

In the Matter of:
Abbott Diabetes Care Inc. vs
Dexcom, Inc.

Dr. David Rodbard
May 24, 2023

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1 UNITED STATES PATENT AND TRADEMARK OFFICE

2
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD
4

5 ABBOTT DIABETES CARE, INC.
6 Petitioner

7 v.

8 DEXCOM, INC.
9 Patent Owner

10
11 Case No. IPR2022-00909
12 Patent 10,702,215
13

14
15 DEPOSITION OF DR. DAVID RODBARD

16 Washington, D.C.

17 May 24, 2023
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19
20

21 Reported by: John L. Harmonson, RPR

22 Job No. 977422

May 24, 2021

9:03 a.m.

Deposition of DR. DAVID RODBARD, taken at the
offices of Baker Botts, LLP, 700 K Street, NW,
Washington, DC, pursuant to 37 C.F.R. § 42.53(d),
the Federal Rules of Civil Procedure, and the
Scheduling Order filed in this proceeding, by
Notice, before John L. Harmonson, a Registered
Professional Reporter and Notary Public of the
District of Columbia, who officiated in
administering the oath to the witness.

A P P E A R A N C E S

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EXAMINATION INDEX

WITNESS	PAGE
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DR. DAVID RODBARD	
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Examination by Mr. Saraswat

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EXHIBIT INDEX

(Exhibits incorporated by reference; not attached)

NUMBER	DESCRIPTION	PAGE
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Abbott Diabetes Exhibits:

Exhibit 1001	US Patent 10,702,215	
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Exhibit 1002	Declaration of Dr. David Rodbard	
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Exhibit 1004	DexCom STS Continuous Glucose Monitoring System User's Guide	
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Exhibit 1008	US Patent 6,565,509	
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Exhibit 1035	Supplemental Declaration of Dr. David Rodbard	
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Exhibit 1036	"GlucoWatch G2 Biographer (GW2B) Alarm Reliability During Hypoglycemia in Children"	
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EXHIBIT INDEX (Cont.'d)

NUMBER	DESCRIPTION	PAGE
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DexCom Exhibits:

Exhibit 2014	FreeStyle Navigator User's Guide	
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P R O C E E D I N G S
MORNING SESSION
9:03 a.m.

Whereupon,
DR. DAVID RODBARD,
after having been first duly sworn or affirmed, was
examined and did testify under oath as follows:

EXAMINATION

BY MR. SARASWAT:

Q. Good morning, Dr. Rodbard.

A. Good morning.

Q. My name is Anant Saraswat, and with me
is Richard Giunta. We represent the patent owner
DexCom.

I would like to start by going over some
ground rules which I think should be familiar from
the last time you and I were here. I'll be asking
you some questions today about a supplemental
declaration you provided in case IPR2022-00909. Do
you understand that?

1 A. Yes.

2 Q. When I refer to "this case" or "this
3 matter," do you understand that I'm referring to
4 IPR2022-00909?

5 A. Yes.

6 Q. Now, you must give verbal answers to my
7 questions so that the court reporter can record
8 them. Do you understand that?

9 A. Yes.

10 Q. If I ask you a question, you're required
11 to answer unless your lawyer instructs you not to.
12 Do you understand?

13 A. Yes.

14 Q. If at any point you need to take a
15 break, please let me know. Okay?

16 A. Very good.

17 Q. All right. Are you taking any kind of
18 medication today that would impair your ability to
19 give truthful and correct answers to my questions
20 today?

21 A. No.

22 Q. Is there any reason why you can't give

truthful and correct answers to my questions today?

A. No.

Q. Okay. So I'm going to hand you a document that's been previously marked Exhibit 1001.

(Exhibit 1001, previously marked for identification, incorporated by reference hereto.)

BY MR. SARASWAT:

Q. Do you recognize Exhibit 1001?

A. Yes.

Q. This is US Patent Number 10,702,215; correct?

A. Yes.

Q. If I refer to the '215 patent, will you understand I'm referring to US Patent Number 10,702,215?

A. Yes.

Q. Are you familiar with the term "person of ordinary skill in the art"?

A. Yes.

Q. So if during my questioning I refer to a

1 POSA or POSITA, will you understand that I'm
2 referring to a person of ordinary skill in the art?

3 A. Yes.

4 Q. All right. Are you familiar with the
5 term "continuous glucose monitoring"?

6 A. Yes.

7 Q. So if during my questioning I refer to
8 CGM, will you understand I'm referring to
9 continuous glucose monitoring?

10 A. Yes.

11 Q. So I'm going to hand you another
12 document that's been previously marked
13 Exhibit 1035.

14 (Exhibit 1035, previously marked for
15 identification, incorporated by reference
16 hereto.)

17 BY MR. SARASWAT:

18 Q. Do you recognize Exhibit 1035?

19 A. Yes.

20 Q. Okay. And Exhibit 1035 is the
21 supplemental declaration that you prepared for this
22 matter; is that correct?

1 A. Correct.

2 Q. And if during my questioning I refer to
3 the reply declaration, will you understand I'm
4 referring to Exhibit 1035?

5 A. Yes.

6 Q. I'll sometimes switch back and forth
7 between those terms.

8 Did you do anything to prepare for
9 today's deposition?

10 A. Yes.

11 Q. what did you do?

12 A. I met with one of the lawyers by video
13 periodically.

14 Q. which lawyer did you meet with?

15 A. Mr. Clarke Stavinotha.

16 Q. And other than meeting with
17 Mr. Stavinotha by video, did you meet with anybody
18 else in preparation for today's deposition?

19 A. I met very briefly with Mr. Williams.

20 Q. Okay. How long total would you say were
21 your meetings with Mr. Stavinotha and Mr. Williams
22 to prepare for today's deposition?

1 A. Nine hours.

2 Q. Did you review any documents in
3 preparation for today's deposition?

4 A. Yes.

5 Q. Which ones did you review?

6 A. I reviewed this reply declaration, which
7 I call the supplemental declaration, and I reviewed
8 my previous declaration, the original declaration.
9 And I reviewed the '215 patent.

10 Q. Other than your two declarations and the
11 '215 patent, did you review any other documents in
12 preparation for today's deposition?

13 A. Yes.

14 Q. Which ones?

15 A. I have to go back and think about it. I
16 reviewed Harper, Shariati, Say, Kamath, Tsalikian.

17 Q. That last one that you mentioned, is
18 that -- I just want to make sure because I'm
19 probably not pronouncing it correctly. Is that the
20 exhibit that you -- how do you spell that?

21 A. T-s-a -- no, T-s-i-l-a-k-i-a-n [sic].

22 Q. So could you please quickly turn to

1 Paragraph 21 in your supplemental declaration.

2 A. Yes.

3 Q. And do you see that in Paragraph 21 on
4 page 9, it's about the third line down on page 9,
5 there is a reference to a 2004 study by Tsalikian,
6 et al., 1036.

7 A. Yes, I do.

8 Q. So earlier when I asked you about the
9 documents you reviewed and you mentioned Tsalikian,
10 were you referring to Exhibit 1036?

11 A. That's correct.

12 Q. Okay, great. Thanks. I was pronouncing
13 it "Tsalikian" the whole time.

14 A. I may have misspelled it.

15 Q. How many hours did you spend preparing
16 the supplemental declaration?

17 MR. WILLIAMS: Objection to form.

18 THE WITNESS: 16 hours.

19 BY MR. SARASWAT:

20 Q. Is there anything in your supplemental
21 declaration that you wish to correct?

22 A. No.

1 Q. So let's stick with Exhibit 1035. And
2 could you please look at Paragraph 27 in
3 Exhibit 1035.

4 A. 27, you said?

5 Q. Paragraph 27. Are you there?

6 A. Yes.

7 Q. Okay, great.

8 So in Paragraph 27 of your reply
9 declaration, in the first sentence you note that
10 the Guide has a real-time alarm with a
11 user-settable threshold with a range from 60 to
12 90 milligrams per deciliter. Is that correct?

13 A. Yes.

14 Q. So why would -- why would the Guide have
15 that threshold be user settable?

16 MR. WILLIAMS: Objection to form.

17 THE WITNESS: This is to provide
18 flexibility for the user.

19 BY MR. SARASWAT:

20 Q. Okay. And how -- so when you say
21 provide flexibility to the user, you mean that the
22 user is able to set his or her own threshold for

1 that alarm?

2 A. Yes.

3 Q. Okay. How would the user know what
4 value to set that threshold at?

5 A. well, recall that there may be thousands
6 of users, and they may have different -- different
7 thoughts about how they're going to set it. So
8 there is not necessarily any one answer.

9 Q. And when you say that different users
10 may have different thoughts about where to set the
11 threshold, why is that? Why would different users
12 want to set the threshold at different levels?

13 A. Many different reasons.

14 Q. Like what?

15 A. Different people have different levels
16 of concern about hypoglycemia. Some people never
17 have hypoglycemia; they wouldn't care. I wouldn't
18 say that. It's not an issue for them. Other
19 people have a lot of concern or fear of
20 hypoglycemia. So this would adjust how, if you
21 will, aggressive they are in terms of setting a
22 threshold.

1 Q. And what is hypoglycemia?

2 A. Hypoglycemia is a low blood glucose
3 level.

4 Q. How does a person know what is a low
5 glucose level for them?

6 A. Well, I guess the best way is if you
7 measure the glucose and if the glucose level is
8 low, then you know that you're low. So that's a
9 way to check or verify that one is low.

10 Q. Okay. Now, if you have two different --
11 let's say you're talking about two different users
12 with different physical characteristics. Could --
13 and let's call them user A and user B.

14 A. Yeah.

15 Q. Could a value that's considered low for
16 user A be not considered low for user B?

17 A. Yes.

18 Q. Okay. So what are the factors that
19 determine what is considered a low glucose value
20 for a given individual patient?

21 MR. WILLIAMS: Objection to scope.

22 THE WITNESS: There's several factors.

1 One is that when a person is experiencing
2 hypoglycemia that is lower than typical for
3 themselves, they may become symptomatic.

4 BY MR. SARASWAT:

5 Q. Okay. So you said typical for
6 themselves. So is it the case that two different
7 patients might have two different glucose levels
8 that are considered typical for that patient?

9 MR. WILLIAMS: Objection to form.

10 Scope.

11 THE WITNESS: Different patients may
12 have different customary blood levels, and they may
13 have different levels that seem to be hypoglycemic
14 for them.

15 BY MR. SARASWAT:

16 Q. Okay. So if you got -- again, my two
17 users, user A and user B. Is it the case that if
18 one of them has a certain blood glucose level they
19 might feel perfectly fine, but if the other one has
20 the exact same blood glucose level that person
21 might feel sick?

22 A. Yes.

1 Q. Okay. And why is that?

2 MR. WILLIAMS: Objection to scope.

3 THE WITNESS: Again, many factors might
4 enter into that. People have different sensitivity
5 to hypoglycemia. Some people have no symptoms when
6 they're actually hypoglycemic, and other people may
7 be having a lot of symptoms when they're
8 hypoglycemic. There are other factors at play as
9 well.

10 BY MR. SARASWAT:

11 Q. So you mentioned just now that if two
12 people are hypoglycemic, one person may experience
13 symptoms and the other person may not. But I guess
14 my question is, is it possible that if patient A
15 has a certain blood glucose level you would
16 consider that patient to be hypoglycemic, but
17 patient B could have the same blood glucose level
18 and they would not be considered hypoglycemic?

19 MR. WILLIAMS: Objection to form.
20 Scope.

21 THE WITNESS: That depends whether we're
22 thinking about the patient's point of view or the

1 doctor's point of view.

2 BY MR. SARASWAT:

3 Q. what do you mean?

4 A. well, they could both be at 65. One
5 could be experiencing symptoms; the other would be
6 experiencing no symptoms. And there are a lot of
7 reasons why that might be.

8 From the doctor's point of view, they
9 would both be regarded as hypoglycemic by most
10 docs, not all docs, or other observers because
11 their glucose levels at 65 are below the level of
12 70. We regard any glucose level below 70 as
13 indicating hypoglycemia level 1.

14 Q. Okay.

15 A. So from the doctor's point of view,
16 they're both hypoglycemic, but from the patient's
17 point of view one is experiencing symptoms of
18 hypoglycemia and the other one is not.

19 Q. Okay. So looking back at Paragraph 27
20 again of Exhibit 1035, so again in that first
21 sentence of Paragraph 27, you refer to the low
22 glucose alert in the Guide. Do you see that?

1 A. Yes.

2 Q. And what you say in that sentence is:
3 "The function that produces that low glucose alarm
4 in the Guide involves comparing 'real-time
5 continuous glucose measurements' to a user-settable
6 threshold within a target range (selected by the
7 user from 60 milligrams per deciliters to
8 90 milligrams per deciliter) and which, when
9 triggered, produces white text on a black
10 background."

11 Do you see that?

12 A. Yes.

13 Q. So what does selected mean?

14 A. The control device has one or more
15 buttons that allow the user to select one of these
16 levels.

17 Q. So does that mean that there's some
18 predetermined set of levels, and then the user can
19 select one of those levels?

20 A. Yes.

21 Q. Okay. Now, after that first sentence in
22 Paragraph 27 that we just read, you cite pages 9

1 and 54 from Exhibit 1004. Do you see that?

2 A. Yes.

3 Q. And Exhibit 1004 is the Guide; correct?

4 A. It's the User Guide, yes. It's the
5 instructions for the User Guide.

6 Q. And that Exhibit 1004 is the document
7 that you're referring to as the Guide in that first
8 sentence; correct?

9 A. That's the instructions for use of the
10 Guide.

11 Q. All right. So I'm going to hand you a
12 document that's been previously marked
13 Exhibit 1004.

14 (Exhibit 1004, previously marked for
15 identification, incorporated by reference
16 hereto.)

17 BY MR. SARASWAT:

18 Q. Do you recognize Exhibit 1004?

19 A. Yes.

20 Q. This is the Guide that you referred to
21 in Paragraph --

22 A. Yes.

1 Q. -- 27; correct?

2 And just please make sure I finish my
3 question before you answer so we get a clean
4 record.

5 MR. WILLIAMS: wait until he stops
6 talking, take a break, and then answer.

7 THE WITNESS: Okay.

8 BY MR. SARASWAT:

9 Q. So in -- so looking back at Paragraph 27
10 in Exhibit 1035 just for a second, you cite pages 9
11 and 54 from Exhibit 1004. Do you see that?

12 A. Yes.

13 Q. All right. So in the Guide, which is
14 Exhibit 1004, can you please turn to page 54. Are
15 you there?

16 A. 52. 53.

17 Q. It might be stapled in a weird way. I
18 think you had it.

19 A. Here is 54.

20 Q. Okay. So you're looking at page 54 of
21 the Guide; correct?

22 A. Yes.

1 Q. And do you see that page 54 is in
2 Section 4.2 of the Guide, which is entitled
3 "Responding to High and Low Glucose Alerts"?

4 A. Yes.

5 Q. Okay. And so about two-thirds of the
6 way down the page do you see that there is a figure
7 that's labeled "Low Glucose Alert Screen"?

8 A. Yes.

9 Q. And that figure shows a number of
10 80 milligrams per deciliter?

11 A. Yes.

12 Q. And milligrams per deciliter, that's a
13 unit for measuring blood glucose level?

14 A. Correct.

15 Q. Now can you please turn to page 50 of
16 the Guide.

17 A. Yeah.

18 Q. Do you see that page 50 is the first
19 page of Section 4?

20 A. Yes.

21 Q. Okay. Can you please read pages 50 and
22 51 to yourself and let me know when you're done.

1 A. Yes, I've read it.

2 Q. So do you see that on page 51 there is a
3 mention of that same 80 milligrams per deciliter
4 figure that we earlier saw mentioned on page 54?

5 A. I have to go back and see what was on
6 54. Let's see. Okay.

7 Q. So it says on page 51, near the end of
8 that paragraph on page 51, it says: "The default
9 high and low glucose alerts are set at
10 80 milligrams per deciliter (4.4 millimoles per
11 liter) and 200 milligrams per deciliter (11.1
12 millimoles per liter) but can be changed to fit
13 your personal diabetes goals (see Section 7.3.2)."

14 Do you see that?

15 A. Yes.

16 Q. So when it refers to the default high
17 and low glucose alert levels at 80 milligrams per
18 deciliter and 200 milligrams per deciliter, it's
19 referring to default values in the device that's
20 being described in the Guide; correct?

21 A. Yes.

22 Q. So how does the device know what those

1 default high and low thresholds are?

2 MR. WILLIAMS: Objection to form.

3 Scope.

4 THE WITNESS: Someone put them into the
5 device.

6 BY MR. SARASWAT:

7 Q. who is that someone?

8 A. I would assume -- this is speculation --
9 that it would be the manufacturer.

10 Q. Okay. So those are defaults that are
11 programmed into the device by the manufacturer at
12 the factory?

13 MR. WILLIAMS: Objection to form.

14 THE WITNESS: The defaults are
15 programmed in, I assume, at the factory.

16 BY MR. SARASWAT:

17 Q. Okay. Now, in that sentence that we
18 just looked at, it says there are default values,
19 and then it says that those default values "can be
20 changed to fit your personal diabetes goals (see
21 Section 7.3.2)."

22 Do you see that?

1 A. Yes.

2 Q. All right. So can we please look at
3 page 78 of the Guide.

4 A. Here we go.

5 Q. Are you there?

6 A. Yes.

7 Q. All right. So do you see that
8 Section 7.3.2 starts here on page 78?

9 A. Yes.

10 Q. And the title of Section 7.3.2 is
11 "Setting High and Low Glucose Alert Levels
12 (milligrams per deciliter units)." Correct?

13 A. Yes.

14 Q. Now, at the bottom of page 78 there is a
15 figure that shows the 80 milligrams per deciliter
16 default value. Do you see that?

17 A. Yes.

18 Q. And then underneath that figure it says,
19 quote: "Use the up or down arrows to increase or
20 decrease the low glucose alert value by
21 10 milligrams per deciliter."

22 Do you see that?

1 A. Yes.

2 Q. And then if we go to the next page,
3 page 79, up at the top it says: "You may select
4 low glucose alert values from 60 milligrams per
5 deciliter to 90 milligrams per deciliter. Select
6 the value recommended by your diabetes management
7 team by pressing the OK button."

8 Do you see that?

9 A. Yes.

10 Q. So is this functionality that's
11 described here on pages 78 and 79 in which the user
12 uses the arrow keys to select low glucose values
13 between 60 and 90 milligrams per deciliter an
14 example of a user selecting a low glucose alert
15 value?

16 A. Yes.

17 Q. So in the Guide, what are the different
18 options for how a user's low glucose alert value
19 can be set?

20 MR. WILLIAMS: Objection to form.

21 THE WITNESS: The low glucose alert
22 value can be set by the manufacturer, which is the

1 default, or the user can modify that if they so
2 desire.

3 BY MR. SARASWAT:

4 Q. Okay. So if I'm a user, one option I
5 have for setting my low glucose alert value is to
6 use the default value that was programmed into the
7 system. Right?

8 A. Yes.

9 Q. And another option I have is to select
10 one of these values from 60 to 90 milligrams per
11 deciliter. Right?

12 A. Yes.

13 MR. WILLIAMS: Objection to form.

14 BY MR. SARASWAT:

15 Q. Now, we just looked at the
16 Guide -- withdrawn.

17 So we just looked at the Guide's
18 disclosure of using up or down arrows to select a
19 low glucose alert value; right?

20 A. Yes.

21 Q. Are there also systems where a user or a
22 medical provider can directly input a threshold

1 value into the system rather than selecting one?

2 MR. WILLIAMS: Objection to form and
3 scope.

4 THE WITNESS: I don't know.

5 BY MR. SARASWAT:

6 Q. Could a keyboard be used to directly
7 input a threshold value into a system?

8 MR. WILLIAMS: Objection to form and
9 scope.

10 THE WITNESS: No.

11 BY MR. SARASWAT:

12 Q. why not?

13 A. The glucose sensor is a tiny little
14 device worn on the abdomen or here (indicating).
15 It needs to be small, light, and unobtrusive. So
16 that there is no practicable way in which a
17 keyboard could be attached, to my knowledge.

18 Q. So I know you're saying you aren't aware
19 of a system that has a keyboard. But suppose
20 hypothetically I have a CGM device that was like
21 the size of a BlackBerry and it has a keyboard on
22 it. Could I use that keyboard to type in my

1 glucose alert threshold alert to the device?

