UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

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

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

DECLARATION OF BRIAN D. GROSS

EXHIBIT 2243
Brian D. Gross
11-21-2024
By: V. Guerrero, CSR,RDR,RMR,CRR
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DEXCOM
EXHIBIT 1208

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I, Brian D. Gross, BSEE, M.Sc., do hereby declare as follows:

I. INTRODUCTION AND ENGAGEMENT

1. My name is Brian D. Gross, and I have been retained as an independent expert on behalf of Dexcom, Inc. in connection with the above-captioned Petition for Inter Partes Review ("IPR") to provide my analyses and opinions on certain technical issues related to U.S. Patent No. 11,298,056 (hereinafter "the '056 Patent"). Specifically, I have been asked to provide my opinions regarding whether claims 13 and 29 of the '056 Patent would have been obvious to a person having ordinary skill in the art ("POSITA") as of April 2009. After reviewing the prior art discussed herein, it is my opinion that each of claims 13 and 29 of the '056 Patent would have been obvious to a POSITA.

2. I am being compensated at my usual and customary rate for the time I spent in connection with this IPR. My compensation is not affected by the outcome of this IPR.

3. On July 24, 2023, I submitted a declaration with testimony in support of an IPR Petition challenging claims 1-12, 14-28, and 30 of the '056 Patent. My testimony in sections II. Background and Qualifications (¶¶4-8 below), IV. Materials Considered and Information Relied upon Regarding The '056 Patent (¶¶10-11 below), V. Understanding of Patent Law (¶¶12-24 below), VI. The '056 Patent (¶¶25-30 below), VII. State-of-the-Art and Level of Skill in the Art (¶¶31-61 below)

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are substantively identical to corresponding paragraphs of my July 24, 2023, declaration. In addition, subsections VIII.A through VIII.D.1 of Ground 1 (¶¶62-115 below) are substantively identical to corresponding paragraphs of my July 24, 2023, declaration. While section VIII.D.2 (¶¶116-118 below) relies on analysis and explanation of the prior art previously presented in my July 2023 declaration, herein I present that analysis and explanation in the context of claim 13. Finally, section IX (¶¶119-147 below) on claim 29 consist of testimony not previously presented in my July 24, 2023, declaration.

II. BACKGROUND AND QUALIFICATIONS

4. Among other qualifications elaborated in my CV (EX1209), I receive my Bachelor of Science in Electrical and Biomedical Engineering (BSEE) in 1990 and my Masters of Science in Biomedical Engineering (M.Sc.) in 1991.

5. In 1991 and 1992, I worked as a scientist in product development engineering at VivaScan. At VivaScan, my work included designing and building microprocessor-controlled instrumentation in many cases, from discrete components. The efforts at VivaScan focused on physiological monitoring and included research and development related to determining glucose and other analytes in the blood as manifest U.S. Patent No. 5,372,135 ("the '135 Patent") for "Blood constituent determination based on differential spectral analysis" of which I am a co-inventor.

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6. From 2003 through 2013, I was co-investigator of a bioengineering research partnership with the Massachusetts Institute of Technology focused on ICU patient monitoring and including the development and application of physiological monitoring concepts and algorithms.

7. From 2006 through 2014, I was a Principal Scientist of Patient Care and Monitoring Solutions at Philips where my work related to physiological monitoring. For example, in February 2008, some of my work on recognizing that gaps in monitored data due to poor network quality could be resolved by caching missed data and transmitting this data when sufficient bandwidth became available was filed as U.S. Provisional Application 61/032,532 on "optimizing physiological monitoring based on available but variable signal quality," which later became U.S. Patent Application 12/918,822 and published as U.S. Publication 2011/0002223 related to "physiological monitoring over a healthcare network." From 2014 to 2022, I was a Fellow Scientist and Clinical System Architect at Philips where I taught, trained, mentored, and supervised, members of the organization with less experience, as well as drove risk management and design tradeoff decisions for the Businesses and Research groups.

8. In 2014 I was appointed by the International Standards Association to serve on the IEC-TC62/SC 62D/JWG 22 as a technical and clinical expert in medical device design. There I participated and led multi-national and multi-domain experts

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in drafting global safety standards pertaining to medical devices and their design. As a final example of my experience, I participated in technical and clinical research, and co-authored scores of papers including an abstract on how "delayed intravenous insulin therapy initiation is associated with mortality in the ICU," which was presented to the SCCM 40th Critical Care Congress in 2011.

III. SCOPE OF OPINION

9. I have been asked to provide my opinions regarding whether claims 13 and 29 of the '056 patent would have been unpatentable to a person of ordinary skill in the art (POSITA) as of April 2009 in view of:

- U.S. Patent Publication 2009/0085768 to Patel (EX1212, "Patel-2009");
- An FAQ webpage, features and benefits fact sheet, and sensor features user guide for the Medtronic MiniMed Paradigm® REAL-Time System archive of the Medtronic Diabetes website in October 2007 (EX1211, "Paradigm® REAL-Time"); and
- U.S. Patent Publication No. 2007/0093786 (EX1251, "Goldsmith").

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IV. MATERIALS CONSIDERED AND INFORMATION RELIED UPON REGARDING THE '056 PATENT

10. In preparing this declaration, I have reviewed the following materials bearing Exhibit Nos. that I understand are being referenced in the IPR which this declaration accompanies:

A. 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")
1209	Curriculum Vitae of Brian Gross
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")
1214	U.S. Provisional Patent Application No. 60/976,886 ("Patel-2009 provisional")
1215	U.S. Patent Application Publication No. 2008/0119705 to Patel et. al. ("Patel-2008")
1217	U.S. Patent No. 6,641,533 to Causey et. al. ("Causey")
1219	U.S. Patent Application Publication No. 2006/0202859 to Mastrototaro et. al. ("Mastrototaro")
1222	U.S. Patent Application Publication No. 2004/0122353 to Shahmirian et al. ("Shahmirian")
1225	McGarraugh, Geoffrey. "The chemistry of commercial continuous glucose monitors." Diabetes technology & therapeutics 11.S1 (2009): S-17.

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1226	U.S. Patent Application Publication No. 2004/0193025 to Steil et al.
1227	Choleau, C., 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): 647-654.
1228	Velho, G., et al. "In vivo calibration of a subcutaneous glucose sensor for determination of subcutaneous glucose kinetics." *Diabetes, American Diabetes Association* 1.3 (1988): 227-233.
1229	Mastrototaro, John J. "The MiniMed continuous glucose monitoring system." Diabetes technology & therapeutics 2.1, Supplement 1 (2000): 13-18.
1230	U.S. Patent No. 6,424,847 to Mastrototaro et al.
1231	Poitout, V., 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): 658-663.
1232	U.S. Patent Application Publication No. 2006/0224109 to Steil et al.
1233	Keenan, D. Barry, et al. "Delays in minimally invasive continuous glucose monitoring devices: a review of current technology." *Journal of diabetes science and technology* 3.5 (2009): 1207-1214.
1235	Armstrong, Siân. "Wireless connectivity for health and sports monitoring: a review." *British journal of sports medicine* 41.5 (2007): 285-289.
1236	Pantelopoulos, Alexandros, and Nikolaos Bourbakis. "A survey on wearable biosensor systems for health monitoring." *2008 30th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*. IEEE, 2008.
1237	Excerpts from Diabetes forecast, November 2007
1238	Excerpts from Diabetes forecast, August 2007

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1239	Buckingham, Bruce, Kimberly Caswell, and Darrell M. Wilson. "Real-time continuous glucose monitoring." *Current Opinion in Endocrinology, Diabetes and Obesity* 14.4 (2007): 288-295.
1240	Buckingham, Bruce. "Clinical overview of continuous glucose monitoring." *Journal of Diabetes Science and Technology* 2.2 (2008): 300-306.
1242	Excerpts from Smith, Steven W. *The scientist and engineer's guide to digital signal processing.* California Technical Pub., 1997.
1243	Shenoi, Belle A. *Introduction to digital signal processing and filter design.* John Wiley & Sons, 2006.
1245	Breton, Marc D., et. al. "Optimum Subcutaneous Glucose Sampling and Fourier Analysis of Continuous Glucose Monitors." *Journal of Diabetes Science and Technology* 2.3 (2008): 495-500.
1246	Burge, Mark R., et. al. "Continuous Glucose Monitoring: The Future of Diabetes Management." *Diabetes Spectrum* 21.2 (2008): 112-119.
1251	U.S. Patent Application Publication No. 2007/0093786 to Goldsmith and Hayes ("Goldsmith").

11. I have also relied on my professional experience in formulating the opinions expressed in this declaration.

V. UNDERSTANDING OF PATENT LAW

12. I am not an attorney. For the purposes of this declaration, I have been informed about certain aspects of the law that are relevant to my opinions. My understanding of the law was provided to me by the Petitioner's attorneys.

13. I understand that when considering the scope of the claims of a patent that the patent claim terms should generally be given the ordinary meaning that the

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terms would have to a person of ordinary skill in the art in question after reading the patent as of the earliest claimed priority date.

14. I understand that the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the term appears, but in the context of the entire patent, including the specification. I further understand that the principal considerations regarding the scope and meaning of the claims are the plain language of the claim (including the surrounding claim language and context), the patent specification, and the prosecution history. I understand that while a claim is to be read in light of the specification, one must generally avoid importing limitations into the claim from the specification. I am also informed that the prosecution history can often inform the meaning of the claim by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be. I applied these understandings when considering the scope and meaning of the claims of the '056 patent.

15. I understand that a prior art reference anticipates an asserted claim, and thus renders the claim unpatentable, if all elements of the claim are disclosed in that prior art reference, either explicitly or inherently (i.e., necessarily present or implied).

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16. I further understand that a claim is unpatentable if it would have been obvious. Obviousness of a claim requires that the claim would have been obvious from the perspective of a POSITA at the time the alleged invention was made. I understand that a claim could have been obvious from a single prior art reference or from a combination of two or more prior art references.

17. I understand that an obviousness analysis requires an understanding of the scope and content of the prior art, any differences between the alleged invention and the prior art, and the level of ordinary skill in evaluating the pertinent art.

18. I further understand that a claim would have been obvious if it unites old elements with no change to their respective functions, or merely substitutes one element for another known in the field, and that combination yields predictable results. While it may be helpful to identify a reason for this combination, I understand that there is no strict requirement of finding an express teaching, suggestion, or motivation to combine within the references. When a product is available, design incentives and other market forces can prompt variations of it, either in the same field or different one. If a POSITA can implement a predictable variation, obviousness likely bars its patentability. For the same reason, if a technique has been used to improve one device and a POSITA would recognize that it would improve similar devices in the same way, using the technique would have been obvious. I understand that a claim would have been obvious if common sense

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directs one to combine multiple prior art references or add missing features to reproduce the alleged invention recited in the claims.

19. I further understand that certain factors may support or rebut the obviousness of a claim. I understand that such secondary considerations include, among other things, commercial success of the patented invention, skepticism of those having ordinary skill in the art at the time of invention, unexpected results of the invention, any long-felt but unsolved need in the art that was satisfied by the alleged invention, the failure of others to make the alleged invention, praise of the alleged invention by those having ordinary skill in the art, and copying of the alleged invention by others in the field. I understand that there must be a nexus—a connection—between any such secondary considerations and the alleged invention. I also understand that contemporaneous and independent invention by others is a secondary consideration tending to show obviousness.

20. I am not aware of any allegations by the named inventors of the '056 patent or any assignee of the '056 patent that any secondary considerations tend to rebut the obviousness of any Challenged Claim of the '056 patent.

21. I understand that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the descriptions found in the patent being considered.

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22. I understand that other challenges to the patentability of a patent, including patent ineligibility, enablement, written description, and definiteness or clarity of claim language, cannot be raised in IPR proceedings before the Board.

23. I understand that Petitioner has the burden of proving unpatentability by a preponderance of evidence, which means that the claims are more likely than not unpatentable.

24. The analysis in this declaration is in accordance with the above-stated legal principles.

VI. THE '056 PATENT

25. As part of my analysis, I reviewed and considered the '056 patent (EX1201) titled "Methods and Systems for Early Signal Attenuation Detection and Processing" which I understand issued from U.S. Application 17/411,154 on April 12, 2022. The following highlights general aspects of the '056 patent and is not meant to describe my full understanding of the patent or its prosecution history.

A. Specification

26. 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.)

27. The transmitter unit "receives analyte related sensor data" from the sensor and transmits this data to the receiver unit. (EX1201, 11:27-37.) The

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transmitter unit is described as operating on approximate radio frequency bands of 315-322MHz or 400-470MHz. (EX1201, 9:15-22.) The communication link between the transmitter and receiver is discussed as including various infrared, Bluetooth®, 802.11x, or other wireless communication protocols. (EX1201, 7:25-33.)

28. The '056 patent defines "analyte related sensor data herein and throughout [the] specification" as both "current signal received from the analyte sensor" and "current signal which has undergone … processing routines including, for example filtering, clipping, digitizing," encoding, conditioning, or further processing. (EX1201, 11:37-44, 14:21-23.) For example, unprocessed or uncalibrated sensor data is processed with "calibration data such as [a] sensitivity ratio." (EX1201, 12:54-61.) Calibration "ensure[s] the analyte related data signals … are correctly converted to corresponding analyte levels," but various conditions render calibration unsuitable. (EX1201, 10:62-66, 11:6-8.) The '056 patent then 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 was not properly calibrated [and] analyte related sensor data was not processed:"

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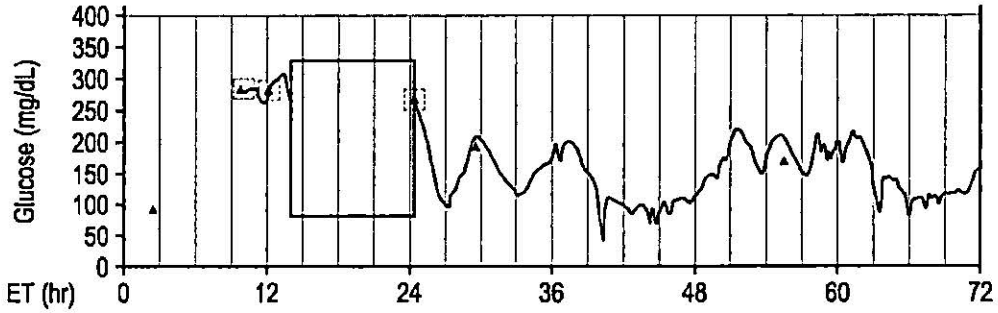


FIG. 7A

(EX1201, 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:

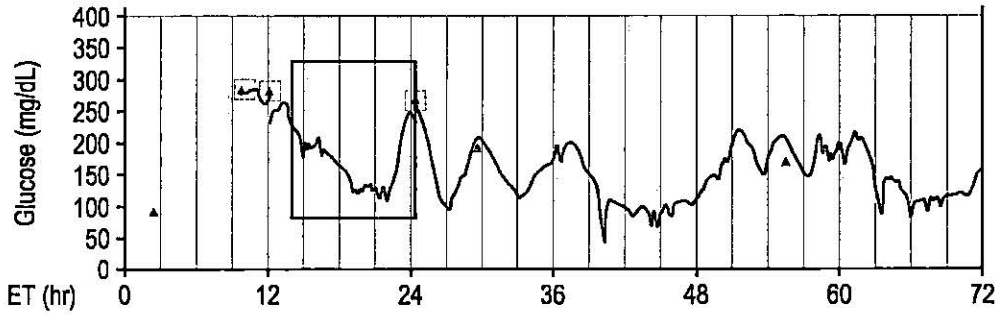


FIG. 7B

(EX1201, 12:47-13:5, Fig. 7B.)

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B. Prosecution History

29. I understand that the '056 Patent (EX1201) issued from U.S. Patent Application No. 17/411,154 filed August 25, 2021 (EX1202), which claims priority to the April 29, 2009 filing of Provisional Application 61/173,600 through a series of continuation applications.

30. I have reviewed U.S. Patent Application No. 17/411,154 and its prosecution file history. (EX1202).

VII. STATE-OF-THE-ART AND LEVEL OF SKILL IN THE ART

A. State-of-the-Art

31. The '056 patent pertains to glucose monitoring systems, including:

- two and three-electrode sensors that generate analyte signals (EX1201, 1:34-37);
- calibration to determine a "sensitivity ratio" that is used to convert sensor data to analyte levels (EX1201, 12:47-61);
- signal processing (*e.g.*, filtering, clipping, digitizing, conditioning) (EX1201, 5:58-64, 11:37-44); and
- RF transmission (*e.g.*, 315-322MHz, 400-470MHz, Bluetooth, 802.11x/WLAN). (EX1201, 7:25-33, 9:15-22.)

