pump and the REAL-Time continuous glucose monitoring sensor and transmitter. Ex. 1011 at 18. These two components are reproduced below.



The Petition asserts that the component depicted on the left, which includes a sensor combined with the MiniLink REAL-Time Transmitter, corresponds to the glucose sensor of claim element [1.B] and the data processing and transmitter unit

of claim element [1.C]. Pet. at 31-36. The MiniMed Paradigm insulin pump depicted on the right allegedly corresponds to the “receiver unit comprising . . . a display” of claim element [1.F]. *Id.* at 41. The “insulin pump displays glucose trend graphs for 3-hour and 24-hour periods.” Ex. 1011 at 24. However, Ex. 1011 does not disclose that the insulin pump, *i.e.*, the alleged 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,” as recited by claim element [1.K], nor does it disclose element [1.L] in which the processed sensor data is displayed as a second line graph.

Medtronic, the manufacturer of the Paradigm pump, also offered the CareLink™ Personal software. Ex. 1011 at 11. The software was installed “on a personal computer running Windows® 98SE, ME, 2000, XP, or Vista.” *Id.* A user could upload their glucose readings from the insulin pump to the CareLink™ software using a “connectivity device, such as a Paradigm Link® Blood Glucose Monitor or ComLink™ device, with an appropriate cable.” *Id.* at 12. After the data was uploaded to the PC, a user could create historical reports using the CareLink™ software. *Id.* The Reports page from the CareLink™ software is shown below:



Ex. 1011 at 12. Examples of historical reports available through the CareLink™ software are described in the CareLink™ Personal Getting Started guide. See Ex. 2007.⁵

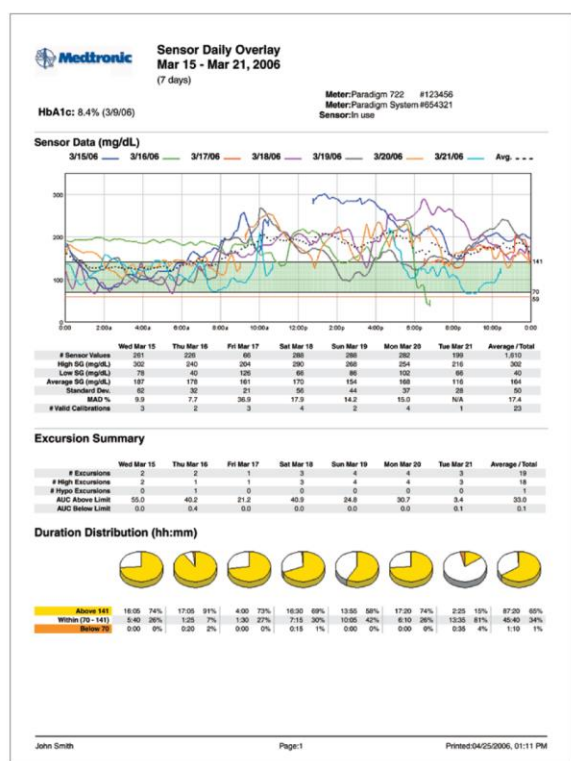
⁵ The CareLink™ Personal Getting Started guide (Ex. 2007) was downloaded from a corresponding link on page 4 of Petitioner's Ex. 1011. See Ex. 2008 (Declaration of Nathaniel E Frank-White of the Internet Archive).

The CareLink™ Personal Getting Started guide explains that “[r]eports are displayed in PDF format” and “can be viewed online, saved, printed and/or e-mailed.” Ex. 2007 at 16. 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.



Ex. 2007 at 14; *see also id.* at 13, 15-19.

While the historical reports include line graphs, they do not represent real-time outputs of glucose data to the display of a Paradigm® REAL-Time Insulin Pump. Rather, the opposite is true—the historical reports allow a patient to look back at glucose data days or weeks after it was collected and stored in, and then uploaded from, the Paradigm® REAL-Time Insulin Pump. The historical reports are also not

viewed on the Paradigm® REAL-Time Insulin Pump—they are PDF documents viewed on, or printed from, the user’s PC. *Id.* at 16.

Exhibit 1011 also includes FAQs. In situations when the Paradigm® REAL-Time Insulin Pump is unable to receive glucose data, the FAQ states:

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 (emphasis added). This FAQ describes (1) re-populating glucose data in the insulin pump and (2) a data gap that would be noticed in a historical report if the system is out-of-range for longer than 40 minutes. From this, the Petition concludes that “when transmission is out-of-range for less than 40 minutes, gaps in continuous monitoring (CGM) are entirely repopulated and **do not persist in historical graphs.**” Pet. at 45 (emphasis added). As explained above and as the FAQ makes clear, the data gap would appear in “historical reports,” which are provided by the CareLink™ software. The FAQ does **not** disclose details about what a user would see on the display of their insulin pump—the alleged “receiver unit.” As

explained in more detail below, the Petition fails to show that Ex. 1011 discloses backfilling data gaps in the trend graphs displayed on the insulin pump.

C. Patel-2008 (Ex. 1015)

Patel-2008 was published on May 22, 2008 and is related to provisional application no. 60/866,409, filed on Nov. 17, 2006. The Petition points out that Patel-2008 displays “missing data with ‘a blank white space during the time no data was received.’” Pet. at 100 (citing Ex. 1015 at [0057], Fig. 7(b)). But the Petition does not allege that Patel-2008 discloses backfilling the “blank white space,” *i.e.*, the alleged data gap.

D. Causey (Ex. 1017)

U.S. Patent 6,641,533 to Causey *et al.* is a continuation of U.S. Patent No. 6,248,067. U.S. Patent 6,248,067 is cited on the face of the 056 Patent. Causey “relates to remote programmers and/or handheld personal data assistants (PDA) for use with medical devices and, in particular embodiments, to a PDA that includes a medical device to facilitate testing and monitoring of a patient’s condition[.]” Ex. 1017 at 1:21-25. Causey does not teach, and the Petition does not allege that Causey teaches, a glucose monitoring system “for backfilling data gaps,” as recited in claim 1, or that “is configured to detect an adverse condition, wherein the adverse condition results in the receiver unit displaying a data gap,” as recited in claim element [1.I]. Causey merely teaches updating data in graphs with revised data, *i.e.*, Causey does

not disclose or contemplate a gap that is subsequently backfilled. *See* Ex. 1017 at 15:63-65 (“the calibrated data using results from the characteristic meter 2300 can be displayed to provide a user with updated trend and glucose level data”).

