

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. IPR2022-00909
Patent No. 10,702,215

DECLARATION OF DR. BARRY KEENAN

DexCom Exhibit 2002 Abbott v. DexCom IPR2024-00840
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I, Dr. Barry Keenan, declare:

1. I have been retained by Wolf, Greenfield & Sacks, P.C., counsel for Patent Owner DexCom, Inc., to submit this declaration in connection with Patent Owner's Preliminary Response for the *Inter Partes* Review of claims 1-5, 12, 19, and 23 (the "Challenged Claims") of U.S. Patent No. 10,702,215 ("the '215 patent"). I am being compensated for my time at my standard rate of \$250.00 per hour, plus actual expenses. My compensation is not dependent in any way upon the outcome of the *inter partes* review of the '215 patent.

I. PERSONAL AND PROFESSIONAL BACKGROUND

2. I received by Bachelor of Engineering with honors in Electronic Systems from the University of Ulster in Northern Ireland in 1995. I received my Ph.D. in biomedical engineering from the University of Ulster in 1998.

3. I have over 25 years' experience in the medical device industry, including experience with R&D, program management, new product development, and regulation. This experience includes work with continuous glucose monitoring ("CGM") devices. For example, during my time at Medtronic Diabetes, I developed the Medtronic SmartGuard™ technology, which combines CGM with insulin delivery, and oversaw clinical trials. I also have extensive software engineering experience in the context of medical devices, including CGM devices.

For example, while at Medtronic, I developed algorithms for the Paradigm® Veo™ and CGMS® iPro2™ devices.

4. I am a Fellow of the American Institute for Medical and Biomedical Engineering (AIMBE). I have participated in expert panels on CGM. I am also a named inventor on 40 patents or patent applications, including patents related to closed loop glucose regulation and glucose sensor calibration.

5. My curriculum vitae is provided as Exhibit 2009.

II. MATERIALS REVIEWED AND CONSIDERED

6. My findings, as explained below, are based on my years of education, research, experience, and background in the field of continuous glucose monitoring, as well as my investigation and study of relevant materials for this declaration. When developing the opinions set forth in this declaration, I assumed the perspective of a person having ordinary skill in the art, as set forth in Section IV below. In forming my opinions, I have reviewed and considered the '215 patent (Ex[1001]), the declaration of Dr. Rodbard (Ex[1002], "Rodbard") and the materials cited therein, and the following documents:

Exhibit	Description
2001	U.S. Patent App. Pub. No. 2011/0131307 ("Bazzal")
2002	U.S. Patent App. Pub. No. 2012/0185416 ("Baras")
2003	U.S. Patent App. Pub. No. 2007/0107973 ("Jiang")
2004	U.S. Patent App. Pub. No. 2005/0280521 ("Mizumaki")

Exhibit	Description
2006	A. Kamath, A. Mahalingam and J. Brauker, “Methods of Evaluating the Utility of Continuous Glucose Monitor Alerts”, <i>Journal of Diabetes Science and Technology</i> , Vol. 4, Issue 1, January 2020 (“Kamath”)
2007	Glucose level graph from deposition of David Rodbard
2009	Curriculum vitae of Barry Keenan, Ph.D., MBA, PMP
2010	Excerpt of <i>A Dictionary of Computing</i> , Sixth Edition, Oxford University Press (2008) (“Oxford”)
2012	Printout of https://web.archive.org/web/20061123145947/https://www.broadcaststore.com/store/model_detail.cfm?id=18790
2013	Deposition Transcript of David Rodbard, taken January 18, 2023 (“Rodbard-Dep”)
2014	Abbott Freestyle Navigator Continuous Glucose Monitoring System: User’s Guide
2015	Medtronic User Guide: Guardian Real-Time Continuous Glucose Monitoring System

III. MY UNDERSTANDING OF PATENT LAW

7. In developing my opinions, I discussed various relevant legal principles with Patent Owner’s attorneys. Though I do not purport to have prior knowledge of such principles, I understood them when they were explained to me and have relied upon such legal principles, as explained to me, in the course of forming the opinions set forth in this declaration. My understanding in this respect is as follows:

8. I understand that “*inter partes* review” (IPR) is a proceeding before the United States Patent & Trademark Office for evaluating the patentability of an issued patent’s claims based on prior-art patents and printed publications.

9. I understand that, in this proceeding, Petitioner has the burden of proving that the challenged claims of the ’215 patent are unpatentable by a preponderance of the evidence. I understand that “preponderance of the evidence” means that a fact or conclusion is more likely true than not true.

10. I understand that, in IPR proceedings, claim terms in a patent are given their ordinary and customary meaning as understood by a person of ordinary skill in the art (“POSA”) in the context of the entire patent and the prosecution history pertaining to the patent. If the specification provides a special definition for a claim term that differs from the meaning the term would otherwise possess, the specification’s special definition controls. If a claim element is expressed as a “means” for performing a specified function, I understand that it covers the corresponding structure described in the specification and equivalents of the described structure. I have applied these standards in preparing the opinions in this declaration.

11. I understand that determining whether a particular patent or printed publication constitutes prior art to a challenged patent claim can require determining the effective filing date (also known as the priority date) to which the

challenged claim is entitled. I understand that for a patent claim to be entitled to the benefit of the filing date of an earlier application to which the patent claims priority, the earlier application must have described the claimed invention in sufficient detail to convey with reasonable clarity to the POSA that the inventor had possession of the claimed invention as of the earlier application's filing date. I understand that a disclosure that merely renders the claimed invention obvious is not sufficient written description for the claim to be entitled to the benefit of the filing date of the application containing that disclosure.

12. I understand that for an invention claimed in a patent to be patentable, it must be, among other things, new (novel—*i.e.*, not anticipated) and not obvious from the prior art. My understanding of these two legal standards is set forth below.

A. Anticipation

13. I understand that, for a patent claim to be “anticipated” by the prior art (and therefore not novel), each and every limitation of the claim must be found, expressly or inherently, in a single prior-art reference. I understand that a claim limitation is disclosed for the purpose of anticipation if a POSA would have understood the reference to disclose the limitation based on inferences that a POSA would reasonably be expected to draw from the explicit teachings in the reference when read in light of the POSA's knowledge and experience.

14. I understand that a claim limitation is inherent in a prior art reference if that limitation is necessarily present when practicing the teachings of the reference, regardless of whether a person of ordinary skill recognized the presence of that limitation in the prior art.

B. Obviousness

15. I understand that a patent claim may be unpatentable if it would have been obvious in view of a single prior-art reference or a combination of prior-art references.

16. I understand that a patent claim is obvious if the differences between the subject matter of the claim and the prior art are such that the subject matter as a whole would have been obvious to a person of ordinary skill in the relevant field at the time the invention was made. Specifically, I understand that the obviousness question involves a consideration of:

- the scope and content of the prior art;
- the differences between the prior art and the claims at issue;
- the knowledge of a person of ordinary skill in the pertinent art; and
- if present, objective factors indicative of non-obviousness, sometimes referred to as “secondary considerations.”

17. I understand that in order for a claimed invention to be considered obvious, a POSA must have had a reason for combining teachings from multiple

prior-art references (or for altering a single prior-art reference, in the case of obviousness in view of a single reference) in the fashion proposed.

18. I further understand that in determining whether a prior-art reference would have been combined with other prior art or with other information within the knowledge of a POSA, the following are examples of approaches and rationales that may be considered:

- combining prior-art elements according to known methods to yield predictable results;
- simple substitution of one known element for another to obtain predictable results;
- use of a known technique to improve similar devices in the same way;
- applying a known technique to a known device ready for improvement to yield predictable results;
- applying a technique or approach that would have been “obvious to try,” *i.e.*, choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.
- known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;

- some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior-art reference or to combine prior-art reference teachings to arrive at the claimed invention. I understand that this teaching, suggestion or motivation may come from a prior-art reference or from the knowledge or common sense of one of ordinary skill in the art.

19. I understand that for a single reference or a combination of references to render the claimed invention obvious, a POSA must have been able to arrive at the claimed invention by altering or combining the applied references.

IV. PERSON OF ORDINARY SKILL IN THE ART (“POSA”)

20. I have been informed and understand that for purposes of assessing whether prior-art references disclose every element of a patent claim (thus “anticipating” the claim) and/or would have rendered the claim obvious, the patent and the prior-art references must be assessed from the perspective of a person having ordinary skill in the art (“POSA” or “POSITA”) to which the patent is related, based on the understanding of that person at the time of the patent claim’s priority date. I have been informed and understand that a POSA is presumed to be aware of all pertinent prior art and the conventional wisdom in the art, and is a person of ordinary creativity. I have applied this standard throughout my declaration.

21. The '215 patent involves technology in the field of continuous glucose monitoring ("CGM"). I have been asked to provide my opinions as to the state of the art in this field by late 2012. I use this timeframe because the face of the '215 patent indicates an earliest claimed priority date of October 30, 2012. *See* Ex[1001], page 2, item (60). Whenever I offer an opinion in this declaration about the knowledge of a POSA, the manner in which a POSA would have understood the claims of the '215 patent or its description, the manner in which a POSA would have understood the prior art, or what a POSA would have been led to do based on the prior art, I am referencing the late 2012 timeframe, even if I do not say so specifically in each case.

22. Dr. Rodbard proposes the following definition of a POSA:

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.

Rodbard, ¶ 25. For the purposes my analysis this Declaration, I have adopted Dr. Rodbard's POSA definition, because I believe Dr. Rodbard's conclusions are incorrect even under this definition, as I explain below.

23. By 2012, I held a Ph.D. in biomedical engineering and a Bachelor of Engineering in Electronic Systems, and I had 7 years of experience with CGM. Therefore, I was a person of more than ordinary skill in the art during the relevant timeframe. However, I worked with many people who fit the characteristics of the POSA, and I am familiar with their level of skill. When developing the opinions set forth in this declaration, I assumed the perspective of a person having ordinary skill in the art, as set forth above.

V. THE '215 PATENT

24. The '215 patent relates to "processing analyte sensor data from a continuous analyte sensor" (Ex[1001], 1:30-33), where "glucose" may be the sensed "analyte" (*id.*, 1:65-66).

25. As compared to conventional self-monitoring systems that required blood samples to be taken with uncomfortable finger pricks several times per day, continuous analyte sensors provide an improved diabetes management system

because they continuously monitor analyte sensor data and, in addition to providing real-time warning of a currently-occurring hyperglycemic (high blood glucose) or hypoglycemic (low blood glucose) event, can also provide predictive warnings to “alert the diabetic user of hyperglycemic or hypoglycemic events before they occur.” Ex[1001], 1:49-2:11 (“Conventionally, a person with diabetes carries a self-monitoring blood glucose (SMBG) monitor, which typically requires uncomfortable finger pricks to obtain blood samples for measurement. Due to the lack of comfort and convenience associated with finger pricks, a person with diabetes normally only measures his or her glucose levels two to four times per day. ... Another device that some diabetics use to monitor their blood glucose is a continuous analyte sensor. ... 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. One of the major perceived benefits of a continuous analyte sensor is the ability of these devices to have alarms to alert the diabetic user of hyperglycemic or hypoglycemic events before they occur.”).

A. Challenged Claims

26. The Challenged Claims include two independent claims – claim 1 (method) and claim 19 (system) – that recite similar subject matter in different form. In his expert report, the Petitioner’s expert, Dr. Rodbard, grouped the language of each of these claims into what he calls “elements” and labelled each

element. *See* Ex[1002] (“Rodbard”), ¶ 41 & Appendix B. For the purposes of my analysis below, I adopt that labeling.

27. Each independent claim (and thus every Challenged Claim) recites evaluating, or a processor configured to evaluate, sensor data two different ways:

using a **first function**¹ to determine whether a **real time glucose value** meets one or more **user settable first criteria** (Elements 1[a] and 19[c]); and

using a **second function** to determine whether a **parameter indicative of glucose value** meets one or more **non-user**² **settable second criteria** (Elements 1[b] and 19[d]).

28. Claim 1 recites providing an output including a first hypoglycemic indicator if the one or more user settable first criteria are met, and an output including a second hypoglycemic indicator if the one or more non-user settable second criteria are met. *See* Elements 1[c]-1[d].

29. Similarly, claim 19 recites the processor as configured to activate first and second hypoglycemic indicators, respectively, if the user settable first and the non-user settable second criteria are met. *See* Elements 19[e]-[f].

¹ Emphases is added herein unless otherwise indicated.

² Element 1[b] and some other claim elements omit the hyphen that element 19[d] includes in “non-user settable.” Herein, I use “non-user” when referring to any claim element.

B. Specification

30. The '215 patent discloses a system that provides alarms under different circumstances, including: (1) when a real-time glucose value meets a *user settable* threshold and (2) when a prediction parameter indicative of a glucose value meets *non-user settable* criteria.

31. Figure 5 illustrates a continuous trace of glucose values over a 24-hour period. Ex[1001], 9:55-57 (“FIG. 5 is an illustration of a continuous trace of glucose values measured during a time frame in accordance with an embodiment of the disclosure.”). As Figure 5 illustrates:

there are three threshold values or limits used in the monitoring of the glucose values in some embodiments: TV_1 , TV_2 and TV_P . TV_1 may be settable by the user and generally defines the upper limit or upper glucose value that a user may operate at before being alerted by the monitor. Similarly, TV_2 may be settable by the user and generally defines the lower limit or lower glucose value that a user may operate at before being alerted by the monitor. TV_P is the predictive threshold, e.g., the threshold against which a predicted value is compared.

Ex[1001], 21:50-58.

32. TV_P may represent a dangerously low glucose value and, unlike TV_1 and TV_2 , “does not have a particular glucose value given” in Figure 5 (below) “because TV_P *may not be settable by the user*; it may be a fixed value or permanent value set during factory settings” or it “may be adaptively determined

based on TV_2 .” Ex[1001], 21:62-22:13 (“As shown, TV_P does not have a particular glucose value given. This is because TV_P may not be settable by the user; it may be a fixed value or permanent value set during factory settings. ... In some embodiments, TV_P may be adaptively determined based on TV_2 ...”).

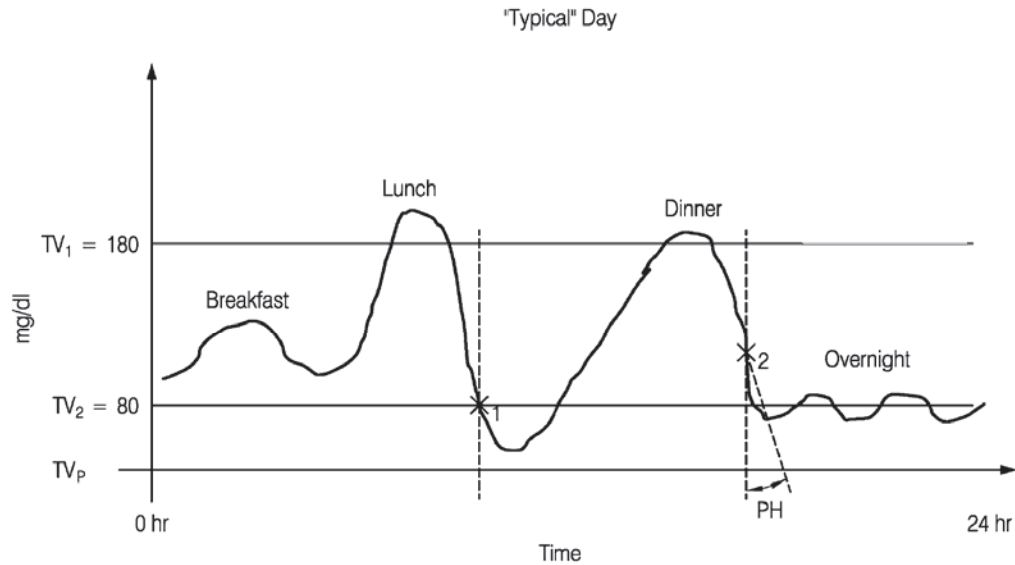


FIG. 5

33. The '215 patent's specification explains that a "hypoglycemic indicator" may comprise a "flag." Ex[1001], 28:37-41 ("In some embodiments, the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with it, depending on whether the first evaluation using the first criteria (x_1) or the second evaluation using the second criteria (x_2) were met."). Two such "flags" are shown in Figure 5: "a **threshold** flag x_1 and a **predictive** flag x_2 ." *Id.*, 21:44-47 ("Referring now to FIG. 5, an example of a continuous trace of glucose values measured during a time frame and having a threshold flag x_1 and a

predictive flag x_2 located thereon is shown.”). Flag x_1 “may be configured to alert the user that a first threshold, e.g., TV_2 , has been met.” *Id.*, 22:14-16. Flag x_2 “may be configured to alert the user that a second threshold, e.g., TV_P , is predicted to be met within a predetermined or predefined time frame or time horizon PH.” *Id.*, 22:29-32.

34. Flag x_1 indicates that a real-time glucose value meets a *user settable* criterion (threshold TV_2). Ex[1001], 21:55-57 (“Similarly, TV_2 may be settable by the user and generally defines the lower limit or lower glucose value that a user may operate at before being alerted by the monitor.”), 22:14-16 (“Flag x_1 may generally be considered a threshold flag, and may be configured to alert the user that a first threshold, e.g., TV_2 , has been met.”).

