

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2023-01251
U.S. Patent No. 11,298,056

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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EXHIBIT LIST

LIST OF NEWLY FILED EXHIBITS

Exhibits concurrently filed with Petitioner's Reply To Patent Owner's

Response:

No.	Description
1050	Eugene Wright, Jr., M.D., et. al., <i>Ambulatory Glucose Profiling</i> , The Journal of Family Practice 64.12 (Supp., 2015)
1051	Excerpt from Wayback Paradigm2
1052	Affidavit of Nathaniel E Frank-White, including Exhibit A ("Supplemental Paradigm REAL-Time Archive")
1053	Deposition Transcript of Eugene E. Wright Jr., M.D. (July 25, 2024)
1054	Deposition Transcript of Aaron Striegel, Ph.D. (July 24, 2024)
1055	Declaration of Andrew Ahmann M.D. In Support of Dexcom's Reply, dated September 4, 2024
1056	Unused
1057	Reply Declaration of Brian D. Gross, dated September 6, 2024
1058	U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Medtronic MiniMed Guardian RT, Premarket Approval P980022/S011, dated July 18, 2005. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf/P980022S011A.pdf on August 26, 2024.
1059	U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Medtronic MiniMed Guardian RT, Summary of Safety and Effectiveness Data (SSED). Retrieved from

No.	Description
	https://www.accessdata.fda.gov/cdrh_docs/pdf/P980022B.pdf on August 26, 2024.
1060	Unused
1061	The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, <i>Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes</i> , New England Journal of Medicine 359:14 (2008)
1062	Richard M. Bergenstal, M.D., et. al., <i>Effectiveness of Sensor-Augmented Insulin-Pump Therapy in Type 1 Diabetes</i> , New England Journal of Medicine 363:4 (2010)
1063	Howard Wolpert, M.D., <i>Establishing a Continuous Glucose Monitoring Program</i> , Journal of Diabetes Science and Technology, 2:2 (2008)
1064	John Mastrototaro, et. al., <i>Accuracy of Real-Time Continuous Glucose Monitoring in the MiniMed Paradigm System</i> , American Diabetes Association 67 th Scientific Sessions, Diabetes 56 (Supp. 2007)
1065	Linkedin Profile of Wesley Scott Harper
1066	Plaintiff's Opening Claim Construction Brief (ECF 135), <i>Abbott Diabetes Care, Inc., et al. v. Dexcom, Inc.</i> , Case No. 1:21-cv-00977-KAJ (July 13, 2022, D. Del.)
1067	Expert Declaration of Majid Sarrafzadeh, Ph.D. in Support of Abbott's Opening Claim Construction Brief (ECF 137), <i>Abbott Diabetes Care, Inc., et al. v. Dexcom, Inc.</i> , Case No. 1:21-cv-00977-KAJ (July 13, 2022, D. Del.) (excerpt)

LIST OF PREVIOUSLY-FILED EXHIBITS

Petitioner previously filed the following exhibits:

No.	Description
1001	U.S. Patent No. 11,298,056 (“the ’056 Patent”)
1002	Excerpts from Prosecution File History of U.S. Patent Application No. 17/411,154 (“Harper ’154 file history”)
1003	Excerpts from Prosecution File History of U.S. Patent Application No. 17/245,719 (“Harper ’719 file history”)
1004	Excerpts from Prosecution File History of U.S. Patent Application No. 16/228,910 (“Harper ’910 file history”)
1005	Excerpts from Prosecution File History of U.S. Patent Application No. 15/061,774 (“Harper ’774 file history”)
1006	Excerpts from Prosecution File History of U.S. Patent Application No. 13/925,694 (“Harper ’694 file history”)
1007	Excerpts from Prosecution File History of U.S. Patent Application No. 12/769,635 (“Harper ’635 file history”)
1008	Declaration of Brian Gross, dated July 24, 2023 (“Gross Decl.”)
1009	Curriculum Vitae of Brian Gross
1010	Affidavit of Nathaniel E. Frank-White (“Internet Archive Affidavit”)
1011	Exhibits A and B to Affidavit of Nathaniel E. Frank-White (“Paradigm® REAL-Time Archive”)
1012	U.S. Patent Application Publication No. 2009/0085768 to Patel et al. (“ <i>Patel</i> -2009”)
1013	Prosecution File History of U.S. Patent Application No. 12/056,651 (“ <i>Patel</i> -2009 file history”)
1014	U.S. Provisional Patent Application No. 60/976,886 (“ <i>Patel</i> -2009 provisional”)

No.	Description
1015	U.S. Patent Application Publication No. 2008/0119705 to Patel et al. (“ <i>Patel-2008</i> ”)
1016	Excerpts from Prosecution File History of U.S. Patent Application No. 11/931,363 (“ <i>Patel-2008</i> file history”)
1017	U.S. Patent No. 6,641,533 to Causey et al. (“ <i>Causey</i> ”)
1018	Excerpts from Prosecution File History of U.S. Patent Application No. 09/935,827 (“ <i>Causey</i> file history”)
1019	U.S. Patent Application Publication No. 2006/0202859 to Mastrototaro et al. (“ <i>Mastrototaro</i> ”)
1020	U.S. Patent Application 11/322,568 to Mastrototaro (“ <i>Mastrototaro</i> ’568 Application”)
1021	Excerpts from Prosecution File History of U.S. Patent Application No. 11/322,568 (“ <i>Mastrototaro</i> file history”)
1022	U.S. Patent Application 10/335,256 to Shahmirian et al. (“ <i>Shahmirian</i> ’568 Application”)
1023	U.S. Patent Application Publication No. 2004/0122353 to Shahmirian et al. (“ <i>Shahmirian</i> ”)
1024	Excerpts from Prosecution File History of U.S. Patent Application No. 10/335,256 (“ <i>Shahmirian</i> ’256 file history”)
1025	Geoffrey McGarraugh, <i>The Chemistry of Commercial Continuous Glucose Monitors</i> , Diabetes Technology & Therapeutics 11.S1 (2009)
1026	U.S. Patent Application Publication No. 2004/0193025 to Steil et al.
1027	C. Choleau et al., <i>Calibration of a Subcutaneous Amperometric Glucose Sensor Implanted for 7 Days in Diabetic Patients: Part 2. Superiority of the One-Point Calibration Method</i> , Biosensors and Bioelectronics 17.8 (2002)

