UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2024-00521
U.S. Patent No. 11,298,056
Issued: April 12, 2022
Application No. 17/411,154
Filed: August 25, 2021

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

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

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LIST OF EXHIBITS

No.	Description
1201	U.S. Patent No. 11,298,056 ("the '056 Patent")
1202	Excerpts from Prosecution File History of U.S. Patent Application No. 17/411,154 ("Harper '154 file history")
1203	Excerpts from Prosecution File History of U.S. Patent Application No. 17/245,719 ("Harper '719 file history")
1204	Excerpts from Prosecution File History of U.S. Patent Application No. 16/228,910 ("Harper '910 file history")
1205	Excerpts from Prosecution File History of U.S. Patent Application No. 15/061,774 ("Harper '774 file history")
1206	Excerpts from Prosecution File History of U.S. Patent Application No. 13/925,694 ("Harper '694 file history")
1207	Excerpts from Prosecution File History of U.S. Patent Application No. 12/769,635 ("Harper '635 file history")
1208	Declaration of Brian Gross, dated February 9, 2023 ("Gross Decl.")
1209	Curriculum Vitae of Brian Gross
1210	Affidavit of Nathaniel E. Frank-White ("Internet Archive Affidavit")
1211	Exhibits A and B to Affidavit of Nathaniel E. Frank-White ("Paradigm® REAL-Time Archive")
1212	U.S. Patent Application Publication No. 2009/0085768 to Patel et al. ("Patel-2009")
1213	Prosecution File History of U.S. Patent Application No. 12/056,651 ("Patel-2009 file history")
1214	U.S. Provisional Patent Application No. 60/976,886 ("Patel-2009 provisional")

No.	Description
1215	U.S. Patent Application Publication No. 2008/0119705 to Patel et al. ("Patel-2008")
1216	Unused
1217	U.S. Patent No. 6,641,533 to Causey et al. ("Causey")
1218	Unused
1219	U.S. Patent Application Publication No. 2006/0202859 to Mastrototaro et al. ("Mastrototaro")
1220	Unused
1221	Unused
1222	Unused
1223	U.S. Patent Application Publication No. 2004/0122353 to Shahmirian et al. ("Shahmirian")
1224	Unused
1225	Geoffrey McGarraugh, *The Chemistry of Commercial Continuous Glucose Monitors*, Diabetes Technology & Therapeutics 11.S1 (2009)
1226	U.S. Patent Application Publication No. 2004/0193025 to Steil et al.
1227	C. Choleau et al., *Calibration of a Subcutaneous Amperometric Glucose Sensor Implanted for 7 Days in Diabetic Patients: Part 2. Superiority of the One-Point Calibration Method*, Biosensors and Bioelectronics 17.8 (2002)
1228	G. Velho et al., *In Vivo Calibration of a Subcutaneous Glucose Sensor for Determination of Subcutaneous Glucose Kinetics*, Diabetes, American Diabetes Association 1.3 (1988)
1229	John J. Mastrototaro, *The MiniMed Continuous Glucose Monitoring System*, Diabetes Technology & Therapeutics 2.1 (2000)
1230	U.S. Patent No. 6,424,847 to Mastrototaro et al.

No.	Description
1231	V. Poitout et al., *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*, Diabetologia 36 (1993)
1232	U.S. Patent Application Publication No. 2006/0224109 to Steil et al.
1233	D. Barry Keenan, Ph.D. et al., *Delays in Minimally Invasive Continuous Glucose Monitoring Devices: A Review of Current Technology*, Journal of Diabetes Science and Technology 3.5 (2009)
1234	*Unused*
1235	S. Armstrong, *Wireless Connectivity for Health and Sports Monitoring: a Review*, British Journal of Sports Medicine (2007)
1236	Alexandros Pantelopoulos & Nikolaos Bourbakis, *A Survey on Wearable Biosensor Systems for Health Monitoring*, 30th Annual International Conference of the IEEE EMBS Conference (2008)
1237	Excerpts from Diabetes Forecast, November 2007
1238	Excerpts from Diabetes Forecast, August 2007
1239	Bruce Buckingham et al., *Real-Time Continuous Glucose Monitoring*, Current Opinion in Endocrinology, Diabetes & Obesity 14.4 (2007)
1240	Bruce Buckingham, M.D., *Clinical Overview of Continuous Glucose Monitoring*, Journal of Diabetes Science and Technology 2.2 (2008)
1241	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.

No.	Description
1242	Excerpts from Steven W. Smith, *The Scientist and Engineer's Guide to Digital Signal Processing*, California Technical Pub. (1997)
1243	B.A. Shenoi, *Introduction to Digital Signal Processing and Filter Design*, John Wiley & Sons (2006)
1244	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.
1245	Marc D. Breton Ph.D. et al., *Optimum Subcutaneous Glucose Sampling and Fourier Analysis of Continuous Glucose Monitors*, Journal of Diabetes Science and Technology 2.3 (2008)
1246	Mark R. Burge, MD et al., *Continuous Glucose Monitoring: The Future of Diabetes Management*, Diabetes Spectrum 21.2 (2008)
1247	Adam Heller & Ben Feldman, *Electrochemical Glucose Sensors and Their Applications in Diabetes Management*, Chem. Rev. 108 (2008)
1248	U.S. Patent No. 5,391,250 to Cheney et al.
1249	List of Challenged Claims
1250	"ABBOTT'S INITIAL CLAIM CHARTS" served Dec. 20, 2023 in *Abbott Diabetes Care Inc. v. DexCom Inc.*, No. 1-23-cv-00239 (D. Del.)[1]

[1] While EX1250 is marked as "HIGHLY CONFIDENTIAL–OUTSIDE ATTORNEYS' EYES ONLY," footnote 1 states that Abbott made this designation "[o]nly out of an abundance of caution based on the citation of documents produced

No.	Description
1251	U.S. Patent Application Publication No. 2007/0093786 to Goldsmith and Hayes ("Goldsmith")
1252	*Unused*
1253	Scheduling Order, *Abbott Diabetes Care Inc. v. DexCom Inc.*, No. 1-23-cv-00239 (D. Del. Sep. 19, 2023)

by DexCom and marked as such." Id. at 1 n.1 (emphasis added). As EX1250 is a cover pleading that includes no citations to confidential documents, Petitioner DexCom does not file this exhibit under seal.

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

1. Real Party-In-Interest

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

2. Related Matters

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

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

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

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Petitioner consents to service via email at the above email addresses and the email address of Dexcom-Harper@klarquist.com.

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

Dexcom, Inc. ("Petitioner") respectfully requests *inter partes* review ("IPR") of claims 13 and 29 of U.S. Patent 11,298,056 ("the '056 patent," EX1201), allegedly owned by Abbott Diabetes Care Inc. ("Patent Owner"). For the reasons set forth below, these claims should be found unpatentable and cancelled.

I. INTRODUCTION

The present Petition challenges 13 and 29, which each depends directly from independent claim 1. Petitioner's August 1, 2023, petition in IPR2023-01251 explained how the *Patel*-2009/Paradigm Combination renders obvious claim 1. The Board instituted IPR based on that petition on February 5, 2024. Petitioner now files this additional petition in IPR2024-00521, building off the exact same base combination of IPR1251-01251 to show the unpatentability of claims 13 and 29, which were recently asserted in the Related Litigation.

As claims 13 and 29 depend from claim 1, the showing for the claim 1 elements are unchanged from those already presented in the first-filed petition. This new petition explains how the *Patel*-2009/Paradigm Combination renders claim 13 unpatentable under Patent Owner's apparent district court construction of the recited "sensor misposition error." And claim 29, which relates to use of a watch as a secondary receiver within the claimed system, is rendered obvious by the addition of secondary reference Goldsmith (EX1251) to the combination. Goldsmith teaches the benefits and implementation details of using a watch monitoring device within a

glucose monitoring system and, like Patel-2009, is a Medtronic patent publication. For the reasons explained further below, the Board should institute this petition and find claims 13 and 29 unpatentable. Institution would allow the Board to efficiently resolve these unpatentability issues in one forum.

The '056 patent claims a glucose monitoring system in which a receiver unit wirelessly receives processed glucose sensor data and then displays that data in graph form. The supposed innovation is display of a data gap on the graph when there is an adverse condition (e.g., a communication error) and then later backfilling this gap upon correction of the adverse condition (e.g., communication being re-established). The '056 patent illustrates the data gap feature and backfill in FIG. 7A and FIG. 7B, respectively:

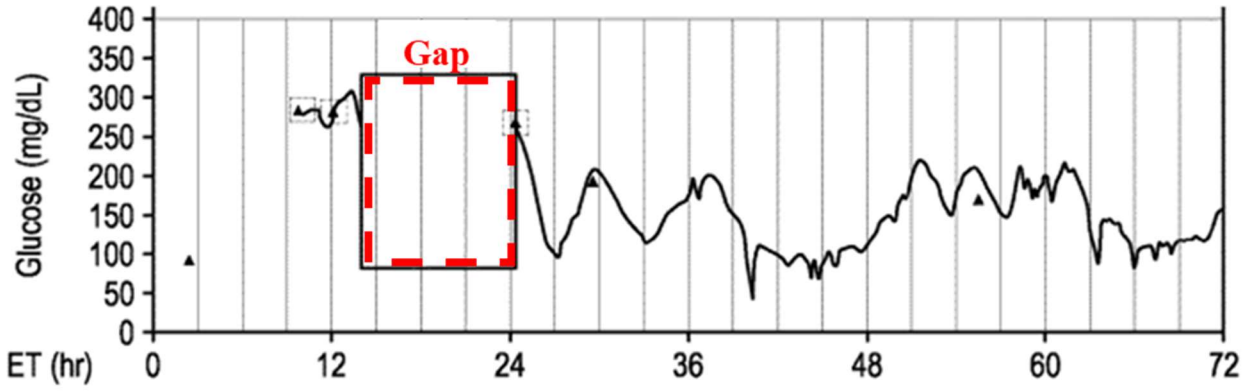


FIG. 7A

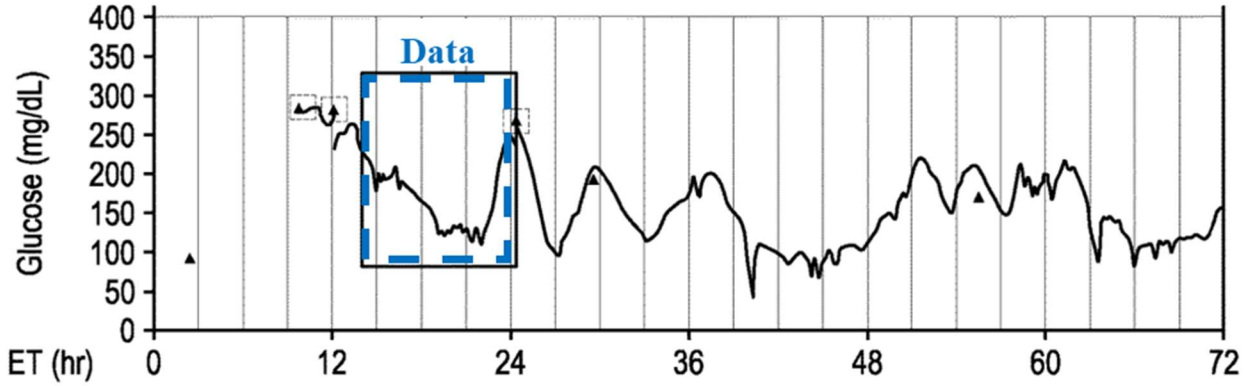
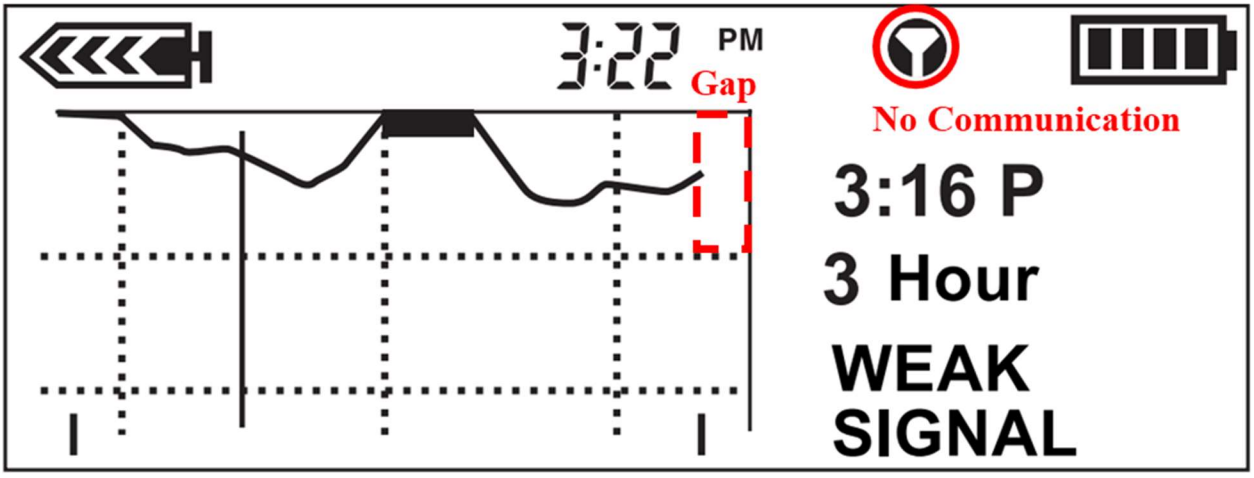


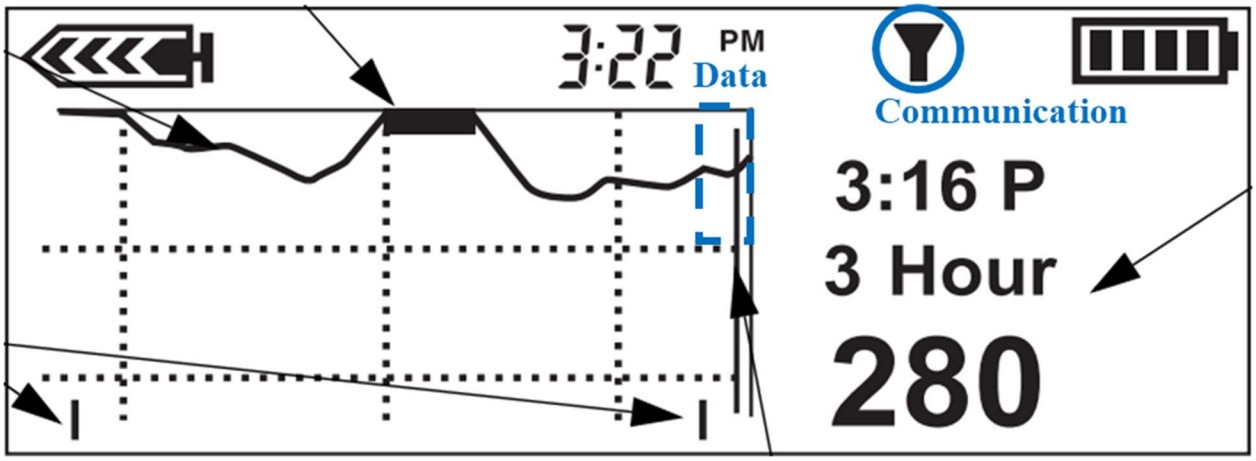
FIG. 7B

EX1201, Fig. 7A (annotated in red) & Fig. 7B (annotated in blue); *see also id.*, 12:26-39 & 12:47-13:5. However, this simplistic feature was well-known before the alleged invention and plainly described in the prior art.

Over a year earlier, a Medtronic user manual described the same backfill features in the same context of wirelessly monitoring and graphically displaying glucose sensor data, explaining that "even though your system is 'out of range,' continuous glucose monitoring (CGM) data can be re-populated." EX1211 ("Paradigm® REAL-Time"), 8. It shows how prior to re-population (backfill) of data, a data gap is displayed:



EX1211, 8, 73 (excerpted; annotated in red). After communications resume, these data gaps are re-populated (backfilled):



Id., 8, 64 (excerpted; annotated in blue).

In a patent application with priority to October 2007, Patel-2009 (EX1212), Medtronic disclosed storing calculated glucose values in a glucose sensor transceiver during failed communication and synchronizing these values from the transceiver to a monitoring device when communication is re-established. EX1212, [0086]. Together, Patel-2009 and Paradigm® REAL-Time render obvious claim 13; a

combination with a third Medtronic CGM publication, Goldsmith (EX1251), renders obvious claim 29.

II. IDENTIFICATION OF CHALLENGE

A. Statement Of Relief Requested

Petitioner requests *inter partes* review of claims 13 and 29 of the '056 patent on the following statutory grounds:

	Reference(s)	**Basis**	**Claims**
Ground 1	Patel-2009 (EX1212) and Paradigm® REAL-Time (EX1211)	35 U.S.C. § 103	13
Ground 2	Patel-2009, Paradigm® REAL-Time, and Goldsmith (EX1251)	35 U.S.C. § 103	29

Sections VI-VIII present evidence of unpatentability and establish a reasonable likelihood that Petitioners will show each challenged claim is unpatentable.

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

Petitioner authorizes Account No. 02-4550 to be charged for any fees, including those enumerated in 37 C.F.R. § 42.15.

III. THE BOARD SHOULD NOT USE ITS DISCRETION TO DENY INSTITUTION OF THIS PETITION

A. Section 325(d) Does Not Warrant Discretionary Denial

Neither art nor argument advanced by this petition is substantially similar to those previously before the office. *See Advanced Bionics, LLC. v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7-9 (PTAB Feb. 13, 2020). Paradigm® REAL-Time was not before the examiner. EX1201, 1-7. Although Patel-2009 and Goldsmith were among 700 references submitted via IDS, neither was relied on or discussed by the Examiner. *Hum Indus. Tech., Inc. v. Amsted Rail Co., Inc.*, IPR2023-00538, Paper 15 at 68-69 (PTAB Aug. 11, 2023) (finding that "Examiner's initials on an IDS citing almost 50 references" did not "indicate that the Examiner sufficiently evaluated or appreciated the relevance of either reference" and that "Petitioner's showing of a reasonable likelihood of unpatentability … satisfies the second prong of Advanced Bionics and weighs strongly against exercising our discretion to deny institution"). Moreover, Patel-2009 was submitted more than a decade into prosecution when the Examiner's office action and allowance only considered double patenting. EX1202, 237-241. Finally, prosecution focused on U.S. Publications to Hayter and Kamath, not on the combinations and arguments in this petition. *See supra* III.B.

Even if the Examiner had evaluated the references relied on herein, the Examiner materially erred in allowing claims 13 and 29 for failing to appreciate the disclosures and teachings in those references discussed in the Grounds below, which show that the challenged claims are unpatentable and should have never been allowed. Because these key teachings in the prior art were not previously considered by the Office, this petition should not be denied under Section 325(d). *Hum*, IPR2023-00538, Paper 15 at 68-69.

Nor does 325(d) warrant discretionary denial based on the earlier-filed petitions in IPR2023-01251 and IPR2023-01252. The present Petition challenges claims 13 and 29, which were not previously challenged using the same art or arguments. As noted above and in the concurrently-filed explanation of material differences between multiple petitions, on August 1, 2023, Petitioner filed two petitions for *inter partes* review of U.S. Patent No. 11,298,056 (the '056 patent). Petition 1 (IPR2023-01251) challenges claims 1-12, 14-28, and 30. While Petition 2 (IPR2023-01252) challenged claims 13 and 29, it did so based on a challenge to the effective filing date of the challenged claims and did not rely on the art or arguments presented herein. Moreover, as institution of Petition 2 was discretionarily denied, the Office has not reached the merits of that challenge, much less in a final written decision. Thus, these other Board proceedings do not warrant Section 325(d) denial here in IPR2024-00521.

B. Parallel District Court Proceedings

Patent Owner asserts the '056 patent against Petitioner in the Related Litigation, with trial set for March 2026. EX1253, 14. Any IPR based on this petition would conclude well in advance of that date and thus the Board should not discretionarily deny institution in view of the district court case.

C. This Petition Should Be Instituted Despite Institution On Different Claims Of The Same Patent In IPR2023-01251

The November 2019 Consolidated Trial Practice Guide ("TPG") includes a section entitled, "Parallel Petitions Challenging the Same Patent." TPG, 59-61. Contemporaneous with this petition, Petitioner files a 5-page brief explaining, *inter alia*: a) why institution of both this petition and the previously filed Petition 1 is warranted; b) why ranking this petition relative to Petition 1 would be inappropriate, as the present petition challenges only newly asserted claims that were not challenged in Petition 1; and (c) ranking Petition 3 second to the extent a ranking is required.