35. The specification repeatedly describes a first function that makes determinations of whether a “real time” glucose value meets a criterion such as a threshold value. *See, e.g.:*

- Ex[1001], Abstract (“evaluating sensor data using a *first function* to determine whether a *real time glucose value* meets a first threshold”),
- 2:24-26 (“evaluating sensor data using a *first function* to determine whether a *real time glucose value* meets one or more first criteria”),

- 22:16-25 (“flag x₁ operates to notify the user in *real time*...when a threshold has been met or crossed” such as “[w]hen the user’s *glucose value* is determined to meet that predetermined user set value”)
- 23:66-24:3 (“processor module 214 may be configured to *evaluate sensor data* using a first function to determine whether a *real time glucose* value meets one or more first predetermined criteria”)
- 28:20-27 (“processor module 214 may be configured to activate a hypoglycemic indicator” if a “set of instructions has met its criteria,” where “the first set of instructions may determine [a] first threshold has been met...using *real time* data”).

36. Predictive flag x₂ indicates when a “predicted value” (which a POSA would have understood is a parameter indicative of a glucose value, as I discuss in § VII.A.2.b.i, a parameter indicative of a glucose value) meets TV_P (one or more non-user settable criteria). *See* Ex[1001], 21:58-66 (“TV_P is the predictive threshold, e.g., the threshold against which a predicted value is compared. ... As shown, TV_P does not have a particular glucose value given. This is because TV_P may not be settable by the user; it may be a fixed value or permanent value set during factory settings.”), 22:29-35 (“Flag x₂ may generally be considered a

predictive flag...to alert the user that a second threshold, e.g., TV_P , is predicted to be met...”).

37. The specification describes a second function to determine whether a *predicted* glucose value meets non-user settable criteria. See, e.g.:

- Ex[1001], Abstract (“evaluating sensor data using a second function to determine whether a *predicted* glucose value meets a second threshold”),
- 2:45-49 (“evaluating sensor data using a second function to determine whether the *predicted* glucose value meets one or more second criteria”),
- 18:14-20 (“processor module 214 may provide a predictive alert ... when a severe hypoglycemic event is *predicted* to occur in the near future...”),
- 21:57-22:13 (TV_P is a “predictive threshold” that “may not be settable by a user” and, “the prediction horizon, PH, may be preset or adaptively selected based on another *parameter associated with prediction, for example*, based on TV2 selected and/or TV_P .”),
- 22:46-47 (referring to “*prediction* parameters (TV_P and PH)”,

- 22:29-35 (“Flag x₂ may generally be considered a *predictive* flag...to alert the user that a second threshold, e.g., TV_P, is predicted to be met...”),
- 28:20-30 (“processor module 214 may be configured to activate a hypoglycemic indicator if either the first criteria is met or if the second criteria is *predicted* to be met. In some embodiments ... the second set of instructions may determine second threshold is predicted to be met at 9:00 pm in block 530, using the 20 minute prediction horizon.”).

38. The '215 patent states that the “processor module 214 may be configured to evaluate sensor data using a *second function*,” which is a parameter indicative of glucose value, as I explain in § VII.A.2.b.i below, “*to determine whether a predicted glucose value* meets one or more predictive alarm criteria.” Ex[1001], 26:57-60. In addition, the patent also states, when discussing Figure 6, that “in block 530, the *second set of instructions* or criteria may include any algorithm or algorithms suitable for evaluating sensor data to determine whether a glycemic state (hyper- or hypo-glycemia) is *predicted*, for example, by determining if a data point is predicted or projected to cross a predetermined threshold.” *Id.*, 25:8-17, Figure 6 (below). As can be seen below, block 530 in

Figure 6 recites “evaluate sensor data using a *second function* to determine if one or more second criteria are met.”

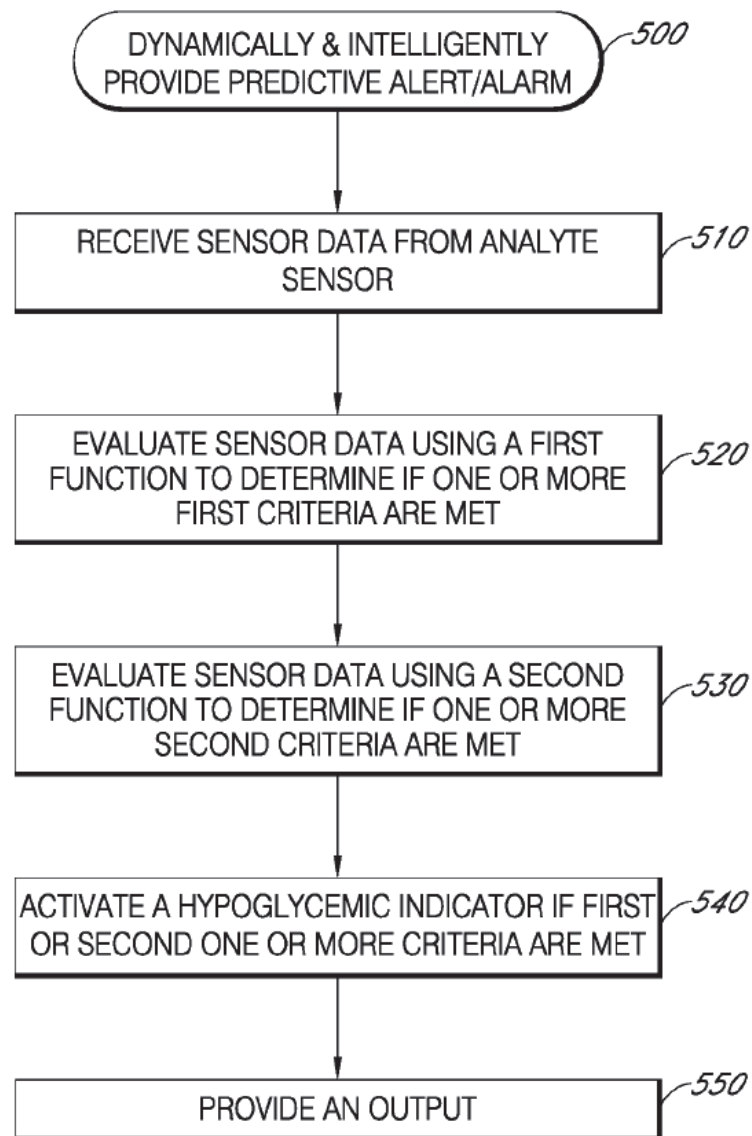


FIG. 6

'215 Patent, Fig. 6

39. The second function may make the determination I discuss in the previous paragraph using a suitable algorithm such as algorithms based on “polynomial and autoregressive models...Kalman Filtering (KF), artificial neural networks, statistical and numerical logical algorithms and machine learning.” Ex[1001], 25:8-17 (“Similar to block 520, *in block 530, the second set of instructions or criteria may include any algorithm or algorithms suitable for evaluating sensor data to determine whether a glycemic state (hyper- or hypoglycemia) is predicted*, for example, by determining if a data point is predicted or projected to cross a predetermined threshold. *Suitable algorithms include algorithms based on polynomial and autoregressive models, algorithms based on Kalman Filtering (KF), artificial neural networks, statistical and numerical logical algorithms, and machine learning.*”).

40. Figures 4A-F illustrate the difference between alerts generated based on a first function that determines whether a real-time glucose value meets one or more first criteria (Figures 4A-4B), and those generated based on a second function

that determines whether a parameter indicative of a glucose value one or more second criteria (Figure 4D). Figures 4B illustrates:

a low alert screen that can be displayed responsive to a host's analyte concentration falling below a lower boundary (see boundaries 182).

In this example screen, a host's glucose concentration has fallen to 55 mg/dL, which is below the lower boundary set in FIG. 4A, for example.

Ex[1001], 17:41-46. “Boundaries 182” are settable by the user. *Id.*, 17:25-30 (FIG. 4A’s “trend graph shows upper and lower boundaries 182... these boundaries 182 can be configured or customized by a user...”).

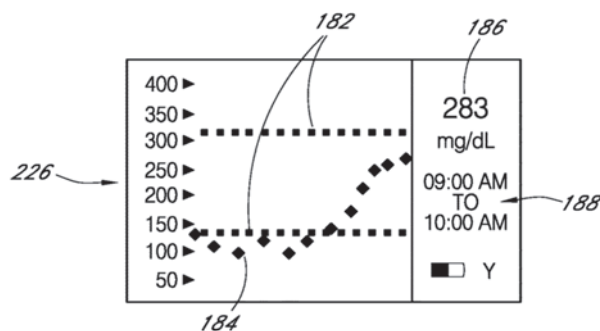


FIG. 4A

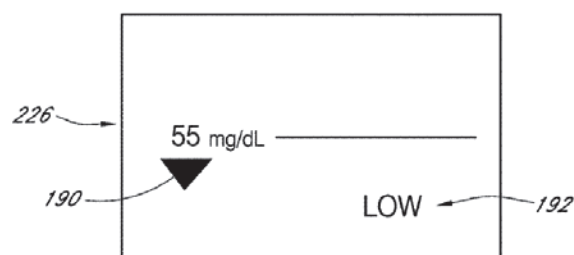


FIG. 4B

41. Figure 4D “is a screenshot ... illustrating one embodiment of an alert indicting that the user’s blood glucose *is dropping* and *will soon be* in a low range” so that the alert is generated based on a parameter (a *predicted* glucose value) indicative of a glucose value rather than on the real-time glucose value. Ex[1001], 18:7-10.

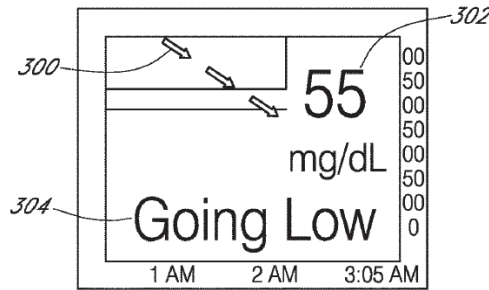


FIG. 4D

C. Prosecution History of the '215 Patent

42. The application that led to the '215 patent was filed on November 15, 2019. Ex[1001], page 1, item (22). All pending claims were rejected for non-statutory double patenting over various claims of U.S. Patent No. 9,119,528 in a December 13, 2019 Office Action. Ex[1003] at 138-158. The applicants responded by filing a terminal disclaimer, after which point the examiner allowed the claims. Ex[1003], 116, 82-84.

D. Distinction over the Prior Art

43. The '215 patent states that alarms should be “accurate, so that a user does not become de-sensitized from their alarm going off, such that they ignore it because it has become a nuisance.” Ex[1001], 2:8-11.

44. The desensitization that I refer to in the previous paragraph was known as “alarm fatigue.” I have reviewed the transcript of the deposition of Dr. Rodbard (“Rodbard-dep.,” Ex[2013]), and Dr. Rodbard agrees with my understanding of what “alarm fatigue” is. *See* Rodbard-Dep., 32:13-33:24.

45. A POSA would have understood that predictive alarms are more complicated than real time glucose value alarms, as the former require making a prediction. For example, in the '215 patent the examples of algorithms used for predictive alerts include “algorithms based on polynomial and autoregressive models, algorithms based on Kalman Filtering (KF), artificial neural networks, statistical and numerical logical algorithms, and machine learning.” Ex[1001], 25:8-17. In contrast, the real-time alerts are activated simply by comparing a glucose reading to a threshold. *See, e.g.*, Ex[1001], 18:66-19:14 (“...As the processor module 214 receives as inputs multiple EGV's at time-spaced intervals, it processes the inputs by comparing each one to the programmed values. If the user's blood glucose value crosses one of the thresholds, the processor module 214 outputs an alert....”).

46. Furthermore, a POSA would have understood that the prevailing view in the art was that predictive alarms were inaccurate and caused high incidences of false alarms. *See, e.g.*, Kamath (Ex[2006]), 65 (describing a study of prior art “alerts designed explicitly to predict glucose excursions” where 65% of the alarms were false alarms); Navigator (Ex[2014]), 68-69 (warning that predictive alerts in prior art product “cannot be relied on exclusively for notification” of low/high glucose).

47. A POSA would have understood that these false alarms could create safety issues because they could cause users to ignore *all* alarms. *See, e.g.*, Ex[1001], 19:54-55 (noting that “excessive alerts can be annoying to the user, and can decrease patient compliance”); Rodbard-Dep., 33:3-24 (explaining that alarm fatigue could lead to a “safety problem” because “[i]f there was a serious or if there was some condition that needed to be handled in some way and the alarm goes off, the alarm or alert is sounded but the person is no longer responding to that alert, then the condition may persist longer than it would have otherwise and that could have some deleterious consequences.”).

48. A POSA would also have understood that prior art predictive alarms used user-settable criteria, and a POSA would further have understood that user-settable criteria allowed the user to adjust the predictive alarm if it generated too many false alarms. My testimony regarding a POSA’s understanding of the prior art is corroborated by a number of factors, as I explain in paragraphs 49-54 below.

49. First, I have 25 years’ experience with medical devices, including glucose monitors, and first worked on glucose monitoring in 2005. Every prior art CGM system of which I am aware that had any predictive glucose alert/alarm used user-settable criteria for the alarm.

50. Second, I have reviewed Dr. Rodbard’s report, and he does not cite any example of a prior art product having non-user settable thresholds for

predictive glucose alerts/alarms. This is consistent with my understanding that no such devices existed in the prior art.

51. Third, as I discuss in my analysis below of the prior art cited in Dr. Rodbard’s report, all of the prior art references that Dr. Rodbard relies on to show predictive alerts, namely Harper (Ex[1005]), Shariati (Ex[1007]), and Say (Ex[1008]) have user-settable thresholds for predictive alerts.

52. Finally, documentation for various prior art commercially-available systems with predictive alerts corroborates that those systems had user-settable thresholds for predictive alerts, as shown in the table below.

Product	Predictive Alerts? (Y/N)	Predictive Alert Threshold User-Settable? (Y/N)
Abbott Freestyle Navigator	Y (Ex[2014], p. 8 – referring to “four glucose alarms” including “Projected [Low/High] Glucose”)	Y (e.g., Ex[2014], p. 67 – stating that “projected low alarm” notifies user in advance of reaching “your threshold”, p. 68 – noting that the “sensitivities” for “projected” alarms can be “set”, p. 70 – saying the user can “Set, review, or change the PROJECTED [Low/High] glucose alarm”)
Medtronic MiniMed Guardian Real-Time	Y (Ex[2015], p. 32 – referring to “predictive glucose alerts”)	Y (Ex[2015], p. 32 – “The Predictive alerts calculate when you will reach your Low or High Glucose Limits”, p. 28

		“After you turn the Glucose alerts On, then you need to set the high and low Glucose Limits recommended by your healthcare professional”)
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53. Ex[2015] is a document that is entitled “User Guide – Guardian® REAL-Time Continuous Glucose Monitoring System” and bears the Medtronic logo. In addition, the document bears a 2006 copyright date on the third page. I am familiar with Medtronic product documentation from my employment at Medtronic. I obtained this document from the website manualslib.com by going to the URL <https://www.manualslib.com/download/857315/Medtronic-Guardian-Real-Time.html>. I have used the website manualslib.com in the past and know that it is considered a reputable source for product manuals. Based on my familiarity with Medtronic’s documentation and the website manualslib.com, I believe that Ex[2015] is an accurate copy of a Medtronic Guardian Real-time User Manual published prior to 2012. In addition, based on my familiarity with Medtronic’s documentation and business practices, it is my opinion that Ex[2015] exhibit accurately describes the operation of the version of the Guardian Real-Time product that was commercially available at the time the exhibit was published.

54. Ex[2014] is a document bearing the title “FreeStyle Navigator Continuous Glucose Monitoring System User’s Guide” and bears the Abbott name

and logo. The document also bears a 2008 copyright date on the last page. I obtained this document from the website manualslib.com by going to the URL <https://www.manualslib.com/download/918550/Abbott-Freestyle-Navigator.html>.

Based on my familiarity with the website manualslib.com, I believe that Ex[2014] is an accurate copy of a Freestyle Navigator user guide. In addition, based on my familiarity with general practices for user guides in the medical device industry, it is my opinion that Ex[2014] accurately describes the operation of the version of the Freestyle Navigator that was commercially available at the time the exhibit was published.

55. As can be seen from my discussion of the patent in Sections V.A-V.B above, the inventors of the '215 patent did not follow the conventional thinking (which I describe in the paragraphs above in this section) and instead developed a system in which predictive alerts use *non-user settable* thresholds.

VI. CLAIM CONSTRUCTION

A. “second function to determine whether a parameter indicative of glucose value meets ... ” (all Challenged Claims)

56. I understand that the Challenged Claims are independent claims 1 and 19 as well as various dependent claims that depend from either claim 1 or claim 19.

57. Claims 1 and 19 both recite a “second function to determine whether a parameter indicative of glucose value meets...” Thus, all the Challenged Claims include this limitation.