As discussed in this section, these were each well-known, fundamental concepts of glucose monitoring by April 2009. (*See* Paragraphs 32-49.)

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1. Sensors With Working and Counter Electrodes

32. Analyte sensors with "two or three-electrode (work, reference, and counter electrodes) configuration[s]" were well known to a POSITA by April 2009. This knowledge is illustrated by the references in paragraphs 33-35 below.

33. For example, a May 2009 article on "The Chemistry of Commercial Continuous Glucose Monitors" by McGarraugh provides:

- a typical glucose sensor "includes three electrodes: a GOx working electrode, a counter electrode, and an Ag/AgCl reference electrode" (EX1225, S-19); and
- each of the Medtronic Guardian REAL-Time, DexCom™ STS™-7, and Abbot FreeStyle Navigator® "measure[d] the current flowing from an oxidation (electron-producing) reaction at a working electrode to a reduction (electron-consuming) reaction at a counter electrode." (EX1225, S-19.)

34. Medtronic's U.S. Publication 2006/0202859 to Mastrototaro discloses a sensor with three sensor electrodes 20:

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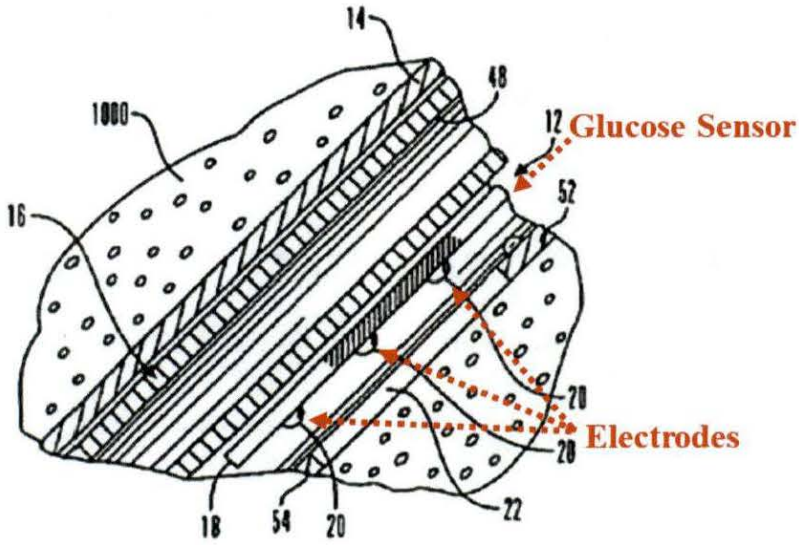


FIG. 6

(EX1219, [0045], Fig. 6 (annotated in red).)

35. Medtronic's U.S. Publication 2004/0193025 labels the counter (CNT) electrode in a similar figure:

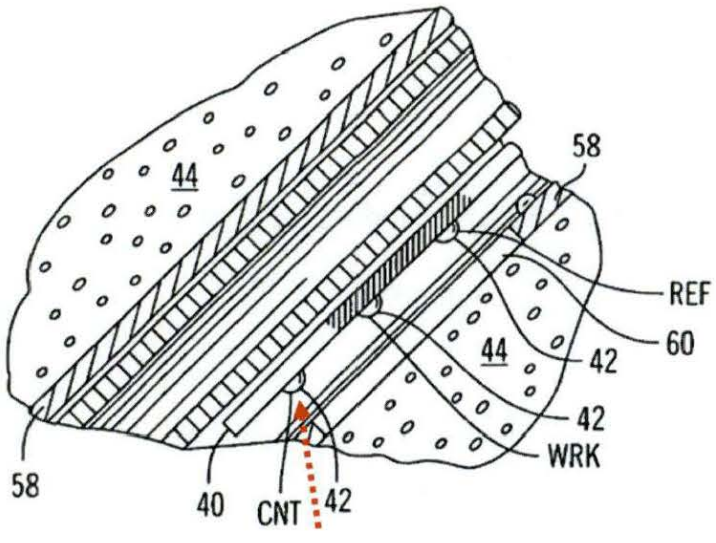


FIG. 4

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(EX1226, [0038], Fig. 4 (annotated in red).)

36. Therefore, it is my opinion that skilled artisans were familiar with sensor configurations including work and counter electrodes.

2. Sensor Sensitivity In Calibration

37. Sensor calibration was well known to a POSITA by April 2009. As illustrated by the references in paragraphs 38-39 below, glucose sensor calibration was typically performed by using blood glucose reference values to determine a sensitivity coefficient or ratio between sensor current and glucose concentration, which was later applied to convert sensor current to glucose concentration.

38. For example, a 1988 article titled "In vivo calibration of a subcutaneous glucose sensor for determination of subcutaneous glucose kinetics" by Valho et. al. "defined a method for calibrating *in vivo* a subcutaneous glucose sensor" as "determining, for a given sensor, the variation in the current corresponding to a change in BG [(blood glucose)] concentration. This in vivo sensitivity coefficient was then used to determine from the sensor output an apparent subcutaneous glucose concentration..." (EX1228, 227; *see also* 228 (discussing the sensitivity coefficient as the "ratio between decrease in the sensor current and the decrease in glucose concentration.") "The *in vivo* sensitivity coefficient" is then "used to calculate apparent subcutaneous glucose level" by dividing "current by the sensitivity coefficient" after subtracting baseline (I_0). (EX1228, 228-229.) Similarly, a 2002

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article on "Calibration of a subcutaneous amperometric glucose sensor implanted for 7 days in diabetic patients Part 2: Superiority of the one-point calibration method" by Choleau et. al. provides:

> [T]he sensor sensitivity S is determined from a single blood glucose determination as the ratio between the concomitant sensor current I and the blood glucose concentration G. Subsequently, the glucose concentration can be estimated at any time from the current I as $G(t) = I(t)/S$.

(EX1227, 648.)

39. According to a 2000 article titled "The MiniMed Continuous Glucose Monitoring System" by Mastrototaro, the Medtronic CGMS associates interstitial glucose concentration to electrical current in nanoamperes (nA) using a calibration based on blood glucose readings. (EX1229, S-15.) Consistently, Medtronic's U.S. Patent 6,424,847 provides that calibration involves calculating a calibration factor called a sensitivity ratio (SR) (blood glucose level/Valid ISIG value).... used to convert the Valid ISIG value (Nano-Amps) into a blood glucose level (mg/dl or mmol/l)." (EX1230, 11:28-33.)

40. Therefore, skilled artisans knew that calibration is associated with the sensitivity of the glucose sensor and were familiar with using blood glucose reference values to determine a sensor sensitivity ratio and with applying this sensitivity ratio to convert sensor signals to glucose concentrations. A POSITA knew that both the data relied on to calibrate the sensor and the resulting coefficients used

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to convert sensor signals to glucose concentrations are associated with the sensitivity of the glucose sensor.

3. Microprocessor Computations

41. Processing sensor signals with various algorithms and processing routines was well known to a POSITA by 2009. This knowledge is illustrated by the references in paragraphs 42-45 below.

42. As discussed in an article titled "A glucose monitoring system for on line estimation in man of blood glucose concentration using a miniaturized glucose sensor inserted in the subcutaneous tissue and a wearable control unit" by Poitout et al., the necessity of sampling, filtering, storing, and processing glucose sensor electrical current values before conversion to real-time glucose concentrations was well known by 1993. (EX1231, 661.) For example, early glucose monitors had memory to store 8,000 electrical current values and used algorithm procedures to filter and process signals. (EX1231, 659, 662.)

43. 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, Medtronic's U.S. Patent 6,641,533 to Causey used a sensor monitor and microprocessor to smooth and store signals received from the sensor and to determine corresponding analyte levels. (EX1217, 22:18-22.) Meanwhile, Medtronic's U.S. Publication 2006/0224109 provides that before filtering and

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calibration, sensor signals are processed from analog current (Isig) to digital sensor values (Dsig) which are stored in a buffer. (EX1232, [230].)

44. A 2009 article titled "Delays in Minimally Invasive Continuous Glucose Monitoring Devices: A Review of Current Technology" by Keenan et al., the Medtronic Guardian RT used a "seventh-order finite impulse response filter … decimated to a 5-minute sample time interval" resulting in 8.25 minutes delay to smooth the sensor's electrical current signal with a moving average. (EX1233, 1211.) Similarly, Medtronic's U.S. Patent 6,424,847 provides for sampling electrical current every 10 seconds and storing averaged sampling intervals in memory. (EX1230, 8:42-60.) Finally, a 2008 article titled "Optimum Subcutaneous Glucose Sampling and Fourier Analysis of Continuous Glucose Monitoring" by Breton et al. computed the maximum sampling frequency (*i.e.*, Nyquist Rate) for accurately determining blood glucose from interstitial glucose accounting for noise as longer than 5 minute and optimally 18 minutes. (*See also* EX1245, 497-98.) A POSITA would recognize that these filtering, averaging, and sampling procedures would induce a lag (*e.g.*, 8.25 minutes) between when sensor data is measured and when processed glucose data is displayed and that data would need to be stored in memory at various points during processing. A POSITA would also recognize that data could be scheduled to update in accordance with one of more sampling intervals (*e.g.*, every 10 seconds, minute, or 5 minutes, 18 minutes, etc.).

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45. A POSITA would have known to store sensor signals or other data used by a processor in performing any of the processing routines described above. For example, Chapter 28 of the 1997 publication Scientist and Engineer's Guide to Digital Signal Processing by Steven W. Smith acknowledges the role of memory in executing processing routines on page 509: "One of the biggest bottlenecks in executing DSP [Digital Signal Processing] algorithms is transferring information to and from memory. This includes data, such as samples from the input signal and the filter coefficients, as well as program instructions, the binary codes that go into the program sequencer. For example, suppose we need to multiply two numbers that reside somewhere in memory. To do this, we must fetch three binary values from memory, the numbers to be multiplied, plus the program instruction describing what to do." (EX1242, p. 509). Example processor architecture, including memory for storing data to be processed, is shown in Smith as well:

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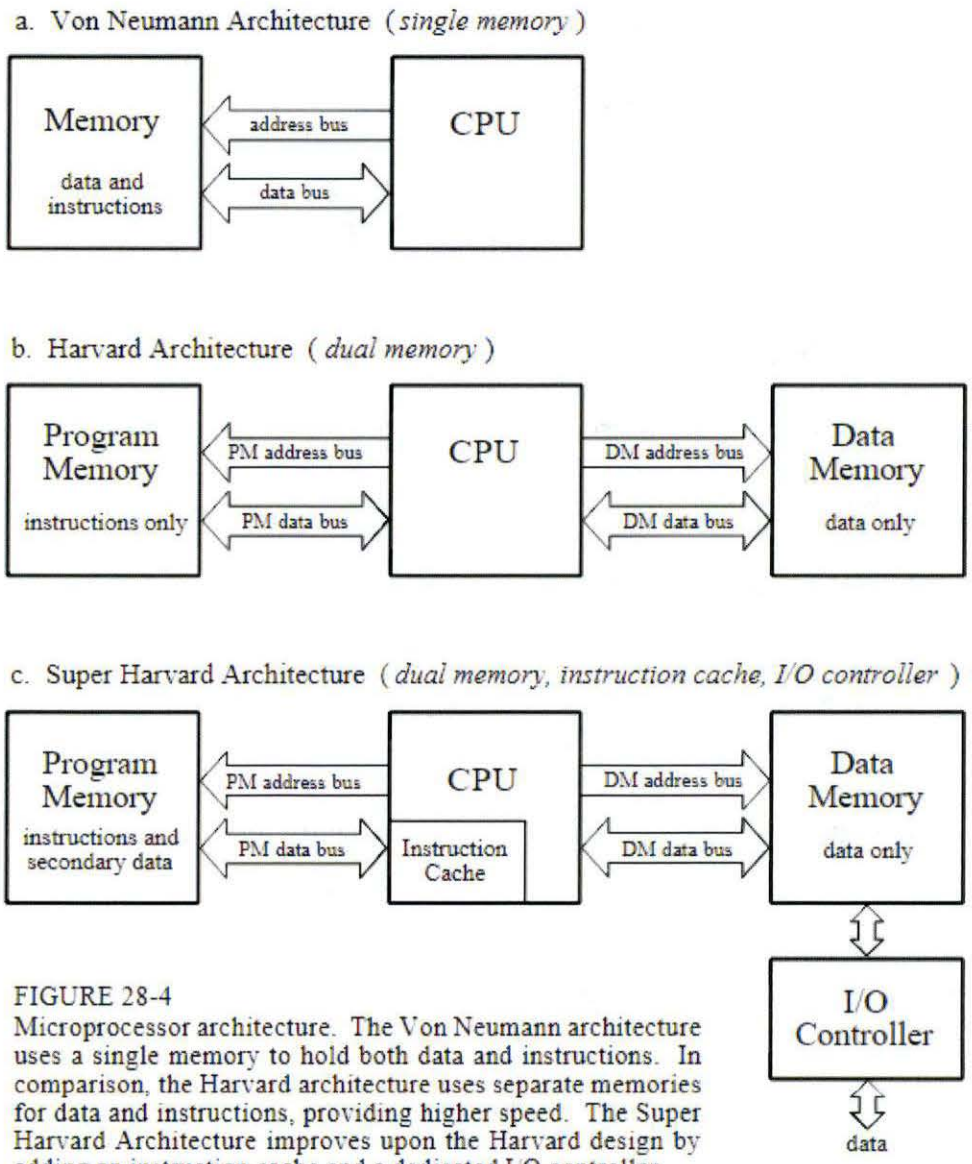


FIGURE 28-4
Microprocessor architecture. The Von Neumann architecture uses a single memory to hold both data and instructions. In comparison, the Harvard architecture uses separate memories for data and instructions, providing higher speed. The Super Harvard Architecture improves upon the Harvard design by adding an instruction cache and a dedicated I/O controller.

(EX1242, p. 511.) The above description regarding the reliance upon memory and the storage of data while performing processing tasks is applicable to systems with more modern processors as well. For example, the 2006 publication Introduction to Digital Signal Processing and Filter Design by B. A. Shenoi provided an example digital signal processing system:

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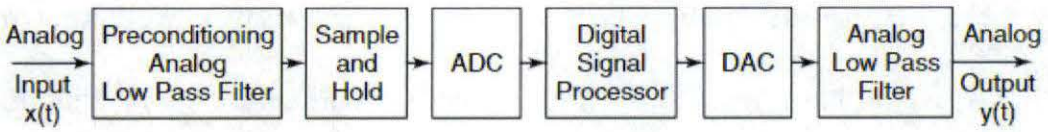


Figure 1.17 Example of a digital signal processing system.

(EX1243, p. 23). Shenoi further described that "[t]he basic elements in digital filters are the multipliers, adders, and delay elements, and they carry out multiplication, addition, and shifting operations on numbers according to an algorithm determined by the transfer function of the filters or their equivalent models," and that "[t]he coefficients of the transfer function and the sample values of the input signal can be stored in the memory of the digital filter hardware or on the computer (PC, workstation, or the mainframe computer)." (EX1243, p. 23). Shenoi further acknowledged that digital signal processing is used in biomedical systems. (EX1243, p. 2). By 2009, memory and processing technology was more advanced than the technology discussed in these articles and could, for example, hold more data than memories developed in 2006.

46. Therefore, skilled artisans were familiar with filtering, smoothing, clipping, digitizing, conditioning, and other processing routines for sensor signals using a microprocessor and knew that sensor data is stored in memory (*e.g.*, processor cache, buffer, RAM) throughout these routines to run computations.

4. Bluetooth Communication

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47. By April 2009, Bluetooth communication was well known to a POSITA, would have been considered one of few options for short range medical device communications, and was an obvious choice for radio frequency communications.

48. For example, 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.) Bluetooth was used widely, including for physiological monitoring with medical devices. For example, "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.)

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

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B. Ordinary Level Of Skill In The Art

50. I understand that a person of ordinary skill in the art ("POSITA") is a hypothetical person who has the experience and skills of a typical person working in the field of the alleged invention at the time the invention was allegedly made.

51. As of April 2009, I believe that a POSITA would have 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 transmit 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.

