

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

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,119,528
UNDER 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42.100 *et seq.***

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List of Exhibits

Exhibit	Description
1001	U.S. Patent No. 9,119,528 (the “528 patent”)
1002	File History for U.S. Patent No. 9,119,528
1003	Declaration of Dr. David Rodbard
1004	Curriculum Vitae of Dr. David Rodbard
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™ STS™ 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-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

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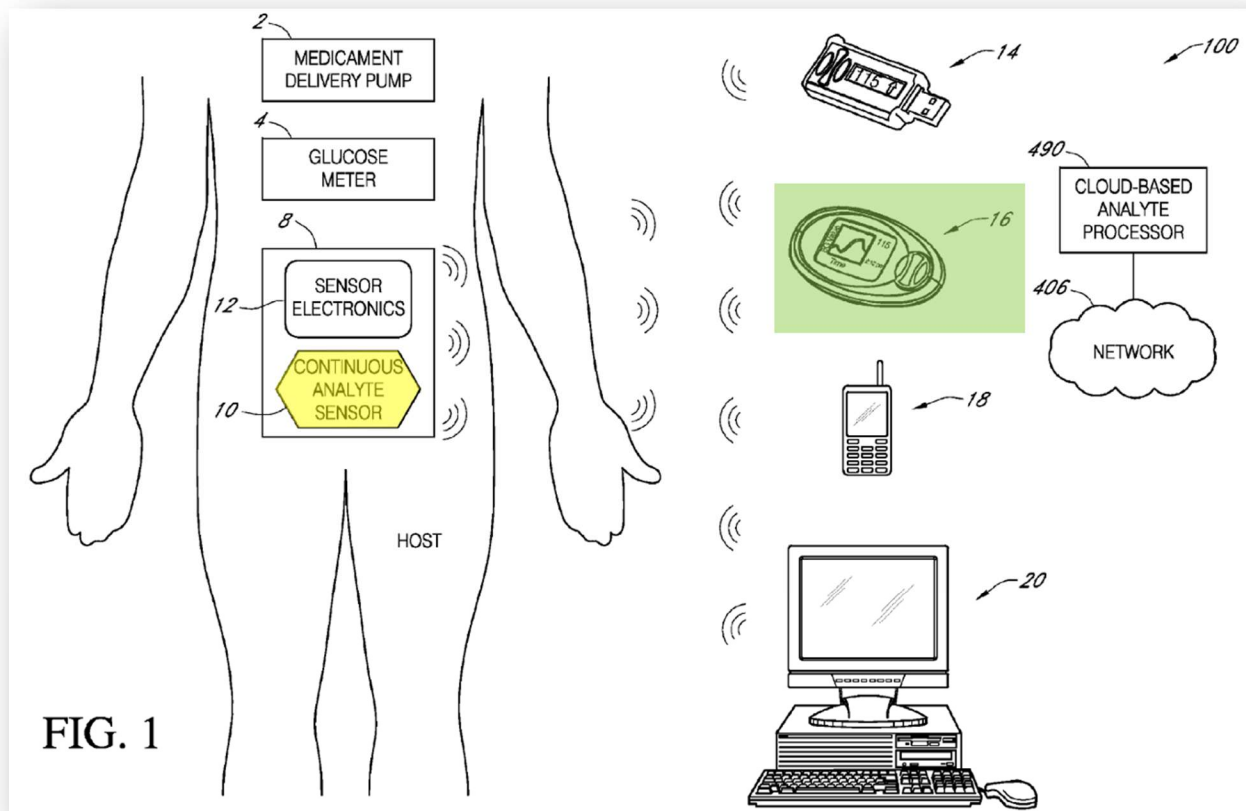
Exhibit	Description
1017	Premarket Approval (PMA) Order, FreeStyle Navigator Continuous Glucose Monitoring System (Mar. 12, 2008), https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050020A.pdf
1018	Garry M. Steil et al., <i>Feasibility of Automating Insulin Delivery for the Treatment of Type 1 Diabetes</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
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.
1028	Approved Judgment, In the High Court of Justice, Business and Property Courts of England and Wales, Intellectual Property List (ChD) Patents Court, [2024] EWHC 36 (Pat)
1029	European Patent No. 2,914,159
1030	<i>Abbott Diabetes Care Inc. et al v. DexCom, Inc.</i> , No. 1:23-cv-00239, Dkt. 54 (D. Del. Sept. 19, 2023) (“Scheduling Order”)
1031	Stuart A. Weinzierl 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)

I. INTRODUCTION

Abbott Diabetes Care Inc. (“Abbott” or “Petitioner”) petitions for *inter partes* review of claims 1-3, 5, 11-13, 16-20, 24-26, 28, 34-36, and 39-43 (the “Challenged Claims”) of U.S. Patent No. 9,119,528 (Ex-1001, “’528 patent”), assigned to DexCom, Inc. (“DexCom”).

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). This petition makes similar arguments for the ’528 claims corresponding to the ’215 claims that were found unpatentable, and demonstrates unpatentability for the ’528 claims corresponding to the other two ’215 claims that were found to be patentable.

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.

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.

DexCom, however, was the assignee on published patent applications and the publisher of user’s guides disclosing such CGM systems, years before the priority date of the ’528 patent. For example, DexCom’s Brauker patent application publication (Ex-1005) discloses a CGM system with both (1) a real time, user settable low glucose alarm, and (2) a predicted, non user settable low glucose alarm. Ex-1005, [0011], [0015].

Moreover, DexCom’s STSTM Continuous Glucose Monitoring System User’s Guide (Ex-1008) (“STS Guide”) discloses a CGM system with (1) a user settable low glucose alarm, and (2) a non user settable low glucose alarm. Ex-1008, 54, 56. Both alarms in STS Guide are real time alarms, and it would have been obvious to add a predicted alarm because predicted alarms (and their benefits) were well known.

II. STANDING, MANDATORY NOTICES, AND FEE AUTHORIZATION

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the ’528 patent is available for IPR and that Petitioner is not barred or estopped from requesting an IPR challenging the ’528 patent on the grounds identified in this petition.

B. Real Parties-in-Interest

The real parties-in-interest are Abbott Diabetes Care Inc., Abbott Diabetes Care Sales Corp., and Abbott Laboratories. Abbott Diabetes Care Inc. is the Petitioner. Abbott Diabetes Care Inc. is directly owned by Abbott Laboratories. Abbott Diabetes Care Inc. directly owns Abbott Diabetes Care Sales Corp.

C. Related Matters

Petitioner identifies the following related matters.

- The '528 patent is the parent of the '215 patent, which was challenged in IPR2022-00900. The Board found claims 1-4, 19 and 23 of the '215 patent to be unpatentable. Both parties have filed notices of appeal to the Court of Appeals for the Federal Circuit.
- The '528 patent is asserted against Abbott Diabetes Care Inc. and Abbott Diabetes Care Sales Corp. as a counterclaim for infringement in *Abbott Diabetes Care Inc. et al v. DexCom, Inc.*, No. 1:23-cv-00239 (D. Del). DexCom asserted the '528 patent in its Answer, Affirmative Defenses, and Counterclaims, electronically served on Petitioner Abbott Diabetes Care Inc. on May 12, 2023, and hand-served on Abbott Diabetes Care Sales Corp. on May 15, 2023. Petitioner asserts that the '528 patent is not infringed.

D. Counsel Information

Petitioner designates the following counsel:

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Pursuant to 37 C.F.R. § 42.10 (b), Petitioner has filed a power of attorney with the above designation of counsel.

E. Service Information

Service information is provided in the designation of counsel above. Petitioner consents to service of all documents via electronic mail at the email addresses above and at Abbott-IPR@cov.com.

F. Payment of Fees Under 37 C.F.R. §42.103

This petition is accompanied by the fees set forth in 37 C.F.R. § 42.15(a). Please charge or credit Deposit Account No. 60-3160 with any shortage or

overpayment of fees associated with this petition and any other fees incurred by Petitioner.

III. SUMMARY OF CHALLENGE

- **Ground I:** Claims 1-2, 11-12, 16, 18-20, 24-25, 34-35, 39, and 41-43 would have been anticipated and/or obvious based on Brauker (Ex-1005) under 35 U.S.C. §§ 102, 103.
- **Ground II:** Claims 3 and 26 would have been obvious based on Brauker in view of Guerra (Ex-1006) under 35 U.S.C. § 103.
- **Ground III:** Claims 5 and 28 would have been obvious based on Brauker in view of Guerra and Hughes (Ex-1007) under 35 U.S.C. § 103.
- **Ground IV:** Claims 13 and 36 would have been obvious based on Brauker in view of Hughes under 35 U.S.C. § 103.
- **Ground V:** Claims 16, 17, 39, and 40 would have been obvious based on Brauker in view of STS Guide (Ex-1008) under 35 U.S.C. § 103.
- **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 under 35 U.S.C. § 103.
- **Ground VII:** Claims 5 and 28 would have been obvious based on STS Guide in view of Brauker, Guerra, and Hughes under 35 U.S.C. § 103.
- **Ground VIII:** Claims 13 and 36 would have been obvious based on STS Guide in view of Brauker and Hughes under 35 U.S.C. § 103.

- **Ground IX:** Claims 16 and 39 would have been obvious based on STS Guide in view of Brauker and Say (Ex-1009) under 35 U.S.C. § 103.