2 MR. WILLIAMS: Objection to form and
3 scope.

4 THE WITNESS: I don't think it would be
5 practicable to use an external device to do that.

6 BY MR. SARASWAT:

7 Q. well, so -- all right. Let's look back
8 at the Guide for a second, and look at page 50. I
9 think the stapling makes flipping through kind of
10 strange.

11 MR. WILLIAMS: what page did you say?

12 MR. SARASWAT: 50.

13 BY MR. SARASWAT:

14 Q. So do you see at the bottom of page 50
15 there is a picture of some kind of device?

16 A. Yes.

17 Q. So what is that a picture of?

18 A. That is a picture of the readout device
19 for the particular CGM.

20 Q. So is this device that's shown here
21 something that's worn on the user's body?

22 A. No.

1 Q. But this device that's shown here has
2 arrow keys; right? Do you see that kind of towards
3 the right?

4 A. Yes.

5 Q. So those are the arrow keys that are
6 used to select the glucose levels that we talked
7 about earlier; right?

8 A. Yes.

9 Q. So if that device were bigger and it had
10 a keyboard on it like an old BlackBerry, could that
11 keyboard be used to enter a threshold?

12 MR. WILLIAMS: Objection; form and
13 scope.

14 THE WITNESS: Probably, yes.

15 BY MR. SARASWAT:

16 Q. So earlier when I was asking you about
17 the device that's pictured on page 50 of the Guide,
18 you used the term "readout device." Do you recall
19 that?

20 A. Yes.

21 Q. What did you mean by that?

22 A. This is the device that will display the

1 glucose value and other data.

2 Q. Okay. And could you turn to page 37,
3 please.

4 A. 37.

5 Q. So on page 37, there is a section
6 heading 2.4 entitled "Telling your STS Receiver you
7 have Inserted a New STS Sensor." Do you see that?

8 A. Yes.

9 Q. So is the receiver the readout device
10 you were talking about earlier?

11 A. Yes.

12 Q. And so it's getting glucose data from a
13 separate physical device which is the sensor; is
14 that correct?

15 A. Correct.

16 Q. Okay. So could you please turn back to
17 Exhibit 1035, which is your supplemental
18 declaration.

19 A. Yes.

20 Q. And could you please look at
21 Paragraph 21 which starts at the bottom of page 8.
22 You can just go ahead and read it to yourself and

1 let me know when you're done.

2 A. Okay.

3 Q. So in Paragraph 21, you discuss
4 predictive alerts; right?

5 A. Yes.

6 Q. And one of the references you cite in
7 Paragraph 21 is Exhibit 1036; correct?

8 A. Yes.

9 Q. And 1036 is that Tsalikian reference you
10 mentioned earlier; correct?

11 A. Correct.

12 Q. So I'm going to hand you a document
13 that's been marked Exhibit 1036.

14 (Exhibit 1036, previously marked for
15 identification, incorporated by reference
16 hereto.)

17 BY MR. SARASWAT:

18 Q. So do you recognize Exhibit 1036?

19 A. Yes.

20 Q. This is the Tsalikian reference that you
21 cite in Paragraph 21 of your supplemental
22 declaration; right?

1 A. Yes.

2 Q. And the title of Exhibit 1036 is
3 "GlucoWatch G2 Biographer (GW2B) Alarm Reliability
4 during Hypoglycemia in Children." Do you see that?

5 A. Yes.

6 Q. So 1036 is about a product called the
7 GlucoWatch G2 Biographer; correct?

8 A. Yes.

9 Q. Do you know about that product?

10 A. I know about that product.

11 Q. From what?

12 A. This goes way back to approximately 1999
13 when they were first studying this, or even '98.
14 So this is an old product that was around and was
15 known and in fact was known to be not very good.

16 Q. So could you please look at the abstract
17 on page 1.

18 A. Yes.

19 Q. And there is a "Background" section
20 under the abstract. Do you see that?

21 A. Yes.

22 Q. And the second sentence in the

1 background section says: "This device is equipped
2 with two types of alarms to detect hypoglycemia."

3 Do you see that?

4 A. Yes.

5 Q. And then it says, the fourth sentence in
6 the background sentence, says: "The 'down alert'
7 alarm is triggered when extrapolation of the
8 current glucose trend anticipates hypoglycemia to
9 occur within the next 20 minutes."

10 Do you see that?

11 A. Yes.

12 Q. So this down alert alarm -- sorry,
13 withdrawn.

14 This down alert in the GlucoWatch G2
15 Biographer is a predictive alert; right?

16 A. It claims to be.

17 Q. Do you -- you said it claims to be. Do
18 you have any reason to believe it's not?

19 A. Yes.

20 Q. why?

21 A. Glucose measurements by the GlucoWatch
22 were often or usually delayed relative to blood

1 glucose.

2 Q. But it's -- but it was using whatever
3 glucose measurement it got, even if it might have
4 been delayed, to do a prediction; correct?

5 A. I believe so.

6 Q. So the down alert is a predictive alert;
7 right?

8 MR. WILLIAMS: Objection to form.

9 THE WITNESS: With a caveat.

10 BY MR. SARASWAT:

11 Q. And that caveat being what?

12 A. That the glucose being measured is
13 already delayed. So by the time they extrapolate
14 it ahead 20 minutes by some method, it may no
15 longer be really predictive.

16 Q. So it's trying to do a prediction, but
17 you're saying the prediction may not be very
18 accurate because the glucose level that the
19 prediction is analyzing is delayed. Is that right?

20 A. Yes.

21 Q. So can you please turn to page 2 in
22 Exhibit 1036. And up near the top of the page,

1 it's around the third line of text, the sentence
2 that says: "The GW2B is equipped with an alarm
3 that sounds when either 1) the measured glucose
4 drops below the level set by the user (hypoglycemia
5 alarm) or 2) the trend of consecutive glucose
6 values projects that this glucose level will be
7 reached in 20 minutes (down alert alarm)."

8 Do you see that?

9 A. Yes.

10 Q. what does that mean?

11 A. This device has two -- two alerts or
12 alarms. In this case they're calling it alarm.
13 And one is ostensibly real-time, disregarding for
14 the moment the fact that the glucose may be delayed
15 by the time it's measured by the Gluowatch, and
16 the other is said to be a predictive alarm that's
17 extrapolated glucose 20 minutes from the present
18 time.

19 Q. So just so I understand, the down alert
20 sounds if the trend of glucose values shows that
21 the target glucose level will be reached in 20
22 minutes?

1 A. That's correct, yeah.

2 Q. So is this saying that the down alert
3 alarm, which is predictive, sounds if the trend of
4 glucose values projects that a certain glucose
5 level will be reached within 20 minutes?

6 A. Yeah. If you read the next two
7 sentences, they say that they're trying to
8 counterbalance the 20-minute lag of the original
9 measurement.

10 Q. And so the -- this trend of consecutive
11 glucose values, that includes past glucose
12 readings; correct?

13 A. Yes.

14 Q. So in the Gluowatch, the predictive
15 alert considers additional data other than just the
16 current glucose value; correct?

17 MR. WILLIAMS: Objection to form.

18 THE WITNESS: Yes.

19 BY MR. SARASWAT:

20 Q. I'm going to hand you another document
21 that was previously marked Exhibit 1008.

22 (Exhibit 1008, previously marked for

1 identification, incorporated by reference
2 hereto.)

3 BY MR. SARASWAT:

4 Q. Do you recognize Exhibit 1008?

5 A. Yes.

6 Q. This is the Say reference that you
7 discussed in your declarations; correct?

8 A. Yes.

9 Q. Can you please turn to Column 54. And
10 look at the paragraph starting at line 62. Just
11 let me know when you're there.

12 A. Yes.

13 Q. So you see there is a paragraph that
14 starts with the words "In one embodiment"?

15 A. Yes.

16 Q. And it says: "In one embodiment of the
17 invention, the data storage and controller module
18 258 is trainable; for example, the data storage and
19 controller module 258 may store glucose readings
20 over a predetermined period of time, e.g., several
21 weeks. when an episode of hypoglycemia or
22 hyperglycemia is encountered, the relevant history

1 leading to such event may be analyzed to determine
2 any patterns which might improve the system's
3 ability to predict future episodes. Subsequent
4 data might be compared to the known patterns to
5 predict hypoglycemia or hyperglycemia and deliver
6 the drug accordingly."

7 Do you see that?

8 A. Yes.

9 Q. So am I understanding that -- withdrawn.

10 So in that passage that we just read, am
11 I correct that Say is describing a technique for
12 predicting hypoglycemia or hyperglycemia that
13 relies on an analysis of historic glucose data?

14 MR. WILLIAMS: Objection to form and
15 scope.

16 THE WITNESS: Could you repeat the
17 question? I want to get the exact wording of your
18 question.

19 BY MR. SARASWAT:

20 Q. I'll ask it a different way.

21 So that passage that we just read from
22 Say which was at Column 54, line 62 to Column 55,

1 line 5, that's describing techniques for predictive
2 alerts; right?

3 MR. WILLIAMS: Objection to form and
4 scope.

5 THE WITNESS: Not exactly.

6 BY MR. SARASWAT:

7 Q. Okay. What is it describing?

8 A. I would interpret that to mean it is
9 describing a way to detect patterns that have an
10 increased risk of hypoglycemia being associated
11 with them.

12 Q. Well, so if we look at column 54,
13 line 66, it says: "When an episode of hypoglycemia
14 or hyperglycemia is encountered, the relevant
15 history leading to such event may be analyzed to
16 determine any pattern which might improve the
17 system's ability to predict future episodes."

18 Do you see that?

19 A. Yes.

20 Q. So it's talking about trying to predict
21 hypoglycemia or hyperglycemia; correct?

22 MR. WILLIAMS: Objection to form and

1 scope.

2 THE WITNESS: It's trying to determine
3 risk factors by means of a retrospective analysis
4 of data.

5 BY MR. SARASWAT:

6 Q. And it's doing that retrospective
7 analysis for the purpose of trying to predict
8 future hypoglycemia or hyperglycemia?

9 A. It says trying to help predict.

10 Q. And it's trying to help predict future
11 hypoglycemia or hyperglycemia episodes using an
12 analysis of historical glucose data; correct?

13 MR. WILLIAMS: Objection to form and
14 scope.

15 THE WITNESS: Yes.

16 BY MR. SARASWAT:

17 Q. So when I'm doing a predictive alert --
18 so withdrawn.

19 So predictive alerts need to consider
20 additional information like historical trend data
21 in addition to current glucose values; correct?

22 MR. WILLIAMS: Objection to form.

1 THE WITNESS: Yes and no.

2 BY MR. SARASWAT:

3 Q. Can you explain?

4 A. It isn't necessary to have historical
5 data in order to make a prediction. Based on the
6 current and recent data, very recent data, like in
7 the last half hour.

8 Q. Okay. But even in the example you just
9 described where you're using recent data from like
10 the last half hour, it's still using -- the
11 prediction is still using additional data points
12 beyond just the current glucose value; correct?

13 A. Yes.

14 Q. So to do a predictive alert, you need
15 some information beyond just the current glucose
16 value; is that correct?

17 A. Usually.

18 Q. Are you aware of any system that uses
19 just the current glucose value for a predictive
20 alert?

21 MR. WILLIAMS: Objection to form.

22 THE WITNESS: One can simply assume that

1 the next glucose value is going to be the same as
2 the glucose value it is right now. That's one way
3 of predicting.

4 BY MR. SARASWAT:

5 Q. Are you aware of any system that uses
6 that technique?

7 A. I'm not aware of a commercial system
8 that does that. But simply assuming the last value
9 is going to carry over is used in various places
10 and various applications.

11 Q. Like what?

12 A. You can assume that tomorrow's Dow Jones
13 is going to be the same as today.

14 Q. But that's not a medical application?

15 A. No, that's not a medical application.
16 You can assume that my body temperature tomorrow is
17 going to be the same as today. My body weight
18 might be the same as today.

19 So that is a method.

20 Q. But you aren't aware of any systems that
21 use that method for glucose value prediction;
22 correct?

1 A. No, I'm not aware of any.

2 Q. So we were talking for a while now about
3 predictive alerts.

4 A. Yeah.

5 Q. Now, for a real-time alert, it's
6 possible to just compare the real-time glucose
7 value to a threshold; correct?

8 MR. WILLIAMS: Objection to form.

9 THE WITNESS: Yes.

10 BY MR. SARASWAT:

11 Q. So are predictive alerts more
12 complicated than real-time alerts because they
13 require determining the current value and some
14 additional information to make a prediction?

15 MR. WILLIAMS: Objection to form.

16 THE WITNESS: I would say they're
17 different. Predictive alerts are different than
18 real-time alerts.

19 BY MR. SARASWAT:

20 Q. And one way they're different is that
21 predictive alerts are considering additional data
22 beyond just the real-time glucose value; right?

1 A. Correct.

2 Q. Okay. And so would you agree that kind
3 of whatever -- whatever analysis that needs to be
4 done to make the prediction is going to be more
5 complicated at least because there is some
6 additional data point that needs to be considered?

7 MR. WILLIAMS: Objection to form.

8 THE WITNESS: Your question hinges on
9 the word "complicated." So I'm not exactly sure
10 what your interpretation of that might be.

11 BY MR. SARASWAT:

12 Q. I mean there's additional analytical
13 steps that would need to be taken to account for
14 the additional information that needs to be
15 considered; correct?

16 A. Yes.

17 Q. And so that -- that need to use
18 additional information in addition to a real-time
19 value to make a prediction will make the predictive
20 alert necessarily less accurate than a real-time
21 alert; right?

22 MR. WILLIAMS: Objection to form and

1 scope.

2 THE WITNESS: Usually.

3 BY MR. SARASWAT:

4 Q. Are there any circumstances in which --
5 okay. Sorry. Withdrawn.

6 So you said usually. What did you mean
7 by that?

8 A. I mean usually but not absolutely
9 necessarily.

10 Q. Why not?

11 A. Under certain circumstances, the
12 real-time value may be subject to large error and
13 the predicted value, at least for small steps in
14 the future, may be more accurate than the real-time
15 value.

16 Q. But in that circumstance, wouldn't the
17 prediction inherit be an inaccuracy of the
18 real-time glucose reading?

19 MR. WILLIAMS: Objection to form.

20 THE WITNESS: The next measurement or
21 some future measurement would very likely have the
22 same kind of error as the real-time measurements to

1 the point where the estimate was made. But the
2 predicted value could be somewhat ironically more
3 accurate than the -- than a single data point.

4 MR. WILLIAMS: At some logical breaking
5 point, I would like to take a break. We've gone
6 about an hour.

7 MR. SARASWAT: We can take a break now.

8 MR. WILLIAMS: Great.

9 MR. SARASWAT: Ten minutes? Does that
10 work?

11 (Recess taken.)

12 BY MR. SARASWAT:

13 Q. So, Dr. Rodbard, I'm going to hand you a
14 document previously marked as Exhibit 2014.

15 (Exhibit 2014, previously marked for
16 identification, incorporated by reference
17 hereto.)

18 BY MR. SARASWAT:

19 Q. Do you recognize Exhibit 2014?

20 A. Yes.

21 Q. This is the FreeStyle Navigator Guide
22 that you discussed in your supplemental

1 declaration; correct?

2 A. Yes.

3 Q. So on the cover of Exhibit 2014, it says
4 "FreeStyle Navigator, Continuous Glucose Monitoring
5 System Users Guide."

6 Do you see that?

7 A. Yes.

8 Q. Are you familiar with this Navigator
9 system?

10 A. Yes.

11 Q. How?

12 A. I've seen it. I've seen it and I have
13 been aware of the Navigator system for many years.

14 Q. So can you please look at the very last
15 page of the document. Actually, I meant the cover
16 page at the end. Yeah, that page.

17 So we're on the last page of
18 Exhibit 2014, and do you see towards the bottom
19 there is a line that says "Abbott Diabetes, Inc.,
20 1650 Alameda, California, 94502" and then
21 "Copyright 2008 Abbott"?

22 A. Yes.

1 Q. Do you have any reason to believe that
2 the copyright date is inaccurate?

3 MR. WILLIAMS: Objection.

4 THE WITNESS: I have no knowledge.

5 MR. WILLIAMS: Objection to scope.

6 THE WITNESS: I have no knowledge about
7 when this document might have been copyrighted.

8 BY MR. SARASWAT:

9 Q. Do you have any reason to believe that
10 this document was not published by 2008?

11 MR. WILLIAMS: Objection; scope.

12 THE WITNESS: I have no knowledge as to
13 when this was published, other than what it says,
14 "Copyright 2008." So...

15 BY MR. SARASWAT:

16 Q. Okay. Let's turn to page 68 in this
17 document. Are you there?

18 A. Page 68.

19 Q. Okay. So at the top it says Section A,
20 "Set, Review or Change the Alarm Settings." Do you
21 see that?

22 A. Yes.

1 Q. And then there is a heading that says
2 "About Glucose Alarms."

3 A. Yes.

4 Q. So do you see, it's underneath the first
5 two figures, there is a paragraph that begins with
6 the words "In addition to alerting"?

7 A. Yes.

8 Q. So that paragraph, it says: "In
9 addition to alerting you of a high or low glucose
10 condition, the system can also alert you before you
11 reach such a high or low glucose condition. These
12 alarms are called the projected high and projected
13 low glucose alarms."

14 Do you see that?

15 A. Yes.

16 Q. So are these projected high and
17 projected low glucose alarms predictive alerts?

18 MR. WILLIAMS: Objection to form.

19 THE WITNESS: Yes.

20 BY MR. SARASWAT:

21 Q. So now if we look at the next paragraph,
22 it starts with "These alarms are designed." Do you

1 see that?

2 A. Yes.

3 Q. So it says: "These alarms are designed
4 to help you take action as soon as you are
5 notified. Projected low and projected high glucose
6 alarms increase the overall ability to detect a
7 condition of low or high glucose; however, they
8 cannot be relied on exclusively for notification of
9 all low and high glucose conditions."

10 Do you see that?

11 A. Yes.

12 Q. So the Navigator Guide is saying that
13 the predictive alerts cannot be relied on
14 exclusively for notification of all low and high
15 glucose conditions. Correct?

16 A. Yes.

17 Q. why is that?

18 MR. WILLIAMS: Objection to form and
19 scope.

20 THE WITNESS: I'll tell you why. There
21 are a lot of lawyers out there. So you never
22 guarantee anything. You don't guarantee your car

1 will start.

2 So a system can be actually very good,
3 but anybody who is writing a manual proactively,
4 defensively, especially in the medical-legal arena
5 is going to put in a statement like that, which
6 basically says nothing is perfect. With all due
7 respect, sir.

8 BY MR. SARASWAT:

9 Q. Now let's look at the next paragraph.
10 It says: "High and low glucose threshold alarms
11 can detect a low or high glucose condition more
12 often than projected high and projected low glucose
13 alarms (see alarm performance under performance
14 characteristics for more information)." Right?

15 A. Yes.

16 Q. So the threshold alarm that it's
17 referring to here are based on the real-time
18 glucose value; correct?

19 MR. WILLIAMS: Objection to form.

20 THE WITNESS: Yes.

21 BY MR. SARASWAT:

22 Q. what does it mean that the real-time

1 alarms can detect low or high conditions more
2 often?

3 MR. WILLIAMS: Objection to form and
4 scope.

5 THE WITNESS: The threshold alarms will
6 almost by definition pick up any time there is a
7 low -- a low, below the stated boundary or limit,
8 and they will pick up a high. The predictive
9 alarms may -- may not detect all of those events.

10 BY MR. SARASWAT:

11 Q. So does that mean that the real-time
12 alarms are more accurate?

13 MR. WILLIAMS: Objection to form.

14 THE WITNESS: It means that the
15 predictive alarms can have some false negatives.

16 BY MR. SARASWAT:

17 Q. But the threshold -- but the real-time
18 glucose values will not have the false negatives?

19 A. There is a caveat to that. That's
20 assuming the real-time is very accurate, or almost
21 perfectly accurate.

22 Q. But the real-time alerts and the

1 predictive alerts are both going to be using the
2 same measured real-time glucose values in their
3 calculations; correct?

4 MR. WILLIAMS: Objection to form and
5 scope.

6 THE WITNESS: I don't know. When the
7 system is designed, they may be using different
8 thresholds or other aspects of the calculation.