V. LEVEL OF ORDINARY SKILL IN THE ART

The Petition states that:

In the 2009-2010 timeframe, the POSITA had a Bachelor of Science degree in biomedical engineering, or a similar field, such as electrical, or software, or computer engineering, and two years of industry experience or research working with medical devices and systems for measuring biomedical signals. Such systems might include those for determining levels of blood analytes, such as glucose, in a patient and transmitting indications of such levels to a receiving device for reporting the measurements. Additional education, such as a Master’s degree could substitute for the industry experience, or vice versa. EX1008, ¶51.

Paper 3 at p. 13. For purposes of this Preliminary Response, Patent Owner does not dispute Petitioner’s definition of a POSITA.

VI. CLAIM CONSTRUCTION

Based on the current record, Patent Owner does not believe that any claim terms require construction in order to reach a decision to deny institution. Patent Owner reserves the right, however, to address the construction of any terms in this or any other proceeding involving the 056 Patent.

VII. PETITIONER HAS NOT MET ITS BURDEN OF PROVING A REASONABLE LIKELIHOOD THAT THE CLAIMS ARE UNPATENTABLE

The Petition presents no basis to institute *inter partes* review. As explained below, the Petition fails to show a “reasonable likelihood” that the Challenged Claims are obvious under any of the three presented grounds. 35 U.S.C. § 314(a).

A. Legal Standard

Obviousness is a question of law based on underlying findings of fact. *In re Kubin*, 561 F.3d 1351, 1355 (Fed. Cir. 2009). The factual findings include: “(1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any.” *Id.*; *see also Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). Even “if all the elements of an invention are found in a combination of prior art references,” which is not the case here, the factfinder should further consider whether a person of ordinary skill in the art would be motivated to combine those references, and whether in making that combination, a person of ordinary skill would have a reasonable expectation of success. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1164 (Fed. Cir. 2006); *see also Abiomed, Inc. v. Maquet Cardiovascular, LLC*, IPR2017-01204, -01205, Paper 9 at 8-12 (P.T.A.B. Oct. 23, 2017).

B. Ground 1: Patel-2009 in view of Paradigm® REAL-Time Documentation Does Not Render the Claimed Inventions Obvious

The Petition admits that Patel-2009 is missing important aspects of the Challenged Claims. Specifically, the Petition concedes:

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. Thus, Patel-2009 does not disclose:

- Element [1.I]: “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” (Ex. 1001 at 15:65-16:3);
- Element [1.K]: “wherein the receiver unit is configured to output to the display, after the adverse condition is corrected, processed sensor data for the time period corresponding to the adverse condition such that the data gap is backfilled” (*id.* at 16:8-12); or
- Element [1.L]: “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” (*id.* at 16:13-20).

To remedy these deficiencies, the Petition relies on the Paradigm® REAL-Time documentation. But as previewed above and explained in more detail below, the Paradigm® REAL-Time documentation also does not disclose at least claim elements [1.K] and [1.L].

Also missing from both references, as well as the combination, is claim element [1.E], which recites that the data processing and transmitter unit is configured to “transmit the processed sensor data over a Bluetooth wireless communication link,” and claim element [1.F], which recites that the receiver unit is configured to receive “the processed sensor data over the Bluetooth wireless communication link.”

Moreover, Petitioner’s alleged motivation to combine Patel-2009 and Paradigm® REAL-Time is fraught with hindsight and based on conclusory assertions.

1. Neither Patel-2009 nor Paradigm® REAL-Time Documentation Expressly or Inherently Discloses Elements [1.K] and [1.L]

Claim elements [1.F] through [1.I] require a “*receiver unit comprising . . . a display*, wherein the receiver unit is configured to . . . output to *the display* of the receiver unit, a first line graph that is a substantially continuous depiction of the processed sensor data over time, 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.” Ex. 1001 at 15:52-16:3 (emphasis added). Claim element [1.K] recites, “wherein the receiver unit is configured to output to *the display*, after the adverse condition is corrected, processed sensor data for the time period corresponding to the adverse condition such that the data gap is backfilled.” Pet. at 45 (emphasis added). Claim 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.” Pet. at 46 (emphasis added).

Thus, collectively, claim elements [1.F] through [1.I], [1.K], and [1.L] require a receiver unit that is configured to output to, and display on, its display a line graph having a gap where, on the same display, the gap is subsequently backfilled by a line graph that fills in at least a portion of the initially displayed gap. The Paradigm® REAL-Time documentation does not disclose outputting to the display of the insulin pump, the alleged receiver, a line graph where the gap is subsequently backfilled.

The Petition alleges that the 3 and 24-hour trend graph “output to the display” of the insulin pump referred to in the Paradigm® REAL-Time documentation (Ex.

1011) is the claimed “first line graph” recited by claim element [1.H] and that the 3 and 24-hour trend graph displays a data gap that is backfilled “after the adverse condition is corrected” as recited by claim element [1.K]. Specifically, the Petition contends that:

Paradigm® REAL-Time discloses that when the transmitter and insulin pump are out of transmission range, the “transmitter holds 40 minutes worth of memory, so ... continuous glucose monitoring (CGM) data can be re-populated in the insulin pump.” EX1011, 8. If the “[t]ransmitter and insulin pump are out-of-range for longer than 40 minutes, only the last 40 minutes will be re-populated” and a data gap will persist for the remainder. *Id.* Thus, when transmission is out-of-range for less than 40 minutes, gaps in continuous glucose monitoring (CGM) data are entirely repopulated and do not persist in historical graphs. EX1011, 8. EX1008, ¶¶60, 112.

Pet. at 45.