The '528 patent was filed on January 16, 2013 and claims priority to a provisional application filed on October 30, 2012. Each of the asserted references is available as prior art under 35 U.S.C. § 102 (pre-AIA),¹ as shown in the following table.

Exhibit	Reference	Date(s)	Availability as Prior Art
Ex-1005	U.S. Patent Application Publication No. 2007/0208244 (“Brauker”)	September 6, 2007 (published)	§ 102(b)
Ex-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”)	July 27, 2011 (publicly accessible)	§ 102(b)
Ex-1007	Colleen S. Hughes et al., <i>Hypoglycemia Prevention via Pump Attenuation and Red-Yellow-Green “Traffic” Lights Using Continuous Glucose</i>	September 1, 2010 (publicly accessible)	§ 102(b)

¹ Because the application for the '528 patent was filed prior to March 16, 2013, the pre-AIA conditions for patentability apply.

Exhibit	Reference	Date(s)	Availability as Prior Art
	<i>Monitoring and Insulin Pump Data</i> , Journal of Diabetes Science and Technology, 4(5), 1146-1155 (Sept. 2010) (“Hughes”)		
Ex-1008	DexCom™ STS™ Continuous Glucose Monitoring System User’s Guide (“STS Guide”)	October 23, 2007 (publicly accessible)	§ 102(b)
Ex-1009	U.S. Patent No. 6,565,509 (“Say”)	May 20, 2003 (issued)	§ 102(b)

IV. THE ’528 PATENT

A. Overview of the ’528 Patent

The purported invention of the ’528 patent is combining (1) a user settable real time low glucose alert with (2) a non user settable predicted low glucose alert, “where an alert will sound for whichever condition is met first (threshold or prediction).” Ex-1001, 21:50-53; *see also* Ex-1003 ¶¶34-36.

B. Prosecution History

The ’528 patent was filed on January 16, 2013, claiming priority to U.S. Provisional Application No. 61/720,286, 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; *see also* Ex-1003 ¶37.

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.” Ex-1002, 1298-1310; *see also* Ex-1003 ¶38.

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). Ex-1002, 1342-1371; *see also* Ex-1003 ¶39.

In response, on April 23, 2015, DexCom argued that Harper and Botvinick “neither disclose[] nor suggest[] an evaluation of whether a predicted glucose value meets one or more non user settable criteria.” Ex-1002, 1385, 1397; *see also* Ex-1003 ¶40.

In a Notice of Allowance, the examiner stated that Botvinick did not disclose non user settable criteria. Ex-1002, 1414; *see also* Ex-1003 ¶41. DexCom had failed during prosecution to disclose that its own Brauker application (Ex-1005) and its own product’s user guide (Ex-1008) disclosed non user settable criteria.

C. Challenged Claim Listing

1. Claim 1

1[pre]	A method of activating a hypoglycemic indicator based on continuous glucose sensor data, the method comprising:
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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;
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;
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.

2. Claim 2

2	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.
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3. Claim 3

3	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.
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4. Claim 5

5	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.
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5. Claim 11

11	The method of claim 1, wherein the one or more user settable first criteria comprises a first threshold that is configured to be user
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	settable.
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6. Claim 12

12	The method of claim 11, wherein the one or more non user settable second criteria comprises a second threshold that is not user settable.
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7. Claim 13

13	The method of claim 1, wherein the one or more non user settable second criteria comprises a prediction horizon.
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8. Claim 16

16	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.
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9. Claim 17

17	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.
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10. Claim 18

18	The method of claim 1, wherein providing an output comprises
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	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.
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11. Claim 19

19	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.
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12. Claim 20

20	The method of claim 1, wherein the user is a host or a healthcare provider.
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13. Claim 24

24[pre]	A system for processing data, the system comprising:
24[a]	a continuous analyte sensor configured to be implanted within a body; and
24[b]	sensor electronics configured to receive and process sensor data output by the sensor, the sensor electronics including a processor configured to:
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;
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;
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.

14. Claim 25

25	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.
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15. Claim 26

26	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.
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16. Claim 28

28	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.
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17. Claim 34

34	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.
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18. Claim 35

35	The system of claim 34, wherein the one or more non user settable second criteria comprises a second threshold that is not user settable.
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19. Claim 36

36	The system of claim 24, wherein the one or more non user settable
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	second criteria comprises a prediction horizon that is not user settable.
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20. Claim 39

39	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.
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21. Claim 40

40	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.
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22. Claim 41

41	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.
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23. Claim 42

42	The system of claim 24, wherein the one or more non user settable
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	second criteria are programmed at the factory in such a way that no user is able to modify the non user settable second criteria.
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24. Claim 43

43	The system of claim 24, wherein the user is a host or a healthcare provider.
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V. LEVEL OF ORDINARY SKILL

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. Ex-1003 ¶43.

VI. CLAIM CONSTRUCTION

In IPR proceedings, claims are construed in accordance with their “ordinary and customary meaning” in light of the specification. 37 C.F.R. § 42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). For purposes of this petition, Petitioner does not believe that any specialized constructions are necessary. Petitioner also reserves the right to dispute in a different forum whether the Challenged Claims meet the requirements under 35 U.S.C. §§ 101 or 112.

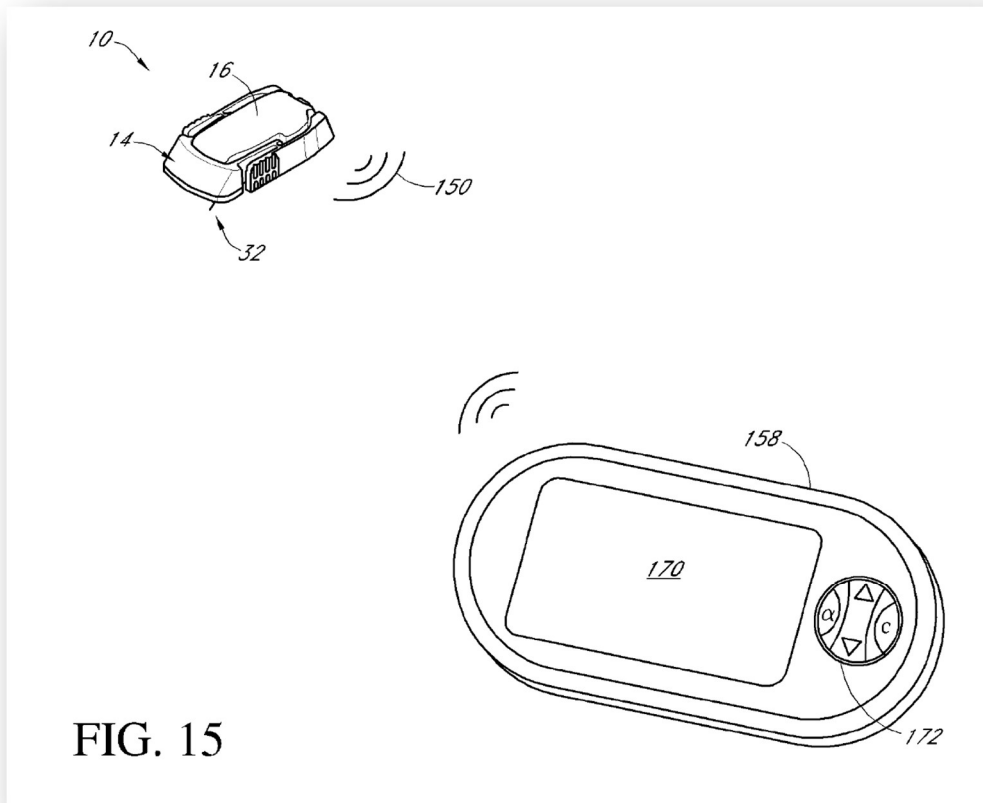
VII. OVERVIEW OF THE PRIOR ART²

A. Brauker (Ex-1005)

Brauker was published on September 6, 2007, and is prior art under 35 U.S.C. § 102(b). Despite DexCom being the initial assignee of the Brauker application, Brauker was not of record during prosecution of the '528 patent.

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:

² All of the prior art references are from the same field of endeavor as the claimed invention and thus are analogous art. See Section V of Ex-1003 for technology background.



Ex-1005, Fig. 15.

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. Ex-1003 ¶¶47-51. 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 “the receiver comprises programming configured to estimate glucose data for a future time” and “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]; *see also* Ex-1003 ¶49. 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. Ex-1003 ¶49.

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.*

B. Guerra (Ex-1006)

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 ¶74. It is thus prior art under pre-AIA 35 U.S.C. §102(b). Guerra was cited in an IDS along with over 180 other references, but not relied upon or otherwise meaningfully addressed by the examiner during prosecution of the ’528 patent.

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); see also Ex-1003 ¶¶ 52-53.

C. Hughes (Ex-1007)

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 ¶74. It is prior art under 35 U.S.C. § 102(b). Hughes was not of record during prosecution of the ’528 patent.