58. For the reasons I explain below, it is my opinion that a POSA reading the specification of the '215 patent would have understood the specification to limit the second function to being predictive.

1. The Specification’s Statements That the Invention Is Directed to Predictive Alarms

59. The '215 Patent says: “the present systems and methods relate to providing accurate predictive alarms to a user.” Ex[1001], 1:30-33. Based on the plain language of this statement, it is my opinion that a POSA would have understood that this is a statement that the invention is limited to systems/methods that provide predictive alarms. Dr. Rodbard likewise agreed at his deposition that the statement I quoted above from Ex[1001], 1:30-33 shows that the patent’s systems and methods relate to providing predictive alarms. Rodbard-Dep., 33:25-34:18.

60. Dr. Rodbard had earlier in his deposition noted that the “present systems and methods” language at Ex[1001], 1:30-31 appears underneath the word “BACKGROUND,” and that because of this, Dr. Rodbard didn’t “know if this is talking about something in the past or something which is about to appear in the subsequent material on these pages.” Rodbard-Dep., 22:19-24. I did not see this

opinion expressed in Dr. Rodbard's declaration, so this appears to be a new opinion. I disagree with this opinion because, based on my review of the specification as a whole, it is clear that the statement in question does in fact refer to the invention claimed in the patent, and not to the prior art, for a number of reasons. First, the statement refers to "the *present* systems and method," which would suggest to a POSA that the statement is not about the prior art. In addition, beneath the statement in question is a header with the language "DESCRIPTION OF RELATED ART," and that section (from 1:43-2:12) appears to be discussing the prior art. Moreover, I have reviewed the file history of the '215 patent, and I note that in the original specification as filed, the "Description of Related Art" header appeared as a subsection under the "BACKGROUND" header, which suggests that the applicants intended for the "BACKGROUND" section to encompass both their description of their invention and their description of the prior art related to their invention. *See* Ex[1003], page 237.

61. Based on my review, the specification of the '215 patent uses the words "alert" and "alarm" interchangeably; thus, in my analysis below, I may use the terms "predictive alerts/alarms" or "predictive alert/alarm." *See, e.g.:*

- Ex[1001], 9:58-60 ("FIG. 6 is a flowchart illustrating a process for dynamically and intelligently providing a prediction alert/alarm in accordance with an embodiment of the disclosure."),

- 9:64-67 (“FIG. 8 is a flowchart illustrating a process for dynamically and intelligently monitoring the status after an alert/alarm has been triggered in accordance with an embodiment of the disclosure.”),
- 17:5-6 (“predictive alert/alarm”),
- 23:25-32 (“FIG. 6 is a flowchart 500 illustrating a process for dynamically and intelligently providing a prediction alert/alarm in accordance with an embodiment of the disclosure. As explained above, providing a predictive alert/alarm is highly desirable as it may minimize and/or prevent the number of hypoglycemia and/or hyperglycemia episodes a user experiences.”),
- 30:34-36 (“Such alerts may be a nuisance to the user, causing them to suspend (e.g., snooze) alert/alarm feature of the monitor.”),
- 30:40 (“If the user has suspended the alert/alarm feature”),
- 30:45-48 (“Referring now to FIG. 7, an example of a continuous trace of glucose values measured during a time frame showing different scenarios that may cause an alert/alarm to be repeated is shown.”), Fig. 6 (element 500 reciting “alert/alarm”).

I also understand that Dr. Rodbard did not dispute that the terms alert and alarm are equivalent for the patent's purpose. *See* Rodbard-dep., 18:15-20:20.

62. A POSA also understood that the statement “the present systems and methods relate to providing accurate predictive alarms to a user” (Ex[1001], 1:30-33) limits the invention by limiting the second function. This is because, based on my review of the specification, the specification only describes predictive alerts/alarms as being provided by the second function, and only describes the second function as providing predictive alerts/alarms. *See, e.g.:*

- Ex[1001], 2:26-28 (“...evaluating sensor data using a second function to determine whether a predicted glucose value meets one or more second criteria...”),
- 2:45-49 (“...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.”),
- 3:3-19 (“In an embodiment of the first aspect, the second function comprises a Kalman Filter to determine the predicted glucose value ... In an embodiment of the first aspect, the second function comprises a prediction horizon that is not user settable. ... In an

- embodiment of the first aspect, the second function comprises a prediction horizon that is adaptively set by the processor module based on the first threshold.”),
- 3:40-49 (“In a second aspect, a system for processing data is provided, the system comprising: ... sensor electronics configured to receive and process sensor data output by the sensor, the sensor electronics including a processor configured to: ... evaluate sensor data using a second function to determine whether a predicted glucose value meets one or more second criteria”),
 - 3:66-4:9 (“In an embodiment of the second aspect, the evaluating sensor data using a second function determine whether the predicted glucose value meets one or more second criteria comprises evaluating a dynamic risk of the predicted glucose value. ... In an embodiment of the second aspect, the second function utilizes a first order autoregressive model to determine the predicted glucose value.”),
 - 4:24-40 (“In an embodiment of the second aspect, the second function comprises a Kalman Filter to determine the predicted glucose value using as an input an estimate of the rate of change of the blood glucose. ... In an embodiment of the second aspect, the

- second function comprises a prediction horizon that is not user settable. ... In an embodiment of the second aspect, the second function comprises a prediction horizon that is adaptively set by the processor module based on the first threshold.”),
- 26:56-60 (“Consequently, in some embodiments, the processor module 214 may be configured to evaluate sensor data using a second function to determine whether a predicted glucose value meets one or more predictive alarm criteria.”),
 - 29:39-45 (“In such an example, the child host may receive an audible alarm, while the parent may receive a detailed glucose log. ... In other embodiments, if the second function predicts that the second threshold will be met first, an alarm is provided to a user.”),
 - 37:15-17 (“Inactivation conditions for the real-time alert (first function) and predictive alert (second function) may be the same or different.”).

In addition, Dr. Rodbard agreed that the specification does not discuss the first function in relation to predictive alerts/alarms. Rodbard-Dep., 35:14-21.

a. Dr. Rodbard’s contrary arguments are unpersuasive

63. I have reviewed Dr. Rodbard’s declaration (Ex[1002]), and based on my review, the only place where Dr. Rodbard offers any counter-arguments against

DexCom’s proposed construction from the litigation is in footnote 4. *See* Ex[1002], ¶ 63 n.4. In this footnote, Dr. Rodbard offers two arguments against construing the “second function” to be one that is limited to providing predictive alerts/alarms. *See id.* For the reasons I explain below, I disagree with both of Dr. Rodbard’s arguments.

64. **First**, Dr. Rodbard states: “Claims 1 and 19 of the ’215 Patent recite that the ‘second function’ is used to output ‘hypoglycemic *indicators*,’ not only alerts or alarms.” Ex[1002], ¶ 63 n. 4 (emphasis in original). However, nowhere does Dr. Rodbard explain what he thinks the supposed distinction is between an indicator and an alert/alarm. In fact, to the contrary, Dr. Rodbard states multiple times that alerts and alarms are both examples of indicators. *See, e.g., E.g.,* Ex[1002], ¶¶ 30 (“indicators, such as alerts and alarms”), 32 (“indicators, including alerts and/or alarms”), 34; *see also* Rodbard-Dep., 15:4-8 (agreeing that “alerts and alarms are both examples of indicators”).

65. Moreover, even if the Board were to construe the second function as providing a predictive “hypoglycemic indicator,” Dr. Rodbard’s argument for Ground 1 fails because the Guide’s hypoglycemic indicator is not predictive, as I discuss in Section VII.A.1 below.

66. **Second**, Dr. Rodbard says: “[a]dditionally, the claims do not limit the second function to providing ‘predictive’ indicators—providing indicators based

on a ‘predicted glucose value’ is introduced in dependent claim 5, which I understand is presumed to be narrower than claim 1.” Ex[1002], ¶ 63 n. 4. However, claim 5 recites “evaluating a *dynamic risk* of the predicted glucose value.” Thus, claim 5 would still be narrower than claim 1 even if the “second function” recited in claim 1 is interpreted as providing a predictive alert/alarm/indicator. Dr. Rodbard also admitted this. See Rodbard-Dep., 82:6-83:4.

2. Even If the Board Finds the “Second Function” Not Limited to Predictive Alerts, Dr. Rodbard’s Argument For Ground 1 Fails Because It Fails to Give Meaning to All Terms in Elements 1[b]/19[d]

67. Elements 1[b] and 19[d] both recite “a second function to determine whether a parameter indicative of glucose value meets one or more non-user settable second criteria.” See, Ex[1002], Appendix B. As Dr. Rodbard admitted, his argument for Ground 1 reads the “second function” onto an alleged Guide function that does the same thing the Guide’s alleged first function does – it compares a real-time glucose value against a threshold. See Rodbard-Dep., 68:18-22 As detailed below, in making this argument, Dr. Rodbard ignores the relevant portions of the ’215 Patent’s specification entirely, fails to give meaning to the claimed “first” and “second” functions, and reads “parameter indicative of” entirely out of the claims.

a. Dr. Rodbard Ignores the Relevant Portions of the Specification

68. Dr. Rodbard confusingly lumps his Element 1[b] arguments for Grounds 1 and 2 together in the same section. *See* Rodbard, § X.A.1.c, ¶ 62 (“In my opinion the User’s Guide alone (Petition Ground 1) or in combination with Harper (Petition Ground 2) discloses element 1[b].”). In what appears to be his Ground 1 argument over “[t]he Guide alone,” Dr. Rodbard says:

The automatic Low Glucose Alarm thus involves comparing glucose values to the non user settable threshold set at 55 mg/dL, which is “evaluating sensor data using a second function to determine whether a parameter indicative of glucose value meets one or more non user settable criteria” as claimed.

Rodbard, ¶ 62.

69. Because Dr. Rodbard did not cite the specification of the ’215 patent in discussing the “second function” limitation, he ignores statements in the “SUMMARY” section of the ’215 patent that describe the “second function,” including those making clear that it determines “whether a *predicted* glucose value meets the one or more second criteria.” Ex[1001], 2:27-28; *see also id.*, 3:48-49, 3:67-4:2. Dr. Rodbard also ignores other relevant portions of the specification, as I explain in Sections VI.A.2.a.i-VI.A.2.a.ii below.

70. I am also informed and understand that the Petition cites Ex[1001], 4:31-32 in support of the same argument that Dr. Rodbard advances in paragraph

62 of his declaration. That single specification line the Petition cites is in the “SUMMARY,” and nowhere refers to a “second function” or a “parameter.” Ex[1001], 4:31-32. That line teaches that “the one or more second criteria comprises a second threshold that is not user settable” (*id.*), but a POSA would not have understood this to inform the proper interpretation of the other language in Elements 1[b]/19[d] requiring a “second function” and a “parameter indicative of” a glucose value.

i. Second Function

71. Dr. Rodbard ignores the portions of the ’215 Patent’s specification that describe the “second function” and the “second set of instructions” that implement the second function. *See e.g.*, Ex[1001], 25:3-5 (“At **block 530**, processor module 214 may be configured to evaluate the sensor data using a **second set of instructions**”), Fig. 6 (**block 530** labeled “Evaluate Sensor Data Using a **Second Function** ...”). Dr. Rodbard agreed that the specification describes the “second set of instructions” as implementing the “second function.” *See* Rodbard-Dep., 74:20-75:3.

72. I have reviewed Section X.A.1.c of Dr. Rodbard’s report, which is the section where Dr. Rodbard analyzes Element 1[b] with respect to the Guide alone. In this entire section, Dr. Rodbard never cited the specification of the ’215 patent in his analysis of the “second function” language in Element 1[b]. *See* Rodbard,

¶¶ 62-63 & n.4. Dr. Rodbard confirmed at his deposition that he did not cite the specification because he “didn’t believe it was necessary” to do so. Rodbard-Dep., 48:4-23.

73. As I noted in Section V.B above, the specification repeatedly describes the second function not as applying a real-time glucose value to a threshold, but instead using an “algorithm” to evaluate a predicted glucose value. *See, e.g.:*

- Ex[1001], Abstract (“evaluating sensor data using a ***second function*** to determine whether a ***predicted*** glucose value meets a second threshold”);
- *Id.*, 2:45-55 (“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. In an embodiment of the first aspect, the ***second function*** comprises an artificial neural network model... to determine the ***predicted*** glucose value. In an embodiment of the first aspect, the ***second function*** utilizes a first order autoregressive model to determine the ***predicted*** glucose value.”);
- *Id.*, 22:29-35 (flag x₂ is “a ***predictive*** flag ... to alert the user that a ***second*** threshold, e.g., TV_P, is ***predicted to be met***”);
- *Id.*, 25:8-17 (“the ***second*** set of instructions ... may include any algorithm ... suitable for evaluating sensor data to determine whether a glycemic state

... is *predicted*,” including algorithms based on “polynomial and autoregressive models ... Kalman Filtering (KF), artificial neural networks, statistical and numerical logical algorithms and machine learning”);

- *Id.*, 28:20-30 (processor module 214 “activate[s] a hypoglycemic indicator” if a “set of instructions has met its criteria,” where “the *second* set of instructions may determine [whether a] second threshold is *predicted to be met*”);
- *Id.*, 29:43-45 (“if the *second function predicts* that the second threshold will be met first, an alarm is provided to the user”);
- *Id.*, 37:15-17 (“Inactivation conditions for the real-time alert (first function) and *predictive alert (second function)* may be the same or different.”)

ii. Parameter Indicative Of

74. Dr. Rodbard also ignores everything the specification says about “parameters.” *See, e.g.:*

- Ex[1001], 21:57-22:13 (TV_P is a “*predictive* threshold” for “glucose value” that “may *not be settable* by a user” and is a “*parameter* associated with prediction”);
- *Id.*, 22:40-45 (“*prediction* algorithm *parameters*”);

- *Id.*, 22:46-52 (TV_P is a “*prediction parameter*[.]” that “may be invisible to the user and *preset or fixed*,” or “determined from the sensor manufacturer”).

75. During his deposition, Dr. Rodbard stated that he believes “parameter indicative of glucose value... includes a glucose value or includes specifically a realtime glucose value or a substantively realtime glucose value.” Rodbard-Dep., 90:1-4. In support of his argument, Dr. Rodbard stated that “‘parameter’ just means literally ‘para’ and ‘meter’ means for to measure, or for measuring.” Rodbard-Dep., 90:12-14. Based on my review of the ’215 patent and my own knowledge and experience as a POSA, I disagree with Dr. Rodbard that “parameter indicative of glucose value” includes the real-time glucose value, because under Dr. Rodbard’s interpretation, a “parameter indicative of [X]” would be the same thing as “[X]” itself, and Dr. Rodbard has not explained why this comports with how a POSA would use the term “parameter indicative of.”

VII. THE GROUNDS FAIL TO DEMONSTRATE UNPATENTABILITY OF ANY CHALLENGED CLAIM

76. In my opinion, the Grounds discussed in Dr. Rodbard’s Declaration (Ex[1002]) fail to demonstrate the unpatentability of any Challenged Claim, for the reasons I explain below.

A. Ground 1 (Obviousness of Claims 1-3, 12, 19 and 23 over the Guide)

1. Ground 1 Fails Because the Proper Construction of “Second Function” Requires a Predictive Alert/Alarm

77. As I explained in § VI.A, the “second function” in elements 1[b]/19[d] is properly construed as a “function that provides a predictive alert/alarm.”

78. I have reviewed the Guide, and the Guide does not disclose predictive alerts/alarms. Moreover, Dr. Rodbard does not allege that the Guide discloses the claimed “second function” under the construction I have advocated above. *See also* Rodbard-Dep., 49:21-50:2. Thus, under the correct construction of “second function” Ground 1 fails.

2. Ground 1 Fails Even If the Board Does Not Adopt DexCom’s Construction of “Second Function”

a. Ground 1 Fails to Meet Elements 1[b]/19[d]

i. Dr. Rodbard does not explain his reasoning

79. In Paragraph 27 of his report, Dr. Rodbard stated that he “interpreted the claims in accordance with the ordinary and customary meaning as understood by one of ordinary skill in the art at the relevant time.” However, Dr. Rodbard does not explain anywhere in his report what “ordinary meaning” he applied to the term “second function.”

80. Dr. Rodbard’s rationale for why the Guide alone meets the “second function” consists of the following:

The automatic Low Glucose Alarm thus involves comparing the glucose values to the non user settable threshold set at 55 mg/dL, which is “evaluating sensor data using a second function to determine whether a parameter indicative of glucose value meets one or more non user settable criteria” as claimed.

Ex[1002], ¶ 62. This statement never explains what the alleged ordinary meaning is of the “second function.”

b. Dr. Rodbard’s Assertion That the Claimed “Second Function” and “Parameter” Are Met by Comparing a Sensor’s Real-Time Glucose Value to a Threshold Fails

81. Claims 1 and 19 both draw a distinction between evaluating “a *real time* glucose value” (1[a], 19[c]) and evaluating “a *parameter indicative of* [a] glucose value” (1[b], 19[d]).