Petitioner’s arguments are misleading. The cited portions of the Paradigm® REAL-Time FAQ (Ex. 1011 at 8) do not describe backfilling a gap that once existed on the 3- or 24-hour trend graph displayed on the insulin pump. Rather, the only alleged gap that is described in the FAQ is one that would persist in “historical reports” if the transmitter and insulin pump are out-of-range for longer than 40 minutes. Ex. 1011 at 8. As explained above, historical reports are generated by the user’s PC using the CareLink™ software. *See, e.g.*, Ex. 1011 at 11-12; *see also* Ex.

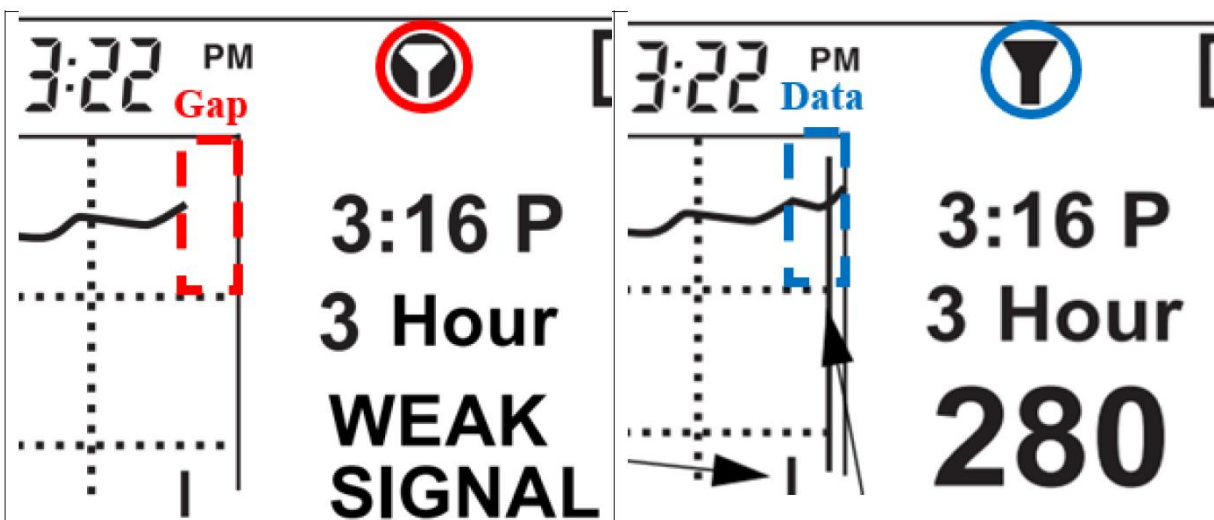
2007 at 16. These historical reports are not output to the display of the Paradigm® REAL-Time Insulin Pump, which Petitioner equates to the receiver unit of claim 1.

Moreover, Petitioner's Exhibit 1011 does not disclose that data re-populated ***in the insulin pump*** "is output to the display [of the insulin pump] . . . such that the data gap is backfilled." Rather, the Paradigm® REAL-Time FAQ only describes re-populating data in the memory of the insulin pump so that it is available to be uploaded to a computer for the purpose of historical reports and analysis. *See* Ex. 1011 at 8 ("If your system is out-of-range for longer than 40 minutes, when reviewing ***historical reports*** you would notice [a] 'data gap' where information is missing during this period of time.") (emphasis added); *id.* at 7 ("The insulin pump stores the last 90 days of CGM system data, which can be downloaded for historical analysis."). The referenced "data gap" is a gap in the CareLink™ historical reports, not a data gap on the display of the insulin pump. Thus, to the extent the Paradigm® REAL-Time documentation discloses filling in any gap, it is only for purposes of filling in all or a portion of what would have been depicted (but for re-populating missing data) as a gap in a historical report.

Because the Paradigm® REAL-Time documentation does not disclose displaying a data gap in the 3 and 24-hour trend graph on the display of the Paradigm® REAL-Time Insulin Pump and, subsequently, backfilling that displayed gap on the display of the Paradigm® REAL-Time Insulin Pump with data, the

Paradigm® REAL-Time documentation does not disclose claim element [1.K.]. The Petition relies on only the Paradigm® REAL-Time documentation for this claim element and, thus, the combination of Patel-2009 and Paradigm® REAL-Time cannot render obvious claim 1.

Further obfuscating the evidence, the Petition mischaracterizes two figures from the Paradigm® REAL-Time documentation (Ex. 1011 at 31). Specifically, the Petition juxtaposes two annotated artist renderings of the Paradigm® REAL-Time Insulin Pump display taken from different chapters of the user guide to create the impression that the guide discloses displaying a data gap in a line graph that is subsequently filled in on the same display. *See* 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.

Petitioner’s characterization of the user guide is deceptive and misleading. As an initial matter, 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. The user guide does not describe any relationship between the two artist renderings reproduced on pages 46 and 47 of the Petition (pages 64 and 73 of the user guide) or the left and right portions of Petitioner’s composite figure. 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) whereas the left portion is from a portion of Chapter 6, titled “Sensor alarm conditions” (*see id.* at 73).

Further, the hypothetical scenario illustrated in Chapter 6 is not the same hypothetical scenario illustrated in Chapter 5. The user manual explains that:

Sensor icons

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

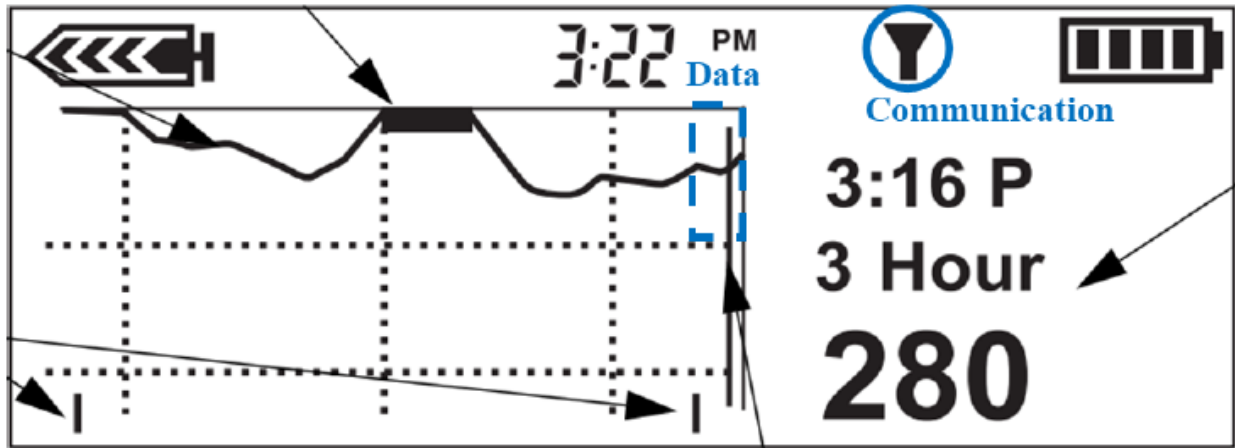
The sensor icon  appears once you start your sensor. (Refer to Chapter 4 for starting your sensor.)

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

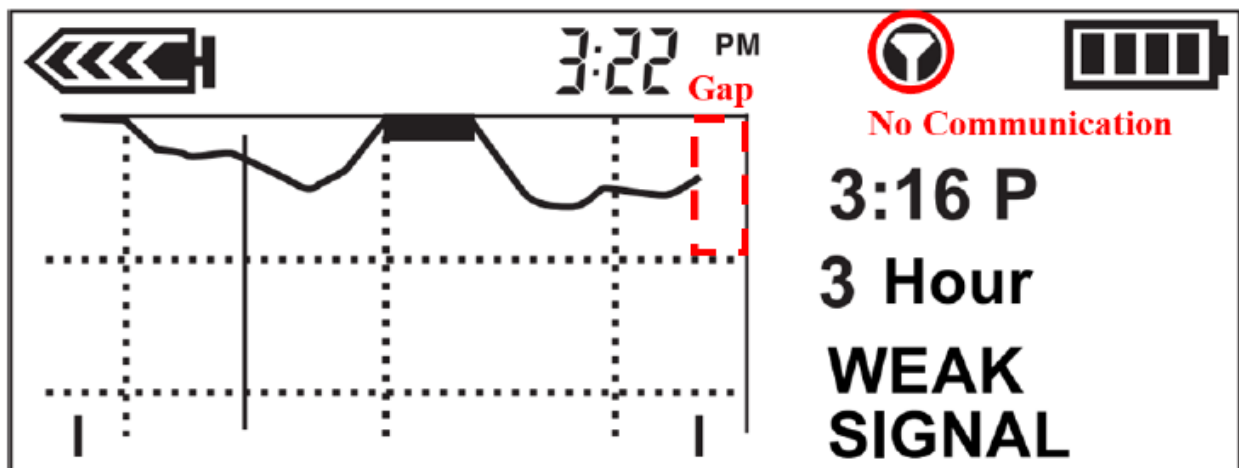
When your sensor and transmitter are connected, and communication is lost this icon  will re-appear.

Id. at 43.

The illustration in Chapter 5 (reproduced below from page 47 of the Petition) shows that the insulin pump is in communication with the transmitter at 3:22 PM.



In contrast, the illustration in Chapter 6 (reproduced below from page 46 of the Petition) shows that the insulin pump was not in communication with the transmitter at 3:22 PM. They are not, as Petitioner is attempting to portray, a sequence of events in time, nor could they be since both are showing the exact same time of 3:22 PM.



It is apparent that the technical illustrator arbitrarily chose to reuse portions of the Chapter 5 rendering for the note in Chapter 6. There 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.

Based on the incorrect characterization of a sequential relationship between the renderings, the Petition concludes “that Paradigm® REAL-Time discloses that data gaps in continuous glucose monitoring (CGM) data are re-populated with glucose data stored by the transmitter such that these gaps do not appear in historical graphs.” However, the explanation accompanying the figure in no way suggests that the area in the blue box was at one time displayed as a gap and then later backfilled to complete the real-time line graph shown on the insulin pump.

Indeed, the Petition tacitly admits that the Paradigm® REAL-Time documentation (Ex. 1011) does not expressly disclose this element. *See* Pet. at 47 (“Comparing these two graphs, POSITAs **would recognize** that a data gap existing during reception failure is re-populated once communication is re-established.”) (emphasis added). There is no disclosure of any sequence in the manual that would lead a POSITA to “recognize that a data gap existing [on the display] during reception failure is re-populated [on the display] once communication is re-established.” The Gross Declaration simply parrots the Petition without further explanation or analysis and should be given no weight. *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (P.T.A.B. Aug. 24, 2022) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”) (Precedential).

By arguing what a POSITA would allegedly “recognize” when reviewing the two unrelated figures, Petitioner is effectively arguing that the Paradigm® REAL-Time documentation inherently discloses backfilling a data gap on the display. Petitioner is mistaken. “[T]he limitation at issue *necessarily* must be present’ in order to be inherently disclosed by the reference.” *Southwire*, 870 F.3d at 1311 (emphasis in original). Nowhere does the Petition argue that the disputed limitations are “necessarily” present in the disclosures of the Paradigm® REAL-Time documentation. Nor could it because a gap displayed on a trend graph certainly need not be backfilled and may remain a gap, as with Petitioner’s past CGM products and the system described in the Patel-2008 reference relied on for Ground 3, which also do not backfill data gaps on their trend graph displays. *See, e.g.*, Ex. 2001 at 38-40; Ex. 2002 at 9, 93; Ex. 1015 at Fig. 7(a).

Because neither Patel-2009 nor the Paradigm® REAL-Time documentation discloses elements [1.K] and [1.L], and because the combination does not cure this deficiency, the Petition does not establish a reasonable likelihood that the Challenged Claims are unpatentable over Patel-2009 and Paradigm® REAL-Time.

