

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Abbott Diabetes Care Inc.,
Petitioner,

v.

DexCom, Inc.,
Patent Owner.

Case No. IPR2024-00840
Patent No. 9,119,528

**DECLARATION OF DAVID RODBARD, M.D. IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,119,528**

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I. INTRODUCTION

1. I, David Rodbard, M.D., declare as follows.

2. I have been retained as a technical consultant on behalf of Abbott Diabetes Care Inc. (“Abbott” or “Petitioner”), who I understand is the petitioner in the present proceeding. I have been asked to consider whether the references listed as Exhibits 1005-1009 below disclose or render obvious the limitations recited in claims 1-3, 5, 11-13, 16-20, 24-26, 28, 34-36, and 39-43 of U.S. Patent No. 9,119,528 (Ex-1001, “’528 patent”). I have also been asked to consider the state of the art and the “prior art,” i.e., references, available before the time of the alleged invention of the ’528 patent. My opinions are provided in this declaration.

3. I am being compensated at my standard consulting rate for my time. My compensation is in no way contingent on the results of these or any other proceedings relating to the ’528 patent.

II. BACKGROUND AND QUALIFICATIONS

4. A description of my professional background and qualifications is provided below. An additional account of my work experience and qualifications is included in my curriculum vitae, which is Ex-1004.

5. In 1960, I received a Bachelor of Science in the Division of Sciences from State University of New York at Buffalo. In 1964, I received a Doctor of Medicine from Case Western Reserve University School of Medicine. From 1964 to 1965, I

performed my internship at King County Harborview Hospital in Seattle, Washington.

From 1965 to 1966, I conducted my residency at Hahnemann Hospital at Drexel University.

6. From 1966 through 1969, I worked as a Clinical Associate for the Endocrinology Branch of National Institute of Child Health and Human Development, NIH. From 1969 through 1971, I was a Senior Staff Fellow for the Endocrinology Branch of the NIH. From 1971 through 1979, I was a Senior Investigator for the Endocrinology and Reproduction Research Branch of the NIH. From 1979 through 1990, I was the Head of the Biophysical Endocrinology Section for the Endocrinology and Reproduction Research Branch of the NICHD, NIH. From 1981 through 1990, I was the Coordinator of the Computers in Clinical Medicine Elective for the Clinical Center of the NIH, and was also the Chief of the Laboratory of Theoretical and Physical Biology, and the Head of the Theoretical Biology Section of the NICHD, NIH. From 1990 through 1996, I was the Director of the Division of Computer Research and Technology (DCRT) of the NIH, subsequently renamed as the Center for Information Technology, NIH. From 1996 through 1998, I was Director and Assistant Vice President at the Information Resources Outreach and Liaison Activities for the Association of American Medical Colleges. From 1999 through 2007, I was the Managing Director and Managing Research Scientist for the American Institutes for Research. Since 2007, I have been the President and Chief Scientific Officer for

Biomedical Informatics Consultants LLC. Since 2018, I have been a Deputy Editor to the journal Diabetes Technology and Therapeutics.

7. At the NIH, from 1982 through 1990, I conducted basic biomedical research in biomathematics, biostatistics, biophysics, biochemistry, and physical chemistry. I developed novel graphical displays such as the Ambulatory Glucose Profile (AGP) for analysis of glucose data obtained using memory-equipped glucose meters. From 1990 through 1996, I directed strategic planning and administration of a program in computational biosciences, including biomathematics, biostatistics, biophysics, image processing, genetics, and genomics. I developed novel methods for display and analysis of quality of glycemic control involving simultaneous consideration of efficacy (HbA1c) and risk of hypoglycemia, and display and analysis of clinical data such as blood glucose values, insulin dosages, food intake, exercise, frequency and severity of episodes of hypoglycemia, and possible factors contributing to or causing those episodes. I introduced the use of several specialized types of graphical displays and the methods of exploratory data analysis for analysis of glucose, insulin, and ancillary data from people with diabetes mellitus.

8. When I was the Director at the Information Resources Management Outreach and Liaison Activities for the Association of American Medical Colleges from 1996 through 1998, I developed a new constituency for AAMC, the Chief

Information Officers, and other senior information technology leaders of the Nation's academic medical centers and hospitals.

9. From 1999 through 2006, I was the Managing Research Scientist and Managing Director for the American Institutes for Research (AIR). I was the Principal Investigator and Project Director for several simultaneous ongoing research projects, including but not limited to, "Design, Development, and Optimization of Human Factors for Software for the Analysis and Interpretation of Self-Monitoring of Blood Glucose by Patients with Diabetes Mellitus," "Design and Development of New Graphical Methods to Assist Pediatricians in the Screening of Children and Adolescents for Hypertension," "Usability Studies of a 'Comprehensive Diabetes Management System,'" "Evaluation of the Human Factors and Usability of Components of an Electronic Medical Record (EMR) System, AHLTA," "Development of Algorithms for a Computer Assisted Decision Support System (CADS) to Assist Primary Care Physicians in the Management of Patients with Type 1 and Type 2 Diabetes Mellitus."

10. Currently, I am the Deputy Editor for the journal Diabetes Technology and Therapeutics. I am also the President and Chief Scientific Officer for the Biomedical Informatics Consultants LLC. I perform consultative services for major pharmaceutical firms, medical device companies, and other organizations regarding

computer applications in diabetes and endocrinology, analysis of continuous glucose monitoring (CGM) data, and clinical decision support systems related to diabetes.

11. I have received several awards including the U.S. Public Health Service Award (USPHS) Commendation Medal in 1984, the Meritorious Service Medal of the NIH in 1993 and 1986, the Sydney H. Ingbar Distinguished Service Award from the Endocrine Society in 1981 (previously designated as the Ayerst Award), the Young Investigator Award in the Clinical Radioassay Society in 1979, and the Chiba Medical Society Award in Japan in 1993.

12. I am a member of the American Diabetes Association, and of the Editorial Board of the journal Diabetes Technology and Therapeutics. I also perform peer reviews for multiple journals regarding diabetes and endocrinology, including Diabetes Care, Diabetes Obesity and Metabolism, and Journal of Diabetes Science and Technology. I was previously a member of the American Medical Informatics Association (AMIA), the American Association for the Advancement of Science, the American Physiological Society, the American Society of Biochemistry and Molecular Biology, the American Statistical Association, the Biometrics Society, The Endocrine Society, Healthcare Information Management and Systems Society (HIMSS), the European Association for the Study of Diabetes (EASD), and the Federation of American Societies of Experimental Biology and Medicine (FASEB). I have also previously served as a member or as an associate member of the Editorial

Boards of the journals Analytical Biochemistry, Journal of Clinical Endocrinology and Metabolism, and the American Journal of Physiology (Endocrinology, Metabolism, and Gastrointestinal Physiology).

13. I have published more than three hundred journal and conference papers covering topics such as diabetes care and management, glycemic control, continuous glucose monitoring, hyper- and hypoglycemia risk monitoring, and related areas, and mathematical and statistical methods for analysis of essential clinical data relevant to people with diabetes.

14. A list of my publications can be found in my curriculum vitae, attached as Appendix A. I am also a named inventor on seven U.S. Patents and Patent Applications, including several related to diabetes care technology. For example, I am a named inventor on U.S. Patent No. 8,758,245 entitled “Systems and methods for pattern recognition in diabetes management.” This patent relates to a diabetes management system that may be used to analyze and recognize patterns for a large number of blood glucose or interstitial fluid glucose concentration measurements and other physiological parameters related to the glycemia of a patient. The system may identify a plurality of pattern types from the data including a hypoglycemic pattern, a hyperglycemic pattern, blood glucose variability patterns, and comparisons of glucose patterns.

III. MATERIALS REVIEWED

15. I am not an attorney and offer no legal opinions, but in my work, I have had experience studying and analyzing patents and patent claims from the perspective of a person skilled in the art. See Section VI.C below for the level of ordinary skill in the art for this declaration.

16. In preparing this declaration, I reviewed the '528 patent, including the claims of the patent in view of the specification, and I have reviewed the prosecution history of the '528 patent and numerous publications and technical references from and preceding the time of the alleged invention. More specifically, I have reviewed each of the following:

Exhibit	Description
1001	U.S. Patent No. 9,119,528 (the "'528 patent")
1002	File History for U.S. Patent No. 9,119,528
1005	U.S. Patent Application Publication No. 2007/0208244 ("Brauker")
1006	Stefania Guerra et al., <i>A Dynamic Risk Measure from Continuous Glucose Monitoring Data</i> , Diabetes Technology & Therapeutics, 13(8), 843-852 (Aug. 2011) ("Guerra")
1007	Colleen S. Hughes et al., <i>Hypoglycemia Prevention via Pump Attenuation and Red-Yellow-Green "Traffic" Lights Using Continuous Glucose Monitoring and Insulin Pump Data</i> , Journal of Diabetes Science and Technology, 4(5), 1146-1155 (Sept. 2010) ("Hughes")
1008	DexCom TM STS TM Continuous Glucose Monitoring System User's Guide ("STS Guide")
1009	U.S. Patent No. 6,565,509 ("Say")
1010	FreeStyle Navigator Continuous Glucose Monitoring System User's Guide ("Navigator Guide")
1011	Giovanni Sparacino, et al., <i>Glucose Concentration Can Be Predicted Ahead in Time from Continuous Glucose Monitoring Sensor Time-</i>

Exhibit	Description
	<i>Series</i> , IEEE Transactions on Biomedical Engineering, 54(5), 931-937 (May 2007) (“Sparacino”)
1012	U.S. Patent No. 10,702,215 (“215 patent”)
1013	Paul G. Hayter et al., <i>Performance Standards for Continuous Glucose Monitors</i> , Diabetes Technology & Therapeutics, 7(5), 721-726 (2005) (“Hayter”)
1014	Andrea Facchinetti et al., <i>A New Index to Optimally Design and Compare Continuous Glucose Monitoring Glucose Prediction Algorithms</i> , Diabetes Technology & Therapeutics, 13(2), 111-119 (2011) (“Facchinetti”)
1015	Aaron J. Kowalski, <i>Can We Really Close the Loop and How Soon? Accelerating the Availability of an Artificial Pancreas: A Roadmap to Better Diabetes Outcomes</i> , Diabetes Technology & Therapeutics, 11(1), S-113-S-119 (Sept. 2009) (“Kowalski”)
1016	U.S. Patent No. 5,973,613
1017	Premarket Approval (PMA) Order, FreeStyle Navigator Continuous Glucose Monitoring System (Mar. 12, 2008), https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050020A.pdf
1018	Garry M. Steil et al., <i>Feasibility of Automating Insulin Delivery for the Treatment of Type 1 Diabetes</i> , Diabetes, 55, 3344-3350 (Dec. 2006)
1019	JPMorgan, North America Equity Research, Diabetes Care ADA 2006: Spotlight On Continuous Glucose Monitoring (June 11, 2006)
1020	Bruce Buckingham et al., <i>Prevention of Nocturnal Hypoglycemia Using Predictive Alarm Algorithms and Insulin Pump Suspension</i> , Diabetes Care, 33(5), 1013-1017 (May 2010)
1021	Eyal Dassau et al., <i>Real-Time Hypoglycemia Prediction Suite Using Continuous Glucose Monitoring</i> , Diabetes Care, 33(6), 1249-1254 (June 2010)
1022	Boris P. Kovatchev et al., <i>Symmetrization of the Blood Glucose Measurement Scale and Its Applications</i> , Diabetes Care, 20(11), 1655-1658 (Nov. 1997)
1023	David C. Klonoff et al., <i>Innovations in Technology for the Treatment of Diabetes: Clinical Development of the Artificial Pancreas (as Autonomous System)</i> , Journal of Diabetes Science and Technology, 5(3), 804-826 (May 2011)
1024	U.S. Patent No. 8,160,669

Exhibit	Description
1025	B. Wayne Bequette, <i>Continuous Glucose Monitoring: Real-Time Algorithms for Calibration, Filtering, and Alarms</i> , Journal of Diabetes Science and Technology, 4(2), 404-418 (Mar. 2010)
1026	Cesar C. Palerm et al., <i>Hypoglycemia Prediction and Detection Using Optimal Estimation</i> , Diabetes Technology & Therapeutics, 7(1), 3-14 (2005)
1027	Declaration of Sylvia D. Hall-Ellis, Ph.D.
1031	Stuart A. Weinzimer et al., <i>Fully Automated Closed-Loop Insulin Delivery Versus Semiautomated Hybrid Control in Pediatric Patients With Type 1 Diabetes Using an Artificial Pancreas</i> , Diabetes Care, 31(5), 934-939 (May 2008)
1032	Helen R. Murphy et al., <i>Closed-Loop Insulin Delivery During Pregnancy Complicated by Type 1 Diabetes</i> , Diabetes Care, 34, 406-411 (Feb. 2011)

IV. RELEVANT LEGAL STANDARDS

17. 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 forming my opinions. I have applied the following understanding of the law:

18. I have been informed that a patent claim may be “anticipated” if each element of that claim is present either explicitly or inherently in a single prior art reference, and that the elements should be arranged in the reference as in the claim. Petitioner’s counsel has informed me that for a claimed limitation to be inherently present, the prior art need not expressly disclose the limitation, so long as the claimed limitation necessarily flows from a disclosure in the prior art.

19. I have been informed that a patent claim can be considered to have been obvious to a person of ordinary skill in the art at the time the application was filed. This means that, even if all of the requirements of a claim are not found in a single prior art reference, the claim is not patentable if the differences between the subject matter in the prior art and the subject matter in the claim would have been obvious to a person of ordinary skill in the art at the time the application was filed.

20. I have been informed that a determination of whether a claim would have been obvious should be based upon several factors, including, among others:

- the level of ordinary skill in the art at the time the application was filed;
- the scope and content of the prior art; and
- what differences, if any, existed between the claimed invention and the prior art.

21. I have been informed that a single reference can render a patent claim obvious if any differences between that reference and the claims would have been obvious to a person of ordinary skill in the art. Alternatively, the teachings of two or more references may be combined in the same way as disclosed in the claims, if such a combination would have been obvious to one having ordinary skill in the art. In determining whether a combination based on either a single reference or multiple references would have been obvious, it is appropriate to consider, among other factors:

- whether the teachings of the prior art references disclose known concepts combined in familiar ways, and when combined, would yield predictable results;
- whether a person of ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;
- whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by those skilled in the art;
- whether a person of ordinary skill would have recognized a reason to combine known elements in the manner described in the claim;
- whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and
- whether the innovation applies a known technique that had been used to improve a similar device or method in a similar way.

22. Petitioner’s counsel has informed me that one of ordinary skill in the art has ordinary creativity and is not an automaton. Petitioner’s counsel has informed me that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered.

23. I understand that various objective or “real world” factors may be indicative of non-obviousness. I understand that such factors include:

- the commercial success of the claimed invention;
- the existence of a long-felt, unresolved need for a solution to the problem solved by the claimed invention;
- failed attempts to solve the problem solved by the claimed invention;
- copying of the claimed invention;
- unexpected results of the claimed invention;
- praise for the claimed invention by others in the relevant field; and
- willingness of others to accept a license under the patent because of the merits of the claimed invention.

V. TECHNOLOGY BACKGROUND

A. Diabetes and the Clinical Risk with Low Glucose Values

24. One of the major risks threatening people with diabetes (Type 1 or Type 2, and other forms of diabetes) is the risk of experiencing a hypoglycemic (low blood sugar) episode. When glucose levels in the blood, bodily tissues and brain reach low levels, for whatever reason, people may experience a number of symptoms (hunger, nervousness, sweating, dizziness, confusion, among others), and this may progress in extreme cases to coma, seizures, heart palpitations, cardiac arrhythmias (rhythm anomalies), and even death. It may also result in falls, motor vehicle accidents, injuries to those operating machinery, and risks to other people in the environment. Accordingly, hypoglycemia is one of the most feared complications of diabetes. This

can occur in people whether they are taking insulin or medications that may stimulate secretion of insulin. Usually, hypoglycemia and impending hypoglycemia can be treated quickly and easily by the patient himself/herself, e.g., by consuming some sugar (glucose or sucrose) in small quantities (usually 15 grams), with repeated consumption if needed.

25. Repeated exposure to hypoglycemia can result in adverse consequences, with loss of ability to respond to hypoglycemia based on the autonomic nervous system: there may be attenuated or absent responses to the “counter-regulatory hormones” such as adrenalin (epinephrine), cortisol, growth hormone, or glucagon.

B. “Finger Stick Method” to Measure Capillary Blood Glucose (CBG) Using Blood Glucose Monitors (BGM), and Its Limitations

26. Prior to mid-1980s, the only way to measure glucose was by sending a blood sample to the hospital or clinical laboratory. People could get an estimate of glucose if the glucose was very high by measurement of levels of glucose that were literally overflowing into the urine. There was no corresponding way to measure blood glucose when the glucose levels were low. In the 1980s, blood glucose meters became available. A drop of blood was placed on specially treated paper pads, usually blotted and washed, and then entered into a glucose meter using a “reflectometer.” This provided a reasonably accurate, affordable, and available method for people to measure glucose levels in their body. Unfortunately, this required doing a “finger

stick”—using a sharp metal lancet to prick the finger and then having to squeeze out a drop of blood. These meters usually required use of calibration or spot checking with reference materials containing known glucose concentrations, and was time consuming and physically painful due to the need to draw blood from the very sensitive fingertips or rarely from other sites. The quality of these “blood glucose meters” was initially very poor with large errors but has steadily improved over the years, so that less blood was needed, the procedures were simplified (no blotting or washing of the test-strips), faster time to display the result, less interference from substances other than glucose, and better accuracy. In the mid-1980s, some blood glucose meters were equipped with electronic memories that could store up to 500 glucose test results (with date and time and possibly other data (relationships to meals, exercise, amount of insulin injected, etc.)). This relieved the individual person with diabetes of the need to transcribe the values into a computer to generate analyses of the glucose (and other) data.

27. The biggest drawback with blood glucose monitors (BGMs) was the fact that most people usually checked their blood glucose only a few times of day, and perhaps not on every day, because of cost, inconvenience, pain (and bleeding) at the site of the “finger prick” or “finger stick”. If someone was testing 2–4 times daily they were doing well. However, to really understand glucose patterns, it is necessary to test at least 8 times daily: before and after meals, at bedtime, and overnight, e.g. at 4 AM.