No.	Description
1028	G. Velho et al., <i>In Vivo Calibration of a Subcutaneous Glucose Sensor for Determination of Subcutaneous Glucose Kinetics</i> , Diabetes, American Diabetes Association 1.3 (1988)
1029	John J. Mastrototaro, <i>The MiniMed Continuous Glucose Monitoring System</i> , Diabetes Technology & Therapeutics 2.1 (2000)
1030	U.S. Patent No. 6,424,847 to Mastrototaro et al.
1031	V. Poitout et al., <i>A Glucose Monitoring System for on line Estimation in Man of Blood Glucose Concentration Using a Miniaturized Glucose Sensor Implanted in the Subcutaneous Tissue and a Wearable Control Unit</i> , Diabetologia 36 (1993)
1032	U.S. Patent Application Publication No. 2006/0224109 to Steil et al.
1033	D. Barry Keenan, Ph.D. et al., <i>Delays in Minimally Invasive Continuous Glucose Monitoring Devices: A Review of Current Technology</i> , Journal of Diabetes Science and Technology 3.5 (2009)
1034	Unused
1035	S. Armstrong, <i>Wireless Connectivity for Health and Sports Monitoring: a Review</i> , British Journal of Sports Medicine (2007)
1036	Alexandros Pantelopoulos & Nikolaos Bourbakis, <i>A Survey on Wearable Biosensor Systems for Health Monitoring</i> , 30th Annual International Conference of the IEEE EMBS Conference (2008)
1037	Excerpts from Diabetes Forecast, November 2007
1038	Excerpts from Diabetes Forecast, February 2007
1039	Bruce Buckingham et al., <i>Real-Time Continuous Glucose Monitoring</i> , Current Opinion in Endocrinology, Diabetes & Obesity 14.4 (2007)

No.	Description
1040	Bruce Buckingham, M.D., <i>Clinical Overview of Continuous Glucose Monitoring</i> , Journal of Diabetes Science and Technology 2.2 (2008)
1041	U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Paradigm Real Time System, Premarket Approval, dated April 7, 2006. Retrieved from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P980022S013 on July 21, 2023.
1042	Excerpts from Steven W. Smith, <i>The Scientist and Engineer's Guide to Digital Signal Processing</i> , California Technical Pub. (1997)
1043	B.A. Sheno, <i>Introduction to Digital Signal Processing and Filter Design</i> , John Wiley & Sons (2006)
1044	Medtronic Inc., News Release: Medtronic Receives FDA Approval for World's First Insulin Pump with Real-Time Continuous Glucose Monitoring, dated April 13, 2006. Retrieved from https://web.archive.org/web/20060427084431/http://wwwp.medtronic.com:80/Newsroom/NewsReleaseDetails.do?itemId=1144875806140&lang=en_US on July 21, 2023.
1045	Marc D. Breton Ph.D. et al., <i>Optimum Subcutaneous Glucose Sampling and Fourier Analysis of Continuous Glucose Monitors</i> , Journal of Diabetes Science and Technology 2.3 (2008)
1046	Mark R. Burge, MD et al., <i>Continuous Glucose Monitoring: The Future of Diabetes Management</i> , Diabetes Spectrum 21.2 (2008)
1047	Adam Heller & Ben Feldman, <i>Electrochemical Glucose Sensors and Their Applications in Diabetes Management</i> , Chem. Rev. 108 (2008)
1048	U.S. Patent No. 5,391,250 to Cheney et al.
1049	List of Challenged Claims

I. INTRODUCTION

While the challenged claims are long, the supposed “innovation” is simple and common sense: display or “backfill” previously missing data in a line graph, once that data becomes available. The prior art teaches doing this with the same conventional CGM system and functions recited in the claims.

With respect to Grounds 1 & 2, PO disputes only elements 1.K (displaying backfilled data) and 1.L (in a second line graph). There is no dispute that Paradigm REAL-Time (EX1011) (hereinafter, “Paradigm”) teaches displaying CGM data as a line graph in 3-hour and 24-hour “History” trend graphs on the pump display; no dispute that an adverse condition (e.g., weak signal) results in the pump not receiving data for a period of time and displaying a data gap in the trend graphs to indicate the missing data; and no dispute that, once the adverse condition is resolved, Paradigm teaches *receiving and storing* the missing data on the pump. The dispute is whether Paradigm teaches that repopulated data is displayed on the trend graphs. It does, and the claims are obvious.

For Ground 3, PO disputes only elements 1.I, 1.K and, 1.L. In addition to repeating its Ground 1/2 arguments, PO challenges formalities, e.g., arguing no incorporation by reference. These arguments also fail.

PO’s dependent claim arguments also fail, and all challenged claims should be found unpatentable and canceled.

II. ALL CHALLENGED CLAIMS UNDER GROUNDS 1 AND 2 ARE OBVIOUS

For Grounds 1 and 2, PO does not mention, let alone dispute, the “motivation” to apply Paradigm’s teachings to Patel-2009; nor does PO challenge the reasonable expectation of success in displaying repopulated data in trend graphs on the pump/receiver display.

PO admits that Paradigm “teaches re-populating [CGM] data in the pump’s memory” (POR, 18) and that historical “data was viewable as a trend graph on the pump” for a rolling 24 hours (*id.*, 21). *See also* EX2013, ¶177; EX1011, 64. PO’s sole argument is that POSITAs would expect the pump to deviate from normal operation and withhold available data from users, supposedly because that data could also be viewed at later times using separate hardware running separate software. This strained reading fails because any plausible read of Paradigm teaches the display of backfilled data as claimed in Elements 1.K and 1.L.