52. A POSITA may be part of an interdisciplinary team with others having relevant experience in the areas set forth above and/or with clinicians involved in diagnosis, treatment, and patient management relevant to the use of medical devices for monitoring physiological signals. This definition of a POSITA would not differ materially for a date of April 2010.

53. As elaborated in my CV, my skills and experience met or exceeded those of a POSITA at the relevant time, and today. (*See* paragraphs 4-8 above.)

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Unless otherwise noted, however, in this declaration my opinions present the viewpoint of a hypothetical POSITA.

54. In my view, a POSITA would have had broad working knowledge of glucose monitoring technology, including at least: (a) knowledge of subcutaneous glucose sensors as discussed with sensor electrodes above and the knowledge and skills to use amperometric sensors that measured current flowing from the glucose oxidase (GOx) catalyzed oxidation of glucose at a working electrode to a corresponding reduction reaction at a counter electrode; (b) knowledge of calibration as discussed with sensitivity in calibration above and the knowledge and skill to use of blood glucose reference values to calculate the sensitivity coefficient of a glucose sensor and to apply this sensitivity coefficient to convert current from an amperometric glucose sensor to commensurate glucose concentrations; (c) knowledge of signal processing as discussed with microprocessor computations above and the knowledge and skills to smooth, filter, digitize, encode, condition, calibrate, and convert signals from a glucose sensor into calculated glucose concentration values, save these values in memory as necessary to perform processing and computations, and ultimately display these values numerically and graphically; (d) knowledge of wireless and Bluetooth communication as discussed above and the knowledge and skills to implement Bluetooth and other wireless

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communication protocols between multiple devices like transceivers, monitors/receivers, cell phones, PDAs, personal computers and insulin pumps.

55. A POSITA would have been aware of commercially available glucose monitoring systems through scientific journals and magazines, including continuous glucose monitoring systems from Dexcom, Abbott, and Medtronic, like the Medtronic MiniMed Paradigm® REAL-Time System. 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 programing 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, and regenerating it once the system recovered.

56. In addition to specific knowledge of glucose monitoring, a POSITA would have been skilled in fundamental technologies and techniques in biomedical, electrical, and computer engineering, including programming a microprocessor with programs stored in memory. First, a POSITA would have been skilled in programing a microprocessor to run calibration, calculation, or filtering algorithms and other processing routines on glucose data. A POSITA would have also known how to program a microprocessor to store glucose data throughout processing, including

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electrical current values, smooth sensor signals, average sampling intervals, digital sensor values (Dsig), and calculated glucose values in various types of memory like a processor cache or buffer, RAM, or flash memory. A POSITA would have been skilled at programming a microprocessor to detect the failed reception of glucose data, sensor instability, rapidly changing glucose values, glucose level excursions, faulty or interrupted glucose readings, and other conditions associated with measuring, transmitting, receiving, and calibrating glucose data. A POSITA would have been skilled a programming a microprocessor to respond to these conditions by, for example, prompting or delaying calibration, storing glucose data in memory, and displaying a gap in graphed glucose levels when glucose data is not received. To this point, a POSITA would have known to program a microprocessor to display glucose data using a graphical user interface. Finally, a POSITA would have been skilled in bi-directional communication protocols, including verifying receipt of transmitted information, echoing received information, and retransmitting or synchronizing information between two devices over a wireless communication link. A POSITA would have known that any devices which perform these functions (*i.e.*, transceiver, monitor, PDA, cell phone, insulin pump) have a processor.

57. For example, based at least on their education in biomedical, electrical, software, or computer engineering and corresponding experience, a POSITA would have known how to program and reprogram microprocessor-controlled devices,

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including transceivers and monitors, to perform computations, monitoring, detection, alarm, data management, display and other functions associated with physiological monitoring. A POSITA would have consulted members of their interdisciplinary team as necessary to program these devices and functions.

58. As an additional example, 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 malfunctions with system components (*e.g.*, transceiver, monitor), and that failed communication would cause data to be unavailable and lead to the inability to display this data. In addition, a POSITA would also have recognized from reviewing any of the Patel-2009 (EX1212), Paradigm REAL-Time (EX1211), Patel-2008 (EX1215), or Shahmirian (EX1223) references that failed communication would cause missing data that could not be displayed. A POSITA would have been motivated to correct calibration errors, including requesting blood glucose reference values and prompting calibration, when conditions preventing calibration resolve or otherwise as necessary to continue the display of accurate glucose concentrations to a user.

59. As a further example, based on their education and experience in physiological monitoring, a POSITA would have known that the failure to convert sensor signals to calculated analyte concentrations could be caused by a variety of

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conditions, including faulty or interrupted sensor readings and calibration errors based on, for example, sensor instability, extreme temperatures, extreme glucose levels, rapid glucose changes, and issues with blood glucose reference values. A POSITA would understand that failure to calculate analyte concentrations would cause missing analyte data and lead to the inability to display this missing data. In addition, a POSITA would also have recognized from reviewing either of the Paradigm REAL-Time (EX1211) or Causey (EX1217) references that each of these conditions would cause missing data that could not be displayed.

60. In order to apprise users that analyte data is missing without presenting inaccurate data, a POSITA would have found it obvious to display a gap to indicate when analyte data is missing due to failed communication, failed calibration, or another condition. When failed communication or failed/delayed calibration is resolved and previously missing data becomes available, a POSITA would have found it obvious to display previously missing data to the user in order to present as much accurate data as possible to assist in diabetes management, insulin dosing decisions, and prevention or treatment of hyper and hypo-glycemia. (EX1211, 15, 18, 23-27; EX1212, [0004], [0006]; *see also e.g.*, EX1229; EX1237, 17; EXS1239-1240.) In addition, a POSITA would have found it obvious to display previously missing data by filling-in/re-populating this data is analytes graphs. A POSITA would recognize that retransmitting, synchronizing, and re-populating missing

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glucose data necessarily entails storing this data and the time of each missing glucose data point.

61. Finally, a POSITA would have known that a transceiver is comprised of a transmitter and a receiver. A POSITA also would have known that a transmitter and antenna are required to transmit signals, that a receiver and antenna are required to receive signals, and that cell phones, PDAs, and other devices that transmit and receive radio frequency communications have both an antenna and a transceiver.

VIII. GROUND 1: CLAIM 13 IS OBVIOUS OVER PATEL-2009 AND PARADIGM® REAL-TIME

A. Patel-2009 (EX1212) Is Supported By Its Provisional Application (EX1214)

62. U.S. Patent Publication 2009/0085768 ("Patel-2009", EX1212) is titled "Glucose sensor transceiver."

63. I understand that Patel-2009 published from U.S. Application No. 12/056,651 and that Patel-2009 claims priority to U.S. Provisional Application No. 60/976,886 ("the '886 Provisional", EX1214).

64. I have reviewed Patel-2009, including claim 1 directed to "[a] telemetered characteristic sensor transceiver for exchanging data with at least one remote device." (EX1212, p.9.) I have also reviewed the 60/976,886 provisional application. (EX1214.)

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65. Based on my review, it is my opinion that the '886 Provisional Application (EX1214) supports claim 1 of Patel-2009 (EX1212). In support of this conclusion, I note that page 31 of the '886 Provisional includes a claim that is substantially similar to claim 1 of Patel-2009, with only minor revisions highlighted below:

> 1. A telemetered characteristic sensor transceiver for exchanging data with at least one remote device, the transceiver comprising:
> a housing~~; a sensor connector coupling the housing to~~ detachably coupled to a sensor located on a body of a user ~~for~~, the sensor producing a signal indicative of a user characteristic;
> a processor formed within the housing and ~~coupled to~~ in communication with the sensor ~~connector~~ for processing the signal ~~received from~~ produced by the sensor;
> a transmitter coupled to the processor for transmitting data to at least one remote device;
> a receiver coupled to the processor for receiving data from the at least one remote device; and
> a memory coupled to the processor for storing data,
> wherein the processor performs calculations using at least one of the signal ~~received from~~ produced by the sensor, the data received from the at least one remote device and the data stored in the memory, and ~~stores~~ performs at least one of storing the calculations in the memory ~~or transmits~~ and transmitting the calculations to the at least one remote device through the transmitter.

66. It is also my opinion that the '886 Provisional supports claim 1 of Patel-2009 as detailed in the chart below:

60/976886 Provisional	Patel-2009 Claim 1
(EX1214, p.9) [0007] The present invention relates to a telemetered characteristic sensor transceiver for exchanging data with at least one remote device. The transceiver	It is my opinion that this paragraph [0007] supports the follow elements of claim 1 of Patel-2009:

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comprising a housing, a sensor connector coupling the housing to a sensor located on a body of a user for producing a signal indicative of a user characteristic, a processor formed within the housing and coupled to the sensor connector for processing the signal received from the sensor, a transmitter coupled to the processor for transmitting data to at least one remote device, a receiver coupled to the processor for receiving data from the at least one remote device, and a memory coupled to the processor for storing data. Preferably, the processor performs calculations using at least one of the signal received from the sensor, the data received from the at least one remote device and the data stored in the memory, and stores the calculations in the memory or transmits the calculations to the at least one remote device through the transmitter.	A telemetered characteristic sensor transceiver for exchanging data with at least one remote device, the transceiver comprising: the sensor producing a signal indicative of a user characteristic; a processor formed within the housing and in communication with the sensor for processing the signal produced by the sensor; a transmitter coupled to the processor for transmitting data to at least one remote device; a receiver coupled to the processor for receiving data from the at least one remote device; and a memory coupled to the processor for storing data
(EX1214, p.10) [0012] In accordance with another embodiment of the present invention, the processor calculates sensor glucose values using at least one of the signal received from the sensor, the data received from the at least one remote device and the data stored in the memory. Preferably, a rate of exchanging data between the transceiver and the at least one remote device is dynamically changed depending on a characteristic of the calculated sensor glucose values. Preferably, a glucose calculation algorithm for calculating the sensor glucose values is stored in the memory.	It is my opinion that this paragraph [0012] supports the follow elements of claim 1 of Patel-2009: a transmitter coupled to the processor for transmitting data to at least one remote device; and a memory coupled to the processor for storing data, 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

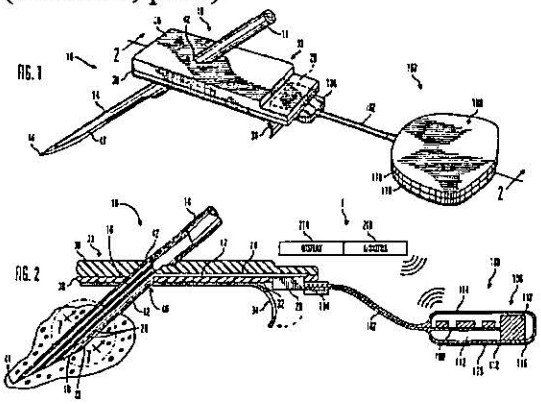
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Preferably, the processor stores the calculated sensor glucose values in the memory or transmits the calculated sensor glucose values to the at least one remote device through the transmitter. Preferably, the calculated sensor glucose values are secured via an encryption scheme before transmission to the at least one remote device.	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) [0013] In accordance with another embodiment of the present invention, the receiver receives calibration data from the at least one remote device and the processor stores the received calibration data in the memory. Preferably, the processor performs a calibration using at least one of the calibration data stored in the memory, the signal received from the sensor and the calculated glucose sensor values. Preferably, a calibration algorithm for performing the calibration is stored in the memory.	It is my opinion that this paragraph [0013] supports the follow elements of claim 1 of Patel-2009: a processor formed within the housing and in communication with the sensor for processing the signal produced by the sensor; a receiver coupled to the processor for receiving data from the at least one remote device;
(EX1214, p.19-20) [0050] As shown in FIGS. 1, 2 and 8A, the telemetered characteristic sensor transceiver 100 is coupled to a sensor set 10 by a cable 102 through a connector 104 that is electrically coupled to the connector block 28 of the connector portion 24 of the sensor set 10. In alternative embodiments, the cable 102 may be omitted, and the telemetered characteristic sensor transceiver 100 may include an appropriate connector (not shown) for direct connection to the connector portion 24 of the sensor set 10 or the sensor set 10 may be modified to	It is my opinion that this paragraph [0010] supports the follow elements of claim 1 of Patel-2009: a housing detachably coupled to a sensor located on a body of a user,

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have the connector portion 24 positioned at a different location, such as for example, on the top of the sensor set 10 to facilitate placement of the telemetered characteristic sensor transceiver over the subcutaneous sensor set 10. This would minimize the amount of skin surface covered or contacted by medical devices, and tend to minimize movement of the sensor set 10 relative to the telemetered characteristic sensor transceiver 100. In further alternative embodiments, the cable 102 and the connector 104 may be formed as add-on adapters to fit different types of connectors on different types or kinds of sensor sets. The use of adapters would facilitate adaptation of the telemetered characteristic sensor transceiver 100 to work with a wide variety of sensor systems… (EX1214, p.20) [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… (EX1214, p.21) [0054] Referring to FIG. 8B, the printed circuit board 108 of the telemetered characteristic sensor transceiver 100 includes a sensor interface 122, processing electronics 124, timers 126, and data formatting electronics 128. In preferred embodiments, the sensor interface 122, processing electronics 124, timers 126, and data formatting electronics 128 are	

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formed as separate semiconductor chips; however, alternative embodiments may combine the various semiconductor chips into a single customized semiconductor chip. The sensor interface 122 connects with the cable 102 that is connected with the sensor set 10. In preferred embodiments, the sensor interface is permanently connected to the cable 102. However, in alternative embodiments, the sensor interface 122 may be configured in the form of a jack to accept different types of cables that provide adaptability of the telemetered characteristic sensor transmitter 100 to work with different types of sensors and/or sensors placed in different locations of the user's body… (EX1214, p.50)  (EX1214, p.52)	

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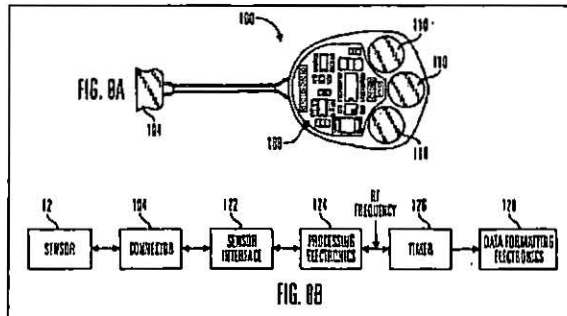


FIG. 8B

(EX1214, p.56)

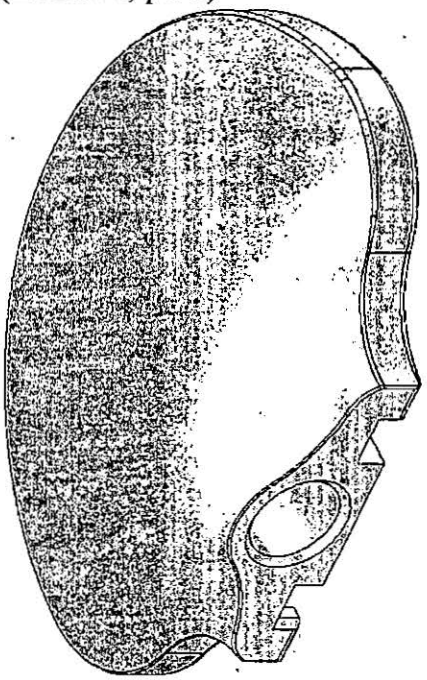
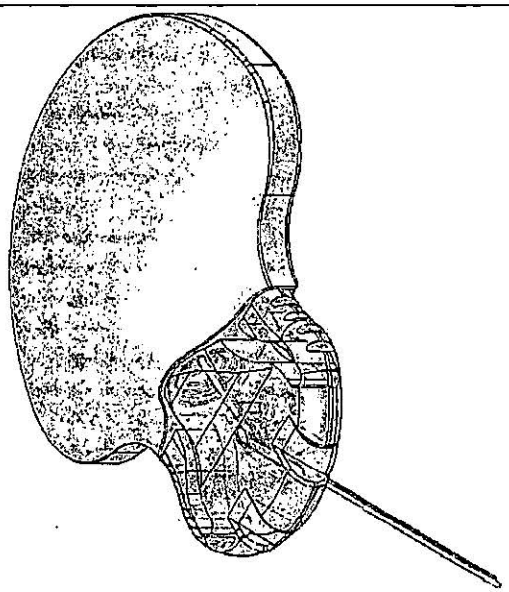


FIG. 13

(EX1214, p.61)

 FIG. 18	
(EX1214, p.24) [0062] In further embodiments, the transceiver 100 may transmit the data to a medication delivery device, such as an infusion pump or the like, as part of a closed loop system. This would allow the medication delivery device to compare sensor results with medication delivery data and either sound alarms when appropriate or suggest corrections to the medication delivery regimen. In preferred embodiments, the transceiver 100 includes a receiver for receiving data from the medication delivery device such that the transceiver 100 can compare sensor results with medication delivery. The transceiver 100 may also use the receiver to receive updates or requests for additional sensor data.	It is my opinion that this paragraph [0062] supports the follow elements of claim 1 of Patel-2009: a receiver coupled to the processor for receiving data from the at least one remote device;

67. Therefore, it is my conclusion that claim 1 of Patel-2009 (EX1212) and all elements of this claim are well supported by the '886 Provisional (EX1214).