D. The *General Plastic* Factors Weigh Against Discretionary Denial

When serial petitions are filed against a patent, the Board evaluates seven factors to determine whether to deny institution under § 314(a). *General Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16 (PTAB

Sept. 6, 2017) (Precedential) ("General Plastic factors"). These factors weigh against discretionary denial.

First Factor: There is no overlap in challenged claims between Petition 3 and Petition 1, and thus this petition should not be considered a "follow-on" to Petition 1. *See Volkswagen Grp. Of Am., Inc., v. Carucel Invs., L.P.*, IPR2019-01573, Paper 7 at 7 (PTAB Jan. 22, 2020) (second petition covering different claims is not a "follow-on petition").

While the present Petition challenges two of the same claims as previously challenged in Petition 2—which relied on a challenge to the '056 patent's effective filing date, and cited Patent Owner's own previously published application as prior art to challenge all 30 claims of the '056 patent—Petition 2 was not instituted on discretionary grounds, leaving no common claims between the present Petition and any instituted proceeding. Additionally, neither of the two claims challenged in Petition 3 have had their patentability previously considered by the Board on the merits, let alone on the prior art grounds presented herein.

As such, this factor weighs against discretionary denial, or is at best neutral.

Second, Fourth, and Fifth Factors: although Petitioner "knew of the prior art asserted" in this petition when Petitioner filed Petition 1, Petition 1 did not challenge claims 13 and 29. When filing Petition 1, Petitioner noted that Patent Owner was asserting "at least claim 1" but that "Patent Owner has not limited the

asserted claims and thus currently is presumed to assert all 30 claims." *E.g.*, IPR2023-01251, Paper 2 at 4. However, given word count limits, the apparent lack of an infringement theory, and the unforeseeability of Patent Owner's claim interpretations, Petition 1 did not challenge claims 13 and 29.

Faced with guessing which claims Patent Owner might ultimately assert when Petition 1 was filed, and given the plain reading of claims 13 and 29, Petitioner reasonably did not anticipate Patent Owner asserting those claims using the apparent claim interpretations in Patent Owner's December 20, 2023, infringement contentions. In particular, Patent Owner for the first time in these contentions apparently interprets:

- claim 13: "sensor misposition error" as satisfied by a signal loss; and
- claim 29: "secondary receiver unit …configured to receive processed sensor data *from the data processing and transmitter unit*" as encompassing a receiver unit indirectly receiving data from a device *other than* the data processing and transmitter unit, notwithstanding the direct communication shown in the '056 patent at Fig. 1 and discussed at 5:4-8 ("[a]lso shown in FIG. 1 is an optional secondary receiver unit 106 which is operatively coupled to the communication link and configured to receive data transmitted from the data processing and transmitter unit 102").

Upon first learning on December 20, 2023 that claims 13 and 29 were being asserted based on these unforeseen apparent claim interpretations, Petitioner acted diligently, and within seven weeks prepared and filed Petition 3, which is based on this newly offered interpretation from Patent Owner.

Thus, factors 2, 4, and 5 weigh against discretionary denial or are at least neutral.

Third Factor: While Petitioner filed Petition 3 after institution decisions were reached on Petitions 1 and 2, it had completed substantial work on Petition 3 before these decisions and filed it on the due date for the Board to issue these decisions, February 9, 2024. Most importantly, the grounds and arguments presented by Petition 3 are not informed by the Board decisions or Patent Owner arguments in the first two IPRs. Petitioner's arguments are unchanged as to the overlapping claim elements found in claim 1, from which challenged claims 13 and 29 depend. As to those overlapping elements, Petitioner repeats without substantive modification the mapping from Ground 1 of Petition 1 and is using neither the Petition 1 POPR nor the institution decision to modify arguments that were previously unsuccessful, nor shifting its prior art arguments for this petition.

Moreover, the only "new" claim mappings are for claims that were not previously at issue in Petition 1. The need for Petition 3 only arose after the Patent Owner formally asserted new claims 13 and 29 (based on unforeseen apparent claim

interpretations) over 4 months after Petitioner filed Petitions 1 and 2, and just seven weeks before the present Petition was filed. The intervening time to prepare this petition, its supporting declaration, and statements addressing the differences between petitions is not unreasonable.

This factor weighs against discretionary denial.

Sixth Factor: Institution of this petition will not inefficiently impact "the finite resources of the Board." While Petition 1 and Petition 3 challenge different claims, the claims in Petition 3 depend from claim 1, challenged in Petition 1. As such, though it does not challenge claim 1, Petition 3 again *maps* claim 1, due to Board rules preventing incorporation of prior petitions. As to these common claim 1 limitations mapped in Petition 3, however, Petitioner presents identical prior art and arguments as presented in Petition 1 without substantive modification. With this petition, Petitioner merely adds mapping for the additional limitations of the two newly challenged claims, as follows:

- Ground 1 relies on the same art and arguments presented in Petition 1, Ground 1 to map claim 1, adding additional mapping for the limitations of newly asserted claim 13, and
- Ground 2 adds one reference to the Ground 1 references in order to address the limitations of newly asserted claim 29.

Given the timing of Patent Owner's formal assertion of the claims challenged

based on its unforeseen claim interpretations, the present Petition is being filed just over six months after the initial petition. As such, it may not be possible to consolidate the cases into a single IPR proceeding. However, as mentioned above, the consideration of these additional claims will not significantly impact the resources of the Board, and so even if this factor is viewed as weighing slightly in favor of the Board exercising its discretion, this should not be outcome-determinative.

Indeed, in a similar case, in *Cirrus Design Corp. v. Fleming,* IPR2020-00762, despite weighing this factor in favor of exercising its discretion to deny institution due to a seven month delay between petitions, the Board granted institution. *Id.,* Paper 19 (PTAB Oct. 1, 2020). In *Cirrus*, the Board found that this seven-month delay in filing a second petition on claims not challenged in a first petition was "not unreasonable" and declined to exercise its discretion to deny institution. *Id.* at 14. In fact, Petitioner's diligence here is more reasonable than that of the *Cirrus* petitioner. Some claims challenged in Cirrus's second petition were asserted shortly *before* its first petition was filed. *Id.* at 12. *Here*, newly challenged claims 13 and 29 were not formally asserted—and Patent Owner's unforeseen apparent interpretations of them were not offered—until over 4 months *after* Petition 1 was filed. Thereafter, Petitioner diligently prepared Petition 3 to challenge only those new claims under those newly proffered interpretations, filing it just over 7 weeks later.

So, as noted above, even if this factor is viewed as weighing slightly in favor of the Board exercising its discretion, this should not be determinative.

Seventh Factor: For the same reasons given above, institution of this petition should not affect "the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review." Should the Board institute Petition 3, Petitioner would propose that at least the oral argument and final written decision dates for the two proceedings be aligned, either through later consolidation (perhaps after briefing is complete in IPR2023-01251) or some other mechanism.

And, because there are no common claims to Petitions 1 and 3, the Board need not be concerned about estoppel considerations. So, even if the Board determines that consolidation is not feasible or appropriate, it can issue a later Final Written Decision in Petition 3, if needed, in order to meet its statutory obligation to issue a Final Written Decision in IPR2023-01251 within 12 months of institution. Given that Petition 3 repeats the same analysis of claim 1 contained in Petition 1, Ground 1 without substantial modification, in drafting any later Final Written Decision in Petition 3, the Board would be able to rely on the same analysis contained in its Final Written Decision on Petition 1, Ground 1, adding only the analysis necessary to address the additional limitations of claims 13 and 29.

This factor, too, weighs against discretionary denial.

Other Considerations: As the Board noted in *Cirrus*, IPR2020-00762, Paper 19, "[t]he list of the seven *General Plastic* factors is a non-exhaustive one." *Id.* at 15. Patent Owner has now asserted 25 claims of the '056 patent, and a total of 79 claims from three patents in the Related Litigation. The present petition challenges only the *two* claims newly asserted on December 20, 2023 that were not included in Petition 1, the only '056 patent proceeding presently pending before the Board.

In *Cirrus*, petitioner similarly filed an additional IPR petition seven months after its first petition because the patent owner asserted a large number of claims, including some claims not challenged in the first petition. *Id.* The Board instituted review, noting that, given patent owner's assertion of "23 claims against Petitioner in two claim groupings where the assertions were temporally offset from one another. … We do not find it unreasonable that Petitioner determined a second Petition necessary to address newly asserted claims…" *Id.* at 16. Petitioner here acted reasonably and diligently to challenge newly asserted claims 13 and 29 once it received notice of Patent Owner's formal assertion—and unforeseen apparent claim interpretations—thereof.

These "other considerations" also weigh against discretionary denial.

IV. THE '056 PATENT

The '056 patent is titled "Methods and Systems for Early Signal Attenuation Detection and Processing" and issued from U.S. Application 17/411,154 on April 12, 2022.

A. Specification

The '056 patent describes an analyte monitoring system including a sensor unit, a data processing and transmitter unit, and a primary receiver unit. EX1201, 4:56-61; EX1208, ¶¶26-28.

The transmitter unit "receives analyte related sensor data" from the sensor and transmits this data to the receiver unit. EX1201, 11:27-37. The communication link between the transmitter and receiver is discussed as including various infrared, Bluetooth®, 802.11x, or other wireless communication protocols. *Id.*, 7:25-33, 9:15-22.

The '056 patent defines "analyte related sensor data" as including both "current signal received from the analyte sensor, as well as the current signal which has undergone … processing routines" (e.g., filtering, clipping, digitizing, encoding, conditioning). *Id.*, 11:37-44, 14:21-23. Calibration applies "calibration data such as [a] sensitivity ratio" "to ensure the analyte related data signals … are correctly converted to corresponding analyte levels," but various conditions render calibration unsuitable. *Id.*, 10:62-66, 11:6-8, 12:54-61. The '056 patent describes that "when a

scheduled calibration event fails …, the output display of the processed, calibrated sensor data is disabled" resulting in a gap "where the analyte monitoring system **100** was not properly calibrated, [and] analyte related sensor data was not processed:"

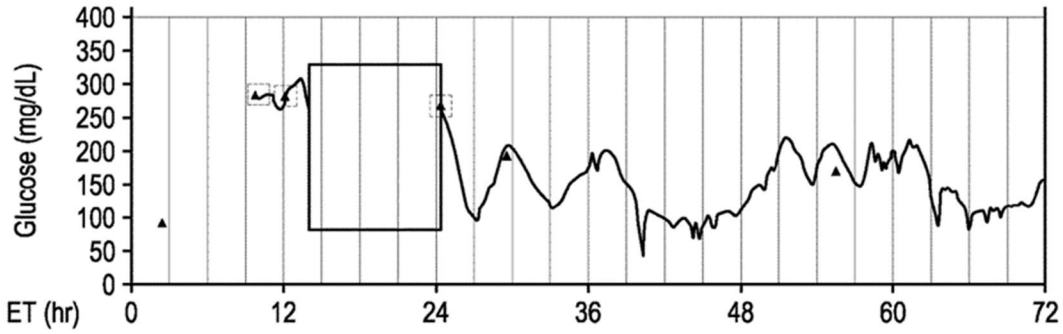


FIG. 7A

Id., 12:32-45, Fig. 7A. The '056 patent specification describes backfilling gaps by processing unprocessed sensor data with the sensitivity ratio from a subsequent calibration:

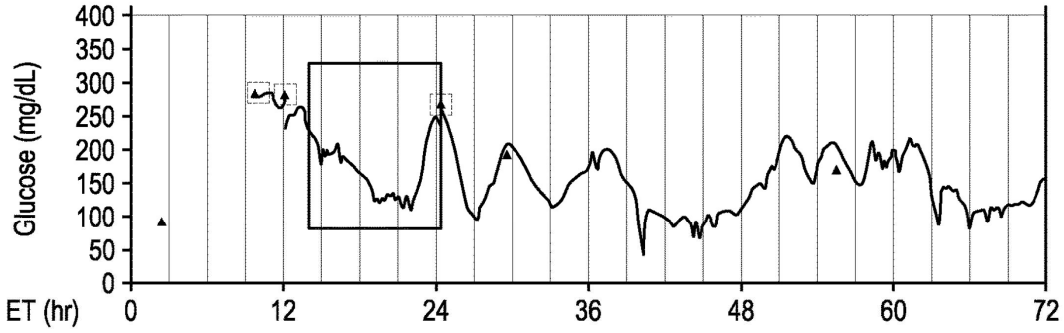


FIG. 7B

Id., 12:47-13:5, Fig. 7B.

B. Prosecution History

The ’056 Patent issued from U.S. Patent Application 17/411,154 filed August 25, 2021 (EX1202), which claims priority to the April 29, 2009 filing of U.S. Provisional Application 61/173,600 through a series of continuation applications: 17/254,719 (EX1203); 16/228,910 (EX1204); 15/061,774 (EX1205); 13/925,694 (EX1206); and 12/769,635 (EX1207).

The only meaningful exchange during prosecution occurred with the initial U.S. Patent Application 12/769,635 (“the ’635 Application”) filed April 28, 2010, and focused on prior art rejections over U.S. Publications 2009/0033482 and 2009/0018424. EX1207, 76-84, 119-126. The ’635 Application was allowed because the examiner found that prior art did “not teach disabling output of sensor data during an adverse condition, where sensor data is still being stored and where the stored data is later retrieved and processed after the adverse condition is no longer present.” EX1207, 43. Prior art considered during prosecution of the ’635 Application did not include the Patel-2009 (EX1212), Paradigm® REAL-Time (EX1211), or Goldsmith (EX1251), references relied on in this petition. EX1207, 9-13, 85-100, 128-187, 203-216; *see infra* IX.A. Subsequent prosecution involved a Section 101 rejection (EX1206, 75-80) and double patenting rejections. EX1206, 35-41, 75-80; EX1205, 36-40; EX1204, 73-78; EX1203, 46-50; EX1202, 237-241.

C. Claims[2]

The ’056 patent’s sole independent claim concerns a “glucose monitoring system for backfilling data gaps” displayed in a line graph of monitored glucose levels, wherein a data gap corresponds with detection of an adverse condition and is backfilled using data stored in transmitter memory during the adverse condition. EX1201, 15:24-16:20. The system includes a glucose sensor which samples biological fluid and provides data; a data processing and transmitter unit which stores, processes, and transmits sensor data; and a receiver unit which displays sensor data. *Id.*, 15:27-64. The transmitter and receiver units each have a processor, a memory, an RF (“radio frequency”) transceiver, and various other components. *Id.*, 15:31-36, 15:52-54.

Dependent claims specify the adverse condition or relate to attributes and functions of the glucose monitoring system. *Id.*, 16:21-18:28.

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

A. State Of The Art

At least the following four features or concepts were well-known in the field of glucose monitoring. EX1208, ¶31.

[2] A claims listing is submitted as EX1249.

1. Sensors With Working, Reference, And Counter Electrodes

The Background of the '056 patent admits that glucose monitoring systems "generally include[d]" sensors with "a two or three-electrode (work, reference and counter electrodes) configuration." EX1201, 1:34-37. This is consistent with other publications, including a May 2009 article, which explained that a typical glucose sensor "includes three electrodes: a Gox working electrode, a counter electrode, and an Ag/AgCl reference electrode." EX1225, S-19. For example, both Patel-2009 and Patel-2008 incorporate U.S. Patent 5,391,250 (EX1212, [0006]; EX1215, [0004]), which discloses manufacturing thin-film sensors with three electrodes, including "a reference electrode and a counter electrode." EX1248, 5:6-16.

Therefore, skilled artisans were familiar with sensor configurations including working and counter electrodes. EX1208, ¶¶32-36, 54.

2. Sensor Sensitivity Calibration Data Was Used To Calibrate Sensors

As early as 1988, it was recognized that "calibrating *in vivo* a subcutaneous glucose sensor" involved determining an "*in vivo* sensitivity coefficient" for the sensor and then using that coefficient "to determine from the sensor output an apparent subcutaneous glucose concentration." EX1228, 227; *see also id.*, 228 (discussing the sensitivity coefficient as the "ratio between the decrease in the sensor current and the decrease in glucose concentration."); EX1208, ¶38. Similarly, a 2002

article on "Calibration of a subcutaneous amperometric glucose sensor…" explains how calibration procedures involved determining a "sensor sensitivity *S*" that is then used to calibrate the sensor data. EX1227, 647; *see also id.*, 648 ("calibration of the system represents a crucial step" and further explaining determination and use of "sensor sensitivity *S*."); EX1229, S-15; EX1230, 11:28-33 (explaining that "calibration involves calculating a calibration factor called a sensitivity ratio (SR)"); EX1208, ¶38.

Therefore, the POSITA understood that calibration data, in the context of monitoring glucose or other analytes, typically included sensitivity information for the sensor, e.g., the sensor sensitivity ratio (aka sensitivity coefficient). EX1208, ¶¶37-40, 54.

3. Microprocessor Computations

The '056 patent implicitly admits that skilled artisans knew how to perform signal processing by providing that sensor signals are processed (EX1201, 5:58-64, 11:37-44) without any details on how this is done. By 1993, the necessity of sampling, filtering, storing, and processing glucose sensor electrical current values before conversion to real-time glucose concentrations was well known. EX1231, 659, 661-662; EX1208, ¶42.

By the early to mid-2000's, Medtronic had developed more advanced procedures for smoothing, filtering, storing, and processing sensor electrical current

signals. For example, a 2002 Medtronic patent described sampling electrical current every 10 seconds and storing averaged sampling intervals in memory. EX1230, 8:42-60; *see also* EX1233, 1211 (describing the Medtronic Guardian RT's finite impulse filter). Additionally, a 2006 Medtronic publication described processing signals from analog current (Isig)clai to digital sensor values (Dsig) stored in a buffer, prior to filtering and calibration. EX1232, [0230]; EX1208, ¶43.

Therefore, a POSITA understood that continuous glucose monitoring systems included processors that processed and stored sensor data in memory, and also stored the resulting output in memory (e.g., processor cache, buffer, RAM). EX1208, ¶¶41-46, 54.

4. Bluetooth Communication

A January 2007 review of "Wireless connectivity for health and sports monitoring" found that most of the literature on healthcare monitoring and tele-medicine related to the application of Bluetooth, described as a short-range cable replacement for device-to-device connections. EX1235, 286-87. Similarly, "A Survey on Wearable Biosensor Systems for Health Monitoring" presented at the International IEEE EMBS Conference in August 2008, studied 25 wearable biosensors and found that 10 used Bluetooth. EX1236, 4888-89.

Therefore, skilled artisans were familiar with implementing Bluetooth communication for short range device-to-device connections in health monitoring applications. EX1208, ¶¶47-49, 54.

B. Level Of Skill In The Art

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. EX1208, ¶51.

The POSITA may be part of an interdisciplinary team with others having relevant experience and/or with clinicians involved in diagnosis, treatment, and patient management relevant to the use of medical devices for monitoring physiological signals. EX1208, ¶52.

In addition to the state-of-the-art discussed above (*see supra* IV.A.1-4), a POSITA would have been aware of commercially available glucose monitoring systems (e.g., the Medtronic Paradigm® REAL-Time) through scientific journals and magazines. A POSITA would have known the importance of data reliability to

glucose monitoring, including anticipating that errors (e.g., communication or calibration failures) would result in missing or inaccurate glucose data. A POSITA would have accounted for missing data using technical concepts known at the time, including programming glucose monitoring systems to detect failures that result in data being unavailable for display (e.g., due to a calibration error or loss of communication), preserving this data in memory, regenerating it once the system recovered, and displaying regenerated data. EX1208, ¶¶54-61.

VI. CLAIM CONSTRUCTION

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

On December 20, 2023, Patent Owner served infringement contentions in related Delaware Case No. 1:23-cv-00239 that show its apparent positions on what is encompassed by the language "sensor misposition error" in claim 13 and "receive processed sensor data from the data processing and transmitter unit" in claim 29.

Petitioner applies these apparent interpretations of "sensor misposition error" and "receive processed sensor data from the data processing and transmitter unit" indicated by Patent Owner's infringement contentions only for the purposes of this IPR Petition, without agreeing that these terms are correctly construed. *Western Digital Corp. v. Spex Techs., Inc.*, IPR2018-00084, Paper 14 at 11 (PTAB Apr. 25, 2018) ("37 C.F.R. § 104(b)(3) does not require Petitioner to express its subjective agreement regarding correctness of its proffered claim constructions … Petitioner's statement that its Petition 'is based *on* the claim constructions urged by Patent Owner' … suffices to identify claim constructions Petitioner is adopting for purposes of the requested review"). (emphasis in original). *see also General Elec. Co. v. Vestas Wind Systems A/S et. al.*, IPR2018-00928, Paper 9 at 14 (PTAB Nov. 5, 2018) ("The plain language of 37 C.F.R. § 42.104(b)(3)–(4) … does not prohibit a petitioner from submitting a construction it believes is incorrect").