9 BY MR. SARASWAT:

10 Q. what do you mean by other aspects of the
11 calculation?

12 A. A predictive alarm may have various
13 factors built into it that modify its sensitivity.

14 Q. But one of the factors that's going to
15 be built into the predictive alarm is the real-time
16 glucose value; right?

17 MR. WILLIAMS: Objection to form and
18 scope.

19 THE WITNESS: I didn't properly
20 understand the question. I wonder if you could
21 repeat that.

22 BY MR. SARASWAT:

1 Q. well, you -- so you said earlier when
2 the system is designed -- sorry. You said earlier
3 a predictive alarm may have various factors built
4 into it that modify sensitivity.

5 So what I'm trying to understand is what
6 did you mean by factors? Like what are the
7 factors?

8 A. A predictive alarm may be using a
9 different threshold than the threshold being used
10 for the real-time alert.

11 Q. Okay. So what you're saying is that the
12 predictive alarm is trying to predict whether a
13 glucose threshold is going to be crossed, and that
14 threshold might be different than the threshold for
15 the predictive alert; right?

16 MR. WILLIAMS: Objection to form.

17 BY MR. SARASWAT:

18 Q. Sorry. I used predictive twice. You're
19 saying the predictive alarm is trying to predict
20 whether a certain glucose level is going to be
21 crossed, and that glucose threshold might be
22 different than the glucose threshold for the

1 real-time alert. Is that what you're saying?

2 A. Yes.

3 Q. Okay. But in order to predict when the
4 threshold is going to be crossed, the predictive
5 alarm needs to analyze some data; correct?

6 A. Yes.

7 Q. And among the pieces of data that the
8 predictive alarm needs to analyze is the real-time
9 glucose value; correct?

10 MR. WILLIAMS: Objection to form and
11 scope.

12 THE WITNESS: Correct.

13 BY MR. SARASWAT:

14 Q. And that real-time glucose value that
15 the predictive alarm is going to use to do its
16 analysis is going to be the same real-time glucose
17 value that the real-time threshold alert is going
18 to be using for its analysis; right?

19 MR. WILLIAMS: Objection to form.

20 THE WITNESS: Not necessarily.

21 BY MR. SARASWAT:

22 Q. why not?

1 A. The real-time alert might be set with a
2 threshold of 70. The predictive alarm may be more
3 conservative and say that, well, as soon as -- if
4 I'm predicting -- if the prediction algorithm
5 thinks that the glucose is going to be 80 but it's
6 not 80 plus or minus 1, it's 80 plus or minus some
7 uncertainty.

8 So the de facto setting for the
9 predictive alarm may be set at 80 in an attempt to
10 give good or optimal -- hopefully optimal
11 performance with respect to the other threshold
12 which was 70.

13 Q. All right. But I think we're talking
14 about two different things. So you're talking
15 about thresholds, and you're saying that the two
16 alarms might have different thresholds; right?

17 But I'm asking about the data that the
18 two different alarms use to determine if their
19 respective thresholds are going to be crossed. Do
20 you understand that?

21 A. Yes.

22 Q. So is it true that one piece of data

1 that the predictive alarm is going to use to
2 determine if its threshold is going to be crossed
3 is the real-time glucose measurement?

4 A. Yes.

5 Q. And is it also true that the real-time
6 alarm is going to use the real-time glucose
7 measurement to determine if the real-time alert
8 threshold has been crossed?

9 MR. WILLIAMS: Objection to form.

10 THE WITNESS: Yes.

11 BY MR. SARASWAT:

12 Q. Okay. So now looking back at page --
13 what were we on? So looking back at page 68, if we
14 look back at the paragraph we were just looking at
15 where it starts with the words "High and low
16 glucose threshold alarms." Do you see that?

17 A. Yes.

18 Q. So we were looking at that sentence that
19 says: "High and low glucose threshold alarms can
20 detect a low or high glucose condition more often
21 than projected high and projected low glucose
22 alarms (see alarm performance under performance

1 characteristics for more information)."

2 Do you see that?

3 A. Yes.

4 Q. So when it says real-time alarms can
5 detect low or high glucose conditions more often,
6 does that mean that the real-time alarms are more
7 accurate than the predictive alarms?

8 MR. WILLIAMS: Objection to form and
9 scope.

10 THE WITNESS: Generally speaking, yes.

11 BY MR. SARASWAT:

12 Q. So now if we keep reading after the
13 closed parentheses, the last sentence of that
14 paragraph says: "Therefore, do not turn off the
15 low and high glucose threshold alarms to rely just
16 on the projected high and projected low glucose
17 alarms." Right?

18 A. That's what it says, yes.

19 Q. Okay. So here the Navigator Guide is
20 expressly warning the user not to turn off the
21 real-time alerts and just rely on the predictive
22 alerts. Correct?

1 A. Yes.

2 Q. why is that?

3 MR. WILLIAMS: Objection to form.

4 Scope.

5 THE WITNESS: I would have to speculate
6 about what the people who wrote this particular
7 sentence might have been thinking. But I would
8 comment that you may be monitoring glucose data. A
9 projection of that glucose data may say, oh, it's
10 going to go low in 15 minutes. And that may be an
11 accurate prediction at that point in time.

12 But then maybe somebody has had a cup of
13 coffee with some sugar in it and so their glucose
14 was rapidly absorbed and they never reached that
15 projection, that projected value.

16 So it's not that anything was the matter
17 with either the real-time or the projected level,
18 but simply that nature changed course, the course
19 of the human being changed and now the projected
20 alarm in this case would have been giving an
21 extra -- an extra alert.

22 BY MR. SARASWAT:

1 Q. So you mentioned that you would need
2 to -- so you mentioned that you would need to think
3 about what the people who wrote this sentence would
4 have been thinking. Right?

5 So do you see that this sentence starts
6 with the word "Therefore" that we just discussed.
7 It appears right after the sentence we were
8 discussing earlier that says that the high and low
9 glucose threshold alarms can detect a high or low
10 glucose condition more often than projected high
11 and projected low glucose alarms?

12 A. Yes.

13 Q. So did they put that sentence there
14 because the predictive alerts will not detect low
15 or high conditions as often?

16 MR. WILLIAMS: Objection to form and
17 scope.

18 MR. SARASWAT: Withdrawn.

19 BY MR. SARASWAT:

20 Q. So is the reason that they put the
21 sentence that says do not turn off the low and high
22 glucose threshold alarms to rely just on the

1 projected high and projected low glucose alarms in
2 the place where they did at the end of that
3 paragraph because the projected low and projected
4 high glucose alarms will not detect low or high
5 glucose condition as often?

6 MR. WILLIAMS: Objection to form and
7 scope.

8 THE WITNESS: The first sentence of this
9 paragraph makes a statement that the high and low
10 glucose threshold alarms detect a high or low
11 condition more often than the projected high or
12 projected low alarms.

13 So they're making that statement as
14 matter of fact, and so evidently that was an
15 observation that someone associated with this
16 product had made.

17 BY MR. SARASWAT:

18 Q. Right. And then after making that
19 observation, they said: "Therefore, do not turn
20 off the low and high glucose threshold alarms to
21 rely just on the projected high and projected low
22 glucose alarms." Correct?

1 MR. WILLIAMS: Objection to form and
2 scope.

3 THE WITNESS: I would skip down to the
4 next paragraph where they say that one should use
5 both the low and high glucose threshold alarms and
6 the projected low and projected high glucose
7 alarms. So that is intended to provide maximum
8 notifications of lows and highs.

9 BY MR. SARASWAT:

10 Q. All right. Now let's go to page 69. So
11 do you see there is a box at the bottom of the page
12 that begins with the word "Caution"?

13 A. Yeah.

14 Q. It says: "Caution: Do not rely solely
15 on the projected glucose alarms for detection of
16 low or high glucose conditions."

17 Do you see that?

18 A. Yes.

19 Q. So here again it's saying not to rely
20 solely on the projected glucose alarms. Correct?

21 MR. WILLIAMS: Objection to form.

22 THE WITNESS: I believe the answer was

1 yes.

2 BY MR. SARASWAT:

3 Q. Okay. So could you please -- so do you
4 see that this section that we were looking
5 at -- withdrawn. Sorry. One second.

6 So do you see that the Section A we were
7 just looking at about glucose alarms spans pages 68
8 and 69?

9 A. And then it continues, evidently.

10 Q. All right. Can you just read pages 68
11 to 69 and let me know when you're done.

12 A. Yes, I've read those two pages.

13 Q. Okay. So earlier when we were talking
14 about these two pages, we saw a couple of examples
15 where it warned the user not to rely solely on the
16 projected alerts. Do you recall that?

17 A. Yes.

18 Q. Now, in pages 68 and 69, did you see any
19 place here in this section where the Navigator
20 warns -- sorry, where the Navigator Guide warns the
21 user not to turn off the predictive alerts and rely
22 solely on the real-time alerts?

1 MR. WILLIAMS: Objection to form and
2 scope.

3 THE WITNESS: Okay. Could you repeat
4 the question, please?

5 BY MR. SARASWAT:

6 Q. Let me try to make it a bit more clear.

7 So there's two kinds of alerts in the
8 Navigator Guide; right? There is a real-time alert
9 and then there's the predictive alert. Right?

10 A. Yes.

11 Q. And as we discussed earlier, there are a
12 number of places here on pages 68 and 69 where it's
13 warning the user you should not turn the real-time
14 alerts off to rely just on the predictive alerts.
15 Correct?

16 A. Yes.

17 Q. Is there any warning telling the user
18 not to do the reverse, meaning is there any place
19 where it warns the user that you should not turn
20 off the predictive alerts and just rely on the
21 real-time alerts?

22 MR. WILLIAMS: Objection to form and

1 scope.

2 THE WITNESS: I don't believe so.

3 BY MR. SARASWAT:

4 Q. So why is that?

5 MR. WILLIAMS: Objection to form and
6 scope.

7 THE WITNESS: As shown on page 69, if
8 someone turned off the projected alarm, there would
9 be a low detection rate. So that's one aspect of
10 it.

11 The other aspect, and that's not
12 addressed on these two pages, is that in general
13 people want or need or like getting a projected
14 alarm.

15 MR. SARASWAT: So actually let's take a
16 short break just for a second because I'm getting
17 an error message on the realtime.

18 (Off the record.)

19 BY MR. SARASWAT:

20 Q. So there are places here in this section
21 we're looking at where it warns the user not to
22 turn the real-time alerts off and just rely on the

1 projected alerts; right?

2 A. Yes.

3 Q. But there is no place here where it
4 warns the user not to turn the projected alerts off
5 and just rely on the real-time alerts; correct?

6 MR. WILLIAMS: Objection to form and
7 scope. Asked and answered.

8 THE WITNESS: That is correct.

9 BY MR. SARASWAT:

10 Q. So why is the Guide giving that first
11 warning I just discussed but not the second
12 warning?

13 MR. WILLIAMS: Objection to form and
14 scope.

15 THE WITNESS: There could be many
16 reasons. The threshold alarm, the real-time alarm,
17 is the, if you will, final arbiter as to whether or
18 not one has crossed -- has reached and touched the
19 boundary. Unless somebody is also wearing a
20 different sensor or has the blood glucose values
21 being checked by a different method -- and there
22 are devices that could be used to double-check the

1 CGM glucose measurement.

2 So we're relying on the threshold alarm
3 for the quote-unquote truth. Although somebody
4 could always say, okay, blood glucose is 70; is
5 that really real? I'll get out my blood glucose
6 meter and test directly and see whether or not the
7 threshold alarm is in fact accurate.

8 So threshold alarms can have errors or
9 inaccuracies. But nevertheless, they are assuming
10 the CGM is properly calibrated and properly
11 functioning. Then they are indicating whether or
12 not an event -- they're being assumed to be good
13 enough to tell whether or not there is an event
14 happening. So one would want to know whether that
15 was the case.

16 BY MR. SARASWAT:

17 Q. All right. Can you look at page 68
18 again.

19 A. Okay.

20 Q. So the second-to-last full paragraph --
21 actually, it's the same paragraph we were looking
22 at. So there is a sentence that begins "High and

1 low glucose threshold alarms." Do you see that?

2 A. Yes.

3 Q. It says: "High and low glucose
4 threshold alarms can detect a low or high glucose
5 condition more often than projected high and
6 projected low glucose alarms (see alarm performance
7 under performance characteristics for more
8 information)."

9 Do you see that?

10 A. Yes.

11 Q. So there is a reference to alarm
12 performance in that parenthetical near the end;
13 right?

14 A. Yes.

15 Q. Now look at page 70, please. And do you
16 see at the very bottom of page 70 it says: "Review
17 the alarm performance data in Section 18 for a
18 detailed analysis of the effectiveness of the
19 glucose alarms"?

20 A. Yes.

21 Q. Do you think that the reference to alarm
22 performance here is the same alarm performance that

1 was referenced on page 68 in that parenthetical
2 that we looked at?

3 MR. WILLIAMS: Objection to form and
4 scope.

5 THE WITNESS: We would have to see.
6 Presumably, because they occur within two pages of
7 each other.

8 BY MR. SARASWAT:

9 Q. So can we turn to page 160 of the
10 Navigator Guide. So at the very top next to the
11 page number it says "Section 18," and underneath it
12 says "Appendix B: Specifications." Do you see
13 that?

14 A. Yes.

15 Q. And the first line of -- and then the
16 first line of text is a header that says
17 "Appendix B: Specifications (continued)."

18 Do you see that?

19 A. where is that again?

20 Q. It's up closer to the top.

21 A. Yes.

22 Q. Okay. And then underneath that, it says

1 "Determination of Alarm Performance." Do you see
2 that?

3 A. Yes.

4 Q. And then the first sentence underneath
5 that header is: "The threshold alarm is
6 characterized below. The projected alarm
7 performance has not been established."

8 Do you see that?

9 A. Yes.

10 Q. So here the Guide is saying that the
11 performance of the predictive alerts has not been
12 established. Right?

13 A. Yes.

14 Q. What is meant by performance here?

15 MR. WILLIAMS: Objection to form and
16 scope.

17 THE WITNESS: I can't say, having read
18 to this point.

19 BY MR. SARASWAT:

20 Q. Does reading the following paragraph
21 give you any understanding of what's meant by
22 performance here?

1 MR. WILLIAMS: Objection to form and
2 scope.

3 THE WITNESS: Okay, I've read that.
4 BY MR. SARASWAT:

5 Q. So do you have an understanding of what
6 they mean by performance here?

7 MR. WILLIAMS: Objection to form and
8 scope.

9 THE WITNESS: I believe so.
10 BY MR. SARASWAT:

11 Q. what does it mean?

12 A. Evidently, they are measuring the
13 hypoglycemic events, hyperglycemic events, true
14 threshold alarms, the true alarm rate, missed alarm
15 rate, the false threshold alarm and the false alarm
16 rate.

17 Q. So does that mean that performance here
18 means accuracy?

19 MR. WILLIAMS: Objection to form and
20 scope.

21 THE WITNESS: The totality of the
22 various things they're measuring could, generally

1 speaking, be regarded as accuracy.

2 BY MR. SARASWAT:

3 Q. Okay. And so earlier when we were
4 talking about pages 68 and 69 of the Navigator
5 Guide, we saw that the Guide warns users not to
6 rely solely on predictive alerts. Right?

7 A. Yes.

8 Q. And is giving that warning because of
9 concerns about the accuracy of the predictive
10 alerts; right?

11 MR. WILLIAMS: Objection to form and
12 scope.

13 THE WITNESS: Presumably.

14 BY MR. SARASWAT:

15 Q. All right. Let's turn to Paragraph 23
16 of Exhibit 1035.

17 A. I'm sorry, which page?

18 Q. Paragraph 23 in Exhibit 1035. It starts
19 on page 10. So the last sentence of
20 Paragraph 23 -- so first of all, before we go
21 there, do you see above Paragraph 23 there is a
22 heading C that says: "Ground 1 renders obvious

1 Claims 1-3, 12, 19, and 23"?

2 A. Yes.

3 Q. And that relates just to the Guide which
4 is Exhibit 1004; right?

5 A. Correct.

6 Q. So the last sentence of Paragraph 23 in
7 Exhibit 1035 says: "In my opinion, the Guide's
8 'real-time glucose value' is within the scope of
9 the ordinary meaning of the term 'parameter
10 predictive of glucose value' at least because the
11 Guide's real-time glucose value is a parameter that
12 indicates a patient's glucose value."

13 Do you see that?

14 A. Yes.

15 Q. So in your opinion, the words
16 "parameter" and "indicative of" have an ordinary
17 meaning; right?

18 MR. WILLIAMS: Objection to form.

19 THE WITNESS: Yes.

20 BY MR. SARASWAT:

21 Q. So what ordinary meaning did you give to
22 the word "parameter"?

1 A. Parameter is something that measures or
2 reflects the glucose value.

3 Q. Did you cite anything in your
4 declaration -- sorry.

5 Did you cite anything in your
6 supplemental declaration that supports the
7 definition you just gave me?

8 A. "Parameter" is a word that is derived
9 from the Greek, which means to measure. So the
10 normal ordinary language for the word "parameter"
11 is something that measures.

12 I also had utilized that in my previous
13 declaration, and we discussed it at the previous
14 deposition.

15 Q. Okay. So would you -- so you referred
16 just now to the fact that "parameter" is derived
17 from the Greek word for measure?

18 A. Yeah.

19 Q. So would you agree that one meaning of
20 the word "parameter" is a numerical or other
21 measurable factor forming one of a set that defines
22 a system or sets the conditions of its operation?

1 MR. WILLIAMS: Objection to form and
2 scope.

3 THE WITNESS: would you read that back
4 again? I want to make sure I get it. Read it
5 slowly.

6 BY MR. SARASWAT:

7 Q. would you agree that one meaning of the
8 word "parameter" is a numerical or other measurable
9 factor forming one of a set that defines a system
10 or sets the conditions of its operation?

11 MR. WILLIAMS: Objection to form and
12 scope.

13 THE WITNESS: Yes.

14 MR. SARASWAT: It's 11:08. Do you want
15 to pause?

16 MR. WILLIAMS: Yeah, this would be good.
17 Thank you.

18 (Recess taken.)

19 BY MR. SARASWAT:

20 Q. So, Dr. Rodbard, before the break we
21 were talking about the meanings of the words
22 "parameter" and "indicative of." Do you recall

1 that?

2 A. Yes.

3 Q. And so you said that in your opinion
4 indicative of has an ordinary meaning. Do you
5 recall that?

6 A. We discussed parameter. We didn't
7 discuss indicative as of yet, to my knowledge.

8 Q. So I'm not asking you what the meaning
9 of indicative of is. I am just asking do you agree
10 that indicative of has an ordinary meaning?

11 A. Yes.

12 Q. So what ordinary meaning did you give to
13 the phrase "indicative of"?

14 A. Indicative needs to be packaged together
15 with the parameter and with the glucose that
16 follows it. I mean, it just means that it is
17 something that measures the glucose.

18 Q. So I think you said earlier that
19 parameter is something that measures the glucose.
20 I'm asking what indicative of means.

21 A. Indicative is some kind of -- it's
22 saying the parameter is indicating what the glucose

1 is. It's just something that's measuring the
2 glucose. The parameter has to indicate what the
3 glucose is.

4 Q. So would you agree that one meaning of
5 indicative of is serving as a sign or indication
6 of?

7 MR. WILLIAMS: Objection to form and
8 scope.

9 THE WITNESS: Yes.

10 BY MR. SARASWAT:

11 Q. All right. So I'm going to hand you a
12 document -- I'm going to hand you a document that
13 was previously marked Exhibit 1002.

14 (Exhibit 1002, previously marked for
15 identification incorporated by reference
16 hereto.)

17 BY MR. SARASWAT:

18 Q. Do you recognize Exhibit 1002?

19 A. Yes.

20 Q. This is the first declaration you
21 submitted in this case; correct?

22 A. Yes.

1 Q. And it's one of the documents you
2 reviewed in preparing for today's deposition;
3 right?

4 A. Yes.

5 Q. So can you please turn to Paragraph 61
6 in Exhibit 1002. Are you there?

7 A. Yes.

8 Q. Okay. So Paragraph 61 is under a
9 heading for Limitation 1[a]; correct?

10 A. Yes.

11 Q. Could you please read Paragraph 61 and
12 let me know when you're done.

13 A. Yes.

14 Q. So in the first sentence you say: "In
15 my opinion, the User's Guide discloses element
16 1[a], at least according to patent owner's
17 interpretation."