This is a major inconvenience—especially the values from overnight (to check whether a person is experiencing a “nocturnal hypoglycemic event,” which might need to be treated by a snack, some rapid acting carbohydrate such as orange juice, glucagon, or might require EMTs and an Emergency Room visit or hospital admission). It might also then require changing the insulin dosage and timing (or doses and timing of other medications) and or times of meals and quantity and quality of foods consumed. Hypoglycemic events can occur at any time of day, not just before meals, or if there has been a delayed meal. This is especially true when a person engages in physical activity, especially “aerobic activity” such as running, tennis, soccer, swimming, etc. It may also occur during or after high intensity interval training such as weight lifting. The presence of gaps in obtaining glucose measurements, e.g., between meals, or following meals, or overnight, makes it possible and even likely that one may fail to detect hypoglycemia when it is occurring. Patterns of hypoglycemia by time of day may be very erratic, especially if a person engages in a variety of activities, changes the timing of meals, has variability in types or amounts of foods, or experiences anorexia, nausea, vomiting, or delayed absorption of food from the stomach and gastrointestinal tract.

28. Because of these serious limitations for monitoring glucose by blood glucose monitors (BGMs), there was a well-recognized need for development of a *continuous* glucose monitor that could continuously measure blood glucose levels, or

blood glucose levels in terms of a proxy such as the glucose levels in the tissue fluids in the body—in the extracellular fluid that surrounds the cells and tissues of the body, which is close to but not exactly the same as the blood glucose.

C. Continuous Glucose Monitoring (CGM) Systems

29. Since the late 1990's, many groups of scientists worldwide worked on development of continuous glucose monitoring (CGM) systems using a glucose sensor that was based on electrochemical methods—with a “needle” placed under the skin and allowed to remain there to measure glucose on a continuous or nearly continuous basis. There were several goals for developing CGM systems:

- a. The ability to alert a person if it appears that the glucose level has reached or will reach an unacceptable or unphysiological level (high or low) that may be deleterious to health;
- b. The ability to control or regulate the administration of fluids or substances that can modulate glucose levels in the body (blood or bloodstream, interstitial fluids), as in CGM-based closed-loop artificial pancreas (autonomous systems) for automated insulin delivery (AID); and
- c. Providing data, advice, education, and instructions to users, their family care-givers, physicians, or other health care providers.

30. Among the groups that developed CGM systems were Abbott and DexCom. For example, one of Abbott's CGM systems is described in the Navigator

Guide (Ex-1010). *See* Section VII.F below. One of DexCom's CGM systems is described in the STS Guide (Ex-1008). *See* Section VII.D below.

31. These CGM systems had the ability to alert a person if it appeared that the glucose level reached an unacceptable or unphysiological level (high or low) that may be deleterious to health. *See, e.g.*, Ex-1008 (STS Guide), 54; Ex-1010 (Navigator Guide), 68.

32. Some CGM systems also had the ability to alert a person if it appeared that the glucose level would reach an unacceptable or unphysiological level (high or low) that may be deleterious to health within a specified period of time. *See, e.g.*, Ex-1010 (Navigator Guide), 68; Ex-1005 (Brauker), Fig. 41. Such predicted or projected glucose alerts and alarms were well known. There was considerable activity from many medical and biomedical engineering researchers, and others, to identify new and improved methods to make predictions of glucose at times in the future. Researchers developed and examined a wide variety of methods, including the following examples: Linear regression, quadratic regression, Kalman filtering, a hybrid infinite impulse response filter, statistical prediction, artificial neural networks, autoregression, and a numerical logical algorithm, among others. *See, e.g.*, Ex-1025 (Bequette); Ex-1026 (Palerm). Buckingham (Ex-1020) and Dassau (Ex-1021) are clinical research studies evaluating five of these methods, and combinations of two or three of these methods,

in terms of their ability to predict hypoglycemia in patients with type 1 diabetes when glucose was lowered in a controlled manner.

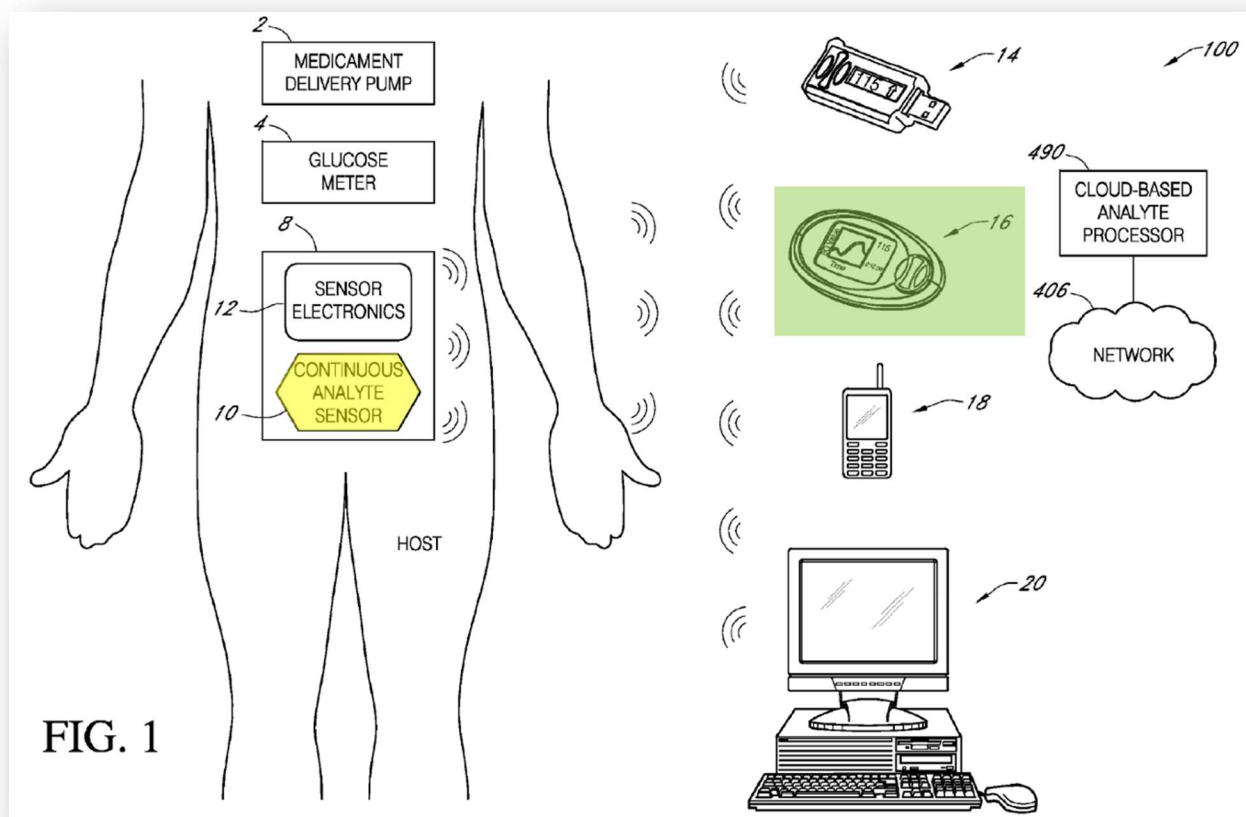
33. It was also well known to use CGM systems to automate control of insulin delivery. For example, Klonoff et al. (Ex-1023) reflects discussions at a November 10, 2010 meeting sponsored by the Food and Drug Administration (FDA) and National Institutes of Health (NIH), that convened researchers from industry, academia, regulatory agencies, and from public and private funding organizations, regarding CGM-based closed-loop artificial pancreas (autonomous systems) for automated insulin delivery (AID) for people with diabetes. Similarly, Kowalski, serving as director of the Juvenile Diabetes Research Foundation (JDRF) Artificial Pancreas Program, discussed multiple goals for a closed-loop artificial pancreas systems to control insulin delivery. Ex-1015, S-115 (“1. Very-low glucose insulin pump shut off”), S-116 (“2. Predictive hypoglycemia minimizing system”), S-116 (“3. Predictive hypoglycemia and hyperglycemia minimizing system”), S-117 (“4. Overnight control: hybrid closed-loop”), S-117 (“5 and 6. Fully closed-loop and multi-hormone systems”). Several of these and related closed-loop systems were being implemented and clinically evaluated during the period 2006-2011, with clinical studies conducted in challenging cases including adults (Ex-1018), pediatrics and adolescents (Ex-1031), and pregnancy (Ex-1032) with type 1 diabetes.

VI. OVERVIEW OF U.S. PATENT NO. 9,119,528

A. Summary

34. The '528 patent is a parent of U.S. Patent No. 10,702,215 (“’215 patent”), for which the Board previously found all but two of the challenged claims unpatentable in IPR2022-00909, Paper 38 at 70-71 (P.T.A.B. Nov. 1, 2023).

35. The '528 patent relates to continuous glucose monitoring (CGM) systems. Ex-1001, 1:14-15. The patent explains that a conventional CGM system “typically includes a sensor that is placed” in a user’s body. *Id.*, 1:48-52. “The sensor measures the concentration of a given analyte within the body, and generates a signal that is transmitted to electronics associated with the sensor.” *Id.*, 1:52-54. Figure 1 depicts an example CGM system.



Ex-1001, Fig. 1 (annotated); *id.*, 9:62-63. The CGM system shown above includes a continuous analyte sensor 10 (yellow) and display device 16 (green), which is a handheld receiver. *Id.*, 9:63-65, 10:4-6, 16:9-13.

36. The patent admits conventional CGM systems had real time, as well as predicted, low glucose alarms. Ex-1001, 29:65-67; *id.*, 1:55-58. The patent states “it is desirable for these alarms to be accurate,” *id.*, 1:58-62, and purports to address this issue by combining (1) a real time, user settable low glucose alert with (2) a predicted, non user settable low glucose alert, “where an alert will sound for whichever condition is met first (threshold or prediction)” in a CGM system, *id.*, 21:50-53.

B. Prosecution History

37. The '528 patent was filed on January 16, 2013, claiming priority to U.S. Provisional Application No. 61/720,286, which was filed October 30, 2012. All pending claims, except dependent claims 9 and 28, were rejected in an October 2, 2014 Office Action as being anticipated by U.S. Application No. 2011/0193704 (Harper et al.), or rendered obvious by Harper in view of U.S. Application Nos. 2011/0225112 (Cameron et al.), 2011/01016011 (Cinar et al.), or 2011/0184267 (Duke et al.). Ex-1002, 1252-1268.

38. In response, on January 2, 2015, DexCom amended the claims to recite that the one or more first criteria are “user settable” while the one or more second criteria are “non user settable.” *Id.*, 1298-1310.

39. In a January 28, 2015 Office Action, the examiner made a new § 103(a) rejection over Harper in view of U.S. Application No. 2005/0177035 (Botvinick). *Id.*, 1342-1371.

40. In response, on April 23, 2015, DexCom argued that prior art references Harper and Botvinick “neither disclose[] nor suggest[] an evaluation of whether a predicted glucose value meets one or more non user settable criteria.” *Id.*, 1385, 1397.

41. The examiner issued a Notice of Allowance on May 4, 2015. *Id.*, 1409-1415.

C. Level of Ordinary Skill in the Art

42. It is my understanding that factors defining the level of ordinary skill in the art include: (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of technology; and (5) the educational level of active workers in the field.

43. A person of ordinary skill in the art (“POSITA”) as of October 2012 would have had a Bachelor’s degree in biomedical engineering, mathematics, statistics, or computer science (or a related or equivalent field), and two or more years of experience researching, developing, designing and/or evaluating (or supervising the same) medical devices for measuring analyte levels, e.g., analyte sensors, including at least some experience in researching, developing, designing and/or evaluating (or supervising the same) methods, systems, or algorithms for providing indicators (e.g., alerts, alarms or other indicators) of analyte levels to users, or equivalent experience. A person with less or different education but more relevant practical experience, or vice versa, may also meet this standard. Each of these POSITAs may be part of an interdisciplinary team with others having the relevant experience set forth above and/or with clinicians involved in diagnosing, treatment and patient management relevant to the use of medical devices for measuring analyte levels, e.g., analyte sensors.

44. I applied this definition of a POSITA in forming my opinion in this declaration.

D. Claim Construction

45. I understand that in this proceeding, the claims should be construed in accordance with their ordinary and customary meaning in light of the specification, as understood by one of ordinary skill in the art.

46. For purposes of my opinions, I have been asked to assume that each claim term should be given its plain and ordinary meaning in light of the specification, and I have therefore applied those plain and ordinary meanings in my analysis.

VII. OVERVIEW OF THE PRIOR ART¹

A. Brauker (Ex-1005)

47. Brauker was published on September 6, 2007, and I understand it is prior art. Despite DexCom being the initial assignee of the Brauker patent application, Brauker was not of record during prosecution of the '528 patent.

48. Brauker discloses a CGM system with a sensor and a receiver. Ex-1005, [0005]. Figure 15 depicts sensor 10 communicating with receiver 158 via transmitter 16:

¹ All of the prior art references are from the same field of endeavor as the claimed invention.

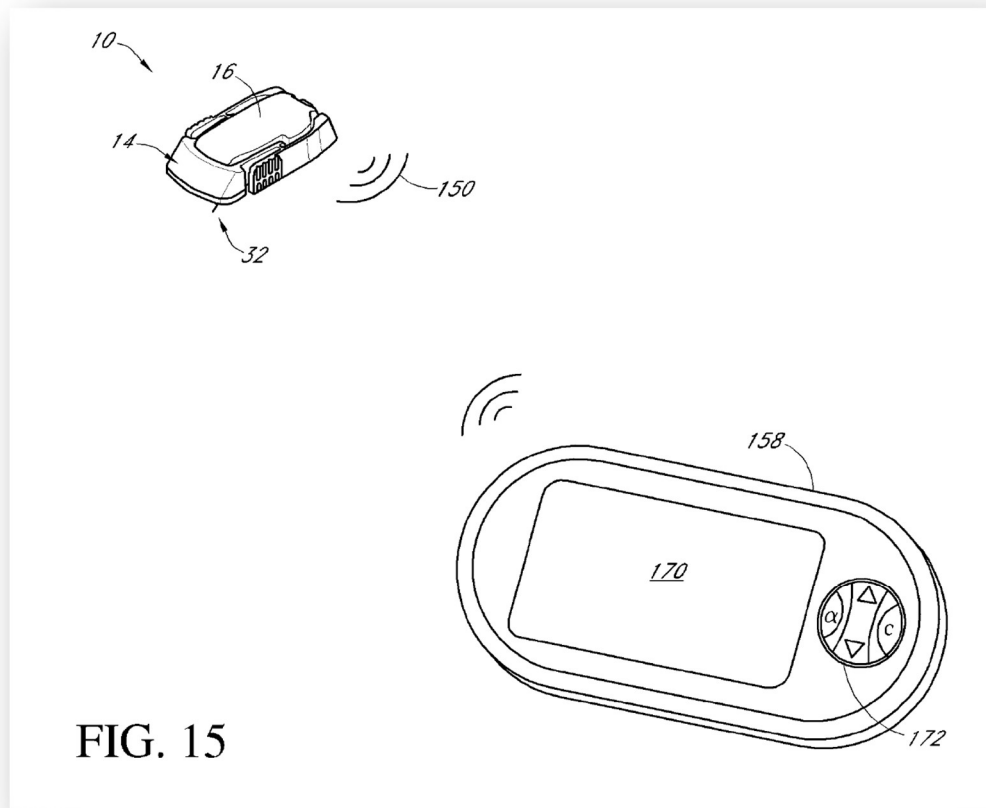


FIG. 15

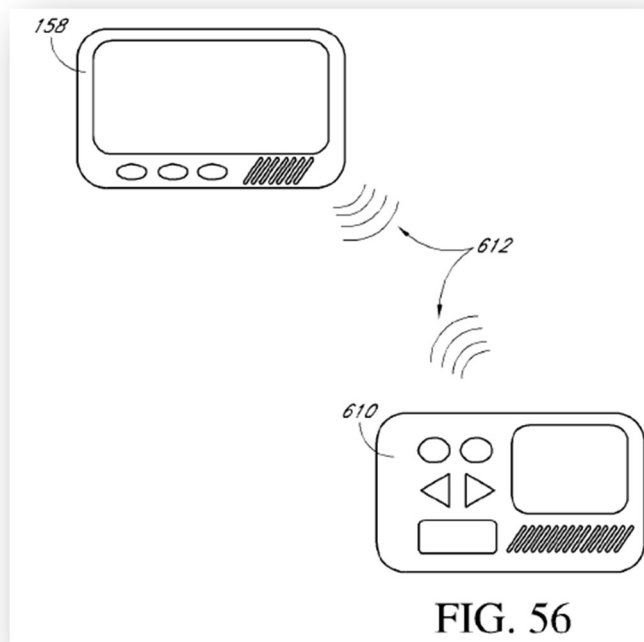
Ex-1005, Fig. 15.

49. In the Summary of the Invention, Brauker describes an “embodiment of the first aspect” that includes both (1) a real time, user settable low glucose alarm, and (2) a predicted, non user settable low glucose alarm. First, the system “comprises an alarm configured to provide at least one of a visual signal, an audible signal, and a tactile signal *when the calibrated signal is below the lower glucose threshold.*” Ex-1005, [0011] (emphasis added). As Brauker explains, “the receiver comprises programming configured to permit a user to set the upper glucose threshold and *the lower glucose threshold,*” meaning the lower glucose threshold is user settable. *Id.*,

[0010] (emphasis added). Second, Brauker teaches that “the receiver comprises programming configured to estimate glucose data for a future time” and that “the system *further comprises* an alarm configured to provide at least one of a visual signal, an audible signal, and a tactile signal *when the estimated glucose data for the future time is below a predetermined threshold.*” *Id.*, [0013]-[0015] (emphasis added). This is a predicted alarm because it is triggered based on “estimated glucose data for the future time.” *Id.*, [0015]. Further, unlike the user settable “lower glucose threshold,” the “predetermined threshold” (i.e., threshold pre-programmed at the factory) is not limited to being user settable.