82. However, despite this distinction, Dr. Rodbard maps the claimed “parameter indicative of [a] glucose value” onto a real-time glucose value and reads both the first and second functions onto a function that compares a real-time glucose value to a threshold. Dr. Rodbard’s implicit constructions fail for the reasons detailed below.

**i. Dr. Rodbard Reads “Parameter Indicative Of”
Out of the Claims**

83. Dr. Rodbard’s argument for Ground 1 reads “parameter indicative of [a] glucose value” onto a real-time glucose value. Rodbard, ¶ 63 (“a POSITA would have understood that ‘a parameter indicative of a glucose value’ includes the purported ‘real time continuous glucose measurements’ used to trigger the Low Glucose Alarm in the User’s Guide....”).

84. Dr. Rodbard alleges that his argument is supported by the ’215 Patent specification at 26:50-60. Dr. Rodbard states:

For example, the ’215 Patent discloses that sensor data includes “*real time glucose values*, (e.g. blood glucose values (BGs)), calibrated glucose values (e.g., estimated glucose values (EGVs)), rate of change of glucose values, direction of change of glucose values, acceleration or deceleration of glucose values, insulin information, event information, historical trend analysis results, and the like[.]” Ex[1001] at 26:50-60 (emphasis added). Thus, a POSITA would have understood that “a parameter indicative of a glucose value” includes the purported “real time continuous glucose measurements” used to trigger the Low Glucose Alarm in the User’s Guide (Ex[1004] at 9), because the ’215 Patent expressly lists “real time glucose values” as an example of sensor data used to indicate a user’s glycemic level.

Rodbard, ¶ 63 (emphasis in original). The full passage Dr. Rodbard relies on is quoted below:

In some embodiments, the sensor data comprises real time glucose values, (e.g. blood glucose values (BGs)), calibrated glucose values (e.g., estimated glucose values (EGVs)), rate of change of glucose values, direction of change of glucose values, acceleration or deceleration of glucose values, insulin information, event information, historical trend analysis results, and the like[.] Consequently, in some embodiments, the processor module 214 may be configured to evaluate sensor data using a second function to determine whether a predicted glucose value meets one or more predictive alarm criteria.

Ex[1001], 26:50-60. Dr. Rodbard focuses on the portion of the cited passage referencing “sensor data” the second function evaluates, and notes that this sensor data comprises “real time glucose values.” Rodbard, ¶ 63. However, Dr. Rodbard ignores that a few lines later, the specification explains that the second function does not determine whether this “sensor data” meets any criteria. Instead, the second function “evaluate[s the] sensor data ... to determine whether” something else – “a *predicted glucose value*” – meets one or more criteria. Ex[1001], 26:56-60. That tracks Elements 1[b]/19[d], which recite that the second function evaluates “sensor data ... to determine whether” something else – “a parameter indicative of a glucose value” – meets one or more criteria.

85. Based on my review of the specification, the specification never characterizes any of the “sensor data” evaluated by the second function as a “parameter indicative of glucose value.”

86. Based on my review of the specification, the specification also never describes the second function as determining whether any value in the sensor data meets one or more criteria. Instead, the specification describes the second function as (1) using an algorithm that evaluates the sensor data to predict a “future glucose value,” and (2) determining whether that predicted future glucose value meets one or more criteria indicative of a future hyper-glycemic or hypo-glycemic state. *See, e.g.,* Ex[1001], 25:7-26:14. For example, the specification says: “in **block 530, the second set of instructions** or criteria may include any algorithm or algorithms suitable for evaluating sensor data to determine whether a glycemic state (hyper- or hypo-glycemia) is predicted, for example, by determining if a data point is predicted or projected to cross a predetermined threshold.” As shown in Figure 6 (below), block 530 uses the term “second function.” The specification then describes various algorithms that the “second set of instructions” / “second function” “may use” to “predict a future glucose value.” Ex[1001], 25:15-26:14. *See also* my discussion of the specification’s references to the “second function” in Section VI.A.2.a.i above.

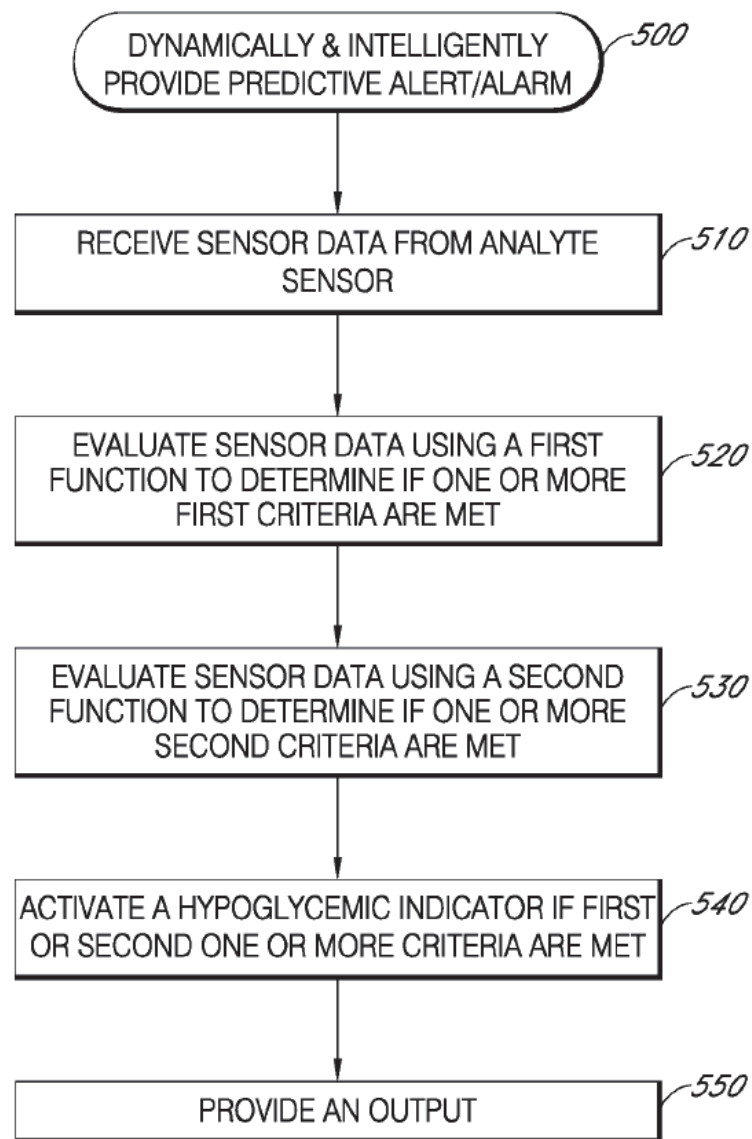


FIG. 6

'215 Patent, Fig. 6

87. Thus, a POSA would have understood that in the specification's description of the second function, it is the predicted glucose value that corresponds to the claimed "parameter indicative of [a] glucose value." Dependent claims 6-7 reciting that "*the parameter* is a predicted glucose value" confirm a "predicted glucose value" is a "parameter indicative of [a] glucose value" in claim 1.

88. As I have explained above in this section, the '215 patent's claims, as well as the specification, draw a clear distinction between a "parameter indicative of a glucose value" (Elements 1[b]/19[d]) and a "real time glucose value" (Elements 1[a]/19[c]). Dr. Rodbard's assertion that "parameter indicative of [a] glucose value" is met by the Guide's real-time glucose values (Rodbard, ¶ 63) is unsupported by any evidence and refuted by the specification.

ii. Dr. Rodbard Fails to Give Proper Meaning to the "Second" Function as Different Than the "First" Function

89. Every Challenged Claim recites not just one function, but a "first function" and a "second function." See Elements 1[a]-1[b] and 19[c]-19[d].

90. In his argument for Ground 1, Dr. Rodbard reads both the "first function" and the "second function" on a comparison between a real-time glucose value and a threshold. See Rodbard, ¶ 61 (Element 1[a] – the Guide's "comparing the glucose values to the lower threshold of the user-set target range" is

‘evaluating sensor data using a first function’ as claimed”); *id.*, ¶ 62 (Element [1b] – “The automatic Low Glucose Alarm thus involves comparing the glucose values to the non user settable threshold set at 55 mg/dL, which is ‘evaluating sensor data using a second function to determine whether a parameter indicative of glucose value meets one or more non user settable criteria’ as claimed.”); *id.*, ¶¶ 90-91 (Dr. Rodbard’s arguments for 19[c]-19[d] relying on his arguments for 1[a]-1[b], respectively). *See also* Rodbard-Dep., 68:18-22.

91. Elements 1[b] and 19[d] do not recite using “the” same function as in Elements 1[a] and 19[c], respectively. Instead, they introduce what a POSA would have understood was “a” new function – “a second function.” As I explained in Section V.A above, the claims require that the second function perform a different function than the first function by evaluating sensor data to make a determination about “a parameter indicative of [a] glucose value,” rather than evaluating sensor data to make a determination about “a real time glucose value” as the first function does.

92. The specification also consistently distinguishes between the first and second functions implemented by first and second “set[s] of instructions” (Ex[1001], 23:39-41 (referring to “first set of instructions” used at “block 520” in Fig. 6), 25:3-5 (referring to “second set of instructions” used at “block 530” in Fig. 6), Fig. 6 (blocks 520 and 530 use a “first function” and “second function,”

respectively). As I detail below, the “first function” compares a real-time glucose value to a user-settable threshold, whereas the “second function” is a more complex function that determines whether a “parameter indicative of [a] glucose value,” *e.g.*, a predicted glucose value, meets a fixed threshold.

93. The ‘215 Patent’s “SUMMARY” (Ex[1001], 2:14) describes the “second function” as employing a technique to determine a predicted glucose value (*id.*, 2:45-47), with non-limiting examples of suitable techniques including an “artificial neural network” (*id.*, 2:50-51, 4:4), an “autoregressive model” (2:54, 4:9-11), and a “Kalman filter” (*id.*, 3:4-5, 4:25-26). *See* Bazzal (Ex[2001]), [0027] (“The Kalman filter is a well-known time domain filter that performs a point-by-point analysis to estimate future states in a dynamic system”); Baras (Ex[2002]), [0050] (“Artificial neural networks are mathematical representations of complex mathematical functions.”). Conversely, the “SUMMARY” describes the “first function” as comparing a “real-time glucose value” to a “glucose threshold” (Ex[1001], 2:33-36, 3:53-57).

94. The ‘215 Patent’s “DETAILED DESCRIPTION” (beginning Ex[1001], 10:15) describes “sensor electronics” (*id.*, 12:38) including a “processor module 214” (*id.*, 10:53). When describing “set[s] of instructions” the “processor module” uses, the patent says “the first set of instructions from block 520 is

different than the second set of instructions from block 530.” *Id.*, 25:5-7, Fig. 6 (below).

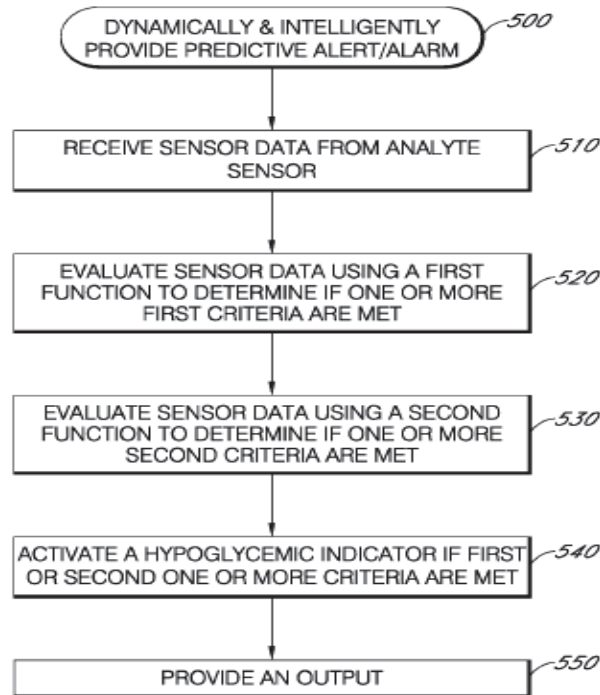


FIG. 6

95. The “first set of instructions” may simply include “an algorithm suitable for determining if a data point has met one or more...criteria.” Ex[1001], 23:40-45. Conversely, the “second set of instructions” may include a suitable “algorithm” capable of predicting a future hyperglycemic or hypoglycemic state based in part on the current glucose value, non-limiting examples of which include algorithms “based on polynomial and autoregressive models, algorithms based on Kalman Filtering (KF), artificial neural networks, statistical and numerical logical algorithms, and machine learning.” *Id.*, 25:8-17.

iii. Dr. Rodbard Reads The First and Second Functions on the Same Function

96. I am informed and understand that in its institution decision, which was issued when the Board did not have a full record of evidence, the Board suggested that the Guide necessarily uses two functions: a “first” that compares a real time glucose value to a user-settable threshold and a “second” that compares the same real time glucose value to a different (non-user settable) threshold.

97. However, as I explain in paragraphs 98-100 below, I respectfully believe that the Board’s suggestion does not comport with a POSA’s understanding of a “function” because it conflates a function with its input parameters.

98. A “function” computes a value based on a set of input parameters that can change across different executions of the function. *See, e.g., Oxford (Ex[2010]), 213* (a “function” is “a []program unit that given values for input parameters computes a value”). Dr. Rodbard acknowledged this well-known proposition at his deposition. *See Rodbard-Dep., 13:14-16.*

99. A POSA understood that applying different input parameters to a “function” does not change the function into two different “functions.” I have reviewed Dr. Rodbard’s declaration, and he offers no evidence to the contrary. Furthermore, at his deposition, Dr. Rodbard agreed that simply applying different input values to a “function” does not convert the function into two different “functions.” *Rodbard-Dep., 13:14-24.*

100. In Dr. Rodbard’s argument for Ground 1, the alleged first and second functions in the Guide do the same thing – they compare a real time glucose value to a threshold input parameter. Thus, in my opinion, given a POSA’s understanding of what a “function” is, Dr. Rodbard has failed to show that these are two different functions.

3. Dependent Claim 3

101. Claim 3 recites the first function as “determining whether an amplitude of rate of change or direction of rate of change meets a rate of change criterion.” Dr. Rodbard argues:

In my opinion, a POSITA would have understood that triggering alerts when glucose values are trending down includes “determining whether an amplitude of rate of change or direction of rate of change meets a rate of change criterion” at least because *the determination that glucose is ‘trending down’ is a rate of change criterion.*

Rodbard, ¶ 80 (emphasis added).

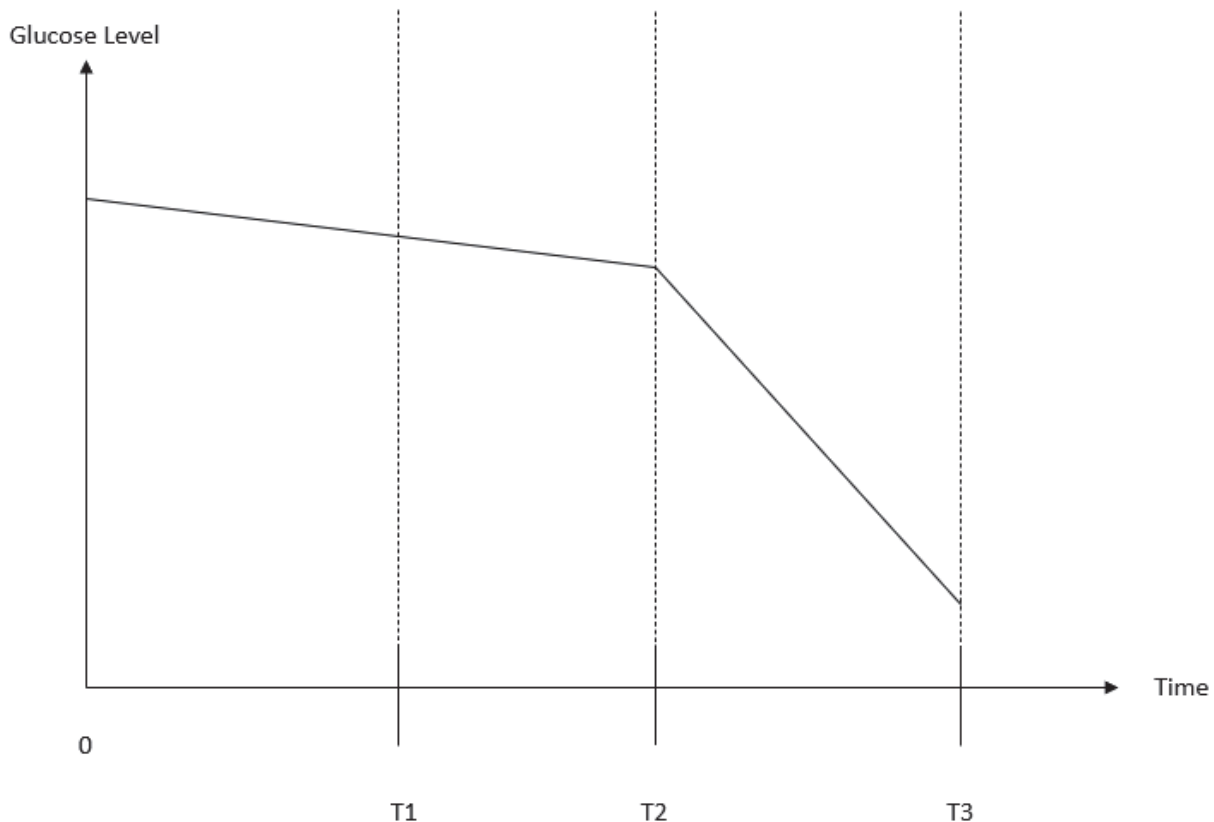
102. A POSA would have understood that glucose “trending down” is a direction of change, not a direction of *rate* of change. This is consistent with how the specification of the ’215 patent refers to things like “rate of change,” “direction,” and “trend.” See, e.g., Ex[1001],

- 23:60-66 (referring separately to “rate of change of glucose values [and] direction of change of glucose values”),

- 12:43-49 (“the processor module may transform sensor data into one or more of the following: filtered sensor data (e.g., one or more filtered analyte concentration values), raw sensor data, calibrated sensor data (e.g., one or more calibrated analyte concentration values), rate of change information, trend information, rate of acceleration/deceleration information, sensor diagnostic information, location information, alarm/alert information, calibration information, smoothing and/or filtering algorithms of sensor data, and/or the like”),
- 14:39-46 (“In some example implementations, the data packages may, as noted, be customizable for each display device, and/or may include any available data, such as a time stamp, displayable sensor information, transformed sensor data, an identifier code for the sensor and/or sensor electronics 12, raw data, filtered data, calibrated data, rate of change information, trend information, error detection or correction, and/or the like”),
- 16:27-43 (“analyze a variation of estimated analyte values, evaluate a stability of the sensor and/or sensor data, detect signal artifacts (noise), replace signal artifacts, determine a rate of change and/or trend of the sensor data, perform dynamic and intelligent

analyte value estimation, perform diagnostics on the sensor and/or sensor data, set modes of operation, evaluate the data for aberrancies, and/or the like”).