18 Do you see that?

19 A. Yes.

20 Q. And the User's Guide you're referring to
21 here is Exhibit 1004; right?

22 A. User's Guide, yes.

1 Q. So limitation 1[a] recites a first
2 function; correct?

3 A. Yes.

4 Q. So what is it in the Guide,
5 Exhibit 1004, that you say meets the first
6 function?

7 MR. WILLIAMS: Objection to form.

8 THE WITNESS: Well, the user-settable
9 first criteria are described in part on page 76,
10 changing your glucose alert settings.

11 And then on page 54 -- on 54, it says
12 that when the STS sensor glucose values are below
13 your low alert setting and trending down, STS
14 receiver will vibrate and display the low alert
15 screen.

16 So in that sense, it is evaluating --
17 this User Guide and the corresponding system
18 evaluates sensor data using a first function which
19 is determining whether the real-time glucose value
20 meets one or more user-settable first criteria.

21 BY MR. SARASWAT:

22 Q. So you mentioned that the user-settable

1 first criteria are described on page 76. But what
2 is the thing in the Guide that you're pointing to
3 that meets the first function?

4 MR. WILLIAMS: Objection to form.

5 THE WITNESS: On page 50: "In addition
6 to discrete glucose values, your STS system will
7 alert you when your glucose levels are outside of
8 your programmed alert levels."

9 So in order to do that, the system must
10 have determined whether the real-time glucose value
11 has met the condition, in this case that there was
12 a low glucose at or below the lower boundary for
13 the target range.

14 BY MR. SARASWAT:

15 Q. So are you saying that the first
16 function that you're pointing to in the Guide
17 determines whether the real-time glucose value is
18 at or below the lower boundary for the target
19 range?

20 MR. WILLIAMS: Objection to form.

21 THE WITNESS: That appears to be
22 correct. Except that that does not include the

1 comment that it must be or should be trending --
2 the glucose should be trending down, in conjunction
3 with low glucose.

4 BY MR. SARASWAT:

5 Q. Okay. So you're saying that the first
6 function determines whether the real-time glucose
7 value is at or below a lower boundary for the
8 target range, and also determines if the glucose is
9 trending down?

10 MR. WILLIAMS: Objection to form.

11 THE WITNESS: Correct.

12 BY MR. SARASWAT:

13 Q. And is that everything the first
14 function does?

15 MR. WILLIAMS: Objection to form.

16 THE WITNESS: Well, the STS sensor
17 evidently can produce an alarm, one or another
18 types of alarms.

19 BY MR. SARASWAT:

20 Q. Can you show me where in your
21 declaration, Exhibit 1002, you mentioned
22 determining whether the glucose is trending down in

1 connection with the first function?

2 MR. WILLIAMS: Objection to form.

3 THE WITNESS: I don't see it in
4 Section A, but it is mentioned elsewhere in my
5 declaration.

6 BY MR. SARASWAT:

7 Q. When you say you don't see it in
8 Section A, do you mean you don't see it in the
9 section regarding limitation 1[a]?

10 A. That is correct.

11 Q. So in the section of your declaration
12 regarding limitation 1[a], which is the limitation
13 that recites the first function, you didn't mention
14 anything about the determination of if the glucose
15 is trending down; right?

16 A. Not in the previous declaration.

17 Q. And in Exhibit 1002, in the section on
18 limitation 1[a], the only thing that you mention
19 the first function doing is comparing the real-time
20 glucose value to a threshold. Right?

21 MR. WILLIAMS: Objection to form.

22 THE WITNESS: I believe that's correct.

1 BY MR. SARASWAT:

2 Q. Now, can you please look at the next
3 section, subsection c of your declaration which
4 relates to limitation 1[b]. Do you see that?

5 A. Yes.

6 Q. Okay. And that section on limitation
7 1[b] starts with Paragraph 62; right?

8 A. Yes.

9 Q. Okay. And the limitation 1[b] recites a
10 second function; correct?

11 A. Yes.

12 Q. Okay. So in the first sentence of
13 Paragraph 62 you say: "In my opinion, the User's
14 Guide alone (Petition Ground 1) or in combination
15 with Harper (Petition Ground 2) discloses element
16 1[b]." Right?

17 A. Yes.

18 Q. All right. Now, your opinion for how
19 the Guide alone meets limitation 1[b] in Ground
20 1 is in Paragraphs 62 and 63; right?

21 A. I'll have to look.

22 Q. Sure.

1 A. Okay, I've read 62 and 63.

2 Q. Okay. So those two paragraphs are where
3 you provide your opinion on how the Guide alone
4 meets limitation 1[b]; right?

5 MR. WILLIAMS: Objection to form.

6 THE WITNESS: That is correct.

7 BY MR. SARASWAT:

8 Q. Okay. So again just focusing on the
9 Guide alone and your opinions on the Guide alone,
10 what is it in the Guide, Exhibit 1004, that you say
11 meets the second function?

12 MR. WILLIAMS: Objection to form.

13 THE WITNESS: Well, the Guide is
14 evaluating sensor data using a second function to
15 determine whether a parameter indicative of glucose
16 value meets one or more nonuser-settable criteria.

17 In the User Guide, it describes a system
18 where there is a device that measures glucose.
19 This is sensor data. It uses a different function
20 than in 1[a], and it is evaluating whether the
21 parameter indicative of a glucose value, which
22 includes the use of a possible real-time glucose

1 value, meets one or more nonuser-settable second
2 criteria.

3 So the distinction between 1[a] and 1[b]
4 is that in 1[b] the system is utilizing a
5 nonuser-settable second criteria.

6 BY MR. SARASWAT:

7 Q. Right. But what I'm trying to
8 understand is what are the things you say in the
9 Guide meet those different words of the claim.

10 So you told me what you think the
11 nonuser-settable second criteria is, and you told
12 me what you think the parameter indicative of
13 glucose value is. But what I want to know is what
14 is it in the Guide that you think is the second
15 function?

16 MR. WILLIAMS: Objection to form.

17 THE WITNESS: The second function being
18 utilized in the STS sensor and described in this
19 booklet, this User's Guide, is the fact that
20 specifically there is a threshold which has been
21 preset at 55 milligrams per deciliter. This is
22 called the low glucose alarm in contradistinction

1 to 1[a] which was corresponding to a low glucose
2 alert.

3 So in the low glucose alarm, the user
4 doesn't set the criterion, which happens to be 55,
5 but that's just one of many possibilities as to
6 where it might be. But this is set in the factory
7 or by the manufacturer, and this is where we're
8 seeing a DexCom STS system doing exactly what is
9 described in 1[b], evaluating sensor data using a
10 second function to determine whether parameter
11 indicative of glucose value meets one or more
12 nonuser-settable second criteria.

13 BY MR. SARASWAT:

14 Q. So in your opinion, the thing in the
15 Guide that meets the second function is something
16 that compares the real-time glucose value to the
17 nonuser-settable 55 milligrams per deciliter
18 threshold. Is that right?

19 MR. WILLIAMS: Objection to form.

20 THE WITNESS: Yes.

21 BY MR. SARASWAT:

22 Q. Okay. Does that second function do

1 anything else?

2 MR. WILLIAMS: Objection to form and
3 scope.

4 THE WITNESS: Yes.

5 BY MR. SARASWAT:

6 Q. what else does it do?

7 A. Evidently it is coupled to an alarm.
8 This is in 1[b], evaluating the sensor data. It
9 doesn't say in 1[b] what you do with that. If you
10 evaluate it and discover that in fact this has been
11 triggered, then the STS system triggers alarms
12 which can be auditory, visual, vibratory, or
13 otherwise.

14 Q. So you said that the function is coupled
15 to something. But the function itself is comparing
16 the glucose value to that 55 milligrams per
17 deciliter threshold; right?

18 A. At this point, we're just doing the
19 comparison.

20 Q. Okay. So I just -- you mentioned
21 something earlier, and I just want to clarify to
22 make sure I understand your terminology.

1 So I think in one of your earlier
2 answers when talking about the Guide, you referred
3 to a low glucose alert and a low glucose alarm. Do
4 you recall that?

5 A. Yes.

6 Q. Okay. And I think you said that the low
7 glucose alarm has the 55 milligrams per deciliter
8 threshold that's fixed. Right?

9 A. Yes.

10 Q. So is the low glucose alert -- so
11 withdrawn.

12 Do you recall earlier this morning you
13 and I were talking about the disclosure in the
14 Guide of an 80 milligram per deciliter default that
15 could then be changed to a value between 60 and
16 90 milligrams per deciliter?

17 A. Yes.

18 Q. So is that the threshold for the low
19 glucose alert?

20 A. The 80 milligrams is the default setting
21 for the low glucose alert.

22 Q. And then there were also other values

1 that the user could set; right?

2 A. Correct.

3 Q. Yeah. I just wanted to make sure I
4 understood the distinction.

5 So the low glucose alert has a threshold
6 that can be programmed into the system or user
7 selectable; right?

8 A. It's user settable.

9 Q. And the default is programmed into the
10 system, which is 80 milligrams per deciliter?

11 A. Let's see. It would be set at the
12 factory. Yeah, we can use the term "programmed."

13 Q. Because I'm getting those two terms
14 confused. So that the low glucose alert is the one
15 that can be programmed in or is user selectable?

16 MR. WILLIAMS: Objection to form.

17 THE WITNESS: There is a confusion in
18 that question because the -- usually when you say
19 "programmed in," that means that it's programmed
20 in, let's say at the factory, and that means that
21 it's set by the factory and therefore it is not
22 user settable.

1 Now, you referred to the default value
2 of 80 milligrams per deciliter, which you're
3 calling programmed in. But that one is -- that
4 threshold of 80 is user settable, specifically in a
5 range from 60 to 90.

6 BY MR. SARASWAT:

7 Q. Okay.

8 A. So my thinking is when we say
9 programmed, something is programmed in, that means
10 it's not user settable.

11 Q. But in the case of the Guide, the
12 80 milligrams per deciliter default value could
13 then be changed by the user to one of those other
14 values between 60 and 90; correct?

15 A. That is correct.

16 Q. So that low glucose threshold can be
17 programmed into the computer system or user
18 selectable?

19 MR. WILLIAMS: Objection to form, scope,
20 and asked and answered.

21 THE WITNESS: In the low glucose alert,
22 the threshold is set up to be user selectable or

1 user -- user settable. when I think of something
2 that is programmed in, I think of something that is
3 in -- put into the system and is not changeable.

4 BY MR. SARASWAT:

5 Q. So are you saying that the threshold for
6 the first function in the Guide is not user
7 settable?

8 A. No. The first function is user settable
9 or selectable.

10 Q. Okay.

11 A. And the fact that there is a default
12 value already sitting there when someone takes it
13 out of the box when they start using the device
14 doesn't detract from the fact that it is in this
15 case but not in the other case, not for the second
16 function, in the first case, it is user settable or
17 selectable.

18 Q. Right. So that default value you
19 mentioned -- I think you used the term "someone
20 taking it out of the box." So that 80 milligrams
21 per deciliter value when someone takes it out of
22 the box, that's a default value that's programmed

1 into the computer system in the device; right?

2 A. well, it's the starting value. But
3 clearly in the context of the low glucose alert,
4 this is intended to be an adjustable or
5 user-settable, user-selectable parameter.

6 Q. Right. So that threshold for the low
7 glucose alert is -- it can be programmed into the
8 system or user selectable because the user can
9 either use whatever value it was when they took it
10 out of the box or they can change it to some other
11 value in the range; right?

12 MR. WILLIAMS: Objection to form.

13 THE WITNESS: I regard the value of 80
14 in the 80 milligrams per deciliter as basically a
15 placeholder for whatever the end user wishes to
16 select or utilize.

17 BY MR. SARASWAT:

18 Q. But if the user didn't -- the device has
19 to work out of the box; right?

20 MR. WILLIAMS: Objection to form.

21 BY MR. SARASWAT:

22 Q. Even if the user does nothing?

1 A. well, actually, there are a few steps
2 beforehand that the user has to do to get the
3 device going. But I regard the value of 80 as user
4 settable. I regard the value of 55 for the --
5 55 milligrams per deciliter for the low glucose
6 alarm as a nonuser-settable value because the
7 User's Guide makes it clear that that cannot be
8 changed. That's irrevocable. That's permanent, so
9 to speak.

10 Q. Right. But the 80 -- the 80 milligrams
11 per deciliter for the low glucose alert can be
12 changed by the user selecting a different value;
13 right?

14 A. I agree.

15 Q. Okay. So that low glucose alert
16 threshold is programmed into the system, which is
17 the 80 milligrams per deciliter default, or user
18 selectable, which is one of the other values that
19 the user can choose. Right?

20 MR. WILLIAMS: Objection to form.

21 THE WITNESS: I don't really make a
22 distinction between the 80 or alternatives such as

1 70 or 60 or 90. I don't regard the 80 as different
2 from the 70, 60 or 90. I see the 80 as a
3 placeholder.

4 The important distinction is that in the
5 case of the 55, it is not user settable, and I
6 could take the device apart, open it up and try to
7 do anything I could. I can't change that 55. So
8 that's a nonuser-settable thing, and I see the 80
9 as -- or the range from 70 to 90 as being
10 different. And that's -- that's two functions.
11 That's why they're called low glucose alert and low
12 glucose alarm.

13 BY MR. SARASWAT:

14 Q. Can you turn back to Exhibit 1035.

15 A. What was that?

16 Q. It's your supplemental declaration.

17 A. Sorry?

18 Q. That's your supplemental declaration.

19 A. Okay. Just a moment.

20 Q. Let's look at Paragraph 32. So in the
21 second sentence of Paragraph 32, you say: "In my
22 opinion, the claim language does not limit the 'set

1 of instructions' to 'instructions to a person or
2 external device' as patent owner argues."

3 Do you see that?

4 A. Yes.

5 Q. So in your opinion, does the word
6 "instructions" have an ordinary meaning?

7 MR. WILLIAMS: Objection to form.

8 THE WITNESS: Instructions would be a
9 teaching or obviously instruction. It's telling
10 someone what to do. Someone or some thing what to
11 do.

12 BY MR. SARASWAT:

13 Q. Okay. So is the definition, quote,
14 detailed information telling how something should
15 be done, operated or assembled, unquote, consistent
16 with your understanding of the word "instruction"?

17 MR. WILLIAMS: Objection to form and
18 scope.

19 THE WITNESS: Generally speaking, yes.
20 That sounds like a dictionary definition.

21 BY MR. SARASWAT:

22 Q. I'm going to show you -- I'm going to

1 hand you another document. It's already in the
2 record. This is the petitioner's reply to patent
3 owner's response. Do you see that?

4 A. Yes.

5 Q. Have you reviewed this reply?

6 A. I did.

7 Q. And you understand that this reply cites
8 your supplemental declaration, Exhibit 1035?

9 A. I believe so.

10 Q. All right. Can you please turn to
11 page 25 of the reply. Do you see the section up at
12 the top of the page, Section C that says: "Say
13 discloses element 19[f]"?

14 A. Yes.

15 Q. So this section of the reply is talking
16 about the Say and Guide combination; right?

17 MR. WILLIAMS: Objection to form.

18 THE WITNESS: I see where it's talking
19 about Say. Yes, that's in conjunction with Ground
20 5. So that is Say and the User Guide.

21 BY MR. SARASWAT:

22 Q. So this section is -- this section, the

1 petitioner is criticizing patent owner for
2 mischaracterizing the Say and Guide combination.

3 Do you see that?

4 A. I haven't actually read it yet.

5 Q. Sure, go ahead.

6 A. Okay, I've read it.

7 Q. And so would you agree that in this
8 section, the reply is criticizing the patent owner
9 for mischaracterizing the Say-Guide combination?

10 MR. WILLIAMS: Objection to form.

11 Scope.

12 THE WITNESS: The petitioner is stating
13 that the portions of Say are not limited to alarms
14 based on the current glucose thresholds and that it
15 is the mandatory setting that's clearly enunciated
16 in the Guide's low glucose alarm that is being used
17 in this combination of Say and User Guide, not the
18 specific numerical value of 55 milligrams per
19 deciliter.

20 So I believe that's what this is
21 speaking to.

22 BY MR. SARASWAT:

1 Q. Okay. So you were just looking at the
2 last sentence right now; correct?

3 A. So it looks like it's two sentences, but
4 that's fine.

5 Q. So at the end of that paragraph, it
6 says -- so at the end of Section C before the
7 heading for Ground 6, it says: "It is the
8 'mandatory setting' of the Guide's glucose alarm
9 that is being used in the combination, not the
10 specific 55 milligrams per deciliter threshold."

11 Do you see that?

12 A. Yes.

13 Q. And there's some citations?

14 A. Yes.

15 Q. So do you agree with that statement that
16 it's the mandatory setting of the low glucose alarm
17 that's being used in the combination, not the 55
18 milligrams per deciliter threshold?

19 MR. WILLIAMS: Objection to form and
20 scope.

21 THE WITNESS: Yes. I agree that the
22 User Guide sets out the concept, the possibility,

1 the example of using a mandatory setting. By doing
2 so, it is indicating that the setting would be
3 nonuser settable because it's obligatorily set back
4 at the factory.

5 That is the essential element of the
6 User Guide of the low glucose alarm that is being
7 combined with Say.

8 BY MR. SARASWAT:

9 Q. Okay. So just so I understand, in the
10 Say-Guide combination that you opined on in this
11 case, the combination used only the mandatory
12 setting from the Guide's low glucose alarm but not
13 the specific value for that setting?

14 A. That's correct.

15 Q. All right. Let's go to Paragraph 33 of
16 Exhibit 1035.

17 A. I'm sorry, which paragraph?

18 Q. Paragraph 33. I just want to make sure
19 I understand all the combinations.

20 A. 1035 is me?

21 Q. 1035 is your supplemental declaration.

22 A. Okay. And we're going to Paragraph 35?

1 Q. 33.

2 A. Okay.

3 Q. I'm just trying to make sure I
4 understand all the combinations.

5 So in Paragraph 33 of the reply
6 declaration, right above Paragraph 33 you refer to
7 a Guide-Harper combination. Do you see that?

8 A. Yes.

9 Q. And that Guide-Harper combination is the
10 combination you used in Ground 2?

11 A. Yes.

12 Q. What is the Guide-Harper combination?

13 MR. WILLIAMS: Objection to form.

14 THE WITNESS: Let me just review what
15 I've written in Paragraph 33.

16 Okay, I've read it. Would you repeat
17 the question in terms of what you're asking?

18 BY MR. SARASWAT:

19 Q. Yeah. I'm just asking if you can
20 describe the Guide-Harper combination for me.

21 A. Okay, very good.

22 MR. WILLIAMS: Objection to form.

1 THE WITNESS: The Guide provides for two
2 different functions. One is based on a
3 user-settable criterion or threshold. The other is
4 based on a nonuser-settable criterion or threshold.
5 So those are -- and of course both Guide and Harper
6 are based on CGM, and they're being utilized or
7 applied from the standpoint of helping the user,
8 typically a patient, determine whether or not
9 they're experiencing a low glucose or for that
10 matter a high glucose.

11 The essential element from the Guide is
12 that we have both user settable and nonuser
13 settable. The Guide does not address predicted or
14 projected glucose values. It is based on real-time
15 or, quote-unquote, substantially real-time glucose
16 data utilizing the patent owner's definition or
17 preferred definition.

18 So what Harper introduces and others may
19 have introduced this previously, is the -- having
20 the device have a mechanism to predict or project a
21 glucose value to some time in the future. And then
22 by doing so, by combining the Guide with its two

1 types of functions and having a predicted glucose
2 or projected glucose as well, that is the essence,
3 the major elements of the Guide-Harper combination.

4 So the Guide-Harper combination still
5 has the real-time glucose alert exactly as in this
6 the -- as described by the Guide for the STS
7 sensor. So it still has the first function, which
8 is user settable, and then it has a second function
9 which is to evaluate projected or predicted glucose
10 value using a nonuser-settable criterion or
11 threshold corresponding to the mandatory setting
12 that was used in the Guide for the low glucose
13 alarm.