50. Along with alarms, Brauker discloses providing therapy recommendations such as “consume carbohydrates” or “inject insulin.” Ex-1005, [0719]. Brauker further discloses customizing therapy recommendations depending on the “severity of medical condition.” *Id.*

51. Brauker further discloses an insulin pump 610 that receives therapy recommendations from a receiver 158 via wireless transmission 612:



Ex-1005, Fig. 56; *see also id.*, [0737]. Brauker discloses that the therapy recommendations include “amount and time of insulin administration.” *Id.*, [0737].

B. Guerra (Ex-1006)

52. Guerra was published in Volume 13, Number 8 of the journal *Diabetes Technology & Therapeutics*, in an issue dated August 2011. Ex-1006. Guerra was publicly accessible at least by July 27, 2011. Ex-1027 ¶ 75. I understand it is thus prior art. Guerra was cited in an Information Disclosure Statement (IDS) along with over 180 other references, but not relied upon by the examiner during prosecution of the ’528 patent.

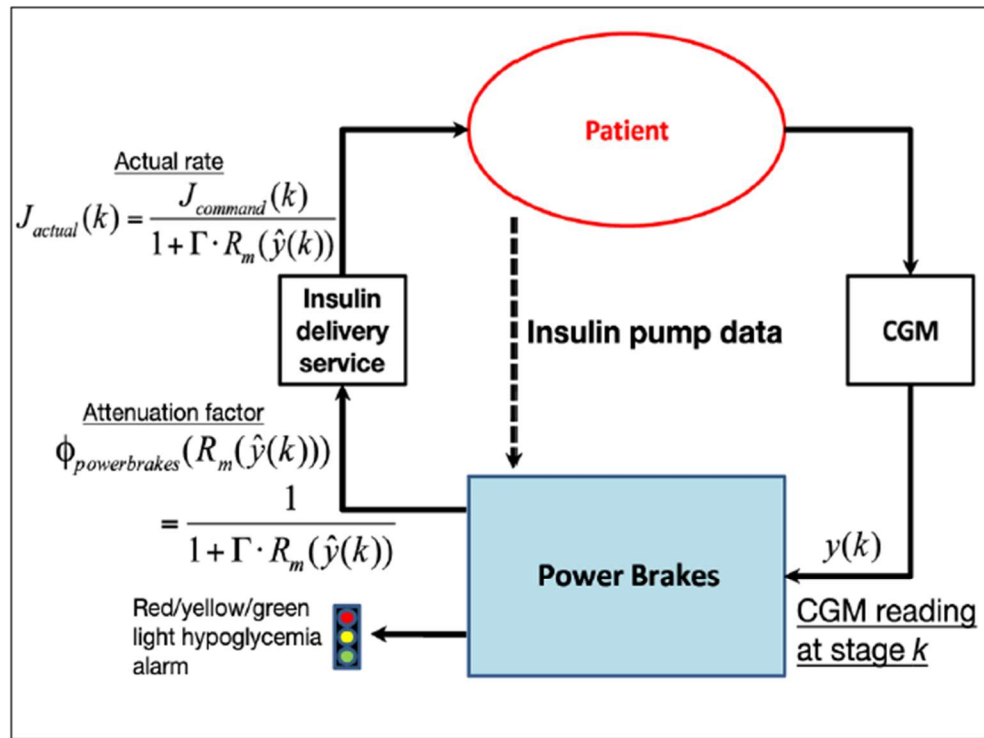
53. Guerra teaches improving the method of measuring risk of low glucose for generation of alarms in CGM systems. Ex-1006, 843. In particular, Guerra

discloses evaluating a *dynamic risk* that considers *the rate of change* of glucose as a threat factor. *Id.* (“A new *dynamic risk (DR)* is proposed to explicitly consider the *rate of change of glucose as a threat factor* for the patient.”) (emphasis added).

C. Hughes (Ex-1007)

54. Hughes was published in Volume 4, Issue 5 of the *Journal of Diabetes Science and Technology*, in an issue dated September 2010. It was publicly accessible at least by September 1, 2010. Ex-1027 ¶ 75. I understand it is prior art. Hughes was not of record during prosecution of the ’528 patent.

55. Hughes discloses a CGM system coupled with an insulin delivery device. Figure 3 depicts an example system from Hughes.



Ex-1007, Fig. 3. Hughes discloses evaluating a risk of hypoglycemia using a dynamic risk function R_m of a predicted glucose value $\hat{y}(k)$.² *Id.*, 1150-51. Hughes further discloses controlling insulin delivery, as well as providing red-yellow-green light alerts based on a dynamic risk function. *Id.*, 1150-51; *see also id.*, 1147 (“In addition, these algorithms are designed to provide a signal to the user indicating one of three possible ‘levels’ of hypoglycemic risk consistent with the formal risk assessment. This signal

² k denotes an index that enumerates successive points in time such that y or $\hat{y}$ represents glucose as a function of time in discrete steps. $y(k)$ represents individual glucose values; $\hat{y}(k)$ represents predicted values of glucose at future time points.

is given in the form of a traffic light: green light indicates no risk of hypoglycemia, yellow light indicates that a risk of hypoglycemia is present, and red light indicates imminent hypoglycemia, either initiating automated rescue action from the controller in a closed-loop setting or suggesting the need for rescue action to the user in an advisory mode.”).

D. STS Guide (Ex-1008)

56. DexCom’s STS Guide was published online and accessible to the public through its website at least as early as October 23, 2007. Ex-1027 ¶ 75. I understand it is thus prior art. The Board previously found that STS Guide was prior art to the ’215 patent (a continuation of the ’528 patent). IPR2022-00909, Paper 38 at 39-41 (P.T.A.B. Nov. 1, 2023).

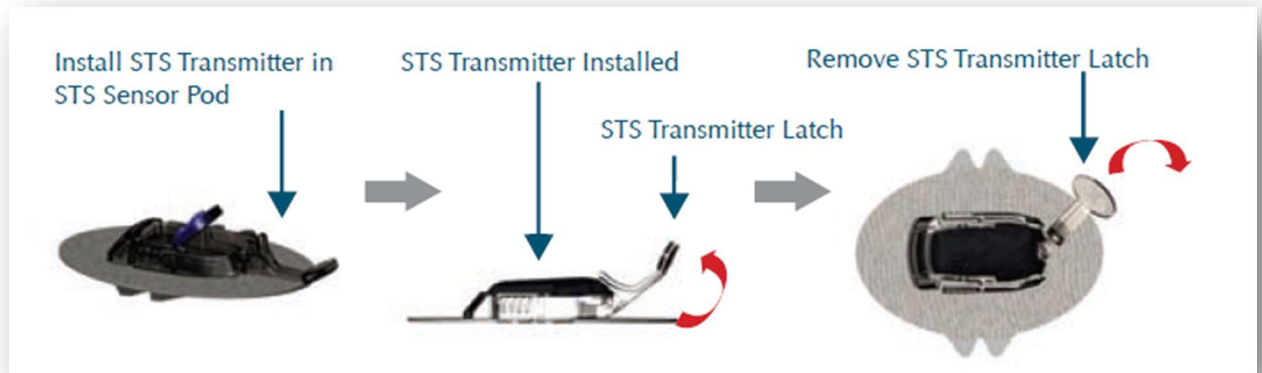
57. DexCom published the STS Guide (Ex-1008), but failed to make the STS Guide of record during prosecution. It is the same “User’s Guide” based on which the Board found unpatentable all but two of the challenged claims of the ’215 patent. IPR2022-00909, Paper 38 at 70-71 (P.T.A.B. Nov. 1, 2023).

58. STS Guide describes a CGM system with a sensor, a transmitter, and a receiver. Ex-1008, 9. The sensor is inserted through the skin of a host’s abdomen to continuously monitor glucose levels for up to 3 days. *Id.*, 10.



Ex-1008, 17.

59. The transmitter is installed on the sensor and wirelessly sends glucose information measured by the sensor to the receiver every 5 minutes:

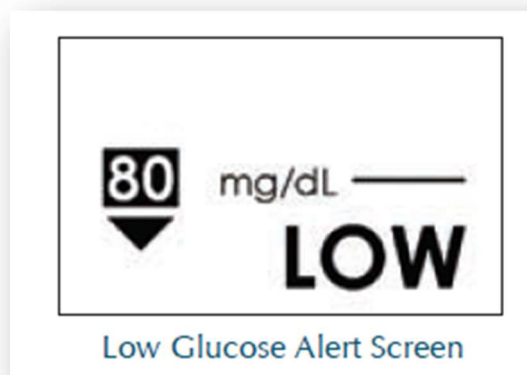


Ex-1008, 18.

60. The receiver displays the received glucose values:

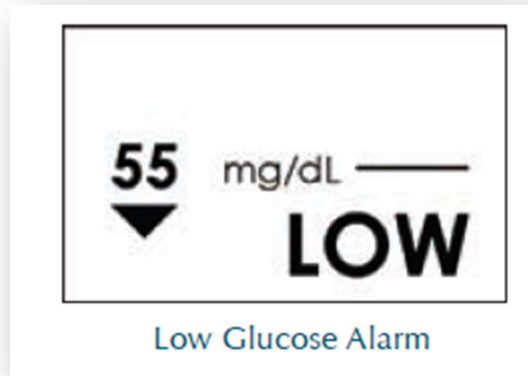


Ex-1008, 20 (annotated). Using the receiver, the user can set a low glucose *alert*. *Id.*, 54. If the glucose value falls below the low glucose threshold, the receiver will vibrate and display the Low Glucose *Alert* Screen:



Ex-1008, 54. The STS Guide also describes a mandatory low glucose *alarm* that the

user cannot change or turn off. *Id.*, 56. If the glucose value falls below 55 mg/dL, the receiver will vibrate and display the Low Glucose **Alarm** Screen:



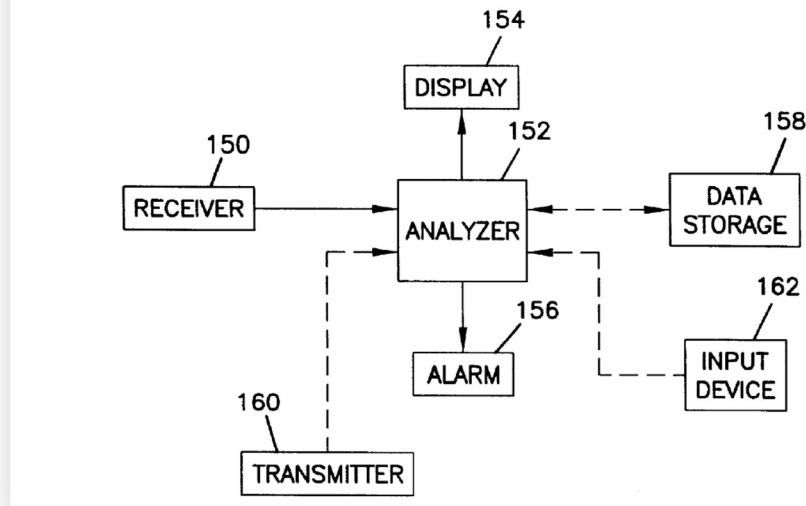
Ex-1008, 56.

E. Say (Ex-1009)

61. Say was issued on May 20, 2003, and I understand it is prior art. Say was not of record during prosecution of the '528 patent. While family members of Say (e.g., U.S. Patent No. 6,990,366) were listed in IDS (along with over 180 other references) during prosecution of the '528 patent, they were not substantively argued by the examiner in any office actions, and there is no indication that the examiner considered any Say family members in combination with the other references discussed herein.

62. Say is directed to CGM systems. Ex-1009, 2:17-23. Say discloses receiver units containing analyzer 152 and display 154. *Id.*, 48:4-9.

FIG. 22



Ex-1009, Fig. 22. Analyzer 152 “determin[es] if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values,” and “activat[es] an alarm system 156 and/or 94 if a threshold value is met or exceeded.” *Id.*, 50:20-24. The output is provided to display 154. *Id.*, 50:32-33. Display 154 “provides a message to the patient to direct the patient in an action.” *Id.*, 50:47-48. “Such messages may include, for example, ‘Eat Sugar’, if the patient is hypoglycemic, or ‘Take Insulin’, if the patient is hyperglycemic.” *Id.*, 50:48-51.

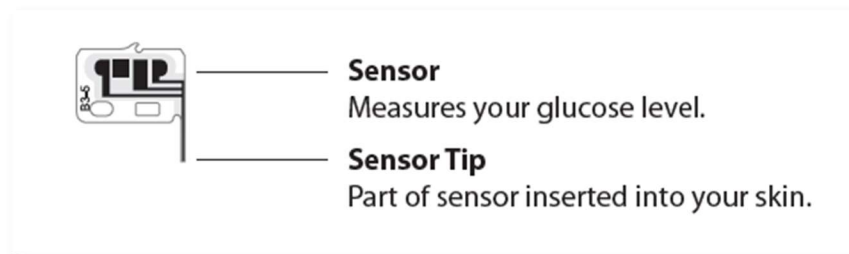
F. Navigator Guide (Ex-1010)

63. FreeStyle Navigator Continuous Glucose Monitoring System User’s Guide (“Navigator Guide”) was published online and available to the public through

Abbott's website at least by December 16, 2010. Ex-1027 ¶ 75. I understand it is thus prior art.

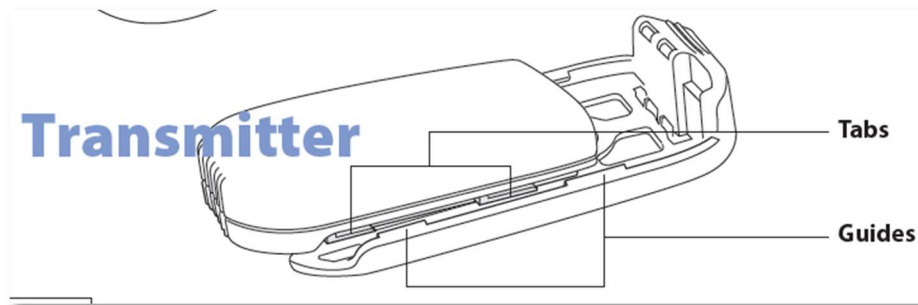
64. The FreeStyle Navigator Continuous Glucose Monitoring System described in the Navigator Guide was used by diabetes patients well before October 30, 2012. The FreeStyle Navigator Continuous Glucose Monitoring System received premarket approval on March 12, 2008. Ex-1017.

65. Navigator Guide describes a CGM system with three components: a sensor, a transmitter, and a receiver. Ex-1010, 3. The sensor is inserted into a host's skin. *Id.* It is "intended to remain in place and provide a continuous glucose reading for up to 5 days." *Id.*



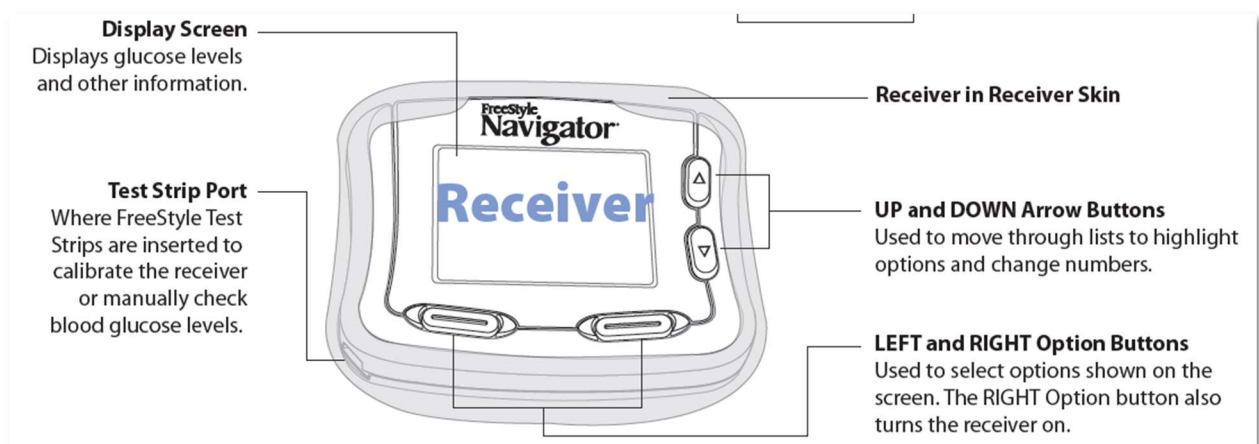
Ex-1010, 3.

66. The transmitter wirelessly sends glucose information measured by the sensor to the receiver every minute:

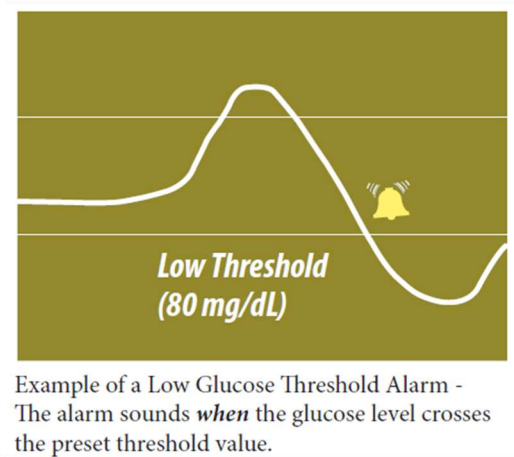


Ex-1010, 3.

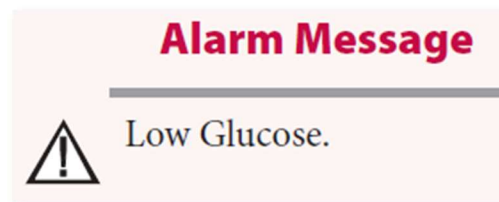
67. The receiver displays glucose values received from the transmitter:



Ex-1010, 3. Using the receiver, the user can set a low glucose alert. *Id.*, 71, 73. If the glucose value falls below the low glucose threshold, the receiver will sound a low glucose threshold alarm:

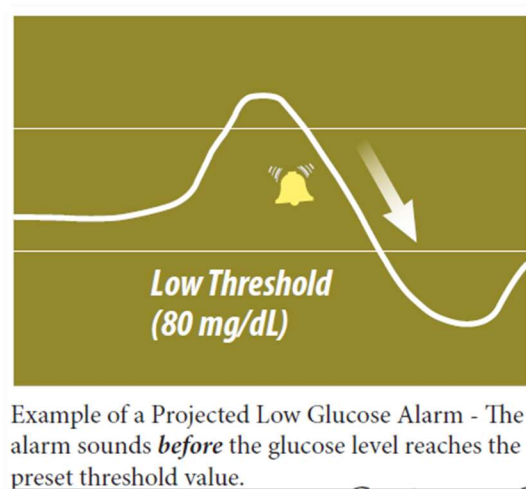


Ex-1010, 68. The receiver also displays an alarm message of “Low Glucose”:



Ex-1010, 96.