2. The Petition Also Fails to Articulate a Legally Sufficient Motivation to Combine Patel-2009 and Paradigm® REAL-Time

The Petition contends that:

One purpose of continuous glucose monitoring is to assist in diabetes management, insulin dosing decisions, and prevention or treatment of

hyper and hypo-glycemia by providing accurate glucose concentrations and trend information in real-time. EX1011, 15, 18, 23-27; EX1012, [0004], [0006]; *see also, e.g.*, EX1029; EX1037, 17; EXs1039-1040. Therefore, POSITAs would have been motivated to detect missing or inaccurate glucose data and convey as much accurate glucose information to a user as possible without providing inaccurate information. In particular, POSITAs would have been motivated to apply the advantages of Patel-2009 to indicate when glucose data is missing and re-populate this display with accurate data synchronized when communication is re-established following failure. EX1012, [0086]. EX1008, ¶¶55, 60, 80.

Pet. at 29. Petitioner's arguments are divorced from the references it relies on.

For example, the Petition does not explain how “re-populat[ing] this display with accurate data synchronized when communication is re-established following failure” would have been recognized based on Patel-2009 and Paradigm® REAL-Time to “assist in diabetes management” when neither reference describes providing accurate information “in real time.” At most, the Paradigm® REAL-Time documentation describe historical reports to retrospectively review past glucose data. But historical reports are not generated by or displayed on the Paradigm® REAL-Time Insulin Pump. Without this explanation, the Petition “ultimately fails ‘to resist the temptation to read into the prior art the teachings of the invention in issue.’” *TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1362 (Fed. Cir. 2019).

Thus, the Petition's failure to articulate a legally sufficient motivation to combine Patel-2009 with the Paradigm® REAL-Time documentation is another reason why the Petition does not establish a reasonable likelihood that the Challenged Claims are unpatentable based on Ground 1.

3. Neither Patel-2009 Nor Paradigm REAL-Time Documentation Expressly or Inherently Discloses Elements [1.E] and [1.F]

Claim element [1.E] recites that “processed sensor data” is transmitted “*over a Bluetooth wireless communication link* using the radio frequency transceiver of the data processing and transmitter unit.” Ex. 1001 at 15:48-51 (emphasis added). Claim element [1.F] recites that the “receiver unit [is] configured to: receive, using the antenna and the radio frequency transceiver of the receiver unit, the processed sensor data over the *Bluetooth wireless communication link*.” *Id.* at 15:52-59 (emphasis added). Although the Paradigm® REAL-Time documentation and Patel-2009 discuss using radio frequency transmissions, neither discloses using Bluetooth.

In an attempt to remedy this deficiency, the Petition states, in conclusory fashion, that “POSITAs would have found it obvious to configure Bluetooth communication links in order to extend the compatibility, operating range, and usability of the system via a standardized, well-established wireless communication protocol” and that “Bluetooth would have been chosen for communication with computers, PDAs, and cell phones as disclosed in Patel-2009.” Pet. at 40. But the

Petition provides no explanation, analysis, or factual support for why Bluetooth would allegedly “extend the compatibility, operating range, and usability of the system” disclosed in Patel-2009, or more specifically, why a POSITA would be motivated to modify Patel-2009 to use Bluetooth.

Petitioner’s lack of any rational underpinning to support its argument is important because Patel-2009 already contemplates using a non-Bluetooth protocol. Specifically, Patel-2009 refers to the 916 MHz and 868 MHz frequency bands for its communication link. Ex. 1012 at [0082]. The 916 MHz or 868 MHz frequency bands are not used for Bluetooth but for private land mobile. *See* Ex. 2009 at 31-32. Bluetooth uses the 2.4 GHz frequency band. *See* Ex. 2010. The Petition does not explain why a POSITA would be motivated to replace Patel-2009’s communication protocol with Bluetooth. For example, there is no explanation or discussion of any kind, much less that is supported by evidence, of (1) any deficiency in the RF transmission technology disclosed by Patel-2009 and the Paradigm® REAL-Time documentation, (2) any benefit or improvement attendant with using Bluetooth, or (3) the lack, or mitigation, of any negative impacts of using Bluetooth. The pertinent question for obviousness is whether a POSITA *would* modify the cited references, not whether a POSITA *could* modify them. *InTouch Techs., Inc. v. VGO Comm’cns, Inc.*, 751 F.3d 1327, 1353-54 (Fed. Cir. 2014) (rejecting expert’s assertions that a

POSITA *could* combine references because there was no “meaningful explanation” for why a POSITA *would* do that).

On the other hand, the evidence Petitioner cites purporting to show that “skilled artisans were familiar with implementing Bluetooth communication for short range device-to-device connections in health monitoring applications” (Pet. at 12) contradicts its alleged motivation to add Bluetooth to the Patel-2009 and Paradigm® combination. For example, Ex. 1035 discusses “[w]ireless connectivity for health and sports monitoring.” Ex. 1035 at 1. This paper focuses on wireless technologies that could potentially replace wired networks to “allow multiple-site data collection, perhaps across the extremities of the body.” *Id.* Thus, the focus of this paper is multi-sensor systems in which sensor data from various sensors are transmitted to a central node. See Ex. 1035, Fig. 1. Critically, the point-to-point systems mentioned in the paper, which are more analogous to a CGM system than a multi-sensor system, did not use Bluetooth. The paper explains that “[w]here telemetering (taking measurements remotely) is seen as simply a means of transferring data from sportsmen or patients to a remote data-logger, the most common method is a simple point-to-point (one transmitter, one receiver) frequency modulation transmission using off-the-shelf radio transmitter-receiver modules.” Ex. 1035 at 2. Another example system for “monitoring of hockey players, transmitting heart rate and breathing data to the rink side” also did not use Bluetooth

Id. at 3. The paper explains that “[a]lthough the idea was clearly for multi-player involvement and transmission via Bluetooth, the system was finally tested on one player, with a data modem fulfilling the task of data transmission.” *Id.*

Petitioner’s other cited reference, Ex. 1036, also concludes that Bluetooth is not well-suited for wearable health-monitoring systems. This paper discusses a survey of features that wearable biosensor systems would have to meet “in order for it to be used in real-life health monitoring scenarios.” Ex. 1036 at 2. The paper concludes that “widely adopted WPAN standards for Body Area Networks (BAN), such as Bluetooth and Zigbee, perform poorly either in providing Quality of Service (QoS) under interference from other ISM band transmissions or in power-saving for long-term maintenance-free operation.” Ex. 1036 at 4.