14 BY MR. SARASWAT:

15 Q. Okay. So I think you mentioned that the
16 Guide has some alarms. Right?

17 A. Yes.

18 Q. Harper also has alarms; correct?

19 A. I believe so.

20 Q. So does the Guide-Harper combination
21 have alarms?

22 MR. WILLIAMS: Objection to form.

1 THE WITNESS: I believe so.

2 BY MR. SARASWAT:

3 Q. So can you tell me, what are the alarms
4 that are in the Guide-Harper combination?

5 MR. WILLIAMS: Objection to form.

6 THE WITNESS: I would have to review the
7 Harper patent to -- let me just see if I described
8 it here.

9 BY MR. SARASWAT:

10 Q. So does the Guide-Harper combination
11 have the Guide's low glucose alarm that has a
12 real-time alarm with a 55 milligrams per deciliter
13 that's nonuser settable?

14 MR. WILLIAMS: Objection to form.

15 THE WITNESS: Harper has the ability to
16 generate an alarm based on a nonuser-settable --
17 I'm sorry. Harper has the ability to generate an
18 alarm using the nonuser-settable approach that was
19 used in the Guide.

20 BY MR. SARASWAT:

21 Q. Right. But the Guide-Harper combination
22 has the Guide's low glucose alarm that is a

1 real-time alarm with a fixed 55 milligrams per
2 deciliter threshold; right?

3 MR. WILLIAMS: Objection to form and
4 scope.

5 THE WITNESS: "A POSITA would have been
6 motivated" -- I'm reading from paragraph 34 -- "to
7 combine Harper's disclosure of using projected
8 glucose values to trigger for alarms for impending
9 hypoglycemia with the nonuser-settable threshold of
10 the low glucose alarm of the Guide."

11 BY MR. SARASWAT:

12 Q. Right. But are you saying that in the
13 Guide-Harper combination, a POSA would have removed
14 the low glucose alarm from the Guide that compares
15 the real-time glucose value to the fixed
16 55 milligrams per deciliter threshold?

17 A. I don't recall. I would have to go back
18 and look at the Harper -- the Harper patent. But
19 actually, one could, if I was a POSITA, and I was
20 taking the information available to me at the time,
21 let's say in 2011 or sometime prior to the date
22 associated with the '215 patent, I could, if I

1 elect, it would have been, so to speak, obvious and
2 I could use the real-time alert from the Guide, I
3 could retain -- I could retain the real-time alarm
4 from the Guide; in other words, have a mandatory
5 55 milligram per deciliter alarm and then in
6 addition utilize the concept and the approach used
7 in the Guide to have a mandatory alarm in addition
8 to the real-time alarm from the Guide.

9 I could then say, well, okay, we're
10 going to have an alarm if the predicted or
11 projected glucose value suggests that there's going
12 to be a high risk for impending hypoglycemia.

13 Q. Okay. So I think what you're saying is
14 in the combination you may have added some
15 functionality based on Harper's disclosure of using
16 prediction, but you're still keeping the Guide's
17 original low glucose alarm that compares a
18 real-time glucose value to a fixed threshold.
19 Right?

20 MR. WILLIAMS: Objection to form.

21 THE WITNESS: I would regard that as an
22 option. In fact, elsewhere in these various

1 documents, one of the other documents under
2 consideration talks about, if you will, retaining
3 the 55 milligrams per deciliter threshold. So the
4 idea of carrying over the User Guide low glucose
5 alarm -- low glucose alert, low glucose alarm with
6 the 55 milligrams per deciliter, that can be
7 utilized in any other alarm system.

8 BY MR. SARASWAT:

9 Q. And did you discuss that option in your
10 declarations?

11 A. I don't recall. I would have to go back
12 and read what I've got here and look at the earlier
13 declaration as well.

14 Q. Well, why don't we take a look at your
15 earlier declaration. Actually, let's look at --
16 let's stick with Exhibit 1035 just for a second.

17 So we were looking at Paragraph 34, and
18 there is a citation to Paragraph 67 to 71 in
19 Exhibit 1002. Do you see that?

20 A. Yes.

21 Q. So why don't we take a look at
22 Paragraph 67 in Exhibit 1002. Are you there?

1 A. Yes.

2 Q. So in Paragraph 67, in the first
3 sentence you say: "It would have been obvious to a
4 POSITA to combine Harper's disclosure of using
5 projected glucose value thresholds and/or rate of
6 change or acceleration of the rate of change
7 thresholds to predict impending hypoglycemia
8 condition with the User's Guide."

9 Do you see that?

10 A. Yes.

11 Q. And then in the rest of Paragraph 67 of
12 Exhibit 1002 you offer an opinion that the "Guide
13 and Harper are analogous art." Do you see that?

14 A. Yes.

15 Q. If we go on to Paragraph 68, you say:
16 "In my opinion, a POSITA would have been motivated
17 to combine Harper's alarm profile with projected
18 glucose thresholds and/or rate of change of glucose
19 or acceleration of rate of change of glucose
20 thresholds with the low glucose alarm from the
21 User's Guide."

22 Do you see that?

1 A. Yes.

2 Q. Okay. And then if we go ahead to
3 Paragraph 70, you say: "A POSITA would have
4 understood from the teachings of both the User's
5 Guide and Harper that additional alarm profiles
6 would increase the accuracy of hypoglycemia
7 warnings and provide additional warning time for
8 users."

9 Do you see that?

10 A. Yes.

11 Q. So your Harper-Guide combination
12 maintains the Guide's low glucose alarm; correct?

13 MR. WILLIAMS: Objection to form.

14 THE WITNESS: It retains the -- it
15 retains the low glucose alert, which would be
16 corresponding to function 1 as described in the
17 '215. I think it's not totally defined whether it
18 includes the low glucose alarm. It retains the low
19 glucose alarm in the sense that it has a function
20 that is non -- that is based on nonuser-settable
21 criteria or thresholds. I don't know that -- let's
22 see.

1 So I think in Paragraph 70 per se I'm
2 not speaking to the low glucose alarm other than to
3 say that the concept, the principle and the
4 practice of using a mandatory setting for
5 thresholds would also be applicable to rate of
6 change of glucose and acceleration of glucose.

7 BY MR. SARASWAT:

8 Q. Okay. But did you offer in your
9 declaration any reason for a POSA to -- withdrawn.

10 So in the Guide-Harper combination, did
11 you offer in your declaration any reason for a POSA
12 to remove the feature from the Guide that compares
13 the real-time glucose value to a fixed
14 55 milligrams per deciliter threshold?

15 MR. WILLIAMS: Objection to form.

16 THE WITNESS: I don't know. I didn't --
17 I don't see the use of a mandatory setting for a
18 threshold in the Harper-Guide combination. That
19 doesn't -- by adding that mandatory setting for a
20 threshold, in other words including a
21 nonuser-settable criterion, that did not speak to
22 whether or not the low glucose alarm of the Guide

1 would be maintained.

2 So I would see that as optional or
3 ambiguous. I would say that is something that
4 could be handled at the discretion of the POSITA or
5 other people involved in building such a system.

6 BY MR. SARASWAT:

7 Q. Can you show me where in your
8 declaration you said that?

9 MR. WILLIAMS: Objection to form.

10 THE WITNESS: It may be under another
11 ground. It may be -- I don't know that it is, but
12 it may be under Ground 4 regarding Shariati.

13 BY MR. SARASWAT:

14 Q. We're talking about the Guide-Harper
15 combination right now.

16 A. Okay.

17 Q. So why didn't you offer any opinion in
18 your declaration -- I'll withdraw the question.
19 I'll start over.

20 why didn't you offer any opinion in your
21 declaration when discussing the Guide-Harper
22 combination regarding whether a POSA would have

1 removed the existing low glucose alarm in the Guide
2 from the combination?

3 MR. WILLIAMS: Objection to form and
4 scope.

5 THE WITNESS: well, there's a page limit
6 or a word limit, a count limit, a word count limit,
7 so we were striving for brevity. And as you are
8 well aware, there's so many potential ramifications
9 that it becomes kind of combinatorial.

10 So I didn't regard it as important
11 because, in my view, one could accomplish the
12 creation of a system like or equivalent to.
13 Certainly similar to or very similar to, nearly the
14 same as the '215, or maybe exactly the same as the
15 '215, either by regarding it as a substitution of a
16 new function or, if you will, the moderation, the
17 adaptation of the function that was embodied within
18 the low glucose alarm.

19 So you can think of that as a new
20 function or you can think of that as an old
21 function which has just been modified.

22 BY MR. SARASWAT:

1 Q. You're aware that there is no word limit
2 in the declarations; correct?

3 A. well, I guess not. I thought there
4 were. Maybe that's just for the patent
5 applications.

6 Q. Okay. So now I think earlier you said
7 that the Guide-Harper combination has a predictive
8 alert as taught by Harper but with a fixed
9 threshold. Do you recall that?

10 A. Yes.

11 Q. where did you say this in your original
12 declaration?

13 A. well, I think it's there. Let's see,
14 where are we?

15 Q. And I can just tell you that your
16 section on the Guide-Harper combination is from
17 Paragraphs 62 to 72.

18 A. Okay, I've finished this. Thank you for
19 giving me the time to do that.

20 If you don't mind refreshing me on your
21 question.

22 Q. So the question was where in your

1 original declaration did you say that the
2 Guide-Harper combination has a predictive alert as
3 taught by Harper but with a fixed threshold?

4 MR. WILLIAMS: Objection to form.

5 THE WITNESS: I believe it is said here
6 in several places. But "A POSITA would have been
7 motivated to combine Harper's alarm profile" --
8 this is Paragraph 68 -- "with projected low glucose
9 thresholds and/or rate of change of glucose or
10 acceleration of rate of change thresholds - with
11 the low glucose alarm." So we're modifying the low
12 glucose alarm from the User's Guide.

13 The thresholds would be previously known
14 criteria for logic to trigger either the low
15 glucose alert or low glucose alarm as described in
16 the User Guide to increase the accuracy prediction
17 of hypoglycemic events or to increase the lead
18 time. Such a combination is nothing more than
19 combining prior art elements according to known
20 methods.

21 And then in Paragraph 70: "A POSITA
22 would have understood from the teachings of both

1 the User Guide and Harper that additional alarm
2 profiles would increase the accuracy of
3 hypoglycemia warnings and provide additional
4 warning time for users."

5 BY MR. SARASWAT:

6 Q. Okay. So you mentioned Paragraph 68 and
7 70 in your answer just now.

8 A. Yes.

9 Q. You don't say anywhere in Paragraph 68
10 or 70 that you would modify the low glucose alarm.
11 You said combine Harper's alarm profile with a low
12 glucose alarm.

13 MR. WILLIAMS: Objection to form.

14 BY MR. SARASWAT:

15 Q. Right?

16 MR. WILLIAMS: Objection to form.

17 THE WITNESS: If you're reciting what I
18 just said, then that may be the case, yeah.

19 BY MR. SARASWAT:

20 Q. Okay. Did you offer any reason in your
21 original declaration to make the threshold for
22 Harper's predictive alerts nonuser settable?

1 MR. WILLIAMS: Objection to form.

2 THE WITNESS: I believe that Harper
3 included the possibility that the criteria could be
4 nonuser settable.

5 BY MR. SARASWAT:

6 Q. where in your declaration did you say
7 that Harper includes the possibility that the
8 criteria could be nonuser settable?

9 MR. WILLIAMS: Objection to form.

10 THE WITNESS: Actually, the nonuser
11 setability is mainly derived from the User Guide.
12 That's why I'm discussing the combination of the
13 User Guide with Harper.

14 BY MR. SARASWAT:

15 Q. Right. But did you offer any reason in
16 your declaration to make the -- withdrawn.

17 Did you offer any reason in your
18 original declaration to apply the nonuser
19 setability of the threshold derived from the Guide
20 to the threshold for Harper's predictive alerts?

21 MR. WILLIAMS: Objection to form.

22 THE WITNESS: I regard that as something

1 that would be obvious to a POSITA, a strong
2 motivation to be able to get predictive alerts.
3 That applies to everybody who was working in the
4 field. People wanted predictive alerts so as to be
5 able to give the person, the patient, the user the
6 ability to do something such as turning off their
7 insulin pump or having lunch or some carbohydrates
8 and caloric intake. So there is certainly a very
9 strong motivation of the entire field for a period
10 of more than ten years to have predictive alerts.

11 The User Guide describes a system, the
12 STS User's Guide, describes a system that does not
13 have predictive alerts. But given that Harper was
14 describing an approach to generate, to monitor the
15 sensor glucose values and go through a logical
16 system, go through an algorithm to generate alerts,
17 it was very obvious that one could combine the User
18 Guide, the static User Guide with the Harper system
19 for prediction or projection of glucose values.

20 BY MR. SARASWAT:

21 Q. Right. So you talked about the
22 desirability of predictive alerts. But did you

1 offer any reason in your declaration why you would
2 take Harper's predictive alerts and make the
3 threshold for Harper's predictive alerts nonuser
4 settable?

5 MR. WILLIAMS: Objection to form.

6 THE WITNESS: I'm glad you asked that.
7 I think that the User Guide has already introduced
8 the fact that when generating low glucose alarms or
9 alerts, there are two options. One option is to
10 make the criteria user settable, and the other
11 option is to make the criteria nonuser settable.

12 And as one can imagine, there can be
13 virtues to both of those approaches so that a
14 POSITA looking at the fact that here we are with
15 nonuser-settable or user-settable criteria for
16 alerts from the User Guide, and then we have either
17 static or real-time criteria -- we have criteria
18 for real-time glucose values, and we also have
19 criteria for alarms based on projected glucose
20 values.

21 So then it becomes, quote-unquote,
22 obvious that one can utilize a mix and match

1 approach. One can combine the two, exactly as
2 we're saying, in combination. So you can use a
3 user-settable criterion for the real-time alerts
4 for various reasons. And one can use a
5 nonuser-settable approach for the predicted alerts.

6 BY MR. SARASWAT:

7 Q. Right. But in your declaration, you
8 didn't offer any reason why a POSITA would have
9 picked the nonuser-settable threshold option for
10 Harper's predictive alerts; correct?

11 MR. WILLIAMS: Objection to form.

12 THE WITNESS: There are only two
13 options, user settable, nonuser settable. That's
14 well within -- so the POSITA can say, well, I can
15 try method A, I can try method B, and see how they
16 work.

17 So it's a very simple matter to go
18 through, if you will, all possible combinations of
19 a very small finite number of options and see which
20 one seems to be working best.

21 BY MR. SARASWAT:

22 Q. Can you show me where in your

1 declaration you offer the explanation you just gave
2 me?

3 A. Let's see if we see that in conjunction
4 with Say. Here's Shariati.

5 Q. well, I just want to focus on the
6 Harper-Guide combination. I want to understand
7 your reasons for Harper and Guide.

8 A. It would be the same for the
9 Harper-Guide combination as for the Say-Guide
10 combination or the -- oh, I see -- Say-Shariati.
11 And in one of those at least we've talked about the
12 fact that when there is a finite number of
13 possibilities, then the POSITA would have the
14 opportunity, it would be obvious, so to speak, one
15 can just test out option A, option B, and see which
16 one works better or seems to be preferable. Or one
17 could offer both.

18 MR. WILLIAMS: Counsel, whenever is
19 convenient, if we can break for lunch soon.

20 MR. SARASWAT: We can do that now.

21 MR. WILLIAMS: Good. Off the record.

22 (Recess taken.)

1 -----

2 AFTERNOON SESSION

3 1:34 p.m.

4 -----

5 BY MR. SARASWAT:

6 Q. So, Dr. Rodbard, right before we took a
7 break for lunch, you and I were discussing the
8 Harper-Guide combination. Do you recall that?

9 A. Yes.

10 Q. And a little bit earlier, we also
11 briefly discussed the Say-Guide combination. Do
12 you recall that?

13 A. Yes.

14 Q. Okay. And I think you had mentioned
15 that for the Say-Guide combination, the specific
16 55 milligrams per deciliter threshold from the
17 Guide is not being used as the nonuser-settable
18 threshold. Is that right?

19 MR. WILLIAMS: Objection to form.

20 THE WITNESS: Yes, I believe that's
21 correct.

22 BY MR. SARASWAT:

1 Q. Okay. So is it also the case that in
2 the Harper-Guide combination, you're not opining
3 that the specific 55 milligrams per deciliter
4 threshold from the Guide would be used as a
5 nonuser-settable threshold?

6 MR. WILLIAMS: Objection to form.

7 THE WITNESS: I believe that's a
8 possibility.

9 BY MR. SARASWAT:

10 Q. Okay. Do you offer an opinion anywhere
11 on the specific threshold that would be the
12 nonuser-settable threshold for predictive alerts in
13 the Harper-Guide combination?

14 MR. WILLIAMS: Objection to form and
15 scope.

16 THE WITNESS: I'm not sure. I would
17 have to go back and take a look at it.

18 BY MR. SARASWAT:

19 Q. why don't you go ahead and take a look.

20 A. Okay. I do not specifically mention the
21 55 milligrams per deciliter setting under Ground
22 2 for the Guide-Harper combination.

1 Q. Do you have an opinion on what the
2 nonuser-settable threshold value would be if a POSA
3 would have made the threshold for Harper's
4 predictive a nonuser settable?

5 MR. WILLIAMS: Objection; scope.

6 THE WITNESS: Well, I believe it would
7 be at least at 55, because by the time the glucose
8 gets to 55, falls as low as 55, then the likelihood
9 of symptoms and other complications already begins
10 to set in. So all I know is that it's above 55.

11 we might very well put it at something
12 like 70, which is the usual guideline for where
13 hypoglycemia begins, remembering that there's
14 sometimes variation between individuals and
15 variation between days on the same individual. So
16 that my own -- I would have an impression that it
17 would be most likely above 70. By the time it gets
18 down to 70, you're already hypoglycemia, or at
19 least technically, definitionally you're at
20 hypoglycemia.

21 So I believe that this is -- the
22 threshold would be somewhat higher. Let us say for

1 sake of argument, somewhere between 70 and a
2 hundred. But I just say that largely based on
3 speculation.

4 BY MR. SARASWAT:

5 Q. Okay. And you didn't offer an opinion
6 in your declaration about a specific value for a
7 nonuser-settable threshold?

8 A. No, I did not.

9 Q. So can we look back at
10 Paragraph 60 -- withdrawn. Sorry.

11 Yeah, can we look at Paragraph 67 of
12 Exhibit 1002, please. Are you there?

13 A. Yes.

14 Q. So you say: "It would have been obvious
15 to a POSITA to combine Harper's disclosure of using
16 projected glucose value thresholds and/or rate of
17 change or acceleration of the rate of change
18 thresholds to predict impending hypoglycemia
19 condition with the User's Guide."

20 Do you see that?

21 A. Yes.

22 Q. And then there is also a mention of the

1 rate of change or acceleration of rate of change in
2 Paragraph 68. Do you see that?

3 A. Yes.

4 Q. Okay. So we were talking quite a bit
5 earlier about predicted glucose value alarms in the
6 Harper-Guide combination. Do you recall that?

7 A. Yes.

8 Q. So is it also your opinion that in the
9 Harper-Guide combination there would be a rate of
10 change or acceleration of rate of change alarm with
11 a fixed threshold for rate of change or
12 acceleration of rate of change?

13 MR. WILLIAMS: Objection to form.

14 THE WITNESS: Yes.

15 BY MR. SARASWAT:

16 Q. Okay. So where in your original
17 declaration did you say that the Harper-Guide
18 combination has a rate of change alarm with a fixed
19 threshold for the rate of change?

20 A. There is at least one entry regarding
21 that, in Paragraph 68. I will read it. "The
22 thresholds for glucose value, the rate of change of

1 glucose and acceleration (second derivative of
2 glucose versus time) would be previously known
3 criteria for logic to trigger either a low glucose
4 alert or low glucose alarm as described in the User
5 Guide to increase the accuracy of the prediction of
6 a hypoglycemic event or to increase the lead time
7 before the event is likely to occur."

8 Q. But the User Guide doesn't have any
9 disclosure of alarms based on rate of change, does
10 it?

11 MR. WILLIAMS: Objection to form and
12 scope.

13 THE WITNESS: Actually, it does in
14 regard to the low glucose alert which requires
15 passing the threshold together with trending down.
16 So clearly the User Guide is thinking about and
17 including the concept of rate of change.

18 BY MR. SARASWAT:

19 Q. But you didn't mention that trending
20 down aspect from the User Guide in Paragraph 68,
21 did you?

22 A. Not in Paragraph 68.

1 Q. Can turn to your reply declaration.
2 Did you mention the disclosure in the
3 User Guide of triggering an alarm based on the
4 glucose value trending down anywhere in your
5 declaration that you're aware of?