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B. The Medtronic Diabetes Website's Publication Of Webpages And Other Information On Paradigm® REAL-Time (EX1211) Was Publicly Accessible And Known By A POSITA

68. I have reviewed the Paradigm® REAL-Time reference (EX1211), including the Features & Benefits Fact Sheet, Frequently Ask Questions Webpage, and Sensor Features User Guide.

69. It is my opinion that, a POSITA would have been aware of Continuous Glucose Monitoring Systems from Medtronic, Dexcom, and Abbott, including the Medtronic MiniMed Paradigm® REAL-Time.

70. A POSITA would have also been aware of scientific publications in the fields of physiological monitoring and diabetes, including the "Journal of Diabetes Science and Technology" and "Current Opinion in Endocrinology, Diabetes and Obesity." For example, a POSITA would have been aware of an August 2007 article titled "Real-time continuous glucose monitoring" by Bruce Buckingham et. al. published in Current Opinion in Endocrinology, Diabetes and Obesity. (EX1239.) This "Real-time continuous glucose monitoring" article introduced the MiniMed Paradigm REAL-Time Continuous Glucose Monitoring System to a POSITA as an FDA approved system with various features including display of glucose graphs. (EX1239, 289-93.) Additionally, a POSITA would have been aware of a March 2008 article titled "Clinical Overview of Continuous Glucose Monitoring" by Bruce Buckingham in the Journal of Diabetes Science and Technology. (EX1240.) This

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"Clinical Overview of Continuous Glucose Monitoring" article also introduced the Paradigm system as one of four continuous glucose monitoring systems available in 2008. (EX1240, 301.) Finally, a POSITA would have been aware of a November 2008 article titled "Continuous Glucose Monitoring: The Future of Diabetes Management" by Mark Burge et al. which discussed the advantages of continuous glucose monitors, including the MiniMed Paradigm REAL-Time System for patients and their utility in preventing and treating hyper and hypoglycemia. (EX1246, 113-115.) Consequently, it is my opinion a POSITA would have known of and investigated the MiniMed Paradigm REAL-Time as a leading continuous glucose monitoring system.

71. A POSITA would have also been aware of magazines like the American Diabetes Association's "Diabetes Forecast." An article titled "Continuous Glucose Monitoring for Kids" in the August 2007 edition of Diabetes Forecast introduced the MiniMed Paradigm REAL-Time system to a POSITA. (EX1238.) A full page advertisement in the November 2007 edition of Diabetes Forecast also introduced the MiniMed Paradigm REAL-Time and directed a POSITA to the Medtronic Diabetes Website (www.medtronicdiabetes.com). (EX1237, 17.) Consequently, it is my opinion a POSITA would have known of and investigated MiniMed Paradigm REAL-Time on the Medtronic Diabetes website.

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C. Patel-2009 And Paradigm® Real-Time Disclose Glucose Monitoring Systems Easily Combined, And The Motivation To Do So With An Expectation Of Success

1. Patel-2009

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

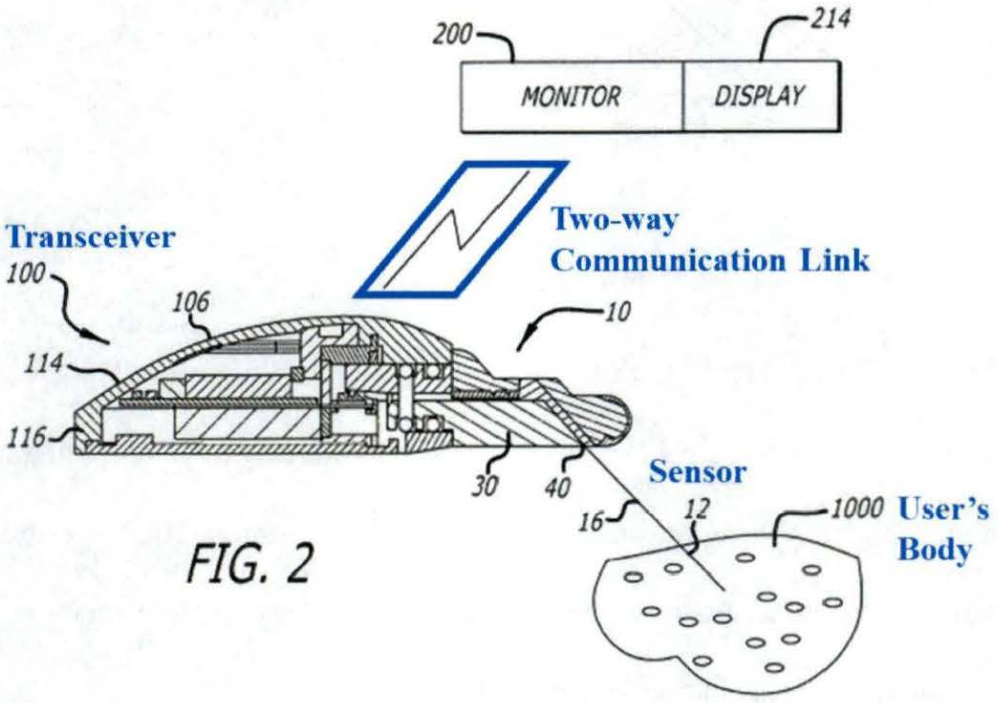


FIG. 2

(EX1212, [0008]-[0009], [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. (EX1212, [0008], [0013]-[0014], [0058], [0061].) The sensor set encompasses a subcutaneous sensor which monitors glucose levels by exposing electrodes to bodily fluid:

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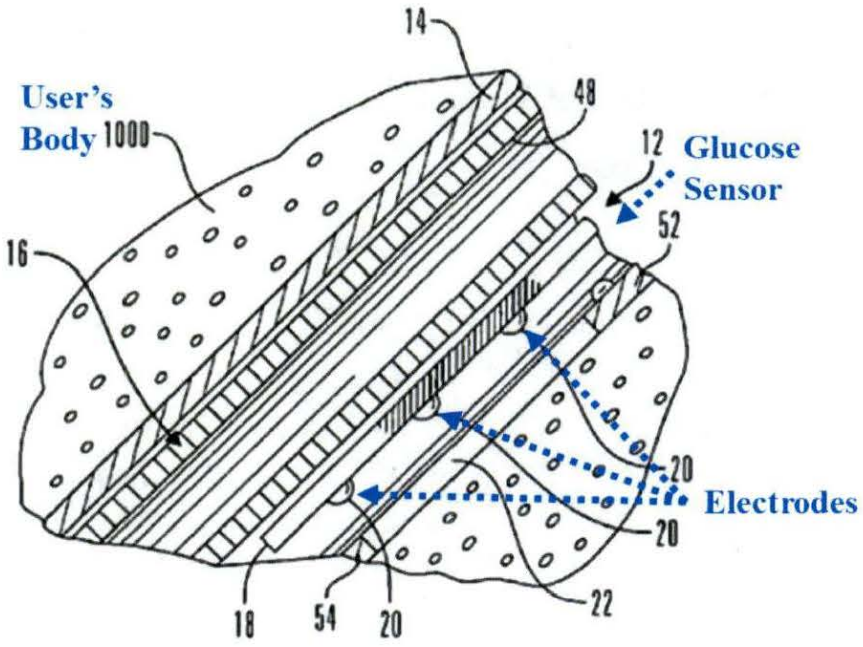


FIG. 6

(EX1212, [0049]-[0051], Fig. 6 (annotated in blue).) The monitor displays glucose levels and trend graphs. (EX1212, [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:

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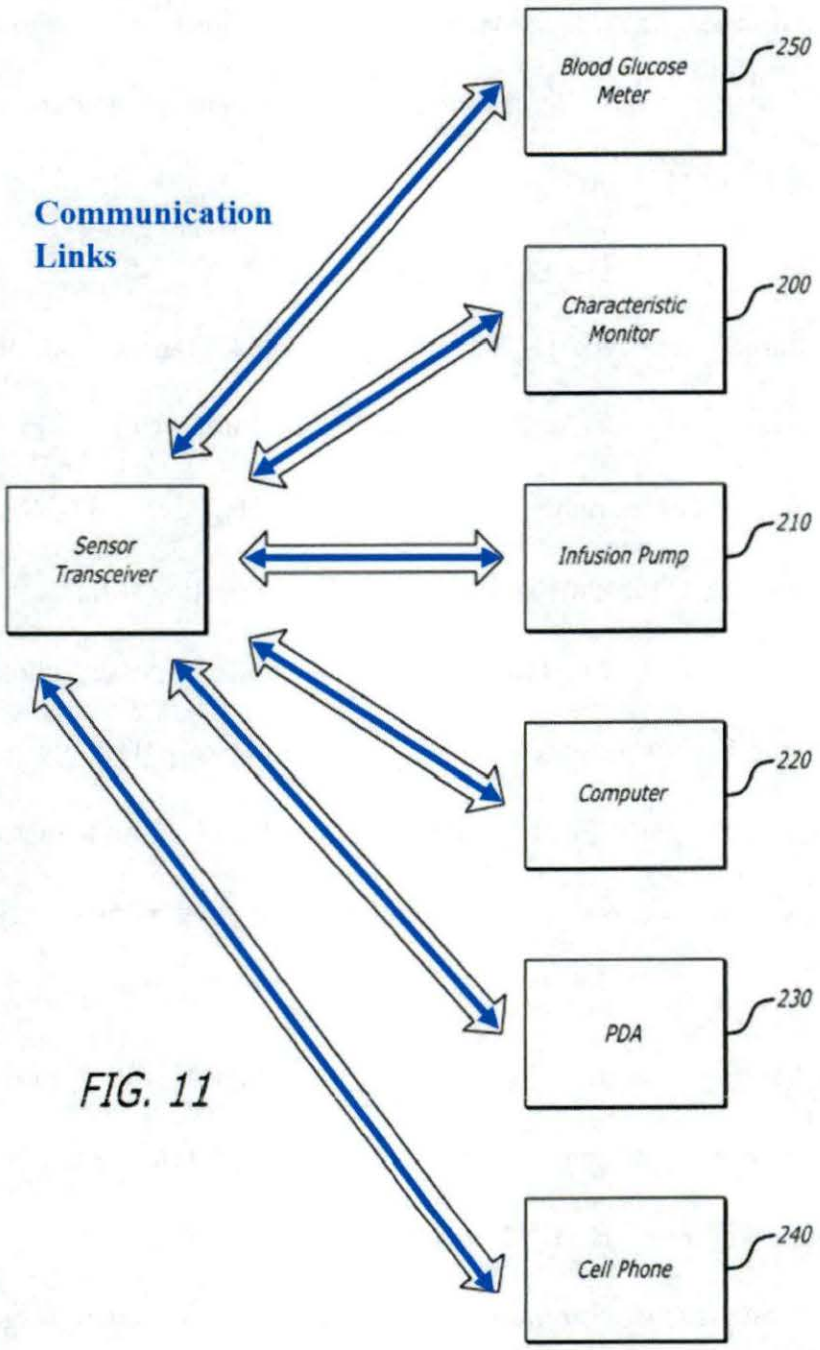


FIG. 11

(EX1212, [0042], [0075]-[0076], [0084], Fig. 11 (annotated in blue).)

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

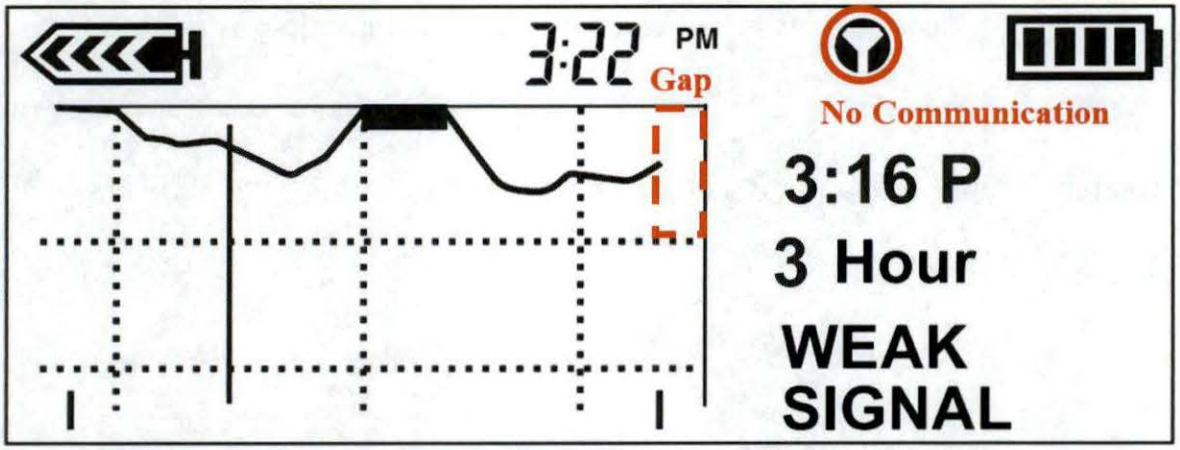
2. Paradigm® REAL-Time

74. Paradigm® REAL-Time (EX1211) discloses a continuous glucose monitoring system comprised of Paradigm® Insulin Pump, MiniLink™ Transmitter, and glucose sensor components. (EX1211, 9, 15, 18, 23-24, 37-38.) The glucose sensor "measures 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. (EX1211, 7, 9, 15, 23-24, 64.)

75. 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 pumps screen. (EX1211, 7-8.)

76. When loss of communication from the transmitter to the insulin pump causes failed reception of glucose data, missed data is displayed as a gap:

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(EX1211, 8, 43, 49, 73 (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). (EX1211, 8.)

3. Combination of Patel-2009 and Paradigm® REAL-Time

77. 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

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gaps" 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 continuous glucose monitoring data stored in transmitter memory. (EX1211 8, 10, 41, 73.)