A. The Patel-2009/Paradigm Combination Satisfies Element 1.K

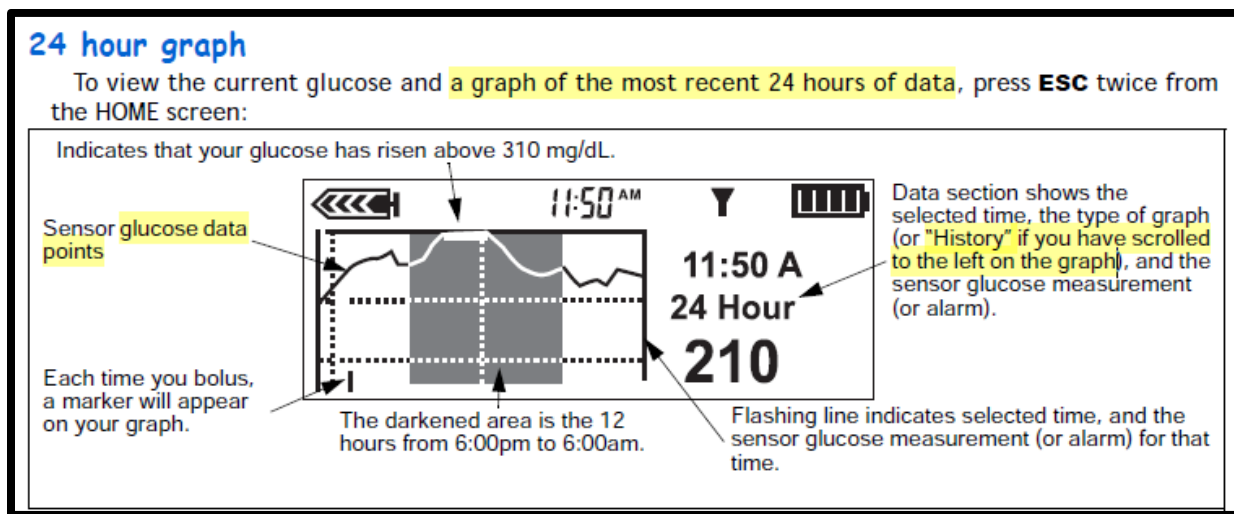
Paradigm teaches display of *repopulated* data in trend graphs and does not cabin the use of repopulated data to storage in memory alone for later use in PDFs viewed on a separate device. Rather, Paradigm emphasizes the utility of the trend graphs in making real-time treatment decisions, confirming the benefit of timely displaying repopulated data in trend graphs on the pump. *E.g.*, EX1011, 9 (“[Trend

graphs] allow you to be proactive in your diabetes treatment ... and take action much earlier.”).

Display of repopulated data is what POSITAs would understand from a plain reading Paradigm, and expert testimony confirms that plain reading.

1. **Paradigm Teaches Displaying Repopulated Data In Its Trend Graphs**

Paradigm describes displaying graphs of “the most recent 24 hours of data” and “the most recent three hours of data” on the pump receiver unit. EX1011, 64. These 3- and 24-hour trend graphs show “glucose data points,” displaying the word “History” when a user scrolls to look at past glucose values.



EX1011, 64 (highlighting added).



Id., 30.

Two Paradigm FAQs on page eight also describe repopulating data. One states the transmitter “holds 40 minutes worth of memory” so that “continuous glucose monitoring (CGM) data can be re-populated in the insulin pump.” EX1011, 8 (hereinafter “First FAQ,” which begins “How much data ...”). The next FAQ describes *displaying* CGM data, and notes what data will be repopulated:

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.***

EX1011, 8 (emphases added) (hereinafter, “Second FAQ”) (quoted by Paper 11 (“DI”), 31); *see also* Pet. (Paper 3), 25-28, 45; EX1008, ¶76; Paper 9, 2. The first sentence describes how CGM “data will be displayed on the insulin pump’s screen” so long as the pump and transmitter are within 6 feet. EX1011, 8. In this context of

displaying, the next sentence states that “the last 40 minutes will be re-populated.” *Id.* Given that the trend graphs display the “most recent 24 [or 3] hours of data” (EX1011, 64), in context, the two FAQs teach that—after resolution of an “out-of-range” condition—a data gap of up to 40 minutes is repopulated on the trend graphs displayed on the screen of the pump.

PO suggests that “one would expect the user guide to teach users about such an important feature if it existed.” POR, 23-24. But it *is* taught. When Paradigm teaches that its trend graphs display “the most recent 24 [or 3] hours of data,” the expected behavior is the *display of all data, including repopulated data*. EX1055, ¶¶ 32-39; EX1057, ¶¶40-46.

The FAQs predictably explain when data would be *missing*, and when data would *not be displayed*. EX1011, 8, 30, 64. If there were an exception to normal operation that excluded available, repopulated data from the trend graphs, one would expect the FAQ to have noted that too. EX1055, ¶36; EX1057, ¶¶45-46. But, there was no reason for Paradigm to belabor expected behavior (displaying *all* stored data).

Any reader would expect that all available data for a given 3- or 24-hour period—including repopulated data—is displayed in the trend graphs. This natural reading aligns with Paradigm’s description of the benefits of providing continuous real time data to users. EX1055, ¶¶36-39; EX1057, ¶¶42-44; EX1011, 9 (trend

graphs “[a]n important benefit” that “help you manage your diabetes more effectively”), 15 (trend graphs “help you understand more about your glucose control”), 18 (“help prevent lows and highs”). It also aligns with the known benefits of providing as much accurate CGM data to patients as possible. EX1008, ¶¶60, 80; EX1055, ¶¶47-62.

2. Paradigm Does Not Restrict Display Of Repopulated Data; Patent Owner’s Focus On CareLink Is Misplaced

PO argues against this normal operation, based on a constrained reading of “historical reports.” POR, 3-4, 18. But historical reports are not limited to later access of data on a separate device running CareLink software. And even if *arguendo* “historical reports” were limited to CareLink PDFs, that would not diminish Paradigm’s teaching to display repopulated data in the trend graphs. EX1055, ¶¶40-46; *see also supra* Section II.A.1. The FAQs warn that *missing* data will not be viewable in “historical reports.” They do not suggest that *available* data stored on the pump (original and repopulated) would be withheld from display on the “History” trend graphs. EX1011, 30, 64.

Moreover, the FAQs do not even mention CareLink, much less uniquely associate “historical reports” with CareLink or limit the import of the FAQs to CareLink. To argue otherwise, PO dodges the portion of the Second FAQ emphasized in the Institution Decision (Paper 11, 31), focusing instead on the last

sentence of the First FAQ. *See* POR, 13 (asserting there is only a “single statement” in “a[n] ... FAQ”), 17-18, 20 (mischaracterizing second FAQ only to distinguish first). The First FAQ’s failure to mention outputting backfilled glucose data to the display (POR, 18) is unsurprising, as the “Q” in that FAQ ends with, “will I lose my data?” *not* “will my lost data be displayed?” EX1011, 8.