6 MR. WILLIAMS: Objection to form.

7 THE WITNESS: Yes, I believe I did.
8 That would have been discussed at least in regard
9 to Claim 3.

10 BY MR. SARASWAT:

11 Q. Did you discuss it anywhere in regard to
12 Claim 1?

13 A. I don't recollect.

14 Q. Actually, let's look at Paragraph 73 of
15 your declaration, Exhibit 1002. Actually,
16 withdrawn.

17 Let's turn to your supplemental
18 declaration, Exhibit 1035.

19 A. which paragraph?

20 Q. Let's look at -- let's look at
21 Paragraphs 33 and 34. So do you see above
22 Paragraph 33 there's a heading for Ground 2?

1 A. Yes.

2 Q. And after Paragraph 34, there is a
3 heading for Ground 3?

4 A. Yes.

5 Q. So Paragraphs 33 and 34 are where you
6 discuss Ground 2 in your reply declaration;
7 correct?

8 A. which paragraphs?

9 Q. 33 and 34.

10 A. Correct.

11 Q. So did you say anywhere in Paragraphs 33
12 and 34 of your reply declaration, Exhibit 1035,
13 that the Guide-Harper combination has a rate of
14 change alarm with a fixed threshold for rate of
15 change?

16 MR. WILLIAMS: Objection to form.

17 THE WITNESS: Okay. Let me get the
18 question again. Sorry.

19 BY MR. SARASWAT:

20 Q. Did you say anywhere in Paragraphs 33 or
21 34 of your reply declaration that the Guide-Harper
22 combination has a rate of change alarm with a fixed

1 threshold for rate of change?

2 MR. WILLIAMS: Objection to form.

3 THE WITNESS: What I do say is that it
4 would have been within -- in Paragraph 33, "it
5 would be within the abilities of a POSITA to modify
6 the operation of the low glucose alarm to utilize
7 the fixed (nonuser settable) threshold setting
8 together or combined with the prediction algorithm
9 of Harper."

10 BY MR. SARASWAT:

11 Q. Right. So there you're referring to the
12 predicted glucose alarm and not to the rate of
13 change alarm. Right?

14 MR. WILLIAMS: Objection to form.

15 THE WITNESS: I do have a closing
16 sentence on Paragraph 34 that: "Moreover, in this
17 context, alarms are either user settable or nonuser
18 settable, and it would have been obvious to a
19 POSITA that either could be used."

20 BY MR. SARASWAT:

21 Q. Okay. But also in Paragraph 34, you're
22 referring to the predicted glucose alarms of

1 Harper; right?

2 MR. WILLIAMS: Objection to form.

3 THE WITNESS: I do mention it in the
4 preceding sentence. But that doesn't mean that the
5 final comment is applicable only to the glucose
6 alarms. For instance, earlier on the page,
7 page 18, Paragraph 33, I talk about "it would have
8 been within the abilities of a POSITA to modify the
9 operation of the glucose alarm to utilize the fixed
10 (nonuser settable) threshold setting together or
11 combined with the prediction algorithm of Harper."

12 BY MR. SARASWAT:

13 Q. Right. So the predictive alert of
14 Harper is a different alert from the rate of change
15 or acceleration rate of change of Harper; right?

16 A. Not entirely. In fact, in order to get
17 a prediction you need to know the rate of change.
18 So clearly the Harper calculations involve rate of
19 change. And the minute one calculates rate of
20 change and knows what it is and how much it varies,
21 then one can set either a user-settable or a
22 nonuser-settable threshold for rate of change.

1 So my interpretation of the last
2 sentence of Paragraph 33 is that speaking of the
3 prediction algorithm of Harper does not restrict
4 one to consideration of only a predicted glucose
5 value per se.

6 Q. well, why don't we -- why don't we look
7 back at your opening declaration, Exhibit 1002.

8 A. Okay.

9 Q. So looking at Paragraph 67 again, you
10 say: "It would have been obvious to a POSA to
11 combine Harper's disclosure of using projected
12 glucose value thresholds and/or rate of change or
13 acceleration of the rate of change thresholds to
14 predict impending hypoglycemia condition with the
15 User's Guide." Correct?

16 A. Yes.

17 Q. So here one of the alarms that you're
18 saying is in your Harper-Guide combination is an
19 alarm that compares the rate of change to a fixed
20 rate of change threshold. Is that right?

21 MR. WILLIAMS: Objection to form and
22 scope.

1 THE WITNESS: I speak to thresholds for
2 rate of change. I speak to and/or rate of change
3 or acceleration of the rate of change threshold.
4 So that's two types of threshold, one for rate of
5 change and one for acceleration of rate of change.
6 In addition to the projected glucose value for
7 which there is yet another threshold.

8 So I have addressed the possibility
9 and/or desirability of having thresholds for rate
10 of change and acceleration of rate of change.

11 BY MR. SARASWAT:

12 Q. Okay. So just so I understand what
13 you're referring to in Paragraph 67 is three
14 different alarms in the Harper-Guide combination,
15 one of which is a predicted glucose value alarm
16 with a fixed threshold for glucose value, the
17 second of which is a rate of change alarm with a
18 fixed threshold for rate of change, and a third of
19 which is an acceleration of rate of change alarm
20 with a fixed threshold for acceleration of rate of
21 change. Is that right?

22 MR. WILLIAMS: Objection to form.

1 THE WITNESS: I'm certainly speaking to
2 three different thresholds, talking about
3 thresholds which can be used to trigger or initiate
4 an alarm. I'm not necessarily speaking about three
5 different alarms.

6 BY MR. SARASWAT:

7 Q. Okay. If you're talking about three
8 different thresholds, why aren't you necessarily
9 speaking about three different alarms?

10 A. Because the logic for glucose, glucose
11 rate of change, glucose acceleration can be used to
12 generate -- they can be combined so that if any of
13 them is shown to be out of balance or triggering an
14 alert, that an alert goes off, or one might require
15 that there be at least two of those going off more
16 or less at the same time, or three of them going
17 off. Or they could be combined in other ways. For
18 instance, one could have an alarm for the predicted
19 glucose but not necessarily also having alarms for
20 rate of change and acceleration of rate of change.

21 Q. Okay. But you did say earlier that you
22 are talking about three different thresholds there;

1 right?

2 A. Yes. We're talking about multiple
3 thresholds for all three of those factors, yeah.

4 Q. And you're saying that the thresholds
5 for all three of those things, glucose value, rate
6 of change and acceleration of rate of change, would
7 be fixed in the Harper-Guide combination; right?

8 MR. WILLIAMS: Objection to form.

9 THE WITNESS: They could be fixed or
10 they could be non-fixed.

11 BY MR. SARASWAT:

12 Q. But so just focusing on -- let's focus
13 on the rate of change for now. Okay? So in your
14 Harper-Guide combination, what are you saying the
15 rate of change threshold will be used for?

16 A. It could be used for nothing. It could
17 be calculated but not -- it could be stored for
18 future reference. So it's not that there's
19 necessarily an auditory, visual or vibratory or
20 other type of alarm going off. Or it could be used
21 to trigger any one of those types of alarms or
22 other types of alarms.

1 So one can have a rate of change
2 essentially telling the user your glucose is
3 dropping very rapidly, which may be important. As
4 we see, we have several patents in this field in
5 general that regard a sharply dropping glucose or a
6 strong negative slope or derivative as one of the
7 possible criteria to give hypoglycemia alerts.

8 So an alert could go off, or in a
9 different embodiment it might not go off.

10 Q. And are you saying that in the
11 Harper-Guide combination there is a fixed threshold
12 for the rate of change?

13 MR. WILLIAMS: Objection to form.

14 THE WITNESS: I'm saying that in view of
15 what we'll call the teachings of the User Guide
16 where clearly there is a one type of alarm which is
17 triggered by user-settable criteria, another type
18 of alarm -- the first was an alert, the second one
19 is an alarm, and we have the low glucose alarm
20 which is triggered by a mandatory setting.

21 The principle of using a mandatory
22 setting is clearly established in the context of

1 providing alerts to users, to patients, to people
2 to warn them that they may be at risk of developing
3 hypoglycemia in the near future.

4 BY MR. SARASWAT:

5 Q. Okay. But the teaching of a mandatory
6 setting in the User Guide is only provided -- well,
7 withdrawn.

8 But the User Guide only provides a
9 teaching of a mandatory setting for glucose value;
10 right?

11 MR. WILLIAMS: Objection to form.

12 THE WITNESS: I disagree because I think
13 the minute that the POSITA or anyone else knows
14 that you can use a user setting, a user-settable
15 threshold or a nonuser-settable criterion or
16 threshold, that teaching, that concept applies not
17 only to glucose but to glucose, rate of change of
18 glucose, and acceleration of rate of change of
19 glucose. That generalizes instantly.

20 BY MR. SARASWAT:

21 Q. But you didn't say what you just told me
22 in your declaration, did you?

1 A. No. Because I think it follows from
2 first principles from the scientific method and
3 engineering development principles.

4 Q. So what value would a POSA have used for
5 the nonuser-settable rate of change threshold?

6 MR. WILLIAMS: Objection to form and
7 scope.

8 THE WITNESS: Actually, we've had it
9 alluded to in several of the documents before us
10 here. I would have to go back and read Harper to
11 see whether he did it. But a value of rate of
12 change of greater than minus 3 milligrams -- when I
13 say greater than, I mean magnitude greater. So
14 minus 3, minus 4, minus 5, anything with a negative
15 value which is below minus 3 milligrams per
16 deciliter would be regarded as an exceptionally
17 steep drop. And there's lots of medical scientific
18 literature for that. People have drawn histograms
19 of what the rate of change is. And by the time you
20 get down to minus 3 milligrams per deciliter,
21 that's clearly a very aberrant value that only
22 occurs in a very small fraction of the CGM

1 recordings that have ever been made.

2 BY MR. SARASWAT:

3 Q. So are you saying that the threshold --
4 that the nonuser-settable threshold for rate of
5 change in the Harper-Guide combination is minus 3?

6 A. That would be a very good starting point
7 for setting that. And the setting could and would
8 be done in the factory in the arms of -- in the
9 hands of the developer of the system.

10 Q. You said minus 3 is a starting point.
11 So would that mean that it could be changed?

12 MR. WILLIAMS: Objection to form.

13 THE WITNESS: Not by the end user. It
14 could be changed by the factory. The factory, the
15 manufacturing plant can decide that no, minus 3 is
16 missing some. So maybe we should start at minus
17 2.5. There is a judgment call in terms of where
18 that setting could or should be made. There is no
19 one universal best or one universal correct.

20 As one varies any threshold, whether
21 it's for glucose or whether it's for rate of change
22 of glucose or acceleration of glucose, that's going

1 to change the true positive rate, the false
2 positive rate, the true negative rate, the false
3 negative rate.

4 so all of those factors change, as we
5 saw when we looked at the Navigator booklet, the
6 Navigator User Guide in the page immediately
7 adjacent to where we were looking. Clearly, the
8 performance changes depending on the threshold.

9 so there is no one ultimate God-given
10 threshold. It's incumbent on the manufacturer, the
11 developer of the system, or the proponent of the
12 system to show that they have picked a reasonable
13 value and that it is optimal or close to optimal
14 for most people most of the time.

15 BY MR. SARASWAT:

16 Q. why would the manufacturer set the
17 threshold value than letting the user set the value
18 for the rate of change threshold?

19 A. Good question. In fact, there's very
20 good reasons for doing that. First of all, for
21 simplicity. Here we're already giving booklets of
22 dozens or hundreds of pages, whether it's for the

1 DexCom STS or whether it's for the Navigator or the
2 FreeStyle Navigator CGM system.

3 we're already placing many burdens on
4 the user, even for that very first selection of a
5 threshold for a low glucose alert. Should it be
6 60, 70, 80, 90? Wow, four choices. Hey, what do I
7 know? what does the typical person, a person
8 unfortunately very often with diabetes, what do
9 they know about that? So they may already be
10 befuddled by that, and they may just actually
11 select the default. So it's a good thing there is
12 a default because they can just skip over that.

13 But now ask them for a threshold for a
14 rate of change. I would say that 99 out of a
15 hundred people, give or take, there is some
16 fuzziness in that number, the vast majority of
17 people with diabetes, or without diabetes, but even
18 those with diabetes don't know what their rate of
19 change is per minute, whether it's minus 1, minus
20 2, minus 3, or plus 1, plus 2, plus 3. So they
21 don't have a clue how to set it.

22 So it's much better if the manufacturer

1 sets it so that it's fixed, and the manufacture
2 wouldn't do it alone. They would have to get some
3 advice from some people who have some data who know
4 something about it. Or even without advice, a
5 manufacturer could just explore different
6 possibilities to see how they perform.

7 So the number one reason for a user
8 settable in this setting -- pardon me, setting, but
9 the number one reason for a non-user settable
10 criterion is simplicity, is relieving the end user
11 of one burden. And the other is for safety.

12 The end user, the patient, may pick a
13 value that's crazy. I mean way out of line with
14 what actual data would show it might be. So for
15 instance, I could pick a positive number when
16 they're looking for hypoglycemia. Well, positive
17 number for the slope means it's going up. So if
18 the glucose is going up you don't need to worry
19 about getting a load. So they could pick -- and
20 that would be an example of an aberrant value, an
21 outlier.

22 But they don't know whether to use minus

1 1, 2 or 3 and then it gets more complicated, are
2 they using milligram per deciliter or millimoles
3 per liter for the glucose measurement? And people
4 can get confused. Maybe they put in the value for
5 a milligram per deciliter when they mean millimole
6 per liter, or vice versa.

7 So safety and simplicity are very strong
8 motivations for a threshold to the nonuser
9 settable.

10 Q. So you mentioned safety and simplicity
11 concerns in your answer just now.

12 A. Yeah.

13 Q. But couldn't those concerns also be
14 addressed by having a default value that the user
15 can then change like we saw in the Guide?

16 MR. WILLIAMS: Objection to form and
17 scope.

18 THE WITNESS: The manufacturer could
19 elect to use a default value. That would still
20 have the danger that someone, some end user could
21 override it with either a dangerous or a
22 nonfunctional value.

1 BY MR. SARASWAT:

2 Q. Now, none of what you just told me about
3 safety or simplicity as being a reason to make the
4 rate of change threshold fixed is in your
5 declaration, is it?

6 MR. WILLIAMS: Objection; form.

7 THE WITNESS: I regard this as what I'll
8 call a general principle for developing medical
9 devices.

10 BY MR. SARASWAT:

11 Q. Okay. But it's not one in your
12 declaration?

13 A. No, it's not specifically mentioned in
14 the declaration.

15 Q. And just so I understand, you're not
16 offering an opinion that there is a specific value
17 for the nonuser-settable threshold for rate of
18 change; correct?

19 MR. WILLIAMS: Objection to form.

20 THE WITNESS: I'm not offering a
21 specific value.

22 BY MR. SARASWAT:

1 Q. And we also mentioned earlier an
2 acceleration of rate of change threshold. Do you
3 recall that?

4 A. Yes.

5 Q. Are you offering an opinion that there
6 is a specific value for a nonuser-settable
7 acceleration rate of change threshold in the
8 Harper-Guide combination?

9 MR. WILLIAMS: Objection to form.

10 THE WITNESS: There would be a
11 motivation to have a nonuser-settable threshold for
12 acceleration.

13 BY MR. SARASWAT:

14 Q. Right. But are you opining on what that
15 threshold would be?

16 A. No, I am not.

17 Q. Let's look at Paragraph 37 of
18 Exhibit 1035.

19 A. which one is 1035?

20 Q. Your supplemental declaration.

21 A. Okay. which paragraph?

22 Q. Paragraph 37. It's on page 20. So it

1 says: "Regardless, in my opinion Guerra renders
2 Claim 5 obvious even under patent owner's
3 interpretation. Guerra's dynamic risk model takes
4 glucose (g) and rate of change of glucose (dg/dt)
5 as inputs."

6 Do you see that?

7 A. Yes.

8 Q. And then there is citation to
9 Exhibit 1006. Right?

10 A. Yes.

11 Q. Then it says: "Guerra teaches that its
12 dynamic risk calculation techniques are applicable
13 to predictive hypoglycemia alert generation."

14 Do you see that?

15 A. Yes.

16 Q. So is Guerra teaching that determination
17 of dynamic risk can be a part of generating
18 predictive hypoglycemia alerts?

19 MR. WILLIAMS: Objection to form.

20 THE WITNESS: Yes.

21 BY MR. SARASWAT:

22 Q. Okay. So is it possible to generate a

1 predictive hypoglycemia alert without attributing
2 dynamic risk?

3 A. Yes.

4 Q. How?

5 MR. WILLIAMS: Objection to form and
6 scope.

7 THE WITNESS: By combining the known
8 record of glucose as a function of time together
9 with an estimate of the slope. When one
10 extrapolates that line or curve, one can predict a
11 glucose at a future point in time.

12 BY MR. SARASWAT:

13 Q. Okay. So it's possible to generate a
14 predictive alert without determining dynamic risk;
15 correct?

16 A. Yes.

17 MR. WILLIAMS: Objection to form.

18 BY MR. SARASWAT:

19 Q. So generating a predictive glucose value
20 by itself isn't enough to meet Claim 5 since you
21 can generate a predictive glucose value without
22 determining dynamic risk; right?

1 MR. WILLIAMS: Objection to form.

2 Scope.

3 THE WITNESS: Doing the prediction using
4 one or more methods to make a predictive glucose
5 value, estimated predicted glucose value, does not
6 exclude the possibility of also using the
7 formalization that we call dynamic risk. So one
8 can do it both ways, that is with explicit
9 consideration of dynamic risk or without
10 consideration of dynamic risk, or even static risk.

11 BY MR. SARASWAT:

12 Q. Okay. But the mere fact that -- the
13 mere fact of generating a predicted glucose value
14 by itself does not meet Claim 5 because generating
15 a predicted glucose value does not necessarily
16 require determining dynamic risk?

17 MR. WILLIAMS: Objection to form and
18 scope.

19 BY MR. SARASWAT:

20 Q. Right?

21 A. I'm going to take a look at Claim 5 just
22 to be sure we're talking about the same thing.

1 Okay. We get into a little semantic issue here.
2 There is dynamic risk as defined in Claim 5.
3 Actually, it's not defined. It's saying that it's
4 using dynamic risk.

5 Claim 5 doesn't necessarily mean that
6 what a person is using dynamic risk as defined by
7 Guerra in that particular article. In fact, even
8 if you don't use static risk as defined by
9 Kovatchev and you don't use the other parts of the
10 Guerra paper that deal with dynamic risk, one can
11 still have essentially a dynamic risk without using
12 capital D, capital R, and without using capitals in
13 the words "dynamic" and "risk." You can have a
14 dynamic risk without the exact specifications of
15 Guerra, et al.

16 But in addition, it turns out that in
17 order to -- in order to calculate a predicted
18 value, you have to consider the expected or
19 estimated rate of change. The minute you include
20 rate of change together with a glucose value, you
21 now have a dynamic risk.

22 And I have, shall we say, explicated on

1 that in some manner in what I call Table 1,
2 pointing out that you can calculate the risk of
3 hypoglycemia the minute that you know the current
4 glucose level ranging from very close to the
5 hypoglycemia to very close to the hyperglycemia
6 region. It's on page 67 in my original
7 declaration.

8 So depending on the glucose level and
9 depending on the rate of change, one can estimate
10 the risk, and that can be done without the Guerra
11 formalization. This is just a common sense,
12 nonmathematical first principles kind of statement
13 about -- obviously if your glucose now is 75 and
14 it's dropping three points per minute, you've got a
15 good possibility that in two minutes you're going
16 to be hypoglycemic. That is you'll be below the
17 level of 70.

18 On the other hand, if your glucose right
19 now is 150 and you're dropping 2 milligrams per
20 deciliter per minute, well, then you've got about
21 40 minutes before you're going to get low, even if
22 that slope stays exactly the same for the next 40

1 minutes.

2 So the concept of dynamic risk as
3 enunciated by Guerra and Sparacino is just taking
4 these two factors into account. They follow from
5 first principles. I would say someone with very
6 limited mathematical or arithmetical abilities can
7 figure out that if you're at 72 and the threshold
8 is 70, you're at high risk. And if you're
9 dropping, you're at more risk. So the whole --
10 what Guerra and Sparacino did was to formalize that
11 principle.