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

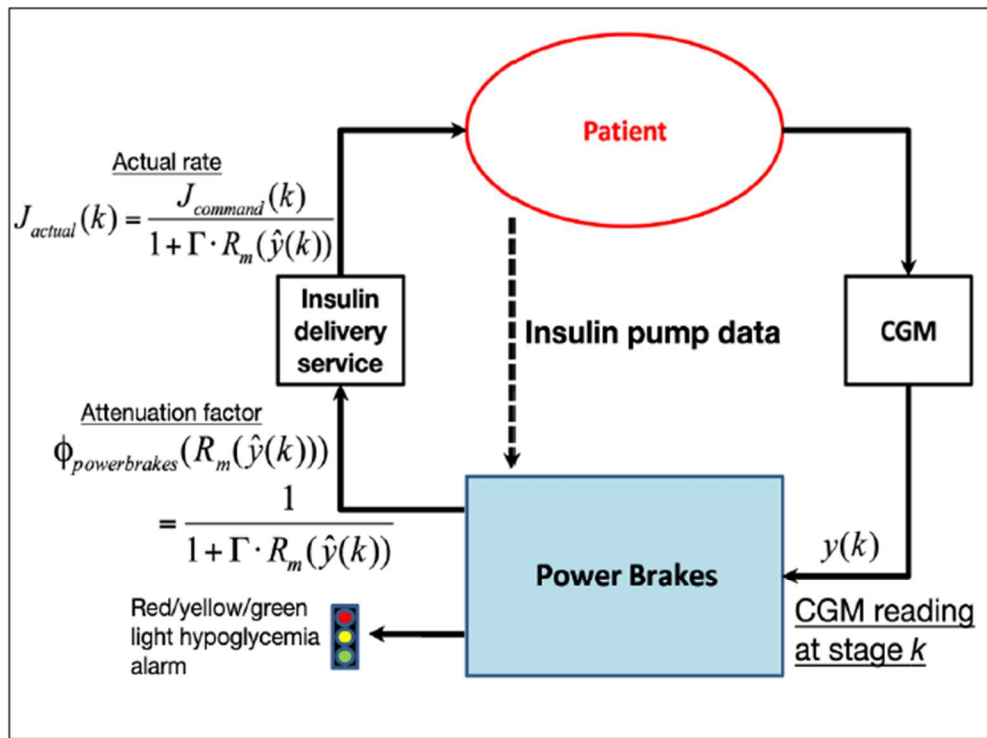


Figure 3. Schematic of Power Brakes.

Ex-1007, Fig. 3. Hughes discloses evaluating a risk of hypoglycemia using a dynamic risk function R_m of a predicted glucose value $\hat{y}(k)$. *Id.*, 1150-51; *see also* Ex-1003 ¶¶54-55. Hughes further discloses controlling insulin delivery, as well as providing red-yellow-green light alerts based on a dynamic risk function. Ex-1007, 1150-51; *see also id.*, 1147.

D. STS Guide (Ex-1008)

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 ¶74. It is thus prior art under 35 U.S.C. § 102(b). 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).

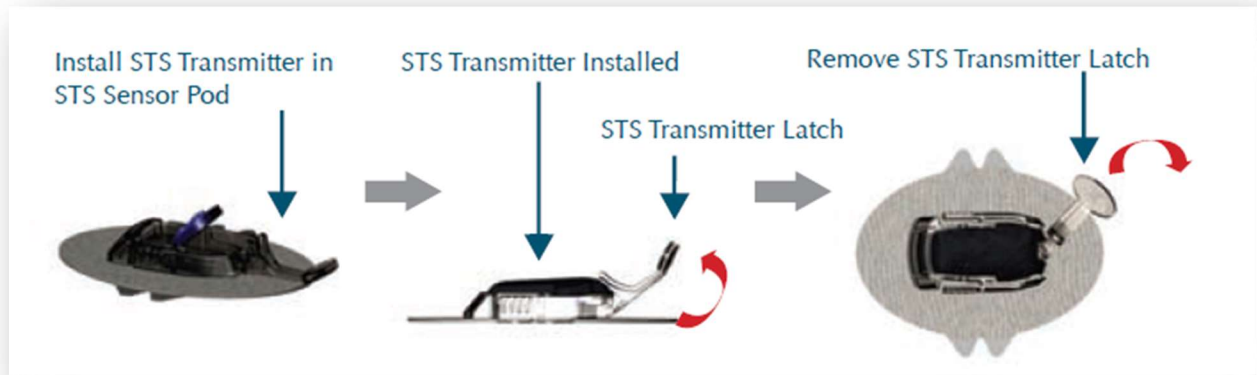
DexCom published the STS Guide (Ex-1008), but failed to make the STS Guide of record during prosecution. It is the same “User’s Guide” based on which the Board found unpatentable all but two of the challenged claims of the '215 patent. IPR2022-00909, Paper 38 at 70-71 (P.T.A.B. Nov. 1, 2023).

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.

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

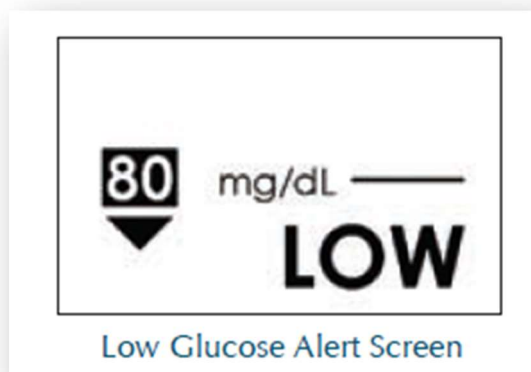


Ex-1008, 18.

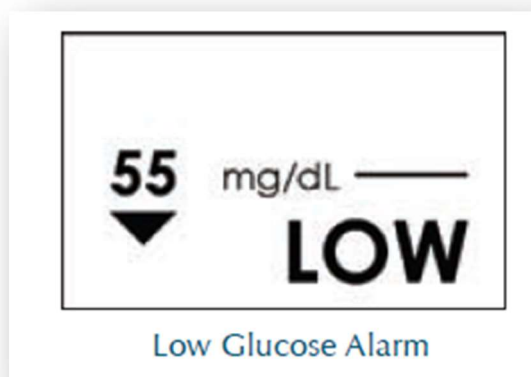
The receiver displays the received glucose values:



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:



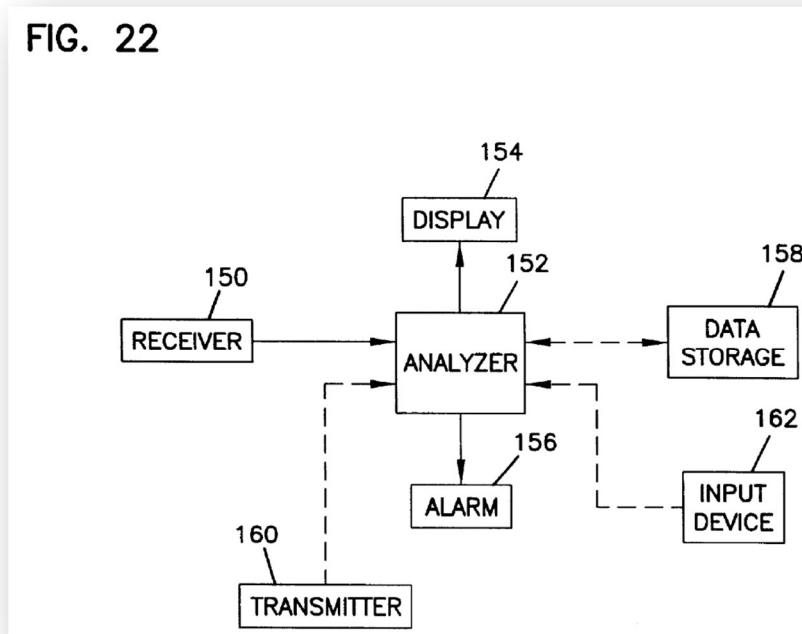
Ex-1008, 56; *see also* Ex-1003 ¶¶56-60.

E. Say (Ex-1009)

Say was issued on May 20, 2003, and is prior art under 35 U.S.C. § 102(b). 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 or otherwise meaningfully addressed 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.

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.



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; *see also* Ex-1003 ¶¶61-62.

VIII. APPLICATION OF PRIOR ART TO THE CHALLENGED CLAIMS

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:”

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); Ex-1003 ¶69. 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].

³ *Italics* indicates claim language.

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;”

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]; Ex-1003 ¶70.

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].

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).

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. Ex-1003 ¶73.

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;”

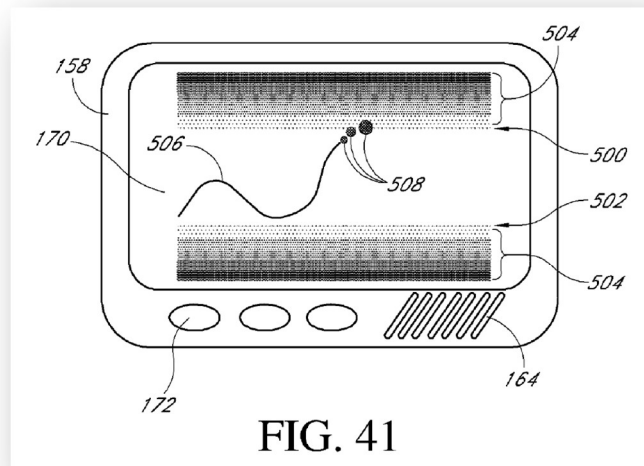
In describing the “first aspect,” Brauker further discloses *evaluating sensor data using a second function to determine* when “the estimated glucose data for the

future time [i.e., *predicted glucose value*] is below a predetermined threshold [i.e., *non user settable second criteria*].”⁴ Ex-1005, [0015]; *see also* Ex-1003 ¶74. 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]. Therefore, Brauker discloses a non user settable predetermined threshold. *Upsher-Smith Lab’ys, Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1322 (Fed. Cir. 2005). In *Upsher-Smith*, a prior art reference disclosed a vitamin that “optionally includes” antioxidants. *Id.* The Federal Circuit held that this “optional inclusion” of antioxidants taught both a vitamin including antioxidants and a vitamin excluding antioxidants, and therefore, the prior art reference “anticipate[d] the asserted claims [that exclude antioxidants] despite no express teaching to exclude the antioxidants.” *Id.*

Similarly, Brauker teaches that thresholds can optionally be user settable or non user settable. In describing another embodiment, Brauker discloses that the

⁴ In considering a similar claim of a European counterpart (Ex-1029) to the ’528 patent, the UK High Court found in January 2024 that Brauker anticipated the claim. Ex-1028, 124 (“Brauker discloses user-settable current alarms and fixed-threshold predictive alarms, and the two types of alarms in combination.”).