A. "sensor misposition error"

Dependent claim 13 recites "[t]he glucose monitoring system of claim 1, wherein the adverse condition comprises a *sensor misposition error*." EX1201, 16:56-57 (emphasis added). In its district court infringement contentions, Patent Owner appears to construe the "sensor misposition error" to be satisfied by a signal loss / communication issue between the "data processing and transmitter unit" and "receiver unit" recited in claim 1. Solely for purposes of this IPR petition, and

reserving the right to dispute such a construction, Petitioner adopts Patent Owner's litigation construction that a "sensor misposition error" encompasses a communication issue between the "data processing and transmitter unit" and "receiver unit." Ground 1 below shows how claim 13 is obvious under this construction. *See infra* VII.F.2.

B. "receive processed sensor data from the data processing and transmitter unit"

Dependent claim 29 recites "[t]he glucose monitoring system of claim 1, further comprising a secondary receiver unit" that "is a watch" and "wherein the secondary receiver unit is configured to *receive processed sensor data from the data processing and transmitter unit*." EX1201, 18:18-24 (emphasis added).

Patent Owner's infringement contentions assert that the claimed "receive processed sensor data from the data processing and transmitter unit" may be satisfied by a watch that receives data from a device other than the "data processing and transmitter unit" recited in claim 1. Solely for purposes of this IPR petition, and reserving the right to dispute such a construction, Petitioner assumes that the claim encompasses such a "receive" action.

In Ground 2, below, Petitioner shows how claim 29 is obvious both under the plain reading of the recited "receive processed sensor data from the data processing and transmitter unit" and under Patent Owner's broader reading of the claim

language that appears to encompass indirect communication from a device that is not the "data processing and transmitter unit" recited in claim 1.

VII. GROUND 1: CLAIM 13 IS OBVIOUS OVER PATEL-2009 IN VIEW OF PARADIGM® REAL-TIME

A. Patel-2009 (EX1212) Is Prior Art

U.S. Publication 2009/0085768 to Patel ("Patel-2009", EX1212) is prior art under at least 35 U.S.C. § 102(e) because its U.S. Patent Application 12/056,651 (EX1213) was filed on March 27, 2008, and contains materially identical disclosure.

While Patel-2009 is prior art based on its March 2008 non-provisional filing date, its prior art status dates back to October 2, 2007, because Provisional Application 60/976,886 supports claim 1 and contains the same disclosures relied on in this petition:

Patel-2009 Claim 1	Support in 60/976,886 Provisional
1. A telemetered characteristic sensor transceiver for exchanging data with at least one remote device, the transceiver comprising:	EX1214, p.9 [0007], p.31
a housing detachably coupled to a sensor located on a body of a user,	EX1214, p.19 [0050], p.20 [0051], p.21 [0054], p.50 Figs.1-2, p.52 Figs. 8A/B, p.56 Fig. 13, p. 61 Fig.18, p.31.
the sensor producing a signal indicative of a user characteristic;	EX1214, p.9 [0007], p.31.
a processor formed within the housing and in communication with the sensor for processing the signal produced by the sensor;	EX1214, p.9 [0007], p.10 [0013], p.31.

a transmitter coupled to the processor for transmitting data to at least one remote device;	EX1214, p.9 [0007], p.10 [0012], p.31.
a receiver coupled to the processor for receiving data from the at least one remote device;	EX1214, p.9 [0007], p.10 [0013], p.24 [0062], p. 31.
and a memory coupled to the processor for storing data,	EX1214, p.9 [0007], p.10 [0012], p.31.
wherein the processor performs calculations using at least one of the signal produced by the sensor, the data received from the at least one remote device and the data stored in the memory, and performs at least one of storing the calculations in the memory and transmitting the calculations to the at least one remote device through the transmitter.	EX1214, p.10 [0012], p. 31.

EX1208, ¶¶62-67; *see Medtronic, Inc. et al. v. Niazi Licensing Corp.*, IPR2018-00609, Paper 8 at 11 (PTAB Aug. 20, 2018) ("we determine *Dynamic Drinkware* requires the … provisional to support just one claim in the … patent").

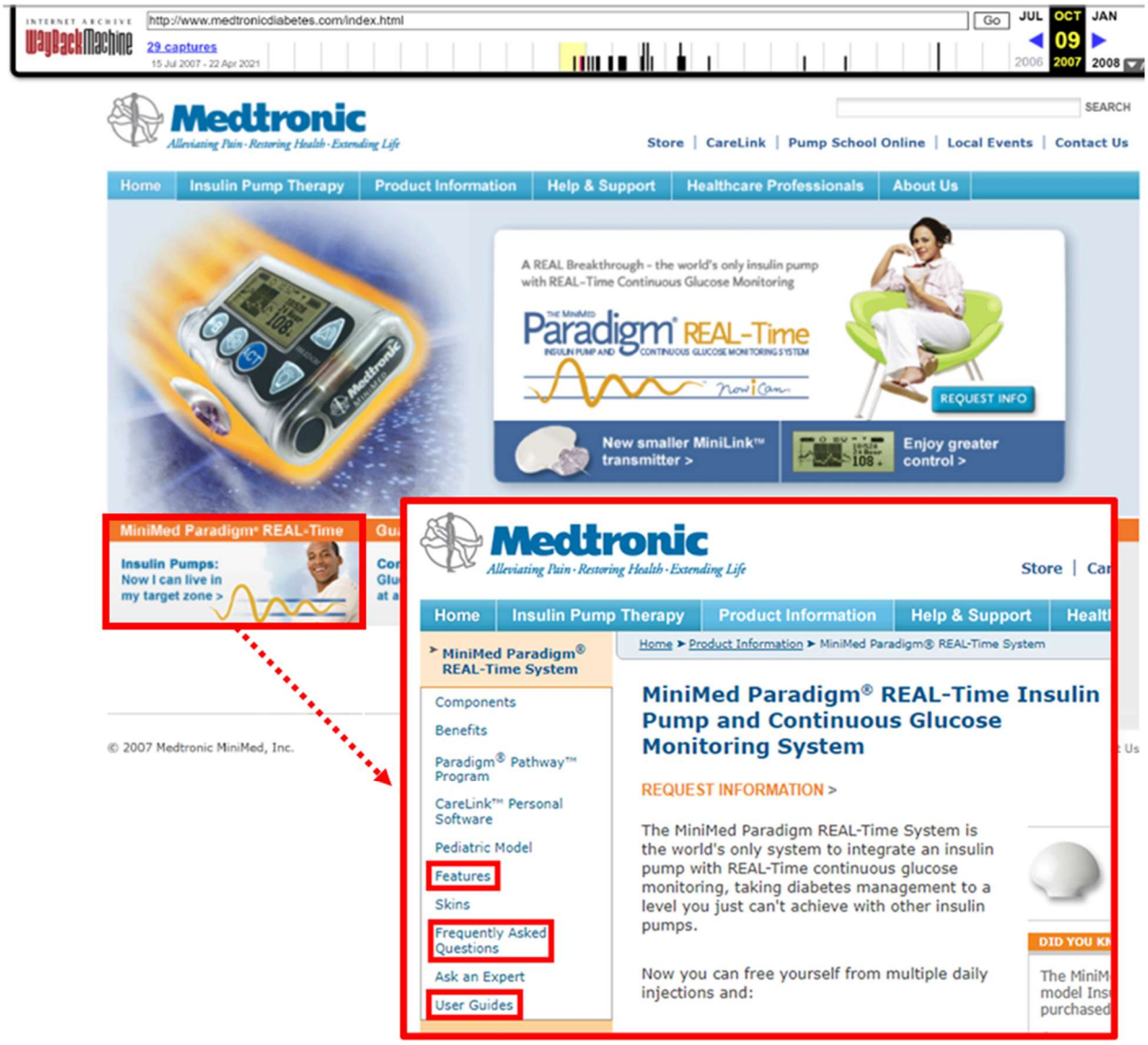
B. Paradigm® REAL-Time (EX1211) Is Prior Art

Paradigm® REAL-Time (EX1211)[3] consists of several pages published on the Medtronic Diabetes Website (www.medtronicdiabetes.com) at least by October

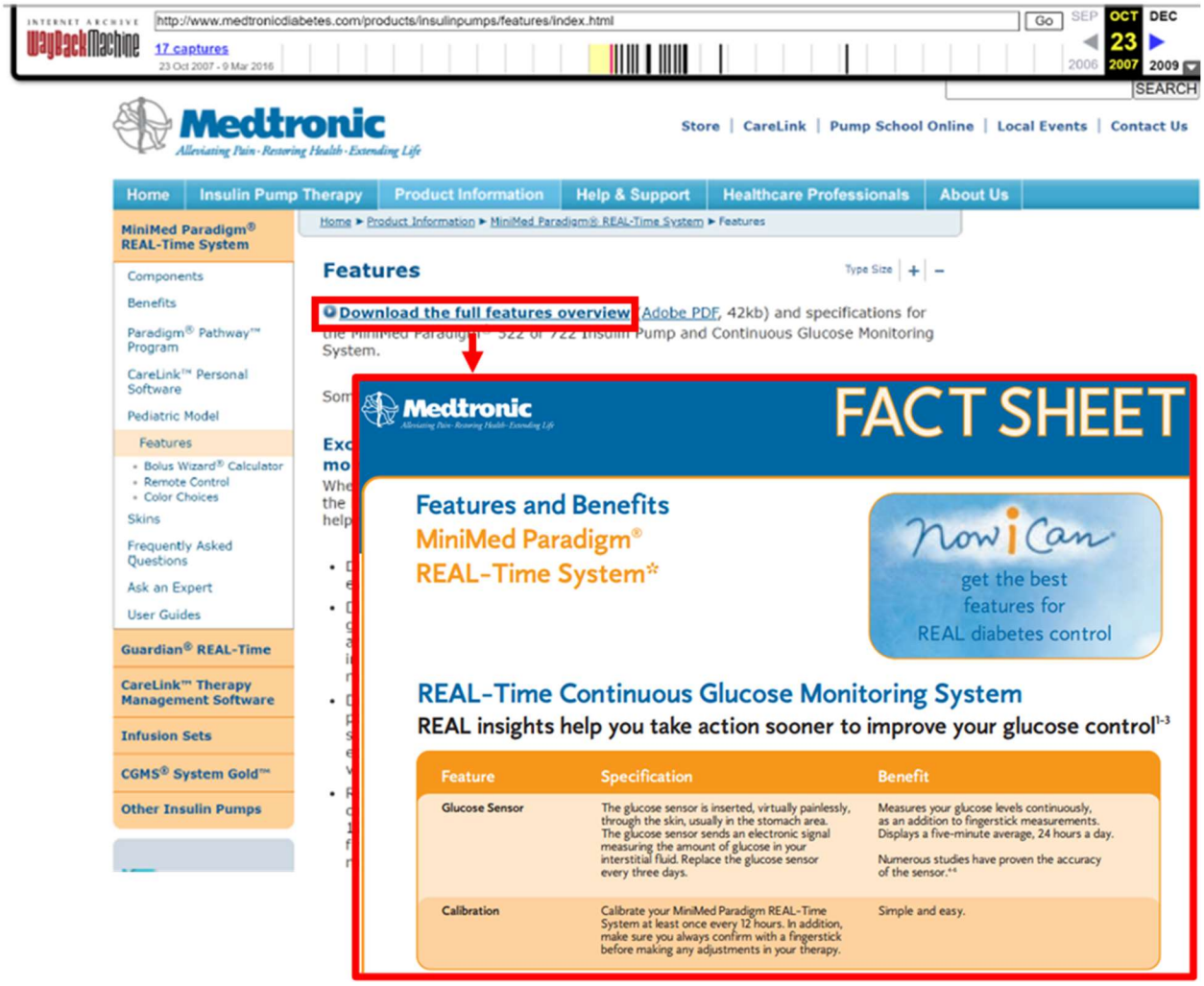
[3] Herein, "Paradigm® REAL-Time" refers to the webpages submitted as EX1211. "Paradigm® REAL-Time Product" refers to the product, which received FDA approval on April 7, 2006. (EXs1241, 1244)

2007, thus making it prior art under § 102(b).

In October 2007, as recorded by the Internet Archive (https://web.archive.org), the Medtronic Diabetes homepage prominently exhibited and linked to the Paradigm® REAL-Time product webpage, which included links to Features, Frequently Asked Questions, and User Guides:



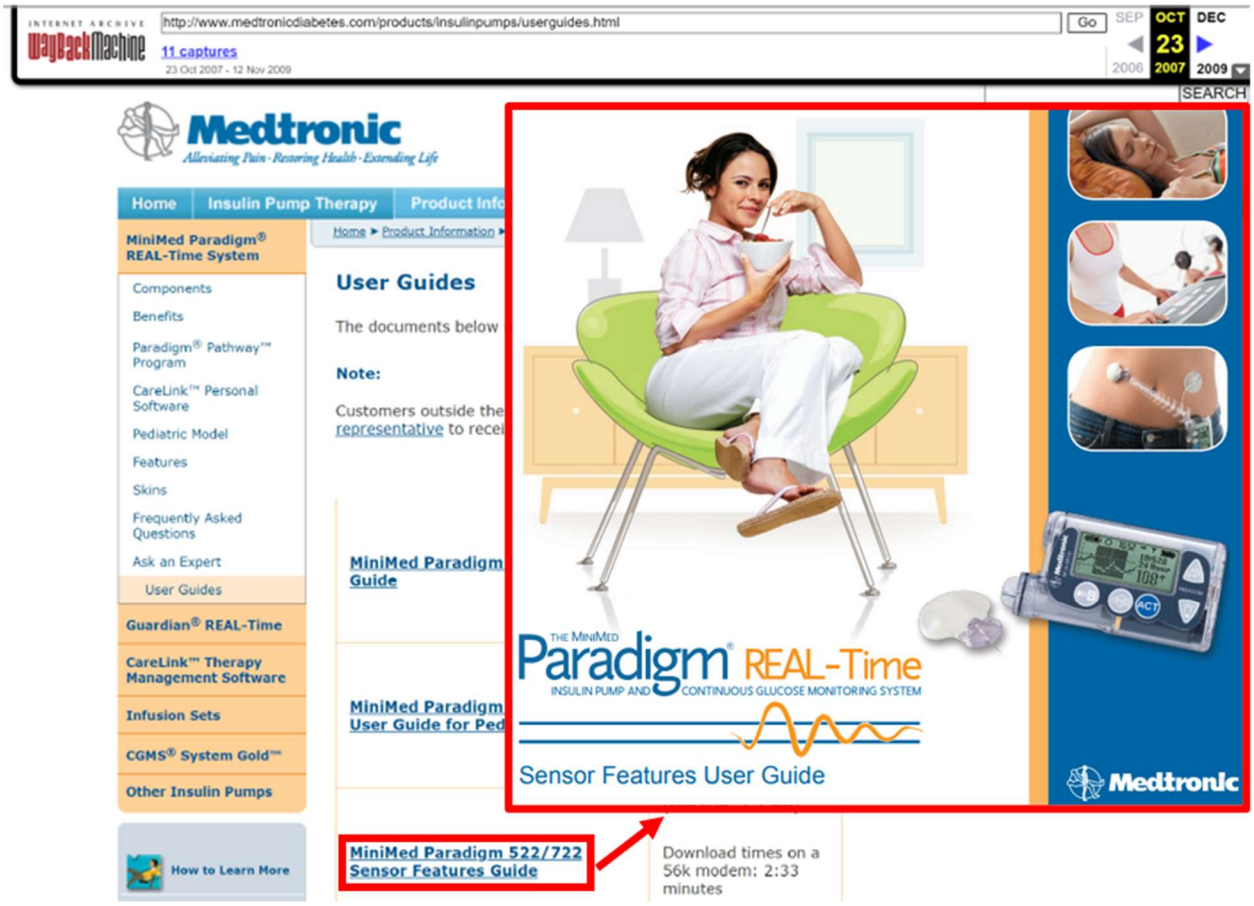
EX1211, 17-20 (excerpted; annotated in red). The "Features" tab opened the Paradigm® REAL-Time "Features" webpage, which included a hyperlink to the Features & Benefits Fact Sheet:



Id., 14-16 (excerpted; annotated in red). This Fact Sheet includes details on the MiniMed Paradigm® Insulin Pump ("Paradigm® Insulin Pump"), MiniLink™ Transmitter, glucose sensor, and glucose monitoring functionality of the Paradigm® REAL-Time System. *Id.*, 22-28.

The "Frequently Asked Questions" tab opened an FAQ webpage on various topics related to the Paradigm® REAL-Time Product. *Id.*, 5-13.

The "User Guides" tab opened a webpage with links to Paradigm® REAL-Time guides, including a "Sensor Features Guide":



Id., 2-4 (excerpted; annotated in red). The Sensor Features Guide provides additional details on the Paradigm® System and glucose monitoring functionality. *Id.*, 29-105.

As discussed in the internet archive affidavit, each of these pages was archived within a single week from October 23 to 30, 2007. EX1210, ¶5; EX1211, 2, 5, 14, 22, 29. This affidavit establishes that Paradigm® REAL-Time is prior art under 35

U.S.C. § 102(b) as a printed publication that was publicly accessible by October 2007. *See*, *e.g.*, *Valve Corp. v. Ironburg Inventions Ltd.*, 8 F.4th 1364, 1374 (Fed. Cir. 2021) (noting USPTO and district court reliance on Wayback Machine to establish prior art public availability); *Crestron Elecs., Inc. v. Intuitive Bldg Controls, Inc.*, IPR2015-01460, Paper 14 at 12, 14 (PTAB Jan. 14, 2016); *Elec. Arts Inc. v. White Knuckle IP, LLC*, IPR2015-01595, Paper 38 at 11 (PTAB Jan. 12, 2017); MPEP § 2128 (II)(E). Public accessibility of Paradigm REAL-Time is further demonstrated by scientific journals and magazines, including a full-page advertisement in the November 2007 edition of the American Diabetes Association's Diabetes Forecast magazine that directed readers to the Medtronic Diabetes website (www.medtronicdiabetes.com). EXs1237-1240, 1246; EX1208, ¶¶55, 68-71.

The Paradigm® REAL-Time reference constitutes a single publication because it describes a single product and was published on a common website. *Haliburton Energy Servs., Inc. v. Dynamic 3D Geosolutions LLC*, IPR2014-01186, Paper 13 at 15-18 (PTAB Jan. 12, 2015); *see also MacSports, Inc. v. Idea Nuevo, Inc.*, IPR2018-01006, Paper 6 at 8-9 (PTAB Nov. 13, 2018) ("[A] collection of webpages that describes a single product, from a single source, … may properly be regarded as being a single printed publication."). Indeed, the Board has considered Internet Archive captures from a single website as a single reference. *Am. Express*

Co. v. Harvey Lunenfeld, CBM2014-00050, Paper 51 at 49-51 (PTAB May 22, 2015).

Alternatively, the Paradigm® REAL-Time reference is a collection of publications that "ordinarily skilled artisans would have considered … together in order to gain a more complete understanding" of the corresponding Medtronic product. *Haliburton*, IPR2014-01186, Paper 13 at 19-20; *see also e.g.*, *Samsung Elecs. Co. Ltd. v. Rosetta-Wireless Corp.*, IPR2016-00622, Paper 48 at 64-65 (PTAB August 21, 2017) (treating Internet Archive captures from a single website as "interrelated teachings that an ordinarily skilled artisan would have known to combine"); *L & P Prop. Mgmt. Co. v. Nat'l Prod. Inc.*, IPR2016-00475, Paper 27 at 23-25 (PTAB July 19, 2017) (same for printed instructions and online user guide).