103. A POSA would have understood that direction of change and direction of *rate* of change are distinct and can differ. For example, a decelerating car moving forward has a positive direction of change (because the distance from the starting point is increasing) but a negative direction of *rate* of change (because the rate of change of distance is getting smaller). The example below illustrates a glucose level that is consistently “trending down” so the direction of change is always negative (decreasing). However, in the T_2 - T_3 time period the rate of change is greater than in the T_1 - T_2 time period, so the direction of the *rate* of change at time T_2 is positive (increasing). I understand that Dr. Rodbard agreed when he was asked about a similar-looking graph shown in Ex[2007]. See Rodbard-Dep., 91:19-96:17; Ex[2007]. Thus, Dr. Rodbard has failed to justify his assertion that “determination that glucose is ‘trending down’ is a rate of change criterion.” Rodbard, ¶ 80.



4. Claims 12 and 23

104. Claims 12 and 23 recite “the hypoglycemic indicator comprises a flag that has a particular set of instructions associated with it” depending on whether the first or second function triggered it. Dr. Rodbard’s argument for claim 23 depends on his argument for claim 12. *See* Ex[1002], ¶ 97 (“In my opinion the User’s Guide discloses claim 23 for the reasons discussed above for claim 12. *Supra*, §X.A.4.”).

105. The specification describes providing “instructions” to a person or an external device. *See* Ex[1001], 4:54-61 (“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”), 19:25-34 (referring to an “instruction mode” with “instructions on how to assist the unconscious user”), 29:13-22. *See also* Rodbard-Dep., 98:18-103:16 (agreeing that these passages described providing instructions to a person or external device).

106. The claim language – the “hypoglycemic indicator” is in an “output” (see Limitations 1[c]-[d], 19[e]-19[g]) – and above-cited portions of the specification make clear to a POSA that the “instructions” associated with the flag in claims 12 and 23 are instructions to a person or an external device.

107. However, Dr. Rodbard identifies no such instructions. In his argument for claim 12, Dr. Rodbard points to different alert patterns that occur under different circumstances. *See* Ex[1002], ¶ 81 (“...the indicators are displayed differently, such as different color and weight of the text/background on the glucose value, based on whether the indicator was triggered by the first function (user settable alert) or second function (non user settable alarm). For example, the figures below and the text within the figures (‘Low Glucose Alert Screen’ and ‘Low Glucose Alarm’), and the use of an additional different and distinct method (e.g., vibration) as a method to notify the host [user], represent a ‘flag’ triggered, in this case by a user settable and non user settable criterion, respectively.”).

However, Dr. Rodbard does not contend that any of these alert patterns present instructions. Rodbard, ¶¶ 81-84. Instead, Dr. Rodbard asserts these alert patterns are “associated” with “processing instructions” the “STS receiver” *executes* that result in outputting the alert patterns. Rodbard, ¶ 82. Thus, Dr. Rodbard fails to give “instructions” its proper meaning, which is that the flag presents “instructions” to a person or external device as I noted above.

B. Ground 2 (Obviousness of Claims 1-3, 12, 19 and 23 over Guide and Harper)

1. Dr. Rodbard Fails to Establish That His Combination Has a Function That Meets Element 1[b] or 19[d]

108. Elements 1[b] and 19[d] each require using a second function to determine whether a parameter indicative of glucose value meets one or more non-user settable second criteria.

109. For Ground 2, Dr. Rodbard argues that Elements 1[b] and 19[d] are met by “the Guide in combination with Harper.” Ex[1002], ¶ 63 n.4; *id.*, ¶ 91 (analysis for Element 19[d] relying on analysis for 1[b]).

110. As I detail below, Dr. Rodbard did not even allege (let alone prove) that any function in the Guide/Harper combination meets *all* the requirements of the second function in 1[b] or 19[d] by determining whether a *parameter indicative of glucose value* meets one or more *non-user settable* second criteria. *See* Rodbard-Dep., 57:19-58:13 (Dr. Rodbard admitted he failed to do so).

a. The Parameters Dr. Rodbard Identified in the Guide/Harper Combination Are Not Alleged To Be Evaluated Against Non-User Settable Criteria

111. Dr. Rodbard alleges that “[e]ach of Harper’s projected glucose value (*i.e.*, a predicted glucose values [*sic*]) and rate of change of glucose value level is a ‘parameter indicative of glucose value’” used to provide a predictive alarm. Rodbard, ¶ 65.

112. As Dr. Rodbard admitted at his deposition (Rodbard-Dep, 57:19-58:13), he never alleges that Harper’s projected glucose value or rate of change thresholds used in the Guide/Harper combination are “non-user settable” criteria as claimed. *See* Rodbard, ¶¶ 62-72. Dr. Rodbard only alleged that the Guide’s Low Glucose Alarm threshold (55 mg/dL) was non-user settable, but that was in connection with Ground 1’s allegation that Elements 1[b]/19[d] were met by the Guide comparing a real-time glucose value to that threshold. Rodbard, ¶ 62. That is ***not*** how Dr. Rodbard alleged that Elements 1[b]/19[d] are met in ***Ground 2***. Rodbard, ¶¶ 64-65.

113. For Ground 2, Dr. Rodbard alleges that a POSA would have modified the Guide’s system to include “***additional*** alarm profiles” from Harper to provide “***additional*** warning time to the user.” Rodbard, ¶ 70. As Dr. Rodbard admitted at his deposition (*see* Rodbard-Dep., 105:22-106:24), his proposed combination only

adds functionality from Harper to the Guide without modifying existing Guide functions.

114. However, even if a POSA would have been motivated to make Dr. Rodbard's proposed Guide/Harper combination as described in the previous paragraph, Dr. Rodbard fails to even allege that the resulting combination has a second function that makes a determination of whether (1) a parameter indicative of glucose value meets (2) one or more non-user settable criteria, as claimed. The Guide's un-modified system does not disclose such a function for the reasons I discussed in § VII.A for Ground 1. Even if the Guide makes a determination of whether something meets non-user settable criteria and thereby satisfies (2), it does so for a real-time glucose value that is not a parameter indicative of glucose value and thus fails to satisfy (1). Indeed, in Dr. Rodbard's analysis of the Guide/Harper combination, he does not allege that any existing *Guide* function meets elements 1[b]/19[d]. Rodbard, ¶¶ 64-65. In Dr. Rodbard's analysis, the sole purpose of the Guide/Harper combination is to provide an *alternative* manner in which Elements 1[b] and 19[d] are allegedly met by the Guide's system as *modified* based on Harper.

115. The "additional" alarm (Rodbard, ¶ 70) added to the Guide based on Harper is not a second function as claimed. Even if Harper's function makes a determination about a parameter (Harper's projected glucose value or rate of

change of glucose value) and thereby satisfies (1), Dr. Rodbard does not even allege (let alone prove) that Harper's function determines whether the alleged parameter meets one or more *non-user settable* criteria to satisfy (2). Rodbard, ¶¶ 64-65.

116. Thus, Dr. Rodbard fails to even allege that the Guide/Harper combination meets either of Elements 1[b] and 19[d] as a whole, let alone any Challenged Claim as a whole.

b. Harper's Criteria are User Settable

117. For Ground 2, Dr. Rodbard alleges that the claimed "parameters" are met by projected glucose value and rate of change of glucose value. *See* Rodbard, ¶ 65. But Harper states that the thresholds for these alleged "parameters" are user settable. Harper, [0202] (describing a "threshold screen in which *a user may select varying glucose threshold* levels at which various alarms will sound for...*projected* low glucose levels and *projected* high glucose levels"), [0281] ("*the rate of change threshold... may be selected and adjusted by the user*"). Dr. Rodbard also admitted at his deposition that Harper's predicted glucose value threshold discussed in paragraph [0202] and rate of change threshold discussed in paragraph [0281] are user-settable. Rodbard-Dep., 110:1-112:7 (discussing Harper, [0202]), 112:8-113:7 (discussing Harper, [0281]).

118. Despite Harper clearly saying that its projected glucose value and rate of change criteria are user settable, Dr. Rodbard said at his deposition: “it’s pretty obvious that to me – it’s pretty obvious, I think, to most people, maybe to everybody, that a criterion such as a predicted alert could also be made on the basis of nonuser settable criteria.” Rodbard-Dep., 113:9-13. I note that Dr. Rodbard provided no evidence to support his statement, nor do I see any evidence in his declaration supporting the proposing that a POSA would have made Harper’s criteria non-user settable. In fact, as I note in § VII.B.1.d below, Dr. Rodbard admits that his proposed combination of Harper and the Guide in Ground 2 *does not* involve any modification of Harper. Given Dr. Rodbard’s lack of evidence, and given that the prevailing view in the prior art was that predictive alerts should be user-settable (as I discussed *supra* § V.D), I do not believe that Dr. Rodbard has shown that making Harper’s projected glucose value or rate of change criteria would have been obvious.

119. In ¶ 64 of his declaration, Dr. Rodbard states: “Harper discloses that a low glucose target indicator may be locked and/or password protected to prevent a user from changing the threshold range values such that it is non user settable. [Harper] at [0088].” However, as I noted above, in his analysis of Ground 2, Dr. Rodbard only alleges that Harper’s *projected* glucose value and *rate of change* of glucose value meet the claimed “parameter indicative of glucose value.” Even if

threshold for the low glucose target indicator were non-user settable (which I disagree with, as I discuss below), Dr. Rodbard does not explain how this is relevant to his analysis of the claims.

120. Furthermore, I disagree with Dr. Rodbard's claim in ¶ 64 of his declaration that the threshold for the low glucose target indicator is not user settable. Dr. Rodbard cites Harper, [0088], but does not provide a quotation. The full language of Harper, [0088] is quoted below:

Referring still to FIG. 3A, lower glucose target indicator 312 and upper glucose target indicator 314 may be represented as horizontal lines and displayed in a different color than the color of the graph line 310. Although solid lines are shown, it is contemplated that dashed lines or other indicators may be used to designate the lower glucose target indicator 312 and the upper glucose target indicator 314. As will be explained in greater detail below, the values corresponding to the lower glucose target indicator 312 and the upper glucose target indicator 314 may be changed by a user. ***In another embodiment, the values of the lower glucose target indicator 312 and the upper glucose target indicator 314 may only be changed by a healthcare professional. In such cases,*** a menu screen allowing a user to change the lower glucose target indicator 312 and the upper glucose target indicator 314 ***may be locked and/or password protected to prevent a user from changing the threshold range values without permission or authorization from a healthcare professional, parent or guardian.***

Harper, [0088] (emphasis added). The text of paragraph [0088] makes clear that even in the embodiment where the “menu screen” for changing the “lower” and “upper” “glucose target indicator[s]” is locked, the patient *can* change the threshold, as long as he or she has “permission or authorization” to do so from a “parent, healthcare professional, or guardian.” *Id.*

121. I note that during his deposition, when he was questioned about paragraph [0088] of Harper, Dr. Rodbard agreed that “when it says ‘without permission,’ I think it’s saying under some circumstances, that could be changed by the user.” Rodbard-Dep., 62:5-64:9.

122. I also note that during his deposition, Dr. Rodbard said that Harper’s low glucose thresholds and projected low glucose thresholds “may or may not be identical,” although he admitted that he did not cite anything in his declaration from Harper showing whether they are the same or different. Rodbard-Dep., 56:23-57:18. If they are the same, this would mean that the threshold for projected glucose level is *user-settable*, meaning that Dr. Rodbard’s argument would fail. *See* Harper, [0202] (“In certain embodiments, the low glucose threshold level may be selected by a user or healthcare provider from a predetermined range (e.g., 60-119 mg/dL) and the high glucose threshold level may be selected by a user or healthcare provider from a second predetermined range (e.g., 120-300 mg/dL). Each of the high and low threshold levels may be changed by the user or healthcare

provider by highlighting the menu item using the selection indicator 1020 and inwardly pressing the jog wheel 230. The user may then scroll through the desired threshold level for the selected menu item.”). If they are different, then Dr. Rodbard’s argument would also fail, because it means he has not identified any criterion that Harper’s “projected glucose value,” which he alleges meets the claimed “parameter indicative of glucose value” (*see* Rodbard, ¶ 65), is compared against.

123. As I noted in ¶ 112 above, Dr. Rodbard admitted at his deposition (Rodbard-Dep, 57:19-58:13) that he never alleges that Harper’s projected glucose value or rate of change thresholds used in the Guide/Harper combination are “non-user settable” criteria as claimed. Dr. Rodbard nevertheless claimed at his deposition that there are certain “things” involved in prediction that are “built into the system” and therefore are “not user settable” because the “user never thinks about them, never knows about them. They’re invisible.” Rodbard-Dep., 58:16-59:18. Dr. Rodbard never mentioned the projected glucose value or rate of change of glucose value thresholds on his list of “things” that are not user settable. However, to the extent Dr. Rodbard claims he meant to contend that Harper’s projected glucose value thresholds or rate of change of glucose value thresholds are not user settable because projected glucose value and rate of change of glucose value are things the “user never thinks about,” this contention is directly refuted by

Harper, which expressly describes both projected glucose value and rate of change of glucose value thresholds as user settable, as I discuss at the beginning of this section (*e.g.* ¶ 117 above, citing Harper, [0202], [0281])). Furthermore, as I noted in Section V.D above, prior art CGM devices that featured predictive alerts/alarms had user-settable thresholds, which also refutes any notion that predicted glucose thresholds were things the “user never thinks about.”

c. To the Extent Dr. Rodbard Alleges That Harper’s Parameters Would Be Compared Against the Guide’s Criteria, That Assertion Fails

124. The only criterion in Harper or the Guide that Dr. Rodbard alleges is non-user settable is the Guide’s 55 mg/dL threshold, but Dr. Rodbard maps that threshold to Elements 1[b]/19[d] only for Ground 1 (Guide alone). *See* Rodbard, ¶ 62.

125. If Dr. Rodbard contends that he should be understood to argue that in the Guide/Harper combination the “one or more non-user settable second criteria” is the Guide’s 55 mg/dL threshold, Dr. Rodbard’s argument for Ground 2 fails. Under that understanding of the Dr. Rodbard’s argument, Dr. Rodbard impermissibly divides up Elements 1[b] and 19[d], to allege that the “second function” is met by Harper, the “non-user settable second criteria” is met by the Guide, and the “parameter indicative of glucose value” is met by Harper, rather

than demonstrating how the Guide/Harper combination meets these claim elements as a whole.

126. Elements 1[b] and 19[d] each recite a specific relationship between the function, parameter and criteria by requiring: “evaluat[ing] sensor data using a *second function* to determine whether a *parameter indicative of glucose value* meets one or more *non-user settable second criteria*.” Thus, to show that either Element 1[b] or 19[d] is met as a whole, Dr. Rodbard would have had to show that the alleged “second function” in *Harper* determines whether the alleged parameter indicative of glucose value *in Harper* meets the alleged non-user settable criteria in *the Guide*. That is, Dr. Rodbard would have had to show that *Harper’s* use of “projected glucose values” or “a rate of change of glucose level” for predicting hypoglycemic conditions (Rodbard, ¶ 65) determines whether *Harper’s* projected glucose value or rate of change of glucose value (Rodbard, ¶ 65) meets the *Guide’s* ““automatic Low Glucose Alarm set at 55 mg/dL”” threshold (Rodbard, ¶ 62, quoting Ex[1004] at 56). However, I see no place in his Declaration (Ex[1002]) where Dr. Rodbard alleges this.

d. Dr. Rodbard Never Establishes a Reason to Modify Harper’s Criteria to Make Them Non-User Settable

127. As I explained *supra* § VII.B.1.a-b, Dr. Rodbard fails to allege that Harper’s projected glucose value threshold and rate of change of glucose threshold

are non-user settable; moreover, Harper teaches that they are user settable. *See, e.g.,* Harper, [0202], [0281].