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 option 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. Ex-1003 ¶74.

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]; *see also* Ex-1003 ¶75.

Obviousness. Brauker also renders this limitation obvious. Ex-1003 ¶¶76-78. As discussed above, Brauker teaches that the predetermined threshold of the “first aspect” (Ex-1005, [0015]) can optionally be user settable or non user settable. Ex-1005, [0035], [0697]-[0698]. It would have been obvious to try a non user settable predetermined threshold. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007); Ex-1003 ¶76.

A POSITA would have understood the advantages of using a non user settable low glucose alarm. Ex-1003 ¶77. 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), 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. Ex-1003 ¶77. 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.⁵ *Id.* A POSITA would have had a reasonable expectation of success. *Id.* 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. Ex-1003 ¶77.

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. Ex-1003 ¶78. 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

⁵ 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.

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. *Id.* A POSITA would have had a reasonable expectation of success. *See id.*; 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.”

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”); Ex-1003 ¶79.

Additional examples of output are discussed in Sections VIII.A.5-6 below for claims 16 and 18. Ex-1003 ¶80.

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.”**

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.”**

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.”**

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.”**

Brauker discloses providing therapy recommendations (i.e., *a particular set of instructions*) such as “consume carbohydrates” or “inject insulin.”⁶ Ex-1005, [0719]. Brauker further discloses customizing therapy recommendations depending on the “severity of medical condition.” *Id.*; *see also id.*, [0248].

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

⁶ 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.

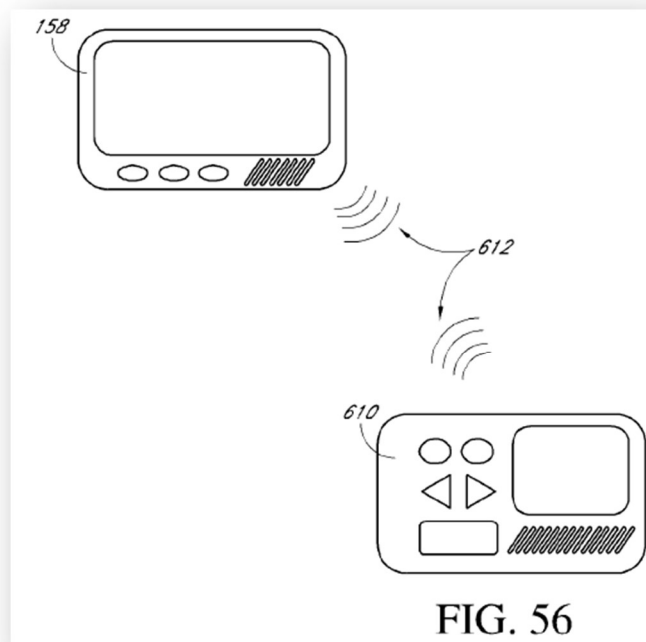
medical condition differs depending on whether the alarm was based on (1) a real time glucose value falling below a user settable threshold, or (2) a predicted glucose value expected to fall below a non user settable threshold. Ex-1003 ¶¶84-85. Therefore, Brauker discloses and/or renders obvious that *the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with each of the two activation scenarios above. Id.* 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 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." *Id.*

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]; *see also* Ex-1003 ¶86.

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.”

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]; *see also* Ex-1003 ¶87.



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-1003, ¶87; Ex-1023, 825.

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.”**

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. Ex-1003 ¶88. 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.⁷

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.”

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 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); Ex-1003 ¶89. 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).

⁷ Brauker discloses other options where thresholds can be user settable, but claim 19 applies only to non user settable criteria.

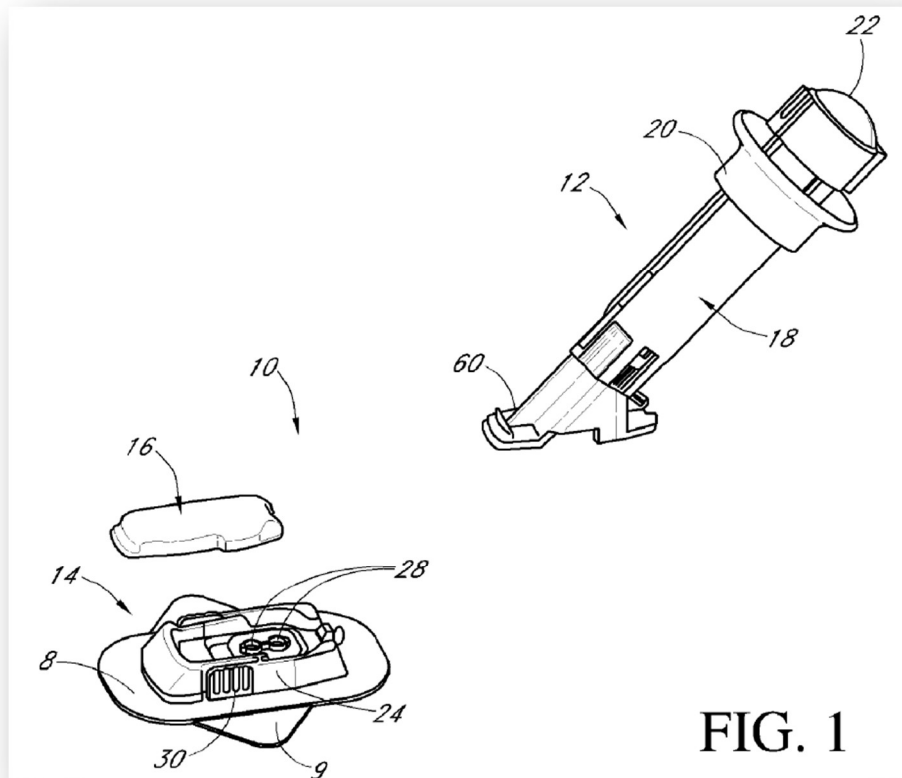
9. Claim 24

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

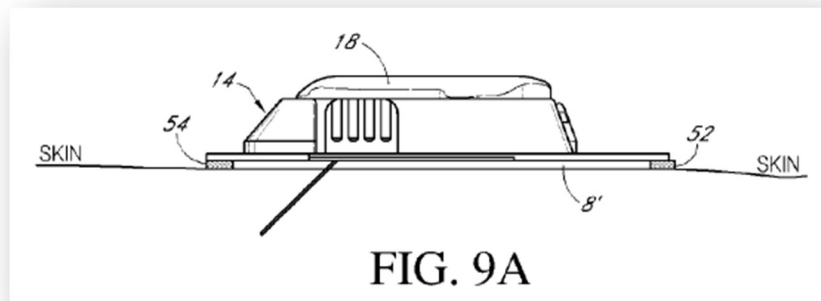
Brauker discloses a “*system* comprising a continuous glucose sensor configured to *produce a signal indicative of a glucose concentration in a host*; and a receiver operably connected to the sensor, wherein the receiver ... comprises programming configured to *calibrate the signal, to display a graphical 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); *see also* Ex-1003 ¶90. 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”

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]; *see also* Ex-1003 ¶91. “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].

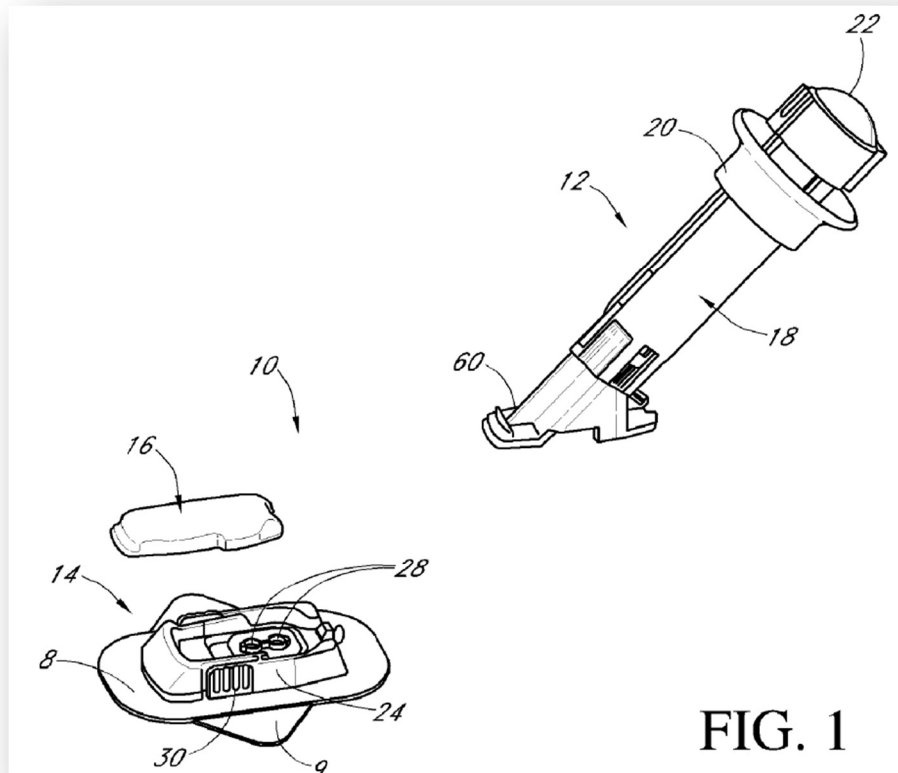


Ex-1005, Fig. 9A.