Notably, PO fails to squarely address the Second FAQ’s language that explicitly teaches “(CGM) data will be displayed on the insulin pump’s screen” and “only the last 40 minutes will be re-populated” after an out-of-range event. EX1011, 8 (quoted by Paper 11, 31); *supra*, 4; EX1057, ¶47.

The use of “historical reports” in a third FAQ (POR, 20-21) does not diminish Paradigm’s teachings. This third FAQ relates to airplane flights, where the transmitter is disconnected from the sensor entirely and thus collects no data, as distinct from the first two FAQs, which contemplate displaying up to 40 minutes of repopulated data. EX1011, 12-13. The third FAQ informs users that when the transmitter is disconnected from the sensor, information will be “missing” and “[w]hen downloading data and reviewing historical reports, you will notice ‘data gap.’” *Id.* In this FAQ’s scenario, there simply is no repopulated data. And the mention of “downloading data” in conjunction with “historical reports” merely provides two different example scenarios when data gaps might appear, and the third FAQ does not restrict “historical reports” to only data later “downloaded” to

CareLink. Like the two FAQs above, the third FAQ neither mentions CareLink nor appears in a section on CareLink. EX1057, ¶48. Moreover, the first two FAQs reference “historical reports” without mention of “downloading,” indicating that “historical reports” encompasses any display of historic data, including CGM “History” on trend graphs. Thus, even if downloaded data were somehow tied to CareLink, “historical reports” are not limited to downloaded data and include historical trend graphs displayed on the pump.

Finally, each FAQ discusses “historical reports” in sections *that do not mention* CareLink. *E.g.*, DI, 31. And the CareLink FAQs (EX1011, 11-12) and CareLink guide (EX2007) *never* discuss “historical reports.” Meanwhile, the 3-hour and 24-hour trend graphs allow users to view and scroll through *historical* sensor glucose data points and alarms. EX1011, 64 (cited by DI, 28-29). Thus, reference to “historical reports” in the FAQs does not limit those FAQs as only relevant to CareLink. EX1057, ¶49.

3. PO Arguments Regarding 31-Day History Only Confirm That Paradigm Teaches The Claimed Backfill

In discussing Paradigm’s 31-day history, PO admits what it cannot dispute: that ***24 hours of historical data is viewable as a trend graph on the pump.*** POR, 21 (“[T]here is nothing in the cited art that suggests the [historical] data was viewable as a trend graph on the pump beyond a rolling 24 hours.”). Here, 24 hours is enough

to satisfy the claims, as the only temporal limitations related to data (as opposed to power) are in claims 23 (one hour) and 26 (12 hours). EX1001, 15:24-18:28.

The Institution Decision did not conflate personal history and trend graphs (POR, 21-23) but rather briefly cited a passage regarding personal history (DI, 28) as part of a much longer explanation of how Paradigm teaches display of 3- and 24-hour histories, supported by many additional citations to Paradigm (DI, 28-31).

**4. A POSITA Would Simply Display
Available CGM Data From Receiver Memory**

PO also argues that a Paradigm-like system could be implemented to avoid displaying repopulated data on the pump. POR, 23; EX2015, ¶47. Even if such an implementation were possible, it does not undermine Paradigm’s teachings to display repopulated data on trend graphs on the pump. EX1057, ¶¶9-21.

PO’s expert (Dr. Striegel) admits that “an absence of data” due to, e.g., an out-of-range condition, “would likely appear as a data gap on the screen.” *Id.*, ¶49. He also admits that the device receives and stores repopulated data. *Id.*, ¶50. Striegel proposes an architecture that includes a volatile display buffer to “feed the display” and a long-term non-volatile memory storing “historical data” that could be *inter alia* “accessed for retrieving discrete data values.” EX2015, ¶¶42-43; EX1057, ¶14. Data stored in such a conventional architecture could *both* be downloaded to a PC *and* accessed and displayed by the pump receiver unit. EX2015, ¶¶42-43.

Striegel errs when he opines—*without explanation of why repopulated data would be treated differently*—that when the “pump receives missing data,” “the data would be stored in the long-term memory” but “would still be missing” from the display buffer. *Id.*; ¶50, EX1057, ¶¶11-17. He purports to support his theoretical design with a discussion of screen size. EX2015, ¶¶51-56. But his pixel size opinions are unsupported; at deposition he could not explain their basis. EX1054, 93:19-98:2; EX1057, ¶¶22-25.

Dr. Striegel also handwaves about supposed “processing costs and power.” EX2015, ¶56. His lack of evidence or explanation confirms that any supposed *additional* processing and power is suspect, especially since the pump is continuously receiving data every five minutes (EX1011, 83), and updating the display accordingly (*id.*, 8). *See also* EX1057, ¶¶13-14, 17-19. While Striegel suggests that these “costs” would influence how a POSITA interpreted Paradigm¹, he admits to at least a “limited benefit for backfilling a data gap” and confirms that the repopulated data was consequential, as 40 minutes would occupy over 20% of the 3-hour trend graph. EX2015 ¶¶54-56; *see also* EX1057, ¶24 (multiple weak signals would lead to a higher percentage). In other words, even if *arguendo* there

¹ Striegel’s proposed implementation would create offsetting inefficiencies. EX1057, ¶¶16-19.

were negligible tradeoffs in processing or power, the POSITA would accept those tradeoffs for the benefit provided by more informative trend graphs. EX1057, ¶¶18-21; EX1055, ¶¶76-81.

PO also argues that in 2009, CGM’s “inaccurate” data counsels a different reading of Paradigm. POR, 28. But even in 2009, CGM provided patients with clinical benefits not available from fingersticks alone and resulted in better clinical outcomes. EX1055, ¶¶76-81; EX1011, 9; EX1044. Moreover, PO fails to explain why there would be any added disincentive to display *repopulated* data; as the alleged “inaccuracy”² would also apply to original data, which was indisputably displayed. EX1055, ¶¶34-39.