128. Dr. Rodbard argued in his Declaration that a POSA would have added Harper's predictive alerts to the Guide to improve alert accuracy and provide additional warning time. Rodbard, ¶ 68. However, nowhere did Dr. Rodbard argue that a POSA had a non-hindsight reason to implement the Guide/Harper combination by **modifying** Harper's projected glucose value threshold and/or rate of change of glucose value threshold to make those thresholds non-user settable.

129. Dr. Rodbard argues that a POSA would have "[c]ombine[d] Harper's alarm profile with the Guide" to create "**additional** alarm profiles." Rodbard, ¶¶ 68, 70. As I discussed *supra* § VII.B.1.b, adding Harper's projected glucose value and/or rate of change of glucose value alarm profiles to the Guide does not result in a combined system that meets Element 1[b] or 19[d], because Harper's projected glucose value and rate of change of glucose thresholds are user settable (Harper, [0202], [0281]), whereas claim Elements 1[b] and 19[d] require **non**-user settable criteria.

130. As Dr. Rodbard acknowledged at his deposition, his proposed Guide/Harper combination does not involve modifying any feature of Harper. *See* Rodbard, ¶ 68 (combination "is nothing more than combining prior art elements according to known methods to yield predictable results"); Rodbard-Dep., 106:21-

24 (“Q. You're not modifying any existing functionality in the Guide, you're adding existing functionality from Harper? A. That's correct.”). *See also* Rodbard-Dep., 104:23-106:20 (also confirming that combination does not involve modifications to Harper, only adding features from Harper to Guide). Thus, Dr. Rodbard never argued that a POSA would have added Harper's alarm profiles using a projected glucose value and/or rate of change of glucose to the Guide, and then would have modified those profiles to destroy the ability Harper expressly describes for the user to set their thresholds.

131. The Guide teaches a number of user-settable “personal glucose alert settings” (Guide, 56) in addition to a *single* non-user settable Low Glucose Alarm threshold of 55 mg/dL. *Id.*, 54-55. Harper teaches that its projected glucose value and rate of change of glucose thresholds are precisely the type of personal *user settable* alerts the Guide describes. Harper, [0202], [0281]. The reasons Dr. Rodbard offers for adding Harper's alerts to the Guide – to provide “additional alarm profiles” that provide “additional warning time to the user” and “improve the effectiveness of the information provided” (Rodbard, ¶¶ 70-71) – are met by adding Harper's *unmodified* alerts (with user-settable thresholds) to the Guide, as Dr. Rodbard admitted at his deposition. Rodbard-Dep., 116:11-118:19.

132. Neither the Guide nor Harper teaches evaluating the Guide/Harper combination's alleged "parameters" – projected glucose value or rate of change of glucose (Rodbard, ¶ 64) – using non-user settable criteria as claimed.

133. Furthermore, Harper's "Projected High" and "Projected Low" alerts use the same user-settable high and low thresholds as Harper's real-time glucose value alerts. *See* Harper, [0202] ("In certain embodiments, when the day alarm time has been set, the menu linearly progresses to a 'Glucose Alarm' threshold screen in which a user may select varying glucose threshold levels at which various alarms will sound for low glucose levels, high glucose levels, projected low glucose levels and projected high glucose levels."), [0203] ("In certain embodiments, a value for the 'Projected Low' item 1050 and value for the 'Projected High' item 1060 may be set in terms of time *t* for each of the day alarms and the night alarms. The projected low value and the projected high value represent how much notice a user wants before an alert screen or alarm is output to notify a user of projected glucose values that will exceed high or low glucose threshold limits."). In other words, the user "set[s]" the projected alerts ***only by specifying a "time *t*"*** representing "how much notice a user wants before" being notified "of projected glucose values that will exceed" the user-set real-time "high or low glucose threshold limits." Harper, [0202]-[0203].

134. Thus, the only way to change the thresholds for Harper’s “Projected” alerts to make them non-user settable in the Guide/Harper combination would have been to change the combination’s real-time alert thresholds to make them non-user settable, because Harper’s “Projected” alerts rely on the real-time alert thresholds, as I explain above. Harper, [0202]-[0203]. However, such a modification is not only unsupported by any evidence establishing a non-hindsight reason to make this dramatic change to what Harper describes, it would also yield a system that fails to meet Elements [1a]/19[c] – which require a real-time alert to use user-settable criteria – and thus would fail to meet any Challenged Claim.

2. Additional Reasons why Dr. Rodbard Fails to Map the Guide/Harper Combination to Any Challenged Claim As a Whole

135. Dr. Rodbard’s Declaration describes an alleged Guide/Harper combination in addressing Element 1[b], but maps that combination only to Elements 1[b] and 19[d]. *See* Ex[1002], ¶¶ 64-66, 90. Dr. Rodbard maps every other element of claims 1 and 19, and every dependent claim challenged in Ground 2, only to the Guide alone rather than to the Guide/Harper combination. As a result, Dr. Rodbard fails to properly address interrelated claim elements.

136. For example, Dr. Rodbard ignores the relationship between the “second hypoglycemic indicator” in Elements 1[d]/19[f] and the “second function” in Elements 1[b]/19[d]. Specifically, the claims require “activat[ing]” (Element

19[f]), or “providing an output including” (Element 1[d]), “a second hypoglycemic indicator if *the* one or more non-user settable second criteria are met.” That determination is made using the “second function” that determines whether “a parameter indicative of glucose value meets one or more non-user settable second criteria” in Elements 1[b]/19[d]. Thus, to show that either of claims 1 and 19 as a whole is met by the Guide/Harper combination in which the “parameter indicative of glucose value” is purportedly met by an alleged Harper parameter (a “projected glucose value” or “rate of change of glucose value,” *see* Rodbard, ¶ 65), Dr. Rodbard would have had to show that the ***Guide/Harper combination*** outputs or activates a “hypoglycemic indicator” when Harper’s alleged parameter meets a non-user settable criterion.

137. Despite that, Dr. Rodbard never mentions Harper or the Guide/Harper combination in the sections addressing Elements 1[d] and 19[f]. *See* Rodbard, ¶¶ 74-75 (Element 1[d]), 94-95 (Element 19[f]). Instead, Dr. Rodbard alleges only that these Elements are met by the Guide alone and its disclosure of generating a Low Glucose alarm when a real-time glucose value is below a threshold of 55 mg/dL. *Id.*

138. Thus, Dr. Rodbard fails to allege that the Guide/Harper combination meets Element 1[d] or 19[f], or that the Guide/Harper combination activates (or provides an output including) a second hypoglycemic indicator when the alleged

parameter in the Guide/Harper combination – Harper’s “projected glucose value” or “rate of change of glucose value” (Rodbard, ¶ 65) – meets one or more non-user settable second criteria as Elements 1[d] and 19[f] require.

C. Ground 3 (Obviousness of Claims 4-5 over Guide in View of Harper and Guerra)

139. Dr. Rodbard states that Ground 3 “builds upon Ground 2” and “add[s] Guerra [only] for certain Elements of dependent claims 4 and 5.” Rodbard, ¶ 98. Dr. Rodbard’s analysis for Ground 3 thus inherits all of Ground 2’s flaws for claim 1, from which claims 4-5 depend, and fails for the same reasons Ground 2 fails.

140. Dr. Rodbard’s argument for claim 5 in Ground 3 fails for an additional reason. Claim 5 recites “evaluating a dynamic risk of the predicted glucose value.” The specification of the ’215 patent explains that “more complex algorithms may be used to define a user’s predicted glycemic state, rather than static thresholds, such as static risk or *dynamic risk models*, where the *input* could include real-time or *predicted values*.” Ex[1001], 24:62-25:2. This confirms what a POSA would have understood claim 5’s language to require – that the predicted glucose value is an *input to* the dynamic risk evaluation.

141. But the function from Guerra that Dr. Rodbard points to for the dynamic risk evaluation does not take the predicted glucose value as an input, it takes *rate of change* as an input. See Rodbard, ¶ 107 (“Guerra discloses a dynamic risk model can be used to evaluate glucose data (either simulated or real data) to

better predict hypoglycemia and hyperglycemia. ... The model disclosed in Guerra includes both glucose level information and trend information (measured as the first time-derivative) of actual glucose measurements.”) (citing Guerra (Ex[1006]), 843-846). *See also* Guerra, 843 (“A new dynamic risk (DR) is proposed to explicitly consider the rate of change of glucose as a threat factor for the patient (e.g., risk levels in hypoglycemia and hyperglycemia are amplified in the presence of a decreasing and increasing glucose trend, respectively).”). This does not meet claim 5.

D. Ground 4 (Obviousness of Claims 1-5, 12, 19, 23 over Shariati)

1. Dr. Rodbard’s Argument for Ground 4 Fails to Show That Elements 1[b]/19[d] Are Met

142. Dr. Rodbard alleges that Shariati discloses a predicted hypoglycemia alarm that compares a “predicted value” to a “threshold” that meets the “at least one non-user settable second criterion” in Elements 1[b] and 19[d]. Rodbard ¶¶ 116 (Element 1[b]), 133 (argument for 19[d] relying on argument for 1[b]).

143. As I discuss below, Dr. Rodbard’s argument is unsupported by the evidence. Dr. Rodbard’s alternative argument that it would have been obvious to modify this threshold to make it non-user settable is likewise unsupported.

a. Dr. Rodbard Fails to Prove that Shariati's Predicted Value Threshold Is Non-User Settable

144. Shariati says “the computer system compares the predicted value against a threshold...which can be programmed into the computer system or user selectable.” Shariati (Ex[1007]), [0571] (*cited* Rodbard, ¶ 117). Dr. Rodbard argues that “[b]ecause Shariati teaches that the threshold can be ‘*programmed into* the computer system’ as an alternative to being ‘user selectable,’ a [POSA] would have understood that a threshold ‘programmed into the computer system’ is non user settable (i.e., a non user settable criteria).” Rodbard, ¶ 117 (emphasis in original). As I discuss below, Dr. Rodbard’s analysis fails for several reasons.

145. **First**, Shariati does not expressly teach – in paragraph [0571] or elsewhere – that the user cannot be the one who “program[s]” the threshold into Shariati’s system. In fact, a POSA would have understood that users could “program” prior art CGM systems. My testimony regarding a POSA’s understanding is corroborated by, for example, the Guide itself. *See, e.g.*, Guide, 51 (“your STS System will alert you when your glucose levels are outside of *your programmed* alert levels”).

146. **Second**, Dr. Rodbard’s assertion that Shariati’s teaching that the threshold “can be ‘*programmed into* the computer system’” means that the threshold is non-user settable (Rodbard, ¶ 117 (emphasis original)) is refuted by Shariati itself. Shariati teaches that its system can be “programmable *by a user*.”

Shariati, [0333] (“In preferred embodiments, the processor module is configured with a *programmable* acquisition time, namely, the predetermined time interval for requesting the digital value from the A/D converter is *programmable by a user* within the digital circuitry of the processor module.”); *see also* Shariati, [0338] (disclosing a “user interface” with a “keyboard”). Shariati’s statement that its system can be “programmable by a user” confirms that Shariati’s teaching that the threshold can be “programmed” does *not* exclude programming by a user, and thus does not mean that the “programmable” threshold is non-user settable as claimed.

147. I understand that during his deposition, Dr. Rodbard contended that the reference to a “user” in paragraph [0333] is a reference to an “engineer or computer scientist” and not and user or doctor because “[p]atients do not deal with [analog] to digital converters.” Rodbard-Dep., 127:12-129:10. I disagree with Dr. Rodbard’s contention for several reasons. First, paragraph [0333] recites the word “user,” and Shariati elsewhere uses the word “user” to refer to an end user. *See, e.g.,* Shariati, [0017] (“the step of determining a calibration state further comprises displaying information indicative of the calibration state on a user interface”), [0301] (“the data stream is typically a raw data signal that is used to provide a useful value of the analyte to a user, such as a patient or doctor, who may be using the sensor.”). Second, paragraph [0333] says “programmable by a user,” and it was common in the art of CGM systems for the word “program” (or variations of

it) to refer to the user changing some setting, as I discuss in ¶ 148 below. Third, I disagree with Dr. Rodbard that an end user would not care about the “time interval for requesting the digital value from the A/D converter” that Shariati says is “programmable by a user.” Shariati, [0333]. Shariati explains that “[a] programmable acquisition time is advantageous in optimizing noise filtration, time lag, and processing/battery power.” *Id.* In my opinion, based on my experience designing glucose monitoring devices and other medical devices for use by patients, patients are indeed concerned with factors such as battery life and are willing and able to adjust settings that optimize for battery life. Indeed, there are many other types of consumer devices, such as cellular phones, that have adjustable settings that can affect battery life, as Dr. Rodbard admitted. Rodbard-Dep., 133:23-134:19. I am aware from my own usage of commonly-available consumer devices that examples of such settings include screen brightness on a laptop computer or cellular phone.

148. **Third**, Dr. Rodbard’s argument is premised on his assertion that “programmable” is limited to actions taken by a computer programmer, and excludes user actions to, for example, change or select device settings. Rodbard-Dep., 141:9-23. I disagree with Dr. Rodbard’s premise, because a POSA would have understood that words like “program” or “programmable” were commonly used to refer to allowing the user to change settings on a device. For example,

people could “program” a VCR. For corroborating evidence, *see, e.g.*, Ex[2012], 2 (describing feature that “lets ***you program*** your VCR”). Likewise, users could “program” a glucose monitor device. For corroborating evidence, *see, e.g.*, Guide, 51 (“your STS System will alert you when your glucose levels are outside of ***your programmed*** alert levels”); Rodbard-Dep., 140:23-141:23 (admitting cited Guide passage describes user-settable threshold); Ex[2015], 4 (referring to “blood glucose meter” that “***you can program*** to automatically transmit blood glucose test results” and to “Leather case” with “Velcro flap” for “easy ***programming*** access”).

149. ***Fourth***, even if the Board were to credit Dr. Rodbard’s assertion that “programmed” in Shariati means programming by “the manufacturer, not a typical user” (Rodbard, ¶ 118), there is no support for Dr. Rodbard’s assertion that Shariati’s statement that the threshold “can be programmed into the computer system or user selectable” (Shariati, [0571]) describes two alternative systems, one of which does not allow the user to select the threshold at all. Rodbard, ¶¶ 117-118. Rather, this statement is consistent, for example, with a system that allows a user to choose whether to leave the threshold at a programmed default value, or change it to a user-selected value. Computer systems with programmed default values the user can override by “selecting” a different option are ubiquitous (e.g., computers have manufacturer-programmed default background images but users can select different images, smart phones have factory default settings the user can

change, etc.). Indeed, as Dr. Rodbard admitted, “programmed” has been used in the art (for example, the Guide) when describing values for low and high glucose thresholds that the user set differently from the factory defaults. Rodbard-Dep., 137:23-139:5, 140:23-142:18. A system feature with a programmed default value that can be changed by the user is in no sense “non-user settable.”

150. I see no evidence cited by Dr. Rodbard that supports his assertion that Shariati’s statement that the threshold “can be programmed into the computer system or user selectable” (Ex[1007], [0571]) describes two alternative systems (Rodbard, ¶ 117), as opposed to a system with a default threshold value the user can override. In fact, when discussing a different feature (a timer), Shariati is clear that the feature being programmable or user selectable refers to a single system having two ways of selecting the feature’s value. Ex[1007], [0583] (“Either the *user or the system* can set the timer. In some embodiments, the timer is a default timer that allows a user to select a mode with a single click for a predetermined time period.”).

151. Shariati also describes a “processor module configured to set a mode selected from a plurality of predetermined modes” where the mode is set “at least in part responsive to a receipt of a user input” via “buttons,” “menus,” or “data transmission.” Ex[1007], [0023]-[0027]. Shariati explains that “[t]he term ‘mode’ as used herein...refers to an automatic *and/or* user configurable setting.”

Ex[1007], [0297]. A POSA would have understood that Shariati's disclosures in [0023]-[0027] and [0297] refute Dr. Rodbard's suggestion that when Shariati describes feature's value as "programmed" or user-selectable it describes two mutually-exclusive systems, as opposed to a single system where the user can select a new value that overrides a default value.