C. Patel-2009 (EX1212)

Patel-2009 (EX1212) discloses a transceiver (100) coupled to a subcutaneous glucose sensor (12) that exchanges data with a monitor over a two-way communication link:

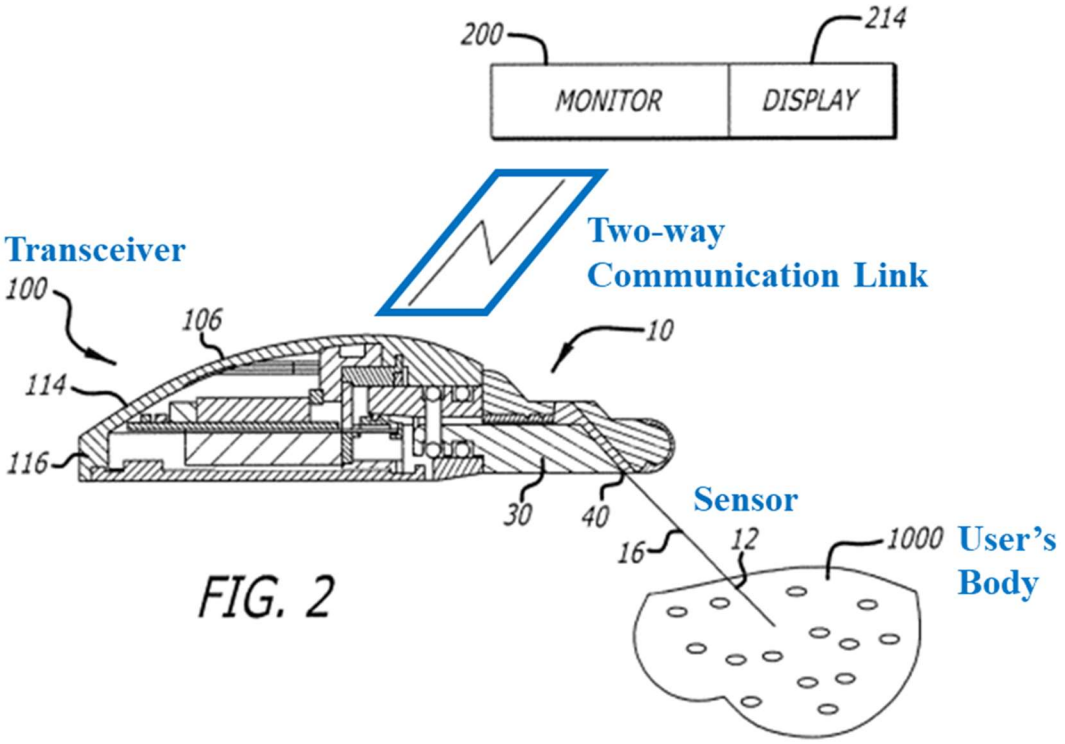


FIG. 2

EX1212, [0008-09], [0037], Fig. 2 (annotated in blue). The transceiver encompasses a processor that calibrates the sensor and calculates glucose values, a memory that stores these calculated glucose values, and a battery. *Id.*, [0008], [0013-14], [0058], [0061]; *see also* EX1214, [0051]. Sensor set (10) encompasses a subcutaneous sensor (12) which monitors glucose levels by exposing electrodes to bodily fluid:

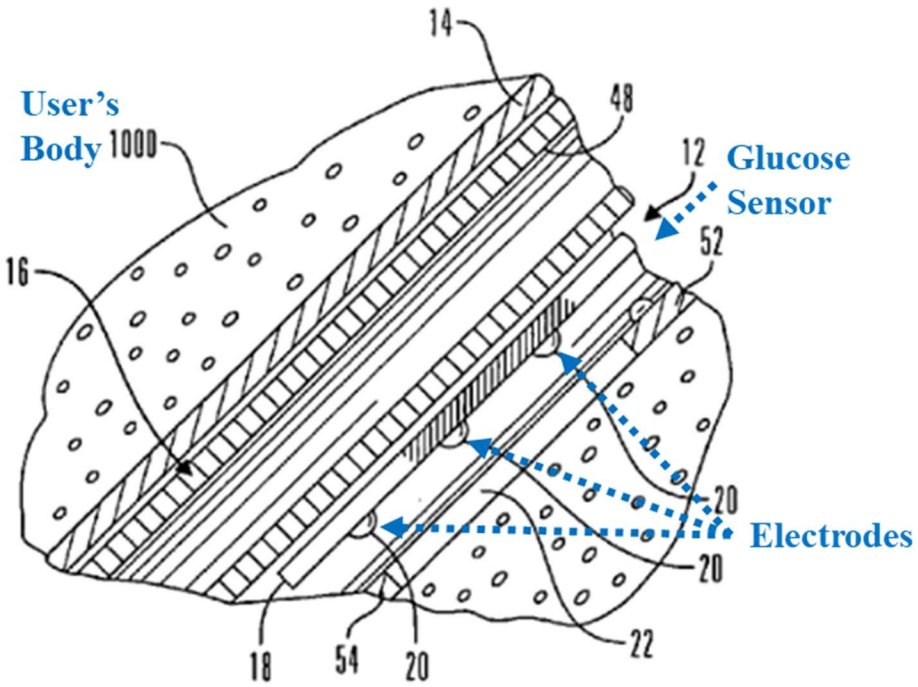


FIG. 6

EX1212, [0049-51], Fig. 6 (annotated in blue). The monitor displays glucose levels and trend graphs. *Id.*, [0066]. Finally, transceiver 100 maintains two-way communication with various devices, including monitor 200, infusion pump 210, PDA 230, cellular phone 240, and blood glucose meter 250 to exchange glucose values, calibration data, and other information:

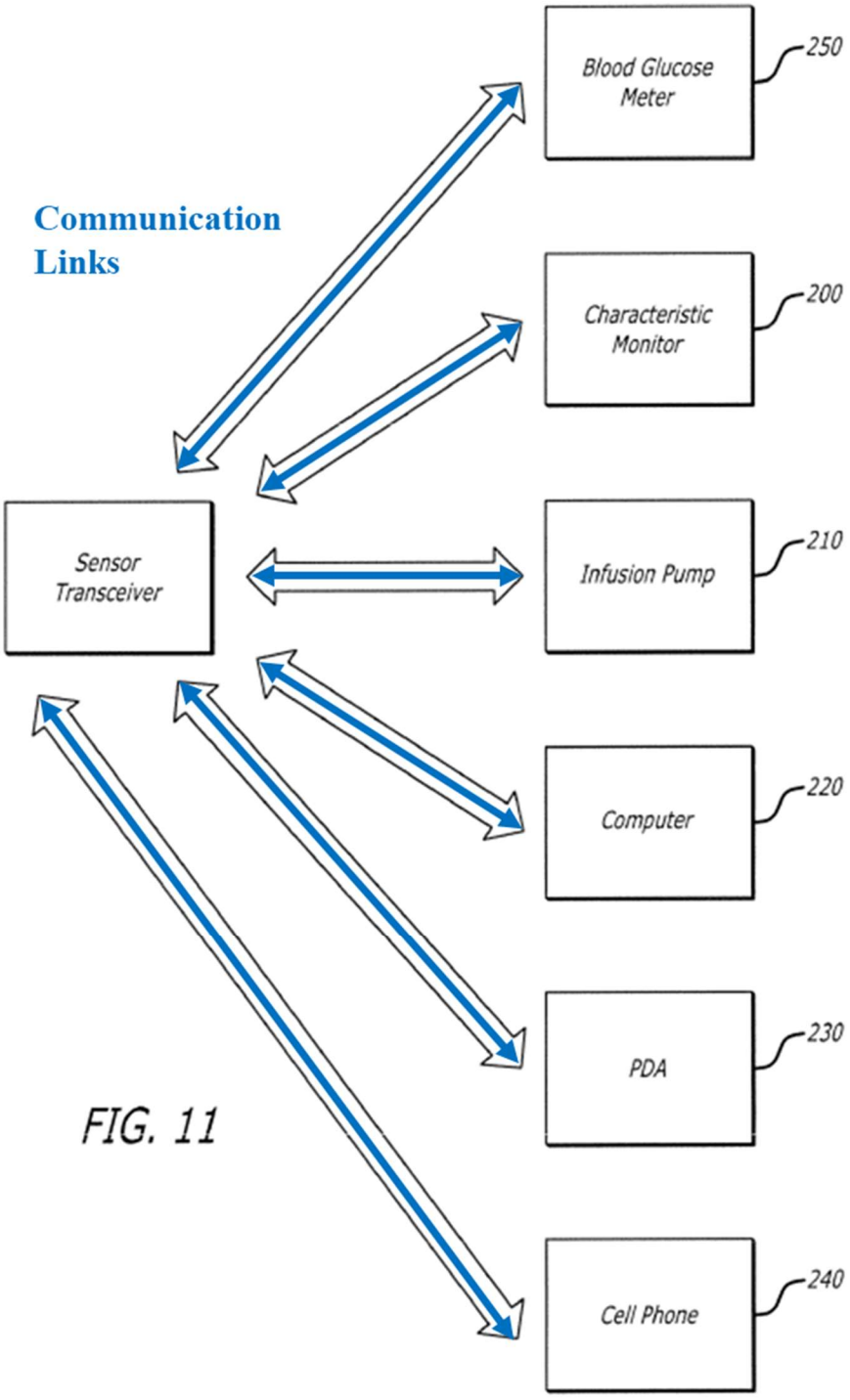


FIG. 11

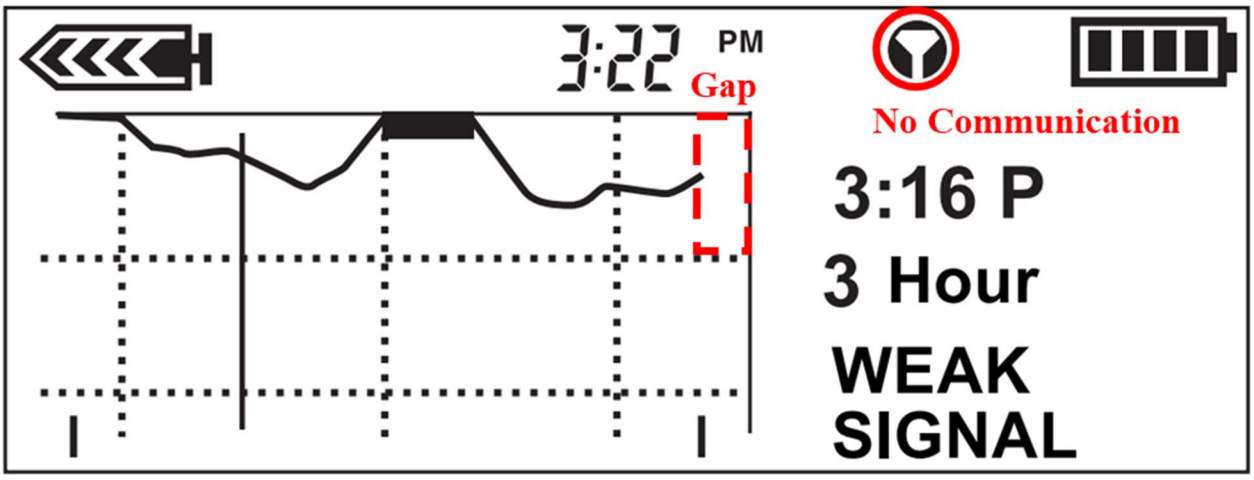
Id., [0042], [0075-76], [0084], Fig. 11 (annotated in blue). EX1208, ¶72.

Glucose values calculated during a loss of communication are synchronized from the transceiver to these remote devices when communication is re-established. EX1212, [0086]; EX1208, ¶73.

D. Paradigm® REAL-Time (EX1211)

Paradigm® REAL-Time (EX1211) discloses a continuous glucose monitoring system comprising Paradigm® Insulin Pump with a user display, MiniLink™ Transmitter, and glucose sensor components. EX1211, 9, 15, 18, 23-24, 37-38. The glucose sensor "measur[es] the amount of glucose in [] interstitial fluid" as an electronic signal, the MiniLink™ Transmitter "[r]eceives and processes signals from the glucose sensor and sends glucose values to the insulin pump through radio frequency (RF)," and the Paradigm® Insulin Pump displays 3 and 24-hour historical glucose graphs updated with average glucose readings every five minutes. *Id.*, 7-9, 15, 23-24, 64. EX1208, ¶74.

As long as continuous glucose data is transmitted from the transmitter to the insulin pump, continuous glucose monitoring ("CGM") data is displayed on the insulin pump's screen. EX1211, 7-8. When loss of communication from the transmitter to the insulin pump causes failed reception of glucose data, missed data is displayed as a gap:



Id., 8, 43, 49, 73 (excerpted; annotated in red). The MiniLink™ Transmitter stores 40 minutes of glucose data that re-populates the insulin pump's display of continuous glucose monitoring (CGM) data following correction of failed reception (e.g., when the transmitter and pump move within transmission range). *Id.*, 8. EX1208, ¶¶75-76.

E. Combination Of Patel-2009 And Paradigm® REAL-Time

Patel-2009 discloses a transceiver that calculates glucose values from sensor signals and stores calculated glucose values during failed communication, a monitor that graphs glucose values received from the transceiver, and the synchronization of glucose data when communication is re-established. EX1212, [0042], [0066], [0086]. The Patel-2009/Paradigm Combination incorporates Paradigm® REAL-Time's "sophisticated network of safety checks and systems" that "detects anything unusual," including failed receipt of glucose data (i.e., weak signal) and calibration errors. EX1211, 71-75. The Patel-2009/Paradigm Combination also incorporates

Paradigm® REAL-Time's display of missing "data gap[s]" when glucose data is not received because the transmitter is out-of-range or transmission fails due to interference, and the re-population of these gaps with glucose data stored in transmitter memory. *Id.*, 8, 10, 41, 73.

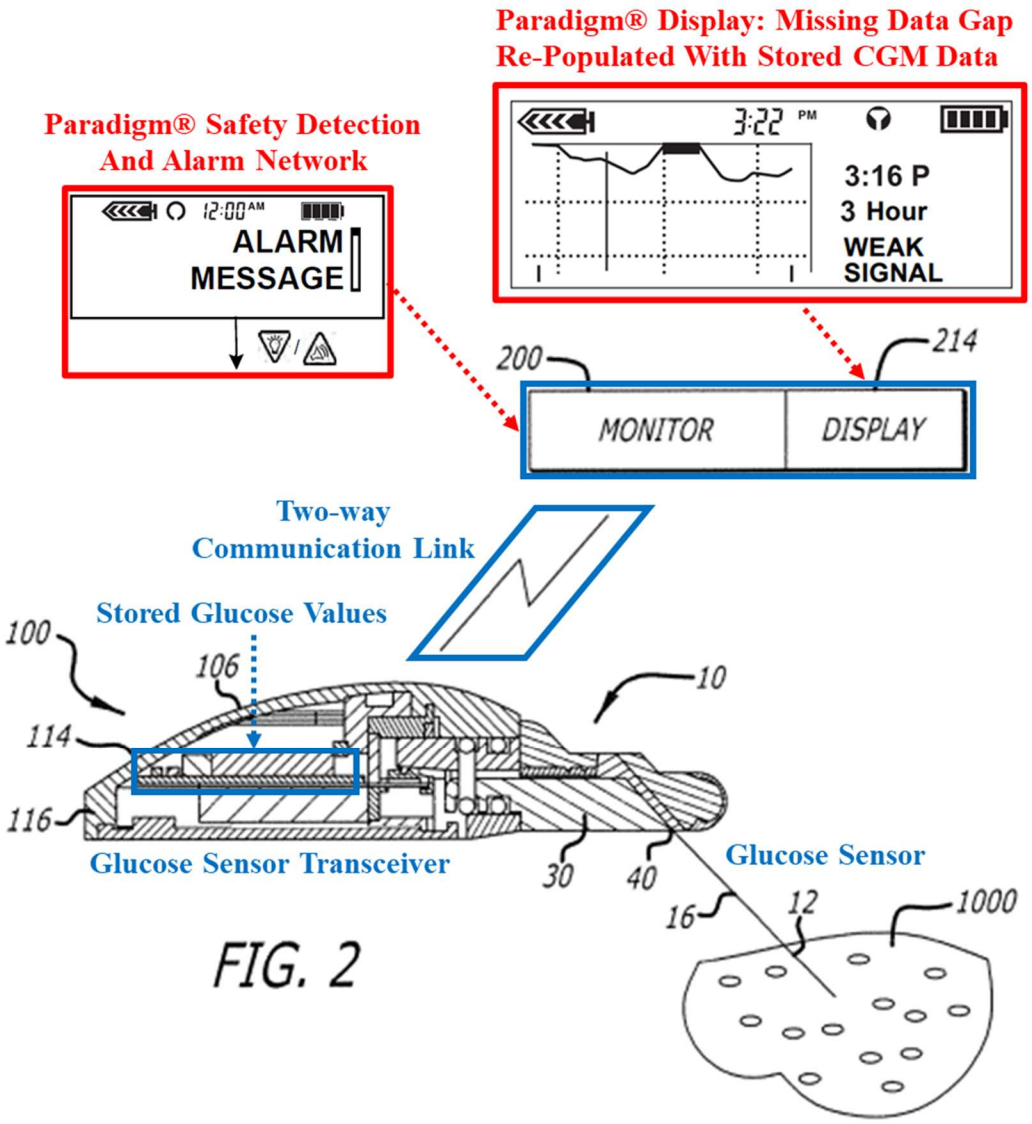


FIG. 2

EX1212, Fig. 2 (annotated in blue for Patel-2009); EX1211, 72-73 (excerpted; annotated in red for Paradigm® REAL-Time). The Patel-2009/Paradigm Combination retains the subcutaneous glucose sensor and glucose sensor transceiver from Patel-2009. EX1212, [0008], [0041], [0049], [0051], [0084], [0086]. EX1208, ¶77.

By incorporating detection and display functionalities from Paradigm® REAL-Time, the Patel-2009/Paradigm Combination results in glucose graphs that accurately display the failed reception of glucose data. EX1211, 8, 71, 73. Then, when communication is re-established, the Patel-2009/Paradigm Combination re-populates gaps in continuous glucose monitoring data with glucose values synchronized from Patel-2009's glucose sensor transceiver. EX1212, [0086]; EX1211, 8. EX1208, ¶78.

1. Motivation To Combine And Expectation Of Success

Patel-2009 discloses displaying glucose trend graphs to a user and provides for specific advantages over previous glucose monitoring systems and preexisting glucose sensor transmitters, including a glucose sensor transceiver that calculates and stores glucose values during failed communication (e.g., when a monitoring device is not in proximity) and synchronization of calculated glucose values from the transceiver to the monitoring device when communication is re-established. EX1212, [0007], [0084], [0086]. However, 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. *See Id.*, [0086]. EX1208, ¶79.

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. EX1211, 15, 18, 23-27; EX1212, [0004], [0006]; *see also*, *e.g.,* EX1229; EX1237, 17; EXs1239-1240. Therefore, a POSITA 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, a POSITA 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. EX1212, [0086]. EX1208, ¶¶55, 59, 60, 80.

A POSITA would have naturally investigated Paradigm® REAL-Time because Patel-2009 provides improvement to previous glucose monitoring systems, and Paradigm® REAL-Time was one of the leading continuous glucose monitoring systems of that time. EX1208, ¶81. A POSITA would have been especially motivated to combine Paradigm® REAL-Time with Patel-2009 because they both relate to similar Medtronic continuous glucose monitoring systems as evidenced by

their visual similarity and common citation to Medtronic's U.S. Patent No. 6,554,798. EX1212, [0068-69], Fig. 1; EX1211, 32; EX1208, ¶¶81-83.

A POSITA would have expected to successfully combine Paradigm® REAL-Time with Patel-2009 because Patel-2009 discloses specific improvements over previous glucose monitoring systems like Paradigm® REAL-Time. EX1212, [0007], [0084-86]. A POSITA would have known how to modify Patel-2009 to perform functions of Paradigm® REAL-Time, for example by modifying the programming of Patel-2009's monitor or by importing programs from the Paradigm® Insulin Pump. EX1208, ¶¶56-57, 84, 85.

F. Ground 1 Claim Mappings

As set out below, the Patel-2009/Paradigm Combination renders claim 13 obvious, including its incorporation of independent claim 1. EX1208, ¶86.