Finally, delaying one or more cycles before displaying data is consistent with the desire to provide as much accurate data as possible to PWDs. EX1008, ¶¶129, 44. PO’s alleged inconsistency (POR, 29) is unavailing because, as Gross describes, any slight delay associated with data processing for any received data (e.g., filtering noise, averaging) enhances the accuracy of the data. EX1008, ¶44.

² PO’s argument is based on a 2004 study; by 2007, Paradigm was 23% more accurate. EX1055, ¶¶63-65.

**5. PO's Other Arguments Do Not Undermine
Paradigm's Teachings To Display The Repopulated Data,
And Evidence Cited by PO Actually Confirms Obviousness**

PO's arguments that FDA guidance, old Dexcom products, or 2016-era design choices impact the 2009 interpretation of prior art publications are also unavailing. POR, 27-31.

**a) The Adjunctive-Use-Only
Regulatory Approvals Confirm Obviousness**

Mr. Gross explained the motivation “to detect missing or inaccurate glucose data and convey as much accurate glucose information to a user as possible.” EX1008, ¶80 (explaining that the “purpose of continuous glucose monitoring is *to assist* in diabetes management, insulin dosing decisions”) (emphasis added); *see also* Pet., 29, 66. Dr. Ahmann corroborates those opinions. EX1055, ¶¶24-30.

PO criticizes Gross because CGM devices were approved only for use in conjunction with “supplemental fingerstick measurements.” POR, 27-28. But these arguments ***confirm*** Gross's opinions that POSITAs would have wanted to provide up-to-date CGM data (e.g., through backfilling trend graphs) to assist PWDs in making in-the-moment decisions, such as when to perform a fingerstick reading. *See* EX1053, 41:3-10; EX1057, ¶34. The FDA approved Paradigm in 2006 “for the purpose of improving diabetes management,” by, among other things, “provid[ing] real-time glucose values . . .” EX1058, 1; EX1041; EX1055, ¶¶29, 51; EX1057,

¶¶51-52. This specifically contemplates that CGM data would be provided to and used by patients. EX1055, ¶¶50-51; *see also id.*, ¶¶47-49 & 52-62; EX1011, 9 (“[Trend graphs] allow you to be proactive ...” and helped users “discover when is the best time to take a fingerstick”), 24; EX1052, 17, 27; *see also* Paper 9, 3. Other Paradigm documentation further supports that the CGM data displayed in the trend graphs is the same as the CGM data later available via the CareLink software. EX1008, ¶¶60, 80; EX1057, ¶50; EX1055, ¶45.

The obviousness inquiry is not limited by the legally separate regulatory process. *Sandoz Inc. v. Abbvie Biotechnology Ltd.*, IPR2017-02106, Paper 13 at 33 (PTAB Apr. 3, 2018) (“[a]n obviousness inquiry ... is not limited to what has gained or could gain FDA approval”); *see also Bayer Pharma AG v. Watson Labs., Inc.*, 874 F.3d 1316, 1326 (Fed. Cir. 2017). Nonetheless, here the regulatory indications confirm a POSITA’s desire to *display* repopulated glucose data *to assist* PWDs with the management and adjunctive treatment of diabetes. EX1057, ¶44; EX1055, ¶39.

**b) Petitioner’s Patents And Products Do Not
 Disprove Obviousness; If Anything, They Confirm It**

PO incorrectly suggests (POR, 29-31) that 2016-era DexCom patents undermine that displaying backfilled data was obvious in 2009, based on pre-2009 publications. To the extent relevant, DexCom’s later patents show that displaying backfilled data was a well-known design choice, thus supporting Gross’s opinion

that doing so was obvious. The '640 Patent describes a system with three options for backfilled data: display it, do not display it, or display it differently (e.g., in a different color). EX2023, 2:6-12, 28:20-24, 28:51-62. It suggests that the default would be to display all data, but provides some reasons one *may* choose to block the display of backfilled data on *some* display devices. *Id.*, 28:32-36, 28:51-56. The '668 Patent described embodiments where the “the backfill data may be presented automatically,” (EX2024 at 6:1-2), and others that omit backfill data or display it differently. *Id.* at 5:1-6:31.

Dexcom’s old products are also irrelevant to obviousness over Paradigm. *Cf. Semiconductor Components Indus., LLC v. Power Integrations, Inc.*, IPR2016-00809, Paper 65 at 4 (PTAB Aug. 4, 2017) (denying discovery because “physical devices that may, or may not, implement features” are irrelevant to what a publication taught). And warnings that CGMs were “not designed to replace a blood glucose meter” (PO, 29) do not undermine Gross’s opinions about the benefits of displaying CGM data. *Supra*, Section II.A.5.a. PO’s conclusory statements that if something were obvious, an old product would have “solved it” (POR, 29), ignores the very nature of the obviousness inquiry.³ Especially so here, when the Paradigm literature shows the problem was solved.

³ PO does not raise, much less establish, any secondary considerations theory.

**c) PO's Arguments Are Not Grounded
In Relevant Experience Or Reliable Sources**

PO's arguments also suffer because Dr. Wright lacks experience during the relevant 2009 timeframe. Dr. Wright treated type-2 diabetes and apparently began using CGMs for that purpose no earlier than 2015. EX1053, 54:3-25, 39:16-40:10; EX1055, ¶¶21, 30, 58. His opinions thus resort to interpretations of summary articles published between 2017-2023. *E.g.*, EX2013, ¶¶57-58, 78, 81 (citing EX2025, EX2016). DexCom's responsive clinician expert, Dr. Ahmann, helped PWDs treat and manage type-1 diabetes using CGM in the relevant 2004-2009 timeframe. EX1055, ¶¶6, 21, *see generally id.*, ¶¶4-8. He explains deficiencies in Dr. Wright's opinions, such as improperly discounting benefits and uses of CGM (*id.*, ¶¶ 47-49, 52-62, 76-83), mis-assessing CGM accuracy in 2009 (*id.*, ¶¶65-75), and misunderstanding approved uses of Paradigm (*id.*, ¶¶50-51). *See also* EX1055, ¶31.

d) Mr. Gross Is A POSITA

PO attempts to discredit Gross who, like the inventor of the '056 patent⁴, is not a "clinician." POR, 26-27. It is undisputed that Gross meets the basic POSITA

⁴ Sole named inventor Harper has a B.S., Bioengineering. EX1065. Gross has a B.S., Electrical and Biomedical Engineering, and a M.S., Biomedical Engineering. EX1008, ¶¶4-5. *Cf. Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005)

definition, with a M.S. in biomedical engineering, deep experience developing systems for measuring biomedical signals, and broad working knowledge of glucose monitoring technology. EX1008, ¶¶51, 54, 4-8; EX1057, ¶¶8, 26-27.