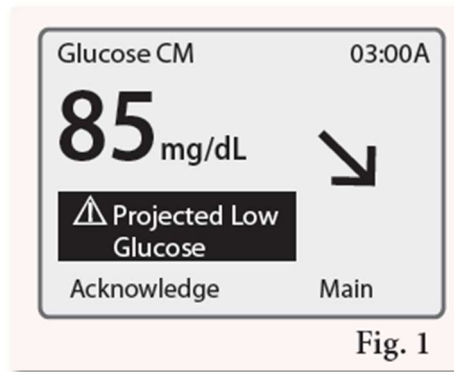
68. The receiver sounds a *projected* low glucose alarm if the projected glucose value is expected to fall below the low glucose threshold:



Ex-1010, 68. The receiver also displays an alarm message of “Projected Low Glucose”:



Ex-1010, 97. Figure 1 below is an example display showing the “Projected Low Glucose” alarm screen:



Ex-1010, 91 (“The system will notify you of any conditions that may need your attention through messages that will be displayed on your receiver screen. You can find out what those messages mean and how to respond to them. For example, see Fig. 1. The messages are arranged alphabetically in the table titled ‘Respond to alarm message’.”).

VIII. CLAIMS ANALYSIS

A. Ground I: Claims 1-2, 11-12, 16, 18-20, 24-25, 34-35, 39, and 41-43 Are Anticipated by Brauker and/or Would Have Been Obvious Based on Brauker

1. Claim 1

- a) 1[pre]: “A method of activating a hypoglycemic indicator based on continuous glucose sensor data, the method comprising:”

69. In an embodiment of the “first aspect,” Brauker discloses *activating a hypoglycemic indicator* (i.e., an indicator of low glucose) *based on continuous glucose sensor data* (i.e., calibrated signal).³ Ex-1005, [0011] (“alarm configured to provide at least one of a visual signal, an audible signal, and a tactile signal **when the calibrated signal is below the lower glucose threshold**”) (emphasis added). The calibrated signal corresponds to the *continuous glucose sensor data* because it is a calibrated version of the signal from “a continuous glucose sensor.” Ex-1005, [0005].

- b) 1[a]: “evaluating sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria;”

70. In describing the “first aspect,” Brauker discloses *evaluating sensor data using a first function to determine* “when the calibrated signal [i.e., *real time glucose value*] is below the lower glucose threshold [i.e., *user settable first criteria*].” Ex-1005, [0011].

³ *Italics* indicates claim language.

71. The “calibrated signal” corresponds to the claimed *real time glucose value* because it is a calibrated version of “a signal indicative of a glucose concentration in a host.” Ex-1005, [0005].

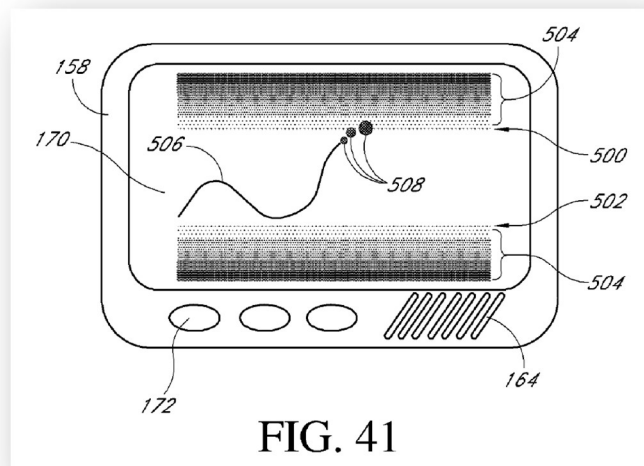
72. The “lower glucose threshold” corresponds to the claimed *user settable first criteria*: “the receiver comprises programming configured to *permit a user to set* the upper glucose threshold and *the lower glucose threshold*.” Ex-1005, [0010] (emphasis added).

73. Brauker’s *first function* takes as input the calibrated signal, and provides as an output whether the calibrated signal is below the lower glucose threshold.

c) 1[b]: “evaluating sensor data using a second function to determine whether a predicted glucose value meets one or more non user settable second criteria;”

74. In describing the “first aspect,” Brauker further discloses *evaluating sensor data using a second function to determine* when “the estimated glucose data for the future time [i.e., *predicted glucose value*] is below a predetermined threshold [i.e., *non user settable second criteria*].” Ex-1005, [0015]. While Brauker does not expressly state whether the “predetermined threshold” of the “first aspect” is user settable or non user settable, Brauker teaches that the predetermined threshold can optionally be user settable or non user settable. Ex-1005, [0035], [0697]-[0698]. In describing another embodiment, Brauker discloses that the predetermined threshold of

the “fourth aspect” is user settable, which suggests that the predetermined threshold of the “first aspect” can optionally be user settable as well. Ex-1005, [0035]. Moreover, in describing an embodiment depicted in Figure 41 (shown below), Brauker discloses that high threshold 500 and low threshold 502 define “clinical risk zones 504” that ***“can be set by a manufacturer, customized by a doctor, and/or set by a user via buttons 172.”*** *Id.*, [0697]-[0698] (emphasis added). One of the options disclosed here is that the clinical risk zones 504 can be set by a manufacturer only (i.e., non user settable). In other options, the clinical risk zones 504 can be set by a doctor or a user (i.e., user settable).



Ex-1005, Fig. 41. Because Brauker teaches that the predetermined threshold can optionally be user settable or non user settable, Brauker discloses a non user settable predetermined threshold.

75. The *second function* of Brauker takes as input “estimated glucose data for the future time,” and provides as an output whether the “estimated glucose data for the future time” is below the “predetermined threshold.” Ex-1005, [0015].

76. **Obviousness.** Brauker also renders this limitation obvious. As discussed above, Brauker teaches that the predetermined threshold of the “first aspect” (Ex-1005, paragraph [0015]) can optionally be user settable or non user settable. *Id.*, [0035], [0697]-[0698]. It would have been obvious to try a non user settable predetermined threshold.

77. A POSITA would have understood the advantages of using a non user settable low glucose alarm. An alarm based on user settable criteria enables the user to tailor the alarm, but lacks the additional safety of a fixed alarm that is guaranteed to be triggered if the user’s glucose is expected to hit a predetermined serious and potentially life-threatening danger level. *See, e.g.*, Ex-1013 (Hayter article), 725 (“The user should never go below 50 mg / dL at any time without an alarm.”). For this reason, another reference, STS Guide, discloses a CGM system with **both** user settable and non user settable alarms. Ex-1008, 56. A POSITA would have known that a user of Brauker’s system could select unrealistic or even unsafe values for the real time, user settable low glucose alarm (disclosed in paragraphs [0010] and [0011] of Brauker), leading to impaired performance of the system or an adverse event for the user. Accordingly, it would have been obvious to ensure that Brauker’s predicted

low glucose alarm (disclosed in paragraph [0015] of Brauker) is non user settable, thus, providing a “safety net” of non user settable criteria.⁴ A POSITA would have had a reasonable expectation of success. Non user settable alarms were well known before the ’528 priority date and had been applied to CGM systems. *See, e.g.,* Ex-1008 (STS Guide), 56. Modifying predicted alarms to be non user settable would involve routine programming of the system of Brauker.

78. Even if Brauker had disclosed a real time glucose alarm and a predicted low glucose alarm only in separate embodiments, it would have been obvious to combine them. As discussed in Section VIII.F.1.c below for limitation 1[b] in Ground V, a POSITA would have known that it is advantageous to use a predicted low glucose alarm in addition to a real time low glucose alarm because a *predicted* low glucose alarm *in advance of potential hypoglycemia* helps prevent hypoglycemia by giving the user more time to act, for example, by consuming carbohydrates or eating sugar, while a *real time* low glucose alarm—*when potential hypoglycemia is a present risk*—helps reduce the risk of hypoglycemia by enabling the user to act immediately in view of the current glucose level. A POSITA would

⁴ Although a POSITA could also add a *real time*, non user settable low glucose alarm, the presence or the absence of such an alarm is not relevant to this limitation, which neither requires nor prohibits such an alarm.

have had a reasonable expectation of success. *See* Section VIII.F.1.c below for limitation 1[b] in Ground V.

- d) **1[c]: “activating a hypoglycemic indicator if either the one or more user settable first criteria or the one or more non user settable second criteria are met; and providing an output based on the activated hypoglycemic indicator.”**

79. See Sections VIII.A.1.b-c above for limitations 1[a]-[b]. Brauker discloses, “In an embodiment of the first aspect, the system further comprises an alarm configured to *provide at least one of a visual signal, an audible signal, and a tactile signal when the calibrated signal is below the lower glucose threshold.*” Ex-1005, [0011] (emphasis added). “In an embodiment of the first aspect, the system further comprises an alarm configured to *provide at least one of a visual signal, an audible signal, and a tactile signal when the estimated glucose data for the future time is below a predetermined threshold.*” *Id.*, [0015] (emphasis added); *see also id.*, [0246] (“hyperglycemic and hypoglycemic alarms are triggered when present or future clinical danger is assessed based on continuous analyte data”).

80. Additional examples of output are discussed in Sections VIII.A.5-6 below for claims 16 and 18.

2. Claim 2

- a) **“The method of claim 1, wherein the evaluating sensor data using a first function to determine whether a real time glucose value meets one or more**

user settable first criteria comprises determining whether the real-time glucose value passes a glucose threshold.”

81. See Section VIII.A.1.b above for limitation 1[a].

3. Claim 11

a) **“The method of claim 1, wherein the one or more user settable first criteria comprises a first threshold that is configured to be user settable.”**

82. See Section VIII.A.1.b above for limitation 1[a].

4. Claim 12

a) **“The method of claim 11, wherein the one or more non user settable second criteria comprises a second threshold that is not user settable.”**

83. See Section VIII.A.1.c above for limitation 1[b].

5. Claim 16

a) **“The method of claim 1, wherein the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with it depending on whether the hypoglycemic indicator was activated based on the first function meeting the one or more user settable first criteria or whether the hypoglycemic indicator was activated based on the second function meeting the one or more non user settable second criteria.”**

84. Brauker discloses providing therapy recommendations (i.e., *a particular set of instructions*) such as “consume carbohydrates” or “inject insulin.”⁵ Ex-1005, [0719]. Brauker further discloses customizing therapy recommendations depending on the “severity of medical condition.” *Id.*; *see also id.*, [0248].

85. As discussed in Section VIII.A.1.d above for limitation 1[c], Brauker discloses and/or renders obvious *the hypoglycemic indicator* being (1) *activated based on the first function meeting the one or more user settable first criteria*, or (2) *activated based on the second function meeting the one or more non user settable second criteria*. A POSITA would have known that the severity and/or urgency of medical condition differs depending on whether the alarm was based on (1) a real time glucose value falling below a user settable threshold, or (2) a predicted glucose value expected to fall below a non user settable threshold. Therefore, Brauker discloses and/or renders obvious that *the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with* each of the two activation scenarios above. For example, it would have been obvious to a POSITA to associate Brauker’s real time, user settable alarm with an accompanying instruction such as, “Consume carbohydrates now

⁵ Brauker’s instructions are similar to Say’s instructions—“Eat Sugar” and “Take Insulin”—that the Board relied on to find unpatentable claim 23 of the ’215 patent. IPR2022-00909, Paper 38 (PTAB Nov. 1, 2023) at 69. Claim 23 of the ’215 patent (Ex-1012) is identical to claim 16 of the ’528 patent, except for the claim from which it depends.

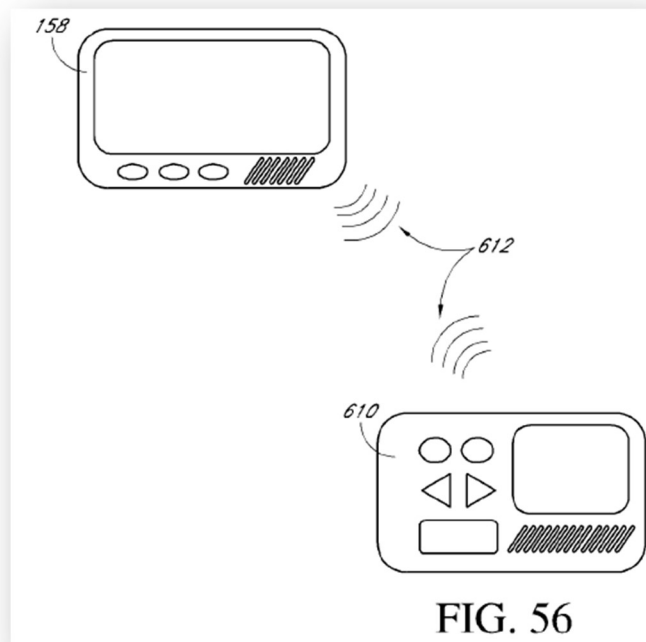
because you are below your target level,” and to associate Brauker’s predicted, non user settable alarm with a different instruction such as, “Consume carbohydrates to prevent hypoglycemia. You are at risk of experiencing hypoglycemia within 30 minutes.”

86. Moreover, as discussed in Section VIII.A.6 below for claim 18, Brauker discloses sending a particular set of instructions to an insulin pump based on “the glucose data (for example, estimated glucose value, rate of change, and/or directional trend) from the glucose sensor.” Ex-1005, [0522].

6. Claim 18

- a) **“The method of claim 1, wherein providing an output comprises transmitting a message to an insulin delivery device including instructions associated with at least one of: a) suspending insulin delivery, b) initiating a hypoglycemia and/or hyperglycemia minimizer algorithm, c) controlling insulin delivery or d) information associated with the hypoglycemia indicator.”**

87. Brauker Figure 56 depicts “a receiver 158 that interfaces with an insulin pump 610 [i.e., *insulin delivery device*], wherein data [i.e., *message*] is transmitted via wireless transmission 612 between the receiver 158 and the insulin pump 610.” Ex-1005, [0737].



Ex-1005, Fig. 56. “[T]he receiver sends therapy recommendations to the insulin pump 610, such as amount and time of insulin administration” (i.e., *instructions associated with at least one of a) suspending insulin delivery, c) controlling insulin delivery or d) information associated with the hypoglycemia indicator*). *Id.*, [0737]. Thus, in “a **closed loop glucose sensor and insulin pump** ... the glucose data (for example, estimated glucose value, rate of change, and/or directional trend) from the glucose sensor is used to determine the amount of insulin, and time of administration, that can be given to a person with diabetes to evade hyperglycemic and hypoglycemic conditions.” *Id.*, [0522] (emphasis added). A POSITA would have known that a “closed loop” system involves automatic control of insulin delivery. Ex-1023, 825; *see also* Section V.C above for discussion of CGM-based closed-loop

artificial pancreas (autonomous systems) for automated insulin delivery (AID).

7. Claim 19

- a) **“The method of claim 1, wherein the one or more non user settable second criteria are programmed at the factory in such a way that no user is able to modify the second criteria.”**

88. As discussed in Section VIII.A.1.c above for limitation 1[b], Brauker discloses and/or renders obvious *one or more non user settable second criteria* (i.e., predetermined threshold of the “first aspect”). A POSITA would have known that a non user settable predetermined threshold is *programmed at the factory in such a way that no user is able to modify*, because it is predetermined and is also non user settable. As discussed in Section VIII.A.1.c above for limitation 1[b], Brauker teaches (as one option) thresholds that can be set by a manufacturer only.⁶ Ex-1005, [0698] (“Clinical risk zones 504 can be *set by a manufacturer*, customized by a doctor, *and/or* set by a user.”) (emphasis added).

8. Claim 20

- a) **“The method of claim 1, wherein the user is a host or a healthcare provider.”**

89. Brauker discloses that *the user* (i.e., the person able to set the “first criteria” and not able to set the “second criteria” of claim 1) *is a host or a healthcare*

⁶ Brauker discloses other options where thresholds can be user settable, but claim 19 applies only to non user settable thresholds.

provider. Ex-1005, [0702] (“appropriate action can be taken by the **user** (for example, patient [i.e., *host*] or caretaker [i.e., *healthcare provider*]) and clinical risk can be preempted.”) (emphasis added). It is the same user that is permitted “to set ... the lower glucose threshold.” Ex-1005, [0010]. Brauker also discloses that a doctor (i.e., *healthcare provider*) and/or a user (e.g., a patient) can set user settable low glucose thresholds. Ex-1005, [0698] (“Clinical risk zones 504 can be set by a manufacturer, ***customized by a doctor, and/or set by a user.***”) (emphasis added).