Thus, neither reference supports Petitioner’s conclusory assertions that skilled artisans would have been motivated to alter the combination of Patel-2009 and the Paradigm® REAL-Time disclosure to use Bluetooth.

The Gross Declaration fares no better than the Petition and improperly “offers only a *verbatim* restatement of the assertion being supported, without any supporting evidence or technical reasoning.” *Xerox*, IPR2022-00624, Paper 9 at 16. The Director has held that failure to provide supporting evidence or technical reasoning “is particularly problematic in cases where, like here, expert testimony is offered not

simply to provide a motivation to combine prior-art teachings, but rather to supply a limitation missing from the prior art.” *Id.*

Ultimately, the assertion that “Bluetooth would have been chosen” to alter the Patel-2009 and Paradigm® REAL-Time combination is insufficient *ipse dixit*—because Petitioner and its expert say so. *See TQ Delta*, 942 F.3d at 1362.

Neither Patel-2009 nor the Paradigm® REAL-Time documentation discloses the use of Bluetooth and the Petitioner and its expert have provided no explanation or evidence of a reason to use Bluetooth in the proposed combination. Accordingly, because claim elements [1.E] and [1.F] are missing from the proposed combination of Patel-2009 and the Paradigm® REAL-Time, this is an additional and independent reason why claim 1 has not been shown to be likely unpatentable under Ground 1.

Claims 2-3, 5-8, 11-12, 17-24, 26-28 and 30 depend from claim 1 and are not likely unpatentable at least because claim 1 has not been shown to be likely unpatentable under Ground 1.

C. Ground 2: Patel-2009 and Paradigm® REAL-Time Documentation in view of Causey Does Not Render the Claimed Inventions Obvious

Ground 2 is directed to dependent claims 4, 9-10, 15-16 and 25. At least for the same reasons as Ground 1, the Petition does not establish a reasonable likelihood that these Challenged Claims are unpatentable.

D. Ground 3: Patel-2008 and Incorporated References Do Not Render the Claimed Inventions Obvious

1. Patel-2008 Does Not Incorporate the Disclosures of Mastrototaro, Shahmirian, and Causey in Their Entireties

The Petition contends that “Patel-2008 ‘specifically incorporate[s] by reference’ the Mastrototaro Application (EX1020), the Shahmirian Application (EX1022), and Causey (EX1017)” and “are ‘effectively part of [Patel-2008] as if [they] were explicitly contained therein.’” Pet. at 74-75. The Petition cites *Harari v. Lee*, 656 F.3d 1331, 1335 (Fed. Cir. 2011) and *Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 906 (Fed. Cir. 2018) for alleged support, but both cases show that the entireties of Mastrototaro, Shahmirian, and Causey are **not** incorporated into Patel-2008.

“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 Sys., Inc. 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. *See Harari*, 656 F.3d at 1335. The broad and unequivocal language in *Harari* and *Paice* were the former, whereas the narrow and specific incorporation language used in Patel-2008 is the latter.

In *Harari*, two passages in the '398 application contained “incorporation by reference” language. *Harari*, 656 F.3d at 1335. The first passage referenced two co-pending applications and then stated: “The disclosures of the two applications are hereby incorporate[d] by reference.” *Id.* In a later passage, the '398 application referenced specific subject matter and the two co-pending applications again, and then stated: “Relevant portions of the disclosures are hereby incorporated by reference.” *Id.* The dispute was whether the entireties of the two co-pending applications, or only portions thereof, were incorporated by reference. *Id.* The Federal Circuit found that “the first incorporation passage incorporates the entire disclosures of the two applications rather than just the portions describing [the specific subject matter].” *Id.* Thus, the “broad and unequivocal language,” “The disclosures of the two applications are hereby incorporate[d] by reference,” controlled, and nothing prevented the patent drafter “from later incorporating again certain ‘relevant portions’” of the applications to direct the reader to specific content. *Id.* at 1335-36.

The Federal Circuit reached the same conclusion in *Paice* for the same reasons. There, the relevant passage stated:

This application discloses a number of improvements over and enhancements to the hybrid vehicles disclosed in the inventor's U.S. Pat. No. 5,343,970 (the “'970 patent”) [*Severinsky*], which is incorporated herein by this reference. Where differences are not

mentioned, it is to be understood that the specifics of the vehicle design shown in the '970 patent are applicable to the vehicles shown herein as well.

Paice, 881 F.3d at 907 (emphasis in original). The Court found that the italicized sentence was “broad and unambiguous” because it stated “that Severinsky ‘is,’ without qualification, incorporated into the ’817 application ‘by *this* reference’— i.e., the reference contained in the sentence.” *Id.* (emphasis in original). “The sentence identifie[d] with detailed particularity the specific material subject to incorporation (Severinsky, and not just particular portions thereof) and where that material can be found (U.S. Patent No. 5,343,970).” *Id.*

By contrast, Patel-2008 is missing broad and unequivocal language sufficient to incorporate the entireties of Mastrototaro, Shahmirian, and Causey into its specification. Rather, in each case, Patel-2008 incorporates by reference specific subject matter found in each of those documents. For example, with regard to Mastrototaro (Ex. 1019)⁶, Patel-2008 provides:

⁶ The Petition refers to U.S. patent application 11/322,568 as Mastrototaro Application (Ex. 1020) and contends that “Mastrototaro Publication 2006/0202859 has substantively identical disclosures to Mastrototaro Application 11/322,568.” Pet. at 75, n.5.

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*** 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] (emphasis added). Thus, Patel-2008 incorporates by reference only “a glucose transmitter 125 and a subcutaneous glucose sensor 130 of the type described” in the references cited in paragraph [0033] and nothing more.