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

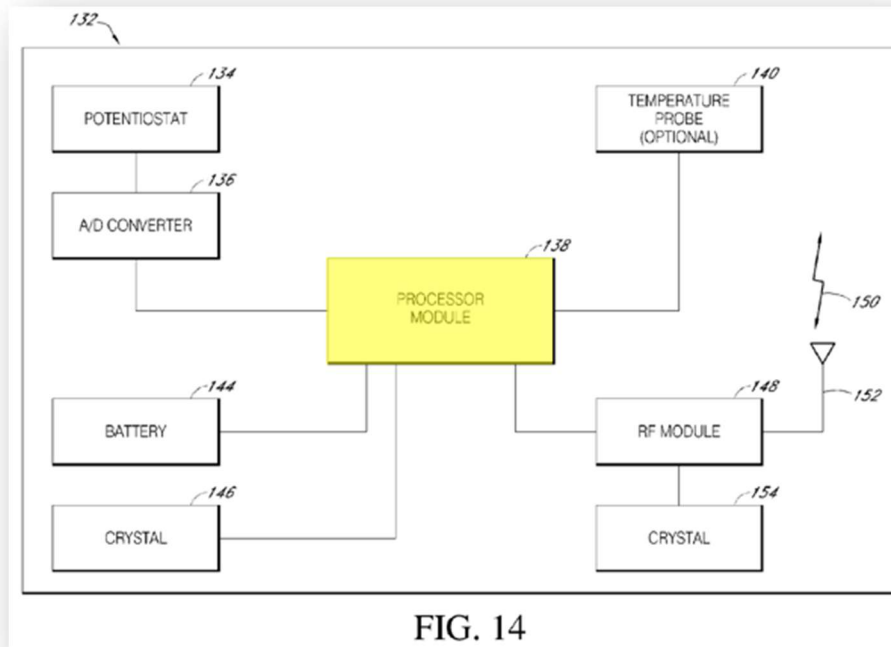
“FIG. 1 is a perspective view of a transcutaneous analyte sensor system 10.”

Ex-1005, [0260].



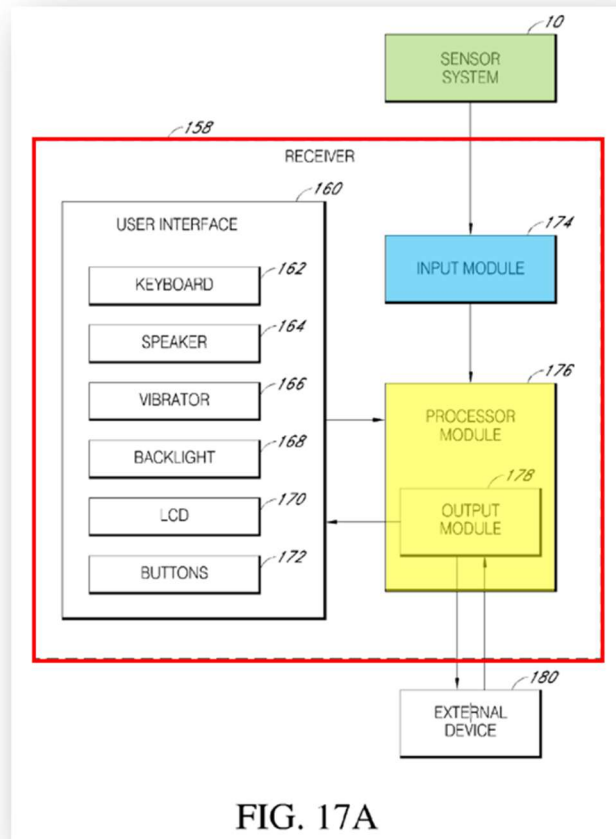
Ex-1005, Fig. 1. “In the preferred embodiment of a system as depicted in FIG. 1, the sensor includes an applicator 12, a mounting unit 14, and an electronics unit 16 [i.e., *sensor electronics*].” *Id.*, [0260]. Brauker discloses that the electronics unit 16 is *configured to receive and process sensor data output by the sensor*. *Id.*, [0263]; Ex-1003 ¶92.

Brauker further discloses that the “sensor electronics” *include a processor*. Ex-1005, [0423]-[0424]; *see also* Ex-1003 ¶93. “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).

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



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]. Ex-1003 ¶94.

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. *See KSR*, 550 U.S. at 421; Ex-1003 ¶95. 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. Ex-1003 ¶95.

- 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;”**

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;”**

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.”**

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.”**

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.”**

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.”**

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.”**

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.”**

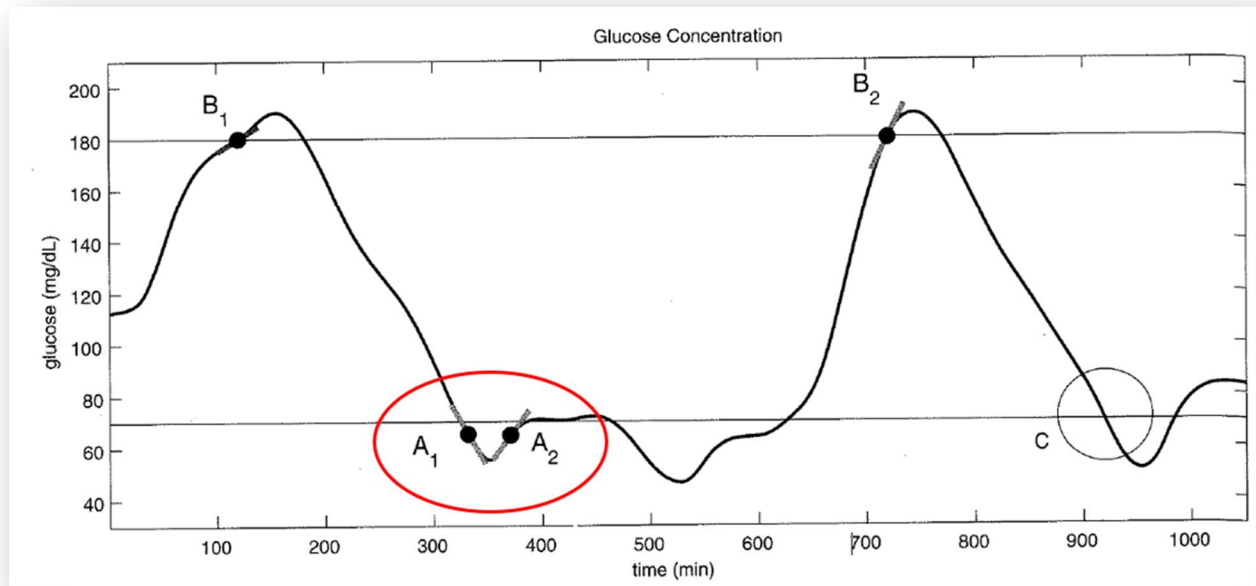
See Section VIII.A.8 above for claim 20.

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.”**

Brauker anticipates and/or renders obvious claim 2. For claim 3, Guerra discloses *determining whether direction of rate of change meets a rate of change criterion*. Ex-1003 ¶105. 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 A₁ and A₂ (shown below in red oval), “the clinical risk associated with points A₁ and A₂ should be different.” Ex-1006, 844.



Ex-1006, 844 (annotated). “In fact, the A_1 situation is more dangerous for the patient than A_2 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).

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. Ex-1003 ¶106. 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-1003 ¶106;

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 ... can provide information indicative of approaching clinical risk.”) (emphasis added).

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 an accurate, advance detection of hypoglycemia, making it possible to reduce the incidence or severity of hypoglycemia). Ex-1003 ¶107. The combination also uses a known technique (i.e., Guerra’s evaluation of rate of change) to improve similar devices in the same way. *Id.*

Reasonable expectation of success. Brauker and Guerra both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. Ex-1003 ¶108. 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. Ex-1003 ¶108.

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.”**

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

- 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.”**

Brauker anticipates and/or renders obvious claim 1. For claim 5, Guerra discloses *evaluating a dynamic risk* of a glucose value. Ex-1003 ¶¶110-11. As discussed 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.

Like Guerra, Hughes discloses evaluating a dynamic risk, and further discloses evaluating a dynamic risk *of the predicted glucose value*, $\hat{y}(k)$.⁸ Ex-1007, 1150; *see also* Ex-1003 ¶112. Specifically, Hughes discloses a risk of hypoglycemia function R_m , which takes as input the *predicted glucose value* $\hat{y}(k)$:

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

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 $\hat{y}(k)$.