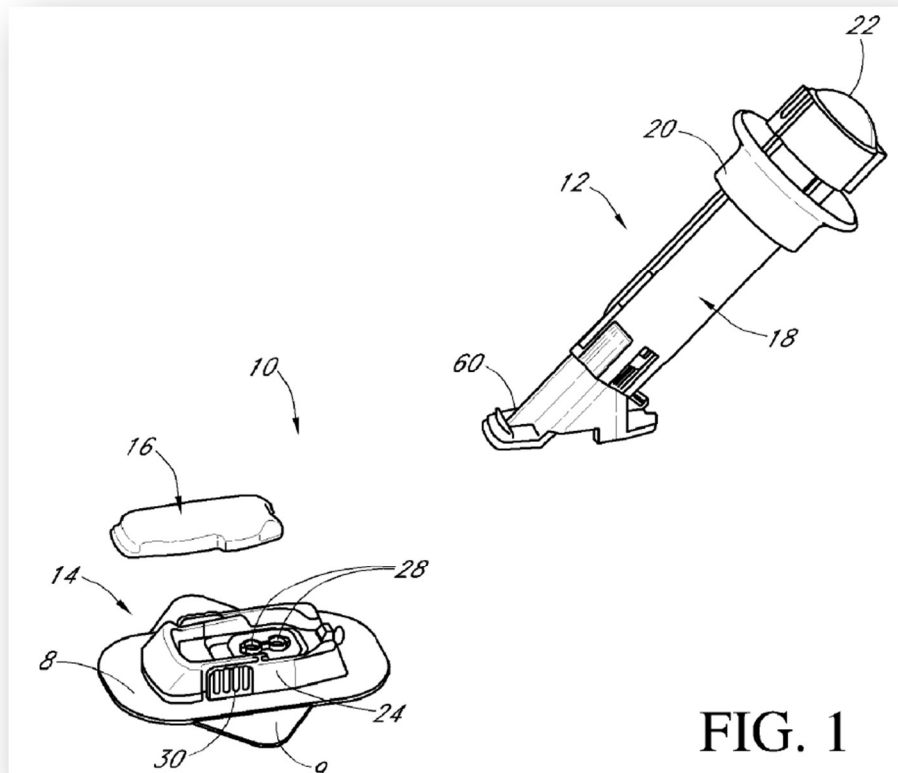
9. Claim 24

a) 24[pre]: “A system for processing data, the system comprising:”

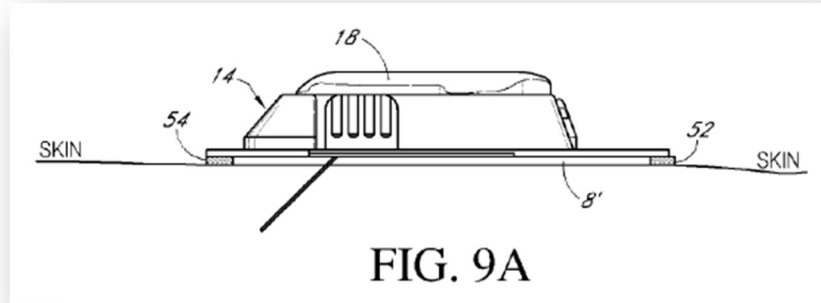
90. Brauker discloses a “***system*** comprising a continuous glucose sensor configured to ***produce a signal indicative of a glucose concentration in a host***; and a receiver operably connected to the sensor, wherein the receiver comprises a user interface, and wherein the receiver further comprises programming configured to ***calibrate the signal, to display a graphical representation of the calibrated signal on the user interface, and to display a directional arrow*** indicative of a direction and a rate of change of the calibrated signal on the user interface.” Ex-1005, [0005] (emphasis added). Additional examples of processing by Brauker’s system are discussed in Sections VIII.A.9.d-f below for limitations 24[c]-[e].

b) 24[a]: “a continuous analyte sensor configured to be implanted within a body; and”

91. Brauker discloses a “system comprising a continuous glucose sensor configured to produce a signal indicative of a glucose concentration in a host.” Ex-1005, [0005]. “FIG. 1 is a perspective view of a transcutaneous analyte sensor system 10” that includes a sensor. Ex-1005, [0260].



Ex-1005, Fig. 1. The sensor is “adapted for transdermal insertion through the skin of a host.” *Id.*, [0261]. Figure 9A depicts “the sensor implanted into the host.” *Id.*, [0387].



Ex-1005, Fig. 9A.

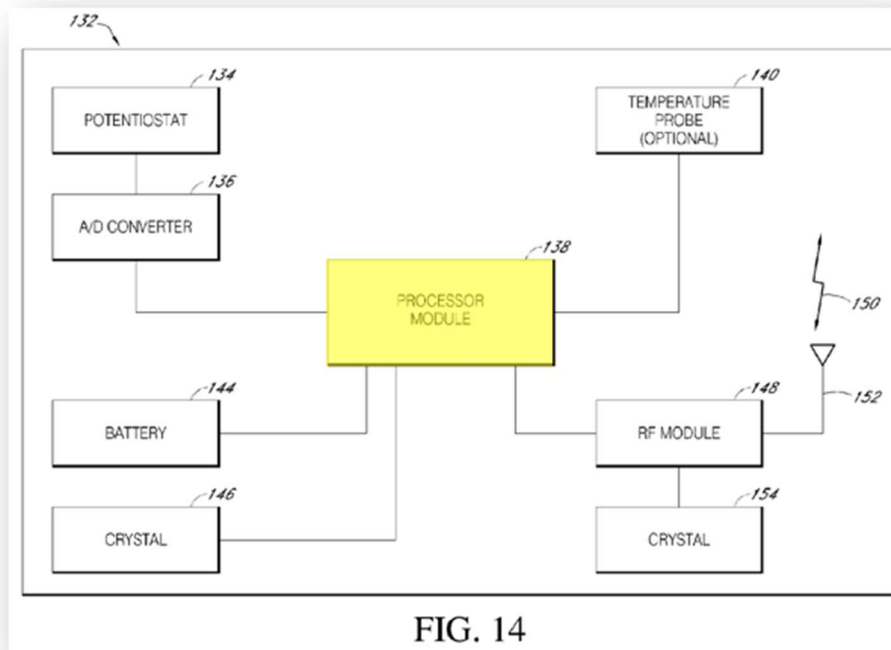
- c) **24[b]: “sensor electronics configured to receive and process sensor data output by the sensor, the sensor electronics including a processor configured to:”**

92. “FIG. 1 is a perspective view of a transcutaneous analyte sensor system 10.” Ex-1005, [0260].



Ex-1005, Fig. 1. “In the preferred embodiment of a system as depicted in FIG. 1, the sensor includes an applicator 12, a mounting unit 14, and an electronics unit 16 [i.e., *sensor electronics*].” *Id.*, [0260]. Brauker discloses that the electronics unit 16 is *configured to receive and process sensor data output by the sensor. Id.*, [0263].

93. Brauker further discloses that the “sensor electronics” *include a processor*. Ex-1005, [0423]-[0424]. “FIG. 14 is a block diagram that illustrates the electronics 132 [i.e., *sensor electronics*] associated with the sensor system 10 in one embodiment.” Ex-1005, [0424].



Ex-1005, Fig. 14 (annotated). As shown in Figure 14 above, Brauker discloses that the sensor electronics include a processor module 138 (yellow).

94. As shown in Figure 17A, Brauker also discloses a receiver 158 (red box), which is operatively linked to the sensor system 10 (green):

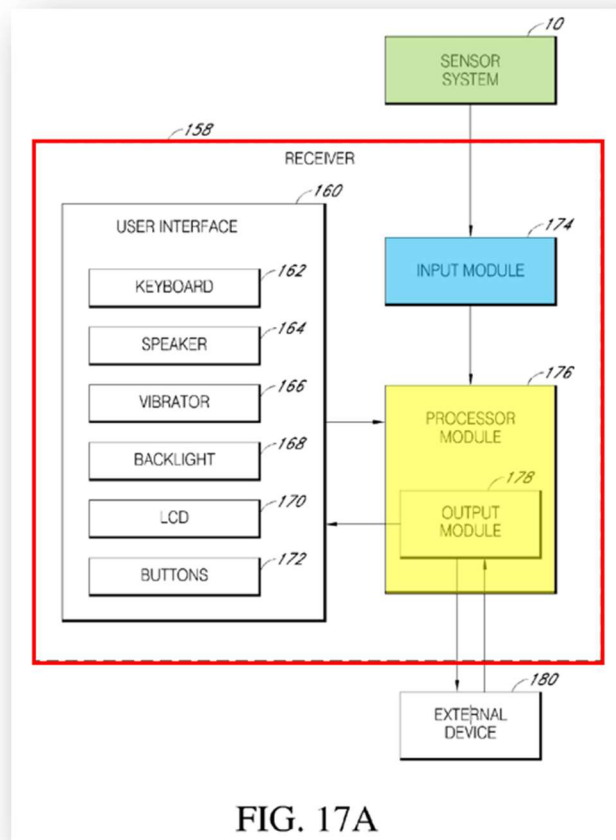


FIG. 17A

Ex-1005, Fig. 17A (annotated). “[T]he receiver 158 [red box], which is operatively linked to the sensor system 10 [green], receives a data stream from the sensor system 10 via the input module 174 [blue].” *Id.*, [0449]. “Once received, the input module 174 sends the data stream to a processor 176 [yellow] that processes the data stream.” *Id.* Brauker further discloses that the receiver electronics could be combined into the sensor electronics. Ex-1005, [0423] (“the sensor electronics and data processing as well as the receiver electronics and data processing ... ***can be incorporated into the wholly implantable glucose sensor***”) (emphasis added). Thus, Brauker discloses *the*

sensor electronics including a processor of the receiver electronics that is configured to perform the steps of evaluating sensor data and activating a hypoglycemic indicator, as discussed in Sections VIII.A.9.d-f below for limitations 24[c]-[e].

95. Alternatively, it would have been obvious to combine the sensor electronics and receiver electronics because Brauker teaches only two options: (1) the receiver electronics residing remotely from the sensor electronics, or (2) the receiver electronics residing in the sensor along with the sensor electronics. A POSITA would have had a reasonable expectation of success combining Brauker's sensor electronics and receiver electronics because the placement of the electronics would have been a routine design choice in Brauker's system.

d) 24[c]: “evaluate sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria;”

96. See Section VIII.A.1.b above for limitation 1[a].

e) 24[d]: “evaluate sensor data using a second function to determine whether a predicted glucose value meets one or more non-user settable second criteria;”

97. See Section VIII.A.1.c above for limitation 1[b].

f) 24[e]: “activate a hypoglycemic indicator if either the one or more user settable first criteria or the one or more non user settable second criteria are met; and provide an output based on the activated hypoglycemic indicator.”

98. See Section VIII.A.1.d above for limitation 1[c].

10. Claim 25

- a) **“The system of claim 24, wherein the evaluating sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria comprises determining whether the real-time glucose value passes a glucose threshold.”**

99. See Section VIII.A.2 above for claim 2.

11. Claim 34

- a) **“The system of claim 24, wherein the one or more user settable first criteria comprises a first threshold that is configured to be user settable.”**

100. See Section VIII.A.3 above for claim 11.

12. Claim 35

- a) **“The system of claim 34, wherein the one or more non user settable second criteria comprises a second threshold that is not user settable.”**

101. See Section VIII.A.4 above for claim 12.

13. Claim 39

- a) **“The system of claim 24, wherein the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with it depending on whether the hypoglycemic indicator was activated based on the first function meeting the one or more user settable first criteria or whether the hypoglycemic indicator was activated based on the second function meeting the one or more non user settable second criteria.”**

102. See Section VIII.A.5 above for claim 16.

14. Claim 41

- a) **“The system of claim 24, wherein providing output comprises transmitting a message to an insulin delivery device including instructions associated with at least one of: a) suspending insulin delivery, b) initiating a hypoglycemia and/or hyperglycemia minimizer algorithm, c) controlling insulin delivery or d) information associated with the hypoglycemia indicator.”**

See Section VIII.A.6 above for claim 18.

15. Claim 42

- a) **“The system of claim 24, wherein the one or more non user settable second criteria are programmed at the factory in such a way that no user is able to modify the non user settable second criteria.”**

See Section VIII.A.7 above for claim 19.

16. Claim 43

- a) **“The system of claim 24, wherein the user is a host or a healthcare provider.”**

103. See Section VIII.A.8 above for claim 20.

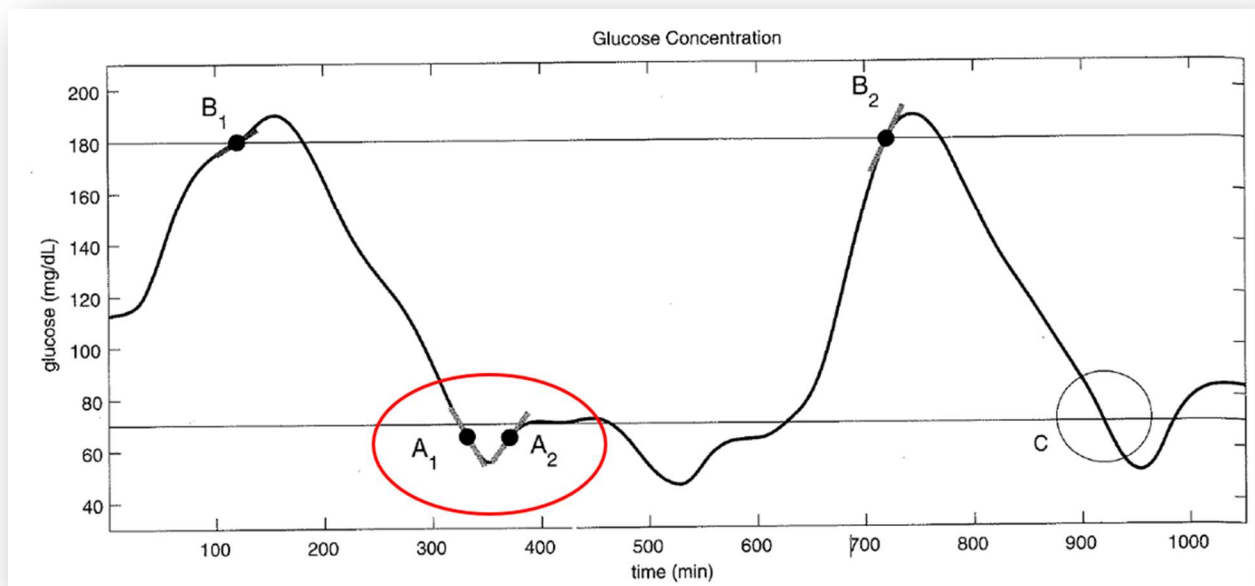
B. Ground II: Claims 3 and 26 Would Have Been Obvious Based on Brauker in View of Guerra

1. Claim 3

- a) **“The method of claim 2, wherein the evaluating sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria further comprises determining whether an amplitude of rate of change or direction of rate of change meets a rate of change criterion.”**

104. Brauker anticipates and/or renders obvious claim 2.

105. For claim 3, Guerra discloses *determining whether direction of rate of change meets a rate of change criterion*. Guerra explains that, with a traditional static risk measure, a glucose value is associated with a static risk score. Ex-1006, 844. In contrast, with a dynamic risk measure, the rate of change is considered in addition to a glucose value. *Id.*, 843 (“A new dynamic risk (DR) is proposed to **explicitly consider the rate of change of glucose as a threat factor** for the patient.”) (emphasis added). Guerra explains that, even though the glucose value is similarly low at points A_1 and A_2 (shown below in red oval), “the clinical risk associated with points A_1 and A_2 should be different.” Ex-1006, 844.



Ex-1006, 844 (annotated). “In fact, the A_1 situation is more dangerous for the patient

than A₂ because in the first case the glycemia is heading deeper in the hypoglycemic region, whereas in the second case a recovering from the hypoglycemia region toward the normoglycemic range is happening.” *Id.* “The above example[] make[s] it clear that *the trend in the glycemia*, which can be inferred from CGM measurements, *should be considered in the risk measure.*” *Id.* (emphasis added).

106. *Motivation to combine.* It would have been obvious to incorporate Guerra’s evaluation of rate of change into the system of Brauker. Brauker and Guerra both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. A POSITA would have known that combining the glucose value with the rate of change of the glucose value with time would provide a more reliable and meaningful low glucose alarm, as Guerra teaches. Ex-1006, 843. Brauker also teaches the importance of considering the rate of change in determining clinical risk. Ex-1005, [0617] (“*the rate of change* of the analyte values, and/or the acceleration of the analyte values can provide information indicative of approaching clinical risk.”) (emphasis added).

107. Moreover, combining Brauker and Guerra would have been combining prior art elements (i.e., Brauker’s low glucose alarm with Guerra’s evaluation of rate of change) according to known methods to yield predictable results (i.e., achieving a sensitive, specific, accurate, advance detection of hypoglycemia, making it possible to reduce the incidence or severity of hypoglycemia). The combination also

uses a known technique (i.e., Guerra's evaluation of rate of change) to improve similar devices in the same way.

108. ***Reasonable expectation of success.*** Brauker and Guerra both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. Furthermore, evaluating rate of change was well known before the '528 priority date and had been applied to CGM systems. *See, e.g.*, Ex-1006 (Guerra), 843; Ex-1007 (Hughes), 1150; Ex-1008 (STS Guide), 54. Incorporating Guerra's evaluation of rate of change would involve routine programming of the system of Brauker.

2. Claim 26

- a) **“The system of claim 25, wherein the evaluating sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria further comprises determining whether an amplitude of rate of change or direction of rate of change meets a rate of change criterion.”**

109. See Section VIII.B.1 above for claim 3.

C. Ground III: Claims 5 and 28 Would Have Been Obvious Based on Brauker in View of Guerra and Hughes

1. Claim 5

- 1. **“The method of claim 1, wherein the evaluating sensor data using a second function to determine whether the predicted glucose value meets one or more second criteria comprises evaluating a dynamic risk of the predicted glucose value.”**

110. Brauker anticipates and/or renders obvious claim 1.

111. For claim 5, Guerra discloses *evaluating a dynamic risk* of a glucose value. As discussed in Section VIII.B.1 above for claim 3, Guerra explains that, with a traditional static risk measure (such as the one originally developed by Kovatchev (Ex-1022)), a glucose value is associated with a static risk score. Ex-1006, 844. In contrast, with a dynamic risk measure, ***the rate of change*** is considered in addition to a glucose value. *Id.*, 843 (“A new ***dynamic risk (DR)*** is proposed to explicitly consider the rate of change of glucose as a threat factor for the patient.”) (emphasis added). As discussed in Section VIII.B.1 above for claim 3, Guerra explains that considering the rate of change of glucose as a threat factor (i.e., *evaluating a dynamic risk*) helps evaluate the risk of hypoglycemia.