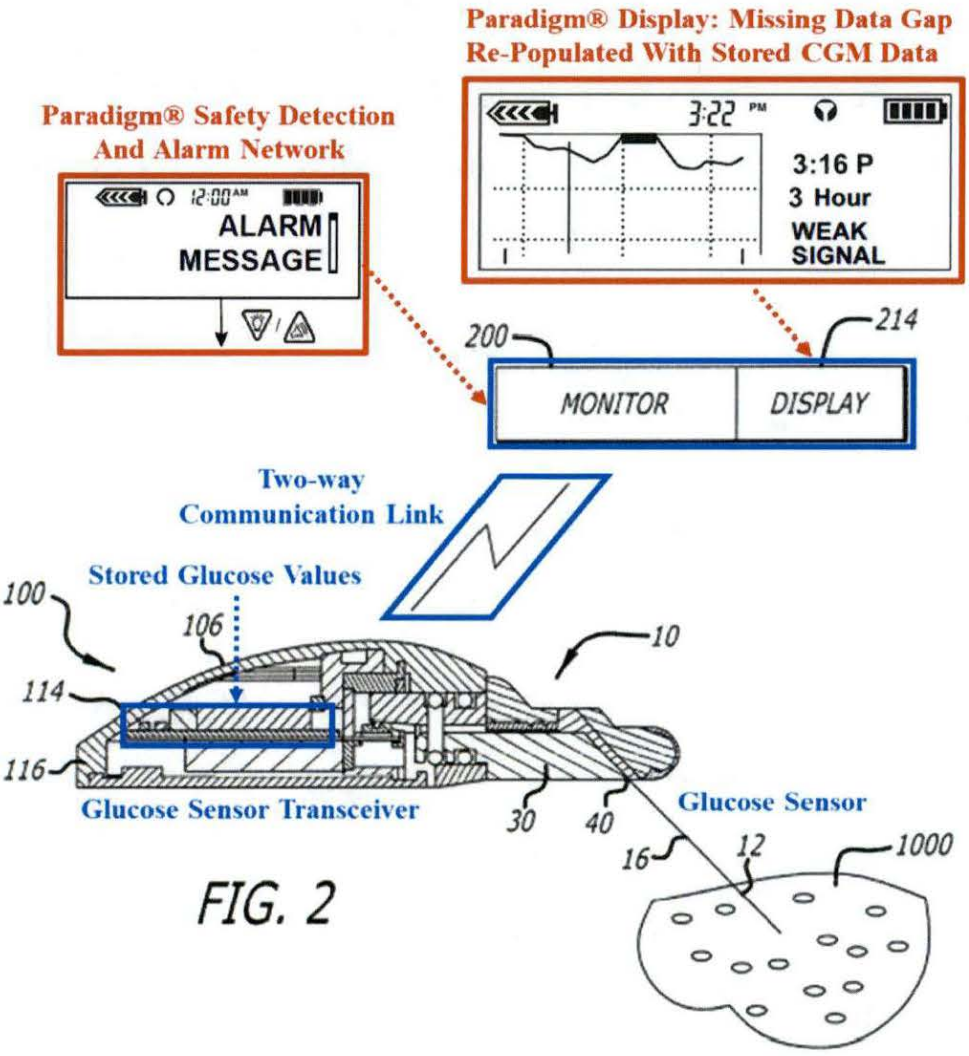


FIG. 2

(EX1212, Fig. 2 (annotated in blue for *Patel*-2009); EX1211, 72-73 (excerpted and annotated in red for Paradigm® REAL-Time).) The Patel-2009/Paradigm

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Combination retains the subcutaneous glucose sensor and glucose sensor transceiver from Patel-2009. (EX1212, [0008], [0041], [0049], [0051], [0084], [0086].)

78. 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; *see also* paragraph 80 below (many diabetes would not require an insulin pump and could effectively use some of the other monitoring disclosed in Patel-2009 to manage their diabetes).)

4. Motivation To Combine And Expectation Of Success

79. Patel-2009 discloses displaying glucose trend graphs to a user and provides for specific advantages over previous glucose monitoring systems and pre-existing 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].)

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80. 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.) A POSITA would also know that not every diabetic would require an insulin pump but would still require a mechanism to display glucose values, and alerts/alarm to assist with diabetes management. 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]; *see also* paragraphs 59-60 above.)

81. 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. (EX1240, 301; *see* paragraphs 55, 69-71 above.) A POSITA would have been especially motivated to combine Paradigm® REAL-Time with Patel-2009 because they both relate to similar Medtronic continuous glucose

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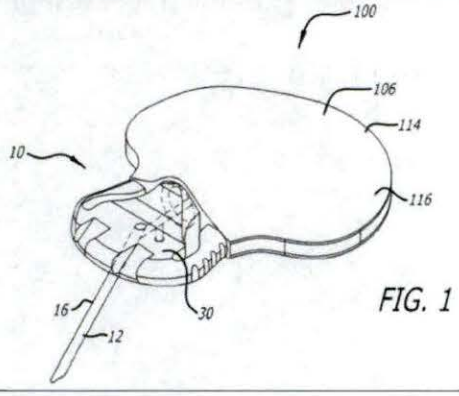
monitoring systems as evidenced by their visual similarity and common citation to Medtronic's U.S. Patent No. 6,554,798. (EX1212, [0068]-[0069], Fig. 1; EX1211, 32.)

82. For example, Patel-2009 and Paradigm® REAL-Time both relate to Medtronic continuous glucose monitoring systems that use radio frequency communication to transmit glucose data measured by a subcutaneous sensor. (*See* paragraphs 72, 74 above.) A POSITA reviewing Patel-2009 would have been directed to incorporate U.S. Patent 6,554,798, which is cited in Paradigm® REAL-Time:

© 2006, Medtronic MiniMed. All rights reserved.
This product is covered by U.S. Patent Nos. 6,551,276; 6,554,798; 6,872,200; 6,936,029; 6,979,326; 6,997,920 and 7,025,743. Other U.S. and/or foreign patents may be pending.

(*Compare* EX1212, [0069] *with* EX1211, 32.) For example,

83. A POSITA would have also noticed similarities between the Glucose Sensor Transceiver in Patel-2009 and the MiniLink™ Transmitter in Paradigm® REAL-Time:

Glucose Sensor Tranceiver	MiniLink™ Transmitter
 FIG. 1	

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(EX1212, Fig. 1)	(EX1211, 30.)

84. Patel-2009 describes improving pre-existing transmitters to provide many advantages, including faster and more frequent calibration, more calculated glucose data points, and networking with more devices. (EX1212, [0007], [0084]-[0085].) A POSITA would have been motivated to make these improvements.

85. A POSITA would have expected success because Patel-2009 discloses specific improvements over previous glucose monitoring systems like Paradigm® REAL-Time. (EX1212, [0007], [0084]-[0086].) A POSITA would have known how to modify Patel-2009 to perform functions of Paradigm® REAL-Time, including by modifying the programing of Patel-2009's monitor or by importing programs from the Paradigm® Insulin Pump. (*See* paragraphs 56-57 above.)

D. Ground 1 Claim Mappings

86. It is my opinion that the Patel-2009/Paradigm Combination renders obvious claim 13 as set out below. As claim 13 depends from claim 1, I also include an analysis of claim 1 here. I note that this claim 1 analysis provided in paragraphs 87-115 below, is substantively identical to the testimony I provide in paragraphs 87-115 of my declaration submitted as EX1008 in IPR2023-01251.

1. Claim 1

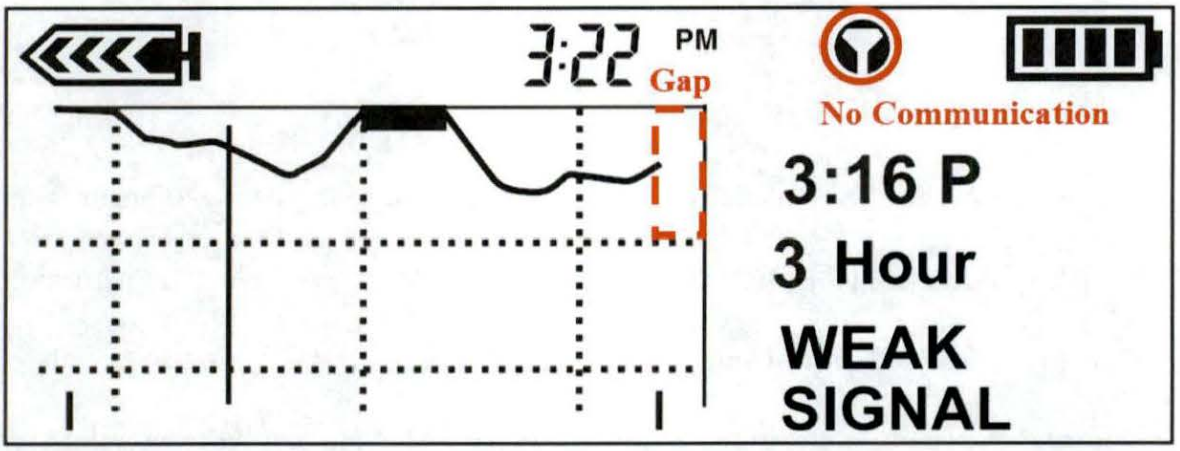
a) [1.A] (preamble)

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

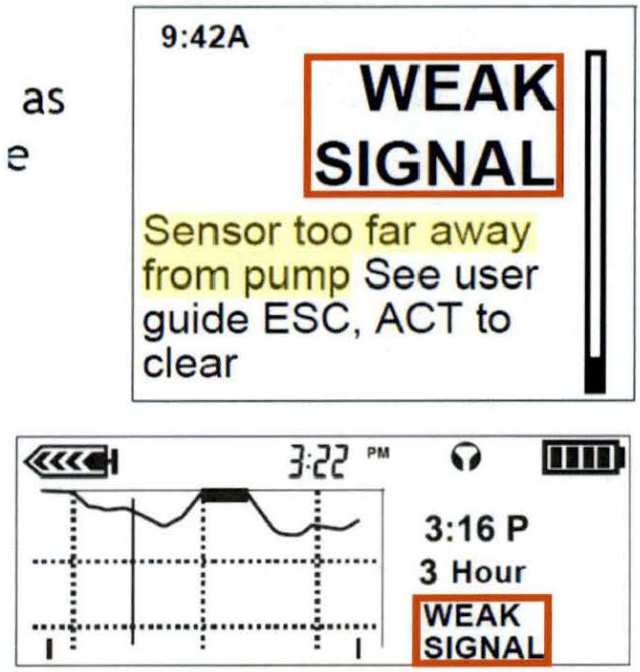
87. Patel-2009 and Paradigm® REAL-Time both disclose CGM systems that display glucose levels to a user. (EX1212, [0042], [0066]; EX1211, 15, 23-24, 37-38, 64.)

88. Paradigm® REAL-Time discloses graphs that display sensor glucose data points. (EX1211, 64.) When glucose data is not received, these graphs display a corresponding gap in glucose values:



(EX1211, 73 (excerpted and annotated in red).) If failed reception persists for the 5 to 40-minute "Missed Data" period, a Weak Signal alarm is triggered to indicate that the "Sensor [is] too far away from [the] pump:"

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(EX1211, 49, 73 (excerpted, annotated in red, and heighted).)

89. A Weak Signal alarm and corresponding missing data gap occur when the "[t]ransmitter and insulin pump are too far apart" for wireless transmission. (EX1211, 8.) 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." (EX1201, 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." (EX1201, 8, *see* paragraphs 112, 114-115 below.)

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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;

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

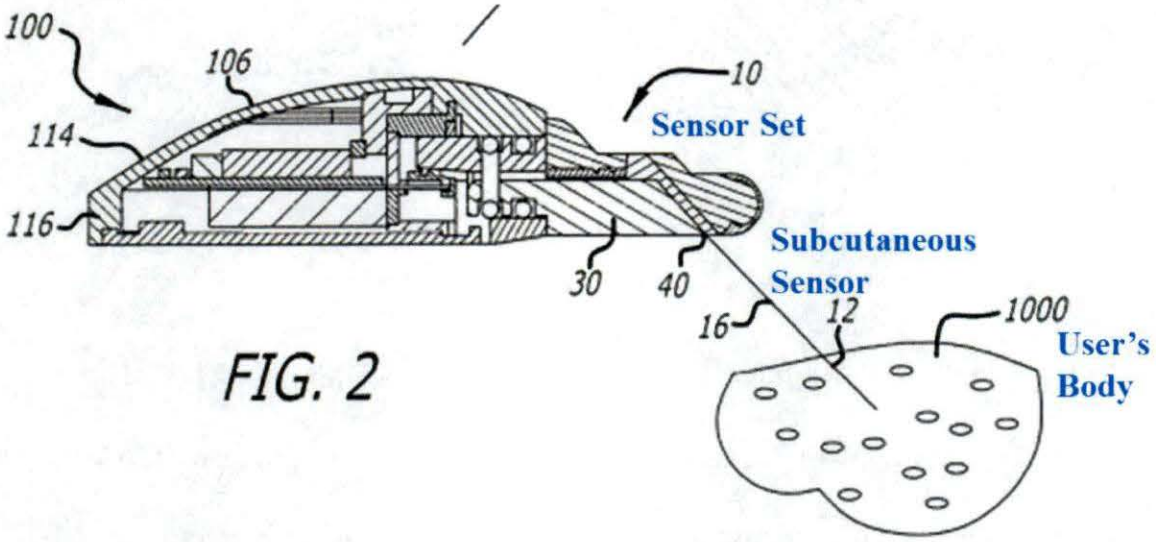


FIG. 2

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

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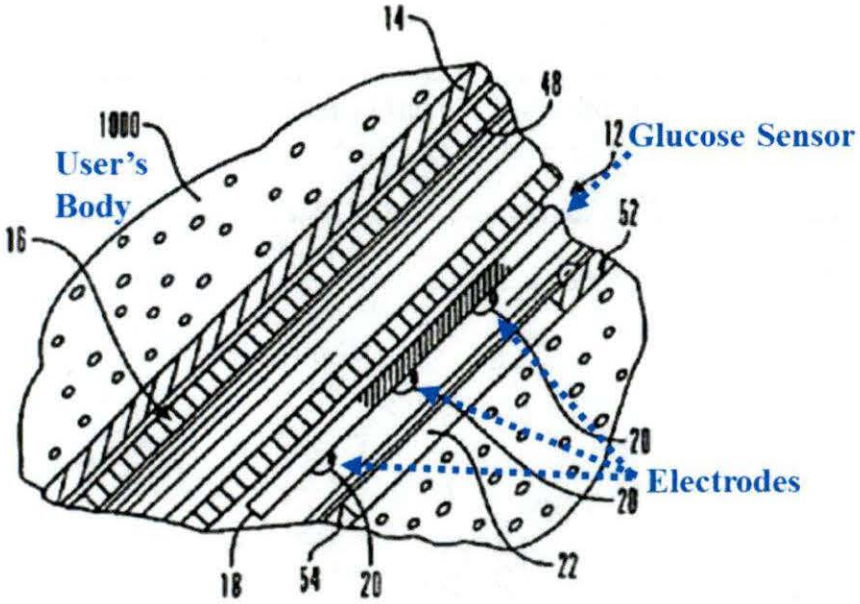
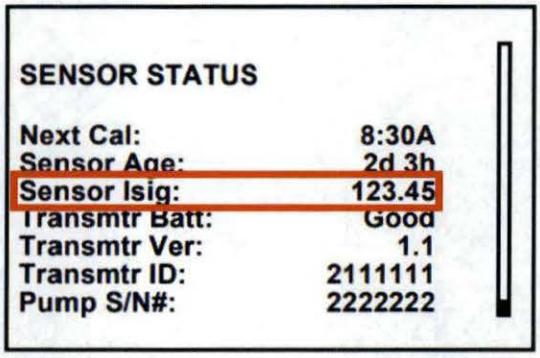


FIG. 6

(EX1212, [0008], [0038], [0049], [0051], Fig. 6 (annotated in blue).)

91. 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:

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(EX1211, 63, 80 (excerpted and annotated in red).)

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:

92. Patel-2009 discloses that "sensor set 10 is connected to the telemetered characteristic sensor transceiver 100, so that the sensor 12 can be used" for taking glucose readings. (EX1212, [0072].) Figure 8A illustrates transceiver 100 coupled to sensor set 10:

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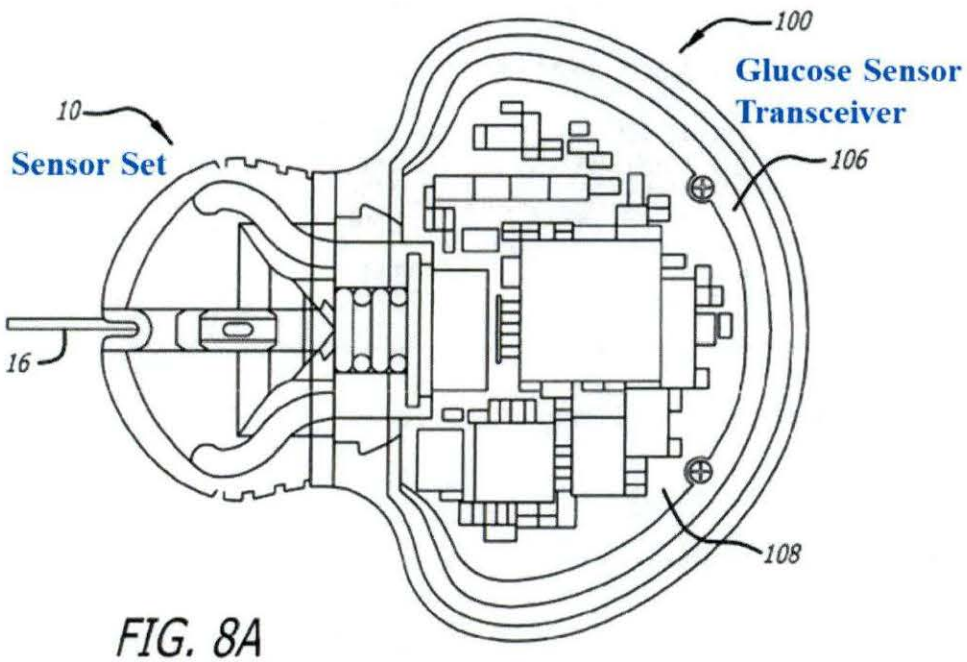


FIG. 8A

(EX1212, 0056, Fig. 8A (annotated).) The glucose sensor transceiver comprises:

> a processor formed within the housing and in communication with the sensor for processing the signal produced by the sensor, a transmitter coupled to the processor for transmitting data to at least one remote device, a receiver coupled to the processor for receiving data from the at least one remote device, and a memory coupled to the processor for storing data.