With regard to Shahmirian (Ex. 1023), Patel-2008 similarly provides:

The connector 110 may be of the type described in U.S. patent application Ser. No. ***10/335,256*** filed on Dec. 12, 2002 and entitled “Relay Device for Transferring Information Between a Sensor System and Fluid Delivery System,” which is specifically incorporated by reference herein.

Ex. 1015 at [0035] (emphasis added). Thus, Patel-2008 incorporates by reference only “connectors ... of the type described in” Shahmirian and nothing more. In fact,

elsewhere the Petition concedes that Patel-2008 merely “incorporates the connector and communication solutions described in Shahmirian[.]” Pet. at 92.

Finally, with regard to Causey (Ex. 1017), Patel-2008 provides:

The PDA/Smartphone 100 may be selected from any number of devices including the very popular BlackBerry® line of devices manufactured by Research in Motion. Other devices include the popular Treo devices produced Palm, Inc (Treo 600, 650, 680, 700w, 700p, 700wx, 750w), the HTC line of devices (AT&T 8525, AT&T Tilt, T-Mobile Dash, T-Mobile Wing, and the like), the Apple iPhone, and the like. Other devices and connectors are of the type described in U.S. Pat. Nos. 6,558,320 and 6,641,533 entitled “Handheld Personal Data Assistant (PDA) with a Medical Device and Method of Using the Same,” and U.S. patent application Ser. No. 10/429,385 entitled “Handheld Personal Data Assistant (PDA) with a Medical Device and Method of Using the Same,” all of which are specifically incorporated by reference herein.

Ex. 1015 at [0034] (emphasis added). Thus, Patel-2008 incorporates by reference only consumer electronic devices (CED) and connectors of the type described in Causey and nothing more.

Thus, in each case, Patel-2008 follows the Federal Circuit’s formula for incorporating specific subject matter. See *Paice*, 881 F.3d at 907. First, it “identifie[s] with detailed particularity the specific material subject to incorporation.”: (i) glucose transmitters and subcutaneous glucose sensors, (ii)

connectors, and (iii) CEDs and connectors. Next, it explains “where that material can be found”: (i) Mastrototaro, (ii) Shahmirian, and (iii) Causey, respectively. Nowhere does Patel-2008 contain broad and unambiguous language that incorporates the entireties of Mastrototaro, Shahmirian, and Causey into its disclosure like in *Harari* and *Paice*. Consequently, those references are **not** “effectively part of [Patel-2008] as if [they] were explicitly contained therein” as the Petition contends. Pet. at 75.

2. The Petition Fails to Articulate a Legally Sufficient Motivation to Combine Patel-2008 and the Incorporated Disclosures

Petitioner argues that, if Mastrototaro, Shahmirian, and Causey are not expressly part of Patel-2008’s disclosure through incorporation by reference, then a POSITA would allegedly have been motivated to combine them. Specifically, Petitioner argues:

POSITAs would have been motivated to combine Mastrototaro, Shahmirian, and Causey with Patel-2008 because ***each is a Medtronic MiniMed continuous glucose monitoring component referenced by citation.***

Pet. at 83-84 (emphasis added) (citing *Mastercard Int’l Inc. v. Stambler*, CBM2015-00044, Paper 32 at 35 (P.T.A.B. July 6, 2016)). Petitioner’s 12-word explanation for why a POSITA would allegedly combine the references is legally insufficient. Indeed, that “the references came from the same field of study and address the same

problem” is insufficient to establish a motivation to combine. *Comcast Cable Commc’ns, LLC v. Promptu Sys. Corp.*, 838 Fed. Appx. 555, 557 (Fed. Cir. 2021), *cert. denied*, 141 S. Ct. 2721 (2021).

Further, nothing in *Patel-2008* teaches or suggests incorporating these disparate teachings into a single system, as required by the claims. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (“[I]t is not enough that the prior art reference discloses part of the claimed invention . . . or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.”) (citations omitted).

The fact that *Patel-2008* cites each of the references is also insufficient to establish a motivation to combine. The Petition’s reliance on *Mastercard* for this point is misguided. In *Mastercard*, the primary cited reference was Nechvatal. The Board found that the Petitioner carried its burden of articulating a motivation to combine when it explained “that Nechvatal’s hash functions improve signing efficiency and that it would be obvious for a person of ordinary skill in the art to combine the teachings of Davies ‘with Nechvatal to implement an electronic funds transfer system in which the transactions are authenticated by digital signatures, as taught by Davies.’” *Mastercard*, CBM2015-00044, Paper 32 at 34-35. The Board noted that “citation by Nechvatal to these articles [the Davies article] **further supports** Petitioner’s contention that one of ordinary skill in the art would have been

motivated to combine Nechvatal with Davies.” *Id.* at 35 (emphasis added). The citation to the articles was thus “further support,” and was not the only support for an already articulated motivation “to combine Nechvatal with Davies.” *Id.*

Finally, even if the Board determines that Patel-2008 incorporates the entirety of Mastrototaro, Shahmirian and Causey to form a single reference, the Petitioner must nevertheless show that “it would have been obvious to modify that reference to arrive at the patented invention.” *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361 (Fed. Cir. 2016). Separately, “[w]hen obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.” *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582 (Fed. Cir. 1996). The Petition does neither.

3. The Combination of Patel-2008, Mastrototaro, Shahmirian and Causey Does Not Expressly or Inherently Disclose element [1.K] and [1.L]

As explained above, claim elements [1.F] through [1.I], [1.K], and [1.L] collectively require a receiver unit that is configured to output to, and display on, its display a line graph having a gap where, on the same display, the gap is subsequently backfilled by a line graph that fills in at least a portion of the initially displayed gap. *See supra* Section VII.B.1.