112. Like Guerra, Hughes discloses evaluating a dynamic risk, and further discloses evaluating a dynamic risk *of the predicted glucose value*, $\hat{y}(k)$.⁷ Ex-1007, 1150. Specifically, Hughes discloses a risk of hypoglycemia function R_m , which takes as input the *predicted glucose value* $\hat{y}(k)$:

⁷ Kovatchev, who developed the original static risk model (Ex-1022), is a co-author of the Hughes article (Ex-1007).

$$\underline{R_m(\hat{y}(k))} = \begin{cases} 10 \cdot \left[.918642 \cdot (\ln(\hat{y}(k)))^{1.29286} - 7.57332 \right]^2 & \text{if } 20 < \hat{y}(k) < 120 \text{ and } \frac{d\hat{y}(k)}{dk} < 0 \\ 100 & \text{if } \hat{y}(k) \leq 20 \\ 0 & \text{otherwise.} \end{cases} \quad (15)$$

Ex-1007, 1150 (annotated). R_m is a *risk* function because it “assess[es] the risk of hypoglycemia.” *Id.* Moreover, it is a risk function of the *predicted glucose value* because it takes as input the “projected [glucose] concentration” $\hat{y}(k)$. *Id.* Finally, R_m is a *dynamic* risk function of a predicted glucose value because it explicitly consider[s] as a hypoglycemia threat factor for the patient, the rate of change $\frac{d\hat{y}(k)}{dk}$ of the predicted glucose value $\hat{y}(k)$, in addition to the predicted glucose value $\hat{y}(k)$.

113. If the predicted glucose value $\hat{y}(k)$ is between 20 and 120 mg/dl **and it is decreasing** $\left(\frac{d\hat{y}(k)}{dk} < 0\right)$ (shown in red box above), then the risk function R_m provides a risk score between 0 and 100, depending on the value of the predicted glucose value $\hat{y}(k)$ (shown in yellow highlight above). Ex-1007, 1150.

114. If, however, the predicted glucose value $\hat{y}(k)$ is between 20 and 120 mg/dl, and it is **increasing or staying the same**, the risk function R_m provides a risk score of 0 (representing no risk, shown in green highlight above). *Id.*

115. ***Motivation to combine.*** It would have been obvious to incorporate Guerra's evaluation of dynamic risk into the system of Brauker, as discussed in Section VIII.B.1 above for claim 3. When incorporating Guerra's evaluation of dynamic risk in Brauker's predicted low glucose alarm, a POSITA would have been motivated to evaluate dynamic risk of the predicted glucose value (as Hughes teaches) because Brauker's predicted low glucose alarm is based on the predicted glucose value. Like Brauker and Guerra, Hughes relates to a CGM system with alerts to reduce the incidence or severity of hypoglycemia.

116. Moreover, combining Brauker, Guerra, and Hughes would have been combining prior art elements (i.e., (1) Brauker's low glucose alarm based on predicted glucose value with (2) Guerra's dynamic risk evaluation according to (3) Hughes's explicit use of predicted glucose value and the rate of change of predicted glucose value to calculate risk of hypoglycemia) according to known methods to yield predictable results (i.e., achieving a sensitive, specific, accurate, advance detection of hypoglycemia, making it possible to reduce the incidence or severity of hypoglycemia). The combination also uses a known technique (i.e., Guerra's dynamic risk (DR) evaluation and Hughes's dynamic risk evaluation R_m utilizing predicted glucose value) to improve similar devices in the same way.

117. ***Reasonable expectation of success.*** Brauker, Guerra, and Hughes all relate to CGM systems with alerts to reduce the incidence or severity of

hypoglycemia. Dynamic risk models and algorithms were well known before the '528 priority date and had been applied to CGM systems. *See, e.g.*, Ex-1006 (Guerra), 843; Ex-1007 (Hughes), 1150. Incorporating Guerra's and Hughes's dynamic risk algorithm and functionality would involve routine programming of the system of Brauker.

2. Claim 28

- a) **“The system of claim 24, wherein the evaluating sensor data using a second function to determine whether the predicted glucose value meets one or more non user settable second criteria comprises evaluating a dynamic risk of the predicted glucose value.”**

118. See Section VIII.C.1 above for claim 5.

D. Ground IV: Claims 13 and 36 Would Have Been Obvious Based on Brauker in View of Hughes

1. Claim 13

- a) **“The method of claim 1, wherein the one or more non user settable second criteria comprises a prediction horizon.”**

119. Brauker anticipates and/or renders obvious claim 1.

120. Brauker does not expressly use claim 13's recited “prediction horizon,” which is the amount of time into the future for estimating the predicted glucose value. But, it would have been obvious that Brauker's “estimated glucose data for the future time” (Section VIII.A.1.c, limitation 1[b]) is associated with a particular prediction

horizon because estimating glucose data for the future time requires knowing how far into the future to estimate.

121. Hughes expressly discloses a prediction horizon and teaches that its prediction horizon τ is “a parameter that must be specified” in computing the “projected [glucose] concentration” $\hat{y}(k)$. Ex-1007, 1150.

122. **Motivation to combine.** It would have been obvious to incorporate Hughes’s prediction horizon in Brauker’s predicted low glucose alarm. Brauker and Hughes both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. A POSITA would have known that, in order to provide a predicted low glucose alarm (as Brauker teaches), one has to know how far into the future the glucose value needs to be predicted, i.e., the *prediction horizon*. As discussed in Section VIII.A.1.c above for limitation 1[b], a POSITA would have known the advantages of using non user settable criteria for a low glucose alarm. Therefore, it would have been obvious to incorporate Hughes’s prediction horizon as a *non user settable* prediction horizon when pairing it with Brauker’s *non user settable* predetermined threshold discussed in Section VIII.A.1.c above for limitation 1[b].

123. Moreover, combining Brauker and Hughes would have been combining prior art elements (i.e., Brauker’s predicted low glucose alarm with Hughes’s prediction horizon) according to known methods to yield predictable results (i.e., achieving a sensitive, specific, accurate, advance detection of hypoglycemia, making

it possible to reduce the incidence or severity of hypoglycemia). The combination also uses a known technique (i.e., Hughes's prediction horizon) to improve similar devices in the same way.

124. ***Reasonable expectation of success.*** Brauker and Hughes both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. The concept of a prediction horizon was well known before the '528 priority date and had been applied to CGM systems. For example, the Facchinetti article also discloses "prediction horizon," and further discloses a method to optimize the choice of the prediction horizon. Ex-1014, 111. Another reference, Sparacino, also discloses a "prediction horizon." Ex-1011, 932. Incorporating Hughes's prediction horizon would involve routine programming of the system of Brauker.

2. Claim 36

- a) **"The system of claim 24, wherein the one or more non user settable second criteria comprises a prediction horizon that is not user settable."**

125. See Section VIII.D.1 above for claim 13.

E. Ground V: Claims 16, 17, 39, and 40 Would Have Been Obvious Based on Brauker in View of STS Guide

1. Claim 16

- a) **"The method of claim 1, wherein the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with it depending on whether the hypoglycemic indicator was activated based on the first function meeting the one or more user settable**

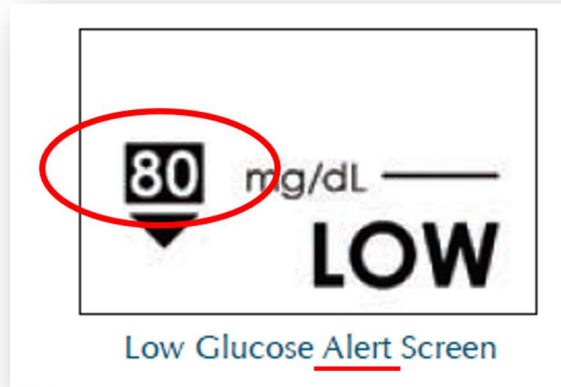
first criteria or whether the hypoglycemic indicator was activated based on the second function meeting the one or more non user settable second criteria.”

126. Brauker anticipates and/or renders obvious claim 1.

127. For claim 16, Brauker discloses providing therapy recommendations (i.e., *a particular set of instructions*) such as “consume carbohydrates” or “inject insulin.”⁸ Ex-1005, [0719]. Brauker further discloses customizing therapy recommendations depending on the “severity of medical condition.” *Id.*

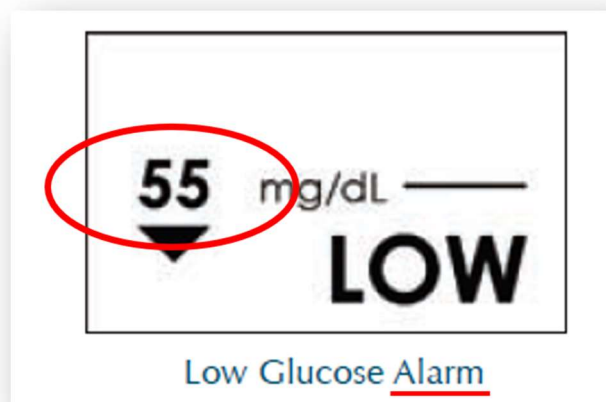
128. STS Guide discloses providing differentiated outputs for a user settable low glucose **alert** and a non user settable low glucose **alarm**. For a user settable low glucose **alert**, a Low Glucose **Alert** Screen is displayed with the glucose value shown on **black** background:

⁸ Brauker’s instructions are similar to Say’s instructions—“Eat Sugar” and “Take Insulin”—that the Board relied on to find unpatentable claim 23 of the ’215 patent. IPR2022-00909, Paper 38 (PTAB Nov. 1, 2023) at 69. Claim 23 of the ’215 patent (Ex-1012) is identical to claim 16 of the ’528 patent, except for the claim from which it depends.



Ex-1008, 54 (annotated) (“When your STS Sensor glucose values are below your Low *Alert* setting and trending down, the STS Receiver will vibrate and display the Low *Alert* Screen.”) (emphasis added); Ex-1008, 79 (“You may select low glucose *alert* values from 60 mg/dL to 90 mg/dL.”) (emphasis added).

129. In contrast, for a non user settable low glucose *alarm*, a Low Glucose *Alarm* screen is displayed with the glucose value shown on *white* background:



Ex-1008, 56 (annotated) (“When the STS Sensor detects a glucose level below 55

mg/dL (3.1 mmol/L) your STS Receiver will vibrate to notify you of a very low glucose value by displaying the [Low Glucose *Alarm*] screen”); *id.* (“You cannot change or turn off the Low Glucose *Alarm*.”) (emphasis added).

130. ***Motivation to combine.*** It would have been obvious to incorporate STS Guide’s differentiated outputs in Brauker’s low glucose alarms with a particular set of instructions. Brauker and STS Guide both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. A POSITA would have known that appropriate action taken by a user would depend on whether the alarm represents an immediate real time hypoglycemia or a predicted hypoglycemia in the future, what actions the user should take, and with what degree of urgency.

131. Therefore, it would have been obvious to a POSITA to associate the Brauker-STS Guide combination’s real time, user settable alarm with an accompanying instruction such as, “Consume carbohydrates now because you are below your target level,” and to associate the Brauker-STS Guide combination’s predicted, non user settable alarm with a different instruction, such as, “Consume carbohydrates to prevent hypoglycemia. You are at risk of experiencing hypoglycemia within 30 minutes.”

132. Moreover, combining Brauker and STS Guide would have been combining prior art elements (i.e., Brauker’s low glucose alarms and particular set of instructions with STS Guide’s differentiated outputs for “alerts” versus “alarms”)

according to known methods to yield predictable results (i.e., providing appropriate instructions to treat or prevent hypoglycemia). The combination also uses a known technique (i.e., STS Guide's differentiated outputs) to improve similar devices in the same way.

133. *Reasonable expectation of success.* Brauker and STS Guide both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. The concept of differentiated outputs was well known before the '528 priority date and had been applied to CGM systems. Ex-1008 (STS Guide), 54, 56. Incorporating STS Guide's differentiated outputs would involve routine programming of the system of Brauker.

2. Claim 17

- a) **“The method of claim 1, wherein the output comprises at least one of an audible, tactile or visual output, and wherein the output is differentiated and/or provides information selectively based on whether the hypoglycemic indicator was activated based on the first function meeting the one or more user settable first criteria or whether the hypoglycemic indicator was activated based on the second function meeting the one or more non user settable second criteria.”**

134. Brauker anticipates and/or renders obvious claim 1.

135. Brauker discloses claim 17's recital that *the output comprises at least one of an audible, tactile or visual output*. Ex-1005, [0011] (“a visual signal, an audible signal, and a tactile signal”).

136. As discussed in Section VIII.E.1 above for claim 16, STS Guide discloses *differentiated outputs* for a user settable low glucose **alert** and a non user settable low glucose **alarm**.

137. **Motivation to combine.** As discussed in Section VIII.E.1 above for claim 16, it would have been obvious to incorporate STS Guide's differentiated outputs in Brauker's real time, user settable low glucose alarm and Brauker's predicted, non user settable alarm.

3. Claim 39

- a) **“The system of claim 24, wherein the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with it depending on whether the hypoglycemic indicator was activated based on the first function meeting the one or more user settable first criteria or whether the hypoglycemic indicator was activated based on the second function meeting the one or more non user settable second criteria.”**

138. See Section VIII.E.1 above for claim 16.

4. Claim 40

- a) **“The system of claim 24, wherein the output comprises at least one of an audible, tactile or visual output, and wherein the output is differentiated and/or provides information selectively based on whether the hypoglycemic indicator was activated**

based on the first function meeting the one or more user settable first criteria or whether the hypoglycemic indicator was activated based on the second function meeting the one or more non user settable second criteria.”

139. See Section VIII.E.2 above for claim 17.

F. Ground VI: Claims 1-3, 11-12, 16-20, 24-26, 34-35, and 39-43 Would Have Been Obvious Based on STS Guide in View of Brauker

1. Claim 1

- a) 1[pre]: **“A method of activating a hypoglycemic indicator based on continuous glucose sensor data, the method comprising:”**

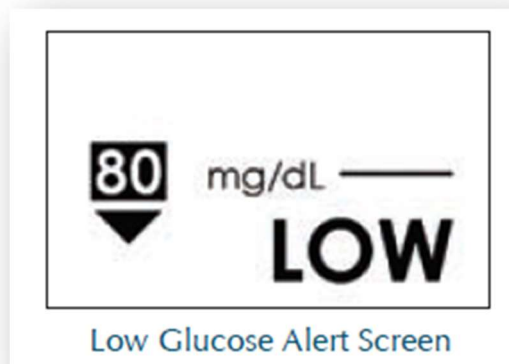
140. STS Guide discloses *activating a hypoglycemic indicator* (i.e., an indicator of low glucose). The system of STS Guide “features adjustable high and *low glucose alerts* to notify you when you are outside of your target glucose levels.”

Ex-1008, 9 (emphasis added); *see also id.*, 54, 56.

141. STS Guide further discloses the low glucose alert being activated *based on continuous glucose sensor data*. Ex-1008, 9 (“The DexCom™ STS™ *Continuous Glucose Monitoring System* provides you with real time *continuous glucose measurements* every 5 minutes for up to 3 days.”) (emphasis added).

- b) 1[a]: **“evaluating sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria;”**

142. STS Guide discloses *evaluating sensor data using a first function to determine* “[w]hen your STS Sensor glucose values [i.e., *real time glucose values*] are below your Low Alert setting and trending down [i.e., *user settable first criteria*],” in which case, “the STS Receiver will vibrate and display the Low Alert Screen [shown below].” Ex-1008, 54; *see also id.*, 78-79.



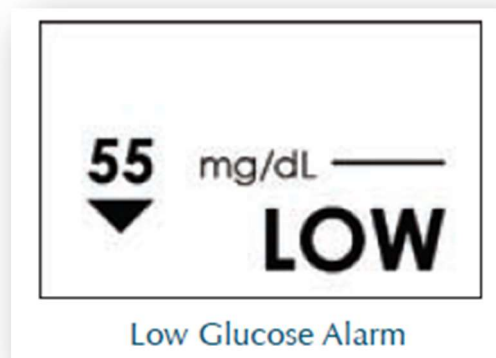
Ex-1008, 54. The Low Alert setting is *user settable*. Ex-1008, 79 (“You may select low glucose alert values from 60 mg/dL to 90 mg/dL.”).

143. STS Guide’s *first function* takes as input the STS Sensor glucose values, and provides as an output whether the STS Sensor glucose values are below the Low Alert setting and trending down.

- c) **1[b]: “evaluating sensor data using a second function to determine whether a predicted glucose value meets one or more non user settable second criteria;”**

144. STS Guide discloses *evaluating sensor data using a second function to determine whether* a real time glucose value is below 55 mg/dL (i.e., *non user*

settable second criteria) for a low glucose alarm. Ex-1008, 56 (“In addition to your personal glucose alert settings, your STS™ Receiver also has an automatic low glucose alarm set at 55 mg/dL.”). The threshold for this low glucose **alarm** (as opposed to the **alert** discussed in Section VIII.F.1.b above for limitation 1[a]) is *non user settable* because “[y]ou cannot change or turn off the Low Glucose Alarm.” Ex-1008, 56; *see also id.*, 79. “When the STS Sensor detects a glucose level below 55 mg/dL (3.1 mmol/L) your STS Receiver will vibrate to notify you of a very low glucose value by displaying the following [Low Glucose Alarm] screen:”



Ex-1008, 56.

145. Brauker discloses detecting whether a *predicted glucose value* is expected to fall below a threshold to provide a low glucose alarm. Ex-1005, [0015] (“In an embodiment of the first aspect, the system further comprises an alarm configured to provide at least one of a visual signal, an audible signal, and a tactile

signal *when the estimated glucose data for the future time is below a predetermined threshold.*") (emphasis added).

146. **Motivation to combine.** It would have been obvious to incorporate Brauker's predicted glucose alarm in the system of STS Guide so that the modified system would additionally determine whether a *predicted* glucose value meets non user settable criteria to provide a low glucose alarm. Notably, DexCom published the STS Guide (Ex-1008) and was also the assignee of the Brauker patent application. Ex-1024 (issued patent version of Brauker), (73). Both STS Guide and Brauker relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. A POSITA would have known the advantages of using a predicted low glucose alarm in addition to a real time low glucose alarm because a *predicted* low glucose alarm *in advance of potential hypoglycemia* helps prevent hypoglycemia by giving the user more time to act, for example, by eating sugar. Ex-1007, 1149 ("prediction increase[s] our ability to prevent hypoglycemia."); Ex-1011, 932 ("glucose can be predicted ahead in time, e.g., with a prediction horizon of 30 min crossing of the hypoglycemic threshold can be predicted 20-25 min ahead in time, a sufficient margin to mitigate the event by sugar ingestion."). In contrast, a *real time* low glucose alarm *when potential hypoglycemia is a present risk* helps prevent hypoglycemia by allowing the user to act in view of the current glucose level.