152. ***Fifth***, two other aspects of Shariati's predictive alert further undercut Dr. Rodbard's reading. Shariati's "predictive algorithm" uses a "free flow algorithm" (Ex[1007], [0566]) that bases its "predict[ion]" of "analyte values" on a "rate of change calculation" (*id.*, [0565]) using a "window of sensor data" over a "***user selectable*** time period" (*id.*, [0563]). Dr. Rodbard's assertion that a threshold for the predictive alert is non-user settable despite the time window for that alert being "user selectable" is not credible. Moreover, Shariati's prediction algorithm relies on a "non-stationary" (i.e., noisy) signal of the analyte value (Ex[1007], [0566]) and a POSA would have understood that noisy signals make predictions less accurate, which promotes a high false alarm rate and weighs against a non-user settable threshold as I noted *supra* § V.D.

b. Dr. Rodbard's alternative "Obviousness" Analysis Fails

153. Dr. Rodbard states:

To the extent Patent Owner argues that Shariati does not expressly disclose that the predicted hypoglycemia alarm threshold is non user

settable, in my opinion it would have been obvious to a POSITA that a threshold “programmed into the computer system” would be non user settable at least because the manufacturer, not a typical user, programs the computer system of CGM systems, such as that disclosed in Shariati, and in CGM systems such as developed and commercialized to date there is no interface through which a user could modify the program on which the computer system operates. *Id.*, ¶118; Ex[1007], [0363-64] (contemplating thresholds set only by the manufacturer: “[c]linical risk zones 444 can be set by a manufacturer, customized by a doctor, ***and/or*** set by a user”)

Rodbard, ¶ 118 (emphasis in original) (citing Ex[1007], [0363]-[0364])). In my opinion, Dr. Rodbard’s obviousness argument fails for multiple reasons.

154. Dr. Rodbard does not cite any evidence in support of his factual allegations that “the manufacturer, not a typical user, programs the computer system of CGM systems” or that “in CGM systems such as developed and commercialized to date there is no interface through which a user could modify the program on which the computer system operates.” Rodbard, ¶ 118. Paragraph 118 of Dr. Rodbard’s Declaration includes the following citation sentence: “See *id.* at [0363-64] (contemplating thresholds set only by the manufacturer: ‘[c]linical risk zones 444 can be set by a manufacturer, customized by a doctor, and/or set by a user via button 302’).” The “*id.*” in this sentence refers to Shariati. However, Dr. Rodbard does not explain how paragraphs [0363]-[0364] show that Shariati

“contemplates thresholds set only by the manufacturer.” Rodbard, ¶ 118. In fact, Shariati refers to thresholds set by “the manufacturer, *customized by a doctor and/or set by a user.*” Ex[1007], [0364]. As I discussed *supra* § VII.D.1.a when discussing Shariati, [0571], Dr. Rodbard fails to establish that the reference to a threshold being settable by the manufacturer, a doctor or a user describes alternative systems, rather than a system with a default setting the user can override or a doctor can “customize[]” (Shariati, [0364]).

155. To the extent Dr. Rodbard’s allegation that a user could not “modify *the program*” in conventional CGM systems means a user could not rewrite the system’s code (Rodbard, ¶ 118), that is irrelevant. Dr. Rodbard alleges 1[b] is met by Shariati because its “*threshold*” is non-user settable. Rodbard, ¶ 117. And as Dr. Rodbard admitted in connection with Element [1a], Shariati, [0364] discloses a user interface (“buttons 302”) via which a user can set its thresholds. Petition, 40 (characterizing Shariati’s clinical risk zones 444 as “thresholds [that] can be ... *set by a user via buttons*”) (emphasis original). Rodbard, ¶ 115.

156. Dr. Rodbard also alleges that “in CGM systems developed and commercialized to date there is no interface through which a user could modify the program on which the computer system operates.” Rodbard, ¶ 118. Dr. Rodbard cites no evidence supporting his characterization of “CGM [Continuous Glucose Monitoring] systems developed and commercialized to date.” Moreover, as Dr.

Rodbard admitted, the Guide, which describes a commercialized product (the STS), discloses allowing the user to change default values programmed into the system; thus, the STS must have had an interface. Guide, 51; Rodbard-Dep., 137:23-139:5. As another example, the user's guide for the Medtronic REAL-Time referred to a "blood glucose meter" that "*you can program* to automatically transmit blood glucose test results" and to "Leather case" with "Velcro flap" for "easy *programming* access"; this corroborates that the MedTronic REAL-Time product also had an interface. Ex[2015], 4. Moreover, at his deposition, Dr. Rodbard admitted that Shariati's "clinical risk zones 444" (Ex[1007], [0363]) are user settable. Rodbard-Dep., 151:5-13. *See also* Rodbard, ¶ 115 ("Shariati discloses that 'the danger zone 444 [i.e., the clinical risk zones 444] can be continuously shown on the screen 304, or the danger zone can appear when the measured and/or estimated analyte values fall into the danger zone 444.' Id. at [0364]. Thus, in my opinion Shariati discloses that the one or more criteria (e.g., the low threshold) is 'user settable' as claimed.").

157. Additionally, even if Dr. Rodbard had substantiated his assertion that some other CGM systems were developed and commercialized having "no interface through which a user could modify the program on which the computer system operates," I do not believe that would be relevant to Ground 4, which is based on what *Shariati* discloses. Nowhere in his obviousness analysis, which is

contained only in paragraph 118, does Dr. Rodbard allege any reason why a POSA would have been motivated, based on some other (unidentified) CGM systems, to remove the user interface Shariati expressly describes, or to remove Shariati's expressly described capability that allows the user to select the predicted glucose threshold.

2. Claim 3

158. Dr. Rodbard's argument for claim 3 in Ground 4 fails for three reasons.

159. *First*, Dr. Rodbard makes no attempt to analyze claim 3 as a whole. Claim 3's "further comprises determining..." language refers to the "evaluating sensor data using a first function..." step from claim 1, which is Element 1[a] (first function using user-settable criteria). But Dr. Rodbard's argument for claim 3 purports to show how claim 3's additional limitations are met by Shariati's disclosure relied on to meet "element *1[b]*" (second function using *non-user settable* criteria). Rodbard, ¶ 123. Thus, even if every factual allegation in Dr. Rodbard's analysis of claim 3 were true (which I do not believe Dr. Rodbard has demonstrated), his analysis still fails to show claim 3 is obvious.

160. *Second*, Dr. Rodbard cites Shariati's disclosure of an arrow showing the directional trend of analyte concentration and says "[d]isplaying this directional arrow on the receiver would involve 'determining whether a[] ... direction of rate

of change meets a rate of change criterion’ as claimed.” Rodbard, ¶ 123.

However, Dr. Rodbard does not explain in his declaration *why* displaying the directional arrow would involve determining anything about the *rate* of change.

161. **Third**, a POSA would have understood that Shariati’s “directional arrow” Petitioner identified could be displayed without determining the rate (as opposed to direction) of change. As I explained *supra* § VII.A.3, direction of change is different than direction of rate of change. Furthermore, Dr. Rodbard admitted that knowing the direction of change alone is sufficient to show a directional arrow. Rodbard-Dep., 156:7-12 (admitting knowing direction of change alone is sufficient to show directional arrow). Thus, in my opinion, Dr. Rodbard failed to show that Shariati’s trend direction “involve[s]” (Rodbard, ¶ 123) determining whether anything meets “a *rate* of change criterion” as claim 3 requires.

3. Claim 5

162. Dr. Rodbard cites a passage from Shariati referring to a “dynamic” algorithm that takes the analyte value or rate of change as input. Rodbard, ¶ 125 (“Shariati also explains that the clinical risk alarms can include ‘dynamic and intelligent estimative algorithms based on analyte value [and/or] rate of change, ...’ that ‘provide greater accuracy, more timeliness in pending danger, avoidance of false alarms, and less annoyance for the patient.’ Id. at [0353].”). As I discussed

in Section VII.C, however, claim 5 requires that the dynamic risk evaluation take the predicted glucose value as input. Dr. Rodbard never explains what he believes the relationship is between the “dynamic” algorithms and the predicted glucose value, nor does he does not argue that the “dynamic” algorithms take a predicted glucose value as an input. Thus, Dr. Rodbard has failed to show that Shariati meets claim 5.

4. Claims 12 and 23

163. As I discussed in Section VII.A.4 above, these claims require “instructions” to a person or external device. However, Dr. Rodbard identifies no such instructions in Shariati. Dr. Rodbard argues that Shariati meets the claim because Shariati discloses “processing instructions” that cause the “screen” to “output[] different displays based on different conditions (e.g., whether measured or estimated values are used).” Rodbard, ¶ 128. However, Dr. Rodbard does not allege that the different displays represent instructions to a user or external device; thus, the “processing instructions” Shariati’s system allegedly executes in generating different visual alerts fail to meet claim 12 or 23 for the same reasons that similar instructions in the Guide fail. *See* Section VII.A.4 above.

E. Ground 5 (Obviousness of Claims 19 and 23 over Say in View of Guide)

164. Dr. Rodbard’s argument for Ground 5 fails because Dr. Rodbard fails to establish that Elements 19[c] and 19[d] are both met by the Say/Guide

combination. Dr. Rodbard offers two alternative theories, alleging that: (1) Elements 19[c] and 19[d] are met by Say's disclosure alone (Rodbard, ¶¶ 142-142), or (2) Element 19[c] is met by Say and Element 19[d] is met by modifications a POSA allegedly would have made to Say based on the Guide (Rodbard, ¶¶ 142, 144-149). These arguments fail for the reasons addressed separately in § VII.E.1 and § VII.E.2 below.

1. Dr. Rodbard Fails to Establish That Say Meets Both Elements 19[c] and 19[d]

a. Dr. Rodbard Fails to Establish That Say's Rate of Change or Acceleration of Rate of Change Thresholds Are Not User Settable As Required by Element 19[d]

165. Dr. Rodbard alleges Element 19[d] is met by "Say's comparison of the rate of change or acceleration of the rate of change to a threshold rate or acceleration (e.g., to warn of impending hypoglycemia)." Rodbard, ¶ 143. To purportedly establish that these thresholds are non-user settable, Dr. Rodbard alleges:

Say's threshold "*may be programmable* by the patient and/or a medical professional," (Ex[1008], 45:28-31) (emphasis added), which in my opinion suggests to a POSITA that the threshold value may also not be settable by a user. For example, Say describes "actual threshold values that are *designed into* the alarm system 104" that may include criteria for voltage or current or other electrical signals emanating from the sensor, and/or may be calibrated so as to correspond to interstitial fluid glucose concentrations . . . that

correlate to the above-mentioned blood glucose levels.” Id. at 45:23-26 (emphasis added). Say therefore teaches hypoglycemic warnings configured with thresholds that are not programmable by the user but rather designed into the system and/or set by people who do not use the system themselves (e.g., medical professionals and/or engineers or programmers acting on the recommendations of medical professionals).

Rodbard, ¶ 143 (emphasis in original). This analysis fails for at least three reasons addressed below.

i. Dr. Rodbard Does Not Explain His Theory

166. Dr. Rodbard fails to explain *why* anything he cited from Say “suggests to a POSITA” (Rodbard, ¶ 143) that the rate of change or acceleration thresholds are not user settable. Neither Say 45:28-31 nor Say 45:23-26 refers to a “user.” The only individuals referenced in either passage are a “patient and/or a medical professional.” Say, 45:31. If Dr. Rodbard’s position is that a “medical professional” is not a user, so a threshold set by a medical professional is not settable by a user, he does not say this. If Dr. Rodbard’s position is that the use of the word “may” means there is a Say embodiment where the threshold is factory set and not changeable by the medical professional or patient, he does not say this. If Dr. Rodbard’s position is that that threshold values “designed into” the system are fixed values the user cannot change as opposed to default values the user can override, he does not say this either.

167. At his deposition, Dr. Rodbard stated that for “impending hypo[glycemia]” or “impending hyper[glycemia],” “it's much more difficult or maybe impossible for the patient or the healthcare provider to set a threshold.” Rodbard-Dep., 167:22-168:3. I do not see this opinion offered anywhere in Dr. Rodbard’s declaration, nor any evidence to support it, and Dr. Rodbard admitted he did not offer this opinion. Rodbard-Dep., 169:10-170:6. Moreover, given that prior art devices with predictive alarms had user-settable thresholds, as I discussed in § V.D above, I disagree that users would have found it difficult or impossible to set thresholds for impending hypoglycemia/hyperglycemia alarms.

ii. Say Does Not Teach That Any Threshold Value Is “Designed Into” the System

168. Dr. Rodbard alleges that Say discloses that its thresholds “are not programmed by the user but rather designed into the system and/or set by people who do not use the system themselves (e.g., medical professionals and/or engineers or programmers acting on the recommendations of medical professionals.).” Rodbard, ¶ 143. I disagree that this is what Say discloses.

169. Say never describes an embodiment where a threshold value is set by the factory or programmed by a medical professional in a manner the user cannot customize. Dr. Rodbard cites Say, 45:23-26 for the “designed into” language he relies on. Rodbard, ¶ 143. That passage is part of a larger passage from Say:

Examples of threshold values for blood glucose levels are about 60, 70, or 80 mg/dL for hypoglycemia; about 70, 80, or 90 mg/dL for impending hypoglycemia; about 130, 150, 175, 200, 225, 250, or 275 mg/dL for impending hyperglycemia; and about 150, 175, 200, 225, 250, 275, or 300 mg/dL for hyperglycemia. *The actual threshold values that are designed into the alarm system 104 may correspond to interstitial fluid glucose concentrations or electrode measurements (e.g., current values or voltage values obtained by conversion of current measurements) that correlate to the above-mentioned blood glucose levels.* The analyte monitor device may be configured so that the threshold levels for these or any other conditions may be programmable by the patient and/or a medical professional.

Say, 45:17-31 (emphasis added). From its plain language, a POSA would have understood that what this passage means when it says is “designed into the alarm system” is that whatever is the specific measurement technique used to determine the patient’s blood glucose level. That is, blood glucose levels can be measured and determined in various ways (Ex[1001], 11:66-12:3 (discussing “one or more measurement techniques” for measuring glucose)), so if, for example, the system is designed to take interstitial fluid glucose concentration measurements or electrode measurements, then the stored threshold levels “correspond to interstitial fluid glucose concentrations or electrode measurements ... that correlate to the above-mentioned blood glucose levels.” Say, 45:17-31

170. The passage from Say that I discussed in the paragraph above does *not* state there are particular threshold *values* or levels that are factory set to compare against the “interstitial fluid glucose concentrations or electrode measurements.” To the contrary, Say discloses “the threshold *levels* for these ... conditions may be programmable by the patient and/or medical professional.” Say, 45:29-31.

iii. Say’s Alleged Non-User Settable Thresholds Are Not the Thresholds Dr. Rodbard Alleged to Meet 19[d]

171. Dr. Rodbard alleges that in Say, 19[d] is met by “Say’s comparison of the rate of change or acceleration of the rate of change to a *threshold rate or acceleration* (e.g., to warn of impending hypoglycemia).” Rodbard, ¶ 143. But the portions of Say that Dr. Rodbard cites as disclosing a supposedly non-user settable threshold (45:23-26 and 45:28-31) only refer to “threshold values” that “correspond to interstitial fluid glucose concentrations or electrode measurements” that “correlate to ... blood glucose levels” (Ex[1008], 45:23-28) and never refer to a threshold for a rate of change or acceleration of the rate of change at all, let alone one that is not user settable.

172. Furthermore, earlier portions of the paragraph in which the cited passages of Say appear makes clear that the referenced thresholds are “for *blood glucose levels* ... for hypoglycemia ... impending hypoglycemia ... impending

hyperglycemia ... [and] hyperglycemia,” not for rate of change or acceleration of rate of change. Ex[1008], 45:18-23. Say never states that any of these cited thresholds is “a threshold rate or acceleration.” Rodbard, ¶ 143. And a POSA would have understood that they are not. Rate of change and acceleration are not static glucose values measured in mg/dL – they are measured in units having a time element, as Dr. Rodbard acknowledged. *See e.g.*, Jiang (Ex. 2003), [0002] (“rate of change” is “an amount of change per constant control period or unit time”); Mizumaki, (Ex. 2004) [0061] (referring to “an amount of change per unit time, i.e., acceleration”); Rodbard-Dep., 174:16-175:3.

b. Dr. Rodbard Fails to Establish That Say Teaches a User Settable Threshold Meeting Element 19[c] and a Non-User Settable Threshold Meeting Element 19[d]

173. As I explain below, Dr. Rodbard does not consistently address Elements 19[c] and 19[d].

174. Dr. Rodbard points to the *very same disclosure* in Say – teaching that threshold levels “may be programmable by the patient and/or a medical professional” (Say, 45:30-31) – and alleges that this means two different things: (1) that the real-time glucose threshold levels are “*user settable* first criteria” meeting Element 19[c] (Rodbard, ¶ 142); and (2) that the rate of change and acceleration thresholds are “*non-user settable* second criteria” meeting Element 19[d] (Rodbard, ¶ 143).

175. The paragraph from which the cited portion of Say is taken does not disclose that the way the thresholds are “designed into” the system or their ability to be “programmable” is dependent on the particular threshold involved— all the threshold values (plural) are referred to together and treated in the same manner. Ex[1008], 45:23-31 (referring to the “actual threshold values” (plural) designed into the system and “the threshold levels” (plural) that may be programmable). Therefore, Dr. Rodbard’s assertion that Say teaches a system in which one set of thresholds is user settable and another is non-user settable is unsupported by Say.