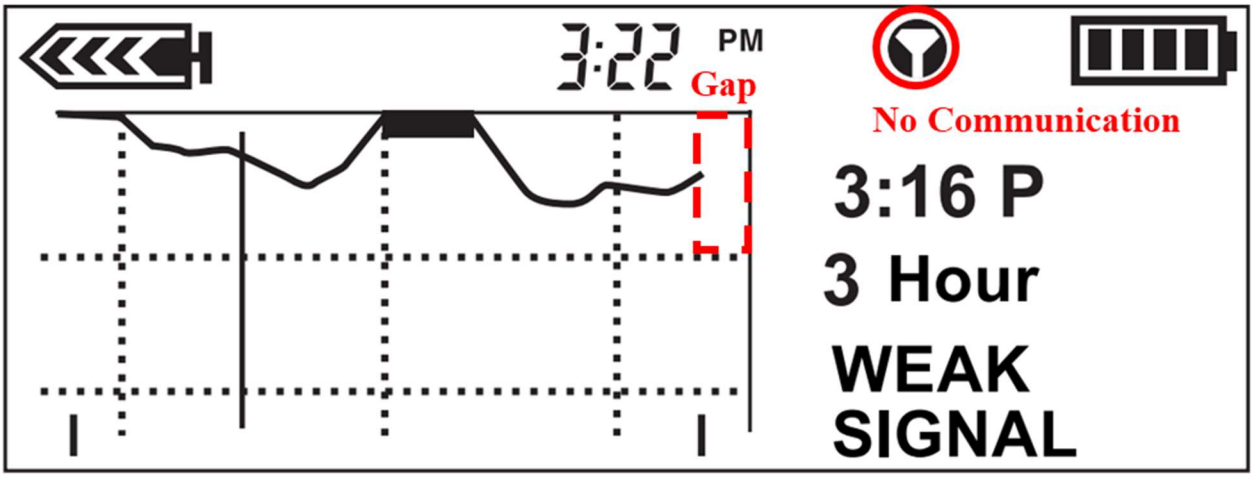
1. Claim 1

a) [1.A] (Preamble)

A glucose monitoring system for backfilling data gaps that occur while a user monitors glucose levels, the glucose monitoring system comprising:

If the preamble is limiting, Patel-2009 and Paradigm® REAL-Time both disclose CGM systems that display glucose levels to a user. EX1212, [0042], [0066]; EX1211, 15, 23-24, 37-38, 64. EX1208, ¶87.

Paradigm® REAL-Time discloses a graph that displays sensor glucose data points. EX1211, 64. When glucose data is not received (*e.g.*, because "[t]ransmitter and insulin pump are too far apart"), this graph displays a corresponding gap in glucose values:



Id., 8, 73 (excerpted; annotated in red). EX1208, ¶88.

When out-of-range, the "transmitter holds 40 minutes worth of memory, so … continuous glucose monitoring (CGM) data can be re-populated in the insulin pump." EX1211, 8. CGM data re-populates the last 40 minutes of missing glucose data so that gaps only remain in historical reports if the transmitter and pump are "out-of-range for longer than 40 minutes." *Id.*; *see infra* VI.F.1.(k). EX1208, ¶89.

b) [1.B]

a glucose sensor, a portion of which is configured to be positioned under skin of the user, wherein the glucose sensor is configured to sample a biological fluid of the user to provide sensor data;

Patel-2009 discloses percutaneous sensor set 10 with electrode-type sensor 12 placed below the skin in a user's body 1000:

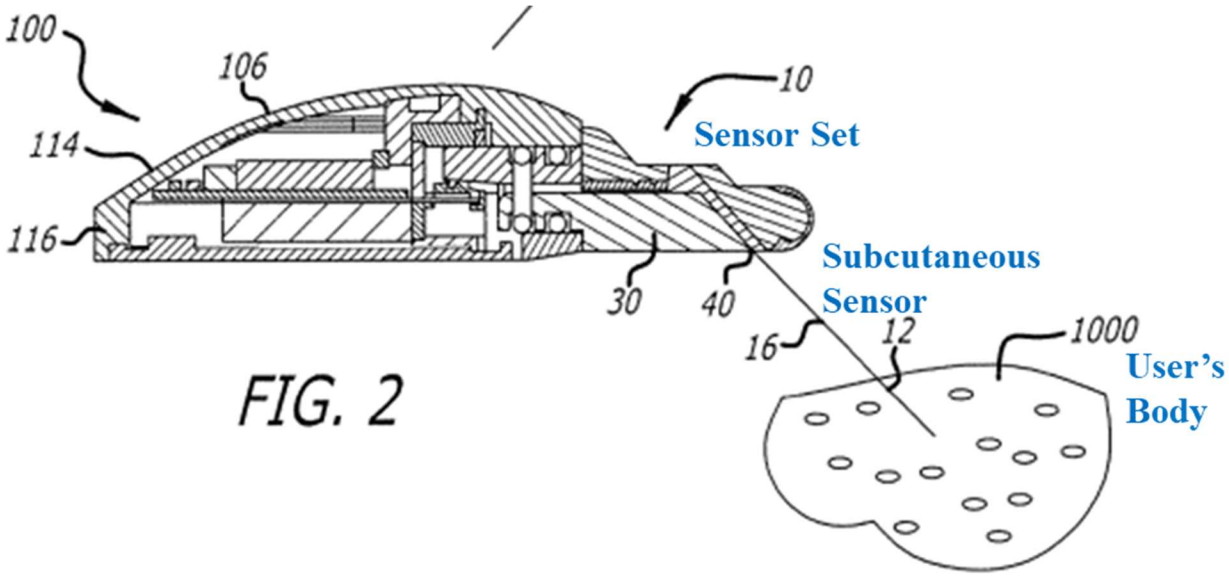


FIG. 2

EX1212, [0041], [0049], Fig. 2 (excerpted, annotated in blue). Sensor 12 produces signals indicative of monitored glucose levels by exposing sensor electrodes 20 to the user's bodily fluids:

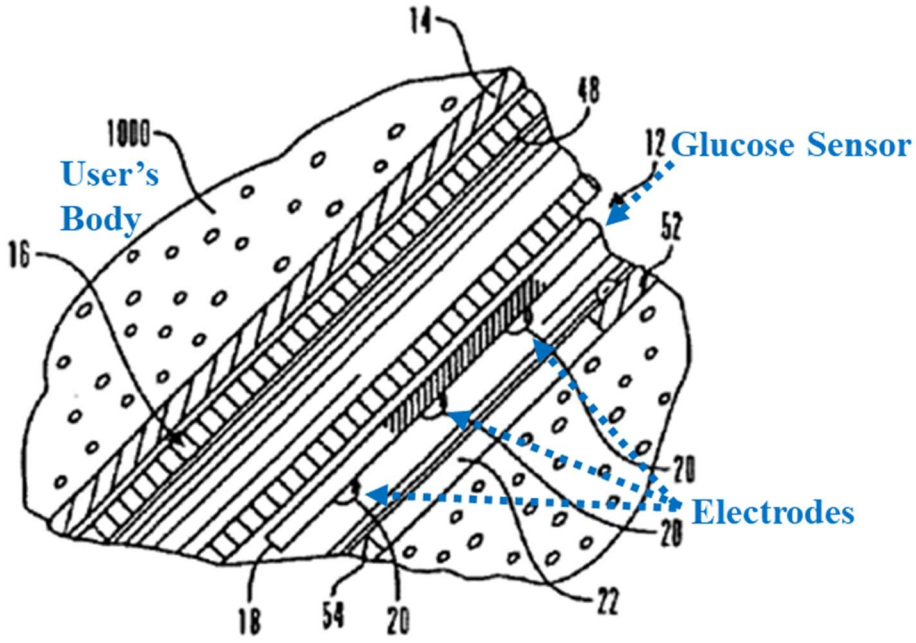
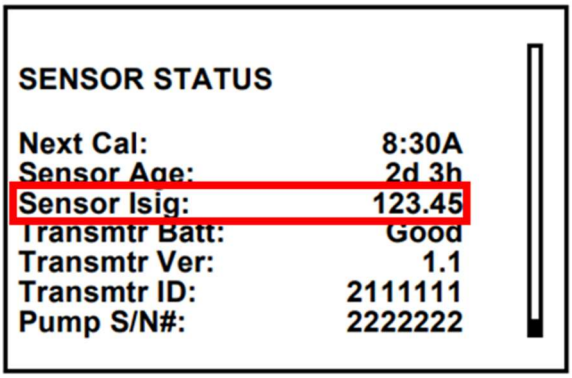


FIG. 6

Id., [0008], [0038], [0049-51], Fig. 6 (annotated in blue). EX1208, ¶90.

Paradigm® REAL-Time also discloses a glucose sensor that "continuously measures glucose from [] subcutaneous tissue as an electronic signal." EX1211, 38. This sensor is inserted through the skin, and "sends an electronic signal measuring the amount of glucose in [] interstitial fluid." EX1211, 23. The sensor current signal ("Isig") is reported in units of nanoamperes (nA) of current, for example 123.45 nA:



Id., 63, 80 (excerpted; annotated in red). EX1208, ¶91.

c) [1.C]

a data processing and transmitter unit coupled to the glucose sensor, the data processing and transmitter unit comprising a power supply, a processor of the data processing and transmitter unit, memory of the data processing and transmitter unit, and a radio frequency transceiver of the data processing and transmitter unit, wherein the data processing and transmitter unit is configured to:

Patel-2009 discloses that "sensor set **10** is connected to the telemetered characteristic sensor transceiver **100**," which satisfies the claimed "data processing and transmitter unit." EX1212, [0072]. Figure 8A illustrates transceiver 100 coupled to sensor set 10:

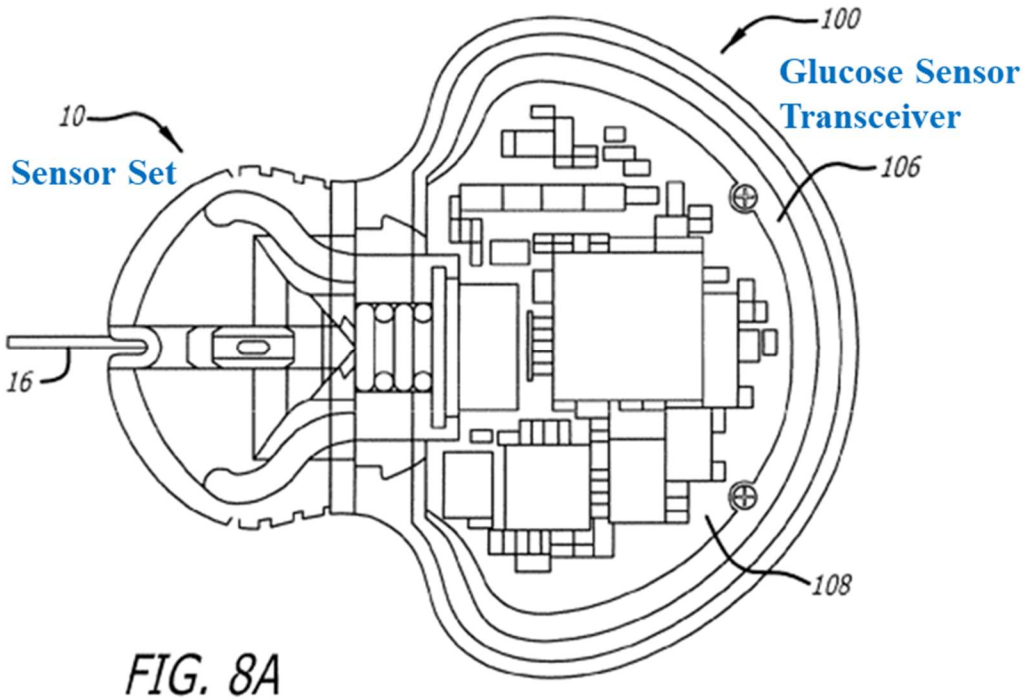


FIG. 8A

Id., [0056], Fig. 8A (annotated in blue). The "sensor transceiver **100** includes … Microprocessor **1120**, Digital to Analog Converter **1122**, Real Time Clock **1126**, EEPROM **1124**, RF Transceiver **1128**, and a battery **1130**, as well as other associated electronics such as an antenna." *Id.*, [0058]; *see also id.*, [0008] (describing "transceiver comprising … a processor …, a transmitter …, a receiver …, and a memory coupled to the processor for storing data") & [0056]; EX1214, [0051] ("The telemetered characteristic sensor transceiver 100 includes a housing 106 that supports a printed circuit board 108, batteries 110, antenna 112, and the cable 102 with the connector 104. The housing 106 may also support a processor for performing calculations and a memory for storing information.") EX1208, ¶92.

Paradigm® REAL-Time also discloses that the MiniLink™ Transmitter connects with a glucose sensor, has a rechargeable battery, and has memory that stores 40-minutes of glucose monitoring data. *See* EX1211, 8, 37, 51 (describing MiniLink™ Transmitter). EX1208, ¶93.

d) [1.D]

receive the sensor data from the glucose sensor and store the sensor data in the memory of the data processing and transmitter unit; 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; and

The Patel-2009 transceiver "perform[s] data calibration and sensor glucose value calculation" to "convert raw sensor signals into calibrated processed glucose values using algorithms stored in the sensor transceiver." EX1212, [0042], [0084], [0090]. The transceiver "calibrate[s] the sensor's readings" with "calibration data" received from a remote device (e.g., a blood glucose meter). *Id.*, [0042], [0064], [0081], [0084]. Calibration is performed by running filtering and calibration algorithms. *Id.*, [0076]. Following calibration, Patel-2009 discloses that the transceiver "appropriately calculate[s] sensor glucose values using the calibrated sensor readings." *Id.*, [0084]. The transceiver logs calculated glucose values and stores them in memory as glucose history. *Id.*, [0013], [0047], [0081], [0083], [0086]. EX1208, ¶94.

Patel-2009 discloses storing sensor data in memory at least during filtering, calibration, and calculation. *See supra* IV.A.3. A POSITA understood that the transceiver's processor stores sensor data in memory (e.g., processor cache, buffer, RAM) while filtering sensor signals, calibrating sensor readings, and calculating glucose values from calibrated sensor readings. EX1208, ¶¶46, 54, 95.

Paradigm® REAL-Time also discloses a calibration algorithm that uses meter blood glucose reference values (i.e., meter BG) to "align[] the glucose sensor … so that continuous glucose monitoring (CGM) readings are representative of [] blood glucose level." EX1211, 10, 37, 61-62, 75, 83. Glucose values are calculated following calibration. *Id.*, 61. EX1208, ¶96.

Patel-2009 and Paradigm® REAL-Time each disclose processing sensor signals with calibration data (e.g., reference values) and sensitivity coefficients associated with sensor sensitivity. A POSITA understood that calibration/calculation algorithms of Patel-2009 and Paradigm® REAL-Time processed sensor readings with "data associated with a sensitivity of the glucose sensor" as calibration data in this context was understood to reflect the sensitivity of the glucose sensor. *See supra* IV.A.2; EX1208, ¶¶37-40, 54. For example, a 2008 article explained how the "calibration process must be repeated … to correct for possible sensitivity changes." EX1247, 2499 (explaining how different devices, including the Medtronic Guardian, updated calibration data throughout sensor life). EX1208, ¶97.

e) [1.E]

transmit the processed sensor data over a Bluetooth wireless communication link using the radio frequency transceiver of the data processing and transmitter unit; and

Patel-2009 provides that the transceiver transmits calculated glucose values to a monitor and other devices. EX1212, [0008], [0013], [0042], [0076]. The transceiver exchanges information over two-way wireless communication links:

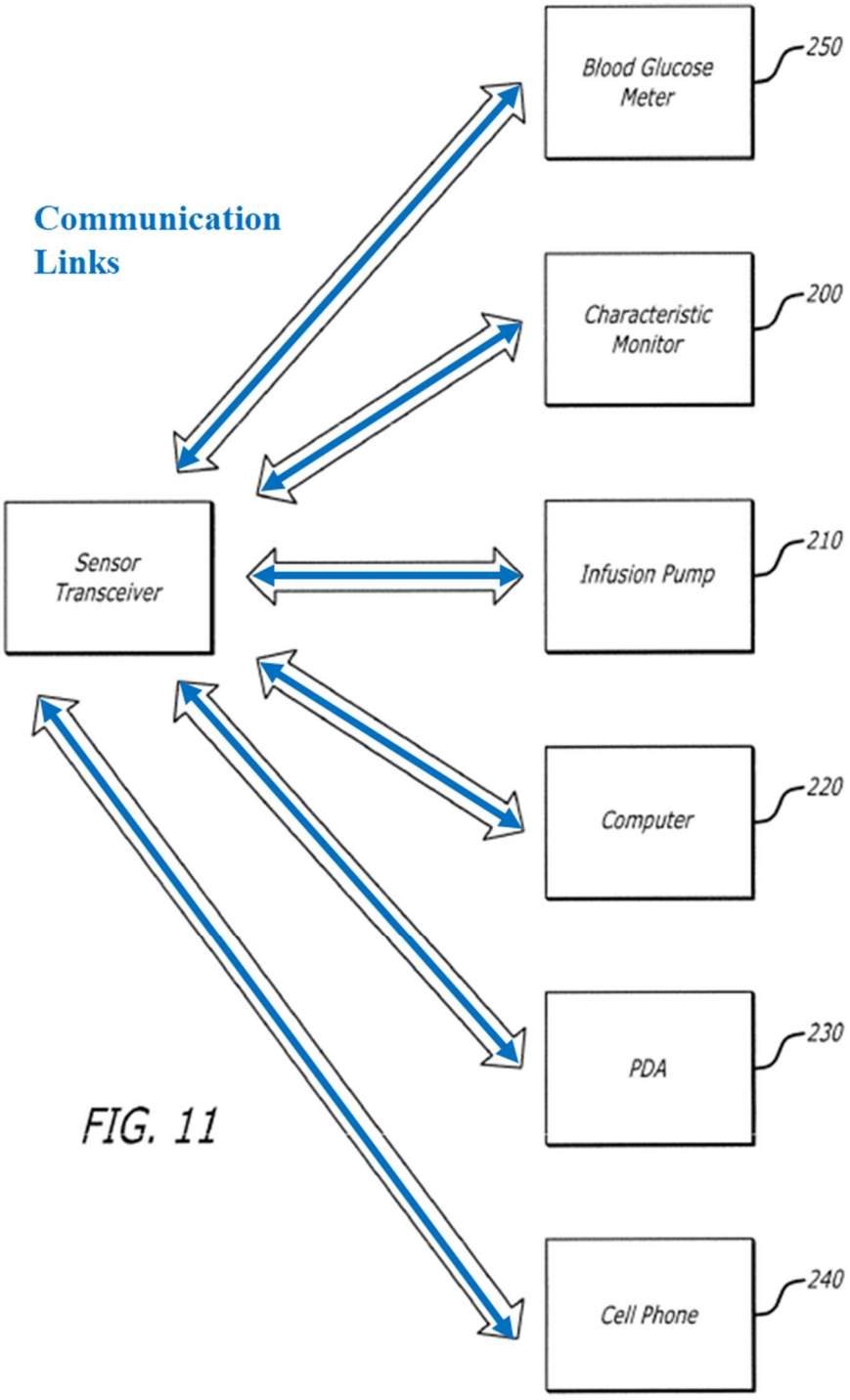


FIG. 11

Id., [0076], Fig. 11 (annotated in blue). The rate, frequency, and other attributes of communication links are configured according to configuration data exchanged with remote devices. *Id.*, [0012], [0082]. EX1208, ¶98.

Paradigm® REAL-Time also discloses that the MiniLink™ Transmitter sends processed "glucose values to the insulin pump" using radio frequency transmission with a six-foot range. EX1211, 8, 23, 51; EX1208, ¶99.

A POSITA 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. EX1208, ¶¶47-49, 54, 56, 61, 100; *see supra* IV.A.4. For example, Bluetooth would have been chosen for communication with computers, PDAs, and cell phones as disclosed in Patel-2009.

f) [1.F]

a receiver unit comprising a processor of the receiver unit, memory of the receiver unit, a radio frequency transceiver of the receiver unit, an antenna, and a display, wherein 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,

Patel-2009 discloses transmission of glucose data over two-way communication links to various devices with a display used to display glucose measurements, including infusion pumps, monitors, personal computers, PDAs, and cellular phones. EX1212, [0042], [0066], [0076], Figs. 2, 11; *see also supra* VI.F.1.(e). EX1208, ¶101.