147. Accordingly, Brauker expressly discloses using both real time and predicted alarms. Ex-1005, [0011], [0015]. Another reference, Navigator Guide, also teaches using both real time and predicted low glucose alarms. Ex-1010, 68 (“In order to get maximum notification of low and high glucose conditions, use both the low and high glucose threshold alarms **AND** the projected low and projected high glucose alarms.”) (emphasis in original). A POSITA would have been particularly motivated to add a ***predicted, non user settable*** low glucose alarm because a POSITA would have known that non user settable criteria tied to hypoglycemia often relate to clinical danger, Ex-1013 (Hayter article), 725 (“The user should never go below 50 mg / dL at any time without an alarm.”), and that it is particularly beneficial to have an advance warning of a clinical danger.⁹

148. Moreover, combining STS Guide and Brauker would have been combining prior art elements (i.e., STS Guide’s low glucose alarm with Brauker’s predicted low glucose alarm) according to known methods to yield predictable results (i.e., achieving a sensitive, specific, accurate, advance detection of hypoglycemia, making it possible to reduce the incidence or severity of

⁹ Although a POSITA could also add a ***predicted, user settable*** low glucose alert, the presence or the absence of such an alert is not relevant to this limitation, which neither requires nor prohibits such an alert.

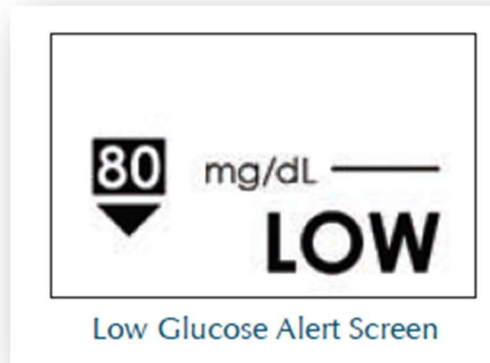
hypoglycemia). The combination also uses a known technique (i.e., Brauker's predicted low glucose alarm) to improve similar devices in the same way.

149. ***Reasonable expectation of success.*** STS Guide and Brauker both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. Predicted low glucose alarms were well known before the '528 priority date and had been applied to CGM systems. *See, e.g.*, Ex-1005 (Brauker), [0015]; Ex-1010 (Navigator Guide), 68; Ex-1007 (Hughes), 1150; Ex-1020 (Buckingham); Ex-1021 (Dassau). Adding Brauker's predicted low glucose alarm would involve routine programming of the system of STS Guide.

150. STS Guide's *second function* (as modified by Brauker) takes Brauker's predicted glucose value as input, and provides as an output whether the predicted glucose value is below STS Guide's non user settable threshold.

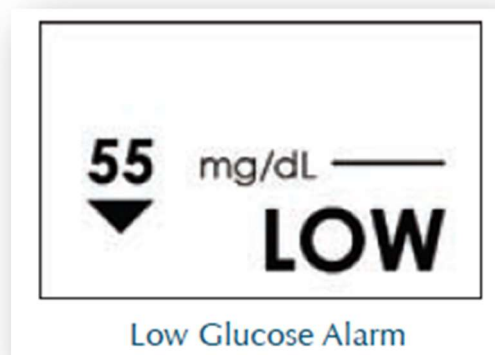
- d) **1[c]: “activating a hypoglycemic indicator if either the one or more user settable first criteria or the one or more non user settable second criteria are met; and providing an output based on the activated hypoglycemic indicator.”**

151. See Sections VIII.F.1.b-c above for limitations 1[a]-[b]. STS Guide discloses that, “[w]hen your STS Sensor glucose values are below your Low ***Alert*** setting and trending down [i.e., *user settable first criteria*], the STS Receiver will vibrate and display the Low ***Alert*** Screen.” Ex-1008, 54 (emphasis added).



Ex-1008, 54.

152. STS Guide also discloses that, “[w]hen the STS Sensor detects a glucose level below 55 mg/dL [i.e., *non user settable second criteria*] your STS Receiver will vibrate to notify you of a very low glucose value by displaying the following [Low Glucose *Alarm*] screen”:



Ex-1008, 56.

153. Additional examples of outputs are discussed in Sections VIII.F.6 & 8 below for claims 16 and 18.

2. Claim 2

- a) “The method of claim 1, wherein the evaluating sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria comprises determining whether the real-time glucose value passes a glucose threshold.”

154. See Section VIII.F.1.b above for limitation 1[a].

3. Claim 3

- a) “The method of claim 2, wherein the evaluating sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria further comprises determining whether an amplitude of rate of change or direction of rate of change meets a rate of change criterion.”

155. STS Guide discloses that “[w]hen your STS Sensor glucose values are below your Low Alert setting and ***trending down*** [i.e., *direction of rate of change meets a rate of change criterion*], the STS Receiver will vibrate and display the Low Alert Screen.” Ex-1008, 54 (emphasis added). Thus, when the direction of rate of change is negative, it *meets a rate of change criterion*. In discussing a similar claim¹⁰ of the ’215 patent, the Board credited my testimony that “the determination that glucose is ‘trending down’ is a rate of change criterion” and concluded that the

¹⁰ Claim 3 of the ’215 patent (Ex-1012) is identical to claim 3 of the ’528 patent, except for the claim from which it depends.

challenged “claim 3 would have been obvious over” STS Guide. IPR2022-00909, Paper 38 at 46 (P.T.A.B. Nov. 1, 2023).

4. Claim 11

- a) **“The method of claim 1, wherein the one or more user settable first criteria comprises a first threshold that is configured to be user settable.”**

156. See Section VIII.F.1.b above for limitation 1[a].

5. Claim 12

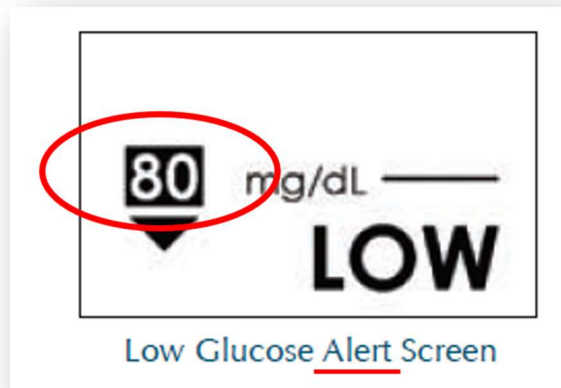
- a) **“The method of claim 11, wherein the one or more non user settable second criteria comprises a second threshold that is not user settable.”**

157. See Section VIII.F.1.c above for limitation 1[b].

6. Claim 16

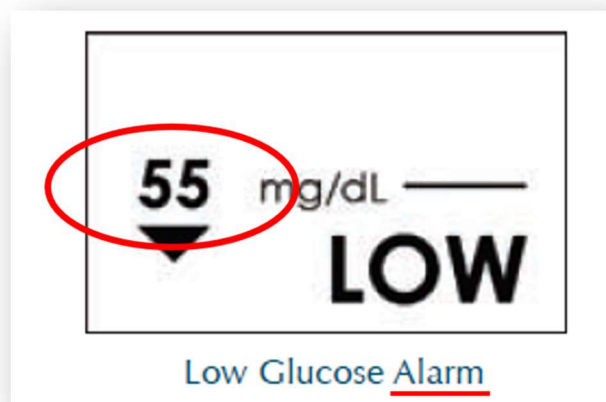
- a) **“The method of claim 1, wherein the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with it depending on whether the hypoglycemic indicator was activated based on the first function meeting the one or more user settable first criteria or whether the hypoglycemic indicator was activated based on the second function meeting the one or more non user settable second criteria.”**

158. STS Guide discloses that, when *the hypoglycemic indicator is activated based on the first function meeting the one or more user settable first criteria*, a Low Glucose *Alert* Screen is displayed with the glucose value shown on *black* background (i.e., *hypoglycemic indicator comprises a flag that has a particular display*):



Ex-1008, 54 (annotated).

159. In contrast, when *the hypoglycemic indicator is activated based on the second function meeting the one or more non user settable second criteria*, a Low Glucose **Alarm** screen is displayed with the glucose value shown on **white** background (i.e., *hypoglycemic indicator comprises a flag that has a particular display*):



Ex-1008, 56 (annotated).

160. Brauker discloses *the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with it depending on* different situations. Specifically, Brauker discloses providing therapy recommendations (i.e., *a particular set of instructions*) such as “consume carbohydrates” or “inject insulin.” Ex-1005, [0719].¹¹ Brauker further discloses customizing therapy recommendations depending on the “severity of medical condition.” *Id.*

161. **Motivation to combine.** It would have been obvious to incorporate Brauker’s particular set of instructions in the system of STS Guide. STS Guide and Brauker both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. A POSITA would have understood the benefits of specific instructions to the user, prompting the user to take action to reduce the likelihood or severity of hypoglycemia. For example, Brauker teaches that using a predicted low glucose alert advantageously provides the user the opportunity to take action. Ex-1005, [0702] (“By providing data in a format that emphasizes the possibility of clinical risk to the patient, *appropriate action can be taken by the user* (for example, patient or caretaker) and clinical risk can be preempted.”) (emphasis added). Hughes also

¹¹ Brauker’s instructions are similar to Say’s instructions—“Eat Sugar” and “Take Insulin”—that the Board relied on to find unpatentable claim 23 of the ’215 patent. IPR2022-00909, Paper 38 (PTAB Nov. 1, 2023) at 69. Claim 23 of the ’215 patent (Ex-1012) is identical to claim 16 of the ’528 patent, except for the claim from which it depends.

teaches the importance of user action. Ex-1007, 1148 (“In order to be effective in reducing the incidence of hypoglycemia, alarms must be accompanied by some type of action.”).

162. Therefore, it would have been obvious to a POSITA to associate STS Guide’s real time, user settable ***alert*** with an accompanying instruction such as, “Consume carbohydrates now because you are below your target level,” and to associate the STS Guide-Brauker combination’s predicted, non user settable ***alarm*** with a different instruction, such as, “Consume carbohydrates to prevent hypoglycemia. You are at risk of experiencing hypoglycemia within 30 minutes.”

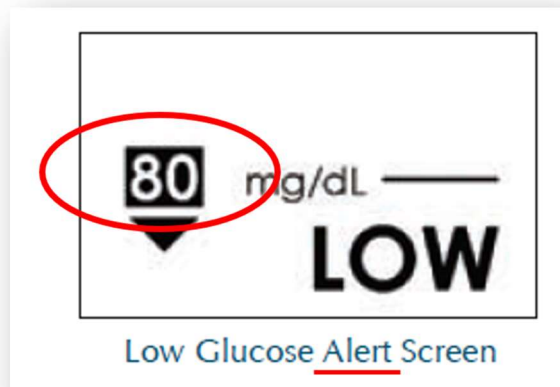
163. Moreover, combining STS Guide with Brauker would have been combining prior art elements (i.e., the STS Guide-Brauker combination’s alerts/alarms with Brauker’s particular set of instructions) according to known methods to yield predictable results (i.e., providing appropriate instructions to treat or prevent hypoglycemia). The combination also uses a known technique (i.e., Brauker’s particular set of instructions) to improve similar devices in the same way.

164. ***Reasonable expectation of success.*** STS Guide and Brauker both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. It would have been within the abilities of a POSITA to add accompanying instructions to the low glucose alert/alarm. Such a modification would involve routine programming of STS Guide’s system.

7. **Claim 17**

- a) **“The method of claim 1, wherein the output comprises at least one of an audible, tactile or visual output, and wherein the output is differentiated and/or provides information selectively based on whether the hypoglycemic indicator was activated based on the first function meeting the one or more user settable first criteria or whether the hypoglycemic indicator was activated based on the second function meeting the one or more non user settable second criteria.”**

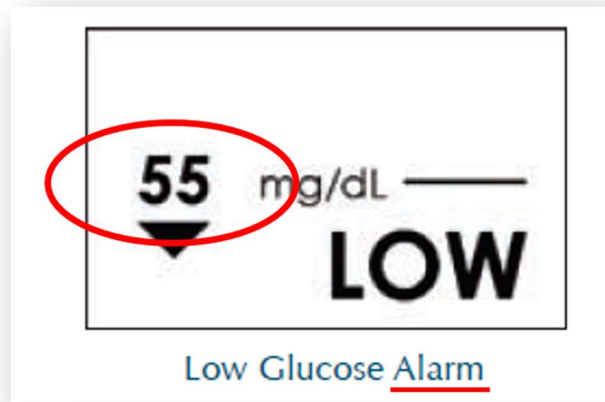
165. STS Guide discloses that, when *the hypoglycemic indicator is activated based on the first function meeting the one or more user settable first criteria*, a Low Glucose **Alert** Screen is displayed with the glucose value shown on **black** background (i.e., *visual output*):



Ex-1008, 54 (annotated).

166. In contrast, when *the hypoglycemic indicator is activated based on the second function meeting the one or more non user settable second criteria*, a Low

Glucose *Alarm* screen is displayed with the glucose value shown on *white* background (i.e., *output is differentiated*):



Ex-1008, 56 (annotated).

8. Claim 18

- a) “The method of claim 1, wherein providing an output comprises transmitting a message to an insulin delivery device including instructions associated with at least one of: a) suspending insulin delivery, b) initiating a hypoglycemia and/or hyperglycemia minimizer algorithm, c) controlling insulin delivery or d) information associated with the hypoglycemia indicator.”

167. As discussed in Section VIII.A.6 above for claim 18 in Ground I, Brauker discloses *transmitting a message to an insulin delivery device including instructions associated with at least one of a) suspending insulin delivery, c) controlling insulin delivery or d) information associated with the hypoglycemia indicator.*

168. ***Motivation to combine.*** It would have been obvious to incorporate Brauker's insulin delivery control in the system of STS Guide. STS Guide and Brauker both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. A POSITA would have known that automatically controlling insulin delivery is beneficial because it can reduce risk of predicted or observed hypoglycemia (by reducing or stopping infusion of insulin). Automated Insulin Delivery (AID) (also described as "Closed Loop" and as "Artificial Pancreas") generally improves quality of glycemic control, and removes the user's burden of manually controlling insulin delivery and the associated risk of user error.

169. Moreover, combining STS Guide and Brauker would have been combining prior art elements (i.e., the STS Guide's CGM system with Brauker's insulin delivery control) according to known methods to yield predictable results (i.e., providing appropriate instructions to treat or prevent hypoglycemia). The combination also uses a known technique (i.e., Brauker's transmission of an output to an insulin pump so as to control the rate of insulin infusion) to improve similar devices in the same way. Hughes teaches that, "[i]n order to be effective in reducing the incidence of hypoglycemia, alarms must be accompanied by some type of action," Ex-1007, 1148, e.g., using an insulin delivery device whose insulin delivery is controlled, which "increase[s] our ability to prevent hypoglycemia," Ex-1007, 1149.

170. ***Reasonable expectation of success.*** STS Guide and Brauker both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. The concept of insulin delivery control was well known before the '528 priority date and had been applied to CGM systems. For example, a 2009 article from Kowalski discloses controlling insulin delivery. Ex-1015, S-115 (“Very-low glucose insulin pump shut off”), S-116 (“Predictive hypoglycemia minimizing system”). Hughes acknowledges that the concept of insulin delivery control was well known. Ex-1007, 1148 (“Buckingham and associates proposed a hypoglycemia prevention method based on insulin pump shutoff: when the predicted glucose concentration reaches a certain value, the pump halts the delivery of insulin.”). Several other diabetologists demonstrated the feasibility of close loop control in adults, children and adolescents, and during pregnancy. Ex-1018; Ex-1031; Ex-1032. Incorporating Brauker’s insulin delivery control would involve routine programming of the system of STS Guide.

9. Claim 19

- a) **“The method of claim 1, wherein the one or more non user settable second criteria are programmed at the factory in such a way that no user is able to modify the second criteria.”**

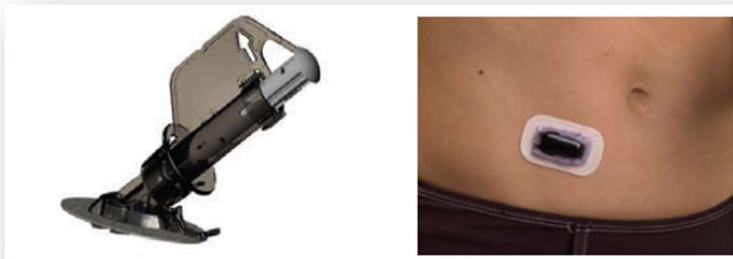
171. As discussed in Section VIII.F.1.c above for limitation 1[b], STS Guide in view of Brauker renders obvious *one or more non user settable second criteria*: “your STS™ Receiver also has an automatic low glucose alarm set at 55 mg/dL”

(i.e., *non user settable second criteria*). Ex-1008, 56. A POSITA would have known that the Low Glucose Alarm setting is *programmed at the factory in such a way that no user is able to modify* because the user is unable to “change or turn off the Low Glucose Alarm.” Ex-1008, 56.

10. Claim 20

a) “The method of claim 1, wherein the user is a host or a healthcare provider.”

172. STS Guide discloses that *the user* (i.e., the person able to set the “first criteria” and not able to set the “second criteria” of claim 1) *is a host*. STS Guide instructs the user to insert a sensor probe into the user’s body:



Ex-1008, 17 (“You [i.e., *user/host*] will insert the sensor probe just beneath the skin (subcutaneous tissue) of your abdomen (belly) using a small needle inside the STS Applicator.”). It is the same user that may set the low glucose threshold. Ex-1008, 79 (“You [i.e., *user/host*] may select low glucose alert values from 60 mg/dL to 90 mg/dL.”).

11. Claim 24

a) 24[pre]: “A system for processing data, the system comprising:”

173. STS Guide discloses “[t]he *DexCom™ STS™ Continuous Glucose Monitoring System* provides you with real time continuous glucose measurements every 5 minutes for up to 3 days” (i.e., *a system for processing data*). Ex-1008, 9; *see also id.*, 10, 14-16. Additional examples of processing by the system of STS Guide are discussed in Sections VIII.F.11.d-f below for limitations 24[c]-[e].