⁸ Kovatchev, who developed the original static risk model (Ex-1022), is a co-author of the Hughes article (Ex-1007).

If the predicted glucose value $\hat{y}(k)$ is between 20 and 120 mg/dl ***and it is decreasing*** ($\frac{d\hat{y}(k)}{dk} < 0$) (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; *see also* Ex-1003 ¶113.

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). Ex-1007, 1150; *see also* Ex-1003 ¶114.

Motivation to combine. It would have been obvious to incorporate Guerra's evaluation of dynamic risk into the system of Brauker, as discussed above for claim 3. Ex-1003 ¶115. 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. *Id.* Like Brauker and Guerra, Hughes relates to a CGM system with alerts to reduce the incidence or severity of hypoglycemia.

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 an accurate, advance detection of hypoglycemia, making it possible to reduce the incidence or severity of hypoglycemia). Ex-1003 ¶ 116. 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. *Id.*

Reasonable expectation of success. Brauker, Guerra, and Hughes all relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. Ex-1003 ¶117. 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. Ex-1003 ¶117.

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.”**

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.”**

Brauker anticipates and/or renders obvious claim 1.

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. Ex-1003 ¶120. 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. *Id.*

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; *see also* Ex-1003 ¶121.

Motivation to combine. It would have been obvious to incorporate Hughes’s prediction horizon in Brauker’s predicted low glucose alarm. Ex-1003 ¶122. 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*. *Id.* 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. *Id.* 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 above for limitation 1[b]. *Id.*

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 an accurate, advance detection of hypoglycemia, making it possible to reduce the incidence or severity of hypoglycemia). Ex-1003 ¶123. The combination also uses a known technique (i.e., Hughes's prediction horizon) to improve similar devices in the same way. *Id.*

Reasonable expectation of success. Brauker and Hughes both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. Ex-1003 ¶124. 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. Ex-1003 ¶124.

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.”**

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

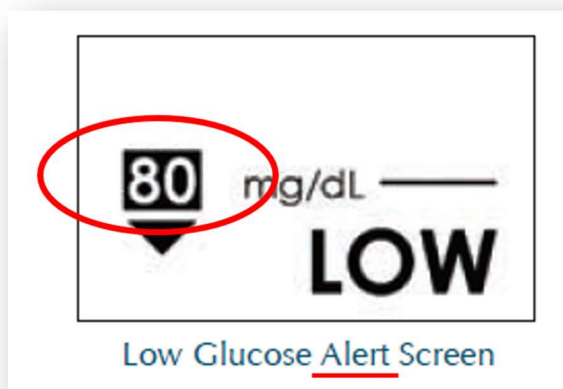
E. **Ground V: Claims 16, 17, 39, and 40 Would Have Been Obvious Based on Brauker in View of STS Guide**

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.”**

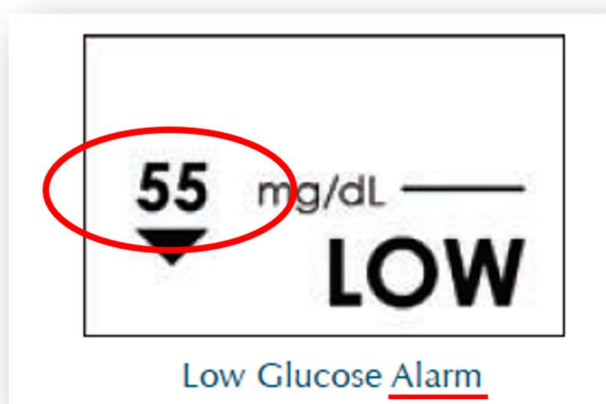
Brauker anticipates and/or renders obvious claim 1. For claim 16, Brauker discloses providing therapy recommendations (i.e., *a particular set of instructions*) such as “consume carbohydrates” or “inject insulin.” Ex-1005, [0719]. Brauker further discloses customizing therapy recommendations depending on the “severity of medical condition.” *Id.*; *see also* Ex-1003 ¶¶126-27.

STS Guide discloses providing differentiated outputs for a user settable low glucose *alert* and a non user settable low glucose *alarm*. Ex-1003 ¶¶128-29. For a user settable low glucose *alert*, a Low Glucose *Alert* Screen is displayed with the glucose value shown on *black* background:



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).

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).

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. Ex-1003 ¶130. 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. *Id.*

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.” Ex-1003 ¶131.

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). Ex-1003 ¶132. The combination also uses a known technique (i.e., STS Guide’s differentiated outputs) to improve similar devices in the same way. *Id.*

Reasonable expectation of success. Brauker and STS Guide both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. Ex-1003 ¶133. 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. Ex-1003 ¶133.

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.”**

Brauker anticipates and/or renders obvious claim 1.

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”); *see also* Ex-1003 ¶¶134-35.

As discussed above for claim 16, STS Guide discloses *differentiated outputs* for a user settable low glucose **alert** and a non user settable low glucose **alarm**. Ex-1003 ¶136.

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. Ex-1003 ¶137.

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.”**

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.”**

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

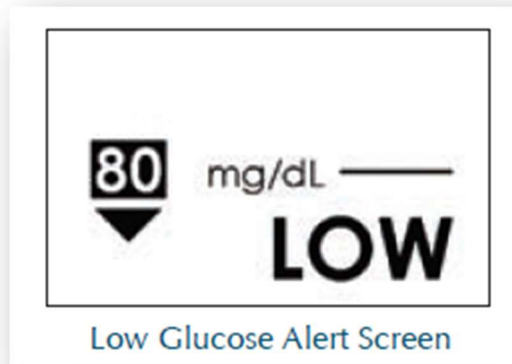
a) 1[pre]

STS Guide discloses *activating a hypoglycemic indicator* (i.e., an indicator of low glucose). Ex-1003 ¶140. 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.

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); *see also* Ex-1003 ¶141.

b) 1[a]

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-1003 ¶142.



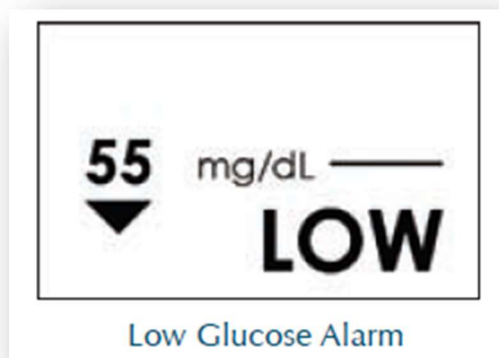
Ex-1008, 54. The Low Alert setting is *user settable*. Ex-1008, 79 (“You may select low glucose alert values from 60 mg/dL to 90 mg/dL.”).

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. Ex-1003 ¶143.

c) 1[b]

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.”); Ex-1003 ¶144. 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.

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); *see also* Ex-1003 ¶145.

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.⁹ Ex-1003 ¶146. 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-1003 ¶146; 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.

⁹ In considering a similar claim of a European counterpart (Ex-1029) to the ’528 patent, the UK High Court found in January 2024 that STS-7 Guide (which has similar disclosures as STS Guide) rendered the claim obvious. Ex-1028, 131-32.

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), 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.¹⁰ Ex-1003 ¶147.

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 an accurate, advance detection of hypoglycemia, making it possible to reduce the incidence or severity of hypoglycemia). Ex-1003 ¶148. The combination

¹⁰ 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.

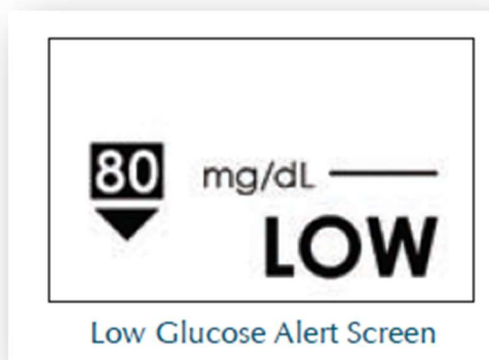
also uses a known technique (i.e., Brauker's predicted low glucose alarm) to improve similar devices in the same way. *Id.*

Reasonable expectation of success. STS Guide and Brauker both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. Ex-1003 ¶149. 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. Ex-1003 ¶149.

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. Ex-1003 ¶150.

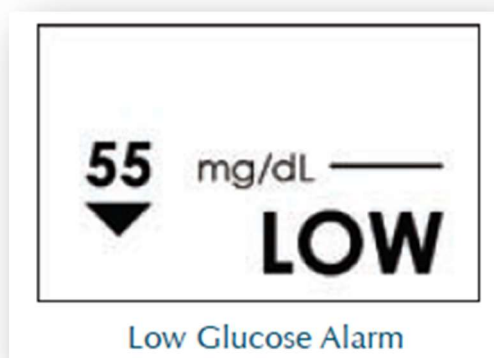
d) 1[c]

See Sections VIII.F.1.b-c above for limitations 1[a]-[b]. STS Guide discloses, “[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); *see also* Ex-1003 ¶151.



Ex-1008, 54.

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; *see also* Ex-1003 ¶152.

Additional examples of outputs are discussed in Sections VIII.F.6 & 8 below for claims 16 and 18. Ex-1003 ¶153.