(EX1212, [0008].) The transmitter and receiver comprise an RF Transceiver. (EX1212, [0058]; *see* paragraph 61 above.) The glucose transceiver also includes a battery. (EX1212, [0058].)

93. 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. (EX1211, 8, 37, 51.)

d) [1.D]

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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

94. Patel-2009 provides that the 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.*, readings from a blood glucose meter). (EX1212, [0042], [0064], [0081], [0084].) Calibration is performed by running filtering and calibration algorithms. (EX1212, [0076].) Following calibration, Patel-2009 discloses that the transceiver "appropriately calculate[s] sensor glucose values using the calibrated sensor readings." (EX1212, [0084]; *see also* EX1223 (Shahmirian discloses a plethora of implementations of for the calibration algorithms).) The transceiver logs calculated glucose values and stores them in memory as glucose history. (EX1212, [0013], [0047], [0081], [0083], [0086].)

95. The processor in Patel-2009 necessarily stores sensor data in memory at least during filtering, calibration, and calculation because a POSITA would understand that the transceiver's processor stores sensor data in memory (*e.g.*,

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processor cache, buffer, RAM) while filtering sensor signals, calibrating sensor readings, and calculating glucose values from calibrated sensor readings. (*See* paragraphs 41-46 above; *see also* EX1223 (Shahmirian discloses a plethora of routines for processing signal, data, and calculated values); EX1226 (Steil also discloses a variety of processing routines relevant to continuous glucose monitoring).)

96. Paradigm® REAL-Time 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. (EX1211, 61.)

97. Therefore, Patel-2009 and Paradigm® REAL-Time render obvious processing sensor signals with calibration data associated with sensor sensitivity (*see* paragraphs 94, 96 above) because a POSITA would understand that calibration uses reference data (*e.g.*, blood glucose reference values) to determine the sensor's sensitivity coefficient based on the ratio of sensor current to blood glucose concentration. (*See* paragraphs 37-40, 54 above.) Glucose levels are then calculated by dividing sensor current signals (*i.e.*, Isig) by the sensitivity coefficient. (*See* paragraphs 37-40, 54 above.)

e) [1.E]

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

98. 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:

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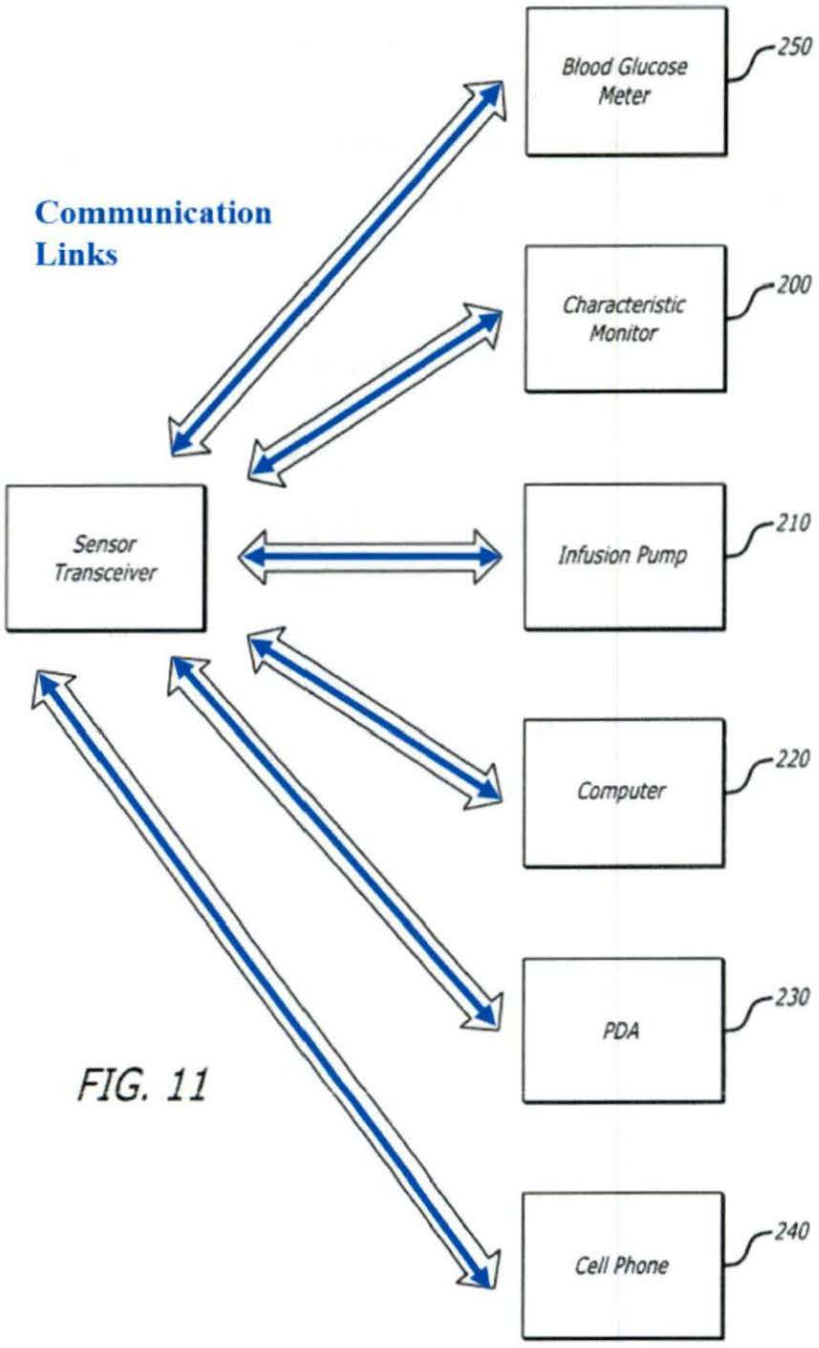


FIG. 11

(EX1212, [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. (EX1212, [0012], [0082].)

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99. Paradigm® REAL-Time supplements Patel-2009 by disclosing 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.)

100. A POSITA would have found it obvious to configure communication links to use Bluetooth protocols for communication with computers, PDAs, and cell phones disclosed in Patel-2009 and as a "short-range cable replacement for device-to-device connections" with the six-foot transmission range disclosed in Paradigm® REAL-Time in order to extend compatibility, operating range, and/or usability of the system via a standardized, well-established wireless communication protocol. (*See* paragraphs 47-49, 54 above.)

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,

101. Patel-2009 discloses transmission of glucose data over two-way communication links to various devices with a display (*e.g.*, Fig. 2, display 214) used to display glucose measurements, including infusion pumps, monitors, personal computers, PDAs, and cellular phones. (EX1212, [0042], [0066], [0076], Figs. 2, 11; *see also* paragraph 98 above.)

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102. Paradigm® REAL-Time also discloses that the insulin pump has a screen that displays glucose values sent from the MiniLink™ Transmitter and a sophisticated network of systems, including on-board data management software, the capacity to be programmed, and memory that stores 90 days of glucose data. (EX1211, 7-8, 23-26, 37, 43-50, 71.)

103. Patel-2009 discloses various receivers with a processor, and transceiver/antenna that receive glucose values. (*See* paragraphs 56, 61 above.) For example, Patel-2009 discloses exchanging data over a wireless connection and maintaining two-way communication links between a transceiver and other devices, such as a personal computer, personal digital assistant (PDA), monitor, or the like. (EX1212, [0043], [0045]). A POSITA would recognize that two-way wireless communication requires a transceiver and that devices (*e.g.*, PDAs, cellular phones, monitors, infusion pumps) receive communications with an antenna and transceiver. (*See* paragraph 61 above.) A POSITA would also recognize that these devices have a processor, which is necessary for communication, processing, and data management functions. (*See* paragraph 51 above,.)

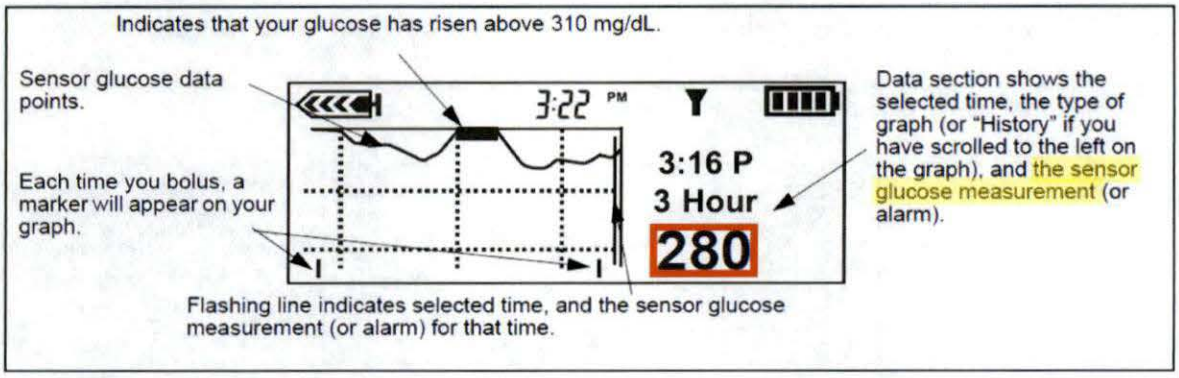
104. Additionally, a POSITA would have found it obvious to configure communication links to use Bluetooth. (*See* paragraphs 47-49, 54 above; *see* also paragraph 100 above.)

g) [1.G]

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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, and highlighted).)

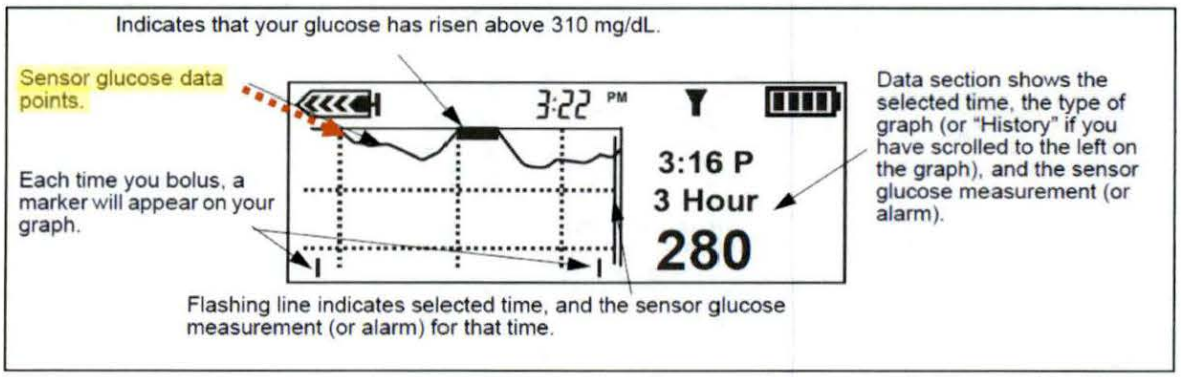
105. Patel-2009 also discloses that the monitor displays glucose levels received from the sensor. (EX1212, [0047], [0066].)

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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,

106. 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, and highlighted).)

107. Patel-2009 also discloses that the monitor displays glucose trends and graphs. (EX1212, [0047], [0066].)

i) [1.I]

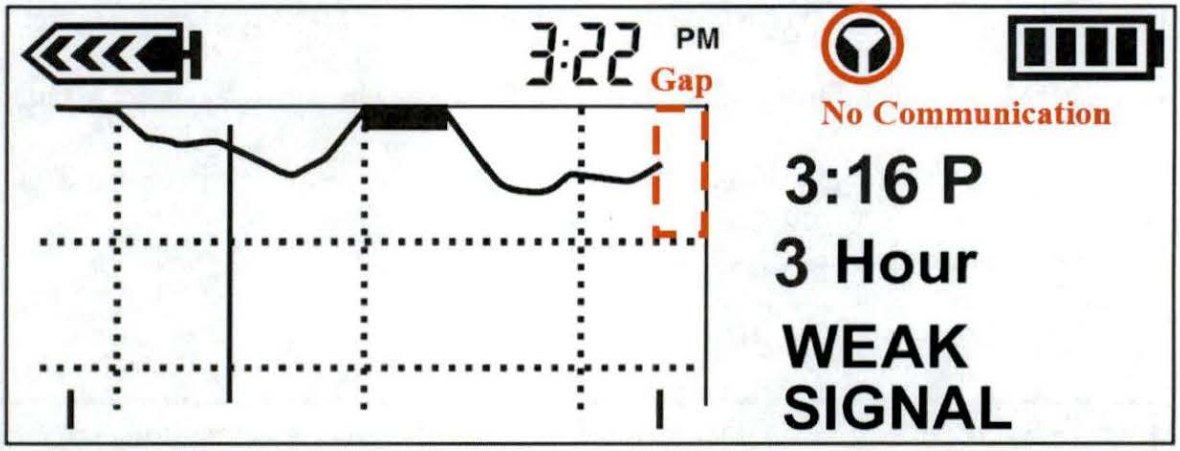
wherein the glucose monitoring system is configured to detect an adverse condition, wherein the adverse condition results in the receiver unit displaying a data gap such that the first line graph displayed on the receiver unit has an end corresponding to a time associated with a start of the adverse condition;

108. Paradigm® REAL-Time discloses "a sophisticated network of safety checks and systems" that "detects anything unusual" and notifies of conditions requiring immediate attention, including weak signals and calibration errors.

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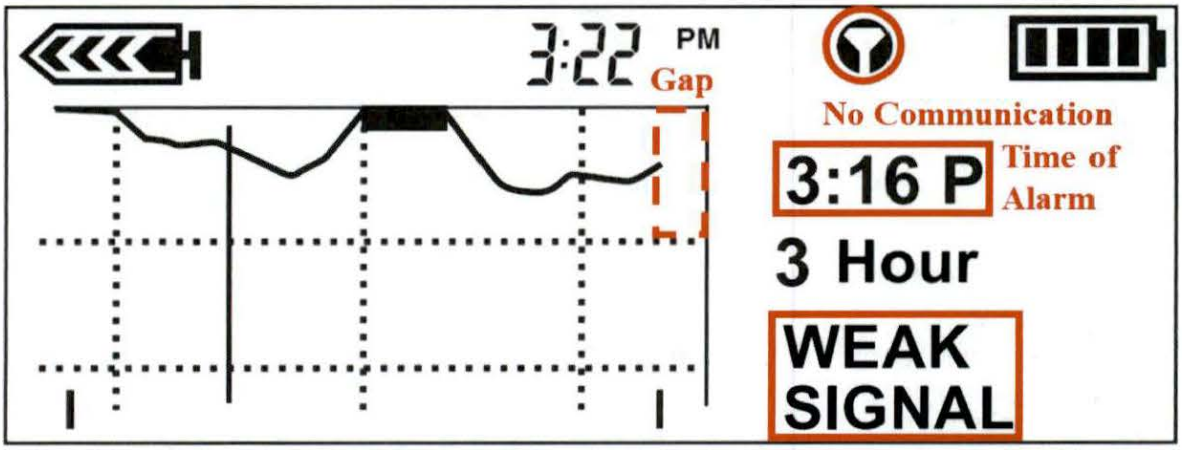
(EX1211, 71, 73-76.) For example, an ( ) icon changes to an ( ) icon when "the sensor is connected to the transmitter and [was] communicating with the pump" but this communication has been lost. (EX1211, 43.) Lost communication causes "failed reception of continuous glucose monitoring (CGM) data." (EX1211, 8.)

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



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

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(EX1211, 8, 49-50, 67, 73 (excerpted and annotated in red).) A "Lost Sensor" alarm is triggered after 40 minutes. (EX1211, 73.) The data gap corresponds with failed reception of glucose data, including the period (*e.g.*, 10 minutes) before a Weak Signal alarm is triggered. (EX1211, 8, 73.)