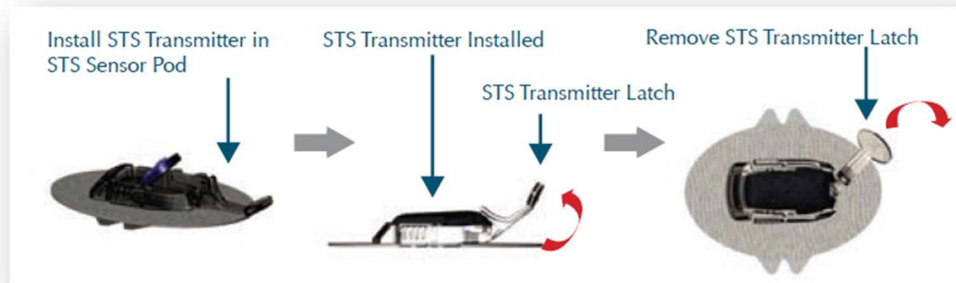
b) 24[a]: “a continuous analyte sensor configured to be implanted within a body; and”

174. “The DexCom STS System consists of three components: the STS Sensor [i.e., *continuous analyte sensor*], the STS Transmitter, and the STS Receiver.” Ex-1008, 9. STS Guide discloses that the STS Sensor is *configured to be implanted within a body*: “[t]he STS™ Sensor is a disposable unit that you *insert into your abdomen (belly)* to continuously monitor your glucose levels for up to 3 days (72 hours).” *Id.*, 10 (emphasis added).

c) 24[b]: “sensor electronics configured to receive and process sensor data output by the sensor, the sensor electronics including a processor configured to:”

175. STS Guide discloses this limitation under DexCom’s apparent interpretation (discussed below), and STS Guide in view of Brauker renders this limitation obvious under the plain meaning of this limitation.

176. STS Guide discloses that the STS Transmitter (i.e., *sensor electronics*) is configured to receive sensor data output by the sensor. STS Guide discloses that the STS Transmitter is installed on the STS Sensor. Ex-1008, 18. The figure below depicts the installation process:



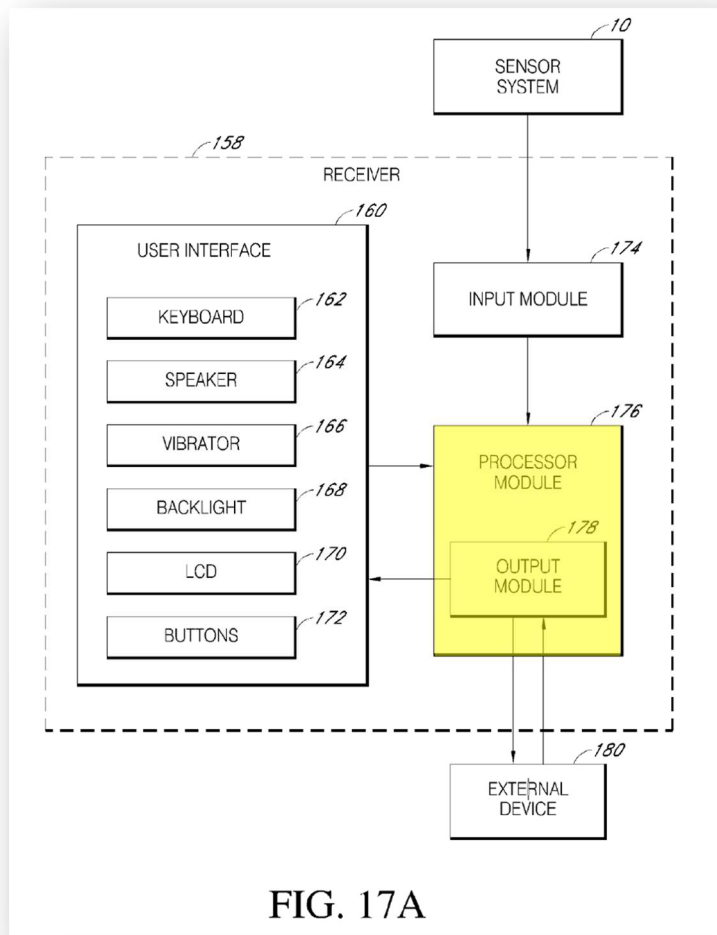
Ex-1008, 18. “The STS Transmitter wirelessly sends glucose information collected by your STS Sensor to your STS Receiver.” *Id.*, 18. Thus, the STS Transmitter is configured to receive sensor data output by the sensor.

177. A POSITA would have known that STS Guide’s STS Transmitter includes a processor because such *sensor electronics* of a CGM system typically includes a processor. Ex-1005, Fig. 14, [0424] (disclosing processor module 138 and RF module 148 of “the electronics 132 associated with the sensor system 10” in a CGM system).

178. Moreover, I understand from counsel that, based on DexCom’s infringement contentions in the co-pending district court litigation, DexCom

apparently understands this limitation to broadly include a processor located remotely from the sensor electronics, for example in a remote receiver.

179. A POSITA would have known that the STS Receiver *includes a processor*. STS Guide discloses that the STS Receiver is “[a] *pager-like device programmed to collect and process data* from the STS Sensor and to display the results as a glucose value (mg/dL or mmol/L).” Ex-1008, 16 (emphasis added). A POSITA would have known that a “pager-like device programmed to collect and process data” includes a processor. *See, e.g.*, Ex-1016, Fig. 5 (depicting a processor in a block diagram of a “typical pager”). A POSITA would also have known that a receiver of a CGM system typically includes a processor. For example, Figure 17A of Brauker illustrates processor 176 (yellow highlight below) in a receiver of a CGM system:



Ex-1005, Fig. 17A (annotated). Based on DexCom's apparent interpretation, therefore, STS Guide discloses a processor (of the STS Receiver) configured to perform the steps of evaluating sensor data and activating a hypoglycemic indicator, as discussed in Sections VIII.F.11.d-f below for limitations 24[c]-[e].

180. Under the plain meaning of this limitation, Brauker further discloses that the receiver electronics could be combined into the sensor electronics. Ex-1005, [0423] ("the sensor electronics and data processing as well as the receiver electronics

and data processing ... *can be incorporated into the wholly implantable glucose sensor*”) (emphasis added). It would have been obvious to try combining the STS Transmitter’s electronics and the STS Receiver’s electronics because Brauker teaches only two options: (1) the receiver electronics residing remotely from the sensor electronics, or (2) the receiver electronics residing in the sensor along with the sensor electronics. A POSITA would have had a reasonable expectation of success combining the STS Transmitter’s electronics and the STS Receiver’s electronics because the placement of electronics would have been a routine design choice for the system of STS Guide. Therefore, STS Guide in view of Brauker renders obvious a processor that is configured to perform the steps of evaluating sensor data and activating a hypoglycemic indicator, as discussed in Sections VIII.F.11.d-f below for limitations 24[c]-[e].

- d) **24[c]: “evaluate sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria;”**

181. See Section VIII.F.1.b above for limitation 1[a].

- e) **24[d]: “evaluate sensor data using a second function to determine whether a predicted glucose value meets one or more non-user settable second criteria;”**

182. See Section VIII.F.1.c above for limitation 1[b].

- f) **24[e]: “activate a hypoglycemic indicator if either the one or more user settable first criteria or the one or more non user settable second criteria are met; and**

provide an output based on the activated hypoglycemic indicator.”

183. See Section VIII.F.1.d above for limitation 1[c].

12. Claim 25

- a) **“The system of claim 24, wherein the evaluating sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria comprises determining whether the real-time glucose value passes a glucose threshold.”**

184. See Section VIII.F.2 above for claim 2.

13. Claim 26

- a) **“The system of claim 25, wherein the evaluating sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria further comprises determining whether an amplitude of rate of change or direction of rate of change meets a rate of change criterion.”**

185. See Section VIII.F.3 above for claim 3.

14. Claim 34

- a) **“The system of claim 24, wherein the one or more user settable first criteria comprises a first threshold that is configured to be user settable.”**

186. See Section VIII.F.4 above for claim 11.

15. Claim 35

- a) **“The system of claim 34, wherein the one or more non user settable second criteria comprises a second threshold that is not user settable.”**

187. See Section VIII.F.5 above for claim 12.

16. Claim 39

- a) **“The system of claim 24, wherein the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with it depending on whether the hypoglycemic indicator was activated based on the first function meeting the one or more user settable first criteria or whether the hypoglycemic indicator was activated based on the second function meeting the one or more non user settable second criteria.”**

188. See Section VIII.F.6 above for claim 16.

17. Claim 40

- a) **“The system of claim 24, wherein the output comprises at least one of an audible, tactile or visual output, and wherein the output is differentiated and/or provides information selectively based on whether the hypoglycemic indicator was activated based on the first function meeting the one or more user settable first criteria or whether the hypoglycemic indicator was activated based on the second function meeting the one or more non user settable second criteria.”**

189. See Section VIII.F.7 above for claim 17.

18. Claim 41

- a) **“The system of claim 24, wherein providing output comprises transmitting a message to an insulin delivery device including instructions associated with at least one of: a) suspending insulin delivery, b) initiating a hypoglycemia and/or hyperglycemia minimizer algorithm, c) controlling insulin delivery or d) information associated with the hypoglycemia indicator.”**

190. See Section VIII.F.8 above for claim 18.

19. Claim 42

- a) **“The system of claim 24, wherein the one or more non user settable second criteria are programmed at the factory in such a way that no user is able to modify the non user settable second criteria.”**

191. See Section VIII.F.9 above for claim 19.

20. Claim 43

- a) **“The system of claim 24, wherein the user is a host or a healthcare provider.”**

192. See Section VIII.F.10 above for claim 20.

G. Ground VII: Claims 5 and 28 Would Have Been Obvious Based on STS Guide in View of Brauker, Guerra, and Hughes

1. Claim 5

- a) **“The method of claim 1, wherein the evaluating sensor data using a second function to determine whether the predicted glucose value meets one or more second criteria comprises evaluating a dynamic risk of the predicted glucose value.”**

193. STS Guide in view of Brauker renders obvious claim 1.

194. As discussed in Section VIII.C.1 above for claim 5 in Ground III, Guerra discloses *evaluating a dynamic risk* and Hughes discloses evaluating a dynamic risk of *the predicted glucose value*.

195. ***Motivation to combine.*** It would have been obvious to incorporate Guerra’s evaluation of dynamic risk (as modified by Hughes to evaluate dynamic

risk of the predicted glucose value) in the system of STS Guide as modified by Brauker, for the same reasons discussed in Section VIII.C.1 above for claim 5 in Ground III. Moreover, STS Guide, Brauker, Guerra, and Hughes all relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia.

2. Claim 28

- a) **“The system of claim 24, wherein the evaluating sensor data using a second function to determine whether the predicted glucose value meets one or more non user settable second criteria comprises evaluating a dynamic risk of the predicted glucose value.”**

196. See Section VIII.G.1 above for claim 5.

H. Ground VIII: Claims 13 and 36 Would Have Been Obvious Based on STS Guide in View of Brauker and Hughes

1. Claim 13

- a) **“The method of claim 1, wherein the one or more non user settable second criteria comprises a prediction horizon.”**

197. STS Guide in view of Brauker renders obvious claim 1.

198. For claim 13, Hughes discloses a prediction horizon and teaches that its prediction horizon τ is “a parameter that must be specified” in computing the “projected [glucose] concentration” $\hat{y}(k)$. Ex-1007, 1150.

199. ***Motivation to combine.*** It would have been obvious to incorporate Hughes’s prediction horizon in the STS Guide-Brauker combination’s non user

settable second criteria, for the same reasons discussed in Section VIII.D.1 above for claim 13 in Ground IV.

2. Claim 36

- a) **“The system of claim 24, wherein the one or more non user settable second criteria comprises a prediction horizon that is not user settable.”**

200. *See* Section VIII.H.1 above for claim 13.

I. Ground IX: Claims 16 and 39 Would Have Been Obvious Based on STS Guide in View of Brauker and Say

1. Claim 16

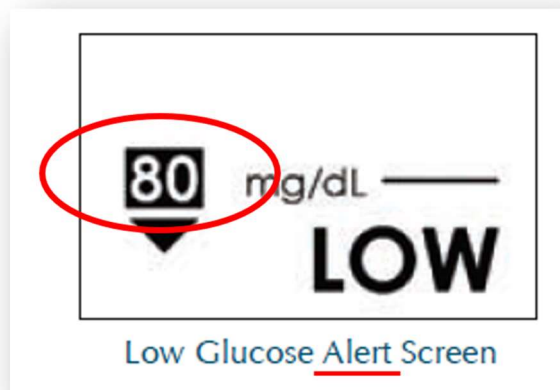
- a) **“The method of claim 1, wherein the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with it depending on whether the hypoglycemic indicator was activated based on the first function meeting the one or more user settable first criteria or whether the hypoglycemic indicator was activated based on the second function meeting the one or more non user settable second criteria.”**

201. In analyzing a similar claim¹² of the '215 patent, the Board found that the combination of Say and STS Guide renders the challenged claim obvious. IPR2022-00909, Paper 38 at 69 (P.T.A.B. Nov. 1, 2023).

202. STS Guide in view of Brauker renders obvious claim 1.

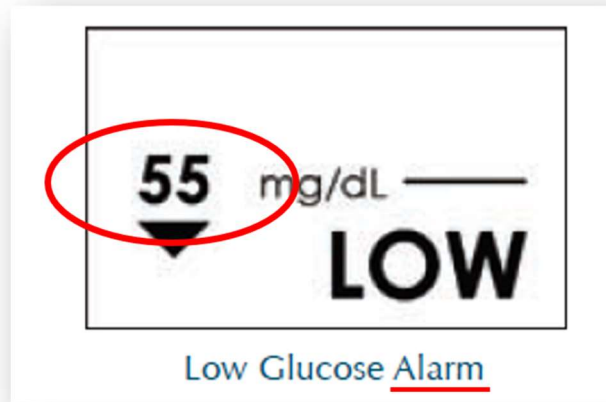
¹² Claim 23 of the '215 patent (Ex-1012) is identical to claim 16 of the '528 patent, except for the claim from which it depends.

203. For claim 16, STS Guide discloses that, when *the hypoglycemic indicator is activated based on the first function meeting the one or more user settable first criteria*, a Low Glucose **Alert** Screen is displayed with the glucose value shown on **black** background (i.e., *hypoglycemic indicator comprises a flag that has a particular display*):



Ex-1008, 54 (annotated).

204. In contrast, when *the hypoglycemic indicator is activated based on the second function meeting the one or more non user settable second criteria*, a Low Glucose **Alarm** screen is displayed with the glucose value shown on **white** background (i.e., *hypoglycemic indicator comprises a flag that has a particular display*):



Ex-1008, 56 (annotated).

205. Say further discloses displaying *a particular set of instructions* to the user: in addition to displaying “symbols or other indicators,” “the display 154 also provides a message to the patient to direct the patient in an action.” Ex-1009, 50:47-48. “Such messages [i.e., *a particular set of instructions*] may include, for example, ‘Eat Sugar’, if the patient is hypoglycemic, or ‘Take Insulin’, if the patient is hyperglycemic.” *Id.*, 50:48-51; *see also* IPR2022-00909, Paper 38 at 69 (P.T.A.B. Nov. 1, 2023).

206. ***Motivation to combine.*** It would have been obvious to incorporate Say’s particular set of instructions in the system of STS Guide (as modified by Brauker). STS Guide, Brauker, and Say all relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. A POSITA would have understood the benefits of specific instructions to the user, prompting the user to

take action to reduce the likelihood or severity of hypoglycemia. For example, Brauker teaches using a predicted low glucose alert advantageously provides the user the opportunity to take action. Ex-1005, [0702] (“By providing data in a format that emphasizes the possibility of clinical risk to the patient, *appropriate action can be taken by the user* (for example, patient or caretaker) and clinical risk can be preempted.”) (emphasis added). Brauker also teaches providing therapy recommendations such as “consume carbohydrates” or “inject insulin.” *Id.*, [0719]. Brauker further discloses customizing therapy recommendations depending on the “severity of medical condition.” *Id.* Hughes also teaches the importance of user action. Ex-1007, 1148 (“In order to be effective in reducing the incidence of hypoglycemia, alarms must be accompanied by some type of action.”).

207. Therefore, it would have been obvious to a POSITA to associate STS Guide’s real time, user settable *alert* with an accompanying instruction such as, “Eat sugar now because you are below your target level,” and to associate the STS Guide-Brauker combination’s predicted, non user settable *alarm* with a different instruction such as, “Eat sugar to prevent hypoglycemia. You are at risk of experiencing hypoglycemia within 30 minutes.”

208. Moreover, combining STS Guide (as modified by Brauker) with Say would have been combining prior art elements (i.e., the STS Guide-Brauker combination’s alerts/alarms with Say’s particular set of instructions) according to

known methods to yield predictable results (i.e., providing appropriate instructions to treat or prevent hypoglycemia). The combination also uses a known technique (i.e., Say's particular set of instructions) to improve similar devices in the same way.

209. ***Reasonable expectation of success.*** STS Guide, Brauker, and Say all relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. It would have been within the abilities of a POSITA to add accompanying instructions to the low glucose alert/alarm. Such a modification would involve routine programming of STS Guide's system (as modified by Brauker).

2. Claim 39

- a) **“The system of claim 24, wherein the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with it depending on whether the hypoglycemic indicator was activated based on the first function meeting the one or more user settable first criteria or whether the hypoglycemic indicator was activated based on the second function meeting the one or more non user settable second criteria.”**

210. See Section VIII.I.1 above for claim 16.

IX. EVIDENCE OF NON-OBVIOUSNESS

211. It is my understanding that in order for evidence of non-obviousness to be relevant, there must be a nexus between the claimed invention and the evidence. I am not aware of any evidence of non-obviousness. I reserve the right to respond to any purported objective evidence of non-obviousness raised by Patent Owner.

X. CONCLUSION

212. I declare 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.

May 1, 2024
Date


David Rodbard, M.D.