Patel-2009 discloses various receivers that have a processor and receive glucose values with a transceiver and antenna. For example, Patel-2009 discloses

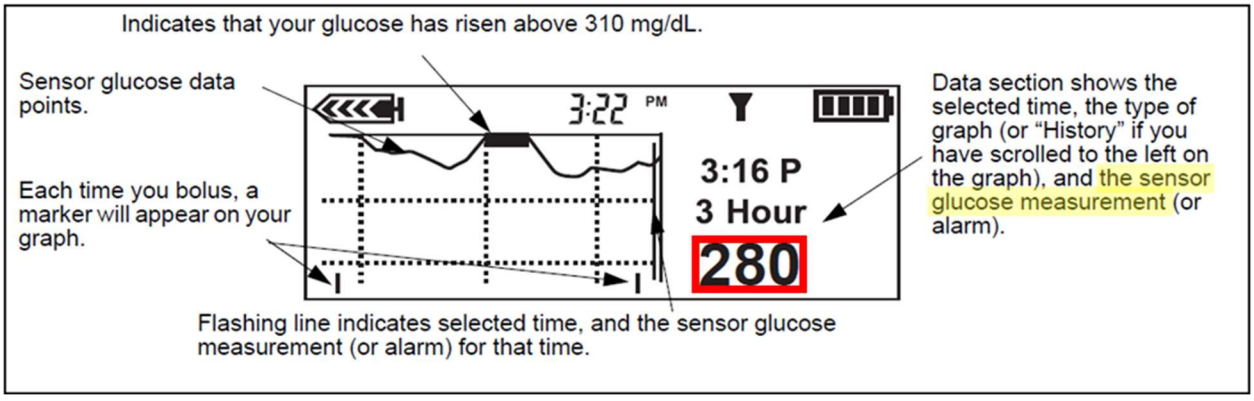
exchanging data with personal computer, personal digital assistant (PDA), or monitor. EX1212, [0043], [0045]. A POSITA would recognize that these devices have a processor and receive communications with an antenna and transceiver. EX1208, ¶¶61, 102-103; *see also* EX1211, 7-8, 23-26, 37, 43-50, 71 (monitoring device and function disclosed by Paradigm® REAL-Time); *infra* VIII.D.1.(f).

As discussed above, a POSITA would have found it obvious to configure communication links to use Bluetooth. EX1208, ¶¶47-49, 54, 56, 100, 104; *see supra* IV.A.4, VI.F.1.(e).

g) [1.G]

output to the display of the receiver unit, a numerical value representing the processed sensor data,

Paradigm® REAL-Time discloses display of numerical sensor glucose values:



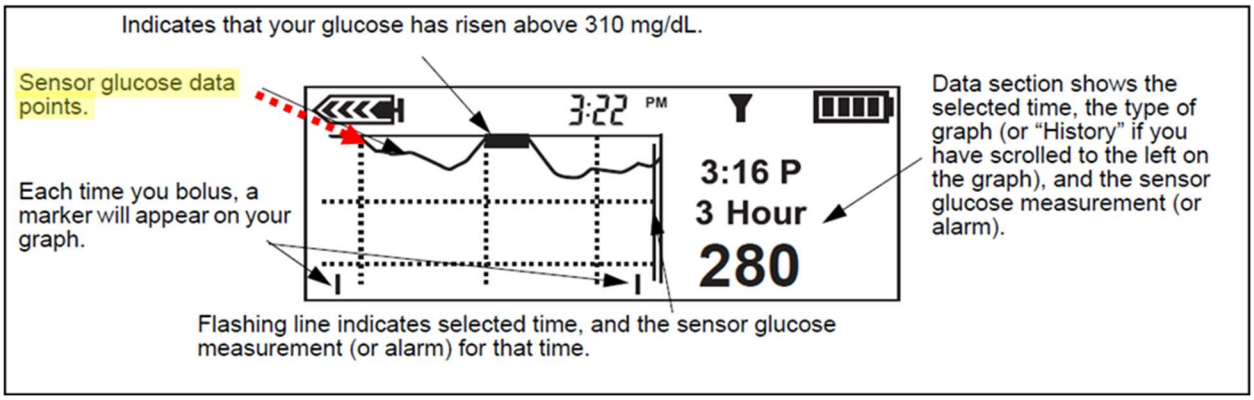
EX1211, 64 (excerpted; annotated in red; highlighted).

Patel-2009 also discloses display of glucose levels. EX1212, [0047], [0066]; EX1208, ¶105.

h) [1.H]

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,

Paradigm® REAL-Time discloses display of 3 and 24-hour glucose graphs with average sensor glucose values that update every five minutes:



EX1211, 7, 24, 64-65 (excerpted; annotated in red; highlighted); EX1208, ¶106.

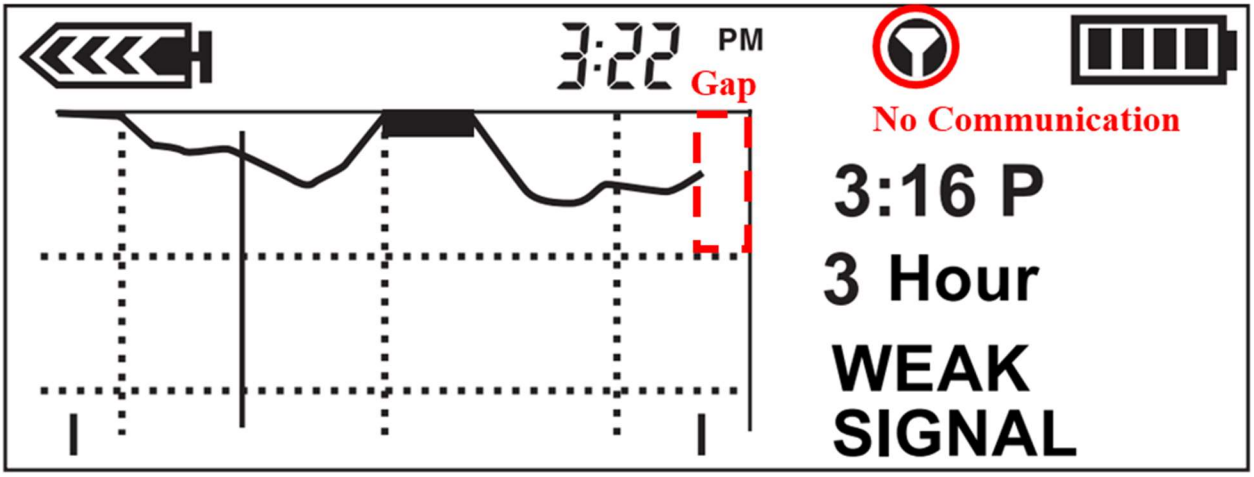
Patel-2009 also discloses display of glucose trends and graphs. EX1212, [0047], [0066]; EX1208, ¶107.

i) [1.I]

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;

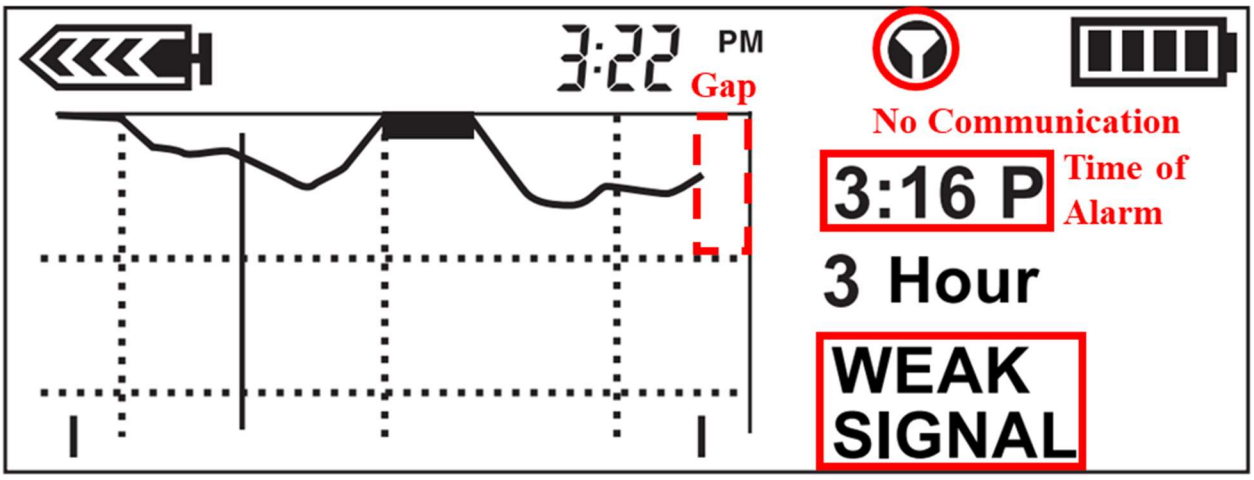
Paradigm® REAL-Time discloses "a sophisticated network of safety checks and systems" that "detects anything unusual" and provides notice of conditions requiring immediate attention, including weak signals and calibration errors. EX1211, 71, 73-76. For example, an ( ) icon changes to an ( ) icon when "the sensor is connected to the transmitter and [was] communicating with the pump" but this communication has been lost. *Id.*, 43. Lost communication causes "failed reception of continuous glucose monitoring (CGM) data." *Id.*, 8. EX1208, ¶108.

"[W]hen the pump does not receive data," the graph displays a "data gap:"



EX1211, 8, 73 (excerpted; annotated in red). If failed reception persists for 5-40 minutes as set in Missed Data,[4] a "Weak Signal" alarm is triggered and shown on the graph "along with the time of the alarm:"

[4] A "Lost Sensor" alarm is triggered after 40 minutes. EX1211, 73.



Id., 8, 49-50, 67, 73 (excerpted; annotated in red). The data gap corresponds with failed reception of glucose data, including the period (e.g., 10 minutes) before a Weak Signal alarm is triggered. *Id.*, 8, 73. EX1208, ¶¶58, 60, 109.

j) [1.J]

wherein, during a time period corresponding to the adverse condition, sensor data, processed sensor data, or both, are stored in the memory of the data processing and transmitter unit;

Patel-2009 discloses that the transceiver calculates and stores glucose data during failed communication. EX1212, [0086]. EX1208, ¶111.

Paradigm® REAL-Time also discloses that the MiniLink™ Transmitter holds 40-minutes of glucose data in memory when the transmitter and insulin pump are out-of-range. EX1211, 8. EX1208, ¶110.

k) [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, and

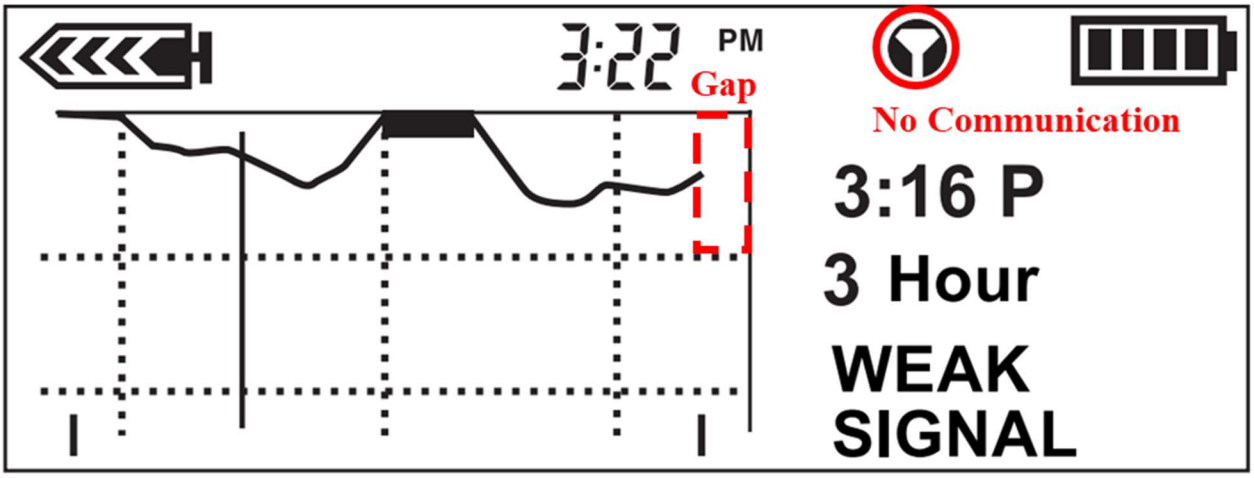
Paradigm® REAL-Time discloses that when the transmitter and insulin pump are out of transmission range, the "transmitter holds 40 minutes worth of memory, so … continuous glucose monitoring (CGM) data can be re-populated in the insulin pump." EX1211, 8. If the "[t]ransmitter and insulin pump are out-of-range 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 re-populated and do not persist in historical graphs. EX1211, 8. EX1208, ¶¶60, 112.

Patel-2009 also discloses that glucose values calculated during failed communication are synchronized from the transceiver to the monitoring device (e.g., infusion pump) when communication is re-established after being lost. EX1212, [0086]. EX1208, ¶¶60, 113.

l) [1.L]

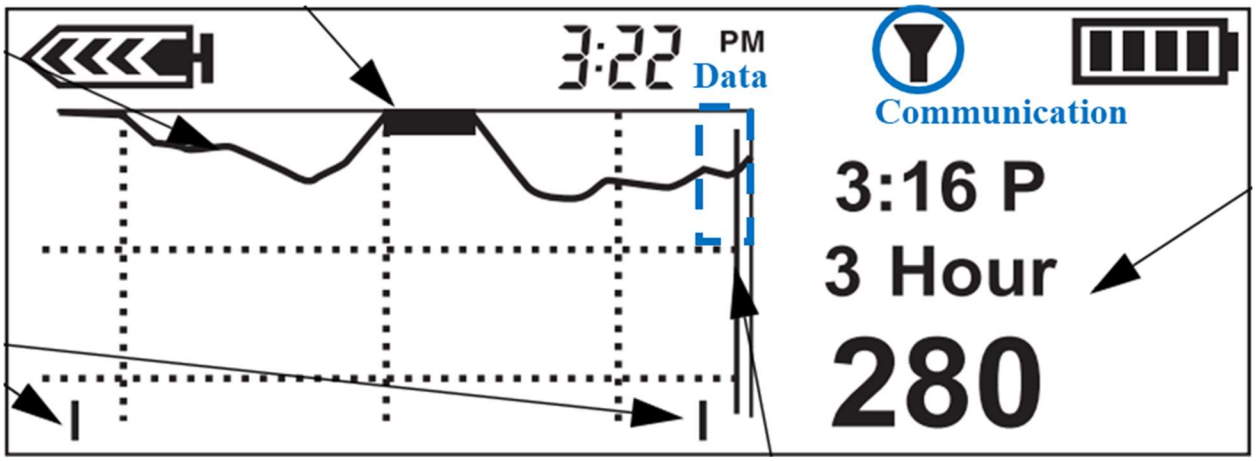
wherein the processed sensor data for the time period corresponding to the adverse condition that is outputted to the display after the adverse condition is corrected comprises a second line graph having a first end corresponding to the time associated with the start of the adverse condition and a second end corresponding to a time associated with an end of the adverse condition.

Paradigm® REAL-Time illustrates a 3-hour glucose graph with a data gap during "failed reception of sensor data from the transmitter to the pump" while "communication is lost:"

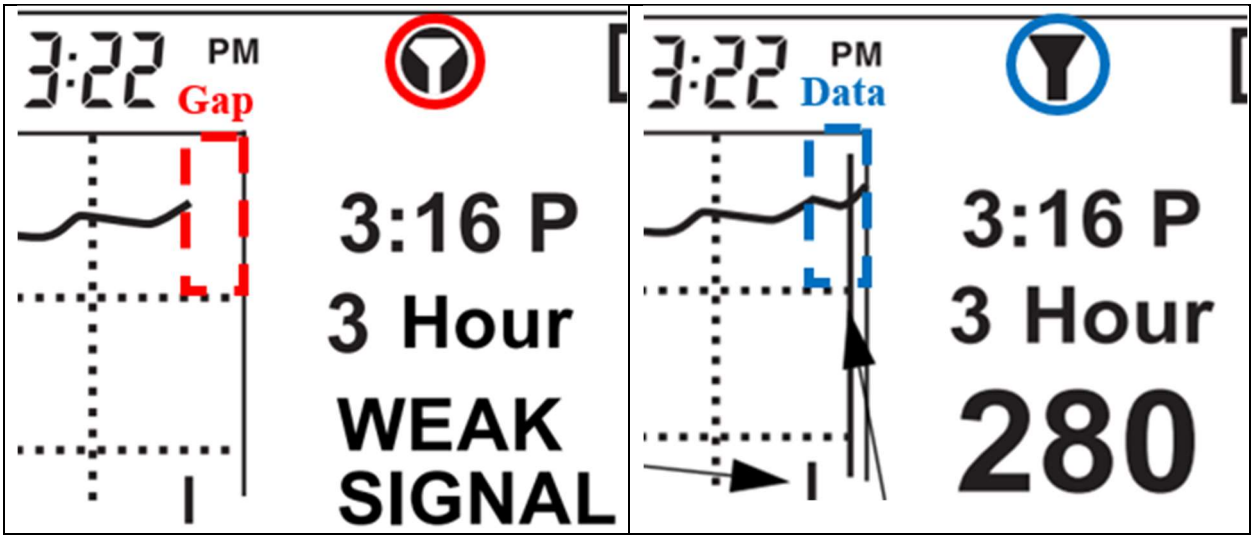


EX1211, 43, 49, 73 (excerpted; annotated in red); *see also supra* VI.F.1.(i). EX1208, ¶114.

A 3-hour graph is also illustrated plotting the same glucose data without a data gap and while the transmitter is communicating with the pump:



EX1211, 43, 64 (excerpted; annotated in blue); *see also supra* VI.F.1.(h). 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. EX1211, 8; *see also supra* VI.F.1.(j)-(k). Comparing these two graphs, a POSITA would recognize that a data gap existing during reception failure is re-populated once communication is re-established:



EX1211, 64 (excerpted; annotated in blue), 73 (excerpted; annotated in red). This re-populated data comprises a line from the beginning to the end of the data gap. *Id.*, 64, 73. EX1208, ¶¶60, 115.

2. Claim 13

The glucose monitoring system of claim 1, wherein the adverse condition comprises a sensor misposition error.

As explained in Section VI.A above, Patent Owner's infringement contentions demonstrate an apparent intent to interpret "sensor misposition error" as associated with communication loss between the data processing and transmitter unit and the receiver unit—*e.g.*, caused by the relative positions of these two units' transceivers.

Under this interpretation, a "sensor misposition error" that encompasses signal loss is rendered obvious by Patel-2009 and Paradigm REAL-Time as this Patel-2009/Paradigm Combination was applied by Petitioner's preceding petition in IPR2023-01251. *See Supra* VII.F.1. For example, the Patel-2009/Paradigm Combination detects lost communications that cause "failed reception of continuous glucose monitoring (CGM) data," as taught by Paradigm. *Supra* VII.F.1.(i) (citing EX1211, 8); EX1208, ¶108. Further, the Patel-2009/Paradigm Combination displays a data gap on the receiver unit's glucose graph if the receiver unit (*e.g.*, a pump or cell phone, *see supra* VII.F.1.(f) (citing *e.g.*, EX1212, [0072], Fig. 11), EX1208, ¶¶72, 101-103; *see also supra* VII.C) fails to receive data for more than a certain amount of time, as taught by Paradigm. *Supra* VII.F.1.(i) (citing EX1211, 8, 73), VII.E (same); EX1208, ¶¶76-78, 109. During this period of signal loss, the Patel-2009/Paradigm combined system saves glucose data in the memory of the on-body unit's transceiver (i.e., the memory of the data processing and transmitter unit), as taught by both Paradigm and Patel-2009. (*Supra* VII.F.1.(j) (citing EX1212, [0086]; EX1211, 8 (describing *inter alia* that "glucose history information is stored on the

transceiver 100" such that "transceiver 100 can continuously calculate glucose values even when a remote device [(*i.e.*, receiver unit)] is not in proximity to the user"); *see* EX1208, ¶¶110-111.) Then, when transmission is re-established and the receiver unit (*e.g.*, pump or cell phone) begins receiving data again, the missing data is re-populated on the receiver, and the display is backfilled with a new graph having a line where the data gap previously existed, in line with the teachings of Paradigm (*see supra* VII.D (EX1211, 8, 43, 49, 73; EX1208, ¶76))—as implemented by the Patel-2009/Paradigm Combination. (*See Supra* VII.E.l (explaining the Patel-2009/Paradigm Combination) (citing EX1211, 8, 73; EX1212, [0086] (Patel-2009 teaching to synchronize the receiver device with glucose values calculated on the sensor/transceiver during once signal has been restored)), VII.F.1.(k) (citing EX1211, 8; EX1212, [0086]), VII.F.1.(j) (citing EX1211, 8, 43, 49, 73); EX1208, ¶¶77-80, 112-115.) EX1208, ¶¶58, 60, 116-117.