12 But this is something that would be
13 known to anybody. Certainly to any patient and to
14 any physician or certified diabetes educator, a
15 parent of a child with diabetes.

16 So this is, I believe, the fundamental
17 principle underlying dynamic risk. And so it uses
18 glucose. It uses rate of change. And this
19 antedates Guerra, because anybody knows that if
20 you're dropping three points per minute and you're
21 at 75, you have a good chance, not a guaranteed
22 chance, but a good chance of crossing the line at

1 70.

2 But if you will allow me to go on to
3 point out what's going on here.

4 Q. well, I don't think I necessarily -- I
5 mean, I think I understand. I understand what
6 you're saying. I understand you to be saying that
7 there are techniques for determining a predicted
8 glucose value that use dynamic risk. But isn't it
9 also true that you could determine a predicted
10 glucose value without determining a dynamic risk?

11 A. That is correct, but let me just comment
12 on that. You want to try to get what the predicted
13 glucose value is. So you can use the actual
14 glucose value right now this second. And if you
15 know what the slope is going to be, then you can
16 calculate out what the glucose is going to be for
17 the next ten, 20, 30 minutes, or whatever, any
18 arbitrary period of time, assuming that slope stays
19 constant, which you don't know ahead of time. But
20 assuming that's the correct slope.

21 Now, what Guerra does is to take the
22 current value of glucose. She maps it. She

1 converts it into a static risk. She points out
2 that a single line, a single equation converts any
3 given glucose, static glucose, real-time glucose
4 into a static risk, SR.

5 And then what she and they do is to then
6 instead of extrapolating the glucose value, they're
7 extrapolating the risk value, which is going to get
8 them the ability -- the same thing.

9 You have to know what the slope of the
10 risk is. So if you know the current risk and the
11 current slope for risk, you can calculate a
12 predicted risk for any given point in time going
13 out into the future. Then you have to set a
14 threshold for what risk level you're willing to
15 accept. Or you can take that dynamic risk and
16 convert it back into a static risk and figure out
17 what glucose level that would correspond to.

18 So everything that's being said in
19 Guerra and with dynamic risk as she develops it is
20 saying that we can -- rather than extrapolating
21 glucose, we can extrapolate risk. Then we have to
22 set a threshold for that risk.

1 Those two approaches will generally
2 speaking give very similar results. Because the
3 relationship of static risk -- excuse me. The
4 relationship of static risk to glucose is nearly
5 linear. It's not linear overall as you go from 40
6 to 400, but it is fairly linear as you go from 70
7 to 75 to 80.

8 So extrapolating risk essentially gets
9 you back to the same kind of result as if you are
10 extrapolating glucose.

11 Q. Okay. Let's look at Paragraph 2 of your
12 reply declaration.

13 A. Is this me, the supplemental?

14 Q. Yes.

15 A. The introduction?

16 Q. Yeah. So paragraph 2 says: "I have
17 been asked to provide my supplemental opinions as
18 to whether Claims 1-5, 12, 19 and 23 (the
19 'Challenged Claims') of the '215 patent are invalid
20 as they would have been anticipated by the prior
21 art or obvious to a person having ordinary skill in
22 the art ('POSITA') as of the earliest claimed

1 priority date."

2 Do you see that?

3 A. Yes.

4 Q. You say: "It remains my opinion that
5 the challenged claims would have been obvious."

6 Do you see that?

7 A. Yes.

8 Q. So am I correct that you're not
9 contending that the challenged claims are
10 anticipated?

11 MR. WILLIAMS: Objection to form.

12 THE WITNESS: I believe the challenged
13 claims were anticipated.

14 BY MR. SARASWAT:

15 Q. But here you say, "It remains my opinion
16 that the challenged claims would have been
17 obvious."

18 A. That's correct. Let's see. We're
19 talking about -- here you're using a legal term
20 "anticipated," perhaps, as opposed to the word
21 "obvious."

22 Q. well, you use the term "anticipated" in

1 the previous sentence. Do you see that?

2 A. I said anticipated by the prior art or
3 obvious.

4 Q. Right. And in the next sentence you
5 say: "It remains my opinion that the challenged
6 claims would have been obvious."

7 Do you see that?

8 A. Yes.

9 Q. So I'm trying to understand your
10 opinion. Is your opinion that the challenged
11 claims are obvious but not anticipated?

12 MR. WILLIAMS: Objection to form.

13 THE WITNESS: I don't know the legal
14 definition of "anticipated." But I believe that
15 these claims would have been obvious to a POSITA,
16 and some of them may have been anticipated as well.

17 BY MR. SARASWAT:

18 Q. which ones do you think would have been
19 anticipated?

20 A. well, let's see. I'm just looking at
21 the appendix from my initial declaration. The
22 Claim 1, the preamble. Claim 1, element 1[a].

1 Claim 1, element 1[b]. It looks like -- I believe
2 they are all -- 1[c] and 1[d] as well are
3 anticipated.

4 I could go on.

5 Q. No, that's okay.

6 Let's look at Paragraph 5 of your
7 supplemental declaration. You say: "The
8 discussion below supplements my original opinions
9 and does not (and is not intended to) override any
10 of my original opinions."

11 Do you see that?

12 A. Correct.

13 Q. So you're not offering any opinions in
14 the supplemental declaration -- withdrawn.

15 So is it your position that you're not
16 offering any opinions in the supplemental
17 declaration that are different from the opinions in
18 your opening declaration?

19 MR. WILLIAMS: Objection to form.

20 THE WITNESS: I am trying to clarify my
21 original deposition -- excuse me, my original
22 declaration. So I'm trying to clarify it.

1 Specifically in the areas where either Dr. Keenan
2 or patent owner have, shall we say, disagreed with
3 some of my points of view.

4 BY MR. SARASWAT:

5 Q. So -- okay. So if the board finds that
6 there is a discrepancy between what you said in
7 your opening declaration, Exhibit 1002, and what
8 you're saying in your supplemental declaration,
9 Exhibit 1035, does that mean that your opening
10 declaration is controlling?

11 MR. WILLIAMS: Objection to form.

12 THE WITNESS: I don't know what
13 controlling means in the legal sense or in the
14 Patent and Trademark Office inter partes dispute
15 situation. But I'm not intending to override. I'm
16 providing in some cases perhaps more detail or more
17 emphasis. But the fundamental principles are
18 staying the same.

19 BY MR. SARASWAT:

20 Q. Okay. But if -- let's say -- let's say
21 the board hypothetically finds there is a conflict
22 between something you said in Exhibit 1002 and

1 something you said in Exhibit 1035. which one
2 should the board believe? Should they believe
3 1002?

4 MR. WILLIAMS: Objection to form and
5 scope.

6 THE WITNESS: Well, as you know, in all
7 human affairs, sometimes you say something better
8 in one place and sometimes you say it better
9 somewhere else. The intent may be the same, the
10 principle may be the same. I don't know whether it
11 is, shall we say, permissible or admissible, but I
12 would like the board to consider both. If I've, so
13 to speak, scored a point on one but not scored a
14 point on the same issue in another, I would hope
15 they would take into account what we might regard
16 or what they might regard as the better statement
17 in either one of these.

18 BY MR. SARASWAT:

19 Q. Okay. But if there is an actual
20 conflict, like suppose you said one thing in the
21 opening declaration and they find that something in
22 your reply declaration contradicts directly the

1 opening declaration, should they believe the
2 opening declaration?

3 MR. WILLIAMS: Objection to form.
4 Scope. And asked and answered.

5 THE WITNESS: What I say here in
6 Paragraph 5 is it's not intended to override. It
7 is conceivable that I've said something different,
8 either today or in the supplemental declaration
9 which is a little bit different. I wouldn't want a
10 minor or secondary or incidental apparent
11 disagreement to blow out both of them.

12 BY MR. SARASWAT:

13 Q. Let's look at Paragraph 8 of your
14 supplemental declaration. There is a table there,
15 and you've got the text of element 1[b] in the
16 left-hand column of that table. Do you see that?

17 A. Yes.

18 Q. And element 1[b] includes the language
19 "parameter indicative of a glucose value." Do you
20 see that?

21 A. Yes.

22 Q. Okay. Now, you have the '215 patent in

1 front of you somewhere; right?

2 A. Pardon me?

3 Q. Do you have the '215 patent somewhere?

4 A. Yeah, coming up.

5 Q. So why didn't you take a look at

6 Claim 6.

7 A. Let's see. We're looking at --

8 Q. Claim 6.

9 A. I'm not sure. It's all the way at the
10 end?

11 Q. Yeah.

12 A. There we go.

13 Q. Okay. And so Claim 6 depends from
14 Claim 1; right?

15 A. Yes, that's a dependent claim.

16 Q. And Claim 6 recites at the end: "and
17 wherein the parameter is a predicted glucose
18 value."

19 Do you see that?

20 A. The parameter is a predicted glucose
21 value. That's correct.

22 Q. So a predicted glucose value is a

1 parameter indicative of a glucose value; right?

2 MR. WILLIAMS: Objection to form and
3 scope.

4 THE WITNESS: A predicted glucose value
5 is one of the possible parameters that would be
6 indicative of a glucose value.

7 BY MR. SARASWAT:

8 Q. Let's look at Paragraph 12 of your
9 supplemental declaration. So you say: "Moreover,
10 patent owner's argument is inconsistent with the
11 specification, which does not require the first and
12 second functions to be different, nor require
13 prediction."

14 A. I was looking at 12. Where am I
15 supposed to read?

16 Q. Paragraph 12 in your supplemental
17 declaration, Exhibit 1035.

18 A. Okay.

19 Q. Are you there?

20 A. Yes. Let me just read it, at least the
21 first sentence. It's "inconsistent with the
22 specification, which does not require the first and

1 second functions to be different, nor require
2 prediction."

3 Q. And then after that there is citation to
4 the patent; right?

5 A. Uh-huh.

6 Q. And you say: "As one example, the
7 specification describes that 'in some embodiments,
8 the first set of instructions from block 520 is
9 different than the second set of instructions from
10 block 530'."

11 Do you see that?

12 A. Yes.

13 Q. And then there is a citation again, and
14 then you say: "Thus, the specification suggests to
15 a POSITA that the first set of instructions may be
16 the same as the second set of instructions."

17 Do you see that?

18 A. Yes.

19 Q. So is it your opinion that the
20 specification suggests that the first and second
21 set of instructions may be the same because the
22 specification says, quote, in some embodiments,

1 unquote, the first and second set of instructions
2 are different?

3 A. Because it says in some embodiments,
4 that is one of the indications but not the only
5 indication that the first set of instructions may
6 be the same as the second set of instructions.

7 Q. Did you cite any embodiment in the '215
8 patent where the first and second set of
9 instructions are the same?

10 MR. WILLIAMS: Objection to form.

11 THE WITNESS: I believe there is one,
12 but I'll have to go looking for it. I don't recall
13 offhand, unless it's one of the things that I'm
14 quoting here. But there is at least one where it
15 indicates that they can be the same.

16 BY MR. SARASWAT:

17 Q. And where did you cite that?

18 A. well, I don't know. I'm looking here.

19 Q. well, so let's take a look at
20 Exhibit 1001.

21 A. Okay.

22 Q. which is the '215 patent.

1 A. The '215.

2 Q. So in Paragraph 12 you have a citation
3 to 37 -- Column 37, line 50 to 60. Do you see
4 that?

5 A. Yeah.

6 Q. So is there any mention of the first set
7 of instructions in that citation?

8 MR. WILLIAMS: Objection to form.

9 THE WITNESS: No, I don't believe there
10 is anything in that section there.

11 BY MR. SARASWAT:

12 Q. And then you also cite to Column 25,
13 lines 3 to 7 in Paragraph 12 of Exhibit 1035. Do
14 you see that?

15 A. Yeah.

16 Q. So let's take a look at Column 25,
17 lines 3 to 7. So that says in the '215 patent,
18 Column 25, lines 3 to 7: "At block 530 processor
19 module 214 may be configured to evaluate the sensor
20 data using a second set of instructions or
21 criteria."

22 And then it says: "In some embodiments,

1 the first set of instructions from block 520 is
2 different from the second set of instructions from
3 block 530."

4 Do you see that?

5 A. Yes.

6 Q. So there is no description there of an
7 embodiment where the two sets of instructions are
8 different; right?

9 MR. WILLIAMS: Objection to form.

10 THE WITNESS: I regard that statement at
11 25, lines 3 to 7 as indicating that there could be
12 or would be or may be embodiments where the second
13 set of instructions is not different than the first
14 set of instructions.

15 So I see this as clearly, when we have
16 an A or a B, in one option those two instructions
17 in 520 and 530 are different. The alternative to
18 that, and almost the only alternative to that, is
19 that they're the same.

20 So this is, as a minimum, implicitly but
21 I believe also explicitly indicating that the
22 instructions can be the same.

1 BY MR. SARASWAT:

2 Q. Right. So I think I understand it's
3 your position that because it says in some
4 embodiments they're different, they may also be the
5 same. Is that your position?

6 A. Correct. But I'm not limited to that.
7 There may be other statements either in this
8 document or other documents that go beyond that and
9 further support that.

10 Q. But you haven't cited any of those
11 embodiments in Paragraph 12?

12 A. Let's see.

13 Q. That you say are there.

14 A. Yes. If the specification, on the last
15 line of Paragraph 12 before the subheading a., the
16 specification teaches the two sets of
17 instructions -- the set of instructions
18 implementing the claimed first and second function
19 may be the same, that would imply that the second
20 function is not limited to a, quote, function that
21 provides predictive alert/alarm.

22 Q. Right. But did you cite anywhere in

1 Paragraph 12 a disclosure from the '215 patent of a
2 system where the first and second set of
3 instructions are the same?

4 A. I did not cite. But I believe there is
5 such a statement in the '215.

6 Q. Okay. So let's -- sticking with the
7 '215 patent, let's look back at the beginning --
8 sorry.

9 MR. WILLIAMS: When you have a chance,
10 we've been going an hour.

11 MR. SARASWAT: Yeah, sure.

12 (Recess taken.)

13 BY MR. SARASWAT:

14 Q. Dr. Rodbard, could we look back at the
15 '215 patent in Column 1. So do you see there is a
16 background section starting above line 30?

17 A. Yes.

18 Q. And then starting at line 30, it says:
19 "The present systems and methods relate to
20 processing analyte sensor data from continuous
21 analyte sensor."

22 Do you see that?

1 A. Yes.

2 Q. Then it says in the next sentence:

3 "More particularly, the present systems and methods
4 relate to providing accurate predictive alarms to a
5 user."

6 Do you see that?

7 A. Yes.

8 Q. So what does relate to mean here?

9 MR. WILLIAMS: Objection to form and
10 scope.

11 THE WITNESS: I find the term somewhat
12 ambiguous. It doesn't, as far as I know, imply --
13 it does not imply an invention of any kind.

14 BY MR. SARASWAT:

15 Q. well, do you see it says in that
16 sentence: "More particularly, the present systems
17 and methods relate to providing active predictive
18 alarms to a user"?

19 A. Yes, I see that.

20 Q. And the claims of the '215 patent are
21 system claims and method claims; right?

22 MR. WILLIAMS: Objection to form.

1 THE WITNESS: Yes.

2 BY MR. SARASWAT:

3 Q. So -- and the claims of the '215 patent
4 are defining what the invention is in the patent;
5 right?

6 MR. WILLIAMS: Objection to form and
7 scope.

8 THE WITNESS: I believe so.

9 BY MR. SARASWAT:

10 Q. So when it says "the systems and methods
11 relate to providing accurate predictive alarms to a
12 user," what does relate to mean?

13 MR. WILLIAMS: Objection to form.
14 Scope. Asked and answered.

15 THE WITNESS: I think it just says it's
16 talking about. The term "relates to" corresponds
17 to what it's talking about.

18 BY MR. SARASWAT:

19 Q. So you would read that second sentence
20 as: More particularly, the present systems and
21 methods talk about providing accurate predictive
22 alarms to a user?

1 MR. WILLIAMS: Objection to form and
2 scope.

3 THE WITNESS: Possibly. I don't know
4 what "relate to" means in this context. It may or
5 may not be connected.

6 BY MR. SARASWAT:

7 Q. When you say may or may not be
8 connected, connected to what?

9 A. To each other.

10 Q. So what's not connected to what?

11 MR. WILLIAMS: Objection to form.

12 THE WITNESS: The question is whether
13 the present systems and methods are connected to
14 providing accurate predictive alarms to a user.

15 BY MR. SARASWAT:

16 Q. So you're saying that "relate to" means
17 they're connected to?

18 A. No, I don't know if they're connected to
19 each other.

20 Q. So in that sentence that starts with the
21 words "more particularly," we see "present systems
22 and methods" and we see "providing accurate

1 predictive alarms." So how could those two things
2 not be connected to each other?

3 MR. WILLIAMS: Objection to form and
4 scope.

5 THE WITNESS: I just regard the term
6 "relate to" as being rather vague. For instance, I
7 don't see the term "accurate predictive alarms" in
8 the independent claims.

9 BY MR. SARASWAT:

10 Q. And so is that why you're not sure what
11 "relate to" means here?

12 MR. WILLIAMS: Objection to form.

13 THE WITNESS: I don't know where this
14 "providing accurate predictive alarms to a user"
15 comes in because that doesn't seem to be the main
16 thrust.

17 BY MR. SARASWAT:

18 Q. So if the main thrust of the claims was
19 providing accurate predictive alarms to a user,
20 then would you read this more particularly sentence
21 as saying that the invention is limited to
22 providing predictive alarms to a user?

1 MR. WILLIAMS: Objection to form and
2 scope.

3 THE WITNESS: I'm trying to reconcile
4 the particular sentence here looking with the one
5 under "Summary" in Column 2, the present systems
6 and methods relate to processing analyte sensor
7 data, period. Then it goes on to talk about alerts
8 and alarms indicative of glycemic conditions. But
9 it doesn't speak to accurate predictive alarms to
10 the user.

11 BY MR. SARASWAT:

12 Q. So I wasn't asking about the summary. I
13 was asking about the sentence in the background
14 section that begins "More particularly." So why
15 were you looking at the summary?

16 MR. WILLIAMS: Objection to form.

17 THE WITNESS: I just happened to see
18 that it also starts with the present systems and
19 methods relate to.

20 BY MR. SARASWAT:

21 Q. Okay. But my question is about the
22 sentence in the background section that starts with

1 the words "More particularly."

2 A. Yeah. Go ahead.

3 Q. So if the thrust of the claims was
4 providing accurate predictive alarms to a user,
5 would you agree that that sentence in the
6 background that starts with the words "More
7 particularly" limits the invention to providing
8 predictive alarms to a user?

9 MR. WILLIAMS: Objection to form.

10 THE WITNESS: I do not see many, if any,
11 places in the '215 that relates to, quote,
12 accurate, end quote, predictive alarms.
13 Specifically the word "accurate."

14 BY MR. SARASWAT:

15 Q. But I'm talking about the claims. So if
16 the thrust of the claims is providing accurate
17 predictive alarms to a user, then would you agree
18 that the sentence in the background starting with
19 the words "More particularly" limits the claims to
20 providing predictive alarms?

21 MR. WILLIAMS: Objection to form.

22 Incomplete hypothetical.

1 THE WITNESS: I was going to say that's
2 hypothetical. Because I don't see the providing
3 accurate predictive alarms in the claims.

4 BY MR. SARASWAT:

5 Q. Right. But if in this hypothetical, if
6 it were determined that the thrust of the claims
7 was to provide accurate predictive alarms to a
8 user, then would you agree that the sentence in the
9 background that starts with the words "More
10 particularly" limits the claims to providing
11 predictive alarms?

12 MR. WILLIAMS: Objection to form.

13 THE WITNESS: As I had written in my
14 reply, the reply declaration, the requirement of a
15 predictive parameter is not introduced until
16 dependent Claims 5 to 7. And -- year, 5, 6 and 7.
17 And alarm is first introduced in an unchallenged
18 dependent Claim 17 and 18 with citations to that.

19 So a POSITA would have understood that
20 the broadly recited second function is not limited
21 to a function that provides a predictive alert or
22 alarm, much less a, quote, accurate, end quote,

1 predictive alert or alarm.

2 BY MR. SARASWAT:

3 Q. Okay. But I was asking you about the
4 sentence in the background section that says:
5 "More particularly, present systems and methods
6 relate to providing accurate predictive alarms to a
7 user." Do you recall that?