2. Claim 2

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

3. Claim 3

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); *see also* Ex-1003 ¶155. Thus, when the direction of rate of change is negative, it *meets a rate of change criterion*. In discussing a similar claim¹¹ of the ’215 patent, the Board credited Abbott’s expert Dr. Rodbard’s testimony that “the determination that glucose is ‘trending down’ is a rate of change criterion,” and concluded that the 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

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

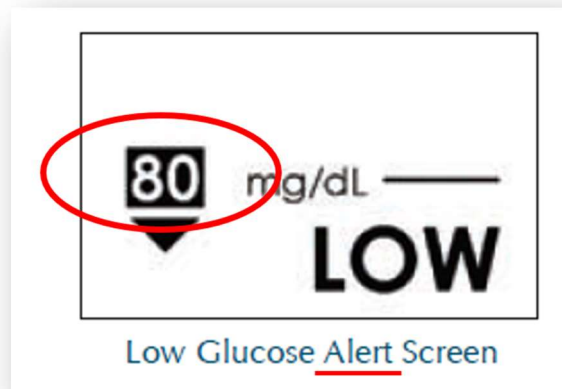
5. Claim 12

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

¹¹ 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.

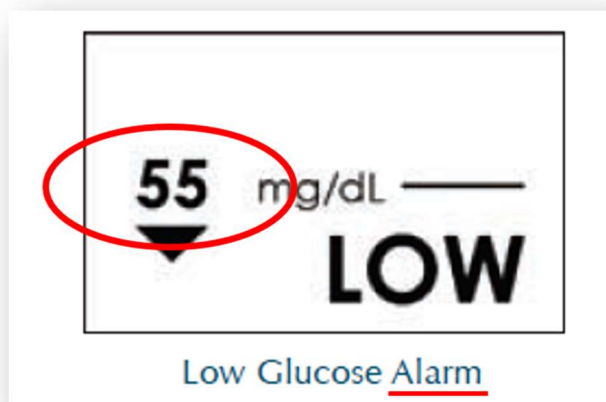
6. Claim 16

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); *see also* Ex-1003 ¶158.

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); *see also* Ex-1003 ¶159.

Brauker discloses *the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with it depending on different situations.* Ex-1003 ¶160. Specifically, Brauker discloses providing therapy recommendations (i.e., *a particular set of instructions*) such as “consume carbohydrates” or “inject insulin.” Ex-1005, [0719]. Brauker further discloses customizing therapy recommendations depending on the “severity of medical condition.” *Id.*

Motivation to combine. It would have been obvious to incorporate Brauker’s particular set of instructions in the system of STS Guide. Ex-1003 ¶161. 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. *Id.* 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 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.”).

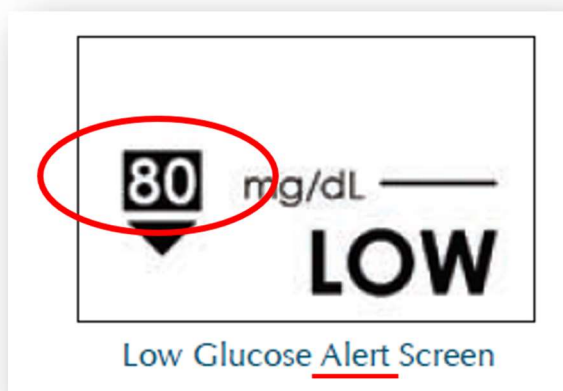
Therefore, it would have been obvious to a POSITA to associate STS Guide’s real time, user settable ***alert*** with an accompanying instruction such as, “Consume carbohydrates now because you are below your target level,” and to associate the STS Guide-Brauker combination’s predicted, non user settable ***alarm*** with a different instruction, such as, “Consume carbohydrates to prevent hypoglycemia. You are at risk of experiencing hypoglycemia within 30 minutes.” Ex-1003 ¶162.

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). Ex-1003 ¶163. The combination also uses a known technique (i.e., Brauker’s particular set of instructions) to improve similar devices in the same way. *Id.*

Reasonable expectation of success. STS Guide and Brauker both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. Ex-1003 ¶164. It would have been within the abilities of a POSITA to add accompanying instructions to the low glucose alert/alarm. *Id.* Such a modification would involve routine programming of STS Guide's system. *Id.*

7. Claim 17

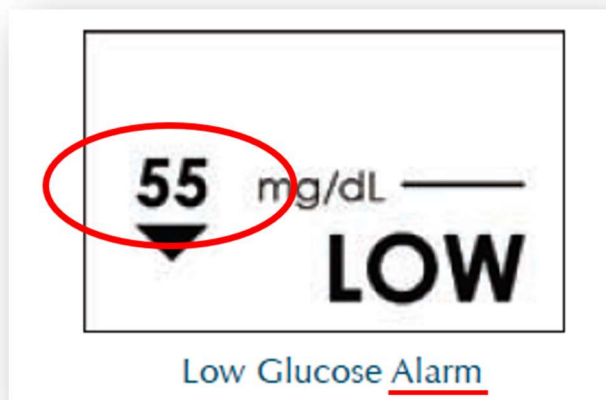
STS Guide discloses that, when *the hypoglycemic indicator is activated based on the first function meeting the one or more user settable first criteria*, a Low Glucose ***Alert*** Screen is displayed with the glucose value shown on ***black*** background (i.e., *visual output*):



Ex-1008, 54 (annotated); *see also* Ex-1003 ¶165.

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); *see also* Ex-1003 ¶166.

8. Claim 18

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*. Ex-1003 ¶167.

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. Ex-1003 ¶168. 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. *Id.*

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). Ex-1003 ¶169. 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. *Id.*; *see also* Ex-1007, 1148-49.

Reasonable expectation of success. STS Guide and Brauker both relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. Ex-1003 ¶170. The concept of insulin delivery control was well known before the ’528 priority date and had been applied to CGM systems. *Id.* For example, Hughes and Kowalski disclose controlling insulin delivery. Ex-1007, 1148; Ex-1015, S-115-16. Several other diabetologists demonstrated the feasibility of close loop control in adults, children and adolescents, and during pregnancy. Ex-1018; Ex-1031; Ex-1032.

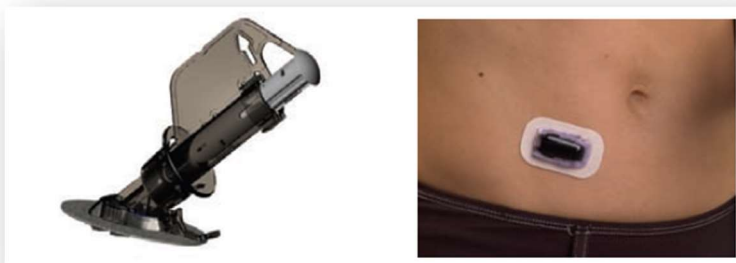
Incorporating Brauker's insulin delivery control would involve routine programming of the system of STS Guide. Ex-1003 ¶170.

9. Claim 19

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 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; Ex-1003 ¶171.

10. Claim 20

STS Guide discloses *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*. Ex-1003 ¶172. 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”). 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”).

11. Claim 24

a) 24[pre]

STS Guide discloses “[t]he *DexComTM STSTM 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; Ex-1003 ¶173. 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].

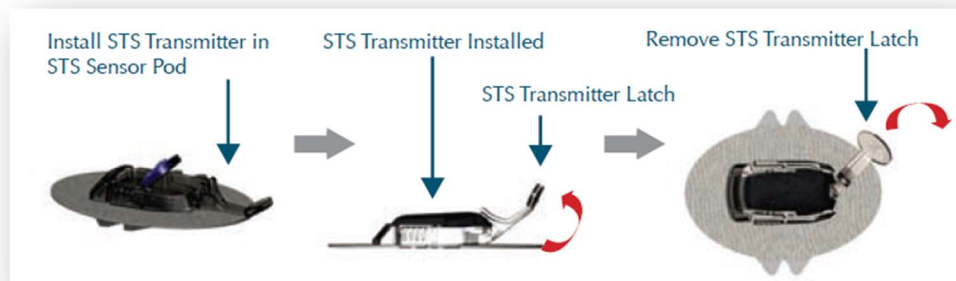
b) 24[a]

“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 STSTM 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); *see also* Ex-1003 ¶174.

c) 24[b]

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. Ex-1003 ¶175.

STS Guide discloses the STS Transmitter (i.e., *sensor electronics*) is *configured to receive sensor data output by the sensor*. Ex-1003 ¶176. 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*.

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-1003 ¶177; 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).

Moreover, 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.