176. Even if Say did disclose that *some* thresholds can be user settable and others not (Say discloses no such thing), Dr. Rodbard points to nothing in Say (or any other reference) suggesting a *reason* why the alleged thresholds for the rate of change or acceleration of rate of change in particular should be made non-user settable (which the Dr. Rodbard alleges to meet 19[d]), while making the real-time glucose threshold user settable (which Dr. Rodbard alleges to meet 19[c]), as opposed to the other way around.

2. Dr. Rodbard’s Alternative Attempt to Meet Element 19[d] by Modifying Say Based on the Guide Fails

177. Dr. Rodbard alternatively alleges that “[r]egardless, as explained below, it would have been obvious to combine Say with the User’s Guide, which discloses the claimed ‘non-user settable second criteria,’ as previously explained

for element 1[b] in Grounds 1 and 2 above.” Rodbard, ¶ 144. For the reasons stated below, I disagree.

178. Dr. Rodbard offers a handful of different reasons why a POSA purportedly would have modified Say’s system based on the Guide. Rodbard, ¶¶ 145-149. As detailed below, those reasons are conflicting, are inconsistent with other arguments Dr. Rodbard advances for Ground 5, and lead to different implementations of the resulting Say/Guide combination. Dr. Rodbard also provides no supportable reason why a POSA would have implemented the Say/Guide combination in a manner meeting claim 19.

a. Adding the Guide’s Alarm to Say Does Not Meet Claim 19

179. Dr. Rodbard alleges a POSA would have been motivated to “add” the Guide’s Low Glucose Alarm to Say’s “alarm system’s features.” Rodbard, ¶ 146. Adding the Guide’s Low Glucose Alarm to Say’s system – as Dr. Rodbard alleges – would simply generate a new alert in Say when the real-time glucose level meets the Guide’s “non-user settable” 55 mg/dL Low Glucose Alarm threshold. Guide, Ex[1004], 56. Such a combination would not change the Guide’s alarm or any of Say’s alarms in any way. Dr. Rodbard fails to demonstrate that this combination meets even Element 19[d] as a whole, let alone claim 19 as a whole.

i. The Combination’s Low Glucose Alarm Does Not Meet 19[d]

180. The Guide’s Low Glucose Alarm, unmodified other than by adding it to Say’s system, fails to meet 19[d] for the reasons discussed I *supra* § VII.A for Ground 1.

ii. The Combination’s Alarm Based on a Rate of Change or Acceleration Does Not Meet 19[d]

181. Element 19[d] requires “using a second function to determine whether a *parameter indicative of a glucose value* meets one or more non-user settable second criteria.” Dr. Rodbard’s argument for Ground 5 maps the “parameter indicative of a glucose value” onto Say’s “rate of change of glucose or acceleration of the rate of change of glucose.” Rodbard, ¶ 143 (“Thus, in my opinion Say’s comparison of the rate of change of glucose or acceleration of the rate of change of glucose to a threshold rate or acceleration (e.g., to warn of impending hypoglycemia) teaches ‘evaluate sensor data using a second function to determine whether a parameter indicative of a glucose value meets one or more non-user settable second criteria’ as claimed.”). Thus, to show obviousness of claim 19 as a whole over the Say/Guide combination, Dr. Rodbard was required to show that the alleged “second function” (*Say’s* evaluating sensor data to determine whether a rate of change or acceleration meets a threshold – Rodbard, ¶ 143) determines whether the alleged parameter indicative of glucose value (*Say’s* rate of change or acceleration of the rate of change – Rodbard, ¶ 143) meets one or more non-user settable criteria.

182. But in the Say/Guide combination that results from adding the Guide's Low Glucose Alarm and "merely combining" the known elements without changing their functions, only the **Guide's** 55 mg/dL Low Glucose Alarm threshold is non-user settable, and Dr. Rodbard does **not** allege that this is the criterion that Say's "second function" compares the rate of change or acceleration of rate of change against. Nor could Dr. Rodbard have alleged this, as the rate of change and acceleration thereof have elements of time and the Guide's 55 mg/dL threshold does not. Jiang, [0002]; Mizumaki, [0061]; Rodbard-Dep., 174:16-175:3 (agreeing that a rate of change threshold requires a time unit), 177:21-178:10 (agreeing that rate of change and acceleration of rate of change cannot be compared against a 55 mg/dL threshold).

183. Thus, Dr. Rodbard never maps all the requirements of Element 19[d] to the Say/Guide combination that results from adding the Guide's alarm to Say.

b. Dr. Rodbard Fails to Establish Any Reason That a POSA Would Have Implemented the Say/Guide Combination In a Manner Meeting Claim 19

184. Dr. Rodbard also says a POSA would have configured "***hypoglycemic and/or*** impending hypoglycemic alarms in Say's" system to include mandatory non-adjustable settings. Rodbard, ¶ 145. As Dr. Rodbard acknowledges, the combination of Say the Guide "would result in hypoglycemic ***and/or*** impending

hypoglycemic indicators each of which could be activated based on user settable *and/or* non-user settable criteria.” Rodbard, ¶ 146.

185. Thus, as shown in the table below, the proposed combination results in four possible implementations of “hypoglycemic and/or impending hypoglycemic alarms”; however, as detailed *infra* §§ XYZ-XYZ, three of these implementations do not meet claim 19, and Dr. Rodbard offers no reason other than hindsight to choose the one implementation that does meet claim 19. Indeed, Dr. Rodbard admitted he did not consider all four possibilities in his declaration. Rodbard-dep., 185:12-186:4 (admitting he did not consider all four possibilities in his declaration).

Implementation	Alarm	User settable	Non-user settable
1 (fails 19[c])	hypoglycemic		X
	impending hypoglycemic		X
2 (fails 19[d])	hypoglycemic	X	
	impending hypoglycemic	X	
3 (fails 19[c] and 19[d])	hypoglycemic		X
	impending hypoglycemic	X	
4 (no non-hindsight reason)	hypoglycemic	X	
	impending hypoglycemic		X

i. Implementation 1

186. In this pairing, the hypoglycemic and impending hypoglycemic alarms use a “mandatory” setting that is “non- adjustable” as Dr. Rodbard suggests (Rodbard, ¶ 145).

187. However, for Limitation 19[c], Dr. Rodbard alleges that Say’s hypoglycemic alarm compares a real-time glucose value to a threshold that allegedly meets Element 19[c]’s requirement of “user settable first criteria.” Rodbard, ¶ 142. Thus, modifying Say’s hypoglycemic alarm to use a “mandatory,” “non-adjustable” threshold would result in a Say/Guide combination that does *not* meet Element 19[c]. Rodbard-Dep., 181:25-182:2.

ii. Implementation 2

188. In this implementation, the hypoglycemic and impending hypoglycemic alarms *both* use user-settable criteria; thus, Element 19[d]’s requirement of a non-user settable criterion cannot be met. Rodbard-Dep., 182:3-12.

iii. Implementation 3

189. Implementation 3 is the *opposite* of what claim 19 requires in terms of applying user settable and non-user settable criteria to a real-time glucose value and parameter indicative of glucose value, respectively. This option fails to meet 19[c]’s requirement that the real-time glucose value – allegedly Say’s hypoglycemic indicator (Rodbard, ¶ 142) – be evaluated using user settable

criteria, and also fails to meet 19[d]’s requirement that the parameter indicative of glucose value – allegedly Say’s rate of change or acceleration used for an impending hypoglycemic indicator (Rodbard, ¶ 143) – be evaluated using non-user settable criteria. Rodbard-Dep., 182:13-183:6.

iv. Implementation 4

190. Dr. Rodbard alleges that 19[d]’s second criteria used to evaluate a parameter indicative of glucose value is met in the Say/Guide combination by Say’s “*threshold rate or acceleration*” against which the rate of change or acceleration is compared “(e.g., to warn of impending hypoglycemia).” Rodbard, ¶ 143. Thus, to meet Element 19[d], Dr. Rodbard needed to provide some evidence-based reason why a POSA would have made Say’s threshold for the “rate of change or acceleration” non-user settable.

191. Yet as I discussed in § VII.E.2.a above, the rationales Dr. Rodbard advances for making this combination do not result in any such modification to Say’s threshold for the rate of change or acceleration.

192. Paragraphs 145-149 of Dr. Rodbard’s Declaration are the paragraphs where Dr. Rodbard offers his opinions on why a POSA would have combined the Guide with Say. These paragraphs cite no evidence other than Say and the Guide, neither of which teaches a non-user settable threshold for a rate of change of glucose level or acceleration of rate of change, or for any threshold used for an

impending hypoglycemic indicator. Dr. Rodbard does not point to any teaching in the Guide or elsewhere in the art of making such thresholds non-user settable.

193. Furthermore, the goal Dr. Rodbard advanced for using a non-user settable threshold, which was to prevent the user from overriding a threshold indicating a “dangerously low glucose” level (Rodbard, ¶¶ 146-148), is achieved by adopting the Guide’s teaching to use a non-user settable threshold for a dangerously low *real-time* glucose value. Dr. Rodbard offered no reason or evidence supporting using a non-user settable threshold for an *impending* hypoglycemic condition in the Say/Guide combination.

3. Dr. Rodbard’s Argument For 19[f] Eliminates Ground 5’s Reliance on a Rate of Change or Acceleration to Meet 19[d]

194. Element 19[f] requires that the system “activate a second hypoglycemic indicator if the one or more non user settable second criteria are met.” Rodbard, page 158. Whether the “second criteria are met” is determined by 19[d]’s “second function.” *Id.*

195. Dr. Rodbard’s argument for 19[f] in Ground 5 cites “Ex[1008], 45:15-31, 46:9-23” as disclosing the “alarm” that Petitioner alleges meets the claimed “second hypoglycemic indicator.” Rodbard, ¶ 151. The cited Say passages refer to alarms based on current *glucose level* thresholds. Say, 45:15-31 (in “alarm system 104 ... [e]xamples of threshold values for blood glucose are ...”), 46:9-23 (describing alarms in “alarm system 104”).

196. Additionally, Dr. Rodbard alleges that in the “combined system” the “threshold value is the [Guide’s] non-user settable Low Glucose Alarm threshold.” Rodbard, ¶ 151. A POSA would have understood that that threshold (in units of “mg/dL,” *see* Guide, 56) is for comparison to a real-time glucose level.

197. Therefore, Dr. Rodbard’s mapping of 19[f] onto an alarm activated based on comparison of a *real-time glucose level* to a threshold eliminates Dr. Rodbard’s reliance in Ground 5 on Say’s rate of change or acceleration thereof to meet 19[d], because it is undisputed that rate of change and acceleration have time components and cannot be compared to a static glucose level threshold of the type Dr. Rodbard relied on to meet 19[f]. Rodbard-Dep., 177:21-178:10.

198. Dr. Rodbard’s analysis for 19[f] in Ground 5 is only consistent with mapping 19[d]’s second function onto a function in the Say/Guide combination that compares a real-time glucose value to a threshold. But Dr. Rodbard fails to demonstrate that such a function meets 19[d] for the numerous reasons discussed I discussed *Supra* § VII.A for Ground 1 (where I explained why Dr. Rodbard failed to show that such a function meets the required “second function”).

F. Ground 6 (Obviousness of Claims 19 and 23 over Say and Shariati)

199. Dr. Rodbard 6 fails to establish that the Say/Shariati combination meets Element 19[d].

200. To the extent Dr. Rodbard suggests that the Say/Shariati Combination is a system with a predictive alarm that the user cannot “disabl[e]” or “circumvent[]” (Rodbard, ¶ 165), this is wrong because neither Say or Shariati discloses a predictive alarm with a non-user settable threshold, as I explained above with respect to Grounds 4 and 5. Dr. Rodbard cites no evidence supporting that it was known to have a non-user settable predictive alarm.

1. Dr. Rodbard’s Alleged Reason for Modifying Say Based on Shariati Is Unsupported

201. Dr. Rodbard’s assertion that a POSA “would have been motivated to incorporate Shariati’s predicted hypoglycemia alarm” into Say (Rodbard, ¶ 164) fails because, as Dr. Rodbard acknowledges, Say already has an alarm that “warn[s] of impending hypoglycemia.” Rodbard, ¶ 143 (citing Ex[1008], 45:53-56).

2. Even If a POSA Were Motivated to Make the Say/Shariati Combination It Fails to Meet Element 19[d]

a. Dr. Rodbard’s Reliance on Say’s Alarm Fails

202. The only disclosure in Say or Shariati that Dr. Rodbard alleges to meet a “parameter indicative of glucose value” in 19[d] in Ground 6 is Say’s rate of change or acceleration thereof. Rodbard, ¶ 160. Dr. Rodbard asserts that Say discloses that these “parameters” are compared against non-user settable thresholds. Rodbard, ¶ 160. This is wrong for the reasons I discussed *supra* § VII.E.1.a with respect to Ground 5.

b. Adding Shariati's Alarm to Say Does Change The Threshold Applied to the Alleged Parameter in the Say/Shariati Combination

203. Dr. Rodbard argues that Say's "rate of change or acceleration of the rate of change in glucose level" are "parameters indicative of glucose value" as in Element 19[d]. Rodbard, ¶ 160. Dr. Rodbard alleges "it would have been obvious to combine Say with Shariati, which discloses the claimed 'non-user settable criteria,' as previously explained for elements 1[b] and 19[d] in Ground 4." Rodbard, ¶ 161.

204. This proposed combination simply adds Shariati's "predicted hypoglycemia alarm" to Say's system. Rodbard, ¶ 161 ("It would have been obvious to incorporate the predicted hypoglycemia alarm of Shariati into Say's alarm system"), 165 (characterizing the combination as "[i]ncluding the programmed predicted hypoglycemia alarm of Shariati in Say's alarm system" and "***nothing more*** than combining prior-art elements according to known methods"), 166 (characterizing the combination as "modify[ing]" Say's system "to incorporate the predicted hypoglycemia alarm of Shariati"). Thus, Dr. Rodbard's Ground 6 Say/Shariati Combination makes no modification to Say's alarm – it merely adds a new alarm from Shariati.

205. Dr. Rodbard 6 alleges that 19[d]'s "parameter" is met by Say's rate of change or acceleration thereof (Rodbard, ¶ 160), but never alleges that a POSA

would have modified the thresholds Say compares these “parameters” against to make those thresholds non-user settable. Given Dr. Rodbard’s failure to establish that these Say thresholds are non-user settable, as I discussed *supra* § VII.E.1.a with respect to Ground 5, the Say/Shariati Combination does not meet 19[d].

c. Ground 6 Fatally Fails to Address Element 19[d] as a Whole

206. Dr. Rodbard’s argument for Ground 6 maps Element 19[d]’s “parameter indicative of a glucose value” onto Say’s “rate of change or acceleration of the rate of change.” Rodbard, ¶ 161. Yet, Dr. Rodbard’s argument for Ground 6 maps Element 19[d]’s “non-user settable criteria” onto Shariati’s ““predicted [analyte] value”” threshold:

Shariati’s ‘computer system determines a predicted [analyte] value for a future time period’ and ‘compares the predicted value against a *threshold’ for predicted hypoglycemia. Id., [0571]...Because Shariati teaches that the threshold can be ‘programmed into the computer system’ as an alternative to being ‘user selectable,’ a POSITA would have understood that a threshold ‘programmed into the computer system’ is a non user settable criteria.*

Rodbard, ¶ 162. *See also* Rodbard-Dep., 186:17-188:9 (agreeing he mapped “parameter” only onto Say and “non-user settable criteria” only onto Shariati).

207. Even if Shariati taught that its threshold was non-user settable (it does not, as I discussed *supra* § VII.D.1), Dr. Rodbard’s mapping of the Say/Shariati

combination fails to demonstrate obviousness of Element 19[d] – let alone claim 19 – as a whole. To show obviousness of claim 19 as a whole over the Say/Shariati combination, Dr. Rodbard was required to show that the alleged “second function” (*Say*’s evaluating sensor data to determine whether a rate of change or acceleration thereof meets a threshold – Rodbard, § X.D.1.e (cited at Rodbard, ¶ 160)) determines whether the alleged parameter indicative of glucose value (*Say*’s rate of change or acceleration of the rate of change – Rodbard, § X.D.1.e (cited at Rodbard, ¶ 160)) meets the alleged non-user settable criteria (Shariati’s threshold for predicted hypoglycemia – Rodbard, ¶¶ 161-162). But Dr. Rodbard never alleges this.

d. Dr. Rodbard Failed to Prove that Shariati’s Thresholds are Non-User Settable

208. Even if Dr. Rodbard is considered to have argued that in the Say/Shariati Combination a “parameter” is compared against the “criteria” Shariati discloses, his assertion that Shariati’s criteria are non-user settable for reasons “explained” in Ground 4 (Rodbard, ¶ 161) fails for the reasons I discussed *supra* § VII.D.1 with respect to Ground 4.

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

I declare under penalty of perjury that the foregoing is true and correct.

Dated: January 26, 2023