PO's expert, Dr. Wright, suggests a conflicting standard⁵, but acknowledged Gross would qualify as a POSITA if "he had worked on a ... team with a clinician," (EX1053, 31:20-25) or "been provided with clinical background in rendering his opinions," (*id.* 33:17-25). Gross *does have experience* working on interdisciplinary teams with clinicians, including designing prior art medical devices that employed backfilling, *and he does* support his opinions with research by clinicians. EX1008, ¶¶4-8, 60, 80; EX1009; EX1039; EX1040. His education and experience make him more than qualified to opine on the perspective of a POSITA working on a team with clinicians. EX1057, ¶¶29-32. To the extent Gross required input from a clinician, it is provided by Dr. Ahmann, a clinician with extensive experience using CGM to

(en banc) (referring to "well-settled understanding that inventors are typically persons skilled in the field"); *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1368 (Fed. Cir. 2002).

⁵ A different Abbott expert, in a proceeding on related patents (*infra* 24-25, n.6) opined, like Gross, that a POSITA "may" be on a team with a clinician. EX1067, ¶¶33-34.

assist type-1 PWDs manage diabetes. EX1055, ¶¶6, 21, 47-49, 53, 55; *see generally id.*, ¶¶18-23; EX1057, ¶28.

e) **Mr. Gross's Opinions Are
Informed By The Prior Art, Not Hindsight**

Gross's opinions (including EX1008, ¶¶54-61) describe a POSITA's skill set and knowledge base. Contrary to PO's assertion of "no evidentiary support" (POR, 27), Gross roots his opinions in his experience *and* prior art teachings. EX1057, ¶¶35-39. Indeed, paragraphs 54-61 cite to nine prior art references. He cites five references in opining, "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." EX1008, ¶60; EX1057, ¶32; *see also id.*, ¶33.

B. **Paradigm Teaches Display Of Data As A Line In The
Trend Graphs, And The Combination Satisfies Element [1.L]**

Element [1.L] adds one thing: the backfilled data gets displayed *as a line*. PO does not dispute that the combination teaches displaying sensor data as a line, [1.H]. Nor does PO contest that the combination teaches displaying a data gap in that line corresponding with an adverse condition, [1.I]. As shown in the discussion of [1.K] above, Paradigm depicts 3- and 24-hour "History" trend graphs, with both original and repopulated data graphed *as a line*. *Supra* 3-4; EX1011, 30, 64, 73; *supra* 4-6. Accordingly, these same disclosures teach element [1.L]. *See Echelon Fitness Multimedia, LLC v. Peloton Interactive, Inc.*, IPR2020-01541, Paper 16 at 26-27

(PTAB Mar. 3, 2021); *Motorola Mobility LLC v. Maxell, Ltd.*, IPR2022-01348, Paper 7 at 35-36 (PTAB Feb. 24, 2023); *see also* DI, 33 (“Petitioner nevertheless adequately alleges that Paradigm REAL-Time teaches or suggests that a data gap in the line graphs is re-populated to the screen of the insulin pump”).

Petitioner relies not “only” on images in chapters 5 and 6 (POR, 33), but also other Paradigm teachings on trend graphs that display all available CGM data (including repopulated data) as a line, and testimony from Gross and Ahmann on how a POSITA would understand those teachings. DI, 33; Pet., 31-45; *supra*, Sections II.A.1-2.

Further, Gross explains that “POSITAs would have found it obvious to display previously missing data by filling-in/re-populating” analyte graphs. EX1008, ¶60; *see also* EX1057, ¶5. Where a disputed limitation ([1.L.]’s displaying data as a line) simply repeats an undisputed element ([1.H.]’s “output to the display . . . a first line graph. . .”), expert testimony is sufficient because [1.L.]’s limitation “simply recites repetition of a known procedure.” *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1330 (Fed. Cir. 2009). Thus, even standing alone (it was not), Gross’s testimony would be enough to establish [1.L.]’s displaying data in a graph as a line.

III. ALL CHALLENGED CLAIMS UNDER GROUND 3 ARE OBVIOUS

The challenged elements (I, K and L) are all satisfied by the combination, and Patel-2008's proper incorporation by reference *and* Gross's articulated motivation to combine each forms a sufficient basis to render the claims obvious.

A. Patel-2008 Incorporates Mastrototaro, Shahmirian, And Causey, And It Also Would Have Been Obvious To Combine Them

Patel-2008 incorporates by reference the Mastrototaro, Shahmirian, and Causey references (Pet., 74-75), making each “effectively part of [Patel-2008] as if [they] were explicitly contained therein.” *Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 906 (Fed. Cir. 2018).

Unlike *Zenon Environmental* (cited by POR, 39-40), Patel-2008's incorporations are not limited to “relevant disclosures” but instead use broad language that incorporates each of the references in their entirety. *See Harari v. Lee*, 656 F.3d 1331, 1335 (Fed. Cir. 2011); EX1015, [0033] (“are specifically incorporated by reference herein”), [0034] (same), [0035] (“is specifically incorporated by reference herein”). This is unchanged by surrounding language that suggests an incorporated reference describes a particular subject matter. *Monolithic Power Sys. Inc. v. Volterra Semiconductor LLC*, IPR2020-01348, Paper 19 at 11-12 (PTAB Mar. 4, 2021). And even were this not the law, PO has not shown that Shahmirian's teachings cited for elements [1.D], [1.F], and [1.I]-[1.K] are unrelated

to “communication solutions” between medical and consumer devices. EX1015, [0035]. The same applies for Mastrototaro and Causey.