8 A. Yes.

9 Q. And when I was asking you what "relate
10 to" means, you said you weren't sure what it means
11 because you didn't see the word "accurate" in the
12 claims. Right?

13 A. I didn't see "accurate," and I didn't
14 see "predictive" function until Claims 5 to 7. So
15 I don't know what the "relates to" means.

16 Q. And is the reason that you do not know
17 what it means is that you don't see the words --
18 you don't see the word "accurate" in the claims?

19 A. I don't see the words "accurate
20 predictive alarms."

21 Q. Okay. why does the fact that you don't
22 see the words "accurate predictive alarms" in the

1 claims impact how you interpret "relate to" in this
2 sentence?

3 MR. WILLIAMS: Objection to form and
4 scope.

5 THE WITNESS: For practical purposes, I
6 don't see any real discussion of accuracy in the
7 '215. We don't see any data about how some
8 presumably new method or a different method is
9 resulting in better accuracy.

10 BY MR. SARASWAT:

11 Q. Right. But we're reading the very, very
12 beginning of the patent. Right? In the background
13 section. This is the first part of the
14 specification other than the part above that talks
15 about applications incorporated by reference. Do
16 you see that?

17 A. This is at the beginning. I agree.

18 Q. So why does the fact that you don't see
19 a reference to "accuracy" supposedly later in the
20 patent affect your ability to understand what the
21 word "relate to" means in this sentence at the
22 beginning?

1 MR. WILLIAMS: Objection to form.
2 Scope.

3 THE WITNESS: I happen to be aware that
4 the -- I believe the term "accuracy" did occur in
5 the parent to this patent, and it was dropped in
6 this patent. So I presume that the people who were
7 doing the patenting had decided not to either focus
8 on or promote or orient themselves to accuracy.

9 BY MR. SARASWAT:

10 Q. So are you saying that you don't know
11 what the word "relate to" means because the word
12 "accuracy" appeared in a parent patent and was
13 removed from this patent?

14 A. That combined with the specifications as
15 well.

16 Q. So why do those two facts, the alleged
17 removal of the word "accuracy" and what might
18 appear later in the specification affect your
19 ability to understand what the word "relate to"
20 means in the second sentence of the background
21 section?

22 MR. WILLIAMS: Objection to form and

1 scope.

2 THE WITNESS: I regard that sentence
3 beginning with "Moreover" as a misstatement.

4 BY MR. SARASWAT:

5 Q. why is it a misstatement?

6 A. Because it's apparently attempting to
7 focus on accurate predictive alarms when I don't
8 believe there is a basis for that.

9 Q. So you think that this sentence starting
10 with the words "More particularly" is focusing on
11 predictive alarms but you just think that that's
12 wrong?

13 A. Accurate predictive alarms. I think the
14 use of "accurate predictive alarms" is wrong
15 because in fact the first sentence of the summary
16 says something somewhat different, which is the
17 present systems and methods relate to processing
18 analyte sensor data. I regard that as
19 incontrovertible.

20 Q. Can we look at Paragraph 16 of your
21 declaration -- sorry, Paragraph 16 of your reply
22 declaration, Exhibit 1035. So you say -- it's in

1 the -- it's in the sentence starting with the word
2 "Moreover." You say: "Moreover, because a
3 predictive aspect is introduced in dependent claims
4 and the parent application specifically claim a
5 predictive function, this shows intent not to limit
6 second function to be predictive in the '215
7 patent."

8 Do you see that?

9 A. Oh, okay. You're looking at my
10 sentence, not the sentence in the '215.

11 Q. Yes.

12 A. Predictive aspect is introduced in
13 dependent claims, correct. The parent application
14 specifically claimed a predictive function but was
15 removed by the people who were doing the patenting,
16 by the inventors. And this shows intent not to
17 limit second function to be predictive. Yes, I
18 believe that statement I'm making here in
19 Paragraph 16 is correct.

20 Q. Okay. And when you talk about a
21 predictive aspect is introduced in dependent
22 claims, the dependent claims you are referring to

1 are Claims 5 to 7?

2 A. Yes, I believe that's what it was.
3 Let's see. That's my recollection, was 5 to 7 as
4 stated in Paragraph 10.

5 Q. Okay. So in your analysis of what the
6 claims of the '215 patent mean, how much weight did
7 you give to the fact that Claims 5 to 7 recite the
8 word "predictive"?

9 MR. WILLIAMS: Objection to form.

10 THE WITNESS: I don't know how one would
11 quantify weight. I would have to go back and read
12 Claims 5 to 7 to see just what they're saying
13 again.

14 BY MR. SARASWAT:

15 Q. well, instead of trying to quantify it,
16 let me ask you this question. Did you give more
17 weight to the recitation of the word "predictive"
18 in Claims 5 to 7 than you gave to the two sentences
19 in the background section at Column 1, lines 30 to
20 33?

21 MR. WILLIAMS: Objection to form.

22 THE WITNESS: I can't say how much

1 weight I put on Claims 5 to 7 versus this one
2 sentence in the quote-unquote background.

3 BY MR. SARASWAT:

4 Q. So it's possible that you gave those
5 claims more weight?

6 MR. WILLIAMS: Objection to form.

7 THE WITNESS: I don't know why I would.
8 I wasn't aware that I was weighting one sentence or
9 one phrase or one dependent claim versus a
10 backgrounder in the main document.

11 BY MR. SARASWAT:

12 Q. I guess I'm just trying to get an
13 understanding, if you have one, of in your analysis
14 of what claims mean, which of those two things do
15 you think was more important? Did you think the
16 recitation of predictive in Claims 5 to 7 was more
17 important, or you think that the language at Column
18 1, lines 30 to 33 were more Important?

19 A. Let me look at Claim 6 and 7.

20 MR. WILLIAMS: Objection to form.

21 THE WITNESS: Well, as I'm sure you are
22 aware, Claims 5, 6 and 7 do speak of a predictive

1 glucose value. But the patent as a whole speaks of
2 many other things as well.

3 BY MR. SARASWAT:

4 Q. Let's look at Paragraph 21 of your
5 supplemental declaration. Let me know when you're
6 there.

7 A. Okay.

8 Q. So in this paragraph, you discuss
9 Exhibit 2006; correct? Among other things.

10 A. Yes.

11 Q. And Exhibit 2006 was the article by
12 Kamath that we talked about earlier; yeah?

13 A. Correct.

14 Q. And you say at the end of this
15 paragraph, at the end of Paragraph 21, you say:
16 "Rather, Kamath demonstrates the benefit of
17 predictive alarms, explaining that the use of
18 predictive alarms 'improved' the sensitivity of
19 GlucoWatch's rate of detecting hypoglycemic events
20 from 8 percent to 77 percent."

21 Do you see that?

22 A. Yes.

1 Q. Now, in preparing your supplemental
2 declaration, you reviewed the patent owner
3 response; right?

4 A. Yes.

5 Q. Okay. Was it your understanding that
6 DexCom had argued in the patent owner response that
7 predictive alerts were useless?

8 MR. WILLIAMS: Objection to form.

9 THE WITNESS: I was not aware of that,
10 and I don't believe I've alleged that, and I don't
11 believe that that's true.

12 BY MR. SARASWAT:

13 Q. I'm going to show you -- one second.
14 Can you pick up Exhibit 1008 again.
15 That is the Say reference.

16 A. I've got Say.

17 Q. Okay. So can you turn to Column 45.
18 And can you look at the paragraph starting at
19 line 8. It starts with the words "The on-skin
20 sensor control." Are you there?

21 A. Yes.

22 Q. So it says: "The on-skin sensor control

1 unit 44 may include an optional alarm system 104
2 that based on the data from the processing circuit
3 109 warns the patient of a potentially detrimental
4 condition of the analyte."

5 Do you see that?

6 A. Yes.

7 Q. And then it says: "For example, if
8 glucose is the analyte, then the on-skin sensor
9 control unit 44 may include an alarm system 104
10 that warns the patient of conditions such as
11 hypoglycemia, hyperglycemia, impending hypoglycemia
12 and/or impending hyperglycemia."

13 Do you see that?

14 A. Yes.

15 Q. So what is potentially detrimental
16 condition of the analyte?

17 MR. WILLIAMS: Objection to scope.

18 THE WITNESS: well, the analyte, in this
19 case glucose, may be too high, which carries with
20 it risks for long-term complications that may be
21 indicative of diabetic ketoacidosis or an
22 accompaniment to diabetic ketoacidosis.

1 The glucose may be too low, which would
2 imply -- which is hypoglycemia, and it could become
3 severe hypoglycemia leading to confusion, coma and
4 death. Those would be detrimental conditions.

5 BY MR. SARASWAT:

6 Q. So there is a -- there is a reference as
7 we just saw to hypoglycemia, hyperglycemia,
8 impending hypoglycemia and/or impending
9 hyperglycemia. Do you see that?

10 A. Yes.

11 Q. Are all four of those things examples of
12 detrimental conditions of the analyte?

13 A. Yes.

14 Q. And those four things are medical
15 conditions that a patient can suffer; right?

16 A. Yes.

17 Q. Okay. And I think you may have touched
18 on this earlier, but why are those considered
19 detrimental conditions?

20 A. well, they can be life-threatening.
21 Someone can black out due to hypoglycemia and drive
22 their tractor-trailer off the road with

1 considerable harm to themselves and others.

2 Likewise, if they're too high, a person
3 may become confused, disoriented, may also black
4 out, may go into a hyperglycemia coma, or may
5 encounter other problems.

6 And the other thing is that when the
7 glucose is high, especially if it's consistently
8 high, high let's say above 180, or high above
9 250 milligrams per deciliter, someone can be at
10 greater risk for heart attack, stroke, dehydration
11 certainly. And long-term complications such as
12 blindness, kidney disease and other microvascular
13 complications such as neuropathy.

14 So certainly there is a real important
15 need to keep the glucose levels within the target
16 range. Target range is generally regarded as being
17 between 70 and 180. Others think we need a
18 tighter -- a tighter target range between, let's
19 say, 70 and 140.

20 So there are lots of compelling reasons
21 to keep the glucose in that range, and as generally
22 recognized throughout the entire medical

1 profession, and I think among the lay public as
2 well.

3 Q. So you mentioned glucose ranges towards
4 the end of your answer there. So I just want to
5 understand. The four conditions that I mentioned
6 earlier, hypoglycemia, hyperglycemia, impending
7 hypoglycemia, impending hyperglycemia, are those
8 all conditions that relate to glucose values being
9 outside of a safe range?

10 MR. WILLIAMS: Objection to form.

11 THE WITNESS: There's a little ambiguity
12 in the answer there. Hyperglycemia and
13 hypoglycemia are examples of glucose being outside
14 of what is generally regarded as a safe target
15 range. By the way, the target range can change for
16 pregnancy and maybe other conditions.

17 Impending hypoglycemia and impending
18 hyperglycemia have a dual meaning. It may mean
19 that they're out of the desirable range or, this is
20 the ambiguity, that it may mean the real-time
21 glucose value is still within range but it looks
22 like it's headed as though it's going out of range.

1 So impending means you haven't hit the brick wall
2 yet, you haven't hit the barrier, the boundary, the
3 threshold, but it looks like in some presumably
4 short-term time range they're going to be out of
5 range.

6 BY MR. SARASWAT:

7 Q. Okay. But those are all conditions that
8 are kind of based on a patient's glucose value?

9 A. Correct.

10 Q. Okay. So we talked about four examples
11 of conditions that are based on a patient's glucose
12 value. Hypoglycemia, hyperglycemia, impending
13 hypoglycemia, impending hyperglycemia. Right?

14 A. Yeah.

15 Q. Aside from those four, are there other
16 medical conditions that a patient could suffer as a
17 result of their glucose value?

18 MR. WILLIAMS: Objection to form and
19 scope.

20 THE WITNESS: Well, in addition to those
21 four items, there are numerous other
22 characteristics of glucose values, the glucose time

1 series that may indicate medical problems.

2 BY MR. SARASWAT:

3 Q. Okay. But I guess what I'm trying to
4 understand is if -- are there other conditions
5 aside from the four conditions that we just
6 mentioned that a patient could be diagnosed with
7 based on their glucose value?

8 MR. WILLIAMS: Objection to form and
9 scope.

10 THE WITNESS: They could be diagnosed
11 with, for instance, excessive glucose variability.

12 BY MR. SARASWAT:

13 Q. Okay.

14 A. And they could be potentially diagnosed
15 with impending onset of diabetes.

16 Q. Okay. So if we keep reading in that
17 paragraph after the first mention of impending
18 hypoglycemia around line 15, it says: "The alarm
19 system 104 is triggered when the data from the
20 processing circuit 109 reaches or exceeds a
21 threshold value."

22 Do you see that?

1 A. Yes.

2 Q. Then it says examples of threshold
3 values for blood glucose levels are about 60, 70 or
4 80 milligrams per deciliter for hypoglycemia; about
5 70, 80 or 90 milligrams per deciliter for impending
6 hyperglycemia; about 130, 150, 175, 200, 225, 250
7 or 275 milligrams per deciliter for impending
8 hyperglycemia; and about 150, 175, 200, 225, 250,
9 275 or 300 milligrams per deciliter for
10 hyperglycemia.

11 Do you see that?

12 A. Yes.

13 Q. And then it says: "The actual threshold
14 values that are designed into the alarm system 104
15 may correspond to interstitial food glucose
16 concentrations or electrode measurements (e.g.,
17 current values or voltage values obtained by
18 current measurements) that correlate to the
19 above-mentioned glucose levels."

20 Do you see that?

21 A. Yes.

22 Q. And then it says: "The analyte monitor

1 device may be configured so that the threshold
2 levels for these or any other conditions may be
3 programmable by the patient and/or medical
4 professional."

5 Do you see that?

6 A. Yes.

7 Q. So when it says "these conditions," is
8 it referring to -- withdrawn.

9 In that last sentence where it says
10 "these or any other conditions," what are the these
11 or any other conditions it's referring to?

12 MR. WILLIAMS: Objection to form and
13 scope.

14 THE WITNESS: Well, obviously, any other
15 conditions is unspecified and it's kind of
16 open-ended. And it could conceivably -- I'm
17 actually having to speculate here as to what the
18 authors of this patent might have been indicating.
19 But it might be a very acute short-term elevation
20 or lowering of the blood glucose for some reason.
21 For instance, exercise can affect glucose both
22 sending it up or bringing it down. Of course

1 various medications affect glucose.

2 So one would be -- I think the four
3 conditions we've talked about, as indicated in the
4 preceding lines around line 20, are the dominant --
5 are the dominating ones, but there could be other
6 conditions that one might want to detect.

7 BY MR. SARASWAT:

8 Q. Okay. So when it uses the word "these,"
9 would you agree it makes sense to interpret the
10 word "these" as referring to the four detrimental
11 conditions mentioned earlier in the paragraph?

12 MR. WILLIAMS: Objection to form and
13 scope.

14 THE WITNESS: The implication or the
15 innuendo is that the word "these" is referring to
16 the four conditions mentioned above.

17 BY MR. SARASWAT:

18 Q. All right. And then the other
19 conditions would refer to some of the other
20 conditions you mentioned during our earlier
21 discussion that could be diagnosed based on glucose
22 level like excessive glucose variability or

1 impending onset diabetes; right?

2 MR. WILLIAMS: Objection to form.

3 THE WITNESS: That would be two possible
4 interpretations of "other conditions."

5 MR. SARASWAT: No further questions.

6 MR. WILLIAMS: Okay. Let's take a quick
7 five minutes. Go off the record.

8 (Recess taken.)

9 MR. WILLIAMS: We don't have any further
10 questions for the witness.

11 MR. SARASWAT: Thank you, Dr. Rodbard.

12 THE WITNESS: Thank you.

13 (Deposition adjourned at 3:58 p.m.)
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21
22

ACKNOWLEDGMENT OF DEPONENT

I, DR. DAVID RODBARD, have read or have had
the foregoing testimony read to me and hereby
certify that it is a true and correct transcription
of my testimony with the exception of any attached
corrections or changes.

DR. DAVID RODBARD

☐ No corrections

☐ Correction sheet(s) enclosed

SUBSCRIBED AND SWORN TO BEFORE ME, the
undersigned authority, by the witness, DR. DAVID
RODBARD, on this the ____ day of

_____, _____.

C E R T I F I C A T E

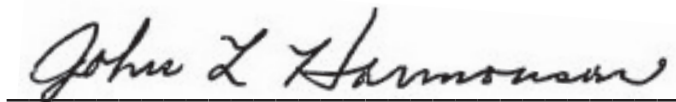
I, JOHN L. HARMONSON, a Notary Public
within and for the District of Columbia, certify
that DR. DAVID RODBARD, the witness whose
deposition is hereinbefore set forth, was duly
sworn by me and that such deposition is a true
record of the testimony given by such witness.

That before completion of the proceedings,
review and signature of the transcript was
reserved.

I further certify that I am not related
to any of the parties to this action by blood or
marriage; and that I am in no way interested in the
outcome of this matter.

I declare under penalty of perjury under the
laws of the United States of America that the
foregoing is true and correct.

IN WITNESS WHEREOF, I have hereunto set
my hand this 24th day of May, 2023.

A handwritten signature in cursive script, reading "John L. Harmonson", is written over a horizontal line.

JOHN L. HARMONSON, RPR
My commission expires: 04/14/26

ERRATA SHEET

CASE: IPR2022-00909
DATE: May 24, 2023
WITNESS: DR. DAVID RODBARD

Reason Codes:

1. To clarify the record.
2. To conform to the facts.
3. To correct transcription errors.

Pg.	Ln.	Now Reads	Should Read	Reason
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
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Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME

THIS ____ DAY OF _____, _____

(Notary Public) MY COMMISSION EXPIRES: _____

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Abbott Diabetes Care Inc.

Petitioner,

v.

DexCom, Inc.

Patent Owner.

IPR2022-00909

Attorney Docket No.: 003168.3438

**PETITIONER'S ERRATA SHEET FOR THE MAY 24, 2023
DEPOSITION OF DAVID RODBARD, M.D.**

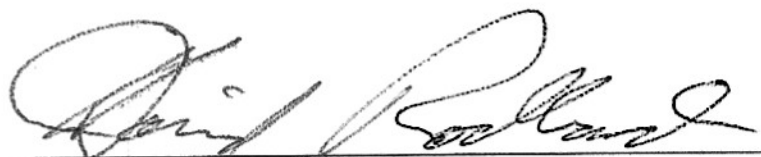
I, David Rodbard, M.D., do hereby make the following corrections to my
May 24, 2023 deposition transcript:

PAGE	LINE	CHANGE/CORRECTION	REASON
14	17-18	"I wouldn't say that. It's not an issue for them." to "I wouldn't say that but it's not an issue for them."	Transcription Error
42	5	"data in order to make a prediction. Based on the" to "data in order to make a prediction based on the"	Transcription Error
46	17	"prediction inherit be an inaccuracy of the" to "prediction inherit the inaccuracy of the"	Transcription Error
63	4-7	"next paragraph where they say that one should use both the low and high glucose threshold alarms and the projected low and projected high glucose alarms." to "next paragraph where they say that one should "use both the low and high glucose threshold alarms and the projected low and projected high glucose alarms.""	Transcription Error
66	9	"low detection rate" to "lower detection rate"	Transcription Error
112	12-13	"equivalent to. Certainly similar to or very similar to," to "equivalent to -- certainly similar to or very similar to,"	Transcription Error
132	5-6	"rate of change. In addition to" to "rate of change, in addition to"	Transcription Error

138	8	"be done in the factory in the arms of -- in the" to "be done in the factory in the terms of -- in the"	Transcription Error
141	9	"load" to "low"	Transcription Error
142	1	"complicated, are" to "complicated. Are"	Transcription Error
172	5-7	"Column 2, the present systems and methods relate to processing analyte sensor data, period." to "Column 2, "The present systems and methods relate to processing analyte sensor data," period."	Transcription Error
172	18-19	"that it also starts with the present systems and methods relate to." to "that it also starts with "The present systems and methods relate to...."	Transcription Error
174	2-3	"Because I don't see the providing accurate predictive alarms in the claims." to "Because I don't see the "providing accurate predictive alarms" in the claims."	Transcription Error
174	16	"year" to "yes"	Transcription Error
190	15	"food" to "fluid"	Transcription Error

I declare under penalty of perjury that, except for any corrections noted above, the transcript is an accurate record of the statements made by me.

Date: June 1, 2023



David Rodbard, M.D.