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); *see also* Ex-1003 ¶179. 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”); Ex-1003 ¶179. A POSITA would also have known that a receiver of a CGM system typically includes a processor. Ex-1003 ¶179. For example, Figure 17A of Brauker illustrates processor 176 (yellow highlight below) in a receiver of a CGM system:

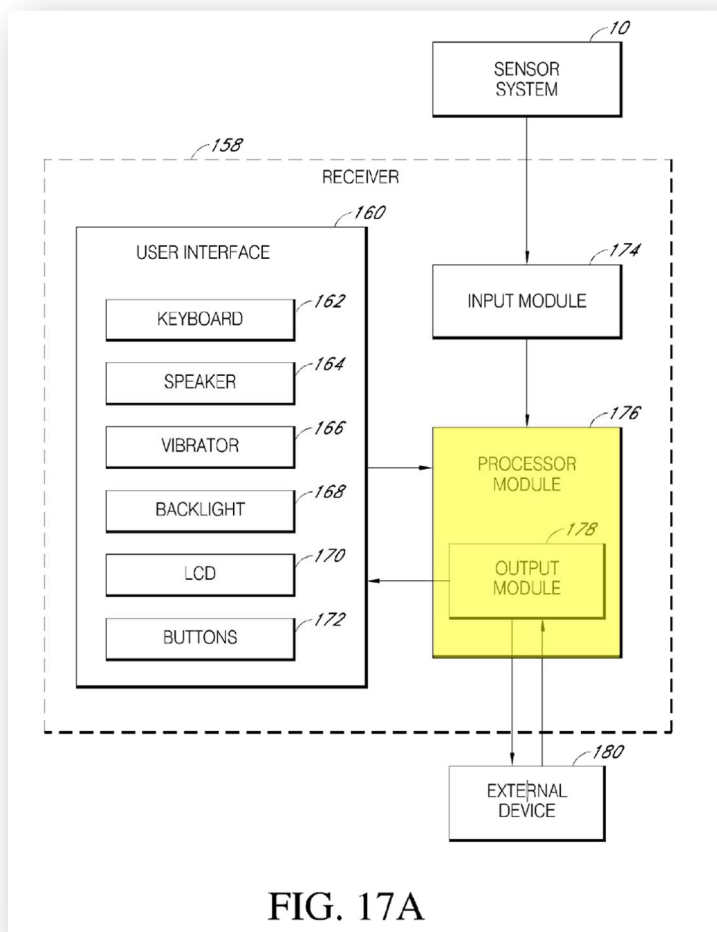


FIG. 17A

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 below for limitations 24[c]-[e]. Ex-1003 ¶179.

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. Ex-1003 ¶180. 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. *Id.* Therefore, STS Guide in view of Brauker renders obvious a processor 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]. *Id.*

d) 24[c]

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

e) 24[d]

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

f) 24[e]

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

12. Claim 25

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

13. Claim 26

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

14. Claim 34

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

15. Claim 35

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

16. Claim 39

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

17. Claim 40

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

18. Claim 41

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

19. Claim 42

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

20. Claim 43

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

STS Guide in view of Brauker renders obvious claim 1.

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*. Ex-1003 ¶194.

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. Ex-1003 ¶195. Moreover, STS Guide, Brauker, Guerra, and Hughes all relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. *Id.*

2. Claim 28

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

STS Guide in view of Brauker renders obvious claim 1. 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; *see also* Ex-1003 ¶¶197-98.

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. Ex-1003 ¶199.

2. Claim 36

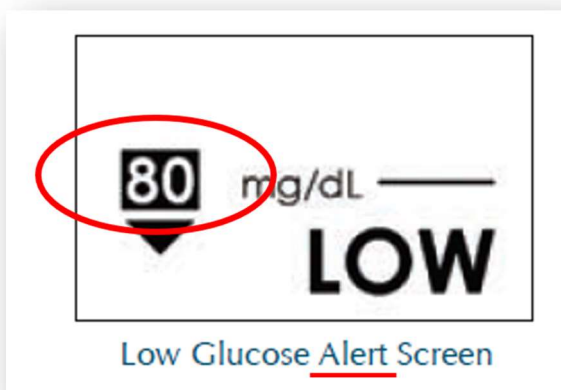
See Section VIII.H.1 above for claim 13.

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

1. Claim 16

In analyzing a similar claim¹² of the '215 patent, the Board found 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).

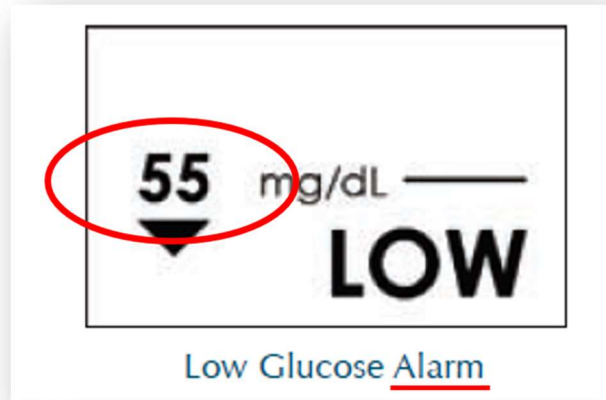
STS Guide in view of Brauker renders obvious claim 1. For claim 16, STS Guide discloses that, when *the hypoglycemic indicator is activated based on the first function meeting the one or more user settable first criteria*, a Low Glucose **Alert** Screen is displayed with the glucose value shown on **black** background (i.e., *hypoglycemic indicator comprises a flag that has a particular display*):



Ex-1008, 54 (annotated); *see also* Ex-1003 ¶¶202-03.

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.

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); *see also* Ex-1003 ¶204.

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); Ex-1003 ¶205.

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).

Ex-1003 ¶206. STS Guide, Brauker, and Say all relate to CGM systems with alerts to reduce the incidence or severity of hypoglycemia. *Id.* 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. *Id.* 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.”).

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.” Ex-1003 ¶207.

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). Ex-1003 ¶208. The combination also uses a known technique (i.e., Say's particular set of instructions) to improve similar devices in the same way. *Id.*

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. Ex-1003 ¶209. Such a modification would involve routine programming of STS Guide's system (as modified by Brauker). *Id.*

2. Claim 39

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

IX. SECONDARY CONSIDERATIONS

Petitioner is unaware of evidence of secondary considerations of non-obviousness. Petitioner reserves the right to rebut any purported objective evidence of non-obviousness raised by DexCom.

X. THE BOARD SHOULD NOT USE ITS DISCRETION TO DENY INSTITUTION

A. 35 U.S.C. § 314(a)

The Board should not exercise its discretion to deny institution under 35 U.S.C. §314(a). No other petitions have been filed against the '528 patent and thus the *General Plastic* factors for serial petitions do not weigh against institution. Under *Apple Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper 11 (March 20, 2020) (precedential), the district court litigation is still at an early stage, and trial on issues including the validity of the '528 patent is not scheduled to occur until July 2026, many months after this Board's likely 2025 due date for a final written decision if this IPR is instituted. Ex-1030 (D. Del. Scheduling Order, Sept. 2023). In addition, the other *Fintiv* factors would not justify denying institution. The district court's claim construction process is just underway as of the filing of this petition. By the time of institution, fact discovery may still be ongoing, but expert discovery and pre-trial motions will not have begun. Discretionary denial is further inappropriate here because this petition presents compelling evidence of unpatentability. Accordingly, the *Fintiv* factors should not be applied to deny institution of this proceeding.

B. 35 U.S.C. § 325(d)

The Board likewise should not deny institution under §325(d). When evaluating discretionary denial arguments under §325(d), the Board reviews: "(1) whether the same or substantially the same art previously was presented to the Office

or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential).

In applying this test, the Board considers the “*Becton, Dickinson*” factors, *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*Becton, Dickinson*”).

Here, the first prong of *Advanced Bionics* is not satisfied. Neither of the primary references, Brauker (assigned to DexCom) or the STS Guide (describing DexCom’s product), were listed on an IDS or otherwise cited in the file history. Brauker and the STS Guide are not the same or substantially the same art previously presented to the Office, and also do not involve the same or substantially the same arguments previously presented to the Office. (The secondary reference Guerra, and certain family members of the secondary reference Say, were listed in an IDS, along with over 180 other documents, but were not substantively argued or otherwise

meaningfully addressed during examination.¹³) Accordingly, any analysis by the Board of 325d issues should end with prong 1. *See, e.g., Fusion Orthopedics, LLC v. Extremity Medical, LLC*, IPR2023-00894, Paper 15 at 34-35 (P.T.A.B. Nov. 17, 2023).

Even were the Board to reach the second prong, it too is not met. The petition reflects the examiner's errors in a manner material to the patentability of the Challenged Claims. Under *Becton, Dickinson* factor (c), Guerra, and certain family members of the secondary reference Say, were listed in an IDS but were not the basis for rejection. The examiner did not and could not have substantively considered them in connection with the Brauker or STS Guide references. Furthermore, under *Becton, Dickinson* factor (f), the examiner erred by overlooking the materiality of Guerra and Say's family members to the challenged claims during examination. *See, e.g., STMicroelectronics, Inc. v. Trustees of Purdue Univ.*, IPR2022-00309, Paper 14 at 12–13 (P.T.A.B. July 6, 2022).

¹³ The Office has proposed changing this aspect of the §325(d) analysis. *See USPTO Notice of Proposed Rulemaking* [including Rules for 325(d) Considerations], 89 Fed. Reg. 28,693, 28,705 (Apr. 19, 2024) (“An initialed Information Disclosure Statement, without more, does not satisfy [the proposed §325(d) discretionary denial] standard.”).

XI. CONCLUSION

Petitioner respectfully requests *inter partes* review and cancellation of claims 1-3, 5, 11-13, 16-20, 24-26, 28, 34-36, and 39-43 of the '528 patent.

Date: May 3, 2024

Respectfully submitted,

By: /Peter P. Chen/

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CERTIFICATION OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that the foregoing complies with the type-volume limitation of 37 C.F.R. § 42.24 and contains 13,979 words based on the word count indicated by the word-processing system used to prepare the paper, and excluding those portions exempted by § 42.24(a).

Date: May 3, 2024

/Peter P. Chen/

Peter P. Chen

Registration No. 39,631

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.105, I hereby certify that on May 3, 2024, I caused a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 9,119,528, supporting exhibits, and Power of Attorney to be served via Priority Mail Express on the Patent Owner at the following correspondence address of record as listed on the USPTO Patent Center:

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