The Petition argues that Shahmirian discloses claim element [1.K]. But in doing so, the Petition rearranges sentences in Shahmirian to make it appear as though

Shahmirian discloses the claimed backfilling feature. See Pet. at 101 (citing Ex. 1023 at [0103]). It does not. The table below compares the sequence of Shahmirian’s disclosure with how it is presented in the Petition:

Shahmirian	Petition
“In still other alternative embodiments, the dedicated key 122 (or other dedicated interface) is used to cause the BG monitoring system 20 to send the most recent sensor data, such as one or more raw sensor data points, one or more calibrated sensor measurements, or the like, to the infusion pump 30. Once the sensor data is received, the infusion pump 30 shows the most recent sensor measurement on the display 100.” (Ex. 1023 at [0103]).	“[T]he 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.”
“In particular alternative embodiments, 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]).	“Once the sensor data is received, ... the most recent sensor measurement” is displayed.”

As shown above, Shahmirian first discloses that, in some embodiments, “[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]. Shahmirian then discloses that, “[i]n particular alternative embodiments,” “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.” *Id.* The Petition, however, reorders these statements to create the impression that Shahmirian discloses backfilling data gaps. It does not. Moreover, Shahmirian describes the cited features as “alternative embodiments,” but the Petition ***never argues*** that a POSITA would modify the different embodiments to meet the claimed invention, much less articulate any rational underpinning for doing so. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (“[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”).

For element [1.K], the Petition also contends that Causey “discloses updating display of glucose data to show newly calibrated glucose values and differences with previously displayed data” (*see* Pet. at 101), but does not explain how this meets the claimed “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. It does not.

Indeed, Petitioner does not contend that Causey discloses “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” as required

by claim element [1.I]. See Ex. 1001 at 15:65-16:3; Pet. at 100-101. That is because Causey does not display any gap at all, let alone one that results from an adverse condition. And because Causey does not disclose displaying a data gap, it also does not disclose outputting “processed sensor data ... such that the data gap is backfilled” as required by claim element [1.K]. See Ex. 1001 at 16:8-12. Instead, Causey displays “the data as it was prior to the new calibration” and then “the newly calibrated (or additional calibration) data.” Ex. 1017 15:59-65. Because there is never a displayed data gap, Causey cannot disclose backfilling a displayed data gap.

In a bid to address this deficiency, Petitioner makes two additional arguments for claim element [1.K], neither of which is legally sufficient. First, the Petition asserts that “[a]dditionally, 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 (citing Ex. 1008 at ¶¶ 58-60, 216) (emphasis added). As with other arguments it makes, Petitioner is effectively arguing that claim element [1.K] is inherent in Causey. Pet. at 102 (“POSITAs **would recognize** ...”) (emphasis added). But Petitioner does not explain why the later retransmitted or newly calibrated data would necessarily be used to “fill in missing data gaps” where it, instead, could be used for other purposes such as for historical reports or displaying differences with previously-displayed data. *LBT IP I LLC v. Apple Inc.*, 2023 WL 3914920, at *3 (Fed. Cir. June 9, 2023) (“Inherency ... may

not be established by probabilities or possibilities.”). In fact, Petitioner’s own products, such as the STS-7, and Patel-2008 did not backfill a data gap, and so this feature cannot be inherent in Causey.

The Petition attempts to support its threadbare conclusion by incorporating without explanation paragraphs 58-60, and 216 of the Gross Declaration (Ex. 1008). Precedent precludes the Board from reaching the merits of the incorporated portions of the Gross Declaration. *Cisco Sys., Inc. v. C-Cation Techs., LLC*, 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.”). The Board should disregard Petitioner’s conclusory assertion that improperly attempts to incorporate arguments from the Gross Declaration.

Second, the Petition asserts 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 conclusion should be rejected because it does not explain why POSITAs would have found this obvious or explain how any evidence demonstrates this fact. The Petition’s cite to the same portions of the Gross Declaration discussed above (Ex. 1008 at ¶¶ 58-60, 216) does not save Petitioner’s conclusory assertion regarding obviousness. *Cisco*, IPR2014-00454,

Paper 12 at 10 (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.”).

Even if the Board were to allow Petitioner to rely on Mr. Gross’ attempt to explain why the combination would be obvious, which is found only in his declaration and not in the Petition, the explanation is deficient. The Gross Declaration asserts 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. However, the Gross Declaration provides no evidence that POSITAs would have understood this about displaying previously missing data, especially in view of the evidence that several prior art references and commercial products did not backfill data gaps. The Board should not credit Mr. Gross’s evidence-free assertions. *TQ Delta*, 942 F.3d at 1362 (holding that expert’s “*ipse dixit*” and “conclusory statements” are “inadequate to support the Board’s fact finding regarding motivation to combine.”). In sum, the Petition and the Gross Declaration engage in “the impermissible *ex post* reasoning and hindsight bias that *KSR* warned against.” *Id.* at 1361.

Because neither Causey nor Shahmirian, nor a combination of them, discloses claim element [1.K], the Ground 3 references cannot render claim 1 and its dependent claims obvious.

Finally, with reference to element [1.L], the Petition asserts that “Patel-2008 discloses a glucose line graph with a missing data gap” and cites FIG. 7(a). *See* Pet. at 102. But then the Petition states, with a single sentence:

POSITAs would have found it obvious to display missing data on the same graph when retransmitted or newly calibrated.

Pet. at 102 (citing Ex. 1008 ¶¶ 60, 218). No explanation, reasoning, or evidence is provided for why POSITAs would have allegedly found this obvious. It is simply stated as a fact. 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. And as explained above, Petitioner’s citation to paragraphs 60 and 218 of the Gross Declaration should be disregarded because the arguments “are not made in the Petition, but are instead incorporated by reference to the cited paragraphs . . . of [the expert] [d]eclaration.” *Cisco*, IPR2014-00454, Paper 12 at 10.

In sum, claim 1 has not been shown to be likely unpatentable under Ground 3. Claims 2-12, 14-18, 20-28 and 30 depend from claim 1 and are not likely unpatentable at least because claim 1 has not been shown to be likely unpatentable under Ground 3.

VIII. CONCLUSION

For the foregoing reasons, the Board should deny institution.

Date: November 10, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the Patent Owner's Preliminary Response to Petition for *Inter Partes* Review Pursuant to 37 C.F.R. § 42.107 in connection with *Inter Partes* Review Case IPR2023-01251 was served on this 10th day of November, 2023 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 Preliminary Response has a total of 11,827 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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