PO’s alternative argument that Patel-2008 incorporates too many references also fails. POR, 41-42. First, there is no requirement to provide extra guidance for multiple incorporations. *Cf. Regents of the Univ. of Minnesota v. AT&T Mobility LLC*, No. CV 14-4669 (JRT/TNL), 2024 WL 758541, at *7 (D. Minn. Feb. 23, 2024) (rejecting arguments that the specification incorporated too many references, in the context of the “original patent rule” for reissued patents). Second, PO ignores the guidance that Patel-2008 does provide. For example, for Causey, Patel-2008 described all three incorporated references (which shared identical specifications) as illustrating the PDA/Smartphone aspect of a diabetes management system. EX1015, [0034]; *see also* Pet., 97-99.

Here, Patel-2008 also provides the motivation to combine in paragraphs [0033]-[0035]. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 664-65 (Fed. Cir. 2000) (“motivation to combine may be found explicitly or implicitly ... in the prior art references themselves”); *Resmed, Inc. v. New York Univ.*, IPR2022-00992, Paper 67 at 58 (PTAB Dec. 7, 2023). Moreover, Gross’s testimony supported this, including that “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* as expressly incorporated into the

diabetes management system of Patel-2008.” Pet., 83-84 (citing EX1008, ¶¶60, 191-192). It is also corroborated by Dr. Ahmann. EX1055, ¶25.

**B. [1.I] And [1.K]: The Combination Teaches
Both A “Missing Data Gap” Upon Detection
Of “Missing Data,” And Displaying Repopulated Data**

For elements [1.I] and [1.K], PO disputes obviousness based on a combination, by improperly attacking references individually. *In re Universal Elecs., Inc.*, No. 2022-1716, 2023 WL 5219774, at *7 (Fed. Cir. Aug. 15, 2023) (“[n]on-obviousness cannot be established by attacking [the] references individually.”)

For element [1.I], Patel-2008 teaches confirming receipt of data and “show[ing] a blank white space” (a gap) “during the time no data was received.” EX1015, [0056]-[0057]. Patel-2008 and the incorporated references teach that communication failures and calibration errors result in missing data. *Id.*; EX1023, [0102], [0111]; EX1017, 22:28-45. The combination teaches [1.I], as Patel-2008’s gap results from such communication failures and calibration errors. POR, 48-50; *cf.* EX2015, ¶49 (PO expert opining that “an absence of data would likely appear as a data gap on the screen”).

For element [1.K], the restoration of missing data is taught by Shahmirian’s retransmission of “any additional sensor data” not received (EX1023, [0103]) and Causey’s “updated trend and glucose level data” to show “newly calibrated ... data.”

EX1017, 15:59-65. Patel-2008, Shahmirian, and Causey all teach that data, including historical data, is displayed to the user. EX1015, [0038], [0052]; EX1023, [0101] (“older and older sensor measurements to be shown on the display”); EX1017, 15:51-56 (“graphs of historical data”). While PO admits that Shahmirian teaches “that the system displays data, which is to be expected during normal operation” (POR 51), it returns to its illogical Ground 1 argument that retransmitted data can *only* be reviewed in subsequent, downloaded reports. As explained above, nothing about the availability of data for subsequent download negates the “normal operation” of displaying, on the pump, all stored data. *Supra*, Section II.A.1-2.

PO’s suggestion that it is impermissible to combine alternative embodiments is unfounded when, as here, the embodiments are discussed in the same paragraph. EX1023, [0103]; *Bos. Sci. Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991 (Fed. Cir. 2009) (finding combination of “two embodiments disclosed adjacent to each other in a prior art patent” was predictable variation); *Apple Inc. v. Gesture Tech. Partners, LLC*, IPR2021-00921, Paper 24 at 25-26 (PTAB Dec. 5, 2022).

**C. [1.L]: POSITAs Would Find It
Obvious To Graph Missing Data As A Line**

As discussed above (*supra* Section II.B), element [1.L]’s addition of graphing backfilled data as a “second line graph” should be considered in context of [1.H], [1.I], and [1.K]. *E.g.*, *Echelon Fitness*, IPR2020-01541, Paper 16 at 26-27. In the

context of filling the gap in Patel-2008’s line graph (Pet. 99-100 (discussing [1.H] and [1.I])), a POSITA would have displayed the missing data as a line on the same graph. Pet. 102; EX1008, ¶¶217-18. Alternatively, POSITAs would have “display[ed] [glucose] information to the patient” according to Patel-2008’s normal line graph operation or would have at least found it obvious to try. *E.g., Perfect Web*, 587 F.3d at 1330-31; *supra* Section II.A.1-2.

IV. ALL CHALLENGED DEPENDENT CLAIMS ARE OBVIOUS

PO raises no separate disputes as to claims 2, 3, 8-12, 14-20, 22-28, or 30.

A. Claim 4

PO contends that Causey only teaches continuing to display glucose data awaiting new calibration and does not teach stopping this display for any reason, including when calibration is delayed. POR, 58-59. PO’s emphasis on the “additional calibration” of data previously calibrated is mistaken, as Causey also teaches that updates show “newly ... calibrated data.” EX1017, 15:43-65. Contrary to PO’s argument, Causey is not limited to previously calibrated data, but encompasses the delayed calibration of uncalibrated data that is not displayed during the delay. Therefore, despite asserting that “Petitioner assumes ... data that was not calibrated ... could not be displayed” (POR, 58), PO does not assert that uncalibrated data is displayed. Indeed, this “assumption” is taught by Causey’s updated display of previously uncalibrated data when “newly calibrated.” Pet., 67 (focusing on

“newly calibrated data”); EX1008, ¶59 (“failure to calculate analyte concentrations would ... lead to the inability to display this missing data”). Therefore, when the calibration is delayed due to faulty or interrupted readings, Causey teaches or suggests that data is not displayed until newly calibrated.

Besides, the Patel-2009/Paradigm/Causey combination of Ground 2 performs calibration on the transceiver, only transmits calibrated data, and displays missing data as a data gap. EX1012, [0013], [0042], [0084]; EX1011, 73. Likewise, the Patel-2008/Mastrototaro/Shahmirian/Causey combination of Ground 3 performs calibration on the monitoring devices (*i.e.*, transmitter) and communicates “calibrated sensor measurements.” EX1023, [0106], Fig. 5(c). In these combinations, uncalibrated data cannot be displayed because it is never transmitted to the display device. PO cannot establish non-obviousness by attacking Causey individually. *In re Universal Elecs.*, 2023 WL 5219774, at *7.