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;

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

111. Patel-2009 also discloses that the transceiver continues to calculate glucose data points during a communication failure and stores glucose history information. (EX1212, [0086].)

k) [1.K]

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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

112. 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 remaining. (EX1211, 8.) Thus, when the transmitter and insulin pump are out-of-range for less than 40 minutes (*e.g.*, a 30-minute swim), data gaps do not persist because they are entirely re-populated once transmission is re-established after being lost. (EX1211, 8; *see also* paragraph 60 above (a POSITA would find it obvious to re-populate missing analyte data when it becomes available after failed communication is resolved).)

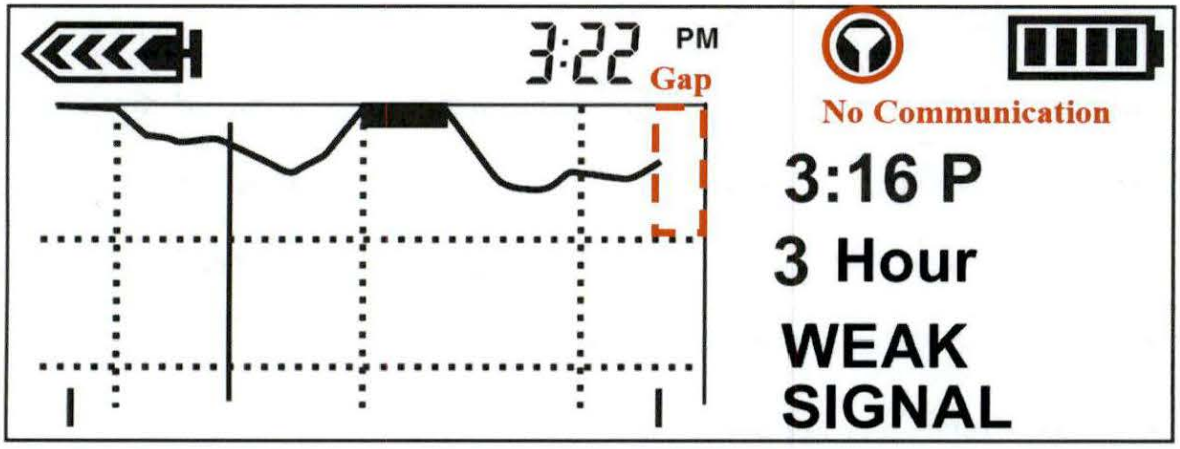
113. Patel-2009 supplements Paradigm® REAL-Time by disclosing that glucose values calculated during failed communication are synchronized from the transceiver to the monitoring device (*e.g.*, infusion pump) when communication is re-established after being lost. (EX1212, [0086].)

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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.

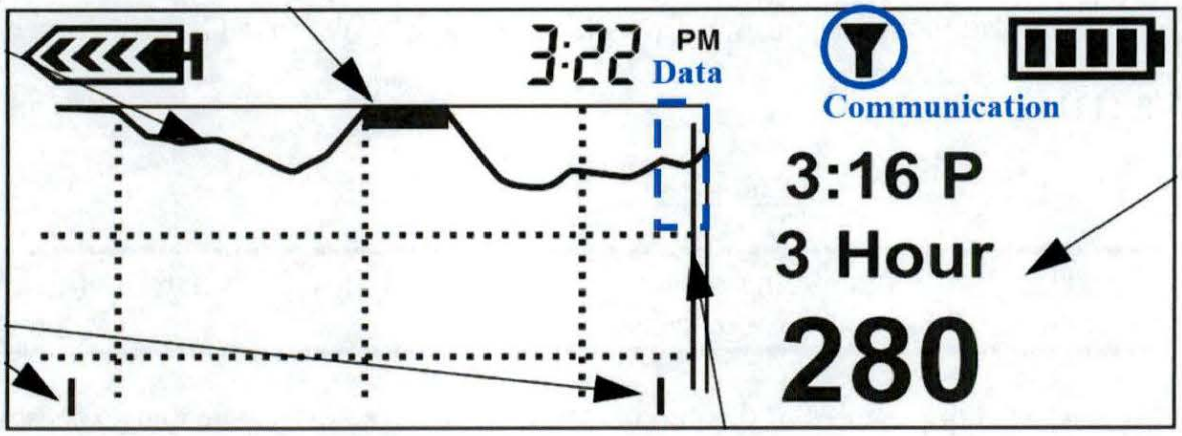
114. Paradigm® REAL-Time illustrates a 3-hour glucose graph with a data gap during "failed reception of sensor data from the transmitter to the pump" while "communication is lost:"



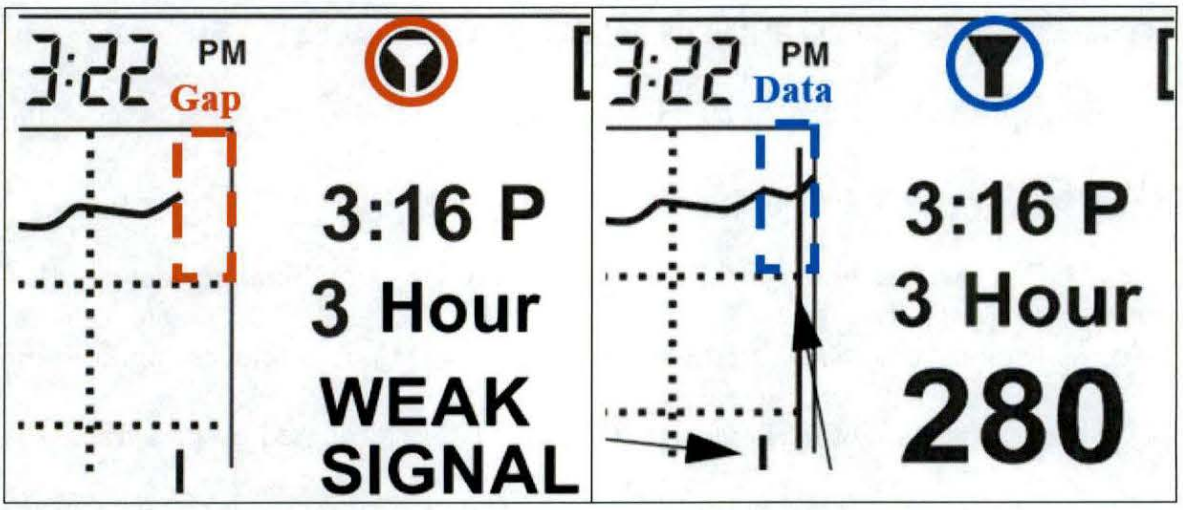
(EX1211, 43, 49, 73 (excerpted and annotated in red); *see* paragraph 109 above.)

115. 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:

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(EX1211, 43, 64 (excerpted and annotated in blue); *see also* paragraph 106 above.) Paradigm® REAL-Time discloses re-populating data gaps with glucose data stored in the transmitter's memory. (EX1211, 8; *see also* paragraph 112 above.) 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 and annotated in blue), 73 (excerpted and annotated in red); *see also* paragraph 60 above (a POSITA would find it obvious to re-populate missing analyte data when it becomes available to fill-in/re-populated data gaps).) This re-

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populated data comprises a line from the beginning to the end of the data gap. (EX1211, 64, 73.)

2. Claim 13

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

116. For purposes of this report, I have been asked to assume that "a sensor misposition error" in claim 13 is satisfied by a signal loss between claim 1's "data processing and transmitter unit" and "receiver unit," *e.g.*, when the receiver unit stops receiving data transmissions from the data processing and transmitter unit. For purposes of this report, I understand that this signal loss might be caused by the relative positions of these two units' transceivers. With this understanding, claim 13 is rendered obvious by the Patel-2009/Paradigm Combination at least for the same reasons explained above as to claim 1 and Elements 1.I-1.L. (*See* paragraphs 108-115 above; *see also* paragraphs 77-80 above.)

117. For example, the Patel-2009/Paradigm Combination detects lost communications that cause "failed reception of continuous glucose monitoring (CGM) data," as taught by Paradigm. (*E.g.*, EX1211, 8 (quoted by paragraph 108 above).) 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* paragraphs 72, 101-103 above) fails to receive data for more than a certain amount

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of time, as taught by Paradigm. (EX1211, 8, 73; *see* paragraphs 76-78, 109 above.) 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. (EX1211, 8; EX1212, [0086] (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* paragraphs 110-111 above.) Then, when transmission is re-established and the receiver unit (*e.g.*, the 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. (EX1211, 8, 43, 49, 64, 71-75, 76; *see also* paragraphs 60, 76, 109, 112, 114-115 above; EX1212, [0086] (Patel-2009 teaching to synchronize the receiver device with glucose values calculated on the sensor/transceiver during once signal has been restored); *see* paragraphs 77-80, 113 above (explaining the Patel-2009/Paradigm Combination).)

118. A 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]; *see also* paragraph 58 above.) 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.) 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."

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

A. Goldsmith (EX1251)

119. U.S. Patent Application Publication No. 2007/0093786 to Goldsmith (EX1251) published on April 26, 2007. Goldsmith is analogous art to the '056 patent, as it describes a system for monitoring and treating blood glucose levels.

120. 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.*, [0050],

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[0009], [0039].) The watch controller device interacts "with one or more devices, such as infusion pumps and analyte monitors." (EX1251, [0085].)

121. Goldsmith's watch controller "interact[s] with one or more devices, such as infusion pumps and analyte monitors" (EX1251, [0085]-[0086]) and displays glucose values 915 and trends 918, as shown in Fig. 9A:

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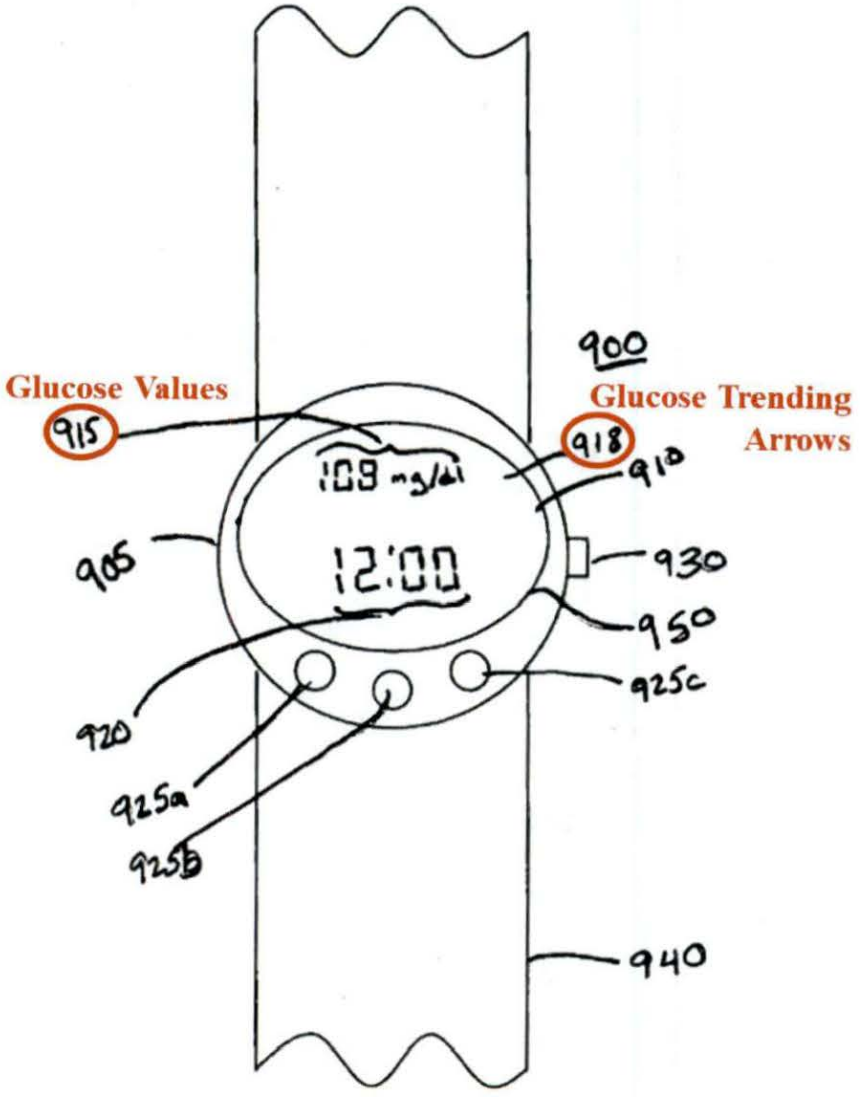


FIG. 9A

(Fig. 9A (annotated in red).)

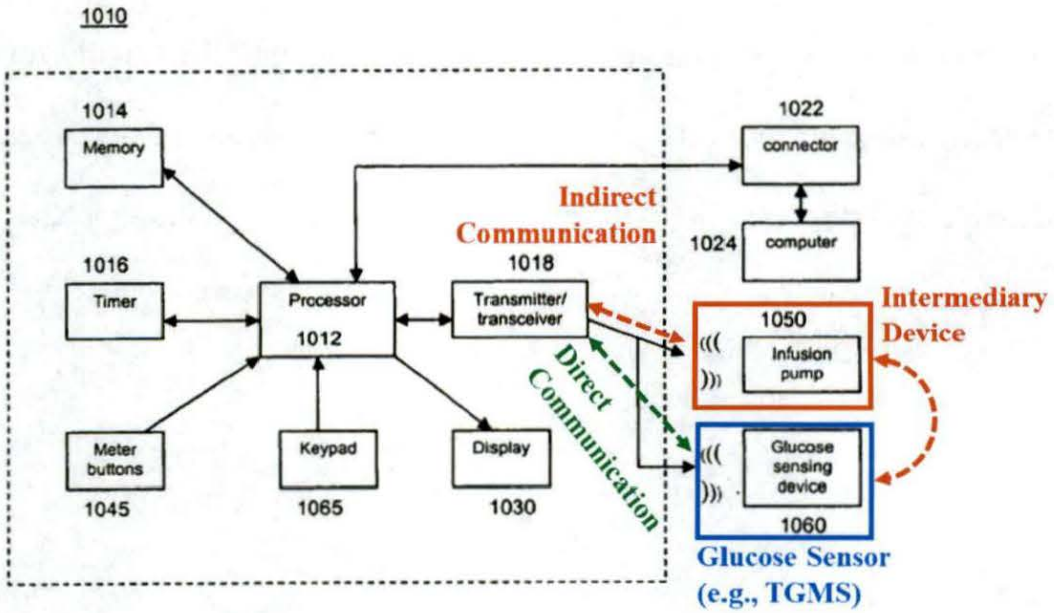
122. Goldsmith teaches that the watch controller device receives sensor data (e.g., glucose values for display on the watch) from a glucose sensor. Goldsmith contemplates at least two different paths of communication between the

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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.").

123. 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



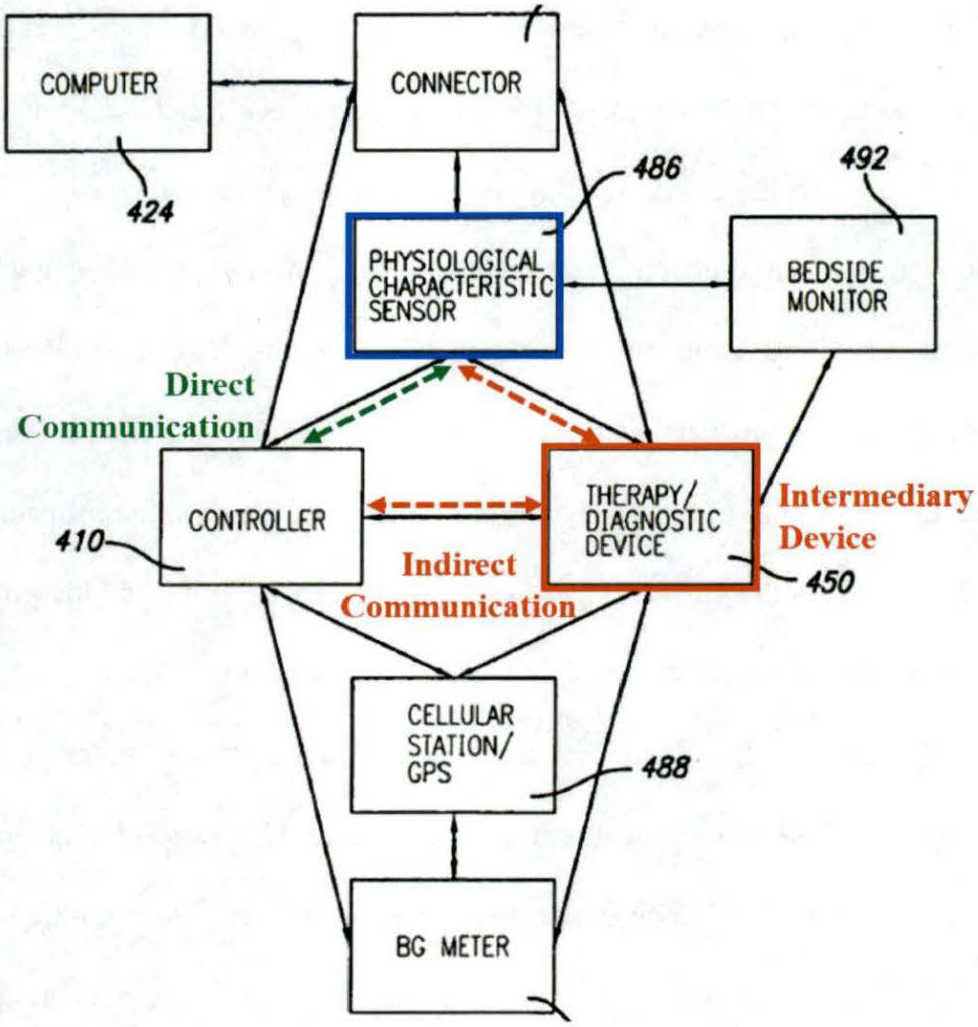
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(EX1251, Fig. 10 (annotated); *see also* EX1251, [0088] ("[T]he transceiver 1018 receives information from an analyte sensing device 1060.")