"Based on their education and experience in physiological monitoring, a POSITA would have known that failed communication could be caused by a variety of errors (*e.g.*, transmission error, reception error, signal error) …, and that failed communication would cause data to be unavailable and lead to the inability to display this data." EX1208, ¶58. For example, The POSITA would understand that signal loss would occur when the receiver device was not "in proximity" to the user, thus causing failure in "communication between the transceiver 100 and the remote

device." EX1212, [0086], EX1208, ¶58 ("A POSITA would also have recognized from reviewing any of the Patel-2009 (EX1212) … that failed communication would cause missing data that could not be displayed."); *see also supra* VII.E ("Patel-2009 discloses a transceiver that calculates glucose values from sensor signals and stores calculated glucose values during failed communication"); EX1208, ¶77. In describing another example of signal/communication loss, Paradigm REAL-Time explains that "[w]ireless transmission between the pump and transmitter … may be interrupted due to the transmitter orientation and the pump position on the body." EX1211, 41; *see also supra* VII.F.1.(i) ("For example, an ( ) icon changes to an ( ) icon when "the sensor is connected to the transmitter and [was] communicating with the pump" but this communication has been lost."); EX1208, ¶108. In this situation, Paradigm REAL-Time teaches that the communication failure may be resolved by "[m]ov[ing] the pump closer to the transmitter or to another position." (EX1211, 41.) Thus, the Patel-2009/Paradigm combination renders obvious claim 13 to the extent "a sensor misposition error" is satisfied by a signal loss between claim 1's "data processing and transmitter unit" and "receiver unit.". EX1208, ¶¶58, 60, 118.

VIII. GROUND 2: CLAIM 29 IS OBVIOUS OVER PATEL-2009, PARADIGM® REAL-TIME, AND GOLDSMITH

Claim 29 depends directly from claim 1 and further recites a "secondary receiver unit" that is a watch and that is *inter alia* "configured to receive processed sensor data from the data processing and transmitter unit." Goldsmith (EX1251) teaches a watch so configured. When implemented in the Patel-2009/Paradigm combination, the teachings of Goldsmith render claim 29 obvious. This is so whether the above-noted claim language requires that the watch receive data *directly* from the data processing and transmitter unit (as the claim plainly reads) or whether that language also encompasses the watch *indirectly* receiving data from a device other than the data processing and transmitter unit, such as a pump or phone (as Patent Owner contends in the Related Litigation).

A. Goldsmith (EX1251)

U.S. Patent Application Publication No. 2007/0093786 to Goldsmith (EX1251) published on April 26, 2007, and is prior art under at least 35 U.S.C. § 102(b). Goldsmith is analogous art to the '056 patent, as it describes a system for monitoring and treating blood glucose levels. EX1251, [0002]; EX1208, ¶119.

Goldsmith, titled "Watch Controller for a Medical Device" (EX1251, 1) discloses "[a]n infusion system that includes a watch controller device and a communication system … for providing convenient monitoring and control of the

infusion pump device in determining the appropriate amount of insulin to deliver." EX1251, Abstract; *see also id.*, [0006], [0010]. "[T]he infusion system includes … a sensing device" that "includes a sensor and a transmitter in communication with the infusion device" via wireless transmission. EX1251, [0018] *see also id.*, [0009], [0039], [0050]. The watch controller device interacts "with one or more devices, such as infusion pumps and analyte monitors." EX1251, [0085]; EX1208, ¶120.

Goldsmith's watch controller "interact[s] with one or more devices, such as infusion pumps and analyte monitors" (EX1251, [0085-86]) and displays glucose values 915 and trends 918, as shown in Figure 9A:

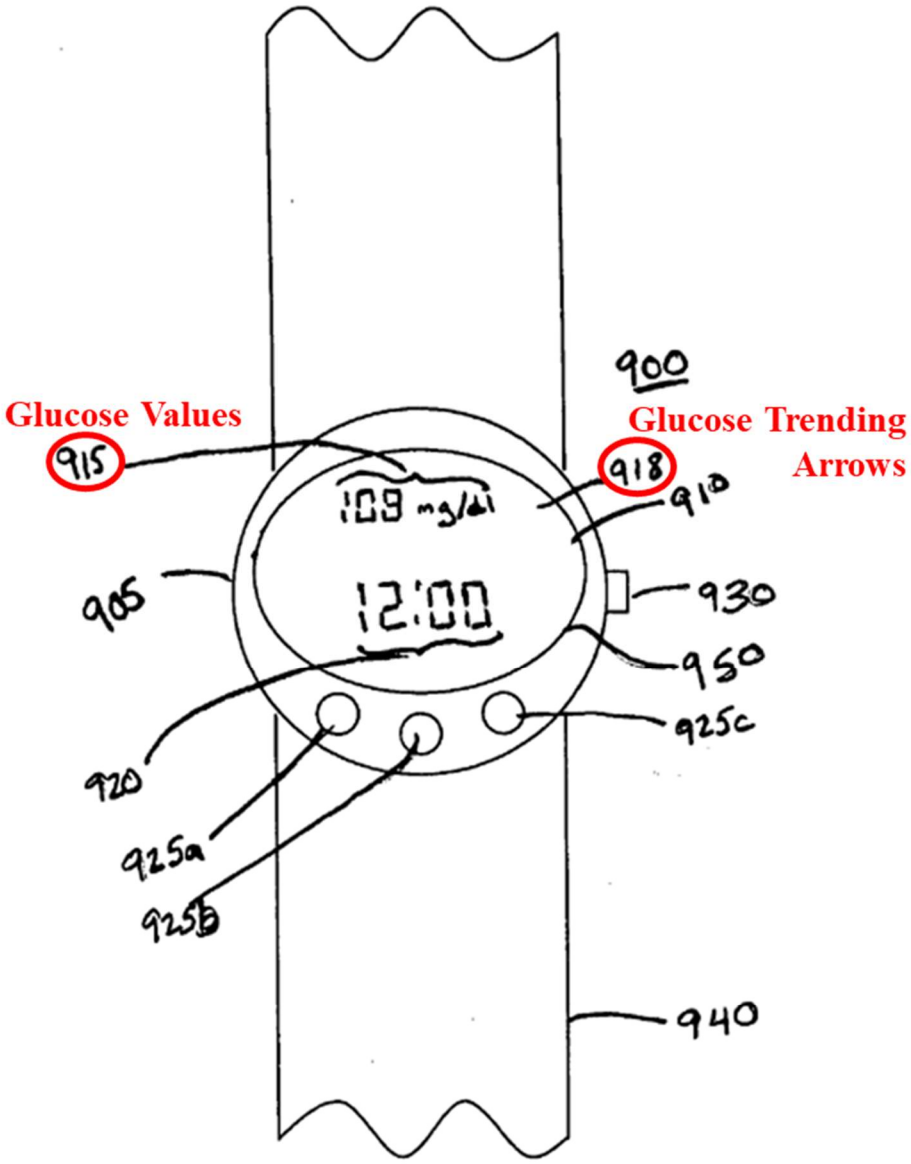


FIG. 9A

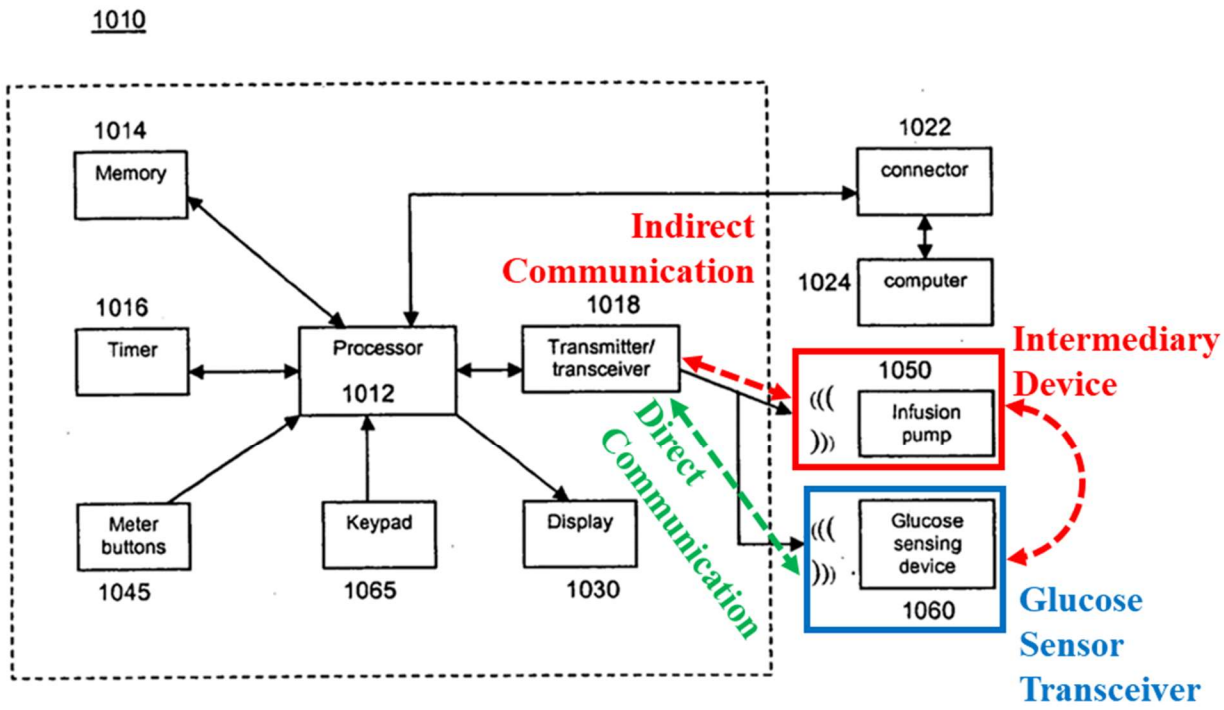
(Fig. 9A (annotated in red).) EX1208, ¶121.

Goldsmith teaches that the watch controller device receives sensor data (e.g., glucose values for display on the watch) from a glucose sensor. Goldsmith contemplates at least two different paths of communication between the controller

device and the sensor. First, Goldsmith teaches that the watch receives sensor data directly from the sensor. *E.g.*, EX1251, [0088] ("[T]he transceiver 1018 receives information from an analyte sensing device 1060."); *id.*, [0087] ("[D]ata may be received directly from a sensor transmitter on the patient's skin."); EX1208, ¶122.

The sensor-to-watch communications are reflected in Goldsmith Fig. 10, which shows an exemplary watch controller device 1010 with its transmitter/receiver 1018 directly communicating with the glucose sensing device 1060, via a communication link (annotated in green):

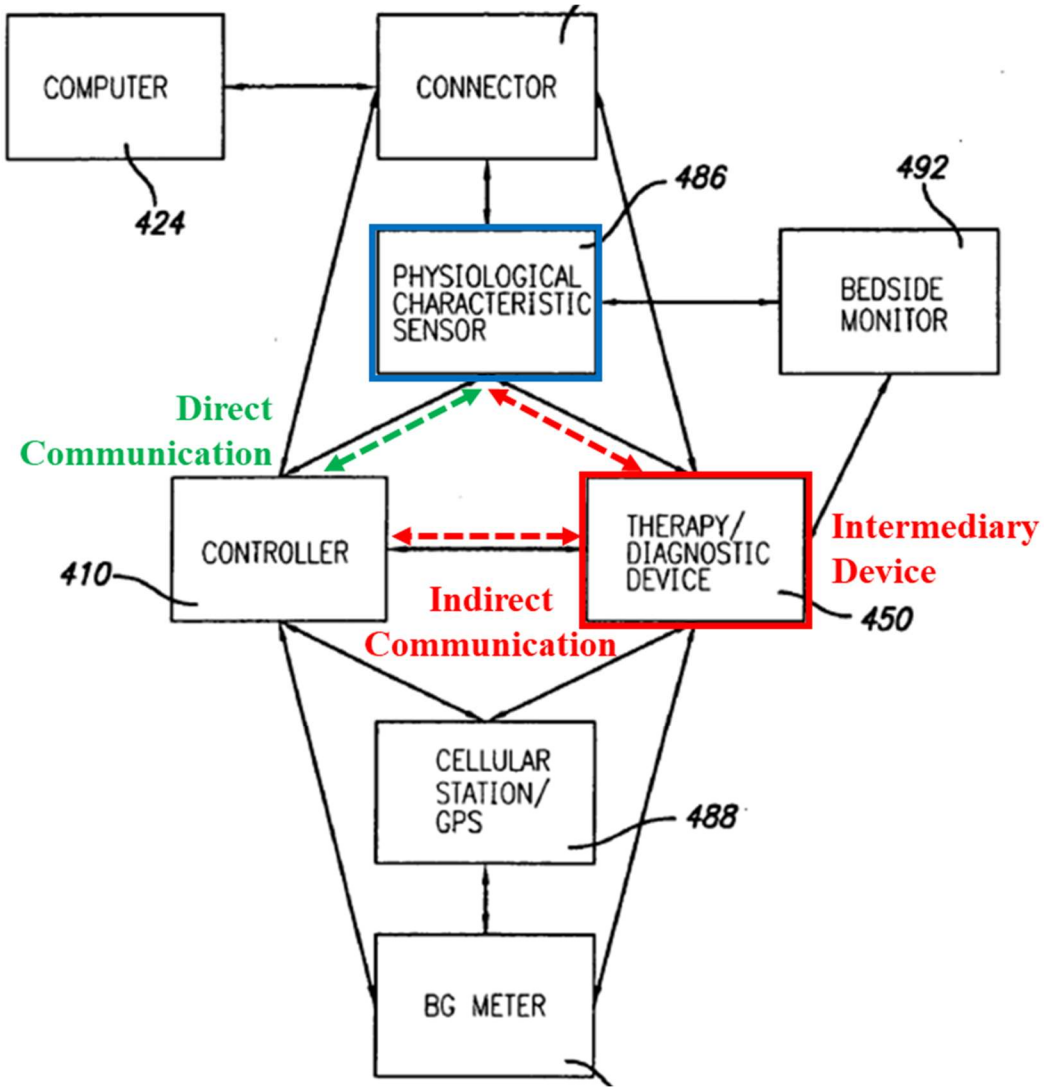
FIG. 10



(EX1251, Fig. 10 (annotated); *see also* EX1251, [0088] ("[T]he transceiver 1018 receives information from an analyte sensing device 1060."); EX1208, ¶123.)

Second, in describing FIG. 10, Goldsmith also teaches that the watch indirectly receives information generated by the glucose sensing device. For example, the information generated by the glucose sensing device 1060 is received by the watch controller device 1010 via an intermediary device (e.g., infusion device/pump 1050). *Id.*, [0090] ("The controller device display 1030 shows information according to communications sent to the watch controller device 1010 from the infusion device 1050."); [0009], [0058]; EX1208, ¶124.

Goldsmith Fig. 7 also shows these different communication links:



(EX1251, Fig. 7 (excerpted, annotated); *see also id.*, [0006], [0049].) Goldsmith teaches that the watch controller is a preferred type of controller. (*E.g.*, EX1251, [0085] ("The watch controller device may have the same functionality as the embodiments discussed above."); EX1208, ¶125.)

Goldsmith teaches the sensor transmitting blood glucose data to both the infusion pump and the controller (which preferably is a watch). *E.g.*, EX1251, [0009] ("The controller device display shows information according to

communications sent to it from the sensing device."); [0018] ("The sensing device includes a sensor and a transmitter in communication with the infusion device. The sensing device may sense an analyte of a bodily fluid of the user and provide continuous monitoring of that analyte."). In some embodiments, the infusion pump sends the data from the sensor to the controller. EX1251, [0058] ("[T]he infusion pump device will always send the data to the controller device."); EX1208, ¶126.

Goldsmith's claims also teach a watch device that receives glucose data through various communication routes. For example, independent claim 1 recites a "watch" with a "receiver adapted to receive information from the infusion device." And claims 14 and 16, which depend in succession from claim 1, specify that the watch's "receiver is further adapted to receive information from an analyte sensing device" (claim 14) such as "a continuous glucose sensor" (claim 16). Claim 17 specifies that the information received by the watch from the sensor is "data representing an analyte level of the user." EX1208, ¶127.

B. Combination Of Patel-2009, Paradigm® REAL-Time, And Goldsmith

Goldsmith discloses an infusion system that includes a watch controller that interacts with an infusion pump or a glucose sensing device (*e.g.*, TGMS sensor) to perform control and display functions, including the display of glucose values and trends. This includes both direct communication between the controller and the

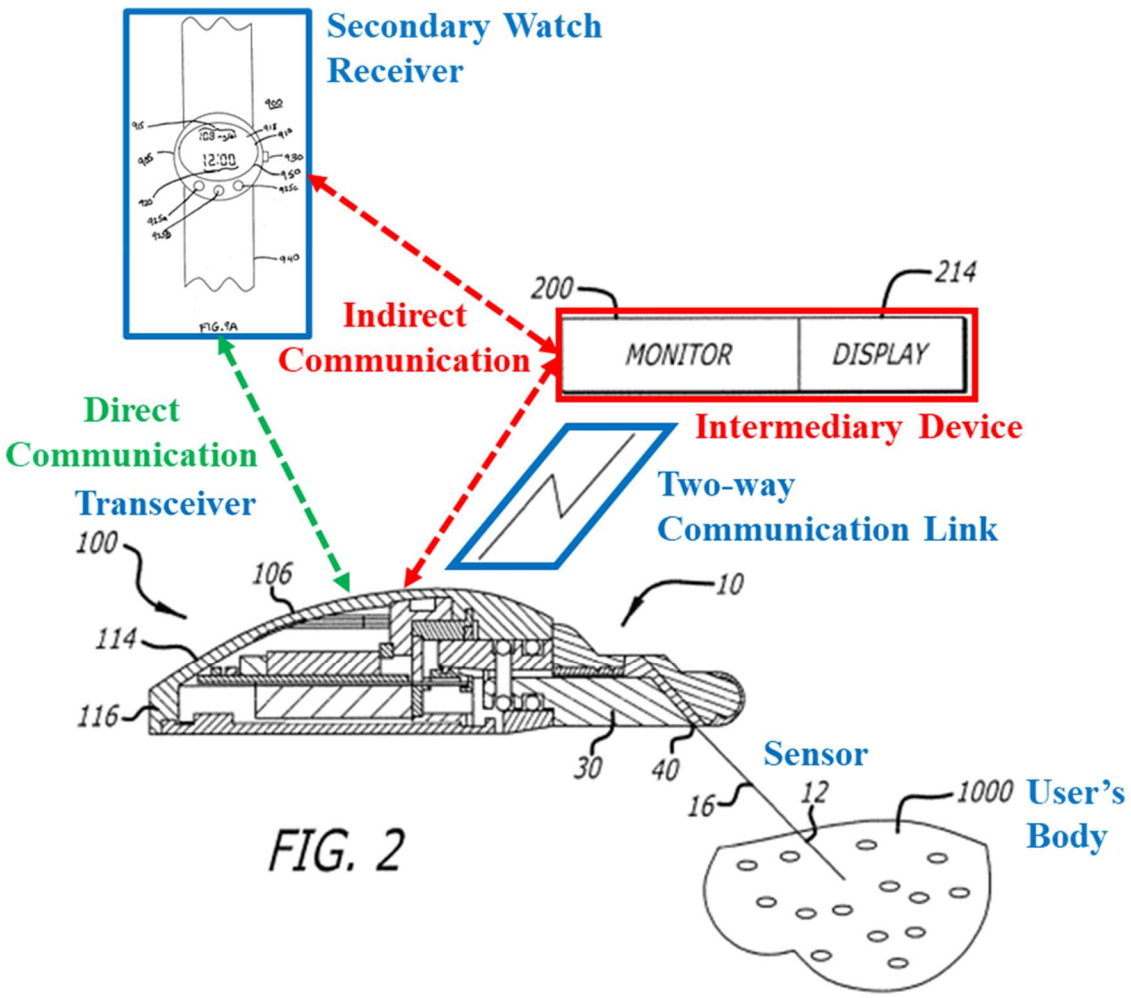
glucose sensing device and indirect communication via the infusion pump. (*See supra* VIII.A.; EX1208 ¶119-128.)

Patel-2009 and Paradigm REAL-Time each disclose glucose monitoring systems with an infusion pump that receives CGM data from a sensing device that includes a subcutaneous glucose sensor coupled to a transmitter or transceiver. (*See supra* VII.C., *see also e.g.*, EX1211, 8, 23-24, 37-38, 51, 53; EX1212, [0040], [0042], [0050], [0056], [0068-69], [0076]; EX 1208 ¶129.)