B. Claims 5-6

Contrary to PO’s arguments (POR, 59, 61), the Petition shows how weak signal / out-of-range events and other communication failures satisfy the claimed “signal error.” Notably, in district court briefing⁶, PO identified “out of range”

⁶ This briefing addressed patents (10,820,842 and 10,952,653) with the same priority claim and materially identical written descriptions as the ’056 patent. EX1066, 8,

scenarios as an example of “signal errors associated with the ... transmitter unit [or] receiver unit.” *See* EX1066, 39; *see also* EX1067, ¶103. As reflected in Abbott’s understanding of “signal error,” radio frequency communication between the transmitter and receiver occurs via transmission and reception of wireless *signals*. Indeed, every reference in Grounds 1 and 3 discusses the communication of wireless signals between a transmitter and receiver. *E.g.*, EX1011, 51; EX1012, [0077]; EX1015, [0045]. Therefore, the Petition’s identification of out-of-range, interference, and other communication errors that disrupt wireless signals sufficiently identifies “signal errors” associated with the transmitter and receiver. For example, Ground 1 discusses how signal interference results in a “Weak Signal alarm indicating failed reception.” Pet., 50. Gross further explains these wireless signals (*i.e.*, RF signals) and associated signal errors. *E.g.*, EX1008, ¶¶58, 119, 207.

C. Claim 7

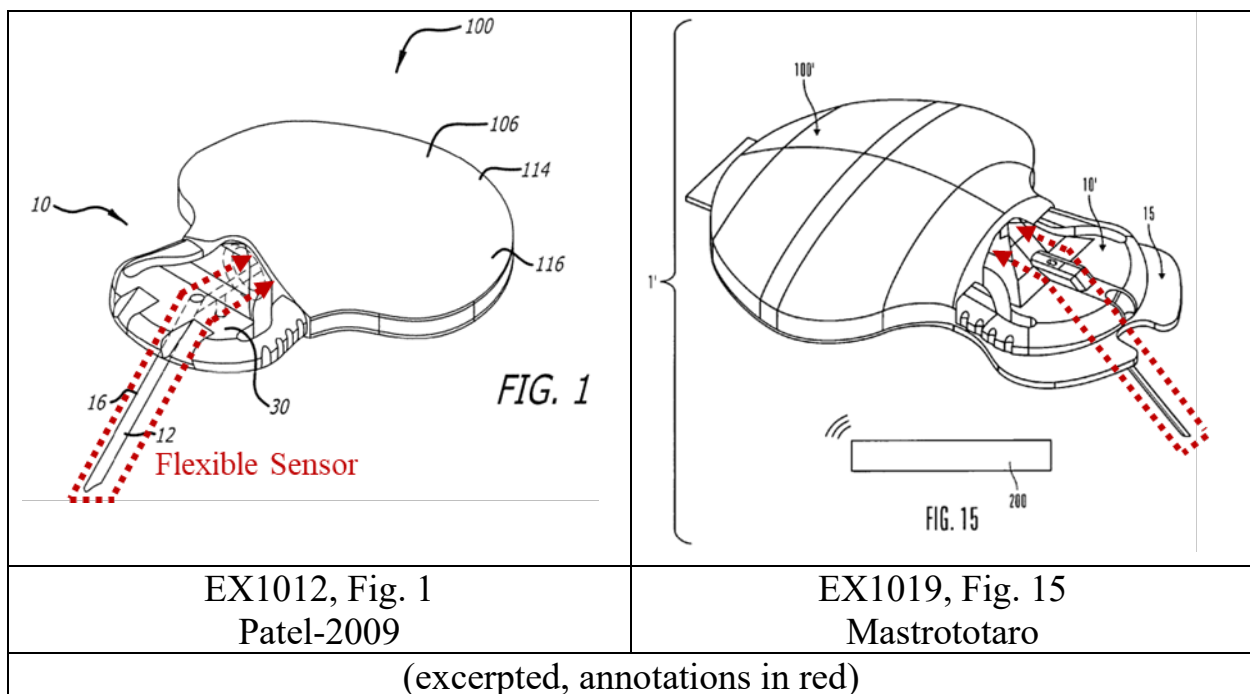
PO cites no evidence disproving that “out-of-range, interference, and other problems with communication, transmission, and/or reception” are system malfunctions. POR, 61-63. Indeed, PO does not even argue that they are not. Thus, the only evidence of record supports finding that these conditions—which result in

38-39. Petitioner does not waive the right to argue any particular meaning of any claim term in district court.

the system temporarily ceasing to perform the function of providing continuous glucose data—are system malfunctions as claimed. EX1008, ¶¶58, 60, 120, 226. This evidence is uncontroverted.

D. Claim 21

As recognized by the POR, Patel-2009 and Mastrototaro include “much of the same disclosure” and illustrate a MiniLink Transmitter from different perspectives. POR, 66-67. Both Patel-2009 and Mastrototaro’s illustrations demonstrate that a portion of the glucose sensor is disposed within the transmitter’s housing:



Indeed, Patel-2009 confirms that “the sensor interface 122,” which is a component of printed circuit board 108 inside the transceiver housing, may be “permanently connected to sensor set 10.” EX1012, [0060]. Likewise, Mastrototaro provided an

embodiment for direct connection between the transmitter and sensor such that “the transmitter 100 was discarded along with the sensor set 10 after the 3 to 5 day use period since they were *directly connected*.” EX1019, [0050] (emphases added). While discussing the same system, Patel-2008 further confirms that “the glucose sensor and glucose transmitter are fused into one device having a small profile.” EX1015, [0051]. Furthermore, based on these disclosures, a POSITA reviewing figure 1 of Patel-2009 and figure 15 of Mastrototaro would recognize that “the data processing transmitter unit and at least a portion of the glucose sensor are disposed within a single integrated housing.” EX1008, ¶¶132, 250.

Respectfully submitted,

Dated: September 6, 2024

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

This brief complies with the type-volume limitation of 37 C.F.R. § 42.24 (a)(1)(i). The brief contains **5,556** words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a). The brief has been prepared in a proportionally spaced typeface using Microsoft Word in a 14-point Times New Roman font.

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

The undersigned certifies that on September 6, 2024, a complete copy of
PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE and
EXHIBITS 1050-1055, 1057-1059 and 1061-1067 were served on Patent Owner
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