124. 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].

125. Goldsmith Fig. 7 also illustrates these different communication links, with direct communication from the sensor 486 to the controller 410 illustrated by the green arrow and indirect communication via an intermediary device (e.g., therapy/diagnostic device 450) illustrated by the red arrows in the annotated Fig. 7 reproduced below:

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(EX1251, Fig. 7 (excerpted, annotated in red, blue, and green); *see also id.*, [0006], [0049].) Goldsmith teaches that its 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.").)

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126. 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.").

127. 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."

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

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128. 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. (*See* paragraphs 119-127 above.) This includes both direct communication between the controller and the glucose sensing device and indirect communication via the infusion pump. (*See* paragraphs 122-127 above.)

129. 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* paragraphs 72, 74 above, *see also e.g.*, EX1211, 8, 23-24, 37-38, 51, 53; EX1212, [0040], [0042], [0050], [0056], [0068]-[0069], [0076].)

130. The Patel-2009/Paradigm Combination includes a subcutaneous glucose sensor and glucose sensor transceiver, as taught by Patel-2009. (*See* paragraph 77 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* paragraphs 72, 92, 94 above (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

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infusion pump, computer, PDA, cellular phone, and blood glucose meter—that receive processed, calculated glucose values transmitted from the glucose sensor transceiver. (*See* paragraphs 72, 98, 101 above (citing EX1212, [0008], [0013], [0042], [0076]).)

131. 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.

132. 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):

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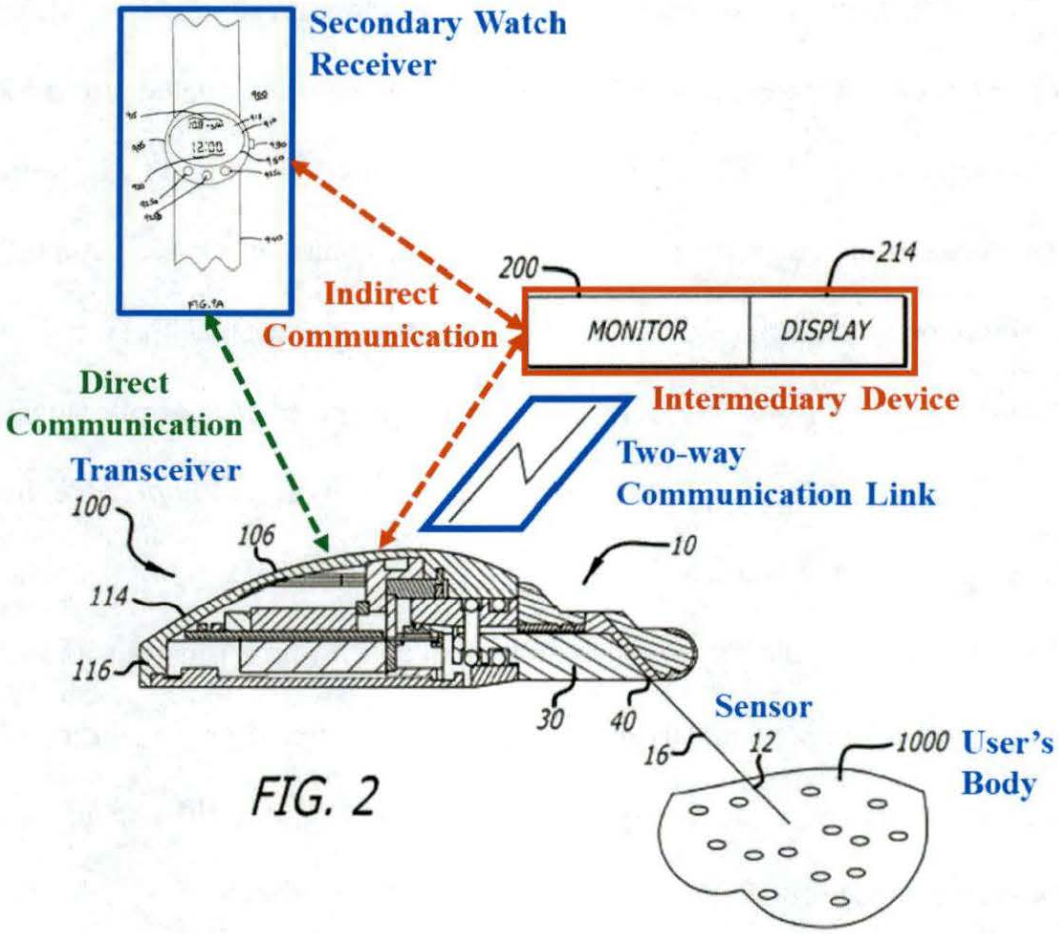


FIG. 2

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

1. Motivation to Combine and Expectation of Success

133. As explained in the following paragraphs, 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].)

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134. 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]-[0076], [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].) 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

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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.

135. 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* paragraphs 55, 81-82 above.) 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.

136. A POSITA would have reasonably expected success in incorporating Goldsmith's watch teachings into the Patel-2009/Paradigm Combination. 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* paragraphs 72, 74, 77-78, 119-127 above.) Based on the progress of development of consumer-grade smart watches (e.g., non-dedicated hardware) 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

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watch controller of Goldsmith, such as Bluetooth-enabled watch model MBW-100 from Sony Ericsson released in 2007[1] and the Fossil Wrist PDA released in 2003[2], thereby further increasing the expectation of success of using the watch controller of Goldsmith in the system of the Patel-2009/Paradigm Combination. 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* paragraphs 72-85, 119-127 above.)

137. 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

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[1] Roche, Jeremy (2007, September 13). *Sony Ericsson Bluetooth Watch MBW-100 review: Sony Ericsson Bluetooth Watch MBW-100.* CNET. https://www.cnet.com/reviews/sony-ericsson-bluetooth-watch-mbw-100-review/

[2] Wikipedia contributors. *Fossil Wrist PDA.* Wikipedia, The Free Encyclopedia. https://en.wikipedia.org/w/index.php?title=Fossil_Wrist_PDA&oldid=1204372783

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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.

C. Ground 2 Claim Mappings

138. It is my opinion that the Patel-2009/Paradigm/Goldsmith Combination renders obvious claim 29. As explained above, the Patel-2009/Paradigm Combination already renders obvious claim 1. (*See* paragraphs 87-115 above.)

1. Claim 29

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

139. 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 paragraph 140 below.

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

140. 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.

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

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141. For purposes of this report, I have been asked to assume that "receive processed sensor data from the data processing and transmitter unit" in claim 29 may be satisfied by (i) direct communication of processed sensor data from the data processing and transmitter unit to the secondary receiver unit or (ii) indirect communication of processed sensor data from the data processing and transmitter unit to the secondary receiver unit via an intermediary device. It is my opinion that claim 29 is rendered obvious regardless of whether it is interpreted to mean that the secondary receiver receives data *directly* from the data processor and transmitter unit, or *indirectly* through an intermediary device, such as an insulin pump, handheld device, or other larger monitor taught by Patel-2009.

142. A 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]-[0014], [0058], [0061].) 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* paragraphs 77, 94 above (citing *e.g.*, EX1212, [0042]).) Processed sensor data is

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communicated from the glucose sensor transceiver to monitoring devices (*e.g.*, monitor, infusion pump, computer, PDA, Cell Phone) as calculated glucose values. (*See* paragraphs 72, 98-103 above (citing *e.g.*, EX1212, [0042], [0076], FIG. 11).) 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].)

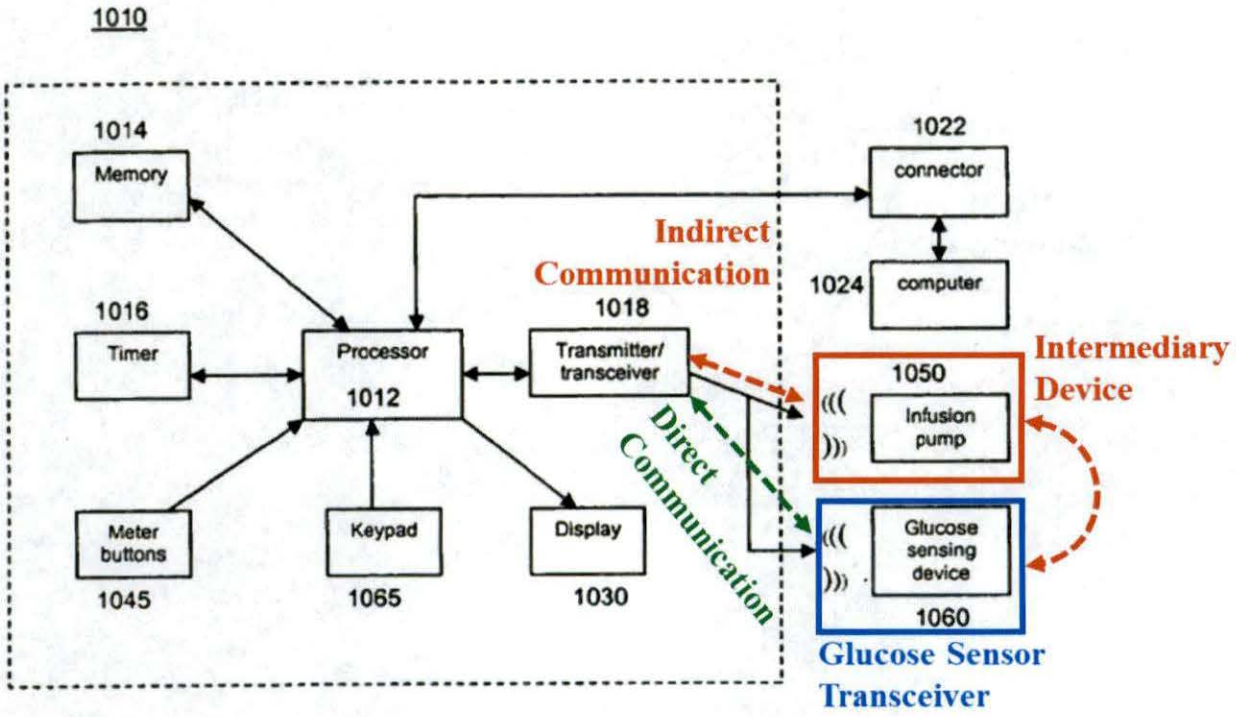
143. Goldsmith teaches both direct and indirect communication between the watch and on-body unit, and thus a POSITA would have found it obvious to implement the watch in this manner within the Patel-2009/Paradigm system. (*See* paragraphs 122-127 above (citing EX1251, [0049], [0058], [0087], FIG. 7).) 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

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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.

144. 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



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(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").) In the context of the Patel-2009/Paradigm Combination, a secondary watch receiver with direct and indirect communication paths would be implemented as:

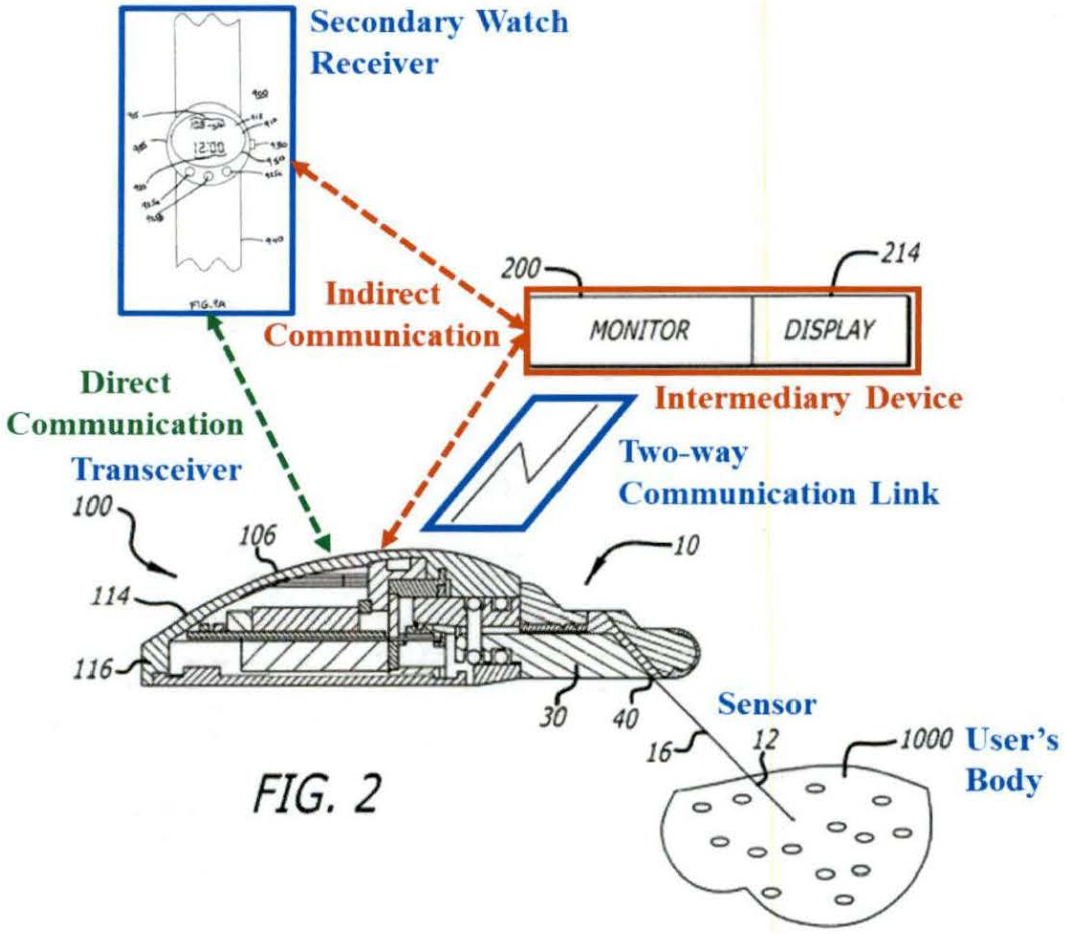


FIG. 2

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

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145. 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].)

146. 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).")

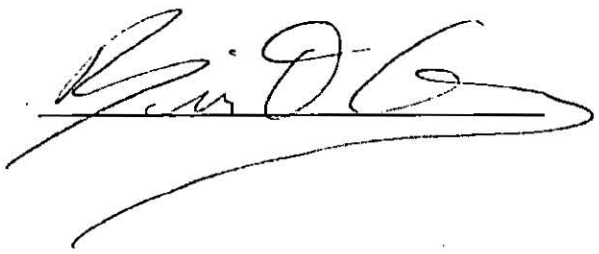
wherein the secondary receiver unit is a watch.

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147. Finally, as implemented in the Patel-2009/Paradigm/Goldsmith system, the watch controller taught by Goldsmith is a watch. (*E.g.*, EX1251, [0010], [0085]-[0091].)

I, Brian Gross, do hereby declare and state, that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: Feb 09, 2024



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