The Patel-2009/Paradigm Combination includes a subcutaneous glucose sensor and glucose sensor transceiver, as taught by Patel-2009. (*See supra* VII.E. above (citing EX1212, [0008], [0041], [0049], [0051], [0084], [0086]).) That glucose sensor transceiver includes a processor "in communication with the sensor for processing the signal produced by the sensor" to "convert raw sensor signals into calibrated processed glucose values using algorithms stored in the sensor transceiver." (*See supra* VII.C., VII.F.1. (citing EX1212, [0008], [0013], [0042], [0084].) The glucose sensor transceiver maintains a two-way communication link with one or more remote monitoring devices—including *e.g.* an infusion pump, computer, PDA, cellular phone, and blood glucose meter—that receive processed, calculated glucose values transmitted from the glucose sensor transceiver. (*See supra* VII.C., VII.F.1. (citing EX1212, [0008], [0013], [0042], [0076]); EX1208, ¶130.)

The Patel-2009/Paradigm/*Goldsmith* Combination adds a watch controller, as taught by Goldsmith, as an additional device for receiving and displaying glucose data and related information. A POSITA would have found it obvious to implement this combined system such that watch controller received processed glucose data from the glucose sensor transceiver or monitor (*e.g.*, insulin pump, cell phone) or both. EX1208, ¶131.

The Patel-2009/Paradigm/Goldsmith Combination supports both direct communication of processed sensor data from the glucose sensor transceiver to the watch controller, as well as indirect communication via an intermediary device (*e.g.*, monitor, infusion pump, cell phone):



(EX1212, Fig. 2; EX1251, Fig. 9A (annotated in blue, red, and green); EX1208, ¶132.)

1. Motivation To Combine And Expectation Of Success

A POSITA would have naturally included a watch device as taught by Goldsmith in the Patel-2009/Paradigm system, to achieve the benefits noted by Goldsmith, such as convenience and reduced noticeability, *e.g.,* the watch is more easily and discretely used to monitor glucose levels and related alarms or other events. EX1251, [0085]; EX1208, ¶133.

While Patel-2009 does not expressly disclose receiving sensor data on a watch, it does teach receiving and displaying glucose data and related information on a variety of devices. EX1212, [0042], [0075-76], [0084], Fig. 11. Goldsmith expressly teaches the benefits of using a watch as a "controller device" in a blood glucose monitoring system. EX1251, [0085]. Goldsmith notes that "[a] watch may be considered a *more socially acceptable* embodiment of a controller device, because it is common for people to wear watches, making it *less noticeable* that a user is using an infusion pump and/or analyte monitor." EX1251, [0085], emphasis added. A POSITA would have understood Goldsmith to be discussing its watch embodiment when stating that "a[] small overall size permits discretion during self-monitoring and makes it easy to carry." EX1251, [0011]; EX1208, ¶134. Goldsmith explains more generally that its controller embodiments, of which the watch is one, "provide convenience and ease of use" and "may cater to the active lifestyles of many insulin dependent diabetics." EX1251, [0011]. For example, a POSITA would recognize that a receiving device embodied in a watch reduces susceptibility to loss or damage (*e.g.,* from dropping) of the device due to being affixed to a user's wrist with a band as described in Goldsmith. EX1251, [0104]. Goldsmith also notes that "[b]ecause watches beep or otherwise alarm, it is less noticeable when a watch alarms to indicate high or low glucose, infusion pump occlusion, or other alarm occurrences." EX1251, [0085]. For at least these express benefits, a POSITA

implementing the Patel-2009/Paradigm Combination would have been motivated to include a watch controller as taught by Goldsmith, as a more convenient, easy, and discrete manner to provide users with glucose data and certain control functionality. EX1208, ¶134.

Moreover, Goldsmith, Patel-2009 and Paradigm® REAL-Time all relate to Medtronic continuous glucose monitoring systems, making Goldsmith's complementary teachings a particularly natural choice for inclusion in the Patel-2009/Paradigm Combination. (*See supra* V.B., VII.E.1.; EX1208 ¶¶55, 81, 82, 135) The complementary and related teachings in these three references would have given a POSITA a reasonable expectation of success that a watch as taught by Goldsmith would be easily incorporated into the Patel-2009/Paradigm system. EX1208, ¶135.

A POSITA would have reasonably expected success in incorporating Goldsmith's watch teachings into the Patel-2009/Paradigm Combination. EX1208, ¶136. Indeed, Goldsmith teaches use of its watch in a glucose monitoring system that includes many of the same basic components as Patel-2009 and Paradigm, such as a sensor coupled to a transmitter and an infusion pump, as well as wireless communication between devices, all designed for monitoring glucose levels in a patient. (*See supra* VII.C., VII.D., VII.E, VIII.A.; EX1208, ¶¶ 72, 74, 77, 78, 120-127, 136.) Based on the progress of development of smart watches and other wrist-worn devices prior to April 2009, a POSITA would have been aware of existing

products having features and computing resources usable to perform the operations of the watch controller of Goldsmith, thereby further increasing the expectation of success of using the watch controller of Goldsmith in the system of the Patel-2009/Paradigm Combination. EX1208, ¶136. A POSITA would have known how to program the system of the Patel-2009/Paradigm combination to communicate with a watch controller device as described in Goldsmith, as each of the disclosures describe using similar wireless transmission protocols, such as Bluetooth and similarly ranged communication protocols, to establish communication links between various devices in the system. EX1251, [0101]; EX1211, 8, 23 51. Given the similarity of technology in storing, processing, transmitting, and displaying sensor data in the Patel-2009/Paradigm Combination and Goldsmith, a POSITA would also expect that the outcome of such combinations would succeed. (*See supra* VII.C., VII.D., VII.E, VIII.A., VIII.B.; EX1208, ¶¶72-85, 120-127, 136.)

The Patel-2009/Paradigm/Goldsmith Combination, implemented as described above, includes the Patel-2009/Paradigm system that monitors and displays glucose data in a manner as described above with respect to claim 1, along with a wirelessly-connected watch that receives glucose data, both directly from the on-body glucose sensor/transmitter device as well as indirectly via the pump or other handheld device, and then displays that glucose data on the watch display. EX1208, ¶137.

C. Ground 2 Claim Mappings

As set out below, the Patel-2009/Paradigm/Goldsmith Combination renders obvious claim 29, including its incorporation of independent claim 1. As explained above, the Patel-2009/Paradigm Combination already renders obvious claim 1. (*See supra* VII.F.1.; EX1208, ¶138.)

1. Claim 1

The Patel-2009/Paradigm Combination renders obvious claim 1 as set out above. *See supra* VII.F.1.

2. Claim 29

The glucose monitoring system of claim 1, further comprising a secondary receiver unit,

As implemented in the Patel-2009/Paradigm/Goldsmith system, the watch controller taught by Goldsmith is a "secondary receiver unit" because it is "optional," it "include[s] a limited number of functions and features," and it is "embodied in a device such as a wrist watch" with a smaller compact housing. EX1201, 5:4-21. A POSITA would recognize the watch controller as a secondary receiver because, rather than performing the principal functions of the Patel-2009/Paradigm/Goldsmith system, it supplements a sensing device and an infusion device / pump or other analyte monitor to display processed sensor data in a more convenient and discrete manner using a smaller, more compact device. For example,

a POSITA would have found it obvious to implement the watch controller "to include a limited number of functions" as discussed in more detail below. EX1208, ¶¶139-140.

wherein the secondary receiver unit is configured to include a limited number of functions as compared with the receiver unit,

As implemented in the Patel-2009/Paradigm/Goldsmith system, the watch controller is "configured to include a limited number of functions as compared with the receiver unit." Goldsmith teaches that the watch controller "interact[s] with a glucose sensor *or* an infusion pump that stores glucose values" and displays values "to indicate the actual level of blood glucose" and, "optionally[,] trending of glucose values." EX1251, [0086], emphasis added. Consistent with these teachings, a POSITA would find it obvious to implement a watch controller as "a display" (EX1251, [0093]) that "[i]n its most simplest form, … is a display only, used to show a BG value and/or graph." (EX1251, [0066].) Limiting the watch implementation to a display would forgo command and interface functions that might be integrated in a receiver. EX1251, [0093]. Consistent with Goldsmith's teachings, a POSITA would have found it obvious to implement the watch with "no user settings and very little memory" and "the functions … all, or substantially all, contained on the infusion pump device." EX1251, [0054]. The size of a watch would lend itself to a

reduced number of functions by virtue of its smaller display, reduced memory, and lesser processing power. EX1208, ¶140.

wherein the secondary receiver unit is configured to receive processed sensor data from the data processing and transmitter unit and

As explained in Section VI.B above, Patent Owner's infringement contentions appear to interpret "receive processed sensor data from the data processing and transmitter unit" as encompassing *indirect* communication between an alleged secondary receiver (smartwatch) and an alleged data processing and transmitter unit (phone or other device), rather than requiring direct communication. However, as explained above, according to a plain reading of the claim, this term would be interpreted as encompassing a secondary receiver unit that directly receives sensor data from the data processing and transmitter unit. Regardless of whether claim 29 is interpreted to mean that the secondary receiver receives data *directly* from the data processor and transmitter unit, or *indirectly* through an intermediary device (*e.g.*, an insulin pump, handheld device, or other larger monitor taught by Patel-2009) it is rendered obvious by the combination of Patel-2009, Paradigm, and Goldsmith. EX1208, ¶141.

The POSITA would have found it obvious for the watch to receive processed sensor data because, in the Patel-2009/Paradigm system, the sensor data already is processed by the electronics coupled to the on-body sensor device. EX1212, [0008],

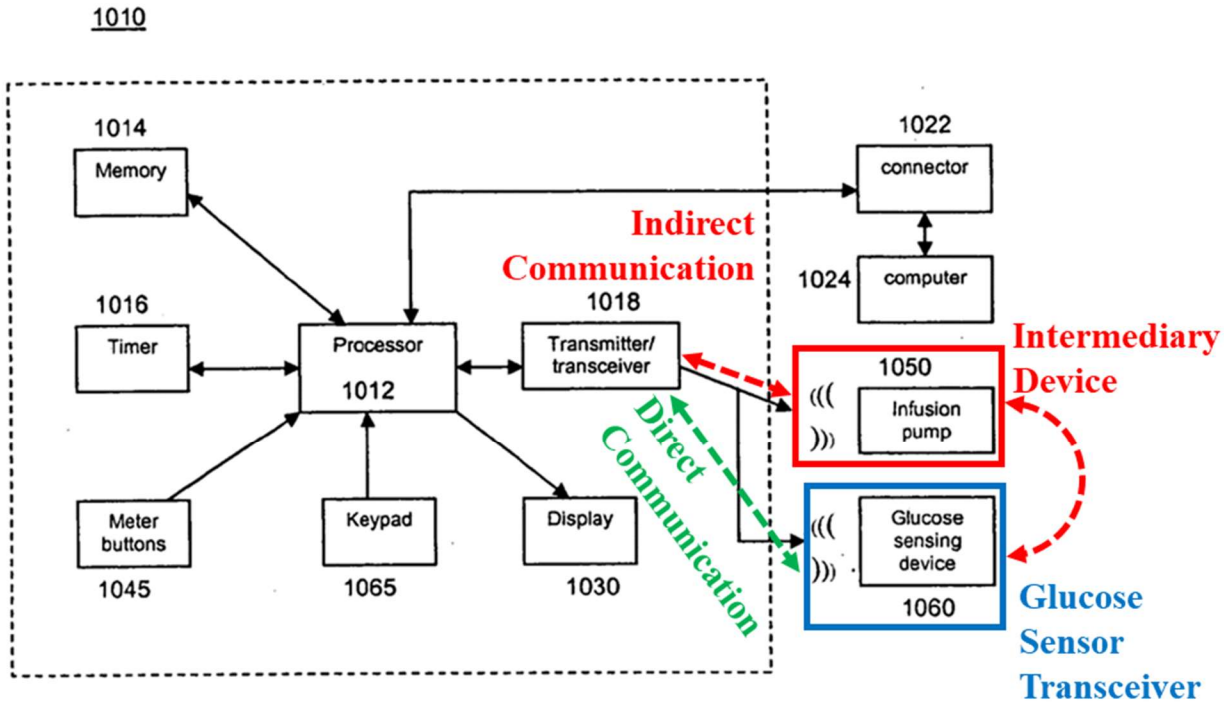
[0013-14], [0058], [0061]; EX1208, ¶142. The Patel-2009/Paradigm/Goldsmith system implements a watch controller "to receive processed sensor data." The Patel-2009/Paradigm Combination includes a glucose sensor transceiver that processes sensor data by *e.g.*, "perform[ing] data calibration and sensor glucose value calculation" to "convert raw sensor signals into calibrated processed glucose values using algorithms stored in the sensor transceiver." (*See supra* VII.E, VII.F.1. (citing *e.g.*, EX1212, [0042]); EX1208, ¶¶77, 94, 142.) Processed sensor data is communicated from the glucose sensor transceiver to monitoring devices (*e.g.*, monitor, infusion pump, computer, PDA, Cell Phone) as calculated glucose values. (*See supra* VII.C., VII.F.1. (citing *e.g.*, EX1212, [0042], [0076], Fig. 11); EX1208, ¶¶72, 98-103, 142.) Therefore, the most obvious way to implement a watch controller "interacting with a glucose sensor or an infusion pump that stores glucose values" to show "glucose values and optionally trending of glucose values" would be for the watch controller to receive processed sensor data in the form of calculated glucose values. EX1251, [0086]; EX1208, ¶142.

Goldsmith teaches both direct and indirect communication between the watch and on-body unit, and thus a POSITA would have found it obvious to implement the watch in this manner within the Patel-2009/Paradigm system. (*See* VIII.A. (citing EX1251, [0049], [0058], [0087], Fig. 7).) Moreover, a POSITA would have recognized the benefits of implementing the system such that processed glucose data

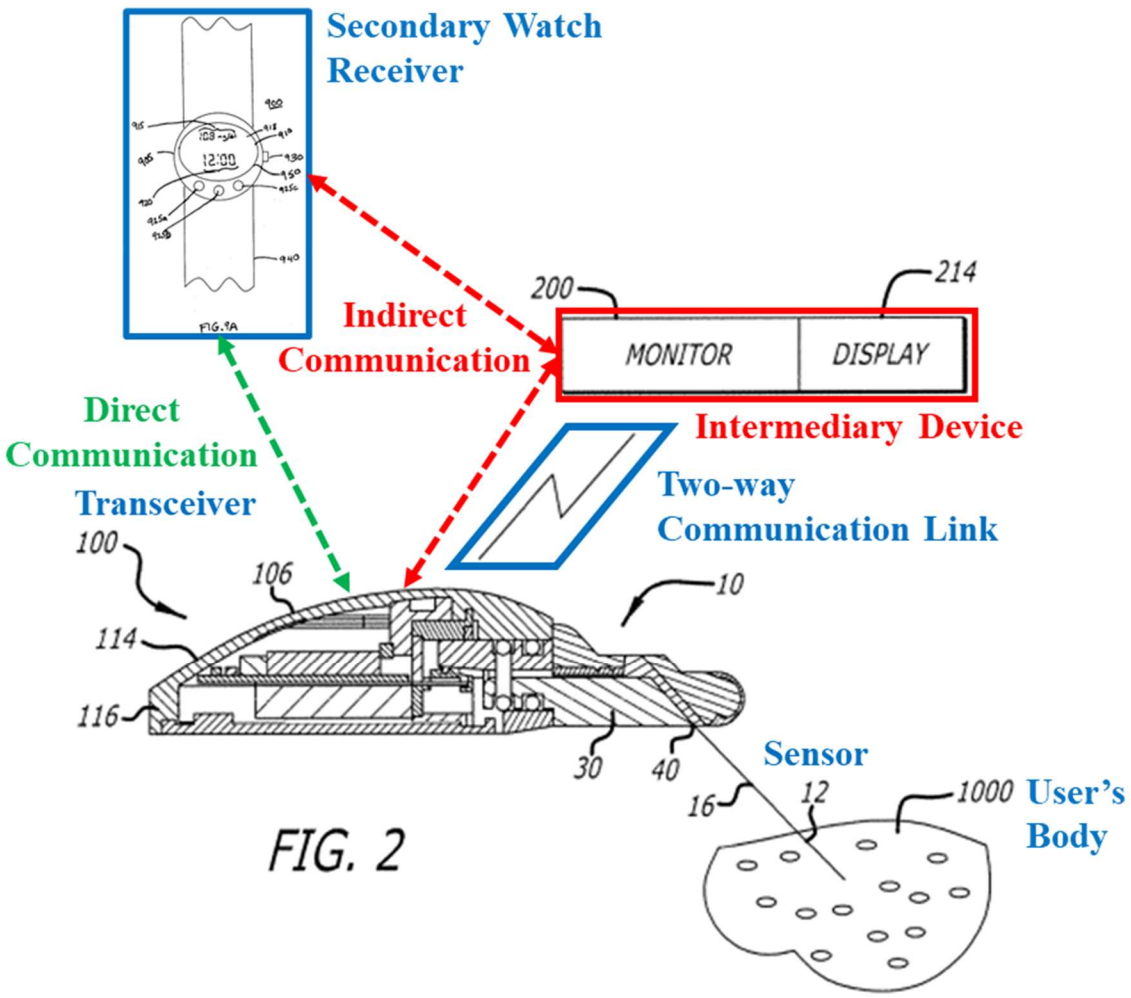
was sent both directly and indirectly to the watch, rendering this implementation further obvious. For example, direct communication would allow the watch to receive (and display) data even when the user was not in proximity to the infusion pump, cell phone, or other monitor device. This aligns with Goldsmith's teachings on use of the watch to provide the user with an easier, more convenient, less obtrusive experience. EX1251, [0006], [0010], [0011], [0085]. Indirect communication, on the other hand, would provide benefits relating to reducing a complexity of programming on the watch by capitalizing on any further data processing that the infusion pump, serving as an intermediary device between the watch and the sensor, could provide. EX1208, ¶¶124-127, 143.

Based on Goldsmith's teachings, a POSITA would implement the watch to receive processed glucose data directly from the glucose sensor transceiver device or from the monitoring device (*e.g.*, infusion pump) of the Patel-2009/Paradigm/Goldsmith Combination*:*

FIG. 10



(EX1251, Fig. 10 (annotated), [0087-88], *see also e.g.*, *id.*, [0086] (describing a watch controller "interacting with a glucose sensor or an infusion pump that stores glucose values" and how "the display may show just glucose values and optionally trending of glucose values"); EX1208, ¶144.) In the context of the Patel-2009/Paradigm Combination, a secondary watch receiver with direct and indirect communication paths would be implemented as:



(EX1212, Fig. 2; EX1251, Fig. 9A (annotated in blue, red, and green).)

First, with respect to direct communication as outlined in blue and represented by the green arrow, Goldsmith teaches that the watch controller's "transceiver 1018 receives information from an analyte sensing device 1060." EX1251, [0088]. As implemented in the Patel-2009/Paradigm/Goldsmith system, a POSITA would recognize that this results in data "received directly from a sensor transmitter on the patient's skin" being displayed by the watch controller device. EX1251, [0087]; EX1208, ¶145.

Second, with respect to indirect communication through an intermediary device as illustrated in red, Goldsmith teaches that "the watch controller device may display data directly from a pump." EX1251, [0087]. As implemented in the Patel-2009/Paradigm/Goldsmith system, a POSITA would recognize that this involves receiving processed sensor data via the monitor (*e.g.*, infusion pump) (e.g., the monitor serving as an intermediary device between the sensor and the watch controller) using the same two-way communication link (illustrated in red) that the watch controller's transmitter/transceiver 1018 uses to transmit communications to the infusion device 1050. EX1251, [0058], [0088], *see also id.*, [0085] ("The watch controller device 900 includes … a communication system (not shown) … for transmitting a communication or command from the user to the infusion device or analyte monitor"); EX1208, ¶146.

wherein the secondary receiver unit is a watch.

Finally, as implemented in the Patel-2009/Paradigm/Goldsmith system, the watch controller taught by Goldsmith is a watch. (*E.g.*, EX1251, [0010], [0085-91]; EX1208, ¶147.)

IX. CONCLUSION

Petitioner requests institution for claims 13 and 29, on the Grounds specified in this petition.

Respectfully submitted,

February 9, 2023

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

This brief complies with the type-volume limitation of 37 C.F.R. § 42.2(a)(1)(i).

The brief contains 13,188 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24 (a).

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

The undersigned certifies that on February 9, 2024 a complete copy of the **Petition for *Inter Partes* Review of U.S. Patent No. 11,298,056 and Exhibits 1201–1215, 1217, 1219, 1223, 1225–1233, 1235–1251, 1253** were served via **Express Mail** on the Patent Owner at the following address of record as listed on the USPTO Patent Center:

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Counsel for Petitioner further certifies that a courtesy copy of the **Petition for *Inter Partes Review* of U.S. Patent No. 11,298,056** was served on litigation counsel for Patent Owner via email to:

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